



Convenience  
Distribution  
ASSOCIATION

Presented by: Anne Barker-Smith



**A. Barker-Smith  
Consulting, LLC**

working together to create food safety



*FSMA's Final Rules -  
Implementation INSPECTIONS  
what we are seeing...*

Presented:  
July 11, 2019



**A. Barker-Smith  
Consulting, LLC**

working together to create food safety

# Objective

- ▶ To understand what an FDA FSMA audit looks like, what FDA is looking for, and where your focus should be...



# Food safety is a big deal...

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention.



This is a significant public health burden that is largely preventable.

# FDA's Food Safety Modernization Act

FSMA was signed into law on January 4, 2011, and it has slowly crept toward realization.

The law includes seven rules with staggered implementation dates, beginning as early as 2015.

- ▶ Preventive Controls for Human Foods
- ▶ Preventive Controls for Animal Feed/Food
- ▶ Produce Rule - (water quality requirements are not yet in affect)
- ▶ Foreign Supplier Verification Rule
- ▶ Sanitary Transportation Rule

# Newest rule to impact you ---

## FDA's Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Rule)

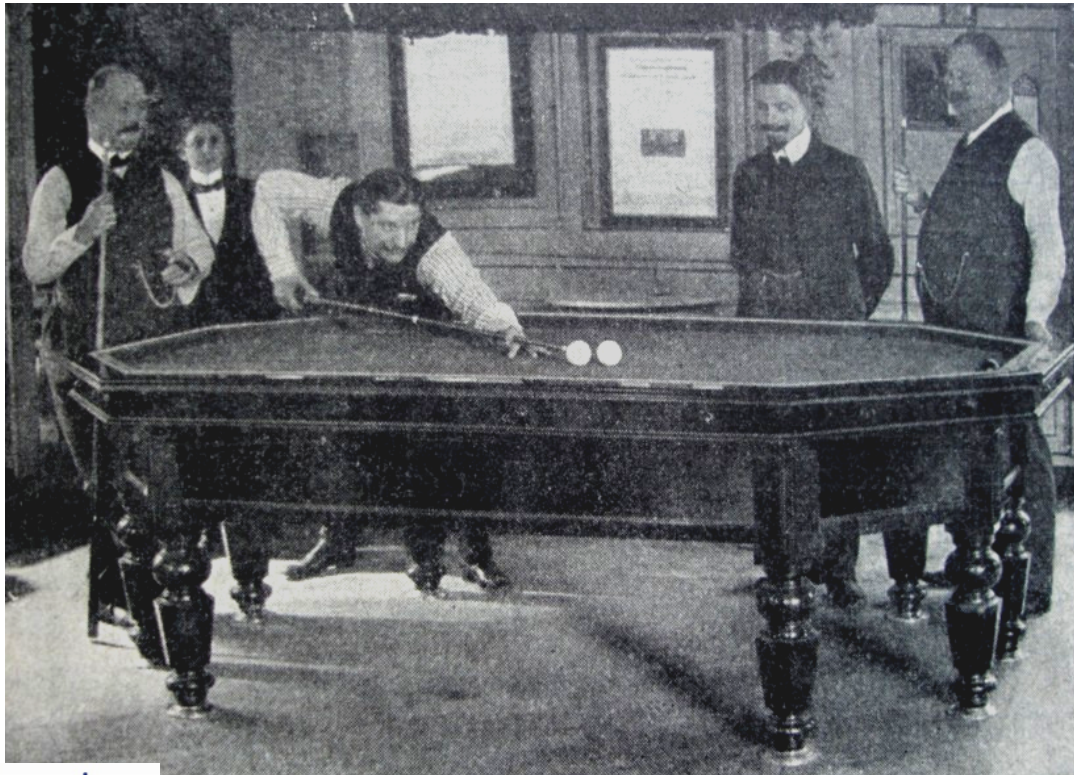
- ▶ The deadline to comply with FDA's IA Rule is quickly approaching – July 26, 2019.
- ▶ If you are a company with over 500 employees, this applies to you!
- ▶ Smaller companies with under 500 employees will have to comply by July 2020 or July 2021 depending on size.

# Like Preventive Controls, IA also requires a Written Plan --

- ▶ **The Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense) final rule** establishes requirements for companies to **create a food defense plan**, aimed at preventing intentional adulteration from acts intended to cause wide-spread harm to public health, including acts of terrorism targeting the food supply.

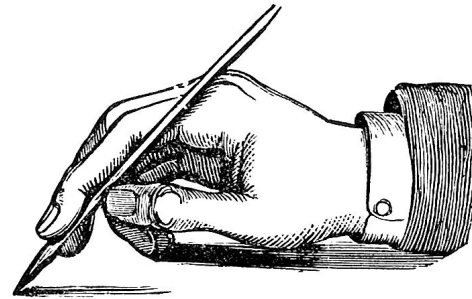
# FSMA is ALL about ... PREVENTION - YOU HAVE TO HAVE A WRITTEN PLAN...

CALLING YOUR SHOT ...  
MAKING YOUR SHOT! ...



DOCUMENTING YOUR SHOT!

- ▶ REMEMBER IF YOU DIDN'T WRITE IT DOWN...



- ▶ YOU DIDN'T DO IT!



# FDA's Top 21 ISSUES taken directly from FDA 483

Inspections ending between 10/1/2017 and 9/30/2018

21 CFR 123.11(b)	<b>Sanitation monitoring</b>	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	188
21 CFR 117.80(c)	<b>Manufacturing, Processing, Packing, Holding - Controls Specifically - Storage</b>	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	175
21 CFR 117.10	<b>Personnel</b>	You did not take a reasonable measure and precaution related to personnel practices. Specifically, ***	161
21 CFR 117.40	<b>Equipment and Utensils - Design and Maintenance</b>	Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against [allergen cross-contact] [contamination]. Specifically, ***	158
21 CFR 117.37	<b>Sanitary Facilities and Control</b>	Your plant did not have adequate sanitary facilities and accommodations. Specifically, ***	143
21 CFR 117.20(b) 21 CFR 110.20(b)(4)	<b>Plant Construction and Design Floors, walls and ceilings</b>	Your plant was not [constructed] [designed] to facilitate maintenance and sanitary operations. Specifically, *** The plant is not constructed in such a manner as to allow [floors] [walls] [ceilings] to be [adequately cleaned and kept clean] [kept in good repair]. Specifically, ***	140
21 CFR 123.6(c)(1)	<b>Food safety hazards (SEAFOOD)</b>	Your HACCP plan does not list the food safety hazards that are reasonably likely to occur. Specifically, ***	117

21 CFR 110.35(c)	<b>Lack of effective pest exclusion</b>	Effective measures are not being taken to [exclude pests from the processing areas] [protect against the contamination of food on the premises by pests]. Specifically, ***	<b>112</b>
21 CFR 123.6(c)(2)	<b>Critical control points</b>	Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards. Specifically, ***	<b>111</b>
21 CFR 117.35(d)	<b>Sanitation of food contact surfaces - frequency</b>	You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against [allergen cross-contact] [contamination of food]. Specifically, ***	<b>93</b>
21 CFR 117.35(a)	<b>Sanitary Operations - Plant Sanitation</b>	You did not clean and sanitize your utensils or equipment in a manner that protects against [allergen cross-contact] [contamination]. Specifically, ***	<b>86</b>
21 CFR 123.6(c)(3)	<b>Critical limits</b>	Your HACCP plan [does not list a critical limit that ensures control of one or more hazards] [lists a critical limit that does not ensure control of one or more hazards]. Specifically,	<b>79</b>
21 CFR 111.70(e)	<b>Specifications - identity, purity, strength, composition</b>	You did not establish product specifications for the [identity] [purity] [strength] [composition] of the finished dietary supplement. Specifically, ***	<b>79</b>
21 CFR 123.6(d)	<b>Signed and dated</b>	Your HACCP plan was not signed and dated [upon initial acceptance] [upon modification] [at least annually]. Specifically, ***	<b>77</b>
21 CFR 110.20(b)(7)	<b>Screening</b>	Failure to provide adequate screening or other protection against pests. Specifically, ***	<b>77</b>
21 CFR 123.6(c)(4)	<b>Monitoring - adequacy</b>	Your HACCP plan lists monitoring [procedures] [frequencies] that do not ensure compliance with the critical limit. Specifically***	<b>77</b>
21 CFR 123.11(c)	<b>Sanitation Records</b>	You are not maintaining sanitation control records that document [monitoring] [corrections of sanitation deficiencies] for [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	<b>76</b>
21 CFR 117.93	<b>Storage and Transportation</b>	<b>You did not store or transport food, including ingredients, under conditions that protect against [allergen cross-contact] [contamination] [deterioration] [adulteration]. Specifically, ***</b>	<b>75</b>





# Sanitation issues 1475 sited events

Reference Number	Short Description	Long Description	Frequency
21 CFR 123.11(b)	<b>Sanitation monitoring</b>	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	188
21 CFR 117.35(a)	<b>Sanitary Operations - Plant Maintenance</b>	You did not [maintain your plant in a clean and sanitary condition] [keep your plant in repair]. Specifically, ***	167
21 CFR 117.37	<b>Sanitary Facilities and Control</b>	Your plant did not have adequate sanitary facilities and accommodations. Specifically, ***	143
21 CFR 117.35(d)	<b>Sanitation of food contact surfaces - frequency</b>	You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against [allergen cross-contact] [contamination of food]. Specifically, ***	93
21 CFR 117.35(a)	<b>Sanitary Operations - Plant Sanitation</b>	You did not clean and sanitize your utensils or equipment in a manner that protects against [allergen cross-contact] [contamination]. Specifically, ***	86
21 CFR 123.11(c)	<b>Sanitation Records</b>	You are not maintaining sanitation control records that document [monitoring] [corrections of sanitation deficiencies] for [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	76
21 CFR 117.35(e)	<b>Sanitation of non-food contact surfaces - frequency</b>	You did not clean your non-food contact surface in a manner and as frequently as necessary to protect against [allergen cross-contact] [contamination]. Specifically, ***	56
21 CFR 117.80(a)	<b>Plant Operations - precautions</b>	You did not [conduct operations in accordance with adequate sanitation principles] [have plant sanitation under the supervision of a competent individual] [take adequate precautions to ensure that production procedures did not contribute to allergen cross-contact and to contamination]. Specifically, ***	52
21 CFR 110.35(a)	<b>Cleaning and sanitizing operations</b>	Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	45
	<b>Failure to clean - general</b>	Failure to clean [food-contact surfaces] [utensils] as frequently as necessary to protect against contamination of food. Specifically, ***	41

# Sanitation ...

21 CFR 117.135(c)(3)	<b>Sanitation Controls Procedures</b>	Your sanitation controls procedures did not ensure [cleanliness of food-contact surfaces] [prevention of allergen cross-contact] [prevention of cross-contamination]. Specifically, ***	24
21 CFR 111.16	<b>Written procedures - cleaning</b>	You did not [establish] [follow] written procedures for cleaning the physical plant. Specifically, ***	18
21 CFR 110.35(d)(3)	<b>Non-food-contact surfaces (S)</b>	Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination. Specifically, ***	16
21 CFR 112.123(a)	<b>Equip &amp; tools - cleanability</b>	You did not use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and maintained. Specifically, ***	14
21 CFR 117.145(a)	<b>Sanitation Controls Monitoring Proced: Establish Implement</b>	You did not [establish] [implement] adequate written procedures for monitoring sanitation controls. Specifically, ***	13
21 CFR 110.35(d)(5)	<b>Shown to be effective</b>	The [facility] [procedure] [machine] used for [cleaning] [sanitizing] of [equipment] [utensils] has not been shown to provide adequate [cleaning] [sanitizing treatment]. Specifically, ***	12
21 CFR 111.25(c)	<b>Procedures - equipment - cleaning, sanitizing</b>	You did not [establish] [follow] written procedures for maintaining, cleaning, and sanitizing, equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements. Specifically, ***	12
21 CFR 117.150(a)(1)	<b>Sanitation Controls Corrective Action Proced: Estab Implemnt</b>	You did not [establish] [implement] adequate written corrective action procedures for sanitation controls. Specifically, ***	12
21 CFR 117.145(c)(1)	<b>Sanitation Controls - Monitoring Records</b>	You did not have sanitation controls monitoring records. Specifically, ***	10



# Sanitation...

21 CFR 123.11(b)	Sanitation monitoring documentation	Your sanitation control records do not accurately document the conditions or practices observed at your firm. Specifically***
21 CFR 110.80(b)(1)	Maintenance of equip., utensils, and finished food packaging	Failure to maintain [equipment] [utensils] [finished food containers] in an acceptable condition through appropriate cleaning and sanitizing. Specifically, ***
21 CFR 117.165(b)	Sanitation Controls Verification Procedures: Establish Implement	You did not [establish] [implement] adequate written sanitation controls verification procedures for [product testing] [environmental monitoring]. Specifically, ***
21 CFR 117.135(c)(3)	Sanitation Controls Procedures	Your sanitation controls procedures did not ensure [cleanliness of food-contact surfaces] [prevention of allergen cross-contact] [prevention of cross-contamination]. Specifically, ***
21 CFR 111.16	Written procedures - cleaning	You did not [establish] [follow] written procedures for cleaning the physical plant. Specifically, ***
21 CFR 110.35(d)(3)	Non-food-contact surfaces (S)	Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination. Specifically, ***
21 CFR 120.6(c)	SSOP records	You do not [always] maintain sanitation standard operating procedure records that document [the monitoring of conditions and practices during processing] [corrections to conditions and practices that were not met]. Specifically, ***
21 CFR 117.145(b)	Sanitation Controls - Monitoring Frequency	Your sanitation controls monitoring frequency was not adequate. Specifically, ***
21 CFR 110.35(e)	Storage of cleaned portable equipment (S)	Failure to store cleaned and sanitized portable equipment in a [location] [manner] which protects food-contact surfaces from contamination. Specifically, ***

# Pest Management issues - sited 398 events

21 CFR 117.35(c)	Pest Control	You did not [exclude pests from your food plant] [use pesticides under precautions and restrictions] to protect against contamination of food. Specifically, ***	183
21 CFR 110.35(c)	Lack of effective pest exclusion	Effective measures are not being taken to [exclude pests from the processing areas] [protect against the contamination of food on the premises by pests]. Specifically, ***	112
21 CFR 110.20(a)(1)	Harborage areas	Failure to [properly store equipment] [remove litter and waste] [cut weeds or grass] that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures. Specifically, ***	45
21 CFR 118.4(c)(1)	Monitoring for rodents	The presence of rodents is not monitored by appropriate monitoring methods. Specifically,***	11
21 CFR 111.16	Written procedures - pest control	You did not [establish] [follow] written procedures for pest control. Specifically, ***	9
21 CFR 118.4(c)(2)	Monitoring for flies	The presence of flies is not monitored by appropriate monitoring methods. Specifically,***	7
21 CFR 110.37(f)	Odor, attractant for pests, harborage	The [conveyance] [storage] [disposal] of [rubbish] [offal] does not minimize the [development of odor] [potential for waste becoming an attractant and harborage or breeding place for pests]. Specifically, ***	5

# Pest Management ...

21 CFR 111.15(d)(2)	Pest control measures	You did not take effective measures [to exclude pests from the physical plant] [to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests]. Specifically, ***	4
21 CFR 111.20(h)	Physical plant - screening against pests	Your physical plant did not use adequate screening or other protection against pests. Specifically, ***	4
21 CFR 111.23(b)	Records - cleaning, pest control	You did not make and keep records of the written procedures for [cleaning the physical plant] [pest control]. Specifically, ***	4
21 CFR 118.10(a)(3)(ii)	Rodent and pest control documentation	You did not maintain records documenting compliance with rodent and other pest control measures. Specifically, ***	4
21 CFR 111.15(d)(1)	Animals and pests in facility	You allowed [animals] [pests] in your physical plant. Specifically, ***	1
21 CFR 112.128(a)	Pest contamination in buildings	You did not take necessary measures to protect against contamination by pests in buildings. Specifically, ***	1



# Personnel issue - 375 sited events

Reference Number	Short Description	Long Description	Frequency
21 CFR 110.10(b)(6)	<b>Failure to wear</b>	Failure to wear [hair nets] [head bands] [caps] [beard covers] [hair restraints] where appropriate. Specifically, ***	<b>54</b>
21 CFR 110.10(b)(3)	<b>Not washed/sanitized when appropriate</b>	Employees did not [wash] [sanitize] hands thoroughly in an adequate hand-washing facility [before starting work] [after each absence from the work station] [at any time their hands may have become soiled or contaminated]. Specifically, ***	<b>44</b>
21 CFR 110.10(b)(7)	<b>Storage of personal items</b>	Personal [clothing] [belongings] were stored in an area where [food is exposed] [equipment or utensils are washed]. Specifically, ***	<b>29</b>
21 CFR 110.10(b)(8)	<b>Personal food/drink/tobacco</b>	<b>Employees were observed to be [eating food] [chewing gum] [drinking beverages] [using tobacco] in areas where [food is exposed] [equipment or utensils are washed]. Specifically, ***</b>	<b>24</b>
21 CFR 110.10(b)(6)	<b>Effective use of hair restraint</b>	Failure to wear [hair nets] [head bands] [caps] [beard covers] [appropriate hair restraints] in an effective manner. Specifically, ***	<b>24</b>
21 CFR 110.10(b)(4)	<b>Unsecured jewelry</b>	Employees failed to remove unsecured jewelry or other objects which might fall into [food] [equipment] [containers]. Specifically, ***	<b>17</b>
21 CFR 108.25(f)	<b>Approved school</b>	Personnel involved in [acidification] [pH control] [heat treatment] [critical factors of the operation] were not under the operating supervision of a person who attended and satisfactorily completed a school approved by the FDA Commissioner. Specifically, ***	<b>17</b>
21 CFR 114.10	<b>Personnel</b>	Operators of processing and packaging systems are not under the operating supervision of a person who has attended and satisfactorily completed a school approved by the Commissioner. Specifically, ***	<b>14</b>
21 CFR 110.10(c)	<b>Training of handlers and supervisors</b>	Appropriate training in food handling techniques and food protection principles has not been provided to [food handlers] [supervisors]. Specifically, ***	<b>14</b>



# Personnel --

21 CFR 110.37(e)(2)	Hand cleaning and sanitizing preparations	Lack of effective hand [cleaning] [sanitizing] preparations. Specifically, ***	14
21 CFR 110.10(b)(1)	Suitable outer garments	Suitable outer garments are not worn that protect against contamination of [food] [food contact surfaces] [food packaging materials]. Specifically, ***	12
21 CFR 110.10(b)(4)	Hand jewelry - remove/cover	Failure to [remove] [adequately cover] hand jewelry which cannot be adequately sanitized during periods where food is being manipulated by hand. Specifically, ***	10
21 CFR 111.14(b)(1)	Personnel - records - written procedures	You did not make and keep written procedures for [preventing microbial contamination from sick or infected personnel] [hygienic practices] [determining personnel qualification requirements]. Specifically, ***	10
21 CFR 110.37(e)(3)	Hand drying	Lack of a sanitary towel service or suitable hand drying devices. Specifically, ***	9
<b>21 CFR 117.305</b>	<b>Training Records - general requirements</b>	Your training records did not meet general record requirements. Specifically, ***	<b>9</b>
21 CFR 110.37(e)(5)	Signs	Lack of posted, readily understandable signs directing employees to wash and sanitize hands as appropriate. Specifically, ***	8
21 CFR 111.14(b)(2)	Personnel - records - training	You did not make and keep documentation of training. Specifically, ***	8
21 CFR 110.10(b)(2)	Personal cleanliness	Employees in contact with [food] [food-contact surfaces] [food-packaging materials] were not maintaining adequate personal cleanliness. Specifically, ***	6
21 CFR 113.10	Supervisors	Supervisors have not satisfactorily completed training in a school approved by the Commissioner for areas under their responsibility. Specifically, ***	6



# Personnel --

21 CFR 110.10(b)(5)	<b>Glove condition</b>	Gloves used in food handling are not maintained in an intact, clean, and sanitary condition. Specifically, ***	6
21 CFR 111.12(c)	<b>Personnel - education, training, experience</b>	Personnel engaged in [manufacturing] [packaging] [labeling] [holding] dietary supplements do not have the education, training, or experience to perform the person's assigned functions. Specifically, ***	6
21 CFR 117.180(d)	<b>PCQI Training Records</b>	<b>You did not have [complete] training records for your preventive controls qualified individual. Specifically, ***</b>	6
21 CFR 113.10	<b>Operators</b>	Operators of [processing systems] [retorts] [aseptic processing systems] [product formulating systems] are not under the operating supervision of a person that has attended and satisfactorily completed, a school approved by the Commissioner. Specifically, ***	5
21 CFR 111.10(b)	<b>Personnel - hygienic practices</b>	Your personnel did not use hygienic practices to the extent necessary to protect against contamination of components, dietary supplements, or contact surfaces. Specifically, ***	5
21 CFR 111.12(b)	<b>Personnel - quality control operations</b>	You have not identified personnel to be responsible for your quality control operations. Specifically, ***	5
21 CFR 112.22(c)	<b>Training for supervisors</b>	You did not employ at least one supervisor or responsible party that has successfully completed appropriate food safety training. Specifically, ***	5
21 CFR 108.35(g)	<b>Approved school</b>	Operators of [retorts] [thermal processing systems] [aseptic processing and packaging systems] [container closure inspections] were not under the operating supervision of a person who attended and satisfactorily completed a school approved by the FDA Commissioner. Specifically, ***	4
21 CFR 111.15(i)	<b>Hand-washing facilities</b>	Your hand-washing facilities [are not adequate] [are not convenient] [do not furnish running water at a suitable temperature]. Specifically, ***	4



# Food Safety Plan - Preventive Controls or HACCP - 3571 sited event -

21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding - Controls	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	175
21 CFR 123.6(b)	HACCP plan implementation	You did not implement the [monitoring] [recordkeeping] [verification] procedures listed in your HACCP plan. Specifically, ***	136
21 CFR 123.6(c)(1)	Food safety hazards	Your HACCP plan does not list the food safety hazards that are reasonably likely to occur. Specifically, ***	117
21 CFR 123.6(c)(2)	Critical control points	Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards. Specifically, ***	111
21 CFR 123.6(c)(3)	Critical limits	Your HACCP plan [does not list a critical limit that ensures control of one or more hazards] [lists a critical limit that does not ensure control of one or more hazards]. Specifically,	79
21 CFR 123.6(d)	Signed and dated	Your HACCP plan was not signed and dated [upon initial acceptance] [upon modification] [at least annually]. Specifically, ***	77
21 CFR 123.6(c)(4)	Monitoring - adequacy	Your HACCP plan lists monitoring [procedures] [frequencies] that do not ensure compliance with the critical limit. Specifically***	77
21 CFR 123.6(c)(5)	Corrective action plan	Your HACCP plan includes a corrective action plan that is not in accordance with 21 CFR 123.7(b) to ensure [affected product is not entered into commerce] [the cause of the deviation was corrected]. Specifically***	73
21 CFR 117.130(a)(1)	Hazard Analysis - Identification of Hazard	Your hazard analysis did not identify a known or reasonably foreseeable hazard that required a preventive control. Specifically, ***	68

# Food Safety Plan - Preventive Controls or SEAFOOD HACCP

21 CFR 123.6(b)	No [SEAFOOD] HACCP plan	You do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur. Specifically, ***	64
21 CFR 123.8(a)(3)	Verification - record review - frequency	You did not review [some of] your [critical control point monitoring] [corrective action] [calibration] [in-process testing] [end-product testing] records [within one week] [within a reasonable time] after the records were made. Specifically, ***	57
21 CFR 111.103	Written procedures - quality control operations	You did not [establish] [follow] written procedures for quality control operations. Specifically, ***	57
21 CFR 111.453	Written procedures - holding	You did not [establish] [follow written] procedures for holding and distributing operations. Specifically, ***	47
21 CFR 111.553	Written procedures - product complaint	You did not [establish] [follow] written procedures for the requirements to review and investigate a product complaint. Specifically, ***	43
21 CFR 110.80	Reasonable precautions	All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source. Specifically, ***	40
21 CFR 123.6(c)(6)	Verification procedures - adequacy	Your HACCP plan lists verification [procedures] [frequencies] that have not been developed in accordance with 21 CFR 123.8(a) to ensure that your HACCP plan is adequate to control food safety hazards, and is being effectively implemented. Specifically, ***	38
21 CFR 117.80(c)(8)	Process Control - Foreign Objects	You did not take an adequate measure to protect against inclusion of metal or extraneous material in food. Specifically, ***	33
21 CFR 123.9(a)	Records - content	Your records do not include the [name and location of the processor or importer] [date and time of the activity the record reflects] [signature or initials of the person performing the operation] [identity of the product and the production code, if any]. Specifically, ***	32

# Calibration - thermometers - 63 sited events

21 CFR 123.8(a)(2)(ii)	<b>Calibration - adequacy</b>	Your process monitoring equipment is not calibrated to ensure that it reads accurately. Specifically, ***	<b>31</b>
21 CFR 123.8(a)(2)	<b>Ongoing verification - complaints, calibration records</b>	Your verification procedures do not include, at a minimum, ongoing verification activities including [review of consumer complaints] [calibration of process monitoring instruments] [review of monitoring, corrective action, and calibration records]. Specifically, ***	<b>11</b>
21 CFR 111.27(b)	<b>Instruments - calibration</b>	You did not calibrate instruments or controls used in manufacturing or testing a component or dietary supplement [before the first use] [at the frequency specified in writing by the manufacturer or at routine intervals or as necessary] to ensure the accuracy and precision of the instruments or controls. Specifically, ***	<b>9</b>
21 CFR 110.40(e)	<b>Lack of thermometer</b>	Lack of an accurate indicating thermometer, temperature measuring device, or temperature recording device in each freezer and cold storage compartment used to store food capable of supporting the growth of microorganisms. Specifically, ***	<b>8</b>
21 CFR 120.11(a)(2)	<b>Calibration, testing - no records</b>	You do not maintain records of [calibration of process-monitoring instruments] [periodic end-product or in-process testing]. Specifically, ***	<b>4</b>

# Facility issues - 726 sited events

Reference Number	Short Description	Long Description	Frequency
21 CFR 117.20(b)	<b>Plant Construction and Design</b>	Your plant was not [constructed] [designed] to facilitate maintenance and sanitary operations. Specifically, ***	140
21 CFR 110.20(b)(7)	<b>Screening</b>	Failure to provide adequate screening or other protection against pests. Specifically, ***	77
21 CFR 110.20(b)(4)	<b>Floors, walls and ceilings</b>	The plant is not constructed in such a manner as to allow [floors] [walls] [ceilings] to be [adequately cleaned and kept clean] [kept in good repair]. Specifically, ***	70
21 CFR 110.80(b)(2)	<b>Manufacturing conditions</b>	Failure to [manufacture] [package] [store] foods under conditions and controls necessary to minimize [the potential for growth of microorganisms] [contamination]. Specifically, ***	58
21 CFR 110.35(a)	<b>Buildings/sanitary</b>	Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition. Specifically, ***	57
21 CFR 117.20(a)	<b>Grounds</b>	You did not keep the grounds around your plant in a condition that would protect against the contamination of food. Specifically, ***	45
21 CFR 110.35(a)	<b>Buildings/good repair</b>	Failure to maintain [buildings] [fixtures] [physical facilities] in repair sufficient to prevent food from becoming adulterated. Specifically, ***	40
21 CFR 110.80(a)(1)	<b>Storage</b>	Failure to store raw materials in a manner that [protects against contamination] [minimizes deterioration]. Specifically, ***	37
21 CFR 110.37(e)	<b>Running water at suitable temperature</b>	Hand-washing facilities lack running water of a suitable temperature. Specifically, ***	27
21 CFR 110.20(b)(4)	<b>Drip and condensate</b>	The plant is not constructed in such a manner as to prevent [drip] [condensate] from contaminating [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	26
21 CFR 110.37(b)(3)	<b>Plumbing As source of contamination</b>	Plumbing constitutes a source of contamination to [food] [water supplies] [equipment] [utensils]. Specifically, ***	24



# Facility issues

21 CFR 110.37(e)(1)	<b>Suitable locations</b>	Failure to provide [hand washing] [hand sanitizing] facilities at each location in the plant where needed. Specifically, ***	12
21 CFR 110.20(b)(6)	<b>Fans/air blowing equipment</b>	Failure to [locate] [operate] fans and other air-blowing equipment in a manner that minimizes the potential for contaminating [food] [food-contact surfaces] [food-packaging materials]. Specifically, ***	11
21 CFR 110.37(b)(4)	<b>Drainage</b>	Plumbing is not [of adequate size and design] [adequately installed and maintained] to provide adequate floor drainage. Specifically, ***	10
21 CFR 110.20(b)(2)	<b>Contamination with microorganisms, chemicals, filth, etc.</b>	Proper precautions to protect [food] [food-contact surfaces] [food-packaging materials] from contamination with [microorganisms] [chemicals] [filth] [extraneous material] cannot be taken because of deficiencies in plant [size] [construction] [design]. Specifically, ***	8
21 CFR 112.126(b)	<b>Buildings - prevent contamination</b>	You did not implement measures to prevent contamination of produce and food contact surfaces through [floors] [walls] [ceilings] [fixtures] [ducts] [pipes] [drip] [condensate]. Specifically, ***	7
21 CFR 110.37(a)	<b>Suitable temp. and pressure</b>	Failure to provide running water [at a suitable temperature] [under suitable pressure] for [processing of food] [cleaning of equipment, utensils and food-packaging materials] [employee sanitary facilities]. Specifically, ***	6
21 CFR 110.37(d)(4)	<b>Doors opening into processing areas</b>	Toilet doors open into areas where food is exposed to airborne contamination, and there are no alternative means taken to prevent such contamination. Specifically, ***	6



# Facility issues

21 CFR 110.40(d)	Holding, conveying, mfg systems - design & construction	Lack of appropriate [design] [construction] to enable [holding] [conveying] [manufacturing] systems to be maintained in an appropriate sanitary condition. Specifically, ***	5
21 CFR 110.40(a)	Food-contact - corrosion resistant	Lack of corrosion-resistant food contact surfaces. Specifically, ***	5
21 CFR 110.20(b)(4)	Spacing of equipment	Aisles or working spaces between equipment and walls are [obstructed] [of inadequate width]. Specifically, ***	5
21 CFR 110.37(b)(5)	Backflow prevention	Lack of backflow protection from piping systems that discharge [waste water] [sewage]. Specifically, ***	5
21 CFR 110.37(b)(2)	Convey sewage	Plumbing is not [of adequate size and design] [adequately installed and maintained] to properly convey sewage and liquid disposable waste from the plant. Specifically, ***	4
21 CFR 110.37(d)(3)	Self-closing doors	Toilet facilities lack self-closing doors. Specifically, ***	4
21 CFR 110.20(a)	Maintenance of grounds	Maintenance of the grounds is inadequate to protect against contamination of food. Specifically, ***	4
21 CFR 111.20(d)(1)(i)	Floors, walls, ceilings	Your [floors] [walls] [ceilings] were not designed and constructed so they can be adequately cleaned and kept clean and in good repair. Specifically, ***	4





# Storage and Distribution were specifically sited for ... 398 events

Reference Number	Short Description	Long Description	Frequency
21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding - Controls Specifically - Storage	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	175
21 CFR 117.93	Storage and Transportation	You did not store or transport food, including ingredients, under conditions that protect against [allergen cross-contact] [contamination] [deterioration] [adulteration]. Specifically, ***	75
21 CFR 111.453	Written procedures - holding	You did not [establish] [follow written] procedures for holding and distributing operations. Specifically, ***	47
21 CFR 110.80(a)(1)	Storage	Failure to store raw materials in a manner that [protects against contamination] [minimizes deterioration]. Specifically, ***	37
21 CFR 111.475(b)(1)	Written procedures - holding; distributing	You did not make and keep written procedures for holding and distributing operations. Specifically, ***	29
21 CFR 110.93	Storage/transportation of finished goods (contamination)	Failure to [store] [transport] finished food under conditions that would protect against [physical] [chemical] [microbial] contamination. Specifically, ***	19
21 CFR 110.80(b)(3)	Holding foods - refrigerate/freezing/heat	Failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents the food from becoming adulterated. Specifically, ***	11
21 CFR 111.155(e)	Components - contamination, deterioration, mix-ups	You did not hold components under conditions that will [protect against contamination] [protect against deterioration] [avoid mix-ups]. Specifically, ***	5



# Where do you start?

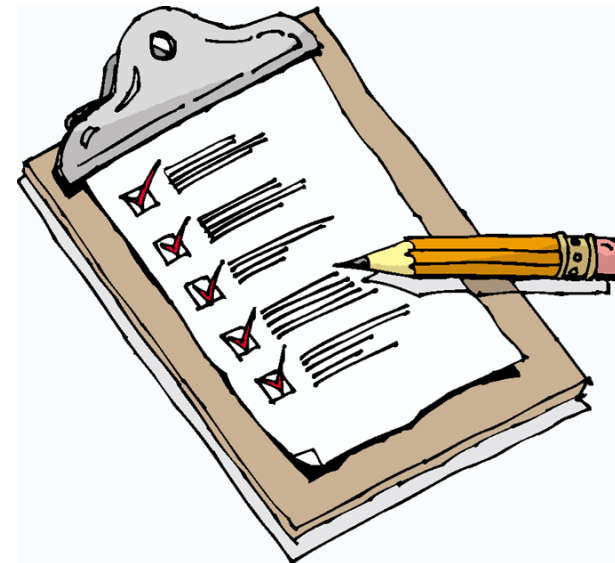
Just...



# Develop a strong Food Safety Plan

Make sure your Food Safety Plan is written - verified and is fully implemented with appropriate records!

- ☑ Complete and verified Flow Diagram
- ☑ Correct Hazard Analysis with all hazards identified and assessed
- ☑ Correct CCP or Preventive Control Steps identified for
  - ☐ Process,
  - ☐ Allergens
  - ☐ Sanitation and
  - ☐ Supply Chain



This Photo by Unknown Author is licensed under [CC BY-NC-ND](https://creativecommons.org/licenses/by-nc-nd/4.0/)

# FSP is an active program... BASED ON YOUR PRODUCT MIX

- ▶ Complete Food Safety Plan Reassessments at least annually and when necessary for CCP failures, significant changes, unanticipated hazards or when new information becomes available.



# Take care of the Basics!

Pest management!



Proper Sanitation!



# PERSONNEL - Hygiene

WASH HANDS / KEEP GLOVES  
CLEAN



## TRAINING!



- ▶ FSPCA - PREVENTIVE CONTROLS FOR HUMAN FOODS - PCQI -- Contact me for course schedule
- ▶ ONLINE TRAINING PROGRAMS FOR WAREHOUSE ASSOCIATES!

<https://absctraining.learnupon.com/store>

- ▶ USE CDA's Coupon code: **ABSCDA15** to get 15% off of all purchases!

# Develop a written Food Defense Plan

- ▶ Monitor your facility for open doors ...
- ▶ Contractors, visitors, guests, even staff who are in restricted areas or who are carrying materials that could intentionally be used to attack the food.
- ▶ Monitor suppliers and products that could be intentionally adulterated for economic gain - or intentionally attacked for food terrorism.
- ▶ Have a written defense plan - with monitoring records!



# Questions???

## Need More Help?

Let us connect you ... with solutions...

- Risk/Compliance Assessment Audit
- Staff and Warehouse Associate Training
- 3<sup>rd</sup> Party Audit Preparation
- Preventive Controls, HACCP, GMP/SSOP & Food Defense, Food Safety Plan Development, Implementation or Review

ONLINE TRAINING PROGRAMS FOR WAREHOUSE ASSOCIATES!

<https://absctraining.learnupon.com/store>

USE CDA's Coupon code: **ABSCDA15** to get 15% off of all purchases!

*Anne Barker-Smith*  
**A. Barker-Smith Consulting, LLC**  
18143 Beaver Dam Road  
Beaverdam, VA 2301  
804-305-2272  
email: [anne@abarker-smithconsulting.com](mailto:anne@abarker-smithconsulting.com)  
[www.abarker-smithconsulting.com](http://www.abarker-smithconsulting.com)

