May 19, 2008

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

RE: Comments on Third-Party Certification Programs for Foods and Feeds
(Docket No. FDA-2008-N-0183)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the use of third-party certification programs for food and feed under the jurisdiction of the Food and Drug Administration (FDA). CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

I. Introduction

The Centers for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards each year in the United States. In the last eighteen months, consumers have faced several significant nationwide outbreaks and recalls of FDA-regulated products, amply demonstrating holes in the safety net guarding U.S. consumers from contaminated foods. Spinach contaminated with a deadly strain of E. coli; peanut butter with Salmonella; pet food with toxic chemicals – these are only a few of the tragedies, each demonstrating a different problem with our system of regulating the food supply. It is time for FDA to take action to better ensure food safety and to protect Americans from these preventable illnesses and deaths.
CSPI is encouraged that FDA is considering new approaches for improving the safety of FDA-regulated products. While we recognize that third-party certification may in fact have a place in a robust food safety system, we urge FDA to remember that certification is not a guarantee of safety or a panacea for the problems that plague the agency. Certification programs may in fact be well-suited to certain commodities, and not all at useful for others. CSPI believes that both produce and imported FDA products may be appropriate for certification programs, provided that those programs are well-regulated and wisely implemented.

II. Third-Party Certification for Produce Commodities

Consumers have seen several large foodborne illness outbreaks linked to domestic produce in the last several years alone. While many of the best growers and processors have instituted more robust safety systems and have adopted marketing agreements for good agricultural practices, compliance is clearly not universal. Unfortunately, FDA’s reliance on voluntary compliance with existing guidelines, education, and awareness has not been effective in preventing foodborne illness from fresh produce.

CSPI has petitioned for FDA to adopt written food safety control plans for produce growers and consider the implementation of a third-party certification system for U.S. growers and processors to ensure that these plans and facilities are reviewed at least once per year. This would build upon existing systems already in use at the state or in the retail sector but would help to tie these audits into the FDA’s system of oversight, without unduly burdening farmers with additional audits and inspector visits. Third-party and state auditing based on consistent standards can play an important role in helping FDA to monitor that the regulations are being fully enforced. Auditors should be subject to federal or state oversight and approval to ensure that they provide consistently reliable services.
III. Third-Party Certification for Imports

Each year the average American eats about 260 pounds of imported foods, accounting for about 13 percent of our annual diet.\(^1\) U.S. imports for 2006 reached a record value of $65.3 billion, roughly $6 billion higher than the year before.\(^2\) Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50 percent over the last decade, and certain countries and commodities are showing exponentially greater increases. The recent series of problems with domestic and imported foods and ingredients are serious, and have resulted in significant declines in consumer confidence. It is clear that FDA must act both quickly and wisely to implement better import protections. Third party certification, if done correctly, may be one way FDA can improve the safety of imported food.

One approach to improving the safety of imports—the voluntary certification program—is already widely used in the retail sector today. While important, this program is truly only the first step to assuring that imported food is safe. CSPI supports FDA’s use of accreditation systems for foreign governments and other public and private entities that will lead to the mandatory certification of imported food. A model for this concept is in the legislation circulated by Representative John Dingell in his recent discussion draft.

Mandatory certification of imports was recommended by the President’s Interagency Working Group on Import Safety for certain products.\(^3\) In addition, the Grocery Manufacturers Association (GMA) “Four Pillars” plan discusses a Mandatory Quality Assurance Program for Importers that acts as a certification requirement. It is clear that government, industry, and consumers all have a vested interest in the creation of a robust and effective certification program.

FDA’s request for comment specifically asks whether there are particular incentives that would encourage participation in a certification program. CSPI believes that a mandatory program is the best way to ensure the safety of imported food. In the alternative, a voluntary approach must contain both strong incentives to participate and appropriate safeguards to ensure that those who don’t participate nonetheless deliver safe products to our ports.

Incentives for participation may include: rewarding certified facilities with the ability to come in through all U.S. ports of entry; less frequent inspections; periodic (rather than pre-market) laboratory testing; and access to the Safe and Secure Food Importation Program. Under this program, no products can be denied entry simply because the source is not certified. But consumers are protected by the requirements that uncertified products must enter through ports where they can be inspected closely and can be tested for contaminants.

Private entities who wish to act as certifying agents must demonstrate to FDA that the business model is sound, without the possibility of conflicts of interest. Further, continued accreditation should be conditioned on successful program, demonstrated in part by an absence of outbreaks caused by products the agent certified, as well as continued compliance with FDA requests.

FDA must also retain the authority to double check the agent’s work without notice through inspections and audits, and must enforce strong penalties for the filing of misleading or false food safety reports.

**IV. Funding for Third Party Certification**

FDA must ensure that any certification program is properly funded in order to carry out a mandate of providing safe food to consumers. Even a voluntary certification program will require start up costs to ensure that activities done using other entities have the requisite.
reliability, including training, accrediting, compensating and auditing the external government or third party inspectors to ensure plants meet federal standards.

Often these proposals are submitted as an alternative to increasing the funding for the agency. However, using third parties requires additional funding for certification and for state implementation. In fact, state and federal agencies need compensation to conduct additional inspections, just as FDA would. In order to assist FDA with the critical funding requirements of a new program, the agency must be able to identify accredited third-party certifying agents, including both foreign national governments (i.e. Canada, New Zealand); regional government (i.e. the European Union); and state governments (i.e. California, New York, or Florida).

Third party certification also would divert resources from FDA inspection to training, accrediting and auditing the third party organizations. Enhancing collaboration with state and local governments should be done. But it should be adequately funded – otherwise the agency will have to divert scarce resources from an already anemic inspection program to a program of third-party oversight which is not a clear win for consumers.

Respectively submitted,

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