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FDA to Issue Food Safety and Security Regulations
Brian Norder
NECFE/Vermont Food Venture Center

In 2002, Congress took many actions in response to the September 11 terrorist attacks. One of them—the Bioterrorism Act—was written, in part, to protect America’s food supply. Many experts believe that this supply is vulnerable to attack and that safeguards need to be built into the system.

The Bioterrorism Act charged the Food and Drug Administration with developing regulations to reduce the threat of terrorism. Gradually, these regulations are emerging from the legislative process and moving toward implementation. Several regulations will impact food producers in the next few months. Three major areas of impact are in the registration of food manufacturers, refinements in existing record-keeping policies, and traceability of raw and finished foods.

Registration will be the first regulation implemented. All foreign and domestic facilities that “manufacture, process, pack or hold food for human or animal consumption in the United States must register with the FDA by December 12, 2003.” Procedures for registration will be outlined in the final rule to be issued by October 10. As you can see, there is a short time between when the rule is published and when compliance is expected.

In all likelihood, the process will be fairly simple. Companies will probably be required to list their basic company info, name, address, contact person(s) and type of food processed. Registrants will likely be asked to fit their product into one of the categories listed in the Code of Federal Regulations, 21CFR170.3. More detailed requirements may develop in the future. Food producers should check the FDA’s web site in early October for registration information (www.cfsan.fda.gov).

The FDA warns that there are companies and individuals advertising that they will register on behalf of food producers (for a fee, of course). Since the regulations have not been finalized and the agency is not currently accepting registrations, these for-fee services should be viewed with caution.

The other changes are not as imminent but will be more onerous to small producers. The record-keeping and traceability requirements revolve around the need for each handler in the food chain to be able to trace their raw materials one step back and their processed goods one step forward. Companies that have implemented HACCP (Hazard Analysis and Critical Control Point) systems will have an easier time as many of the lot tracking and documentation procedures used in HACCP will be helpful in meeting the new regulations.

Companies without HACCP or detailed quality assurance systems will need to develop procedures that can identify which lots of incoming ingredients went into which lots of processed foods, who shipped those foods, and who they were sold to. For companies using distributors, this could be the greatest challenge. As proposed,
Entrepreneurship Profile

Linda Seavey, Vermont Island Foods, South Hero, VT

Linda Seavey, one of Vermont’s newest food entrepreneurs, lives in South Hero, Vermont, where she commutes to her day job as director of campus planning services at the University of Vermont. Since the town of South Hero is located on an island connected to the Vermont mainland by road, Linda thought the name “Vermont Island Foods” was perfect for her fledgling business. Her colorful logo perfectly conveys this island feeling and adds a very decorative touch to her first product, an elegant tasting amaretto chocolate sauce.

Linda’s story sounds familiar but with an important difference. In May, she attended “Recipe to Market,” a one-day seminar/boot camp that she figures put her ahead of the curve in becoming a food entrepreneur. At the seminar, she learned what personal traits are required to undertake the long road to marketing a successful product. She also received information on market research tools, packaging and labeling sources, food safety considerations, and business plan writing, and came away with a new network of classmates to contact in the future.

“Recipe to Market attendees were very inspirational for me,” said Linda. “Maybe they were a little further down the road than me, but I came away knowing the process we all must go through is very similar.” Thinking abstractly about the well-worn steps she will be climbing, she commented, “The process really interests me.”

After the class, Linda started writing her business plan, conducted market research, made finishing touches to her label, and met with Brian Norder, Project Director of the Vermont Food Venture Center in Fairfax, VT, to schedule a test batch of her sauce in his shared-kitchen facility. Later samples will be available for additional market research with potential retail outlets and typical consumers for this type of high-end product. After 15 years of rave reviews from friends and family with her sauce “not getting as far as the ice cream” (i.e. because so many people eat it right from the spoon), Linda is ready to make her dream a reality. In addition, after years of traveling to the Caribbean for eco-tourism, she would eventually like to deal directly with local ingredient suppliers to insure a winning combination for them and for her Vermont Island Foods.

FDA, from P. 1

it seems that producers will need to know exactly which foods and lots the distributor sold to specific customers.

Businesses engaged in transportation and distribution of foods will be held to similar requirements and thus will probably be able to work with producers in developing trace-back and trace-forward protocols.

There will be exemptions specifically related to farm products, restaurant and retail operations where food is sold directly to the consumer.

Implementation will begin with the largest food companies. The final rule is due for publication no later than December 12, 2003. Companies with more than 500 full-time employees (or equivalent) will be given six months to comply. So-called “small” companies, between 10 and 500 employees, will have 12 months to comply. “Very small businesses” of under 10 full-time equivalent will have 18 months from final issuance of the rule.

Again, consult www.cfsan.fda.gov for detailed discussion of the biosecurity guidelines.

Susan Callahan
NECFE’s “Recipe to Market” seminar was designed in response to ever-growing inquires from entrepreneurs who are just starting out, whether they are clients with a defined product concept or those with only a dream of joining the ranks of food entrepreneurs. Fueled by media attention to the Ben and Jerry’s of the food world and employment downsizing, developing a successful food business seems within reach to anyone with a vision and the energy to see it through. Part psychology and part hard facts, “Recipe to Market” fills a void for entrepreneurs who are just starting their journey.

Using their initial enthusiasm as a jumping-off point, NECFE developed a day-long seminar to give clients an overview of important topics that could spell success or failure of their new venture. By investing a day, participants come away with a better sense of “is this really for me and my family” along with a toolbox of resources. While NECFE hopes every would-be entrepreneur will leave class and start working on a business plan, deciding “this isn’t for me” is also a successful outcome. In most cases, the desired end-result is a much clearer roadmap and access to NECFE staff to assist along the way.

The seminar begins with the question, “What is an entrepreneur?” Participants are usually surprised to find there is a very special set of needed characteristics such as risk-taking, enjoys working alone, good health and high energy, creative, passionate, and persistence, to name just a few. Participants are asked to stop and ask themselves if this list sounds familiar. Assessing lifestyle goals, making a personal resource inventory, and need for writing a life mission statement follow.

The nuts and bolts of the seminar unfold in rapid succession. What are current food industry trends? What can we learn from how large food companies develop new products? How does one do market research for a particular product? What are the advantages of being a “small guy” in the marketplace? Oh, and by the way, what is your competition doing and what is the definition of a “specialty food” anyway?

Sprinkled throughout the day are quotes from food entrepreneurs about their journeys to success because nothing means more than advice from someone who has walked down a similar road.

The topics continue in rapid succession: product and process development, packing and labeling, marketing, business structure overview, and food safety and sanitation. While any of the above could be a stand-alone seminar, the goal of the “Recipe to Market” seminar is to facilitate an understanding and overview of what every would-be food entrepreneur must learn and many may have not considered. A valuable resource section in the seminar’s workbook assists in finding information and fleshing out topics for self-study. In addition, a display table in the classroom has a wide range of materials showing participants the food world has thousands of resources.

Networking with their peers is an unexpected class outcome for many participants. Entrepreneurship can be a lonely life, so gradually assembling a personal network can be invaluable. The process is jumpstarted by having class members introduce themselves and work together on solutions.

The day ends with a quote from Vermont’s veteran food entrepreneur, Cathy Bacon of Hillside Farms, “Keep it FUN! Enjoy meeting new people!” The NECFE staff couldn’t agree more.

The next “Recipe to Market” will be held at the University of Vermont on November 5, 2003. To attend this session or to suggest future locations, call Susan Callahan at 802.656.2952 or susan.callahan@uvm.edu.

Hot Stuffing continued on P. 5
One of the most daunting and potentially most expensive aspects of starting a food business is the process of developing and printing a label for the product. There are several different printing processes available, each of which has its own negative and positive characteristics. A detailed discussion will follow a brief introduction of each process.

**Flexography** or flex printing is the standard technique for medium to high volume operations and for those using automatic application. Ultimately, this is where most successful food businesses end up. Cost is the decision driver here because the initial investment can be high.

**Digitally printed** labels represent fairly new technology and allow for small volumes of quality labels at a fairly high per label cost, but with a very low start-up cost. As the technology improves, the cost is likely to drop significantly.

**Thermal transfer printing** is used in most supermarket checkouts, UPS shipping labels, ski lift tickets and many other common functions. It is affordable and can be used to print on white stock or as a custom overprint on pre-printed stock.

**Home computer printed** labels are commonly used for initial start-ups and prototype batches. They are quite limited in their commercial application, as we will see.

**Graphic Design**

The computer programmers’ adage “garbage in/garbage out” or “GIGO” can be well applied to label printing also. Home computer-generated graphics for labels generally are not suited for the more advanced printing techniques, flexography and digital printing. In addition to compromises in visual quality, home-generated graphic designs often need substantial revision before going to press. The expense of pre-press modification to designs can approach what would have been spent on graphic designs often need substantial revision before going to press. The expense of pre-press modification to designs can approach what would have been spent on a professional design in the first place.

To find a good designer, check with colleagues in the food business and look through the yellow pages. Costs vary widely. Often a small, low-overhead design shop can provide top quality at a fraction of the price charged by larger studios.

**Flexography**

The cost of flex printing is very front-loaded for the entrepreneur and can represent a major barrier. The designer should work with the printer early in the process. Labels are die-cut from bulk paper stock. Most printers have a large numbers of dies in inventory in sizes standard for most packages. A uniquely shaped or sized label will require a custom manufactured cutting die at an additional cost of $300 to $500.

The next cost is the printing plates, usually $50 to $75 for each color on the label—more if a photograph is part of the label art. These plates are re-used for all future press runs and should be considered a start-up cost. Plates are usually specific for the brand of press that each printer uses so they don’t easily transfer from one printing company to another. If you decide to switch printers in the future, you will incur plate charges all over again.

It is not unusual to have four to six plates per job. If you are planning several products in your line, you should think about the number of plates you will need. One way to save money is to use the same colors for background and artwork across the product line and just change the black ink plate that has the product name, ingredients, nutrition facts and other unique information.

At press time you will incur charges for press set-up and for changing the ink colors on the press to match your label. This is typically $15 to $20 per color and shows up each time you print. Finally, you have the cost of the label, as quoted in thousands or “m.” It is likely to be expressed on the bid as follows (prices are for illustrative purposes only):

- 1000: $120 per m
- 2500: $80 per m
- 5000: $60 per m
- 10000: $40 per m

As you can see, the printing cost is relatively small and highly volume-sensitive. Nevertheless, you should not tie up money to get the volume discount if you are only projecting the need for 1000 labels over the first year or so. Label coatings and adhesives deteriorate with age and can be useless after a couple of years.

You must specify the type of product and package the label will be applied to, the temperature it is packed at, and the temperature it will be stored at (whether room temp, refrigerator, or frozen; dry or moist). You will also want UV-resistant coating to reduce the chance of color fading. If you will be applying the labels by machine, the label machine specifications must be provided to the printer.

When calculating your label cost for pricing purposes, it is probably best to figure it on the reprint cost, which includes the cost per thousand, pre-press charges and ink changes, but does not include plate and design costs which should be amortized as business start-up costs.

**Digital Label Printing**

This relatively new technology holds great promise for new entrepreneurs who wish to avoid plate charges and high minimums. Again, a professional designer should be used for the design. All work is done on computer and the result is sent to the printer electronically. The result is a high-quality label at a relatively small and relatively small and highly volume-sensitive. Nevertheless, you should not tie up money to get the volume discount if you are only projecting the need for 1000 labels over the first year or so. Label coatings and adhesives deteriorate with age and can be useless after a couple of years.

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**Label Printing Processes Explored**

*Brian Norder, Project Director*

*Vermont Food Venture Center*
best results but digital printing requires no plates, no die-cuts and no ink charge changes. As a result, custom shapes and sizes can be accommodated.

Paper stocks to accommodate all fill and storage temperatures and conditions are available. Color quality is comparable to flex labels but, because they are printed on sheets, they cannot be used on automatic labeling machines, which represents a consideration for volume processing because application of labels can be time consuming.

While the cost per label can be high, the price should come down as the technology becomes more available. Roll-dispensed labels should not be far behind. This may be the process for the future for press runs of under a couple thousand.

**Thermal Transfer Printing**

This is a “do-it-yourself” option that can be hooked to the home computer. For an investment of around $1000, you can get a printer and the software to produce text and scanned-in images. The chief limitation is that this is a monochromatic or one-color process.

Creativity can expand the options greatly by ordering flex-printed labels with blank spaces left for the product name, ingredients, nutritional facts and bar code, all of which can be added by thermal printing. Special paper coatings suitable for thermal overprinting must be specified for this option. This is a particularly attractive option for producers with a wide or seasonal product line where a large number of custom printed labels are cost prohibitive.

**Home Computer Printed Labels**

This technique is best suited for farmstand sales, farmers’ markets, craft and harvest festivals, and small, local retail sales. The paper stocks that are available have the limitation of not being water- or refrigerator-resistant and are prone to fading. The actual cost, once the expense of paper and ink jet cartridges is calculated in, may be surprisingly high, but saving graphic designer costs along with the ease of production make these labels appropriate for some small businesses.

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**Selling Skills for Food Businesses**

Brian Norder, NECFE, Vermont Food Venture Center

One of the more successful parts of the entire NECFE program has been the training workshops offered throughout the region. The latest workshop—“Selling Skills for Small Food Businesses”—builds on this success.

The development of “Selling Skills” came about by accident. After hearing that food entrepreneurs wanted help with marketing, NECFE staffers Bob Weybright of Cornell and Brian Norder of the University of Vermont helped produce a workshop that went into great detail on demographics and consumer behavior, competitive analysis and other aspects of a marketing program. At the end, the general sentiment was, “That was nice, but how do we sell?” That’s when Weybright and Norder realized that start-ups weren’t looking for marketing assistance but rather “nuts and bolts” sales and placement techniques.

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**Specialty Food Businesses**

A daylong seminar in Greenfield, MA which will review the growth of the retail organic market, review basic principles to become a certified processor, identify contacts to assist with the certification process, discuss principles of marketing organic products, and feature presentations from growers and specialty food producers who have successfully completed the process. The seminar is scheduled for late January or early February, 2004 at the Western Massachusetts Food Processing Center.

For a full program and registration information, send an email to: bonita.oehlke@state.ma.us.

Sponsors include NECFE, the MA Specialty Food Association, Massachusetts Independent Certification Inc, and the MA Department of Agricultural Resources.
NECFE Client Follow-up Study Shows Business Growth and Other Positive Outcomes
Michele Cranwell, University of Vermont

A follow-up telephone survey of 299 NECFE clients shows that NECFE services have positively impacted job creation, business growth, and income growth, among other outcomes, and the surveyed clients’ businesses have had a positive impact on rural economic development. Clients also report high levels of satisfaction with NECFE services.

During the months of November 2002 and June 2003, the Center for Rural Studies at the University of Vermont, which is the evaluation team for NECFE, conducted a telephone survey to follow-up with all clients who received NECFE services from 2000 to 2002. The 299 people who participated in the study are representative of the NECFE client population at the confidence level of 95 percent with a margin of error of plus or minus 5 percent. The following information highlights findings of the NECFE client follow-up study.

Clients surveyed have worked with NECFE from six months to three years, with an average of one-and-a-half years. Women own 57 percent of NECFE businesses surveyed and 39 percent are farm-based. Businesses produce from 1 to 600 different types of products, with an average of 20 products. The products produced include tomato-based products, dressings and flavorings, meats, dried products, preserves, baked goods, and packaged produce products, among a slew of others. Product varieties range from gourmet dog biscuits to flavored oils, artisan cheeses, and even personal care products made out of perishable ingredients!

Job Creation and Support

Fifty-nine percent of NECFE clients surveyed own an established business, and this business provides their primary source of income. A little over one-third (36 percent) established their business while working with NECFE. Of the businesses established while working with NECFE, 82 percent created a total of 159 jobs, including 86 part-time and 73 full-time jobs.

NECFE Client Business Stats
- 299 people surveyed to 3 years, averaging 1 year
- 57% women-owned
- 39% farm-based
- 1 to 600 products produced; average 20

NECFE Client Outcomes
- 36% established their business while working with NECFE
- 82% of these clients created 159 (86 PT and 73 FT) jobs while working with NECFE
- NECFE clients surveyed employ 1,516 people, 969 FT and 547 PT
- 47% reported business growth after working with NECFE
- Establishing a longer term relationship with NECFE leads to business growth
- 61% reported their business as their primary source of income

between 1 and 41 full-time jobs with an average hourly wage rate of $9.60. One business employs 550 people. Fifty-nine percent have created between 1 and 40 part-time jobs with an average hourly rate of $7.70. In total, NECFE services support businesses that employ 1,516 people, with 969 full-time jobs and 547 part-time jobs. Twenty-eight percent of those surveyed reported that their business provides employees with medical and health benefits.

Business Growth

Almost half of NECFE clients (47 percent) reported that their business had grown since they began working with NECFE until the time of the survey. Fifteen percent of businesses that were in the planning phase at their initial contact with NECFE are now in the process of expansion. The length of time a business has worked with NECFE impacts business growth. Respondents who used NECFE’s services for an average of three years experienced more growth in their business when compared to those who worked with NECFE for an average of one-and-a-half years and did not experience growth.

Growth in Income and Sales

About one-third (33 percent) of NECFE clients’ annual household income increased because of their business, and 36 percent reported that it stayed the same. The average amount of increase in income is approximately $53,000 with figures ranging from $2,000 to $600,000. Of those who started a business while working with NECFE, 18 percent reported that their annual household income had increased and 37 percent said that it remained stable. Their average increase was $20,000 with a range of $2,000 to $72,000.

The average dollar amount of business sales generated in 2002 or the last year the business was open was approximately $422,000 with a range of $115 to $10,000,000. Two-
thirds of business owners (68 percent) surveyed reported that their business is generating enough income to cover expenses. Of those who started their business while working with NECFE, average sales equal $46,000 with a range of $500 to $250,000.

Impact on Rural Economic Development

NECFE clients were also asked what impact their business has had on rural economic development in their community. Many clients cited that their business has impacted their community by providing a source of high quality food and food security. These businesses provide a selection of high quality, locally grown food that meets the market demand of local people. Several businesses have also established farmers’ markets in their areas, leading to food security. Many also reported that their business have generated jobs for local community members. Others note that their business has improved the tourism industry in their area, because the presence of their business has increased the volume of tourist traffic, and this positively impacts other local businesses. A variety of other positive answers were received, including:

- Improved community relations and networking;
- Increased awareness of local food in area;
- Way of preserving agricultural and farming skills in the area;
- Preserve economic well-being of rural people;
- Rejuvenation of other local farms and businesses;
- Purchase raw ingredients from local/rural businesses.

High Satisfaction with NECFE Services

Clients surveyed received a variety of services offered by NECFE, including receiving educational materials, attending a workshop, receiving general assistance to an inquiry, or short- and long-term direct assistance. Overall, clients reported high levels of satisfaction with these and other NECFE services. Eighty-six percent agreed that NECFE services provided the information and assistance that they needed, and 84 percent indicated that NECFE services met their expectations. Almost two-thirds of clients surveyed stated that NECFE services aided in the success of their business. Because almost all those surveyed reported high levels of satisfaction, 82 percent reported that they would continue to use NECFE services in the future.

Make Space on Your Labels – Trans Fatty Acids are Movin’ In!

Cecilia Golnazarian, University of Vermont

Trans fatty acids has been a topic of controversy in the field of nutrition for some years, often being compared to saturated fatty acids or worse.

What exactly are trans fatty acids? Trans fatty acids are created when hydrogen is bubbled through liquid oils to make them more solid. Partially hydrogenated fats have longer shelf lives than liquid oils because the extra hydrogen raises the fats’ melting point, making them more stable at room temperature. Like saturated fat, trans fat provides the functional characteristics desired for processed foods, for example flaky pie crusts. Trans fats are found in shortenings, margarine, baked goods, cookies, salad dressings, crackers, chips, candies and fried foods, to name a few! Unfortunately, research studies show that trans fats raise the body’s levels of “bad” cholesterol (LDL’s), thereby increasing the risk of heart disease.

At this time, a safe intake level for humans has not been determined – studies are ongoing. This is one reason that the Food and Drug Administration has prepared the Small Entity Compliance Guide for trans fatty acids in nutrition labeling, nutrient content claims, and health claims.

On July 11, 2003, the FDA published a final rule in the Federal Register (68 FR 41434) requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements. But don’t panic yet—the rule doesn’t become effective until January 1, 2006, which allows manufacturers time to use their current stock of labels and redesign labels to include the trans fat. The new label must list the amount of trans fat in a serving on a separate line under Saturated Fat on the Nutrition Facts panel. If the food contains less than 0.5 gram per serving, you are not required to list it—a statement that the food is “not a significant source of trans fat” will be accepted (as long as no claims are made about the fat, fatty acids are movin’ in!...
Transitions at the NECFE – Vermont
Catherine Donnelly, University of Vermont

Over the past summer, a number of personnel changes have occurred at NECFE – Vermont. Pam Durda, our long-time administrative assistant, left NECFE in July to pursue other professional opportunities. We wish to thank Pam for her dedicated service to NECFE and for all of her many efforts to advance the NECFE. We extend to Pam our very best wishes for much success in her new ventures! We are delighted to announce that Jody Farnham has replaced Pam in the role of NECFE administrative assistant. Jody brings to NECFE her previous experience as a business owner, her prior work in public relations, and her prior experience as an administrative assistant. We are thrilled to have Jody on board as part of the NECFE team.

Dr. Todd Silk, Process Authority at NECFE – Vermont, has left the NECFE to assume the position of Microbiology Supervisor at Wyeth Pharmaceuticals in Georgia, VT. We wish Todd much success in his new position. Dr. Cecilia Golnazarian and Brian Norder will continue to handle requests for scheduled processes.

As we move forward, we have a number of exciting projects under development related to our work in support of farmstead cheese producers in the Northeast. We are currently evaluating the feasibility of establishing an Artisan Cheese School and Technical Research Center at the University of Vermont. Over the past three years, we have been overwhelmed with enrollment in our NECFE specialty cheese short courses, and our clients have expressed the desire for extended educational and outreach programming in the specialty cheese area. Working with our NECFE project consultant Jeff Roberts, we have identified some promising funding opportunities to advance these exciting efforts. We will share our future plans as they develop.

For complete information on the FDA’s ruling, check out their website www.cfsan.fda.gov/~dms/transgui.html