

Sir,

I am submitting comments to proposed regulations regarding manufacturing practices for the FDA Animal Feed Safety System. HBH manufactures pet foods and is a company that tries very hard to comply with all FDA and AAFCO rulings, and be a leader in compliance. We have spent the last few months working on SOP's to ensure full compliance by December. I am an attorney that is familiar with regulatory requirements. Our firm is a small manufacturing company (less than 50 employees except during busier seasonal times).

Comment 1: Our company is in the process of complying with contemplated AAFCO Best Manufacturing Practices, and FDA manufacturing guidelines. We incorporate food defect action levels, action levels for poisonous or delirious substances in animal feed, FDA food security training course, AAFCO label requirements, EPA product requirements, EPA guidelines for catastrophic events, C-TPAT compliance (slated for next year), EU import requirements for BSE and genetically modified feed, USDA BSE requirements other than for the EU, an adverse event reporting system, requirement by other countries other than the EU, Homeland Security guidelines for emergencies, FTC requirements for food claims- besides the normal regulatory environment faced by all companies such as OSHA, IRS, etc. etc.

The regulatory environment has become very complex in the last 10 years. Companies that ship internationally anticipate increased regulations. Terrorism, and bio terrorism has increased the complexity of the regulatory environment. BSE restrictions have increased it. Future complexity will come from bird viruses, more BSE, and new problems could be just around the corner.

If the different regulatory agencies could have common requirements for common problems, it would reduce the complexity. BSE and Homeland Security are common problems that could be combined from the different agencies into more streamline requirements.

The FDA-AAFCO team is a shining example of working together to solve problems for all stake holders. In my experience, these two groups represent an ideal working group. Although not all problems are solved in a short turn around time, eventually most issues are addressed thorough and competently.

If other agencies could work together like this, regulatory compliance would be far easier for smaller companies.

Comment 2: A company that sells internationally and nationally, such as HBH, would be expected to comply with all state, national and international requirements. However today, the fastest growing segment of the pet industry is small local bakeries selling dog biscuits from a local corner dog bakery. Or a small dog biscuit company that sells in one to three states. The regulatory environment for these companies is overwhelming. Even reading through the Safety System can present itself as an impossible obstacle. And perhaps the regulatory restrictions are overkill for these companies. Almost all of their products use human food ingredients, not raw meats, etc. Even where there are meat ingredients, much of it is human grade. A "recall" for these companies is many times pulling 2 trays off the shelf when the product goes stale. Both FDA and AAFCO are mandated to require safe products for animals. Using human grade ingredients, branded and purchased as such, should preclude the manufacturers from testing for molds, etc. The requirements and legal ramifications to the companies

supplying human grade products is daunting, so much so that extra testing by the dog bakery is effort not well spent. The FDA has much larger concerns to battle than the small risk that human grade food ingredients may need to be tested.

The FDA has wisely chosen to allow smaller manufacturers more time to comply with the different requirements for manufacturing pet foods. However the FDA may need to set a different standard, a more relaxed standard for pet foods sold only in one state, perhaps up to three states. The risks are low, the numbers of animals effected are low. Yes rules for safety need to be in place, but perhaps rules that are less intense.

Comment 3: The model Feed Program Development Guide of the Feed Safety System seems to draw many references from ISO guidelines. The scope of ISO qualifications are far beyond the skills and abilities of small manufacturers. The present system used by the FDA has provided billions of safe, effective pet meals to millions of pets for decades. To my knowledge, no pet has been killed from an act of bioterrorism, and there are very few pet product recalls, most related to pig ear type chews. The FDA and AAFCO have already effectively reacted in a responsible manner to these problems.

To overlay ISO type requirements on small companies is overwhelming, with little added benefit. The program outlines seems to envision a comprehensive plan, but the practical result could be that manufacturers will continue to make safe and effective pet foods, but now under a much heavier burden of compliance.

The feed safety of the future should be a result of failures in the system.

For small businesses, the FDA should consider incremental guidelines, less restrictive, and consider the results before moving into a comprehensive ISO mentality. The proposed regulations are flexible enough to allow for specialized needs, but the regulations should clearly point out that very small entities must comply with certain regulations regardless, and should fulfill other regulations to the degree that will ensure a safe pet product.

Thank you for the opportunity of submitting comments to the proposals.

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