FDA Reportable Food Registry

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Reportable Food Registry

- Part of the FDA Amendments Act
  - Signed into law on September 27, 2007
  - Amends the Federal Food Drug & Cosmetics Act (FFD&CA), creating Section 417 [21 USC 350f] Reportable Food Registry
- Requires FDA to "Establish a Reportable Food Registry, to which instances of reportable food may be submitted via an electronic portal and a unique number issued to the person submitting the report upon receipt."

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Reportable Food Registry

- Congressional intent: provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect the public health
- Industry compliance became **mandatory** as of **September 8, 2009,** when the electronic portal opened
- Failure to comply is a prohibited act under the FFD&CA

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What is a “reportable food”?

- “Reportable food” – an article of food … which has a *reasonable probability of causing serious adverse health consequences or death to humans or animals*
  - All FDA-regulated foods, except dietary supplements and infant formula.
  - Domestic and imported foods

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Who has to report?

- Instances of reportable food shall be submitted by:
  - A “responsible party,” i.e., the individual who submits the food facility registration under section 415(a), and
  - Voluntarily by federal, state, and local public health officials

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Who is a “responsible party”?

- FFDCA 415(a): “any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States [shall] be registered”
- “does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels”

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Responsible Party:

- Must report as soon as practical, but **no later than 24 hours** after a responsible party determines that an article of food is a reportable food
- Must submit a report through the electronic portal
- Must investigate the cause of the reportable food if the reportable food may have originated with the responsible party

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Responsible Party:

- Must submit initial information; followed by supplemental reports
- Must work with the FDA authorities to follow up as needed
- May need to provide notification to immediate prior sources and immediate subsequent recipients of the article(s) of food
- Must maintain records of report submitted & any notifications made to FDA for 2 years

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A responsible party is not required to report:

- If the adulteration originated with the responsible party; **and**
- the responsible party detected the adulteration prior to any transfer to another person of such article of food; **and**
- the responsible party
  - corrected such adulteration; or
  - destroyed or caused the destruction of such article of food.

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“transfer to another person”

- A transfer to another person occurs when the responsible person releases the food to another person. "Person" is defined in section 201(e) of the FD&C Act as including individuals, partnerships, corporations and associations.

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“transfer to another person”

- FDA does not consider an intra-company transfer in a vertically integrated company to be a "transfer to another person," where the company maintains continuous possession of the article of food.
  - For example, if Company A owns a processing plant, warehouse facility, and distribution facility, the intra-company transfer from the processing plant to the warehouse facility and/or the warehouse facility to the distribution facility would not be considered a transfer to another person.

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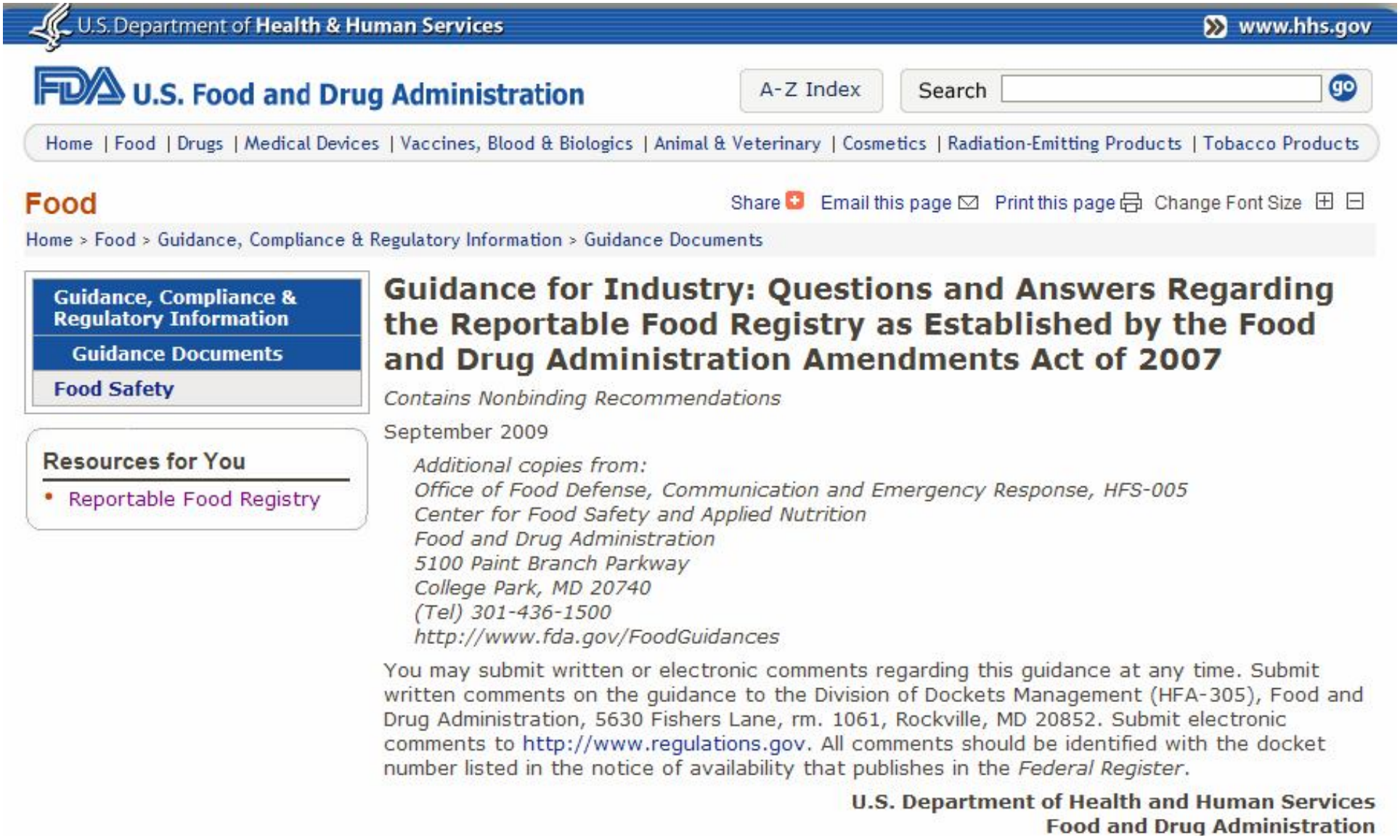
Guidance for Industry

www.fda.gov/ReportableFoodRegistry

Guidance for Industry



U.S. Department of Health & Human Services www.hhs.gov

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Food

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Guidance, Compliance & Regulatory Information
Guidance Documents
Food Safety

Resources for You
- Reportable Food Registry

Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007

Contains Nonbinding Recommendations

September 2009

Additional copies from:
Office of Food Defense, Communication and Emergency Response, HFS-005
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-1500
http://www.fda.gov/FoodGuidances

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration

Guidance for Industry

Is a food that presents a Class I recall situation a reportable food?

http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

Yes. FDA interprets the definition of reportable food to include those foods that would meet the definition of a Class I recall situation. A Class I recall situation is one in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death

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Guidance for Industry

If a reportable food is shipped to a third-party warehouse, but the responsible party maintains ownership and direct control over distribution, must the responsible party submit the reportable food report?

Yes. Transfer to another person occurs when the responsible person releases the food to another person. "Person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations. In this situation, the warehouse operator is a distinct legal person.

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Guidance for Industry

If I received a product from my supplier that I found to be a reportable food and I contain the problem and do not ship any of the reportable food, am I required to submit a report?

Yes. A responsible party that receives a reportable food is required to submit a report even if the responsible party has not shipped the food.

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What are the data elements that a responsible party must include in an initial report to FDA?

1. The registration numbers of the responsible party;
2. The date on which the article of food was determined to be a reportable food;
3. A description of the article of food including the quantity or amount;
4. The extent and nature of the adulteration;
5. The results of any investigation of the cause of the adulteration if it may have originated with the responsible party, when known;

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What are the data elements that a responsible party must include in an initial report to FDA?

6. The disposition of the article of food, when known; and
7. The product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food.

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ICSR number

- Upon submission of a report, a unique Individual Case Safety Report number (ICSR number) will be issued through the Reportable Food electronic portal to the person submitting the report.
- Keep this unique number for submitting amended reports
- Provide the ICSR number to affected suppliers and recipients of the reportable food for reference in their reports.

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Appendix: Instructions for Completing the Reportable Food Registry Report

- Link provided at end of Guidance

SECTION 4: Problem Origination Site

The Problem Origination Site is the site at which the reportable food problem originated. You will see this section if you indicated that you know where the problem originated. If you indicated that you know where the problem originated and that this location is the same as the Location of Reportable Food, the fields will be pre-populated with information that you previously entered regarding the Location of Reportable Food.

Please provide any additional information you might have about the Problem Origination Site to help the FDA respond to this reportable food report.

4.1 Problem Origination Site (first screen)

4.1.1 Problem Origination Site Name

Enter the organizational name of the site at which the problem originated or is suspected to have originated.

4.1.2 Type of Organization

Select the various establishment types which apply to the Problem Origination Site. Please visit http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm096034.htm for codified definitions of establishment types.

4.1.3 Problem Origination Site Country

Select the Problem Origination Site's country from the drop down list of countries.

4.2 Problem Origination Site (second screen)

4.2.1 Street Address

Enter the number and street name of the Problem Origination Site's physical address, and additional information as necessary. Do not enter Post Office Box address information in this field.

4.2.2 City/Town

Enter the city/town of the physical address of the Problem Origination Site.

4.2.3 State

Select the state of the Problem Origination Site from the drop down list. If the Problem Origination Site is not in the United States, this question will appear as State/Province.

4.2.4 ZIP Code

Enter the ZIP Code of the physical address of the Problem Origination Site. If the Problem Origination

Submitting a report

- http://rfr.fda.gov/

Submitting a report

- Required questions are marked with an asterisk (*).
- There is no “save” function (in Ver. 1.0) and the system will time-out if it sits idle for more than thirty minutes.
  - When submitting a Supplemental or Amended Report (new information), you will have to enter required information again.

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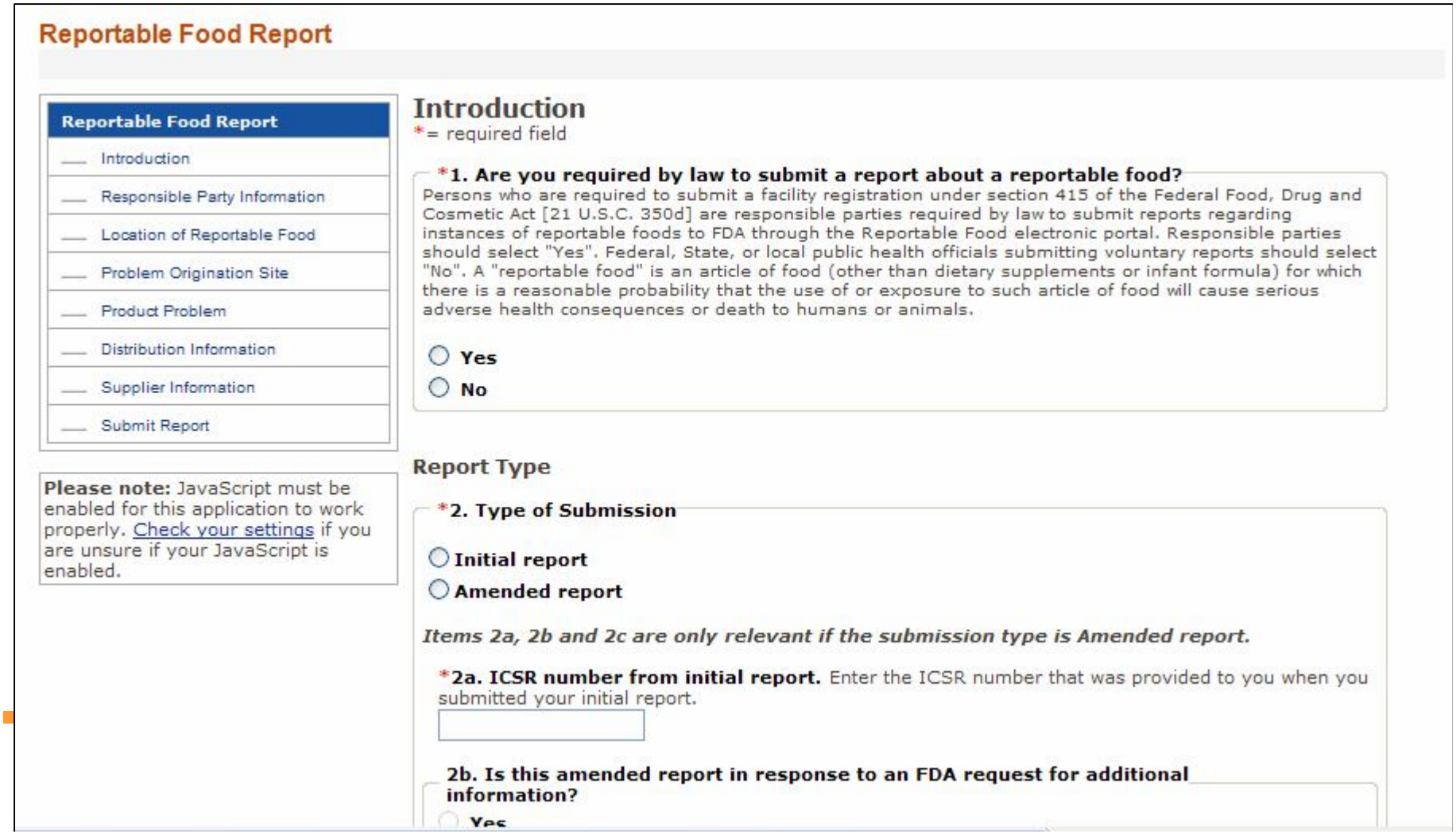
Introduction

- The type of report you are submitting.

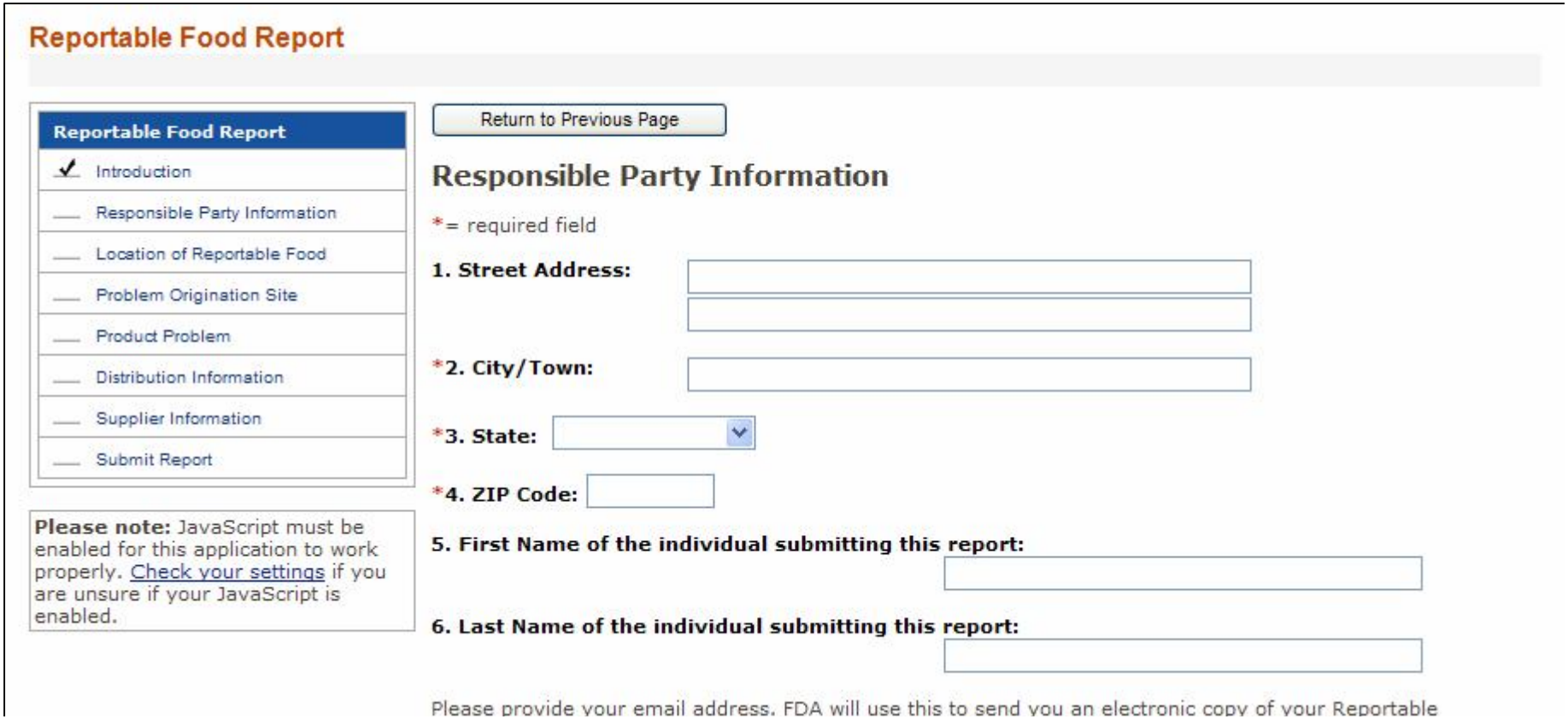


Responsible Party / Reporter Information

- responsible parties must have a **Food Facility Registration Number** for the Responsible Party site and the Location of Reportable Food

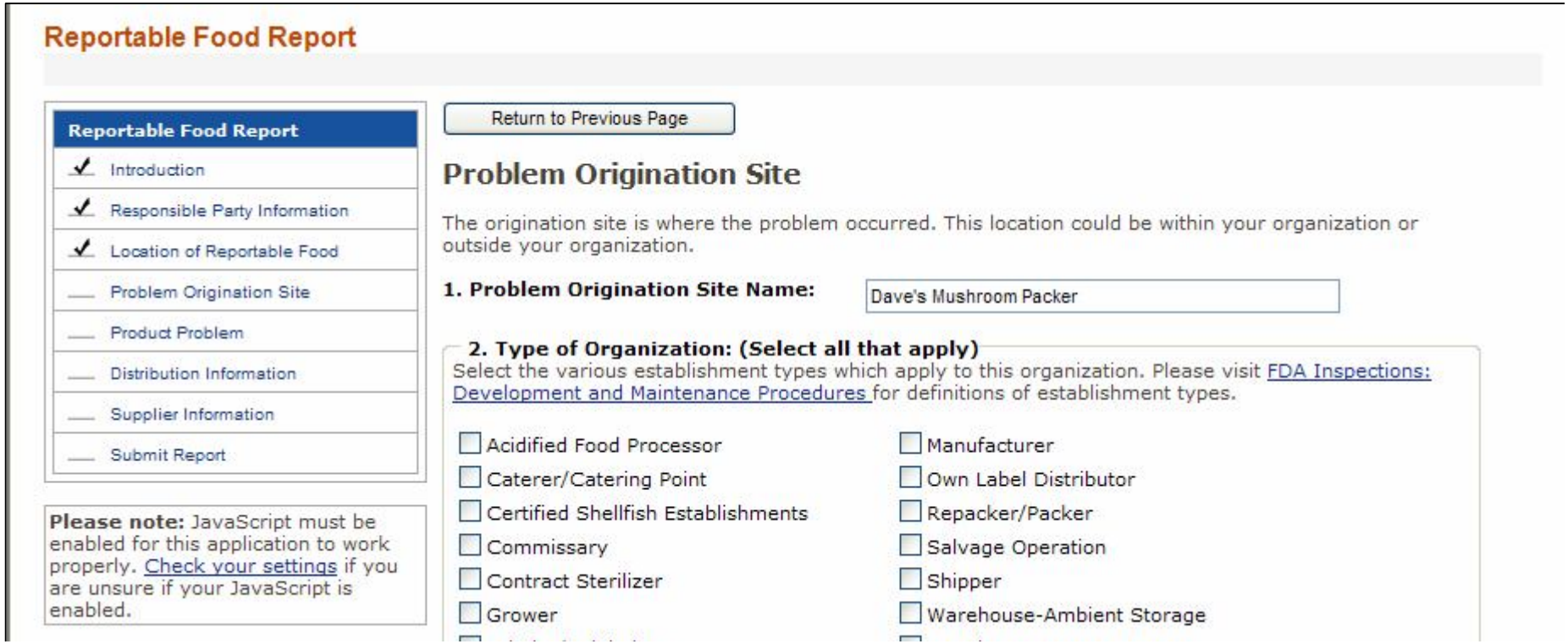
Location of Reportable Food

- The contact information for the site about which you, the responsible party are reporting



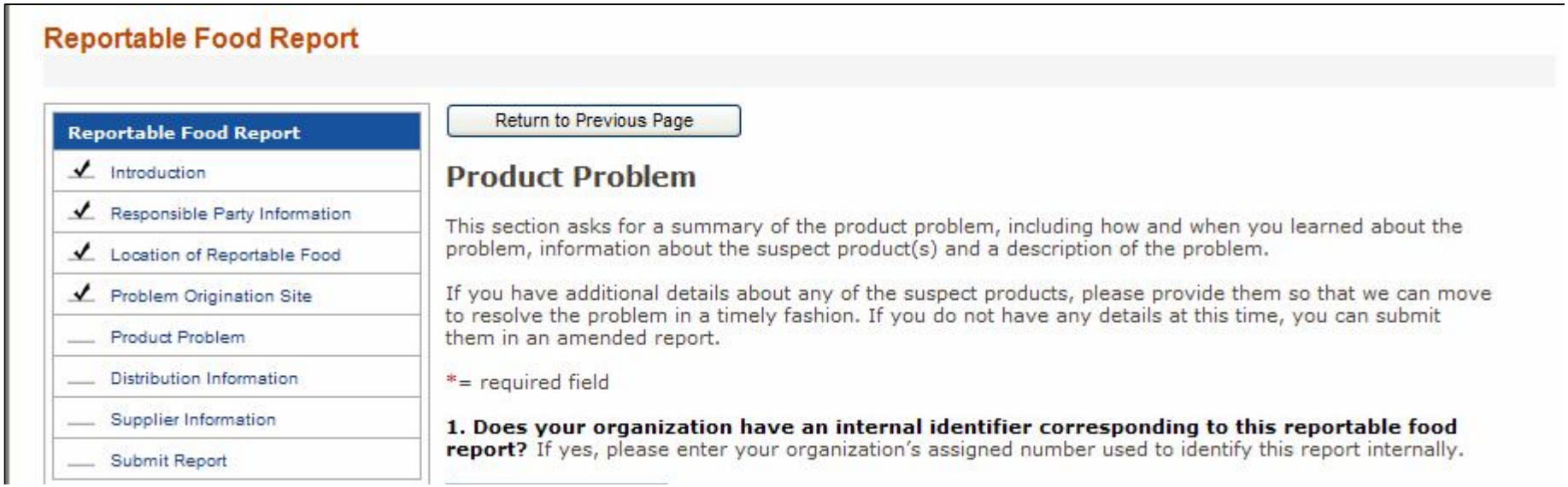
Problem Origination Site

- You will only see this section if you indicate that you know the site at which the problem originated; that is, where the problem started.



Product Problem

- This section asks for a summary of the product problem, including how and when you learned about the problem, information about the suspect products (received or produced), and a description of the problem.



Submit report and Confirmation

- This section provides an opportunity to review your report before submission, instructions for attaching supplemental information to accompany your report, and provides you with an FDA-issued unique identifier number (also known as ICSR number) with which to identify your report.
- Use the Print function to keep a record
- IF YOU ARE PRACTICING, DON'T SUBMIT

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Questions?

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