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 establishment outreach.

4. List the challenges and common issues faced by small and very small establishments.

5. Locate available outreach materials.

6. Describe the role of the EIAO in outreach and in providing compliance guidance.

7. Describe the Agency’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.

SBREFA (Public Law 104-121) contains a variety of provisions, some affecting Federal Agency regulations. For example, SBREFA provides for Congressional review of Federal regulations, including those promulgated by FSIS, before the regulations can take effect.

Under SBREFA, the Agency is responsible for being sensitive to the needs of small and very small establishments 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.

SBREFA also provides a number of protections for small businesses against what they may regard as unfair actions by Federal regulatory agencies. Thus, SBREFA gives small businesses expanded authority to go to court and seek awards for attorneys’ fees and costs when an Agency has been found excessive in its enforcement of regulations. Also, each Federal Agency is required to establish a policy to provide for the reduction, and in some circumstances, the waiver of civil penalties for violations of a regulation. There are two major areas you should be aware of: advocacy, and enforcement fairness.
Definitions

SBA: Small Business Association

Small Establishment: 10-499 employees.

Very Small Establishment: 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.

What qualifies an establishment to be a small business? The definitions FSIS used for the phased in implementation of HACCP were modeled after SBA’s definitions. These are listed above. FSIS allows establishments to “self identify,” meaning that we require no proof that they fall into one category or another.

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 establishment outreach is to provide technical guidance and assistance to small and very small meat and poultry establishments in the United States. Approximately 300 of the establishments we regulate meet the definition of a “large” establishment. The remainder, approximately 5700 establishments, are small and very small establishments. These establishments usually need technical guidance and assistance with the HACCP and food safety regulatory requirements.

The Challenge

Small and very small establishments 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 establishments 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 establishment.
- Reliance upon literature without validating in the establishment'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 Establishment Outreach**

On May 31, 2006, FSIS announced the Small/Very Small Establishment (SVSP) Outreach Program to assist the owners and operators of these establishments 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 establishment 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.

In 2006 10 outreach sessions were held around the country. Five sessions have been held in 2007, with 6 more scheduled for this year.

**EIAO’s Role in Outreach**

The EIAO plays a vital role in helping FSIS meet its obligations to small businesses under SBREFA. With the implementation of the new outreach effort, EIAO’s have been conducting outreach visits in which they meet with establishment owners specifically for the purpose of providing outreach assistance. For example, an EIAO may be doing an assessment at one establishment and, while in the area, visit some small establishments for the purpose of providing outreach assistance to them. This provides an excellent opportunity to meet with establishment owners and open the door for communication without being in the “regulatory” assessment mode.

EIAO’s reach out to help small/very small establishment owners better understand regulatory requirements, explaining what is expected should a establishment undergo a scheduled food safety assessment (FSA), and identifying materials and resources that are available.
PHV’s Role in Outreach/Advocacy

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

As a PHV you may be involved in helping the small and very small establishment owners and operators gain access to information that the agency supplies to assist them.

Be aware that, the EIAO and the PHV must walk a fine line in terms of the assistance you can provide a establishment owner. Because you are a regulator, you cannot provide direct assistance to an establishment owner by suggesting how they design or validate their food safety systems; 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 establishments to these people so they can get the direct assistance they need.

Resources

FSIS’ Outreach and Partnership Staff and State Outreach and Technical Assistance Staff were established because FSIS recognized the unique needs of the small and very small establishments with HACCP implementation. They prepare compliance materials like those listed in the “Food Safety Resources” brochure. These divisions of the Office of Outreach, Employee Education and Training (OOEET) merged into a single division, called the Outreach and Partnership Division (OPD) and service FSIS employees, especially EIAOs in their outreach efforts, small establishment owners and operators, State and local governments, American Indian/Alaska natives, and underserved populations.

To help address some of the challenges and issues, there is 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, CDs on virtually every aspect of HACCP and Food Safety
- Developing a Recall Plan

To get materials you can call (202) 690-6520, or go to the FSIS Webpage at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-plant-outreach

OOEET also works with Contacts and Coordinators, associations, and other groups to promote outreach to small and very small establishments.
These offices /representatives work closely on SBREFA issues and on reporting requirements.

To be Announced, OFO
Rachel Edelstein, OPPD  (202) 205-0495
Victoria Levine, OPPD  (202) 720-5627
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**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. The boards offer an additional avenue of appeal for small business entities. However, the board does not replace our FSIS appeal processes. 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.

FSIS personnel involved in inspection and enforcement activities should be aware that the National Ombudsman and the Fairness Boards provide, in a sense, an alternative avenue of appeal for the small businesses we regulate. In other words, in addition to appealing Agency actions through the FSIS chain of command and in addition to making their concerns known by other means, the owners or managers of small official establishments may also make their concerns known to the National Ombudsman or their regional fairness board.

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

Be aware that FSIS gets “graded” by the Small Business Administration in regard to these efforts. The SBA reports to Congress on how well agencies are doing to meet the goals of SBREFA. In FY 2011, FSIS received the following grades from the SBA:

- A – Timeliness
- A – Quality of follow-up responses
- A – Non retaliation policy
- A – Compliance Assistance
- C – Informs about SBREFA
- A – Overall grade

Comments from small business entities flow through the SBA Contact to FSIS. FSIS reports to the SBA on SBREFA activities through OBPA (Office of Budget and Program Analysis).

**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).

**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 establishment outreach?
5. List four challenges and common issues faced by small and very small establishments.

6. Where can the PHV get outreach materials?

7. Describe the role of the Agency in enforcement fairness.