

December 30, 2010

JAN 3 2011

Food Safety and Inspection Service United States Department of Agriculture 1400 Independence Avenue SW Washington, DC 20250

Re: Petition to Take Regulatory Action to Revise the Labeling Requirements for Eggs

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 FSIS on July 11, 2007, urging FSIS 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 FSIS 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.

Please note that the enclosed petition is to be considered the entirety of the petition content for review before the FSIS, replacing the July 11, 2007 petition FSIS has referred to as "petition to take regulatory action to revise the labeling requirements for eggs." The petition enclosed here is to supplant all of this existing material and to notify FSIS of relevant updated information pursuant to the requirements for citizen petitions, and should serve as the exclusive record of the petition. Please be advised that this submission contains substantively identical information to the original petition, notwithstanding certain information that is now moot and has been omitted and certain items that 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.

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 FSIS' mission ensure the nation's egg supply is properly labeled the proposal is both in the public interest and promotes FSIS' objectives, including the adherence to the Egg Products Inspection Act. Therefore, promulgation of the proposed regulations is not only within FSIS' authority, but constitutes a mandatory duty.

Working to end animal abuse since 1995

¹ 21 U.S.C. § 1031

As such, pursuant to the enclosed submission (which combines the original citizen petition with the aforementioned minor changes), petitioners request FSIS fulfill its statutory mandate and institute the requested rulemaking.

Sincerely,

Cheryl Leahy General Counsel

Enclosures

BEFORE THE UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE

Citizens' Petition to Change the)	
Labeling Requirements for Eggs)	Docket No.
Sold in the United States)	<u> </u>
Updated Version of July 2007 Petition)	
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Submitted to:

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102, Cotton Annex
Washington, D.C. 20250

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

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Citizens' Petition

The undersigned¹ submit this petition pursuant to the Administrative Procedure Act, and specifically 21 U.S.C. sections 321(n), 331, 343, and 371, and the Egg Products Inspection Act ("EPIA") (21 U.S.C. § 1036) to request that the Food Safety and Inspection Service ("FSIS") take regulatory action to revise the labeling requirements for eggs sold in the United States.

Introduction

The labeling of shell eggs² in the United States today fails to reveal to consumers certain material facts that substantially influence their purchasing decisions. Furthermore, following a

¹ 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.

² 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,³ 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. 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. 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. 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

³ 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 FarmedTM Certification Questions & Answers, AMERICAN HUMANE ASSOCIATION, previously available at

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.

⁴ 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

See Sarah Moran, A Good Egg, STAR TRIBUNE: NEWSPAPER OF THE TWIN CITIES, December 1, 2008, Ex. 6. 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." 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. 8

Pursuant to its statutory mandate, the USDA has begun to regulate animal production method labeling—specifically with regard to the intensive confinement of animals—on certain products. For example, the National Organic Program requires producers labeling their products as "Organic" to adhere to qualitative animal confinement standards. In 2002, the USDA issued public notice and request for comments regarding livestock and meat industry production/marketing claims, including the claims 'free range,' 'free roaming,' and 'pasture raised.' Similar provisions have not been adopted for egg labeling. The USDA AMS and FSIS have also developed and implemented the Process Verified Program (PVP), through which the

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⁷ 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.

⁸ 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.

⁹ Cf. Federal Meat Inspection Act, at 21 U.S.C. § 601(n)(1) (2006) (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) (2006) (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) (2006) (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) (2006) ("No labeling or container shall be used for egg products at official plants if it is false or misleading").

¹⁰ 7 C.F.R. § 205.239 (2006) (including access to the outdoors and shelter designed to allow for natural maintenance, comfort behaviors, and opportunity to exercise).

^{11 67} Fed. Reg. at 79,553 (closing comment period on March 31, 2003), Ex. 7; see also Food Safety and Inspection Service: Labeling of FSIS-Regulated, USDA, at 21, at

http://www.fsis.usda.gov/OPPDE/larc/Policies/Label101/Label101.PPT (last visited June 22, 2010) Ex. 10.

USDA oversees, audits, and approves individual production method labeling claims.¹³ FSIS has also taken extensive steps to minimize the dangers of shell eggs, including the risk of salmonella contamination. Misleading labels that have implications for health, safety, and animal welfare should be of great concern to FSIS.

The Federal Trade Commission ("FTC") has stated that promulgation of these requested regulations to "require egg carton labeling as to the egg producers' production methods is more appropriately directed to ... USDA." The USDA's past actions taken under its statutory mandate with regard to similar issues in animal agriculture underscore FSIS as the logical agency to take action here. FSIS shares statutory responsibility for egg labeling and other food packaging. Despite all of this, and despite the prevalence of misrepresentations of egg production methods in the marketplace, FSIS has yet to regulate production method labeling claims in the egg market.

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."

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¹³ Grading, Certification and Verification: LS Process Verified Program, UNITED STATES DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE, available at http://www.ams.usda.gov/AMSv1.0/processverified (last visited October 20, 2010), Ex. 64.

Letter From Mary K. Engle, Associate Director, Division of Advertising Practices, Federal Trade Commission to Erica Meier, Executive Director, Compassion Over Killing (May 29, 2007), Ex. 11

¹⁵ See, e.g., FSIS as a Public Health Regulatory Agency: FSIS Statutes and Your Role, FOOD SAFETY INSPECTION SERVICE, Sept., 2004, at 1-2, available at http://www.fsis.usda.gov/PDF/PHVt-Statutes_Role.pdf (last visited June 22, 2010), Ex. 12.

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.¹⁶

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.¹⁷ The FDA is required to take action to remedy and prevent this.¹⁸ 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.

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.

¹⁶ See infra at pp. 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). ¹⁷ 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, at 21 U.S.C. §§ 301-99 (2010) (enacted June 25, 1938).

¹⁸ See, e.g., Working Agreement Between FTC and FDA, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 13.

- (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.

FSIS is authorized to take all of the requested actions under the Egg Products Inspection Act ("EPIA") (21 U.S.C. §1036) and as a result of its actions in this field, as discussed *infra*.

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. ¹⁹ 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 portion of its life outdoors. But U.S. government standards are weak. ²⁰ 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'

¹⁹ 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. 14. 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. 15.

²⁰ 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. 14. 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. 16; 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. 17.

fed' and 'cage-free,' are generally subjective and not verified."²¹ 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." ²² 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." ²³ 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 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.²⁴ 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

²¹ See Farm Sanctuary, Farm Animal Welfare: An Assessment of Product Labeling Claims, Industry Quality Assurance Guidelines and Third Party Certification Standards 8 (2005), Ex. 18. ²² Id. at 68.

²³ Id at 85

²⁴ 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.

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. 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. Some data further suggest that consumers equipped with greater information about egg production methods will increasingly purchase cage-free eggs, and be less apt to purchase conventionally produced eggs.

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. 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

²⁵ 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.

²⁶ See Sarah Moran, A Good Egg, STAR TRIBUNE: NEWSPAPER OF THE TWIN CITIES, December 1, 2008, Ex. 6. ²⁷ 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. 19.

²⁸ E-mail from Rebecca Wittman, Zogby International, to Gene Baur, President of Farm Sanctuary, (January 10, 2007), Ex. 20.

of its confusing nature.²⁹ 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 eggs³⁰) as "vague and confusing to consumers."³¹ 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, 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 and specifically the EPIA.³²

²⁹ 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 (last visited Aug. 3, 2010), Ex. 21.

³⁰ 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.

³¹ 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. 22.

³² U.S. v. Articles of Drug. 263 F. Supp. 292 at 216 (D.C. Neb. 1967).

B. Misleading egg labels are 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." 33 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 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 purchasers open egg cartons prior to purchase to ensure that none of the eggs are cracked or damaged.

(b) Farm Fresh "Animal Friendly" eggs³⁴ – 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.³⁵

Harris Teeter "All Natural Eggs" Egg Carton Image, Ex. 23.
 Farm Fresh Supermarket Image of In-Store Poster, "AA Eggs," Ex. 24.

³⁵ Farm Fresh Supermarket, at http://www.farmfreshsupermarkets.com/ (last visited May 20, 2010), Ex. 25.

(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." 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. 37

(d) Cal-Maine³⁸ — 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. ³⁹ Cal-Maine offers two other lines of eggs under "Farmhouse" and "Eggland's Best" brands, both of

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³⁶ Giant "Nature's Promise" Omega-3 Natural Brown Eggs Carton Image, Ex. 26.

³⁷ Giant Brands: Welcome!, GIANT, previously available at http://www.giantfood.com/brands/natures_promise.htm (last visited Sept. 19, 2006), Ex. 27. 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 (last visited Sept. 19, 2006), now available at http://apps.ams.usda.gov/plantbook/Query_Pages/PlantBook_Query.asp (last visited Aug. 5, 2010), Ex. 28. Evidence suggests Sauder's is a battery egg supplier. See Caged Hens/Eggs, SAUDER'S EGGS, at 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. 29.

³⁸ Cal-Maine's "Sunny Meadow" Eggs, available at http://www.coastgrocery.com/pages/Products/798 (last visited

³⁸ Cal-Maine's "Sunny Meadow" Eggs, available at http://www.coastgrocery.com/pages/Products/798 (last visited May 20, 2010), Ex. 30.

³⁹ Company, CAL-MAINE FOODS, INC., previously available at http://www.calmainefoods.com/company.htm (last visited Nov. 12, 2008), Ex. 31.

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 Design⁴⁰ "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 number⁴¹ 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" - The inside of the carton states that the eggs are the "best quality Omega-3 egg for your table," which, given 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 batterycage facility, despite the heightened nutritional claims. 43 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

See Nature's Design "All Natural Farm Fresh Eggs," carton image, Ex. 32.
 See carton image showing USDA plant number, Ex. 32.

⁴² See Wild Harvest Natural "Natural Grade A Omega-3 Large White Eggs" carton image at Ex. 33.
⁴³ See Wild Harvest Natural "Natural Grade A Omega-3 Large White Eggs" carton image showing USDA plant number at Ex. 33. 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."

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"⁴⁴ – 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. ⁴⁵ This implies Olivera hens have the opportunity to nest and lie on 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. ⁴⁶ 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

⁴⁴ See Hillandale Farms "All Natural Brown Eggs" carton image, Ex. 34.

⁴⁵ Olivera Egg Ranch "Ranch Pak Eggs" carton image, Ex. 35. Ranch Pak Eggs are produced by Olivera Egg Ranch; this is known because of the plant code, 1463, visible on Ex. 35, 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 available at 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 (last visited Aug. 5, 2010), Ex. 28.

⁴⁶ 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. 36.

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. ⁴⁷ 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. ⁴⁸

(c) Wilcox Farms, "All Natural White" "49 - 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 proudly." 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, 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. ⁵² 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

⁴⁷ Sales, ROSE ACRE FARMS, at http://www.roseacre.com/sales.html (last visited May 20, 2010), Ex 37.

⁴⁸ 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. 38.

⁴⁹ Large All Natural White Eggs, WILCOX FAMILY FARMS, available at

http://www.wilcoxfarms.com/consumer/pop/large all natural 18.html (last visited June 29, 2010), Ex. 39.

⁵⁰ Egg Products: Wilcox Cage-free, WILCOX FAMILY FARMS, previously available at http://www.wilcoxfarms.com/cagefree.html (last visited Sept. 11, 2006), Ex. 40.

⁵¹ Large All Natural White Eggs, WILCOX FAMILY FARMS, available at

http://www.wilcoxfarms.com/consumer/pop/large_all_natural_18.html (last visited June 29, 2010), Ex. 39.

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.⁵³

(e) Nucal Foods, "White Eggs"⁵⁴ — 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, 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. ⁵⁵

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

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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 (last visited Sept. 11, 2006), now available at http://apps.ams.usda.gov/plantbook/Query_Pages/PlantBook_Query.asp (last visited Aug. 5, 2010), Ex. 41. The 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; "Permitted and Pending Concentrated Animal Feeding Operations in Pennsylvania," PENN FUTURE, available at http://www.pennfuture.org/UserFiles/CAFOPermittingSpreadsheet.pdf (last visited September 20, 2010), Ex. 41.

54 Nucal Foods' "White Eggs," available at http://www.nucalfoods.com/egg_info_our_Variety.aspx (last visited Nov. 12, 2008), Ex. 42.

⁵⁵Nucal 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. *California Egg Farm Investigation*, MERCY FOR ANIMALS, *at* http://www.mercyforanimals.org/caeggs/ (last visited September 20, 2010), Ex. 42.

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 cannot tuna and determine if the tuna was caught without harming dolphins. ⁵⁶

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. ⁵⁷ This risk is especially

⁵⁶ 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. 43.

⁵⁷ 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

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.⁵⁸ 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.⁵⁹

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. 60

Especially in light of the special impact misrepresentations have in this context, FSIS must take comprehensive and preventative action in the form of the proposed regulatory scheme

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. 44.

⁵⁸ See Golan, Kuchler & Mitchell, supra note 56, at 13, Ex. 43.

⁵⁹ See Blandford & Fulponi, supra note 57, Ex. 44.

⁶⁰ *Id.* at 13-15 (emphasis added).

in order to fulfill its mandate to halt the widespread mislabeling of eggs in the United States marketplace.

D. 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. 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 Omega-3 fatty acids, one fourth less saturated fat, and one third less cholesterol than conventionally produced (cage) eggs.

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

⁶¹ 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. 45.

⁶² 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. 46.

⁶³ 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/ (last visited Aug. 3, 2010), Ex. 47; 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. 48.

⁶⁴ 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, now available at http://www.enotalone.com/article/8601.html (last visited Aug. 3, 2010), Ex. 49.

⁶⁵ 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. 45.

had 50 percent more folic acid and 70 percent more vitamin B_{12} than eggs from hens confined in factory farms.⁶⁶

The nutritional differences with respect to B_{12} are material to any consumer concerned about nutrition and health. However, this is especially material to vegetarians. Vitamin B_{12} 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_{12} from the sources they choose. ⁶⁷ 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_{12} 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 polyunsaturated fatty acids than U.S. commercial eggs. ⁶⁸ 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." ⁶⁹ 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. ⁷⁰ 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

⁶⁶ A. Tolan et al., Studies on the Composition of food: the chemical composition of eggs produced under battery, deep littler and free-range conditions, 31 BRITISH JOURNAL OF NUTRITION 185 (1974), Ex. 50.

⁶⁸ 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. 51.
⁶⁹ Id.

⁷⁰ Id.

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. 71 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. 72 In another study conducted in Pennsylvania, four pastured poultry producers compared the nutritional soundness of their products with the industry standard. 73 The results indicated that eggs from caged hens are nutritionally inferior to those from pastured hens, containing less vitamin A.⁷⁴ Moreover, the pastured eggs contained omega-6 to omega-3 ratios "considerably better than the standard" (7:1 versus 18:1)⁷⁵, 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. 76 Specifically, the "concentration of (n-3) fatty acid was almost threefold higher in eggs from hens fed on free-range."⁷⁷ 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

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⁷¹ Heather D. Karsten et al., 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. 52.

⁷³ Barbara Gorski, *Nutritional Analysis of Pastured Poultry Products*, 11 AMERICAN PASTURED POULTRY PRODUCERS ASSOCIATION 1 (Winter 2000), Ex. 53.

[,] Ia.

⁷⁵ *Id*.

⁷⁶ C.J. Lopez-Bote et al., Effect of free-range feeding on n-3 fatty acid and α-tocopherol content and oxidative stability of eggs, 72 ANIMAL FEED SCIENCE TECHNOLOGY 33 (1997), Ex. 54.

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.⁷⁸

Given this scientific data, 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 FSIS' statutory and legal mandate to correct such materially misleading labeling.

Marketing claims and images on cartons that falsely imply eggs are from pastured freerange hens essentially make false claims with respect to nutritional content and quality. This is
because cartons which claim that their eggs are "Animal Friendly" or "Naturally Raised," or
feature images of hens outside, for instance, make claims conveying a message to consumers
about both increased nutritional and animal welfare benefits that are often not representative of
the product. That is, these claims and images misrepresent to consumers that the 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

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⁷⁸ See id.; see also, e.g., supra at pp. 7-8, 10-14.

⁷⁹ 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. 55.

argument could be applied to cholesterol, saturated fat, Vitamin A, or Vitamin E. Cartons bearing claims and images that communicate these nutrient content claims to consumers by implying the eggs are from pastured free range hens in fact often contain eggs from caged hens. Because of this, the nutritional information they communicate is false, which constitutes false and misleading advertising as well as claims that misrepresent wholesomeness and healthiness, in violation of the EPIA. This is of course in addition to the misleading message they communicate to consumers from an animal welfare perspective, which is unlawful as discussed elsewhere in this petition. FSIS should consider claims and images indicating hens are raised in an outdoor, pastured setting to be nutritional wholesomeness and health claims as well as animal welfare claims. 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 and misleading..

Because the mislabeling of eggs prevents consumers from making informed nutritional decisions, FSIS must implement the regulations requested in this Petition in order to fulfill its mission of ensuring the nation's egg supply is "wholesome, and correctly labeled and packaged," in addition to the animal welfare reasons discussed herein. Misleading claims and images falsely representing to consumers that eggs are from pastured free-range hens thwarts consumers' ability to make healthier dietary choices if they so choose, in contravention of FSIS' mission to protect the wholesomeness and proper labeling of eggs. By failing to revise the

⁸⁰ 21 U.S.C. § 1036(a) ("the secretary may require by regulations to describe the products adequately and to assure that they will not have false or misleading advertising."); 21 U.S.C. § 1031 ("It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and *properly labeled and packaged*. Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs is injurious to the public welfare and destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products and results in sundry losses to producers and processors, as well as injury to consumers.") (emphasis added).

labeling requirements and regulate labeling in the egg industry, FSIS is allowing misleading labeling to remain prevalent in the egg labeling field.

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 less cruelly 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, FSIS must implement the regulations requested in this Petition. By implementing these regulations, FSIS would not only enable consumers to purchase the products they seek, but it will also allow concerned consumers to identify the higher nutrient products they intend to buy.

E. 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 mortality and increased production. Many egg producers, such as Feather Crest Farms, Inc., Kofkoff Egg Farms, LLC, Pearl Valley Eggs, Inc., Morning Fresh Farms and Wegman's

⁸² About Willamette Egg Farms, WILLAMETTE EGG FARMS, http://www.willamette-egg.com/ourfarm (last visited July 7, 2010), Ex. 56.

Consumer Affairs have opposed the regulatory scheme proposed in this petition. 83 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."84 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. 85 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."86 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,"⁸⁷ and therefore vehemently oppose such regulation.

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

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⁸³ See, e.g., Letter from Feather Crest Farms, Inc., to Food and Drug Administration, (January 18, 2006), Ex. 57.

⁸⁴ 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. 58.

⁸⁵ About Willamette Egg Farms, WILLAMETTE EGG FARMS, http://www.willamette-egg.com/ourfarm (last visited Jul 7, 2010), Ex. 54.

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 (last visited July 2, 2010), Ex. 59.

have continued unabated."88 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."89

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, 90 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. 91 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." 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*. 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

⁸⁸ 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. 60.

⁹⁰ 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.

⁹² See, e.g., Letter from Feather Crest Farms, Inc., to Food and Drug Administration, (January 18, 2006), Ex. 57.

modern cage, cage-free or organic,"⁹³ 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.⁹⁴

F. 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 concerns, discernable differences in nutritional value and health and safety risk results from the

⁹³ 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. 58.

⁹⁴ 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)).

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. 95 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-ofstate 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.⁹⁶

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⁹⁵ 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. 61. 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.

⁹⁶ A.B. 1437, 2009-2010 Gen. Assem., Reg. Sess. (Cal 2010), available at 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. 62.

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." Thus, FSIS 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 FSIS has a duty as a watchdog for the public health and safety, 98 which includes an interest in the accuracy and full disclosures 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, FSIS has not directly and comprehensively exercised its authority over egg labeling, which has resulted in inconsistency between the multiple agencies' application of their respective statutory provisions⁹⁹ and the widespread use of misleading express and implied production method claims on egg labels as described above. The passage of Proposition 2 creates

 ⁹⁷ Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers, 531 U.S. 159, 195 (U.S. 2001).
 ⁹⁸ FSIS ensures public safety by protecting consumers from food borne illnesses through overseeing and enforcing the Federal Meat Inspection Act, Poultry Products Inspection Act and the Egg Products Inspection Act. 9 C.F.R. § 300.2.

⁹⁹ These agencies include the USDA, FDA, and FTC. See the USDA's 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"); see also 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" manner); see also the Egg Products Inspection (EPIA) Act, at 21 U.S.C. §§ 1031, 1036 (requiring assurance of "wholesome...and properly labeled" eggs and prohibiting "false or misleading advertising" and respectively); see also the FTC's FTCA 15 U.S.C. § 45(a)(1) (2007) (prohibiting "deceptive" practices, and the FDA's Food, Drug, and Cosmetic Act (FDCA)); see also 15 U.S.C. § 45(a)(2) (prohibiting "unfair or deceptive acts or practices.").

major changes in the marketplace thus increasing the risk of consumer confusion without FSIS promulgating clear and consistent labeling standards.

Legal Grounds

Egg producers' pervasive misleading labeling of egg labels violates the Egg Products

Inspection Act ("EPIA"), 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. The EPIA requires FSIS to promulgate regulations to correct this mislabeling.

In addition, the USDA AMS and FSIS have developed and implemented the Process Verified Program (PVP), through which the USDA certifies and audits for individual production method labeling claims for producers of livestock, poultry, and eggs. ¹⁰⁰ Therefore, FSIS' by its actions has indicated that production method labeling is within its jurisdiction. Moreover, by playing a central role in the enactment and oversight of the PVP, FSIS has voluntarily entered into the role of de facto regulator of production method claims on meat, poultry, and eggs, including animal welfare claims. FSIS therefore has the legal responsibility and the authority to correct misleading egg labeling by instituting the rulemaking requested herein.

A. FSIS has the legal responsibility to regulate misleading egg labeling.

The USDA, FDA and FTC¹⁰¹ share federal authority to regulate eggs.¹⁰² FSIS, a subagency of USDA, specifically holds authority to regulate false or misleading labeling, ¹⁰³ and has

¹⁰⁰ Grading, Certification and Verification: LS Process Verified Program, UNITED STATES DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE, available at

http://www.ams.usda.gov/AMSv1.0/processverified (last visited October 20, 2010), Ex. 66.

Memorandum of Understanding Between Federal Trade Commission and the Food & Drug Administration, 36 Fed. Reg. 18539 (Sept. 16, 1971), Ex. 61.

Food Labeling, Safe Handling Statements, Labeling of Shell Eggs, Refrigeration of Shell Eggs Held for Retail Distribution, 65 Fed. Reg. 76092-01 (Dec. 5, 2000) (to be codified at 21 C.F.R. Pt. 16, 101, 115), Ex. 62.

the responsibility to promulgate regulations proscribing the use of misleading statements on egg labels. ¹⁰⁴ Both the language of the statute and existing FSIS policy require FSIS to prevent misleading labeling. ¹⁰⁵ Unfortunately, there has been inconsistency between the agencies' application of their respective and substantively identical statutory provisions, which allows widespread mislabeling on egg cartons without regulation. Even so, FSIS possesses the legal authority and responsibility to regulate misleading egg labeling.

In addition, FSIS' role as an agency overall is to protect food safety and public health, including protecting the wholesomeness and proper labeling of eggs. ¹⁰⁶ Because the misleading representations on egg cartons have strong implications for both nutrition and the risk of salmonella infection, which directly implicates both FSIS' authority and mandate to correct this problem and ensure safety and accuracy for consumers, FSIS must take action to correct misleading labeling. ¹⁰⁷

USDA's food safety and mislabeling responsibility was consolidated in FSIS in 1994. ¹⁰⁸
The Egg Products Inspection Act authorizes FSIS to regulate misleading egg labeling. ¹⁰⁹

^{103 21} U.S.C. § 1036(a) ("the secretary may require by regulations to describe the products adequately and to assure that they will not have false or misleading advertising."); 21 U.S.C. § 1031 ("It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and properly labeled and packaged. Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs is injurious to the public welfare and destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products and results in sundry losses to producers and processors, as well as injury to consumers.") (emphasis added).

¹⁰⁴ 9 C.F.R. § 590.411 ("[n]o label, container, or packaging material which bears official identification may bear any statement that is false or misleading.").

FSIS as a Public Health Regulatory Agency: FSIS Statutes and Your Role, FSIS, at 16-17, available at http://www.fsis.usda.gov/PDF/PHVt-Statutes_Role.pdf ("[t]he agency policy is that we put 90% of our inspection resources into food safety issues..., and 10% into 'other consumer protection' activities.' Labeling is one of those other consumer protection activities") (last visited June 28, 2007), Ex. 12.

106 21 U.S.C. § 1031.

¹⁰⁷ The public health and food safety implications of the cage production system and its relationship to misleading labeling are discussed *supra* at 20-26 and *infra* at 48-57.
¹⁰⁸ 7 U.S.C. § 6912.

¹⁰⁹ 21 U.S.C. § 1036.

Although FSIS primarily regulates egg labeling by following its inspection provisions through field offices, ¹¹⁰ FSIS also possesses the broad rule making authority granted by the Secretary of Agriculture under the EPIA. That is, the Secretary has expressly delegated the general statutory authority to implement the EPIA to FSIS. ¹¹¹

As a letter to Erica Meier of Compassion Over Killing from Rex Barnes of the USDA points out, FSIS currently defines the terms "Cage Free" and "Free Range" for poultry and meat products, as well as some of the claims involved in the PVP program, discussed *infra*. The letter suggests that a consistent definition is used by USDA in its internal auditing of producers who have voluntarily elected to be part of the Grade Shield program. However, the enactment and use of these definitions are insufficient to protect consumers from the misleading field of egg labeling—it is not a market-wide program. More to the point, 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 here, such as "animal friendly." Rather, the argument set forth in this petition is that the egg labeling field is misleading overall, given the variety of claims and images facing consumers, discussed *supra*. Consumers need consistent, reliable information. 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, as requested by this petition. Mere voluntary adoption of standards – whether they are private or

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¹¹⁰ 9 C.F.R. § 300.3(a) (2006) ("The organization of FSIS reflects the agency's primary regulatory responsibilities: implementation of the FMIA, the PPIA, and the EPIA. FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.").

⁹ C.F.R. § 300.2(a) (2006) ("The Secretary of Agriculture and Under Secretary for Food Safety have delegated to the Administrator of the Food Safety and Inspection Service the responsibility for exercising the functions of the Secretary of Agriculture under various statutes.").

Letter from Rex A. Barnes, Acting Deputy Administrator, AMS, to Erica Meier, Executive Director, Compassion Over Killing, June 25, 2007 (stating that AMS' definitions of "Cage Free" and "Free Range" are consistent with those applied by FSIS), Ex. 65.

supported by the government in part or in whole – is not adequate to address the confusing and misleading landscape of egg labeling for consumers.

A second statute implemented by FSIS, the Poultry Products Inspection Act ("PPIA"), similarly authorizes the regulation of misleading labeling. Although the PPIA does not authorize FSIS to regulate misleading *egg* labeling, the enabling statute of the PPIA is substantially similar to the enabling statute of the EPIA. Both statutes state that "[i]t is essential, in the public interest, that the health and welfare of consumers be protected by [assuring that egg and poultry products] distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and properly labeled and packaged." The Supreme Court has recognized the "venerable canon" of law that "similar [statutory] language is to be read similarly." The D.C. Circuit has presumed that "Congress is aware of similar language in old statutes, and chooses to repeat that language based on an understanding of relevant law interpreting it." Interpreting the PPIA – a complimentary statute enacted 13 years before the EPIA – 116 courts have held that FSIS "is charged with reviewing the labels affixed to certain commercial food products to ensure that they are truthful, not misleading, and otherwise comply with relevant regulations." 117

Courts have also compared the Federal Meat Inspection Act ("FMIA"), and the PPIA and held that where one statute "empowered the secretary of agriculture to establish regulations," the second statute, with its almost identical language, empowered the secretary to do the same. Given that the relevant statutory language of the EPIA is identical to the PPIA language at issue in that case, courts would likely interpret the EPIA similarly to prevent misleading labels from

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¹¹³ 21 U.S.C. § 1031; 21 U.S.C. § 451.

¹¹⁴ Smith v. City of Jackson, Miss., 544 U.S. 228 (2005).

¹¹⁵ Doe v. DiGenova, 779 F.2d 74 (C.A.D.C. 1985).

¹¹⁶ 21 U.S.C. § 1031; 21 U.S.C. § 451

¹¹⁷ James V. Hurston Assoc., Inc. v. Glickman, 229 F.2d 277, 279 (C.A.D.C. 2000).

¹¹⁸ Borden Co. v. Freeman, 256 F. Supp. 592, 598 (D.C.N.J. 1966).

being affixed to commercial foods. As just shown, FSIS clearly has the authority and duty to regulate misleading labeling and imagery on poultry and meat products. Similarly, FSIS has the authority and duty to regulate misleading labeling and imagery on shell eggs. Therefore, FSIS can and must promulgate regulations requiring the printing of the terms requested herein to prevent misleading egg labeling.

B. USDA's Process Verified Program (PVP) directly oversees and certifies production method labeling; this program places FSIS in a de facto role of regulating animal welfare labeling on livestock, poultry, and eggs.

The USDA AMS and FSIS have also developed and implemented the Process Verified Program (PVP), through which the USDA certifies and audits for individual production method labeling claims. ¹¹⁹ Specifically, FSIS helped to evaluate and implement the program, ¹²⁰ and stressed importance of reviewing animal raising claims for accuracy in the context of PVP. ¹²¹ The PVP includes a multitude of animal welfare production method claims that are mostly otherwise unregulated and undefined by any government agency ¹²² The PVP has no objective criteria for the evaluation of the substance of the claims. Rather, there is a set of procedural

119 Grading, Certification and Verification: LS Process Verified Program, UNITED STATES DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE, available at

http://www.ams.usda.gov/AMSv1.0/processverified (last visited October 20, 2010), Ex 66.

120 See United States Department of Agriculture Food Safety and Inspection Service, Animal Raising Claims, October 14, 2008, page 13, Docket No. FSIS-2008-0026, Docket No. FSIS-2008-0026, available at http://www.fsis.usda.gov/PDF/Animal_Raising_Claims_101408.pdf (last visited October 20, 2010), Ex. 67; Email from Tammie Myrick, Labeling and Consumer Protection Staff, USDA FSIS, to Robert Post (August 16, 2006) (FSIS is forwarding FSIS comments on the Perdue label and the meaning of terms such as "Vegetarian Fed" and "Fresh Chicken." FSIS specifically mentions that they "require feed formulations to be submitted with the label application for evaluation."), Ex. 68.

^{14, 2008,} page 13, Docket No. FSIS-2008-0026, Docket No. FSIS-2008-0026, available at http://www.fsis.usda.gov/PDF/Animal_Raising_Claims_101408.pdf (last visited October 20, 2010), Ex. 67.

122 For example, "Animal Handling," "Humanely Raised," "Raised Cage Free," "Cage Space and Cage-Free Space Requirements," and "Handling and Catching" are all Verified Claims under the PVP that have been authorized for use by specific individual producers. These and many other claims in the PVP make representations about animal welfare. Many of these claims are completely unregulated and undefined by any federal agency, while some are defined, regulated, and/or partly defined or regulated. For a complete list of Verified Claims and producers under the PVP, see Official Listing of USDA Process Verified Programs, USDA, June 29,2010, at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5071588, (last visited October 22, 2010); see also Official Listing of USDA Process Verified Programs, USDA, October 25, 2010, at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 26, 2010), Ex. 69.

guidelines the producers must follow in order to qualify for the PVP. 123 Once a producer is PVP certified, it is permitted to claim "USDA Process Verified" in conjunction with the specific verified claims it has had certified through PVP. 124 Producers that are members of PVP include producers of broiler chickens, beef, pork, veal, and eggs. 125

The PVP program is a de facto regulatory scheme by which producers of animal products (including eggs) are able to use USDA's PVP official seal or obtain USDA's permission to modify it, and can even trademark their version of it, 126 all of which explicitly indicates to the

¹²³ USDA Process Verified Program, AMS Livestock and Seed Program, Audit Review and Compliance Branch. PVP 1001 Procedure, Date Issued 01/15/03, Date Revised 07/10/09, Ex. 70.

¹²⁴ Use the USDA "Process Verified" shield and term, USDA AGRICULTURAL MARKETING SERVICE, available at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&nayID=UsetheUSDAProc ess Verifiedshieldandterm&rightNav1=UsetheUSDAProcess Verifiedshieldandterm&topNav=&leftNay=GradingCert ificationandVerfication&page=UseofPVShieldandTerm&resultType=&acct=lvstksd (last visited October 25, 2010) (stating that companies who are approved under the USDA Process Verified Program may use the "USDA Process Verified" shield and/or term on promotional materials, including labels), Ex. 71.

¹²⁵ Official Listing of Approved USDA Process Verified Programs, USDA, available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 25, 2010); see also Official Listing of USDA Process Verified Programs, USDA, October 25, 2010, at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 26, 2010), Ex. 69. ¹²⁶ 7 C.F.R. § 62.213; see also Department of Agriculture, Agricultural Marketing Service, Quality Systems Verification Programs, 70 Fed. Reg. 58,969 - 58,974 (Oct. 11, 2005) (setting forth the requirements for the official USDA PVP seal use), Ex. 72; see also E-mail from Jeffrey Waite, National Supervisor, Audits, USDA, AMS, Poultry Programs, Grading Branch, to Tabatha Milligan, Food Safety Manager, Perdue Food Group (March 9, 2010) (USDA's AMS notes that a version of their shield was added to Perdue's website that resembles the USDA shield but not exactly in appearance. An image of the shield is attached to the email.) Ex. 73. There are three active "Process Verified" producer-registered trademarks that are part of this program: Trademarks 77846595, filed October 12, 2009, available at http://tess2.uspto.gov/bin/showfield?f=doc&state=4009;fhk6em,2.4 (last visited November 2, 2010); 77809199, filed August 20, 2009, available at

http://tess2.uspto.gov/bin/showfield?f=doc&state=4009:fhk6em.2.5 (last visited November 2, 2010); and 77020425, filed October 13, 2006, available at http://tess2.uspto.gov/bin/showfield?f=doc&state=4009:fhk6em.2.6 (last visited November 2, 2010), Ex. 74. Companies must request the use of the "USDA Process Verified" shield within their Process Verified Program. Companies who use the shield and/or term must have a defined process for ensuring that the shield and/or term are used appropriately. ARC 1001 Procedure and ARC 1001A Policy outline the requirements for companies who use the shield and/or term. The ARC 1001 procedures can be found at

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103489 and the ARC 1001A policy can be found at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103491, available at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=UsetheUSDAProces sVerifiedshieldandterm&rightNav1=UsetheUSDAProcessVerifiedshieldandterm&topNav=&leftNav=GradingCertif icationandVerfication&page=UseofPVShieldandTerm&resultType=&acct=lystksd (last visited November 1, 2010). Ex. 75.

 $[\]frac{126}{126}$ Id. at 14. $\frac{126}{1}$ Id.

¹²⁶ USDA Process Verified Program, AMS Livestock and Seed Program, Audit Review and Compliance Branch, PVP 1001 Procedure, Date Issued 01/15/03, Date Revised 07/10/09; United States Department of Agriculture Food

public that their production methods are approved by the USDA. The core of the PVP is an oversight and auditing process of production method claims, many of which are animal welfare claims. FSIS, through its role in the planning and implementation of the PVP, has therefore shown (1) that it recognizes potential confusion in the marketplace regarding production method claims, (2) that it recognizes there is a need for FSIS' oversight of production method labeling due to the lack of standardization and the need for accountability for labeling claims and (3) more importantly, that FSIS has voluntarily elected to enter into the realm of oversight and de facto regulation of production method labeling. Given this, FSIS clearly has recognized its own authority to regulate and oversee production method labeling, and must act to require the rulemaking requested in this petition in order to correct misleading egg labeling.

In fact, by virtue of its involvement in PVP, FSIS has taken it upon itself to materially change the labeling marketplace for poultry, livestock and eggs. A federal government agency has created another mechanism by which production method claims are certified, but it has done so without actually setting forth a consistent set of objective criteria for evaluating the accuracy of the production method claim. Rather, it defers to the producer to determine how the production method claims are to be defined, and then authorizes the producers to use USDA's

Safety and Inspection Service, Animal Raising Claims, October 14, 2008, page 15, Docket No. FSIS-2008-0026, available at http://www.fsis.usda.gov/PDF/Animal_Raising_Claims_101408.pdf (last visited October 20, 2010) (Mary Poretta, the Program Analyst in the Policy Issuance Division of FSIS, stated that FSIS may not always have the relevant information needed to properly evaluate the animal raising practices described in a producer's animal production protocol. Thus, confusion as to the meaning of production method claims ensues.), Ex. 67.

127 USDA Process Verified Program, AMS Livestock and Seed Program, Audit Review and Compliance Branch, PVP 1001 Procedure, Date Issued 01/15/03, Date Revised 07/10/09; United States Department of Agriculture Food Safety and Inspection Service, Animal Raising Claims, October 14, 2008, page 15, Docket No. FSIS-2008-0026, available at http://www.fsis.usda.gov/PDF/Animal Raising Claims 101408.pdf (last visited October 20, 2010), Ex.

¹²⁸ For example, Perdue uses a "Tenderness Guaranteed" claim that FSIS found "not to be an issue" after review of proposed information provided by Perdue. See Email from Tammie Ballard, Food Technologist, labeling and Program Delivery Division, USDA, FSIS, to Jack Boucher, Assistant National Supervisor, Audits, USDA, AMS, February 17, 2010; Also, Perdue uses "humanely raised" and "cage free" claims and FSIS asked Perdue what "humanely raised" and "cage free" meant to [Perdue] and didn't see it as a "big deal." See E-mail from Jack Boucher, Assistant National Supervisor, Audits, USDA, AMS, to Jeffrey Waite, National Audit Supervisor, Poultry

name and certification in representing the veracity of those claims to the public. ¹²⁹ Not only does this scheme create a de facto role for FSIS as regulator of production method claims, it actually adds to the confusion in the marketplace, given its lack of substantive content with respect to the producer and in relation to the meaning of production method claims. ¹³⁰ This PVP scheme therefore does not correct the problem of the misleading marketplace for shell eggs, and its existence further underscores the need for the regulations requested in this petition, which would provide much-needed clarifying information to the egg-consuming public. FSIS clearly has a direct interest in accurate labeling claims, as well as protection public health through maintenance of a safe and nutritious food supply, and for these reasons is authorized and

Programs, AMS-USDA, June 4, 2009, Ex. 68. Additionally, PVP approved companies such as Murphy-Brown, Seaboard Foods and Premium Standard Farms use "animal handling" claims but do not have their particular standards available for public review. *Official Listing of Approved USDA Process Verified Programs*, USDA, available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 25, 2010); see also Official Listing of USDA Process Verified Programs, USDA, October 25, 2010, at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5071588 (last visited October 26, 2010) (indicating the source of the standards for the certified claims. For example, Cargill and Salmon Creek Farms use the Pork Quality Assurance (PQA) program, which is an industry-developed program, Perdue uses its own privately developed "Perdue's Best Practices," and Bill Mouw and Sparboe use Sparboe's privately developed "Sparboe Production Guidelines"), Ex. 69.

¹²⁹ Use the USDA "Process Verified" shield and term, USDA AGRICULTURAL MARKETING SERVICE, available at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=UsetheUSDAProcessVerifiedshieldandterm&rightNav1=UsetheUSDAProcessVerifiedshieldandterm&topNav=&leftNav=GradingCertificationandVerfication&page=UseofPVShieldandTerm&resultType=&acct=lvstksd (last visited October 25, 2010) (stating that companies who are approved under the USDA Process Verified Program may use the "USDA Process Verified" shield and/or term on promotional materials, including labels), Ex. 71.

¹³⁰ For example, Perdue uses a "Tenderness Guaranteed" claim that FSIS found "not to be an issue" after review of proposed information provided by Perdue. See E-mail from Tammie Ballard, Food Technologist, labeling and Program Delivery Division, USDA, FSIS, to Jack Boucher, Assistant National Supervisor, Audits, USDA, AMS, February 17, 2010, Ex. 68; Also, Perdue uses "humanely raised" and "cage free" claims and FSIS asked Perdue what "humanely raised" and "cage free" meant to [Perdue] and didn't see it as a "big deal." See E-mail from Jack Boucher, Assistant National Supervisor, Audits, USDA, AMS, to Jeffrey Waite, National Audit Supervisor, Poultry Programs, AMS-USDA, June 4, 2009. Additionally, PVP approved companies such as Murphy-Brown, Seaboard Foods and Premium Standard Farms use "animal handling" claims but do not have their particular standards available for public review. Ex. 68 Official Listing of Approved USDA Process Verified Programs, USDA, available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 25, 2010); see also Official Listing of USDA Process Verified Programs, USDA, October 25, 2010, at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5071588 (last visited October 26, 2010) (indicating the source of the standards for the certified claims. For example, Cargill and Salmon Creek Farms use the Pork Quality Assurance (PQA) program, which is an industry-developed program, Perdue uses its own privately developed "Perdue's Best Practices," and Bill Mouw and Sparboe use Sparboe's privately developed "Sparboe Production Guidelines"), Ex. 69.

mandated to correct the misleading egg labeling landscape by implementing the rulemaking requested herein.

C. FSIS currently regulates production method labeling of meat and poultry, and the labeling of eggs more broadly; therefore it can and should impose the requested regulations of production method labeling on eggs

In addition to the traditional, safety-based labeling mandate promulgated by the Agency, ¹³¹ and the de facto regulatory PVP production method scheme discussed *supra*, the USDA has specific statutory authority to regulate misleading labeling. ¹³² FSIS currently regulates the use of various production method terms in the poultry and meat sectors including "Free Range," "Farm Raised," and "Certified Organic." ¹³³ For example, FSIS states that "Farm" or "Country" should not be used on labels if the meat or poultry products are not prepared at a farm or in the country. ¹³⁴

FSIS has, with regard to poultry, recognized the importance of standardizing basic production method claims. For example, it has published a policy regarding the evaluation and validation of basic production methods, including review of affidavits, testimonials and protocols. FSIS already regulates terms such as "free-range" and "free-roaming" as related to poultry production. In another policy statement, FSIS has discussed the meanings of these terms and their role in "ensuring the truthfulness and accuracy in labeling," referring to the

¹³¹ See, e.g., 7 C.F.R. § 56.35 ("all containers bearing official U.S. Grade ... identification shall be labeled to indicate that refrigeration is required").

¹³² See, e.g., 7 U.S.C. § 6503.

USDA Food Safety and Inspection Service: Labeling of FSIS-Regulated, FSIS, at 21, at http://www.fsis.usda.gov/OPPDE/larc/Policies/Label101/Label101.PPT (last visited June 22, 2010) Ex. 10. 134 Id. at 20; 9 C.F.R. § 317.8(b)(2).

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 June 22, 2010), Ex. 76.

United States Standards for Livestock and Meat Marketing Claims, 67 Fed. Reg. 79,552-02, 79,554 (Dec. 30, 2002) (closing comment period on March 31, 2003), Ex. 7.

requirement that "[p]roducers must demonstrate to the Agency that the poultry has been allowed access to the outside."137

Furthermore, FSIS has previously used the EPIA to regulate egg labeling. ¹³⁸ Specifically, the labeling regulation requires that all shell eggs "destined for the ultimate consumer shall be labeled to indicate that refrigeration is required, e.g., 'Keep Refrigerated,' or words of similar meaning." 139 Although this regulation is safety-based, the EPIA also delegates authority to FSIS to prevent misleading labeling. 21 U.S.C. § 1036(b) of the EPIA specifically prohibits false or misleading labeling on containers, or the non-approved use thereof. The relevant provision states that "[n]o labeling or container shall be used for egg products at official plants if it is false or misleading or has not been approved as required by the regulations of the Secretary." ¹⁴⁰ In addition, FSIS has specifically evaluated certain production method claims on an ad hoc basis for individual producers through the Process Verified Program (PVP), such as

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 June 28, 2007), Ex. 77. 138 9 C.F.R. § 590.410

 $^{^{137}}$ 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, (last visited June 22, 2010), Ex. 76.

¹³⁹ *Id*.

¹⁴⁰ 21 U.S.C. § 1036(b) (2006).

assurances of no "animal by-products." Just as FSIS regulates production method claims on poultry and meat products, it should, in order to fulfill its statutory mandate to avoid misleading egg labeling, also regulate production method claims on eggs. The lack of such regulations in the egg sector creates a marketing environment that permits the unfettered use of claims and imagery that misrepresent to consumers actual egg production methods.

D. The proposed regulations are consistent with and are needed to fulfill FSIS' obligation to correct pervasive misleading egg labels.

The EPIA aims to eliminate the common agricultural practices of misbranding and deceiving customers by false labeling. However, egg cartons are adorned with so many misleading images and claims that the whole labeling landscape is essentially misleading. The proposed regulation would allow consumers to exercise effective market choice, and also correct misleading claims by requiring the clear identification of production methods on an egg carton's primary display label. Most importantly, the current practice – allowing voluntary, private standards – is inadequate to protect against rampant misleading labeling. The cases analyzed below illustrate the need for clarifying regulation where industries misrepresent the nature of their products.

Although the following case applies the FDCA instead of the EPIA, both statutes aim to prevent the misleading of consumers and should be treated similarly. The misrepresentation of material facts on egg labels mirrors the situation described in *U.S. v. An Article of Food, etc.*,

United States Department of Agriculture Food Safety and Inspection Service, Animal Raising Claims, October 14, 2008, page 13, Docket No. FSIS-2008-0026, available at

http://www.fsis.usda.gov/PDF/Animal_Raising_Claims_101408.pdf (last visited October 20, 2010), Ex. 67; see also Official Listing of USDA Process Verified Programs, USDA, June 29,2010, at

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5071588 (last visited October 22, 2010), Ex. 69; see also Official Listing of USDA Process Verified Programs, USDA, October 25, 2010, at

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3320450 (last visited October 26, 2010), Ex. 69. ¹⁴² See Stribling v. U.S., 419 F.2d 1350, 1352-53 (8th Cir. 1969) ("where the interpretation of a particular statute at issue is in doubt, the express language and legislative construction of another statute not strictly in pari material but employing similar language and applying to similar persons, things, or cognate relationships may control by force of analogy.").

377 F. Supp. 746, 748 (E.D.N.Y. 1974). In *An Article of Food*, the claim "Diet-Thins" was made on the front panel of a matzo cracker product, but their caloric content was higher than some non-diet crackers. ¹⁴³ In holding that the label was misleading, the court ruled that food products are "misbranded if it appears that any one representation is false or misleading" and "it is not necessary to show that anyone was actually misled or deceived, or that there was intent to deceive. ¹⁴⁴ The prevalent individual misrepresentations on egg labels renders much of the egg industry's packaging misleading, thus necessitating the standardization of clarifying labeling to correct this problem.

Additionally, the *Article of Food* court held that clarifying information printed in small lettering on the side panel of the box did not correct the mislabeling located on the primary panel. Applied to the egg industry, this second holding of *An Article of Food* highlights the need for the promulgation of regulations requiring the standardized prominent placement of clarifying information on the primary display panel of egg cartons. For example, 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. 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

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¹⁴³ An Article of Food, 377 F. Supp. at 748.

¹⁴⁴ *Id.* at 748-739.

¹⁴⁵ *Id.* at 749 ("whether or not the side panel of the Diet-Thins label may accurately describe its virtues for certain special diets which to not appear to involve weight control, the misleading nature of the front panel still justifies condemnation of the seized articles.").

¹⁴⁶ Born Free Egg Carton Label Image, Ex. 78; Born Free All Natural, RADLO FOODS, previously available at http://www.radlo.com/bfAllNaturalEggs.html (last visited Sept. 11, 2006), Ex. 79. Note: it is not clear whether these eggs are currently still being sold under this brand name.

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 expectations. Petitioners request regulations requiring front panel disclosure of production method to correct this otherwise confusing landscape

Petitioners request regulations requiring sufficiently sized front panel disclosure of production method to correct this otherwise confusing landscape. Unfortunately, the process of requesting individual retailers to change their labels on an ad hoc basis is an inefficient and ineffective way of preventing mislabeling. In light of the pervasive misleading labeling throughout the egg industry, 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 as 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 public also supports government regulation of egg labeling. 147

E. "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

¹⁴⁷ 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 visited June 21, 2010), Ex. 80.

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 the 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 "natural" on its packaging, and almost half (48 percent) believe that the "natural" claim indicates that the animals had access to the outdoors. 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,'" 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.

USDA is aware of and has acknowledged the problem of the unregulated "natural" term on food product labels. ¹⁵⁰ 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 FSIS to regulate this term, citing the current definition (which does not even

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 ¹⁴⁸ E-mail from Rebecca Wittman, Zogby International, to Gene Baur, President of Farm Sanctuary, (Jan. 10, 2007),
 Ex. 20.
 ¹⁴⁹ Id.

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 (last visited May 20, 2010), Ex. 21.

apply to eggs¹⁵¹) as "vague and confusing to consumers;" ¹⁵² a claim also echoed by members of Congress. ¹⁵³ Clearly, the industry's call for regulation of this claim indicates the extent of the problem. 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. ¹⁵⁴ Unfortunately, such measures are nevertheless inadequate to address the misleading labels of eggs, because even if later enacted, the standard for "natural" would still not apply to egg labels and would still not be indicative of any improved production methods. ¹⁵⁵ Given the numerous examples ¹⁵⁶ of misleading claims and images relating to animal welfare used by the egg industry, FSIS must require production method disclosure to protect consumers.

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 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

¹⁵¹ 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.

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 22, 2010), Ex. 22.

Pickering Calls for Chicken Labeling Reform; Pickering and California Congressman Ask USDA to Protect Consumers, STATES NEWS SERVICE (May 22, 2007), available http://news.google.com/newspapers?nid=999&dat=20070531&id=gFElAAAAIBAJ&sjid=hhMGAAAAIBAJ&pg=1537,2072472) (last visited June 22, 2010), Ex. 81.

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 C.F.R. Parts 317 and 381), Ex. 49. As of March 20, 2009, the proposed rule on the voluntary claim "Natural" was not published as a final rule. Despite this, the confusion over the term "natural," as evidenced by numerous public comments, further evidences FSIS' awareness of the need for a clear, industry-standardized definition. See 9 C.F.R. Parts 317 and 381, Docket No. FSIS-2008-0027; Federal Register: March 20, 2009, Volume 74, Number 53, Ex. 82.

¹⁵⁵ Id. at 46955-56 (discussing "natural" and animal production methods), Ex. 82.

¹⁵⁶ See, e.g., supra at pp. 11-17.

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." 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. 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.

In fact, 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. Unfortunately, such measures are nevertheless inadequate to address the misleading labels of eggs, because

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¹⁵⁷ 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 (last visited May 20, 2010), Ex. 83.

¹⁵⁸ 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 (last visited May 20, 2010), Ex. 84. More recently, 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 C.F.R. Parts 317 and 381), Ex. 82. 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.

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 C.F.R. Parts 317 and 381), Ex. 82.

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. 160

"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 products¹⁶¹ and the use of "natural" claim on eggs from caged hens is widespread and demonstrably misleading, FSIS must require clarifying production method labeling to protect consumers.

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." 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. The study confirmed that standards of animal welfare are used by consumers as indicators of the safety and healthiness of food. 164

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

 $^{^{160}}$ Id. at 46955-56 (discussing "natural" and animal production methods).

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. 86.

¹⁶² 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. 87.

¹⁶³ Id

¹⁶⁴ *Id*.

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. The public also supports government regulation of egg labeling.¹⁶⁵

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

FSIS is responsible for protecting the public health by ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. ¹⁶⁶ FSIS, as the primary food safety regulatory agency within the USDA ¹⁶⁷ has a direct interest in ensuring that food products are free from harmful contaminants such as salmonella. FSIS in particular also has taken extensive steps to ensure the safety of shell eggs, including the risk of salmonella contamination, and therefore misleading labels which have implications for health, safety, and animal welfare should be of great concern to FSIS.

As discussed *infra*, FSIS clearly has the authority and duty to regulate misleading labeling on shell eggs. With the responsibility to regulate and misleading labeling, and the duty to protect public health, it is clearly within the scope of FSIS's jurisdiction and duties to address the Salmonella Enteritis (SE) issue in shell eggs.

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 visited June 21, 2010), Ex. 80.

¹⁶⁶ 21 U.S.C.A. § 1031.

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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 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 Enteritis (SE), which is transferred from infected hens to the egg before the egg is laid. ¹⁶⁸ Chickens are notoriously susceptible to Salmonella infections and if infected, the egg likely will be as well. ¹⁶⁹ The worst Salmonella outbreak in U.S. history (aside from the latest August 2010 outbreak) caused by eggs sickened hundreds of Americans in 1994. ¹⁷⁰ In 2005, the CDC

¹⁶⁸ Kåre Mølbak & Jakob Neimann, *Risk Factors for Sporadic Infection with Salmonella Enteritidis*, (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. 88.

Anna Vigran, With Salmonella, It's A Chicken-Or-Egg Conundrum, NATIONAL PUBLIC RADIO, August 31, 2010, available at http://www.npr.org/templates/story/story.php?storyId=129472951 (last visited September 13, 2010), Ex. 89.

¹⁷⁰ 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. 90.

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. ¹⁷¹

Due to the recent August 2010 Salmonella outbreak, which has been referred to as "one of the largest shell egg recalls in recent history," more than 500 million eggs were recalled and thousands of people were sickened with Salmonella throughout 14 states, with numbers expected to rise. The outbreak was traced back to two facilities in Iowa, specifically Wright County Egg and Hillandale Farms. 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. Infected rodents spread Salmonella through their feces into the chicken feed thus contributing to the infectious outbreak. 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.

¹⁷¹ 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 (last visited September 15, 2010). Ex. 91.

¹⁷² 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. 90.

¹⁷⁴ 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.

¹⁷⁵ 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. 92.

¹⁷⁶ Jeroen Dewulf, Salmonella Thrives in Caged Housing, 25 WORLD POULTRY, (May 20, 2010), available at http://www.worldpoultry.net/background/salmonella-thrives-in-cage-housing-7481.html (last visited September 13, 2010), Ex. 93.

2. FSIS' Actions and Legal Grounds for FSIS' Authority and Responsibility to Address Salmonella Risk

In July of 2010, FSIS worked closely together with the FDA, 177 which has responded based on its direct duty to "prevent public harm" through regulation of "on-farm activities." ¹⁷⁸ In past recalls related to the risk of Salmonella, FSIS, through its partnership with FDA, has strategized to ensure that egg safety measures are "consistent, coordinated and complimentary" by drafting new Salmonella-control programs commonly referred to as the "egg safety rule" ¹⁷⁹ that aims to "reduce the risk of foodborne illness." The new egg rules include such mandates as farms testing eggs and facilities for salmonella, protecting feed and water from contamination and buying chicks and young hens from supplies that monitor for salmonella. 181 FSIS has also taken actions in the past to address this problem. It has focused on pathogen reduction for eggs and in 1995 with FDA and CDC developed the Foodborne Diseases Active Surveillance Network (FoodNet), which included information collection and a study on Salmonella. 182 In 1998 FSIS and FDA introduced the Salmonella Enteritidis Risk Assessment (SERA), which was developed to establish the risk of SE in shell eggs and Salmonella in liquid egg products to

¹⁷⁷ Press Release, United States Department of Agriculture, Federal Agencies Announce Progress in First Year of Implementing Food Safety Working Group Recommendations, Release No. 0362.10, available at http://www.usda.gov/wps/portal/usda/!ut/p/c4/04 SB8K8xLLM9MSSzPy8xBz9CP0os gAC9wMJ8QY0MDpxBDA09nXw9DFxcXw2ALU 2CbEdFAFsoRU!/?printable=true&contentidonly=true&contentid=2010%2F07%2F0362.xml (last visited October 25, 2010),

Ex. 94. USDA/FSIS and HHS/FDA have established Chief Medical Officer (CMO) positions, with each CMO leading and overseeing all phases of foodborne outbreak investigations including planning, training, early detection, improved communication, response and incorporating lessons learned into prevention based efforts within our programs.

¹⁷⁹ Salmonella Enteritidis Outbreak in Shell Eggs, FOOD AND DRUG ADMINISTRATION, September 17, 2010, available at http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm#ShellEggProducers (last visited October 18, 2010), Ex. 95.

¹⁸⁰ Federal Register, Department of Agriculture, Food Safety and Inspection Service, 9 C.F.R. Part 304, et al., Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, page 38807, Ex.

¹⁸¹ Timothy W. Martin, New Food-Safety Rules Come Amid Egg Probe, WALL STREET J., August 23, 2010, available at http://online.wsj.com/article/SB10001424052748704504204575445981962961848.html (last visited October 27, 2010), Ex. 97.

FDA Testimony, Oversight of Egg Safety, at http://www.fda.gov/NewsEvents/Testimony/ucm115053.htm (last visited November 5, 2010), Ex. 98.

human health and to identify and evaluate potential risk reduction strategies. ¹⁸³After SERA, FSIS and the FDA developed the Egg Safety Action Plan which outlined a broad egg safety strategy, aimed at reducing the incidence of egg-associated SE infections by 50% from 1998 to 2005 and with the goal of eliminating it entirely by 2010. ¹⁸⁴ FSIS also worked with FDA to implement a transportation rule which is meant to reduce salmonella risk in shell eggs and to develop the Food Code to work with state entities to reduce Salmonella risk, as well as the "Fight Bac!" consumer education campaign to promote egg safety. ¹⁸⁵

Given FSIS' authority¹⁸⁶ to address the issue of Salmonella risk and its recent actions surrounding the August 2010 recall due to Salmonella,¹⁸⁷ it is clear that FSIS has the jurisdiction and the responsibility to address issues surrounding Salmonella in shell eggs. Specifically, FSIS' presence at Wright County Egg, one of the farms at the center of the 2010 Salmonella outbreak, demonstrates its apparent awareness of the salmonella-related risk factors present at this

¹⁸³ Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Liquid Egg Products Risk Assessments Technical Meeting, 69 Fed. Reg. 59575-01 (October 5, 2004), available at

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-034N.htm (last visited November 1, 2010), Ex. 99.

¹⁸⁴ Salmonella and Egg Safety, FOOD SAFETY INSPECTION SERVICE, available at

http://www.fsis.usda.gov/oppde/rdad/FRPubs/04-034N/Introduction.pdf (last visited November 1, 2010), Ex. 100. ¹⁸⁵ FDA Testimony, *Oversight of Egg Safety*, at http://www.fda.gov/NewsEvents/Testimony/ucm115053.htm (last visited November 5, 2010), Ex. 98.

¹⁸⁶ The EPIA and the associated regulations (7 C.F.R. Part 59) laid out the requirements to assure that eggs and egg products are wholesome, otherwise not adulterated and properly labeled and packaged. FSIS, through the EPIA, assumed responsibility for supervision over a Salmonella surveillance recognized laboratory program. Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Liquid Egg Products Risk Assessments Technical Meeting, 69 Fed. Reg. 59575-01 (October 5, 2004), available at

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-034N.htm (last visited November 1, 2010), Ex, 99.

¹⁸⁷ Alicia Mundy & Bill Tomson, Egg Inspectors Failed to Raise Alarms: Agriculture Officials Noted Bugs, Trash on Farm at Center of Recall, but Never Notified Agency in Charge of Safety Issues, WALL STREET J., September 10, 2010 (explaining that USDA plant workers noticed cleanliness issues, notified the plant manager of those issues and were in charge of writing a daily review of 22 categories of cleanliness), Ex. 101; see also Salmonella Enteritidis Outbreak in Shell Eggs, FOOD AND DRUG ADMINISTRATION, September 17, 2010, available at http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm#ShellEggProducers (last visited October 18, 2010), Ex. 95.

facility. With FSIS' role as a public health agency, clearly action is required to protect the public and reduce the risk of salmonella. 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, FSIS' duty to protect the public health and safety further demonstrates the necessity for regulations to protect consumers.

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. ¹⁸⁹

A recent study comparing cage to cage-free systems found that there were 20 times greater odds of *Salmonella* infection in caged flocks. ¹⁹⁰ 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." 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

¹⁸⁸ Alicia Mundy & Bill Tomson, Egg Inspectors Failed to Raise Alarms: Agriculture Officials Noted Bugs, Trash on Farm at Center of Recall, but Never Notified Agency in Charge of Safety Issues, WALL STREET J., September 10, 2010, Ex. 101.

¹⁸⁹ 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. 90.

¹⁹⁰ 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 94-100, (2010), Ex. 102.

Adeline Huneau-Salaun, 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. 103.

disease.¹⁹² Eggs can also become infected by SE fecal contamination through the pores of the shells after they're laid.¹⁹³ 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.¹⁹⁴

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. 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. 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. To

¹⁹² Id.

¹⁹³ 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 (last visited September 15, 2010), Ex. 104.

¹⁹⁴ Jeroen Dewulf, Salmonella Thrives in Caged Housing, 25 WORLD POULTRY, (May 20, 2010), available at http://www.worldpoultry.net/background/salmonella-thrives-in-cage-housing-7481.html (last visited September 13, 2010), Ex. 93.

¹⁹⁵ 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 (last visited September 13, 2010), Ex. 105.

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. 92.

¹⁹⁷ 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 (last visited September 13, 2010), Ex. 105.

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. This analysis by the European Food Safety Authority found that there were 43% lower odds of SE contamination in cage-free barns, where hens were raised indoors, than in cage production. 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.

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.²⁰¹ Salmonella-infected feces of rodents (commonly mice and rats) can also contaminate the animal feed which occurs commonly on chicken, turkey and duck farms.²⁰² A single mouse produces 100 droppings a day and each can contain up to

¹⁹⁸ 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 (last visited September 13, 2010), Ex. 106.

²⁰⁰ 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. 88.

²⁰¹ 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, (citing Carrique-Mas, J. J., et al., Persistence and clearance of different Salmonella serovars in building housing laying hens, 137 EPIDEMIOL. INFECT 837–46 (2009)), available at http://www.poultryscience.org/docs/PS_794.pdf (last visited September 13, 2010), Ex. 105. ²⁰² 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. 107.

230,000 SE bacteria.²⁰³ 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.²⁰⁴

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 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 FSIS correcting the misleading egg labeling field in the U.S., the Salmonella issue's link to cage production provides an additional rationale for FSIS to implement the regulations requested in this Petition: the misleading egg labeling field's implication for public safety and health.

FSIS, through its duty to protect public health,²⁰⁵ 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

²⁰³ S.A. Davison et al., *Preharvest HACCP in the Table Egg Industry*, PENN STATE COLLEGE OF AGRICULTURAL SCIENCES (1997), at 11, *available at* http://pubs.cas.psu.edu/FreePubs/pdfs/AGRS72.pdf (last visited September 15, 2010), Ex. 108.

²⁰⁴ Id.

²⁰⁵ See, e.g., FSIS as a Public Health Regulatory Agency: FSIS Statutes and Your Role, FSIS, Sept., 2004, at 1-2, at http://www.fsis.usda.gov/PDF/PHVt-Statutes_Role.pdf (last visited June 22, 2010), Ex. 12. The statutes related to FSIS include the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) which provide the basis for FSIS's ability to perform as a public health agency.

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. FSIS 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. 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. 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

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²⁰⁶ 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. 109; see also Report on Welfare Labeling, FARM ANIMAL WELFARE COUNCIL ("FAWC"), Jun., 2006, Ex. 110. ²⁰⁷ 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&marke r=1&articleId=999516092840 (last visited Sept. 11, 2006), Ex. 111.

standardization of terms regarding cages.²⁰⁸ Article 1(7) of the EC regulation requires certain standardized labeling on how the laying hens were kept:

On packs

On Eggs

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.

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 EÜ: egg producers are required to clearly identify production method on cartons of shell eggs as "cage," "free-range," or "barn laid."

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

²⁰⁸ Commission Regulation 1651/2001, 2001 O.J. (L 220) 5, Ex. 112.

²⁰⁹ 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. 113; 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 (last visited June 21, 2010), Ex. 114.

as European and Australian consumers.' FSIS 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 change cycle if the compliance period is sufficiently long" to allow producers time to change printing plates or other printing mechanisms.²¹⁰

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 eggs²¹¹ are packed under USDA's voluntary egg grading service, a third-party assurance scheme. ²¹² 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

²¹⁰ 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. 43.

²¹¹ "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. 107. 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. 107. ²¹² Egg Carton Labeling, USDA (2006), previously available at

http://www.ams.usda.gov/poultry/consumer/labelingexplained.htm (last visited Sept. 11, 2006), Ex. 115.

identified with the USDA grade shield) cost essentially the same as eggs without the USDA grade shield."²¹³ 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® by Humane Farm Animal Care and American Humane® Certified by the American Humane Association. Egg producers complying with 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. A hen produces 260 eggs per year. A typical U.S. egg operation houses on the order of 100,000 hens, producing 72,000 cases of eggs per year. 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

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http://usda.mannlib.cornell.edu/reports/nassr/ poultry/pec-bbl/lyegan05.pdf (last visited Sept. 12, 2006), Ex. 119. ²¹⁷ Id.

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²¹⁴ Certified Humane, HUMANE FARM ANIMAL CARE, available at http://www.certifiedhumane.org/ (last visited May 21, 2010), Ex. 116. 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. 117. 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. 118.

²¹⁵ 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.

²¹⁶ Chickens and Eggs 2004 Summary, USDA (2005), previously available at http://usda.mannlib.cornell.edu/reports/nassr/ poultry/pec-bbl/lyegan05.pdf (last visited

than battery egg production, which averages \$12.60 per case to produce).²¹⁸ 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. Moreover, there are no close substitutes for eggs, and, as a result, 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. 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. 221 assuming cage-free egg consumers have similar egg consumption habits as the average

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²¹⁸ 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. 107; A. ELSON, The laying hen: systems of egg production, Welfare of the Laying Hen (Perry GC ed., CABI Publishing 2004), Ex. 120.

Richard Bennett & D. Larson, Contingent valuation of the perceived benefits of farm animal welfare legislation: An explanatory survey, 47(2) J. OF AGRIC. ECON. 224, 229-31 (1996), Ex. 121; Richard Bennett, Farm animal welfare and food policy, 22 FOOD POLICY 281, 283-84 (1997), Ex. 122; J.C. Rolfe, Ethical rules and the demand for free-range eggs, 29 J. OF AGRIC. ECON. 85, at 196-99 (2003), Ex. 123; R. M. Bennett & R.J.P. Blaney, Estimating the benefits of farm animal welfare legislation using the contingent valuation method, J. OF AGRIC. ECON. 29, 85-98 (2003), Ex. 124.

²²⁰ Kuo Huang & Biing-Hwan Lin, Estimation of Food Demand and Nutrient Elasticities from Household Survey Data (TB-1887), USDA ECONOMIC RESEARCH SERVICE, at 11, 20-30 (September 2000), Ex. 125. ²²¹ Table 24 – Eggs: Per capita consumption of shell eggs and egg products, ECONOMIC RESEARCH SERVICE, USDA, at http://usda.mannlib.comell.edu/usda/ers/89007/table0024.xls (last visited May 21, 2010), Ex. 126.

egg consumer.²²² 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.

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

²²² 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. 119.

effectuate the goals of the statutes discussed in this Petition, and, in light of the increasing and prevalent nature of the misrepresentations, fall under FSIS' 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 is unfavorable to the petition.

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