

### **Utilizing the Food Safety Plan Builder:**

For the pre-prepared .fsp file contact Jason Breitensen at Precision Ag Services (859-873-6138)

You will then need to download the Food Safety Plan Builder on the FDA website

<https://www.fda.gov/food/guidanceregulation/fsma/ucm539791.htm> . Note, on this site you do not need to complete the contact information. Once downloaded, you can import the .fsp file by selecting File and Open from the menu bar and selecting the .fsp file to open.

There are tabs across the top of this screen. We go through each one below. Tool tips have been built in to guide you through the program and will pop up to instruct you on how to use the section.

#### **Facility Information:**

Complete this with the information for the facility. It currently contains generic information. Include in the designated areas the Facility Description, Employee details (# of employees, # of shifts, etc). Include the Animal Feed products that will be produced from these operations. File currently includes Corn Cobs, Corn Husks and Corn Kernels. Include the primary contacts and designate the individual within the facility or organization who has received the PCQI Training. This individual is responsible for overseeing the writing of the Food Safety Plan and the Hazard Analysis.

#### **Preliminary Steps:**

This tab may serve as a useful framework for organizing and documenting important food safety-related characteristics of the products manufactured at your facility. Although performing these preliminary steps are not required by the PCAF rule, it may be useful to capture this information in your Food Safety Plan. This tab allows you to describe final finished products, distribution, intended use and consumers of the food. Recommended preliminary steps in this tab include:

- Describing the food products and their distribution
- Describing the intended use and consumers or end user of each food product
- Developing flow diagrams and descriptions of the processes
- Verifying the flow diagrams on-site

#### **GMP and other Prerequisite Programs:**

The program only lists out the components of the regulation. We do not think it is necessary to include this information as part of your food safety plan.

#### **Hazard Analysis:**

The file has been completed following a very basic process. In our development we decided to approach 3 process flows from start to finish; Corn Cobs, Corn Husks and Corn Kernels each from Pre-Harvest inspections to their loading on the truck and departure from the facility. At each step we reviewed if a potential hazard was introduced or managed and included it in the analysis. We utilized the same set of justifications designated for that hazard. For simplicity, in the Hazard Analysis we simply refer to these justifications by number:

- Justification 1 – Mycotoxin
- Justification 2 – Salmonella
- Justification 3 – E-Coli
- Justification 4 – Listeria
- Justification 5 – Foreign Materials
- Justification 6 – Pesticides
- Justification 7 – Bovine Spongiform Encephalopathy
- Justification 8 – Seed Treatment
- Justification 9 – Weed Seed

The steps we outlined are a very basic process flow. If you have a different flow of steps or additional steps, you will need to make adjustments to the listing of process steps on this tab and on the Preliminary Steps Tab.

On the Hazard Analysis Tab, there are very specific ways to write out the process step name to keep things in order. For example, our first step is listed as Corn Cobs: Step01: Pre-Harvest Inspection then the next step is Corn Cobs: Step02: Harvest. Essentially these steps go in order, but they have to be ordered 01, 02, 03....10, 11, 12 etc, and written out with the colon punctuation marks exactly as shown.

So your template would be: (Product: Step##: Step Name)

Re-ordering steps is tricky. We can provide assistance here as needed.

**Process Preventive Controls, Food Allergen Preventive Controls, Sanitation Preventive Controls and Supply-Chain Preventive Controls** tabs can be bypassed if you determine that no preventive controls are needed based on the outcome of your hazard analysis.

#### **Recall Plan:**

A recall plan is not required if it is determined that no Preventive Controls are needed. However, we are still advising to include a recall plan as part of the Food Safety Plan. The following are the required elements of the recall plan.

Notification of Direct Consignees

Written 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 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.

#### Notifying the public

Facility/Company should base this process on their own internal guidance. Suggested practice is a press release indicating the lot code on bulk shipments impacted and any other identifiable information. A template press release form is included in the Recall Plan template provided by the Food Safety Preventive Controls Alliance - Preventive Controls for Animal Food First Edition 2016.

Responsibilities should be pre-planned and outlined in the Recall Team. Identify and document a recall coordinator and recall team. Describe the duties and roles of the team. The recall team should include all functions necessary to collect accurate and complete information. Including production, shipping, quality assurance, sales and administrative and include related corporate level departments as applicable.

#### Effectiveness Checks

Include the processes to ensure that all consignees have been notified and have taken appropriate action. What methods are used to conduct these checks? Have a way to track how much volume has been accounted for vs. total volume recalled on a daily basis. A log/spreadsheet should be maintained to account for the volume of the returned material.

#### Disposition of Recalled Product

Describe Disposition Steps. It's unlikely that re-work or reconditioning would be of value for these products. Disposition is likely to include a level of destruction of the material either through incineration or disk/burial. Determine the plan for disposition and how records will be maintained.

#### **Reanalysis Tab**

The remaining tabs include Reanalysis of the food safety plan which must be performed at least every three years by a Preventive Controls Qualified Individual. The food safety plan must also be reanalyzed upon other triggering events.

### **Signature**

The owner, operator, or agent in charge of the facility must sign and date the Food Safety Plan. On this tab you can select if you want to use the Food Safety Builder Tool to apply an electronic signature or you can select a “Manual Signature” to physically sign the printed out plan.

### **Recordkeeping Procedures Tab**

This is a helpful tab to ensure you have addressed the applicable sections of the Food Safety Plan and have accounted for the necessary records.

### **Important Contacts**

This is an optional area to complete for quick retrieval of information in the event of a product recall.

### **Supporting Documents**

This is an optional area where key documents and records can be maintained. Records can also be maintained according to your company record retention policies as long as they extend two years past when the record was created or last relied upon.