



2010 SEP 21 A 10: 22

September 21, 2010

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

Re: Docket Nos. 2006P-0394/CP1 & 2007P-0235/CP1

Dear Sir or Madam:

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 500-596, specifically 5 U.S.C. § 553(e), Compassion Over Killing and other interested parties (together, the "petitioners") submitted a petition for rulemaking to FDA on September 27, 2006, urging FDA to take regulatory action regarding, *inter alia*, the common and pervasive misleading express and implied claims on shell eggs and shell egg cartons sold in the United States. In particular, the petitioners requested that FDA initiate rulemaking to standardize the labeling requirements for shell eggs sold in the United States to indicate to consumers whether such eggs are laid by free-range, cage-free or caged hens. Since the filing of the petition almost four years ago and FDA's tentative response on March 22, 2007, and the response to a similar petition forwarded to FDA by the Federal Trade Commission (Docket No. 2007P-0235, the "FTC Petition") dated December 11, 2007, your office has failed to take any substantive action regarding the issues presented in the petition and supplemental submissions. Almost four years have passed since the submission of this petition for rulemaking. This constitutes unreasonable delay under the law. *See Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987) ("this court has stated generally that a reasonable time for an agency decision could encompass months, occasionally a year or two, but not several years or a decade.") As such, this letter and enclosed submission serves as a final request for FDA to remedy its unreasonable delay and take final action regarding the petition.

Please note that the enclosed petition is to be considered the entirety of Docket 2006P-0394 and merges with the FTC Petition and the November 2008 letter submitted by Compassion Over Killing to FDA. The petition enclosed here is to supplant all of this existing material and to notify FDA of relevant updated information pursuant to the requirements for citizen petitions, 21 C.F.R. § 10.30(b), and should serve as the exclusive record of the petition. Please be advised that this submission contains substantively identical information to both the original petition and the supplemental letter submitted in November 2008, notwithstanding certain information which

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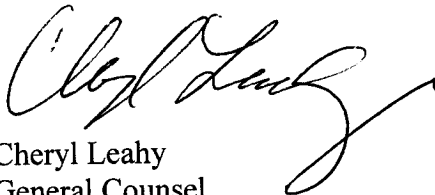
is now moot and has been omitted and certain items which have been updated to reflect currently accurate information and occurrences. The minor omissions and additions do not substantively affect the petition, its call for regulation, or its rationale for regulation.

The proposed regulation satisfies the requirements of 21 C.F.R. § 10.40(a)(2) for publishing proposed regulations in the Federal Register for comment. As the enclosed submission details, there are numerous facts demonstrating reasonable grounds for the proposal, and given the level of confusion that results from the current labeling landscape and FDA's mission to "help[] the public get the accurate, science-based information they need to use . . . foods to improve their health,"<sup>1</sup> the proposal is both in the public interest and promotes FDA's objectives, including the adherence to the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and the Nutrition Labeling and Education Act. Therefore, promulgation of the proposed regulations is not only within FDA's authority, but constitutes a mandatory duty.

As you are no doubt aware, agency inaction is subject to judicial review. Under the APA, courts are given the power to compel agency action "unlawfully withheld or unreasonably delayed" and "hold unlawful and set aside agency action" (including the failure to act) for various reasons. 5 U.S.C. §§ 706, 551 (2006). Thus, the APA allows courts to compel an agency to act when said agency has failed to act or when it has engaged in an unreasonable delay. *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004).

As such, pursuant to the enclosed submission (which combines the original citizen petition and supplemental letter, with the aforementioned minor changes), petitioners request FDA to fulfill its statutory mandate and institute the requested rulemaking. If FDA does not remedy its unreasonable delay and take final action, petitioners will pursue other remedies under the law.

Sincerely,



Cheryl Leahy  
General Counsel

Enclosures

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<sup>1</sup> *What We Do*, U.S. Food and Drug Administration, <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last visited September 13, 2010).

**BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

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**Citizens' Petition to Change the  
Labeling Requirements for Eggs  
Sold in the United States  
Consolidated Version of  
Docket # 2006P-0394  
and Docket # 2007P-0235/CP1**

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Submitted to:

Dockets Management Branch  
Food and Drug Administration  
Room 1061 (HFA-305)  
5630 Fishers Lane  
Rockville, MD 20852

Submitted by:

Compassion Over Killing, Inc.  
P.O. Box 9773  
Washington, DC 20016  
*representing over 30,000 persons nationwide*

Animal Legal Defense Fund, Inc.  
170 East Cotati Ave.  
Cotati, CA 94931  
*representing over 110,000 persons nationwide*

Penn Law Animal Law Project  
University of Pennsylvania Law School  
3400 Chestnut Street  
Philadelphia, PA 19104

Andrea Bock  
5755 W. Byron St.  
Chicago, IL 60634

Rachel Share  
2400 Virginia Ave., NW  
Apt. C-1025  
Washington, DC 20037

## **Citizen Petition**

The undersigned<sup>1</sup> submit this petition pursuant to the Administrative Procedure Act, and specifically 21 U.S.C. sections 321(n), 331, 343, and 371, and the Fair Packaging and Labeling Act (“FPLA”), as amended, specifically, 15 U.S.C. sections 1452, 1453, and 1454, to request that the Food and Drug Administration (“FDA”) take regulatory action to revise the labeling requirements for eggs sold in the United States.

## **Introduction**

The labeling of shell eggs<sup>2</sup> in the United States today fails to reveal to consumers certain material facts that substantially influence their purchasing decisions. Furthermore, following a

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<sup>1</sup> Petitioner Compassion Over Killing, Inc. is a nonprofit animal advocacy organization based in Washington, D.C., representing over 30,000 individual consumers nationwide that, among other things, seeks to correct misleading advertising and educate consumers regarding food production methods. Petitioner Animal Legal Defense Fund (ALDF) is a nonprofit animal advocacy organization based in Cotati, California, representing over 110,000 individual consumers nationwide, which uses the legal system to protect the lives and advance the interests of animals and educate consumers about the treatment of animals in food production. Petitioner Penn Law Animal Law Project is a student-led pro bono project at the University of Pennsylvania Law School, working on legal projects with the goals of improving the lives and legal status of animals and encouraging animal advocacy by supporting advocates and educating the public – including advocating for regulations that would ensure consumers have access to information about how animals are treated during egg production. Petitioner Andrea Bock (formerly Andrea Collias) is an egg consumer and member of Compassion Over Killing. She is representative of a significant number of Compassion Over Killing members who both consume animal products and are concerned about animal welfare. As an educator and a lifelong animal lover, Andrea strives to make informed and conscientious purchasing decisions to ensure that she obtains products that have been more humanely produced, even if it means paying more for these products. Because of unclear labeling, Andrea routinely experiences confusion and frustration in determining whether the eggs she purchases have been produced in a way that is objectionable to her. After learning that labels often misrepresent the true nature in which eggs have been produced, Andrea feels that she has been misled. Because she lacks specialized knowledge of egg production methods, she fears that this will only continue without clearer labeling requirements. Petitioner Rachel Share is an egg consumer and member of Compassion Over Killing. A vegetarian for most of her life, Rachel is concerned about animal welfare issues and endeavors to purchase food products that have been produced in a more humane manner, regardless of price. Rachel typically purchases eggs bearing an “animal friendly” or “natural” claim on the carton, believing them to have been produced by hens not confined in cages. When she became aware that these egg labels are unregulated and unrelated to actual animal production methods, Rachel felt betrayed and deceived. Now, Rachel is unsure of which eggs to purchase and worries that she may be buying eggs from hens who are confined inside wire battery cages, a practice she strongly opposes on ethical grounds. Rachel represents a segment of the population that is misled by the egg industry’s labels despite an attempt at specialized knowledge and concern over animal treatment.

<sup>2</sup> The term “shell eggs” is used to indicate eggs in their shells as opposed to egg products such as Egg Beaters™. See *Scrambled Labels. Egg Production in the United States*, CONSUMERS UNION, previously available at <http://www.eco-labels.org/feature.cfm?FeatureID=1&isPast=1> (last visited Sept. 8, 2006), Ex. 1. The terms “egg[s]” and “shell egg[s]” will be used interchangeably in this petition.

recent increase in consumer interest regarding egg production methods,<sup>3</sup> egg labels now commonly employ misleading express and implied claims, which result in a material and significant difference between the product sold and what it purports to be.

A 2000 Zogby International poll of American adults revealed that 86.2 percent of those polled found the common egg industry practice of confining egg-laying hens in densely crowded cages to be unacceptable.<sup>4</sup> Actual egg production methods are in conflict with public opinion; more than 95 percent of eggs produced and sold in the U.S. come from birds confined in cages.<sup>5</sup> Moreover, several surveys have shown, and the United States Department of Agriculture (“USDA”) has confirmed, that consumers nationwide are willing to pay substantially more for eggs represented to them as produced under standards that ensure some degree of animal welfare.<sup>6</sup> In 2001, the USDA, in its “International Egg and Poultry Review,” discussed the impact of consumers’ animal welfare concerns on the industry, noting that “[a]nother key issue affecting egg production worldwide concerns animal welfare and the ethical treatment of

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<sup>3</sup> *Humane labeling latest niche – American Humane Association certifies food animal producers employing humane standards*, AMERICAN VETERINARY MEDICAL ASSOCIATION (2000),

<http://www.avma.org/onlnews/javma/nov00/s111500d.asp> (last visited Jun 21, 2010), Ex. 2. According to the American Humane Association, 44% of consumers would pay 5% more for food products that provide assurances that animals were “humanely raised.” *Free Farmed™ Certification Questions & Answers*, AMERICAN HUMANE ASSOCIATION, previously available at

[http://www.americanhumane.org/site/PageServer?pagename=pa\\_farm\\_animals\\_ff\\_q\\_and\\_a](http://www.americanhumane.org/site/PageServer?pagename=pa_farm_animals_ff_q_and_a) (last visited Sept. 8, 2006) (citing 1999 survey by Animal Industry Foundation), Ex 3.

<sup>4</sup> *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>5</sup> See Sarah Moran, *A Good Egg*, STAR TRIBUNE: NEWSPAPER OF THE TWIN CITIES, December 1, 2008, Ex. 6.

<sup>6</sup> See, e.g., *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010) (indicating that 80.7 % of respondents to 2000 survey by Zogby International would pay more for eggs from chickens raised in “humane” manner), Ex. 4; see also E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5; see also 67 Fed. Reg. 79,552 at 79,554 (Dec. 30, 2002) (“Since some consumers prefer products from animals that have been raised using [free-range] production practices, producers may seek to improve their returns by appealing to such market niches”), Ex. 7. Fifty-eight percent of consumers are willing to pay an additional 10% or more for meat, poultry, or eggs labeled as “humanely raised.” *Frequently Asked Questions*, THE HUMANE TOUCH, 2010 available at <http://thehumanetouch.org/learn-more/faqs> (last visited May 20, 2010), Ex. 8.

animals.”<sup>7</sup> Given the fact that the public is both unfamiliar with egg production methods and considers them important enough to their purchasing decisions that they will pay more for eggs with perceived higher welfare standards, clear and truthful labeling regulations are needed to protect this market from exploitation. In addition, the public not only supports but recognizes the need for this regulatory scheme, with 80.7 percent of respondents to a survey indicating that they would be willing to pay more for eggs they believe to have been produced in a humane manner.<sup>8</sup>

Pursuant to its statutory mandate, the relevant provisions of which are identical to the enabling statute under which the FDA operates, the USDA has begun to regulate animal production method labeling on a limited number of products – specifically with regard to the intensive confinement of animals.<sup>9</sup> For example, the National Organic Program requires producers labeling their products as “Organic” to adhere to qualitative animal confinement standards.<sup>10</sup> In 2002, the USDA issued public notice and request for comments regarding livestock and meat industry production/marketing claims,<sup>11</sup> including the claims ‘free-range,’ ‘free roaming,’ and ‘pasture raised.’<sup>12</sup> Similar provisions have not been adopted for egg labeling.

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<sup>7</sup> *Tariff and Non-tariff Barriers*, INT’L EGG & POULTRY REV. (U.S. Dep’t of Agric.), Nov. 13, 2001 at 1, *previously available at* <http://www.ams.usda.gov/POULTRY/mncs/InternationalPoultryandEgg/2001Reports/x111301.pdf> (last visited Sept. 11, 2006), Ex. 9.

<sup>8</sup> *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010) (indicating that 80.7 % of respondents to 2000 survey by Zogby International would pay more for eggs from chickens raised in “humane” manner), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>9</sup> *Cf.* Federal Meat Inspection Act, at 21 U.S.C. § 601(n)(1) (2010) (prohibiting labeling of meat or meat products that is “false or misleading in any particular”), the Poultry Products Inspection Act, at 21 U.S.C. § 453(h)(1) (2010) (prohibiting labeling of poultry products that is “false or misleading in any particular”), *esp.* the Egg Products Inspection Act, at 21 U.S.C. §§ 1036(a) (2010) (authorizes USDA to regulate to require egg labels to contain “such other information as the Secretary may require by regulations to describe the products adequately and to assure that they will not have false or misleading labeling”) and 1036(b) (2010) (“No labeling or container shall be used for egg products at official plants if it is false or misleading.”).

<sup>10</sup> 7 C.F.R. § 205.239 (2010) (including access to the outdoors and shelter designed to allow for natural maintenance, comfort behaviors, and opportunity to exercise).

<sup>11</sup> 67 Fed. Reg. at 79,553 (closing comment period on March 31, 2003), Ex. 7.

<sup>12</sup> *Id.* at 79,554, Ex. 7.

Despite such action taken under an identical statutory mandate, and the prevalence of misrepresentation of egg production methods (discussed below), the FDA, which has primary responsibility for egg labeling,<sup>13</sup> has yet to act.

At the point of purchase, consumers interested in specific egg production methods must rely on information provided on the egg carton. The omission of production practices on egg cartons, compounded with the misleading representations regarding these products, impedes the free flow of important information to the consumer. As described in more detail below, examples of misrepresentations on cartons of eggs produced by birds confined in cages include imagery of hens outside or lying on nests, as well as language suggesting a level of animal care that is inconsistent with actual farm practices, such as “Animal Friendly,” and “Naturally Raised.” Furthermore, given the nutritional inferiority of eggs laid by caged versus pastured free-range hens, many express or implied misrepresentations about the level of care given to caged hens amounts to a misrepresentation about the quality and nutritional content of the product.<sup>14</sup>

Egg labels make both factual misrepresentations and imply hens’ living conditions through imagery, both of which can constitute prohibited forms of misbranding under federal fair labeling laws.<sup>15</sup> The FDA is required to take action to remedy and prevent this.<sup>16</sup> Moreover, the prevalence and recent increase of such misrepresentations demand that the FDA go beyond merely exercising its ad-hoc enforcement authority and take general corrective regulatory action by promulgating new regulations, provided herein, pursuant to its statutory mandate.

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<sup>13</sup> See, e.g., *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 10; see also *Enforcement Policy Statement on Food Advertising*, FTC, May, 1994, at 2, available at <http://www.ftc.gov/bcp/policystmt/ad-food.htm> (last visited May 21, 2010), Ex. 11.

<sup>14</sup> See *infra* at 25-28 (discussing nutritional inferiority of cage-produced eggs relative to pastured free-range eggs and FDA’s mandate to cure mislabeling of cage-produced eggs, which obfuscates the nutritional discrepancy).

<sup>15</sup> See, e.g., 21 U.S.C. § 331(a)-(c), (g) (2010) (prohibiting misbranding of food); 21 U.S.C. § 343 (2010) (defining misbranded food); 21 U.S.C. § 321(n) (2010) (describing factors considered in determining whether labeling or advertising is misleading). See generally Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2010) (enacted June 25, 1938).

<sup>16</sup> See, e.g., *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 10.

### **Action Requested**

Petitioners request that the FDA take regulatory action to revise the current labeling requirements for eggs, currently found at Title 21 of the Code of Federal Regulations, Chapter I, Subchapter B, Parts 101, 115, and 160, and/or to promulgate new regulations.

(a) For the purposes of this regulation:

(1) The term “egg” means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea. The term “hen” refers to a female domesticated chicken, turkey, duck, goose, or guinea.

(2) The term “cage” means a structure for confining birds, enclosed on at least one side by a grating of wires or bars that lets in air and light, in which hens do not have the ability to fully spread their wings without touching the sides of that enclosure or other birds.

(3) The term “barn” means a building used for sheltering animals used for food production.

(4) The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article. “Container” means any package or other carton in which shell eggs are packed for household or other ultimate consumers.

(b) All eggs that are moved or are moving in commerce to be sold for retail sale in the United States shall bear the appropriate one of the following designations on their labels:

(1) The labels on egg containers containing eggs that are laid by hens that are not confined to cages, and are given readily and easily available access to outdoor pastures which all hens can access at once, with living vegetation and accessible overhead cover, for the period of their lives during which they produce eggs, excluding actual transport or during the provision of veterinary care by a licensed veterinarian though not for a period to exceed ten (10) days shall bear the designation “Free-Range Eggs.”

(2) The labels on egg containers containing eggs that are laid by hens that are not confined to cages but kept in a barn or other enclosed structure in which they are permitted to move freely for the period of their lives during which they produce eggs, excluding actual transport or during the provision of veterinary care by a licensed veterinarian though not for a period to exceed ten (10) days shall bear the designation “Cage-Free Eggs.”



(3) The labels on egg containers containing eggs that are laid by hens that are confined to a cage for any period of their lives during which they produce eggs, excluding actual transport or during the provision of veterinary care by a licensed veterinarian though not for a period to exceed ten (10) days, shall bear the designation “Eggs From Caged Hens.”

(c) The appropriate designation shall be printed so as to appear prominently and conspicuously on the principal display panel of the egg container in a type size no smaller than 1/8th of an inch and placed with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary use.

(d) This regulation shall be implemented no later than 360 days following its adoption.

The FDA is authorized and mandated to take all of the requested actions under the Federal Food, Drug, and Cosmetics Act (“FFDCA”) as amended, specifically 21 U.S.C. sections 321(n), 331, 343, and 371, and FPLA, as amended, specifically, 15 U.S.C. sections 1452, 1453, and 1454.

### **Statement of Grounds**

#### **I. Factual Grounds**

##### **A. Unregulated production method labeling of eggs misleads consumers.**

Unregulated egg labeling is a widespread source of consumer confusion and misplaced reliance on animal welfare claims that are ultimately false or misleading. For example, a recent *Consumer Reports* discussion warns consumers of food labeling that is persuasive but “meaningless” because of the lack of government standardization to back up the terms.<sup>17</sup> Specifically named are the terms “free-range” or “free-roaming.” The reports states that “stamped on eggs, chicken, and other meat, this label suggests that an animal has spent a good

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<sup>17</sup> See *Food labels can be misleading*, CONSUMER REP., Feb. 2006, previously available at <http://www.consumerreports.org/cro/food/organic-products-206/food-labels-can-be-misleading/> (last visited Sept. 8, 2006), Ex. 12. Only 2% of more than 2000 Americans responding to a Harris Interactive poll were able to correctly identify the definition of “natural” as applied to meat and poultry. *Natural labeling poll*, HARRIS INTERACTIVE QUICKQUERY, 2009, available at <http://www.awionline.org/ht/a/GetDocumentAction/i/21889>, (last visited August 2, 2010), Ex. 13.

portion of its life outdoors. But U.S. government standards are weak.”<sup>18</sup> Egg labeling is not given even this level of protection. A recent comprehensive study assessing product labeling claims, industry quality assurance guidelines and third party certification standards determined that “various humane certification and labeling programs have been developed in response to growing popular concerns about the cruel treatment of farm animals, but their impact at improving animal welfare has been minimal. Food labeling and marketing claims, like ‘grass fed’ and ‘cage-free,’ are generally subjective and not verified.”<sup>19</sup> The report went on to note that “[a]s a result, a significant portion – likely a majority – of poultry and eggs marketed under these claims in the U.S. are produced in a manner inconsistent with the public’s expectations. . . . Due to inconsistency in their application, the claims ‘free-range’ and ‘free roaming,’ particularly when used with poultry and laying hens, are among the least relevant to animal welfare.”<sup>20</sup> Discussing product labeling claims in general, the report concludes that “[i]t is likely consumers grossly over-estimate the animal welfare significance of these claims.”<sup>21</sup> Because of this consumer demand for higher animal welfare standards in the context of an unregulated labeling market, this confusion and ineffectiveness in labeling thrives. Mere voluntary private standards are inadequate to protect against producers misleading consumers.

In fact, there is a special market incentive for sellers to employ deceptive and misrepresentative labeling in the context of egg sales. Recent widely distributed survey evidence

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<sup>18</sup> See *Food labels can be misleading*, CONSUMER REP., Feb. 2006, previously available at <http://www.consumerreports.org/cro/food/organic-products-206/food-labels-can-be-misleading/> (last visited Sept. 8, 2006), Ex. 12. A recent Christian Science Monitor article likewise warns consumers that “producers use labels such as “free-range” or “natural” that conjure up bucolic images but may mean very little . . . Free-range or cage-free: No regulation or standard definition exists for most animals. The USDA regulates the use of the term ‘free-range’ with poultry (not eggs) . . .” Amanda Paulson, *As ‘organic’ goes mainstream, will standards suffer?*, CHRISTIAN SCI. MONITOR, May 17, 2006, available at <http://www.csmonitor.com/2006/0517/p13s01-lifo.html> (last visited May 20, 2010), Ex. 14; see also Melinda Fulmer, *Eco-labels on food called into question*, L.A. TIMES, Aug. 16, 2001, at C1, available at <http://www.organicconsumers.org/Organic/ecolabel082801.cfm> (last visited May 20, 2010), Ex. 15.

<sup>19</sup> See FARM SANCTUARY, FARM ANIMAL WELFARE: AN ASSESSMENT OF PRODUCT LABELING CLAIMS, INDUSTRY QUALITY ASSURANCE GUIDELINES AND THIRD PARTY CERTIFICATION STANDARDS 8 (2005), Ex. 16.

<sup>20</sup> *Id.* at 68.

<sup>21</sup> *Id.* at 85.

has shown that representations regarding welfare-related animal production methods can dramatically increase marketability, with polls indicating that 80.7 percent of respondents would be willing to pay more for eggs from hens raised in what they perceive to be a “humane” manner, 54 percent of consumers would be willing to spend 5-10 percent more for animal welfare standard certified eggs, and an additional 10 percent would be receptive to paying 15-20 percent more for such certified products.<sup>22</sup> Given this demand for higher animal welfare standards in egg production, egg manufacturers are faced with a significantly increased profit potential if they capitalize on this market niche. Without government standards regulating any animal welfare aspect of egg production, companies have an incentive to make a profit without actually meeting consumer expectations.

This incentive is especially alluring, and has resulted directly in the prevalent misrepresentation described herein, as consumers have indicated that many common egg production methods are unacceptable. For instance, in September 2000, Zogby International conducted a poll of U.S. consumers which showed that 86.2 percent of respondents found it unacceptable to densely crowd hens in cages.<sup>23</sup> The strong majority of the public that disapproves of confining hens in cages is in stark contrast to the 95 percent of eggs that come from birds confined in cages.<sup>24</sup> Some data further suggest that consumers equipped with greater

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<sup>22</sup> *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>23</sup> *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>24</sup> See Sarah Moran, *A Good Egg*, STAR TRIBUNE: NEWSPAPER OF THE TWIN CITIES, December 1, 2008, Ex. 6.

information about egg production methods will increasingly purchase cage-free eggs, and be less apt to purchase conventionally produced eggs.<sup>25</sup>

To take a specific example, a recent Zogby poll showed 61 percent of consumers prefer to purchase products with the claim “natural” on its packaging, and almost half (48 percent) believe that the “natural” claim indicates that the animals had access to the outdoors.<sup>26</sup> However, as discussed *infra*, egg cartons often display claims such as “natural,” and there is no regulation of the term to mitigate its confusing effects with respect to animal welfare. Even the USDA is considering regulation of the use of “natural” to include animal welfare considerations because of its confusing nature.<sup>27</sup> In fact, it is animal industry producers and processors who asked the USDA to regulate this term, citing the current definition (which does not even apply to eggs<sup>28</sup>) as “vague and confusing to consumers.”<sup>29</sup> The egg industry is riddled with confusing and misleading imagery and claims such as this one; specific examples are discussed *infra*. Because of a lack of regulation, these claims imply to consumers a false standard of care that causes them to buy a product they otherwise would not buy.

As one would expect, if the current and most common egg production methods are unacceptable to a majority of consumers, and low knowledge of production methods is common,

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<sup>25</sup> Matthew Liebman, ANIMAL LEGAL DEFENSE FUND: REFLECTIONS ON PROPOSITION 2 AND CONSUMER CHOICES (2010), <http://www.aldf.org/article.php?id=1373> (last visited Jun 21, 2010) (citing the correlation between the increased consumer awareness in California of egg production methods following Proposition 2, and the corresponding 180% increase in demand for cage-free eggs, 20% increase in purchase of organic eggs, and decline in demand for battery-cage produced eggs), Ex. 17.

<sup>26</sup> E-mail from Rebecca Wittman, Zogby International, to Gene Baur, President of Farm Sanctuary, (January 10, 2007), Ex. 18.

<sup>27</sup> *Meetings and Events: FSIS to Hold a Public Meeting to Help Define ‘Natural’ Label*, USDA FOOD SAFETY AND INSPECTION SERVICE, Dec. 4, 2006, at [http://www.fsis.usda.gov/News\\_&\\_Events/NR\\_120406\\_01/index.asp](http://www.fsis.usda.gov/News_&_Events/NR_120406_01/index.asp) (last visited Aug. 3, 2010), Ex. 19.

<sup>28</sup> Currently, “natural flavoring” is regulated by 9 C.F.R. 317.2 (2007), 9 C.F.R. 381.118 (2007), and 21 C.F.R. 101.22, which is irrelevant in the context of shell eggs, and egg label regulations, 9 C.F.R. 590.411 (2007) make no reference to “natural” claims on egg packaging, although misleading advertising is purportedly proscribed.

<sup>29</sup> *Producers, Processors Ask USDA to Extend Definition of ‘Natural’*, CATTLE NETWORK, Dec. 13, 2006, available at <http://www.cattlenetwork.com/Producers--Processors-Ask-USDA-To-Extend-Definition-Of--Natural/2006-12-13/Article.aspx?oid=735597> (last visited Aug. 3, 2010), Ex. 20.

sellers have even greater incentive to employ misrepresentations. Sellers nationwide have clearly caved to these incentives, engaging in widespread misrepresentations, and creating the necessity for the corrective regulations called for herein. Given the widespread disapproval of caged confinement, it is logical to infer that consumers aware of the true conditions of these animals – that they were in fact caged – would be much less likely to buy the product. Lack of regulation in this area therefore creates a very real risk that egg companies’ misrepresentations are causing people to buy products they otherwise would not buy. These misrepresentations violate federal law.<sup>30</sup>

## **B. Egg label misbranding is common in the national market.**

Consumers shopping for eggs in grocery stores are faced with many examples of potentially misleading labels. A few examples of both misleading factual claims and misleading imagery follow.

### **1. Factual representations**

(a) *Harris Teeter (“HT”) “All Natural” eggs* - Egg cartons found at a Harris Teeter supermarket as part of HT’s “Naturals” line make the claim that they are “Animal Friendly.”<sup>31</sup> However, HT “Naturals” has two lines of eggs – one is explicitly cage-free and the other makes no such claim. However, both claim to be “Animal Friendly.” This strongly suggests the label with no “Cage-free” claim contains eggs which come from caged birds, which likely contradicts consumer expectations of “Animal Friendly” eggs. Furthermore, labeling on the interior of the carton makes claims that the hens are “happy chickens” who are “lucky enough” to lay HT line eggs. They also state that their hens are “gently cared for.” That these additional claims are made on the interior of the carton makes the claims no less likely to mislead, as most egg

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<sup>30</sup> *U.S. v. Articles of Drug*, 263 F.Supp. 292 at 216 (D.C.Neb. 1967).

<sup>31</sup> *Harris Teeter “All Natural Eggs” Egg Carton Image*, Ex. 21.

purchasers open egg cartons prior to purchase to ensure that none of the eggs are cracked or damaged.

(b) *Farm Fresh “Animal Friendly” eggs*<sup>32</sup> – An in-store advertisement at Farm Fresh grocery store conveys that hens producing its private label eggs are treated in an “Animal Friendly” manner that is likely to be inconsistent with consumers' expectations of what that term means. Further information about this claim is not readily available in stores or on Farm Fresh's website, but evidence suggests these eggs are from hens confined in cages.<sup>33</sup>

(c) *Giant “Nature's Promise” Omega-3 Natural Brown Eggs* – The Giant supermarket store brand claims on its carton that its eggs are from “naturally raised hens.”<sup>34</sup> The idea that an animal is “naturally raised” conveys to the consumer that the living conditions of these hens are traditionally natural – i.e. that the hens are able to nest, roost, and move about freely in natural outdoor settings. Merely having a diet free of antibiotics, synthetic pesticides, and hormones is not adequate to represent consumer impressions of “raising” an animal. “Raising” implies more than just diet; consumers may logically consider “naturally raised” hens to have had natural – outdoor, free-range – living conditions. However, evidence suggests these birds are raised in cages. Giant has two other lines of “Nature's Promise” eggs that are labeled “Cage-free” and “Organic,” which are both described on their website as having “access to the outdoors,” yet no such claim is made on the “Omega-3 Natural Brown Eggs” line.<sup>35</sup>

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<sup>32</sup> *Farm Fresh Supermarket Image of In-Store Poster, “AA Eggs,”* Ex. 22.

<sup>33</sup> FARM FRESH SUPERMARKET, at <http://www.farmfreshsupermarkets.com/> (last visited May 20, 2010), Ex. 23.

<sup>34</sup> *Giant “Nature's Promise” Omega-3 Natural Brown Eggs Carton Image,* Ex. 24.

<sup>35</sup> *Giant Brands: Welcome!*, GIANT, previously available at [http://www.giantfood.com/brands/natures\\_promise.htm](http://www.giantfood.com/brands/natures_promise.htm) (last visited Sept. 19, 2006), Ex. 25. The packing code on the carton is 1153, which corresponds to Sauder's packing plant in Pennsylvania. *List of Plants Operating under USDA Poultry and Egg Grading Programs*, AMS AT USDA, previously available at [http://www.ams.usda.gov/plantbook/Query\\_Pages/plant\\_results.asp](http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp) (last visited Sept. 19, 2006), now available at [http://apps.ams.usda.gov/plantbook/Query\\_Pages/PlantBook\\_Query.asp](http://apps.ams.usda.gov/plantbook/Query_Pages/PlantBook_Query.asp) (last visited Aug. 5, 2010), Ex. 26. Evidence suggests Sauder's is a battery egg supplier. See *Caged Hens/Eggs*, SAUDER'S EGGS, at [http://www.saudereggs.com/caged\\_hens.html](http://www.saudereggs.com/caged_hens.html) (last visited May 20, 2010) (praising the “advantages” of the caging system and criticizing cage-free production), Ex. 27.

(d) *Cal-Maine*<sup>36</sup> — Cal-Maine’s “Sunny Meadow” eggs are misleading to consumers because the brand name itself suggests a free-range environment for hens. In particular, the “Sunny Meadow” title implies that the eggs are produced by hens living in natural surroundings and are afforded the ability to roam freely in spacious, “sunny meadows.” In reality, Cal-Maine is the largest producer of shell eggs in the country, confining millions of hens in battery cages where they are unable to roost, roam freely, or engage in many other natural behaviors.<sup>37</sup> Cal-Maine offers two other lines of eggs under “Farmhouse” and “Eggland’s Best” brands, both of which are advertised as “Cage-free” and “All Natural.” Even though these claims are unregulated and unverifiable at the point of purchase, no similar production method claim is made for “Sunny Meadow” eggs, indicating that the Sunny Meadow eggs are likely produced by hens housed in a conventional battery cage facility, yet the marketing implies otherwise. This causes consumer confusion and hinders the average shopper’s ability to distinguish specialty eggs from the ones that merely purport to be.

(e) Nature’s Design<sup>38</sup> “*All Natural Farm Fresh Eggs*” – These cartons proclaim that the eggs within are “all natural” and “farm fresh,” giving the impression that their hens enjoy a “natural” lifestyle and have free-run of a picturesque “farm.” In reality, the carton’s USDA plant number<sup>39</sup> appears to indicate that these are eggs produced in caged facilities, ensuring that neither of these impressions could be true.

(f) Wild Harvest Natural “*Natural Grade A Omega-3 Large White Eggs*”<sup>40</sup> – The inside of the carton states that the eggs are the “best quality Omega-3 egg for your table,” which, given

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<sup>36</sup> *Cal-Maine’s “Sunny Meadow” Eggs*, available at <http://www.coastgrocery.com/pages/Products/798> (last visited May 20, 2010), Ex. 28.

<sup>37</sup> *Company*, CAL-MAINE FOODS, INC., previously available at <http://www.calmainefoods.com/company.htm> (last visited Nov. 12, 2008), Ex. 29.

<sup>38</sup> See *Nature’s Design “All Natural Farm Fresh Eggs,” carton image*, Ex. 30.

<sup>39</sup> See carton image showing USDA plant number, Ex. 30.

<sup>40</sup> See *Wild Harvest Natural “Natural Grade A Omega-3 Large White Eggs” carton image* at Ex. 31.

the documented nutritional inferiority of caged-produced eggs, could reasonably lead a consumer to believe the eggs are produced in a pastured free-range egg-production facility. However, the USDA plant number on these cartons indicates that they are sourced from a conventional battery-cage facility, despite the heightened nutritional claims.<sup>41</sup> Additionally, the inside label makes explicit as well as implicit animal welfare claims, stating that “On a daily basis, Wild Harvest supports sustainable family farms and humane animal care in order to bring you the purest farm fresh eggs around.” Reasonable consumers likely do not envision conventional battery cage production when informed that the product supports “humane animal care,” nor do they envision battery cage production when told that the eggs are the “purest farm fresh eggs around” and see images of “family farms” used.

(g) Hillandale Farms “*All Natural Brown Eggs*”<sup>42</sup> – Labels such as “farm fresh” are employed, and the carton also depicts a charming barn resting upon an open, green pasture overlooking a sunset. The combined effect of these express and implied claims is to mislead the consumer into thinking that these eggs are obtained from facilities other than the battery cage systems actually in use, perhaps one where the laying hens have even minimal access to the outdoors.

## **2. Misleading imagery**

(a) *Olivera Egg Ranch “Ranch Pak Eggs”* - The Ranch Pak egg carton depicts a chicken on a nest incubating her eggs.<sup>43</sup> This implies Olivera hens have the opportunity to nest and lie on

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<sup>41</sup> See Wild Harvest Natural “*Natural Grade A Omega-3 Large White Eggs*” carton image showing USDA plant number at Ex. 31. The plant number (1153) was linked to a P.O. Box address, but Radlo Foods brand eggs were branded with the same plant number, and that package explicitly states “from caged hens.”

<sup>42</sup> See Hillandale Farms “*All Natural Brown Eggs*” carton image, Ex. 32.

<sup>43</sup> *Olivera Egg Ranch “Ranch Pak Eggs”* carton image, Ex. 33. Ranch Pak Eggs are produced by Olivera Egg Ranch; this is known because of the plant code, 1463, visible on Ex. 33, and able to be tracked through USDA’s website, at *List of Plants Operating under USDA Poultry and Egg Grading Programs*, AMS AT USDA, previously



their eggs. In fact, the owner of Olivera Egg Ranch, Ed Olivera, has made a public statement about his hens being caged and praising the caging system.<sup>44</sup> Hens confined in cages never have the opportunity to nest or lie on their eggs, Olivera's nesting imagery is misleading.

(b) *Rose Acres "White Shell Eggs"* - Rose Acres produces several lines of eggs available in the retail market including "White Shell Eggs," "Brown Shell Eggs," and "Free-Roaming Cage-Free Eggs." While the imagery on the "Free-Roaming Cage-Free Eggs" depicts hens outside, and its website states it is "proud to offer Free-Roaming eggs which come from chickens that are kept in an open, cage-free hen house," no such claims are made regarding its "White Shell Eggs." Yet the imagery on these cartons also depicts hens outside in a similar free-roaming manner, able to peck at the ground and nest.<sup>45</sup> The availability of cage-free products, and that no such claims are made on the "White Shell Eggs," suggests that the implied claim on the "White Shell Eggs" is contrary to Rose Acres' actual production methods, which employ cage confinement.<sup>46</sup>

(c) *Wilcox Farms, "All Natural White"*<sup>47</sup> - Wilcox Farms offers several lines of eggs including "All Natural White" and "Cage-Free." The packages of its "Cage-Free" eggs are clearly marked as such and further depict hens outside. In addition, its website states: "All of the hens producing eggs for the Wilcox Cage-free label are free to run, preen and socialize

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available at [http://www.ams.usda.gov/plantbook/Query\\_Pages/plant\\_results.asp](http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp) (last visited Sept. 11, 2006), now available at [http://apps.ams.usda.gov/plantbook/Query\\_Pages/PlantBook\\_Query.asp](http://apps.ams.usda.gov/plantbook/Query_Pages/PlantBook_Query.asp) (last visited Aug. 5, 2010), Ex. 26.

<sup>44</sup> Matt King, *Free-range Ranch Plans*, THE GILROY DISPATCH, August 23, 2005, available at <http://www.gilroydispatch.com/news/contentview.asp?c=166871> (last visited May 20, 2010), Ex. 34.

<sup>45</sup> Sales, ROSE ACRE FARMS, at <http://www.roseacre.com/sales.html> (last visited May 20, 2010), Ex. 35.

<sup>46</sup> Rose Acres apparently calls its cage confinement systems "pens." *Common Questions*, (Question 9), ROSE ACRE FARMS, <http://www.roseacre.com/eggfaq.html> (last visited May 26, 2010), Ex. 36.

<sup>47</sup> *Large All Natural White Eggs*, WILCOX FAMILY FARMS, available at [http://www.wilcoxfarms.com/consumer/pop/large\\_all\\_natural\\_18.html](http://www.wilcoxfarms.com/consumer/pop/large_all_natural_18.html) (last visited June 29, 2010), Ex. 37.

proudly.”<sup>48</sup> Although no production method claims are made on its packages of “All Natural White” or on its website, the “All Natural White” cartons also include similar imagery of hens outside in a field,<sup>49</sup> though this is unlikely to accurately represent the method of production employed to produce these eggs, which are likely from caged hens.

(d) *Safeway* - The Safeway supermarket store brand depicts two hens foraging outside on its carton of Grade A Large Eggs.<sup>50</sup> One hen is pictured foraging on the ground, suggesting that the hens used to produce these eggs are allowed to move freely, socialize with one another, and are granted access to the outdoors. Yet, the carton bears no “free roaming” label like Safeway’s cartons from free-range hens, indicating that these eggs are most likely from hens confined in cages who are not actually provided the level of care depicted in the image.<sup>51</sup>

(e) *Nucal Foods*, “*White Eggs*”<sup>52</sup> — This egg production facility, located in California, offers white eggs for sale under the name “California’s Finest Eggs Brand.” The egg carton features a chicken roosting on a fence in the middle of an open field, an image that falsely suggests to consumers that hens laying these eggs are raised in a free-range setting. However,

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<sup>48</sup> *Egg Products: Wilcox Cage-free*, WILCOX FAMILY FARMS, previously available at <http://www.wilcoxfarms.com/cagefree.html> (last visited Sept. 11, 2006), Ex. 38.

<sup>49</sup> *Large All Natural White Eggs*, WILCOX FAMILY FARMS, available at [http://www.wilcoxfarms.com/consumer/pop/large\\_all\\_natural\\_18.html](http://www.wilcoxfarms.com/consumer/pop/large_all_natural_18.html) (last visited June 29, 2010), Ex. 37.

<sup>50</sup> See *Lucerne “Grade A Eggs”* carton image, Ex. 39.

<sup>51</sup> The plant tracking number on a carton of Lucerne Eggs from a Washington, D.C. Safeway is 1915. According to the USDA website, that tracking number corresponds with Shady Brae Farms. *List of Plants Operating under USDA Poultry and Egg Grading Programs*, AMS AT USDA, previously available at [http://www.ams.usda.gov/plantbook/Query\\_Pages/plant\\_results.asp](http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp) (last visited Sept. 11, 2006), now available at [http://apps.ams.usda.gov/plantbook/Query\\_Pages/PlantBook\\_Query.asp](http://apps.ams.usda.gov/plantbook/Query_Pages/PlantBook_Query.asp) (last visited Aug. 5, 2010), Ex. 39. That Shady Brae farms facility has over 500,000 hens, manure which is stored below the hens, and a Google images search shows what appears to be long barns; all of these indications are consistent with cage production, making it likely that the Shady Brae Lucerne eggs are from caged hens. *Shady Brae Farms Google Satellite Image*; Penn Future, “Permitted and Pending Concentrated Animal Feeding Operations in Pennsylvania,” available at <http://www.pennfuture.org/UserFiles/CAFOPermittingSpreadsheet.pdf> (last visited September 20, 2010), Ex. 39.

<sup>52</sup> *Nucal Foods’ “White Eggs,”* available at [http://www.nucalfoods.com/egg\\_info\\_our\\_Variety.aspx](http://www.nucalfoods.com/egg_info_our_Variety.aspx) (last visited Nov. 12, 2008), Ex. 40.

without further marketing claims regarding production methods, it is more likely than not that these eggs are produced by hens confined in cages, contrary to the depiction.<sup>53</sup>

### **C. Production method claims are especially material.**

Misrepresentations regarding production method have a specialized effect on consumer choice in various ways that demand comprehensive and corrective government regulation, to a greater extent than is demanded by other types of misrepresentations. This is because production method claims such as hen caging conditions are difficult to verify by sensory perception at the time of purchase or afterward. A consumer cannot evaluate merely by looking at or eating an egg whether it was produced by a hen confined in a cage, in the way that she can verify whether a frozen steak is fresh by either looking at it or tasting it. Cage-free eggs are an example of “credence” goods. Economic goods are often classified as “search,” “experience”, or “credence” goods. USDA economists explain:

Search goods are those for which consumers examine product characteristics, such as price, size, and color, before purchasing. Experience goods are those for which consumers evaluate attributes after purchasing the product. For example, consumers choose particular brands of canned tuna without sampling the product first. Credence goods have attributes that consumers cannot evaluate even in use. For example, consumers cannot inspect particular produce items and determine whether they were grown organically or whether they are the result of biotechnology. Consumers cannot inspect canned tuna and determine if the tuna was caught without harming dolphins.<sup>54</sup>

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<sup>53</sup>Nucal carries a few different lines of eggs laid by free roaming hens, including its “Crack A Smile” and “Horizon Organic” brand eggs. It also produces eggs from cage-free hens, under the “Eggland’s Best,” “Nest Best,” and “Cal Egg” brands. Nucal also offers for sale eggs produced by free-range hens. Each of these egg cartons boasts a free roaming, cage-free, or free-range claim, indicating that Nucal’s “White Eggs” come from caged hens. *Id.* In addition, Nucal sources eggs from cage production; a Nucal supplier, Gemperle, was investigated by animal advocacy group Mercy For Animals in 2008. The investigation showed cage production as well as many animal treatment concerns. Mercy for Animals, “California Egg Farm Investigation,” at <http://www.mercyforanimals.org/caeggs/> (last visited September 20, 2010). *Id.*

<sup>54</sup> Elise Golan, Fred Kuchler & Lorraine Mitchell, *ECONOMICS OF FOOD LABELING*, AGRICULTURAL ECONOMICS REPORT, U.S. DEP’T OF AGRIC., NUMBER 793 (2000) at 7, reprinted in Elise Golan, Fred Kuchler & Lorraine Mitchell, *Economics of Food Labeling*, 24 *Journal of Consumer Policy* 117 (June 2001) (internal citations omitted), Ex. 41.

Cage-free eggs are credence goods just like the tuna. In both cases, consumers cannot evaluate whether animals were harmed in the production method merely by consuming or inspecting the product. In fact, essentially all animal welfare characteristics of food products make them credence goods, as consumers cannot readily determine how animals were treated during production. Animal welfare claims on products, such as egg production method labeling, are classic examples of asymmetric information. The producer has more information and more access to that information (i.e. exactly how the eggs were produced) than the consumer does, increasing the likelihood that the consumer will buy a lower quality good due to its production method (e.g. eggs from hens confined in cages) than they intend to buy.<sup>55</sup> This risk is especially high where the final products themselves are apparently similar, but one is lower quality because of its production method. Producers do not have sufficient incentive to voluntarily label their products – in fact they have an incentive not to. As a result, the market does not supply enough information to allow consumers to make purchasing choices mirroring their individual preferences.<sup>56</sup> This creates a market failure, driving the higher-quality goods (e.g. cage-free eggs) unfairly from the market and deceiving consumers in their purchases.<sup>57</sup>

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<sup>55</sup> Blandford and Fulponi (1999) explain:

Where producers are willing to supply products conforming to animal welfare principles, but consumers are not able to distinguish between these and other goods, there is a dysfunction in the market. Many goods produced by the food industry are best qualified as credence type goods, since their quality cannot be discerned by consumers prior to or after purchase. By definition, a credence type good implies a market with imperfect information: asymmetric information between the buyer and seller, thus a specific type of market failure. Since consumers are not able to distinguish by quality (animal friendly), they may choose the lower quality good and this may drive the higher quality good from the market. Labeling is the standard prescription for dealing with different qualities while permitting consumer choice.

David Blandford & Linda Fulponi, *Emerging Public Concerns in Agriculture: Domestic Policies and International Trade Commitments*, 26(3) EUR. REV. OF AGRIC. ECON., at 409 (1999), Ex. 42.

<sup>56</sup> Golan, Kuchler & Mitchell, at 13, Ex. 41.

<sup>57</sup> Blandford & Fulponi (1999), Ex. 42.

The information asymmetries and market failures surrounding credence goods justify government intervention, especially in the context of the widespread misrepresentations in egg labeling, and such corrective action will improve economic efficiency by helping consumers to target expenditures toward products they most want. USDA economists explain that, under asymmetric information:

mandatory labels targeting asymmetric information are designed to provide consumers with greater access to information and to increase the efficiency of the market. The objective of government intervention in these types of cases is not so much to alter consumption behavior but to increase informed consumption . . . . *effective labeling hinges on the existence of standards, testing, certification, and enforcement services. . . . The government must ensure that quality standards in question are clear and achievable; that testing services, if necessary, are available to measure the validity of labeling claims; that producers (and consumers) are able to certify or otherwise prove the validity of the quality claim; and that a mechanism for enforcing labeling rules exists, including a mechanism to punish producers who make fraudulent claims.*<sup>58</sup>

Especially in light of the special impact misrepresentations have in this context, the FDA must take comprehensive and preventative action in the form of the proposed regulatory scheme in order to fulfill its mandate to halt the widespread mislabeling of eggs in the United States marketplace.

**D. “Natural” and “Naturally Raised” language communicates animal welfare message to consumers.**

One way in which consumers are misled is through the use of the term “natural” on animal-derived food products, which conveys to consumers an animal welfare message indicating that the animals raised for these products at least have access to the outdoors. In egg production, therefore, the “natural” claim would imply that hens are not confined in cages and are provided the ability to walk around outside, which in many cases is false. A 2007 poll by Zogby International showed 61 percent of consumers prefer to purchase products with the claim

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<sup>58</sup> *Id.* at 13-15 (emphasis added).

“natural” on its packaging, and almost half (48 percent) believe that the “natural” claim indicates that the animals had access to the outdoors.<sup>59</sup> Although the public overwhelmingly believes that it is “inappropriate for meat, milk, and eggs from animals who are kept indoors, crowded in cages... to be labeled ‘natural,’”<sup>60</sup> because the use of this claim is not regulated on egg cartons, its extensive use contributes significantly to the misleading labeling landscape, particularly with respect to the level of actual care provided to hens. Without regulations standardizing the full disclosure of production methods, these claims mislead consumers into purchasing a product they perceive to be from more humanely treated hens than is actually the case.

FDA is aware of the vagueness of the term “natural,” and the misleading impression it conveys to consumers. The agency originally solicited comments of the use of the term “natural” on food products in its 1991 Notice of Proposed Rulemaking (“NPR”) for the Nutrition Labeling and Education Act (“NLEA”).<sup>61</sup> In the NPR, FDA recognized that “the meaning and use of the term natural on the label are of considerable interest to consumers and industry.”<sup>62</sup> In the NLEA final rule, FDA declined to define natural because of resource limitations and other agency priorities.<sup>63</sup> Yet, the agency acknowledged that “if the term ‘natural’ is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated.”<sup>64</sup> Given this admission by FDA on a very common claim used on egg cartons, as well as the

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<sup>59</sup> E-mail from Rebecca Wittman, Zogby International, to Gene Baur, President of Farm Sanctuary, (Jan. 10, 2007), Ex. 18.

<sup>60</sup> *Id.*

<sup>61</sup> *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms*, 56 Fed. Reg. 60,466 - 60,467 (Nov. 27, 1991), Ex. 43.

<sup>62</sup> *Id.*

<sup>63</sup> *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms*, 58 Fed. Reg. 2407 (January 6, 1993), Ex. 44.

<sup>64</sup> *Id.*

numerous examples<sup>65</sup> of misleading claims and images relating to animal welfare used by the egg industry, FDA must require production method disclosure to protect consumers.

FDA was again confronted with this issue in 2006 with the submission of a petition from the Sugar Association requesting that the agency define the term natural before a natural claim can be made on foods and beverages under FDA regulation.<sup>66</sup> Unfortunately, FDA has still failed to regulate or even define the term “natural” in the production method context<sup>67</sup> after receiving this petition and a petition from Sara Lee Corporation<sup>68</sup> requesting that the agency establish a definition for the term.<sup>69</sup> The widespread request for agency regulation of the term “natural” emphasizes the importance of the request. In fact, the USDA FSIS acknowledged the need to address such requests pertaining to the “natural” claim in September of 2009 when it began to accept comments on proposed rulemaking regarding the use of this claim on the labels of meat and poultry products.<sup>70</sup> Unfortunately, such measures are nevertheless inadequate to address the misleading labels of eggs, because even if enacted, the standard for “natural” would still not apply to egg labels and would still not be indicative of any improved production methods.<sup>71</sup>

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<sup>65</sup> See, e.g., *supra* at 11-17.

<sup>66</sup> See The Sugar Association, *Citizen Petition re Definition of the term “Natural” for making claims on foods and beverages regulated by the Food and Drug Administration* (Feb. 28, 2006) [Docket No. 2006P-0094/CP1], available at <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-cp00001-toc.htm> (last visited May 21, 2010), Ex. 45.

<sup>67</sup> “FDA... does not currently restrict the use of the term ‘natural’ except on products that contain added color, synthetic substances and flavors as provided for in Title 21 of the Code of Federal Regulations (CFR), section 101.22.” *HFCS is not ‘natural’, says FDA*, NUTRAINGREDIENTS, available at <http://www.nutraingredients-usa.com/Regulation/HFCS-is-not-natural-says-FDA> (last visited June 21, 2010), Ex. 46.

<sup>68</sup> See Sara Lee Corporation, *Citizen Petition re Use of the Term Natural Consistent with USDA’s Food Safety and Inspection Service* (April 13, 2007) [Docket No. 2007P-0147], available at <http://www.fda.gov/OHRMS/dockets/dockets/07p0147/07p-0147-cp00001-02-vol1.pdf>, (last visited Sep. 17, 2010) Ex. 47.

<sup>69</sup> Jane Hoback, *FDA refuses to define natural*, THE NATURAL FOODS MERCHANDISER, available at <http://nfm-online.com/ArticlePage/tabid/66/itemid/2873/Default.aspx> (last visited May 20, 2010), Ex. 48.

<sup>70</sup> Product Labeling: Use of the Voluntary Claim “Natural” in the Labeling of Meat and Poultry Products, 74 Fed. Reg. 46951-01 (proposed Sept. 14, 2009) (to be codified at 9 CFR Parts 317 and 381), Ex. 49.

<sup>71</sup> *Id.* at 46955-56 (discussing “natural” and animal production methods), Ex. 49.

“Natural” conveys to reasonable consumers that animals had access to the outdoors, which is untrue in much of the egg-labeling field. Given that the public has demonstrated its interest in natural products<sup>72</sup> and the use of “natural” claim on eggs from caged hens is widespread and demonstrably misleading, the FDA must require clarifying production method labeling to protect consumers.

USDA has also acknowledged the problem of the unregulated “natural” term on food product labels.<sup>73</sup> In 2007, USDA considered promulgating regulations of the term “natural” in the meat industry when it published a standard for using natural or naturally raised claims. The standard calls for animals raised for the production of meat and meat products to have been raised entirely without antibiotics and growth promotants and to have never been fed avian or mammalian materials. Interestingly, it was animal industry producers and processors who asked USDA to regulate this term, citing the current definition (which does not even apply to eggs<sup>74</sup>) as “vague and confusing to consumers;”<sup>75</sup> a claim also echoed by members of Congress.<sup>76</sup> Clearly, the industry’s call for regulation of this claim indicates the extent of the problem.

When USDA’s standard was initially proposed, criticism abounded that it failed to address the production practices that the average consumer associates with the claim “naturally

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<sup>72</sup> In 2007, a Mintel market survey found that “all natural” is the second most frequent claim made on food labels. See *FDA declines to define ‘natural,’* available at <http://www.care2.com/greenliving/fda-declines-to-define-natural.html> (last visited May 20, 2010), Ex. 50.

<sup>73</sup> *Meetings and Events: FSIS to Hold a Public Meeting to Help Define ‘Natural’ Label*, USDA FOOD SAFETY AND INSPECTION SERVICE (Dec. 4, 2006), available at [http://www.fsis.usda.gov/News\\_&\\_Events/NR\\_120406\\_01/index.asp](http://www.fsis.usda.gov/News_&_Events/NR_120406_01/index.asp) (last visited May 20, 2010), Ex. 19.

<sup>74</sup> Currently, “natural flavoring” is regulated by 9 C.F.R. 317.2 (2007), 9 C.F.R. 381.118 (2007), and 21 C.F.R. 101.22, which is irrelevant in the context of shell eggs, and egg label regulations, 9 C.F.R. 590.411 (2007) make no reference to “natural” claims on egg packaging, although misleading advertising is purportedly proscribed.

<sup>75</sup> *Producers, Processors Ask USDA to Extend Definition of ‘Natural’*, CATTLE NETWORK, Dec. 13, 2006, available at <http://www.cattlenetwork.com/Producers--Processors-Ask-USDA-To-Extend-Definition-Of--Natural/2006-12-13/Article.aspx?oid=735597> (last visited June 21, 2010), Ex. 20.

<sup>76</sup> *Pickering Calls for Chicken Labeling Reform; Pickering and California Congressman Ask USDA to Protect Consumers*, STATES NEWS SERVICE (May 22, 2007), available at <http://news.google.com/newspapers?nid=999&dat=20070531&id=gFEIAAAAIBAJ&sjid=hhMGAAAAIBAJ&pg=1537,2072472> (last visited June 21, 2010), Ex. 51.



raised,” particularly that the animals are raised on pasture and treated humanely. This critique is analogous to the egg industry’s labeling problem. Egg consumers may purchase eggs marketed with the claims “naturally raised” or “natural,” believing them to be produced by hens treated humanely and provided access to pastures, when in reality they are very likely to be the product of hens confined inside battery cages. This problem continues because “the majority of claims citing naturally raised animal production methods are defined at the discretion of the individual company selling the product.”<sup>77</sup> The varied standards are a major source of confusion, which manufacturers have capitalized on by misusing the “natural” label to mislead consumers and increase profits. The FDA must institute clarifying language on egg cartons to prevent consumers from being misled and to protect their interests.<sup>78</sup> Second, the proposed USDA regulation would not apply to eggs or egg products, further underscoring the necessity of clarifying language to correct this and other widespread misleading claims.

FDA is responsible for the regulation and oversight of raw shell eggs, with the jurisdiction and the mandate to correct misleading advertising on egg cartons<sup>79</sup> as well as to

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<sup>77</sup> *USDA Proposes Standards for ‘Naturally Raised’ Meat but Leaves Out All-Important Pasture Requirements*, USDA AGRICULTURAL MARKETING SERVICE (Nov. 28, 2007), available at [http://www.organicconsumers.org/articles/article\\_8647.cfm](http://www.organicconsumers.org/articles/article_8647.cfm) (last visited May 20, 2010), Ex. 52.

<sup>78</sup> Although USDA has published factors it considers in allowing a “natural” claim to be made on a food product, it currently evaluates “natural” labeling claims on a case-by-case basis. *Public Meeting on Product Labeling: Definition of the Voluntary Claim “Natural” on Meat and Poultry Product* LABELING AND CONSUMER PROTECTION STAFF, FOOD SAFETY AND INSPECTION SERVICE (Dec. 12, 2006), available at [http://www.fsis.usda.gov/PDF/Natural\\_Claim\\_Presentation.pdf](http://www.fsis.usda.gov/PDF/Natural_Claim_Presentation.pdf) (last visited May 20, 2010), Ex. 53. More recently, the FSIS has proposed defining the conditions under which the voluntary “natural” claim can be used on the labeling of meat and poultry products. However, even if codified, this standard will not remedy the misleading labeling of eggs, because it will still not standardize “natural” on egg labels, and moreover, will still fail to consider egg production methods within its definition. *Product Labeling: Use of the Voluntary Claim “Natural” in the Labeling of Meat and Poultry Products*, 74 Fed. Reg. 46951-01 (proposed Sept. 14, 2009) (to be codified at 9 CFR Parts 317 and 381), Ex. 49. The term “natural” is used in the Organic Foods Production Act as a synonym for “nonsynthetic”; however, this definition is valid only in the organic foods context because it is used only to distinguish between materials that may and may not be used in organic food production. 7 C.F.R. § 205.2 (2010). This definition is therefore inapplicable to the regulation of labeling in conventional egg production.

<sup>79</sup> See 21 C.F.R. § 1.21(a) (2010).

promote the public health and protect the safety of eggs.<sup>80</sup> In addition to the false advertising issue relating to animal welfare claims, the misleading use of the “natural” and other claims and images on egg cartons are of concern to the FDA from a public health and safety perspective. This relevance to public health and safety further underscores the importance of FDA’s attendance to this issue. For example, the studies demonstrating the nutritional inferiority of eggs from caged hens, discussed *infra* at 29-37, denote that misleading claims and imagery falsely implying a free-range production system communicates false messages to consumers from both an animal welfare perspective and a nutritional perspective, which implicates health and safety issues. Consumers intent on buying nutritionally superior eggs may be enticed into purchasing nutritionally inferior eggs by the “natural” claim, for example, believing such eggs to come from pastured free-range hens.

In addition, a study funded by the European Union about the impact of animal welfare on consumer food choice found that “consumers define animal welfare in terms of natural rearing and humane slaughter and that consumers use animal welfare as an indicator of other, more important, product characteristics such as food safety and quality.”<sup>81</sup> A British study published in the *British Food Journal* in 2002 corroborated those results, revealing that consumers confound the meaning of organic food production and free-range, or animal-friendly, production.<sup>82</sup> The study confirmed that standards of animal welfare are used by consumers as indicators of the safety and healthiness of food.<sup>83</sup>

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<sup>80</sup> “FDA has jurisdiction over the safety of foods generally, including shell eggs, under the FFDCA (21 U.S.C. 301, et seq.).” *Salmonella Enteritidis in Eggs*, 63 Fed. Reg. 96 (May 19, 1998) (citing 21 U.S.C. § 301), Ex. 54.

<sup>81</sup> Gemma C. Harper & Aikaterini Makatouni, *Consumer perception of organic food production and farm animal welfare*, 104 BRITISH FOOD JOURNAL 287 (2002) (internal citations omitted), Ex. 55.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

By the FDA's own agency standards, the "natural" claims being made by the egg industry are misleading when they appear on any carton of eggs other than pastured free-range eggs. According to FDA regulations, labeling "shall be deemed to be misleading if it fails to reveal facts that are material in light of other representations made or suggested by statement, word, design, device or any combination thereof."<sup>84</sup> In essence, the unregulated use of the term "natural" on egg labels is misleading because of the false message that this word conveys to consumers—that the living conditions of these hens are traditionally natural in the sense that the hens are able to nest, roost, and move about freely in natural outdoor settings. Because consumers believe that the term "natural" is relevant to animal welfare, yet there are no standards for the use of this term on egg labels, the egg industry's use of this term is misleading. This example further strengthens the argument that FDA should promulgate the proposed regulations to fulfill the agency's mandate to protect consumers from false advertising, establish clarity in the marketplace, and provide consumers with access to the information they need to make informed decisions.

**E. Recent studies demonstrate the nutritional inferiority of cage-produced eggs to pastured free-range eggs, thereby increasing the need to prevent misleading labels on cage-produced eggs**

A 2007 study analyzed and compared the nutritional content of free-range eggs from hens raised in a pastured setting as compared to USDA's reported nutritional content data for commercial eggs.<sup>85</sup> The eggs tested were from 14 farms across the country, and the results indicated a dramatic difference between the typical commercial eggs (from caged hens) and the free-range pastured eggs in the study. For example, the tested pastured eggs had twice the

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<sup>84</sup> See 21 C.F.R. § 1.21(a).

<sup>85</sup> *Meet Real Free-Range Eggs*, MOTHER EARTH NEWS, available at <http://www.motherearthnews.com/Real-Food/2007-10-01/Tests-Reveal-Healthier-Eggs.aspx> (last visited May 21, 2010), Ex. 56.

Omega-3 fatty acids,<sup>86</sup> one fourth less saturated fat,<sup>87</sup> and one third less cholesterol<sup>88</sup> than conventionally produced (cage) eggs.<sup>89</sup>

Additional studies have confirmed the nutritional inferiority of eggs from caged hens. In 1974, the *British Journal of Nutrition* published an article which concluded that pastured eggs had 50 percent more folic acid and 70 percent more vitamin B<sub>12</sub> than eggs from hens confined in factory farms.<sup>90</sup>

The nutritional differences with respect to B<sub>12</sub> are material to any consumer concerned about nutrition and health. However, this is especially material to vegetarians. Vitamin B<sub>12</sub> occurs naturally only in foods of animal origin and thus vegetarians who limit their intake of animal products have a more material interest in obtaining B<sub>12</sub> from the sources they choose.<sup>91</sup> Vegetarians made aware of these studies may therefore deliberately purchase eggs they believe to be from free-range pastured hens in the hopes of preventing a vitamin B<sub>12</sub> deficiency.

Moreover, in a 1988 study, Dr. Artemis Simopoulos, President of the Center for Genetics, Nutrition and Health, found that pastured eggs in Greece contained 13 times more omega-3

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<sup>86</sup> According to FDA, Omega-3 fatty acids are important to reduce the risk of coronary heart disease, which resulted in FDA's announcement of a qualified health claim for reduced risk of coronary heart disease on certain conventional foods containing Omega-3 fatty acids. See *FDA Announces Qualified Health Claims for Omega-3 Fatty Acids*, UNITED STATES FOOD AND DRUG ADMINISTRATION, available at <http://www.fda.gov/SiteIndex/ucm108351.htm> (last visited Nov. 12, 2008), Ex. 57.

<sup>87</sup> A high intake of saturated fat is linked to high blood cholesterol, stroke, diabetes, and an increased risk of coronary heart disease. See Paula Kurtzweil, *The New Food Label: Help in Preventing Heart Disease*, FDA CONSUMER MAGAZINE (Dec. 1994), available at [http://findarticles.com/p/articles/mi\\_m1370/is\\_n10\\_v28/ai\\_15955606/](http://findarticles.com/p/articles/mi_m1370/is_n10_v28/ai_15955606/) (last visited Aug. 3, 2010), Ex. 58; see also *Diabetes, Heart Disease, and Stroke*, NATIONAL DIABETES INFORMATION CLEARINGHOUSE, available at <http://diabetes.niddk.nih.gov/dm/pubs/stroke/> (last visited May 26, 2010), Ex. 59.

<sup>88</sup> Cholesterol consumption is linked to atherosclerosis, heart disease, stroke, and other health problems. See *Keeping Cholesterol Under Control*, FDA CONSUMER MAGAZINE (Jan./Feb. 1999), previously available at [http://www.fda.gov/fdac/features/1999/199\\_chol.html](http://www.fda.gov/fdac/features/1999/199_chol.html), now available at <http://www.enotalone.com/article/8601.html> (last visited Aug. 3, 2010), Ex. 60.

<sup>89</sup> *Meet Real Free-Range Eggs*, MOTHER EARTH NEWS, available at <http://www.motherearthnews.com/Real-Food/2007-10-01/Tests-Reveal-Healthier-Eggs.aspx> (last visited May 21, 2010), Ex. 56.

<sup>90</sup> A. Tolan, Jean Robertson, C.R. Orton, M.J. Head, A.A. Christie & Barbara A. Millburn, *Studies on the Composition of food: the chemical composition of eggs produced under battery, deep litter and free-range conditions*, 31 BRITISH JOURNAL OF NUTRITION 185 (1974), Ex. 61.

<sup>91</sup> *Id.*

polyunsaturated fatty acids than U.S. commercial eggs.<sup>92</sup> Based on subsequent studies, Dr. Simopoulos has concluded that “the depletion of the (n-3) [omega-3] fatty acids in Western diets is the result of agribusiness [and] modern agriculture.”<sup>93</sup> The traditional Mediterranean diet, with its much lower intake of (n-6) fatty acids and higher intake of (n-3) fatty acids, has been shown to reduce the risk of cardiovascular disease and cancer.<sup>94</sup> Therefore, eggs rich in (n-3) (Omega 3) fatty acids, which have been shown to come from pastured free-range hens, have been scientifically proven to be nutritionally superior to those from caged hens.

More recent studies corroborate these findings. A Pennsylvania State University study recently compared eggs from two groups of “Hy-Line Variety Brown” hens. The first group of hens (“caged hens”) was managed in a commercial facility and raised on a diet standard of the industry (commercial mash), while the other group (“pastured hens”) was allowed to forage different pasture plants and thus raised on a diet of mixed grass and legume plants, supplemented by commercial mash.<sup>95</sup> The study found that the eggs from the pastured hens had a higher concentration of omega-3 fat, vitamin A, and vitamin E than the eggs from caged hens.<sup>96</sup> In another study conducted in Pennsylvania, four pastured poultry producers compared the nutritional soundness of their products with the industry standard.<sup>97</sup> The results indicated that eggs from caged hens are nutritionally inferior to those from pastured hens, containing less

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<sup>92</sup> See Artemis P. Simopoulos, *The Mediterranean Diets: What Is So Special about the Diet of Greece? The Scientific Evidence*, 131 THE JOURNAL OF NUTRITION 3065S (Nov. 2001), available at <http://jn.nutrition.org/cgi/content/full/131/11/3065S> (last visited May 21, 2010), Ex. 62.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Heather D. Karsten, Paul H. Patterson, Robert C. Stout & Gwendolyn W. Crews, *Vitamins A, E and Fatty Acid Composition of the Eggs of Caged Hens and Pastured Hens*, 25 RENEWABLE AGRICULTURE AND FOOD SYSTEMS 45 (2010), available at <http://ddr.nal.usda.gov/dspace/bitstream/10113/41808/1/IND44347774.pdf> (last visited Aug. 3, 2010), Ex. 63.

<sup>96</sup> *Id.*

<sup>97</sup> Barbara Gorski, *Nutritional Analysis of Pastured Poultry Products*, 11 AMERICAN PASTURED POULTRY PRODUCERS ASSOCIATION 1 (Winter 2000), Ex. 64.

vitamin A.<sup>98</sup> Moreover, the pastured eggs contained omega-6 to omega-3 ratios “considerably better than the standard” (7:1 versus 18:1)<sup>99</sup>, which is significant because a leaner ratio has been linked to a reduced risk of cardiovascular disease and cancer, discussed *infra*. Finally, *Animal Feed Science and Technology* published an article in 1997, reporting on a study which concluded that eggs from hens fed grass and a commercial mash diet (termed “free-range hens” in the study) were nutritionally superior to the eggs from hens raised on just a commercial mash diet.<sup>100</sup> Specifically, the “concentration of (*n*-3) fatty acid was almost threefold higher in eggs from hens fed on free-range.”<sup>101</sup> Altogether, these studies compel the conclusion that eggs from caged hens are nutritionally inferior to those from free-range pastured hens. It is important to note that even though not all eggs that qualify as “free-range” are the pastured eggs that were the subject of these studies, examples highlighted in this Petition imply to consumers that those eggs are not merely from free-range hens, but in fact from pastured free-range hens who are afforded meaningful access outdoors and allowed to forage for food.<sup>102</sup>

#### **F. Egg Producers Promote Cage Production, but Many Oppose Regulation Requiring Disclosure of Production Practices**

Despite egg producers’ public claims promoting cage production, many egg producers are strongly opposed to the promulgation of regulations requiring the clear identification of “Eggs From Caged Hens” on egg cartons. For example, Willamette Egg Farms has stated that cage production practices are designed for the welfare of the chickens and has led to decreased

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<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> C.J. Lopez-Bote, R. Sanz Arias, A.I. Rey, A. Castaño, B. Isabel & J. Thos, *Effect of free-range feeding on *n* – 3 fatty acid and  $\alpha$ -tocopherol content and oxidative stability of eggs*, 72 ANIMAL FEED SCIENCE TECHNOLOGY 33 (1997), Ex. 65.

<sup>101</sup> *Id.*

<sup>102</sup> *See id.*; *see also, e.g., supra* at 7-8, 10-14.

mortality and increased production.<sup>103</sup> Many egg producers, such as Feather Crest Farms, Inc., Kofkoff Egg Farms, LLC, Pearl Valley Eggs, Inc., Morning Fresh Farms and Wegman's Consumer Affairs have opposed the regulatory scheme proposed in this petition.<sup>104</sup> Egg producer Willamette Egg Farms asserts that cage production methods "are considered humane and ethical by the leading independent scientific experts on animal welfare and behavior," and help ensure "some of the freshest, safest, cleanest eggs in the world."<sup>105</sup> For example, Willamette Egg Farms highlights the benefit of cage systems, stating, "Although the housing and caging of laying hens may appear to limit their freedom, the system is actually designed for the welfare of the birds as well as for production efficiency," and noted that hens housed in cages produced more eggs, lived longer, and produced cleaner and higher quality eggs.<sup>106</sup> In response to criticism of battery cage egg production, an editorial featured in Feedstuffs, a weekly agribusiness newsletter, argued that "A check of facts demonstrates that hens housed in cages are less stressed and healthier and safer."<sup>107</sup> Despite the fact that major egg industry players and industry publications have publicly supported cage production, many egg producers claim that compliance with the proposed legislation by labeling their egg cartons with "Eggs from Caged Hens" would equate to "convey[ing] to consumers that there is something bad about eggs produced from hens housed in cages,"<sup>108</sup> and therefore vehemently oppose such regulation.

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<sup>103</sup> *About Willamette Egg Farms*, WILLAMETTE EGG FARMS, <http://www.willamette-egg.com/ourfarm> (last visited July 7, 2010), Ex. 66.

<sup>104</sup> *See, e.g.*, Letter from Feather Crest Farms, Inc., to Food and Drug Administration, (January 18, 2006), Ex. 67.

<sup>105</sup> *California Egg Producers Advocate for The Protection Of Consumer Choice*, WILLAMETTE EGG FARMS, <http://www.willamette-egg.com/news/2008/01/29/california-egg-producers-advocate-protection-consumer-choice> (last visited Jul 7, 2010), Ex. 68.

<sup>106</sup> *About Willamette Egg Farms*, WILLAMETTE EGG FARMS, <http://www.willamette-egg.com/ourfarm> (last visited Jul 7, 2010), Ex. 66.

<sup>107</sup> Marian Burros, *More House Salads, Whether the House Likes It or Not*, THE NEW YORK TIMES, January 16, 2008, [http://www.nytimes.com/2008/01/16/dining/16capi.html?\\_r=1](http://www.nytimes.com/2008/01/16/dining/16capi.html?_r=1) (last visited July 2, 2010), Ex. 69.

<sup>108</sup> *Id.*

In contrast to the above comments, poultry scientist and leading expert on animal welfare, Dr. Ian Duncan, notes: “The battery cage systems for laying hens was one of the first invasive husbandry systems to come under criticism on animal welfare grounds. These criticisms have continued unabated.”<sup>109</sup> More specifically, he points out, “[p]ossibly the biggest problem is the lack of a nesting site . . . . The lack of space in battery cages reduces welfare.”<sup>110</sup> Notwithstanding the significant concern amongst experts over the issue of confining hens in wire cages and the objective standard of care animals should receive, consumer perception is the sole criterion to be considered under misleading advertising analysis. About 81% of respondents to a survey indicated that they are willing to pay more for products produced in a humane manner,<sup>111</sup> indicating that they find animal care to be materially important to their purchasing decisions, and over 80 percent oppose the use of cages for egg production.<sup>112</sup> Promulgation of production method labeling requirements would provide consumers with salient information enabling them to make more informed purchasing choices.

Egg producers that submitted comments oppose the full disclosure of production methods on cartons in large part because they are “unnecessary” given that “[e]ggs produced from other than caged housing are always labeled with the type of production to justify a premium price to those consumers that desire and can afford the more expensive eggs.”<sup>113</sup> However, the biggest concern consumers face is the misleading labeling of eggs from caged hens, and the intent of this petition is to remedy the misleading nature of the existing voluntary labeling programs which tend to increase confusion rather than reduce it, discussed *supra*.

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<sup>109</sup> Ian J. Duncan, *Animal Welfare Issues in the Poultry Industry: Is there a Lesson to be Learned?*, 4 JOURNAL OF APPLIED ANIMAL WELFARE SCIENCE 3, July 2001, at 208, Ex. 70.

<sup>110</sup> *Id.*

<sup>111</sup> Poll: *U.S. citizens support humane treatment for egg-laying hens*, CNN.COM (2000), <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited Jun 22, 2010), Ex. 4.

<sup>112</sup> *Id.*

<sup>113</sup> See, e.g., Letter from Feather Crest Farms, Inc., to Food and Drug Administration, (January 18, 2006), Ex. 67.



While egg industry commentators argue that “consumers should be able to make their own, personal informed choice about the type of eggs that they want to purchase, whether from modern cage, cage-free or organic,”<sup>114</sup> and defend caging systems on the one hand, they strongly oppose the full disclosure of egg production methods to consumers at the point of purchase, specifically the identification of “Eggs From Caged Hens.” It is exactly this type of contradictory positioning that threatens consumers and necessitates the regulations requested herein, which seek merely to provide an accurate representation of egg production methods to consumers, enabling them to make more informed choices. In today’s marketplace, the lack of regulations requiring the full disclosure of the applicable production methods allow egg producers to promote and profit from consumer confusion. This is especially concerning in the context of misleading labeling because if there is intent behind a false message, there is a presumption that the false message is the one the consumer receives.<sup>115</sup>

**G. Passage of the Prevention of Farm Animal Cruelty Act in California further illuminates the need for egg-labeling regulation.**

Uniform federal regulation of egg carton labeling is now even more imperative given the recent passage of the Prevention of Farm Animal Cruelty Act (Proposition 2) in California. As states like California enact laws relating to production methods in egg production, and as the FDA has the authority and expertise to address food labels generally, efficiency will also be served by the creation of uniform egg labeling disclosure requirements.

The recent passage of the Prevention of Farm Animal Cruelty Act in California illustrates that consumers oppose the use of battery cages. In addition to encompassing animal welfare

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<sup>114</sup> *California Egg Producers Advocate for The Protection Of Consumer Choice*, WILLAMETTE EGG FARMS, available at <http://www.willamette-egg.com/news/2008/01/29/california-egg-producers-advocate-protection-consumer-choice> (last visited July 7, 2010), Ex. 68.

<sup>115</sup> See *Del Webb Cmtys., Inc. v. Partington*, 2009 U.S. Dist. LEXIS 85616, 36-37 (D. Nev. Sept. 17, 2009) (“where a defendant intentionally misled consumers or the advertisement is literally false, a presumption arises that consumers were in fact deceived and the burden shifts to the defendant to prove otherwise”) citing *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. Cal 1995).

concerns, discernable differences in nutritional value and health and safety risk results from the varying treatment of hens, as discussed *supra* and *infra*. Accordingly, survey data shows that consumers would distinguish between these two products at the point of purchase if given adequate information.

However, with California requiring its egg producers to rely on cage-free production methods, illegitimate profits stand to be made by the many producers who are falsely representing that their eggs are not from hens confined in cages. The misleading egg-labeling described in this Petition presents a potential market failure where California producers will be looking to compete in the national marketplace selling only eggs from cage-free hens. Where eggs from caged hens can be sold – perhaps more cheaply – falsely representing the level and type of care provided, the California producers will not be able to fairly compete or sell their products at the true price the market will bear.<sup>116</sup> This in turn damages consumers, who will be mistakenly purchasing products they otherwise would not buy, and who will be purchasing products in an unfairly noncompetitive marketplace. Moreover, the recent passage of A.B. 1437 further incentivizes the continued employment of misleading claims creating the perception of heightened animal care on its retail products in the nation’s largest egg market, as the bill will require that, as of January, 2015, all whole eggs sold in California sourced from in- and out-of-

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<sup>116</sup> The egg industry’s own economic analysis shows the actual increased cost for cage-free production, which breaks down to a mere cent per egg. See Don Bell, *A Review of Recent Publications on Animal Welfare Issues for Table Egg Laying Hens* 4 (revised January 11, 2006), available at <http://animalscience.ucdavis.edu/Avian/WelfareIssueslayingHens.pdf>, (last visited May 21, 2010) Ex. 71. However, cage-free eggs often sell for significantly more than that (in some cases, upwards of twice the price of cage eggs). Because of the market failures due to misleading claims and imagery, the true value of these eggs to consumers cannot be determined, causing consumers to be harmed by artificially high prices and cage producers unfairly capitalizing on consumers’ willingness to pay more for cage-free eggs, simply by misrepresenting their eggs as cage-free through misleading claims and images.

state come from hens able to stand up, fully extend their limbs, lie down and spread their wings without touching each other or the sides of their enclosure.<sup>117</sup>

The simple full disclosure of production methods would help to correct this problem. Without regulations requiring such disclosure as requested by the Petition, consumers and California egg producers will suffer harm, and companies that engage in false and misleading advertising will be afforded an undeserved and illegal windfall. Where the manufacture of a product brings about externalities such as the likely damage to California egg consumers and producers in this misleading market, courts have held that “federal regulation is both appropriate and necessary.”<sup>118</sup> Thus, the FDA is obligated on grounds of public policy to create a uniform system of federal regulation governing the use of labels on egg cartons.

State governments do not have the authority or the expertise to supervise and respond to regulations created by other state governments with respect to egg labeling. Because the FDA is charged with the regulation of all food and drugs, and because part of its duty as the watchdog for the safety and accuracy of such items is to ensure that necessary disclosures are made on product labels, the agency clearly has the expertise necessary to create an efficient, uniform system of labeling in this context.

To date, however, the FDA has not exercised its authority over egg labeling, which has resulted in inconsistency between the agencies’ application of their respective and verbatim statutory provisions<sup>119</sup> and the widespread use of misleading express and implied production method claims on egg labels as described above.

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<sup>117</sup> A.B. 1437, 2009-2010 Gen. Assem., Reg. Sess. (Cal 2010), *Assembly Bill - ENROLLED*, OFFICIAL CALIFORNIA LEGISLATIVE INFORMATION, available at [http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_1401-1450/ab\\_1437\\_bill\\_20100622\\_enrolled.html](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_1401-1450/ab_1437_bill_20100622_enrolled.html) (last visited Jul 7, 2010), Ex. 72.

<sup>118</sup> *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 195 (U.S.2001).

<sup>119</sup> These agencies include the USDA, FDA, and FTC. See the Federal Meat Inspection Act, at 21 U.S.C. § 601(n)(1) (2010) (prohibiting labeling of meat or meat products that is “false or misleading in any particular”), and the Poultry

## II. Legal Grounds

This pervasive misbranding of egg labels violates several statutory provisions, and frustrates Congress' will that food labeling accurately reflect the essential characteristics of the product being sold without misrepresenting or omitting material facts on which consumers rely. These same statutory provisions empower, and in fact require, action by the FDA to correct such mislabeling.

### **A. The FDA has the legal authority and responsibility to regulate egg label misbranding.**

The FDA is the primary government agency charged with the responsibility of regulating product labels.<sup>120</sup> The FDA is also empowered with the ability to make administrative findings that may result in official action to enjoin false and misleading advertisements.<sup>121</sup> The FDA, the USDA through FSIS and Agricultural Marketing Service ("AMS"), and the Federal Trade Commission ("FTC") share federal authority to regulate eggs.<sup>122</sup> Therefore, the FDA has the legal authority and responsibility to regulate misleading egg labeling.

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Products Inspection Act, *at* 21 U.S.C. § 453(h)(1) (2010) (prohibiting labeling of poultry products that is "false or misleading in any particular" manner).

<sup>120</sup> 21 U.S.C. § 1036(b) (2010); 7 U.S.C. § 6509 (2010); 7 C.F.R. §§ 3.91, 56.35(b), 57.5, and 58.50 (2010). It should be noted that the FDA has not made clear whether it construes these statutes to cover false advertising complaints by consumers regarding animal production methods; however, there are limits to how far any agency can go in ignoring its statutory mandate. *See Chevron U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 843 (1984) (establishing the arbitrary and capricious agency actions standard).

<sup>121</sup> 21 C.F.R. § 10.30(e) (2010).

<sup>122</sup> 21 C.F.R. §§ 16.5, 101.17, 115.50 (2010); 7 U.S.C. §§ 1621, 6503(d) (2010); 15 U.S.C. § 45(a)(2) (1938); *see* 21 U.S.C. § 1043 (2010) ("The Secretary shall promulgate such rules and regulations as he deems necessary to carry out the purposes or provisions of this chapter, and shall be responsible for the administration and enforcement of this chapter except as otherwise provided in section 1034(d) of this title."); 15 U.S.C. § 45(a)(2) (1938) ("The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce."); 7 U.S.C. § 1621 (2006) (noting that it is the congressional intent for "cooperation among Federal and State agencies, producers, industry organizations, and others in the development and effectuation of research and marketing programs to improve the distribution processes"); 7 U.S.C. § 6503(d) (2006) ("The Secretary shall implement the program established under subsection (a) of this section through certifying agents."); 6504 (2006) (governing the labeling of organically produced agricultural products). 21 U.S.C. § 1043 (2006) ("The Secretary shall promulgate such rules and regulations as he deems necessary to carry out the purposes or provisions of this

# **1. Authority pursuant to FFDCA's mandate to cure misleading labeling.**

Correct application of the Federal Food, Drug and Cosmetic Act ("FFDCA") when determining if a label is misleading requires evaluating the "falsity or misleading character of a label or of labeling or of advertising...as read by those to whom [the product] appeals." *See U.S. v. Vitamin Industries, Inc.*, 120 F.Supp. 755, 767 (D.C. Neb. 1955) (collecting cases from the Second, Sixth, Seventh, Ninth and Tenth Circuits). In accord with this position is *U.S. v. Articles of Drug, etc.*, 263 F.Supp. 212, 215-16 (D.C. Neb. 1967), where the court held that

'Misleading' as used within the Act should be determined by the effect that the material (label and labeling) will have on prospective purchasers to whom the claims are addressed...It would defeat the obvious intent of the [FFDCA] to hold such persons to special knowledge or ability. Nor should the Court assume that the buying public will exercise great selectivity and caution in what they choose to believe of what they hear or read.

In other words, the courts in *Articles* and *Vitamin* read the FFDCA to be a law benefiting consumers. The purpose of 21 U.S.C. § 321 is to prevent "people of ordinary understanding and discrimination" from being misled into making purchases they would not otherwise have made.<sup>123</sup>

The FDA is not only permitted but is in fact *required* to act to regulate egg labeling. In its controlling Memorandum of Understanding with the Federal Trade Commission, the FDA confirmed its commitment to prevent deception of the public, and takes primary responsibility for preventing deceptive food labeling.<sup>124</sup>

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chapter, and shall be responsible for the administration and enforcement of this chapter except as otherwise provided in section 1034(d) of this title.").

<sup>123</sup> *Articles*, 263 F.Supp. at 216.

<sup>124</sup> *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 11.

In *Alliance for Bio-Integrity v Shalala*, 116 F.Supp.2d 166, 178 (D.D.C. 2000), the court held that the FDCA “grants the FDA limited authority to require labeling [of foods].” According to 21 U.S.C. §321(n) of the FFDCA,

...in determining whether...labeling or advertising is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary and usual.

If a label or method of advertising fails to reveal facts in such a way, it is deemed “misbranded” and the FDA may require a labeling change.<sup>125</sup> In *Shalala*, the agency action being reviewed was the FDA’s decision not to require labeling of foods modified through rDNA (recombinant deoxyribonucleic acid) technology. The FDA interpreted the rDNA status of the food as not being a material change from non-genetically altered food.<sup>126</sup> This is because it was neither inherently risky to consumer health or safety, nor did it differ in any material way from traditional counterparts.<sup>127</sup> The court, without adopting FDA’s interpretation of the statute, afforded the FDA substantial deference and found its interpretation in that case reasonable.<sup>128</sup>

However, the court also noted in the same discussion that the FDA does retain authority to require specific labeling to cure material fact *omission* and other forms of misbranding.<sup>129</sup> Indeed, the court reasoned that “the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling...[and] if there is

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<sup>125</sup> *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166, 178 (D.D.C. 2000).

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 178-79.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 178, n8.

a [material] difference, and consumers would likely want to know about the difference, then labeling is appropriate.”<sup>130</sup> Thus the FDA is required to regulate labeling to correct misbranding.

The general misbranding described herein fits into the exception carved out by the court in *Shalala*. The labeling of shell eggs in the United States today fails to reveal to consumers certain material facts which substantially influence their purchase decisions. Egg labels now commonly employ misleading express and implied claims, which result in a material and significant difference between the product sold and what it purports to be. As the court in *Shalala* held, a product that “differ[s] significant[ly]...from what it purports to be” is an appropriate product for which to require special labeling.<sup>131</sup> Making purchases they otherwise would not have made is exactly what consumers are doing in the case of egg production method labeling. We are faced with a situation where 95% of eggs are produced by hens confined in cages, which 86.2% of the public finds to be unacceptable,<sup>132</sup> where 80.7% of respondents would pay more for eggs from hens raised in a “humane” manner,<sup>133</sup> and where 76% of consumers indicate that animal welfare is more important to them than lowly priced animal products.<sup>134</sup> Given this, there is a high risk of even blatant factual misrepresentations on cartons.<sup>135</sup> Where

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<sup>130</sup> *Id.* at 179.

<sup>131</sup> *Id.*

<sup>132</sup> Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>133</sup> Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>134</sup> Jayson L. Lusk, Bailey F. Norwood & Robert W. Prickett, *Consumer Preferences for Farm Animal Welfare: Results of a Nationwide Telephone Survey* (2007), available at <http://asp.okstate.edu/baileynorwood/AW2/InitialReporttoAFB.pdf> (last visited Aug. 3, 2010), Ex. 73.

<sup>135</sup> See, e.g., Sales, ROSE ACRE FARMS, at <http://www.roseacre.com/sales.html> (last visited May 20, 2010), Ex. 35; Egg Products, WILCOX FAMILY FARMS, previously available at <http://www.wilcoxfarms.com/cagefree.html> (last visited Sept. 8, 2006), Ex. 38; see also Egg Products: All Natural White, WILCOX FAMILY FARMS, at [http://www.wilcoxfarms.com/consumer/pop/large\\_all\\_natural\\_18.html](http://www.wilcoxfarms.com/consumer/pop/large_all_natural_18.html) (last visited May 20, 2010), Ex. 37; see also Statement of Grounds, Part I, B. of this petition, *supra*, for further discussion.

terms like “Free-range” or “Cage-Free” are not regulated or even defined, companies are allowed to use them with impunity, even where their use defies logical sense. For example, eggs claimed to be “Animal Friendly”<sup>136</sup> or “All Natural” can be from birds confined in cages. This renders the labeling landscape meaningless.<sup>137</sup> The potential for misleading consumers by omissions or misrepresentations through an unregulated market is rampant. This issue fits squarely into the purview of the FDA under the FFDCA.

**2. Authority pursuant to 21 C.F.R. § 1.21 which allows FDA to require affirmative disclosures of material facts necessary to cure misleading labels.**

Additionally, the FDA has broad authority to promulgate regulations in the field of egg labeling requiring disclosure of eggs from caged hens. 21 C.F.R. § 1.21 provides that the FDA may require companies to make affirmative disclosures regarding any material facts required to cure a misleading label. Under 21 C.F.R. § 1.3, such labels include misleading graphic material and need not be text. When this section is taken in conjunction with 7 C.F.R. § 56.35, which mandates that the FDA approve only non-misleading egg packaging, it can only be concluded that FDA approval should be withheld until such packaging is either non-misleading or until the FDA requires additional clarifying labels to correct the misleading representations of the original packages.

This authority is broader than the power to make administrative findings pursuant to 21 C.F.R. §§ 10.30(e) and 1.21. FDA has a statutory mandate to prohibit the introduction or

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<sup>136</sup> Farm Fresh “Animal Friendly” claim on in-store poster. *Farm Fresh Supermarket Image of In-Store Poster, “AA Eggs,”* Ex. 22.

<sup>137</sup> See Umbra Fisk, *Rambled Eggs*, GRIST MAGAZINE, Mar. 22, 2006, available at <http://www.grist.org/advice/ask/2006/03/22/free-range/index.html>, (last visited May 21, 2010), Ex. 74; *Cage-Free Over Easy Please – Are Designer Eggs What They’re Cracked up to be?*, HEALTH MAGAZINE, March 2003, previously available at <http://www.pfda.com/prodServices/Healthcare/ArticleOfMonth.asp?ArticleID=261>, (last visited Sept. 11, 2006), Ex. 75; *Claim some eggs falsely labeled ‘free-range,’* ABC NEWS ONLINE, July 23, 2006, available at <http://www.abc.net.au/news/newsitems/200607/s1694200.htm>, (last visited May 21, 2010), Ex. 76.



delivery of misbranded<sup>138</sup> food into interstate commerce<sup>139</sup> under the FFDCA. Shell eggs are included within FDA's definition of "food,"<sup>140</sup> and the FFDCA's authority-granting provision<sup>141</sup> has been interpreted to apply to the Commissioner of the FDA. FDCA provides that "[t]he authority to promulgate regulations for the efficient enforcement of this chapter ... is vested in the Secretary [of Health and Human Services]."<sup>142</sup> This provision has been interpreted as authorizing the Secretary to "promulgate binding, substantive regulations."<sup>143</sup> This authority has been delegated to the Commissioner of the FDA.<sup>144</sup> In addition, courts have held that the FDA has authority to promulgate binding regulations under Section 701(a) of the Food and Drug Act.<sup>145</sup> Thus, because it is evident that Congress intended 1) to categorically bar the use of misleading egg labels, and 2) to charge the Secretary with the enforcement of such prohibition (as well as with assuring that the statute is in accordance with other requirements), the statute is unambiguous and leaves no room for the FDA to regulate only at its own discretion.

This authority encompasses the specific egg carton labeling regulations set forth in this Petition. In particular, courts have held that if the FDA determines that certain articles of food, as a class, pose an inherent risk or safety consequence to consumers, or differ in some material way from their traditional counterparts, the FDA has authority to require labeling.<sup>146</sup> As the District

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<sup>138</sup> Under 21 U.S.C. § 343(a)(1) and (2), food is deemed misbranded if "its labeling is false or misleading in any particular, or ... its advertising is false or misleading in a material respect."

<sup>139</sup> 21 U.S.C. § 331(a).

<sup>140</sup> 21 U.S.C. § 321(f) defines "food," in part, as "articles used for food or drink for man or other animals."

<sup>141</sup> 21 U.S.C. § 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter ... is vested in the Secretary [of Health and Human Services]").

<sup>142</sup> *Id.* 1182-1183.

<sup>143</sup> *Pharmaceutical Mfrs. Ass'n v. Food and Drug Administration*, 484 F.Supp. 1179, 1182 (D. Del. 1980).

<sup>144</sup> *Id.*

<sup>145</sup> See *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 692-697 (2d Cir. 1975).

<sup>146</sup> *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d. 166, 179 n. 8 (D.D.C. 2000).

Court for the District of Columbia noted in *Shalala*, “[i]f there is a [material] difference, and consumers would likely want to know about the difference, then labeling is appropriate.”<sup>147</sup>

**a. Materiality of misleading production method claims.**

The materiality of production method claims with respect to confining laying hens in cages is well-established. As discussed above, 86.2% of American adults believe the common egg industry practice of confining egg-laying hens in densely crowded cages is unacceptable,<sup>148</sup> although approximately 95% of eggs produced in the United States come from hens in such cages.<sup>149</sup> Given that many consumers find caging unacceptable yet have little knowledge about production methods, the egg industry has the unfettered incentive to mislead consumers. This discrepancy between how eggs in the United States are produced and the false representations made to consumers on egg cartons is “material” under the FFDCA. These representations induce some consumers to purchase products they would not purchase if they knew the eggs came from hens confined in cages. These misleadingly labeled cartons are not “the identical thing that the brand indicates it to be.”<sup>150</sup> Furthermore, the FDA’s own agency standards dictate that the “natural” claims being made by the egg industry are misleading when they appear on any carton of eggs other than pastured free-range eggs because the regulations instruct that labeling “shall be deemed to be misleading if it fails to reveal facts that are material in light of other representations made or suggested by statement, word, design, device or any combination thereof.”<sup>151</sup>

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<sup>147</sup> *Id.* at 179 [citations omitted].

<sup>148</sup> *Poll: U.S. Citizens Support Humane Treatment for Egg-Laying Hens*, REUTERS, CNN, Sept. 20, 2000, at <http://archives.cnn.com/2000/FOOD/news/09/20/food.hens.reut/index.html> (last visited May 20, 2010), Ex. 4; E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 5.

<sup>149</sup> See Sarah Moran, *A Good Egg*, STAR TRIBUNE: NEWSPAPER OF THE TWIN CITIES, December 1, 2008, Ex. 6.

<sup>150</sup> *U.S. v. Ninety-Five Barrels ... Apple Cider Vinegar*, 265 U.S. 438, 44 (1924).

<sup>151</sup> See 21 C.F.R. § 1.21(a).

Given the materiality and widespread use of misleading labels in the egg industry, FDA is authorized and mandated to promulgate broad regulations clarifying egg labels as requested herein under the FFDCA, specifically 21 U.S.C. sections 321, 331, 343 and 371 and the standard articulated in *Shalala*, as well as pursuant to 21 C.F.R. § 1.21. According to the correct interpretation of the FFDCA, a product is “misbranded” when its labels fail to reveal material facts, and it requires that the FDA prevent such misbranding where it is likely to induce ordinary consumers from making purchases they would not otherwise make.<sup>152</sup> 21 C.F.R. § 1.21 not only authorizes FDA to act where express or implicit failures to reveal material facts are deemed misleading, but further expounds that the FDA can affirmatively *require* disclosure of material facts.

There are further legal bases which demonstrate that the authority to regulate egg-labeling is squarely within the FDA’s purview. The first is 21 U.S.C. § 1043, which dictates that the FDA may promulgate such rules and regulations as deemed necessary to carry out its mandate, including that to prevent the misleading of ordinary consumers by food labels.

The Fair Packaging and Labeling Act (15 U.S.C. §§ 1452-1454) gives the FDA authority to issue regulations requiring that all “consumer commodities,” including food products, be labeled to disclose certain product information, such as its net contents, and the name and place of the product’s manufacturer, packer, or distributor.<sup>153</sup> Although this Act does not itself mandate FDA to implement egg-labeling standards, it does demonstrate that doing so is wholly consistent with and encompassed by its present food-labeling authority. Likewise, the Nutrition Labeling and Education Act (“NLEA”) (Public Law 101-535) also demonstrates that instituting egg-labeling regulations are fully within FDA’s authority, as the NLEA gives FDA the authority to

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<sup>152</sup> See *supra* at 35-36.

<sup>153</sup> FPLA Introduction, FEDERAL TRADE COMMISSION, *available at* <http://www.ftc.gov/os/statutes/fpla/outline.shtm> (last visited Jul 15, 2010).

require nutrition labeling on foods regulated by the agency, and to require that all nutrient content and health claims are in accordance with existing FDA regulations. Even recent agency actions reinforce FDA's egg-labeling authority; an FDA ruling requiring producers of non-pasteurized eggs to take certain actions to help curtail the incidence of Salmonella Enteritidis relied on FDA's authority to mandate the labeling of shell eggs after the December 2000 enactment of 65 Fed. Reg. 76092, and this further demonstrates that the regulation of egg labeling is squarely within the purview of FDA's authority.<sup>154</sup>

FDA's mandate to promulgate the regulations requested in this Petition is such that a decision not to regulate would be arbitrary, capricious, and contrary to law. In *Federal Security Adm'r v. Quaker Oats Co.*, farina manufacturers were labeling their products as "enriched" when there was no consistent definition of that term. The FDA determined pursuant to its authority under 21 U.S.C.A. § 341 of the FFDCA that it was necessary to establish regulations standardizing the definitions of "farina" and "enriched farina" in order to avoid consumer confusion regarding the meaning of these terms. Farina manufacturers challenged the rule and won in the Court of Appeals, which found that the risk of consumer confusion was too speculative to justify a finding that the regulations would promote "honesty and fair dealing" under the statute. The Supreme Court reversed, finding that testimony before the agency regarding the likelihood that variation in composition of farina products would result in consumer confusion was sufficient to meet the requirements of the statute regarding honesty and fair dealing. It stated:

Taking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values, there was sufficient evidence of 'rational probative force', to support the

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<sup>154</sup> 74 Fed. Reg. 33033-01 (July 9, 2009) (to be codified at 21 C.F.R. pts. 16, 18).

Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue.<sup>155</sup>

In the egg-labeling context, the lack of regulation of misleading egg labels is likely to result in consumer confusion that is strongly analogous to that described in *Quaker Oats*. As in that case, wherein there was an increasing demand for vitamin-enriched farina that led the FDA to promulgate regulations standardizing its definition, there is today an increasing demand for cage-free and free-range eggs. Likewise, as in *Quaker Oats*, there is a general lack of consumer knowledge regarding the nature of the eggs currently available in the marketplace. Thus, because of inadequate labeling and a lack of standardized definitions, consumers may be similarly unable to purchase the product they desire. In fact, the likelihood of consumer confusion is even greater in this case since it is often possible for a consumer to believe, based on package design and text labels, that she is purchasing eggs from hens allowed to roam outside when, in reality, the eggs are just the opposite. In contrast, prior to the regulations promulgated in *Quaker Oats*, the products labeled “enriched farina” did generally include some of the vitamins that consumers believed them to contain and were therefore not as egregious an example of misinformation. Here, should the FDA decline to create a uniform system for egg labels, its decision will necessarily be arbitrary and capricious, since it has in the past promulgated standardizing regulations in an analogous situation that was even less likely to result in consumer confusion than the egg packaging in the instant case.

The FDA is permitting egg producers to deceive consumers by using false or misleading claims that imply a higher level of care than is actually the case, particularly with respect to the practice of confining hens in cages. Such a failure to regulate the misleading egg labeling field on the part of the FDA amounts to an abdication of statutory responsibility. The Supreme Court

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<sup>155</sup> *Federal Security Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 228-229 (U.S. 1943).

has held that where it is found that the agency “‘consciously and expressly adopted a general policy’ that is so extreme as to amount to an abdication of its statutory responsibilities,”<sup>156</sup> this failure can be considered arbitrary, capricious, and contrary to law.

**b. Materiality of nutritional inferiority of conventionally-produced eggs.**

Recent scientific studies have shown a physical nutritional difference between eggs from caged hens and pastured free-range hens. A reasonable consumer could justifiably consider eggs from caged hens to be nutritionally inferior to pastured free-range eggs due to this data, and seek out the latter. These nutritional differences are physical, material to reasonable consumers, and have health implications for consumers seeking the higher nutrient content of pastured eggs. The misleading egg labeling field includes cartons that often falsely represent to consumers that inferior eggs from caged hens are pastured free-range eggs. Consumers now not only face an inherent risk of purchasing misbranded eggs because of their reliance on materially misleading labels with respect to animal welfare, but they also face a health and safety consequence by being misled into purchasing nutritionally inferior eggs. This additional material difference between eggs produced by caged hens and those that are not further establishes the FDA’s statutory and legal mandate to correct such materially misleading labeling.

**c. FDA must not allow misleading labeling on AMS Graded-marked Egg Cartons**

Additionally, where egg packaging is marked with an official USDA grade, the FDA is required to regulate any labels on such packaging to ensure that they are not misleading. Pursuant to 7 C.F.R. § 56.35, “No label, container, or packaging material which bears official identification may contain any statement that is false or misleading. No label, container, or

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<sup>156</sup> *Heckler v. Chaney*, 470 U.S. 821, 833 n. 4 (1985) (quoting *Adams v. Richardson*, 480 F.2d 1159 (1973) (en banc)).

packaging material bearing official identification may be printed or prepared for use until the printers' or other final proof has been approved by the Administrator in accordance with the regulations in . . . the Federal Food, Drug, and Cosmetic Act[.]”<sup>157</sup> The term “official identification” refers to the grademark placed on egg packaging.<sup>158</sup> Under the Federal Food, Drug, and Cosmetic Act referenced in 7 C.F.R. § 56.35, the FDA must promote “honesty and fair dealing,” a clause which the Supreme Court characterized as requiring “truthful and informative labeling.”<sup>159</sup> Many of the factual representations referenced *supra* currently employ the USDA grademark.<sup>160</sup> For example, Giant’s “Nature's Promise Naturals Large Omega-3 Brown Eggs” are labeled “Grade A,”<sup>161</sup> and Wilcox “All Natural White Eggs” are “Grade AA.”<sup>162</sup>

Thus, because the CFR itself requires that egg packaging must not be misleading and because all grademarked USDA egg packages must be granted final approval under FDA standards requiring truthful and informative labeling where necessary, the FDA has a mandatory duty to regulate labels on all USDA grademarked egg packaging to ensure that they are not misleading.

Therefore, the misleading labels used throughout the egg industry falsely implying that eggs from caged hens are pastured free-range eggs should especially be of concern to the FDA. FDA is mandated to regulate food labeling, which includes nutrition labeling, must reform the labeling requirements of eggs if it is to fulfill its mission of “helping the public get the accurate,

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<sup>157</sup> 7 C.F.R. § 56.35 (2010).

<sup>158</sup> *Id.*

<sup>159</sup> *Federal Security Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230 (U.S. 1943) (holding that an FDA regulation regarding vitamin enriched foods was appropriate because the FFDCA *required* regulation of both truthful and informative labeling, and of other measures necessary to prevent consumer confusion).

<sup>160</sup> See images at Ex. 21, 24, 28, 30, 31, 32, 37, 40 which show egg cartons currently employing the USDA grademark.

<sup>161</sup> See Giant’s “Nature’s Promise Naturals Brown Omega-3 Eggs” *carton image* at Ex. 24.

<sup>162</sup> See Wilcox Farms “All Natural White Eggs” *carton image* at Ex. 37.

science-based information they need to use medicines and foods to improve their health.”<sup>163</sup> The nutritional inferiority of eggs from caged hens heightens the materiality of these misleading labels and strengthens FDA’s jurisdiction over and mandate to correct the misleading field of egg labeling.

These misleading cartons overwhelmingly tend to falsely represent pastured free-range production, rather than mere cage-free or non-pastured free-range.<sup>164</sup> This misleading landscape heightens the materiality of the nutritional differences FDA is authorized and required to regulate not only the misbranding of food products,<sup>165</sup> but also the nutrition labeling of most foods regulated by FDA,<sup>166</sup> including eggs.<sup>167</sup> Because studies reveal that eggs from caged hens are nutritionally inferior to those from pastured free-range hens, the misbranding of egg cartons materially misleads both socially conscious consumers about the animal welfare implications of the particular eggs and health-conscious consumers about their nutrient content. False representations that eggs are free-range materially mislead reasonable consumers into believing that the hens producing those eggs are not confined in cages and that those eggs are significantly healthier than is actually the case. If the mislabeling in the egg industry persists, consumers will continue to be misled, as they are unable to identify and purchase the products they intend to purchase.

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<sup>163</sup> *FDA’s Mission Statement*, UNITED STATES FOOD AND DRUG ADMINISTRATION, *previously available at* <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Nov. 12, 2008), *now available at* <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited May 21, 2010), Ex. 77.

<sup>164</sup> *See supra* at 11-20.

<sup>165</sup> *See, e.g.*, 21 U.S.C. § 331(a)-(c), (g) (2006) (prohibiting misbranding of food); 21 U.S.C. § 343 (2006) (defining misbranded food); 21 U.S.C. § 321(n) (2006) (describing factors considered in determining whether labeling or advertising is misleading). *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2006) (enacted June 25, 1938).

<sup>166</sup> 21 U.S.C. § 343(q).

<sup>167</sup> *See, e.g.*, *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 10; *see also Enforcement Policy Statement on Food Advertising*, FTC, May 1994, at 2, *available at* <http://www.ftc.gov/bcp/policystmt/ad-food.htm> (last visited Aug. 3, 2010), Ex. 11.



### **3. Material nutritional disparity additionally gives FDA egg-labeling authority pursuant to jurisdiction over nutritional labeling.**

The nutritional differences between eggs from caged hens and eggs from free-range pastured hens strengthens the assertion that FDA should implement the regulations requested in this Petition, given that FDA has jurisdiction over nutrient content claims and nutrition labeling, and the mandate to maintain truthful labeling.<sup>168</sup> Specifically, the Nutrition Labeling and Education Act (“NLEA”), passed by Congress in 1990, amended the Federal Food, Drug, and Cosmetic Act (“FFDCA”) to require certain nutrition information to be displayed on foods regulated by FDA.<sup>169</sup> The NLEA provides FDA with specific authority to require nutrition labeling of most foods regulated by the agency. It also gives FDA the authority to require that all nutrient content claims (i.e. “high fiber,” “low fat,” etc.) and health claims be consistent with agency regulations.<sup>170</sup> According to FDA’s mission statement, the agency is responsible for “helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”<sup>171</sup>

Because of the nutritional implications, claims and images that falsely imply eggs are from pastured free-range hens essentially make false nutrient content claims, in violation of 21 U.S.C. 343(q) and its regulations. This is because cartons which claim “Animal Friendly,” “Naturally Raised,”<sup>172</sup> or have images of hens outside, for instance, make nutritional as well as an animal welfare claims. That is, these claims and images misrepresent to consumers that the

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<sup>168</sup> 21 U.S.C. 343(q). The nutrition labeling regulations are codified at 9 C.F.R. Part 317, Subpart B, and Part 381, Subpart Y.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *FDA’s Mission Statement*, UNITED STATES FOOD AND DRUG ADMINISTRATION, *previously available at* <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Nov. 12, 2008), *now available at* <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited May 21, 2010), Ex. 77.

<sup>172</sup> AMS created voluntary standards for the claim “naturally raised” in January, 2009, but this standard does not consider production methods. United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived From Such Livestock, 74 Fed. Reg. 3541-01 (proposed Jan. 21, 2009), Ex. 78.

eggs are healthier than conventional (cage) eggs, which is in essence a nutrient content claim – the same as “Omega-3 enriched,” for example. The example of Omega-3 is particularly salient, but this argument could be applied to cholesterol, saturated fat, Vitamin A, or Vitamin E. Because cartons bearing claims and images which communicate these nutrient content claims to consumers often contain eggs from caged hens, the nutritional information they communicate is false and therefore in violation of 21 U.S.C. 343(q) and its regulations. This is of course in addition to the misleading message they communicate to consumers from an animal welfare perspective, prohibited by 21 U.S.C. §§321(n), 331, and 343(a). With respect to Omega-3 in particular, the Center for Science in the Public Interest (CSPI) submitted a complaint to FDA<sup>173</sup> last year urging the agency to stop seven egg producers from implying their eggs can reduce the risk of heart disease.<sup>174</sup> The group argued that the producers’ use of Omega-3 claims on egg cartons<sup>175</sup> is misleading and constitutes a nutrient content claim.<sup>176</sup> Given that Omega-3 (and heart-healthy) claims on cartons are to be considered nutrient content claims, FDA should consider claims and images indicating hens are raised in an outdoor, pastured setting to be nutrient content claims as well. Given the nutritional differences between pastured free-range eggs and eggs from caged hens, a claim or image representing the latter as the former is a false nutrient content claim.

In addition, by failing to implement the regulations requested herein despite the misleading egg labeling field, FDA is enabling manufacturers to make misleading implied

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<sup>173</sup> Letter from Center for Science in the Public Interest, to Kathleen Ellwood, Director, Nutrition Program and Labeling Staff (June 21, 2007), *available at* <http://cspinet.org/new/pdf/omega3letter.pdf>, (last visited May 21, 2010) Ex. 79.

<sup>174</sup> *Egg Producers Deceive Consumers, Violate Law with Bogus Omega-3 Claims*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *available at* <http://www.cspinet.org/new/200706211.html> (last visited May 21, 2010), Ex. 80.

<sup>175</sup> “Land O’ Lakes claims that ‘omega-3 All-Natural Eggs’ are a ‘good source of heart-healthy nutrition’—even though the FDA has not set standards of Omega-3 claims and eggs contain too much saturated fat and cholesterol to meet FDA’s definition of healthy.” *Id.*

<sup>176</sup> 21 C.F.R. § 101.13(i)(3) (2010).

nutrient content claims in general. According to 21 C.F.R. § 101.13, an implied nutrient content claim is any claim that either (a) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., “high in oat bran”); or (b) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams (g) of fat”).<sup>177</sup> A nutrient content claim—whether explicit or implicit—may not be made on the label or in labeling of foods unless the claim is made in accordance with federal regulations.<sup>178</sup>

Because the mislabeling of eggs prevents consumers from making informed nutritional decisions, FDA must also implement the regulations requested in this Petition in order to fulfill its mission of assisting consumers in maintaining healthy dietary practices.<sup>179</sup> The NLEA directs the Secretary of the Department of Health and Human Services (the department which includes FDA) to require nutritional information on labels to be conveyed in a manner which enables the public to readily observe and comprehend it and to understand its relative significance in the context of a total daily diet. The Act evinces the intent that the labeling requirements are intended to enable consumers to make healthier choices when purchasing food products. In 21 U.S.C.A. § 343(q), for instance, the statute indicates that the Secretary may order certain required information to be highlighted on the label “if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.”<sup>180</sup> Misleading claims and images falsely representing to consumers that eggs are from pastured free-range hens

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<sup>177</sup> 21 C.F.R. § 101.13.

<sup>178</sup> *Id.*

<sup>179</sup> *FDA’s Mission Statement*, UNITED STATES FOOD AND DRUG ADMINISTRATION, *previously available at* <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Nov. 12, 2008), *now available at* <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited May 21, 2010), Ex. 77.

<sup>180</sup> 21 U.S.C.A. § 343(q).

thwarts the consumers' ability to make healthier dietary choices if they so choose, in contravention of FDA's mandate. By failing to revise the labeling requirements and regulate labeling in the egg industry, FDA is neglecting and contradicting its mission of assisting consumers in maintaining healthy dietary practices.

Misrepresentative claims and images on egg cartons (e.g. "Animal Friendly," "naturally raised hens," images of hens nesting, in fields or pastures, etc.) make express and implied claims indicating to consumers that the eggs come from hens that are treated more humanely and produce more nutritious eggs than is actually the case. Because the nutrition studies are freely available, a reasonable consumer would be justified in choosing to purchase pastured free-range eggs because they are nutritionally superior to eggs from caged hens. The current labeling requirements in the egg industry, however, do not ensure that consumers will be able to identify the products they seek to purchase. To remedy this situation, FDA must implement the regulations requested in this Petition. By implementing these regulations, FDA would not only enable socially conscious consumers to purchase the more humane products they seek, but it will also allow concerned consumers to identify the higher nutrient superior products they intend to buy.

#### **B. The FSIS of the USDA Recognizes the Importance of Standardizing Production Claims.**

The Food Safety and Inspection Service ("FSIS") of the USDA has recognized the importance of standardizing basic production method claims.<sup>181</sup> It has published a policy regarding the evaluation and validation of basic production methods, including review of

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<sup>181</sup> FSIS recently proposed defining the "natural" claim, and even considered whether to extend this term to encompass production methods. They also claimed to be working with the AMS to make the "natural" claim standard consistent with the "naturally raised" standard promulgated by the AMS. Product Labeling: Use of the Voluntary Claim "Natural" in the Labeling of Meat and Poultry Products, 74 Fed. Reg. 46951-01 (proposed Sept. 14, 2009) (to be codified at 9 CFR Parts 317 and 381), Ex. 49.

affidavits, testimonials and protocols.<sup>182</sup> The FSIS thus regulates terms such as “free-range” and “free-roaming,” but not for egg products. In another policy statement, FSIS has discussed the meaning of these terms and its role in “ensuring the truthfulness and accuracy in labeling,” referring to the requirement that “[p]roducers must demonstrate to the Agency that the poultry has been allowed access to the outside.”<sup>183</sup>

To date, however, the FDA has not exercised its authority over egg labeling, which has resulted in inconsistency between the agencies’ application of their respective and verbatim statutory provisions<sup>184</sup> and the widespread use of misleading express and implied production method claims on egg labels as described above.

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<sup>182</sup> OFFICE OF POLICY, PROGRAM, AND EMPLOYEE DEVELOPMENT, FOOD SAFETY AND INSPECTION SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL PRODUCTION CLAIMS OUTLINE OF CURRENT PROCESS, *available at* <http://www.fsis.usda.gov/OPPDE/larc/Claims/RaisingClaims.pdf> (last visited May 21, 2010), Ex. 81.

<sup>183</sup> FOOD SAFETY INSPECTION SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE, FACT SHEETS: MEAT AND POULTRY LABELING TERMS, *at* [http://www.fsis.usda.gov/Fact\\_Sheets/Meat\\_&\\_Poultry\\_Labeling\\_Terms/index.asp](http://www.fsis.usda.gov/Fact_Sheets/Meat_&_Poultry_Labeling_Terms/index.asp), (last visited May 21, 2010), Ex. 82.

Another FSIS policy statement notes:

FSIS has permitted the application of “animal production claims,” i.e., truthful statements about how the animals from which meat and poultry products are derived or raised, on the labeling of meat and poultry products. For many years, animal production claims have served as an alternative to the use of the term “organic” on the labeling of meat and poultry products in the absence of a uniformly accepted definition. Thus, producers may wish to continue the use of animal production claims on meat and poultry labeling. Examples of animal production claims are “No Hormone Implants Used in Raising,” “Raised Without Added Hormones,” “No Antibiotics Used in Raising,” “Corn Fed,” “Fed An All Vegetable Diet,” “Raised In An Open Pasture,” and “Free-range.” The system FSIS has in place for evaluating the necessary supporting documentation to ensure the accuracy of animal production claims, such as producer affidavits and raising protocols, will continue to be used whenever these types of claims are made.

FOOD SAFETY INSPECTION SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE, USING THE CLAIM “CERTIFIED ORGANIC BY . . .” ON MEAT AND POULTRY PRODUCT LABELING, *previously available at* <http://www.fsis.usda.gov/OA/background/organic.htm> (last modified Mar. 2, 2000) (last visited Sept. 11, 2006), Ex. 83.

<sup>184</sup> See the Federal Meat Inspection Act, *at* 21 U.S.C. § 601(n)(1) (2010) (prohibiting labeling of meat or meat products that is “false or misleading in any particular”), and the Poultry Products Inspection Act, *at* 21 U.S.C. § 453(h)(1) (2006) (prohibiting labeling of poultry products that is “false or misleading in any particular” manner).

**C. The current regulations do nothing to prevent the egg label misbranding discussed herein.**

Among other provisions, the FDA has the authority pursuant to 21 U.S.C. § 321(n) (2010) to correct the common egg label misbranding described above. Although there are several FDA regulations that address the direct issue of the labeling of shell eggs, none of these regulations deal with the omission or misrepresentation of material facts regarding basic egg production method.

There are two current FDA regulations that address the issue of the labeling of shell eggs. First, 21 C.F.R. § 101.17(h) simply requires that all shell eggs bear a statement regarding safe handling instructions:

(1) The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement:

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.<sup>185</sup>

This subsection focuses on mislabeling that would affect human health, guarding against inadvertent bacteria consumption. The remainder of the regulation details the FDA's powers for enforcing this regulation.

Second, 21 C.F.R. § 101.9 (2010) concerns nutrition labeling of foods generally. This provision states that "nutrition information relating to food shall be provided for all products intended for human consumption" on the outer label of such product. Shell eggs are exempt from the outer package labeling requirement if the label is clearly on the inner package (presumably

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<sup>185</sup> 21 C.F.R. § 101.17(h) (2010).

because consumers can open the package at the store to view the nutrition label before purchase).<sup>186</sup>

These two provisions do nothing to address the common omission or misrepresentation of material facts or misleading imagery regarding basic egg production method described in detail above.<sup>187</sup> In fact their narrow focus on health suggests to businesses labeling eggs that there is no federal oversight or interest in the misrepresentation of material facts or misleading imagery or other representations regarding production method, and this promotes misleading labeling with impunity, in complete contradiction to the will of Congress as expressed in the FFDCA and FPLA.

**D. The proposed regulations are consistent with and fulfill the FDA's mandate to correct egg label misbranding.**<sup>188</sup>

Misbranding was one of the chief evils Congress sought to stop in enactment of the FFDCA.<sup>189</sup> A food has been misbranded under the FFDCA<sup>190</sup> if “its labeling is false or misleading in any particular.”<sup>191</sup> A food is also misbranded if its label omits material facts.<sup>192</sup> There is no requirement that consumers actually are deceived, and such a product need not be

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<sup>186</sup> 21 C.F.R. § 101.9(j)(14) (2010) (“Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.”).

<sup>187</sup> Nor do any of the currently proposed agency regulations regarding egg labeling address these issues.

<sup>188</sup> While the discussion has focused on the FFDCA which provides sufficient authority for the FDA to act, petitioners note that sections of the FPLA, specifically 15 U.S.C. § 1453, requires an accurate statement of the identity of the food sold (“The commodity shall bear a label specifying the identity of the commodity . . .”). *See* 15 U.S.C. § 1453(a)(1) (2010).

<sup>189</sup> 62 *Cases of Jam v. U.S.*, 340 U.S. 593, 596 (1951).

<sup>190</sup> 21 U.S.C. §§ 301-395 (2010).

<sup>191</sup> *Id.* at § 343(a)(1).

<sup>192</sup> *Id.* at § 321(n).

deleterious to human health.<sup>193</sup> This standard would cover misleading imagery, discussed *supra*, as well as misleading factual claims or implications.

In addition, labels may be misleading even if the relevant information is somewhere on the package along with a potentially misleading contradictory representation. For example, in *Article of Food*, the court found a package with the claim “diet thins” on the front of the container to impermissibly mislead consumers even where the side panel provided factually accurate clarifying information.<sup>194</sup>

Egg producer Radlo Foods, which distributes three lines of eggs (All Natural, Cage-Free, and Cage-Free Organic) under the brand name Born Free, has voluntarily elected to disclose the phrase, “From Caged Hens” on the side panel of its All Natural Eggs.<sup>195</sup> This is a positive step for consumers, as it is currently the only example of which petitioners are aware of an egg producer in the United States providing such information on packaging. However, given *Article of Food*, the brand name “Born Free” on the front panel may be considered to be misleading to consumers who might interpret that as meaning hens are “free” or cage-free, even where the side panel’s “From Caged Hens” provides clarifying information. Therefore, the clarifying phrase has been placed on the side panel, which would not comply with the regulations proposed herein, for the reasons set forth in *Article of Food*. Consumers need a clear and consistent set of

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<sup>193</sup> *U.S. v. An Article of Food, etc.*, 377 F.Supp. 746, 748-749 (E.D.N.Y. 1974) (where plaintiffs asserted that the name “diet thins” on front panel of product implied crackers were lower in caloric content than other crackers, the court did not require actual deception or health risks:

A food product may be subject to condemnation even though it is not deleterious [citing *Libby, McNeil & Libby v. United States*, 148 F.2d 71 (2d Cir. 1945)]. It is not necessary to show that anyone was actually misled or deceived, or that there was any intent to deceive. As the Supreme Court stated in *United States v. 95 Barrels-Cider Vinegar*, 265 U.S. 438, 442 (1924), [t]he statute . . . condemn[s] every statement, design and device which *may* mislead or deceive. [emphasis added by Court]).

<sup>194</sup> *Id.* at 749 (“whether or not the side panel of the Diet-Thins label may accurately describe its virtues for certain special diets which do not appear to involve weight control, the misleading nature of the front panel still justifies condemnation of the seized articles.”).

<sup>195</sup> *Born Free Egg Carton Label Image*, Ex. 41; *Born Free All Natural*, RADLO FOODS, *previously available at* <http://www.radlo.com/bfAllNaturalEggs.html> (last visited Sept. 11, 2006), Ex. 84. Note: it is not clear whether these eggs are currently still being sold under this brand name.



expectations. Petitioners request regulations requiring front panel disclosure of production method to correct this otherwise confusing landscape. Regulation is required under 21 U.S.C. § 321(n).

The FDA has promulgated food labeling requirements in contexts similar to the one discussed here, apart from concerns regarding human health, for example under 21 C.F.R. §§ 101.93, 101.95 (2006) (which comprise Subpart F, entitled “Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims”). These requirements deal with statements for dietary supplements, and use of the terms “fresh,” “freshly frozen,” “fresh frozen,” etc.<sup>196</sup> The FDA has also addressed food origin claims in other contexts, such as limitations on producers labeling food products as artificially (synthetically) or naturally flavored,<sup>197</sup> and calling for comments on what constitutes a minimally processed food.<sup>198</sup>

Quoting the Supreme Court in *United States v. 95 Barrels*, 265 U.S. 438, 442-43 (1924), the court in *An Article of Food* held that the fact that a label *could* mislead or deceive was sufficient to bring about the need for agency action.<sup>199</sup> The test to apply is not the test of the “reasonable consumer,” but rather of the “ignorant...unthinking and...credulous consumer.”<sup>200</sup> Indeed, “[e]ven a technically accurate description of a food or drug’s content may violate [the FFDCA] if the description is misleading in other respects.”<sup>201</sup> In *U.S. v. An Article of Food, etc.*, 377 F.Supp. 746, 748 (E.D.N.Y. 1974), the court held that “[i]n order to sustain a seizure [of a misbranded product], [one] need not prove that all the label representations are both false and

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<sup>196</sup> 21 C.F.R. §§ 101.93, 101.95 (2010).

<sup>197</sup> See 21 C.F.R. § 101.22.

<sup>198</sup> See 58 Fed. Reg. 2407 (Jan 6, 1993), Ex. 44.

<sup>199</sup> *An Article of Food*, 377 F.Supp. at 749.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* (citing *U.S. v. An Article of Food — Nuclomin*, 482 F.2d 581[ 584] (8th Cir. 1973) (emphasis added)).

misleading. A food is misbranded if it appears that any *one* representation is false or misleading” (emphasis in original).<sup>202</sup>

Those consumers in need of the greatest deal of protection from predatory false and misleading advertising are those who are most likely to believe what they see and read without doing their own independent research. Statutes like the FFDCA exist for exactly this reason: they allow even the most credulous consumer to have access to honest and trustworthy information upon which they may base their decisions, and they seek to enjoin less scrupulous producers from taking advantage of gullible purchasers.<sup>203</sup> The common omission and misrepresentation of material facts on egg labels models the situation described in *An Article of Food*.

**E. The proposed regulations remedy the common general misbranding of eggs described herein.**

The proposed regulations correct the general misbranding of eggs described in detail above. Labeling egg packages as “Free-Range Eggs,” “Cage-Free Eggs,” or “Eggs From Caged Hens” provides the material facts required by consumers in order to exercise effective market choice, and to obtain the product of their choice based on the most basic identification of the relevant production method used – aligning the represented method with the actual method. The proposed regulations also correct misleading express and implied claims by providing an accurate, informative, and unequivocal statement as to basic production method, alleviating the need to engage in costly, time-consuming, and repetitive ad hoc enforcement actions addressing

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<sup>202</sup> Citing *U.S. v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952), cert. denied, 344 U.S. 928 (1953).

<sup>203</sup> *Article of Food*, 377 F.Supp. at 749 (reiterating the “ignorant, the unthinking and the credulous consumer” standard) (internal quotes omitted).

the numerous examples of misrepresentations present in the market today. The public also supports government regulation of egg labeling.<sup>204</sup>

**F. The Connection Between Production of Eggs from Caged Hens and Risk of Salmonella Contamination Provides an Additional Basis for FDA's Responsibility to Correct Misleading Egg Labeling**

The FDA is responsible for protecting the public health by assuring “the safety, efficacy, and security of...the nation’s food supply.”<sup>205</sup> FDA is responsible for the regulation and oversight of raw shell eggs, with the jurisdiction and the mandate to correct misleading advertising on egg cartons<sup>206</sup> as well as to promote the public health and protect the safety of eggs.<sup>207</sup> With the responsibility and authority to regulate and inspect shell eggs, and the duty to protect public health, it is clearly within the scope of FDA’s jurisdiction and duties to address the Salmonella Enteritidis (SE) issue in shell eggs. Studies indicate that eggs from farms using the cage production method have an increased risk of becoming contaminated with SE, due largely in part to the sheer volume of chickens housed in extremely close, unsanitary conditions where the concentration of manure is much higher than at non-cage production facilities. There is a connection between SE risk and cage production methods, discussed *infra*. Given this, and the massive August 2010 egg recall caused by an SE outbreak from cage production facilities, it is clear that regulations are necessary for consumers who wish to purchase cage-free or free-range

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<sup>204</sup> Jayson L. Lusk, Bailey F. Norwood & Robert W. Prickett, *Consumer Preferences for Farm Animal Welfare: Results of a Nationwide Telephone Survey* (2007), available at

<http://asp.okstate.edu/baileynorwood/FAW/files/Robspaper.pdf> (last accessed June 21, 2010), Ex. 73.

<sup>205</sup> FDA’s *Mission Statement*, UNITED STATES FOOD AND DRUG ADMINISTRATION, previously available at <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Nov. 12, 2008), now available at <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited May 21, 2010), Ex. 77.

<sup>206</sup> 21 U.S.C. § 1036(b) (2010); 7 U.S.C. § 6509 (2010); 7 C.F.R. §§ 3.91, 56.35(b), 57.5, and 58.50 (2010) see *supra* at 34 (section II (A)(1)) for discussion on this point.

<sup>207</sup> “FDA has jurisdiction over the safety of foods generally, including shell eggs, under the FFDCA (21 U.S.C. §§ 301-99 (2006) (enacted June 25, 1938).” *Salmonella Enteritidis in Eggs*, 63 Fed. Reg. 96 (May 19, 1998) (citing 21 U.S.C. § 301), Ex. 54.

products in order to mitigate their health risk to prevent them from being misled into purchasing eggs from caged hens.

### **1. The Threat of Salmonella Infection in Eggs**

Most cases of food borne Salmonella in the United States are associated with the consumption of shell eggs. The predominant Salmonella serotype in shell eggs is Salmonella Enteritidis (SE), which is transferred from infected hens to the egg before the egg is laid.<sup>208</sup> Chickens are notoriously susceptible to Salmonella infections and if infected, the egg likely will be as well.<sup>209</sup> The worst Salmonella outbreak in U.S. history (aside from the latest August 2010 outbreak) caused by eggs sickened hundreds of Americans in 1994.<sup>210</sup> In 2005, the CDC estimated that infected eggs in a more typical year cause over 100,000 cases of human Salmonella poisoning, referring to the salmonella outbreaks as akin to an epidemic.<sup>211</sup>

Due to the recent August 2010 Salmonella outbreak, which has been referred to as “one of the largest shell egg recalls in recent history,”<sup>212</sup> more than 500 million eggs were recalled and thousands of people were sickened with Salmonella throughout 14 states, with numbers expected to rise.<sup>213</sup> The outbreak was traced back to two facilities in Iowa, specifically Wright County

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<sup>208</sup> Kåre Mølbak & Jakob Neimann, *Risk Factors for Sporadic Infection with Salmonella Enteritidis*, Denmark, (2002) (Den.), 12, (published by FSIS), available at <http://www.fsis.usda.gov/oppde/rdad/frpubs/04-034n/introduction.pdf>. (last visited September 13, 2010), Ex. 85.

<sup>209</sup> Anna Vigran, *With Salmonella, It's A Chicken-Or-Egg Conundrum*, August 31, 2010, available at <http://www.npr.org/templates/story/story.php?storyId=129472951> (last visited September 13, 2010), Ex. 86.

<sup>210</sup> *Frequently Asked Questions and Answers: FDA's Investigation into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs*, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, August 27, 2010, available at <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm> (last visited September 15, 2010), Ex. 87.

<sup>211</sup> *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food - 10 States*, CDC-MMWR Weekly, 2008, available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5813a2.htm?s\\_cid=mm5813a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5813a2.htm?s_cid=mm5813a2_e) (last visited September 15, 2010), Ex. 88.

<sup>212</sup> *Frequently Asked Questions and Answers: FDA's Investigation into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs*, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, August 27, 2010, available at <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm> (last visited September 15, 2010), Ex. 87.

<sup>213</sup> *Id.*

Egg and Hillandale Farms.<sup>214</sup> At these particular farms, FDA inspectors who inspected the facilities after the outbreak found populations of “rats, mice and maggots” living inside of the egg-laying houses.<sup>215</sup> Infected rodents spread Salmonella through their feces into the chicken feed thus contributing to the infectious outbreak.<sup>216</sup> This current Salmonella occurrence serves as evidence of the serious public health dilemma posed by SE in eggs and further demonstrates the clear need for clarifying regulation and educating the public on production methods.

## **2. FDA’s Actions and Legal Grounds for FDA’s Authority and Responsibility to Address Salmonella Risk**

In light of the August 2010 SE outbreak, the FDA has responded through its direct duty to “prevent public harm” through regulation of “on-farm activities.”<sup>217</sup> Congress authorized the FDA to promulgate regulations relating to food safety through the FFDCA and the Public Health Service Act (PHSA).<sup>218</sup> Both the FFDCA and the PHSA have been interpreted broadly by the courts due to the prevailing purpose of the FDA and the statutes to “protect public health.”<sup>219</sup> In light of the recent recall of Salmonella-infected eggs, the FDA must, as mandated,<sup>220</sup> take measures to ensure the health of the consumer. The FDA is also mandated, through the FFDCA, to prevent “the adulteration or misbranding of any food and likewise disallow introduction of

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<sup>214</sup> Hillandale Farms is also referred to in Section (B)(1)(g) in the Petition, as the labeling of their egg cartons is misleading to consumers. Thus, the uninformed consumer, tricked into thinking he/she is buying free-range eggs when really buying caged eggs, is unwittingly putting their health at risk. Consequently, the issue of misleading advertising is directly related to the use of battery cages and the increased risk of Salmonella associated with them.

<sup>215</sup> *Questions and Answers Concerning 483 Inspectional Observations*, September 3, 2010, available at <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm224855.htm> (last visited September 15, 2010), Ex. 89.

<sup>216</sup> Jeroen Dewulf, *Salmonella Thrives in Caged Housing*, World Poultry, Vol. 25, May 20, 2010, available at <http://www.worldpoultry.net/background/salmonella-thrives-in-cage-housing-7481.html> (last visited September 13, 2010), Ex. 90.

<sup>217</sup> Vanessa Burrows, *FDA Authority to Regulate On-Farm Activity*, CRS Report for Congress, Order Code RS22939 (August 14, 2008), CRS 3, Ex. 91.

<sup>218</sup> *Id.*, (citing Federal Food, Drug and Cosmetic Act of 1938, as amended, 21 U.S.C. §§ 301 *et seq.*; Public Health Service Act of 1944, as amended, 42 U.S.C. §§ 201 *et seq.*).

<sup>219</sup> *Id.* at 4.

<sup>220</sup> “FDA has jurisdiction over the safety of foods generally, including shell eggs, under the FFDCA (21 U.S.C. §§ 301-99 (2006) (enacted June 25, 1938).” *Salmonella Enteritidis in Eggs*, 63 Fed. Reg. 96 (May 19, 1998) (citing 21 U.S.C. § 301), Ex. 54.

adulterated or misbranded food into the streams of commerce.”<sup>221</sup> The FDA has jurisdiction over the safety of foods generally, including shell eggs, under section 201 of the FFDCA.<sup>222</sup> The PHSA<sup>223</sup> authorizes the FDA to make and enforce such regulations as “are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States or from one State into any other State.”<sup>224</sup> Therefore, under the FFDCA and the PHSA, FDA has the direct authority to regulate a type of food when the food may act as a transmitter of disease, and Salmonella-contaminated eggs are interpreted to be a vector of disease.<sup>225</sup> Because the PHSA has likened shelled eggs containing salmonella as “transmitters of disease” and has explicitly given the FDA authority to regulate “transmitters of disease,” it is clear that the FDA has authority over shelled eggs within this context.

Given these two statutes and their interpretation by the courts and by the FDA, and FDA’s own action in responding to the August 2010 Salmonella outbreak, it is clear that FDA has the jurisdiction and the responsibility to address issues surrounding Salmonella in shell eggs. As such, the labeling regulations requested in this petition are required to inform consumers about caging - a key aspect of the production method, which has implications for public health and safety as well as nutrition and animal welfare. In the SE context and its link to cage production methods, the FDA’s duty to protect the public health and safety further demonstrates the necessity for regulations to protect consumers.

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<sup>221</sup> See, e.g., 21 U.S.C. § 331(a)-(c), (g) (2010) (prohibiting misbranding of food); 21 U.S.C. § 343 (2010) (defining misbranded food).

<sup>222</sup> *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Proposed Rule*, 69 Fed. Reg. 56824-01, Vol. 69, No. 183, September 22, 2004, at 5, available at <http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/UCM155358.pdf> (citing 21 U.S.C. 321) (last visited September 13, 2010), Ex. 92.

<sup>223</sup> *Id.* (citing 42 U.S.C. 201 *et seq.*).

<sup>224</sup> *Id.* (citing section 361(a) of the PHS Act (42 U.S.C. 264(a)).

<sup>225</sup> *Id.*

### 3. Cage Production and its Link to a Higher Salmonella Risk

Numerous studies demonstrate an express link between the cage system of egg production and the increased risk of outbreak of SE in eggs. The August 2010 outbreak of SE that caused the recall of more than a half-billion eggs was traced back to Wright County Egg and Hillandale Farms, both large-scale battery cage egg facilities in Iowa.<sup>226</sup>

A recent study comparing cage to cage-free systems found that there were 20 times greater odds of *Salmonella* infection in caged flocks.<sup>227</sup> One other study concluded that, after close study of 519 flocks, the risk of SE infection in caged flocks were “significantly higher ... than in on-floor flocks (cage-free)” and that the infection risk increased with the “number of hens housed in the cage poultry-house.”<sup>228</sup> The study attributed the higher risk of contamination to the fact that “cage poultry houses are difficult to clean and disinfect” and that cage houses typically use a “common egg conveyor belt” that links houses together which further boosts the spread of disease.<sup>229</sup> Eggs can also become infected by SE fecal contamination through the pores of the shells after they’re laid.<sup>230</sup> The higher density of animals found in the cage production system as compared with the cage-free or free-range system constitutes a risk factor for Salmonella.<sup>231</sup>

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<sup>226</sup> *Frequently Asked Questions and Answers: FDA’s Investigation into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs*, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, August 27, 2010, available at <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm> (last visited September 15, 2010), Ex. 87.

<sup>227</sup> S. Van Hoorebeke et al., *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*, 94 PREVENTATIVE VETERINARY MEDICINE (2010) 94-100, Ex. 93.

<sup>228</sup> Adeline Huneau-Salaün, et al., *Risk factors for Salmonella enterica subsp. enterica contamination in 519 French laying hen flocks at the end of the laying period*, 89 PREVENTATIVE VETERINARY MEDICINE 51-58 (2009), Ex. 94.

<sup>229</sup> *Id.*

<sup>230</sup> *Fact Sheets: Egg Products Preparation, Shell Eggs from Farm to Table*, FOOD SAFETY AND INSPECTION SERVICE, September 7, 2010, available at [http://www.fsis.usda.gov/factsheets/focus\\_on\\_shell\\_eggs/index.asp](http://www.fsis.usda.gov/factsheets/focus_on_shell_eggs/index.asp) (last visited September 15, 2010), Ex. 95.

<sup>231</sup> Jeroen Dewulf, *Salmonella Thrives in Caged Housing*, World Poultry, Vol. 25, May 20, 2010, available at <http://www.worldpoultry.net/background/salmonella-thrives-in-cage-housing-7481.html> (last visited September 13, 2010), Ex. 90.

Some practices that increase the occurrence of Salmonella in cage production include: (1) the sheer number of birds increases the volume of potentially contaminated feces and dust, (2) manure pits, coupled with the fact that hen movement is restricted to cages, makes factory farms an attractive environment for salmonella-infected rodents, and (3) the complexity of the system makes it difficult to thoroughly clean and disinfect the cages.<sup>232</sup> Diseases are further spread by “manure pits,” located under concentrated hen houses and utilized by large, concentrated factory farms to catch chicken excrement. These manure pits fill up quickly and can be overloaded, which attracts rodents and provides them greater access to the hen sheds. This further increases the risk of spread of disease. In the recent August 2010 outbreak, Wright County Egg in Galt, Iowa had manure piled 4 to 8 feet high.<sup>233</sup> The manure pits also create a high volume of contaminated fecal dust, which can increase the spread of salmonella among the flocks. In cage-free and free-range housing systems, there are fewer, less concentrated animals and the open structure of the housing does not allow for manure to pile up in one centralized place.<sup>234</sup> To support the ban against barren battery cages, the EU conducted a peer-reviewed survey of more than 5,000 egg operations across two dozen countries finding that for every type of Salmonella studied within every category of production system examined, there was a significantly higher risk of Salmonella infection in cage production.<sup>235</sup> This analysis by the European Food Safety Authority found that there were 43% lower odds of SE contamination in cage-free barns, where

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<sup>232</sup> P. S. Holt et al., *Emerging Issues: Social Sustainability of Egg Production Symposium, The Impact of Other Housing Systems on Egg Safety and Quality* POULTRY SCIENCE, at 3, available at [http://www.poultryscience.org/docs/PS\\_794.pdf](http://www.poultryscience.org/docs/PS_794.pdf) (last visited September 13, 2010), Ex. 96.

<sup>233</sup> *Questions and Answers Concerning 483 Inspectional Observation*, CENTER FOR FOOD SAFETY AND NUTRITION, September 3, 2010, available at <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm224855.htm> (last visited September 15, 2010), Ex. 89.

<sup>234</sup> P. S. Holt et al., *Emerging Issues: Social Sustainability of Egg Production Symposium, The Impact of Other Housing Systems on Egg Safety and Quality*, POULTRY SCIENCE 3, available at [http://www.poultryscience.org/docs/PS\\_794.pdf](http://www.poultryscience.org/docs/PS_794.pdf) (last visited September 13, 2010), Ex. 96.

<sup>235</sup> European Food Safety Authority, *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, available at [www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620761896.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761896.htm). (last visited September 13, 2010), Ex. 97.



hens were raised indoors, than in cage production.<sup>236</sup> Additionally, a study conducted by the American Journal of Epidemiology, concluded that people who ate eggs from caged hens had almost double the probability of contracting Salmonella food poisoning compared to those who did not eat eggs from hens confined in cages.<sup>237</sup>

The cage production system also increases the risk for contamination of feed specifically and thus puts entire flocks at risk for contracting Salmonella. Highly dense battery cage facilities are difficult to clean and disinfect between flocks because of the complexity of the cage system (stacked cages and conveyor belts within and between hen houses) and this potentially results in the spread of Salmonella from flock to flock.<sup>238</sup> Salmonella-infected feces of rodents (commonly mice and rats) can also contaminate the animal feed which occurs commonly on chicken, turkey and duck farms.<sup>239</sup> A single mouse produces 100 droppings a day and each can contain up to 230,000 SE bacteria.<sup>240</sup> By defecating in feed troughs where chickens eat, on egg belts, and in other areas near the hens and the eggs, rodents can quickly spread infection throughout the chicken house and contaminate hens and their eggs with Salmonella.<sup>241</sup>

The above-mentioned links between caged hens and increased risk of SE in the eggs produced by caged hens is evidence that the shortcomings of egg carton labeling is misleading

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<sup>236</sup> *Id.*

<sup>237</sup> Kåre Mølbak and Jakob Neimann, *Risk Factors for Sporadic Infection with Salmonella Enteritidis*, 12 (2002) (Den.) (published by FSIS), available at <http://www.fsis.usda.gov/oppde/rdad/frpubs/04-034n/introduction.pdf>. (last visited September 13, 2010), Ex. 85.

<sup>238</sup> P. S. Holt, et al., *Emerging Issues: Social Sustainability of Egg Production Symposium, The Impact of Other Housing Systems on Egg Safety and Quality* POULTRY SCIENCE 3, (citing Carrique-Mas, J. J., et al., *Persistence and clearance of different Salmonella serovars in building housing laying hens*, 137 EPIDEMIOL. INFECT 837-846 (2009)) available at [http://www.poultryscience.org/docs/PS\\_794.pdf](http://www.poultryscience.org/docs/PS_794.pdf) (last visited September 13, 2010), Ex. 96.

<sup>239</sup> *Prevention of Salmonella Enteritidis in Shell Eggs During Production; Proposed Rule*, 69 Fed. Reg. 56824-01 (September 22, 2004), at 13, available at <http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/UCM155358.pdf> (citing 21 U.S.C. 321) (last visited September 13, 2010), Ex. 92.

<sup>240</sup> S.A. Davison et al., *Preharvest HACCP in the Table Egg Industry*, PENN STATE COLLEGE OF AGRICULTURAL SCIENCES, 1997, 11, available at <http://pubs.cas.psu.edu/FreePubs/pdfs/AGRS72.pdf> (last visited September 15, 2010), Ex. 98.

<sup>241</sup> *Id.*

the average, reasonable consumer into purchasing eggs that could potentially increase their chances of illness. In addition to the reasons discussed *supra* in this Petition setting forth the factual and legal bases for FDA correcting the misleading egg labeling field in the U.S., the Salmonella issue's link to cage production provides an additional rationale for FDA to implement the regulations requested in this Petition: the misleading egg labeling field's implication for public safety and health.

The FDA, through its duty to protect public health, has the authority and responsibility to ensure truth in labeling on egg cartons. Given the plethora of data available which illustrates that caged hens are producing eggs at a significantly higher risk of disease, it is clear that the public health is at risk without proper labeling and that a reasonable consumer would be justified in seeking out cage-free or free-range eggs in order to mitigate this health risk. Consumers have a right to make informed, accurate egg purchases. However, with the current misleading egg labeling field, the consumer's health and preferences are inadequately protected. Misleading labeling not only communicates false animal welfare treatment but also communicates a false sense of healthiness and wholesomeness. A consumer with the intent of purchasing cage-free eggs may be misled into purchasing an egg carton with a free-roaming chicken depicted on the label, for example. That consumer may well be buying eggs from caged-hens (despite the misleading free-range images) and thus also be at a higher risk for exposure to Salmonella. The FDA has a direct interest in shielding consumers from a labeling system that communicates false messages to the public and that puts their health at risk. The most effective way to inform the public and to ensure that the average consumer is offered the opportunity to make informed decisions concerning their own health is through accurate labeling on egg cartons as requested in this Petition.

**G. Corrective regulation in the European Union and Australia alleviates confusion and protects consumer interests.**

Misleading and false advertising in egg labeling has been a concern in the European Union (“EU”) as well as in the United States. Public concern about animal welfare has been increasing, and with it, the need for labeling regulations.<sup>242</sup> The EU has responded to this concern with regulatory action requiring the labeling of eggs. EU eggs must have a code on them – “1” stands for Free-Range eggs, “2” stands for Barn eggs (i.e. cage-free Eggs), and “3” for Eggs from caged hens.<sup>243</sup> European Commission Regulation (EC) No 1651/2001, 2001 O.J. (L 220) 5 (Ex. 43) cites and adopts Council Directive 1999/74/EC of July 19, 1999, and requires standardization of terms regarding cages.<sup>244</sup> Article 1(7) of the EC regulation requires certain standardized labeling on how the laying hens were kept:

<i>On packs</i>	<i>On Eggs</i>
Free-range eggs	Free-range
Barn eggs [cage-free]	Barn
Eggs from caged hens	Cage

These terms may be supplemented by indications referring to the particular characteristics of the respective farming method.

The terms on the eggs may be replaced by a code designating the producer’s distinguishing number permitting to identify the farming method provided that the meaning of the code is explained on the pack.

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<sup>242</sup> *Fresh Calls for Welfare Labels*, FARMER’S WEEKLY INTERACTIVE, Jun. 19, 2006, at <http://www.fwi.co.uk/Articles/2006/06/19/95387/Fresh+calls+for+welfare+labels.html> (last visited May 21, 2010), Ex. 99; see also *Report on Welfare Labeling*, FARM ANIMAL WELFARE COUNCIL (“FAWC”), Jun., 2006, Ex. 100.

<sup>243</sup> *International – Egg Labeling*, ROYAL SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS (“RSPCA”), previously available at <http://www.rspca.org.uk/servlet/Satellite?pagename=RSPCA/RSPCARedirect&pg=InternationalCampaigns&marker=1&articleId=999516092840> (last visited Sept. 11, 2006), Ex. 101.

<sup>244</sup> Commission Regulation 1651/2001, 2001 O.J. (L 220) 5, Ex. 102.

This simple and clear system is effective for a jurisdiction as diverse in language, culture, and industry as the EU's 27 member states. The establishment of similar standards in the U.S. would be relatively simple. American consumers' concerns on production methods and right to clear labeling are at least as strong as European consumers'.

Likewise, Australia acted to address concerns arising from misleading and false advertising in egg labeling. In response to growing public concern about animal welfare resulting from misleading egg labeling, Australia adopted standards similar to the EU: egg producers are required to clearly identify production method on cartons of shell eggs as "cage," "free-range," or "barn laid."<sup>245</sup>

The establishment of similar egg labeling standards would be relatively simple in the U.S., where American consumers' concerns about egg production methods are at least as strong as European and Australian consumers.' FDA is obligated to promulgate egg labeling regulations, as requested in this Petition, for the protection of American consumers.

### **Economic Impact**

#### **I. The costs of the regulation would be negligible.**

Under the proposed regulation, egg producers who report using cage systems would face no additional costs. There is no price premium for cage eggs (which represent 95-98% of all eggs produced) relative to cage-free eggs, and thus no economic incentive to mislabel cage-free eggs as eggs from caged hens. Producers who report using cage systems would not require inspections to verify housing claims; and the costs of labeling changes "may be absorbed in the normal label

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<sup>245</sup> *The Facts about Egg Labeling*, AUSTRALIAN EGG CORPORATION LIMITED, previously available at <http://www.eggs.org.au/index.asp?pageid=377>, (last visited Nov. 12, 2008), Ex. 103; see also *From Label to Liable: Scams, Scandals and Secrecy*, VOICELESS, May 2007, at [http://www.voiceless.org.au/images/stories/reports/Voiceless\\_Label\\_to\\_Liable\\_Report.pdf](http://www.voiceless.org.au/images/stories/reports/Voiceless_Label_to_Liable_Report.pdf) (last visited June 21, 2010), Ex. 104.

change cycle if the compliance period is sufficiently long” to allow producers time to change printing plates or other printing mechanisms.<sup>246</sup>

Only egg producers who report using cage-free or free-range systems, which amount to less than 5% of eggs produced, would face additional costs. These producers’ housing claims would need to be verified by an annual inspection. These costs are likely to be insignificant. Around one-third of U.S. table eggs<sup>247</sup> are packed under USDA’s voluntary egg grading service, a third-party assurance scheme.<sup>248</sup> The USDA states the service costs are insignificant: “This assurance is available at little or no additional cost to consumers – eggs graded by USDA (eggs identified with the USDA grade shield) cost essentially the same as eggs without the USDA grade shield.”<sup>249</sup> There is no reason to believe a third-party assurance scheme for layer housing would be any more costly than USDA egg grading. In fact, annual inspection of housing systems would involve considerably less labor than egg grading.

Several animal welfare certification schemes for cage-free eggs already exist in the United States, including Certified Humane<sup>®</sup> by Humane Farm Animal Care and American Humane<sup>®</sup> Certified by the American Humane Association.<sup>250</sup> Egg producers complying with

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<sup>246</sup> See Elise Golan, Fred Kuchler & Lorraine Mitchell, *ECONOMICS OF FOOD LABELING*, AGRICULTURAL ECONOMICS REPORT, U.S. DEP’T OF AGRIC., NUMBER 793 (2000) at 16, reprinted in Elise Golan, Fred Kuchler & Lorraine Mitchell, *Economics of Food Labeling*, 24 *Journal of Consumer Policy* 117 (June 2001) (internal citations omitted), Ex. 41.

<sup>247</sup> “Table eggs” are defined as “eggs consumed as shell eggs, as opposed to eggs that are used to make egg products.” *Prevention of Salmonella Enteritidis in Shell Eggs During Production*, 69 Fed. Reg. 56824, at 56827 (Sept. 22, 2004) (codified at 21 C.F.R. pt. 16, 118), (“Table eggs” are also synonymous with “market eggs.”), Ex. 105. See Don Bell, *Table Egg Layer Flock Projections and Economic Commentary* (2003), available at <http://animalscience.ucdavis.edu/Avian/uepeconmemo203.htm> (last visited May 21, 2010), Ex. 106.

<sup>248</sup> *Egg Carton Labeling*, USDA (2006), previously available at <http://www.ams.usda.gov/poultry/consumer/labelingexplained.htm> (last visited Sept. 11, 2006), Ex. 107.

<sup>249</sup> *Id.*

<sup>250</sup> *Certified Humane*, HUMANE FARM ANIMAL CARE, available at <http://www.certifiedhumane.org/> (last visited May 21, 2010), Ex. 108. There is additionally a certification scheme called “Animal Welfare Approved” (AWA) created by the Animal Welfare Institute (AWI) which has the highest requirements for certification. However, at present, no egg producers who supply supermarkets are compliant with the AWA scheme. *Animal Welfare Approved*, ANIMAL WELFARE INSTITUTE, available at <http://www.animalwelfareapproved.org/> (last visited May 27, 2010), Ex. 109. Sparboe Companies, LLC also has their own production guidelines. *Animal Care*, Sparboe Farms, available at <http://www.sparboe.com/documents/SparboeProductionGuidelines.pdf> (last visited May 27, 2010), Ex. 110.

these certifications pay a \$500 annual inspection fee and a royalty fee of \$0.04 per case of 30 dozen eggs. In the United Kingdom, the RSPCA administers the Freedom Foods label on eggs, charging an annual inspection fee of \$200 per 6,000 hens and a royalty fee of \$0.07 per case of 30 dozen eggs.<sup>251</sup> A hen produces 260 eggs per year.<sup>252</sup> A typical U.S. egg operation houses on the order of 100,000 hens, producing 72,000 cases of eggs per year.<sup>253</sup> Thus the HFAC, AHA, and RSPCA certifications would cost a typical producer \$0.04-0.07 for royalties and \$0.006–0.05 for inspections per case of cage-free eggs. Total certification costs would be \$0.05–0.12 per case. Cage-free eggs cost between \$14.11 and \$17.60 per case to produce (12 to 40 percent more than battery egg production, which averages \$12.60 per case to produce).<sup>254</sup> Mandatory certification and labeling would thus increase cage-free costs between 0.3 and 0.9 percent.

While cage-free egg producers would face slightly higher costs as a result of labeling, they would benefit from the reduction of inaccurate labeling claims that now cause unfair competition. Moreover, cage-free labeling costs could be passed on to cage-free egg consumers without loss of revenues. As discussed at length above, in surveys, consumers report a willingness to pay higher prices for eggs with animal welfare labels. Indeed, recent research suggests consumers are willing to pay an average of between 17- to 60-percent more for eggs with welfare assurances.<sup>255</sup> Moreover, there are no close substitutes for eggs, and, as a result,

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<sup>251</sup> Calculated based on exchange rates available at <http://www.oanda.com> on May 21, 2010, these figures would be \$160 per year for 6,000 hens, and \$0.06 per case of 30 dozen eggs.

<sup>252</sup> *Chickens and Eggs 2004 Summary*, USDA (2005), previously available at <http://usda.mannlib.cornell.edu/reports/nassr/poultry/pec-bbl/lyegan05.pdf> (last visited Sept. 12, 2006), Ex. 111.

<sup>253</sup> *Id.*

<sup>254</sup> Don Bell, *Table Egg Layer Flock Projections and Economic Commentary* (2003), available at <http://animalscience.ucdavis.edu/Avian/uepeconmemo203.htm> (last visited May 21, 2010), Ex. 106; A. ELSON, *The laying hen: systems of egg production*, WELFARE OF THE LAYING HEN (Perry GC ed., CABI Publishing 2004), Ex. 112.

<sup>255</sup> Richard Bennett & D. Larson, *Contingent valuation of the perceived benefits of farm animal welfare legislation: An explanatory survey*, 47(2) JOURNAL OF AGRICULTURAL ECONOMICS 224, 229-231 (1996), Ex. 113; Richard Bennett, *Farm animal welfare and food policy*, 22 FOOD POLICY 281, 283-84 (1997), Ex. 114; J.C. Rolfe, *Ethical rules and the demand for free-range eggs*, 29 JOURNAL OF AGRICULTURAL ECONOMICS 85 at 196-99 (2003), Ex.

consumers continue to purchase virtually the same number of eggs as prices increase. The own-price elasticity of demand for shell eggs in the United States is  $-0.057$ .<sup>256</sup> Thus, a 0.3 to 0.9-percent increase in the retail price of cage-free eggs would decrease demand 0.02 to 0.05 percent. At this elasticity, producers could, as a group, pass increased costs on to consumers without any loss in profits. Cage-free egg consumers, in turn, would increase their annual average per capita expenditures on shell eggs by perhaps \$0.03 to \$0.09 for the roughly 260 eggs they consume per year,<sup>257</sup> assuming cage-free egg consumers have similar egg consumption habits as the average egg consumer.<sup>258</sup> As mandatory corrective disclosure of basic production method would not affect production costs for 95-98% percent of producers, and would increase production costs for 2-5 percent of producers by at most 0.9 percent, and as these costs could be passed onto consumers with no loss in revenue, certification should have no significant effect on the productivity of wage earners, businesses, or government; on the supplies of important materials, products, or services; on employment; or on energy supply or demand.

### **Environmental Impact**

This petition qualifies for categorical exclusion under 21 C.F.R. §§ 25.15, 25.30(h) and 25.30(k) (2006), and therefore does not require the preparation of an environmental assessment or an environmental impact statement. The action requested in this petition will not have any significant effect on the quality of the human environment. In accordance with the requirements of 21 C.F.R. § 25.15, we assert that we are not aware of any extraordinary circumstances.

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115; Bennett, R. M. and Blaney, R.J.P. *Estimating the benefits of farm animal welfare legislation using the contingent valuation method*, JOURNAL OF AGRICULTURAL ECONOMICS 29, 85-98 (2003), Ex. 116.

<sup>256</sup> Kuo Huang & Biing-Hwan Lin, *Estimation of Food Demand and Nutrient Elasticities from Household Survey Data (TB-1887)*, USDA ECONOMIC RESEARCH SERVICE, 11, 20-30 (September 2000), Ex. 117.

<sup>257</sup> Table 24 – Eggs: Per capita consumption of shell eggs and egg products, ECONOMIC RESEARCH SERVICE, USDA, at <http://usda.mannlib.cornell.edu/usda/ers/89007/table0024.xls> (last visited May 21, 2010), Ex. 118.

<sup>258</sup> *Chickens and Eggs 2004 Summary*, NATIONAL AGRICULTURAL STATISTICS SERVICE, USDA (2005), previously available at <http://usda.mannlib.cornell.edu/usda/nass/PoulProdVa/2000s/2005/PoulProdVa-04-29-2005.pdf> (last visited Sept. 12, 2006), Ex. 110.

## **Conclusion**

As described herein, the labeling of shell eggs in the United States today fails to reveal to consumers certain material facts which substantially influence their purchase decisions and egg labels commonly employ misleading express and implied claims which result in a material and significant difference between the product sold and what it purports to be, all in violation of federal law. The focus of this Petition is not to advocate on behalf of the integrity of specific claims such as “free-range,” “cage-free,” or any of the unregulated misleading terms used as examples, but to demonstrate that the egg labeling field is misleading overall. The most efficient and effective way to remedy the common and persistent mislabeling of eggs is to require simple disclosure of production method on all egg cartons. The proposed market-wide regulation requiring the identification of “Free-Range Eggs,” “Cage-free Eggs,” or “Eggs From Caged Hens” on cartons, as appropriate based on actual production methods, is the most efficient and effective way to deliver accurate information expected by consumers, while alleviating the need to engage in costly, time consuming, and repetitive ad hoc enforcement actions addressing the numerous examples of misrepresentations present in the market today. The proposed regulations effectuate the goals of the statutes discussed in this Petition, and, in light of the increasing and prevalent nature of the misrepresentations, fall under FDA’s authority to prohibit misleading labeling on food products.



**Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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Erica Meier, Executive Director  
Compassion Over Killing, Inc.,  
P.O. Box 9773  
Washington, DC 20016