A Quick Look at the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)

Judy Anderson, Cornell University

September 11, 2001 has forever changed the sense of safety and security in the United States. In response, the US Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“The Bioterrorism Act” or “The Act”) (PL.107-188). President Bush signed it into law on June 12, 2002. Title III of the Act provides for protecting the food and drug supply of the United States. The FDA has 18 months from the signing of the Act to issue final regulations for each section. However, the stipulations actually spelled out will take effect in 18 months (Dec. 2003) whether or not the FDA has the further regulations finalized.

Unless your business falls under one of the listed exemptions, the regulations as interpreted will apply to all food processing facilities, regardless of size.

The following very brief summary of sections 301, 302, 303, 305, 306 and 307 gives the highlights that most likely will affect the smaller food processing businesses. A large part of Title III is devoted to ensuring the safety of imported foods, especially those that will not receive further processing.

Other sections that are not detailed here address issues such as marking of a food product that is refused entrance to the US, notifying states when evidence points to a serious threat, awarding grants to states, territories and Indian tribes to offset the cost of required programs and inspections, authority to commission other federal agencies to conduct examinations and inspections, as well as many other issues. These section titles include: 308. Authority to Mark Articles Refused Admission into United States; 309. Prohibition Against Port Shopping; 310. Notices to States Regarding Imported Food; 311. Grants to States for Inspections; 312. Surveillance and Information Grants and Authorities; 313. Surveillance of Zoonotic Diseases; 314. Authority to Commission Other Federal Officials to Conduct Inspections; and 315. Rule of Construction.

All sections apply to human and animal food and food additives.


**Title III – Protecting the Safety and Security of the Food and Drug Supply**

**Subtitle A - Protection of Food Supply**

**Sec. 301. Food Safety and Security Strategy**

This section requires relevant federal agencies, food industry, consumer and producer groups, scientific organizations, and the States, to develop a comprehensive strategy regarding bioterrorist threats to the food supply, especially imported foods for humans and animals. The strategy adopted shall address threat assess-
Entrepreneur Profile

Eli and Ada Martin of Martin’s Kitchen

Eli Martin and his wife Ada have been in the food business for over 15 years. What started as a bulk food business in their home has evolved into homemade fruit and vegetable products, which they bring to a local farm and craft market by horse and buggy.

Their current product lines began at the suggestion of the market manager of the first craft market they attended who suggested that the Martins add homemade pickles to their line. They did, and homemade jams and jellies, salsas, and apple butter followed. In 1995, when they began to produce tomato products such as salsa and chili sauce, the NYS Dept. of Agriculture and Markets sent them to the Food Venture Center and Dr. Don Downing for a review of recipes and process. Since then, the Martins have used many of the services of the Food Venture Center and now NECFE.

During the late ’90s, as the Martin’s business grew, they experimented with selling at several regional markets in the Canandaigua and the Elmira areas of New York. But nothing could compare to the success they experienced at the Windmill Farm and Craft Market in Penn Yan, a few miles from their home. The location could not be more perfect as the two Menonites must transport their goods to the market via their horse and carriage.

Eli actively takes advantage of marketing opportunities that come his way, such as NYS Small Scale Food Processing Association meetings held during the NYS Farmers’ Direct Marketing Conference, the Finger Lakes Culinary Bounty (FLCB) trade shows, and the Pride Of NY.

After seeing their products at this year’s FLCB show, the chef at Bully Hill Vineyard & Restaurant ordered Martin’s Bread and Butter Pickles in 5 gallon containers. “At first, I was reluctant to take the job,” Eli explains. “It meant reformulating the recipe and I thought the profit margin would be too low. But then I calculated the labor and materials savings from filling the individual jars and the added exposure of having our pickles served at the restaurant and I decided to do it.” Again, there was reason to call Downing and Padilla-Zakour for approval on the necessary adjustments to the schedule process. Jars of the pickles are sold in the restaurant’s gift shop.

In January 2001, Eli attended the NxLevel™ business training classes offered by NECFE. Using business planning and management skills that he learned in the class, Eli has been making some strategic business decisions to help him to continue to grow. “The class helped me to focus on my business and take it in different directions,” he says.

Recently, the Martins gave up the bulk food part of their business to concentrate on their homemade products and co-packing operation. With the help of their son Javan, and daughters Erma and Lilian, Eli and Ada prepare, hand-fill, process, and label products in their licensed commercial kitchen located in the building that once housed their retail bulk food business. Co-packing opportunities are expanding. The day I called to talk to Eli about this article, the Martins were processing a half a ton of apples with Amy Nicholson of Red Jacket Orchards, Geneva, NY. Amy, who is starting a new line of applesauce and apple butter for the New York City Green Markets is using the Martins’ facility for co-packing. Ven-

Profile—continued on P.3
Adams at the Green Markets have to grow and process products sold there themselves. Eli says that he has another co-packing customer who will be bottling tea in his facility. Both clients were referred by NECFE.

Eli has attended many of the workshops offered through the Food Venture Center and now NECFE. From the “Better Process Control School” to the “Advanced Marketing Workshop” he is constantly seeking to improve his processing and business skills. Last fall at the “Advanced Marketing Workshop,” Eli used his products’ profile in a professional marketing consultant’s value-mapping program with remarkable results and came up with new ideas to market his products. He is presently working on revising his marketing brochure based on the results of a survey done as part of the marketing workshop.

On the technical side, Eli often seeks out the expertise of the Food Venture Center for issues of product safety. When a newly trained FDA inspector arrived at his facility last summer with technical inquiries, Eli sought out Padilla-Zakour and Downing for advice on interpretation of regulatory compliance. His records were reviewed and confirmed to be adequate.

I asked Eli what advice he has for specialty processors. He offered the following tip: recently he bought a new pH meter, which was a little more expensive than some models, but much easier to stabilize for testing. He found it easier to get consistent and accurate results even though he now needs two buffers to calibrate it. Eli’s first meter was a good starting tool but did not stand up under regular and frequent use. As a result of this experience, Eli says that it is important to choose processing instruments for functionality over price.

Eli and Ada’s dedication to hard work and entrepreneurial spirit is deeply rooted in their lifestyle. It is their goal to build a business to generate enough revenue to support their children and their families when the time comes. To this end, Eli is ever learning more about his trade and looking for new opportunities to grow their business without compromising their fundamental commitment to simple living.

Cheryl Leach

**NECFE Activities Highlighted in Washington, DC**

Bob Weybright, Cornell University

On Tuesday, March 4, two team members from NECFE traveled to Washington, DC, to participate in a U.S. Senate exhibition of food and agriculture projects from land-grant colleges and universities around the country. The event, sponsored by the National Association of State Universities and Land-Grant Colleges, was held to highlight the results of projects made possible by federal investment in food and agriculture research and education. NECFE representation at the exhibition was by Dr. Cathrine Donnelly, Associate Director, and Bob Weybright, Business and Marketing Specialist. The exhibition was the closing activity after a day designated for representatives from land grant colleges and universities to schedule personal meetings with their senators as well as other legislators interested in their respective organizations projects.

The NECFE exhibit was one of 35 chosen from all projects currently in progress at land grant institutions around the country and funded by federal sources. A competitive selection process determined participation in the exhibit. A unique element of the NECFE project that sets it apart from most of the other projects is the multi-state and multi-disciplinary collaboration, which is a primary component upon which the center is based.

The focus of the information provided by NECFE is summarized with the following excerpt from the exhibit application:

“The NECFE has provided direct assistance or training to more than 2,000 entrepreneurs in the areas of food safety, food processing, and business development and marketing, complemented by appropriate referrals to existing local service providers. An expanded and growing network of partnering organizations in the Northeast is benefiting both the service providers and the small-scale processors, by making the support system more effective and complete. There are very few organizations that are established to provide critical food safety and processing information to small-scale food entrepreneurs to achieve food safety and assure compliance with local and Federal food safety regulations. NECFE educational programs, including one-on-one counseling and tailored workshops and publications, provide direct knowledge transfer in a wide array of topics in food safety, product and business development, and marketing strategies, to future and established entrepreneurs who typically have limited access to the knowledge and resources due to economic constraints. By helping very small food enterprises with these technical issues, we are assisting the development of small-scale food business in the Northeast. By providing entrepreneurs with the right tools and continued support when starting and operating a food venture, we expect to increase their opportunities for economic growth and sustainability.”

Over 800 individuals attended the exhibition. Invited attendees included U.S. senators, senatorial staff personnel, as well as the press. Individuals stopping by the NECFE booth were treated to samples of New York State-produced onion jelly and Vermont-made maple syrups flavored with fruit purees. Two companies made all of the 700 sample-size products given out at the event: Luciano Sacheli’s of Potter, NY, and Hillsdale Lane Farm of Randolph, Vermont. What made the gifts unique was that both of these farm businesses have used a variety of NECFE services. NECFE was the only exhibitor able to have exhibition attendees directly and immediately enjoy the benefits made possible in part by the federal funding.

The day was a long but successful adventure. It started at 8:00 a.m. when exhibitors were to report to off-site security for a personal identity and background check and a thorough vehicle inspection. At 2:00, exhibitors were able to begin setting up displays for the 5:00 reception. At 7:30, the reception ended and it was time to pack up and get some rest. Comments from those just learning about NECFE were exciting. The fact that clients of the NECFE project had made products to be displayed and given away reinforced the fact that small-scale food processors are real businesses making excellent quality products. The support they receive through projects such as the Northeast Center for Food Entrepreneurship is invaluable.
A Study of Agriculture in the Netherlands

For a week this spring, I had the opportunity to visit The Netherlands with LEAD NY Class IX. The LEAD NY program is a leadership-training program for the people in the food and agriculture industry of NYS. The objective of the study trip was to relate to the key issues of food safety (biotech), labor, environment/urbanization, trade and energy to the top six agricultural and food industries in the Netherlands. These include retail, food processing, fresh market, dairy, crop and/or fisheries and horticulture. Through this tour we expected to gain a new perspective on how the cultural and food industries in other countries correlate to the United States, and, in particular, to New York State. Although The Netherlands is one-third the size of New York, it is the third largest exporter of agricultural products in the world.

The cheese department at a Royal Ahold supermarket in The Netherlands.

The trip, an ambitious venture, packed more than 16 stops into five days and evenings! Agricultural and related businesses we visited include: the Aalsmeer Flower Auction; DeRuiters, a greenhouse flower grower; several farm tours including an organic dairy/cheese processor, and a robotic dairy operation and a farm stay at a potato, onion and beet farm; supermarkets; produce distributor (Bakker) and food processor (Unilever); a wind power cooperative; and tours of harbor, ports and the U.S. Embassy in The Hague.

Several days were spent in The Netherlands Northeastern region’s newest “polder.” A polder is land reclaimed from the sea. This particular polder was drained beginning in the 1930s, completed in the ’60s and is now a planned community of business, farm and homes.

In Lelystad, the group was divided into pairs and hosted by local farmers. For the afternoon and evening, Eric Evers, who owns a potato, onion, and sugar beet farm picked up my partner and me. As we drove by the expanse of flat uninterrupted fields of remarkably straight crop rows we could see the seashells that remain in the rich reclaimed soil. We had an extensive tour of the farm, and then sat and talked of how life on their farm evolved. Eric bought the vegetable farm from his father who had been the original owner when the land was reclaimed. Ellen teaches music in their home to help supplement the family’s income.

The grounds of the farm are impeccably tidy and most of the farm equipment was new within the last five years. This farm also has a modern windmill, like many of the farms on the polder. These modern windmills dot the polder landscape and provide 3 percent of the energy used on the farms. Typically, there is one windmill per farm and it generates up to $50,000 per year in excess energy sold to the power company.

We visited two dairy farms while in Wageningen. First we stopped at a 140-cow farm that uses robotic milking machines. The machines run 24 hours a day and are programmed with the statistics of each cow’s milking capacity and schedule; an ear tag identifies the cow. It was a fascinating procedure, but the cows’ physical appearance belied the lack of routine human inspection that they would have had if the usual procedures were used.

The striking difference was apparent when we visited an organic dairy/cheese dairy later that day. Jan van de Voort’s 100 head of Jersey cows were clean, alert and well fed. The high fat content milk of the Jersey is used exclusively for Jan’s farmstead organic cheese that has a taste that is a cross between a Gouda and Parmesan. It is sold in Holland and exported throughout the European Union.

In Wageningen, we spent an afternoon at Alterra, a world-renowned agricultural experiment station. It is The Netherlands’ center of expertise on rural areas, their sustainable use, including aspects such as water, wildlife, forests, the environment, soils, landscape, climate and recreation, as well as various other aspects relevant to the development and management of the environment.

Next we visited an Albert Heijn supermarket—the largest supermarket chain in the world, owned by Royal Ahold of the Netherlands, which also owns Tops Markets and Stop and Shop stores in the U.S. It became apparent how seriously Hollanders take their cheese—the cheese department features entire walls filled from ceiling to floor with wheels of cheese, and a staff person on duty at all times. (See photo).

According to the Netherlands “2002 Agricultural Economic Report,” con-
Consumer spending on foods has increased somewhat as a result of higher prices. There has been a shift in consumption from beef and veal to quicker and more easily prepared poultry meat. The sale of organic foods increased by 23 percent - yet is still only 1.3 percent of the total consumption of food. Supermarkets are taking a larger share of the consumer Euro, around 80 percent of total sales. Specialty shops dealing in vegetables and meats and organic foods have dropped to 15 percent of the food Euro. Within the Dutch retail trade, three large concerns have a market share of around 67 percent—Albert Heijn, Dutch Ahold and Unilever.

The itinerary for the rest of the week was a whirlwind tour of key aspects of the Netherlands agricultural landscape.

- The agricultural American Embassy in The Hague. Although we arrived the day the US went to war with Iraq, we kept our appointment with U.S. and Dutch representatives who spoke to us on trade and food safety issues.
- Bakker. Wholesale produce distributor, selling exclusively to Albert Heijn supermarket chain. Their’s is an interdependent relationship based on a long history and trust. Bakkers has developed a long and trusted relationship with the farmers (suppliers) and work with them to assure quality products through tracking and tracing of each pallet of produce that arrives at Bakker’s distributions center.
- Unilever in Delft. This facility manufactures 60,000 tons of Hellmann’s Mayonnaise, peanut butter and a variety of salad dressings a year that are sold in the EU. The manager who gave us a guided tour of the plant was not familiar with the concept of small-scale specialty food processing as we know it in the U.S.
- Dutch Organic International Trade Organic Food Company (DO IT). Dutch distribution center for organic products to a worldwide market. DO IT invests in small farms and companies in Third World countries to support the social goals of fair trade and fair prices to fight poverty. Their products cannot be shipped to the U.S. because they do not meet U.S. organic verification standards.
- Friends of the Earth. A 70,000-member organization of a worldwide network campaigning for sustainable agriculture. They provided statistics about subsidies that many of the commodity crop farmers receive, with tobacco being the most subsidized.

What have I learned from my visit to The Netherlands and how can it benefit my work here in New York State? The Dutch are resourceful people who recognize when change is important for survival in business. The Dutch government is interested and invested in sustainable agriculture and policy changes have been made to promote a transition toward this end. Since change often means that someone may experience inconvenience or reversal of fortune, the Dutch believe that “the good of the whole is more important than the individual but the individual is well compensated for any inconvenience.” Therefore, farmers are open to the fact that where they are farming today may be a suburb in 20 years, but they will be fairly compensated and/or relocated. Although The Netherlands is the third largest exporter of agricultural products, much of what is exported is non-food such as flowers. Whether it is exported, or imported all products move through the one of the most modern seaports in the world, Rotterdam, for redistribution throughout the EU. Presently, Dutch farmers are highly subsidized by the Dutch government and the European Union.

In spite of the differences of the basis for success of American and Dutch agriculture, I believe that the most important idea I can bring away is the need to be flexible and open to new ideas, and to keep up with changing society and economies.

Cheryl Leach
ments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

Sec. 302. Protection Against Adulteration of Food

This section gives high priority to increasing the number of inspections of food imports with the greatest priority given to inspections to detect intentional adulteration. It also gives high priority to making improvements to the FDA information management systems for imported foods to detect intentional adulteration, and facilitate the importation of food that is in compliance with the Act.

Sec. 303 Administrative Detention

This amendment authorizes the FDA to order the detention of food if an officer or qualified FDA employee finds credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals and it specifies that the detention must be approved by an official at the district director level or higher.

Sec. 305. Registration of Food Facilities

This adds a new section to require registration for food facilities. The owner, operator, or agent in charge of a domestic or foreign facility must submit a registration to the Secretary. The registration period proposed is October 12, 2003 to December 12, 2003.

This registration shall contain the name and address of each facility, and all trade names under which, the registrant conducts business and, when determined necessary, the general food category as identified under 21 CFR 170.3. It requires that the registrant file in a timely manner, any changes to such information. It also requires notification to the registrant of receipt of the registration and assignment of a registration number to each facility. The compilation and maintenance of an up-to-date list of registered facilities is also required. The Act protects the list and any registration documents from disclosure under Section 552 of Title V, U.S. Code.

A facility is defined as any factory, warehouse, or establishment domestic or importer that manufactures, processes, packs, or holds food. Specifically excluded are farms, restaurants, other retail food establishments, non-profit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except vessels engaged in processing as defined in 21 CFR 123.3(k). [Note: This also covers animal feed and dietary supplement manufacturers.] Limits foreign facilities to those that manufacture, process, pack, or hold food only if food from such facility is exported to the U.S. without further processing or packaging outside the U.S.

The Act provides for and encourages the use of electronic methods of registration; however, paper registration is allowed. Failure to register will be considered a prohibited act.

Finally, it requires that an article of food offered for import from an unregistered foreign facility be held at the port of entry until the facility is registered.

Sec. 306. Maintenance and Inspection of Records for Foods

This section amends Chapter IV to authorize access to certain records when there is a reasonable belief that an article of food is adulterated and presents a serious threat to humans or animals. It applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food. It excludes farms and restaurants. It also excludes information such as recipes, financial data, personnel data, research data, and sales data (other than shipment data regarding sales). It directs the agency to take appropriate measures to ensure protection of sensitive information from disclosure. The section makes it a prohibited act to refuse to permit access to or copying of any required record or to fail to establish or maintain any required record.

The procedure of proposed and final regulations are required within 18 months of enactment to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. These records are required to be kept for two years.

The agency is required to consider the size of a business in promulgating the regulations.

Sec. 307. Prior Notice of Imported Food Shipments

Notice of arrival of imported food shipments will be required. The notice shall provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. If notice is not provided, the article shall be refused admission.

The Act requires regulations that specify the period of advance notice shall be no less than the minimum amount of time necessary to receive, review, and appropriately respond to such notification. It also states that the period may not exceed five days and that an article of food offered for import without prior notice, shall be held at the port of entry until the importer, owner, or consignee complies.
Welcome back to Abigail’s Vermont Applesauce

Let’s revisit Abigail to see how she might employ her Internet marketing plan to get people to come to her new website.

Remember that Abigail had decided to use her site to market and sell her product, and she is on a tight budget.

Abigail’s target audience is a health-conscious mother who is concerned about what snacks she feeds her children. She is well educated, drives a Volvo, and works full-time in an executive position. She enjoys jazz, classical and talk radio, and likes to shop in health food and co-op stores. She reads a variety of books, reads the daily newspaper and Vermont Life magazine (or similar arts magazines). She plays tennis and skis in the winter. She has a computer at work and at home, and shops online for clothes, home fashions and things for her children. Her income is over $50,000 per year.

Abigail’s website is now completed and she has decided on her title, description and keywords:

• Title: Abigail’s Vermont Applesauce: all natural, low-sugar, great taste.
• Description: Abigail’s Vermont applesauce is made with Vermont apples, is low in sugar and tastes great. Special flavors add variety. Buy some now.
• Keywords: Applesauce, Vermont, low-sugar applesauce, all natural applesauce, specialty foods, Abigail’s Vermont Applesauce, Vermont Apples, fruit, healthy snack, Vermont specialty foods

She has written her homepage text to focus on her keywords AND readability for the user:

Applesauce that is all natural, low in sugar and made in Vermont! Abigail’s Applesauce offers a healthy snack alternative that you and your children will love because we believe in blending natural fruits together to create a taste that you will enjoy every time. We sell our applesauce by the case on the website and offer a FREE sample for first-time buyers. If you can’t get to our local stores in Vermont to give it a taste, just fill out our form to get your free sample of Abigail’s Applesauce today! When you come back, just enter the special code from the sample and get 10% off your first case.

Abigail’s Vermont Applesauce: Great Taste from the Green Mountains

Abigail gets her first log file report, and while the numbers are small, they are growing. She is encouraged to see that several of her links and both Yahoo! and Google have shown up as referrers. She is also very happy to see that many people are coming directly to the site as well. This is what she did to get that result:

Listed her URL with:
• her apple suppliers
• the State of Vermont
• Vermont Specialty food producer websites

Added her URL to the following items:
• Jar labels
• Business Cards
• Brochure

Created an e-mail newsletter with coupons and a “refer to a friend” link. (Free trial for several months allows her to experiment and see if this will work.)

Experimented with Google
• Put in for a free listing
• Decided to create a Google Ad Word Box for a small amount of money

What’s next?

Revisiting your marketing plan and budget should be done every six months, even for a small business. You’ll need to update your website, add new items and take away the old. You may want to put out another e-mail newsletter or offer a special discount. Making your site and your marketing fresh and up-to-date will help you to get, grow and keep your customers.

Resources

Check out these resources referenced in the article for more information.

http://www.searchenginwatch.com
Search Engine Watch – gives you more information than you probably want about search engines – but tells you how to get listed with them all.

http://www.constantcontact.com
Constant Contact – an e-mail marketing tool that allows you to create announcements, newsletters and other marketing pieces that you can e-mail to a specific list. They offer a 60-day free trial so you can see if you get any results!

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Food Business Incubation Summit 2003
2nd National Conference and Education Symposium
Clarion Hotel and Conference Center, 1 Atwood Drive, Northampton, MA

Sponsored by: The Northeast Center for Food Entrepreneurship (NECFE), a collaboration of Cornell University and the University of Vermont; Franklin Co. Community Development Corporation’s Greenfield Kitchen. Partnered with: Rutgers University/NJAES, Food Innovation Research & Extension (FIRE Center)

Building on last year’s conference, the 2-day conference and symposium will re-unite food processing technical and business support professionals from across the country to review best practices for food business venture centers and incubator facilities. Plans include a full agenda of educational and regulatory topics relevant to economic development sectors daily operations. Included will be updates on current regulatory issues that may affect the facilities and processors.

Topics:
- Labeling: Nutritional, country of origin, and health claims.
- Food Safety - FDA’s Facility Registration Rule Explained, current and pending effect on the economic development sector.
- Food establishment guidelines for design, installation, equipment and construction recommendations.
- Developing a stakeholder committee, setting goals and objectives of the committee, and gathering of primary and secondary constituent data to support the project.
- Overview of user and operating agreements, documentation of facility’s policies and procedures.
- Tour an operating shared-use food processing facility established in 2002 and meet some actual processors of the Franklin County CDC’s Food Processing Center in Greenfield, MA – to be held in conjunction with an evening reception on Sept. 17th.

SAVE THE DATE
SEPTEMBER 17 & 18, 2003

www.nysaes.cornell.edu/necfe