



**NATIONAL CHICKEN COUNCIL**

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***SUBMITTED ELECTRONICALLY***

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

**Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Foods for Animals; Docket No. FDA-2011-N-0922; 79 Fed. Reg. 58476 (Sept. 29, 2014)**

Dear Sir or Madam:

The National Chicken Council (NCC) is pleased to submit these comments on the Food and Drug Administration's (FDA's) supplemental proposed rule, *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, as part of FDA's implementation of the FDA Food Safety Modernization Act (FSMA). NCC represents the vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC's members would be directly affected by the proposed requirements for food for animals.

NCC appreciates the careful attention FDA has given to comments received on the initial proposed rule and the opportunity to review and comment on this supplemental proposed rule. Implementing FSMA requires carefully considering a wide range of issues whose effects will ripple through the entire food industry, and NCC applauds FDA's efforts to engage all stakeholders during the rulemaking process. Strong collaboration with the regulated industry and other stakeholders is critical for the effective implementation of FSMA, and NCC encourages FDA to maintain this collaborative approach throughout and after FSMA implementation.

NCC supports efforts to promote safe manufacturing and distribution practices for pet food and animal feed (collectively referred to in these comments as "animal feed" or simply "feed") by implementing FSMA. NCC's members have years of experience with risk-based and science-based food safety programs under the Food Safety and Inspection Service's (FSIS's) Hazard Analysis and Critical Control Point (HACCP) regulations, and we believe FSMA's hazard analysis and preventive controls requirements will greatly enhance our nation's already strong food safety system.

NCC submits these comments to identify concerns and propose solutions regarding two specific issues that remain in the supplemental proposed rule:

- **Feed mills operating as part of vertically integrated chicken farming and processing operations should be exempt from the proposed rule or subject to the “very small business” provisions of the rule.**
- **Byproducts from meat or poultry human food production should not be subject to FSMA’s preventive controls or good manufacturing practice (GMP) requirements while in FSIS-regulated official establishments.**

In addition to these comments and those we provided earlier in response to the initial Proposed Rule, NCC also generally supports the positions of aligned food and feed industry trade associations.

**NCC Recommends Focusing on Functional Ownership of the Animals and Feed Used in Broiler Farming and Processing Operations Rather than Formal Ownership of Land**

As a general principle, NCC recommends that FDA adopt a functional approach that looks at whether a single entity maintains ownership of the animals and feed used in an animal farming operation rather than formal ownership of land when determining whether to exempt or exclude certain activities from regulation under the proposed rule. NCC appreciates FDA’s recognition in the supplemental proposed rule of the “variety of farming models for raising animals” and the commensurate challenges in drafting a rule that addresses all models in a risk-based manner. <sup>1/</sup> NCC believes that this functional approach, rather than a formalistic approach turning on technical ownership of land, will allow FDA to better tailor its regulations in an efficient and risk-based manner while maintaining a high level of public health protection.

The vast majority of chicken in the United States is produced using a vertically integrated business model. A chicken processor owns its own breeding hen flocks (which supply the eggs that are hatched to become broilers) and hatcheries. Usually, the integrator contracts out to independent farmers the task of raising newly hatched chicks until they are ready to be harvested, although the chickens and feed remain the property of the integrator throughout the grow-out process. The chickens are raised on the contract farms under conditions laid out in a contract with the chicken integrator and are fed exclusively a diet provided by the integrator. Grower contracts contain very specific requirements for facility design, provisions related to animal care and handling, and specific requirements about not altering the company’s feed or feeding schedules. Integrators also maintain trained personnel tasked with visiting farms and flocks and providing technical advice for proper animal care and feeding. Thus, although broiler flocks are usually raised on land owned by someone else, integrators retain ownership of the chickens and the feed and have a vested interest in ensuring the chickens are properly cared for. Some NCC members also own the farms on which the chickens are raised. Other than the technical aspect of who holds title to the land on which the chickens are raised, however, there are few, if any, practical differences between how the chickens are cared for. In other words, from a public health protection standpoint, the two systems are comparable.

Most broiler integrators also own and operate their own feed mills (referred to in these comments as “integrated mills”) to supply the farms raising the integrator’s chickens. Working with in-house veterinarians and poultry nutrition experts, integrators’ feed mills provide diets specifically tailored to their chickens. The feed mills are vertically integrated to allow the integrator to control the quality and cost of feed, which is a crucial input in the chicken farming process. Typically, a single feed mill will service multiple contract grow-out farms for a company within a given region. An integrator-

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<sup>1/</sup> 79 Fed. Reg. 58476, 58482 (Sept. 29, 2014).

owned feed mill typically will supply only farms raising that integrator's chickens. <sup>2/</sup> Because they are used solely to feed an integrator's flocks, integrated feed mills typically produce only a handful of different feed formulations at a time for only one specie, compared to potentially hundreds of formulations for multiple species produced at an independent feed mill—thereby greatly reducing any variability in quality. Integrated feed mills handle a fairly stable rotation of ingredients and use a consistent manufacturing process normally controlled by a batch process computer, thereby helping to ensure feed safety. <sup>3/</sup> Further, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) inspects chicken products to ensure that the product contains no unapproved residues or other substances derived from the feed that could render the product unsafe for humans to consume. And, unlike independent feed mills, which might send trucks to deliver multiple feeds to various customers on any given day, integrated feed mills distribute feed in closed-loop circuits: a truck transports feed from the mill to generally the same group of farms, returning empty directly to the integrated feed mill to pick up a new load of the same feed, thereby reducing the risk of cross-contact among different feeds and the potential for an errant delivery. Again, taken together, all these aspects of a vertically integrated business model comprise a robust quality system that is highly protective of the public health.

FDA in the preamble to the supplemental proposed rule distinguishes between “fully vertically integrated farming models” and “contract farming.” <sup>4/</sup> Although this description accurately reflects ownership and capital structure within the broiler industry, we do not believe it is particularly informative for making a risk-based determination as to the applicability of the animal feed preventive control rule. In both types of business organization, the integrator owns the chickens and the feed, and the integrator has every incentive to ensure it is providing safe, wholesome, nutritious feed for its chickens, as every chicken that cannot be brought to market results in a financial loss to the integrator. As such, integrated broiler feed mills have in place robust and company-specific procedures to ensure that they are producing safe and nutritionally appropriate feed for the integrator's chickens. In many cases, integrated feed mills are certified to stringent ISO standards or other benchmarks, rendering additional regulation unnecessary for controlling risk.

Accordingly, we urge FDA to take a functional approach to integrated feed mills and to recognize that all integrated broiler feed mills—regardless of who owns the land on which the chickens consuming the feed are raised—present very low feed safety risks that are appropriately managed through existing safety programs. Because the integrator directly bears all the costs of a potential

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<sup>2/</sup> In rare, emergency situations, such as a natural disaster that damages or destroys a feed mill, an integrator-owned feed mill may supply another integrated company on a temporary basis to protect animal welfare.

<sup>3/</sup> Integrated feed mills already follow mill-specific feed-safety procedures to control for feed safety, and many also follow FDA's medicated feed GMPs. Representative examples of the types of controls in place in integrated feed mills in the broiler industry include: feed manufacturing guides developed by nutrition experts in the corporate office, corporate feed mill specialists who work with each feed mill to ensure quality and safety, annual feed safety training for feed mill managers, pest management programs, testing of incoming ingredients (including residue analysis), rapid-turnaround analytical testing of finished feed, quality requirements in purchase specifications for incoming ingredients, comparison of inventories to theoretical levels to ensure ingredients are used at the expected rate, ingredient supplier visits, certification of scales used to weight ingredients and finished products, and complaint-handling and recall procedures. Through these programs, integrated feed mills already have in place robust feed safety programs. Additional regulation is both unnecessary and risks drawing focus away from these mill-specific programs.

<sup>4/</sup> 79 Fed. Reg. 58476, 58482. We continue to refer in our comments to all of NCC's member companies as being “vertically integrated.” When relevant to the discussion, we differentiate between contract farming and integrator-owned farming using the language from FDA's preamble.

feed safety issue, NCC's members have natural incentives to ensure they have robust feed safety programs in place. <sup>5/</sup>

### **The Definition of "Farm" Should be Revised to Include Vertically Integrated Contract Farms**

In keeping with this functional approach, NCC recommends that FDA revise the definition of "Farm" to include vertically integrated operations that use contract farming. We recommend the following definition, with our recommended addition underlined:

Farm means an establishment under one ownership in one general physical location, or a collection of establishments contracted with or owned by a single company to raise animals owned by the company (including any feed mills owned by the company to supply those establishments), devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.

This revision is appropriate to ensure that feed from an integrated feed mill supplied to contract farms used in the vertically integrated production model is treated the same as feed from an integrated feed mill used to supply farms owned by the company. This proposed definition is also specific to contract farming in animal production and will not affect the use of the term "farm" in other areas of FDA's proposed regulations.

### **FDA Should Codify the Definition of "Very Small Business" As Proposed In the Supplemental Proposed Rule with Additional Clarification**

NCC supports the proposed definition of "very small business" set forth in supplemental proposed section 507.3 as "a business that has less than \$2,500,000 in total annual sales of food for animals, adjusted for inflation." <sup>6/</sup> As FDA explained in the supplemental proposed rule, this figure is appropriately reflective of the size of firms in the animal feed industry. A very small firm producing a limited variety of formulas could easily exceed the \$1,000,000 initially proposed. NCC strongly supports setting a threshold of at least \$2.5 million (and strongly opposes the much lower, \$10,000 threshold alluded to in FDA's summary of comments received on the initial Proposed Rule), as a lower threshold would subject numerous businesses to costly regulations out of line with the revenue generated by their operations and could drive many firms out of the industry. In supporting FDA's supplemental proposed definition of "very small business," we offer the following specific comments to clarify the intended meaning of the definition:

- ***Define "Sales" as an Exchange of a Commodity for Money with an Outside Party. We recommend FDA define what constitutes a "sale," either in the definitions in proposed section 507.3 or in guidance accompanying the final rule. We recommend FDA use the following definition: "Sales means, for purposes of this part, the exchange of a commodity for money or other valuable consideration with a third party not under common ownership or control with the party providing the commodity." "Ownership" should be interpreted as a controlling stake in the company. We believe this definition is necessary to make clear that intra-company transfers do not constitute a "sale" of animal feed, even if the company might debit one corporate account and credit another for accounting, tax, or other purposes.***

**Our proposed definition draws on the common dictionary definition of a "sale" as "the**

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<sup>5/</sup> Further, imposing different requirements on vertically integrated broiler companies based solely on land ownership risks conferring an arbitrary competitive advantage of parts of the industry.

<sup>6/</sup> 79 Fed. Reg. 58479, 58510 (proposed 21 C.F.R. § 507.3, "Very Small Business").

exchange of a commodity for money or other valuable consideration.” <sup>7/</sup> This definition necessarily involves multiple parties, as one business cannot “exchange” something with itself, and money transferred between corporate accounts is not “valuable consideration” because the corporation neither gains anything of value nor commits itself to doing something to its detriment. We do not believe it is necessary to apply the preventive controls requirements to wholly intra-company operations. As explained above, a company has every incentive to ensure that feed it supplies to itself is produced safely, and the company has full control over and access to all information about the production of that feed. Further, excluding intra-company transfers from “sales” is consistent with the “farm” exemption from facility registration under current 21 C.F.R., 1.227, whereby a “farm” includes “[f]acilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership,” <sup>8/</sup> as well as the revised the “farm” definition offered in the Supplemental Proposed Rule for preventive controls for human food. <sup>9/</sup> Finally, we recommend that FDA interpret “ownership” as owning a sufficiently large stake in the company such that the “owner” can exercise control over the company. In some instances, an integrator may purchase a sufficiently large stake in a feed mill operation such that it has de facto control over the feed mill. In such an instance, a functional approach would dictate that the feed mill be treated as owned by the integrator, so long as the feed mills’ products are dedicated to the same vertically integrated business operation.

- **Calculate sales using a three-year average.** We recommend that FDA clarify in guidance accompanying the final rule that the \$2.5 million dollar level of sales would be calculated using the average annual sales figure from the previous three years. Using an average would ensure that a very small business would not suddenly find itself subject to the preventive controls requirements merely due to an unusual fluctuation in sales.
- **Exclude unusual spikes in “sales” due to emergency situations from the calculation to determine eligibility for “very small business” classification.** As referenced earlier, occasionally a disaster will render an integrated broiler feed mill non-operational. Many feed mills are located in parts of the country susceptible to tornados and severe weather, and large-scale natural disasters such a hurricane can damage or destroy multiple feed mills at once. Damage to or destruction of a feed mill presents a serious animal welfare concern, as multiple flocks of chickens are dependent on the mill for sustenance. In emergency situations such as these, the integrator may turn to a nearby feed mill owned by another integrator for a temporary emergency supply of feed to ensure the survival of the chickens. The feed usually is provided either on a “barter” basis or at a predetermined price to cover the costs of production. Depending on the scope and severity of the disaster, it could take months or possibly one or two years before the damaged feed mill is operational again. <sup>10/</sup> We recommend that FDA be careful not to create a situation whereby “very small business” feed mills are dissuaded from providing emergency assistance out of fear

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<sup>7/</sup> Oxford English Dictionary, “Sale, n.2,” definition 1.A (2014).

<sup>8/</sup> 21 C.F.R. § 1.227(a)(3)(ii).

<sup>9/</sup> 79 Fed. Reg. 58524, 58562–63 (Sept. 29, 2014) (proposed § 1.227, definition of “farm,” subsection (3)(i); proposed § 1.328, definition of “farm,” subsection (3)(i)).

<sup>10/</sup> For example, it took years for some feed mill operations to fully recover from the devastation wrought by Hurricane Katrina, and it typically takes about one-to-two years to build a new feed mill operation from scratch.

of losing their “very small business” status. We suggest that FDA develop a formal or informal process whereby a feed mill can document feed provided in such an emergency situation and exclude that emergency production from its “very small business” three-year average sales calculation. 11/

- ***Maintain the proposal to calculate “very small business” using sales of animal feed.*** NCC supports FDA’s proposal to determine eligibility for a “very small business” based on sales of animal feed. Broiler integrators, although not small companies in terms of annual revenue from the sale of chicken, are not in the business of producing animal feed as a source of revenue and should not be viewed as part of the feed industry unless they voluntarily choose to enter the feed market by offering feed for sale to outside parties. Using only sales of animal feed ensures that FDA is focusing its resources on companies that participate meaningfully in the animal feed market, rather than companies that supply feed only to themselves (or a negligible amount of feed to the open market).
- ***Calculate eligibility for integrated feed mills based on sales for an individual facility.*** As explained, integrated feed mills are operated to supply feed to integrator-controlled farms in geographically distinct areas and are appropriately viewed as generally operating independently from one another. If excess feed were diverted from one integrated feed mill to the open market (which is not usually done) such that it would lose its “very small business” status, that action should not affect whether other feed mills owned by the same integrator but otherwise unrelated to the mill in question should be subject to the preventive controls requirements. Therefore, NCC recommends that FDA treat eligibility for the “very small business” classification for integrated feed mills on a feed facility-by-feed facility basis, not a corporate basis. FDA has authority under FFDCA § 418(m) to exempt or modify requirements “with respect to facilities that are solely engaged in the production of food for animals other than man.” Exercising that authority to consider operations on a feed facility-by-feed facility basis with respect to integrated feed mills that do not generally supply feed to the open market would be appropriate in this situation.

In summary, we urge FDA to define “very small businesses” in a way that would encompass feed mills operating within an integrated business model.

### **FDA Should Not Subject Meat or Poultry By-Products in FSIS-Regulated Official Establishments to the Proposed Rule Given Existing FSIS Regulations**

FDA appears to propose to require official establishments diverting by-products derived from meat, offal, poultry, and oil seed meal to the animal food chain to comply with the proposed GMPs, hazard analysis, and preventive controls requirements for animal food in Part 507. 12/ NCC strongly objects to this proposal and firmly believes it is unnecessary to ensure animal food safety. NCC recommends that FDA not subject official establishments that direct human food by-products derived from meat and poultry to the animal food supply chain to proposed Part 507, given existing Food

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11/ Alternatively, we request that FDA use its authority under FFDCA Section 418(m) to exempt from the Final Rule integrated feed mills producing feed for another integrator to address such an emergency situation.

12/ 79 Fed. Reg. 58476, 58488 (Sept. 29, 2014). For ease of reference we refer to these products collectively as “meat and poultry.”

Safety and Inspection Service (FSIS) requirements governing these materials and continuous inspection by FSIS personnel in these establishments. 13/

The official establishments that produce these by-products fall under FSIS jurisdiction and are subject to regulatory Sanitation Standard Operating Procedures (SSOPs) and hazard analysis and critical control point (HACCP) requirements. In addition, FSIS has existing requirements that specifically address diversion to animal feed. Further, these materials generally are handled by renderers who further process the materials to ensure their safety for use as animal feed, and any animal food producer obtaining these byproducts would be subject to the Proposed Rule. Finally, these renderers are subject to FDA's existing requirements to reduce the risk of the spread of bovine spongiform encephalopathy (BSE). Thus, by-products derived from meat and poultry products are subject to a comprehensive food safety regime. There is no gap that might make animals vulnerable under the current system, and thus there is no need for additional regulation under Part 507. Additional regulatory requirements would not improve food safety, but rather would create duplicative and unnecessary regulation.

If FDA decides that official establishments under FSIS jurisdiction should be subject to requirements under the Proposed Rule, then NCC recommends that FDA allow these facilities to comply with the same modified requirements it proposes for other human food facilities that divert by-products to the animal food chain. Requiring that FSIS-regulated official establishments comply only with the GMPs for holding and distribution would be sufficient because existing FSIS regulatory requirements would continue to apply and human food by-products derived from meat and poultry and diverted to animal food present no greater food safety risk than the other human food by-products, given the existing BSE regulations remaining in place. Finally, should FDA conclude that it believes official establishments diverting human-food meat or poultry byproducts to animal food use require this additional oversight, NCC recommends that FDA collaborate with FSIS to determine what additional regulations may be required and allow FSIS to establish and oversee this requirement.

### **Special Training Will Be Critical For Efficient Implementation**

As explained in our earlier comments to this docket, proper training of FDA investigators and supporting personnel will be essential for efficiently implementing any final rule. NCC encourages FDA to prepare detailed training materials and investigator guidance on both the requirements of the final rule and the unique aspects of the animal feed or food industry in question. For example, open-air feed mills are very different from the human-food, drug, and device manufacturing facilities FDA investigators are accustomed to inspecting. NCC also encourages FDA to collaborate closely with the regulated industry in developing these training and guidance materials to ensure that all parties have a full and accurate understanding of the new requirements. NCC would be pleased to work with FDA to develop any materials that may be relevant to the regulation of our member companies.

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13/ Please see our earlier comments submitted on this docket in response to the initial Proposed Rule for a full explanation of the legal and regulatory structure under which FSIS-regulated official establishments operate and the jurisdictional elements of the FFDCIA and the Poultry Products Inspection Act (and the Federal Meat Inspection Act) that provide FSIS jurisdiction over these establishments.

## Conclusion

NCC supports FDA's FSMA implementation efforts and appreciates the opportunity to comment on this Supplemental Proposed Rule. We strongly urge FDA to incorporate these comments into the final rule, and we would be pleased to provide any additional information that may be of assistance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is written in a cursive style with a large initial "A".

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National Chicken Council