# *New food safety regulations on the horizon*

**By Charles Graham**

As I sit down to write this article for *Pecan South*, we've just finished up the holiday season and the kids have started school again. It's a new year and I was pondering the idea of actually choosing a new novel to read over the next few weeks, something I haven't had the time to do for several years.

But then it happened, the U.S. Food and Drug Administration published the first 2 proposed rules associated with the Food Safety Modernization Act. The 2 documents tallied 670 and 547 pages, thus providing me with over 1,200 pages of "pleasure" reading. That's more than any of the Harry Potter books I had read with my boys over the years. And while I doubt the new proposed rules make the *New York Times* best seller list, it is a must read for people in the produce industry.

I can already hear a couple of growers accusing me of having too much eggnog over the holidays and spending too much time babbling about the FSMA. But at the same time, there are still a lot of growers out there that don't know what the FSMA is all about. So let's begin by reviewing how we got to this point.

Food Safety efforts are nothing new, with the first national food safety law being the Pure Food and Drug Act of 1906. This was replaced by the Federal Food, Drug, and Cosmetic Act of 1938. Over the years, the FD&C Act has been strengthened by additional amendments such as the Food Additives Amendment in 1958, the Color Additives Amendments of 1960, and the Animal Drugs Amendments of 1968. One of the more recent changes of the FD&C Act was the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. But fundamentally, there has not been a major overhaul of the food safety laws since 1938 despite dramatic changes in food production and distribution patterns.

President Obama organized a White House Food Safety Working Group in 2009 to identify measures needed to upgrade the U.S. food safety laws for the 21st Century, coordinate Federal efforts, and develop short-term and long-term agendas to make food safer. On July 7, 2009, the workgroup released its report "Implementing a National Public Health Approach to Food Safety: Report to the President." This report included recommendations for a new public health-focused approach to the safety of all food based on 3 core principles: (1) Prioritizing prevention, (2) strengthening surveillance and enforcement, and (3) improving response and recovery.

This report led to the U.S. Senate and House of Representatives passing the Food Safety Modernization Act (FSMA) (Pub. L. 111-353) in December 2010. The FSMA was signed into law by President Obama on Jan. 4, 2011. The responsibility for ensuring the safety of all domestic and imported fruits and vegetables consumed in the United States belongs to the Food and Drug Administration (FDA).

The new law directs the FDA to focus more on preventing food safety problems rather than primarily reacting to problems after they occur. Additionally, the FDA is provided with new enforcement authorities to help them achieve higher rates of compliance with prevention-based and risk-based safety standards and to better respond to and contain problems when they do occur. In addition, the law gives the FDA important new tools to better ensure the safety of imported foods and directs them to build an integrated national food safety system.

A high priority is placed on identifying and implementing measures that can reduce the incidence of food-borne illness associated with produce and maintain a high level of consumer confidence. Produce is vulnerable to contamination with microorganisms of public health significance (e.g., bacteria and viruses that can cause disease), as well as chemical, physical, and radiological contaminants at many points along the Farm-to-Table continuum.

On Jan. 4, 2013, the 2-year anniversary of President Obama signing the FSMA into law, the U.S. Food and Drug Administration proposed 2 new food safety rules that will help prevent food-borne illness. The first rule, *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, would require makers of food to be sold in the United States, whether produced at a foreign- or domestic-based facility, to develop formal food safety plans for preventing their food products from causing food-borne illness. Specifically, the proposed rule would establish requirements for: a written food safety plan; hazard analysis; preventive controls for hazards that are reasonably likely to occur; monitoring; corrective actions; verification; and associated records.

FDA's second proposed rule, *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. This rule proposes science- and risk-based standards for the safe production and harvesting of fruits and vegetables. New standards are proposed in the following major areas: worker training and health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals; equipment, tools, and buildings; and sprouts.

The proposed produce rule covers most fruits and vegetables while

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## *FOOD SAFETY*

they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

While the FDA proposes to cover tree nuts that do not meet the criteria currently proposed for "rarely consumed raw", the guidances recognize that many tree nuts receive commercial processing to adequately reduce pathogens and, thus, may be eligible for an exemption under proposed § 112.2(b). The proposed rule's main food safety concerns relevant to on-farm growing, harvesting, packing, and holding of tree nuts pertain to those nuts that would be sold raw and untreated. The FDA is currently requesting comments on their treatment of tree nuts in this proposal.

In the past, it has been argued in some types of legislation that tree nuts were not covered because they were not produce under some definitions. To remedy this disagreement, the FDA outlines their definition of produce, fruit and vegetable. For the purpose of this rule, the FDA proposes to define the term "produce" to mean any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and would include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. Within the definition of "produce," the FDA further defines that a fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond), such that fruit would mean the harvestable or harvested part of a plant developed from a flower.

A vegetable is defined as the edible part of an herbaceous plant (such as cabbage and potato) or fleshy fruiting body of a fungus (such as white button and shiitake) grown for an edible part, such that vegetable would mean the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs. With this definition, the FDA is proposing to specifically include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs, and specifically exclude food grains. They request comments on their proposed definition of "produce."

Some farms would not be covered by the rule, or would be eligible for a partial exemption based on factors including the monetary value of their food sales and to whom they sell. The partial exemption would still subject eligible farms to certain modified requirements, and could be withdrawn in certain circumstances.

I've been asked by several growers if they were exempt from the

proposed rule. If you answer "NO" to all of the following questions, then you are covered by the proposed rules: Is your produce rarely consumed raw? Is your produce for personal/on-farm consumption? Does your farm manufacture/process, pack, or hold produce that is not a Raw Agricultural Commodity (RAC)? Is your produce intended for commercial processing with a "kill step"? Does your farm on average (in the previous 3 years) have less than $25,000 annual food sales? Does your farm on average (in the previous 3 years) have less than $500,000 annual food sales, AND a majority of the food (by value) is sold directly to "qualified end-users"? A "Qualified End-User" is the consumer of the food ("consumer" is not a business) OR a restaurant or retail food establishment that is located - (i) in the same State as the farm that produced the food; OR (ii) not more than 275 miles from such farm. If you answered "YES" to any of those questions, you will be exempt under the proposed new rules.

The proposed rules will be available for comment for 120 days from the time of their issuance on Jan. 4, 2013. The FDA will consider all comments received during the 120 days for both rules and then consider revising the proposed rules after reviewing the validity of the comments before publishing the final rule in the Federal Register. The proposed rule and supporting documents are filed in FDA's official docket on http://www.regulations.gov and also can be accessed at the FSMA website http://www.fda.gov/Food/FoodSafety/FSMA/default.htm

The two proposed rules would become effective 60 days after the final rule is published. The FDA is proposing that larger farms be in compliance with most of the Produce Safety requirements 26 months after the final rule is published in the Federal Register. Small and very small farms would have additional time to comply, and all farms would have additional time to comply with certain requirements related to water quality. Current costs of implementation are estimated to be $4,697 for very small farms, $12,972 for small farms, and $30,566 for large farms. However, these are just best estimates as very limited data is available for calculating the costs.

While the provisions in these proposed rules are too numerous to discuss them all in this article, it is important for me to point out that the rules were written with some flexibility to accommodate future changes in science and technology. In section § 112.12 of the proposed rule, the FDA lists the specific requirements established in this rule for which they believe

alternatives may be appropriate and the circumstances under which such alternatives could be used. The provisions contained in the proposed rule would provide significant flexibility by allowing individual farms to develop alternative standards suitable to their operations with appropriate scientific support.

For example, let's discuss one of the standards in the Biological Soil Amendments of Animal Origin subsection. This standard will greatly impact native pecan producers that also are cattle producers and often graze cattle for a few months each year. If a biological soil amendment of animal origin is untreated or originates from grazing animals, then the minimum application to harvest period is 9 months. If the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements of §112.54(c) to meet the microbial standard in §112.55(b) and is applied to the field in a manner that minimizes the potential for contact with covered produce during and after application, then minimum application interval to harvest is 45 days.

You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of § 112.12. A grower may establish and use an alternative to any of the requirements listed in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part (including meeting the same microbiological standards, where applicable), and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval. (c) Scientific data and information used to support an alternative to a requirement listed in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of the rule.

Simplified, the pecan industry has 120 days to submit any data or factual information that may help the agency to conduct, as warranted, a thorough and robust quantitative assessment of risk associated with pecan production and harvesting practices. Even after the final rule is published and becomes effective, the pecan industry still has the opportunity to conduct scientific research to develop an alternative to the requirements of the rule. Now is not the time to be passive or the industry will have to live with the final outcome.

I've also been approached by several growers with the same question, "How am I supposed to figure out all of the things I going to have to implement to stay in business?" The FDA has stated that they will publish guidance, as appropriate, to provide updates on current thinking with respect to best practices in produce safety. Additionally, education and outreach through mechanisms like the Produce Safety Alliance and other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities and trade associations) will be the foundation of their intended compliance strategy. FDA aims to assist farmers in gaining the food safety knowledge they will need to comply with a final produce safety rule.

Finally, the FDA is also requesting the produce industry to comment about whether the FDA should require that covered farms, as described in proposed § 112.4(a), register with FDA. Currently, the FDA is unaware of any nationwide database of farms, that would enable them to identify the names and locations of all entities subject to the proposed regulations.

In addition, while inspection is intended to be only a relatively minor part of the overall compliance effort, the FDA anticipates performing inspections for enforcement purposes. The FDA suggests they would use the covered farm registration information to create a database that would be used to allocate inspection resources. Comments may be submitted using the following methods:

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Submit written submissions in the following ways:

• Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

All submissions received must include the Agency name and Docket No. FDA-2011-N-0921 and Regulatory Information Number RIN 0910-AG35 for this rulemaking.

You can send questions to FSMA@fda.hhs.gov ▮