Food and Drug Administration

CFSAN Online Submission Module (COSM)

Offices of Food Additive Safety (OFAS) Submissions Help Guide

COSM OFAS Submissions Help Guide

INTRODUCTION

This Guide will briefly introduce you to the CFSAN Online Submission Module (COSM) and illustrate how to create an OFAS Regulatory submission. COSM uses a common design and format for presenting questions to you to assist in creating submissions for OFAS. The common elements and question types are outlined below and are presented here as an aid for first time OFAS COSM users.

Note: Prior to using this Guide, you should familiarize yourself with the COSM Registration Help Guide. This Guide gives information relevant to the following OFAS submissions:

- Food Contact Notification (FCN) (Form 3480)

- Food Master File (FMF) for a Food Contact Substance (Form 3480)

- Pre-Notification Consultation (Form 3480)

- Color Additive Petition (CAP) (Form 3503)

- Color Master File (CMF) (Form 3503)

- Food Additive Petition (FAP) (Form 3503)

- FMF for Food Additives (Form 3503)

- Biotechnology Final Consultation (Form 3665)

- New Protein Consultation (Form 3666)

- Generally Recognized as Safe Notice (Form 3667)

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1. General Information for OFAS Submissions

The following information is common for all OFAS submissions.

a. Creating Submissions

After logging in to the COSM you are presented with your "Home" page. Click on one of the available submission types on the Home page. The submission types were selected during the Registration process and are represented by "Menu Cards".
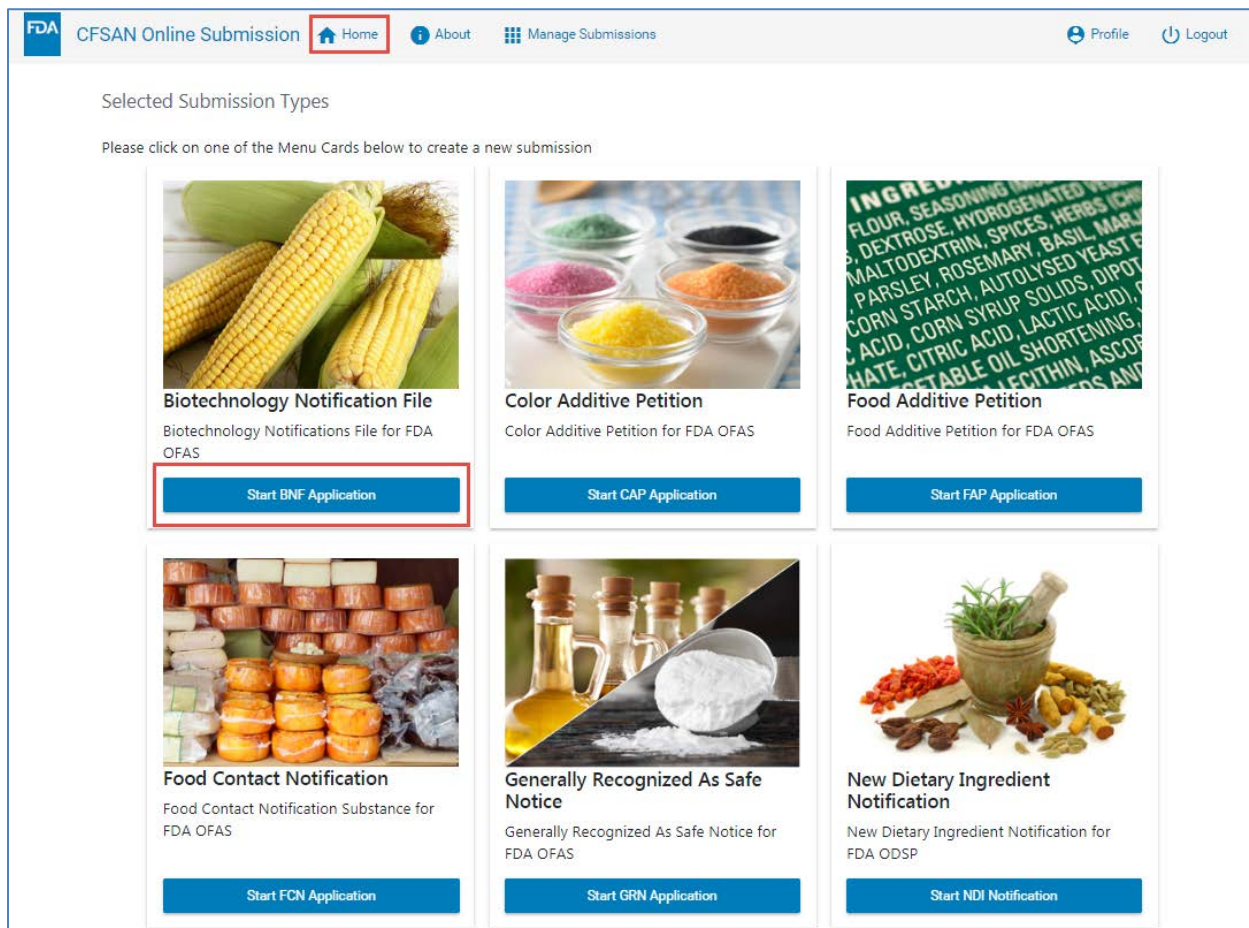

Figure 1: COSM's Home Page

b. Summary Page Information

Upon selecting the submission type from the Home page, the system will open the Summary page for the selected submission. Each OFAS submission type has different sections. You may go to any section in any order you choose. The following example illustrates the Biotechnology Final Consultation (Form 3665) summary page and available sections.

Figure 2: Biotechnology Final Consultation Summary Page and Available Sections

You may enter data into sections of a submission, "leave" the submission in a draft status and return to complete the submission later. Each section on the Summary page will display a check mark upon its completion (Figure 2).

Figure 2: Biotechnology Final Consultation Summary Page and Available Sections (continued)

You should ensure that all sections are complete before attempting to download the final submission package.

c. **Tracking Numbers**

The COSM will create a unique tracking number for each submission. It is important to understand that the tracking number is *not* the submission number. The submission number does not become available until after the submission has been accepted by the FDA.

Figure 3: Tracking Number

d. **Mandatory Fields**

All Mandatory fields/questions are designated by an asterisk symbol (*). Mandatory fields must be completed before moving on to the next screen. If any of the required fields are not completed, you will be prompted to enter the missing information before proceeding to the next section.

e. **Date Selection**

You are prevented from entering a future date when completing a date field.

f. **Contact Information**

The information required in this section is identical for all OFAS submissions. The following steps should be followed to complete the Contact Information section in the COSM.

Step 1

Click the "Update" button next to the "Contact Information" section on the Submission Summary page. The "Contact Information" section is displayed.

Figure 4: Submission Summary Page

Step 2

Click the **"Auto-fill the Data"** drop-down button on the right side of the Contact Information section or manually enter the information in this section.

Figure 5: Contact Information Section

The "Auto-fill the Data" drop-down button on the right side of the Contact Information section contains all the contacts that you entered through the Manage Contacts screen. Select a name from the list box and the remaining contact information will be completed; then edit the contact fields if necessary but note that if you change the data on the Contact Information screen it does *not* update the data in your Manage Contacts list.

Provide the Notifier information for all mandatory fields (*) in the "Notifier Information" section (Table 1). Provide the Agent or Attorney information in the "Agent/Attorney Information" section if applicable (optional).

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Table 1: Contact Information Section

Field	Description
A) Notifier	**Contact Description:** The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the submission.
B) Agent/Attorney	**Contact Description:** Any agent or attorney who is authorized to act on behalf of the person who is responsible for the submission.
* Name of Contact Person	Provide the contact person's name.
* Company	Enter the full name of the company.
* Position	Title of the contact person.
Doing Business As	The alternate or "local" name of the company.
* Mailing Address Line 1	The street name and number or post office box number
* Mailing Address Line 2	Optional; can be used for building number, suite number, or other information that doesn't fit on the first line.
* Country	The country for the contact person's mailing address. Defaults to 'United States of America.' For foreign addresses, select the appropriate country from the pull-down menu.
* Zip or Postal Code	The zip code for the contact person's mailing address. For addresses outside the United States, enter the postal code, if any.
* City	The city for the contact person's mailing address.
* State or Province	The state, province, or territory for the contact person's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
* Email Address	Provide email address.
* Telephone	Provide telephone number.
Fax Number	Provide fax number.

Step 3

Once the Contact Information section has been completed, click the "Save and Continue" button to return to the Summary Page.

2. <u>Question Types for OFAS Submissions</u>

There are a number of different types of questions within OFAS submissions. Below is a list of the various types.

a. Yes/No Radio Buttons

For this type of question, you select a single option from a list. Each item is chosen by clicking the circle/radio button. Only one option can be selected. You can use the keyboard (by pressing the "tab" key) or mouse to make your choice. A different choice can be made by selecting a different radio button.
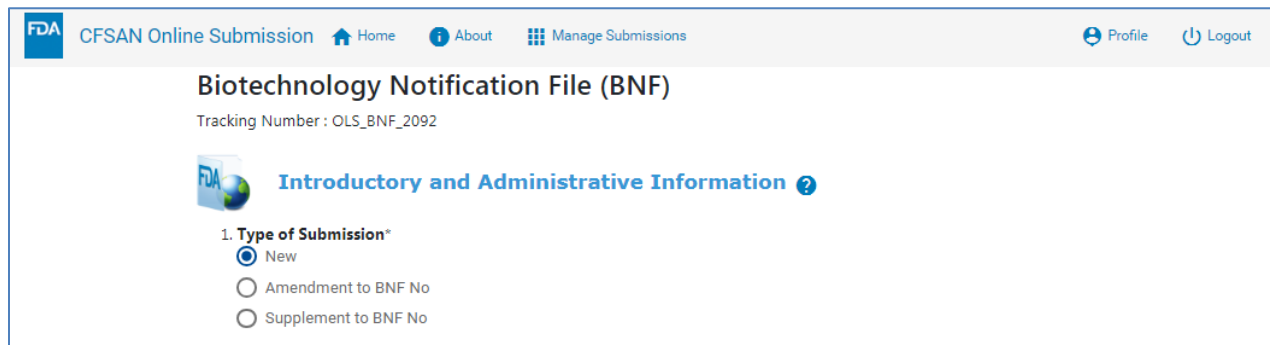
Figure 6: Yes/No Radio Button

b. Document Upload

In this type of question, you click the blue "+ Drag and Drop or Select File" button to upload/attach any document relevant to the question or section of the submission. When you click the blue Drag and Drop button your local pc/laptop will display a box to select your file. Once you select the file it will be loaded into the document component as shown below. Alternatively, if you have a file directory already open on your local pc/laptop you can use the mouse to "drag" the file from the file directory and "drop" it onto the document component.

(1) The following file types/formats are accepted: pdf, xls, xlsx, mol, cdf, sdf.

(2) Multiple documents may be added. Various options may also be available such as "Redacted", "Confidential", "Studies", etc. You may make these selections as necessary to specify a type or category of document.
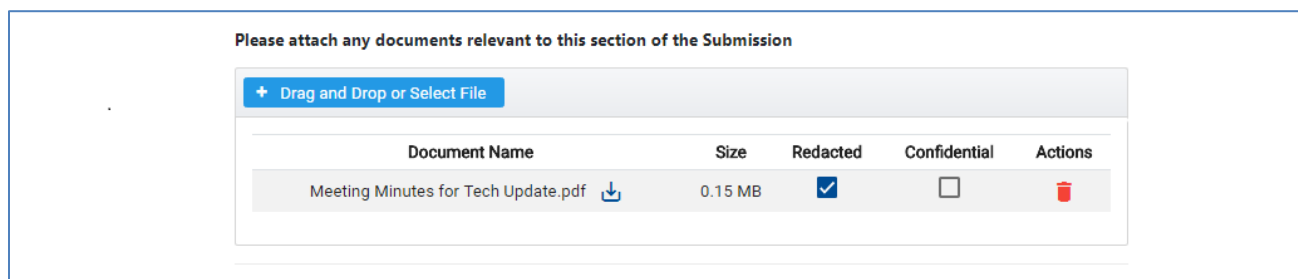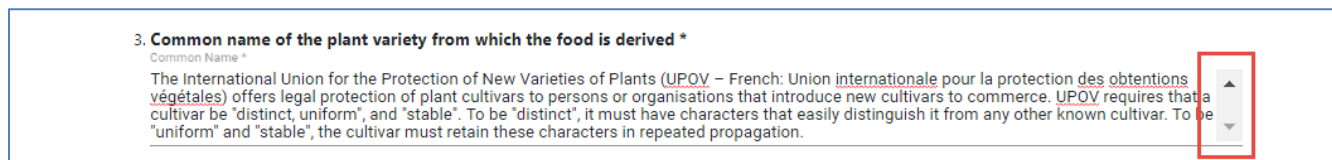
(3) The red trashcan button is used to delete a document.

Figure 7: Document Upload

c. Free Form/Multi-Line Entry

In this type of question, you can type several lines of text. The text box grows and becomes "scrollable" to accommodate as much text as you need to enter.

Figure 8: Free Form/Multi-Line Entry

d. Expanding

In this type of question, answering "Yes" results in additional questions being displayed. It expands so you can see additional questions below. These additional questions expand when the answer is "Yes" and contract when the answer is "No".

Figure 9: Expanding Entry

e. Single-line entry

In this type of question, you are able to enter no more than a single line of text.
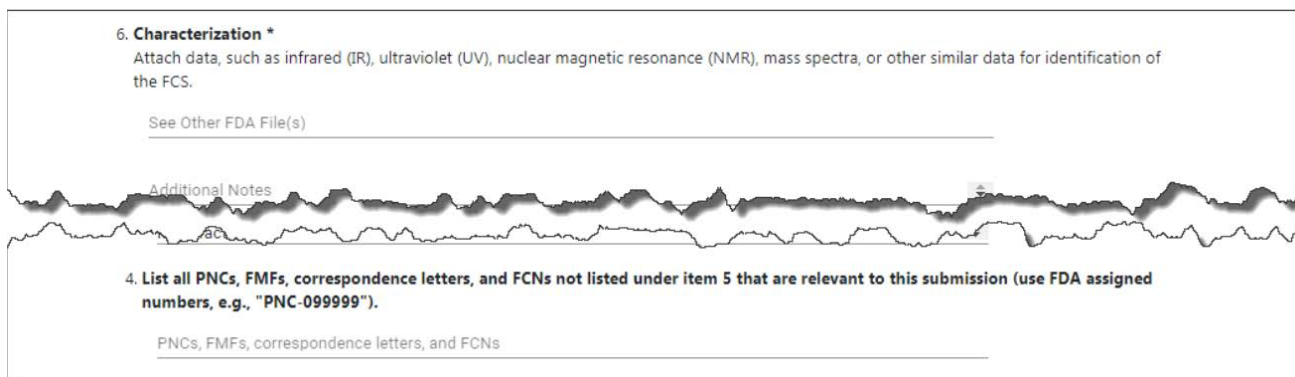
Figure 10: Single-line Entry
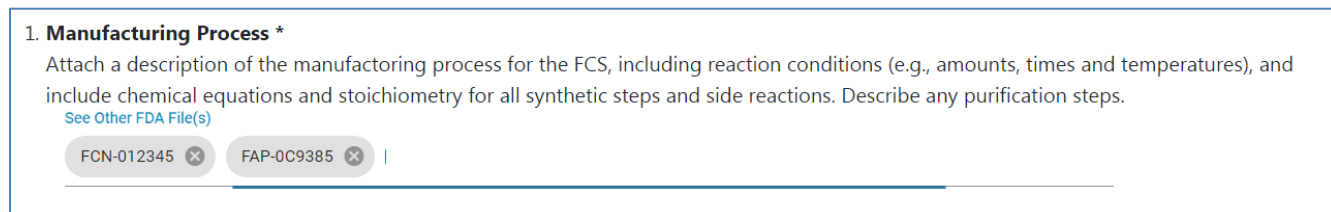
f. Submission References

These questions often display a label such as "See Other FDA File(s)" or they will contain specific instructions to list relevant submissions. Enter this information using FDA assigned numbers, i.e., "PNC-099999".

Figure 11: Questions that ask for Submission References

When you enter these submission numbers and press the "Enter" key or a comma, these entries turn into discreet bits of data called "chips". Please see below. Using this format allows the system to easily distinguish one submission number from the next and helps you to type in more accurate references. Please note that the COSM does not verify the accuracy of the submission numbers.

Figure 12: Completed Submission References

g. Table Entries

Table entries allow you to add one or more rows of data for a single question. Each row repeats the same types of data. You enter different values on each row. The example below shows how these tables operate. Click the "Add…" button to create a new row in the table; complete the data and then click the "Add…" button again for the next row. Alternatively, you can click the "Add…" button repeatedly to enter as many rows as necessary and then complete the data all at once. If you wish to delete a row, click the red trashcan icon and the row is discarded.

Figure 13: Table Entries

h.   Attachment Entries

The List of Attachments Section displays all the documents you have appended to the submission during the completion process. These documents are placed in the folders when you upload them during the question and answer sections throughout the submission. In the list of attachments, you can also upload documents not explicitly asked for within the submission. These might include References, Environmental Studies, Confidential Environmental Information or any other documents you feel are necessary to complete the submission.

The image below shows the folder structure for the Biotechnology Final Consultation (Form 3665) notification. Each submission type will have a different set of folders.

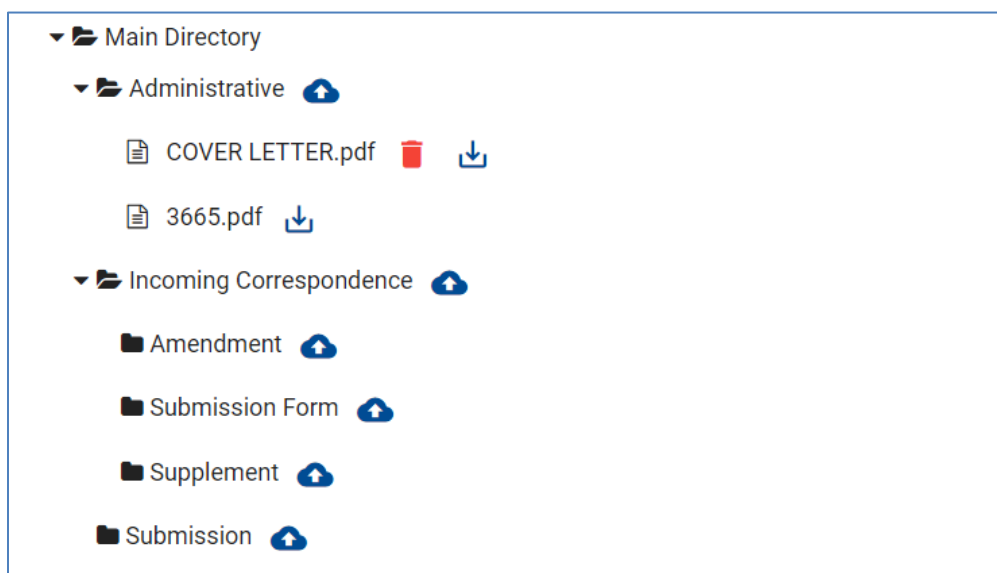**Note:** Documents cannot be renamed once they have been uploaded to the COSM.

Figure 14: Attachment Entries

Adding Documents

Click on the "cloud" icon next to the intended folder. COSM then allows you to select a file from your local machine. Once uploaded the document will appear in the selected folder.

Deleting Documents

1. Only documents that are uploaded from the List of Attachments page can be deleted from the List of Attachments page. Those documents will display a red trashcan icon next to them.

2. For documents that were added from the question and answer sections you must return to those sections to delete them.

ABBREVIATIONS AND ACRONYMS	
BNF	Biotechnology Notification File
CAP	Color Additive Petition
CMF	Color Master File
COSM	CFSAN Online Submission Module
FAP	Food Additive Petition
FCN	Food Contact Notification
FMF	Food Master File
OFAS	Offices of Food Additive Safety