1 Senior Management Commitment

1.1 Senior Management Commitment and continual improvement

FOCUS	BRC #	BRC Requirement	CFR Rule Section #	110/111	Does BRC Exceed, or is it Comparable or Not Applicable From the CFR?	Comments
	Statement of Intent	The site's senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Food Safety and to processes which facilitate continual improvement of food safety and quality management			NA	
1.A-G	**1.1.1**	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legal products to the specified quality and its responsibility to its customers. This shall be: • signed by the person with overall responsibility for the site • communicated to all staff .	Final Rule § 117.310 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion (Final Rule § 117.310 (a)) and upon any modification (Final Rule § 117.310(b)).	N/A	Comparable	Preventive Controls Rule requires a signature of a company official or agent on the food safety plan. FDA deems this as direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan.
2.A	**1.1.2**	The site's senior management shall ensure that clear objectives are defined to maintain and improve the safety, legality and quality of products manufactured, in accordance with the food safety and quality policy and this Standard. These objectives shall be:			Exceeds	PREVENTIVE CONTROLS RULE does not require the site to document food safety objectives and monitor those objectives.

		• documented and include targets or clear measures of success • clearly communicated to relevant staff • monitored and results reported at least quarterly to site senior management.			
	1.1.3	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, annually as a minimum, to review the site performance against the Standard and objectives set in clause 1.1.2. The review process shall include the evaluation of: • previous management review action plans and timeframes • results of internal, second-party and/or third-party audits • customer complaints and results of any customer feedback • incidents, corrective actions, out-of-specification results and non-conforming materials • review of the management of the systems for HACCP, food defence and authenticity • resource requirements. Records of the meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.		Exceeds	PREVENTIVE CONTROLS RULE does not address requirement for management review meetings.
	1.1.4	The site shall have a demonstrable meeting programme which enables food safety, legality and quality issues to be brought to the attention of senior management at least monthly and		Exceeds	PREVENTIVE CONTROLS RULE does not address requirement for a formal meeting program to address food
		allows for the resolution of issues requiring immediate action.			safety, legality and quality issues by senior management.

1.A.3.c	**1.1.5**	The company's senior management shall provide the human and financial resources required to produce food safely and in compliance with the requirements of this Standard.		Exceeds	PREVENTIVE CONTROLS RULE does not specify the requirement for senior management to provide required resources to produce food safely and meet PREVENTIVE CONTROLS RULE requirements. By law, senior management is obligated to meet the PREVENTIVE CONTROLS RULE regulations and produce safe food.
3.0 Training	**1.1.6**	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews: • scientific and technical developments • industry codes of practice • new risks to authenticity of raw materials • all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.		Exceeds	PREVENTIVE CONTROLS RULE does not address requirement for senior management to have in place a system to ensure that the site is kept informed of key events that impact on the processing of safe food.
	1.1.7	The site shall have a genuine, original hard copy or electronic version of the current Standard available and be aware of any changes to the Standard or protocol that are published on the BRC website.		Not applicable	Not applicable
	1.1.8	Where the site is certificated to the Standard it shall ensure that announced recertification audits occur on or before the audit due date indicated on the certificate.		Not Applicable	Not Applicable

	1.1.9	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for Global Standard for Food Safety certification. Relevant departmental managers or their deputies shall be available as required during the audit.		Not Applicable	Not Applicable	
2.B Business Assessments: 1. The operation shall conduct periodic assessments of the business to expose and mitigate anomalies and vulnerabilities. 2. The operation must document assessments and the corrective action taken, and retain assessment and audit reports permanently for authorized review.	**1.1.10**	The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: (1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and (ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3). (2) The corrective action procedures must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or	Comparable	111.140, The QC Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained.111.560b, The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit. 110 =N/A	PREVENTIVE CONTROLS RULE does not specify root cause analysis as an integral part of corrective actions. FDA regulatory inspections generate nonconformities that require effective corrective actions by the site

			misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. (b) Corrective action in the event of an unanticipated food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply: (i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not 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. (b) Corrective action in the event of an unanticipated food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply: (i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or (iii) A review of records in accordance with § 17.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance		

		with the food safety plan, or appropriate decisions were not made about corrective actions. (2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must: (i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and (ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required. (c) Corrections. You do not need to comply with the requirements of paragraphs (a) and (b) of this section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety. (d) Records. All corrective action (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i). section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or		

			(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety. (d) Records. All corrective action (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).		
	1.2	**Organisational structure, responsibilities and management authority**			
	Statement of Intent	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality.		Comparable	It is implicit in the PREVENTIVE CONTROLS RULE requirement for a food safety plan that the organizational structure and lines of communication are established.
1.G.1 - Management shall maintain an organization chart that documents the organization structure, reporting relationships and decision-making paths.	**1.2.1**	The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.		Exceeds	PREVENTIVE CONTROLS RULE does not require an organizational chart nor the identification of alternates when required.
2.1.C The operation must have work contracts for all workers on file.	**1.2.2**	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.		Exceeds	PREVENTIVE CONTROLS RULE does not specifically identify the requirement for the documentation of work instructions.

	2 The Food Safety Plan – HACCP				
	FUNDAMENTAL Statement of Intent	The company shall have a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles.	Final Rule § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, and other records.	Comparable	Final Rule § 117.330 recognizes food safety plans prepared in accordance with HACCP principles stating that to the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of the Final Rule. Further the Final Rule states that relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human Preventive Controls Rule, is acceptable. This appears to satisfy 2.4.3.1. *Additional Observations:* Similarities: some of the HACCP philosophy applies to the final rule approach; the food safety plan can cover a product or group of products; the hazard analysis requirement includes consideration of all hazards that are known or reasonably foreseeable; the use of process controls, monitoring and corrective actions is similar; Differences: preventive controls can include controls other than process controls, such as sanitation controls and allergen controls; the hazard analysis limits preventive controls from those hazards that are “reasonably foreseeable” to those that are “hazards requiring preventive controls”, preventive controls are only required for hazards requiring preventive controls

					based on the outcome of a firm's hazard analysis; SOPs and work instructions are not required by the Final Rule.
	2.1	**The HACCP food safety team – Codex Alimentarius Step 1**			
7.B.5 The operation's hazard control coordinator, managers and production workers must be trained in appropriate quality control methods.	**2.1.1**	The HACCP plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality/technical, production operations, engineering and other relevant functions. The team leader shall have an in-depth knowledge of HACCP and be able to demonstrate competence and experience. The team members shall have specific knowledge of HACCP and relevant knowledge of product, process and associated hazards. In the event of the site not having appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.		Exceeds	PREVENTIVE CONTROLS RULE does not require the creation of a formal Food Safety Team to guide the development and ongoing management of the HACCP Plan (Food Safety Plan). PREVENTIVE CONTROLS RULE does encourage the establishment of Food Safety Team. PREVENTIVE CONTROLS RULE requires a Preventive Controls Qualified Individual who must prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of a food safety plan every three years or whenever changes occur that would require reanalysis. The Preventive Controls qualified individual is not explicitly responsible for communicating essential information to relevant personnel.

7.B.2 The Hazard Control Plan establishes monitoring points (called critical control points) in the production process, sets parameters for each point, assigns workers to monitor and record product quality at those points, and requires them to identify and report any product or processing nonconformance.	**2.1.2**	The scope of each HACCP plan, including the products and processes covered, shall be defined.		Comparable	The food safety plan of the BRC Standard is based on CODEX HACCP whereas the PREVENTIVE CONTROLS RULE food safety plan is based on the Preventive Control approach. The two methods are comparable and deliver the same outcomes.

	2.2	Prerequisite programmes				
8.A.2 **The operation must set environmental control parameters and list them in product specifications or production procedures. 8.B Cleanability of Facility** **9.A Equipment Management**	**2.2.1**	The site shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list: • cleaning and sanitising • pest control • maintenance programmes for equipment and buildings • personal hygiene requirements • staff training • purchasing • transportation arrangements • processes to prevent cross-contamination • allergen controls The control measures and monitoring procedures for the prerequisite programmes must be clearly documented and shall be included within the development and reviews of the HACCP.	117.135	Exceeds	111 Subparts G-L Production and Process Control System FSMA's preventive controls rule, 21 CFR 117.5(e), exempts finished dietary supplements (DS) from the requirements for preventive controls and a supply-chain program if they are in compliance with 21 CFR 111, and with adverse event reporting. FSMA directly affects *dietary ingredient* (DI) manufacturers. Only finished DS products are exempted from subparts C and G or Part 117.	The BRC Standard follows the CODEX HACCP approach where Prerequisite Programs are the foundation of the Food Safety Plan. PREVENTIVE CONTROLS RULE incorporates Prerequisite type programs directly into the Food Safety Plan in the form of Preventive Controls. This is comparable to the BRC approach. However, in PREVENTIVE CONTROLS RULE, some Prerequisite Programs may be considered as GMPs where no documented controls or records are required. Differences: preventive controls can include controls other than process controls, such as sanitation controls and allergen controls; the hazard analysis limits preventive controls from those hazards that are "reasonably foreseeable" to those that are "hazards requiring preventive controls", preventive controls are only required for hazards requiring preventive controls based on the outcome of a firm's hazard analysis; SOPs and work instructions are not required by the Final Rule

	2.3	Describe the product – Codex Alimentarius Step 2				
7.I The operation shall classify all materials and products in the production process and control them according to documented procedures:	**2.3.1**	A full description for each product or group of products shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list: • composition (e.g. raw materials, ingredients, allergens, recipe) • origin of ingredients • physical or chemical properties that impact food safety (e.g. pH, aw) • treatment and processing (e.g. cooking, cooling) • packaging system (e.g. modifi ed atmosphere, vacuum) • storage and distribution conditions (e.g. chilled, ambient) • target safe shelf life under prescribed storage and usage conditions.	117.130 (c) (2) (i)	Comparable	**111.205**	PREVENTIVE CONTROLS RULE requires that the product formulation be considered in the hazard analysis. PREVENTIVE CONTROLS RULE does not require the documentation of the Product Description as part of the Preventive Control approach. However it does recommend that a Product Description be completed as a part of the process in developing the Food Safety plan, outlines the information that it should entail and provides a draft Product Description Form to help record the information (FSPCA Guidance documents).
	2.3.2	All relevant information needed to conduct the hazard analysis shall be collected, maintained, documented and updated. The company will ensure that the HACCP plan is based on comprehensive information sources, which are referenced and available on request. As a guide, this may include the following, although this is not an exhaustive list: • the latest scientific literature • historical and known hazards associated with specific food products • relevant codes of practice • recognised guidelines • food safety legislation relevant for the production and sale of products • customer requirements.	Final Rule § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records.	Exceeds	N/A	PREVENTIVE CONTROLS RULE does not specifically require the site to collect, maintain, document and update relevant information needed to perform the Hazard Analysis. Final Rule § 117.330 recognizes food safety plans prepared in accordance with HACCP principles stating that to the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of the Final Rule.

	2.4	**Identify intended use – Codex Alimentarius Step 3**			
	2.4.1	The intended use of the product by the customer, and any known alternative use, shall be described, defining the consumer target groups, including the suitability of the product for vulnerable groups of the population (e.g. infants, elderly, and allergy sufferers).	117.130 (c) (2) (viii)	Comparable	PREVENTIVE CONTROLS RULE do require that the intended use of the product be considered in the Hazard Analysis.
	2.5	**Construct a process flow diagram – Codex Alimentarius Step 4**			
7.G Production Clow Chart The operation must document product-related processes using flow diagrams, process maps, procedures and checklists, etc., to ensure the production of safe, quality products that meet product specifications.	**2.5.1**	A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP scope, from raw material receipt through to processing, storage and distribution. As a guide, this should include the following, although this is not an exhaustive list: • plan of premises and equipment layout • raw materials including introduction of utilities and other contact materials (e.g. water, packaging) • sequence and interaction of all process steps • outsourced processes and subcontracted work • potential for process delay • rework and recycling • low-risk/high-risk/high-care area segregation • finished products, intermediate/semi-processed products, by-products and waste.		Exceeds	PREVENTIVE CONTROLS RULE do not require a Flow Diagram as part o the development of the Food Safety Plan but does recommend it as a ste in the Hazard Analysis.

	2.6	**Verify flow diagram – Codex Alimentarius Step 5**			
	2.6.1	The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit and challenge at least annually. Daily and seasonal variations shall be considered and evaluated. Records of verified flow diagrams shall be maintained.		Exceeds	PREVENTIVE CONTROLS RULE do not require a Flow Diagram as part of the development of the Food Safety Plan but does recommend it as a step in the Hazard Analysis.
	2.7	**List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to control identified hazards – Codex Alimentarius Step 6, Principle 1**			
7.K Control of Contaminants During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people.	**2.7.1**	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and allergen risks (refer to clause 5.3). It shall also take account of the preceding and following steps in the process chain.	117.130	Comparable	PREVENTIVE CONTROLS RULE requires that a Hazard Analysis be performed to identify reasonably foreseeable hazards (biological, chemical, physical) to determine when preventive controls are require.
7.K Control of Contaminants During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people.	**2.7.2**	The HACCP food safety team shall conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels. Consideration shall be given to the following: • likely occurrence of hazard • severity of the effects on consumer safety • vulnerability of those exposed • survival and multiplication of micro-organisms of specific concern to the product • presence or production of toxins, chemicals or foreign bodies	117.130	Comparable	PREVENTIVE CONTROLS RULE requires that a Hazard Analysis be performed to identify reasonably foreseeable hazards (biological, chemical, physical) to determine when preventive controls are require.

		• contamination of raw materials, intermediate/semi-processed product, or finished product. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.			
7.K Control of Contaminants During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people.	**2.7.3**	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the specific hazard validated. Consideration may be given to using more than one control measure.	117.135 **111.205b1** **110.80.13.i**	Comparable	PREVENTIVE CONTROLS RULE requires Preventive Controls be implemented to minimize potential hazards to an acceptable safe level o prevent them from occurring.
	2.8	**Determine the critical control points (CCP) – Codex Alimentarius Step 7, Principle 2**			
7.D The operation must identify critical control points (CCPs) in a CCP Responsibilities Chart to monitor potential hazards identified in the Production Hazard Analysis	**2.8.1**	For each hazard that requires control, control points shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree. Critical control points (CCPs) shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier step, to provide a control measure.	117.135 **111.205b1** **110.80.13.i**	Comparable	PREVENTIVE CONTROLS RULE requires that Preventive Controls be established to control “Process Hazards” (CCPs) and other hazards requiring control (formerly referred to Prerequisite Programs).

	2.9	**Establish critical limits for each CCP – Codex Alimentarius Step 8, Principle 3**			
7.D.3 Qualified workers must set critical limits (maximum or minimum parameters and tolerances) for each critical control point	**2.9.1**	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be: • measurable wherever possible (e.g. time, temperature, pH) • Supported by clear guidance or examples where measures are subjective (e.g. photographs).	117.135 **111.205b1** **110.80.13.i**	Comparable	The Final Preventive Controls Rule uses the term “parameters” rather tha “critical limits” as in the BRC Standard Parameters must be established at each Preventive Control and be appropriate to the hazard, process an the facility.
7.D.3 Source data and justification for critical limits must be documented and retained.	**2.9.2**	The HACCP food safety team shall validate each CCP. Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.	117.160	Comparable	PREVENTIVE CONTROLS RULE requires that the site must validate tha the preventive controls identified and implemented are adequate to control the hazard as appropriate to the natur of the preventive control and its role in the facility’s food safety system. Validation must: Be performed or overseen by a PC qualified individual Be done prior to the implementation o the food safety plan Be performed as necessary to demonstrate control measures can be implemented as designed: Within 90 days after production of the applicable food begins OR

					Within a reasonable timeframe with justification Must be performed if there are change that may impact control of the hazard Must be performed if a reanalysis indicates the need for it
	2.10	**Establish a monitoring system for each CCP – Codex Alimentarius Step 9, Principle 4**			
7.E The operation must assign workers to monitor, record and manage corrective actions for each critical control point	**2.10.1**	A monitoring procedure shall be established for each CCP to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of CCPs and wherever possible provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: • on-line measurement • off-line measurement • continuous measurement (e.g. thermographs, pH meters etc.). Where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product.	117.145 **111.205b1** **111.255c** **110.80.13.i**	Comparable	PREVENTIVE CONTROLS RULE requires the site to develop and implement Monitoring Procedures for each Preventive Control and as appropriate for the nature of the preventive control. Monitoring Procedures shall include frequency and record keeping
7.F 1. The operation must design and publish forms and logs to record the control point monitoring data in production records.	**2.10.2**	Records associated with the monitoring of each CCP shall include the date, time and result of measurement and shall be signed by the person responsible for the monitoring and verified, when appropriate, by an	117.145 **111.255c**	Comparable	PREVENTIVE CONTROLS RULE requires records of all monitoring of Preventive Controls.

		authorised person. Where records are in electronic form there shall be evidence that records have been checked and verified.			PREVENTIVE CONTROLS RULE makes provision for “Exception Records” where a record is generated only when a limit is not met (eg. Temperature of Freezer)
	2.11	**Establish a corrective action plan – Codex Alimentarius Step 10, Principle 5**			
7.N.1.a Production records include pre-production inspections, process monitoring records, critical control point records, control limit records, deviation logs and corrective action reports 7.N.4 Workers should record unexpected findings, process failures or unusual occurrences at any processing step in a deviation log and report them to the quality manager or HACCP coordinator immediately for corrective action 7.P.3,4 3.Workers must document corrective actions taken to return the process within critical limits, and any preventative actions taken in a Corrective Action Report. a. Workers must record the disposition of potentially affected product (rework or disposal). 4. HACCP coordinator or quality manager must review all Corrective Action Reports and take additional actions as required.	**2.11.1**	The HACCP food safety team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control.	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: (1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance 117.165. **111.140** **111.560b**	Comparable	PREVENTIVE CONTROLS RULE requires that Corrective Actions be established when monitoring identifies that the Preventive Control parameter are not met. Corrective Actions must be appropriat to the nature of the hazard and nature of the Preventive Control and describe the steps to be taken. Procedures mu describe the steps, identify and correc the problem, reduce the likelihood tha the problem will recur and all affected food is evaluated for safety eg.and prevented from entering commerce if determined to be unsafe or does not comply with regulation. PREVENTIVE CONTROLS RULE do not specifically require “nominated personnel” to manage corrective actions.

	2.12	**Establish verification procedures – Codex Alimentarius Step 11, Principle 6**			
7.T A HACCP-trained coordinator must verify that CCP monitoring records are current, accurate and include required corrective action reports.	**2.12.1**	Procedures of verification shall be established to confirm that the HACCP plan, including controls managed by prerequisite programmes, continues to be effective. Examples of verification activities include: • internal audits • review of records where acceptable limits have been exceeded • review of complaints by enforcement authorities or customers • review of incidents of product withdrawal or recall. Results of verification shall be recorded and communicated to the HACCP food safety team.	§117.155 & §117.160 § 117.155 Verification. (a) Verification activities. Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system: (1) Validation in accordance with § 117.160. (2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145). (3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150). (4) Verification of implementation and effectiveness in accordance with § 117.165; and (5) Reanalysis in accordance with § 117.170.	Comparable	PREVENTIVE CONTROLS RULE requires that the site must implement verification activities to confirm that th Preventive Controls are being conducted as documented and effecti in producing the expected food safety outcomes. Must verify that monitoring is being conducted appropriately, appropriate decisions are made about corrective actions. Verification of implementation and effectiveness of the preventive controls. Reanalysis is done appropriately and fully documented
	2.13	**HACCP documentation and record keeping – Codex Alimentarius Step 12, Principle 7**			
7.T.2 The HACCP coordinator must develop a schedule and assign a worker to verify each CCP	**2.13.1**	Documentation and record keeping shall be sufficient to enable the site to verify that the HACCP controls, including controls managed by prerequisite programmes, are in place and maintained.	Subpart F – Requirements Applying to Records that must be Established and Maintained. §117.310. **111.123a** Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.	Comparable	PREVENTIVE CONTROLS RULE requires that the site generate and maintain records pertaining to the Foo Safety Plan.

	2.14	Review the HACCP plan			
7.V **Assessing the Hazard Control Plan** 1.The operation must conduct a self-assessment of the HACCP program annually at a minimum. 2.Self-assessments must validate the process flow, hazard analysis and HACCP chart. 3.The operation must document: a.Changes to the program b.Training delivered to workers c.Any changes to CCPs	**2.14.1**	The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and prior to any changes which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list: • change in raw materials or supplier of raw materials • change in ingredients/recipe • change in processing conditions, process flow or equipment • change in packaging, storage or distribution conditions • change in consumer use • emergence of a new risk (e.g. known adulteration of an ingredient) • following a recall • new developments in scientific information associated with ingredients, process or product. Appropriate changes resulting from the review shall be incorporated into the HACCP plan and/or prerequisite programmes, fully documented and validation recorded.	§117.170 – Reanalysis **111.140** Quality Control Operations are documented and meet all requirements. The QC Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained.	Exceeds	PREVENTIVE CONTROLS RULE requires that the Food Safety Plan undergo a “reanalysis” at least once every three years.

3. Food safety and quality management system

3.1 Food safety and quality manual

	Statement of Intent	The company's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe product.			
	3.1.1	The site's documented procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual.	§117.126 (a) 1 --Requirement for a Food Safety Plan. The site must prepare and implement a written food safety plan. §117.305(a) requires that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records	Comparable	
	3.1.2	The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to relevant staff.	§117.126--Requirement for a Food Safety Plan A food safety plan is required that includes a hazard analysis, preventive controls (which may include process controls, food allergen controls, sanitation controls and/or other controls), monitoring procedures, corrective action procedures, verification procedures and a recall plan.	Exceeds	The Preventive Controls Food Safety Plan does not include procedures or practices related to quality. The Preventive Controls does not address the requirement for written procedures to be readily available to staff.

2.G The operation must have procedures to control documents related to production, product quality, worker safety and work operations that include: a.Approval of documents prior to issue b.Review and revision as required including re-approval c.Documented changes and current revision status d.Ensuring documents remain legible and readily identifiable e.Ensuring correct versions of relevant documents are available at points of use f.Preventing obsolete documents from unintended use	3.1.3	All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This shall include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language).		Exceeds	The Preventive Controls does not address the quality or language of written procedures.
	3.2	**Documentation control**			
	Statement of Intent	The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use.			
2.G.1 .The operation must have procedures to control documents related to production, product quality, worker safety and work operations that include: a.Approval of documents prior to issue b.Review and revision as required including re-approval c.Documented changes and current revision status d.Ensuring documents remain legible and readily identifiable e.Ensuring correct versions of relevant documents are available at points of use f.Preventing obsolete documents from unintended use	3.2.1	The company shall have a procedure to manage documents which form part of the food safety and quality system. This shall include: • a list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes or amendments to documents • the system for the replacement of existing documents when these are updated.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically identify procedures to manage the food safety plan documents.

	3.3	**Record completion and maintenance**			
	Statement of Intent	The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.	Preventive Control Rule Subpart F ‘‘Requirements Applying to Records that Must be Established and Maintained’’ identifies the requirements of records related to the Food Safety Plan must be original, true copies or electronic, contain actual values or observations captured	Comparable	The Preventive Control Rule does not provide the detail regarding recordkeeping as described in the BR Standard.
			in real time, accurate, indelible and legible and detailed to provide history of work performed. Also identifies retention times		
2.G.1 .The operation must have procedures to control documents related to production, product quality, worker safety and work operations that include: a.Approval of documents prior to issue b.Review and revision as required including re-approval c.Documented changes and current revision status d.Ensuring documents remain legible and readily identifiable e.Ensuring correct versions of relevant documents are available at points of use f.Preventing obsolete documents from unintended use	**3.3.1**	Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss.	Preventive Control Rule Subpart F ‘‘Requirements Applying to Records that Must be Established and Maintained’’ identifies the requirements of records related to the Food Safety Plan must be original, true copies or electronic, contain actual values or observations captured in real time, accurate, indelible and legible and detailed to provide history of work performed. Also identifies retention times	Comparable	
2.J.1 The operation must maintain a Records Management System and follow established procedures to ensure the organized storage, retention and protection of all records and supporting data that includes:	**3.3.2**	Records shall be retained for a defined period with consideration given to: • any legal or customer requirements • the shelf life of the product. This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing). As a minimum, records shall be retained for the shelf life of the product plus 12 months.	§117.315 (a) 1 All records required by this part must be retained at the plant or facility at least 2 years after the date they were prepared. **111.605** You must keep written records required by this part for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.	Comparable	
	3.4	**Internal audits**			
	FUNDAMENTAL Statement of Intent	The company shall be able to demonstrate it verifies the effective application of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety.			

2.B The operation shall conduct periodic assessments of the business to expose and mitigate anomalies and vulnerabilities. 2. The operation must document assessments and the corrective action taken, and retain assessment and audit reports permanently for authorized review.	**3.4.1**	There shall be a scheduled programme of internal audits throughout the year with a scope which covers the implementation of the HACCP programme, prerequisite programmes and procedures implemented to achieve this Standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least annually.	§ 117.170 Reanalysis. The site must conduct a reanalysis of the food safety plan as a whole once every 3 years or when necessary, such identification of a new hazard, adjustment to the process or operation, addition of a new product or a problem in the food safety plan requires investigation. The reanalysis must be performed or overseen by the Preventive Controls Qualified Individual. § 117.160 Validation. The site must validate that the preventive controls are implemented in accordance with § 117.135 (the food safety plan) and are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system. The validation of the preventive controls: (1) Must be performed (or overseen) by a preventive controls qualified individual: (i)(a) Prior to implementation of the food safety plan; or (b) When necessary to demonstrate the control measures can be implemented as designed: (1) Within 90 calendar days after production of the applicable food first begins; or (2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins; (ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and (iii) Whenever a reanalysis of the food safety plan reveals the need to do so. § 117.165 Verification of implementation and effectiveness. (a) Verification activities. You must verify that the	Exceeds	The Reanalysis, Verification Activities and Validation would focus on the Foo Safety Plan and not include quality control systems.

			preventive control and its role in the facility's food safety system: (1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy); (2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard; (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and (4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls 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.		
2.B.5.C 5.Third-Party Audits – conduct assessments as required by company policy: a.Business finances and operations b.Partnerships, joint ventures, contracts and agreements c.Use certified, impartial auditors	**3.4.2**	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (i.e. not audit their own work).	§ 117.160 Validation. The validation must be performed or overseen by the Preventive Controls Qualified Individual. § 117.170 Reanalysis. The reanalysis must be performed or overseen by the Preventive Controls Qualified Individual.	Exceeds	The Preventive Controls rule does not require audits be performed by an independent individual.
	3.4.3	The internal audit programme shall be fully implemented. Internal audit reports shall identify conformity as well as non-conformity and the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	§ 117.190 Implementation Records The site must establish and maintain records of verifications, validations and reanalysis. § 117.150 Corrective Actions The site must establish and implement written corrective actions procedures that must be taken if preventive controls are not properly implemented. **111.140** The QC Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained	Comparable	The Preventive Control Rule does not provide the detail of audit activities (reanalysis) as described in the BRC Standard.

7.D.2.b 2.Critical control points must be located at all potentially hazardous points in the production flow to detect defects and prevent nonconforming product from receiving further processing. a.CCPs must include detailed monitoring procedures. b.Procedures must define inspection frequencies. c.Forms and reporting methods must be issued	**3.4.4**	I In addition to the internal audit programme there shall be a programme of documented nspections to ensure that the factory environment and processing equipment is maintained in a suitable condition for food production. These inspections shall include: • hygiene inspections to assess cleaning and housekeeping performance • fabrication inspections to identify risks to the product from the building or equipment. The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas		Exceeds	The Preventive Control Rule does not refer to monthly internal audits or GMI Inspections but is does require weekly verification of all Preventive Controls.
	3.5	**Supplier and raw material approval and performance monitoring**			
	3.5.1	**Management of suppliers of raw materials and packaging**			
16.B 1. Suppliers must be evaluated, qualified and selected based on specified criteria. 2.The operation must periodically assess supplier performance to ensure that qualified suppliers continue to provide acceptable materials and services. 3.The operation must document supplier nonconformance and corrective action taken and retain for two years.	**Statement of Intent**	The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including packaging) to the safety, authenticity, legality and quality of the final product are understood and managed	Subpart G – Supply-Chain Program covers: § 117.405 Requirements to establish and implement a supply-chain program § 117.410 General requirements applicable to a supply-chain program § 117.415 Responsibilities of the receiving facility. § 117.420 Using approved suppliers § 117.425 Determining appropriate supplier verification activities. § 117.430 Conducting supplier verification activities for raw materials and other ingredients § 117.435 Onsite audit § 117.475 Records documenting the supply chain program FSMA's preventive controls rule, 21 CFR 117.5(e), exempts finished dietary supplements (DS) from the requirements for preventive controls and a supply-chain program if they are in compliance with 21 CFR 111, and with adverse event reporting. FSMA directly affects *dietary ingredient* (DI) manufacturers. Only finished DS products are exempted from subparts C and G or Part 117.	Exceeds	The Preventive Control Rule does not specify supplier and raw material approval performance monitoring requirements. The Preventive Controls requires a supply-chain program when the site determines that a supplier is providing material with a hazard and requires th supplier to implement controls to address the risk. The site must take the appropriate activities in approving a supplier (including the frequency of conducting the activity) and includes performing a Hazard Analysis, including the nature the hazard, applicable to the material by assessing • where preventive controls are applied, (supplier or supplier's

					supplier), the supplier's procedures, • practices and processes related t the safety of the material • Suppliers' conformance to FDA requirements (e.g. FDA warning letters, etc.) • Supplier's food safety performanc history, (testing results, audit results and supplier response to non-conformances) • Other factors such as supplier's storage and transportation practices.
	3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials including packaging to identify potential risks to product safety, legality and quality. This shall take into account the potential for: • allergen contamination • foreign-body risks • microbiological contamination • chemical contamination • substitution or fraud (see clause 5.4.2). Consideration shall also be given to the significance of a raw material to the quality of the final product. The risk assessment shall form the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring. The risk assessments shall be reviewed at least annually.	§ 117.410 General requirements applicable to a supply-chain program require the supply-chain program of a site to: • Use approved suppliers, • Determine appropriate supplier verification activities and frequencies, • Conduct and document supplier verification activities, • Appropriate supplier verification activities include: • Onsite audits • Sampling and testing of materials, • Other appropriate supplier verification activities based on supplier performance and risk associated with the materials **111.75a2iiD** Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification), and procedures for disqualification. **110.80.2&3 Processes and controls**	Exceeds	The Preventive Control Rule does not require the site to undertake a formal risk assessment of the supplied materials to identify risks to legality ar quality.

16.B Supplier Qualification Suppliers must be evaluated, qualified and selected based on specified criteria. The operation must periodically assess supplier performance to ensure that qualified suppliers continue to provide acceptable materials and services. The operation must document supplier nonconformance and corrective action taken and retain for two years.	**3.5.1.2**	The company shall have a documented supplier approval and ongoing monitoring procedure to ensure that all suppliers of raw materials, including packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval and monitoring procedure shall be based on risk and include one or a combination of: • certification (e.g. to BRC Global Standards or other GFSI-recognised scheme) • supplier audits, with a scope to include product safety, traceability, HACCP review and good • manufacturing practices, undertaken by an experienced and demonstrably competent product safety auditor or, for suppliers assessed as low risk only, supplier questionnaires. Where approval is based on questionnaires, these shall be reissued at least every 3 years and suppliers will be required to notify the site of any significant changes in the interim. The site shall have an up-to-date list of approved suppliers.	§ 117.410 General requirements applicable to a supply-chain program require the supply-chain program of a site to: • Use approved suppliers, • Determine appropriate supplier verification activities and frequencies, • Conduct and document supplier verification activities, • Appropriate supplier verification activities include: • Onsite audits • Sampling and testing of materials, • Other appropriate supplier verification activities based on supplier performance and risk associated with the materials. **111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product. **111.75a** Components are sampled, tested, and confirmed (released) prior to use in production. **111.75a2iiD** Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification), and procedures for disqualification. **§110.80.2&3 Processes and controls**	Comparable	The Preventive Controls Rule does no provide the level of detail as describe in the BRC Standard.
14.A.3 The operation must document supplier inputs and materials used to produce each batch to the maximum extent feasible	**3.5.1.3**	Where raw materials are purchased from agents or brokers, the site shall know the identity of the last manufacturer or packer or for bulk commodity products the consolidation place of the raw material. Information to enable the approval of the manufacturer, packer or consolidator, as in clause 3.5.1.2, shall be obtained from the		Exceeds	The Preventive Controls Rule does no address specific requirements when purchasing raw materials from agents or brokers.

		agent/broker or directly from the supplier, unless the agent/broker is themselves certificated to the BRC Global Standard for Agents and Brokers.			
	3.5.1.4	The procedures shall define how exceptions to the supplier approval processes in clause 3.5.1.2 are handled (e.g. where raw material suppliers are prescribed by a customer) or where information for effective supplier approval is not available (e.g. bulk agricultural commodity products) and instead product testing is used to verify product quality and safety. When a site produces customer-branded product the relevant exceptions shall be identified to the customer.		**Exceeds**	The Preventive Controls Rule does no address exceptions to the Supply-Cha Program.
	3.5.2	**Raw material and packaging acceptance and monitoring procedures**			
	Statement of Intent	Controls on the acceptance of raw materials including packaging shall ensure that these do not compromise the safety, legality or quality of products and where appropriate any claims of authenticity.			
16.B 1. The operation must follow a written procedure for the inspection of all raw materials and packaging to ensure materials meet product specifications. a.Incoming inspection logs and raw material inventory report must be on file for review. b.All raw materials must be entered into the inventory list when received and when released to production. The operation must have quality certifications, letters of guarantee or similar documentation for all raw materials, ingredients, cannabis extracts, etc., used in the process. d.Documentation must be retained for two years.	**3.5.2.1**	The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (clause 3.5.1.1). Raw material including packaging acceptance and its release for use shall be based on one or a combination of: • product sampling and testing • visual inspection on receipt • certificates of analysis – specific to the consignment	§ 117.80 Processes and controls. (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. **111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product. **111.75a** Components are sampled, tested, and confirmed (released) prior to use in production. **111.75a2iiD** Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification), and procedures for disqualification. **110.80.2&3 Processes and controls**	Exceeds	The Preventive Controls Rule does no specify incoming packaging, raw material and ingredients acceptance procedures. Raw materials and other ingredients must comply with FDA regulations pertaining to contamination and adulteration of food.

		• certificates of conformance. A list of raw materials including packaging and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined, implemented and reviewed.			
	3.5.3	**Management of suppliers of services**			
	Statement of Intent	The company shall be able to demonstrate that where services are outsourced the service is appropriate and any risks presented to food safety, legality and quality have been evaluated to ensure effective controls are in place.		Exceeds	The preventive controls rule does not specifically address approval and monitoring of out sourced services su as laundry or maintenance of equipment.
16.B 1. The operation must follow a written procedure for the inspection of all raw materials and packaging to ensure materials meet product specifications. a.Incoming inspection logs and raw material inventory report must be on file for review. b.All raw materials must be entered into the inventory list when received and when released to production. The operation must have quality certifications, letters of guarantee or similar documentation for all	**3.5.3.1**	There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include, as appropriate: • pest control • laundry services • contracted cleaning • contracted servicing and maintenance of equipment • transport and distribution • off-site storage of ingredients, packaging or products • laboratory testing • catering services • waste management.	**111.75**(C) You maintain documentation of how you qualified the supplier	Exceeds	The preventive controls rule does not specifically address approval and monitoring of out sourced services su as laundry or maintenance of equipment
	3.5.3.2	Contracts or formal agreements shall exist with the suppliers of services that clearly define service expectations and ensure		Exceeds	The preventive controls rule does not specifically address approval and monitoring of out sourced services su

		potential food safety risks associated with the service have been addressed.			as laundry or maintenance of equipment
	3.5.4	**Management of outsourced processing**			
	Statement of Intent	Where any process step in the manufacture or packing of a product which is included within the scope of certification is subcontracted to a third party or undertaken at another site, this shall be managed to ensure it does not compromise the safety, legality, quality or authenticity of the product.		Exceeds	The preventive controls rule does not address outsourced processing.
	3.5.4.1	The company shall be able to demonstrate that where part of the production process or final packing is outsourced and undertaken off-site this has been declared to the brand owner and, where required, approval granted.		Exceeds	The preventive controls rule does not address outsourced processing.
	3.5.4.2	The company shall ensure that subcontractors are approved and monitored by successful completion of either: • certification to the applicable BRC Global Standard for Food Safety or other GFSI-recognised scheme • a documented site audit with a scope to include product safety, traceability, HACCP review and good manufacturing practices by an experienced and demonstrably competent product safety auditor.		Exceeds	The Preventive Controls Rule does no address the engagement qualification for subcontractors.
	3.5.4.3	Any outsourced processing or packing operations shall:		Exceeds	The Preventive Controls Rule does no address the engagement qualification for subcontractors.

		• be undertaken in accordance with established contracts which clearly define any processing and/or packing requirements and product specification • maintain product traceability.			
	3.5.4.4	The company shall establish inspection and test procedures for products where part of the processing or packing have been outsourced, including visual, chemical and/or microbiological testing, dependent on risk assessment.		Exceeds	The Preventive Controls Rule does no address the inspection and test procedures for products where part of the processing or packing have been outsourced.
	3.6	**Specifications**			
	Statement of Intent	Specifications shall exist for raw materials including packaging, finished products and any product or service which could affect the integrity of the finished product.	**111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product.	Exceeds	The preventive controls rule does not specially address the requirement for the site to maintain specifications for raw and packaging materials or finish product. The preventive control rule would address any risks to the safety of the final product via the Hazard Analysis, the identification of potential hazards, and the implementation of preventive controls.
16.C Incoming Goods Inspection The operation must have a documented inspection process for all incoming goods that documents all nonconformances to specifications. The inspection process must identify inspection parameters and sampling procedures. Goods must be inspected for (as applicable to the product):	3.6.1	Specifications for raw materials and packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements. The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).	**111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product.	Exceeds	The preventive controls rule does not require specifications for raw and packaging materials.

7.J Product Specifications 1. The operation shall document product specifications for each final product produced for sale or transfer	**3.6.2**	Accurate, up-to-date specifications shall be available for all finished products. These shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.	**111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product.	Exceeds	Finished product specifications is not required by the Preventive Controls Rule. Microbiological and chemical limits are indirectly addressed; hazard that require a preventive control need be addressed
	3.6.3	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place.		Exceeds	The preventive controls rule does not specially address the requirement for the site to maintain specifications for raw and packaging materials or finish product.
	3.6.4	Specifications shall be reviewed whenever products change (e.g. ingredients, processing method) or at least every 3 years. The date of review and the approval of any changes shall be recorded.		Exceeds	The preventive controls rule does not specially address the requirement for the site to maintain specifications for raw and packaging materials or finish product.
	3.7	**Corrective action**			
7.A.3 The QMS shall require continuous assessment, corrective action for nonconformance, accurate and detailed documentation	**FUNDAMENTAL Statement of Intent**	The site shall be able to demonstrate that it uses the information from identified failures in the food safety and Quality management system to make necessary corrections and prevent recurrence.	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: (1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and (ii) The presence of an environmental pathogen or appropriate indicator organism detected through the	Exceeds	Under the preventive control rule corrective action is triggered when it has been identified that a preventive control was not properly implemented • Appropriate action is then taken t identify and correct a problem tha has occurred with implementation of a preventive control. • Appropriate action is taken to reduce the likelihood that the problem will recur. • All affected food is evaluated for safety; and all impacted food is

		environmental monitoring conducted in accordance with § 117.165(a)(3). (2) The corrective action procedures must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not 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. (b) Corrective action in the event of an unanticipated food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply: (i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not 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. (b) Corrective action in the event of an unanticipated food safety problem.		prevented from entering into commerce. • All steps and information is documented. The preventive control rule does not provide the detail as described in the BRC standard.

		(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply: (i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or (iii) A review of records in accordance with § 17.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions. (2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must: (i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and (ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required. (c) Corrections. You do not need to comply with the requirements of paragraphs (a) and (b) of this section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety. (d) Records. All corrective action (and, when appropriate, corrections) taken in accordance with this section must		

			be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i). section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety. (d) Records. All corrective action (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i). **111.113b** Quality Control Personnel may authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency. **111.1b** Quality Control has not approved and released product in any form that does not meet the specifications unless Quality Control approved deviations have been documented. **111.140** The QC Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained. **111.560b** The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.		rocedures for quality related non-
	3.7.1	The site shall have a documented procedure for handling and correcting failures identified in the food safety and quality system. .	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control	Exceeds	The Preventive Controls Rule does not require written corrective action procedures for quality related non-conformities.

7.P. 1. Workers must document all nonconformances to critical limits in a Critical Control Points Log. 2. All nonconformances must be reported to the HACCP coordinator or quality manager immediately. 3. Workers must document corrective actions taken to return the process within critical limits, and any preventative actions taken in a Corrective Action Report. a. Workers must record the disposition of potentially affected product (rework or disposal). 4. HACCP coordinator or quality manager must review all Corrective Action Reports and take additional actions as required.	3.7.2	Where a non-conformity places the safety, legality or quality of products at risk this shall be investigated and recorded including: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • the action to address the immediate issue • an appropriate timescale for correction • the person responsible for correction • verification that the correction has been implemented and is effective • identification of the root cause of the non-conformity and implementation of any necessary actions to prevent recurrence.	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control	Exceeds	The Preventive Controls Rule does n require written corrective action procedures for quality related non-conformities

	3.8	**Control of non-conforming product**			
	Statement of Intent	The company shall ensure that any out-of-specification product is effectively managed to prevent release.	111.170 Rejected components, packaging, labeling, and products are appropriately quarantined and dispositioned.	Exceeds	The preventive controls rule does not address non-conforming product, othe than requiring corrective actions if the is a deviation from a preventive contro which is a distinguishable process. The labelling and segregation of non-conforming product is not addressed other than stating that impacted produ would be prevented from entering commerce.
	3.8.1	There shall be documented procedures for managing non-conforming products. These procedures shall include: • the requirement for staff to identify and report a potentially non-conforming product • clear identification of a non-conforming product (e.g. direct labelling or the use of IT systems) • secure storage to prevent accidental release (e.g. physical or computer-based isolation) • referral to the brand owner where required • defined responsibilities for decision making on the use or disposal of products appropriate to the issue (e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession) • records of the decision on the use or disposal of the product • records of destruction where a product is destroyed for food safety reasons.	**111.180** Records have been established and are being maintained to meet the requirements of Subpart G.	Exceeds	The preventive controls rule does not address non-conforming product, othe than requiring corrective actions if the is a deviation from a preventive contro which is a distinguishable process. The labelling and segregation of non-conforming product is not addressed other than stating that impacted produ would be prevented from entering commerce.

	3.9	Traceability			
14.A 1.The operation must have a documented traceability system that tracks products from the production site to the consumer distribution point. 2.The operation must be able to identify products by batch number in the production records. 3.The operation must document supplier inputs and materials used to produce each batch to the maximum extent feasible.	**FUNDAMENTAL Statement of Intent**	The site shall be able to trace all raw material product lots (including packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa.	**111.410d** Records are maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution.	Exceeds Comparable to another section of FSMA (Sec. 204)	The preventive control rule does not address the requirement to trace all ra material product lots (including packaging) from its suppliers through stages of processing and dispatch to customers and vice versa. FDA has already established traceability requirements under regulation stemming from the 2002 Bioterrorism Act, and traceability is a component of sec 204 FMSA which is separate from the Final Preventive Controls Rule. Preventive Control Rule requires a sit to develop a recall plan, but only for foods with a hazard requiring a preventive control.
	3.9.1	Identification of raw materials, including primary and any other relevant packaging, processing aids, intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.	**111.415e** Procedures have been established to identify unlabeled materials that will be held for future labeling operations.	Exceeds Comparable to another section of FSMA (Sec. 204)	Traceability is not covered by the Preventive Controls Rule.
	3.9.2	The site shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material including primary packaging to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency, as a minimum annually, and results shall be retained for inspection. Full traceability should be achievable within 4 hours.		Exceeds Comparable to another section of FSMA (Sec. 204)	Traceability is not covered by the Preventive Controls Rule.

	3.9.3	The company shall ensure that its suppliers of raw materials have an effective traceability system. Where a supplier has been approved based on a questionnaire, instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test. Where a raw material is received directly from a farm or fish farm, further verification of the farm's traceability system is not mandatory.		Exceeds Comparable to another section of FSMA (Sec. 204)	Traceability is not covered by the Preventive Controls Rule.
	3.9.4	Where rework or any reworking operation is performed, traceability shall be maintained.	**111.415e** Procedures have been established to identify unlabeled materials that will be held for future labeling operations.	Exceeds Comparable to another section of FSMA (Sec. 204)	Traceability is not covered by the Preventive Controls Rule.
	3.10	**Complaint handling**			
	Statement of Intent	Customer complaints shall be handled effectively and information used to reduce recurring complaint levels.		Exceeds	The preventive control rule does not address the requirements regarding th management of customer complaints.
14.D. 1. The operation must follow a documented complaints procedure to ensure all complaints are recorded, evaluated and followed up. 2.Procedure must include a defined timeline for response to complaints, persons responsible for complaint procedures and actions taken. 3.Procedure must indicate methods for resolution of complaints, including corrective action required in the production process. 4.The operation shall retain complaints records for two years; do not destroy complaints records related to open litigation or active product recall.	3.10.1	All complaints shall be recorded, investigated and the results of the investigation of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.	**111.553** Procedures have been established describing how product complaints will be received, investigated, and documented. **111.560a** All product complaints have been reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality. **111.560b** The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.	Exceeds	The preventive control rule does not address the requirements regarding th management of customer complaints however, the FSMA encourages revie of consumer complaints", even though a process is not defined within the Ru for doing so.

	3.10.2	Complaint data shall be analysed for significant trends. Where there has been a significant increase in a complaint or a serious complaint, root cause analysis shall be used to implement on going improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.	**111.560a** All product complaints have been reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality. **111.560b** The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.	Exceeds	The preventive control rule does not address the requirements regarding th management of customer complaints.

	3.11	Management of incidents, product withdrawal and product recall			
14.B Product Recall Program 1.The operation must have a documented Product Recall Program	**Statement of Intent**	The company shall have a plan and system in place to manage incidents effectively and enable the withdrawal and recall of products should this be required	§ 117.139 Recall Plan For food with a hazard requiring a preventive control: (a) You must establish a written recall plan for the food. (b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the food being recalled ,including how to return or dispose of the affected food; (2) Notify the public about any hazard presented by the food when appropriate to protect public health; (3) Conduct effectiveness checks to verify that the recall is carried out; and (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.	Comparable	
2.3A Crisis Management Plan 1.The operation must have a documented Crisis Management Plan that management reviews and updates annually	**3.11.1**	The company shall have documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality. This shall include consideration of contingency plans to maintain product safety, quality and legality. Incidents may include: • disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications events such as fire, flood or natural disaster malicious contamination or sabotage. Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products.		Exceeds	The Preventive Controls Rule does no address documented procedures to manage incidents and potential emergency situations that impact food legality or quality.

14.B Product Recall Program 1.The operation must have a documented Product Recall Program a. Depth of Distribution – Methods and support resources to rapidly analyze and determine the extent of distribution affected: consumer, retail, wholesale or a combination of channels. b.Recall Classification – Procedures that ensure appropriate and rapid assessment and classification of risk level and require the appropriate level and urgency of response (e.g., FDA Class I, II, III). c.Supply Chain Notification – Contact and tracking procedures that verify all consignees in the distribution chain, including related product suppliers, are notified and take appropriate action. d.Regulatory Notification – Procedures for communication with federal, state and local authorities, including the public health department, within 24 hours (sooner as required). e.Public Warning Process – Procedures to assess the need for an alert to the public that a product under recall presents a serious hazard to health. These warnings are reserved for urgent situations and typically involve collaboration with the FDA. F Recall Coordinator – A worker with the skills, training, job description and authority to effectively execute the requirements of the position including coordinating team training and mock tests and managing documentation and corrective action. g.Recall Team – Workers, suppliers, third-party professionals and others	**3.11.2**	The company shall have a documented product withdrawal and recall procedure. This shall include as a minimum: • identification of key personnel constituting the recall management team, with clearly identified responsibilities • guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained • an up-to-date list of key contacts (including out-of-hours contact details) or reference to the • location of such a list (e.g. recall management team, emergency services, suppliers, customers, certification body, regulatory authority) • a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner • details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authority and legal expertise) • a plan to handle the logistics of product traceability, recovery or disposal of affected product, and stock reconciliation. The procedure shall be capable of being operated at any time.	§ 117.139 Recall Plan For food with a hazard requiring a preventive control: (a) You must establish a written recall plan for the food. (b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; (2) Notify the public about any hazard presented by the food when appropriate to protect public health; (3) Conduct effectiveness checks to verify that the recall is carried out; and (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.	Comparable	

14.C Recall Mock Test 1.The operation must conduct a "mock recall" test:	**3.11.3**	The product recall and withdrawal procedures shall be tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary.	§ 117.139 Recall Plan For food with a hazard requiring a preventive control: (3) Conduct effectiveness checks to verify that the recall is carried out.	Exceeds	The Preventive Controls Rule does no specify a minimum frequency for effectiveness tests of the recall program.
	3.11.4	In the event of a product recall, the certification body issuing the current certificate for the site against this Standard shall be informed within 3 working days of the decision to issue a recall.		Not Applicable	
	3.12	**Customer Focus and Communication**			
	Statement of Intent	The company shall ensure that any customer-specific policies or requirements are understood, implemented and clearly communicated to relevant staff and, where appropriate, suppliers of raw materials, packaging and services.		Exceeds	The Preventive Control Rule does not address the requirement for the site to have a formal plan directing the focus and communication to customers.
2.B.b Analyzes markets and customer preferences	**3.12.1**	Where a company is requested to follow specific customer requirements, codes of practice, methods of working etc., these shall be made known to relevant staff within the site and implemented.		Exceeds	The Preventive Control Rule does not address the requirement for the site to have a formal plan directing the focus and communication to customers.
	3.12.2	Effective processes shall be in place for communicating customer-specific requirements to the suppliers of raw materials and services as applicable.		Exceeds	The Preventive Control Rule does not address the requirement for the site to have a formal plan directing the focus and communication to customers.

4. Site Standards					
	4.1	**External standards**			
	Statement of Intent	The production site shall be of suitable size, location and construction, and be maintained to reduce the risk of contamination and facilitate the production of safe and legal finished products.			
	4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes.		Exceeds	PREVENTIVE CONTROLS RULE do not address local activities and site environment.
17.F Written procedure must detail maintenance requirements for the external grounds, building exteriors, signage, parking areas, lighting, storage and trash areas, trash collection, litter clean up and general appearance.	**4.1.2**	The external areas shall be maintained in good order. Where buildings are surrounded by grassed or planted areas, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to avoid contamination of the product.	§117.20 Plant and Grounds **111.15a** Grounds have been properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc.	Comparable	The Preventive Control Rule addresse ground conditions and maintenance, covering equipment storage, litter, waste, weed and grass related to pes maintenance of roads, parking lo adequate drainage, waste treatment a adjacent land.
8.B Cleanability of Facility The operation's structures must be constructed of easily cleanable materials (non-porous) and maintained in good repair. All surfaces, such as roofs, ceilings, walls, floors, windows, vents, drains and overhead fixtures (e.g., pipes, air vents and lights) should be readily cleanable.	**4.1.3**	The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).	§117.35 Sanitary operations **111.15a5** Production Facility is maintained in a clean and sanitary condition and in a proper state of repair.	Comparable	The Preventive Control Rule does n specifically address exterior buildi fabric. However, potential pest ingre is covered under 117.35.

	4.2	Security			
	Statement of Intent	Security systems shall ensure that products are protected from theft or malicious contamination while under the control of the site.			
6.C Security Risk Assessment An annual Security Risk Assessment must review all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials, information).	4.2.1	The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements to reduce risks shall be implemented and reviewed at least annually.		Comparable	Food Defence and intentional contamination is outside the scope of Preventive Controls. It is addressed in separate Preventive Control Rule "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration." This proposed rule is expected to be finalized May 31 2016
6.1A Physical Barriers The operation must apply methods to prevent unauthorized access to buildings, production areas and products, shipping/receiving, storage and parking areas. **6.1D Facility Access Controls** The operation must have documented procedures to control access to the operation's facilities. Procedure should detail access for workers, contractors, managers and visitors including customers, inspectors, law enforcement and regulators.	4.2.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.		Exceeds	Preventive Controls do not address specific access controls to the site.
	4.2.3	External storage tanks, silos and any intake pipes with an external opening shall be locked.	§117.20	Comparable	Preventive Controls requires sites to take adequate precautions to protect food in outdoor bulk vessels. Does not specifically state that they must be locked.
	4.2.4	Where required by legislation, the site shall be registered with, or be approved by, the appropriate authority.		Comparable	USFDA requires all food facilities be licensed.

	4.3	**Layout, Product Flow and Segregation**			
	FUNDAMENTAL Statement of Intent	The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.			
7.G Production Flow Charts 1.The operation must document product-related processes using flow diagrams, process maps, procedures and checklists, etc., to ensure the production of safe, quality products that meet product specifications. 2.The operation layout must provide physical separation of production processes to ensure product quality. 3.Production flow should separate incoming material, staging	**4.3.1**	There shall be a map of the site which designates areas (zones) where product is at different levels of risk from contamination; that is: • high-risk areas • high-care areas • ambient high-care areas • low-risk areas • enclosed product areas • non-product areas. See Appendix 2 for guidelines on defining the production risk zones. This zoning shall be taken into account when determining the prerequisite programmes for the particular areas of the site.		Exceeds	Preventive Control Rule does not require a site map illustrating product risk zones.
	4.3.2	The site map(s) shall define: • access points for personnel • access points for raw materials (including packaging) • routes of movement for personnel • routes of movement for raw materials • routes for the removal of waste • routes for the movement of rework • location of any staff facilities including changing rooms, toilets, canteens and smoking areas • production process flow.		Exceeds	Preventive Control Rule does not require a site map.

	4.3.3	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination. Contractors working in product processing or storage areas shall be the responsibility of a nominated person.	**111.10** Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated. **117.10 Personnel** (a) *Disease control.*	Exceeds	No mention of visitors or contractors i the Preventive Controls Rule.
7.G 2.The operation layout must provide physical separation of production processes to ensure product quality. 3.Production flow should separate incoming material, staging, manufacturing, processing, finishing, packaging, inspection and storage functions to the maximum extent practical.	**4.3.4**	The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. The process flow, together with the use of demonstrably effective procedures, shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products.		Comparable	The Current GMPs (PREVENTIVE CONTROLS RULE) broadly address prevention of product contamination. They do not address the mechanism how this is to be achieved.
7.G 2.The operation layout must provide physical separation of production processes to ensure product quality.	**4.3.5**	Where high-risk areas are part of the manufacturing site, there shall be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (including drains). The location of transfer points shall not compromise the segregation between high-risk areas and other areas of the factory. Practices shall be in place to minimise risk of product contamination (e.g. the disinfection of materials on entry).	**111.20c1** Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, dietary supplements, packaging, and labels that will be used. **111.20c3** Areas have been provided to separate the manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements	Exceeds	Preventive Controls Rule does not ha requirements based upon defined risk zones as in BRC.
7.G 2.The operation layout must provide physical separation of production processes to ensure product quality.	**4.3.6**	Where high-care areas are part of the manufacturing site there should be physical segregation between these areas and other parts of the site. Segregation shall take into account the flow of product, nature of		Exceeds	PREVENTIVE CONTROLS RULE do not have requirements based upon defined risk zones as in BRC

		materials (including packaging), equipment, personnel, waste, airflow, air quality and utilities provision (including drains). Where physical barriers are not in place, the site shall have undertaken a documented risk assessment of the potential for cross-contamination, and effective, validated processes shall be in place to protect products from contamination.			
7.B Hazard Control Plan – HACCP The operation must develop and maintain an ongoing Hazard Control Plan to ensure product quality throughout the production process. **7.G** 2.The operation layout must provide physical separation of production processes to ensure product quality.	**4.3.7**	Where ambient high-care areas are required a documented risk assessment shall be completed to determine the risk of cross-contamination with pathogens. The risk assessment shall take into account the potential sources of microbiological contamination and include: • the raw materials and products • flow of raw materials, packaging, products, equipment, personnel and waste • airflow and air quality • utilities (including drains). Effective processes shall be in place to protect the final product from this contamination. These processes may include segregation, management of process flow or other controls.		Exceeds	Preventive Controls Rule does not ha requirements based upon defined risk zones as in BRC

8.C.1.e Adequate workspace must be available for all activities and processes.	4.3.8	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions.	**111.20a** All facilities are of adequate size, construction, and design for their intended use. **111.20b** There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding. **111.20c3** Areas have been provided to separate the manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements	Exceeds	The Current GMPs (Preventive Controls Rule) broadly address prevention of product contamination. They do not have a requirement for sufficient working space and storage capacity.
	4.3.9	Temporary structures constructed during building work or refurbishment etc. shall be designed and located to avoid pest harbourage and ensure the safety and quality of products.		Exceeds	The Current GMPs (Preventive Controls Rule) broadly address prevention of product contamination. There is no mention of temporary structures.
	4.4	**Building fabric Raw material handling, preparation, processing, packing and storage areas**			
	Statement of Intent	The fabrication of the site, buildings and facilities shall be suitable for the intended purpose.	§117.20 **111.20a** All facilities are of adequate size, construction, and design for their intended use.	The BRC Requirements 4.4.1 – 4.4.13 exceed the Current GMPs (Preventive Controls Rule)	Preventive Controls Rule covers Plan construction and design that includes equipment storage, allergen cross contact, protection of outdoor bulk vessels, floors, walls and ceilings to b kept clean, condensate control, adequate and shatter proof lighting, adequate ventilation – dust, odors, vapors, allergen cross contact. The BRC Requirements 4.4.1 – 4.4.1 are broadly addressed in the Current GMPs (Preventive Controls Rule)
8.B Cleanability of Facility The operation's structures must be constructed of easily cleanable materials (non-porous) and maintained in good repair. All surfaces, such as roofs, ceilings, walls, floors, windows, vents, drains and overhead fixtures (e.g., pipes, air vents and lights) should be readily cleanable.	4.4.1	Walls shall be finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	**111.20d1i** Walls, floors, ceilings can be adequately cleaned and kept in good repair. 117.20.4 Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact		

	4.4.2	Floors shall be suitably hard wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious, be maintained in good repair and facilitate cleaning.	§117.20 **111.20** **110.20**		
17.B Plumbing Contamination Sewer and water pipes must be placed to avoid possible contamination of product or equipment in the event of a leak or dripping condensation. Preventative measures should be documented and implemented as applicable.	4.4.3	Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety. Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage.	117.20 **111.20** **110.20**		
	4.4.4	Where sites include high-risk or high-care facilities, there shall be a map of the drains for these areas which shows the direction of flow and location of any equipment fitted to prevent the back-up of waste water. The flow of drains shall not present a risk of contamination of the high-risk/care area.	117.20 **111.20** **110.20**		
8.B Cleanability of Facility The operation's structures must be constructed of easily cleanable materials (non-porous) and maintained in good repair. All surfaces, such as roofs, ceilings, walls, floors, windows, vents, drains and overhead fixtures (e.g., pipes, air vents and lights) should be readily cleanable.	4.4.5	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.	117.20 **111.20** **110.20**		
	4.4.6	Where suspended ceilings or roof voids are present, adequate access to the void shall be provided to facilitate inspection for pest activity, unless the void is fully sealed.	117.20 **111.20** **110.20**		

8.B Cleanability of Facility The operation's structures must be constructed of easily cleanable materials (non-porous) and maintained in good repair. All surfaces, such as roofs, ceilings, walls, floors, windows, vents, drains and overhead fixtures (e.g., pipes, air vents and lights) should be readily cleanable.	**4.4.7**	Where there is a risk to product, windows, and roof glazing which is designed to be opened for ventilation purposes, shall be adequately screened to prevent the ingress of pests.	117.20 **111.20** **110.20**		

	4.4.8	Where they pose a risk to product, glass windows shall be protected against breakage.	117.20 **111.20** **110.20**		
	4.4.9	**Doors** shall be maintained in good condition: • External doors and dock levellers shall be close fitting or adequately proofed. • External doors to open product areas shall not be opened during production periods except in emergencies. Where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.	117.20 **111.20** **110.20**		
8.A Environmental Controls The operation must maintain appropriate lighting, ventilation, air quality (viable and non-viable airborne contaminants), temperature, pressure and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing and storage.	**4.4.10**	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.	117.20 **111.20** **110.20**		
7.K.2.c Contaminants include insects or insect parts, feathers, fingernails, cosmetics, jewelry, hair, feces, mold, decomposition or visible growth, visible adulterants, lubricants, glass shards from glassware or lighting, metal shavings from equipment, staples, plastic, wood splinters, stones, sand and foreign plant parts	**4.4.11**	Where they constitute a risk to product, bulbs and strip lights – including those on electric fly-killer devices – shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place.	117.20 **111.20** **110.20**		

8.A Environmental Controls The operation must maintain appropriate lighting, ventilation, air quality (viable and non-viable airborne contaminants), temperature, pressure and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing and storage.	4.4.12	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.	117.20 **111.20** **110.20**		
17.C Ventilation and Exhaust Fans Ventilation equipment and fans must maintain safe air quality and vent and/or filter any noxious odors or dangerous airborne contaminants. Air quality standards must meet worker safety requirements and product quality specifications (see 8.A Environmental Controls).	4.4.13	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas.	117.20 **111.20** **110.20**		

	4.5	Utilities – water, ice, air and other gases			
	Statement of Intent	Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.			

20.D Drinking Water 1. Adequate potable water must be available to ensure clean, safe water for production, sanitation and worker consumption. **10.B Water Use Risk Assessment** The operation must complete a water use risk assessment at start up and every five years at a minimum or when any material change (substantive enough to require changes to standard operating procedures) is made to the Water Use Plan. Retain assessment documents for two years. The risk assessment should document: Pollution from chemicals, lubricants and solvents Inflow, outflow, flood risk Risk of untreated water contamination d.Alternate water sources e.Potential environmental damage or pollution from water sourcing or discharge **10.C Water Quality Analysis** 1. The operation must analyze water quality at the frequency defined in the Water Use Plan (annual testing recommended unless conditions require more) and retain records for at least two years.. 2. The operation uses laboratory performing water analyses certified to ISO 17025 level or equivalent standard.	**4.5.1**	All water used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points, scope of the test and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.	§117.37 & §117.80 **111.15e, 111.15f3, 111.23** **110.37**	Exceeds	Preventive Controls Rule requires tha water and ice used in the production o food must be safe and of adequate sanitary quality. Preventive Controls Rule does not require microbiological or chemical testing of water annually.

	4.5.2	An up-to-date schematic diagram shall be available of the water distribution system on site, including holding tanks, water treatment and water recycling as appropriate. The diagram shall be used as a basis for water sampling and the management of water quality.		Exceeds	Preventive Controls Rule does not require a water distribution schematic diagram.

	4.5.3	Where legislation specifically permits the use of water which may not be potable for initial product cleaning (e.g. for the storage/washing of fish), the water shall meet the designated legal requirements for this operation.	§117.37 & §117.80	Does not Meet	Preventive Controls Rule requires tha water and ice used in the production o food must be safe and of adequate sanitary quality.
	4.5.4	Air, other gases and steam used directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.	§117.40 **111.27a7** Process gases that are used and contact dietary supplements, components, and contact surfaces must be controlled so as not to cause contamination (e.g. filters).	Comparable	Preventive Controls Rule requires tha air and other gases used in food production must be treated so as to n contaminate food.
	4.6	**Equipment**			
	Statement of Intent	All food-processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.	117.40	BRC requirements 4.6.1 and 4.6.2 exceed Preventive Controls Rule section 117.40.	The Current GMPs (Preventive Controls Rule) require that equipment be designed to be cleanable and constructed of non-toxic material. BRC requirements 4.6.1 and 4.6.2 ar addressed in Preventive Controls Rul section 117.40.

9.B Equipment Design 1.Equipment must be constructed of materials appropriate for the intended purpose, preclude contamination of products and promote sanitation.	4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.	117.40 **111.27** **110.40**		
	4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.	117.40 **111.27** **110.40**		

	4.7	**Maintenance**			
	Statement of Intent	An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.	117.53	BRC requirements 4.7.1 – 4.7.7 exceed the PREVENTIVE CONTROLS RULE section 117.35.	The Current GMPs (Preventive Controls Rule) require the site to maintain building structures and equipment in a clean state and in adequate repair. BRC requirements are addressed in PREVENTIVE CONTROLS RULES section 117.53. PREVENTIVE CONTROLS RULE do not provide detail concerning, maintenance programs and their implementation as required in the BR standard.

9.A Equipment Management 1. All production equipment must be documented on a Master Equipment List that identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools.	**4.7.1**	There shall be a documented planned maintenance schedule or condition monitoring system which includes all plant and processing equipment. The maintenance requirements shall be defined when commissioning new equipment.	111.35		
7.N Production Records 1.The operation must maintain accurate production records for each batch (or lot) of product it produces. a.Production records include pre-production inspections, process monitoring records, critical control point records, control limit records, deviation logs and corrective action reports.	**4.7.2**	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken	111.30		
	4.7.3	Where temporary repairs are made, these shall be controlled to ensure the safety or legality of a product is not jeopardised. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale.			

	4.7.4	The site shall ensure that the safety or legality of product is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment.			
19.I Product Protection During Cleaning Raw materials, work-in-process, finished goods and packaging materials must be removed from the area during cleaning. “Cleaning” includes cleaning production lines between product runs, sanitizing equipment surfaces and general cleaning of fixtures, floors, walls, tables, doors, etc., in the work area	4.7.5	Maintenance activities undertaken in high-risk and high-care areas shall respect the segregation requirements of the area. Wherever possible tools and equipment shall be dedicated for use in the area and be retained in the area.			
	4.7.6	Materials used for equipment and plant maintenance and that pose a risk by direct or indirect contact with raw materials, intermediate and finished products, such as lubricating oil, shall be food grade and of a known allergen status.			
	4.7.7	Engineering workshops shall be kept clean and tidy and controls shall be in place to prevent transfer of engineering debris to production or storage areas.			

	4.8	**Staff facilities**			
	Statement of Intent	Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. The facilities shall be maintained in good and clean condition.			
20.E Changing Area If the operation requires protective gowns and other protective clothing in production areas: Workers must have a clean, organized location for gowning and changing clothes.	4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).	**111.10** Appropriate change rooms are available if needed and there is adequate storage of personal effects.	Exceeds	The Final Preventive Controls Rule makes no per se mention of change rooms or showers. This section of the Final Preventive Controls Rule implies that employees are changing from street clothes but does not explicitly state as such. The Final Rule does not mention visitors.
20.E.1.b The operation shall provide lockers for storage of personal clothes, jewelry and other items	4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.	**111.10** Appropriate change rooms are available if needed and there is adequate storage of personal effects.	Exceeds	The Final Preventive Controls Rule makes no per se mention of change rooms or showers. This section of the Final Preventive Controls Rule implies that employees are changing from street clothes but does not explicitly state as such. The Final Rule does no mention visitors.
	4.8.3	Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing.		Exceeds	PREVENTIVE CONTROLS RULES does not address the storage of outdoor clothing or personal items.

	4.8.4,5	Where an operation includes a high-risk area, personnel shall enter via a specially designated changing facility at the entrance to the high-risk area. The changing facilities shall meet the following requirements: • Clear instructions shall be provided for the order of changing into and out of dedicated protective clothes to prevent the contamination of clean clothing. • Protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside the high-risk area. • Hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing (i.e. hand-washing after hair covering and footwear has been put on, but before handling clean protective clothing). • Prior to entry to high-risk areas, hand-washing and disinfection shall be provided and used. • Dedicated footwear shall be provided to be worn in the high-risk area with an effective system to segregate areas for wearing high-risk and other footwear (i.e. a barrier or bench system). By exception the use of boot-wash facilities is accepted where these demonstrably provide an effective control of footwear to prevent the introduction of pathogenic material into high-risk areas. A programme of environmental monitoring shall be established to assess the effectiveness of footwear controls.		Exceeds	PREVENTIVE CONTROLS RULE do not have requirements based upon defined risk zones as in BRC

20.A Toilet and Hand Washing Facilities 1. The operation must provide clean, modern toilets with hand-washing sinks and maintain them in a clean and sanitized condition.	4.8.6	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide as a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.	§117.37 **111.15i** Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing of personnel. **110.37** *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.	Exceeds	PREVENTIVE CONTROLS RULE requires the site to provide adequate hand washing facilities for employees PREVENTIVE CONTROLS RULE do not specify the detailed design and requirements of hand washing station as in BRC.
20.A.2 Toilet facilities should be in an area separate from all processing areas or far enough away so as not to pose a risk to processing. Doors should not open directly into production or storage areas. 20.A.7 Signage must be in place to remind workers to wash/sanitize hands.	4.8.7	Toilets shall be adequately segregated and shall not open directly into production or packing areas. Toilets shall be provided with hand-washing facilities comprising: • basins with soap and water at a suitable temperature • adequate hand-drying facilities • advisory signs to prompt hand-washing. Where hand-washing facilities within toilet facilities are the only facilities provided before re-entering production, the requirements of clause 4.8.6 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production.	§117.37 **111.15h** Bathrooms are provided and are of adequate number and location. 110.037 *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:	Exceeds	PREVENTIVE CONTROLS RULE requires the site to provide adequate toilet for employees. PREVENTIVE CONTROLS RULE do not specify the detailed design and requirements of toilet facilities as in BRC.

4.G Smoking and Tobacco Products Smoking, vaporizing (including e-cigarettes) and the use of oral tobacco products are prohibited in all production, storage and work areas and any area not specifically designated as a smoking area.	**4.8.8**	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.	§117.10 **111.10** Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources. 110.10 (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco	Comparable	PREVENTIVE CONTROLS RULE requires the site to confine smoking to areas away from food production.
4.F Eating and Drinking Written procedures must prohibit employees from eating, drinking, gum chewing and spitting in product handling areas. Closed containers of clearly marked drinking water kept separate from production materials are acceptable if documented in facility procedures and enforced.	**4.8.9**	All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste.	§117.10 **111.10** Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources. 110.10 (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco	Comparable	PREVENTIVE CONTROLS RULE requires the site to confine eating and storage employee lunches to areas away from food production.
	4.8.10	Where catering facilities are provided on the premises, they shall be suitably controlled to prevent contamination of products (e.g. as a source of food poisoning or introduction of allergenic material to the site).		Exceeds	PREVENTIVE CONTROLS RULE do not address catering facilities.

	4.9	**Chemical and physical product contamination control , Raw material handling, preparation, processing, packing and storage areas**			
	Statement of Intent	Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product.			
	4.9.1	**Chemical control**			
	4.9.1.1	Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include as a minimum: • an approved list of chemicals for purchase • availability of material safety data sheets and specifications • confirmation of suitability for use in a food-processing environment • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times a designated storage area with restricted access to authorised personnel use by trained personnel only.	§ Sanitary operations.117.35(b) (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food packaging materials. **111.15c3** Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been identified, used, and held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials. 110.10 (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin	Comparable	
	4.9.1.2	Where strongly scented or taint-forming materials have to be used, for instance for building work, procedures shall be in place to prevent the risk of taint contamination of products.		Exceeds	PREVENTIVE CONTROLS RULE do not address strongly scented or taint forming materials.

	4.9.2	**Metal control**			
7.K Control of Contaminants The operation shall identify and implement appropriate control systems and devices such as visual inspection, metal detectors, magnets, traps, sieves, filters, screens and x-ray screeners designed to prevent, collect or detect contaminants in raw materials, work-in-process and finished goods.	**4.9.2.1**	There shall be a documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. This shall include a record of inspection for damage and the investigation of any lost items. Snap-off-blade knives shall not be used.	§117.40 **111.27a2** Equipment and utensils are of appropriate design so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. 110.40 (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.	Exceeds	PREVENTIVE CONTROLS RULE requires that the design, construction, and use of utensils must preclude the adulteration of food with metal. PREVENTIVE CONTROLS RULE do specify that a record of inspection for damage or lost items be implemented
	4.9.2.2	The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided. Staples, paper clips and drawing pins shall not be used in open product areas. Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.		Exceeds	PREVENTIVE CONTROLS RULE do not address the controls of foreign bo hazards (staples, paper clips, etc).
	4.9.3	**Glass, brittle plastic, ceramics and similar materials**			
9.B.2.C Equipment Design: 2.The following types of equipment and materials are not recommended: a.Corrosive metals (iron, unfinished steel) b.Glass (unless accompanied by product controls and safety training) c.Brittle plastic	**4.9.3.1**	Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination.	§117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. §117.130(c)(2)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is	Comparable	Preventive Controls Rule does not contain specific requirements for / against the use of temporary fastener wood pallets, glass inspections etc.

			reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.		
7.K.3 Procedures must identify worker actions if glass breakage occurs or if glass or brittle plastic is detected in production or storage areas	**4.9.3.2**	Documented procedures for handling glass and other brittle materials (other than product packaging) shall be in place where open products are handled or there is a risk of product contamination. These procedures shall include as a minimum: • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination.	§ 117.30 § 117.80 Processes and controls. (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.	Comparable	PREVENTIVE CONTROLS RULE do not require documented procedures f glass or brittle plastic unless it is identified by the Hazard Analysis as requiring a preventive control.
7.K.3 Procedures must identify worker actions if glass breakage occurs or if glass or brittle plastic is detected in production or storage areas	**4.9.3.3**	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • specifying those staff authorised to carry out the above points • recording the breakage incident.		Exceeds	PREVENTIVE CONTROLS RULE do not specify cleaning procedures for broken.

	4.9.4	**Products packed into glass or other brittle containers**			
	4.9.4.1	The storage of the containers shall be segregated from the storage of raw materials, product or other packaging.		Exceeds	PREVENTIVE CONTROLS RULE do not address the segregated storage o glass and brittle plastic containers.
	4.9.3.4.2	Systems shall be in place to manage container breakages between the container cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure: • the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line • the effective cleaning of the line or equipment which may be contaminated by fragments of the container; cleaning shall not result in the further dispersal of fragments, for instance by the use of • high pressure water or air • the use of dedicated, clearly identifiable cleaning equipment (e.g. colour coded) for removal of • container breakages; such equipment shall be stored separately from other cleaning equipment • the use of dedicated, accessible, lidded waste containers for the collection of damaged containers and fragments • a documented inspection of production equipment is undertaken following the cleaning of a breakage to ensure cleaning has effectively removed any risk of further contamination. • Authorisation is given for production to restart following cleaning the area around the line is kept clear of broken glass.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address systems be implemented to manage container breakages.

	4.9.3.4.3	Records shall be maintained of all container breakages on the line. Where no breakages have occurred during a production period, this shall also be recorded. This record shall be reviewed to identify trends and potential line or container improvements.		Exceeds	PREVENTIVE CONTROLS RULE do not specify that records be generated and maintained where container breakage occurs during production. These type of events would be recorded under Corrective Action requirements.
	4.9.5	**Wood**			
	4.9.5.1	Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, the condition of wood shall be continually monitored to ensure it is in good condition and free from damage or splinters which could contaminate products.		Exceeds	Preventive Controls Rule does not contain specific requirements for / against the use of wood pallets.
	4.10	**Foreign body detection and removal equipment**			
	Statement of Intent	The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies.	**111.365h,I** Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection. **111.365a-g** Precautions have been taken to prevent contamination, such as micro, filth, chemical, foreign material, etc., throughout the manufacturing process. 110.80 (8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means	Exceeds	The BRC standard contains more information and detailed requirements on foreign body detection and controls The Preventive Controls Rule addresses foreign material prevention through the hazard analysis and the establishment of preventive controls. foreign material is a risk that is identified in a company's hazard analysis requiring a preventive contro monitoring and record keeping should be put in place to control for that risk.

	4.10.1	**Foreign body detection and removal equipment**			
7.K Control of Contaminants During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people. The operation shall identify and implement appropriate control systems and devices such as visual inspection, metal detectors, magnets, traps, sieves, filters, screens and x-ray screeners designed to prevent, collect or detect contaminants in raw materials, work-in-process and finished goods.	**4.10.1.1**	A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination. Typical equipment to be considered may include: • filters • sieves • metal detection • magnets • optical sorting equipment • X-ray detection equipment • other physical separation equipment (e.g. gravity separation, fluid bed technology).	§ 117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. §117.130(c)(2)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.	Comparable	
7.K Control of Contaminants During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people. The operation shall identify and implement appropriate control systems and devices such as visual inspection, metal detectors, magnets, traps, sieves, filters, screens and x-ray screeners designed to prevent, collect or detect contaminants in raw materials, work-in-process and finished goods.	**4.10.1.2**	The type, location and sensitivity of the detection and/or removal method shall be specified as part of the site's documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or the packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified.	§117.130(c)(2)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate. § 117.160 would require that the preventive controls be adequate to control the hazard as appropriate to the nature of the preventive control and its purpose in the food safety plan. The preventive control would be required to be validated as effective in controlling the hazard.	Comparable	
	4.10.1.3	The site shall ensure that the frequency of the testing of the foreign-body detection and/or removal	§ 117.145 would require that monitoring procedures be written and performed at a frequency to provide assurance that the preventive controls are applied consistently.	Comparable	

		equipment is defined and takes into consideration: • specific customer requirements • the site's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.	§ 117.150 would require that corrective actions be written and to be taken if preventive controls are not properly implemented in controlling the hazard including evaluate all impacted food and prevent affected food from entering commerce.		
	4.10.1.4	Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and where possible instigate preventive action to reduce the occurrence of contamination by the foreign material.	§ 117.150 would require that corrective actions be written and describe the actions taken to identify and correct the problem, reduce the likelihood the problem reoccurring	Comparable	
	4.10.2	**Filters and sieves**			
	4.10.2.1	Filters and sieves used for foreign-body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product. Material retained or removed by the system shall be examined and recorded to identify contamination risks.	As indicated above the Final Preventive Controls Rule would establish a system that would provide assurance that hazards identified in the hazard analysis would be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility would not be adulterated. Thus, if foreign material is a risk that is identified in a company's hazard analysis as requiring a preventive control then preventive controls, monitoring and record keeping should be put in place to control that risk.	Comparable	The PREVENTIVE CONTROLS RUL does not provide the detail regarding sieves and filters that is described in the BRC Standard.
	4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified this shall be recorded and the potential for contamination of products investigated and appropriate action taken.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address requirements for inspection and maintenance of filte and sieves.

	4.10.3	**Metal detectors and X-ray equipment**			
	4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective method of protection (e.g. use of X-ray, fine sieves or filtration of products).	§ 117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. §117.130(c)(2)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.	Comparable	
	4.10.3.2	The metal detector or X-ray equipment shall incorporate one of the following: • an automatic rejection device, for continuous in-line systems, which shall either divert contaminated product out of the product flow or to a secure unit accessible only to authorised personnel • a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs) • in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address technical operating parameters for metal detectors or X-ray equipment.
	4.10.3.3	The site shall establish and implement documented procedures for the operation and testing of the metal detection or X-ray equipment. This shall include as a minimum:	§ 117.155 would require that the preventive controls be verified to assure the controls are implemented and effective. § 117.160 would require that the preventive controls be adequate to control the hazard as appropriate to the	Comparable	

		• responsibilities for the testing of equipment • the operating effectiveness and sensitivity of the equipment and any variation to this for particular products • the methods and frequency of checking the detector recording of the results of checks.	nature of the preventive control and its purpose in the food safety plan. The preventive control would be required to be validated as effective in controlling the hazard.		
	4.10.3.4	Metal detector checking procedures shall be based on good practice and shall as a minimum include the following: • Use of test pieces incorporating a sphere of metal of a known diameter selected on the basis of risk. • The test pieces shall be marked with the size and type of test material contained. • Tests carried out using separate test pieces containing ferrous metal, stainless steel and typically non-ferrous metal, unless the product is within a foil container where ferrous only may be applicable. • A test that both the detection and rejection mechanisms are working effectively under normal working conditions. • Checks that test the memory/reset function of the metal detector by passing successive test packs through the unit at typical line operating speed. • Checks of failsafe systems fitted to the detection and rejection systems. In addition, where metal detectors are incorporated on conveyors, the test piece shall be passed as close as possible to the	§ 117.145 would require that monitoring procedures be written and performed at a frequency to provide assurance that the preventive controls are applied consistently.	Comparable	

		centre of the metal detector aperture and wherever possible be carried out by inserting the test piece within a clearly identified sample pack of the food being produced at the time of the test. Where in-line metal detectors are used the test piece shall be placed in the product flow wherever this is possible and the correct timing of the rejection system to remove identified contamination shall be validated.			
	4.10.3.5	The site shall establish and implement corrective action and reporting procedures in the event of the testing procedure identifying any failure of the foreign-body detector. Action shall include a combination of isolation, quarantining and re-inspection of all product produced since the last successful test.	§ 117.150 would require that corrective actions be written and to be taken if preventive controls are not properly implemented in controlling the hazard including evaluate all impacted food and prevent affected food from entering commerce.	Comparable	
	4.10.4	**Magnets**			
	4.10.4.1	The type, location and strength of magnets shall be fully documented. Documented procedures shall be in place for the inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address technical operating parameters nor maintenanc and inspection requirements for magnets.
	4.10.5	**Optical sorting equipment**			
	4.10.5.1	Each unit shall be checked in accordance with the manufacturer's instructions or recommendations. Checks shall be documented.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address technical operating parameters for magnets.

	4.10.6	**Container cleanliness – glass jars, cans and other rigid containers**			
9.E Product Containers Buckets, bins, trays, tubs, racks, sinks, etc., used to process or store product or ingredients must be food grade and kept clean and sanitized at all times; cleaning must be logged and logs retained for two years.	**4.10.6.1**	Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating with the packaging container (e.g. jars, cans and other pre-formed rigid containers). This may include the use of covered conveyors, container inversion and foreign-body removal through rinsing with water or air jets.	§ 117.130(b) (3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food.	Comparable	
	4.10.6.2	The effectiveness of the container cleaning equipment shall be checked and recorded during each production. Where the system incorporates a rejection system for dirty or damaged containers, the check shall incorporate a test of both the detection and effective rejection of the test container.	§ 117.155 would require that the preventive controls be verified to assure the controls are implemented and effective.	Comparable	
	4.11	**Housekeeping and hygiene**			
	FUNDAMENTAL Statement of Intent	Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised.			
	4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.	§ 117.35 Sanitary operations - (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against	Comparable	

			contamination of food, food contact surfaces, or food-packaging materials.		
19.A.2 Operation must have written sanitation and cleaning procedures for all equipment and areas.	**4.11.2**	Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. Cleaning procedures for processing equipment, food contact surfaces and environmental cleaning in high-care/high-risk areas shall as a minimum include the: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records and responsibility for verification. The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved	§117.35(b)(1), requires that both cleaning compounds and sanitizing agents be safe and adequate under the conditions of use. Final Rule § 117.35(d), requires that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food. Final Rule § 117.35(d)(2) would require in wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces be cleaned and sanitized before use and after any interruption during which the food- contact surfaces may have become contaminated. § 117.35(e); non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials. § 117.80 (c)(1) Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning. Final Rule 117.135 (3) (c) requires that sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Final Rule § 117.80(c)(1), which would require that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. § 117.40 is very specific to the construction of the equipment, § 117.35(d)(1) & (2) are specific on wet and dry cleaning to address potential allergen or microbial contamination.	Exceeds	PREVENTIVE CONTROLS RULE do not have requirements based upon defined risk zones as in BRC.

			Final Rule § 117.135(3)(i) & (ii) would require that sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. Sanitation controls. Sanitation controls must include procedures, practices and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the: (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; (ii) Prevention of allergen cross contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product, such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. **111.415a** Procedures have been established for cleaning and sanitizing all filling and packaging equipment and utensils. **111.16** Procedures have been established for cleaning of the plant. **111.23** Records have been maintained for plant cleaning, pest control, and water quality (where required) and in accordance with Subpart P **111.25c** Procedures have been established for the cleaning and sanitization of all utensils and equipment. **111.35b1iii** Procedures for maintenance, cleaning, sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation are maintained. 110.80.13.ii Adequate cleaning and sanitizing of all food-contact surfaces and food containers **110.80.7.b.2** Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning		

	4.11.3	As a minimum for food contact surfaces, processing equipment and for environmental cleaning in high-care/high-risk areas, limits of acceptable and unacceptable cleaning performance shall be defined. This shall be based on the potential hazards (e.g. microbiological, allergen, foreign-body contamination or product-to-product contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques (see glossary), microbiological testing or chemical testing as appropriate. Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard the cleaning and disinfection procedures and frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.	§ 117.155 would require that the preventive controls be verified to assure the controls are implemented and effective. § 117.160 would require that the preventive controls be adequate to control the hazard as appropriate to the nature of the preventive control and its purpose in the food safety plan. The preventive control would be required to be validated as effective in controlling the hazard **111.27d1** Equipment, utensils, etc. must be disassembled as necessary to assure maintenance, cleaning, and sanitization. **110.80.7.b.2** Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning **111.30d** Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use.	Exceeds	PREVENTIVE CONTROLS RULE do have environmental monitoring requirements but they are not specific to defined risk zones as in BRC.

	4.11.4	The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning.	§ 117.155 would require that the preventive controls be verified to assure the controls are implemented and effective. § 117.160 would require that the preventive controls be adequate to control the hazard as appropriate to the nature of the preventive control and its purpose in the food safety plan. The preventive control would be required to be validated as effective in controlling the hazard.	Exceeds	PREVENTIVE CONTROLS RULE does not specifically address resources, scheduling and training and dismantling equipment for cleaning in place (CIP).
	4.11.5	The cleanliness of equipment shall be checked before equipment is released back into production. The results of checks on cleaning, including visual, analytical and microbiological checks, shall be recorded and used to identify trends in cleaning performance and instigate improvements where required.	§ 117.155 would require that the preventive controls be verified to assure the controls are implemented and effective. § 117.160 would require that the preventive controls be adequate to control the hazard as appropriate to the nature of the preventive control and its purpose in the food safety plan. The preventive control would be required to be validated as effective in controlling the hazard. **111.30d** Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use.	Exceeds	
	4.11.6	Cleaning equipment shall be: • hygienically designed and fit for purpose • suitably identified for intended use (e.g. colour coded or labelled) • cleaned and stored in a hygienic manner to prevent contamination.	§117.35(b)(1), requires that both cleaning compounds and sanitizing agents be safe and adequate under the conditions of use. 117.135(c)(3) Sanitation controls. Sanitation controls include procedures, practices and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the	Exceeds	PREVENTIVE CONTROLS RULE does not have requirements based upon defined risk zones (high-care and high-risk) as in BRC.

		Equipment used for cleaning in high-care and high-risk areas shall be visually distinctive and dedicated for use in that area.	facility and the food, procedures, practices, and processes for the: (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; (ii) Prevention of allergen cross contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards		
	4.11.7	**Cleaning in place (CIP)**			
	4.11.7.1	Cleaning-in-place (CIP) facilities, where used, shall be monitored and maintained to ensure their effective operation.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address CIP Facilities
	4.11.7.2	A schematic diagram of the layout of the CIP system including process piping circuits shall be available. There shall be an inspection report or other validation that: • systems are hygienically designed with no dead areas, limited interruptions to flow streams and good system drain ability • scavenge/return pumps are operated to ensure that there is no build-up of CIP solutions in the vessels • spray balls and rotating spray devices effectively clean vessels by providing full surface coverage and are periodically inspected for blockages • CIP equipment has adequate separation from active product lines (e.g. through the use of double seat valves, manually controlled links, blanks in pipework or make-or-break connections with proxy		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address CIP Facilities

		switches as interlocks) to prevent or safeguard against cross-contamination. • The system shall be revalidated following alterations or additions to the CIP equipment. A log of changes to the CIP system shall be maintained.			
	4.11.7.3	The CIP equipment shall be operated to ensure effective cleaning is carried out: • The process parameters, time, detergent concentrations, flow rate and temperatures shall be defined to ensure removal of the appropriate target hazard (e.g. soil, allergens, vegetative micro- • organisms, spores). This shall be validated and records of the validation maintained. • Detergent concentrations shall be checked routinely. • CIP process verification shall be undertaken by analysis of rinse waters and/or first product through the line for the presence of cleaning fluids or by tests of ATP (bioluminescence techniques), allergens or micro-organisms as appropriate. • Detergent tanks shall be kept stocked up and a log maintained of when these are drained, cleaned, filled and emptied. Recovered post-rinse solutions shall be monitored for a build-up of carry-over from the detergent tanks. • Filters, where fitted, shall be cleaned and inspected at a defined frequency.		Exceeds	PREVENTIVE CONTROLS RULE do not specifically address CIP Facilities

	4.12	**Waste/waste disposal**			
	Statement of Intent	Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.	§117.20 (a) (4) requires operating systems for waste treatment and disposal so that they do not present a source of contamination. §117.37 (f) requires that rubbish and any offal be conveyed, stored and disposed of to minimize odour or becoming an attractant or harbourage of pests and to protect against contamination. **111.15a4** Waste treatment and disposal is adequate and does not provide a source of potential contamination. **111.15j2,3** Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc. **111.15j4** Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. **110.37** *Rubbish and offal disposal*. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces	Comparable	

11.4D Waste Solvent Disposal 1. The operation must safely handle, store and dispose of all flammable solvents, flammable materials, chemicals and waste in accordance with all applicable laws and regulations.	4.12.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail regarding waste disposal as is found in the BRC Standard.
21.E Waste Container Control All inside and external areas where waste collection containers are located must be well maintained and clean. 2.If required by security procedures, external waste containers must be locked. 3.Waste must be removed daily or more often if necessary to prevent overflowing containers. 4.All waste canisters, dumpsters, etc., should be equipped with easily closable lids	4.12.2	External waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be: • clearly identified • designed for ease of use and effective cleaning • well maintained to allow cleaning and, where required, disinfection • emptied at appropriate frequencies • covered or doors kept closed as appropriate.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail regarding waste disposal as is found in the BRC Standard.
	4.12.3	If unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in secure product or waste disposal and shall provide records which include the quantity of waste collected for destruction or disposal.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail regarding waste disposal as is found in the BRC Standard.

	4.13	Management of Surplus Food and Products for Animal Feed			
	Statement of Intent	Effective processes shall be in place to ensure the safety and legality of by-products of the primary processing activity of the site.			
	4.13.1	Surplus customer-branded products shall be disposed of in accordance with customer-specific requirements. Customer brand names shall be removed from packed surplus products under the control of the factory before the product enters the supply chain unless authorised otherwise by the customer.		Exceeds	PREVENTIVE CONTROLS RULE do not provide specific requirements for the site to manage surplus customer-branded products.
	4.13.2	Where customer-branded products which do not meet specification are sold to staff or passed on to charities or other organisations this shall be with the prior consent of the brand owner. Processes shall be in place to ensure that all products are fit for consumption and meet legal requirements.		Exceeds	PREVENTIVE CONTROLS RULE do not provide specific requirements for the site to manage surplus customer-branded products.
	4.13.3	By-products and downgraded/surplus products intended for animal feed shall be segregated from waste and protected from contamination during storage. Products for animal feed shall be managed in accordance with relevant legislative requirements.	§117.95 require that food-by products held for distribution as animal food without further processing by the human food processor must be held in conditions to prevent contamination.	Exceeds	PREVENTIVE CONTROLS RULE do not address requirements for the site manage surplus customer-branded products
	4.14	Pest control			
18.A Pest Management Plan 1.The operation must develop and implement a pest management plan to protect products, production areas, storage areas, packaging, equipment and supplies from pests and disease, discourage pest populations and prevent disease.	**Statement of Intent**	The whole site shall have an effective preventive pest control programme in place to minimise the risk of infestation and there shall be the resources available to respond rapidly to any issues which occur to prevent risk to products.	§117.35 (c) Pest control. Pests must not be allowed in any area of a food plant. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect	Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.

			against the contamination of food, food-contact surfaces, and food-packaging materials. **111.15d1,2** Procedures have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc **111.15d3** Pest control procedures have been established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc. 110.20.7 Provide, where necessary, adequate screening or other protection against pests 110.35.2.c *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials		
	4.14.1	If pest activity is identified it shall not present a risk of contamination to products, raw materials or packaging. The presence of any infestation on site shall be identified in pest control records and be part of an effective pest management programme to eliminate or manage the infestation such that it does not present a risk to products, raw materials or packaging.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.
	4.14.2	The site shall either contract the services of a competent pest control organisation, or shall have appropriately trained staff, for the regular inspection and treatment of the site to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service scope shall be clearly defined and reflect the activities of the site.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Contro that is in the BRC Standard.

	4.14.3	Where a site undertakes its own pest control, it shall be able to effectively demonstrate that: • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the sitestaff undertaking pest control activities meet any legal requirements for training or registration		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Contro that is in the BRC Standard.

		• sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood • dedicated locked facilities are used for the storage of pesticides.			
18.C.1.b Regular device monitoring must reference trap numbers and locations.	**4.14.4**	Pest control documentation and records shall be maintained. This shall include as a minimum: • an up-to-date plan of the full site, identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and for the contractor • details of pest control products used, including instructions for their effective use and action to be • taken in case of emergencies • any observed pest activity • details of pest control treatments undertaken.	**111.23** b) You must make and keep records of the written procedures for cleaning the physical plant and for pest control	Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Contro that is in the BRC Standard.

18.C.1,2,3 Pest Control Devices	**4.14.5**	Bait stations or other rodent control devices shall be appropriately located and maintained to prevent contamination risk to product. Toxic rodent baits shall not be used within production or storage areas where open product is present except when treating an active infestation. Where toxic baits are used these shall be secured. Any missing bait stations shall be recorded, reviewed and investigated.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.

	4.14.6	Fly-killing devices and/or pheromone traps shall be correctly sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Contro that is in the BRC Standard.
	4.14.7	In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk product and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.
	4.14.8	Records of pest control inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the site to ensure that all of the relevant recommendations made by its contractor or in-house expert are carried out in a timely manner.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.
18.B.2 Pest Contaminant Inspections	**4.14.9**	An in-depth, documented pest control survey shall be undertaken at a frequency based on risk, but as a minimum annually, by a pest control expert to review the pest control measures in place. The survey shall:		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Contro that is in the BRC Standard.

		• provide an in-depth inspection of the facility for pest activity • review the existing pest control measures in place and make any recommendations for change. The timing of the survey shall be such as to allow access to equipment for inspection where a risk of stored product insect infestation exists.			
	4.14.10	Results of pest control inspections shall be assessed and analysed for trends on a regular basis, but, as a minimum: • in the event of an infestation • annually. This shall include a catch analysis from trapping devices to identify problem areas. The analysis shall be used as a basis for improving the pest control procedures.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.
	4.14.11	Employees shall understand the signs of pest activity and be aware of the need to report any evidence of pest activity to a designated manager.		Exceeds	PREVENTIVE CONTROLS RULE do not provide the detail of Pest Control that is in the BRC Standard.
	4.15	**Storage facilities**			
	Statement of Intent	All facilities used for the storage of ingredients, in-process product and finished products shall be suitable for its purpose.			
	4.15.1	Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment, understood by relevant staff and	§ 117.40(e) requires that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device,	Exceeds	

15.D Storage Area Construction All storage areas should be constructed of easily cleaned materials (non-porous, non-toxic) and with limited unreachable, difficult-to-clean areas. All products must be stored a minimum of 6 inches off the ground. Air filters or scrubbers should be installed and used as appropriate. **15.E Cleaning** All storage areas must be clean, well ventilated and free from condensation, sewage, dust, dirt, chemicals or other contaminants. Stored products and packaging should be clean and free from dust, debris and contaminants. Cleaning schedules and logs must be current and retained for review; product must be protected or removed during cleaning.		implemented accordingly. These may include, as appropriate: • managing chilled and frozen product transfer between temperature-controlled areas • segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake • storing materials off the floor and away from walls • specific handling or stacking requirements to prevent product damage..	or temperature-recording device so installed as to show the temperature accurately within the compartment. § 117.20(b)(4) requires that that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials		

15.A.3 Product storage areas must only be used to store raw cannabis, components of cannabis products, final cannabis products, packaging and labeling related to cannabis products.	**4.15.2**	Where appropriate, packaging shall be stored away from other raw materials and finished product. Any part-used packaging materials suitable for use shall be effectively protected from contamination and clearly identified to maintain traceability before being returned to an appropriate storage area. Obsolete packaging shall be stored in a separate area and systems shall be in place to prevent accidental use.		Exceeds	Preventive Controls Rule doesn't specifically address requirements specific to storage rooms. The following section does address th requirements generally. § 117.20 (b) (4) plant construction an design. Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes, including (4) be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean ar kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, foo contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between

					equipment and walls and are adequately unobstructed and of adequate width to permit employees t perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.
8.A.1 The operation must maintain appropriate lighting, ventilation, air quality (viable and non-viable airborne contaminants), temperature, pressure and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing and storage.	**4.15.3**	Where temperature control is required, the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a 4-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products.	§ 117.40(e) requires that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment. **111.455** Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration. **111.20d1iv** Temperature and humidity control equipment is of adequate design for its intended function and is functioning properly.	Exceeds	
8.A.2 The operation must set environmental control parameters and list them in product specifications or production procedures.	**4.15.4**	Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions.		Exceeds	PREVENTIVE CONTROLS RULE do not address controlled atmosphere storage.
	4.15.5	Where storage outside is necessary, items shall be protected from contamination and deterioration. Items shall be checked for		Exceeds	PREVENTIVE CONTROLS RULE do not address outdoor storage.

		suitability before being brought into the factory.			
	4.15.6	The site shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life.		Exceeds	PREVENTIVE CONTROLS RULE do not address outdoor storage.
	4.16	**Dispatch and transport**			
	Statement of Intent	Procedures shall be in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products.	§117.93 requires that storage and transportation of food must be under conditions that protect against allergen cross contamination, and biological, chemical and physical contamination of the food.	Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard.
	4.16.1	Documented procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate: • controlling temperature of loading dock areas • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.		Exceeds	The Preventive Controls Rule does no specifically mention these exact requirements. However, §117.130(c)(2)(vii) would require that the hazard evaluation consider transportation and storage.. For example, biological hazards are more likely to be a hazard requiring a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biologic hazards are controlled.

6.4.B.1.c Vehicle security, vehicle inspections and sanitation requirements	**4.16.2**	All vehicles or containers used for the dispatch of products shall be inspected prior to loading to ensure that they are fit for purpose. This shall ensure that they are: • in a clean condition • free from strong odours which may cause taint to products • in a suitable condition to prevent damage to products during transit • equipped to ensure any temperature requirements can be maintained. Records of inspections shall be maintained.		Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard
	4.16.3	Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load. Temperature data-logging devices which can be interrogated to confirm time/temperature conditions or a system to monitor and record at predetermined frequencies the correct operation of refrigeration equipment shall be used and records maintained.		Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard.
	4.16.4	Maintenance systems and documented cleaning procedures shall be available for all vehicles and equipment used for loading/unloading. There shall be records of the measures taken.		Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard
	4.16.5	The company shall have documented procedures for the transport of products, which shall include:		Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard.

		• any restrictions on the use of mixed loads • requirements for the security of products during transit, particularly when vehicles are parked and unattended • clear instructions in the case of vehicle breakdown, accident or failure of refrigeration systems, which ensure the safety of the products is assessed and records maintained.			
	4.16.6	Where the company employs third-party contractors, all the requirements specified in this section shall be clearly defined in the contract and verified or the contracted company shall be certificated to the Global Standard for Storage and Distribution or similar GFSI-recognised scheme.		Exceeds	The Preventive Controls do not provid the detail that is in the BRC standard

5. Product control						
		5.1 Product design/development				
		Statement of Intent	Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.		Exceeds	The Preventive Contr address the activity c and development.
		5.1.1	The company shall provide clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).		Exceeds	The Preventive Contr address the activity c and development.
		5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.		Exceeds	The Preventive Contr address the activity c and development.
		5.1.3	Trials using production equipment shall be carried out where it is necessary to validate that product formulation and manufacturing processes are capable of producing a safe product of the required quality.		Exceeds	The Preventive Contr address the activity c and development.

		5.1.4	Shelf-life trials shall be undertaken using documented protocols reflecting conditions experienced during storage, transport and handling. Results shall be recorded and retained and shall confirm compliance with relevant microbiological, chemical and organoleptic criteria. Where shelf-life trials prior to production are impractical, for instance for some long-life products, a documented science-based justification for		Exceeds	The Preventive Contr address the activity c and development.

	5.2	**Product Labelling**			
	Statement of Intent	Product labelling shall comply with the appropriate legal requirements and contain information to enable the safe handling, display, storage and preparation of the product within the food supply chain or by the customer.		Exceeds BRC requirements 5.2.1 and 5.2.4 exceed Preventive Controls Rule.	The Preventive Control Rule does not provide the detail on labelling requirements at the level of the BRC Standard. FDA regulations require labels meet a appropriate US requirements. Some aspects of labels are addresse through preventive controls for allergens.
13.A.3 Specific label language and packaging requirements vary by state and locality; check state and local laws and keep procedures current and on file.	**5.2.1**	All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer. There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe.	**111.70** For all products that bear expiration date or a statement of product shelf life, the shelf life must be supported. **111.403** Procedures have been established for all packaging and labeling operations. **111.410b** Packaging and labels are controlled for issuance and are reconciled after use. **111.410c** Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record. **111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product.		
	5.2.2	There shall be effective processes in place to ensure that labelling information is reviewed whenever changes occur to: • the product recipe		Exceeds	

		• raw materials • the supplier of raw materials • the country of origin of raw materials • legislation			
	5.2.3	Where a product is designed to enable a claim to be made to satisfy a consumer group (e.g. a nutritional claim, reduced sugar), the company shall ensure that the product formulation and production process is fully validated to meet the stated claim.			
	5.2.4	Where the label information is the responsibility of a customer or a nominated third party the company shall provide: • information to enable the label to be accurately created • information whenever a change occurs which may affect the label information.			
	5.3	**Management of allergens**			
7.L Control of Allergens If allergens are used in any product or product component, the operation must implement written procedures to control the purchase, storage, handling and integration of allergens; workers must be trained and demonstrate required controls.	**FUNDAMENTAL** **Statement of Intent**	The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling in the country of sale.	§ 117.135(c)(2)(i) (c) Preventive controls include, as appropriate to the facility and the food: (2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for: (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and (ii) Labelling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.	BRC requirements 5.3.1 to 5.3.8 exceed Preventive Controls Rule section 117.35 (2).	Management of allergens is addresse in the Preventive Controls Rule throug hazard analysis and the requirement t determine whether allergen controls a needed as a preventive control. FDA provides flexibility to the facility t determine the allergen control procedures and practices are needed ensure food is protected from allergen

7.L Control of Allergens If allergens are used in any product or product component, the operation must implement written procedures to control the purchase, storage, handling and integration of allergens; workers must be trained and demonstrate required controls.	**5.3.1**	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination by allergens (refer to glossary). This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced.			
7.L.2 The operation must document and maintain a current and complete list of all potential allergens and sensitizing chemicals used.	**5.3.2**	The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products.			
	5.3.3	A documented risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross-contamination is avoided. This shall include: • consideration of the physical state of the allergenic material (i.e. powder, liquid, particulate) • identifi cation of potential points of cross-contamination through the process flow • assessment of the risk of allergen cross-contamination at each process step			

		• identifi cation of suitable controls to reduce or eliminate the risk of cross-contamination.			
7.L.3 Allergens and allergen-containing materials must be handled and stored using methods that avoid cross-contaminating all other materials, raw materials or work-in-process with allergens.	**5.3.4**	Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into products not containing the allergen. This shall include as appropriate: • physical or time segregation while allergen-containing materials are being stored, processed or packed • the use of separate or additional protective overclothing when handling allergenic materials • use of identifi ed, dedicated equipment and utensils for processing • scheduling of production to reduce changes between products containing an allergen and products not containing the allergen • systems to restrict the movement of airborne dust containing allergenic material • waste handling and spillage controls • restrictions on food brought onto site by staff , visitors, contractors and for catering purposes.			
	5.3.5	Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.			
7.L.4 All allergens must be clearly labeled; all allergen-containing products must be labeled as required by the FDA Food Allergen Labeling and Consumer Protection Act of 2004.	**5.3.6**	Where the nature of the production process is such that cross-contamination from an allergen cannot be prevented, a warning should be included on the label. National guidelines or codes of practice shall be used when making such a warning statement.			

7.L.5 The operation shall maintain a documented allergen validation process to verify sanitary conditions including testing methods such as enzyme-linked immunosorbent assays (ELISA), adenosine triphosphate (ATP) swabs or equivalent methods.	**5.3.7**	Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the site shall ensure that the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented.			
	5.3.8	Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be validated to ensure they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.			
	5.4	**Product Authenticity, claims and chain of custody**			
	Statement of Intent	Systems shall be in place to minimise the risk of purchasing fraudulent or adulterated food raw materials and to ensure that all product descriptions and claims are legal, accurate and verified.			
	5.4.1	The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials. Such information may come from: • trade associations • government sources • private resource centres.		Exceeds	The Preventive Control Rule does not require the site to have processes in place to access information on historical and developing threats to th supply chain which may present a risk of adulteration or substitution of raw materials.

2.B.1 The operation shall conduct periodic assessments of the business to expose and mitigate anomalies and vulnerabilities.	**5.4.2**	A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. This shall take into account: • historical evidence of substitution or adulteration • economic factors which may make adulteration or substitution more attractive • ease of access to raw materials through the supply chain • sophistication of routine testing to identify adulterants • nature of the raw material. The vulnerability assessment shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risk. It shall be formally reviewed annually.		Exceeds	The Preventive Control Rule does not require the site to perform vulnerabilit assessment shall be carried out on al food raw materials or groups of raw materials to assess the potential risk adulteration or substitution.
	5.4.3	Where raw materials are identified as being at particular risk of adulteration or substitution appropriate assurance and/or testing processes shall be in place to reduce the risk.		Exceeds	The Preventive Control Rule does not address the risk of intentional adulteration or substitution. Intentiona adulteration is addressed in a separat proposed rule “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.”

2.H.2 The operation must not make unsubstantiated medical claims and must provide an accurate representation of the level of medical expertise available.	**5.4.4**	Where products are labelled or claims are made on finished packs which are dependent on a status of a raw material including: • specific provenance or origin • breed/varietal claims • assured status (e.g. GlobalGAP) • genetically modified organism (GMO) status • identity preserved • named specific trademarked ingredients the status of each batch of the raw material shall be verified. The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The site shall undertake documented mass balance tests at a frequency to meet the particular scheme requirements or at least every 6 months in the absence of a scheme-specific requirement.		Exceeds	The Preventive Control Rule does not address the requirement of the site to perform a verification of raw ingredien where product labels or claims (Halal, Kosher, Organic) are dependent on th status of the raw material.
2.H.2 The operation must not make unsubstantiated medical claims and must provide an accurate representation of the level of medical expertise available.	**5.4.5**	Where claims are made about the methods of production (e.g. organic, Halal, Kosher) the site shall maintain the necessary certification status in order to make such a claim.		Exceeds	The Preventive Control Rule does not address the requirement of sites making claims about method of production (Organic, Kosher, Halal) to be certified to make such a claim.
	5.4.6	The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.		Exceeds	The Preventive Control Rule does not address the requirement of sites, making claims, to document process flow of the production of products and apply controls to ensure the integrity o the product claims.

	5.5	**Product Packaging**			
13.A Packaging and Labeling Specifications The operation must document written procedures for labels and packaging materials including selection of materials, design, inspection, approval, storage, handling and rejection processes.	**Statement of Intent**	Product packaging shall be appropriate for the intended use and shall be stored under conditions to prevent contamination and minimise deterioration.	§ 117.80 Processes and controls. (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. § 117.20 (b)(4) The facility shall be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact. § 117.93 Storage and transportation of food must be conditions that will protect against allergen cross contact and against biological, chemical and physical contamination of food, as well as against deterioration of the food and the container. **111.70** Specifications have been established for components, in-process materials, labels, packaging components, and finished product. **111.75f** Packaging and labeling materials are visually examined, at a minimum, and are reviewed against the supplier's invoice to determine conformance with specifications. **111.455** Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration	Comparable	
	5.5.1	When purchasing or specifying food contact packaging the supplier of packaging materials shall be made aware of any particular characteristics of the food (e.g. high fat content, pH or usage conditions such as microwaving) which may affect packaging suitability. Certificates of conformity or other evidence shall be available for product packaging to confirm it complies with relevant food safety legislation and is suitable for its intended use.	§ 117.135 Preventive Controls and Subpart G Supply-Chain Program.	Comparable	The Preventive Controls Rule has the ability to manage risks related to packaging through the application of hazard analysis and the requirement t determine whether packaging controls are needed as a preventive control. A potential risk related to packaging can be controlled through the Supply-Chain Program.

	5.5.2	Product liners and bags purchased by the company for use in direct contact with ingredients, or work in process, shall be appropriately coloured and resistant to tearing to prevent accidental contamination.		Exceeds	The Preventive Controls Rule does no address specific requirements and details for food product liners and bag that have direct contact with food.
	5.6	**Product inspection and laboratory testing**			
12.A Product Testing Plan 1.The operation must ensure all products sold or transferred are free from contaminants and adulterants as specified in the product testing plan and/or product specification	Statement of Intent	The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.			
	5.6.1	**Product inspection and testing**			
12.A Product Testing Plan 1.The operation must ensure all products sold or transferred are free from contaminants and adulterants as specified in the product testing plan and/or product specification. 2.The operation must develop a testing plan that addresses all risks to products. 3.A qualified worker must review all test lab reports to ensure: 4.All test standards are subject to federal, state and local laws and regulations.	5.6.1.1	There shall be a scheduled programme of testing covering products and the processing environment, which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.		Exceeds	Finished product testing and raw material testing is not required by the Preventive Controls Rule. However product testing may be used as a verification that the preventive control are consistently implemented and are effectively and significantly minimizing or preventing the hazards.

12.A.3 A qualified worker must review all test lab reports	5.6.1.2	Test and inspection results shall be recorded and reviewed regularly to identify trends. The significance of external laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.		Exceeds	The management and review of produ test and inspection results is not addressed in the Preventive Controls Rule.
	5.6.1.3	The site shall ensure that a system of ongoing shelf-life assessment is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and aw. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product.		Exceeds	The Preventive Controls Rule does no require the site to have a system of ongoing shelf-life assessment.
	5.6.2	**Laboratory testing**			
12.E Microbiological Testing All products must be tested for aerobic plate count. Product test results must validate that less than one colony forming unit (CFU) per gram of tested material is present for E. coli or Salmonella species or the product shall be rejected. Products must be tested for the presence of yeast and molds. Test reports must include method reference.	5.6.2.1	Pathogen testing shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the production and storage areas and have operating procedures to prevent any risk of product contamination.		Exceeds	The Preventive Controls Rule does no address pathogen testing requiremen A separate section of FSMA addresses ‘‘Laboratory Accreditation For Analyses Of Foods’’ (see section 202 of FSMA).which creates a new section 422 in the FD&C Act addressing laboratory accreditation fo the analyses of foods, including use o accredited laboratories in certain circumstances, limited to testing for regulatory purposes.

	5.6.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and shall include consideration of: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements • processes for obtaining product samples • disposal of laboratory waste.	**111.310** Laboratory facilities used are adequate for testing of components, in-process materials, and dietary supplements.	Exceeds	The Preventive Controls Rule does no address GMPs for testing laboratories that are on site taking samples.
12.A.3.a a. Testing laboratory is certified to ISO 17025, FOCUS Standard or equivalent	5.6.2.3	Where the company undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025. Documented justification shall be available where accredited methods are not undertaken.		Exceeds	The Preventive Controls Rule does no address laboratory accreditation requirements. A separate section of FSMA addresses ‘‘Laboratory Accreditation For Analyses Of Foods’’ (see section 202 of FSMA).which creates a new section 422 in the FD&C Act addressing laboratory accreditation fo the analyses of foods, including use o accredited laboratories in certain circumstances, limited to testing for regulatory purposes.
	5.6.2.4	Procedures shall be in place to ensure reliability of laboratory results, other than those critical to safety and legality specified in clause 5.6.2.3. These shall include: • use of recognised test methods, where available • documented testing procedures • ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required • use of a system to verify the accuracy of test results (e.g. ring or proficiency testing) • use of appropriately calibrated and maintained equipment.	**111.303** Procedures have been established for laboratory operations. **111.310** Laboratory controls have been established and have been approved by Quality Control. **111.315** Parameters have been set for laboratory controls for sampling plans, criteria for examination and testing methods, etc.	Exceeds	The Preventive Controls Rule does no require the site to have in place procedures to ensure reliability of laboratory results.

	5.7	**Product release**			
12.L.2 The operation shall designate a qualified staff member to review each test result against the product specification. If the product meets all specifications, the staff member shall release the batch of product to the next step in the process	Statement of Intent	The site shall ensure that finished product is not released unless all agreed procedures have been followed.	**111.420c** Quality Control Unit has dispositioned each batch of repackaged or relabeled dietary supplement prior to release for distribution. **111.123a** Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.	Exceeds	The Preventive Controls Rule doe not require the site to have in plac positive release procedures for finished product.
12.L.2 The operation shall designate a qualified staff member to review each test result against the product specification. If the product meets all specifications, the staff member shall release the batch of product to the next step in the process	**5.7.1**	Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and release authorised.	**111.123a** Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.	Exceeds	

6. Process Control

6.1 Controls of operations

	FUNDAMENTAL Statement of Intent	The site shall operate to documented procedures and/or work instructions that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan.	Subpart C – Hazard Analysis and Risk-based Preventive Controls. § 117.126 (a) Requirement for a food safety plan (1) You must prepare or have prepared a written food safety plan.	Exceeds	The Preventive Controls Rule does n address procedures for consistently meeting quality characteristics.

7.N Production Records The operation must maintain accurate production records for each batch (or lot) of product it produces. Production records include pre-production inspections, process monitoring records, critical control point records, control limit records, deviation logs and corrective action reports.	6.1.1	Documented process specifications and work instructions shall be available for the key processes in the production of products to ensure product safety, legality and quality. The specifications as appropriate shall include: • recipes – including identification of any allergens • mixing instructions, speed, time • equipment process settings • cooking times and temperatures • cooling times and temperatures • labelling instructions • coding and shelf-life marking • any additional critical control points identified in the HACCP plan. Process specifications shall be in accordance with the agreed finished product specification.	**111.205b1** The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. **111.355** Manufacturing processes have been designed to produce a product that consistently meets specifications.	Exceeds	Process specifications are not require by the Final Preventive Controls Rule Under the Hazard Analysis and Risk-Based Preventive Controls the site is required to document a process flow diagram, a product description and process parameters applied to contro food safety risks. Allergen identification is covered unde Labelling requirements.
7.N Production Records The operation must maintain accurate production records for each batch (or lot) of product it produces. Production records include pre-production inspections, process monitoring records, critical control point records, control limit records, deviation logs and corrective action reports.	6.1.2	Process monitoring, such as of temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification.	**111.255c** The Batch Record follows the master record and each step is performed appropriately.	Exceeds	Monitoring of the process quality specifications is not required by the Preventive Controls Rule. Under the Hazard Analysis and Risk-Based Preventive Controls the site is required to monitor and record and process parameters applied to contro food safety risks.
	6.1.3	In circumstances where process parameters or product quality are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system that is routinely tested.		Exceeds	The Preventive Controls Rule does no require in-line monitoring devices to b equipped with a failure alert system. The Preventive Controls Rule does no provide the detail as is described in th BRC Standard.

	6.1.4	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).		Exceeds	The Preventive Controls Rule does no require the validation and verification quality process parameters. The food safety parameters are required to be validated and verified.
	6.1.5	In the case of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status and quality of the product to determine the action to be taken.		Exceeds	The Preventive Controls Rule requires that Corrective Action be implemented when there is any failure in the application of the preventive controls (food safety parameters). The Preventive Controls Rule does no require the procedures to determine t quality status of product when there is failure in delivering the quality process parameters.
	6.2	**Labelling and Pack Control**			
	Statement of Intent	The management controls of product labelling activities shall ensure that products will be correctly labelled and coded.		Exceeds	The Preventive Controls Rule does no address management of labelling activities to the degree that is describe in the BRC Standard.
	6.2.1	There shall be a formal process for the allocation of packaging materials to packing lines and control in the packing area which ensures that only the packaging for immediate use is available to the packaging machines. Where off -line coding or printing of packaging materials occurs, checks shall be in place that only correctly printed material is available at the packaging machines.	**111.410b** Packaging and labels are controlled for issuance and are reconciled after use. Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations	Exceeds	The Preventive Controls Rule does no address management of labelling activities to the degree that is describe in the BRC Standard.

	6.2.2	Documented checks of the production line shall be carried out before commencing production and following changes of product. These shall ensure that lines have been suitably cleared and are ready for production. Documented checks shall be carried out at product changes to ensure all products and packaging from the previous production have been removed from the line before changing to the next production.		Exceeds	The Preventive Controls Rule does no address management of labelling activities to the degree that is describe in the BRC Standard.
	6.2.3	Documented procedures shall be in place to ensure that products are packed into the correct packaging and correctly labelled. These shall include checks: • at the start of packing • during the packing run • when changing batches of packaging materials • at the end of each production run. The checks shall also include verification of any printing carried out at the packing stage including, as appropriate: • date coding • batch coding • quantity indication • pricing information • bar coding • country of origin.	**111.410c** Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record	Exceeds	The Preventive Controls Rule does no address management of labelling activities to the degree that is describe in the BRC Standard.

	6.2.4	Where on-line vision equipment is used to check product labels and printing, procedures shall be in place to ensure that the system is correctly set up and capable of alerting or rejecting product when packaging information is out of specification.		Exceeds	The Preventive Controls Rule does no address management of labelling activities to the degree that is describe in the BRC Standard.
	6.3	**Quantity-weight, volume and number control**			
	Statement of Intent	The site shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirements.	**111.415g** Procedures have been established to sample a representative number of units to assure compliance with specifications. **111.420b** Representative samples of each batch of repackaged or relabeled dietary supplement have been examined to determine if they conform to specifications. **111.420c** Quality Control Unit has dispositioned each batch prior to release for distribution	Exceeds	The Preventive Controls Rule does no address management of quantity (weight, volume and numbers) labellir activities to the degree that is describe in the BRC Standard
	6.3.1	The frequency and methodology of quantity checking shall meet the requirements of appropriate legislation governing quantity verification, and records of checks shall be retained.		Exceeds	The Preventive Controls Rule does no address management of quantity (weight, volume and numbers) labellir activities to the degree that is describe in the BRC Standard
	6.3.2	Where the quantity of the product is not governed by legislative requirements (e.g. bulk quantity), the product must conform to customer requirements and records shall be maintained.		Exceeds	The Preventive Controls Rule does no address management of quantity (weight, volume and numbers) labellir activities to the degree that is describe in the BRC Standard

	6.4 Calibration and control of measuring and monitoring devices				
	Statement of Intent	The site shall be able to demonstrate that measuring equipment is sufficiently accurate and reliable to provide confidence in measurement results.		Exceeds	The Preventive Controls Rule does no address calibration of devices used to measure preventive controls to the degree that is described in the BRC Standard The Preventive Controls Rule require that devices used to monitor and verif preventive controls be calibrated.
9.A.1.C All production equipment must be documented on a Master Equipment List that identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools. The Master Equipment List should include the following as applicable: c.Maintenance and calibration requirements and work performed	**6.4.1**	The site shall identify and control measuring equipment used to monitor critical control points, product safety and legality. This shall include as a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse.	§ 117.165 Verification of implementation and effectiveness. (a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system: (1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy) **111.25a,b** Procedures have been established for calibration of all instruments, controls, automated, mechanical, and electronic equipment, etc. **111.27a6** Instruments and controls that are used in all areas must be accurate and precise (calibrated where necessary), maintained, and adequate in number. **111.35b4** Records are available of calibrations, inspections, and checks of any automated, mechanical, or electronic equipment.	Exceeds	The Preventive Controls Rule require that devices used to monitor and verif preventive controls be calibrated.

9.A.1.a,b 1. All production equipment must be documented on a Master Equipment List that identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools. The Master Equipment List should include the following as applicable: a. Name/description, serial number, supplier and supplier contact b. Date received, installed and activated, condition at receipt and current location	**6.4.2**	All identified measuring devices, including new equipment, shall be checked and where necessary adjusted: • at a predetermined frequency, based on risk assessment • to a defined method traceable to a recognised national or international standard where possible. Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform.		Exceeds	The Preventive Controls Rule does no address identification and manageme of calibration of devices to the degree that is described in the BRC Standard

	6.4.3	Reference measuring equipment shall be calibrated and traceable to a recognised national or international standard and records maintained. The uncertainty of calibration shall be considered when equipment is used to assess critical limits.		Exceeds	The Preventive Controls Rule does no address the calibration of reference measuring equipment.
9.C.2 Documented calibration procedures must define frequency of testing, testing methods, accepted range of variation and corrective action process.	**6.4.4**	Procedures shall be in place to record actions to be taken when the prescribed measuring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall be taken to ensure at-risk product is not offered for sale.		Exceeds	The Preventive Controls Rule requires that Corrective Action be implemented when there is any failure in the application of the preventive controls i.e. inaccurate measurement of preventive control parameters). The Preventive Controls Rule does no require the procedures be documente to for cases where quality parameters are not met.

7. Personnel					
7.1 Training Raw material handling, preparation, processing, packing and storage areas					
	FUNDAMENTAL Statement of Intent	The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.	Current §110.10(c) provides guidance that personnel responsible for identifying sanitation failures or monitoring preventive controls should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.	Comparable	
3 .A Training Program	**7.1.1**	All relevant personnel, including agency-supplied staff, temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.	§ 117.4(b)(1) establishes that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. **111.14** (2) Documentation of training, including the date of the training, the type of training, and the person(s) trained	Comparable	
3. Training Program	**7.1.2**	Where personnel are engaged in activities relating to critical control points, relevant training and competency assessment shall be in place.	Current §110.10(c) provides guidance that personnel responsible for identifying sanitation failures or monitoring preventive controls should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices	Comparable	

3. Training Program	**7.1.3**	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: • identifying the necessary competencies for specifi c roles • providing training or other action to ensure staff have the necessary competencies • reviewing the eff ectiveness of training • the delivery of training in the appropriate language of trainees.		Exceeds	The Preventive Controls Rule does no require the site to put in place documented programmes covering th training needs of relevant personnel. § 117.180(d) sets forth record keeping requirements relating to training recor specifically that all applicable training the development and application of ris based preventive controls must be documented in records, including the date of the training, the type of trainin and the person(s) trained. The Preventive Controls Rule does no address training to the degree it is described in the BRC Standard
3.B Food Safety Traing	**7.1.4**	All relevant personnel, including engineers, agency-supplied staff and temporary staff and contractors, shall have received general allergen awareness training and be trained in the site's allergen-handling procedures.		Exceeds	The Preventive Controls Rule does no require that all relevant personnel, including engineers, agency-supplied staff and temporary staff and contractors, have general allergen awareness training and be trained in the site's allergen-handling procedure
2.I Records Management **2.J Records Inventory List**	**7.1.5**	Records of all training shall be available. This shall include as a minimum: • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider.	§ 117.180(d) sets forth record keeping requirements relating to training records specifically that all applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained. **111.14** (2) Documentation of training, including the date of the training, the type of training, and the person(s) trained	Comparable	

2.I Records Management **2.J Records Inventory List**		Where training is undertaken by agencies on behalf of the company, records of the training shall be available.			
	7.1.6	The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.		Exceeds	The Preventive Controls Rule does no require the site routinely review the competencies of its staff or specify the training mechanism (refresher training coaching, mentoring or on-the-job experience).
	7.2	**Personal hygiene Raw material handling, preparation, processing, packing and storage areas**			
	Statement of Intent	The site's personal hygiene standards shall be developed to minimise the risk of product contamination from personnel, be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility.	**111.10** Procedures have been established that define work requirements for personnel to prevent microbial contamination from illness or hygienic practices.		
4.A Worker Cleanliness 1.Workers must practice personal cleanliness including: a.Outer garments such as smocks, aprons and lab coats must be clean and appropriate for the assigned tasks. b.Nails must be trimmed and clean. c.Work shoes must be clean and free of external debris or contaminants; when practical, workers should change into designated work shoes while in the facility. d.If foot dips are required and operational, workers must clean shoes according to procedures (see 17.D Foot Disinfectant Dips).	**7.2.1**	The requirements for personal hygiene shall be documented and communicated to all personnel. This shall include as a minimum the following requirements: • watches shall not be worn • jewellery shall not be worn, with the exception of a plain wedding ring or wedding wristband • rings and studs in exposed parts of the body, such as ears, noses, tongues and eyebrows, shall not be worn • fingernails shall be kept short, clean and unvarnished • false fingernails and nail art shall not be permitted	§ 117.10 (b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food. (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	Exceeds	The Preventive Controls Rule does no address personal hygiene requiremen to the degree of detail that is describe in the BRC Standard.

		• excessive perfume or aftershave shall not be worn. • Compliance with the requirements shall be checked routinely.	§ 117.10 (b)(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. § 117.10 (b) (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials. **111.10** Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated.		

4.B Hand Sanitation All workers must wash and sanitize their hands before and after doing any work, after each visit to a toilet, after handling contaminated material, after smoking, eating or drinking, and at any other time when their hands may have become contaminated. Disposable protective gloves must be in stock and available. Gloves must be discarded when damaged and after using toilets, eating or contacting a foreign substance.	7.2.2	Hand-washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.	§ 117.10 (b)(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. **111.10** Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated. **110.10** (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.	Comparable	
4.C Wounds and Infections 1.A written policy must prohibit workers with open and/or infected wounds on exposed parts of the body, or those showing signs of infectious illness, from working with exposed product or in product storage areas. 2.Workers with observable or reportable infections must be excused from work according to the organization's procedures. 3.Management must evaluate all situations and take corrective action when any communicable disease is observed and document the corrective action taken. 4.The operation can establish procedures to cover wounds with bandages and/or gloves to eliminate contamination risk.	7.2.3	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and contains a metal detectable strip. These shall be site issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn.	§ 117.10 Personnel. (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.	Comparable	

	7.2.4	Where metal detection equipment is used, a sample from each batch of plasters shall be successfully tested through the equipment and records shall be kept.		Exceeds	The Preventive Controls Rule does no require band aids be detectable by metal detector.
	7.2.5	Processes and written instructions for staff shall be in place to control the use and storage of personal medicines, so as to minimise the risk of product contamination.		Exceeds	The Preventive Controls Rule does no require the site to have in place processes and written instructions for staff to control the use and storage of personal medicines, so as to minimise the risk of product contamination.
	7.3	**Medical screening**			

	Statement of Intent	The company shall have procedures in place to ensure that employees, agency staff, contractors or visitors are not a source of transmission of food-borne diseases to products.	**111.10** (a) *Preventing microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material, including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. Such measures include the following: (1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists; and (2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could result in microbial contamination of any components, dietary supplements, or any contact surface **110.10** *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.	Exceeds	The Preventive Controls Rule does no require the site to have procedures to prevent employees or visitors from being a source of food contamination.

4.C Wounds and Infections A written policy must prohibit workers with open and/or infected wounds on exposed parts of the body, or those showing signs of infectious illness, from working with exposed product or in product storage areas. Workers with observable or reportable infections must be excused from work according to the organization's procedures. Management must evaluate all situations and take corrective action when any communicable disease is observed and document the corrective action taken. The operation can establish procedures to cover wounds with bandages and/or gloves to eliminate contamination risk.	**7.3.1**	The site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working with open food. The site shall have a procedure which enables notification by employees, including temporary employees, of any relevant symptoms, infection, disease or condition with which they may have been in contact or be suffering from.	§ 117.10 Personnel. (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.	Comparable	
4.C Wounds and Infections A written policy must prohibit workers with open and/or infected wounds on exposed parts of the body, or those showing signs of infectious illness, from working with exposed product or in product storage areas. Workers with observable or reportable infections must be excused from work according to the organization's procedures. Management must evaluate all situations and take corrective action when any	**7.3.2**	Where there may be a risk to product safety, visitors and contractors shall be made aware of the types of symptoms, infection, disease or condition which would prevent a person visiting areas with open food. Where permitted by law, visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas.	§ 117.10 Personnel. (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors	Exceeds	The Preventive Controls Rule does no specifically require the site to have visitors complete a health questionnai or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to entering the raw material, preparation processing, packing and storage area
	7.3.3	There shall be documented procedures for employees, contractors and visitors relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required.		Exceeds	The Preventive Controls Rule does no specifically require the site to have documented procedures for employee contractors and visitors may be suffering from or have been in contac with an infectious disease. relating to action to be taken where they

	7.4	Protective clothing Employees or visitors to production areas			
	Statement of Intent	Suitable site-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas.	§ 117.10 (b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food. (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. **111.10** Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources.	Comparable	

			(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.		

	7.4.1	The company shall document and communicate to all employees (including agency and temporary personnel), contractors or visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. high-care or high-risk areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, use of canteen and smoking areas).	§ 117.4(b)(1) establishes that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.	Exceeds	The Preventive Rule does not require the site to document and communicat to all employees (including agency an temporary personnel), contractors or visitors the rules regarding the wearin of protective clothing in specified work areas. The Preventive Controls Rule requires that individuals engaged in the manufacturing, processing, packing o the holding of food in that they receive training appropriate to their job responsibilities.
	7.4.2	Protective clothing shall be available that: • is provided in sufficient numbers for each employee • is of suitable design to prevent contamination of the product (as a minimum containing no external pockets above the waist or sewn-on buttons) • fully contains all scalp hair to prevent product contamination • includes snoods for beards and moustaches, where required, to prevent product contamination.	§ 117.10 the management of the establishment must take reasonable measures and precautions to ensure the following: (b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food. (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, bread covers, or other effective hair restraints. (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	Comparable	

	7.4.3	Laundering of protective clothing shall take place by an approved contracted or in-house laundry using defined criteria to validate the effectiveness of the laundering process. The laundry must operate procedures which ensure: • adequate segregation between dirty and cleaned clothes • effective cleaning of the protective clothing • protective clothing for high-risk or high-care areas is commercially sterile following the washing and drying process • cleaned clothes are supplied protected from contamination until use (e.g. by the use of covers or bags). Washing of protective clothing by the employee is exceptional but shall be acceptable where the protective clothing is to protect the employee from the products handled and the clothing is worn in enclosed product or low-risk areas only.		Exceeds	The Preventive Controls rule does no specifically require the site to have in place a laundering program for protective clothing. The Preventive Controls Rule does n have requirements based upon define risk zones as in BRC.
	7.4.4	Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, this shall be audited either directly or by a third party. The frequency of these audits should be based on risk.		Exceeds	The Preventive Controls Rule does n have requirements based upon define risk zones as in BRC. The Preventive Controls Rule does no have a requirements that laundering programs must be audited.
	7.4.5	Protective clothing shall be changed at an appropriate frequency, based on risk. For	§ 117.10 the management of the establishment must take reasonable measures and precautions to ensure the following:	Exceeds	The Preventive Controls Rule does no address the frequency of cleaning protective clothing.

		high-risk and high-care areas the protective clothing shall be changed at least daily.	(b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.		The Preventive Controls have requirements based risk zones as in BRC.
	7.4.6	If gloves are used, they shall be replaced regularly. Where appropriate, gloves shall be suitable for food use, of a disposable type, of a distinctive colour (blue where possible), be intact and not shed loose fibres.	§ 117.10 the management of the establishment must take reasonable measures and precautions to ensure the following: (b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	Exceeds	The Preventive Controls address the management used in the site to the deg described in the BRC Sta
	7.4.7	Where items of personal protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and sanitised at a frequency based on risk.		Exceeds	The Preventive Controls address the cleaning and non-launderable protectiv