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DATE 7/10/2012

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

Re: Docket No. FDA-2012-N-0430 - Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information; 77 Fed. Reg. 27779 (May 11, 2012)

The Pet Food Institute (PFI) thanks the U.S. Food and Drug Administration (FDA or the Agency) for the opportunity to submit this statement in response to the Agency's May 11, 2012 request for comments regarding FDA's proposed information collection of voluntary submissions of food facility profile information (the Request for Comments).

PFI represents the manufacturers of over 98% of the food for cats and dogs produced in the United States. This is an \$18.3 billion domestic market with an additional \$1.3 billion in export sales. In addition, PFI represents the manufacturers and suppliers of equipment, ingredients and other goods and services to the pet food industry. PFI members are committed to producing safe and nutritious pet food, and fully support FDA's efforts to implement its statutory authority based on the best information available about the industries the Agency regulates.

In the Request for Comments, the Agency proposed requesting information including the following:

- The facility type (e.g., manufacturer/processor, repacker/packer, or warehouse/holding facility);
- The products, and hazards (e.g., biological, physical, chemical) and preventive control measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures, e.g., seafood and juice, or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive control measures; and
- Other facility information (e.g., food safety training, facility size, operational schedule, and number of employees).

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PFI's comments address each of these topics in turn, along with general statements regarding the burden associated with collecting and submitting the information FDA has proposed to request.

Regarding Collection of Information on "Facility Type"

We agree that information regarding facility type is practical and appropriate for the FDA to possess. However, this information is redundant in that the Agency already requests this information on an optional basis when the facility registers under the Bioterrorism Preparedness and Response Act of 2002. Currently, when completing the requirements in the Food Facility Registration Module (Form 3537) Section 9 "Type of Activity Conducted at the Facility" and Section 11(b) "General Product Category – Food for Animal Consumption", facilities provide FDA virtually the same information FDA requests here.

Regarding Collection of Information on "Products, Hazards and Preventive Controls"

As FDA moves forward with implementation of the Food Safety Modernization Act (FSMA), it will be critical for the Agency to prioritize its limited resources and to understand what firms are high-risk and non-high-risk for inspection scheduling purposes. However, the information FDA proposes to seek here is not the most efficient or effective means to make those determinations.

Often, pet food manufacturing facilities make diverse types of products which may require multiple, diverse safety plans tailored to individual products. Moreover, each written food safety and food defense plan may be a complex document that can be subject to change as new hazards are identified or better approaches for controlling risk are identified. As discussed more fully below, maintaining and updating these voluntary submissions to FDA would constitute a significant reporting burden.

Pet food production facilities may appear to be similar, but each facility is unique in terms of the ingredients selected, the recipes followed, the equipment and processes used, and/or the products created. It is the food safety team at each facility who will need to identify potential hazards and then assess whether identified potential hazards are reasonably likely to occur within the confines of that facility. For example, it is likely that the same ingredient could be identified as a potential hazard in some facilities and not in others, depending on how the ingredient is processed, stored, or handled within a particular site. A specific type of hazard may be controlled by different methods or techniques in different facilities, even when different facilities use similar manufacturing processes.

While it may be helpful to FDA to review voluntarily submitted facility identified potential hazards and associated preventive controls to assist in the Agency's preparation of guidance documents, these voluntary submissions alone are not likely to prove helpful in determining risk status of individual facilities, as the Request for Comments would indicate. As previously stated, the safety of the food produced at a particular facility cannot be measured simply by reviewing identified hazards and preventive controls, but must be determined within the context of the facility's application of the food safety plan and adherence to good verification procedures. PFI has stated in earlier comments (FDA-2011-N-0238, Preventive Controls for Registered Human Food and Animal Food/Feed Facilities - August 22, 2011) that food safety and food defense plans are reviewed most appropriately by the Agency during on-site facility inspections in the context of the operations at the facility. We believe that

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to obtain a true picture of a facility's potential risk, FDA must observe how a written plan is applied in practice.

As the Agency is aware, food and feed safety or quality-assurance plans contain sensitive, often proprietary information about a facility's products or manufacturing processes or methods. Companies treat these documents as confidential business information (CBI) and, should the companies choose to submit them to FDA, they expect FDA to treat them as CBI, as well. The challenge of safeguarding the confidentiality of volunteered information is magnified when those records are in electronic form. Data could be compromised through hacking or other unauthorized release (i.e. WikiLeaks scenario). Furthermore, a data storage device could be lost as has occurred in the past with other agencies. PFI would like to emphasize to FDA the importance of developing adequate procedures to preserve the confidentiality of facility records to which FDA may access under FSMA. Of equal, if not greater, importance is the need to preserve the confidentiality of facilities' vulnerability assessments and food/feed defense plans, which if inappropriately disclosed, could compromise the facility's security. FDA should provide companies who submit CBI or other confidential information to the Agency with clear instruction on how to appropriately identify this information to ensure that it maintains its confidential nature.

PFI would like to describe to the agency scenarios in which information could be released publicly. Information could be released in response to a Freedom of Information Act request. Alternatively FDA could release a report summarizing submission data such as percentage of companies that volunteer this information. Due to the possibility for the information to be misunderstood, particularly information on identified potential hazards, PFI urges the Agency to give special consideration to issues relating to the release of data (intentional or unintentional).

PFI urges FDA to articulate how it plans to protect the confidential nature of such records and encourages FDA not to request the electronic submission of such plans.

Lastly, one potential unintended consequence of requesting the voluntary submission of this information could be the over representation of information submitted by those facilities with less complex or less thorough hazard analyses or preventive control programs because such programs could be entered into FDA's system more easily. Companies with more extensive hazard analyses or preventive controls might be less inclined to enter information into the facility profile because it may not be practical to provide complete information and because incomplete information would give FDA an inaccurate view of the situation within a facility. Under this scenario, FDA would have an inaccurate view of the level of hazard analysis conducted by facilities and the preventive controls in place because the facilities with the most comprehensive information would not have utilized the system due to the burdens associated with it.

Regarding Collection of "Other Facility Information"

PFI does not believe that the collection of data described in the Request for Comments under "Other Facility Information" is relevant to a facility's risk status (e.g., facility size, operational schedule, and number of employees). A facility's food safety risk is not determined by its size, operational schedule or number of employees. It would be helpful if the Agency could explain how collection of the data listed under "Other Facility Information" could enhance FDA's ability to make a risk determination for a particular facility or would otherwise improve the Agency's ability to exercise its regulatory authority.

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Regarding more effective means to determine the risk status of particular facilities.

The Request for Comments states that the information it is proposing to collect “will help us to determine whether a firm is high-risk or non-high-risk. We will use the profile information to assist us in determining the frequency at which we will inspect the firm.” [77 Fed. Reg. at 27779]. The FSMA sets forth the criteria on which FDA is required to base this assessment [21 USC § 421(a)(1)]. PFI recognizes the difficulties inherent in making such a facility-specific determination for the many facilities FDA regulates. However, as discussed more fully above, aside from the collection of information listed under “Facility Type”, PFI does not believe that the information outlined in the Request for Comments will prove helpful to the Agency in making its risk determination. Hazard analyses and preventive controls cannot be evaluated effectively outside the facility for which they were developed. Plus, material listed under “Other Facility Information” is not relevant to safety and may be considered business confidential. If this information were collected at a high volunteer rate, the FDA would then have to demonstrate how it will effectively gather, mine, secure and utilize the information. It is our belief that the effort needed to implement such steps would prove to be more time consuming to the FDA than the return on investment would warrant.

The Request for Comments also states that facilities that voluntarily submit the food facility profile information would benefit from interaction with better-informed investigators and potentially reduced inspection duration. However, an investigator may have preconceived ideas about the appropriateness of a preventive control for the identified hazard without the context of the entire manufacturing process for the facility. PFI recognizes FDA’s need to prioritize inspections and to educate inspectors on potential hazards and appropriate control processes. PFI is willing to partner with FDA to provide industry-specific information based on products produced and develop risk facility criteria for the pet food industry through a more efficient and effective process.

Additionally, PFI has concerns that the information requested in the Request for Comments will not remain voluntary in practice. For example, the Agency could compel companies to “voluntarily” submit information by spotlighting companies through public communication based on whether they have submitted information. This potential practice would be inappropriate and effectively would render submission mandatory.

If FDA proceeds with collecting the proposed voluntary information, PFI encourages the Agency to make great efforts to ensure that all online forms clearly and distinctly indicate which information is mandatory and which is voluntary. Similar to the scenario described above, failure to clearly indicate which information is voluntarily provided would have the practical effect of rendering such information to be mandatory.

Concern that FDA grossly underestimates the frequency of facility profile updates and burden associated with them

The Request for Comments estimates the burden associated with the proposed collection of information. Based on the fact that a facility’s hazard analysis and preventive controls may be revised frequently, PFI believes that the estimated number of facility updates of voluntary profile information is low by several-fold if the facility intends to provide accurate and up-to-date information. Furthermore, information related to hazard analysis and preventive controls is likely to be complex and lengthy, making it likely that substantial time will be needed to enter information on hazard analysis and

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preventive controls beyond FDA's estimate and only reflect the time to complete the on-line portal, ignoring the many hours of preparation which may be in addition to the process used to complete the mandatory Hazard Analysis. In practice, individuals responsible for facility registration are not likely to be intimately familiar with the food safety plans and will need to seek input from the appropriate facility employee(s) in order to accurately enter the data, thereby extending the amount of time and effort to input and update the requested information. Also, because facilities are to keep information in their registration profile current, significant time may need to be devoted to performing updates.

In conclusion, the Pet Food Institute appreciates this opportunity to provide its views on the collection of voluntary facility profile information. We look forward to continued interactions with the Agency on how risk determinations can be made most efficiently and effectively and other regulatory actions related to food safety and implementation of various provisions of FSMA.

Sincerely,

A handwritten signature in black ink, appearing to read "Duane Ekedahl".

Duane Ekedahl
President