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DRAFT: FSSC 22000– FSMA Comparison

Scope of Evaluation and Summary

This evaluation was done to demonstrate how FSSC 22000 compares against each point of the proposed FDA requirements relative to cGMPs, Preventive Controls, and the Foreign Supplier Verification program. It should be noted that this document provides a summary. The full text comparison mapping the FSSC 22000 requirements against the related sections of the proposed rules can be found in a corresponding document.

In this document, a section header may indicate that FSSC 22000 "exceeds" the FDA requirements while the sub headers all list "comparable". This is because in many instances the FSSC 22000 standard contains additional points that have no corresponding FDA requirement. In our opinion, in many cases these make the FSSC 22000 requirements more stringent and/or are more explicit.

FDA, both in the preventive controls and cGMPs, lays out objectives that can be considered a "destination" for food safety. The level of detail provided in FSSC 22000 provides a map that meets this expectation, and in some cases, is more detailed and/or stringent in the requirements. FSSC 22000 also emphasizes communication of food safety information both within an organization (including to management) as well as externally, as with vendors, customers, and other stakeholders. The approach of FSSC 22000 is a truer "management systems" approach. There are no elements of the FDA preventive control and cGMP requirements that are clearly lacking in FSSC 22000.

Overall, FSSC 22000 often exceeds FDA requirements, either by being clearer about the specific expectations or by applying the requirements more broadly within a facility (e.g., strong sanitation requirements including documentation regardless of whether it is a PRP or operational PRP). A facility that has FSSC 22000 certification is in an excellent place with regard to compliance with PC rules as currently written. Any additional requirements added in the final rule can be easily added to the FSSC 22000 standard within the existing framework.

With respect to FDA's proposed FSVP, FSSC 22000 is more similar to option 2, which expects a facility to have the requisite expertise to determine the appropriate verification activities based on supplier risk.

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food		
§ 117.10 Personnel.	TS/ ISO 22002-1 / 13	Exceed
(a) Disease control	TS/ ISO 22002-1 /13.6	Comparable
(b) Cleanliness (garments, hand-washing, jewelry, gloves, hairnets, etc.)	TS/ ISO 22002-1 / 13.8	Different
(c) Education and training	TS/ISO 22002-1 /13.1; ISO 22000: 6.2.2	Comparable
(d) Supervision. (ensuring compliance)	ISO 22000: 6.2.2	Different
§ 117.20 Plant and grounds.		
(a) Grounds (equipment, roads, drainage, waste treatment and disposal)	TS/ ISO 22002-1 /4	Exceed
(b) Plant construction and design (interior space, prevent contamination, bulk vessels, lighting, ventilation, pests)	TS/ ISO 22002-1 / 5 and 6	Exceed
§ 117.35 Sanitary operations.	TS/ ISO 22002-1 / 8, 11 and 12	Exceed
(a) General maintenance	TS/ ISO 22002-1 /8.1	Comparable
(b) Substances used in cleaning and sanitizing; storage of toxic materials (toxic material control)	TS/ ISO 22002-1 / 5.7 and 11.2	Exceeds
(c) Pest control.	TS/ ISO 22002-1 /12	Exceeds
(d) Sanitation of food-contact surfaces	TS/ ISO 22002-1 /8.3 and 11	Comparable
(e) Sanitation of non-food-contact surfaces.	TS/ ISO 22002-1 / 8	Comparable
(f) Storage and handling of cleaned portable equipment and utensils.	TS/ ISO 22002-1/8.5	Comparable
§ 117.37 Sanitary facilities and controls.	TS/ ISO 22002-1 / 6 and 7	
(a) Water supply.	TS/ ISO 22002-1 /6.2	Exceed
(b) Plumbing. (floor drainage, cross contamination)	TS/ ISO 22002-1 /7.4	Exceed
(c) Sewage disposal.	TS/ ISO 22002-1 / 7.4	Exceed
(d) Toilet facilities.	TS/ ISO 22002-1 /13.2	Comparable

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
(e) Hand-washing facilities.	TS/ ISO 22002-1 /13.2	Exceed
(f) Rubbish and offal disposal.	TS/ ISO 22002-1 /7	Exceed
§ 117.40 Equipment and utensils. (cleanable, maintenance, food-contact surfaces, holding, conveying, manufacturing systems, cold storage, monitoring instruments, compressed air)	TS/ ISO 22002-1 /6 and 8	Comparable
§ 117.80 Processes and controls.		
(a) General (sanitation, quality control, cross-contact control, testing, contaminated food protocols)	TS/ ISO 22002-1 / 8, 10 and 11	Exceed
(b) Raw materials and ingredients. (inspection, microorganism control, aflatoxin/natural toxin compliance, pest control, rework control, frozen/liquid/dry raw material controls, allergens)	TS/ ISO 22002-1 /9	Exceed
(c) Manufacturing operations. (finished product, microorganisms, temperature controls, controlling pH or a_w, W.I.P., foreign material, disposal, heating, batters, filling, ice)	TS/ ISO 22002-1 / 10.2, 10.4	Exceed
§ 117.93 Warehousing and distribution. (protect against cross-contamination, other contamination, deterioration of food/container)	TS/ ISO 22002-1 /16	Exceed
§ 117.110 Defect action levels. (compliance with FDA and FD&C Act,	Add'l FSSC 22000 Req. 3	Comparable
§ 117.126 Requirement for a food safety plan.		
(a) Food safety plan.	ISO 22000: 4.2.1 and 7.6.1	comparable
(b) Contents of a Food Safety Plan. (hazard analysis, preventive controls, procedures and	ISO 22000: 7	Exceed

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
frequency, corrective actions, verification procedures, recall plan)		
(c) Qualified individual.	ISO 22000: 5.5	Exceed
§ 117.130 Hazard analysis.		
(a) Requirement for a hazard analysis.	ISO 22000: 7.4	Exceed
(b) Hazard identification (biological, chemical, physical, radiological)	ISO 22000: 7.4	Comparable
(c) Hazard evaluation. (formulation, equipment, raw materials, transportation, manufacturing, packaging, storage/distribution, sanitation)	ISO 22000: 7.4.3	Exceed
§ 117.135 Preventive controls for hazards that are reasonably likely to occur. (Written preventive controls, parameters controlling hazards)	ISO 22000: 7.4.4 and 7.6.3	Comparable
(1) Process controls.	ISO 22000: 7.6.2	Comparable
(2) Food allergen controls.	TS/ ISO 22002-1/10.3 and ISO 22000: 7.5	Comparable
(3) Sanitation controls.	ISO 22000: 7.5	comparable
(4) Recall plan.	TS/ ISO 22002-1/15	Comparable
(5) Other controls.	ISO 22000: 7.5	Comparable
§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur. (written plan, notifications, effectiveness checks, disposal)	TS/ ISO 22002-1/15	
§ 117.140 Monitoring.	ISO 22000: 7.6.4	Comparable
§ 117.145 Corrective actions.	ISO 22000: 7.6.5, ISO 22000: 7.10	Exceed
(a) Corrective action procedures.	ISO 22000: 7.6.5, 7.10	Comparable
(b) Corrective action in the event of an unanticipated problem. (reanalysis)	ISO 22000: 7.6.5, 7.10	Comparable
(c) Documentation.	ISO 22000: 7.6.5, 7.10	Comparable
§ 117.150 Verification.	ISO 22000: 8	Exceed
(a) Validation. (qualified individual, scientific/technical information)	ISO 22000: 8.2	Exceed
(b) Monitoring.	ISO 22000: 7.8 and 8.4.3	Comparable

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
(c) Corrective actions.	ISO 22000: 7.8	Comparable
(d) Implementation and effectiveness. (calibration, monitoring records)	ISO 22000: 8.4	Exceed
(e) Written procedures for verification activities.	ISO 22000: 8	Comparable
(f) Reanalysis (at least once every 3 years, new hazard information, ineffective P.C., qualified individual)	ISO 22000: 8.5.2	Exceed
(g) Documentation.	ISO 22000: 8	Comparable
§ 117.155 Requirements applicable to a qualified individual. (prep food safety plan, validation of PC's, records review, reanalysis, required training	ISO 22000: 5.5	Comparable
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals		
§ 1.502 What foreign supplier verification program (FSVP) must I have?		
(a) General. (for each food imported)		
(b) Low-acid canned foods.		
§ 1.503 Who must develop my FSVP and perform FSVP activities? (qualified individual)	ISO 22000: 5.4 and 5.5	Comparable
§ 1.504 What review of a food and foreign supplier's compliance status must I conduct? (FDA warning letter, import alert, cert requirements)	TS/ ISO 22002-1/9.2; Add'l FSSC 22000 Req 3	Different; Comparable
§ **1.505 What hazard analysis must I conduct?**		

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
a) Requirement of a hazard analysis. (for each food imported)	TS/ ISO 22002-1/9.2	Comparable
(b) Potential hazards. (RLTO)	ISO 22000: 7.3.3.1	Comparable
(c) Hazard evaluation. (ingredients, condition of establishment, transportation, harvesting/ raising/ manufacturing/ processing/ packing, storage, sanitation)	ISO 22000: 7.3.3.1	Comparable
(d) Review of hazard analysis developed by foreign supplier	TS/ ISO 22002-1 /9.2	Comparable
e) Microbiological hazards in raw agricultural commodities that are fruits or vegetables.	TS/ ISO 22002-1 /9.2 and ISO 22000: 7.3.3.1	Comparable
§ **1.506 What foreign supplier verification and related activities must I conduct?**		
a) List of foreign suppliers.	ISO 22000: 5.6.1	Exceeds
b) Foreign supplier verification procedures.	TS/ ISO 22002-1 / 9.2	
c) Purpose of supplier verification.		
d) No hazards identified. (only required to comply with paragraph (a) of this section with respect to food.		
e) Hazards controlled by you. (must document at least annually)	ISO 22000: 7.4	Comparable
f) Hazards controlled by your customer	ISO 22000: 7.3.3.1	Different
Option 1 for Requirements for Hazards Not Controlled by You or Your Customer		
(g) Hazards controlled or verified by your foreign supplier. (must conduct the verification activities)		
1) Hazards controlled by your foreign supplier for which there is a reasonable probability that	TS/ ISO 22002-1/9.2	Different- although an audit is an option for FSSC22000, it is not required as is being

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
exposure to the hazard will result in serious adverse health consequences or death to humans or animals. (must conduct and document the onsite auditing activities, or obtain documentation, initial onsite audit/ subsequent periodic onsite audits)		proposed by FDA in this option
2) Other hazards. (periodic onsite auditing, lot-by-lot sampling and testing, review of foreign supplier's food safety records)	TS/ ISO 22002-1/9.2 and 9.3	Comparable
(3) Requirements of onsite auditing		
(4) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority	TS/ ISO 22002-1/9.2	Comparable
(5) Review of results of verification activities.	TS/ ISO 22002-1/9	Comparable
6) Independence of qualified individuals conducting verification activities.	TS/ ISO 22002-1/9.2	Different- FSSC22000 specifies that audits must be "appropriate"
Option 2 for Requirements for Hazards Not Controlled by You or Your Customer		
(1) Other hazards. (periodic onsite auditing, lot-by-lot sampling and testing, review of foreign supplier's food safety records)	TS/ ISO 22002-1/9.2	Comparable
(2) Requirements of onsite auditing.	TS/ ISO 22002-1/9.2	Comparable
(3) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. (may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable)	TS/ ISO 22002-1/9.2	Comparable

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
(4) Review of results of verification activities. (promptly review results of verification activities that you conduct or obtain)		
(5) Independence of qualified individuals conducting verification activities.		
§ 1.507 What investigations and corrective actions must I conduct under my FSVP? (review complaints, prompt investigation of adulterated product, corrective actions)		Not explicitly required by FSSC 22000
§ **1.508 How must I reassess the effectiveness of my FSVP?**		
a) Timing. (except as otherwise specified, reassessment within 3 years of establishment and of last reassessment)	ISO 22000: 8.5.2	Exceeds
(b) Reassessment and implementation of changes.		
§ **1.509 How must the importer be identified at entry?** (designate a U.S. agent/representative as importer of food, obtain a DUNS number, for each line of entry of food product-name and DUNS number provided electronically to U.S. C.B.P.)	n/a	This is not required by FSSC 22000 except under the umbrella of addl'l FSSC 22000 Req 3
§ **1.510 How must I maintain records of my FSVP?**		
a) Records of FSVP.		
b) Record availability.		
c) Record quality.		
(d) Record retention.(at least 2 years after their use is discontinued-"e.g., because you no longer import a particular food, you no longer use a particular		

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
foreign supplier, or you have changed your FSVP procedures")		
§ 121.126 Requirement for a food defense plan.	TS/ ISO 22002-1/18	
(a) *Food defense plan.*	TS/ ISO 22002-1/18	Different
(b) *Contents of a food defense plan.* (identification of actionable process steps, focused mitigation strategies, corrective action procedures, written verification procedures)	TS/ ISO 22002-1/18	Different
§ 121.130 Identification of actionable process steps.	TS/ ISO 22002-1/18	Comparable
(a) *Key activity types.* (bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, mixing and similar activities)	TS/ ISO 22002-1/18.2	Comparable
(b) *Vulnerability assessment.* (for each food type, evaluate to ID and prioritize points, steps, procedures based on vulnerability, ID actionable steps)	TS/ ISO 22002-1/18.1 and 18.2	comparable
§ 121.135 Focused mitigation strategies for actionable process steps. (written focused mitigation strategies, monitoring, corrective actions, verification)	TS/ ISO 22002-1/18.2	Different- FSSC22000 does not require monitoring, corrective actions and verification
§ 121.140 Monitoring. (actual values, accurate/ indelible/ legible, detailed, signatures, production code)		FSSC22000 does not address monitoring of these areas
§ 121.310 Additional requirements applying to the food defense plan. (signed and dated, completion and modification)		
§ 121.310 Additional requirements applying to the food defense plan.		

FDA's Proposed Requirement	FSSC22000 Requirement	How does FSSC22000 compare to the FDA requirement?
(at least 2 years, onsite, electronic ok if accessible)		
§ 121.320 Requirements for official review. (promptly available)		
§ 121.325 Public disclosure.		
§ 121.401 Compliance.		