

Small Business Regulatory Enforcement Fairness Act (SBREFA)

Objectives

Upon completion of this module the trainee will be able to:

1. Describe what SBREFA is and the purpose it serves.
2. Identify the two areas of emphasis under SBREFA.
3. Describe the goal of small and very small plant outreach.
4. List the challenges and common issues faced by small and very small plants.
5. Locate available outreach materials.
6. Describe the role of the EIAO in outreach and in providing compliance guidance.
7. Describe the EIAO's role in enforcement fairness.

Introduction

SBREFA is a regulatory reform statute which was signed into law on March 29, 1996. SBREFA applies to all branches of government and gives small businesses a greater voice in the development and enforcement of Federal regulations.

Under SBREFA, the Agency is responsible for being sensitive to the needs of small and very small plants and, through the Agency's outreach program, small businesses are encouraged to participate in the rulemaking process. FSIS Notice 18-01 describes the regulatory requirements that FSIS must meet under SBREFA, and what FSIS is doing to meet the goals of SBREFA.

Definitions

Small Plant: 10-499 employees.

Very Small Plant: Less than 10 employees or less than \$2.5 million in annual sales.

National Ombudsman and Fairness Boards are a forum for small businesses to report compliance or enforcement experiences with Federal regulatory agencies.

Ombudsman: A person who has a proxy to represent someone. In government, an Ombudsman represents persons who complain about alleged wrongdoings of the public administration. In the Small Business Administration, the National Ombudsman represents small businesses in their dealings with Federal regulatory agencies.

Key Areas of Emphasis

We will talk about SBREFA and your role as an EIAO in terms of two key areas. These areas of emphasis are advocacy and enforcement fairness.

Advocacy (Compliance Assistance or Outreach)

Agencies must assist small businesses in understanding and complying with the regulations. The goal of small and very small plant outreach is to provide technical guidance and assistance to small and very small meat and poultry plants in the United States. Approximately 300 of the plants we regulate meet the definition of a “large” plant. The remainder, approximately 5700 plants, are small and very small plants. These plants usually need technical guidance and assistance with the HACCP and food safety regulatory requirements.

The Challenge

Small and very small plants may:

- Lack resources.
- Lack knowledge.
- Have language barriers.
- Not belong to associations that provide resources.
- Hold the belief that old methods result in safe products.

This is why we devote so much time and attention to compliance assistance efforts, including the outreach conducted by EIAO trained employees.

Common Issues

Some common issues that arise with small plants include the:

- Difficulty in finding scientific support for the hazard analysis.
- Difficulty in understanding how to reassess or address new issues as they arise in the plant.
- Reliance upon literature without validating in the plant’s environment.
- Belief that “We’ve done it this way for years and no one has died from eating our product.”
- Concern that new regulatory requirements are being applied to “put them out of business”.
- Inability to attend training.

Small/Very Small Plant Outreach

On May 31, 2006, FSIS announced the Small/Very Small Plant (SVSP) Outreach Program to assist the owners and operators of these plants in understanding and complying with regulatory requirements. EIAO's have been designated as the key position within OFO for conducting outreach to small and very small plant owners. The majority of the issues small businesses face when meeting FSIS regulatory requirements deal with the food safety system design and this makes the EIAO a natural choice to reach out to these businesses.

EIAO's Role in Outreach

The EIAO plays a vital role in helping FSIS meet its obligations to small businesses under SBREFA, and these responsibilities are spelled out in the EIAO job description and performance elements. With the implementation of the new outreach effort, EIAO's have been conducting outreach visits in which they meet with plant owners specifically for the purpose of providing outreach assistance. For example, an EIAO may be doing an assessment at one plant and, while in the area, visit some small plants for the purpose of providing outreach assistance to them. This provides an excellent opportunity to meet with plant owners and open the door for communication without being in the "regulatory" assessment mode.

EIAO's reach out to help small/very small plant owners better understand regulatory requirements, explaining what is expected should a plant undergo a scheduled food safety assessment (FSA), and identifying materials and resources that are available. As an EIAO, you can share printed guidance materials and identify resources provided by the Agency, as well as other resources such as meat associations, agricultural extension agents, and local universities to name a few. EIAO's should always carry USDA printed guidance materials with them when doing an outreach visit or assessment.

It is important to note that questions may arise during these outreach visits that you, as the EIAO, will not be able to answer on the spot. If that is the case, take notes, tell the plant owner that you will get them the answer, and follow up with the frontline supervisor (FLS) that oversees the plant. This is a good opportunity for the FLS to work with the IIC to get the answer to the plant owner. Again, this is improving communication between not only the industry and FSIS, but within FSIS itself.

Be aware that, as an EIAO, you must walk a fine line in terms of the assistance you can provide a plant owner. Because you are a regulator, you cannot provide direct assistance to a plant owner by suggesting how they design or validate their food safety systems. You are not to write the HACCP Plan, SSOP's or to dictate CCP's or create additional burdens. When issues arise where you, as the EIAO, are not able to provide assistance, such as writing a HACCP plan, refer them to the list of contacts and coordinators. The contacts and coordinators can do what we cannot because of our regulatory role. Our job is to refer the small and very small plants to these people so they can get the direct assistance they need.

You may also be called upon to participate in courses or roundtable discussions as a technical expert or to conduct local workshops on topics of concern for the industry. When holding a workshop, get the word out! Invite all of the plants in the area. Don't hold

a workshop for a single plant. It is important to know the needs of your audience and use the technical guidance materials and HACCP workbook as your guide. Stress to the plants that this is not HACCP training per the regulation rather it is an avenue where important information will be shared.

Resources

FSIS' Strategic Initiatives, Partnerships, and Outreach (SIPO) staff prepares compliance materials like those listed in the "Food Safety Resources" brochure. SIPO services FSIS employees, especially EIAO's in their outreach efforts, small plant owners and operators, State and local governments, American Indian/Alaska natives, and underserved populations.

To help address some of the challenges and issues, SIPO has created an extensive library of free outreach materials. Some have been translated into Spanish, Chinese, Korean, and Vietnamese and include materials such as:

- Guidebook for Preparation of HACCP Plans.
- 13 Generic HACCP Models.
- Booklets, videos, CD's on virtually every aspect of HACCP and Food Safety.

To get materials you can call SIPO at (202)690-6520, or go to the FSIS Webpage at: http://www.fsis.usda.gov/Science/small_very_small_plant_outreach/

SIPO also works with Contacts and Coordinators, associations, and other groups to promote outreach to small and very small plants.

Enforcement Fairness

Through the provisions of SBREFA, the Small Business Administration (SBA) appoints a National Ombudsman and creates ten Regulatory Fairness Boards, made up of small businesspersons.

National Ombudsman and Regional Regulatory Fairness Boards

In the SBA, a National Ombudsman is appointed to represent small businesses in their dealings with Federal regulatory agencies. In addition, there are ten Regulatory Fairness Boards located throughout the US. Members of the boards are small business owners who have been elected by other small business owners. Meetings of the Fairness Boards, called Fair Regulatory Enforcement Hearings, are open to the public; however, the public rarely attends. Attendance is generally made up of small businesses who want to air their concerns, and Federal agency representatives. EIAO's regularly attend these meetings as part of their SBREFA responsibilities.

While the National Ombudsman and Fairness Boards may communicate small business concerns to the Agency and Congress, they cannot reverse Agency decisions. Small businesses may contact the National Ombudsman or Fairness Boards about their complaints regarding Agency regulatory, compliance or enforcement decisions. The National Ombudsman and Fairness Boards also provide a venue for small businesses to

participate in the Agency's regulatory process by providing comment through the SBA/ONO on new regulations before they can take effect. Through the SBA, companies can use their small business status to influence Congress.

Some things to keep in mind regarding the National Ombudsman and the Fairness Boards are that they provide an avenue of appeal for small entities but they do not replace FSIS appeal processes and cannot overturn or adjudicate Agency decisions. Their focus is on "unfairness" in regulatory decisions or enforcement actions.

More information on enforcement fairness, such as a Calendar of Events, Fairness Board members, and how to file comments can be obtained at the following website: <http://www.sba.gov/ombudsman>

Agency Role

The Agency's role in enforcement fairness is to ensure non-retaliation for regulated establishments, to attend Fair Regulatory Enforcement Hearings, and to provide official responses to complaints and comments filed by industry through the Small Business Administration/Office of the National Ombudsman (SBA/ONO).

EIAO's Role in Enforcement Fairness

EIAO's regularly attend the Fair Regulatory Enforcement Hearings to represent both FSIS and USDA. While at the meeting, the EIAO will usually provide a brief summary regarding the mission of FSIS and relay any issues of concern mentioned about FSIS or USDA to OFO Headquarters. The focus of the Fairness Board meetings is on "unfairness" in regulatory decisions and enforcement actions.

Keep in mind that when attending one of these meetings:

- You should conduct yourself in a professional manner.
- It is not your role to resolve any issues at the meeting.
- It is not your role to answer questions on the spot or on behalf of other agencies.
- Your role is to take notes on issues that pertain to FSIS or USDA and relay that information to OFO Headquarters.

A report on what transpired at the meeting is required if an FSIS issue was raised, or an issue was raised with another USDA agency which did not have a representative there. Write down the information on behalf of all agencies and notify OFO Headquarters because USDA has only a short time to respond. If an FSIS-related issue was raised, the Agency will get a formal "comment" with a request to answer in writing through the Department.

Be aware that FSIS gets "graded" by the Small Business Administration in regard to these efforts. Therefore, the EIAO's role in this area is viewed by the Agency as an important one.

Workshop

1. S _____ B _____ R _____ E _____ F _____ A _____

2. The two areas of emphasis under SBREFA are:
 - a. _____
 - b. _____

3. Which area of emphasis does outreach fall under?

4. What is the goal of small and very small plant outreach?

5. List four challenges and common issues faced by small and very small plants.

6. Where can the EIAO get outreach materials?

7. Describe the role of the EIAO in outreach and in providing compliance assistance?

8. Why can't the EIAO directly assist a plant in writing or improving upon their HACCP plan?

9. Describe the EIAO's role in enforcement fairness.