



NGFN FOOD SAFETY FAQ

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CURRENT SITUATION AND BACKGROUND

WHY IS THERE SO MUCH CONCERN ABOUT PRODUCE AND CONTROL OF BACTERIA ON PRODUCE?

Over the last 10 years Center for Disease Control (CDC) has reported a doubling of incidents of illness related to food borne bacteria. [Figures reported in 1999](#) reflected that 76 million Americans become ill as a result of food borne illness each year, with 325,000 hospitalizations, and 5,000 deaths. Several major outbreaks in the last few years have been [traced to “ready to eat” bagged, fresh produce](#). Media attention to the outbreaks, the scope of illness and human suffering, and FDA’s inability to respond and contain the problem are contributing to concern for the safety of the U.S. food system in general and several fresh produce items in particular. This situation has also had direct consequences for producers of products which have been implicated in food borne illness outbreaks.

WHAT FARMS ARE REGULATED UNDER CURRENT FDA LAWS?

FDA laws directly affect only farms that process food for resale (take raw products and change them by cooking, juicing, mixing, etc.) them into food. However, any time FDA believes that a farm may be the source of a public health problem such as a food borne illness outbreak it can pursue those concerns in whatever way it deems appropriate. Farms with certain processing facilities such as a cider press are regulated under this Act.

WHICH TYPES OF FARMS ARE REGULATED UNDER CURRENT FDA LAWS?

FDA regulates the activities of food facilities except those handling and processing meat and poultry. Additionally the FDA regulates the activities of seafood processing facilities, though not aquaculture ponds. Those types of facilities not regulated by FDA are regulated by USDA’s FSIS (Food Safety Inspection Services), a department under APHIS (Animal Plant Health Inspection Services).

WHAT IS A “FOOD FACILITY”?

A “food facility” that is required to register with FDA is [defined](#) in the [2002 Bioterrorism Preparedness Act](#) as a business that: manufactures, processes, packs, or holds food for consumption in the United States, regardless of whether the food from the facility enters interstate commerce. Several specific types of food facilities are identified as exempt from reporting requirements, including: restaurants and other retail food establishments; and certain nonprofit food establishments.

HOW DOES THE DEFINITION OF “FOOD FACILITY” RELATE TO FARMS?

Farms are not considered to be “food facilities.” The [2002 Bioterrorism Preparedness Act](#) clarifies that washing, trimming of outer leaves, and cooling produce is considered to be part of the harvesting process and, therefore, is excluded from the rules. The definition of “farm” also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm. See [this document on the FDA site](#).

GOOD AGRICULTURAL PRACTICES (GAPS)

WHAT ARE GAPS?

Good Agricultural Practices (GAPs) in the United States were developed in the early 1990s originally by Cornell University Extension as a voluntary set of guidelines designed to improve food safety. GAPs is a system of developing plans, training, and documentation of best practices on the farm to minimize the risk of health



problems from products leaving the farm. In the mid 1990s USDA in cooperation with State Departments of Agriculture began training and certifying producers and packers under GAPs and Good Handling Practices (GHPs). In 1998 FDA established a single set of federally recognized GAPs and GHPs by issuing a guidance document: [“Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”](#).

WHAT IS A “GUIDANCE DOCUMENT”?

GAPs and GHPs are considered to be “guidance documents”. Unlike a regulation, a guidance document is not mandatory. It is a set of recommendations to industry and/or regulators delineating practices which, if followed, ensure those practices are in compliance with regulations. A guidance document reflects the Agency’s current thinking. The process by which a guidance document is developed is not as lengthy or rigorous as the process of developing a regulation. [FDA’s 1998 guidance document](#) has been under review as of its tenth anniversary.

HOW ARE GAPs USED IN THE MARKETPLACE? AREN’T THEY BEING USED AS A DE FACTO FORM OF REGULATION BY PRIVATE FOOD PURCHASERS? WHAT IS MEANT BY “SUPERMETRICS”?

In addition to FDA GAPs, some private parties, including buyers and producer groups, have added requirements onto FDA GAPs. These additional requirements are often referred to as supermetrics, and are generally audited by private firms. These supermetrics are required by some buyers to demonstrate that they are so committed to food safety that their requirements go beyond approved guidance documents. These requirements often place producers at the nexus of conflicting mandates because food safety supermetrics can conflict with conservation and habitat improvement goals that are increasingly important to farms and to the general public. There is no scientific evidence that the additional requirements of buyer supermetrics increase food safety. Rather supermetrics seem to make food safety into a marketing issue by allowing buyers to claim that because of their stringent requirements, the food they sell is safer. As a result of these additional GAPs definitions, and the many different scenarios in which supermetrics can be required by some buyers, producers are often faced with conflicting requirements and the need for multiple audits. This situation has led to the coining of the term “audit fatigue”.

IS THERE MORE THAN ONE TYPE OF GAPs?

Looking at GAPs globally, the [United Nation’s Food and Agricultural Organization](#) (FAO) notes that a “multiplicity” of GAP standards have been developed with various objectives, such as:

- Ensuring safety and quality of produce in the food chain
- Capturing new market advantages by modifying supply chain governance
- Improving natural resources use, workers health and working conditions, and/or
- Creating new market opportunities for producers and exporters in developing countries.

HOW DO GAPs RELATE TO ORGANIC CERTIFICATION?

Organic certification is not equivalent to GAPs certification. Although the practices of organic agriculture assure that food safety standards are being met on some key areas (see [article by James Riddle, UMN](#)), the fundamental risk factors addressed in GAPs to minimize introduction of illness pathogens (sanitation, hygiene and water quality) are not addressed by the organic certification process or its supported production practices. For a detailed description of food safety requirements that are intrinsic to the National Organic Program.

WHAT IS A “FEDERAL MARKETING ORDER”?



A federal marketing order is a legal instrument authorized by Congress through the [Agricultural Marketing Agreement Act of 1937](#) and administered under the Authority of USDA Agricultural Marketing Services (AMS). Orders are created, at the request of industry representatives, through a [formal rulemaking process](#) conducted by USDA. The purpose of marketing orders and agreements is to help assure order in the marketplace without compromising consumer choice. In other words: to create the benefits of coordination within an industry without monopolization and elimination of competition. Local administrative committees or boards, composed of growers and/or handlers, administer fruit, vegetable and specialty crop marketing orders. Currently, there are [32 active marketing order programs](#). Committees and boards collect assessments from handlers to cover operational and administrative costs. State Departments of Agriculture have similar authority within their jurisdiction.

WHAT IS A “MARKETING AGREEMENT”? WHAT IS THE DIFFERENCE BETWEEN A MARKETING ORDER AND A MARKETING AGREEMENT?

A marketing agreement is similar to a marketing order in content and intent, but whereas a marketing order is mandatory, a marketing agreement is voluntary, similar to the difference between a regulation and guidance document (see above), the process of developing a marketing order is more rigorous and time consuming than the process of developing a marketing agreement.

WHAT IS THE CALIFORNIA LEAFY GREENS MARKETING AGREEMENT (LGMA)?

In response to the proliferation of GAPs supermetrics (required by buyers), and in an attempt to reach a single standard for buyer approval for fresh cut greens for fresh consumption, the Western Growers Association has developed the “[LGMA](#)” and promoted it in California and Arizona as an alternative to GAPs. It is a voluntary agreement, implemented by the California Department of Agriculture.

There are concerns about the LGMA among many groups as well as by small and mid-size producers. Critics argue that in the rush to address buyer concerns, and to develop a single solution acceptable to all buyers, this agreement was developed with little involvement of small and medium scale producers, or environmental or consumer groups. As a result, the current proposal has not identified common ground on requirements related to wildlife habitat management, and conflicts with federally mandated clean water and soil erosion practices. Further, there are no provisions to modify costs or requirements for farms which operate at different scales of production, nor those farms which produce a diversity of crops or include livestock in crop rotations. As a result these groups feel that the LGMA will not support increased sustainability in the food system and will put limits or barriers on small- and mid-size producers.

USDA INSPECTION UNDER FOOD SAFETY INSPECTION SERVICES (FSIS)

WHAT FACILITIES ARE REGULATED AND INSPECTED BY USDA FSIS?

Food facilities that process livestock into meat, poultry; aquaculture ponds; and also eggs are all regulated by USDA [FSIS](#). Some states also manage their own inspection programs for product that will not be moved across state lines (however [new administrative rules](#) may change this). In addition, very small plants that process only for the owner of the livestock are classified as exempt.

WHAT IS HACCP?

Hazard analysis critical control point (HACCP) is a tool for the evaluation of food processing methods. A HACCP plan looks for specific points in production that can ELIMINATE or REDUCE a risk to an acceptable level. Examples of



risk reductions steps include heating or cooking to control microbial contamination or interventions to control chemical or physical risk. HACCP is mandated in meat, poultry, seafood, low acid canned food (LACF) and juice and therefore is a regulated system. The HACCP system is verified through a third party audit or a USDA or FDA food safety officer. USDA FSIS requires a HACCP plan for each product manufactured in a meat processing plant. (Definition adapted from Nancy C. Flores, Ph.D. Associate Professor, Extension Food Technology Specialist, New Mexico State University)

WHAT ARE THE COSTS OF FSIS COMPLIANCE AND HOW HAVE THESE COSTS AFFECTED SMALL- AND MID-SIZED MEAT PROCESSORS?

The USDA Economic Research Service (ERS) [indicates](#) that the costs of inspection for products from small and very small plants is higher for the plants, producers, and consumers. Inspections represent 4-8 cents on the pound of product costs from small and very small plants and about a cent per pound from very large plants. In part, the cost differences are due to the fixed costs of inspection which impact lower-volume plants more greatly than large volume plants. At a time when there is a growing need for more meat processing facilities, the implementation of HACCP requirements has [contributed to the closure of several small-scale meat processing plants](#), and threatens still more. ([Full ERS report](#))

PENDING LEGISLATION AND OTHER REGULATORY INITIATIVES

HOUSE BILL (HR.2749): FOOD SAFETY ENHANCEMENT ACT

Originating in the Energy and Commerce Committee and passed by the House of Representatives on July 29th, 2009, this bill intends to increase FDA oversight of food facilities (see above), domestic and foreign, by adding a series of new authorities to FDA and by imposing fees on food facilities to support the costs of these new authorities. Under [HR.2749](#) FDA would be required to increase the frequency of inspection of many facilities including those dealing in food from foreign sources. This bill also grants FDA the authority to order recalls of suspect food, and to impose fines for non-compliance. Exemptions from FDA regulation are included for certain food facilities including grain handling facilities who process for resale to producers, and for food facilities who sell more than 50% of their products directly to end consumers.

SENATE EQUIVALENT BILL (S.510): FOOD SAFETY ENHANCEMENT ACT

Currently the Senate Health and Education, Labor and Pensions (HELP) Committee is preparing to consider a bill first introduced by Senator Durbin (D, IL) as [S.510](#). This bill addresses many of the same issues as HR.2749. It is likely to be passed through the Senate quickly in Fall 2009, once the health care reform process is complete.

NATIONAL LEAFY GREENS MARKETING AGREEMENT (NLGMA)

Beginning in 2007, major produce industry groups requested that USDA AMS investigate the creation of a National Leafy Greens Marketing Agreement (NLGMA) along the lines of the California LGMA (see the [proponents web page](#)). The national effort is being touted as stakeholder based, although smaller industry groups have again (as in the California process) noticed that they have been left out of the process of developing the proposal (see testimony at Monterey LGMA hearings: [Dave Runsten, CAFF](#) and [Joanne Baumgartner, Wildfarm Alliance](#)). There is reason to believe that the USDA hearing and review process, which will take approximately 2 years, will result in a clear recognition that the Marketing Agreement approach to food safety is not appropriate. Minimally, the lessons learned in the California agreement will likely be applied to a national version.



CONCERNS ABOUT CURRENT FOOD SAFETY INITIATIVES

WHAT WILL BE THE FINANCIAL IMPACT OF HR.2749, ESPECIALLY ON SMALL PRODUCERS OR PRODUCERS OF A DIVERSE ARRAY OF CROPS?

HR.2749 levies a flat registration fee on all non-exempt food facilities of \$500, regardless of facility size, volume, or complexity. In addition, the costs of preparing for and passing food safety audits will be borne by each facility.

WILL CURRENT OR PROPOSED FOOD SAFETY REGULATIONS AFFECT FARMERS MARKETS?

Thus far no existing or proposed regulations will place further regulatory or inspection burdens on farmers markets. Most farmers markets are directly under the regulatory oversight of their local city or county and state Health Departments.

WILL CURRENT OR PROPOSED FOOD SAFETY REGULATIONS AFFECT A PRODUCER'S ABILITY TO SELL DIRECTLY TO FOOD RETAILERS OR WHOLESALERS SUCH AS SUPERMARKETS?

Nothing in the current collection of FDA Food Safety Enhancement Acts and USDA Marketing Agreements directly limit a producer's ability to sell directly to food retailers or wholesalers. As of now, many, if not most, retailers and wholesalers have in place food safety requirements on fresh produce vendors (see "supermetrics", above). As a result, only products from registered food facilities have unrestricted access to all resale sectors. Producers which are exempt from federal regulation, and therefore are unregistered, are not able to access these markets (which represent the vast majority of U.S. food sales) unless they comply with each retailer's or wholesaler's food safety requirements. It is currently not clear how exempt producers will protect their limited rights to sell through all resale sectors.

WHAT WILL THE HOUSE AND SENATE BILLS CHANGE?

Until they are finalized and reconciled through the conference process, this question cannot be definitively answered. Speculating, a likely outcome will be that the FDA will be granted greater power to recall foods and impose fines for non-compliance. FDA will also probably be expected to increase dramatically its inspection regime, and there will likely be some user fees required to help address those costs. It is also reasonable to assume that FDA will be expected to develop and formalize traceback protocols to assure that adulterated food can be isolated quickly with minimum possible harm to consumers and to industry.

ORGANIZATIONS AND RESOURCES PROMOTING SUSTAINABLE AND ORGANIC AGRICULTURE INTERESTS IN THE FOOD SAFETY DEBATE

- [National Sustainable Agriculture Coalition \(NSAC\)](#)
- [National Organic Coalition \(NOC\)](#)
- [Food and Water Watch](#)
- [Institute for Agriculture and Trade Policy \(IATP\)](#)
- [Community Alliance with Family Farms \(CAFF\)](#)
- [Northeast Organic Farming Association \(NOFA\)](#)



- [Maine Organic Farming and Gardening Association \(MOFGA\)](#)
- [Pennsylvania Association for Sustainable Agriculture \(PASA\)](#)

RESOURCES FOR ADDRESSING FOOD SAFETY ISSUES

Links to assist with development of on farm food safety plans or to prepare for GAP audits:

- [Online GAPs training](#)
- [Primus self audit resources](#)