



**FOOD ANIMAL CONCERNS TRUST**

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July 23, 2018

RE: Docket Number: FDA-2018-D-0388; Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability.

To Whom It May Concern:

Food Animal Concerns Trust (FACT) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) draft Guidance for Industry #245 entitled "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." Food Animal Concerns Trust (FACT) is a Chicago based consumer advocacy organization that identifies and advocates for steps livestock producers should take to keep their animals from being the cause of human disease including advocating for safe feed.

Guidance for Industry #245 (GFI#245) should lead to safer feed and subsequently healthier animals and safer food. Instead, the Guidance as drafted is likely to lead more sick animals and more sick people. Draft GFI #245 suggests that *Salmonella* is not a hazard in the feed of food producing animals and thus does not need to be controlled. In doing this, draft GFI#245 ignores the risk of contaminated feed to human and animal health. Draft GFI#245 bases the finding of limited risk by ignoring evidence from the U.S. Department of Agriculture (USDA) and the U.S. Centers for Disease Control and Prevention (CDC) on serotypes of *Salmonella* that cause illness in food producing animals and in humans. Draft GFI#245 also fails to take into consideration specific outbreaks of illness in animals and subsequent infections in humans that have been caused by *Salmonella* contaminated feed. Finally, draft GFI#245 ignores recommendations by both the USDA and the American Feed Industry Association on controlling *Salmonella* in feed and undermines efforts by these organizations to improve the safety of feed.

On page 35 of draft GFI#245 there is a list of examples of *Salmonella* serotypes known to cause illness in specific animal species. This list is not based upon the available evidence of the types of *Salmonella* causing illness in food animals in the U.S. State veterinary diagnostic laboratories submit isolates of *Salmonella* from clinically ill animals to the National Veterinary Services Laboratories (NVSL) for serotyping. USDA describes these *Salmonella* isolates as being "associated with higher than expected morbidity and mortality, more severe disease, or more persistent disease conditions in groups, herds, or flocks."<sup>1</sup> The NVSL uses these submissions to report the most common serotypes among clinical isolates for each major food producing animal

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<sup>1</sup> USDA Antimicrobial Resistance Action Plan. Page 15. Available from:  
<https://www.usda.gov/sites/default/files/documents/usda-antimicrobial-resistance-action-plan.pdf>

species.<sup>2</sup> As described by USDA these are all serotypes that cause illness in food producing animals but, except in a few cases, they are not included in the examples serotypes that cause illness in food producing animals listed by FDA in draft GFI#245. FDA's list of examples clearly misses many of the most common serotypes of *Salmonella* that cause animal illness in the U.S. If these were only examples, this would be misleading but feed manufacturers would still need to make sure that other serotypes were not a cause of illness in the animals for which they mix feed. Draft GFI#245 (page 25) precludes this by stating that since these serotypes are not commonly found in feed, "you may determine that *Salmonella* is not a known or reasonably foreseeable hazard for your animal food, or is not a hazard requiring a preventive control, if you manufacture livestock or poultry food."

In addition to ignoring the evidence in the NVSL on what serotypes of *Salmonella* cause illness in food producing animals in the U.S. draft GFI#245 ignores reports of outbreaks of illness in food animals associated with *Salmonella* contamination in feeds. Researchers at the CDC tied an international human outbreak of *Salmonella* Agona to contaminated feed<sup>3</sup>. Agona is currently one of the top serotypes of *Salmonella* causing illness in pigs. Other recent research has shown that feed can be a source of *Salmonella* infection in pigs<sup>4</sup> and poultry and subsequently in humans consuming animal products<sup>5</sup>.

By focusing on a few rarely found serotypes of *Salmonella* instead of examining the available evidence for the serotypes of *Salmonella* that under current livestock raising conditions cause most of the illness in food animals, draft GFI#245 puts animal health at risk. It also puts human health at risk since many of the serotypes causing illness in animals are also important causes of illness in humans (e.g. Typhimurium; Newport; 4,[5],12:i:-; Heidelberg, Infantis).

Draft GFI#245, by suggesting that *Salmonella* in feed is not a hazard to be controlled, also directly contradicts guidance by the USDA on controlling *Salmonella* in Poultry. USDA's DRAFT FSIS Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Raw Poultry<sup>6</sup> specifically recommends that farms use feed that is free of *Salmonella* and refers producers to a feed industry initiative to control *Salmonella* in feed (page 47).

The American Feed Industry Association (AFIA) has also taken steps to promote the control of *Salmonella* in feed. AFIA has produced a document<sup>7</sup> on control of *Salmonella* in feed and also

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<sup>2</sup> *Salmonella* Serotypes Isolated from Animals and Related Sources: January 1-December 31, 2016. Available from: <https://www.cdc.gov/national-surveillance/pdfs/Salmonella-serotypes-isolated-animals-and-related-sources-508.pdf>

<sup>3</sup> Crump et al. 2002. Bacterial contamination of animal feed and its relationship to human foodborne illness. Available from: <https://academic.oup.com/cid/article/35/7/859/307143>

<sup>4</sup> Molla et al. 2010. *Salmonella* enterica in commercial swine feed and subsequent isolation of phenotypically and genotypically related strains from fecal samples. Available from: <http://aem.asm.org/content/76/21/7188.long>

<sup>5</sup> Reiter et al. 2012. Feed as a source of *Salmonella* contamination in poultry: two outbreaks in 2010 and 2011.

Available from:

[http://www.wtm.at/smart\\_users/uni/user94/explorer/143/WTM/Archiv/2012/10\\_Jahre\\_AGES\\_Artikel\\_8\\_Art\\_122\\_3.pdf](http://www.wtm.at/smart_users/uni/user94/explorer/143/WTM/Archiv/2012/10_Jahre_AGES_Artikel_8_Art_122_3.pdf)

<sup>6</sup> Available from: <https://www.fsis.usda.gov/wps/wcm/connect/6732c082-af40-415e-9b57-90533ea4c252/Controlling-Salmonella-Campylobacter-Poultry-2015.pdf?MOD=AJPERES>

<sup>7</sup> AFIA. 2010. *Salmonella* Control Guidelines. Available from:

[http://www.afia.org/rc\\_files/789/SALMONELLA%20CONTROL%20GUIDELINES%202010.pdf](http://www.afia.org/rc_files/789/SALMONELLA%20CONTROL%20GUIDELINES%202010.pdf)

administers the Safe Feed/Safe Food program,<sup>8</sup> a voluntary feed safety certification program that includes *Salmonella* controls.

FDA in draft GFI#245 totally undermines the efforts of the USDA and the feed industry to promote *Salmonella* controls by suggesting that *Salmonella* not be considered a hazard in feed and therefore not need to be controlled.

FACT recommends that the last two sentences in the first paragraph after the bullet points on page 35 of draft GFI#245 be deleted. In their place, GFI#245 should reference the NVSL list of *Salmonella* serotypes as additional examples of *Salmonella* serotypes causing illness in food producing animals. Any suggestion that *Salmonella* is not a hazard to be controlled in feed should be removed.

FDA's primary mission is protecting public health. By suggesting that *Salmonella* is not a hazard in the feed of food producing animals and ignoring the overwhelming evidence that many serotypes of *Salmonella* cause illness in food producing animals and that *Salmonella* in food producing animals can lead to sick people, FDA in draft GFI#245 undermines public health and animal health. Draft GFI#245 also undermines the efforts of the USDA and the animal feed industry to make feed and food safer. FACT asks that FDA in finalizing GFI#245 makes clear that *Salmonella* is a hazard to be controlled in the feed of food producing animals. Failure to make this change will directly put animal and human health at risk.

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<sup>8</sup> Available from: <http://www.safefeeds safefood.org/main/home.cfm>