definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
130.17(c)	13	2	26	25	650
130.17(i)	1	2	2	2	4
Total					654

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 2004, through September 30, 2007, and information from firms that have submitted recent requests for temporary marketing permits.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6887 Filed 4–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0188]

Food Protection Plan; Outreach Activities; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a public docket to receive information and comments related to its comprehensive Food Protection Plan (the Plan) released in November 2007. The new Plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. FDA is establishing this docket for the purpose of soliciting comments from its stakeholders on the Plan and the questions set forth in this notice.

DATES: Submit written or electronic comments by July 31, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. To ensure timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. All comments to FDA on the Plan should be submitted through the docket.

FOR FURTHER INFORMATION CONTACT: Kari Barrett, Office of the Commissioner (HF–60), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–9831, FAX: 301–827–2866.

SUPPLEMENTARY INFORMATION:

I. Background

For more than 100 years, FDA has protected the health of Americans by ensuring the safety of the food supply (other than meat, poultry, and processed egg products that are regulated by the U.S. Department of Agriculture). Every day across the country people eat out, buy groceries, cook meals for their families, and feed their pets. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. Specifically, FDA is responsible for the safety of 80 percent of all food sold in the United States.

The U.S. food supply is one of the safest in the world. Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, new trends in demographics, consumption, food production technology, and business practices all pose challenges for maintaining this safe food supply. For example, consumers today want the convenience of opening a bag of salad that is already prepared. In the past a single head of lettuce that was contaminated may have resulted in one family being ill. Now, a contaminated head of lettuce may be processed with many others and be placed into bags of convenience salad that many consumers can buy. These bags of salad, if contaminated, could result in hundreds of illnesses.

The supply of food consumed in the United States is increasingly imported, introducing a greater challenge for improving the information FDA has regarding conditions under which food is produced in foreign countries. The United States trades with over 150 countries and territories with products coming into over 300 U.S. ports. Fifteen percent of the food supply by volume in the United States is imported. Sixty percent of fresh fruits and vegetables are imported. More than 75 percent of seafood is imported. Although many foreign countries have well developed regulatory systems to ensure food safety, others have systems that may not be able to ensure food safety to the same degree.

FDA also faces the challenge of foodborne illnesses caused by known hazards as well as new threats. In 1999, the Centers for Disease Control and Prevention estimated that there were approximately 76 million cases per year of illness from foodborne agents in the United States, with 325,000 hospitalizations and 5,000 deaths. Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are aware. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase. In addition, the recent incident in which vegetable protein products were contaminated with melamine was a deliberate act for economic gain. Although this was not considered an act of terrorism, it resulted in the sickness and death of cats and dogs.

Another important challenge is effective communication. FDA, States, and industry receive food safety

information in various ways, such as consumer complaints, inspection data, positive test results, adverse event reports and other reports of illness. FDA is committed to improving information flow to improve detection and response to signs of trouble. These challenges call for a new approach to protecting our food supply from unintentional and deliberate contamination. In May 2007, the Secretary of Health and Human Services and the Commissioner of Food and Drugs charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep pace with these changes. FDA issued the Plan in November 2007. The Plan outlines a strategy to strengthen an already safe food system for humans and animals, and builds upon advances in science and technology to safeguard the nation's food supply. The Plan represents a proactive approach that uses science and modern technology to identify potential hazards ahead of time. By preventing most harm before it can occur, enhancing our intervention methods at key points in the food production system, and strengthening our ability to respond immediately when problems are identified, FDA can provide a food protection framework that helps keep the American food supply safe.

The Plan provides a comprehensive and integrated strategy that encompasses three core elements: Prevention, intervention, and response. The prevention element includes promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses. The intervention element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain from production to consumption. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly. The response element bolsters FDA's emergency response efforts by increasing the speed and efficiency of response. It includes improved communication and coordination with other Federal, State, and local government agencies and industry during and after emergencies. When there is an emergency, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders.

FDA is committed to strengthening the nation's food protection system through implementation of this Plan. The Plan incorporates several crosscutting principles including:

- Focus on risks over a product's life cycle from production to consumption;
- Target resources to achieve maximum risk reduction;
- Address both unintentional and deliberate contamination; and
- Use science and modern technology systems.

In addition, the Plan includes key steps under each of the three core elements including:

1. Prevention:
- Promote increased corporate responsibility to prevent foodborne illnesses;
- Identify food vulnerabilities and assess risks; and
- Expand the understanding and use of effective mitigation measures.

2. Intervention:
- Focus inspections and sampling based on risk;
- Enhance risk-based surveillance; and
- Improve the detection of food system ''signals'' that indicates contamination.

3. Response:
- Improve immediate response; and
- Improve risk communications to the public, industry, and other stakeholders.

The strategy outlined in the Plan involves, in part, the agency actively pursuing input from its stakeholders. The agency will be conducting various formal and informal outreach activities with its domestic and international stakeholders. The objective of this notice is to provide stakeholders an opportunity to comment on the Plan. To help achieve this objective, stakeholders are encouraged to review and comment on the Plan found at *http://www.fda.gov/oc/initiatives/advance/food.html*. In particular, FDA is interested in comments addressing the following questions:

Core Element #1: Prevention

1.1 What are best practices, and what are the principal benefits of and challenges to implementing the key prevention steps in the Plan? How do these vary by stakeholder (e.g., producers, manufacturers, retailers, consumers, Federal/State government, and foreign countries)?

1.2 What, if any, significant gaps are there in the key prevention steps and the associated FDA actions listed in the Plan?

1.3 In targeting resources to achieve maximum risk reduction through prevention the Plan focuses on high risk identification. What, if any, are the limitations to this approach? What criteria should the agency consider in defining high risk? What are specific areas of modeling, analysis, and research likely to significantly advance high risk identification? How would these areas of work promote effective and efficient high risk identification? What would be the key challenges to implementation?

1.4 What are potential data sources other than FDA data to inform the risk based approach? What are the obstacles to obtaining such data?

1.5 The Plan proposes new legislative authorities to strengthen FDA's ability to prevent food problems. They include: (1) Allowing FDA to require controls against intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain, (2) authorizing FDA to issue additional preventive controls for high-risk foods, and (3) requiring FDA facilities to renew their FDA registration every 2 years and allowing FDA to modify the registration categories. What would be the principal benefits and limitations of each of these proposed authorities? In implementing these proposed authorities, how could the benefits be best leveraged and the limitations mitigated?

Core Element #2: Intervention

2.1 What are best practices, and what are the principal benefits and challenges to implementing the key intervention steps in the Plan? How do these vary by stakeholder (e.g., producers, manufacturers, retailers, consumers, Federal/State government, and foreign countries)?

2.2 What, if any, significant gaps are there in the key intervention steps and the associated FDA actions listed in the Plan?

2.3 In targeting resources to achieve maximum risk reduction through intervention the Plan focuses on risk-based surveillance. What, if any, are the limitations to this approach? What are specific strategies likely to significantly advance effective risk-based surveillance? How would these strategies promote effective and efficient risk-based surveillance? What would be the key challenges to implementation?

2.4 The Plan proposes legislative authority for FDA to accredit highly qualified third parties for food inspections. What would be the principal benefits and limitations of an accreditation program? What criteria should a third party meet to qualify as an accrediting organization?

2.5 Concerning imports, the Plan proposes legislative authority to require electronic import certification for shipments of designated high risk products. It also proposes legislative authority to refuse admission of imported food if FDA inspection is

delayed, limited, or denied. What would be the principal benefits and limitations of these proposals? In implementing these proposals how could the benefits be best leveraged and the limitations mitigated?

Core Element #3: Response

3.1 What are the best practices, and what are the principal benefits and challenges to implementing the key response steps in the Plan? How do these vary by stakeholder (e.g., producers, manufacturers, retailers, consumers, Federal/State government, and foreign countries)?

3.2 What, if any, significant gaps are there in the key response steps and the associated FDA actions listed in the plan?

3.3 The Plan proposes two new legislative authorities to strengthen FDA's response capability: (1) Empowering FDA to issue a mandatory recall of food products when voluntary recalls are not effective, and (2) providing FDA enhanced access to food records during emergencies. What would be the principal benefits and limitations of each of these proposed authorities? In implementing these proposed authorities, how could the benefits be best leveraged and the limitations mitigated?

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 26, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6833 Filed 4–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0183]

Third-Party Certification Programs for Foods and Feeds; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on the use of third-party certification programs for foods and feeds, including pet foods. An increasing number of firms that sell foods to the public, such as retailers and food service providers, are requesting that their suppliers become certified as meeting food (and feed) safety and quality standards as a condition of doing business. FDA seeks more information on the existence and use of these types of programs to better understand how they can help to ensure that food products are safe, secure, and meet FDA requirements.

DATES: Submit written or electronic comments by May 19, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Sharon Lindan Mayl, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

Ensuring the safety of food for human and animal use is a shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but it is ultimately the responsibility of industry to ensure that food and feed intended for consumption in the United States meet applicable FDA standards. An increasing number of firms that sell foods and feeds (hereinafter foods) to the public, such as retailers and food service providers, are requesting that their suppliers, both foreign and domestic, become certified as meeting food safety and quality standards as a condition of doing business. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third parties to assist them in meeting U.S. requirements. FDA is seeking comment on current practices of third-party certification programs that work with food products and to ensure the supply chain is safe, secure, and meet FDA requirements.

A. Current Use of Voluntary Third-Party Certification Programs for Foods

A growing number of food firms require their suppliers to ensure their products are produced using ''best practices'' for food safety, quality, and security and that the supply chain is safe and secure. These firms often require their suppliers to meet nationally or globally recognized food safety standards and to verify that these standards are met through a third-party certification program. For example, the Global Food Safety Initiative requires food suppliers to have a factory audit certification against internationally recognized standards, which include the Safe Quality Food, British Retail Consortium, International Food Standard, and GlobalGAP. The Global Aquaculture Alliance has also established standards for aquaculture production and processing and created an accrediting body for certifiers from 30 countries. These types of private sector developed programs are being used in many foreign countries, as well as the United States.

B. Interagency Working Group on Import Safety

On July 18, 2007, the President issued Executive Order 13439 to establish the Interagency Working Group on Import Safety (Working Group). On November 6, 2007, the Working Group released an ''Action Plan for Import Safety: A Roadmap for Continual Improvement'' (Action Plan) (*http://www.importsafety.gov/report/actionplan.pdf*). The Action Plan contains 14 broad recommendations and 50 specific short- and long-term action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. The Action Plan stresses the importance of the private sector's responsibility for the safety of its products and the importance of ongoing private-sector mechanisms and experience as a basis for ongoing, substantive public-private collaboration. The public and private sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.