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July 6, 2011

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

**Re: Docket #FDA-2011-N-0366-001 FDA Food Safety Modernization Act:
Focus on Inspections and Compliance**

Pet Food Institute (PFI) is pleased to submit comments on FDA Food Safety Modernization Act: Focus on Inspections and Compliance Docket #FDA-2011-N-0366-001. Members of PFI deeply appreciate FDA's willingness to accept input from all segments of the food and animal feed (including pet food) industries regarding these issues. Our comments support and supplement our oral statements provided at the public meeting held on June 6, 2011

Pet Food Institute represents those member companies which produce over 98% of the dog and cat food (defined as "pet food" by the Association of American Feed Control Officials-AAFCO) sold in the US marketplace. In 2010 this industry was worth \$18.9 B domestically with an additional \$1.3 B in export sales. Members include large multi-national companies as well as national, regional and smaller companies. The industry itself is made up of many other non-members as well. PFI does its best to represent all of these, recognizing that neither small nor large companies should have a regulatory advantage over the other. PFI also represents the suppliers to this industry, and they are fully engaged in both regulatory and international trade issues.

Judicious and considered application of the agency's new inspection mandate and compliance authorities can enhance the safety of the Nation's food supply. These provisions of the law are critical to protecting public health and safety and to ensuring consumers' confidence in foods and brands. Pet food was the first industry affected by the intentional adulteration of ingredients with melamine and related compounds beginning in 2007. PFI members worked closely with FDA-CVM to identify and respond to an unimaginable economic adulteration that led to increased emphasis on identification of all kinds of issues with imported products and ingredients. In this case, it was pet food where the problem was identified, but the missing link in most conversations is that the adulteration actually occurred in a food grade ingredient. The pet food industry reacted quickly to reduce the opportunity for such a problem to recur, and welcomes the opportunity to comment on the Inspections and Compliance portion of the FSMA discussion.

Enforcement Authorities

For all of these new tools, we recommend that the Agency apply their use judiciously and that they only be leveraged in cases where there is credible evidence of a risk to food safety and that they be applied only when firms are non-compliant, non-responsive, and/or repeat offenders. In addition, we recommend that Codes of Practice be established to outline the guidelines for use of these authorities to clarify for the Agency and for the food and feed producing industries as to exactly what the key parameters for enforcement will be, and that the guidelines be provided to the food producing industry prior to making them binding by regulation. Members of PFI are also concerned about how uniformity of inspection and application of the regulations will be guaranteed by the Agency. Varying interpretations of regulations between FDA Districts have been a continuing challenge for feed and pet food companies in the past and the new tools will likely be subject to the same variations of interpretation, with significantly more potential for impact.

How do you suggest FDA employ the use of its revised administrative detention authority in a preventive controls environment?

Members of Pet food Institute believe that FDA's new authorities should always be used after voluntary actions by the manufacturer and the persons who hold the recalled product in commerce have been exhausted. The FDA must not use this authority without significant understanding of the outcomes of such action, including the outcomes that may result when it is later discovered that the action was unnecessary.

State Regulators question...

Not applicable

How do you see FDA implementing food facility registration suspension, and under what authorities should FDA use its suspension authority?

PFI members believe that suspending a food facility registration is tantamount to ruining the credibility of the facility and indeed the entire company. The authorities granted to FDA under FSMA are should be taken only in the instance of a last resort.

Under what circumstances should FDA use its mandatory recall authority?

Mandatory recall authority should only be used in the case that the affected company has not responded to a Class I recall request in a timely manner and when there is a certainty that harm will be caused should the product not be removed from commerce..

It is imperative that the ability to order a mandatory recall remain at the level of the Commissioner and not be delegated to lower offices of the Agency. Since a recall of any nature has the potential to negatively affect not only the reputation of the affected company, but the associated industry as a whole, it must be dealt with in a thoughtful manner. As outlined for administrative detention, if enforcement action is taken and later discovered it was unnecessary it is requested that FDA issue a public statement exonerating firms to assist in restoring consumer trust

Guidance must be published as soon as possible to clarify for the agency and the food and feed producing industries as to exactly what the parameters for a mandatory recall will be and how uniformity of inspection and application of the regulations will be guaranteed by the Agency. Uniformity of application of regulations will become even more significant under FSMA because many more food and feed producing companies now fall under the purview of FDA.

All food and feed producers are not the same. The challenges that each producer faces are unique, not just to the company, but to each facility and each ingredient that each facility uses to produce each individual product. Every ingredient has its own set of contractual specifications in addition to definitions, but ingredients are sourced from many different providers and by many different avenues, depending on the part of the country in which each facility is located. There is inherent variability within each agricultural ingredient as well. Those who inspect food and feed producing plants must recognize that food and feed plants are not the same, and that they are each even more different than medical device and/or drug facilities. We appreciate that the Agency recognized the differences between food and animal feed including pet food and is preparing two separate regulations.

Under what circumstances do you envision FDA using food facility registration suspension in conjunction with ordering a mandatory recall?

The suspension of facility registration should be an action of last resort by the Agency. It should only be applied to a facility that has been shown to be clearly unable to meet the clearly delineated and publicly available FDA guidance to produce safe products. Suspension of facility registration would be extraordinarily harmful to any food or feed producer, and would likely be perceived as affecting all of a company's facilities, even if it was limited to the suspension of registration of only one facility.

The decision to suspend a facility's registration should remain at the level of the Commissioner and not be delegated to lower offices of the agency.

Frequency and Targeting of Facility Inspections

What data sources are available that could assist with the designation of high risk/non-high risk facility inventories? What data sources could assist with targeting foreign firms for inspection?-

FDA must first clearly define what is meant by "facility inventory". All comments below relate to product inventories at facilities which have been designated as "high-risk"

FDA should use the data which they have collected over the many years from multiple sources including industry, state governments, and historical data from facilities that FDA inspects under the Bioterrorism Act. The Agency should use historical information which has been collected from cooperating agencies such as: AAFCO and Association of American Food and Drug Officials (AAFDO). This information can assist in designation of those facility inventories deemed to be of

high risk. That data, no matter if it is easily accessible, is the best source of information for the Agency to use when evaluating risk. It should be combined with recall information housed in the Agency as well. Those two reports, along with the RFR should provide FDA with the data points needed to begin evaluations.

Facilities producing food for human consumption which are repeat offenders should be targeted for the highest inspection rate. Again, taking a risk-based approach to protecting public health safety would require foods directly consumed by humans to be prioritized.

In regards to foreign inspection - Data collected on refusal of goods or ingredients at the port should be the first stop for FDA in determining what should be observed regarding foreign facilities. If a firm has a history of non-compliance, then that is where the Agency should begin.

FDA should be cognizant of bi-lateral agreements with other countries and be careful not to cause a disruption in trade. It is especially important that FDA choose an approach that is reasonably flexible and can be adapted to a variety of circumstances. As it will not be feasible nor will it make sense to evaluate comparability in many cases, a tiered evaluation strategy may serve FDA best. For example, FDA might divide countries into the following categories:

- 1) Countries clearly in step with the U.S. – Where there is already strong evidence that a country has a robust regulatory system, FDA should consider the most efficient “arrangement” or “agreement” that will permit FDA to accept that government’s inspections towards the foreign inspection requirements. The most efficient arrangement might be a comparability decision, but it might also be a Memorandum of Agreement (MOA) or some other vehicle. Evidence of a robust regulatory system could come from many places, such as FDA experience or comparability assessments that are in progress, even if they are not complete. FDA also may be able to use other indicators to assess a government’s inspection abilities, such as whether a foreign government is an accredited auditor under the FSMA certification scheme FDA is setting up or is recognized by or consistent with a respected framework like the Global Food Safety Initiative (GFSI). Importantly, inspections conducted by foreign governments in these countries should “count” towards FDA’s attainment of the statute’s foreign inspection goal.
- 2) Countries not in step with the U.S. – Conversely, where there is strong evidence that significant work is needed to bring a country’s inspection program up to required standards, steps towards capacity building efforts may be more appropriate. FDA should consider the need to focus its inspection resources in these countries, taking into account all relevant factors.

- 3) Countries needing further assessment – For those countries that are not clearly in one of the first two categories, a case-by-case approach is most appropriate. The International Comparability Assessment Tool (ICAT) may be most useful for countries in this category. Depending on the circumstances, FDA may want to devote its inspection resources to these countries as well.

What criteria should FDA consider when defining its high risk and non-high risk facility inventories? If the criteria you suggest require the use of data that FDA does not currently collect or possess, how should FDA acquire that information?

Section 201 of FSMA requires FDA to allocate inspection resources according to the known safety risk of facilities based on six factors. These factors include 1) identified safety risks of food within facility, 2) compliance history of facility, 3) rigor and effectiveness of facility’s hazard analysis and preventive controls, 4) foods meet criteria of Section 801, 5) food has received certification under Section 801 or 806 as appropriate, and 6) other criteria deemed appropriate. Based on these criteria a risk matrix can be implemented to assign risk levels to facilities.

Again, the definition of “high risk/ non-high risk facility inventories” has not yet been determined by the Agency, or at least shared publicly so defining what those inventories are is difficult at best. Does it apply to product within the facility, in warehouses, all products or just some? FDA needs to provide clarification regarding its thoughts before complete comments can be made.

Risk designation should be science-based and cannot be static. Facility inventories that fall into the high-risk category for inspection will change over time (with both additions and deletions) as FDA learns more about the risks associated with categories of products and as the agency tracks the compliance of individual facilities. Thus, it is impossible to compile a static list of high-risk facility inventories, and FDA should not attempt to do so. Furthermore, any database of high-risk facility inventories at any given time should be used only for FDA’s internal purposes. Such a compilation should not be made public because consumers could easily misunderstand its meaning to suggest there is an increased risk related to consumption of a product—when, in fact, most facilities will have adequate controls in place to prevent such risk to consumers.

How should FDA evaluate or “weigh” the criteria to determine risk? What factor(s) should be considered the most important and should this vary depending on the circumstances?

In evaluating criteria for risk, it would appear that a continuum exists from highest to least risky regarding a scientific evaluation of potential for microbiological contamination:

- > fresh, raw products for consumption by humans;
- > minimally processed food for consumption by humans;
- > raw products brought into the home for consumption by pets;

- > animal parts (chews) for consumption by pets;
- > minimally processed food for consumption by pets;
- > shelf stable* products for consumption by humans or pets;
- > food for consumption by food producing animals.

**"Shelf stable" refers to a process(es) that allows processed food products of any kind to be held without refrigeration for an extended period of time.

Weighted criteria should be based on individual facilities rather than the industry as a whole. The challenges that each facility faces are unique based on ingredients used, processing, and the final product produced. There is inherent variability between facilities and those who inspect manufacturing sites must recognize that food and feed facilities are not the same. Facilities producing food for human consumption should always receive the lion's share of observation by FDA. This is a fairly obvious conclusion. Products clearly labeled "dog food", "cat food", "gerbil food", "horse feed", etc., are clearly not intended for human consumption. We appreciate that the Agency recognized the differences between food and animal feed including pet food and is preparing two separate regulations.

Further, the FDA should consider facility track record, including willingness to respond in event of food safety situations and assign higher risk to non-responsive facilities/firms

Retorted shelf stable pet foods meet the same low acid canning rules as for human food. Shelf stable dry pet foods are much like the same types of human food in that processing requirements and very low water activity (Aw) reduce the possibility of any microbial growth if stored in a clean, dry place.

Common sense handling of all food products should be followed by the consumer including, but not limited to: not touching your face until you wash your hands after handling/preparing any food, keeping food preparation equipment and areas away from animal contact; washing hands after touching animals, their food, their bowls, toys, etc.; and generally using good hygienic procedures. Individuals with compromised immunity such as newborns, infants, young children, the elderly and the ill may need apply more stringent methods of hygiene when dealing with either food or feed products on a case by case basis.

Manner of Inspection in a Preventive Controls Environment

What inspection approaches could FDA use to satisfy the domestic and foreign inspection frequency mandates, including by working with State and local governments?

This mandated level of inspections is extraordinary. It will require an increased level of cooperation with state feed regulatory officials and foreign government officials. All of whom **must** have sufficient training for the wide variety of food & feed facilities they will be expected to inspect. The necessity of training and educating the large number of additional inspectors that will be required to

perform the obligations laid on the Agency by FSMA provides a unique opportunity to reinforce the critical importance of uniformity of application of interpretations of regulations and guidance by all Agency staff. This is especially true for those who are currently involved at the inspector and inspector supervisory levels. Making the parameters under which inspections will be run, and against which evaluations will be made, available to the industry prior to application of those parameters will help industry associations, state regulators, the Agency and educators to educate association member and non-member companies as to the realities that now exist. This should also increase the ability of facilities, which have not fallen under FDA's narrower purview to comply with the new regulations in a timely manner.

Inspection protocols must be implemented consistently and the Agency must properly hire staff and get them trained appropriately. It is essential that inspectors are uniformly trained to insure inspections and enforcement actions are equitable across firms and geographical regions.

What inspection tools (e.g. new technologies) could FDA use to meet the domestic and foreign frequency mandates?

There are a number of new analytical tools available, however, the Agency must make its own decisions about which are appropriate and how the results provided by those tools can be applied.

How might FDA use firm's written preventive control plans that will be required under section 103 of FSMA or information from those plans, to prioritize FDA's work and develop inspectional strategies?

In regards to using a firm's written preventive control plans to prioritize FDA's inspection plans, each plan is specific to the facility, the region and the products produced. The Agency has extensive history with such plans and understands the Critical Controls that are often used in development of such plans. Providing information, such as preventive control plans, in advance of FDA's inspections will not facilitate inspection efficiency and could be detrimental to the food defense plan of the facility. Remote reviewing of a food safety plan does not provide the necessary context for understanding the special circumstances of each facility.

It is the responsibility of the company to determine on its own what the risk factors are for each discrete facility and ingredient/product mix and determine the controls it needs for that plan only. It would be virtually impossible for FDA to keep a catalogue current of facility plans which are "living documents" changing as products, ingredients or formulations change. It would be excessively burdensome to require facilities to submit plans to the agency every time they are revised. Review of outdated plans would not present any benefits to the agency as a means of preparing for on-site inspections and could create confusion for inspectors when they visit facilities. Furthermore, all of these documents would, out of necessity, be commercially confidential and would require an additional level of security, while providing no real food safety benefit.

How should FDA work with foreign governments with respect to inspections of those food facilities in their countries that offer food products for import to the United States?

When working with foreign governments to implement FSMA, we appreciate the FDA has an unprecedented task ahead. The US is party to the WTO Sanitary and Phytosanitary Agreement. It appears that some parts of FSMA can anticipate challenges by other parties to that agreement. The US government approach for many years in animal feed has been that, "USDA is the agency of record and will do the facility inspections in the US, for the country of export. Your inspectors don't need to evaluate our facilities." Currently USDA-APHIS handles all approvals to countries requiring pet food certification under a long term agreement with FDA-CVM, because FDA simply doesn't have enough manpower to deal with the thousands and thousands of certificates currently required for export. We recommend FDA, USDA, USTR and Industry work together to discuss details before implementing regulation that could cause significantly impact trade and/or cause on trade disruption.

Pet food exports alone account for over \$1.3 billion in export sales to the benefit of the US. Other animal feed exports also provide additional revenue to the US farmer. The pet food industry is very concerned about the ramifications that aggressive action under FSMA could have on exports and thus a direct and cumulative effect on US farmers and ranchers as well as on producers of feed. Both USDA FAS and USTR have been queried as to their understanding of this requirement and how the administration of such activity would be accomplished via the Embassy network, and they are currently evaluating the potential effects of the FSMA..

It is important that the Agency clarify, sooner rather than later, how it views its activities in foreign inspections moving forward and disclose any conversations which are ongoing with its counterpart agencies. The US must be very respectful of the agreements already in place and not over reach the requirements of the SPS Agreement. Further, it is also important that FDA develop a guidance document to help foreign facilities know what to expect during an FDA inspection.

Improving the RFR

Regarding improvements to the Reportable Food Registry, the very first item that must be dealt with is clarifying the definition of "transfer". The concept put forth by FDA that calls for any movement of a product, even without change of ownership, to be a legal "transfer" is adverse to normal practice in commercial trade. Simply put, transfer of a product does not occur until the buyer takes physical and economic control of a product. That means that the truck driver is not the owner of a load of wheat, nor is he the owner of the loaves of bread manufactured from that wheat unless he is selling the product on behalf of himself. As long as the product is owned by the bakery (producer of the bread), transfer has not occurred until the final seller takes possession.

Any definition of “transfer” that is outside of the normal commercial use of the word is not useful and cannot be enforced. A whole new system of distribution would have to be developed to fit the current language.

Since enforcement of the RFR should begin at the ingredient level, the amount of affected finished products subject to recall should be reduced over time. Further, the Agency’s ability to now recoup financial expenses created by recall enforcement adds another level of financial responsibility. The need for recalls should be reduced but may not be completely eliminated.

What information is necessary to enable a consumer to accurately identify whether the consumer is in possession of a reportable food?

The purpose of the RFR is to provide a “reliable mechanism to track patterns of adulteration in food which would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health.” The Agency also should recognize that the RFR was not designed as a retailer or **consumer notification mechanism**. Use of the RFR to provide timely retail-level recall information for grocery stores would likely require redesigning the RFR system. Rather than requiring separate submissions of this information through the RFR, it would be far more efficient for FDA to use the information in company-developed recall press releases to prepare the notices required to be posted in grocery stores.

What methods could best be used by grocery stores to inform consumers of information to enable them to identify whether they possess a reportable food?

Section 211 of the Act addresses the need to alert consumers that a product has been recalled through postings at grocery stores. Recall press releases prepared by the recalling firm include consumer-oriented information and serve as the most direct and accurate source of information for recalls. It might be possible that a standardized press release format be developed to make the use of the recall press releases easier for consumers to find out the information that they need. Grocery stores could easily post press releases at shelf or other conspicuous location to inform consumers

Are there other approaches to getting key information in the hands of consumers in real time that FDA should also consider pursuing?

Providing more information to consumers about food safety failures and recalls under the current alert system becomes mind-numbingly detailed and people not directly involved only skim those headlines. The FDA alert emails require the consumer to stop and click thru two URLs to get to the issue, IF they know where to look, so making that information more prominent could be helpful. Publishing the information on the web is one way to get the information out, but perhaps explaining the outcomes of consuming the recalled product could happen a bit earlier in the statement.

Handling food properly is a skill that for many years was taught in school in Health classes, but along the way teaching those basic life skills has been removed from the curriculum. It would be beneficial to all food producers if FDA and USDA could take on the education of the public to reiterate safe food handling procedures more broadly. Most food safety failures occur with some type of contribution by the public. That means that doing simple things like going straight home from the grocery store with perishable items, or washing down your counters before, during and after food preparation, proper storage of foods, and cooking and storing foods properly need to be a large part of FDA's and USDA's outreach in Public Service Announcements.

All consumers are not reachable through web based announcements, but neither are they necessarily accessible through frequent customer cards. Membership clubs may be able to send recorded phone calls quickly to all purchasers possibly affected by a recall. However, many of the same privacy issues encountered by centralized identification discussions at the government level can arise from the idea that "someone knows everything you buy". Providing information to consumers will continue to be an ongoing effort on behalf of food producers and the Agency. Point of Purchase materials in stores of all sizes that supply food to people and pets are a great way to encourage people to take notice of the things they can do to protect themselves and their pets.

Who should FDA consider a grocery store subject to the consumer notification requirement in section 417(h) of the FD&C Act?

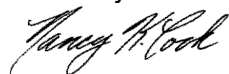
The definition of "grocery stores" is confusing because limiting it to chains of at least 15 physical locations has ramifications for smaller locally owned stores and their customers. The huge variety of stores is well known, but it is likely that AAFDO and the state regulators have a complete list of individual stores, convenience stores, and small operators who must have the ability to be informed when recalls or warnings occur. Many, many small distributors source their products from big box stores and they must have access to the information as well as their individual consumers.

What methods are grocery stores currently using to provide notice of food recalls to consumers?

Not applicable

In conclusion, Members of Pet Food Institute appreciate the opportunity to provide comments on the Inspections and Compliance portions of the FSMA. We look forward to the prospect of further discussions in our continuing participation in process of development and implementation of the mandates of the FDA Food Safety Modernization Act. Please do not hesitate to contact me with further inquiries or for clarification.

Sincerely,



Nancy K. Cook
Vice President