

BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATION

Citizens' Petition to Change the
Labeling Requirements for Eggs
Sold in the United States

Docket No. 2006P.0394

Submitted to:

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

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Submitted by:

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Citizen Petition

The undersigned¹ submit this petition pursuant to the Administrative Procedure Act, specifically 21 U.S.C. sections 321(n), 331, 343, and 371, and the Fair Packaging and Labeling Act (“FPLA”), as amended, specifically, 15 U.S.C. sections 1452, 1453, and 1454, to request that the Food and Drug Administration (“FDA”) take regulatory action to revise the labeling requirements for eggs sold in the United States.

Introduction

The labeling of shell eggs² in the United States today fails to reveal to consumers certain material facts which substantially influence their purchasing decisions. Furthermore, following a recent increase in consumer interest regarding egg production method,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% of those polled found the common egg industry practice of confining egg-laying hens in densely crowded cages

¹ Petitioner Compassion Over Killing, Inc. is a nonprofit animal advocacy organization based in Washington, D.C., representing over 9,000 individual consumers nationwide that among other things seeks to correct misleading advertising and educate consumers regarding food production methods. 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.

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, 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,

³ A recent investigation by Golin/Harris International, Inc., commissioned by the egg industry group United Egg Producers, indicates that 50% of consumers consider production method important when choosing between food products, while 51% admit they have little knowledge about the actual production practices. *Laying Out the Facts*™, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2. According to the American Humane Association, 44% of consumers would pay 5% more for food products that provide assurances that animals were “humanely raised.” *Free Farmed*™ Certification Questions & Answers, AMERICAN HUMANE ASSOCIATION, 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.

to be unacceptable.⁴ Actual egg production methods are in conflict with public opinion; more than 98% of eggs produced and sold in the U.S. come from birds confined in cages.⁵ Furthermore, a recent study on behalf of the United Egg Producers revealed that while half of those polled consider production methods important when making purchasing decisions, 51% admit they have little knowledge of actual production practices,⁶ necessitating clear and fair labeling to remedy this discrepancy. 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 egg products represented to them as produced under standards that ensure some form of animal welfare.⁷ 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 animals.”⁸ 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

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 Sept. 11, 2006), Ex. 4 and E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 4A.

⁵ *Industry History*, UNITED EGG PRODUCERS CERTIFIED, at <http://www.uepcertified.com/industryhistory.html> (last visited Sept. 8, 2006), Ex. 5.

⁶ *Id.*; *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2.

⁷ *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 Sept. 11, 2006) (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 and E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 4A.; *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2 (indicating that 75% of American consumers “will choose food products certified as protecting animal care over those that are not”), Ex. 2; 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. 6.

⁸ *Tariff and Non-tariff Barriers*, INT’L EGG & POULTRY REV. (U.S. Dep’t of Agric.), Nov.13, 2001 at 1, available at <http://www.ams.usda.gov/POULTRY/mncs/InternationalPoultryandEgg/2001Reports/x111301.pdf> (last visited Sept. 11, 2006), Ex. 7.

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, “56% of consumers agree with the need for government regulation to ensure animal welfare, even if it means it will cost more in the grocery store.”⁹

Pursuant to its statutory mandate, the relevant provisions of which are identical to the enabling statute under which the FDA operates, the USDA has begun to regulate animal production method labeling on a limited number of products – specifically with regard to the intensive confinement of animals.¹⁰ For example, the National Organic Program requires producers labeling their products as “Organic” to adhere to qualitative animal confinement standards.¹¹ In 2002, the USDA issued public notice and request for comments regarding livestock and meat industry production/marketing claims,¹² including the claims ‘free range,’ ‘free roaming,’ and ‘pasture raised.’¹³ Similar provisions have not been adopted for egg labeling.

Despite such action taken under an identical statutory mandate, and the prevalence of misrepresentation of egg production methods (discussed below), the FDA, which has primary responsibility for egg labeling,¹⁴ has yet to act.

⁹ An additional 23% cannot decide. This survey also found that nearly half (44%) of consumers “agree with both industry self-regulation and government regulation.” *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2.

¹⁰ *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”)

¹¹ 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).

¹² 67 Fed. Reg. at 79,553 (closing comment period on March 31, 2003), Ex. 6.

¹³ *Id.* at 79,554, Ex. 6.

¹⁴ *See, e.g., Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 8; *see also Enforcement Policy Statement on Food Advertising*, FTC, May, 1994, at 2, available at <http://www.ftc.gov/bcp/policystmt/ad-food.htm> (last visited Sept. 11, 2006), Ex. 9.

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 of hens lying on nests, as well as language suggesting a level of animal care that is inconsistent with consumers' expectations, such as "Animal Friendly" and "Certified Animal Care."¹⁵

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.¹⁶ The FDA is required to take action to remedy and prevent this.¹⁷ Moreover, its prevalence and recent increase demands 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:

¹⁵ See, e.g., *Sales*, ROSE ACRE FARMS, at <http://www.roseacre.com/sales.html> (last visited Sept. 8, 2006), Ex. 26; *Egg Products*, WILCOX FAMILY FARMS, at <http://www.wilcoxfarms.com/cagefree.html> (last visited Sept. 8, 2006), Ex. 27.

¹⁶ See, e.g., 21 U.S.C. § 331(a)-(c), (g) (2006) (prohibiting misbranding of food); 21 U.S.C. § 343 (2006) (defining misbranded food); 21 U.S.C. § 321(n) (2006) (describing factors considered in determining whether labeling or advertising is misleading). See generally Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2006) (enacted June 25, 1938).

¹⁷ See, e.g., *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 8.

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

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

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

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

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

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

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

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

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

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

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

Statement of Grounds

I. Factual Grounds

A. Unregulated production method labeling of eggs misleads consumers.

Unregulated egg labeling has been 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.¹⁸ 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."¹⁹ 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

¹⁸ See *Food labels can be misleading*, CONSUMER REP., Feb. 2006, at <http://www.consumerreports.org/cro/food/organic-products-206/food-labels-can-be-misleading/> (last visited Sept. 8, 2006), Ex. 10.

¹⁹ *Id.* 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 Sept. 8, 2006), Ex. 11; 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 Sept. 8, 2006), Ex. 12.

fed' and 'cage free,' are generally subjective and not verified."²⁰ The report went on to note that "As 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."²¹ 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."²² 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 indicating they would be willing to spend 5-10 percent more for animal welfare standard certified eggs, and an additional 10 percent saying they would be receptive to paying 15-20 percent more for such certified products.²³ Given this demand for

²⁰ See FARM SANCTUARY, FARM ANIMAL WELFARE: AN ASSESSMENT OF PRODUCT LABELING CLAIMS, INDUSTRY QUALITY ASSURANCE GUIDELINES AND THIRD PARTY CERTIFICATION STANDARDS 8 (2005), Ex. 13.

²¹ *Id.* at 68.

²² *Id.* at 85.

²³ *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 Sept. 11, 2006), Ex. 4 and E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 4A.; *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006) (further indicating that 75 percent of respondents would choose food products certified as protecting animal care over those that are not), Ex. 2.

higher animal welfare standards in egg production, egg manufacturers are faced with a significantly increased profit potential if they capitalize on this market niche. Without government standards regulating any animal welfare aspect of egg production, companies have an incentive to make a profit without actually meeting consumer expectations, but rather by merely making claims stating or implying that they do.

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.²⁴ In a 2004 Golan/Harris poll for the United Egg Producers, 75% of respondents stated they would choose food products certified as protecting animal care over those that are not certified, and 77% of consumers would consider switching brands to a specified product if their usual brand were not certified as protective of animal care.²⁵ However, 51% admit they have low knowledge of animal care in egg production.²⁶ The strong majority of the public that disapproves of confining hens in cages is in stark contrast to the 98% of eggs which come from birds confined in cages.²⁷ As one would expect, if the current and most common production methods with regard to eggs 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

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 Sept. 11, 2006), Ex. 4 and E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 4A.

²⁵ *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2.

²⁶ *Id.*

²⁷ *Industry History*, UNITED EGG PRODUCERS CERTIFIED, at <http://www.uepcertified.com/industryhistory.html> (last visited Sept. 8, 2006), Ex. 5.

in widespread misrepresentations, and creating the necessity of the corrective regulations called for herein. Given the widespread disapproval of caged confinement, it is logical to infer that if consumers were aware of the true conditions of these animals – that they were in fact caged – they 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.²⁸

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

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

1. Factual representations

(a) *Sauder's Eggs*²⁹ - Sauder, a United Egg Producers' Certified company, offers for sale "grade A extra large" eggs. The package does not disclose the actual production method of these eggs, but includes the phrase "Certified Animal Care."³⁰ This language implies that the hens laying these eggs are treated in a manner that is likely to be inconsistent with consumers' expectations as evidence suggests these eggs are from hens confined in cages.³¹ If so, "Certified Animal Care" would imply to consumers that these eggs were produced under standards promoting animal welfare. This misleads a consumer base comprised of 86.2% who disapprove of caging hens.³²

²⁸ *U.S. v. Articles of Drug*, 263 F.Supp. 292 at 216 (D.C.Neb. 1967).

²⁹ *Sauder's Egg Carton Image*, Ex. 14.

³⁰ *Id.*; see also *Animal Welfare*, SAUDER'S EGGS, at <http://www.saudereggs.com/animal.html> (last visited Sept. 19, 2006) Ex. 14A.

³¹ See *Caged Hens/Eggs*, SAUDER'S EGGS, at http://www.saudereggs.com/caged_hens.html (last visited Sept. 19, 2006) (praising the "advantages" of the caging system and criticizing cage-free production), Ex. 14B.

³² *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 Sept. 11, 2006), Ex 4.

(b) *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.

(c) *Farm Fresh "Animal Friendly" eggs*³⁴ – 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

(d) *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."³⁶ 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

³³ *Harris Teeter "All Natural Eggs" Egg Carton Image*, Ex. 15; see also *HT Difference Products: HT Naturals Eggs, Natural*, HARRIS TEETER, at <http://www.harristeeter.com/default.aspx?pageId=302&productid=252> (last visited Sept. 11, 2006), Ex. 15A.

³⁴ *Farm Fresh Supermarket Image of In-Store Poster, "AA Eggs,"* Ex. 16.

³⁵ FARM FRESH SUPERMARKET, at <http://www.farmfreshsupermarkets.com/> (last visited Sept. 8, 2006), Ex. 17.

³⁶ *Giant "Nature's Promise" Omega-3 Natural Brown Eggs Carton Image*, Ex. 18.

“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

2. Misleading imagery

(e) *Olivera Egg Ranch “Ranch Pak Eggs”* - The Ranch Pak egg carton depicts a chicken on a nest incubating her eggs.³⁸ 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.³⁹ Hens confined in cages never have the opportunity to nest or lie on their eggs; Olivera’s nesting imagery is misleading.

(f) *Davidson's Safest Choice “Pasteurized Shell Eggs”* - Davidson’s egg container depicts a hen sitting on a nest with eggs and a sunny field in the background.⁴⁰ This imagery suggests free roaming hens with the opportunity to nest and be outside. Yet, evidence suggests these are conventionally cage-confined animals.

(g) *Rose Acres “White Shell Eggs”* - Rose Acres, a United Egg Producers Certified company, 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

³⁷ Giant has a Cage-Free brand and an Organic brand, both of which should require cage-free hens. The Omega-3 line makes no such claim. *Giant Brands: Welcome!*, GIANT, at http://www.giantfood.com/brands/natures_promise.htm (last visited Sept. 19, 2006), Ex. 19. 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, at http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp (last visited Sept. 19, 2006), Ex. 20. 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 Sept. 19, 2006) (praising the “advantages” of the caging system and criticizing cage-free production), Ex. 14B.

³⁸ *Ranch Pak Eggs, Olivera Egg Ranch Egg Carton Image*, Ex. 21. Ranch Pak Eggs are produced by Olivera Egg Ranch; this is known because of the plant code, 1463, visible on Ex. 21, and able to be tracked through USDA’s website, at *List of Plants Operating under USDA Poultry and Egg Grading Programs*, AMS AT USDA, at http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp (last visited Sept. 11, 2006), Ex. 22.

³⁹ 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 Sept. 8, 2006), Ex. 23.

⁴⁰ *Davidson’s Safest Choice Egg Carton Image*, Ex. 24; *Why Pasteurized Shell Eggs*, DAVIDSON’S SAFEST CHOICE: NATIONAL PASTEURIZED EGGS, at http://www.safeeggs.com/why_our_egg/index.html (last visited Sept. 11, 2006), Ex. 25.

"Free-Roaming Cage-Free Eggs" depicts hens outside, and its website states it is "proud to offer Free-Roaming eggs which come from chickens that are kept in an open, cage-free hen house," no such claims are made regarding its "White Shell Eggs." Yet the imagery on these cartons also depicts hens outside in a similar free-roaming manner, able to peck at the ground and nest.⁴¹ 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.⁴²

(h) *Wilcox Farms, "Vita Eggs"* - Wilcox Farms, a United Egg Producers certified company, offers several lines of eggs including "Vita Egg" 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."⁴³ Although no production method claims are made on its packages of "Vita Egg" or on its website, the "Vita Egg" cartons also include similar imagery of hens outside in a field,⁴⁴ though this is unlikely to accurately represent the method of production employed to produce these eggs.

(i) *Safeway, "Lucerne Eggs"* - Safeway supermarket's private label eggs depict a grown hen next to a chick pecking at the ground, and barn in a field.⁴⁵ This imagery implies that hens are allowed to move freely and have contact with their chicks after the eggs have been laid

⁴¹ *Sales, ROSE ACRE FARMS*, at <http://www.roseacre.com/sales.html> (last visited Sept. 11, 2006), Ex 26.

⁴² Rose Acres apparently calls its cage confinement systems "pens." *Common Questions, (Question 9)*, ROSE ACRE FARMS, <http://www.roseacre.com/eggfaq.html> (last visited Sept. 21, 2006), 26A.

⁴³ *Egg Products: Wilcox Cage Free*, WILCOX FAMILY FARMS, at <http://www.wilcoxfarms.com/cagefree.html> (last visited Sept. 11, 2006), Ex. 27.

⁴⁴ *Egg Products: Vita Egg*, WILCOX FAMILY FARMS, at <http://www.wilcoxfarms.com/vitaegg.html> (last visited Sept. 14, 2006), Ex. 28.

⁴⁵ *Safeway "Lucerne Eggs" Carton Image*, Ex. 29.

and even hatched. Evidence suggests, however, that Lucerne's production facility uses a conventional cage confinement system.⁴⁶

C. Production method claims are especially material.

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

Search goods are those for which consumers examine product characteristics, such as price, size, and color, before purchasing. Experience goods are those for which consumers evaluate attributes after purchasing the product. For example, consumers choose particular brands of canned tuna without sampling the product first. Credence goods have attributes that consumers cannot evaluate even in use. For example, consumers cannot inspect particular produce items and determine whether they were grown organically or whether they are the result of biotechnology. Consumers cannot inspect canned tuna and determine if the tuna was caught without harming dolphins.⁴⁷

⁴⁶ The plant tracking number on a carton of Lucerne Eggs from a Washington, D.C. Safeway is 1207. *See id.* According to the USDA website, that tracking number corresponds with Ohio Fresh Eggs. *List of Plants Operating under USDA Poultry and Egg Grading Programs*, AMS AT USDA, at http://www.ams.usda.gov/plantbook/Query_Pages/plant_results.asp (last visited Sept. 11, 2006), Ex. 30. Ohio Fresh Eggs operates a battery hen facility, making it likely these eggs are from caged hens. *See FACT SHEET: Ohio Fresh Eggs Draft Permits to Install and Draft Permits to Operate for Croton Egg Farm*, OHIO DEPARTMENT OF AGRICULTURE, Nov. 5, 2003, at <http://www.ohioagriculture.gov/pubs/divs/lepp/curr/lepp-fs-ohiofreshegg-110503.stm> (last visited Sept. 11, 2006), Ex. 31 (describing Ohio Fresh's battery barns).

⁴⁷ 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. 32.

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.⁴⁸ This risk is especially high where the final products themselves are apparently similar, but one is lower quality because of its production method. Producers do not have sufficient incentive to voluntarily label their products. As a result, the market does not supply enough information to allow consumers to make purchasing choices mirroring their individual preferences.⁴⁹ 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.⁵⁰

⁴⁸ Blandford and Fulponi (1999) explain:

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

David Blandford & Linda Fulponi, *Emerging Public Concerns in Agriculture: Domestic Policies and International Trade Commitments*, 26(3) EUR. REV. OF AGRIC. ECON., at 409 (1999), Ex. 33.

⁴⁹ Golan, Kuchler & Mitchell, at 13, Ex. 32.

⁵⁰ Blandford & Fulponi (1999), Ex. 33.

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.*⁵¹

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

II. Legal Grounds

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

⁵¹ *Id.* at 13-15 (emphasis added).

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

The FDA is the primary government agency charged with the responsibility of regulating product labels.⁵² The FDA is also empowered with the ability to make administrative findings that may result in official action to enjoin false and misleading advertisements.⁵³ The FDA and FSIS share federal authority to regulate eggs.⁵⁴ Therefore, the FDA has the legal authority to regulate misleading egg labeling.

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

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

In other words, the courts in *Articles* and *Vitamin* read the FDCA to be a law benefiting consumers. The purpose of 21 U.S.C. § 321 is to prevent “people of ordinary understanding and discrimination” from being misled into making purchases they would not otherwise have made.⁵⁵

⁵² 21 U.S.C. § 1036(b) (2006); 7 U.S.C. § 6509 (2006); 7 C.F.R. §§ 3.91, 56.35(b), 57.5, and 58.50 (2006). It should be noted that the FDA has not made clear whether it construes these statutes to cover false advertising complaints by consumers regarding animal production methods; however, there are limits to how far any agency can go in ignoring its statutory mandate. See *Chevron U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 843 (1984) (establishing the arbitrary and capricious agency actions standard).

⁵³ 21 C.F.R. § 10.30(e) (2006).

⁵⁴ 65 Fed. Reg. 76092-01 (Dec. 5, 2000) (to be codified at 21 C.F.R. Pt. 16, 101, 115), Ex. 34.

⁵⁵ *Articles*, 263 F.Supp. at 216.

The FDA is not only permitted but is in fact *required* to act to regulate egg labeling. In its controlling Memorandum of Understanding with the Federal Trade Commission, the FDA confirmed its commitment to prevent deception of the public, and takes primary responsibility for preventing deceptive food labeling.⁵⁶

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

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

If a label or method of advertising fails to reveal facts in such a way, it is deemed “misbranded” and the FDA may require a labeling change.⁵⁷ In *Shalala*, the agency action being reviewed was the FDA’s decision not to require labeling of foods modified through rDNA (recombinant deoxyribonucleic acid) technology. The FDA interpreted the rDNA status of the food as not being a material change from non-genetically altered food.⁵⁸ This is because it was neither inherently risky to consumer health or safety, nor did it differ in any material way from traditional counterparts.⁵⁹ The court, without adopting FDA’s interpretation of the statute, afforded the FDA substantial deference and found its interpretation in that case reasonable.⁶⁰

⁵⁶ *Working Agreement Between FTC and FDA*, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), Ex. 8.

⁵⁷ *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166, 178 (D.D.C. 2000).

⁵⁸ *Id.*

⁵⁹ *Id.* at 178-79.

⁶⁰ *Id.*

However, the court also noted in the same discussion that the FDA does retain authority to require specific labeling to cure material fact *omission* and other forms of misbranding.⁶¹ Indeed, the court reasoned that “the determination that a product differ materially from the type of product it purports to be is a factual predicate to the requirement of labeling...[and] if there is a [material] difference, and consumers would likely want to know about the difference, then labeling is appropriate.”⁶² Thus the FDA is required to regulate labeling to correct misbranding.

The general misbranding described herein fits into the exception carved out by the court in *Shalala*. The labeling of shell eggs in the United States today fails to reveal to consumers certain material facts which substantially influence their purchase decisions. Egg labels now commonly employ misleading express and implied claims, which result in a material and significant difference between the product sold and what it purports to be. As the court in *Shalala* held, a product that “differ[s] significant[ly]...from what it purports to be” is an appropriate product for which to require special labeling.⁶³ Making purchases they otherwise would not have made is exactly what consumers are doing in the case of egg production method labeling. We are faced with a situation where over half of the consumer base has little knowledge of production methods, but 77% of consumers would consider switching brands for a product certified as protective of animal care if their current product were not, 75% would choose food products protecting animal care over those that are not,⁶⁴ and 98% of eggs are produced by hens confined in cages, which 86.2% of the public finds to be unacceptable.⁶⁵ Given this, there is a

⁶¹ *Id.* at 178, n8.

⁶² *Id.* at 179.

⁶³ *Id.*

⁶⁴ *Laying Out the Facts*TM, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2.

⁶⁵ *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 Sept. 11, 2006), Ex. 4 and

high risk of even blatant factual misrepresentations on cartons.⁶⁶ Where terms like “Free Range” or “Cage-Free” are not regulated or even defined, companies are allowed to use them with impunity, even where their use defies logical sense. For example, eggs claimed to be “Animal Friendly”⁶⁷ or “Certified Animal Care”⁶⁸ can be from birds confined in cages. This renders the labeling landscape meaningless.⁶⁹ The potential for misleading consumers by omissions or misrepresentations through an unregulated market is rampant. This issue fits squarely into the purview of the USDA under the FDCA.

B. The FSIS of the USDA recognizes the importance of standardizing production claims.

The Food Safety and Inspection Service (“FSIS”) of the USDA has recognized the importance of standardizing basic production method claims. It has published a policy regarding the evaluation and validation of basic production methods, including review of affidavits, testimonials and protocols.⁷⁰ The FSIS thus regulates terms such as “free-range” and “free-roaming,” but not for egg products. In another policy statement, FSIS has discussed the meaning of these terms and its role in “ensuring the truthfulness and accuracy in labeling,” referring to the

E-mail from Rebecca Wittman, Zogby International, to Gene Bauston, President, Farm Sanctuary (Sept. 18, 2000), Ex. 4A.

⁶⁶ See, e.g., Sales, ROSE ACRE FARMS, at <http://www.roseacre.com/sales.html> (last visited Sept. 8, 2006), Ex. 26; Egg Products, WILCOX FAMILY FARMS, at <http://www.wilcoxfarms.com/cagefree.html> (last visited Sept. 8, 2006), Ex. 27 and Egg Products: Vita Egg, WILCOX FAMILY FARMS, at <http://www.wilcoxfarms.com/vitaegg.html> (last visited Sept. 14, 2006), Ex. 28; see also Statement of Grounds, Part I, B. of this petition, *supra*, for further discussion.

⁶⁷ Farm Fresh “Animal Friendly” claim on in-store poster. *Farm Fresh Supermarket Image of In-Store Poster*, “AA Eggs,” Ex. 16.

⁶⁸ *Sauder’s Egg Carton Image*, Ex. 14.

⁶⁹ See Umbra Fisk, *Rambled Eggs*, GRIST MAGAZINE, Mar. 22, 2006, available at <http://www.grist.org/advice/ask/2006/03/22/free-range/index.html>, (last visited Sept. 11, 2006), Ex. 35; *Cage-Free Over Easy Please – Are Designer Eggs What They’re Cracked up to be?*, HEALTH MAGAZINE, March 2003, available at <http://www.pfda.com/prodServices/Healthcare/ArticleOfMonth.asp?ArticleID=261>, (last visited Sept. 11, 2006), Ex. 36; *Claim some eggs falsely labeled ‘free range.’* ABC NEWS ONLINE, July 23, 2006, available at <http://www.abc.net.au/news/newsitems/200607/s1694200.htm>, (last visited Sept. 11, 2006), Ex. 37.

⁷⁰ 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 Sept. 11, 2006), Ex. 38

requirement that “[p]roducers must demonstrate to the Agency that the poultry has been allowed access to the outside.”⁷¹

To date, however, the FDA has not exercised its authority over egg labeling, which has resulted in inconsistency between the agencies’ application of their respective and verbatim statutory provisions⁷² and the widespread use of misleading express and implied production method claims on egg labels as described above.

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

Among other provisions, the FDA has the authority pursuant to 21 U.S.C. § 321(n) (2006) to correct the common egg label misbranding described above. Although there are several FDA regulations that address the direct issue of the labeling of shell eggs, none of these

⁷¹ 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 Sept. 11, 2006), Ex. 39

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, at <http://www.fsis.usda.gov/OA/background/organic.htm> (last modified Mar. 2, 2000) (last visited Sept. 11, 2006), Ex. 40.

⁷² See the 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”), and the Poultry Products Inspection Act, at 21 U.S.C. § 453(h)(1) (2006) (prohibiting labeling of poultry products that is “false or misleading in any particular”).

regulations deal with the omission or misrepresentation of material facts regarding basic egg production method.

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

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

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.⁷³

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

Second, 21 C.F.R. § 101.9 (2006) concerns nutrition labeling of foods generally. This provision states that "nutrition information relating to food shall be provided for all products intended for human consumption" on the outer label of such product. Shell eggs are exempt from the outer package labeling requirement if the label is clearly on the inner package (presumably because consumers can open the package at the store to view the nutrition label before purchase).⁷⁴

These two provisions do nothing to address the common omission or misrepresentation of material facts or misleading imagery regarding basic egg production method described in detail

⁷³ 21 C.F.R. § 101.17(h) (2006).

⁷⁴ 21 C.F.R. § 101.9(j)(14) (2006) ("Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.")

above.⁷⁵ In fact their narrow focus on health suggests to businesses labeling eggs that there is no federal oversight or interest in the misrepresentation of material facts or misleading imagery or other representations regarding production method, and this promotes misleading labeling with impunity, in complete contradiction to the will of Congress as expressed in the FFDCA and FPLA.

D. The proposed regulations are consistent with and fulfill the FDA's mandate to correct egg label misbranding.⁷⁶

Misbranding was one of the chief evils Congress sought to stop in enactment of the FFDCA.⁷⁷ A food has been misbranded under the FFDCA⁷⁸ if “its labeling is false or misleading in any particular.”⁷⁹ A food is also misbranded if its label omits material facts.⁸⁰ There is no requirement that consumers actually are deceived, and such a product need not be deleterious to human health.⁸¹ This standard would cover misleading imagery, discussed *supra*, as well as misleading factual claims or implications.

In addition, labels may be misleading even if the relevant information is somewhere on the package along with a potentially misleading contradictory representation. For example, in *Article of Food*, the court found a package with the claim “diet thins” on the front of the

⁷⁵ Nor do any of the currently proposed agency regulations regarding egg labeling address these issues.

⁷⁶ While the discussion has focused on the FFDCA which provides sufficient authority for the FDA to act, petitioners note that sections of the FPLA, specifically 15 U.S.C. § 1453, requires an accurate statement of the identity of the food sold (“The commodity shall bear a label specifying the identity of the commodity . . .”). See 15 U.S.C. § 1453(a)(1) (2006).

⁷⁷ 62 *Cases of Jam v. U.S.*, 340 U.S. 593, 596 (1951).

⁷⁸ 21 U.S.C. §§ 301-395 (2006).

⁷⁹ *Id.* at § 343(a)(1).

⁸⁰ *Id.* at § 321(n).

⁸¹ *U.S. v. An Article of Food, etc.*, 377 F.Supp. 746, 748-749 (E.D.N.Y. 1974) (where plaintiffs asserted that the name “diet thins” on front panel of product implied crackers were lower in caloric content than other crackers, the court did not require actual deception or health risks:

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

container to impermissibly mislead consumers even where the side panel provided factually accurate clarifying information.⁸²

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.⁸³ This is a positive step for consumers, as it is currently the only example of which petitioners are aware of an egg producer in the United States providing such information on packaging. However, given *Article of Food*, the brand name "Born Free" on the front panel may be considered to be misleading to consumers who might interpret that as meaning hens are "free" or cage-free, even where the side panel's "from caged hens" provides clarifying information. Therefore, the clarifying phrase has been placed on the side panel, which would not comply with the regulations proposed herein, for the reasons set forth in *Article of Food*. Consumers need a clear and consistent set of expectations. Petitioners request regulations requiring front panel disclosure of production method to correct this otherwise confusing landscape. Regulation is required under 21 U.S.C. § 321(n).

The FDA has promulgated food labeling requirements in contexts similar to the one discussed here, apart from concerns regarding human health, for example under 21 C.F.R. §§ 101.93, 101.95 (2006) (which comprise Subpart F, entitled "Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims"). These requirements deal with statements for dietary supplements, and use of the terms "fresh," "freshly frozen," "fresh frozen," etc.⁸⁴ The FDA has also addressed food origin claims in other contexts,

⁸² *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.")

⁸³ *Born Free Egg Carton Label Image*, Ex. 41; *Born Free All Natural*, RADLO FOODS, at <http://www.radlo.com/bfAllNaturalEggs.html> (last visited Sept. 11, 2006), Ex. 41A.

⁸⁴ 21 C.F.R. §§ 101.93, 101.95 (2006).

such as limitations on producers labeling food products as artificially (synthetically) or naturally flavored,⁸⁵ and calling for comments on what constitutes a minimally processed food.⁸⁶

Quoting the Supreme Court in *United States v. 95 Barrels*, 265 U.S. 438, 442-43 (1924), the court in *An Article of Food* held that the fact that a label *could* mislead or deceive was sufficient to bring about the need for agency action.⁸⁷ The test to apply is not the test of the “reasonable consumer,” but rather of the “ignorant...unthinking and...credulous consumer.”⁸⁸ Indeed, “[e]ven a technically accurate description of a food or drug’s content may violate [the FFDCFA] if the description is misleading in other respects.”⁸⁹ In *U. S. v. An Article of Food, etc.*, 377 F.Supp. 746, 748 (E.D.N.Y. 1974), the court held that “[i]n order to sustain a seizure [of a misbranded product], [one] need not prove that all the label representations are both false and misleading. A food is misbranded if it appears that any *one* representation is false or misleading” (emphasis in original).⁹⁰

Those consumers in need for the greatest deal of protection from predatory false and misleading advertising are those who are most likely to believe what they see and read without doing their own independent research. Statutes like the FFDCFA exist for exactly this reason: they allow even the most credulous consumer to have access to honest and trustworthy information upon which they may base their decisions, and they seek to enjoin less scrupulous producers from taking advantage of gullible purchasers.⁹¹ The common omission and misrepresentation of material facts on egg labels models the situation described in *An Article of Food*.

⁸⁵ See 21 C.F.R. § 101.22.

⁸⁶ See 58 Fed. Reg. 2407 (Jan 6, 1993), Ex. 42.

⁸⁷ *An Article of Food*, 377 F.Supp. at 749.

⁸⁸ *Id.*

⁸⁹ *Id.* (citing *U.S. v. An Article of Food — Nuclomin*, 482 F.2d 581[, 584] (8th Cir. 1973) (emphasis added).

⁹⁰ Citing *U. S. v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952), cert. denied, 344 U.S. 928 (1953).

⁹¹ *Article of Food*, 377 F.Supp. at 749 (reiterating the “ignorant, the unthinking and the credulous consumer” standard) (internal quotes omitted).

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

The proposed regulations correct the general misbranding of eggs described in detail above. Labeling egg packages as “Free-Range Eggs,” “Cage-Free Eggs,” or “Eggs From Caged Hens” provides the material facts required by consumers in order to exercise effective market choice, and to obtain the product of their choice based on the most basic identification of the relevant production method used – aligning the represented method with the actual method. The proposed regulations also correct misleading express and implied claims by providing an accurate, informative, and unequivocal statement as to basic production method, alleviating the need to engage in costly, time-consuming, and repetitive ad hoc enforcement actions addressing the numerous examples of misrepresentations present in the market today. The public also supports government regulation of egg labeling.⁹²

F. Corrective regulation in the European Union 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.⁹³ 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.⁹⁴ European Commission Regulation (EC) No 1651/2001, 2001 O.J. (L 220) 5

⁹² *Laying Out the Facts*™, GOLIN/HARRIS INTERNATIONAL, 2004, at <http://www.meatami.com/Content/PressCenter/AnimalCarePresentations/Head.pdf> (last visited Sept. 18, 2006), Ex. 2.

⁹³ *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 Sept. 11, 2006), Ex. 44; *See also Report on Welfare Labeling*, FARM ANIMAL WELFARE COUNCIL (“FAWC”), Jun., 2006, Ex. 45.

⁹⁴ *International – Egg Labeling*, ROYAL SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS (“RSPCA”), at <http://www.rspca.org.uk/servlet/Satellite?pagename=RSPCA/RSPCARedirect&pg=InternationalCampaigns&marker=1&articleId=999516092840> (last visited Sept. 11, 2006), Ex. 46.

(Ex. 43) cites and adopts Council Directive 1999/74/EC of July 19, 1999, and requires standardization of terms regarding cages. Article 1(7) of the EC regulation requires certain standardized labeling on how the laying hens were kept:

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

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

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

This simple and clear system is effective for a jurisdiction as diverse in language, culture, and industry as the EU's 25 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'.

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 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.⁹⁵

Only egg producers who report using cage-free or free-range systems, which amount to only 2% 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 eggs⁹⁶ are packed under USDA's voluntary egg grading service, a third-party assurance scheme.⁹⁷ The USDA states the service costs are insignificant: “This assurance is available at little or no additional cost to consumers – eggs graded by USDA (eggs identified with the USDA grade shield) cost essentially the same as eggs without the USDA grade shield.”⁹⁸ 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.

Two animal welfare certification schemes for cage-free eggs already exist in the United States: Humane Farm Animal Care and Free Farmed.⁹⁹ Egg producers complying with these certifications pay a \$400 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,

⁹⁵ 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. 32.

⁹⁶ “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), Ex. 47; “Table eggs” are also synonymous with “market eggs.” See Don Bell, *Table Egg Layer Flock Projections and Economic Commentary* (2003), available at <http://animalscience.ucdavis.edu/Avian/uepeconmemo203.htm> (last visited Sept. 8, 2006), Ex. 48.

⁹⁷ *Egg Carton Labeling*, USDA (2006), at <http://www.ams.usda.gov/poultry/consumer/labelingexplained.htm> (last visited Sept. 11, 2006), Ex. 49.

⁹⁸ *Id.*

⁹⁹ *Certified Humane*, HUMANE FARM ANIMAL CARE, available at <http://www.certifiedhumane.org/> (last visited Sept. 11, 2006), Ex. 50, and *Farm Animals: What does 'Free Farmed' Mean?*, AMERICAN HUMANE, available at http://www.americanhumane.org/site/PageServer?pagename=pa_farm_animals_ff_mean (last visited Sept. 11, 2006), Ex. 51.

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.¹⁰⁰ A typical U.S. egg operation houses on the order of 100,000 hens, producing 72,000 cases of eggs per year.¹⁰¹ Thus the HFAC, AHA, and RSPCA certifications would cost a typical producer \$0.04-0.07 for royalties and \$0.006-0.05 for inspections per case of cage-free eggs. Total certification costs would be \$0.05-0.12 per case. Cage-free eggs cost between \$14.11 and \$17.60 per case to produce (12 to 40 percent more than battery egg production, which averages \$12.60 per case to produce).¹⁰² 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.¹⁰³ 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 -0.057.¹⁰⁴ Thus, a 0.3 to 0.9-

¹⁰⁰ *Chickens and Eggs 2004 Summary*, USDA (2005), available at <http://usda.mannlib.cornell.edu/reports/nassr/poultry/pec-bbl/lyegan05.pdf> (last visited Sept. 8, 2006), Ex. 52.

¹⁰¹ *Id.*

¹⁰² Don Bell, *Table Egg Layer Flock Projections and Economic Commentary* (2003), available at <http://animalscience.ucdavis.edu/Avian/uepeconmemo203.htm> (last visited Sept. 8, 2006), Ex. 48; A. ELSON, *The laying hen: systems of egg production*, WELFARE OF THE LAYING HEN. (Perry GC ed., CABI Publishing 2004), Ex. 53.

¹⁰³ Richard Bennett & D. Larson, *Contingent valuation of the perceived benefits of farm animal welfare legislation: An explanatory survey*, 47(2) JOURNAL OF AGRICULTURAL ECONOMICS 224 at 229-231 (1996), Ex. 54; Richard Bennett, *Farm animal welfare and food policy*, 22 FOOD POLICY 281, 283-284 (1997), Ex. 55; J.C. Rolfe, *Ethical rules and the demand for free range eggs*, 29 JOURNAL OF AGRICULTURAL ECONOMICS 85 at 196-199 (2003), Ex. 56; Bennett, R. M. and Blaney, R.J.P. *Estimating the benefits of farm animal welfare legislation using the contingent valuation method*, JOURNAL OF AGRICULTURAL ECONOMICS 29, 85-98 (2003), Ex. 57.

¹⁰⁴ Kuo Huang & Biing-Hwan Lin, *Estimation of Food Demand and Nutrient Elasticities from*

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,¹⁰⁵ assuming cage-free egg consumers have similar egg consumption habits as the average egg consumer.¹⁰⁶ As mandatory corrective disclosure of basic production method would not affect production costs for 98 percent of producers, and would increase production costs for 2 percent of producers by at most 0.9 percent, and as these costs could be passed onto consumers with no loss in revenue, certification should have no significant effect on the productivity of wage earners, businesses, or government; on the supplies of important materials, products, or services; on employment; or on energy supply or demand.

Environmental Impact

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

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

Household Survey Data (TB-1887), USDA ECONOMIC RESEARCH SERVICE, 11, 20-30 (September 2000), Ex. 58.

¹⁰⁵ *Table 24 – Eggs: Per capita consumption of shell eggs and egg products*, ECONOMIC RESEARCH SERVICE, USDA, at <http://usda.mannlib.cornell.edu/usda/ers/89007/table0024.xls> (last visited Sept. 21, 2006), Ex. 59.

¹⁰⁶ *Chickens and Eggs 2004 Summary*, NATIONAL AGRICULTURAL STATISTICS SERVICE, USDA (2005), available at <http://usda.mannlib.cornell.edu/usda/nass/PoulProdVa//2000s/2005/PoulProdVa-04-29-2005.pdf> (last visited Sept. 12, 2006), Ex. 52.

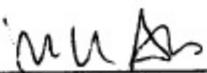
commonly egg labels employ misleading express and implied claim which result in a material and significant difference between the product sold and what it purports to be, all in violation of federal law. The proposed regulations would correct this, effectuate the goals of the statutes discussed herein, and in light of the increasing and prevalent nature of the misrepresentations, best fulfill the FDA's mandate to prohibit the misbranding of food products.

Certification

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



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