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Carmen Rottenberg  
Administrator  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
331-E Jamie L. Whitten Federal Bldg.  
Washington, DC 20250-3700

**Re: Petition to Amend 9 CFR § 381.82, 381.36(f)(3), § 381.76(b)(6)(iv) to Treat Avian Leukosis as a Trimmable Condition**

Dear Administrator Rottenberg:

The National Chicken Council (NCC) respectfully submits this petition requesting that the Food Safety and Inspection Service (FSIS) amend its regulations to recognize avian leukosis as a trimmable condition. Specifically, we request that FSIS (1) amend 9 C.F.R. § 381.82 to treat lesions that could be suspected as being caused by avian leukosis as a trimmable condition and not a condition that requires whole bird condemnation, and (2) that FSIS remove the provisions in 9 C.F.R. § 381.36(f)(3) and § 381.76(b)(6)(iv) related to checking the first 300 birds from an incoming flock for avian leukosis in all poultry slaughter establishments operating under the New Poultry Inspection System (NPIS). Amending the regulations is supported by scientifically and economically sound rationales: avian leukosis does not present a food-safety risk, modern understanding of the avian disease is much more advanced than when FSIS first developed its policy, the condition is not a systemic disease, modern vaccination and breeding programs have all but eliminated avian leukosis, and amending the regulation would reduce unnecessary regulatory burdens.

**I. Requested Actions**

NCC requests that FSIS amend the following regulations to recognize avian leukosis as a trimmable condition and to eliminate the requirement of a 300-bird check by FSIS at the

beginning of each flock in all poultry slaughter establishments operating under NPIS: 9 C.F.R. § 381.82; 9 C.F.R. § 381.36(f)(3); and § 381.76(b)(6)(iv). The current regulations read as follows:

9 CFR § 381.82

Carcasses of poultry affected with any one or more of the several forms of the avian leukosis complex shall be condemned.

9 C.F.R. § 381.36(f)(3)

Each young chicken establishment operating under NPIS must provide a location at a point along the production line after the carcasses are eviscerated at which an inspector may safely and properly inspect for leukosis the first 300 carcasses of each flock together with associated viscera either uniformly trailing or leading, or otherwise identified with the corresponding carcass. The leukosis inspection area must provide a minimum of 200 foot-candles of shadow-free lighting on the surface where the viscera are inspected.

9 CFR § 381.76(b)(6)(iv)

(6) The following requirements are applicable to the NPIS:

...

(iv) *Inspection for Avian Visceral Leukosis.* (A) Establishments that slaughter young chickens must notify the inspector-in-charge prior to the slaughter of each new flock to allow the inspection of viscera as provided in §381.36(f)(3).

(B) If there is evidence that a flock may be affected by avian visceral leukosis, the inspector-in-charge is authorized to adjust inspection procedures as needed to ensure adequate inspection of each carcass and viscera for that condition. The inspector-in-charge is also authorized to require the establishment to adjust its processing operations as needed to accommodate the adjusted inspection procedures.

We propose to amend the regulations as follows, with proposed delete portions crossed out, and proposed additions bolded:

9 CFR § 381.82

Carcasses of poultry affected with **lesions attributable to** any one or more of the several forms of the avian leukosis complex ~~shall be condemned~~ **may be passed for food after complete removal and condemnation of all affected tissues.**

9 C.F.R. § 381.36(f)(3)

~~Each young chicken establishment operating under the New Poultry Inspection System must provide a location at a point along the production line after the carcasses are eviscerated at which an inspector may safely and properly inspect for leukosis the first 300 carcasses of each flock together with associated viscera either uniformly trailing or leading, or otherwise identified with the corresponding carcass. The leukosis inspection area must provide a minimum of 200 foot candles of shadow free lighting on the surface where the viscera are inspected.~~

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## II. Support for Requested Actions

### a. Treating Avian Leukosis as a Trimmable Condition Would Not Impair Food Safety

FSIS's existing avian leukosis regulations are based on an outdated, 1950's era understanding of poultry diseases. Modern poultry science has clearly identified the etiology of avian leukosis, and widespread industry efforts have effectively eradicated the clinical forms of the disease in commercial broiler flocks. Moreover, FSIS and sister public health authorities have long recognized that avian leukosis does not pose a food safety risk to humans. Therefore, NCC believes that it is scientifically appropriate to amend FSIS's regulations to treat potential leukosis lesions as a trimmable condition and to eliminate the FSIS leukosis check for incoming flocks.

Since at least 1996, processors have had to provide sound, scientifically supportable justifications to support their food safety systems under the Pathogen Reduction/Hazard

Analysis and Critical Control Point (HACCP) Final Rule.<sup>1</sup> NPIS likewise is driven by science-based decision-making, allowing FSIS to focus its resources on food safety rather than addressing quality issues and customer specifications. Now is an appropriate time to revisit FSIS's approach to avian leukosis to ensure that it, too, reflects sound scientific principles.

When the poultry disposition regulations first were written in the 1950's, the etiology of many poultry diseases were unknown. Because scientific understanding was more limited, many of the condemnation determinations were based on imperfect information or parallels drawn from other species.<sup>2</sup> When avian leukosis inspection procedures were developed, the etiology of leukosis was largely unknown. Scientists now understand that leukosis is caused by two different types of viruses: a herpes virus known as Marek's Disease and a group of retroviruses known as the Avian Leukosis Complex. Marek's Disease is typically associated with younger birds, while Avian Leukosis Complex affects birds closer to maturity (age 16 weeks or older).

Modern treatment and flock handling practices, though, have effectively eliminated these diseases in commercial broiler and breeder operations. Nearly all birds are vaccinated against Marek's Disease as embryos or chicks, and the disease prevalence has been effectively eliminated from commercial flocks.<sup>3</sup> Scientists have learned that some retroviruses (known as endogenous retroviral fragments) are associated with the chicken's genome and are passed vertically from one generation to the next. Retroviruses not associated with the genome (known as exogenous virus) may cause disease, but selective breeding and biosecurity practices have virtually eliminated Avian Leukosis Complex from U.S. broiler, broiler-breeder, and primary breeding flocks.<sup>4</sup>

In rare cases, carcasses have been identified that have tissues (a spleen, liver, or feather follicle, for example) with "suspicious" lesions that might be attributed to leukosis. In these cases, per current FSIS regulations, these carcasses and associated viscera are condemned. Tissues from some of these condemned carcasses and "normal" (control) carcasses have been submitted to the Poultry Diagnostic and Research Center (PDRC) in Athens, GA, for viral genomic analysis (lab

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<sup>1</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 61 Fed. Reg. 38806 (July 25, 1996).

<sup>2</sup> For example, one poultry-associated lesion was identified as "squamous cell carcinoma" because the lesions looked like those found in Hereford cows. For over 40 years, these lesions continued to be identified incorrectly. From a product viability standpoint, when two or more of these lesions were present, the entire carcass was condemned because there was "evidence of metastasis," in spite of evidence to the contrary. FSIS Notice 17-01, 5/17/01, New Disposition Instructions for Avian Keratoacanthoma. After years of erroneous identification, in May 2001, FSIS published a Notice that correctly identified the lesion as a hyperkeratotic lesion, a keratoacanthoma, and now the lesion is allowed to be trimmed. *Id.*

<sup>3</sup> Modernization of Poultry Slaughter Inspection; Proposed Rule, 77 Fed. Reg. 4408, 4422 (Jan. 27, 2012).

<sup>4</sup> Of the few carcasses that are condemned for avian leukosis, most likely in fact have some other non-leukosis condition. Avian leukosis is typically identified by white spots. White spots are not a symptom unique to avian leukosis and can be caused by various more common conditions that do not lead to whole bird condemnations. Confirming avian leukosis involves costly and time-consuming laboratory analysis. Because one or two carcasses do not justify that cost, establishments rarely challenge an inspector's preliminary leukosis determination.

reports accompany the petition). The first four samples of the eight samples submitted were “suspects” for leukosis lesions, while the last four were “controls” without lesions. The samples were tested for Marek’s Disease, Reticuloendotheliosis virus (REV), exogenous Leukosis virus (Non-chromosomal retrovirus, Group J), and endogenous Leukosis (retroviral fragments located within the chromosome, Group A-E). As expected, because all the birds were vaccinated, all the tissues were positive for Marek’s, regardless of whether they were from “suspect” or “control” samples. Likewise, all samples were positive for endogenous Leukosis, which is passed from the parents to their progeny. However and most importantly, due to selective breeding and biosecurity practices, none of the samples were positive for REV – the potentially avian disease-causing exogenous Leukosis viruses.<sup>5</sup>

Thus, through the development of vaccines and careful selection practices in the development of the genetic breeding stock, the clinical manifestations and lesions of these diseases have been virtually eliminated. The Agency’s own data supports the conclusion that avian leukosis is a “rare manifestation” in broilers.<sup>6</sup> Even as early as 1984, according to the Agency’s data, avian leukosis was present in only 0.017 percent of young chickens slaughtered.<sup>7</sup> That number is less than 0.001% today.<sup>8,9</sup>

Furthermore, as the Agency itself has recognized, avian leukosis “is not transmissible to humans” and “does not present a human health concern,”<sup>10</sup> a fact the Agency has acknowledged since at least 1997.<sup>11</sup> The viruses that cause leukosis are species-specific and cannot be transmitted to humans. The National Institutes of Health (NIH) has declared that neither virus “is associated with disease in healthy adult humans.”<sup>12</sup> Comprehensive literature reviews of Marek’s Disease and Avian Leukosis Complex have also concluded that neither disease presents any apparent risk to public health.<sup>13</sup>

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<sup>5</sup> PDRC, 953 College Station Road, Athens, GA 30605 Case# 125237 (Suspects), and Case# 125238, (Controls). Case# 123946 with suspects (1-4) and controls (5-8).

<sup>6</sup> *Id.* at 4421.

<sup>7</sup> *Id.* at 4422.

<sup>8</sup> In the 18-year history of the HAACP-Based Inspection Models Project (HIMP), where USDA determines if a flock is affected with leukosis, few, if any leukosis flocks were identified. Indeed, with the number of affected carcasses being so low, one might speculate that those lesions recorded as “leukosis” are more than likely an error in either disposition and/or recordkeeping.

<sup>9</sup> Of the few carcasses that are condemned for avian leukosis, most likely in fact have some other non-leukosis condition. Avian leukosis is typically identified by white spots. White spots are not a symptom unique to avian leukosis and can be caused by various more common conditions that do not lead to whole bird condemnations. Confirming avian leukosis involves costly and time-consuming laboratory analysis. Because one or two carcasses do not justify that cost, establishments rarely challenge an inspector’s preliminary leukosis determination.

<sup>10</sup> *Id.* at 4421–22.

<sup>11</sup> See 62 Fed. Reg. 31553, (June 10, 1997) (“Aesthetic conditions with no known food safety concerns include leukosis, other tumors, and airsacculitis.”).

<sup>12</sup> National Institutes of Health, NIH Guidelines for Research Involving Recombinant DNA Molecules 44, app’x B.V (Oct. 2011).

<sup>13</sup> H.G. Purchase and R.L. Witter, *Public Health Concerns From Human Exposure to Oncogenic Avian Herpesvirus*, 189 J. Am. Vet. Med. Ass’n 1430 (1986); E.S. Johnson, *Poultry Oncogenic Retroviruses and Humans*,

However, despite avian leukosis being a rare and non-systemic condition, FSIS's regulations still require that any carcass that has a single potential leukosis lesions be condemned along with its viscera. This is inconsistent with current inspection practices and imposes a needless burden on operations by requiring that viscera be maintained with the carcasses.<sup>14</sup> Flock-wide checks are unnecessary because vaccinations and breeding have effectively eliminated the risk of flock-wide avian leukosis. Checking flocks specifically for avian leukosis and treating the condition as a whole-bird condemnable condition reflects outdated inspectional approaches that are not scientifically sound given modern flock management practices and an evolved scientific understanding of leukosis. Establishments would, and should, be required to remove any visible lesions, regardless of whether they are associated with leukosis or another condition.<sup>15</sup> However, building a separate inspection station to FSIS standards, requiring FSIS to inspect the first 300 birds of each flock, and condemning whole carcasses due to potential signs of leukosis, imposes an unnecessary burden on establishments and inspectors with no corresponding public health benefit. As a result, NCC respectfully requests that FSIS remove those requirements from 9 C.F.R. § 381.36(f)(3) and § 381.76(b)(6)(iv).

In summary, the FSIS avian leukosis check and whole bird condemnation requirement serve no meaningful public health purpose and continuing to mandate these requirements reflects outdated inspection practices that are not scientifically sound given today's understanding of leukosis and modern flock management practices. A scientifically based inspection system should treat avian leukosis consistent with any other trimmable condition where establishments are required to remove any visible lesions, regardless of whether they are associated with leukosis or another condition.

#### **b. The Current Regulations Impose Cost on the Industry and Consumers with No Discernible Public Benefit**

FSIS's current approach to avian leukosis imposes costs that yield no benefits. Avian leukosis does not present a risk to human health or a food safety issue. If leukosis lesions are found, they can be trimmed, and the remaining parts of the carcass would remain safe and wholesome. The current regulations, however, result in needless waste of entire carcasses and needlessly consume Agency resources. Moreover, by maintaining avian leukosis as a whole-bird-condemnable

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18 Cancer Detection & Prevention 9 (1994); K.A. Schat and H.N. Erb, *Lack of Evidence That Avian Oncogenic Viruses Are Infectious for Humans: A Review*, 58:345-358 Avian Diseases (2014); K.A. Schat, *History of the First-Generation Marek's Disease Vaccines: The Science and Little-Known Facts*, 60:715-724 Avian Diseases (2016).

<sup>14</sup> *Poultry Inspection: The Basis for a Risk-Assessment Approach* published by the National Research Council (US) Committee on Public Health Risk Assessment of Poultry Inspection Programs. Washington (DC): National Academies Press (US); 1987. ISBN-10: 0-309-03743-3.

<sup>15</sup> Indeed, the white spots on livers associated with leukosis can be caused by numerous other conditions. Industry experience is that testing the few birds that are condemned for leukosis shows the birds actually had a different, trimmable condition.

condition, establishments are required to implement systems for keeping viscera associated with carcasses. This adds additional burdens to production, as entire processing operations must be designed to maintain viscera with carcasses through the inspection point, again with no public health benefit. Moreover, establishments entering NPIS have had to reconfigure lines and make other changes to build inspection stands that do not further public health. Given that processing plants have finite space, the space used for inspection stands could be better devoted to other uses. Incrementally, these costs and inefficiencies add up, resulting in overall higher production costs without any corresponding public benefit. They also needlessly tie up FSIS resources that could be better devoted to other inspection activities.

NPIS was intended to be a voluntary inspection program whereby establishments would receive greater operational flexibility and control in exchange for more rigorous, science-based food safety oversight. In short, the program was intended to improve food safety outcomes and generate cost efficiencies for both plants and FSIS. But requiring 300 bird checks by FSIS as well as treating the rare occurrence of lesions suspected as being caused by leukosis as a condemnable condition runs counter to these principals and detracts from the advantages of modernized inspection. These regulations pose a potential barrier to establishments opting into NPIS. Thus, requiring 300 bird checks by FSIS and condemning all flocks/carcasses that exhibit potential leukosis lesions has caused the industry and the Agency to forego potential cost savings associated with making better use of resources, all without any offsetting benefit to food safety.

### **c. Amending the Regulation is Consistent with the President's Regulatory Reform Agenda**

Treating avian leukosis as a trimmable condition and removing the 300-bird check for leukosis would provide regulatory cost savings and reduce the regulatory burden for chicken processors, outcomes that align with the President's and the Secretary's regulatory reform initiatives.

Since first taking office, the President has initiated several regulatory reform measures intended to decrease regulatory burden on industry, eliminate ineffective or unnecessary regulations, and make the federal government more efficient. Executive Order (EO) 13771 on Reducing Regulation and Controlling Regulatory Costs states that it is the policy of the executive branch to be "prudent and financially responsible in the expenditure of funds, from both public and private sources," and it requires that for each new regulation issued, at least two existing regulations must be eliminated to offset the cost of the new regulation.<sup>16</sup> The White House Office of Management and Budget's (OMB's) guidance documents on how the EO should be implemented state that regulatory actions that produce cost savings, including regulatory actions that expand

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<sup>16</sup> Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Feb. 3, 2017).

consumption and/or production options, qualify as “EO 13771 deregulatory actions” for purposes of offsetting future regulations.<sup>17</sup>

Allowing establishments to treat avian leukosis as a trimmable condition and allowing establishments to establish their own leukosis disposition programs is consistent with these directives. It would streamline regulation and inspection, reduce burdens on American companies, direct government resources more efficiently, and ensure that regulations are science-based and effective.

## **Conclusion**

For the reasons stated herein, NCC respectfully requests that FSIS (1) amend 9 C.F.R. § 381.82 to treat potential leukosis lesions as a trimmable condition and not a condition that requires whole bird condemnation, and (2) remove the requirements in 9 C.F.R. § 381.36(f)(3) and § 381.76(b)(6)(iv) related to FSIS leukosis checks on incoming flocks. The scientific evidence supports that there is no increased food safety risk with this change, and it would reduce regulatory burdens on industry.

Thank you for your consideration of this petition. Please do not hesitate to contact me if I can provide any additional information.

Sincerely,



Ashley B. Peterson, Ph.D.  
Senior Vice President, Scientific and Regulatory Affairs  
National Chicken Council

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<sup>17</sup> See M-17-21, Memorandum: Guidance Implementing Executive Order 13771, Titled “Reducing Regulation and Controlling Regulatory Costs,” Apr. 5, 2017 (“Generally, “one-time” regulatory actions (i.e., those actions that are not periodic in nature) that expand consumption and/or production options would qualify as EO 13771 deregulatory actions.”); Memorandum: Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, Titled “Reducing Regulation and Controlling Regulatory Costs,” Feb. 2, 2017 (“Any existing regulatory action that imposes costs and the repeal or revision of which will produce verifiable savings may qualify.”)