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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549-4561



11008004

February 25, 2011

Denise A. Horne  
Corporate Vice President,  
Associate General Counsel and  
Assistant Secretary  
McDonald's Corporation  
2915 Jorie Boulevard  
Oak Brook, IL 60523

Act: 1934  
Section: \_\_\_\_\_  
Rule: 14a-8  
Public  
Availability: 02-25-2011

Re: McDonald's Corporation  
Incoming letter dated January 18, 2011

Dear Ms. Horne:

This is in response to your letter dated January 18, 2011 concerning the shareholder proposal submitted to McDonald's by The Humane Society of the United States. We also have received a letter from the proponent dated February 22, 2011. Our response is attached to the enclosed photocopy of your correspondence. By doing this, we avoid having to recite or summarize the facts set forth in the correspondence. Copies of all of the correspondence also will be provided to the proponent.

In connection with this matter, your attention is directed to the enclosure, which sets forth a brief discussion of the Division's informal procedures regarding shareholder proposals.

Sincerely,

Gregory S. Belliston  
Special Counsel

Enclosures

cc: Leana Stormont  
The Humane Society of the United States  
2100 L Street, NW  
Washington, DC 20037

February 25, 2011

**Response of the Office of Chief Counsel**  
**Division of Corporation Finance**

Re: McDonald's Corporation  
Incoming letter dated January 18, 2011

The proposal encourages McDonald's to create a plan for transitioning its U.S. locations to cage-free eggs.

There appears to be some basis for your view that McDonald's may exclude the proposal under rule 14a-8(i)(12)(ii). In this regard, we note that proposals dealing with substantially the same subject matter were included in McDonald's proxy materials in 2009 and 2010 and that the 2010 proposal received less than six percent of the vote. Accordingly, we will not recommend enforcement action to the Commission if McDonald's omits the proposal from its proxy materials in reliance on rule 14a-8(i)(12)(ii). In reaching this position, we have not found it necessary to address the alternative basis for omission upon which McDonald's relies.

Sincerely, 

Rose Zukin  
Attorney-Adviser

**DIVISION OF CORPORATION FINANCE  
INFORMAL PROCEDURES REGARDING SHAREHOLDER PROPOSALS**

The Division of Corporation Finance believes that its responsibility with respect to matters arising under Rule 14a-8 [17 CFR 240.14a-8], as with other matters under the proxy rules, is to aid those who must comply with the rule by offering informal advice and suggestions and to determine, initially, whether or not it may be appropriate in a particular matter to recommend enforcement action to the Commission. In connection with a shareholder proposal under Rule 14a-8, the Division's staff considers the information furnished to it by the Company in support of its intention to exclude the proposals from the Company's proxy materials, as well as any information furnished by the proponent or the proponent's representative.

Although Rule 14a-8(k) does not require any communications from shareholders to the Commission's staff, the staff will always consider information concerning alleged violations of the statutes administered by the Commission, including argument as to whether or not activities proposed to be taken would be violative of the statute or rule involved. The receipt by the staff of such information, however, should not be construed as changing the staff's informal procedures and proxy review into a formal or adversary procedure.

It is important to note that the staff's and Commission's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these no-action letters do not and cannot adjudicate the merits of a company's position with respect to the proposal. Only a court such as a U.S. District Court can decide whether a company is obligated to include shareholder proposals in its proxy materials. Accordingly a discretionary determination not to recommend or take Commission enforcement action, does not preclude a proponent, or any shareholder of a company, from pursuing any rights he or she may have against the company in court, should the management omit the proposal from the company's proxy material.



# THE HUMANE SOCIETY OF THE UNITED STATES

February 22, 2011

**Via electronic mail at [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov), hard copy to follow**

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Office of Chief Counsel  
Division of Corporation Finance  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

Re: Shareholder Proposal Submitted to McDonald's Regarding Cage-free Eggs in the Aftermath of the 2010 *Salmonella* Contaminated Egg Recall

Ladies and Gentlemen:

The Humane Society of the United States (the "Proponent") is the beneficial owner of common stock of McDonald's Corporation (the "Company") and has submitted a shareholder proposal (the "Proposal") to the Company seeking a shareholder advisory vote to *encourage* McDonald's to create a plan for transitioning its U.S. locations to cage-free eggs. We are responding to the no action request letter dated January 18, 2011 sent to the Securities and Exchange Commission by the Company. The Company contends that the Proposal may be excluded from the Company's 2011 proxy statement by virtue of Rule 14a-8(i)(12) (duplicative of prior proposal) and Rule 14a-8(i)(3) (vague and misleading).

We have reviewed the letter sent by the Company seeking no action relief. We urge the Staff to avoid application of Rule 14a-8(i)(12) in a manner that deprives shareholders of the opportunity to review an issue of new urgency and interest, inconsistent with the Commission's underlying purpose in adopting the rule. In addition, we document that the Proposal is not misleading or inaccurate.

A copy of this letter is being emailed concurrently to Denise A. Horne, Corporate Vice President – Associate General Counsel and Assistant Secretary, McDonald's Corporation.

As explained more fully below, this resolution presents a matter of first impression for the Staff. Specifically, that issue is whether a resolution for which the language and actions look similar to a prior proposal, and therefore which would generally be considered excludable under Rule 14a-8(i)(12) can nevertheless under radically changed circumstances be found to be nonexcludable. As discussed below, the need to apply the rule consistent with underlying investor interests was anticipated by the Commission in its adoption of the current rule in 1983. Proposing Release, 47 Fed Reg 47420, Oct. 26, 1982.

## BACKGROUND

### I. Unprecedented Egg Recall in 2010 Sets Stage for Increasing Investor Concern

A 2010 multistate outbreak of *Salmonella*<sup>1</sup> led to the largest egg recall in history—more than a half billion eggs. As the U.S. Food and Drug Administration (FDA) concluded in a 2010 press release: “Egg-associated illness caused by *Salmonella* is a serious public health problem.”<sup>2</sup> The decision by the Proponent to file the Proposal, despite a steep burden under SEC Rule 14a-8(i)(12), must be understood in light of this enormous crisis, and the increased attention that this issue therefore demands from McDonald’s investors.

*Salmonella* poisoning is the most commonly diagnosed foodborne bacterial illness in the United States,<sup>3</sup> costs the country billions,<sup>4</sup> and remains the leading cause of food-related death.<sup>5</sup> Eggs are the leading cause of human *Salmonella* infection.<sup>6</sup> In 1994, a single egg-related outbreak sickened more than 200,000 Americans.<sup>7</sup> More typically, the FDA estimates that *Salmonella*-tainted eggs sicken 142,000 Americans every year.<sup>8</sup>

Because *Salmonella* can infect the ovaries of hens, eggs from infected birds can be laid with the bacteria prepackaged inside.<sup>9</sup> *Salmonella* can then survive sunny-side-up, over-easy, and scrambled cooking methods according to research funded by the American Egg Board.<sup>10</sup> Infants and young children have been found to be at especially high risk.<sup>11</sup> Although thousands die from food poisoning every year in the United States, the vast majority of

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<sup>1</sup> Centers for Disease Control and Prevention. 2010. Investigation Update: Multistate Outbreak of Human *Salmonella* Enteritidis Infections Associated with Shell Eggs. [www.cdc.gov/salmonella/enteritidis/](http://www.cdc.gov/salmonella/enteritidis/). Last accessed Feb. 17, 2011.

<sup>2</sup> U.S. Food and Drug Administration. 2010. FDA: New Final Rule to Ensure Egg Safety, Reduce Salmonella Illnesses Goes Into Effect. [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218461.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218461.htm). Accessed Jan. 18, 2011.

<sup>3</sup> Chittick P, Sulka A, Tauxe RV, and Fry AM. 2006. A summary of national reports of foodborne outbreaks of *Salmonella* Heidelberg infections in the United States: clues for disease prevention. *Journal of Food Protection* 69(5):1150-3.

<sup>4</sup> Bryan FL and Doyle MP. 1995. Health risks and consequences of *Salmonella* and *Campylobacter jejuni* in raw poultry. *Journal of Food Protection* 58(3):326-44.

<sup>5</sup> Scallan E HRM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerging Infectious Diseases* 17(1). [www.cdc.gov/EID/content/17/1/7.htm](http://www.cdc.gov/EID/content/17/1/7.htm).

<sup>6</sup> Patrick ME, Adcock PM, Gomez TM, et al. 2004. *Salmonella* Enteritidis infections, United States, 1985-1999. *Emerging Infectious Diseases* 10(1):1-7.

<sup>7</sup> Hennessy TW, Hedberg CW, Slutsker L, et al. 1996. A national outbreak of *Salmonella* Enteritidis infections from ice cream. *The New England Journal of Medicine* 334(20):1281-6.

<sup>8</sup> U.S. Food and Drug Administration. 2009. FDA Improves Egg Safety. [www.fda.gov/ForConsumers/ConsumerUpdates/ucm170640.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm170640.htm).

<sup>9</sup> Gast RK and Beard CW. 1990. Production of *Salmonella* Enteritidis-contaminated eggs by experimentally infected hens. *Avian Diseases* 34(2):438-46.

<sup>10</sup> Davis AL, Curtis PA, Conner DE, McKee SR, and Kerth LK. 2008. Validation of cooking methods using shell eggs inoculated with *Salmonella* serotypes Enteritidis and Heidelberg. *Poultry Science* 87(8):1637-42.

<sup>11</sup> Trevejo RT, Courtney JG, Starr M, and Vugia DJ. 2003. Epidemiology of salmonellosis in California, 1990-1999: morbidity, mortality, and hospitalization costs. *American Journal of Epidemiology* 157(1):48-57.

victims suffer only acute, self-limited illnesses. *Salmonella* poisoning, however, can result in chronic arthritic joint inflammation<sup>12</sup> and persistent irritable bowel syndrome in children.<sup>13</sup>

#### A. Linkages of *Salmonella* Risk to Caged Hens

Numerous credible studies and sources suggest a link between caged hens and *Salmonella*, and that moving to a cage free system reduces the risks. This year, all 27 countries of the European Union (EU) are phasing out the use of these barren cages. To study the public health implications of this move, an EU-wide *Salmonella* survey was launched in which more than 30,000 samples were taken from more than 5,000 operations across two dozen countries. This represents the best available data set comparing *Salmonella* infection risk between different laying hen housing systems. Without exception, for every *Salmonella* serotype grouping reported and for every type of production system examined, there were significantly higher *Salmonella* rates found in operations that confine hens in cages.<sup>14</sup>

The European Food Safety Authority analysis found 43% lower odds of *Salmonella* Enteritidis contamination in cage-free barns, where hens are raised indoors, than in cage production. In organic egg production the odds of *Salmonella* contamination were 95% lower and in free-range production the odds were 98% lower.<sup>15</sup> For *Salmonella* Typhimurium, the second most common source of *Salmonella* poisoning in the United States,<sup>16</sup> there was 77% lower odds of infection when hens were raised in barns compared to cages and 93% lower odds in organic and free-range systems. For the other *Salmonella* serotypes found, compared to operations with hens in cages there was 96% lower odds in barn-raised flocks, 98% lower odds in organic flocks, and 99% lower odds in free-ranging birds. That translates into at least 25-times greater odds of contamination on factory farms that confine hens in cages compared to cage-free production. The European Food Safety Authority analysis concluded: "Cage flock holdings are more likely to be contaminated with *Salmonella*."<sup>17</sup>

Since this comprehensive survey was completed, fifteen scientific studies have been published comparing *Salmonella* risk in caged and cage-free facilities. Without exception, each of them

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<sup>12</sup> Ternhag A, Törner A, Svensson A, Ekdahl K, and Giesecke J. 2008. Short- and long-term effects of bacterial gastrointestinal infections. *Emerging Infectious Diseases* 14(1):143-8.

<sup>13</sup> Saps M, Pensabene L, Di Martino L, et al. 2008. Post-infectious functional gastrointestinal disorders in children. *The Journal of Pediatrics* 152(6):812-6.

<sup>14</sup> European Food Safety Authority. 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of *Salmonella* in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal 97. [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). Accessed March 15, 2010.

<sup>15</sup> European Food Safety Authority. 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of *Salmonella* in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal 97. [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). Accessed March 15, 2010.

<sup>16</sup> Centers for Disease Control and Prevention. 2010. Preliminary FoodNet data on the incidence of infection with pathogens transmitted commonly through food--10 States, United States, 2009. *Morbidity and Mortality Weekly Report* 59(14):418-422. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a2.htm>. Accessed Jan. 14, 2011.

<sup>17</sup> European Food Safety Authority. 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of *Salmonella* in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal 97. [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). Accessed March 15, 2010.

found higher rates of *Salmonella* in typical<sup>18</sup> battery cage production units.<sup>19,20,21,22,23,24,25,26,27,28,29,30,31,32,33</sup>

A recent article in the trade publication *World Poultry*, titled "*Salmonella* Thrives in Cage Housing," acknowledged that "the majority of the studies clearly indicate that a cage housing system has an increased risk of being *Salmonella*-positive in comparison to non-cage housing systems."<sup>34</sup> Cage-free hens experimentally infected with *Salmonella* may even clear the infection faster than caged hens.<sup>35</sup>

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<sup>18</sup> i.e. dry manure per U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services. 2000. Part II: Reference of 1999 Table Egg Layer Management in the U.S.. Layers '99, p. 42. [nahms.aphis.usda.gov/poultry/layers99/Layers99\\_dr\\_PartII.pdf](http://nahms.aphis.usda.gov/poultry/layers99/Layers99_dr_PartII.pdf). Accessed Aug. 24, 2010 and Spelling FR and Whiting NE. 2007. Environmental Management of Concentrated Animal Feeding Operations (CAFOs) (Boca Raton, FL: CRC Press, p. 387), assuming a cage-free flock size of 20,000 versus a battery cage flock size of 100,000.

<sup>19</sup> Van Hoorebeke S, Van Immerseel F, Schulz J, et al. 2010. Determination of the within and between flock prevalence and identification of risk factors for *Salmonella* infections in laying hen flocks housed in conventional and alternative systems. *Preventive Veterinary Medicine* 94(1-2):94-100.

<sup>20</sup> Snow LC, Davies RH, Christiansen KH, et al. 2010. Investigation of risk factors for *Salmonella* on commercial egg-laying farms in Great Britain, 2004-2005. *Veterinary Record* 166(19):579-86.

<sup>21</sup> 2010. Annual Report on Zoonoses in Denmark 2009. National Food Institute, Technical University of Denmark.

<sup>22</sup> Van Hoorebeke S, Van Immerseel F, De Vylder J et al. 2010. The age of production system and previous *Salmonella* infections on-farm are risk factors for low-level *Salmonella* infections in laying hen flocks. *Poultry Science* 89:1315-1319.

<sup>23</sup> Huneau-Salaün A, Chemaly M, Le Bouquin S, et al. 2009. Risk factors for *Salmonella enterica* subsp. Enteric contamination in 5 French laying hen flocks at the end of the laying period. *Preventative Veterinary Medicine* 89:51-8.

<sup>24</sup> Green AR, Wesley I, Trampel DW, et al. 2009. Air quality and bird health status in three types of commercial egg layer houses. *Journal of Applied Poultry Research* 18:605-621.

<sup>25</sup> Namata H, Méroc E, Aerts M, et al. 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4):323-36.

<sup>26</sup> Mahé A, Bougeard S, Huneau-Salaün A, et al. 2008. Bayesian estimation of flock-level sensitivity of detection of *Salmonella* spp., Enteritidis and Typhimurium according to the sampling procedure in French laying-hen houses. *Preventive Veterinary Medicine* 84(1-2):11-26.

<sup>27</sup> Pieskus J, et al. 2008. *Salmonella* incidence in broiler and laying hens with the different housing systems. *Journal of Poultry Science* 45:227-231.

<sup>28</sup> European Food Safety Authority. 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of *Salmonella* in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal 97. [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). Accessed March 15, 2010.

<sup>29</sup> Snow LC, Davies RH, Christiansen KH, et al. 2007. Survey of the prevalence of *Salmonella* species on commercial laying farms in the United Kingdom. *The Veterinary Record* 161(14):471-6.

<sup>30</sup> Methner U, Diller R, Reiche R, and Böhlend K. 2006. [Occurrence of salmonellae in laying hens in different housing systems and inferences for control]. *Berliner und Münchener tierärztliche Wochenschrift* 119(11-12):467-73.

<sup>31</sup> Much P, Österreicher E, Lassnig H. 2007. Results of the EU-wide Baseline Study on the Prevalence of *Salmonella* spp. in Holdings of Laying Hens in Austria. *Archiv für Lebensmittelhygiene* 58:225-229.

<sup>32</sup> Mollenhorst H, van Woudenberg CJ, Bokkers EG, de Boer IJ. 2005. Risk factors for *Salmonella enteritidis* infections in laying hens. *Poultry Science* 84(8):1308-13.

<sup>33</sup> Federal Institute for Risk Assessment. 2005. Pilot study on the prevalence of *Salmonella* spp. in flocks of laying hens in Germany. [http://www.bfr.bund.de/cm/208/pilotstudie\\_zum\\_vorkommen\\_von\\_salmonella\\_spp\\_bei\\_herden\\_von\\_legehennen\\_in\\_deutschland.pdf](http://www.bfr.bund.de/cm/208/pilotstudie_zum_vorkommen_von_salmonella_spp_bei_herden_von_legehennen_in_deutschland.pdf). Accessed Jan. 11, 2011.

<sup>34</sup> 2009. *Salmonella* thrives in cage housing. *World Poultry* 25(10):18-9.

<sup>35</sup> De Vylder J, Van Hoorebeke S, Ducatelle R, et al. 2009. Effect of the housing system on shedding and colonization of gut and internal organs of laying hens with *Salmonella* Enteritidis. *Poultry Science* 88:2491-5.

The leading U.S. egg industry trade group has claimed that caging hens is “better for food safety,”<sup>36</sup> but in response to a landslide vote in California to ban the practice, the editor-in-chief of the trade journal *Egg Industry* admitted that such claims are “invalid...unconvincing, unsupportable and easily refuted.”<sup>37</sup> A review funded by the American Egg Board concluded the link between the cage confinement of hens and *Salmonella* risk is inconclusive,<sup>38</sup> but only by ignoring nearly 90% of the data published over the last five years (at least 5198 of the 5907 flocks studied).<sup>39</sup>

## B. Cage Production Factors That Increase *Salmonella* Risk

The reason cage operations have consistently been found to be at such higher risk for *Salmonella* is multifactorial. From the European Food Safety Authority analysis:

In general, the higher prevalence [of *Salmonella*] in cage flocks might partly be explained by the fact that hens in the more intensive systems have a higher risk of being infected due to a relatively large flock size and higher density of hens. Moreover, cages can be difficult to disinfect and the housing may harbour breeding populations of rodents and other potential vectors such as flies or litter beetles. *Salmonella* has been shown to be more persistent in consecutive cage flocks compared with non-cage flocks in which the infection is more easily cleaned out during the empty period between flocks.<sup>40</sup>

### ***Factor 1: Greater volume of fecal dust***

Cage production facilities confine greater numbers of birds in a single building, as the caged birds are stacked in vertical tiers. There are single cage egg factories in the United States that cage millions of hens.<sup>41</sup> Such high densities of birds can produce a larger volume of contaminated airborne fecal dust, which may be responsible in part for the elevated threats to food safety posed by battery cage operations.<sup>42</sup> The latest national USDA survey of the domestic egg industry found that sheds confining more than 100,000 birds were four times more likely to be contaminated with *Salmonella*. The average number of hens confined in *Salmonella* tainted sheds in the United States was 109,777,<sup>43</sup> much higher than cage-free operations typically hold.

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<sup>36</sup> Gregory C. 2009. Letter to members of United Egg Producers. [www.unitedegg.org/](http://www.unitedegg.org/). Accessed March 15, 2010.

<sup>37</sup> Shane S. 2008. Proposition 2: Isolated anomaly...or national trend?. *Egg Industry*, December, p. 4. [www.eggindustry-digital.com/eggindustry/200812/#pg4](http://www.eggindustry-digital.com/eggindustry/200812/#pg4). Accessed March 15, 2010.

<sup>38</sup> Holt PS, Davies RH, Dewulf J et al. 2011. The impact of different housing systems on egg safety and quality. *Poultry Science* 90:251-262.

<sup>39</sup> For more information see, HSUS, “American Egg Board-Funded Review Scrambles the Science,” at [http://www.humanesociety.org/issues/confinement\\_farm/facts/egg\\_board\\_review\\_scrambled\\_science.html](http://www.humanesociety.org/issues/confinement_farm/facts/egg_board_review_scrambled_science.html).

<sup>40</sup> European Food Safety Authority. 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of *Salmonella* in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal 97. [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). Accessed March 15, 2010.

<sup>41</sup> Ohio Department of Agriculture Livestock Environmental Permitting Program. 2010. [www.agri.ohio.gov/apps/lepp\\_permits/lepp\\_permits.aspx](http://www.agri.ohio.gov/apps/lepp_permits/lepp_permits.aspx). Accessed April 9, 2010.

<sup>42</sup> Namata H, Méroc E, Aerts M, et al. 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4):323-36.

<sup>43</sup> U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services. 2000. *Salmonella enterica* serotype Enteritidis in table egg layers in the U.S. National Animal Health Monitoring



### **Factor 2: More rodent disease vectors**

The preponderance of disease-carrying rodents, flies, and other pests in battery cage sheds is another factor contributing to increased *Salmonella* infection rates in cage systems. Rodent infestations are closely tied to *Salmonella* rates.<sup>44</sup> The manure pits typical of many cage operations are considered “ideal nesting grounds for rodents.”<sup>45</sup> Indeed, rodents have been found to be “particularly persistent” in cage operations because they can breed in manure pits and gain access to feeders without interference from the birds, who are confined in cages.<sup>46</sup> With more flocks per site, cross contamination between houses may also play a role in facilitating the rodent-borne spread of infection between hens in battery cage operations.<sup>47</sup>

### **Factor 3: More insect disease vectors**

According to the latest edition of Commercial Chicken Meat and Egg Production, the leading poultry science text,<sup>48</sup> one of many disadvantages of battery cage systems is that flies “are generally a greater nuisance” compared to cage-free production.<sup>49</sup> More than merely an annoyance, flies are considered vectors for *Salmonella* on egg farms.<sup>50</sup> According to Richard Axtell, a Professor Emeritus of Entomology: “By far the greatest populations of flies occur in the caged-layer houses that are widely used for commercial egg production.”<sup>51</sup> Scientists with the Food and Drug Administration agree: “In the poultry industry, the greatest numbers of houseflies and other disease-carrying flies occur in caged-layer houses (poultry houses with laying hens in cages for commercial egg production), where the flies breed in accumulated manure beneath the cages.”<sup>52</sup> In contrast, in cage-free broiler chicken houses, flies are “rarely a problem.”<sup>53</sup>

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System, Layers '99. [http://nahms.aphis.usda.gov/poultry/layers99/Layers99\\_dr\\_Salmonella.pdf](http://nahms.aphis.usda.gov/poultry/layers99/Layers99_dr_Salmonella.pdf). Accessed March 15, 2010.

<sup>44</sup> Garber L, Smeltzer M, Fedorka-Cray P, Ladely S, and Ferris K. 2003. *Salmonella enterica* serotype Enteritidis in table egg layer house environments and in mice in U.S. layer houses and associated risk factors. *Avian Diseases* 47(1):134-42.

<sup>45</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>46</sup> Davies RH. 2005. Pathogen populations on poultry farms. In: Mead GC (ed.), *Food Safety Control in the Poultry Industry* (Cambridge, England: Woodhead Publishing Limited, p. 114).

<sup>47</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>48</sup> Dale N. 2002. Book review: *Commercial Chicken Meat and Egg Production*. *The Journal of Applied Poultry Research* 11(2):224-5.

<sup>49</sup> Bell DD. 2001. Cage management for layers. In: Bell DD and Weaver WD Jr (eds.), *Commercial Chicken Meat and Egg Production*, 5th Edition (Norwell, MA: Kluwer Academic Publishers).

<sup>50</sup> Olsen AR and Hammack TS. 2000. Isolation of *Salmonella* spp. from the housefly, *Musca domestica* L., and the dump fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: Muscidae), at caged-layer houses. *Journal of Food Protection* 63(7):958-60.

<sup>51</sup> Axtell RC and Arends JJ. 1990. Ecology and management of arthropod pests of poultry. *Annual Review of Entomology* 35:101-26.

<sup>52</sup> Olsen AR and Hammack TS. 2000. Isolation of *Salmonella* spp. from the housefly, *Musca domestica* L., and the dump fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: Muscidae), at caged-layer houses. *Journal of Food Protection* 63(7):958-60.

<sup>53</sup> Axtell RC and Arends JJ. 1990. Ecology and management of arthropod pests of poultry. *Annual Review of Entomology* 35:101-26.

#### **Factor 4: Most difficult to disinfect**

*Salmonella* can survive for more than two years in dried chicken feces,<sup>54</sup> but can often be eliminated from laying hen houses with thorough cleaning and disinfection. Experts have noted, however, that cage operations are the “most difficult to clean properly”<sup>55</sup> because of the “difficulty to efficiently disinfect the cages.”<sup>56</sup> The manure pits common in cage systems, which may not even be cleared between flocks, pose additional hygiene challenges.<sup>57</sup> From a poultry science journal:

“[C]age houses are intrinsically difficult to clean and disinfect to a good standard. Cages are normally organised in 3-12 tier stacks with associated complicated structures including dropping boards/belts drinkers, automatic egg belts, and feeder systems....Residual feed in particular may facilitate the multiplication of *Salmonella* after washing. In many cases older houses have no drainage, and electrical systems may not be water-proof. Because of these limitations, some buildings have only been ‘dry-cleaned’, which is normally...not satisfactory to achieve elimination of *Salmonella*.”<sup>58</sup>

This has been validated in other countries. The Danish Veterinary and Food Administration states: “Experience shows that battery cage systems are particularly difficult to clean and disinfect.”<sup>59</sup> Research performed by the British Veterinary Laboratories Agency found “that there are particular problems with the disinfection of cage layer farms. This may be due to the larger flocks of birds kept at higher densities, which result in a larger volume of contaminated faecal material and dust, and the difficult access for cleaning in and around the cages.”<sup>60</sup>

In comparison, cleaning and disinfecting equipment in cage-free facilities has been found to be more than twice as effective in combating *Salmonella* than attempts to disinfect battery cage operation equipment.<sup>61</sup> Even saturating a battery cage operation with formaldehyde-spiked steam for 24 consecutive hours at more than 140 degrees Fahrenheit—considered a gold standard treatment<sup>62</sup> found to effectively sterilize cage-free houses for *Salmonella*—may not

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<sup>54</sup> Davies RH and Breslin M. 2003. Persistence of *Salmonella* Enteritidis Phage Type 4 in the environment and arthropod vectors on an empty free-range chicken farm. *Environmental Microbiology* 5(2):79-84.

<sup>55</sup> Gradel KO. 2004. Disinfection of *Salmonella* in poultry houses. Ph.D. thesis, February. University of Bristol Department of Clinical Veterinary Science.

<sup>56</sup> Namata H, Méroc E, Aerts M, et al. 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4):323-36.

<sup>57</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>58</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>59</sup> The Danish Veterinary and Food Administration. 2004. The national *Salmonella* control programme for the production of table eggs and broilers 1996-2002. *Fødevare Rapport* 6, March.

<sup>60</sup> Davies R and Breslin M. 2003. Observations on *Salmonella* contamination of commercial laying farms before and after cleaning and disinfection. *The Veterinary Record* 152(10):283-7.

<sup>61</sup> Davies R and Breslin M. 2003. Observations on *Salmonella* contamination of commercial laying farms before and after cleaning and disinfection. *The Veterinary Record* 152(10):283-7.

<sup>62</sup> Gradel KO. 2004. Disinfection of *Salmonella* in poultry houses. Ph.D. thesis, February. University of Bristol Department of Clinical Veterinary Science.

effectively disinfect battery cage sheds.<sup>63</sup> To combat the rise of food poisoning caused by *Salmonella*, CDC researchers have called for a “sanitary revolution in farm-animal production.”<sup>64</sup>

#### **Factor 5: More gut colonization and shedding of *Salmonella* in caged-hens**

Research published in *Poultry Science* suggests another reason that chickens raised on bedding, rather than in bare, wire cages, have lower risk. On bedding, chickens may acquire natural gut flora that competitively prevents *Salmonella* colonization.<sup>65</sup> Chicks would normally obtain natural microflora from their mothers and the environment. In industrial systems, however, chicks are no longer raised by hens but by incubators, after which they are confined in barren wire cages, potentially delaying or preventing the development of the normal adult gut flora helpful in preventing *Salmonella* infection.<sup>66</sup> Faster declines in *Salmonella* shedding have also been noted in experimentally infected cage-free hens compared to those confined in barren cages.<sup>67</sup>

#### **Factor 6: Stress due to confinement**

Physiological stress may also play a role.<sup>68</sup> In general, “the bulk of the evidence suggests that chronic or prolonged stress generally inhibits the immune response to infection, thus potentially rendering animals more susceptible to infectious disease.”<sup>69</sup> Specifically, research has shown that stress hormones can increase *Salmonella* colonization and systemic spread in chickens.<sup>70</sup> The stress hormone noradrenaline can boost the growth rate of *Salmonella* bacteria by orders of magnitude;<sup>71</sup> at the same time stress-related corticosteroids can impair the immune system.<sup>72</sup> A USDA researcher recently concluded that “there is increasing evidence to demonstrate that stress can have a significant deleterious effect on food safety.”<sup>73</sup>

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<sup>63</sup> Gradel KO, Jørgensen JC, Andersen JS, and Corry JEL. 2004. Monitoring the efficacy of steam and formaldehyde treatment of naturally *Salmonella*-infected layer houses. *Journal of Applied Microbiology* 96(3):613-22.

<sup>64</sup> Crump JA, Griffin PM, and Angulo FJ. 2002. Bacterial contamination of animal feed and its relationship to human foodborne illness. *Clinical Infectious Diseases* 35(7):859-65.

<sup>65</sup> Santos FB, Sheldon BW, Santos AA Jr, and Ferket PR. 2008. Influence of housing system, grain type, and particle size on *Salmonella* colonization and shedding of broilers fed triticale or corn-soybean meal diets. *Poultry Science* 87(3):405-20.

<sup>66</sup> Reynolds D. 2004. Tenants of the last 1.5 metres. *Microbiologist* 5(3):26-30.

<sup>67</sup> De Vylder J, Van Hoorebeke S, Ducatelle R, et al. 2009. Effect of the housing system on shedding and colonization of gut and internal organs of laying hens with *Salmonella* Enteritidis. *Poultry Science* 88:2491-5

<sup>68</sup> Humphrey T. 2006. Are happy chickens safer chickens? Poultry welfare and disease susceptibility. *British Poultry Science* 47(4):379-91.

<sup>69</sup> de Passillé AM and Rushen J. Food safety and environmental issues in animal welfare. *Revue Scientifique et Technique de l'Office International des Epizooties* 24(2):757-66.

<sup>70</sup> Methner U, Rabsch W, Reissbrodt R, and Williams PH. 2008. Effect of norepinephrine on colonisation and systemic spread of *Salmonella enterica* in infected animals: Role of catechol siderophore precursors and degradation products. *International Journal of Medical Microbiology* 298(5-6):429-39.

<sup>71</sup> Bailey MT, Karaszewski JW, Lubach GR, Coe CL, and Lyte M. 1999. In vivo adaptation of attenuated *Salmonella* Typhimurium results in increased growth upon exposure to norepinephrine. *Physiology and Behavior* 67(3):359-64.

<sup>72</sup> Shini S, Kaiser P, Shini A, and Bryden WL. 2008. Biological response of chickens (*Gallus gallus domesticus*) induced by corticosterone and a bacterial endotoxin. *Comparative Biochemistry and Physiology. Part B.* 149(2):324-33.

<sup>73</sup> Rostagno MH. 2009. Can stress in farm animals increase food safety risk? *Foodborne Pathogens and Disease* 6(7):767-76.

### C. Increased Flock Risk Directly Increases Food Safety Risk

Contemporary studies universally show higher *Salmonella* rates in dust and manure samples from cage operations provide convincing evidence that measures to eliminate cages will likely improve the safety of the food supply. USDA researchers have found that “[f]locks with high levels of manure contamination were 10 times as likely to produce contaminated eggs as were flocks with low levels,” concluding that flocks with the highest levels of contamination “appeared to pose the greatest public health threat.”<sup>74</sup> A key finding of a joint World Health Organization and Food and Agriculture Organization of the United Nations *Salmonella* risk assessment was that “[r]educing flock prevalence results in a directly proportional reduction in human health risk. For example, reducing flock prevalence from 50% to 25% results in a halving of the mean probability of illness per serving [of eggs].”<sup>75</sup>

Infected hens can lay infected eggs. Eight studies have been published comparing *Salmonella* contamination rates of the eggs themselves from barren cage production versus typical cage-free systems. Not a single one showed more *Salmonella* in cage-free eggs. All eight studies either found no *Salmonella* in eggs from either system or a trend towards higher infection rates in eggs from caged hens compared to barn-raised birds.<sup>76,77,78,79,80,81,82,83</sup>

In 1994-1995, a study was conducted at a California egg farm with both cage and cage-free housing systems, including three battery cage sheds and three cage-free barns. The prevalence of *Salmonella* in pooled egg samples from caged hens was nearly three times that of eggs from the cage-free (barn-raised) hens.<sup>84</sup> Though the farm’s free-range eggs were found to have higher rates, this was attributed to exceptional circumstances in that a creek “entirely

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<sup>74</sup> Henzler DJ, Kradel DC, and Sischo WM. 1998. Management and environmental risk factors for *Salmonella enteritidis* contamination of eggs. *American Journal of Veterinary Research* 59(7):824-9.

<sup>75</sup> World Health Organization and the Food and Agriculture Organization of the United Nations. 2002. Risk assessments of *Salmonella* in eggs and broiler chickens. Microbiological risk assessment series 2. [www.fao.org/DOCREP/005/Y4392E/Y4392E00.HTM](http://www.fao.org/DOCREP/005/Y4392E/Y4392E00.HTM). Accessed March 15, 2010.

<sup>76</sup> Barnett JL. 1998. The welfare and productivity of hens in a barn system and cages. A report for the Rural Industries Research and Development Corporation.

<sup>77</sup> Barbosa Filho JAD, Silva MAN, Silva IJO, and Coelho AAD. 2005. Egg quality in layers housed in different production systems and submitted to two environmental conditions. *Brazilian Journal of Poultry Science* 8(1):23-8.

<sup>78</sup> Food Safety Authority of Ireland. 2003. Bacteriological safety of eggs produced under the Bord Bia Egg Quality Assurance Scheme (EQAS).

<sup>79</sup> Kinde H, Read DH, Chin RP, et al. 1996. *Salmonella* Enteritidis, phage type 4 infection in a commercial layer flock in southern California: bacteriologic and epidemiologic findings. *Avian Diseases* 40(3):665-71.

<sup>80</sup> U.K. Food Standards Agency. 2004. Report of the survey of *Salmonella* contamination of U.K. produced shell eggs on retail sale. March 18. [www.food.gov.uk/multimedia/pdfs/fsis5004report.pdf](http://www.food.gov.uk/multimedia/pdfs/fsis5004report.pdf). Accessed March 15, 2010.

<sup>81</sup> Little CL, Walsh S, Hucklesby L, et al. 2006. Survey of *Salmonella* contamination of non-U.K. produced shell eggs on retail sale in the north west of England and London. Final report - Project B18012, November 15. U.K. Food Standards Agency.

<sup>82</sup> Little CL, Rhoades JR, Hucklesby L et al. 2008. Survey of *Salmonella* contamination of raw shell eggs used in food service premises in the United Kingdom, 2005 through 2006. *Journal of Food Protection* 71:19-26.

<sup>83</sup> Humphrey TJ, Whitehead A, Gawler AHL, Henley A, Rowe B. 1991. Numbers of *Salmonella enteritidis* in the contents of naturally contaminated hens’ eggs. *Epidemiology and Infection*. 106:489-496.

<sup>84</sup> Kinde H, Read DH, Chin RP, et al. 1996. *Salmonella* Enteritidis, phage type 4 infection in a commercial layer flock in southern California: bacteriologic and epidemiologic findings. *Avian Diseases* 40(3):665-71.

composed of sewage effluent” bordered the property.<sup>85</sup> More recently, the U.K. Food Standards Agency tested eggs from grocery stores. While 9 out of the 2,376 egg samples from caged hens came up positive for *Salmonella*, none of the 785 cartons of cage-free eggs tested was contaminated.<sup>86</sup> Testing foreign eggs coming into the country, the scientists found 132 of 1,329 samples of eggs from caged birds tainted with *Salmonella*, but, once again, none of the sampled eggs from cage-free facilities were found to be positive with the pathogen.<sup>87</sup>

Eating eggs from caged birds has been specifically tied to human illness. In a 2002 prospective case-control study published in the *American Journal of Epidemiology*, people who recently ate eggs from caged hens had about twice the odds of being sickened by *Salmonella* compared to people who did not eat eggs from hens kept in cages. Those eating cage-free eggs were not at significantly elevated risk.<sup>88</sup> The only other study ever published comparing egg types at a consumer level found nearly 5 times lower odds of *Salmonella* poisoning in consumers who chose free-range eggs.<sup>89</sup>

#### **D. While McDonald’s is Downplaying Risks Associated With Battery-caged Hens, The Recall Has Been a Wake-up Call For Numerous Other Organizations to Begin Incorporating Cage-free Eggs Into Their Products.**

In the months following the egg recall, these, among many other, companies and schools, etc. started incorporating cage-free eggs into their products:

- Unilever
- Kraft Foods (the world’s largest food company)
- Krispy Kreme Doughnuts
- Carnival Cruise Lines
- Royal Caribbean
- Norwegian Cruise Lines
- Ruby Tuesday
- Virgin America
- AMTRAK
- Otis Spunkmeyer
- UFood Grill
- Brattleboro Memorial Hospital
- Union Hospital

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<sup>85</sup> Kinde H, Read DH, Ardans A, et al. 1996. Sewage effluent: likely source of *Salmonella* Enteritidis, phage type 4 infection in a commercial chicken layer flock in southern California. . *Avian Diseases* 40(3):672-6.  
s. *Avian Diseases* 40(3):665-71.

<sup>86</sup> U.K. Food Standards Agency. 2004. Report of the survey of *Salmonella* contamination of U.K. produced shell eggs on retail sale. March 18. [www.food.gov.uk/multimedia/pdfs/fsis5004report.pdf](http://www.food.gov.uk/multimedia/pdfs/fsis5004report.pdf). Accessed March 15, 2010.

<sup>87</sup> Little CL, Walsh S, Hucklesby L, et al. 2006. Survey of *Salmonella* contamination of non-U.K. produced shell eggs on retail sale in the north west of England and London. Final report - Project B18012, November 15. U.K. Food Standards Agency.

<sup>88</sup> Mølbak K and Neimann J. 2002. Risk factors for sporadic infection with *Salmonella* Enteritidis, Denmark, 1997-1999. *American Journal of Epidemiology* 156(7):654-61.

<sup>89</sup> Parry SM, et al. 2002. Risk factors for salmonella food poisoning in the domestic kitchen--a case control study. *Epidemiology and Infection* 129:277-285.

- St. Vincent Hospital
- United General Hospital
- Rutland Regional Medical Center
- St. Charles Health Care
- Syracuse University
- San Diego State University
- The International Culinary Schools at the Art Institutes
- Western Connecticut State
- Arkansas Culinary School
- Boston College
- University of Maryland
- University of California at Davis
- Stanford University
- University of Central Arkansas
- New Mexico State University
- Columbia College
- University of Wyoming
- University of San Diego
- University of North Texas

## ANALYSIS

### **I. The Issue of Exclusion Based on Substantial Duplication of the Proposal With Prior Proposals Should Be Viewed in Light of Extraordinary Changing Circumstances.**

Although McDonald's correctly asserts that the Proposal deals with a similar topic to two prior proposals—the use by McDonald's restaurants of eggs produced by cage-free hens—in this case HSUS believes the SEC should apply Rule 14a-8(i)(12) in a manner to reflect extraordinary circumstances which are likely lead to inevitable increase in investor interest in this topic. This reflects the underlying purpose of the rule.

This resolution presents a matter of first impression for the Staff, namely whether a resolution for which the language and actions look similar to a prior proposal, and therefore which would generally be considered excludable under Rule 14a-8(i)(12) can nevertheless under dramatically changed circumstances be found to be nonexcludable. Arguably, this circumstance was anticipated by the Commission in its adoption of the current rule in 1983. Proposing Release, 47 Fed Reg 47420, Oct. 26, 1982.

Even though the Proposal deals with the same subject matter as a previous resolution, the social and political climate surrounding egg safety—specifically with regard to the cage confinement of hens—is so vastly different today than it was last time McDonald's shareholders voted on a similar resolution, that it would be inconsistent with the purposes of the rule to prevent shareholders from reviewing the issue again.

At the time of the adoption of the current “substantially the same subject matter” rule, the Commission said the ultimate focus should not be on the specific language or actions requested by the rule but rather whether a proposal addresses “substantially the same subject matter” raised by the prior proposal. The principal thrust of that conversation related to whether a shareholder could make modest changes in language to avoid the proposal being seen as the “substantially the same as” a prior proposal that did not get sufficient votes for reintroduction. The language “substantially the same as” had been the prior standard. The Commission, at the time of the rule change, stated its perception that security holders of a number of companies were being called upon to vote over and over again on issues on which they have shown little interest. Thus the focus of the rule change was in preventing shareholders from having to re-deliberate on a matter which was in essence unchanged and of little interest to shareholders.

However, in the current case, the underlying interest expressed by the Commission in adoption of the rule is not applicable. Here, timely real-world circumstances have changed so dramatically that the “substantive concerns” of shareholders are actually quite different today than they were when a proposal involving a substantially similar topic was previously voted upon. McDonald’s does not do business in a vacuum. Likewise, matters that affect shareholder value and investor interest cannot be measured in a timeless void that ignores massively changed circumstances in the real world. Namely, in this case, substantial concern of the risk of foodborne illness and the threat posed by *Salmonella* contaminated eggs, and increased awareness of this problem brought to light following the unprecedented 2010 *Salmonella* outbreak and subsequent egg recall. The economic consequences of this issue raise serious concerns, concerns that are now apparent in the wake of the 2010 egg recall. For example, *USA Today* reported that wholesale egg prices jumped 40 percent following the recall.<sup>90</sup> Such significant and unexpected increases in wholesale egg prices undoubtedly affect the Company and consumer confidence and subsequent demand for the Company’s products. As trade journal *Poultry International* warned, consumer confidence in shell eggs could be greatly eroded by subsequent recalls including the one that occurred in November 2010.<sup>91</sup>

In response to the proposal of the new Rule 14a-8(i)(12), the Commission faced concern from the investor community that in many instances the new rule could be overly broad and inappropriate given changing investor concerns and interests. Because of this, the Commission noted that in adoption of the new rule that application of the rule would “continue to involve difficult subjective judgments.... The Commission believes that by focusing on substantive concerns addressed in a series of proposals, an improperly broad interpretation of the new rule will be avoided....[The Commission] anticipates that those judgments will be based upon a consideration of the substantive concerns raised by a proposal rather than the specific language or actions proposed to deal with those concerns.” 1983 Release, Exchange Act Release No. 20,091

The current Proposal tests the situation in which changing circumstances have made “substantive concerns raised by the proposal” dramatically different even though the “specific language or actions” arguably have not. With the massive egg recall, investors now have cause to be far more attentive to issues of *Salmonella* risk.

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<sup>90</sup> Julie Schmit and Philip Brasher, “Wholesale egg prices are up about 40% since the start of a major recall,” *USA Today*, Aug. 25, 2010.

<sup>91</sup> Simon Shane, “The US egg industry and the salmonella recall,” *Poultry International*, Feb. 2011.

Even though the Proposal deals with a similar subject matter as a previous resolution, the social political and economic climate surrounding egg safety—specifically with regard to the cage confinement of hens—is so vastly different today as a result of the recall than it was last time McDonald’s shareholders voted on a similar resolution, that it would be inconsistent with the rule’s purposes, to prevent shareholders from reviewing the issue at this time. We recognize that this is a new twist to application of Rule 14a-8(i)(12) but believe allowing the Proposal to go forward is consistent with the intent of the Commission in adopting the rule in 1983. We urge the Staff to disallow exclusion under Rule 14a-8(i)(12).

## **II. McDonald’s Incorrectly Asserts That The Proposal Contains False and Misleading Statements.**

### **A. McDonald’s inaccurately claims the Proposal misleadingly implies the recall was related to the use of eggs from caged hens.**

Although the Company asserts the Proposal implies the recall was due to the fact eggs involved in the recall were from caged hens, instead, the Proposal accurately portrays the facts that concerns related to risks associated with caged hens have included the *Salmonella* issue, that the media picked up on this concern in coverage of the recall and that, in fact, the recall was of eggs derived from caged hens. In no place in the Proposal does it say the caging of hens caused the particular *Salmonella* outbreak. Moreover, there was ample evidence to support concern about how battery caged hens increase the risk of *Salmonella*.

### **B. McDonald’s inaccurately claims the Proposal cited media articles that incorrectly blamed caged hens for the *Salmonella* outbreak and 2010 egg recall.**

The articles cited in the Proposal by major media outlets correctly framed the issue as one in which the increased risks of battery cages are asserted as a concern raised in the aftermath of the recalls, not as the cause of the recalls. To our knowledge, none of the articles cited in the Proposal directly attributed the recall to the fact that eggs were from caged hens. Instead, the media seized on the relative risks of eggs from caged hens, and talked about the recall being a potential “wake-up call” to give more serious attention to cage-free egg sources. The paragraph in question in the Proposal states:

This issue was thrust into the public spotlight in 2010, following the massive recall of half a billion battery cage eggs due to *Salmonella* infection. The food safety consequences of using cages to confine laying hens are now a major social concern. Following the recall, a CNN story asked: “Are cages to blame for egg recall?” A *San Francisco Chronicle* headline read, “Egg recall heats up debate over caging chickens” and a *USA Today* headline read, “Salmonella Outbreak Spurs Push against Industrial Farms.” For *The New York Times*, Nicholas Kristof wrote, “Let’s hope this salmonella outbreak is a wake-up call... We can overhaul our agriculture system so that it’s ... safer ... starting with a move toward cage-free eggs.”

Here are a couple of examples of treatment of this issue from some of the coverage cited in the Proposal:



- CNN story: “Are battery cages to blame?”

The Humane Society is calling on the Iowa egg industry to phase out the use of battery cages, where egg-laying hens are crammed into tiny cages, contenting that they’re not only inhumane but that they threaten food safety.

Dr. Michael Greger, HSUS Director of Public Health and Animal Agriculture, “Every one of the quarter billion eggs involved in this recall came from hens confined in these tiny cages where they can barely move for their entire lives.” ... On the stacking of hens in cages vertically: “That leads to this huge load of contaminated airborne fecal dust, which is what spreads *Salmonella* around. Swarms of flies and rodents that breed in these massive manure pits beneath the cages. Two of the reasons why overwhelming scientific evidence has proven that this extreme confinement of hens in cages leads to increased *Salmonella* contamination. ... Every single one of the eight scientific studies published in the last five years found that, comparing cage to cage-free operations, found that the cage operations have elevated *Salmonella* risk.”<sup>92</sup>

- The *New York Times* column written by Nicholas Kristof titled “Cleaning the henhouse” said:

Repeated studies have found that cramming hens into small cages results in more eggs with salmonella than in cage-free operations. As a trade journal, *World Poultry*, acknowledged in May: ‘salmonella thrives in cage housing.’ ...

So let’s hope this salmonella outbreak is a wake-up call. Commercial farming can’t return to a time when chickens wandered unfenced and were prey to foxes (and Irish setters). But we can overhaul our agriculture system so that it is both safer and more humane — starting with a move toward cage-free eggs.<sup>93</sup>

**C. McDonald’s misleadingly claims: “none of the FDA’s findings even remotely suggests that the selection of housing type for egg-laying hens was a potential cause of the circumstances leading to the recall.”**

McDonald’s is incorrect in assuming or implying the 2010 egg recall was unrelated to the cage confinement of hens or that the FDA study was a rejection of the suggestion of the link to housing type. The FDA-identified problems with overflowing manure and infestations of rodents and flies, all of which are issues known to be exacerbated by cage housing. Cage production facilities confine greater numbers of birds in a single building, as the caged birds are stacked in vertical tiers. Such high densities of birds produce a proportionally larger volume of manure. The latest national USDA survey of the domestic egg industry found that sheds confining more than 100,000 birds were four times more likely to be contaminated with *Salmonella*. The average number of hens confined in *Salmonella* tainted sheds in the United

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<sup>92</sup> Jane Velez-Mitchell, “Are battery cages to blame?” CNN, August 20, 2010, video available at <http://www.cnn.com/video/#/video/us/2010/08/20/jvm.egg.recall.cages.hln>.

<sup>93</sup> Nicholas Kristof, “Cleaning the henhouse,” *New York Times*, September 1, 2010, available at <http://www.nytimes.com/2010/09/02/opinion/02kristof.html>.

States was 109,777,<sup>94</sup> much higher than cage-free operations typically hold. The preponderance of disease-carrying rodents, flies, and other pests in battery cage sheds is another factor contributing to increased *Salmonella* infection rates in cage systems. Rodent infestations are closely tied to *Salmonella* rates.<sup>95</sup> The manure pits typical of many cage operations are considered “ideal nesting grounds for rodents.”<sup>96</sup> Indeed, rodents have been found to be “particularly persistent” in cage operations because they can breed in manure pits and gain access to feeders without interference from the birds, who are confined in cages.<sup>97</sup> With more flocks per site, cross contamination between houses may also play a role in facilitating the rodent-borne spread of infection between hens in battery cage operations.<sup>98</sup>

According to the latest edition of Commercial Chicken Meat and Egg Production, the leading poultry science text,<sup>99</sup> one of many disadvantages of battery cage systems is that flies “are generally a greater nuisance” compared to cage-free production.<sup>100</sup> More than merely an annoyance, flies are vectors for *Salmonella* on egg farms.<sup>101</sup> According to Richard Axtell, a Professor Emeritus of Entomology: “By far the greatest populations of flies occur in the caged-layer houses that are widely used for commercial egg production.”<sup>102</sup> FDA scientists agree: “In the poultry industry, the greatest numbers of houseflies and other disease-carrying flies occur in caged-layer houses (poultry houses with laying hens in cages for commercial egg production), where the flies breed in accumulated manure beneath the cages.”<sup>103</sup> In contrast, in cage-free broiler chicken houses, flies are “rarely a problem.”<sup>104</sup>

While the Company is quick to point out the FDA found the recall was partially related to “uncaged hens” at one egg producer’s facility, it fails to cite the FDA’s description of the “uncaged” hens in question. On page 3 of the FDA’s Inspectional Observations of Quality Egg

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<sup>94</sup> U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services. 2000. *Salmonella enterica* serotype Enteritidis in table egg layers in the U.S. National Animal Health Monitoring System, Layers '99. [http://www.aphis.usda.gov/animal\\_health/nahms/poultry/downloads/layers99/Layers99\\_dr\\_Salmonella.pdf](http://www.aphis.usda.gov/animal_health/nahms/poultry/downloads/layers99/Layers99_dr_Salmonella.pdf). Accessed Feb. 19, 2011.

<sup>95</sup> Garber L, Smeltzer M, Fedorka-Cray P, Ladely S, and Ferris K. 2003. *Salmonella enterica* serotype Enteritidis in table egg layer house environments and in mice in U.S. layer houses and associated risk factors. *Avian Diseases* 47(1):134-42.

<sup>96</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>97</sup> Davies RH. 2005. Pathogen populations on poultry farms. In: Mead GC (ed.), *Food Safety Control in the Poultry Industry* (Cambridge, England: Woodhead Publishing Limited, p. 114).

<sup>98</sup> Carrique-Mas JJ and Davies RH. 2008. *Salmonella* Enteritidis in commercial layer flocks in Europe: legislative background, on-farm sampling and main challenges. *Brazilian Journal of Poultry Science* 10(1):1-9.

<sup>99</sup> Dale N. 2002. Book review: *Commercial Chicken Meat and Egg Production*. *The Journal of Applied Poultry Research* 11(2):224-5.

<sup>100</sup> Bell DD. 2001. Cage management for layers. In: Bell DD and Weaver WD Jr (eds.), *Commercial Chicken Meat and Egg Production*, 5th Edition (Norwell, MA: Kluwer Academic Publishers).

<sup>101</sup> Olsen AR and Hammack TS. 2000. Isolation of *Salmonella* spp. from the housefly, *Musca domestica* L., and the dump fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: Muscidae), at caged-layer houses. *Journal of Food Protection* 63(7):958-60.

<sup>102</sup> Axtell RC and Arends JJ. 1990. Ecology and management of arthropod pests of poultry. *Annual Review of Entomology* 35:101-26.

<sup>103</sup> Olsen AR and Hammack TS. 2000. Isolation of *Salmonella* spp. from the housefly, *Musca domestica* L., and the dump fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: Muscidae), at caged-layer houses. *Journal of Food Protection* 63(7):958-60.

<sup>104</sup> Axtell RC and Arends JJ. 1990. Ecology and management of arthropod pests of poultry. *Annual Review of Entomology* 35:101-26.

LLC (Exhibit 4 in McDonald's no action letter) the agency defined "uncaged" birds as "chickens having escaped [from cages]."

This is a critical distinction. The egg production system the HSUS cites (in its resolution) as problematic from a food safety standpoint is one that uses cages to confine birds; this is the system used by both facilities linked to the recall. The production system the HSUS asks (in its resolution) that McDonald's shareholders consider is cage-free production (in which no birds are confined in cages).

Just because some caged birds may escape from their cages and end up wandering around the facility does not make them "cage-free" birds – that is, the birds were still raised in a cage facility, even if those individual birds managed, at some point (perhaps after becoming contaminated—as a result of their cage confinement) to escape from their cages. As the data above imply, merely because a bird has escaped its cage would not render it lower risk. It is still a "caged" bird for purposes of the risk factors described above.

The reason this distinction is critical is because even birds who have escaped cages may suffer from the *Salmonella* contamination that is closely linked to the respective facility's use of cages. Moreover, the link is indeed strong, despite McDonald's claim that *Salmonella* contamination is not linked to cages. It is so strong, in fact, that a 2010 article in the poultry industry publication *World Poultry* carried the headline, "Salmonella Thrives in Cage Housing."

**D. McDonald's inaccurately claims HSUS' Proposal "incorrectly implies that eggs used in McDonald's were subject to the recent egg recall."**

In fact, the Proposal does not imply that McDonald's used eggs that were recalled. Pointing out that egg safety became a greater social concern in 2010 as a result of the recall is vastly different than stating that McDonald's eggs were linked to that recall.

However, the Proposal does *accurately* state McDonald's exclusive use of eggs from caged hens in the United States represents a food safety concern. This assertion is based on all of the above scientific evidence regarding *Salmonella* contamination in battery cage egg production, making it neither false nor misleading.

**E. McDonald's also inaccurately suggests the Proposal ignores "the fact that McDonald's quality and food safety requirements for its suppliers currently meet or exceed all applicable standards of the U.S. Department of Agriculture."**

Even though the Company's suppliers may be in compliance with standards of the U.S. Department of Agriculture (USDA), the fact that the battery cage system exacerbates risks of underlying factors in *Salmonella* outbreaks—flies, rodents, etc. places McDonald's battery cage egg source facilities under increased pressure and expense to minimize the risks of *Salmonella*.

In addition, it is critical to point out that McDonald's uses both shell (whole) eggs as well as liquid eggs in its products. As the Company states on its website: "At McDonald's, we only use

fresh...shell eggs for breakfast sandwiches, or pure liquid eggs...for scrambled or folded eggs.”<sup>105</sup>

This is relevant because the USDA has limited authority to regulate eggs for safety.<sup>106</sup> Although the USDA has some oversight over shell eggs, mainly pertaining to USDA’s voluntary fee-based shell egg grading program (grading of shell eggs for size and quality)<sup>107</sup>, the Administration FDA has primary authority to regulate eggs for food safety. The FDA’s control includes shell eggs, and the authority to prevent the spread of communicable diseases by regulating foods that may act as a vector of disease, as eggs do for *Salmonella*.<sup>108</sup> FDA.<sup>109</sup> So for McDonald’s to assert that it meets or exceeds “all applicable standards of the US Department of Agriculture” is grossly misleading, at best, because the USDA standards are not the only ones that McDonald’s must adhere to.

So what about McDonald’s liquid eggs? The USDA does regulate food safety for liquid eggs, which are required to be pasteurized, 21 U.S.C. §§1031-1056. Any requirement by McDonald’s that its egg suppliers comply with this federal law is misleading so far as public health is concerned. Pasteurization does not guarantee that eggs cannot cause people to become sickened by *Salmonella*. According to a USDA risk assessment titled “Evaluating the Effectiveness of Pasteurization for Reducing Human Illnesses from *Salmonella* spp. in Egg Products,”<sup>110</sup> even if all liquid eggs were pasteurized strictly to governmental standards (5 log reduction), pasteurized liquid eggs alone could still sicken thousands of Americans every year. In fact, the report concludes: “it is reasonable to assume that people become exposed to *Salmonella* by consuming pasteurized egg products.”

Accordingly, it’s inaccurate for McDonald’s to imply that meeting “all applicable” USDA guidelines results in *Salmonella*-free eggs—first, because USDA guidelines do not exclusively govern the eggs used by McDonald’s and secondly, because, as the 2010 egg recall made appallingly clear, existing voluntary USDA grading programs and guidelines don’t result in *Salmonella*-free eggs. Notwithstanding McDonald’s claims, the bottom line for the Company and shareholders is that dealing in eggs from caged hens puts consumers at increased risk,

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<sup>105</sup> McDonald’s, web page, “Dairy & Eggs: We answer your questions about our milk, eggs and yogurt.” [http://www.mcdonalds.com/us/en/food/food\\_quality/see\\_what\\_we\\_are\\_made\\_of/your\\_questions\\_answered/dairy\\_eggs.html](http://www.mcdonalds.com/us/en/food/food_quality/see_what_we_are_made_of/your_questions_answered/dairy_eggs.html). Accessed Feb. 19, 2011.

<sup>106</sup> See e.g. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*

<sup>107</sup> USDA, Agricultural Marketing Service, “Regulations Governing the Voluntary Grading of Shell Eggs: 7 CFR Part 56, March 30, 2008 (describing the program AMS administers: “The voluntary program provides for interested parties a national grading service based on official U.S. standards, grades, and weight classes for shell eggs. The costs involved in furnishing this grading program are paid by the user of the service.”).

<sup>108</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, and Public Health Service Act, 42 U.S.C. § 201 *et. seq.*

<sup>109</sup> USDA has responsibility for implementing the Egg Products Inspection Act, 21 U.S.C. § 1031 *et. seq.*; 7 C.F.R. pt. 56, and AMS, Shell Egg Grading and Certification, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3004376>. See also FDA’s concurrent authority over shell eggs at: FDA, Investigations Operations Manual 3.2.1.4. (2009), available at, <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>; 74 Fed. Reg. 33030 (July 9, 2009) (through which FDA regulates the prevention of *Salmonella* in shell eggs.); see also, the FDA’s statement that “FSIS and the FDA share authority for egg safety and are working together toward solving the problem of SE in eggs” available at, [http://www.fsis.usda.gov/factsheets/focus\\_on\\_shell\\_eggs/index.asp#8](http://www.fsis.usda.gov/factsheets/focus_on_shell_eggs/index.asp#8). Accessed Feb. 16, 2011).

<sup>110</sup> Latimer HK, Marks HM, Coleman ME et al. Evaluating the effectiveness of pasteurization for reducing human illnesses from *Salmonella* spp. in egg products: results of a quantitative risk assessment. *Foodborne Pathog Dis.* 2008;5:59-68.

and thereby increases risks for the Company and its shareholders. The recent recall of more than half a billion eggs from caged hens, and the science discussed above demonstrate this reality beyond any reasonable dispute.

### Conclusion

In light of the arguments above, we urge the Staff to apply Rule 14a-8(i)(12) consistent with its underlying purposes, and therefore disallow exclusion. In addition, the Company has not met its burden of proof under Rule 14a-8(i)(3) regarding false and misleading statements. Therefore, we request that the Staff inform the Company that the SEC proxy rules require denial of the Company's no-action request.

Sincerely,



Leana Stormont  
Attorney

cc:

Denise A. Horne, Corporate Vice President – Associate General Counsel and Assistant Secretary, McDonald's Corporation (via electronic mail at [denise\\_horne@us.mcd.com](mailto:denise_horne@us.mcd.com))

Matt Prescott, Director of Corporate Outreach, The Humane Society of the United States (via electronic mail at [mprescott@humanesociety.org](mailto:mprescott@humanesociety.org))

## Shareholder Resolution Regarding Food Safety

**RESOLVED** that, due to food safety concerns recently highlighted by the largest egg recall in U.S. history, shareholders *encourage* McDonald's to create a plan for transitioning its U.S. locations to cage-free eggs, as scientific studies have documented that cage-free egg facilities have significantly lower rates of *Salmonella* contamination than cage facilities.

### SUPPORTING STATEMENT

McDonald's statement that, "[f]ood safety is [our] number one priority," contradicts its exclusive domestic use of eggs from caged hens. The best available science—a study conducted by the European Food Safety Authority of more than 5,000 egg operations across 25 countries—found that cage-free facilities are significantly less likely to harbor *Salmonella*. Numerous other scientific studies published since 2005 have drawn the same conclusion. As the title of a 2010 *World Poultry* report read: "*Salmonella* Thrives in Cage Housing."

Additionally, a Johns Hopkins School of Public Health-funded study recommended phasing out cages for hens—a move also supported by The Center for Food Safety, The Consumer Federation of America and The Center for Science in the Public Interest.

This issue was thrust into the public spotlight in 2010, following the massive recall of half a billion battery cage eggs due to *Salmonella* infection. The food safety consequences of using cages to confine laying hens are now a major social concern. Following the recall, a CNN story asked: "Are cages to blame for egg recall?" A *San Francisco Chronicle* headline read, "Egg recall heats up debate over caging chickens" and a *USA Today* headline read, "Salmonella Outbreak Spurs Push against Industrial Farms." For *The New York Times*, Nicholas Kristof wrote, "Let's hope this salmonella outbreak is a wake-up call... We can overhaul our agriculture system so that it's ... safer ... starting with a move toward cage-free eggs."

Burger King, Subway, Wendy's, Quiznos, Sonic, IHOP, Denny's, Arby's, Cracker Barrel, Golden Corral, Carl's Jr., Hardee's, Kraft Foods, Sara Lee, Hellmann's and numerous other U.S. companies use cage-free eggs. In the U.K., McDonald's eggs are 100% cage-free.

**Unlike its U.S. competitors and U.K. counterpart, McDonald's U.S. doesn't use cage-free eggs.** McDonald's U.S. can begin rectifying this problem and better meet its own commitments on food safety by developing a plan to phase in cage-free eggs. We therefore believe it is in shareholders' best interest to vote FOR this resolution, which would simply *encourage* the company to move in that direction.



Denise A. Home  
Corporate Vice President  
Associate General Counsel  
Assistant Secretary  
2915 Jorie Boulevard  
Oak Brook, IL 60523  
(630) 623-3154  
email: denise\_home@us.mcd.com

Rule 14a-8(i)(12)(ii)  
Rule 14a-8(i)(3)

January 18, 2011

**BY ELECTRONIC MAIL**

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Chief Counsel  
100 F Street, N.E.  
Washington, D.C. 20549  
[shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov)

**Re: McDonald's Corporation – Shareholder Proposal Submitted by the Humane Society of the United States**

Ladies and Gentlemen:

I am the Corporate Vice President, Associate General Counsel and Assistant Secretary of McDonald's Corporation (the "Company"). The Company is submitting this letter pursuant to Rule 14a-8(j) under the Securities Exchange Act of 1934 to notify the Securities and Exchange Commission of the Company's intention to exclude from its proxy materials for its 2011 annual meeting of shareholders a shareholder proposal (the "Proposal") submitted by The Humane Society of the United States (the "Proponent"). We request confirmation that the staff will not recommend to the Commission that enforcement action be taken if the Company excludes the Proposal from its 2011 proxy materials in reliance on Rule 14a-8(i)(12)(ii), or alternatively, in reliance on Rule 14a-8(i)(3).

A copy of the Proposal and the Proponent's supporting statement, together with related correspondence received from the Proponent, is attached as Exhibit 1.

In accordance with Staff Legal Bulletin No. 14D (November 7, 2008), this letter and its exhibits are being e-mailed to [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov). In accordance with Rule 14a-8(j), a copy of this letter and its exhibits also is being sent to the Proponent.

The Company currently intends to file its 2011 preliminary proxy materials with the Commission on or about March 3, 2011 and to file definitive proxy materials on or about April 8, 2011.

**THE PROPOSAL AND PRIOR PROPOSALS**

The Proposal requests that the Company include in its 2011 proxy materials the following resolution:

“RESOLVED that, due to food safety concerns recently highlighted by the largest egg recall in U.S. history, shareholders *encourage* McDonald’s to create a plan for transitioning its U.S. locations to cage-free eggs, as scientific studies have documented that cage-free egg facilities have significantly lower rates of *Salmonella* contamination than cage facilities.” (emphasis in original)

The Company previously received from the Proponent, and included in its proxy materials for its 2010 and 2009 annual meetings of shareholders, the following proposals (together, the “Prior Proposals”):

*2010 Proposal*

“RESOLVED, that, in keeping with McDonald’s stated commitments to food safety, animal welfare and environmental issues, shareholders encourage the company to switch five percent of the eggs it purchases for its U.S. locations to “cage-free” eggs by January 2011.”

*2009 Proposal*

“RESOLVED, shareholders request that the Board of Directors adopt a policy to phase-in the use of cage-free eggs at our United States locations, in keeping with our company’s stated commitment to be an industry leader on animal welfare issues.”

A copy of the 2010 Proposal, including the supporting statement, is attached as Exhibit 2. A copy of the 2009 Proposal, including the supporting statement, is attached as Exhibit 3.

**BASES FOR EXCLUSION**

**Rule 14a-8(i)(12)(ii) – The Proposal Deals with Substantially the Same Subject Matter as Two Proposals Included in the Company’s Proxy Materials in the Last Five Years, and the More Recent of Those Proposals Did Not Receive the Support Required for Resubmission**

Rule 14a-8(i)(12)(ii) permits exclusion of a shareholder proposal if “the proposal deals with substantially the same subject matter as another proposal or proposals that has or have been previously included in the company’s proxy materials within the preceding 5 calendar years...[and] the proposal received...less than 6% of the vote on its last submission to shareholders if proposed twice previously within the preceding 5 calendar years.”

***The Proposal Deals with Substantially the Same Subject Matter as the Prior Proposals***

The Proposal and the Prior Proposals all deal with substantially the same subject matter—the use by McDonald’s restaurants of eggs produced by cage-free hens. The action requested of the Company is virtually the same in the Proposal and the Prior Proposals. The Proposal requests that “shareholders *encourage* McDonald’s to create a plan for transitioning its U.S. locations to cage-free eggs.” Similarly, the 2010 Proposal requests that “shareholders encourage the company to switch five percent of the eggs it purchases for its U.S. locations to ‘cage-free’ eggs.” And the 2009 Proposal asks that “shareholders request that the Board of Directors adopt a policy to phase-in the use of cage-free eggs at our United States locations.” In short, each of the three resolutions asks the Company to increase its use of cage-free eggs at its U.S. restaurants.

There are insignificant differences in the wording of the resolutions, relating to the reasons why the Proponent believes that shareholders should encourage the use of cage-free eggs. The Proposal



indicates that use of cage-free eggs would address “food safety concerns,” while the 2010 Proposal states that the Proponent is concerned about “food safety, animal welfare and environmental issues,” and the 2009 Proposal purports to address concerns about “animal welfare issues.” These minor differences in the Proponent’s stated rationale do not alter the fact that all of the proposals seek only one thing—a vote on whether the Company should increase its use of cage-free eggs.

Rule 14a-8(i)(12) does not require that a proposal be exactly the same as prior proposals in order to be excluded. All that is required is that the proposals deal with “substantially the same subject matter.” Proposals do not need to be worded the same way, or be based on the same rationale or supporting statement, to be deemed to involve the same “subject matter.” The Commission made that clear in 1983, when the Commission amended Rule 14a-8(i)(12)’s previous requirement that, to be excluded, a proposal must be “substantially the same proposal” as prior proposals. *SEC Release No. 34-20091* (August 16, 1983). In its 1983 release, the Commission made clear that questions concerning whether proposals deal with substantially the same subject matter “will be based upon a consideration of the substantive concerns raised by a proposal rather than the specific language or actions proposed to deal with those concerns.”

The staff has routinely permitted exclusion of proposals that substantially duplicate prior proposals, despite minor variations in language from year to year. See, e.g., *Abbott Laboratories* (January 27, 2010) (proposals dealing with the use of animals in research and product testing); *Tyson Foods* (November 10, 2009) (proposals seeking use of controlled-atmosphere killing for slaughter of chickens). And, the staff has recently addressed whether the Proponent’s various proposals relating to cage-free eggs involve the same subject matter. Last year, the staff permitted Kroger to exclude a proposal submitted by the Proponent that sought to have “shareholders encourage the Board of Directors to ensure that all of Kroger’s private label eggs are “cage-free” by June 2011.” *The Kroger Co.* (March 31, 2010). In *Kroger*, the company had previously included in its proxy statements two other proposals submitted by the Proponent, one asking shareholders to “encourage our Corporation to establish a schedule for increasing the percentage of eggs stocked from hens not confined to battery cages” and the other asking shareholders to “encourage the Corporation to commit to a time-frame in which it will phase out its sale of eggs from hens confined in battery cages.” Despite the variations in terminology and requested timeframes for implementation, the staff agreed that all of the proposals dealt with substantially the same subject matter.

#### ***The 2010 Proposal Did Not Receive the Support Necessary for Resubmission***

The 2010 Proposal was submitted to shareholders for a vote at the Company’s 2010 annual meeting of shareholders. Because the Proposal deals with substantially the same subject matter as the Prior Proposals, the Proposal would be eligible for resubmission at the Company’s 2011 annual meeting only if the 2010 Proposal received at least 6% of the vote at the 2010 annual meeting of shareholders. As reported in the Company’s Current Report on Form 8-K filed on May 24, 2010, 33,042,542 votes were cast “for” the 2010 Proposal and 593,239,933 votes were cast “against” the proposal. Accordingly, based on the calculation method set forth in *Staff Legal Bulletin* No. 14, Question F. 4 (July 13, 2001), the 2010 Proposal received only 5.2% of the vote at the Company’s most recent annual meeting of shareholders. Because the Proposal did not receive at least 6% of the vote, the Proposal is excludable under Rule 14a-8(i)(12)(ii).

#### **Rule 14a-8(i)(3) – The Proposal Contains False and Misleading Statements**

Rule 14a-8(i)(3) permits exclusion of a proposal and supporting statement if either is contrary to the Commission’s proxy rules. One of the Commission’s proxy rules, Rule 14a-9, prohibits false or misleading statements in proxy materials. The staff has indicated that a company may exclude statements contained in a proposal, or may exclude a proposal in its entirety, where the proposal contains statements

that “directly or indirectly impugn...personal reputation” or that the company “demonstrates objectively” are “materially false and misleading.” See *Staff Legal Bulletin No. 14B* (September 15, 2004).

*The Proposal Implies that the Recall Was Related to the Use of Caged Hens*

The Proposal’s supporting statement contains the following headlines:

- “The best available science...found that cage-free facilities are significantly less likely to harbor *Salmonella*.”
- “As the title of a 2010 *World Poultry* report read: “*Salmonella* Thrives in Cage Housing.”
- “...a Johns Hopkins School of Public Health-funded study recommended phasing out cages for hens...”
- “This issue was thrust into the public spotlight in 2010, following the massive recall of half a billion battery cage eggs due to *Salmonella* infection.”

The Proposal and supporting statement place the blame for the 2010 egg recall on *Salmonella* contamination caused by caged housing for egg-laying hens. Ostensibly to support this position, the Proponent cites a number of media story headlines and selected excerpts from a newspaper column.

The notion that the egg recall or *Salmonella* contamination resulted from caged hens, however, is wholly unsupported by any factual evidence. The U.S. Food and Drug Administration (“FDA”) investigated the *Salmonella* outbreak and the related egg recall and found that the likely sources of *Salmonella* infection were improper or lacking bio security controls, unsanitary conditions, shipments of contaminated chicks or hens, and tainted animal feed. Following an investigation of the egg producers associated with the recall, the FDA issued inspectional observational reports detailing the significant, objectionable conditions observed by the FDA’s investigators. Copies of the FDA’s reports, as well as the FDA’s summary of its observations, are attached as Exhibit 4. As these reports and the summary show, none of the FDA’s findings even remotely suggests that the selection of housing type for egg-laying hens was a potential cause of the circumstances leading to the recall. In fact, one of the FDA’s observations was that *uncaged* hens at one egg producer’s facility were observed cross-contaminating the chicken housing areas. Because the Proposal asserts that the *Salmonella* outbreak was caused by caging hens, the Proposal is excludable under Rule 14a-8(i)(3).

*The Proposal Incorrectly Implies that Eggs Used in McDonald’s Restaurants Were Subject to the Recent Egg Recall*

Beginning in April 2010, several hundred people in the United States were affected by a highly publicized *Salmonella* outbreak linked to eggs from two different egg producers. The recall related to this outbreak was the largest of its type in many years. The companies suspected of producing the contaminated eggs instituted a massive recall, involving approximately 500 million eggs. The recall had and continues to have a significant adverse effect on the companies that produced the eggs and the restaurants and other retailers whose customers were impacted by *Salmonella*-contaminated eggs.

The suppliers that provide eggs to McDonald’s restaurants did not purchase any eggs or egg products that included eggs supplied by any company involved in the recall. Nevertheless, the Proposal implies that McDonald’s restaurants served *Salmonella*-contaminated eggs and that transitioning to cage-free eggs will serve to eliminate similar food safety concerns in the future. The Proposal states, for example, that the Company should transition to cage-free eggs in its U.S. restaurants “due to food safety concerns highlighted by the largest egg recall in U.S. history.” In addition, the Proposal’s supporting statement states that “[t]his issue was thrust into the public spotlight in 2010, following the massive recall of half a billion battery cage eggs due to *Salmonella* infection.” The supporting statement also states that

“McDonald’s U.S. can begin rectifying this problem and better meet its own commitments on food safety by developing a plan to phase in cage-free eggs.”

The Proposal attempts to link the Company to last year’s nationwide egg recall. By tying the ultimate objective of the Proposal—transitioning to the use of eggs from cage-free hens—to the recent and well-publicized egg recall, the Proposal improperly implies that eggs supplied to McDonald’s restaurants were part of the recall. The Company’s suppliers have confirmed that the recall had no impact on the eggs supplied to McDonald’s restaurants. The Proponent’s attempt to call into question the safety of products served at McDonald’s restaurants ignores this fact, as well as the fact that McDonald’s quality and food safety requirements for its suppliers currently meet or exceed all applicable standards of the U.S. Department of Agriculture. For these reasons, the Proposal is excludable under Rule 14a-8(i)(3).

### CONCLUSION

For the reasons set forth above, it is our view that the Company may exclude the Proposal from its 2011 proxy materials under Rule 14a-8(i)(12)(ii). We request the staff’s concurrence in our view or, alternatively, confirmation that the staff will not recommend any enforcement action to the Commission if the Company so excludes the Proposal. Alternatively, in the event the staff does not concur that the Proposal may be excluded under Rule 14a-8(i)(12)(ii), it is our view that the Company may exclude the Proposal from its 2011 proxy materials under Rule 14a-8(i)(3). We request the staff’s concurrence in our view or, alternatively, confirmation that the staff will not recommend any enforcement action to the Commission if the Company so excludes the Proposal.

If you have any questions or need additional information, please feel free to contact me at (630) 623-3154. Because we will be filing a preliminary proxy statement, we would appreciate hearing from you at your earliest convenience. When a written response to this letter is available, I would appreciate your sending it to me by email at [denise\\_horne@us.mcd.com](mailto:denise_horne@us.mcd.com) or by fax at (630) 623-3512.

Sincerely,



Denise A. Horne  
Corporate Vice President,  
Associate General Counsel and  
Assistant Secretary

cc: Kristie Middleton  
The Humane Society of the United States  
Alan L. Dye  
Hogan Lovells

Enclosures

**Exhibit 1**

**Copy of the Proposal and  
Correspondence**

---

**From:** Kristie Middleton [kmiddleton@humanesociety.org]  
**Sent:** Wednesday, December 08, 2010 8:13 AM  
**To:** Santana Gloria  
**Cc:** Kristie Middleton  
**Subject:** Resolution from Humane Society of the U.S. for 2011 Proxy  
**Attachments:** image001.gif; 2011 HSUS McDonalds Shareholder Packet.pdf

Dear Ms. Santana,

Attached please find a resolution for inclusion in the proxy for the 2011 McDonald's Corporation annual meeting and a letter confirming our ownership of McDonald's Corporation common stock. If you have any questions, please let me know.

Warm regards,

Kristie Middleton  
Corporate Outreach Manager  
[kmiddleton@humanesociety.org](mailto:kmiddleton@humanesociety.org)  
t 301.721.6413 | cell 757.763.0626

The Humane Society of the United States  
2100 L Street NW | Washington, DC 20037  
[humanesociety.org](http://humanesociety.org)





**THE HUMANE SOCIETY  
OF THE UNITED STATES**

**OFFICERS**

Dr. David Clark, DVM, MS  
Chief of Veterinary Services  
Jennifer Leary, M.D., M.P.H.  
CEO  
Linda J. Conner, Esq.  
Legal Counsel  
Cathy Smith  
President of HSUS  
Richard H. Johnson  
Executive Vice President & COO  
E. Thomas Roberts  
Secretary & CFO  
Archie H. Burns, DVM  
Chief Veterinary Officer  
& Chief Animal Care  
Wynn A. Smith, Esq.  
Project Counsel & COO  
David B. Fickel  
Executive

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Chief of Fundraising  
Christy L. Hardy  
Chief of Communications  
Christy Johnson  
Chief of Marketing &  
Special Management  
Victoria B. Lawson, Esq.  
Animal Protection Director  
Henry King, Esq.  
Government Affairs  
Dale Peterson  
Public Services  
Robert G. Beck, Ph.D., DVM  
Medical Director &  
Foundation Programs  
Andrea White, Esq., Esq.  
Animal Care Services  
& Professional Services  
John M. Soper  
Communications Director  
Kathleen L. Seymour, Ph.D.  
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John J. White  
Frank G. White  
Richard E. White, Ph.D.  
William L. White, Esq.  
Andrew J. White  
Ken White  
David C. White, Esq.  
Linda White

December 8, 2010

Ms. Gloria Santona  
Corporate Secretary  
McDonald's Corporation  
One McDonald's Plaza  
Oak Brook, IL 60523-1928  
Via UPS and email ([gloria.santona@us.mcd.com](mailto:gloria.santona@us.mcd.com))

Dear Ms. Santona:

Enclosed with this letter is a shareholder proposal submitted for inclusion in the proxy statement for the 2011 annual meeting and a letter from 'The Humane Society of the United States' (HSUS) brokerage firm, Deutsche Bank, confirming ownership of McDonald's Corporation common stock. The HSUS has held at least \$2,000 worth of common stock continuously for more than one year and intends to hold at least this amount through and including the date of the 2011 shareholder meeting.

Please contact me if you need any further information or have any questions. If McDonald's will attempt to exclude any portion of this proposal under Rule 14a-8, please advise me within 14 days of your receipt of this proposal. I can be reached at 301-721-6413 or [kmiddleton@humanesociety.org](mailto:kmiddleton@humanesociety.org). Thank you for your assistance.

Very truly yours,

Kristie Middleton  
Corporate Outreach Manager

Enclosures: 2011 Shareholder Resolution  
Copy of Deutsche Bank letter

Deutsche Bank Alex. Brown



2000 Avenue of the Stars, Suite 910-N  
Los Angeles, CA 90067

Tel 310-788-6200

Fax 310-788-6222

Toll Free 800-877-2539

December 8, 2010

Ms. Gloria Santana  
Corporate Secretary  
McDonald's Corporation  
One McDonald's Plaza  
Oak Brook, IL 60523-1928


RE: Shareholder Proposal for Inclusion in the 2011 Proxy Materials

Dear Ms. Santana:

This letter serves as confirmation to verify that The Humane Society of the United States (HSUS) is the beneficial owner of at least \$2,000.00 in market value of McDonald's Corporation common stock. The HSUS has continuously held at least \$2,000.00 in market value for at least one year prior to and including the date of this letter.

Please contact me at 310-788-6203 if you need any additional information.

Sincerely,

  
Julie Ann Mohr  
Vice President  
Regulatory Analyst

## Shareholder Resolution Regarding Food Safety

**RESOLVED** that, due to food safety concerns recently highlighted by the largest egg recall in U.S. history, shareholders *encourage* McDonald's to create a plan for transitioning its U.S. locations to cage-free eggs, as scientific studies have documented that cage-free egg facilities have significantly lower rates of *Salmonella* contamination than cage facilities.

### SUPPORTING STATEMENT

McDonald's statement that, "[f]ood safety is [our] number one priority," contradicts its exclusive domestic use of eggs from caged hens. The best available science—a study conducted by the European Food Safety Authority of more than 5,000 egg operations across 25 countries—found that cage-free facilities are significantly less likely to harbor *Salmonella*. Numerous other scientific studies published since 2005 have drawn the same conclusion. As the title of a 2010 *World Poultry* report read: "*Salmonella* Thrives in Cage Housing."

Additionally, a Johns Hopkins School of Public Health-funded study recommended phasing out cages for hens—a move also supported by The Center for Food Safety, The Consumer Federation of America and The Center for Science in the Public Interest.

This issue was thrust into the public spotlight in 2010, following the massive recall of half a billion battery cage eggs due to *Salmonella* infection. The food safety consequences of using cages to confine laying hens are now a major social concern. Following the recall, a CNN story asked: "Are cages to blame for egg recall?" A *San Francisco Chronicle* headline read, "Egg recall heats up debate over caging chickens" and a *USA Today* headline read, "Salmonella Outbreak Spurs Push against Industrial Farms." For *The New York Times*, Nicholas Kristof wrote, "Let's hope this salmonella outbreak is a wake-up call... We can overhaul our agriculture system so that it's ... safer ... starting with a move toward cage-free eggs."

Burger King, Subway, Wendy's, Quiznos, Sonic, IHOP, Denny's, Arby's, Cracker Barrel, Golden Corral, Carl's Jr., Hardee's, Kraft Foods, Sara Lee, Hellmann's and numerous other U.S. companies use cage-free eggs. In the U.K., McDonald's eggs are 100% cage-free.

Unlike its U.S. competitors and U.K. counterpart, McDonald's U.S. doesn't use cage-free eggs. McDonald's U.S. can begin rectifying this problem and better meet its own commitments on food safety by developing a plan to phase in cage-free eggs. We therefore believe it is in shareholders' best interest to vote FOR this resolution, which would simply *encourage* the company to move in that direction.



**Exhibit 2**

**Copy of the 2010 Proposal**

## Humane Society of the United States Shareholder Resolution

RESOLVED, that, in keeping with McDonald's stated commitments to food safety, animal welfare and environmental issues, shareholders encourage the company to switch five percent of the eggs it purchases for its U.S. locations to "cage-free" eggs by January 2011.

### SUPPORTING STATEMENT

Burger King, Wendy's, Denny's, Quiznos, Carl's Jr., and Hardee's all use cage-free eggs in the U.S. In the U.K., 100% of McDonald's eggs are cage-free and McDonald's Australia is moving in this direction. In Europe, McDonald's has committed to exclusively use cage-free whole eggs. Keith Kenny, senior director of McDonald's European supply chain, called this "the right thing to do" and said that it is "the latest step in McDonald's evolution from being a fast food company to a company that serves good food, fast."

However, unlike its U.S. competitors and some of its foreign counterparts, McDonald's U.S. does not use any cage-free eggs. This is problematic for the following reasons:

1. McDonald's has stated its "commitment to ensuring animals are free from cruelty, abuse and neglect," which is contrary to its exclusive domestic use of eggs from hens confined in cages. McDonald's U.S. suppliers provide each hen just 72 square inches of cage space (*less than a letter-sized sheet of paper*) on which to spend nearly their whole lives; this is not even enough room for hens to spread their wings.

The prestigious Pew Commission on Industrial Farm Animal Production—an independent panel including former U.S. Agriculture Secretary Dan Glickman—concluded that battery cages should be phased out. The *Netherlands Journal of Agricultural Science* reported that on a zero-to-ten animal welfare scale, battery cages rank 0.0; typical U.S. cage-free production scored nearly 6.0.

2. McDonald's states that "[f]ood safety is [our] number one priority," but the *American Journal of Epidemiology* reported that eating eggs from caged hens results in 250% increased likelihood of contracting *Salmonella*. The Center for Food Safety, Consumer Federation of America and Center for Science in the Public Interest have all opposed battery cages and the Pew Commission recommendations were also based on food safety concerns.
3. McDonald's states that it has "a long-standing record of industry leadership in environmental conservation" but major environmental organizations—including Natural Resources Defense Council, the Sierra Club, the Union of Concerned Scientists and Greenpeace—have all opposed battery cage egg production.
4. McDonald's exclusive use of eggs from caged hens in the U.S. is inconsistent with emerging legislative trends; most notably, California and Michigan have outlawed the use of battery cages (with phase-out periods).

By using even five percent cage-free eggs, McDonald's U.S. can keep pace with its domestic competitors and foreign counterparts and better meet its own commitments to animal welfare, food safety and the environment. We therefore believe it is in shareholders' best interest to vote FOR this resolution, which would simply *encourage* the company to use some cage-free eggs in the U.S. by 2011.

**Exhibit 3**

**Copy of the 2009 Proposal**

## Shareholder Resolution

Whereas, in our 2008 Corporate Responsibility Report, McDonald's Corporation (the Corporation) commits to "ensure industry-leading animal husbandry practices" and our "Animal Welfare Guiding Principles" express our "commitment to ensuring animals are free from cruelty, abuse and neglect."

McDonald's has implemented cage-free egg purchasing policies in other countries: we have committed to phase out all 'caged' whole eggs in our EU restaurants by the end of 2010 and 100% of the Corporation's UK egg sales are already cage-free. Conversely, no eggs sold by McDonald's-US are cage-free. McDonald's-US not only lags behind McDonald's-UK, but also behind domestic competitors. Burger King, Denny's, Carl's Jr., and Hardee's all use cage-free eggs in the US. As a result, "industry-leading best practices" increasingly mean shunning battery cage confinement. In addition to these competitors, other major players in the restaurant and food-service industries and scores of universities are already moving in that direction.

Typically, caged egg-laying hens are confined in wire battery cages so small the birds cannot even spread their wings. Under McDonald's current guidelines, our US suppliers need only provide hens a mere 72 square inches of cage space—less than a letter-sized sheet of paper—on which to spend nearly their whole lives.

The prestigious Pew Commission on Industrial Farm Animal Production—an independent panel including former US Secretary of Agriculture Dan Glickman—concluded after an extensive two-year study that battery cages for laying hens should be phased out on animal welfare and food safety grounds.

In October 2008, *The New York Times* editorial board noted: "[Industrial farming] means endless rows of laying hens kept in battery cages so small that the birds cannot even stretch their wings. No philosophy can justify this kind of cruelty, not even the philosophy of cheapness." [emphasis added]

In November, Californians overwhelmingly passed the Prevention of Farm Animal Cruelty Act, criminalizing the confinement of laying hens in battery cages (with a phase-out period), punishable by jail time and fines. California, in addition to being our nation's most populous state, is the birthplace of McDonald's, and home to more than 600 McDonald's restaurants.

The Corporation's own US Animal Welfare Council member Diane Halverson states: "The standard industry practice of confining laying hens in battery cages is an institutionalized cruelty that must be abolished."

**RESOLVED**, shareholders request that the Board of Directors adopt a policy to phase-in the use of cage-free eggs at our United States locations, in keeping with our company's stated commitment to be an industry leader on animal welfare issues.

### SUPPORTING STATEMENT

In the proponents' opinion, our company risks loss of business and reputation by not switching to cage-free eggs; our lack of progress on this issue in the US belies our animal welfare policy. By phasing in cage-free eggs, McDonald's can keep pace with competitors and better meet public expectations and our own commitments to animal welfare.

We urge you to vote FOR the resolution.

**Exhibit 4**

**FDA Inspectional Observation Reports and Summary of Observations**

Source: <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm224855.htm>

### **Additional Information**

**Quality Egg LLC is the legal name of the business in Iowa, which includes a number of layer farms, pullet farms and a feed mill.**

The (layer) farms operate as Quality Egg LLC, Wright County Egg Division. The pullet farms operate under Quality Egg LLC, (DeCoster) Farms or (DeCoster) Feed Mill and are DBA's (Doing Business As) Quality Egg LLC's for the Quality LLC Feed Mill which supplies feed for Wright County Egg Division and also to Hillandale Farms.

Generally speaking the names are often used interchangeably among Quality Egg, Wright County Egg and (DeCoster) Farms.

**Among the observations noted by FDA investigators at Wright County Egg were the following:**

**Failure to fully implement and follow procedures in its *Salmonella* Enteritidis Prevention Plan. Examples include:**

- Failure to prevent stray poultry, wild birds, cats and other animals from entering poultry houses. Outside access doors to manure pits were pushed out by the weight of manure which was piled in some cases four to eight feet high thereby providing openings into the poultry houses for wildlife or other animals.
- Animals, including rodents, were able to enter the poultry houses due to structural damage that included things like missing siding and air vents or gaps at the bottom of doors.
- Failure to eliminate birds from laying houses and to control rodents or flies: investigators observed bird nests and birds in one poultry house, live rodents in at least one poultry house at several plants, and live and dead flies that were too numerous to count in poultry houses at certain plants.
- Live flies were observed on and around egg belts and walkways to different sections of the egg laying areas.
- Live flies were crushed underfoot when employees walked in the aisles at work and there were live and dead maggots observed in the manure pit at one plant.
- Investigators observed the failure to implement practices to protect against the introduction or transfer of *Salmonella* Enteritidis between and among poultry houses.
- Specifically, investigators observed a lack of separate entrances to each poultry house, thus requiring the use of shared corridors between certain houses.
- Employees were observed failing to change protective clothing when moving from one house to another, and failed to clean and sanitize equipment prior to moving between poultry houses at one plant.

## Hillandale Farms

The 483 for Hillandale covers observations made at two separate plants, each consisting of multiple houses. This inspection was conducted August 19-26, 2010.

### Among the observations noted by FDA investigators:

- Failure to fully implement and follow procedures in its *Salmonella* Enteritidis Prevention Plan. Examples:
  - Failure to eliminate entryways for rodents and other pests into the egg production facilities. Failure to bait and seal rodent burrow holes in the egg production facilities and to eliminate the potential rodent or pest harborage places near the structures.
  - Failure to eliminate standing water adjacent to the manure pits or to eliminate liquid manure.
- Investigators observed that the company failed to maintain documentation that 19-week-old pullets were monitored for *Salmonella* Enteritidis, or raised under SE-monitored conditions.
- Failure to take steps to make sure that SE isn't transferred into or among poultry houses: Investigators observed uncaged hens tracking manure from the manure pits to the caged house areas.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10
	FEI NUMBER 3006481643, 3004793793, 3005280357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
 TO: Mr. Peter A. DeCoster, COO FEI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
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CITY, STATE AND ZIP CODE Galt, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer
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**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**  
 THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE (S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

Observations listed below cover inspections of your egg laying farms/plants inspected from 08/12/2010 through 08/30/2010. Inspections of Layers 1, 3 and 6 included record review and environmental assessments of all houses. Inspections of Layers 2 and 4 included record review of all houses and environmental assessments for Layer 2 - Houses 7 and 11 and Layer 4 - House 3.

- FEI: 3006481643 - Quality Egg LLC, Plant/Layer 1, 2615 280<sup>th</sup> Street, Galt, IA 50101
- FEI: 3004793793 - Wright Co. Egg, Plant/Layer 2, 2550 270<sup>th</sup> Street, Clarion, IA 50525
- FEI: 3005280357 - Quality Egg LLC, Plant/Layer 3, 2674 270<sup>th</sup> Street, Clarion, IA 50525
- FEI: 3004797952 - Wright Co. Egg, Plant/Layer 4, 2680 250<sup>th</sup> Street, Clarion, IA 50525
- FEI: 3006481709 - Quality Egg LLC Environ, Plant/Layer 6, 2865 310<sup>th</sup> Street, Dows, IA 50071
- FEI: 3003073159 - Quality Egg LLC Feed Mill, 2624 Highway 69, Galt, IA 50101

I. You failed to fully implement and follow your written SE prevention plan.

Specifically,

a) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/1/10, reads in part (Page 8, under section (b) (4) [redacted] (b) (4) [redacted]). This had not been accomplished as evidenced by the following observations:

- Layer 3 - House 1 - approximately 2x6 inch wood board was observed on the ground with approximately 8 frogs living underneath.
- Layer 3 - House 15 - unused wooden structures were observed located approximately 5 feet from the exterior of the building.
- Layer 3 - Houses 11 and 12 - grass approximately 12 inches high was observed in between Houses 11 and 12.

SEE REVERSE OF THIS PAGE.	EMPLOYEE SIGNATURE <i>Katherine M. Taylor</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Katherine M. Taylor Investigator	DATE ISSUED 08/30/10
	<i>[Signature]</i>	Nicole J. Clausen, Investigator	



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10 FEI NUMBER 3006481643, 3004793793, 3005280357
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
TO: FEI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
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CITY, STATE AND ZIP CODE Gal, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer
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b) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 13, under section (b) (4) 7, (b) (4) 8, (b) (4) 9, (b) (4) 10, (b) (4) 11, (b) (4) 12, (b) (4) 13, (b) (4) 14, (b) (4) 15, (b) (4) 16, (b) (4) 17, (b) (4) 18, (b) (4) 19, (b) (4) 20, (b) (4) 21, (b) (4) 22, (b) (4) 23, (b) (4) 24, (b) (4) 25, (b) (4) 26, (b) (4) 27, (b) (4) 28, (b) (4) 29, (b) (4) 30, (b) (4) 31, (b) (4) 32, (b) (4) 33, (b) (4) 34, (b) (4) 35, (b) (4) 36, (b) (4) 37, (b) (4) 38, (b) (4) 39, (b) (4) 40, (b) (4) 41, (b) (4) 42, (b) (4) 43, (b) (4) 44, (b) (4) 45, (b) (4) 46, (b) (4) 47, (b) (4) 48, (b) (4) 49, (b) (4) 50, (b) (4) 51, (b) (4) 52, (b) (4) 53, (b) (4) 54, (b) (4) 55, (b) (4) 56, (b) (4) 57, (b) (4) 58, (b) (4) 59, (b) (4) 60, (b) (4) 61, (b) (4) 62, (b) (4) 63, (b) (4) 64, (b) (4) 65, (b) (4) 66, (b) (4) 67, (b) (4) 68, (b) (4) 69, (b) (4) 70, (b) (4) 71, (b) (4) 72, (b) (4) 73, (b) (4) 74, (b) (4) 75, (b) (4) 76, (b) (4) 77, (b) (4) 78, (b) (4) 79, (b) (4) 80, (b) (4) 81, (b) (4) 82, (b) (4) 83, (b) (4) 84, (b) (4) 85, (b) (4) 86, (b) (4) 87, (b) (4) 88, (b) (4) 89, (b) (4) 90, (b) (4) 91, (b) (4) 92, (b) (4) 93, (b) (4) 94, (b) (4) 95, (b) (4) 96, (b) (4) 97, (b) (4) 98, (b) (4) 99, (b) (4) 100. This had not been accomplished as evidenced by the following observations:

- Non-chicken feathers were observed inside Layer 3 - House 3. One live wild bird was observed flying above chicken cages inside Layer 1 - House 9. Wild birds were observed flying inside and outside of Layer 1 - Houses 11 and 12. Pigeons were observed roosting in an air vent where the screening was damaged on south side of the Layer 1 - House 14.
- Two birds' nests were observed on the outside structure of Layer 3 - between Houses 1 and 2 approximately 7 - 12 feet from the manure pit doors. Layer 3 - House 8 had a bird's nest and birds were observed under the edges of metal siding on the south wall.
- Chicken manure located in the manure pits below the egg laying operations was observed to be approximately 4 feet high to 8 feet high at the following locations: Layer 1 - House 1; Layer 3 - Houses 2, 7, 17, and 18. The outside access doors to the manure pits at these locations had been pushed out by the weight of the manure, leaving open access to wildlife or domesticated animals.
- Exterior structural damage allowing entrance to the interior of the laying houses was observed in Layer 1 - Houses 1, 3, 4, 7, 8, 11 and 12; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 2, 11, 13, 14, 15 and 18; Layer 4 - House 3. Observations included: holes in exterior siding, missing siding, holes and/or gaps in the concrete foundation and air vent screens either missing or damaged.
- The east and west doors located on the second floor egg laying areas of Layer 1 - Houses 1 - 14; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 3, 4, 5, 6, 9, 11, 15, 16, 17, and 18; Layer 4 - House 3 were observed to have gaps at the bottom and sides ranging from a 1/2 inch to 2 inches.

c) Your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 7, under section (b) (4) 7, (b) (4) 8, (b) (4) 9, (b) (4) 10, (b) (4) 11, (b) (4) 12, (b) (4) 13, (b) (4) 14, (b) (4) 15, (b) (4) 16, (b) (4) 17, (b) (4) 18, (b) (4) 19, (b) (4) 20, (b) (4) 21, (b) (4) 22, (b) (4) 23, (b) (4) 24, (b) (4) 25, (b) (4) 26, (b) (4) 27, (b) (4) 28, (b) (4) 29, (b) (4) 30, (b) (4) 31, (b) (4) 32, (b) (4) 33, (b) (4) 34, (b) (4) 35, (b) (4) 36, (b) (4) 37, (b) (4) 38, (b) (4) 39, (b) (4) 40, (b) (4) 41, (b) (4) 42, (b) (4) 43, (b) (4) 44, (b) (4) 45, (b) (4) 46, (b) (4) 47, (b) (4) 48, (b) (4) 49, (b) (4) 50, (b) (4) 51, (b) (4) 52, (b) (4) 53, (b) (4) 54, (b) (4) 55, (b) (4) 56, (b) (4) 57, (b) (4) 58, (b) (4) 59, (b) (4) 60, (b) (4) 61, (b) (4) 62, (b) (4) 63, (b) (4) 64, (b) (4) 65, (b) (4) 66, (b) (4) 67, (b) (4) 68, (b) (4) 69, (b) (4) 70, (b) (4) 71, (b) (4) 72, (b) (4) 73, (b) (4) 74, (b) (4) 75, (b) (4) 76, (b) (4) 77, (b) (4) 78, (b) (4) 79, (b) (4) 80, (b) (4) 81, (b) (4) 82, (b) (4) 83, (b) (4) 84, (b) (4) 85, (b) (4) 86, (b) (4) 87, (b) (4) 88, (b) (4) 89, (b) (4) 90, (b) (4) 91, (b) (4) 92, (b) (4) 93, (b) (4) 94, (b) (4) 95, (b) (4) 96, (b) (4) 97, (b) (4) 98, (b) (4) 99, (b) (4) 100. This had not been accomplished as evidenced by the following observation:

- Un-baited, unsealed holes appearing to be rodent burrows located along the second floor baseboards were observed inside Layer 1 - Houses 1 - 9 and 11 - 13; Layer 2 - Houses 7 and 11; Layer 3 - Houses 1, 3, 4, 5, and 6; Layer 4 - House 3.

d) Your "Quality Egg Bio-Security Plan", created on 5/1/10 and updated on 8/11/10, reads in part (Page 12, under section (b) (4) 7, (b) (4) 8, (b) (4) 9, (b) (4) 10, (b) (4) 11, (b) (4) 12, (b) (4) 13, (b) (4) 14, (b) (4) 15, (b) (4) 16, (b) (4) 17, (b) (4) 18, (b) (4) 19, (b) (4) 20, (b) (4) 21, (b) (4) 22, (b) (4) 23, (b) (4) 24, (b) (4) 25, (b) (4) 26, (b) (4) 27, (b) (4) 28, (b) (4) 29, (b) (4) 30, (b) (4) 31, (b) (4) 32, (b) (4) 33, (b) (4) 34, (b) (4) 35, (b) (4) 36, (b) (4) 37, (b) (4) 38, (b) (4) 39, (b) (4) 40, (b) (4) 41, (b) (4) 42, (b) (4) 43, (b) (4) 44, (b) (4) 45, (b) (4) 46, (b) (4) 47, (b) (4) 48, (b) (4) 49, (b) (4) 50, (b) (4) 51, (b) (4) 52, (b) (4) 53, (b) (4) 54, (b) (4) 55, (b) (4) 56, (b) (4) 57, (b) (4) 58, (b) (4) 59, (b) (4) 60, (b) (4) 61, (b) (4) 62, (b) (4) 63, (b) (4) 64, (b) (4) 65, (b) (4) 66, (b) (4) 67, (b) (4) 68, (b) (4) 69, (b) (4) 70, (b) (4) 71, (b) (4) 72, (b) (4) 73, (b) (4) 74, (b) (4) 75, (b) (4) 76, (b) (4) 77, (b) (4) 78, (b) (4) 79, (b) (4) 80, (b) (4) 81, (b) (4) 82, (b) (4) 83, (b) (4) 84, (b) (4) 85, (b) (4) 86, (b) (4) 87, (b) (4) 88, (b) (4) 89, (b) (4) 90, (b) (4) 91, (b) (4) 92, (b) (4) 93, (b) (4) 94, (b) (4) 95, (b) (4) 96, (b) (4) 97, (b) (4) 98, (b) (4) 99, (b) (4) 100. This had not been accomplished as evidenced by the following observations:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE KMT NSC	EMPLOYEE(S) NAME AND TITLE (Print or Type) Katherine M. Taylor, Investigator Nicole J. Clausen, Investigator	DATE ISSUED 08/30/10
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Leawood, KS 66214-3340 (913) 752-2100		DATE(S) OF INSPECTION 8/12/10-8/30/10
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: <i>Mr. Peter A. DeCoster, CEO</i>		FBI NUMBER 3006481643, 3004793793, 3005280357
FIRM NAME Quality Egg LLC	FBI: 3004797952, 3006481709, 3003073159	
STREET ADDRESS 2674 Highway 69	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer	
CITY, STATE AND ZIP CODE Galt, Iowa 50101		
<ul style="list-style-type: none"> <li>Dark liquid which appeared to be manure was observed seeping through the concrete foundation to the outside of the laying houses at the following locations: Layer 1 - Houses 1, 2, 3, 4, 5, 8, 11, 12 and 14; and Layer 3 - Houses 1, 8, 13 and 17.</li> <li>Standing water approximately 3 inches deep was observed at the southeast corner of the manure pit located inside Layer 1 - House 13.</li> </ul> <p>2. You failed to take steps to ensure there is no introduction or transfer of SE into or among poultry houses. This was evidenced by the following observations:</p> <p>Specifically,</p> <p>a) There was only one entry doorway to access egg laying areas located on every other house. Entrances for houses on Layer 1 and Layer 2 were located on even numbered houses. Entrances for houses on Layer 3 and Layer 4 were located on odd numbered houses. For example, at Layer 3 and Layer 4 - House 1 had a doorway and this same doorway had to be used to gain entrance to House 2.</p> <p>b) Employees working within the houses did not wear or change protective clothing when moving from house to house. An employee at Layer 6 - House 3 was observed walking out of House 3 with a metal scraper and into House 2 without changing protective clothing and without cleaning/sanitizing equipment between the houses.</p> <p>c) Un-caged birds (chickens having escaped) were observed in the egg laying operation in contact with the egg laying birds at Layer 3 - Houses 9 and 16. The un-caged birds were using the manure, which was approximately 8 feet high, to access the egg laying area.</p> <p>d) Layer 3 - House 11, the house entrance door to access both House 11 and 12 was blocked with excessive amounts of manure in the manure pits.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>KMT</i> <i>NJC</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Katherine M. Taylor Investigator Nicole J. Clausen Investigator
		DATE ISSUED 8/30/10

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10
	FEI NUMBER 3006481643, 3004793793, 3005280357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
TO: Mr. Peter A. DeCoster, COO FEI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE Galt, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer

**3. You failed to achieve satisfactory rodent and pest control as evidenced by the following.**

Specifically,

a) There were between 2 to 5 live mice observed inside the egg-laying houses as follows:

Layer #	House #	Total Live Mice Observed
1	1	2
1	5	2
1	10	2
2	11	5
3	2	4
3	5	4
3	7	2
3	9	2
3	11	2
3	14	3
4	3	3

b) Live and dead flies too numerous to count were observed at the following locations inside the egg laying houses: Layer 1 - Houses 3, 4, 6, 8, 9, 11 and 12; Layer 2 - Houses 7 and 11; Layer 3 - Houses 3, 4, 5, 6, 7, 8, 15, 16, 17 and 18. The live flies were on and around egg belts, feed, shell eggs and walkways in different sections of each egg laying area. In addition, live and dead maggots too numerous to count were observed on the manure pit floor located in Layer 2 - House 7.

**4. You did not document the monitoring of rodents and other pest control measures.**

Specifically, your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 8/1/10, reads in part (Page 7, under section (b) (4), bullet 3), (b) (4) "Inspection of traps and bait stations were not conducted every 7-14 days as evidenced by:

- Layer 1 did not have documented ((b) (4)) rodent inspections of Houses 1 - 14 after 7/15/10.
- Layer 2 did not have documented ((b) (4)) rodent inspections of Houses 1 and 2; Houses 3 - 14 had rodent inspections documented for 7/7/10 and an additional week that was not dated. The two inspections conducted would not adequately cover inspections every 14 days from 7/7/10 - 8/12/10.
- Layer 3 did not have documented ((b) (4)) rodent inspections of Houses 1 - 11 after 7/14/10; Houses 12 - 18 after 7/15/10.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <u>KMC</u> <u>NSC</u>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <u>Katherine M. Taylor, Investigator</u> <u>Nicole J. Clausen, Investigator</u>	DATE ISSUED <u>8/30/10</u>
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10
	FEI NUMBER 3006481643, 3004793793, 3005280357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
TO: Mr. Peter A. DeGoster, COO FEI: 3004797932, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE Galt, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer

- Layer 4 did not have documented (b) (4) rodent inspections of Houses 1, 2, 6, 7, 13 and 16; Houses 3 and 4 after 7/8/2010; Houses 10, 11, 12, 14, 15, 17 and 18 after 7/9/2010. Houses 5, 8, and 9 had a single week of rodent inspections documented but the date the inspection occurred was not recorded.

5. You did not maintain records documenting compliance with biosecurity measures.  
Specifically, your "Quality Egg Bio-security Plan", created on 5/1/10 and updated on 08/11/10, reads in part (Page 5, under section (b) (4) 2. (b) (4))

- You did not document washing and disinfection of your dead hen truck and manure equipment prior to moving from farm to farm.
- You did not maintain records documenting the washing and disinfection of the trailers used for the movement of pallets to laying houses under (b) (4).

6. You failed to document the signature or initials of the person performing the operation of inspecting rodent activity logs at the time in which the inspection is performed.  
Specifically, review of your (b) (4) documentation for Layer 1 - Houses 1 - 14; Layer 2 - Houses 3 - 13; Layer 3 - Houses 1 - 18; Layer 4 - Houses 3, 4, 5, 6, 8, 9, 10, 11, 12, 14, 15, 17 and 18 did not contain a signature(s) or initial(s) of the person(s) performing the rodent inspections at the time they were performed.

7. All required records do not include your name and the location of your farm.  
Specifically, your (b) (4) forms, (b) (4) and (b) (4) (b) (4) form for monitoring fly activity, rodent activity and evaluation of hen house cleaning (respectively) did not contain your name. Additionally, some of the (b) (4) forms and (b) (4) did not identify the layer site location where the monitoring occurred.

8. On 8/14/10, the following observations were noted at the Quality Egg LLC Feed Mill located at 2624 Hwy 69 Galt, IA 50101 FEI: 3003073159

- Specifically,
- Birds were observed roosting and flying, chicks heard chirping in the storage and milling facility. In addition, nesting material was observed in the feed mill closed mixing system, ingredient storage and truck filling areas.

SEE REVERSE OF THIS PAGE	EMPLOYER(S) SIGNATURE <u>KMC</u> <u>NJC</u>	EMPLOYEE(S) NAME AND TITLE (Print or Type) <u>Katherine M. Taylor, Investigator</u> <u>Nicole J. Clausen, Investigator</u>	DATE ISSUED <u>8/30/10</u>
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/12/10-8/30/10 PRI NUMBER 3006481643, 3004793793, 3005280357
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
TO: FBI: 3004797952, 3006481709, 3003073159

FIRM NAME Quality Egg LLC	STREET ADDRESS 2674 Highway 69
CITY, STATE AND ZIP CODE Oak, Iowa 50101	TYPE OF ESTABLISHMENT INSPECTED Shell Egg Manufacturer

- Raw ingredient bins and feed sensors accessible from roof of facility had rusted holes and feed grain level sensors ajar to the outdoor environment. These included:
  - Ingredient storage bin 12, containing salt, had a rusted gap about a 1/2 inch wide the length of the lid of the roof level covered ingredient bin chute.
  - Ingredient storage bin 21 containing ground corn had a hole approximately 3 inches by 1/2 inch wide at the base of the roof level covered ingredient bin chute.
  - At the base of the feed grain level sensor leading into ingredient storage bin 21, containing ground corn, there was an open hole.
  - Feed grain level sensor leading into ingredient storage bin 7, containing meat and bone meal, was off to the side with approximately a 2 inch gap. Avian like feces was observed on top of this feed sensor.
  - Finished feed tanks 4 and 18 did not have covers on top of the finished feed tank chutes.
- Outdoor whole kernel corn grain bins 4 and 6 observed to have the topside doors/lids open to the environment and pigeons were observed entering and leaving these openings. Birds were also observed sitting/flying around and over the openings.

9. Samples collected during the course of this inspection and tested by an FDA laboratory revealed the following positive analytical results for *Salmonella* Enteritidis:

- Specifically,
- On 8/13/2010, an environmental sample was collected from Layer 2, house 7 manure swab from row 1 - left side.
  - On 8/16/2010, an environmental sample was collected from Layer 2, house 11 at manure scraper blade from row 3 - right side.
  - On 8/13/2010, an environmental sample was collected from Layer 4, house 3 at walkway 1 - right side and walkway 3 - right side.
  - On 8/14/2010, a sample of meat and bone meal was collected from ingredient bin 7 located at your feed mill.
  - On 8/17/2010, a sample of finished feed "Developer" pullet feed was collected from the feed mill.
  - On 08/16/2010, an environmental sample was collected from the roof level covered ingredient bin chute 8; Second Floor ingredient bin cover 19 (ingredient bin 19 holds ground corn) located at your feed mill.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Katherine M. Taylor</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Katherine M. Taylor Investigator	DATE ISSUED 08/30/10
	<i>Nicole J. Clauson</i>	Nicole J. Clauson Investigator	

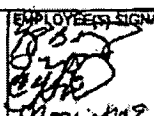
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

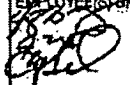
Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC374(b)) provides:


"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to the health. A copy of such report shall be sent promptly to the Secretary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100		DATE(S) OF INSPECTION 8/19/10-8/26/10 FEI NUMBER 3004354976, 3004404403, 3006481690
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: <i>Cary W Bartness, General Manager</i>		
FIRM NAME Hilldale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main	
CITY, STATE AND ZIP CODE New Hampton, IA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer	
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES (S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE (S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.		
Observations listed below cover inspections of your egg laying farms/plants inspected from 08/19/2010 through 08/26/2010.		
FEI: 3004354976 - Hilldale Farms of Iowa, Inc, 19 1/2 West Main, New Hampton, IA 50659 FEI: 3004404403 - Hilldale Iowa II, LLP, 13706 230th St, West Union, IA 52175 (referred to as West Union) FEI: 3006481690 - Hilldale Farms, LLC, 13998 140th St, Aiden, IA 50006 (referred to as Aiden)		
1. You did not maintain documentation that the 19 week old pullets in house 4 at the Aiden facility were "SE monitored" or were raised under "SE monitored" conditions, including environmental testing records for pullets.		
2. The written SE prevention plan was not fully implemented and followed.		
Specifically, a) Your document "Hilldale II LLP Bio-security Plan" (referenced in your Hilldale II LLP Salmonella Enteritidis Prevention Plan) created 5/1/10 states on p. 7 under the section entitled, "**** (b) (4) ****" states, you will "**** (b) (4) ****" You failed to follow your plan as evidenced by the following observations on 8/23/10:		
<ul style="list-style-type: none"> <li>• West Union House 1 - There were 3 unsealed rodent holes observed along east wall.</li> <li>• West Union House 4 - There were 16 unsealed rodent holes along row 1. Two live rodents were observed entering into 2 of the rodent holes.</li> <li>• West Union House 5 - There were approximately 20 unsealed rodent holes on south wall along row 7. A rodent was observed running into one of the rodent holes.</li> <li>• West Union House 8 - There were 26 unsealed rodent holes on the south wall of the house. In addition, there were 5 unsealed rodent holes on the east side of the house.</li> </ul>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>[Signature]</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jeffrey B. Mandy, Investigator Eugene R. Lambert, Investigator Carmen Y. Fisher, Investigator Monica M. McClure, Investigator Gerardo A. Ramirez, Investigator David T. Hill, Investigator
		DATE ISSUED 8/26/10

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 90th St Lenexa, KS 66214-3340 (913) 752 2100		DATE(S) OF INSPECTION 8/19/10-8/26/10  FEI NUMBER 3004354976, 3004404403, 3006481690
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Gary V Bortness, General Manager		
FIRM NAME Hillendale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main	
CITY, STATE AND ZIP CODE New Hampton, IA 50659		TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer
In addition the section entitled, "..." (b) (4) ... also found on p. 7 states the following: "... (b) (4) ..." (b) (4) (b) (4) ... (b) (4) ... (b) (4) (b) (4) ... (b) (4) ... (b) (4) (b) (4) ... (b) (4) ... (b) (4) "... You failed to follow your plan as evidenced by the following observations on 8/23/10: • West Union House 1 - There was an approximate 1 inch gap in the east door. • West Union House 3 - There was an approximate 12 inch wide gap in the lower level door on the west side of the house. There was an approximate 2 inch gap on each side of the east door. There was a hole observed on the metal siding on the north end approximately 3x3 inches. • West Union House 5 - There was an approximate 1.5 inch gap in east door. • West Union House 6 - There was an approximate 6 inch gap on the outside of the east door and an approximate 3 inch gap in the damaged door on the east side of the building. • West Union House 7 - There was an approximate 2 inch gap in the rear entrance door. • West Union House 8 - There was an approximate 2 inch gap in the door on the east side of the house. b) Your document "Hillendale Iowa LLC Bio-security Plan" (referenced in your Hillendale Iowa LLC Salmonella Enteritidis Prevention Plan) created 5/1/10 states on p. 7. "... (b) (4) ..." (b) (4) (b) (4) ... (b) (4) ... (b) (4) (b) (4) ... (b) (4) ... (b) (4) (b) (4) ... You failed to follow your plan as evidenced by the following observations on 8/20/10: • Alden House 1 - A 15 feet by 3 feet wide section of siding was missing from the south side of the house, leaving a 15-foot by 2 inch opening into the barn. An approximate 2 inch gap was observed in the back sliding door. • Alden House 3 - An approximate 5 inch gap was observed in the metal siding near the south door. Holes were observed in the metal siding near the south doors, approximately 3 inches in diameter. • Alden House 6 - An approximate 2 inch gap was observed in the rear door and an approximate 2 feet by 2 foot hole was observed on the north side of the building.		
SEE REVERSE OF THIS PAGE	EMPLOYEE SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Gregory A. Meedy, Investigator Joseph E. Lambert, Investigator Carmen K. Fisher, Investigator Ivanca M. Miller, Investigator Gerardo K. Ramirez, Investigator Brian T. Hall, Investigator
		DATE ISSUED 8/26/10



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Leawood, KS 66214-3340 (913) 752 2100		DATE(S) OF INSPECTION 8/19/10-8/26/10 FEI NUMBER 3004354976, 3004404403, 3006481690
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Gary W. Bortner, General Manager		
FIRM NAME Hillandale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main	
CITY, STATE AND ZIP CODE New Hampton, IA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer	
<p>* Alden House 7 - Light was observed coming in around the perimeter of the west door due to inadequate seal. No seal was on the north rear manure door.</p> <p>* Alden House 8 - Holes were observed in the walls on the north side of the building, approximately 1 foot by 2 feet, protruding into the manure pit.</p> <p>* Alden House 9 - An approximate 1 inch gap was observed on the manure pit door at the west end of the house. Two holes were observed in the building: 1 hole, approximately 2 inches in diameter, on the south side of the building underneath the walkway and a hole on the right side of the entrance door approximately 2 inches in diameter.</p> <p>c) Your document "Hillandale Iowa LLC Bio-security Plan" (referenced in your Hillandale Iowa LLC, Salmonella Enteritidis Prevention Plan) created 5/1/10 states under (b) (4) on page 12, (b) (4). You failed to follow your plan as evidenced by the following observations on 8/20/10:</p> <ul style="list-style-type: none"> <li>* Alden House 2 - Standing water approximately 3/4 inch deep was observed on the floor adjacent to the manure pit where the foot bath was located inside the building.</li> <li>* Alden House 8 - Liquid manure was observed leaking into the east section of the first floor. Plant manager reported that a water line leak occurred several weeks ago causing the manure pit to flood.</li> </ul> <p>d) Your document "Hillandale II, LLP Bio-security Plan" (referenced in your Hillandale II, LLP, Salmonella Enteritidis Prevention Plan) created 5/1/10 states under (b) (4) on page 12, (b) (4). You failed to follow your plan as evidenced by the following observation on 8/23/10:</p> <ul style="list-style-type: none"> <li>* West Union House 7 - Liquid manure was observed streaming out of an approximate 6 inch gap of the east door of the manure pit. Plant manager reported a water leak had occurred.</li> </ul> <p>e) Your document "Hillandale Iowa LLC Bio-security Plan" (referenced in your Hillandale Iowa LLC Salmonella Enteritidis Prevention Plan) created 5/1/10 states on page 8, (b) (4). You failed to follow your plan as evidenced by the following observation on 8/20/10:</p> <ul style="list-style-type: none"> <li>* Alden House 7 - Weeds, approximately 12 inches tall, were observed growing along the exterior wall around the entire house.</li> </ul>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Gregory B. Moody	EMPLOYEE(S) NAME AND TITLE (Print or Type) Gregory B. Moody, Investigator Joseph E. Lambert, Investigator Carmen V. Fisher, Investigator Mortimer M. McIlroy, Investigator Gerardo P. Ramirez, Investigator Guenther T. Hall, Investigator
		DATE ISSUED 8/26/10

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Kansas City District Office 11630 W 80 <sup>th</sup> St Lenexa, KS 66214-3340 (913) 752 2100	DATE(S) OF INSPECTION 8/19/10-8/26/10	
		FEI NUMBER 3004354976, 3004404403, 3006481690
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: <i>Gary W Bartness, General Manager</i>		
FIRM NAME Hillandale Farms of Iowa, Inc	STREET ADDRESS 19 1/2 West Main	
CITY, STATE AND ZIP CODE New Hampton, IA 50659	TYPE OF ESTABLISHMENT INSPECTED Egg Manufacturer	
<p>3. You failed to take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. This is evidenced by the following observations on 8/23/10:</p> <ul style="list-style-type: none"> <li>• West Union House 7 - Approximately 35 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.</li> <li>• West Union House 4 - Approximately 14 un-caged hens were tracking manure from the manure pit into the upper level of the caged hen house area.</li> </ul> <p>4. All required records did not include the location of the farm and the signature or initials of the person who performed the operation.</p> <p>Specifically,</p> <ul style="list-style-type: none"> <li>• The "Fly Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 8/6/10, 8/13/10, and 8/20/10 did not include the specific farm location of the fly monitoring and the name or initials of the person who performed the inspection.</li> <li>• The "Rodent Monitoring Form" for the West Union site (Houses 1, 2, 3, 4, 5, 6, 7, 8, and 9) performed on the dates 7/12/10, 7/19/10, 8/2/10, and 8/23/10 did not include the specific farm location of the rodent monitoring and the name or initials of the person who performed the inspection.</li> <li>• The "Moving Tape Fly Count" for the Alden site (Houses 1, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/29/10, 8/12/10, and 8/19/10 did not include the specific farms of the houses inspected.</li> <li>• The "Post B Gone" rodent activity logs for the Alden site (Houses 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) performed on the dates 7/22/10, 7/29/10, 8/5/10 and 8/19/10 did not include the specific location of the farm inspected and did not always include the name or initials of the person who performed the inspection.</li> </ul> <p>5. Your written SE plan titled "Hillandale Iowa LLC Salmonella Enteritidis Prevention Plan" and "Hillandale II LLP Salmonella Enteritidis Prevention Plan" did not include the signature of your plan administrator.</p> <p>6. Samples collected during the course of this inspection and tested by a FDA laboratory, revealed the following positive analytical test results: Spent water from egg wash station from Plant 5, sampled on 8/19/2010, tested positive for Salmonella enteritidis.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jeffrey B. Moody, Investigator Joseph E. Lambert, Investigator Carmen Y. Fisher, Investigator Monica M. McClure, Investigator Ronald A. Ramirez, Investigator Robert T. Hill, Investigator
		DATE ISSUED 8/26/10