



United States Department of Agriculture

Food Safety and  
Inspection Service

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Washington, D.C.  
20250

JUN 21 2019

Mr. Mark Kennedy  
Director of Legal Affairs  
Physicians Committee for Responsible Medicine  
5100 Wisconsin Avenue, NW Suite 400  
Washington, DC 20250-3799

Dear Mr. Kennedy:

The Food Safety and Inspection Service (FSIS) has completed its review of the March 14, 2013, petition and the May 6, 2013, addendum you submitted on behalf of the Physicians Committee for Responsible Medicine (PCRM). The petition requests that FSIS: 1) declare and regulate feces as an adulterant; 2) amend FSIS regulations that prescribe mandatory safe handling statements (9 CFR 317.2(l)(2), 381.125(b)(2)(i), and 381.125(b)(2)(ii)) to require that all meat and poultry product labels uniformly disclose the presence of feces; and 3) amend the FSIS regulations at 9 CFR 381.96 to remove the word "wholesome" from the official inspection legend for poultry and include an explicit warning that the product may contain feces.

We have decided to deny your petition because we disagree with the petition's underlying assumption that meat and poultry products bearing the mark of inspection are likely to be contaminated with feces. We also have determined that the labeling changes you are requesting are inconsistent with the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*) and would result in labeling of meat and poultry products that is misleading to consumers. Therefore, for the reasons discussed below, we are denying your petition.

Request to Declare and Regulate Feces as an Adulterant

Regarding your first request, we disagree that FSIS needs to take action to declare and regulate feces as an adulterant. The Agency's existing regulations and policies comprehensively address the disposition of adulterated meat and poultry products from various sources, including carcasses with fecal contamination. Under the FMIA and the PPIA, all meat and poultry carcasses and parts thereof and other meat and poultry products that are found to be adulterated must be condemned and destroyed for human food purposes, except when they can be made not adulterated through trimming or reprocessing in accordance with implementing regulations (21 U.S.C. 604 and 455(c)). FSIS regulations prescribe that condemned meat and poultry carcasses and parts are prohibited for human food and must be disposed of as inedible by an approved method (see 9 CFR part 314 and 381.95). Pursuant to these regulations, FSIS policies address the disposition of carcasses and carcass parts condemned for any reason. This includes carcasses adulterated from extensive fecal contamination that cannot be removed through trimming or reprocessing.

In the petition and May 2013 addendum, you note that FSIS enforces a “zero tolerance” safety standard for visible fecal material on carcasses and carcass parts at Federally inspected meat and poultry establishments (see 62 FR 63254; Nov. 28, 1997). You also assert that a policy that addresses only visible feces is inadequate because it does nothing to address fecal material that is not visible to the human eye. According to the petition, “[i]f neither plant workers nor the inspectors see the feces, a carcass contaminated with feces will pass through the plant for sale to consumers.” You assert that FSIS needs to implement a more comprehensive policy that addresses all fecal contamination, including fecal contamination that is not visible. We disagree.

Fecal contamination is a visible food safety defect that can be removed by trimming or reprocessing. FSIS’s existing regulations and policies require that meat and poultry slaughter establishments implement measures to prevent and control contamination of carcasses by fecal material. For example, as noted in your petition, 9 CFR 310.18(a) requires that establishments that handle livestock carcasses and carcass parts prevent fecal contamination and promptly remove contamination if it occurs. In addition, 9 CFR 381.65(g) requires that official poultry establishments develop, implement, and maintain written procedures to prevent contamination with fecal material and enteric pathogens throughout the entire slaughter and dressing operation. Thus, under the current regulations, establishments must take action to prevent fecal contamination before it occurs and take action to control any incidental contamination that may occur during the slaughter process.

Under both the FMIA and PPIA, FSIS inspectors are required to conduct a post-mortem inspection of each carcass (21 U.S.C. 455(b) and 21 U.S.C. 604). In addition, FSIS inspectors inspect a statistically valid random sample of carcasses for visible fecal material. During these inspection activities, FSIS inspectors will take action against any carcass or part found to be contaminated, to ensure that contaminated product does not enter the human food chain.

In addition, FSIS hazard analysis and critical control point (HACCP) regulations require meat and poultry establishments to design and adopt effective controls to prevent the occurrence of pathogens that are not visible (see 61 FR 38806, Pathogen Reduction (PR); Hazard Analysis and Critical Control Point (HACCP) Systems; July 25, 1996). Pathogens on carcasses can originate as a result of contamination during slaughter and dressing operations and can indicate a loss of process control. As noted in your petition, under the PR/HACCP final rule, slaughter establishments are required to conduct generic *E. coli* testing of meat products to monitor their ability to maintain process control (9 CFR 310.25). Under 9 CFR 381.65(g), poultry slaughter establishments are required to conduct sampling and analysis for microbial organisms at the pre-and post-chill points in the process to monitor their ability to maintain process control. These testing requirements ensure that establishments are monitoring their ability to prevent product contamination by pathogens which can originate, in part, from fecal material, on an ongoing basis. Thus, FSIS policies and regulatory requirements address fecal contamination risks beyond the “zero tolerance” visible material standard.

Existing FSIS regulations and policies ensure that adulterated meat and poultry products are identified and removed from the consumer supply chain during slaughter and processing and address various sources of adulteration, including product contamination by fecal material. Under the existing system, carcasses and parts with visible fecal contamination are not eligible to bear the mark of inspection and must be condemned if the contamination cannot be removed through trimming or reprocessing.

In your petition, you state that FSIS must condemn all carcasses contaminated by feces, including feces that are not visible. However, you do not explain how FSIS inspectors would identify carcasses affected with feces that cannot be seen. You also state that FSIS must implement “stringent and proactive rules, policies, and enforcement measures to prevent continued fecal contamination of meat and poultry” but do not identify any specific additional measures that you believe FSIS should take to “regulate feces as an adulterant.” Therefore, we do not believe that the actions requested in your petition would meaningfully address fecal contamination and associated food safety concerns at federally inspected meat and poultry establishments.

#### Referenced Studies

Your petition asserts that FSIS regularly passes at inspection meat and poultry contaminated with feces. To support this assertion, you reference various studies in which raw poultry products were sampled and tested positive for generic *E. coli* and other non-pathogenic bacteria commonly associated with the gastrointestinal tract. Based on these findings, you appear to assume that the presence of intestinal bacteria, such as generic *E. coli*, on a product means that fecal material is also present on the product. We disagree with this assumption.

First, the purpose of the USDA study referenced in your petition was to evaluate whether the number of *E. coli* bacteria in carcass rinses from young chicken slaughter establishments could be monitored for the purpose of microbial process control.<sup>1</sup> The study results focused on *E. coli* distributions at the rehang and post-chill locations in the process and on the relationship between *E. coli* and other bacteria for purposes of monitoring process control. There is nothing in this study that suggests that a carcass that tests positive for generic *E. coli* is also contaminated with fecal material.

In addition, you reference PCRM's own testing results from 2012 that you state shows that 48% of supermarket chicken samples tested positive for “feces,” and a 2013 Consumer Reports investigation that you state shows that more than half of ground turkey samples from retail stores tested positive for “fecal bacteria.” We disagree with your characterization of these results. Although feces may contain intestinal bacteria, the presence of generic *E. coli* or other bacteria on a product does not mean that the product is also contaminated with fecal material. As noted above, fecal contamination is a visible defect that can be removed by trimming or reprocessing. Thus, there is a difference between fecal contamination and the presence of bacteria on a product. The presence of *E. coli* and other enteric bacteria on meat or poultry products indicates that the bacteria is likely associated with the intestinal tract. It does not mean that the product tested positive for “feces” or “fecal bacteria” as stated in your petition.

#### Request for Mandatory Label Disclosure and Warning of the Presence of Feces

Regarding your request to amend mandatory safe handling statements on meat and poultry product labels to uniformly disclose the presence of feces, we have determined that the labeling statements you are requesting would be inconsistent with the FMIA and PPIA. To support the request, you assert that fecal material is an adulterant in all raw meat and poultry products. You also assert that because FSIS cannot guarantee that any meat or poultry product is free from

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<sup>1</sup> Altekruse SF, Berrang ME, Marks H, et al. Enumeration of *Escherichia coli* cells on chicken carcasses as a potential measure of microbial process control in a random selection of slaughter establishments in the United States. *Appl Environ Microbiol.* 2009;75(11):3522-3527.

fecal contamination, labels that do not uniformly disclose the potential presence of fecal material are false and misleading. We disagree.

First, we reject the petition's underlying assumption that meat and poultry products that bear the mark of inspection are likely to be contaminated with feces. As noted above, fecal contamination is a visible food safety defect that can be removed by reprocessing or trimming. Although fecal material may contain pathogens and other bacteria that cannot be detected by visual examination, the fecal material itself can be visually detected and removed. In addition, under the existing regulations, establishments must take action to prevent fecal contamination before it occurs and take action to control any incidental contamination that may occur during slaughter.

As discussed above, FSIS enforces a zero-tolerance safety standard for visual fecal material and does not allow products contaminated by feces to enter commerce because they would be adulterated under the FMIA or PPIA. Thus, the appropriate course of action to address a meat or poultry carcass or part thereof contaminated by feces that cannot be removed by trimming or reprocessing would be to condemn the carcass or part, not declare the presence of feces in the product's labeling. Additionally, while your petition and addendum assert that chicken carcasses absorb fecal material from the scald vat or chiller, you do not include any data or scientific studies to support this assertion. Therefore, because FSIS does not allow carcasses or parts with visible fecal contamination to enter commerce, the label statement that a meat or poultry product "may be permeated with feces" requested in your petition would be false and misleading to consumers.

#### Request to Revise the Poultry Inspection Legend to Remove the Term "Wholesome" and Explicitly Warn of the Presence of Feces

In addition to the labeling changes requested above, you also request that FSIS amend the official poultry inspection legend to remove the word "wholesome" and to explicitly warn consumers that the product may contain feces. You state that FSIS has regulatory discretion over the text of the inspection legend and assert that because "fecal contamination is common and even expected," the statement "inspected for wholesomeness" prescribed in 9 CFR 381.96 is false and misleading. We disagree.

First, as discussed above, we disagree with the petition's underlying assumption that meat and poultry products that bear the mark of inspection are likely to be contaminated with feces. FSIS enforces a zero tolerance for visible fecal contamination and would not apply the mark of inspection to products contaminated by feces. Thus, we disagree with your assertion that poultry products that bear the mark of inspection may not be wholesome.

We also disagree with your assertion that USDA has regulatory discretion to revise the text of the poultry inspection legend to suggest that the product is somehow unwholesome. The PPIA states that "the term 'official inspection legend' means any symbol... showing that an article was inspected for wholesomeness..." (21 U.S.C. 453(m)). The PPIA also requires that product labels bear the official inspection legend (21 U.S.C. 453(n)(12)). These statutory provisions clearly require that the labeling of poultry products bear an inspection legend that shows that the product was inspected for wholesomeness. A statement that warns that a product "may contain feces" as requested in your petition is inconsistent with the PPIA and would be misleading to consumers because it suggests that the product may be unwholesome. As discussed above, under the PPIA, poultry products that are unwholesome or otherwise adulterated must be condemned and cannot bear the mark of inspection, except when they can be made not

adulterated through trimming or reprocessing in accordance with implementing regulations (21 U.S.C. 455(c)).

For the reasons discussed above, we are denying your petition. Your petition has been published to the FSIS website, in accordance with Agency regulations. We will publish this letter as well. If you have any questions concerning the status of your petition, you may contact Mary Porretta, Petitions Manager, Issuances Staff, at (202) 720-5627.

Sincerely,

A handwritten signature in cursive script, appearing to read "Roberta Wagner".

Roberta Wagner  
Assistant Administrator  
Office of Policy and Program Development