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Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: FDA's position on pathogens in raw pet foods

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After many years of anticipation, discussion and prognostication, 2016 finds many FDA-regulated animal food facilities facing the reality of the Food Safety Modernization Act's (FSMA) preventive controls compliance. The FDA's final rule *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals* was published in November, 2015 so the time for speculation is over. The groundwork for achieving compliance should start with a complete understanding what the new requirements actually are for the products produced.

For pet food manufacturers, this includes understanding the new authority FSMA provides FDA over raw pet food operations. In the final rule, FDA states : "*We are taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the Food Safety Modernization Act (FSMA). The rule is intended to build an animal food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system.*"

This paper explores FDA's evolving and expanded authority in animal foods, addressing key industry concerns with the FDA's determination of pathogens as adulterants in raw pet food and the final rule's requirements for product testing and environmental monitoring to address these hazards

The FDA's legal authority over raw pet food

In General.—The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

The Food Safety Modernization Act; Section 103 (https://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf)

Section 103 of FSMA applies to "food," which is not limited to human food. Section 201(f) of the FD&C Act defines "food" to include "articles used for food or drink for man or other animals." FDA concluded that the differences between human and animal food are best addressed through separate rulemakings. Section 418(m) of the FD&C Act authorizes the Secretary, by regulation, to modify the requirements for compliance under the section with respect to facilities that are engaged solely in the production of food for animals other than man. (http://legcounsel.house.gov/Comps/FDA_CMD.pdf)

The Agency concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal food and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal derived products for human consumption.

Requirements for pet food manufacturing

Comments in the preventive controls for animal food final rule (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm) that specifically address the rule's applicability to the production of pet food provide the simplest evidence of required compliance:

(Comment 6) Many comments from pet owners are generally supportive of the rule; however, some request additional regulations and oversight for pet food. Many comments state that pet food should meet the same standards as human food. Some comments request that pet food be required to be tested for safety.

(Response 6) The CGMP requirements in subpart B are intended to serve as baseline standards for producing safe animal food across all types of animal food facilities, including pet food facilities. For discussion of the relevance of the CGMP requirements to pet food, see

Response 163. Many pet food facilities (as well as facilities producing other animal food) will be subject to the preventive controls requirements of subpart C. These provisions require the pet food manufacturer to identify and evaluate potential hazards for the pet food to determine whether a preventive control is required (see § 507.33). These could be hazards to the pet consuming the pet food or the person handling the pet food (*e.g., Salmonella*). The preventive controls provisions also include requirements for product testing for pathogens or other hazards and environmental monitoring for pathogens under certain circumstances (see § 507.49), in order to help ensure the safety of the pet (animal) food.

(Comment 163) Some comments state that the risks for pet food, especially with respect to pathogens, are different than the risks for livestock feed, and therefore FDA should issue two sets of CGMPs. Some comments say that CGMPs for pet food should be modeled after the human food CGMPs because of the high level of care people provide and demand for their pets, pets may eat or sleep with humans, and pet owners often store pet food close to human food.

(Response 163) We (FDA) believe the single set of CGMPs can serve as baseline standards for producing safe animal food across all types of animal food facilities and animal food. We considered the diverse needs of industry and the ultimate goal of animal food safety as we finalized the CGMP regulations. We believe the final requirements are flexible enough to be applied appropriately in various animal food production settings. For example, § 507.19(b) contains requirements for the cleaning of animal food-contact surfaces of equipment and utensils to protect against contamination of animal food. We do not specify exactly how this is to be done (except some requirements for cleaning with wet processing of animal food), knowing that what constitutes adequate cleaning will depend on the plant and the animal food. (See Response 182).

Pet food manufacturers that must comply with CGMP's (subpart B) and the Hazard Analysis and Risk Based Preventive Controls (subpart C) portions of the final rule face several challenges unique to the products they produce, starting with the raw materials and ingredients used. Animal food production, including pet food, often uses by products from human food manufacturing, which can include materials from both FDA and USDA regulated entities. While the preventive controls rules address the overlap in compliance between human and animal food where possible, those that use USDA regulated products as raw materials, such as meat and poultry, must navigate the regulatory variations distinct to each case, with the understanding that they must meet the requirements for producing these products.

However, regardless of raw material source, the receiving facility is responsible for ensuring any and all raw material used as ingredients comply with all of the requirements of the preventive controls for animal food final rule.

Pet food raw materials: Are pathogens adulterants?

In certain circumstances, raw by-products derived from animal products produced in compliance with USDA regulations can contain pathogens. Examples include *Salmonella*, which can be pathogenic to both animals and humans, but is not always considered an adulterant under USDA. It may be found in poultry and other raw meat products, and there for any by-products, which, if subsequently used in FDA regulated pet/animal food, may pose questions regarding raw materials suitability that will be addressed next.

While the USDA regulated supplier may be in full compliance, hazards related to the use of these raw materials must be addressed in the pet food manufacturer's hazard analysis, and take into consideration what controls may or may not be required to reduce or eliminate this potential hazard once the receiving plant accepts these raw materials.

This paper is not meant to discuss all hazards, it simply uses this reference to provide an example applicable to hazards in raw materials where the receiving facility must assess their risk and severity and implement appropriate controls. Other examples would include any raw materials that could potentially contain microbial hazards, regardless of source or regulatory agency responsible for oversight of supplying facility.

The final rule states that:
(*c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.*

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

The rule requires pet food manufacturers to address raw material hazards as part of the hazard analysis, and if a hazard requiring a preventive control is identified, preventive controls must be implemented to control or minimize that hazard. If no control (i.e., lethality) is

applied at the receiving facility, or at subsequent steps further in the supply chain, consideration must be given to the fact that the hazard may have the potential to impact the end user/consumer (the animal) and could also include those that would likely handle the product during feeding (humans).

For example, if the product produced is a raw pet food with no lethality step that:

1. Supports the survival and/or growth of pathogens, and
2. Is produced using raw materials that include meat and/or poultry by-products, which include a known or reasonably foreseeable microbial hazard, and
3. The intended use/consumer is domestic household pets, and
4. Distribution and storage requires refrigerated temperatures.

A careful hazard analysis conducted by (or overseen) a Preventive Controls Qualified Individual or PCQI, that meets the requirements of the rule would include an assessment of the risks associated with using raw materials known to contain pathogens in a process that does not include any lethality capable of reducing/eliminating that hazard.

One method of significantly minimizing this risk would be to ensure, through raw material testing and other preventions that the raw materials used do not contain pathogens. Consideration should also be given to using an environmental testing/monitoring in the receiving facility — if the PCQI determines this to be another appropriate verification activity based on product, packaging and product exposure to the environment during processing.

Based on the above example, simply purchasing raw materials from facilities operating in regulatory compliance, whether it's animal by product raw materials from a USDA approved facility, or FDA/preventive controls regulated by products, would not address raw material concerns such as those described.

Product testing and environmental monitoring for verification

The final rule states that to verify that preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards, you must conduct activities that include product testing and environmental monitoring, as appropriate to the facility, the animal food, and the nature of the preventive control (§ 507.49(a)(2) and (a)(3)). It further requires that you must establish and implement written procedures for product testing and for environmental monitoring (§ 507.49(b)(2) and (b)(3)).

To determine if product testing and environmental monitoring are warranted depends on the facility and its animal food product, as well as the nature of the preventive control and its role in the facility's food safety system. A slight variation in circumstances that would lead one facility to conclude that such testing programs were not required could lead a different facility to the opposite conclusion.

A facility that identifies an environmental pathogen as a hazard requiring a preventive control such as sanitation controls would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity, or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the animal food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system.

While FDA declined the request to require *Salmonella* testing as part of the environmental monitoring component, they also stated they believe that most facilities producing pet foods will identify *Salmonella* spp. as a known or reasonably foreseeable hazard that requires a preventive control verified by environmental monitoring (other than those subject to part 113 that are exempt from subpart C with respect to microbiological hazards regulated under part 113). FDA also declined the request to exempt livestock food or animal food other than pet food from the provisions for environmental monitoring, although they did note that the use of environmental monitoring by a livestock or poultry food facility as a verification of a preventive control would be the exception rather than the norm.

The term "product testing" means testing any animal food product, whether raw materials or other ingredients, in-process animal foods, or finished products and, thus, product testing can be directed to any of these animal food products. For example, testing raw materials and other ingredients could be verification of a supplier; testing in-process material after a kill step could be verification of process control; testing finished product could be verification of the food safety plan as a whole, and capture a problem introduced during manufacture, including from contaminated raw materials and other ingredients, if raw materials and other ingredients had been tested before use. Product testing generally is not the most effective means of measuring the adequacy of cleaning and sanitation programs, but such testing is common to track a facility's overall hygienic production measures.

The rule places no restrictions on who conducts testing. However, facilities have a responsibility to choose the appropriate testing methods, test kits or testing labs that will produce reliable and accurate test results. The rule does not specify the format of test results, pro-

vided that the record documenting testing satisfies the recordkeeping requirements of subpart F.

Developing a testing program

Product testing and environmental monitoring program requirements in the final rule provide flexibility based on the product, process, facility and equipment. With those requirements in mind, there are additional choices a manufacturer must make that will have a direct impact on the success of the program.

Procedures for product testing must:

- Be scientifically valid;
- Identify the test microorganism(s) or other analyte(s); the test(s) conducted, the analytical method(s) used and the laboratory
- Specify the procedures for identifying samples, and their relationship to specific lots >Include the procedures for sampling, including frequency and the number of samples
- Include corrective action procedures

Procedures for environmental testing must:

- Be scientifically valid,
- Identify the test microorganism(s); the test(s), the analytical method(s) and the laboratory
- Identify the number & locations of sites to be tested
- Identify the timing and frequency for collecting and testing samples, (all which must be adequate to determine whether preventive controls are effective;
- Include corrective action procedures

Past experience with the meat and poultry industry, as well as the third party food testing industry has underscored the need for careful consideration in the development of a robust testing program. These choices are some of the most critical decisions a facility must make, and start with determining whether to perform testing in house or to use a third party laboratory, either are acceptable for verification testing.

The choice of pathogen testing methods must consider other factors such as turnaround times, compatibility with the product matrix being tested. For product testing, utilizing testing options available from a test kit developer such as Neogen Corporation (Lansing, Mich.) produces reliable test results across an array of products, provides access to valuable technical support and meets the recordkeeping capabilities the rule requires. The results of any testing program plays a critical role in protecting consumer safety, as well as brand protection, so careful considerations should be given to these choices.

The requirements for environmental monitoring are a verification activity that a facility would conduct to verify that one or more preventive controls are consistently implemented and are significantly minimizing or preventing the hazards requiring a preventive control. They would be established as appropriate to the facility, the animal food, and the nature of the preventive control. The rule provides flexibility for the facility to determine the test methodologies and the thresholds appropriate for the environmental pathogen being monitored to verify the effectiveness of the facility's preventive control.

About the author

Ms. Wester is an experienced veteran in food safety having held advanced positions in both domestic and international food safety firms. She is currently president of her own consulting company, PA Wester Consulting, which utilizes her experience in food safety management system, auditor competence and food testing as an active SME on a wide range of projects. She is an FSPCA trained lead instructor for the PCQI preventive controls course as well as a trainer for food safety auditor personnel certification.

About Neogen

Neogen offers tests for all the major pathogens, including Salmonella, Listeria spp., Listeria monocytogenes and E. coli O157:H7, in a choice of formats. Its tests include the ANSR® test system that offers rapid molecular detection, and the Reveal® lateral flow test system, which combines an immunoassay with chromatography for a rapid result.