FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

EXAMPLE FOOD SAFETY PLAN
DRY EXTRUDED DOG AND CAT FOOD

Owner, operator, or agent in charge: *Arnold Zipfel, General Manager, ABC Pet Food 6/2/2016*

This manual was created to assist participants in the Food Safety Preventive Controls Alliance's *Preventive Controls for Animal Food* course in an attempt to reinforce learning.

All examples are hypothetical. Application of preventive controls requires in-depth knowledge of actual operating conditions, thus information in the curriculum and in this example plan may not be directly applicable to a specific operation. Assistance from a *Preventive Controls Qualified Individual* is necessary to ensure compliance with FDA regulations.

1st Edition, June 2016

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1. Background Information

Food Safety Team Members

Name	Position
I.R. Charge*	Plant manager
F.S. Leader	Production supervisor
I.M. Quality	Quality supervisor
I.M. Fixer	Maintenance supervisor
**Preventive Controls Qualified Individual*. Attended FSPCA Course for Animal Food June 2016. Completion certificate is in personnel file.	

Facility Overview

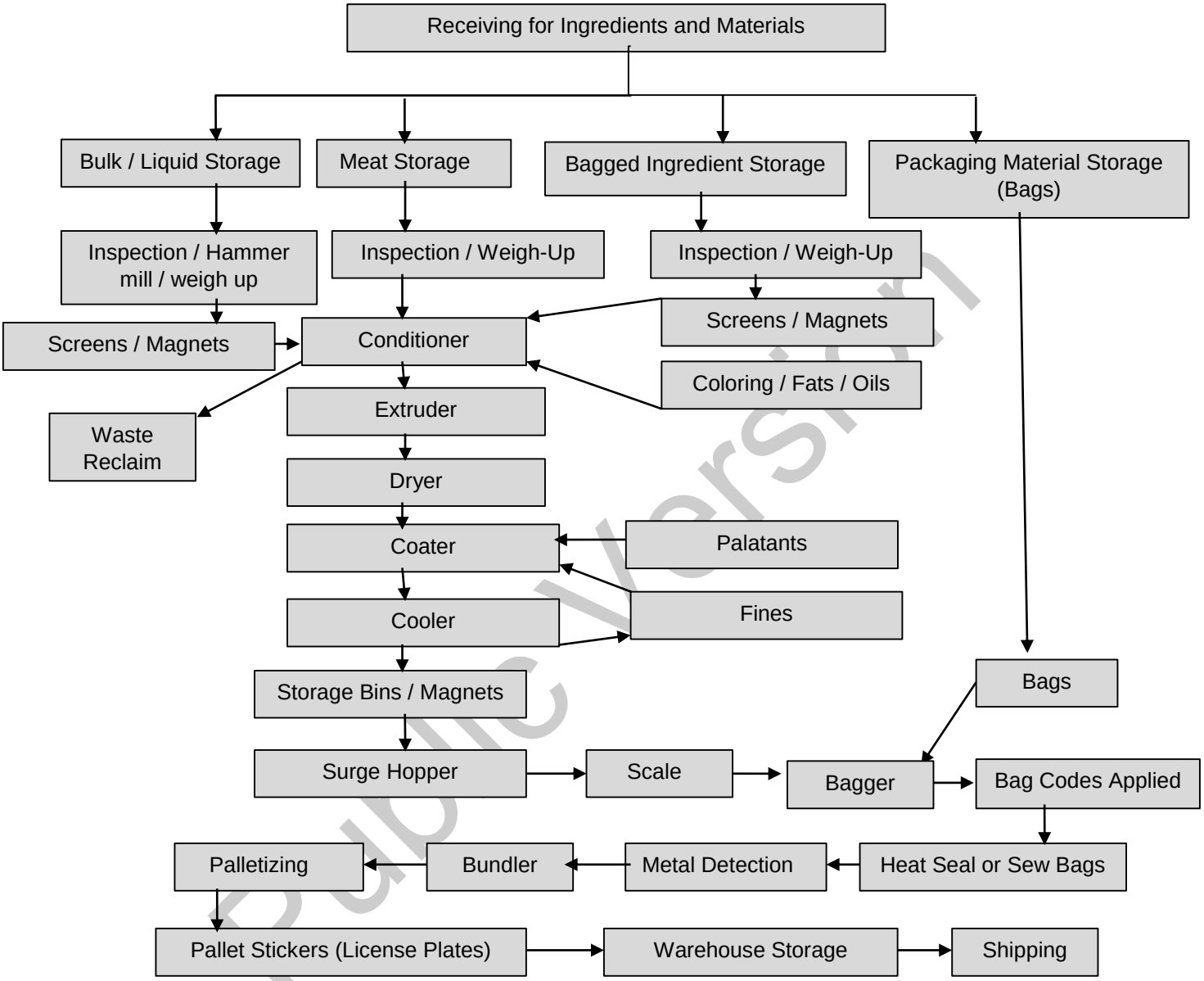
- **Facility Description:** The facility was built in the 1980s and runs one shift, 5 days per week.
- **Product Description:** Complete and balanced food for all life stages of dogs and cats. Dry extruded kibble is packaged in differing bagged net weights.
- **Intended Use:** Fed as a complete ration to dogs or cats at all life stages. Fed as is, directly from the bag and stored in a cool, dry environment.

Hazard Evaluation Rubric

Critical | Moderate | Negligible

		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Flow Diagram



2. Hazard Analysis and Preventive Controls Determination

**Note that these sections are abridged; typical may likely require multiple pages. Additional justification may be necessary to attached, particularly for when it is determined that hazards do <u>not</u> require a preventive control (i.e. historical data to support thiamine levels in incoming vitamin premix are in accordance with the COA is appropriate to include).*

Table 1. Hazard Analysis

Identification			**Evaluation**				**Preventive Control(s)**	
(1)	(2)		(3)	(4)	(5)	(6)	(7)	(8)
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*		Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Ingredients	B	*Salmonella* spp.	I – High	A – High	Yes	FDA *Salmonella* CPG 690.800	Process Control: Extrusion temperature	1
							Sanitation control: Post-extruder surface sanitizing	2
	C	Thiamine deficiency	II- Medium	C – Low	No	COA used by known supplier with historical data to confirm values	n/a	n/a
	P	Foreign material : metal, plastic, bone, glass, wood	II- Medium	B - Medium	Yes	Ingredients may include non-ferrous metal that may not be caught by magnet	Process Control: Metal detection in finished pet foods	3
Bulk receiving	B	*Salmonella* spp.	I – High	A – High	Yes	FDA *Salmonella* CPG 690.800	Process Control: Extrusion temperature	1
							Sanitation control: Post-extruder surface sanitizing	2
	C	None	n/a	n/a	n/a	n/a	n/a	n/a
	P	Foreign material : metal, plastic, glass, wood	II- Medium	B - Medium	Yes	Foreign material, especially metal, may enter receiving grate	Process Control: Metal detection in finished pet foods	3
Mixing	B	None	n/a	n/a	n/a	n/a	n/a	n/a
	C	Thiamine deficiency	II- Medium	C – Low	No	COA used by known supplier with historical data to confirm values	n/a	n/a
	P	Metal	II- Medium	B - Medium	Yes	Mixer paddles made of metal	Process Control: Metal detection in finished pet foods	3

3. Preventive Controls and Management Components

**Note that these sections are abridged; typical may likely require multiple pages (i.e. Preventive Control #3 is not shown).*

Table 2. Description of Preventive Controls

Preventive Control(s)					Management Components					
(1)	(2)	(3)	(4)	(5)	(6)				(7)	(8)
					Monitoring (if applicable)					
Hazard Requiring a Preventive Control	Appropriate Control for *Hazard Requiring a Preventive Control*	PC Number	PC Category	Parameters (if applicable)	What	How	Frequency	Who	Corrective Action(s) and/or Correction(s)	Records
Salmonella spp.	Extrusion temperature	1	Process Control	Extruder barrel temperature > 178°F (instantaneous 10^6 reduction)	Automation system	Extruder records, thermometer readings	Continuous with exception alarms	Shift operator running the automation system	Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate	Extruder records, validation documents, corrective action records, and training, thermometer accuracy, thermometer calibration, and verification records
Salmonella spp.	Post-extruder surface sanitizing	2	Sanitation control	Any residual material on post-extruder surfaces or 200 ppm sanitizer concentration	Visual inspection of surfaces, sanitizer concentration	SOP 201.2	Before operations begin and end of daily production	Sanitation team member	Correction: If residual material is observed on the animal food-contact surface, re-clean and re-sanitize. If sanitizer is not at the proper concentration, make a new solution. Corrective action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate	Daily Sanitation Sheet, corrective action and correction records, training records, environmental monitoring records

**Note that these sections are abridged; typical may likely require multiple pages (i.e. Preventive Control #3 is not shown).*

Table 3. Description of Verification Activities

Activity	Description of Activity

Type of Validation	• Extrusion temperature
	  ○ IFT Report to FDA: Kinetics of Microbial Inactivation, 2000
	  ○ AFIA *Salmonella* Control Guidelines, 2010
	  ○ Bianchini et al. in 2012.
	  ○ Internal process data: minimum required temperature = 175.6 F
	• Post-extruder surface sanitizing
	  ○ n/a

Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.

Type of Verification of Implementation and Effectiveness	• Extrusion temperature
	  ○ Daily checks to confirm thermometer accuracy
	  ○ Quarterly calibration of thermometers
	  ○ Test and hold procedures per SOP 506.3
	• Post-extruder surface sanitizing
	  ○ Environmental monitoring per SOP 213.6
	  ○ Product testing when necessary per SOP 213.7

Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

Supporting SOPs

**Note that these sections are abridged; typical may likely require multiple pages (i.e. SOP 213.6, 213.7, and 506.3 are not shown, but are referenced in Tables 1, 2, or 3).*

Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Pet Food Example

SOP 201.2: Finished Product Animal Food Contact Surface Sanitizing

Purpose: Cleaning and sanitizing of the finished product animal food contact surfaces (equipment and utensils) are important to reduce cross-contamination or recontamination with environmental pathogens that may impact animal food safety.
Frequency: Before operations begin and at the end of daily production
Who: Sanitation team member
Procedure:

1. Remove gross material with a squeegee.
2. Wipe surface with a clean cloth dipped in ABC cleaning solution (2 oz. per gallon).
3. Rinse surface with clean water. Detergent remaining on the surface may inactivate the sanitizer.
4. Spray surface with 200 ppm quaternary ammonium compound solution, ensuring that entire surface is covered. Sanitizer must contact surface for 1 minute per label directions.
5. Allow surface to air dry, about 5 minutes.

Monitoring: Inspect animal food contact surfaces for residual material and cleanliness. Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation Sheet
Corrections: If residual material is observed on a surface, re-clean and sanitize. If quaternary ammonium compound solution is not at the proper concentration, make a new solution.
Corrective Action: Identify and correct the problem; reduce the likelihood that the problem will recur; evaluate all affected animal food for safety; prevent affected animal food from entering commerce as necessary; reanalyze the food safety plan when appropriate
Records: Daily Sanitation Sheet
Verification: Supervisor (daily) and PCQI (within 7 working days) reviews Daily Sanitation Sheet

4. Recall Plan

Reviewed by: *Signature*, Title

Date: June 2, 2016

This model Recall Plan identifies information that is either required or recommended to facilitate an effective and efficient recall. While a Recall Plan is required by the *Preventive Controls for Animal Food* regulation, no specific format and content is specified. This model contains questions and templates that can be used to develop an individualized Recall Plan. A Recall Plan must be developed as part of your Food Safety Plan records.

Recall Team

Assignment	Person	Contact Information
Facility Manager Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Responsibility:		
Publicity and Public Relations Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Responsibility:		
Sales & Marketing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Nutritionist or Veterinarian Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Purchasing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Quality Assurance Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Accountant Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Attorney Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Administrative Support		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
FDA Recall Coordinator		Office: xxx-xxx-xxxx

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe your product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	**If no recall is needed**: Document why not and action.
News media story on problem with a type of animal food you produce	Assemble recall team, review internal records		**If recall is needed**: • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		

Information Templates for FDA Communication

Product Information

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product labels
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Bag label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

Codes (Lot Identification Numbers):

- Lot number(s) involved: _____
- Lot numbers coding system: *Describe how to read your product code: -*
  _____

  _____
- Expected shelf life of product: _____

Recall Firm Contacts

Provide this information to FDA for clear communication:

Manufacturer name: [Name and address]

Position	Name, Title	Contact Information
RECALL coordinator		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Most responsible individual		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxFax: xxx-xxx-xxxx email: xxxxxxxxxx
Public contact:	*May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator focus on retrieving product and resolving the issue*	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx

Notification of the public

The public will be notified via press release using the template provided below:

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]
[--No Other Products Affected--]

Contact
Consumer:
1-xxx-xxx-xxx

Media Contact:
xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- **[insert lot codes]**

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	[insert product codes(s)]	[insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

Recall Strategy

Reason for the Recall

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (toxic metal, medication, prohibited animal protein), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL lot(s) subject to recall, or just a portion of the lot(s) subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved	
If a State agency is involved in this recall, identify Agency and contact.	

Volume of Recalled Product

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • distributor level	
• customer level	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

Distribution Pattern

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
▪ wholesalers/distributors	
▪ repackers	
▪ manufacturers	
▪ retail	
▪ consumers (internet or catalog sales)	
▪ foreign consignees (specify whether they are wholesale distributors, retailers or users)	
▪ Geographic areas of distribution, including foreign countries	

Consignee List

Commercial customers

Name	*Street Address*	*City*	*State*	*Recall contact name*	*Contact phone number*	*Recalled product **was** shipped?*	*Recalled product **was** sold?*	*Recalled product **may have** been shipped or sold*

Level in the distribution chain

Level	Included		Rational if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Notification of customers

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Appropriate disposal of recalled animal food

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

5. Implementation Records

**Necessary components include: 1. validation, 2. verification of monitoring, 3. verification of corrective actions, 4. calibration of process monitoring equipment, 5. product testing, and 6. records review.*

In this example, the validation information that is appropriate to include is: the abstract of the IFT Report to FDA, the AFIA Salmonella Guidelines, the abstract of Bianchini et al., 2012, and the internal process data to support the minimum required temperature. For brevity, this information is not included in this example food safety plan.

Items 2 to 6 are typically included in various forms, which may or may not be part of the food safety plan. This example displays examples of supporting forms and a list of where to find the completed records, which are stored outside the food safety plan.

Supporting Forms

**Note that these sections are abridged; typical may likely require multiple pages (i.e. examples of all other forms referenced in Table 2 Column 8).*

Pet Food Example

Hazard Analysis	PRODUCT: Dry extruded dog and cat food		PAGE X of Y
PLANT NAME	ABC Pet Food Manufacturer	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

DATE: _____ **Daily Sanitation Sheet**

Procedure	Prior to Operations (_____)	End (_____)	Comments or Corrections	Initials
Cleaning Animal Food-Contact Surfaces				
• Surface of equipment or utensil cleaned w/ squeegee				
• Surface wiped with clean cloth dipped in detergent Detergent type and strength: _____				
• Surface rinsed with clean water				
Sanitizing of Animal Food-Contact Surfaces • Entire surface sprayed with sanitizer Sanitizer type and strength: _____				
• Allow at least 1 minute contact time of sanitizer				
• Allow surface to air dry (apx. 5 minutes)				
• ***Inspected for residual material and cleanliness				
• ***Sanitizer concentration measured: 200 ppm				

Supervisor signature: _____ Date: _____
Verification of reviewer signature: _____ Date: _____

Corrective Action Form PAGE 1 of X
PLANT NAME: ABC Pet Food Company
ADDRESS: 123 Street, Anywhere, USA

Product Name:	Code or Lot Number:
Date of Record:	
Date and Time of Problem:	
Description of Problem and Root Cause:	
Actions Taken to Correct the Problem:	
Person Taking Action (name and signature) :	
Amount of Product Involved in Problem:	
Evaluation of Product Involved with Problem:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date:

Locations of Records

Record Type	Location	Form
Training Records	Individual Personnel File, Human Resources Headquarters	Hard copy with electronic backup
Verification of Monitoring (extrusion temperature records and daily sanitation sheets)	Control room computer in file named “Daily PC Monitoring Records”	Electronic
Verification of Corrective Actions	Control room computer in file named “CA and Corrections”	Electronic
Calibration of Process Monitoring and Verification Instruments (thermometer accuracy and calibration records)	Control room computer in file named “Thermometer Records”	Electronic
Product Testing	Quality Assurance Manager Office File Cabinet	Hard copy
Records Review	Plan Manager Office File Cabinet	Hard copy with electronic backup