

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

November 22, 2013

Re: Preventive Controls Rule: FDA-2011-N-0920 and RIN 0910-AG36
Produce Standards Rule: FDA-2011-N-0921, and RIN 0910-AG35

Dear FDA:

The undersigned 283 organizations, co-ops, farms, farmers' markets, and food businesses jointly submit these comments on the Tester-Hagan provisions, also referred to as the qualified exemptions, in the proposed rule for Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

I. Background and Summary

The Food Safety Modernization Act exempts small-scale, direct-marketing farmers and facilities from the new standards on growing and harvesting produce and the hazard analysis and risk-based preventative controls requirements. Since the provisions for the Tester-Hagan qualified exemption are largely the same in both rules, we will refer to farmers and/or facilities jointly as "producers" unless the comment refers to only one in particular.

The Tester-Hagan provision is vital for protecting vulnerable, small-scale producers who are providing safe, healthy food for their local communities. With the rapidly growing interest in locally produced food, this protection is in the best interest of consumers as well as the farmers and food businesses.

There are three areas of concern with FDA's proposed provisions implementing the Tester-Hagan provision: (1) who is covered; (2) what they are exempt from; and (3) the procedures for revoking the exemption. Each of these issues is explained below.

II. Who is covered: the test for qualifying for the Tester-Hagan exemption should be based on sales of food that is regulated under FSMA

Under the proposed regulations, a producer is eligible for a "qualified exemption" if:

- During the previous three-year period, the average annual monetary value of the food sold directly to individual consumers or to restaurants and retailers in the same State or within 275 miles exceeded the average annual monetary value of the food sold to all other buyers during that period; and
- The average annual monetary value of all food sold during the previous three-year period was less than \$500,000, adjusted for inflation with 2011 as the baseline year.

The FDA's definition of food includes **all** food sold by the farmer or food processor, not just the food that is subject to the agency's jurisdiction or regulated under FSMA. As a result, sales of meat and grains will all be counted toward the \$500,000 gross sales limit. Therefore, for example, a grass-fed beef producer with a small orchard who sells \$600,000 in beef and \$10,000 of fruit will be subject to all of the new FSMA requirements for growing and harvesting produce, even though the FDA and FSMA do not regulate beef.

This interpretation does not fulfill the intent of the Tester-Hagan provision to protect small-scale, direct-marketing producers of fruits, vegetables, and processed foods from the extensive new federal regulations. Instead, it effectively forces grain and livestock farmers to avoid any diversification, harming farmers financially and discouraging environmentally responsible land use. From a food safety standpoint, it does not make sense to treat the small-scale production of produce the same as large-scale production, simply because the same person is producing other types of food as well.

We urge the FDA to use its discretion under the law to revise the proposed regulations so that the gross sales test is measured by the sales of food subject to regulations under FSMA.

III. What the exemption covers: qualified facilities should be exempt from both the HARPC and the CGMP requirements

The qualified exemption provided in the Preventive Controls proposed rule is only from Subpart C, the Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirement. FDA proposes that these small, direct-marking facilities should still be subject to Subpart B, Current Good Manufacturing Practices.

The CGMPs cover everything from personnel cleanliness, education and training, the grounds and area around the facility, plant construction and design, operational aspects, sanitary facilities and controls, equipment and utensils, processes and controls, raw materials and ingredients, and warehousing and distribution. These types of process-based regulations typically favor large operations and are not often feasible or cost-effective for small-scale operations.

To our knowledge, every state already regulates food handlers, processors, and manufacturers. Many local governments have additional regulations. As with the HARPC requirement, we believe that the state and local regulation is sufficient for small-scale, direct-marketing producers.

We urge the FDA to use its discretion under the law to exempt qualified facilities from Subchapter B as well as Subchapter C.

IV. The procedure: Producers with qualified exemptions should be provided with due process if the FDA considers revoking their exemption

In addressing the issue of revoking a producer's exemption, the FDA's proposed rules establish extremely short and unreasonable deadlines. The FDA's stated rationale is that "either of the two circumstances that could result in our determination that an exemption should be withdrawn

... warrant prompt compliance with the rule in the interest of public health.” 78 Fed. Reg. at 3613.

Yet the FDA is empowered to revoke the exemption absent any immediate threat to public health. The FDA may revoke the exemption if a foodborne illness outbreak is linked to the farm, whether or not the farm appears to be the cause. Moreover, the FDA may revoke the exemption if it determines it is necessary to “protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated” with the farm. These are not urgent situations.

If there is truly an immediate risk to the public health, the FDA has other options to address the problem. The agency has multiple enforcement tools at its disposal, such as:

- Seeking an injunction or temporary restraining order under 21 U.S.C. 332;
- Seizing the food at issue under 21 U.S.C. §334(a);
- Administrative detention of the food under 21 U.S.C. §334(h)

We therefore urge the agency to provide appropriate due process before revoking any producer’s exemption. Specific items are outlined below.

A. The notice of revocation

The agency proposed rule provides that it will give only a general statement of the basis for the revocation in its initial letter to the producer. The result is that a producer will be left guessing as to what the problem is and will have to mount a defense against an unknown set of allegations. We urge the FDA to amend the proposed regulations and provide that the agency’s notice of intent to revoke a producer’s exemption should include a **specific** statement of the reasons, so that the producer can respond to the specific issues of concern.

B. Evidentiary standards

The proposed rule provides no standards for what the FDA must show in order to begin an investigation of a producer or to revoke a producer’s exemption. We urge the FDA to establish that it must have probable cause before initiating an investigation of an exempt farmer or food facility, and to present clear and convincing evidence for revoking the exemption.

C. The response and hearing process:

Under the proposed rules, a producer that wishes to contest the withdrawal of its exemption has only 10 calendar days to submit a written appeal that includes all of the facts and supporting documentation. While it would be appropriate to require the notice of appeal to be filed promptly, it is completely unrealistic to expect a producer to be able to marshal all of the arguments and relevant documents on what could be a multitude of issues raised by FDA.

In addition, under the proposed rules, the producer is not entitled to a hearing. After the decision is made, with or without a hearing, the FDA’s proposed regulations also fail to provide standard post-decision procedural protections, such as motion for reconsideration and a motion for stay.

We urge the FDA to amend the proposed regulations to provide producers with at least 90 days to compile the information and documents that support their continued qualified exemption. In addition, producers should have a right to hearing before their exemption is revoked and be provided the standard post-decision procedural protections.

D. Time for compliance:

Under the proposed regulations, a producer has only 60 days from the date of the original letter to come into compliance with all of the regulations. In comparison, large-scale farms have two years and large-scale facilities have one year to come into compliance with the proposed regulations initially. Small-scale producers are given an additional year, while very small scale producers are given two extra years to come into compliance, if they are not exempted under Tester-Hagan.

It is wholly unrealistic to expect a small or very small producer (the only ones that would qualify for the Tester-Hagan provision) to comply with all of the requirements within sixty days when it has been functioning under the qualified exemption. In effect, a small producer whose exemption is revoked will almost certainly go out of business.

The FDA's proposed regulations have significant implications not only for existing producers, but also for anyone who is considering starting a farm or food business. What rational person would start a new business knowing the he or she could be forced to comply with complicated, expensive regulations with only 60 days notice? At a time when multiple government programs seek to encourage new and beginning farmers, the FDA's proposed regulations will have precisely the opposite effect.

We urge the FDA to amend the proposed regulations to provide that, if the exemption is revoked, the producer shall have two years from the time of the final determination to comply with all of the FSMA regulations. Alternatively, FDA could consider provisions that would require compliance with only those portions of the FSMA regulations that formed the basis for the revocation.

E. Options for reinstating the exemption or otherwise modifying the requirements:

We urge the FDA to include a provision allowing farms and food facilities to be able to address the specific issue(s) of concern and either maintain or requalify for the exemption.

V. Documentation

The FDA specifically sought comments on the issue of whether farmers should have to comply with record keeping requirements in order to prove that they qualify under the Tester-Hagan exemption. The provisions governing farms in the Tester-Hagan exemption make no mention whatsoever of submitting documentation to FDA. *See* FSMA Sec. 419(f). In contrast, FSMA specifically requires that a "qualified facility" – i.e. a facility that qualifies for the Tester-Hagan

exemption – submit documentation to the FDA that demonstrates specific things. *See* FSMA Sec. 418(1)(2).

The difference in the statutory language between the two sections is significant. Congress expressed its intention to required facilities that fell within the Tester-Hagan exemption to submit documentation. By omitting any such requirement for farms that fall within the Tester-Hagan exemption, Congress implicitly expressed its intention that such farms should **not** have to comply with similar requirements. *See Sosa v. Alvarez–Machain*, 542 U.S. 692, 711, n. 9, 124 S.Ct. 2739, 159 L.Ed.2d 718 (2004) (“When the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended.”).

The agency should not require that a farm that is exempted under the Tester-Hagan amendment comply with the new record-keeping requirements of the proposed rules, nor develop and maintain any documents outside the farm’s regular course of business.

Conclusion

The undersigned organizations and food businesses respectfully urge FDA to amend the proposed regulations as outlined above.

Submitted by:

National and Regional Nonprofits

Alliance for Natural Health USA
Carolina Farm Stewardship Association
Community Food and Justice Coalition
Family Farm Defenders
Farm and Ranch Freedom Alliance
Farm-to-Consumer Legal Defense Fund
Food Democracy Now!
GMO Free USA
Indian Nations Conservation Alliance
Keep Food Legal
Local Food Association
National Family Farm Coalition
National Health Freedom Action
National Latino Farmers & Ranchers Trade Association
North American Maple Syrup Council, Inc.
Roots of Change
Rural Coalition/Coalición Rural
Rural Development Leadership Network
Soil Resources Initiative
Weston A. Price Foundation
www.WeAreOne.cc

Western Organization of Resource Councils (WORC)

State and Local Nonprofits

Community Farm Alliance (KY)
Cooperris Inc
CT-NOFA
Dakota Resource Council (ND)
Dakota Rural Action (SD)
Farmworker Association of Florida
Hawaii Farmers Union United
Hawaii Island School Garden Network
Idaho Organization of Resource Councils (ID)
Illinois Stewardship Alliance
Land Loss Prevention Project (NC)
Maine Alternative Agriculture Association
Manes and Tails Organization
Massachusetts Farm Bureau Federation
Michigan Land Trustees
NC Interfaith Power & Light
Nebraska Sustainable Agriculture Society INC-NSAS
Northeast Organic Farming Association of New York, Inc.
NOFA/RI
Northern Plains Resource Council (MT)
Oregon Rural Action
PortFish, Ltd. (WI)
Powder River Basin Resource Council (WY)
Soule Homestead Education Center (MA)
Texas Organic Farmers and Gardeners Association
The Second Chance Foundation, NYC
Urban Poultry Association of Texas, Inc.
Western Colorado Congress

CASA del Llano, INC (TX)
Chattanooga Sustainable Farmers (TN)
Community Alliance for Global Justice (WA)
Growing Awareness Urban Farm (NM)
Hawaii Public Seeds Initiative (HI)
Hub City Farmers' Market (SC)
Inter-Faith Food Shuttle (NC)
Keep Alpine Beautiful (TX)
Long Branch Environmental Education Center (NC)
Marion County Economic Development Commission (SC)
Maui Coffee Association (HI)
Oscar Romero Catholic Worker House (OK)

Seattle Tilth (WA)
Slow Food Austin (TX)
Sustainable Food Center (TX)
Taos County Economic Development Corp (NM)
Tasting Awareness (NY)
The Lord's Acre (NC)
Thrive (OR)
Transplanting Traditions Community Farm (NC)
Viroqua Biodynamic Group (WI)
Wellspring Education Center and Organic Farm (WI)

Co-Ops

Brea Plum (TX)
Cad-Re Feeds (AK)
Eastern Carolina Organics (NC)
EverGreen Farm (WY)
Health Nut Betty (CA)
Moontower Community Agricultural Co-op (TX)
New River Organic Growers Association, Inc (NC)
Ocean beach People's Organic food Co-op (CA)
Willimantic Food Coop (CT)

Food Businesses and Food Hubs

Aiken Organics (SC)
Black Mountain Farmers Market (NC)
Brightside Bamboo (NC)
Butterworks Farm LLC (VT)
Casa Somerset (KS)
Cook for Good (NC)
Divine Nourishment (HI)
Fire From The Mountain (NC)
Food FWD (NC)
Foreign Affairs Oriental Market (NC)
Front Porch Pickings (FL)
HOFA (HI)
Laura's Cupcakery (TX)
Maui Epicure LLC (HI)
Maui Living Grains (HI)
Mill-King Market & Creamery (TX)
Millstone Meadows Farm (NC)
Natural Grocers (CO-based, with stores in Arizona, Idaho, Kansas, Missouri, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Texas, Utah, and Wyoming)
Rimrack Fish (NH)
Savoy Sorbet (TX)

Southampton Farm (TX)
Texas Honeybee Guild (TX)
Coterie Market LLC (TX)
New Growth Associates (RI)
NMHomegrown (NM)

Farms

4150 Hui Farm (HI)
5N Farm (TX)
63rd St. Farm (CO)
A Thyme for Peace (WA)
Akin Farm (TX)
Andrews Farm (TX)
Anichini - Moore Ranch & Farm (OK)
Arizona Sprouthouse LLC (AZ)
Arnosky Family Farm (TX)
Asheville Ecovillage Eggs (NC)
Avant Garden Farm and Venue (NC)
Ayrshire Farm (NC)
Back to Earth Farms (NC)
Banner Greenhouses
Barbara's Magic Garden (CO)
Barn Door Nursery and Produce (NC)
Bean Tree Farm (AZ)
Bear Tooth Farm (NC)
Big Muddy Urban Farm (NE)
Bird's Haven Farms (OH)
Boggy Creek Farm (TX)
Bootstrap Farm (OK)
Boulder Belt Eco-Farm (OH)
Brian Findeisen Trust (TX)
Cane Creek Asparagus & Company (NC)
Cerro Vista Farm (NM)
City Farm Austin (TX)
Coto Family Farms (NC)
Currie Cattle Co. (NC)
Dancing Roots Farm (OR)
Dancing Turtles Ranch (TX)
DC White, LLC (SC)
Deer Run Farm (WI)
Delta Farm, LLC (SC)
Denison Farms LLC (OR)
Dickey Farms (AR)
Dog & Cart Farm (NC)
Dog Mountain Farm (WA)

Dollie Wolfe & Paul Mader Produce & Products (CA)
Downriver Orchard (WA)
Dry Ridge Farm (NC)
Eden's Organic Farm (TX)
Everett Heritage Farm (GA)
Fat Bottomed Farm (ID)
Fickle Creek Farm (NC)
Fiddler's Green Farm, Inc. (CA)
Flat Peach Microfarm (TX)
Forge Ahead Farm (TX)
Fort Hill Farm (CT)
Fowler Farm (SC)
French Brother's Farm (TX)
From the Garden (TX)
Gaining Ground Farm (NC)
Galaxy Farm (CA)
Goingsnake Farm (OK)
Good Earth Organic Farm (TX)
Goss Farm (NC)
Grandma's Organic Farm (WI)
Grassfield Farms LLC (VA)
Graybill Farmstead (TX)
Green Hills Harvest (MO)
Hammond Farm (TX)
Harvest Table Farm (VA)
Hawkeye Indian Cultural Center (NC)
Henneke Farms (TX)
Hidden Valley Dairy LLC (TX)
Hideaway Acres (NC)
High Lonesome Farm (NY)
Hilltop Place Ranch (TX)
Huckleberry Ridge Farm (NC)
Indian Hills Farm (TX)
J Appel Lanai Garden (HI)
Janes Garden Flowers and Herbs (KY)
JBG Organic, Inc (TX)
Jessicas Stand/ DLOP (FL)
JPR Acres, LLC (MN)
JuJo Acres Farm (PA)
KA Johnson (MT)
Khakalaki Farm (SC)
Knopp Branch Farm (TX)
Laiku Organic Farm (HI)
LavaRockFarm (HI)
Let's Go Farm (CA)
Lightsey Farms (TX)

Linda's Gardens (SD)
Local Appetite Growers LLC (AL)
Long Shadow Farm (CO)
Macias Farms (NM)
MamaSprings Farm (NC)
Milk and Honey Farm (HI)
Miller Farms (NC)
Mill-King Market & Creamery (TX)
Millstone Meadows Farm (NC)
Morning Star Farm (NM)
Morning Sun Organics (OR)
Muddy Fork Farm, LLX (OH)
Native Roots (NC)
Nelson Family Farm (NC)
Nevermore Farm (CA)
New Model Farm (TX)
Ninja Cow Farm (NC)
North Forty Farm (MA)
North Frontier Foods (MT)
North Pulaski Farms (AR)
NorthWind Organic Farm (WI)
Oak Grove Farm (NC)
Olala Farms (CA)
Osceola Jerseys, LLC (WA)
Our Farm (OK)
Owl Hollow Farm (TN)
Paper Moon Farm, LLC (NC)
Peters Point Organics (SC)
Pin Oak Place (IA)
Plantry (NC)
Pond Ridge Farm (NY)
Prairie Song Farms (IA)
Prodigal Farm (NC)
Ragtime Ranch Family Farm (TX)
Rancho Harbor Hills (CA)
Restoration Farm (NC)
Rockin J Cattle (CO)
Rocky Ridge Ranch (WA)
Rogue Harbor Farm (NC)
Roland Farm (TX)
Ron's Roots (SC)
Sailing Windward Farm (HI)
Sand Hill Farm (MD)
SheerLark Farm (AL)
Sherry Lane Farm (NC)
Shootingstar farm (ID)

Skull Valley Lavender Farm (AZ)
Sonrisa Farm (TN)
Spirit Creek Farm (WI)
Spring Song Organics (FL)
St. Anne's Chapel/Oak Grove Farm (NC)
Star Creek Country (TX)
Stockbridge Farms, LLC (NC)
Stonebridge Farm (CO)
Sunny Kapoho Citrus LLC (HI)
Sunset Hill (CA)
Sunshower Farms (HI)
Taylor Farm (TX)
Tecolote Farm (TX)
Terra Bella Farm (MO)
Texas Worm Ranch (TX)
The Maui Nursery (HI)
The Red Hot Green Chile Place (NM)
Threshold Farm (NY)
Tranquility Hills Farm (FL)
Tucker's Station Farms (KY)
Turkey Creek Farms (SC)
Turtle Ledge Farm (CT)
Waterfowl Farm (ID)
Weathervane Farm CSA, LLC (CO)
Wellspring Organic CSA Farm (WI)
WFBH (VA)
Whirlaway Farm (VA)
Windcrest Farm (NC)
Windy Hill Farm (TX)
Woodyard / Priddy Farm (TX)
Zbarfarms (X)

Farmers Markets

Alpine Farmers Market (TX)
Capitan Farmers Market (NM)
Cary Downtown Farmers Market (NC)
Cobblestone Farmers Market (NC)
Colorado Farm and Art Market (CO)
Columbia Farmers Market (MO)
Copper Street Farmers' Market (NM)
Cortez Farmers Market (CO)
Farmers' Market on the Square (KY)
Longview Farmers Market (TX)
Osage Hills Farmers' Market (OK)
Polk Tailgate Market (NC)

Quarry Farmers & Ranchers Market (TX)
Smith Citrus (AZ)
Wren Thicket Market (AR)

For more information, contact: Judith McGeary, Esq, Farm and Ranch Freedom Alliance,
Judith@FarmAndRanchFreedom.org, 254-697-2661