



June 3, 2015

Via: www.regulations.gov

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

Re: Docket No. FDA-2014-D-1180 Guidance for Industry – Ensuring Safety of Animal Feed Maintained and Fed On-Farm

The American Feed Industry Association, based in Arlington, Va., is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. Founded in 1909 as the American Feed Manufacturers Association, the name changed to AFIA in 1985 to recognize the importance of all types of companies involved in the feed manufacturing industry—from commercial and integrated feed manufacturers, to ingredient suppliers, pet food manufacturers and equipment manufacturers. AFIA is also the recognized leader on international industry developments and holds membership in the International Feed Industry Federation.

Members include more than 575 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies, which supply other products, services and supplies to feed manufacturers.

The feed industry makes a major contribution to food and feed safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. More than 75 percent of the commercial feed in the U.S. is manufactured by AFIA members. Approximately 70 percent of the non-grain ingredients, including soybean meal, distillers co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

The U.S. feed industry is committed to producing animal food in an efficient and sustainable manner. AFIA shares this mission through four focal points, which we believe are the guide for a sustainable future: the optimization of energy and our natural resources; the enhancement of precision to our animal nutrition programs through new, efficient and productive technologies; to provide consumers with a better understanding and appreciation of today's food production system; and to give support to our local communities.

AFIA has promoted animal food safety across the U.S. for more than 100 years. Over a decade ago, AFIA developed its hallmark Safe Feed/Safe Food Certification Program. Since then, 600-plus facilities have been certified, and the program has grown from one basic program to several under the Safe Feed/Safe Food umbrella. Animal food safety does not stop when the feed leaves the manufacturer. It remains important throughout the entire value chain, including on the farm.

AFIA is pleased the Food and Drug Administration has highlighted the importance of maintaining safe animal food on the farm. AFIA strongly feels the draft guidance for industry can be improved, however. AFIA is disappointed the agency did not hold a national conference on feed use on-farm. Many of our comments would have been unnecessary if the agency had asked for concepts and principles of using feed on-farm. Chief among these would be the relationship between the manufacturer and customer is paramount in discovering any problems with the feed. FDA should tell customers to contact the manufacturer/distributor first to detail any issues related to the feed. Many customers are already doing this. However, many of the issues brought up are unrelated to the feed and instead involve changes in temperature, debt and/or credit, on-farm forage production and others.

Moreover, the tone of this document reads as if farms need to be protected from feed manufacturers. That is a poor characterization of the real relationship between feed manufacturers and farms. There are major interactions between on-farm customers and manufacturers on a daily basis throughout the country. It is a serious omission that FDA did not acknowledge this relationship and, in particular, failed to encourage communication with feed manufacturers when customers have concerns.

AFIA is very interested how FDA plans to disseminate this information to producers. There are many producer groups and trade associations—AFIA among them—that are willing to partner with FDA in this process, provided some changes are made to the document.

AFIA's comments are based on the page number of the draft guidance. The text below will include the original text along with proposed changes. The underlined text represents new additional language while the deleted language is stricken through. All changes are in bold. AFIA also provides justification for the changes and general comments on the draft guidance for industry.

Specific comments:

Proposed changes: Page 4

Paragraph 2:

Feed contaminant, for purposes of this guidance, means any biological, chemical, or physical, ~~or radiological~~ agent that if present in feed has the potential to cause illness or injury to animals or humans. (See Appendix A for examples of feed contaminants).

Paragraph 5:

The presence of a feed contaminant in feed does not necessarily mean that it is unsafe for animal consumption. Only when the contaminant present in the feed reaches the level

(e.g., concentration of biological, chemical, or physical, ~~or radiological~~ agent) that is reasonably likely...

Under IV.

We encourage you to consider the following principles and practices as means of ensuring the safety of the feed you give your animals:

A. Ensure feed is obtained and transported from a source that significantly minimizes feed risks to an acceptable level.

B. A. Know what feed contaminants may be present in your animals' feed and the measures known to prevent such contaminants from becoming unacceptable feed risks;

B. Obtain feed from safe and reliable sources;

C. Recognize unexpected changes in the feed at your farm (e.g., changes in color, smell, texture, or appearance);

AFIA recommends including radiological hazards as a subcategory of chemical hazards, as that is how they are scientifically categorized. Additionally, there is no evidence the risk warrants its own specific category in the U.S. It is redundant and unnecessary.

The use of the word "safe" throughout this document is concerning to AFIA. In this section, FDA suggests farms to buy feed from safe sources. In section V. F., FDA encourages farms to buy fertilizers, pesticides and other chemicals from safe sources. The word "safe" has varying meanings. AFIA encourages FDA to reduce the amount of subjective language used in this draft guidance. Instead, phrases such as "significantly minimized risks", "unadulterated feed" or "reduce to an acceptable level" should be used. FDA holds feed manufacturers to these metrics. The same language should be used in this document.

Feed must be transported safely in addition to simply obtaining it from safe and reliable sources. Feed manufacturers often deliver feed to the farm, yet both the farms and third parties may be responsible for transporting feed. AFIA recommends FDA reference transportation and also believes the new subpart is the most important; therefore, it should be listed first in the list of subparts.

Proposed changes: Page 5

Under A. 1

1. Identify feed contaminants that may be associated with your farm. Both U.S. Department of Agriculture (USDA) Cooperative Extension Service (in conjunction with land-grant universities) and FDA's Center for Veterinary Medicine (CVM) have information they can provide to help you learn more about contaminants ~~likely to~~ **that may** occur at your type of feeding operation. Some useful information may be obtained by performing web searches under the following programs:

The language in A.1 can be improved. FDA appears to say that some contaminants are *more* likely than others based on certain parameters on the farm. However, that is not what the text says

Proposed changes: Page 6

Under B. 1

~~**1. Know the requirements for animal feed in your state. Many states have requirements designed to help ensure feed safety, including requirements relating to maximum tolerance levels² for certain contaminants in animal feed. Do not provide your animals feed that contains feed contaminants above the maximum tolerance levels (where they exist). Your state feed control officials will be able to help provide information on your state's requirements.**~~

Under B. 2

~~**12. Do not provide your animals feed products ...**~~

Under B. 3

~~**23. Obtain feed from safe and reliable sources. Examples of safe reliable feed sources may include commercial suppliers known for delivering safe feed products. Ask each of your suppliers whether they are operating under an animal feed quality assurance program and if medicated feed is produced in compliance with applicable current Good Manufacturing Practice (CGMP) regulations (21 CFR part 225).**~~

Under B. 4

~~**34. Ensure the safety specifications³ of the feed are met. There are several ways to do this, such as, reviewing the supplier's Certificate of Analysis (COA) indicating safety specifications of the feed are met, or reviewing results of analytical laboratory testing of feed samples completed by a qualified testing facility⁴ that uses appropriate analytical methods. This may include ensuring your manufacturer has a quality and feed safety program.**~~ In addition, a simple physical examination of the feed may identify abnormalities. Using several of these safety specification measures would help increase assurance that animal feed products you receive are safe.

Under B. 5

~~**45. Store, transport, and offer the feed to animals in a manner that will prevent or significantly minimize: infestation of the feed with pests (e.g., rodents and insects), pet (e.g., dogs and cats) contact with the feed, cross contamination of feeds (e.g., medicated feed and non-medicated feed), and introduction of agents into the feed (e.g., pesticides, pathogens, molds, or foreign materials) or conditions (e.g., elevated moisture levels) that can cause unacceptable feed risks.**~~

Removing B.1 would make the section more clear. It applies to feed manufacturers, not on-farm producers.

As stated above, "safe" is so broad that it loses meaning. The succeeding sentences describe a reliable feed source, therefore AFIA recommends using that language.

AFIA urges FDA to keep this guidance practical. On a practical level, feed manufacturers cannot provide COAs for all 173 million tons of livestock feed produced in the U.S. without noticeably increasing costs. Instead, FDA should encourage farmers to have a conversation with the feed manufacturer about their quality and/or safety program(s) already in place. Many industry-wide quality programs already exist, such as AFIA's Safe Feed/Safe Food Certification Program explained earlier.

The storage and transportation of feed must also account for varying feed types. These varying types must be stored and transported separately. A good example would be ensuring medicated feed is not mixed with non-medicated feed or ruminant with non-ruminant feed containing restricted-use protein. There are many other examples as well.

Proposed changes: Page 7

Under B.6

56. Take steps to prevent or significantly minimize the occurrence of feed contaminants in feed. The occurrence of mycotoxins in grain and other feed commodities can be prevented or significantly minimized by providing environmental conditions during storage and transport that prevent or significantly minimize the growth of mycotoxin-producing molds. Implementation of an effective pest control program can prevent or ~~eliminate~~ **significantly minimize** contamination caused by pests. Additionally, regular and adequate cleaning of animal feeding areas, **including storage areas** and equipment can prevent or significantly minimize the occurrence of feed contaminants caused by the accumulation of filth. Your local agricultural extension service may provide guidance on pest control and good storage practices. For more information, see the website for the USDA Cooperative State Research Education and Extension Service education and outreach programs on Pest Management; <http://www.csrees.usda.gov/nea/pest/pest.cfm>.

Under B. 7

67. Observe feed consumption patterns of your animals. Unexpected changes in feed consumption patterns ~~may~~ **can** be ~~an~~ **good** indicator of the occurrence of feed contaminants or unacceptable feed risks in the feed.

Under B. 8

78. Make sure any equipment...

Words like "eliminate" only make the document less practical. It is impossible to eliminate all contaminants on a farm. Minimizing contaminants to the point they do not constitute a hazard is practical, and necessary.

It is important storage areas be adequately cleaned when appropriate. FDA should also consider breaking this paragraph into three or four separate points as at least three topics are covered in this one paragraph.

Changes in feed consumption patterns can indicate many things—most likely that animals are sick, not that the feed contains contaminants. AFIA agrees that feed consumption patterns should be observed closely but the language in B.7 needs to reflect that feed contamination is only one possibility.

Proposed changes: Page 9

Under D. 7

7. Ensure tanks, pipes, and other equipment used to store and convey water are made of materials which do not introduce feed contaminants into the animals' drinking water. **Where appropriate, use backflow preventers to prevent siphoning back from the delivery point, which may prevent or significantly minimize the introduction of non-feed contamination to the farm.**

Under E. 4

4. Ensure all farm workers observe biosecurity measures ~~(such as ensuring clothes and footwear taken into or through animal production areas are free of organic debris, are disinfected, etc.)~~ and personal hygiene practices to ~~prevent or~~ significantly minimize the introduction of feed contaminants.

Although backflow preventers may not be directly related to dry feed, they may help prevent contamination at the delivery point from the water/liquid feed supply. Backflow preventers will not be appropriate for all farms, however. Care should also be given to ensure the delivery point remains free of contamination.

The language in E.1 seems to imply FDA is telling farmers where to build barns. If a livestock barn is built in an area, it would become impossible to store these other things. AFIA finds this to be a confusing point.

The example in E.4 should be removed. Organic debris could be almost anything from a blade of grass to dust. What level of clothing disinfection is FDA suggesting here? Many industries have individualized biosecurity guides. FDA should encourage farmers to read those. "Developing Biosecurity Practices for Feed and Ingredient Manufacturers" is available within the resource center on AFIA's website, www.afia.org.

Proposed changes: Page 10

Under F. 3

3. Obtain pesticides, fertilizers and other agricultural chemicals from ~~safe and~~ reliable sources.

Under F. 5

5. Not store pesticides, fertilizers and other agricultural chemicals with, or adjacent to, feed or animals. ~~Prevent animals from consuming pasture and crops containing pesticides, fertilizers, or other agricultural chemicals which~~

~~could lead to violative residues in milk, eggs, or edible tissues of food-producing animals.~~ For further information regarding pesticide storage, you should read the product labeling and/or seek assistance from the appropriate regulatory agency (EPA or the USDA).

Under G. 2

2. Ensure when receiving or subdividing feed, that you **maintain its identity and keep the label/invoice accessible** ~~store the feed with its labeling/invoice attached or displayed on the container/bin~~ to ensure important product information is maintained and accessible.

Earlier in the document the term “safe” deals with animal food but here it deals with pesticides and fertilizers. AFIA feels “reliable sources” adequately describes FDA’s intent.

F.5 relates to storage of pesticides, fertilizers and chemicals, not use. The middle sentence can be stricken because it is a reflection of how pesticides, fertilizers and chemicals are used. It is also redundant as F.4 already discusses “the potential for exposing animals to these substances.”

AFIA suggests animal food being received or held must be “identified,” and that important information be kept in a safe place. It is also important to connect the feed with the information. But this can be done in numerous ways (computer system, numbering bins and labels, including lot codes with product descriptions) that does not require the impractical label on a bin. The concern should be about identification, not necessarily labeling of containers and bins.

AFIA also believes that G.4a-b should be moved above G.1-3. It is appropriate to list what is required by law first and then list what FDA recommends in addition to what is required.

Proposed changes: Page 11

Under I.2

2. Provide feed safety training **for** ~~which can be easily comprehended by~~ your employees.

Another example of subjective language can be found in I.2. AFIA agrees feed safety training should be provided to all employees but is concerned with what is meant by “easily comprehended”.

Proposed changes: Page 12

Under J.

Establish and implement measures so you will know the origins of feed used on your farm. Having such information becomes particularly important in cases where feed is recalled and will help ensure timely and effective removal from your farm and the market of feed products ~~manufactured and distributed by commercial feed establishments~~ that may have an adverse effect on animal or human health.

Under K.2

... The feed testing facility you contact may be able to advise you on proper sampling procedures. **It is important to follow these procedures as collection, handling and storage of a sample can affect the results. Sampling and sample size will significantly impact the analytical results.**

The second sentence in J is cumbersome, and feed quality/safety is important beyond just commercial feed establishments.

It is uncommon for producers to take aseptic samples of feed and therefore great care should be taken when recommending the taking of samples. The results of these tests are only as good as the representative sample that was taken—that is why following the producers is so important. FDA should also note that samples taken from open containers and a contamination is found, it may not have occurred at the feed manufacturer. Instead, it could have been contaminated on-farm. On-farm contamination is quite common and can be the result of feed samples taken from the feed bin, bunk or feeder. Bins and buildings that are not adequately sealed can be a cause of feed contamination for feed stored in such facilities.

Proposed changes: Page 12

Under L. 1-2

1. Take immediate measures to ensure the product is not fed to animals.
- 2. Contact the feed manufacturer/vendor about your concerns.**
- 32.** Review the FDA web site on reporting problems to the FDA at ...

AFIA feels this is the most important change in the entire document. In fact, AFIA is very disappointed the agency did not include this in the draft. If producers feel there is an issue with their feed, it is important to involve the feed manufacturer. Feed manufacturers are the ones who determine a reportable food, and they need the information from the farmers. If there is a problem, the manufacturer needs to know so they can prevent further distribution of the feed supply. The earlier they are contacted, the quicker they can prevent other problems.

Proposed changes: Page 13

Under L. 3-4

43. Promptly consult your veterinarian once you become aware that animal feed purchased for use on the farm ~~may cause or~~ has caused a negative effect on animal health.

54. If you suspect there could be negative effects on human health from ingestion of food products derived from animals that have eaten contaminated feed, you should promptly contact your local and state health departments.

AFIA recommends altering the language in the current L.3 as it may not be effective to consult a veterinarian prior to feeding animals.

Pages 14 and 15 will cause confusion. By listing these examples of contaminants and risks, FDA implies these are the major concerns. Perhaps worse, it implies these are the only concerns. What about swine and equine? Investigators going onto farms may use only this list as well, from experience AFIA members say state and federal investigators tend to rely on lists when performing inspections. AFIA does not recommend listing *some* feed contaminants and *some* unacceptable feed risks. Instead, FDA should encourage on-farm producers to reach out to producer groups and trade associations that provide guidance on recognizing potential contaminants and risks.

Finally, AFIA has presented in-depth information on its SF/SF family of programs (www.safefeedsafefood.org) that have operated for more than 10 years in the feed industry marketplace. Formerly, FDA mentioned species specific quality assurance programs to producers in FDA Warning Letters to the facility that had one or more illegal residues in meat, milk, eggs or fish. AFIA assumes mention of these programs was removed due to agency legal concerns about providing guidance in a Warning Letter.

However, this is a guidance document, and it would seem appropriate to provide that guidance to the producer community. At a minimum the agency should make mention of industry quality assurance and feed safety programs so that producers are aware of them.

AFIA will continue efforts to increase and promote feed safety. It is a prime reason the association was created in 1909. AFIA's members will continue working with their customers on farms to provide high quality, safe feed for their animals, as they have done for more than 100 years.

AFIA urges the agency to hold a national meeting about on-farm feed safety to promote this guidance document.

AFIA appreciates FDA's consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Sellers".

Richard Sellers
Senior Vice President, Legislative and Regulatory Affairs
American Feed Industry Association