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## How Would You Like Your Eggs: A History of U.S. Egg Regulation and Current Controversies

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How Would You Like Your Eggs: A History of U.S. Egg  
Regulation and Current Controversies

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This paper is submitted in satisfaction of the course requirement.

## Abstract

Government regulatory efforts concerning eggs are in the news due to a serious salmonella outbreak during the summer of 2010. Given the widespread concern this outbreak raised, there are already anecdotal reports of a negative impact on egg demand. This paper attempts to look at one aspect of eggs as a food commodity: the legal regime that regulates eggs as an item in the food supply. First, it will attempt an initial historical exploration of egg regulation in the 20th century. A web of different legal authorities sometimes seem to run overlapping circles around each other. The paper will address recent significant changes in egg safety regulation, driven mostly by the Food and Drug Administration and legislative changes to the overall food safety system. It will close by reviewing the recent *salmonella* enteritidis scare and possible future changes in the egg regulation system.

## I. Introduction and Background on Eggs as Food

Eggs have been a major part of human food consumption for thousands of years and across varied cultures around the world. Their use stretches across the great cultures of the East and West, from the eggs of hens in ancient Rome and the European continent to various fowl on the Indian subcontinent and in China.<sup>1</sup> In Western cooking, while certain reptiles such as the turtle provide sought-after eggs, most consumption is of poultry eggs: chickens and other fowl.<sup>2</sup> Today, worldwide consumption of poultry shell eggs continues to steadily increase as large developing nations, such as the Brazil-Russia-India-China (“BRIC”) bloc, raise their standard of living and consume more protein.<sup>3</sup> As consumption increases, producers are following, with egg production increasing in the past decade as well, particularly amongst larger industrial entities looking to capitalize on the “livestock revolution” brought about by economic advancement.<sup>4</sup> Of interest for our purposes, however, is that fact that high income per capita countries like the United States have seen slower or even declining growth in egg consumption, especially as compared to the rapid growth of relatively lower income nations.<sup>5</sup> It seems probable that

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<sup>1</sup> ENCYCLOPEDIA OF FOOD AND CULTURE 558 (Solomon H. Katz, ed., 2003).

<sup>2</sup> *See, e.g.*, CAMBRIDGE WORLD HISTORY OF FOOD 499 (Kenneth F. Kiple & Kriemhild Conee Ornelas, eds., 2000) (canvassing different types of eggs eaten in Western cultures and noting, for example, that “quail eggs, as hard-cooked, shelf-stable, packaged products, are now featured on many gourmet food counters in the United States).

<sup>3</sup> Food and Agriculture Organization Poultry in the 21st Century Conference: Avian Influenza and Beyond, Martin Upton, *Scale and structures of the poultry sector and factors inducing change: intercountry differences and expected trends*, at 1 (2007), available at <http://www.fao.org/AG/againfo/home/events/bangkok2007/en/background.html> (industry analysis paper prepared for the United Nations food security organization in conjunction with an international conference on poultry and egg consumption).

<sup>4</sup> *Id.* at 2.

<sup>5</sup> *Id.* at 3.

other influences, besides merely economic trends, have spurred this de-emphasis away from eggs as a food product in wealthier nations.<sup>6</sup>

In the United States, egg consumption has declined quite significantly since the halcyon first half of the twentieth century, when Americans consumed, for example, over 375 eggs per person on an annual basis in 1950.<sup>7</sup> Such consumption is measured not just as shell egg consumption but also as consumption of eggs in other prepared food products.<sup>8</sup> Throughout this paper, I will attempt to focus its discussion on both modes of consumption. In recent years, American per capita egg consumption has consistently been over 100 eggs less than the 1950s peak.<sup>9</sup> While a comprehensive explanation of this decline is beyond the scope of this paper, two contributing factors can be suggested. One concerns continuing controversy and attention to the health effects of high egg consumption. Eggs contain a high degree of dietary cholesterol and important scientific research has been conducted into possible increased risk of cardiovascular disease from their consumption.<sup>10</sup> On the other hand, the evidence is far from conclusive as to such a correlation, and other studies in recent decades have questioned advice that urges patients

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<sup>6</sup> *Id.* (“The decline in egg consumption in high-income countries suggests that the effect of income growth may have reached a peak and demand may be more strongly influenced by changes in consumer taste.”).

<sup>7</sup> U.S. Department of Agriculture Economic Research Service, *Food Availability Data Set: Spreadsheets: Eggs*, (Feb. 1, 2010), <http://www.ers.usda.gov/Data/FoodConsumption/FoodAvailSpreadsheets.htm#eggs>.

<sup>8</sup> USDA Economic Research Service, *Food Availability Data Set: Documentation: Estimating supply and disappearance of major foods*, (Mar. 29, 2010), <http://www.ers.usda.gov/Data/FoodConsumption/FoodAvailDoc.htm>.

<sup>9</sup> See *supra*, note 7 (showing that consumption steadily fell from the 1950s through the 1990s but has remained roughly stable just below 250 eggs per person per year since then).

<sup>10</sup> See, e.g., Luc Djoussé & John M. Gaziano, *Egg Consumption and Risk of Heart Failure in the Physicians’ Health Study*, 117 CIRCULATION 512 (2008) (concluding that infrequent egg use likely only modestly increases mortality but that there was a stronger correlation between egg consumption and mortality amongst diabetics).

to refrain from eating eggs.<sup>11</sup> Nonetheless, the controversy seems quite probably to have contributed to some of the declining American egg consumption patterns, especially given that egg prices have also generally declined on an inflation-adjusted basis over the past fifty years.<sup>12</sup> However, while discussion of egg consumption and health impacts are a real issue, the federal government's regulatory role is limited to its incorporation of healthy eating advice into the Dietary Guidelines for Americans<sup>13</sup> and using those guidelines to regulate certain food consumption, such as public school lunch programs.<sup>14</sup>

Thus, this paper will put the eggs and chronic disease issue to the side and focus on a second possible impact on the consumption of eggs: federal and state regulatory efforts aimed at the safety and quality of shell egg and other egg products. Government regulatory efforts concerning eggs are in the news due to a serious salmonella outbreak during the summer of 2010.<sup>15</sup> Given the widespread concern this outbreak raised, there

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<sup>11</sup> See, e.g., Frank B. Hu, et al., *A Prospective Study of Egg Consumption and Risk of Cardiovascular Disease in Men and Women*, 281 JOURNAL AM. MED. ASSOC. 1387 (1999) (suggesting that consuming up to one egg per day is unlikely to substantially increase the risk of cardiovascular disease amongst healthy individuals).

<sup>12</sup> See Deborah J. Brown and Lee F. Schrader, *Cholesterol Information and Shell Egg Consumption*, 72 AM. J. AGRICULTURAL ECON. 548 (1990) (using statistical analysis to argue that heavily publicized cholesterol information concerning eggs restrained demand more than would be expected for a product whose price is declining).

<sup>13</sup> See USDA CENTER FOR NUTRITION POLICY AND PROMOTION, DIETARY GUIDELINES FOR AMERICANS 12, 2010 (2011) (avoiding direct statements urging reduction of egg consumption but recommending limitation of dietary cholesterol to 300 milligrams per day); 7 U.S.C. § 5301 et seq. (2006) (mandating release of updated government dietary guidelines every five years).

<sup>14</sup> 42 U.S.C. § 1758(f) (2006) (requiring schools that receive school lunch funding to manage programs consistent with the Dietary Guidelines).

<sup>15</sup> See, e.g., U.S. Centers for Disease Control and Prevention, *Investigation Update: Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs* (Dec. 2, 2010), <http://www.cdc.gov/salmonella/enteritidis/> (final investigation details); William Neuman, *Egg Recall Expanded after Salmonella Outbreak*, N.Y. TIMES, Aug. 19, 2010 at B1.

are already anecdotal reports of a negative impact on egg demand.<sup>16</sup> This paper attempts to look at one aspect of eggs as a food commodity: the legal regime that regulates eggs as an item in the food supply. First, it will attempt an initial historical exploration of egg regulation in the 20th century. A web of different legal authorities sometimes seem to run overlapping circles around each other. The paper will address recent significant changes in egg safety regulation, driven mostly by the Food and Drug Administration (“FDA”) and legislative changes to the overall food safety system. It will close by reviewing the recent *salmonella* enteritidis (“salmonella”) scare and possible future changes in the egg regulation system.

## **II. Early Food Regulation: the Pure Food and Drug Act**

The modern age of gradually federalized food safety and quality regulation substantially began with the Pure Food and Drug Act of 1906 (“1906 Act”).<sup>17</sup> This also marks the beginning of egg regulation because of the 1906 Act’s expansive “food” definition. While somewhat circular linguistically on closer inspection, “food” consists of “all articles used for food...by man or other animals, whether simple, mixed, or compound,” clearly embracing eggs.<sup>18</sup> The 1906 Act introduced the “adulteration” and “misbranding” concepts into federal law as the fundamental categorization used to separate safe food whose quality met those of buyer’s expectations from unsafe and

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<sup>16</sup> See Molly Peterson, *Egg Recall May Be Linked to Salmonella-Bacteria Illness in 14 U.S. States*, BLOOMBERG (Aug. 19, 2010), <http://www.bloomberg.com/news/2010-08-19/egg-recall-expands-as-illness-reported-in-10-states-salmonella-suspected.html> (interviewing economist who predicted “consumers holding off buying eggs because of health concerns will dampen demand and lower prices, more than any supply disruption”).

<sup>17</sup> Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>18</sup> *Id.* at 769.

potentially fraudulent food that did not.<sup>19</sup> These concepts remain as basic elements of the federal food regulatory system through today and were even integrated into a more specific egg and egg product regime established later in the 20th century. The historical record is unclear as to whether eggs were a topic of legislative conversation at the time of the 1906 Act's enactment but attention does seem to have been focused elsewhere on products like fresh meat.<sup>20</sup> Interestingly, an early treatise on the new Act does not even contain a line in its index for eggs despite entries for such products as Baltimore oysters and cranberries and other seemingly less ubiquitous or important food products as compared to eggs.<sup>21</sup> The federal government now regulated eggs but they seem to have mostly been brought along for the ride.

### **III. Twentieth Century Regulation through 1970: State Regimes**

At the time of the 1906 Act's passage, any existing government regulation of food products would have occurred through state and local regulations. Such regulatory activity had existed in certain places and for selected products since the early colonial times and in a more widespread form since the mid nineteenth century.<sup>22</sup> Such regulation serves as the default legal regime, in the absence of federal law on the point and deriving from the American state's inherent police power over health and welfare issues. More

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<sup>19</sup> See *id.* at 769, § 7, and 770, § 8.

<sup>20</sup> See, e.g., Ilyse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, 75 AM. J. PUB. HEALTH 18 (1985) (discussing changes in food industry and certain publicized scandals but not noting any special concerns about eggs); ARTHUR P. GREELEY, *THE FOOD AND DRUGS ACT, JUNE 30, 1906: A STUDY WITH TEXT OF THE ACT, ANNOTATED, THE RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE ACT, FOOD INSPECTION, DECISIONS, AND OFFICIAL FOOD STANDARDS* 164 (1907).

<sup>21</sup> ARTHUR P. GREELEY, *THE FOOD AND DRUGS ACT, JUNE 30, 1906: A STUDY WITH TEXT OF THE ACT, ANNOTATED, THE RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE ACT, FOOD INSPECTION, DECISIONS, AND OFFICIAL FOOD STANDARDS* 164 (1907).

<sup>22</sup> See Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984).



archival research is necessary to more fully understand the exact state regulatory picture specifically regarding eggs at the turn of the century and during the early years of general federal adulteration and misbranding regulation. But at least one recent government document suggests that the first three states, South Dakota, Illinois, and Iowa, began regulating eggs as a specific product in 1919.<sup>23</sup>

We also know the nature of state regulation by the 1960s so we can supplement secondary evidence by inferring its development into more specialized regimes over the course of the 20th century. A 1970 House report references a U.S. Department of Agriculture (“USDA”) survey of state egg regulation regimes, conducted in the late 1960s.<sup>24</sup> By 1968, all states (assuming that all states had returned the USDA survey) had a shell egg regulatory regime in place.

“Shell egg” is a term of art in egg regulation, often defined by what it is not. It is not the other major consumed egg substance subject to regulation, an “egg product.” Federal law defines “egg products” as “dried, frozen, or liquid eggs.”<sup>25</sup> We should make a brief digression on the nature of “egg products.” For most consumers, egg products bring to mind such products as egg substitutes or eggnog or the like. Many of these consumer products, however, are exempted from direct, specific egg regulation through exemption authority given to the USDA in federal law.<sup>26</sup> Examples include imitation

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<sup>23</sup> USDA, AGRICULTURAL MARKETING SERVICE, AH-75, EGG-GRADING MANUAL 51 (2000) [hereinafter USDA EGG-GRADING MANUAL].

<sup>24</sup> See H.R. REP. NO. 91-1670, at 8 (1970) [hereinafter EGG PRODUCTS ACT REPORT].

<sup>25</sup> See 21 U.S.C. § 1033(f).

<sup>26</sup> See *id.* (creating exception authority for products “which contain eggs only in a small proportion” and for products which generally have not been “in the judgment of the Secretary, considered by consumers as products of the egg food industry.”)

eggs, eggnog mix, and sandwiches containing eggs.<sup>27</sup> The reasoning behind such exemptions seems to be that such consumer products will already have had their egg product component ingredients inspected. Thus, egg product in egg regulatory parlance refers only infrequently to consumer products and more regularly to bulk products used in institutional and commercial settings such restaurants, hospitals, bakeries, and food manufacturers.<sup>28</sup> Shell eggs are never explicitly defined, at least in federal statutes and regulations, most likely because their meaning is assumed to be self-evident. Indeed, one has difficulty describing a shell egg without either using the word “egg” in the definition or resorting to elaborate descriptive attempts around using the word “egg.” For the purposes of federal and state regulation, no case or legislative debate ever seems to have questioned the self-evident meaning of “shell egg,” those whole eggs laid by poultry and sold in commerce in their whole form. The quality and condition of shell eggs, on the other hand, has been a source of dispute, to be discussed later.

Returning to a discussion of state regulation in the first half of the twentieth century, we know that states regulated shell eggs as a specific food product. However, the nature of this regulation differed from state to state. In some states, regulation was limited to grade and labeling requirements for retail egg sales. Grading is a procedure where a general standard is applied to the quality of specific eggs being inspected.<sup>29</sup> On

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<sup>27</sup> See 9 C.F.R. 590.5 (2010).

<sup>28</sup> USDA, Food Safety and Inspection Service, *Fact Sheet: Shell Eggs from Farm to Table* (April 20, 2011), [http://www.fsis.usda.gov/factsheets/focus\\_on\\_shell\\_eggs/index.asp#11](http://www.fsis.usda.gov/factsheets/focus_on_shell_eggs/index.asp#11) [hereinafter *Shell Eggs from Farm to Table*].

<sup>29</sup> See USDA, AGRICULTURAL MARKETING SERVICE, AMS 56, UNITED STATES STANDARDS, GRADES, AND WEIGHT CLASSES FOR SHELL EGGS 2 (2000) (“Consumers can purchase officially graded product with the confidence of receiving quality in accordance with the official identification.”).

its face, it does no more than provide a standardized reference point to consumers in order to make more informed buying decisions. For this reason, labeling requirements often complement grading laws; grading not shared with the public and used only for regulatory purposes tends to be seen as both less useful in ensuring the integrity of the product market and also possibly more likely to invite abuse. When a grade is labeled on a particular product, the knowledgeable consumer, familiar with the general standard a grade represents, can match it against the actual egg they are holding in their hands.

This information-enhancing regulation was carried out in all states by the time of the 1968 survey.<sup>30</sup> But a significant number of states limited their regulation to grading and labeling.<sup>31</sup> Those that went beyond this basic regulation varied in the extent of additional regulation. A large majority of states regulated and restricted the sale of eggs categorized by the industry as “rejected” for various reasons, such as functional value, whether the egg is edible, or whether it is cracked or leaking.<sup>32</sup> Such problems can indicate safety issues, as will be apparent when exploring the recent salmonella concerns later in the paper. A smaller number of states, about half, went further and restricted the sale of dirty eggs or of un-candled eggs.<sup>33</sup> An even smaller number of states restricted the sale of another less-than-perfect type of egg, “checked” eggs. Checked eggs are eggs with cracks that do not permeate the membrane lining and thus their contents are intact.<sup>34</sup> Their permissibility during certain eras could be at least one of the factors leading to that

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<sup>30</sup> See EGG PRODUCTS ACT REPORT, *supra*, note 24 at 8.

<sup>31</sup> *Id.* at 8-9.

<sup>32</sup> *Id.* at 8.

<sup>33</sup> Candling is a process, largely automated today, where light is used to illuminate both “interior defects” and difficult-to-spot shell cracks. See *Shell Eggs from Farm to Table*, *supra*, note 28.

<sup>34</sup> EGG PRODUCTS ACT REPORT, *supra*, note 24, at 8; see 9 C.F.R. 590.5 (2010).

familiar supermarket occurrence, the dutiful shopper scrupulously checking their eggs for cracks (other obvious factors include retail store handling of the egg and transport conditions).

At the time of the congressional report, most states regulated egg products, as generally defined above, only through their general food safety and quality regulations than those states that had specific regulations focused on egg products. In a handful of states, even general food regulation did not reach egg products.<sup>35</sup> In many states, regulation of shell eggs or egg products, if any, often did not reach as far as trade in these eggs or products between manufacturers or producers and wholesale or institutional buyers, such as bakeries or restaurants.

The system of state regulation prior to federal consolidation of control later in the twentieth century suggests one point deserving of further research. The division of food safety regulation between the FDA and USDA, particularly for perishable items such as eggs and meat, has been roundly criticized as inefficient and possibly complicit in allowing lax regulation on certain safety animal welfare issues.<sup>36</sup> But we know that the division of responsibilities is at least reflected in a division of regulatory regimes as far back as the state regulation earlier in the twentieth century. Perhaps these regimes were enforced by the same state agency but perhaps not. Thus, the only conclusion to be drawn here, at least, would be to urge caution before claiming that institutional arrangements are mostly about turf protection and too-cozy industry relations. Historical

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<sup>35</sup> EGG PRODUCTS ACT REPORT, at 9.

<sup>36</sup> *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-487T, HUMANE METHODS OF SLAUGHTER ACT: WEAKNESSES IN USDA ENFORCEMENT (2010); Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and The Case for a Single Food-Safety Agency*, 59 FOOD DRUG COSM. L.J. 441 (2004).

practice also often plays a part and may play a part in the structure of egg regulation, given its origins in state-level regimes.

#### **IV. Egg Regulation Through 1970: USDA Grading and Standards of Quality**

The Egg Products Act Report discusses another aspect of state egg regulation that allows us to begin transitioning toward the federal role in egg regulation. It notes that a number of important egg consumption states have grade and quality standards that differ from a consistent set of standards that most states follow.<sup>37</sup> The consistent set of standards many states followed was not a mere coincidental convergence. First, a decade after the passage of the Pure Food and Drug Act, Congress passed the Farm Products Inspection Act of 1917, an initial authorization to begin grading eggs and allowing producers to voluntarily participate in grading inspection of the product.<sup>38</sup> A 1946 federal statute replaced the 1917 law with the Agricultural Marketing Act and gave authority to the Secretary of Agriculture to carry out certain agricultural market-enhancement activities, including quality standards.<sup>39</sup> Specifically, this was accomplished through a broad delegation to the Secretary of authority to “develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.”<sup>40</sup> The standards remained voluntary both as to whether states would follow them and also as to whether producers would participate in the USDA’s grade and quality inspection program. A series of different bureaus, offices, services, and administrations have been responsible for egg grading and inspection since 1917 and the

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<sup>37</sup> EGG PRODUCTS ACT REPORT, *supra*, note 24, at 9.

<sup>38</sup> 7 U.S.C. § 492 (repealed 1955); USDA EGG-GRADING MANUAL, *supra* note 23, at 51.

<sup>39</sup> 7 U.S.C. 1621 et seq. (2006).

<sup>40</sup> 7 U.S.C. 1622(c) (2006).

serpentine transfer of authority amongst them would be a worthy archival project in its own right. Generally, though, the modern administration of the egg grade inspection program resided, and continues to reside, in the USDA's Agricultural Marketing Service, continuously in charge of the program since 1972.<sup>41</sup> The AMS also is responsible for producing and disseminating market information, something it does each week through the egg market news reports.<sup>42</sup>

At least one court has heard a challenge arguing that the AMS grading and inspection scheme should be considered to preempt state and local regulation. But the nature of the argument sheds light both on why the argument was not successful and also on the structure of the federal-state egg regulation regime. In *L&L Started Pullets, Inc. v. Gourdine*,<sup>43</sup> a group of egg producers argued that federal regulation and intervention into the market through rulemakings and inspections affecting *producers* should preempt New York State and New York City regulation of consumer egg products on *retail* store shelves. The court distinguished the two regulatory interventions as not overlapping, especially given that federal grading inspections remain voluntary. It thus rejected the preemption claim:

The inspection and labeling of consumer bought eggs falls within the historic police powers of the state. Therefore, to prevail plaintiffs must show either a clear and manifest congressional intent to invalidate all state and city laws within this field of regulation, or that the federal scheme of

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<sup>41</sup> See National Archives and Records Administration, *Records of the Agricultural Marketing Service*, (last accessed Apr. 25, 2011), <http://www.archives.gov/research/guide-fed-records/groups/136.html>.

<sup>42</sup> See 58 USDA AMS EGG MARKET NEWS REP. 35.

<sup>43</sup> 592 F. Supp. 367 (D.C.N.Y. 1984).

regulation actually conflicts with the state and city scheme. Plaintiffs have failed to establish either of these bases for preemption.<sup>44</sup>

Such thinking informs the structure of the egg regulation system to this day, with the federal government restricting its regulatory efforts in large part to stages of the “farm-to-table” process prior to retail sale and the state and local agriculture or health agencies focusing on retail, institutional, and restaurant regulation and monitoring with limited interventions into the production process occurring in some select states.<sup>45</sup>

## **V. Eggs and the Federal Food, Drug, and Cosmetics Act**

The next step in our march through the history and current structure of U.S. egg regulation moves us away from interaction between state and federal regulators and back to the FDA’s broad food and drug safety statutory authority, first granted in the Pure Food and Drug Act. This authority was substantially reaffirmed and strengthened in the Federal Food, Drug, and Cosmetics Act (“FDCA”) of 1938.<sup>46</sup> Early court cases affirmed FDA’s broad authority to seize “adulterated” goods.<sup>47</sup> These early cases established principles that continue to define the FDA’s authority under the FDCA (even though the cases themselves interpreted the Pure Food and Drug Act). These include that the “adulteration” provision contains no intent requirement so adulterated food, even if it is no longer intended for human or animal consumption, remains adulterated under the FDCA. Even more important for our purposes, *Hipolite Egg* saw the Court expansively

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<sup>44</sup> *Id.* at 372.

<sup>45</sup> For additional cases upholding the state’s ability to regulate consumer egg sales under its police powers, see *Rose Acre Farms, Inc. v. Madigan*, 956 F.2d 670 (7th Cir. 1992); *Ex parte Foley*, 158 P. 1034 (Cal. 1916).

<sup>46</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938).

<sup>47</sup> See *United States v. Thirteen Crates of Frozen Eggs*, 208 F. 950 (D.C.N.Y. 1913); *Hipolite Egg Co. v. United States*, 220 U.S. 45 (1911).

interpret the nature of interstate commerce, a necessary condition for meaningful FDA authority over the eggs. There, the Court ruled that adulterated eggs containing an external chemical and delivered to a bakery for use there in production could still be seized by the FDA even though they were no longer actually moving in interstate commerce and would not be sold whole to consumers.<sup>48</sup> Of course, this decision occurred during the Court's *Lochner* Era and it is certain that a modern Court, with a much more expansive Commerce Clause jurisprudence, would uphold a robust FDCA. Regardless, this issue seems settled in the case of eggs, as research has not turned up any modern cases challenging FDA egg regulation on arguments as to the scope of the FDCA.

What has the FDA done with its general authority under the FDCA to regulate food, including eggs? Until recently, it chose not to engage in specific rule-making and a regime of specific, detailed regulatory proscriptions and prescriptions. Instead, it seems to have pursued a strategy with two pillars: first, enforcement through spot inspections on a periodic basis or as a result of attention (from consumers or other sources) paid to particular instances of adulteration. A former USDA official analogized this enforcement method to highway speed patrols: "It's only illegal when you get caught."<sup>49</sup> A second principle of FDA regulation was to avoid using its broad authority in such a way as to intrude on the regulatory spheres of other federal agencies, primarily components of the USDA, involved in egg regulation and of the state and local authorities. This reticence

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<sup>48</sup> See *Hipolite Egg*, *supra*, note 47, at 58.

<sup>49</sup> Timothy W. Martin & Alicia Mundy, *FDA's New Rules Signal Closer Look at Egg Farms*, WALL STREET JOURNAL, Aug. 24, 2010, at A4. ("If a company was taking shortcuts, it would only become apparent if there was illness involved or if there was an audit performed by the FDA.").



moderated somewhat in the past fifteen years or so as FDA has take the role of lead and coordinating agency in responding to *salmonella* disease control.

Thus, we can summarize egg regulation through 1970. At the state-level, many health departments regulated retail sales of consumer egg products and shell eggs, including spot checks for both quality and safety issues, through either general health regulation or through specific language relating to eggs. Many states, generally through their agriculture departments, administered mandatory or voluntary grading and quality inspection programs at the production stage. In many states, these inspection regimes were pegged to the USDA's national grade and quality standards (and many egg producers relied on the USDA's continuous inspection service although the service, if not the standards depending on the location, remained a voluntary one). In certain key states, however, the state-level grading and quality standards differed in material ways from the USDA national standards. All the while, the FDA maintained general regulatory authority under first the Pure Food and Drug Act and then the FDCA to inspect producers, transporters, and retailers upon suspicion of adulteration or mislabeling of all egg-derived products, both those labeled as "egg products" and as "shell eggs." The FDA exercised this authority from time-to-time in the case of producers and transporters but not at all in the case of retailers (in keeping with its policy of refraining from retail food regulation).<sup>50</sup>

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<sup>50</sup> For an overview of egg regulation prior to 1970, *see generally* EGG PRODUCTS INSPECTION ACT REPORT, *supra*, note 24.

## VI. The Egg Products Inspection Act of 1970

1970 marks a line in the sand because it is during this legislative session that Congress passed the Egg Products Inspection Act (“EPIA”).<sup>51</sup> EPIA marks the most extensive federal legislative attention ever paid to eggs as a specific regulatory target. EPIA also forms a triumvirate with the FDA Egg Safety Rule<sup>52</sup> and USDA regulations setting up voluntary grading and inspection under the authority of the Agricultural Marketing Act of 1946. These three regulatory actions, one statutory and the other two administrative rulemakings, are the three most detailed federal efforts dealing with eggs.

A common perception (misperception?) concerning the nature of federal egg regulation suggests that the FDA controls shell egg regulation and the USDA controls egg products regulation.<sup>53</sup> While to a great extent functionally true, this statement also stems from ambiguities present in EPIA and from historical practice since its enactment. After exploring the Act, a reconceptualization of the legal architecture for federal egg regulation will be proposed.

EPIA acknowledges the danger of salmonella and has support in a preventive theory of continuous inspection rather than relying solely on adulteration or misbranding seizures under general FDCA authority.<sup>54</sup> In USDA testimony concerning the bill, administration officials spoke in strong support of enhanced protections for both eggs *and*

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<sup>51</sup> Pub. L. No. 91-597, 84 Stat. 1620 (1970).

<sup>52</sup> Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33030 (July 9, 2009) (codified at 21 C.F.R. pts. 16 and 118).

<sup>53</sup> See, e.g., PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 35-36 (3d ed. 2008); DONNA U. VOGT, CONG. RESEARCH SERV., RS20338, FEDERAL REGULATORY STRUCTURE FOR EGG SAFETY: A FACT SHEET (1999).

<sup>54</sup> See EGG PRODUCT INSPECTION ACT REPORT, *supra*, note 24 (“Lack of legislation for effective regulation of handling and disposition of poor quality eggs and for inspection of egg products to prevent adulteration or misbranding is injurious to the public welfare.”).

egg products.<sup>55</sup> Yet the federal government has never mandated continuous inspection of shell eggs. Bifurcation of both inspection methods and of regulatory responsibilities began in earnest with the EPIA. Deeper archival research is needed to attempt a reconstruction of what led to this bifurcation, especially given that EPIA and subsequent historical practice have always left enough ambiguity to suggest the possibility of a uniform regulatory approach.

EPIA's approach becomes clear as soon as one moves past committee testimony and the broad brush strokes of the congressional statement of findings.<sup>56</sup> In the congressional declaration of policy<sup>57</sup>, each of the major principles in EPIA is stated: 1) Inspection of certain egg *products*; 2) Mandatory standards concerning keeping certain undesirable types of shell eggs out of the food supply; 3) Uniformity of quality standards for shell eggs; and 4) Relatively broad grants of regulatory authority to prevent "adulteration" or "misbranding" of both eggs and egg products.

A few key points emerge from the definitions section of the statute.<sup>58</sup> "Adulteration" and "misbranding" are defined almost identically with their respective definitions in FDCA.<sup>59</sup> These similar definitions suggest another point of departure for future investigation: since USDA has substantially implemented the EPIA, have FDA and

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<sup>55</sup> *Id.* at 1 ("Thus, we must make every effort to assure that eggs *and* egg products, that is, liquid, frozen, or dried eggs, are safe and wholesome for consumers.") (emphasis added) (testimony of Richard E. Lyng, Assistant Secretary of Agriculture).

<sup>56</sup> See 21 U.S.C. § 1031 (2006) ("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.").

<sup>57</sup> 21 U.S.C. § 1032 (2006).

<sup>58</sup> 21 U.S.C. § 1033 (2006).

<sup>59</sup> Compare 21 U.S.C. § 1033(a) ("Adulterated") and (l) ("Misbranded") (2006) with 21 U.S.C. § 342 ("Adulterated Food") and § 343 ("Misbranded Food").

USDA given differing interpretations to the meanings of “adulteration” and “misbranding” and, if so, are those differences justified by structural, textual, or other differences between the FDCA and the EPIA? Since enactment of the EPIA, one portion of the “adulteration” definition was triggered when the FDA approved irradiation as a technique for eliminating salmonella from shell eggs.<sup>60</sup> Only FDA approval would exempt irradiation from the “adulteration” definition’s ban on any intentional radiation.<sup>61</sup>

The “adulteration” definition is detailed and covers both eggs and egg products. But the EPIA also gives mutually exclusive definitions for eggs versus egg products.<sup>62</sup> In this way, subsequent provisions of the statute will divide the inspection regime by carefully applying certain provisions only to egg products. EPIA also codifies into law a series of definitions for rejected eggs, previously present only as part of the AMS voluntary grading and quality standards.<sup>63</sup> Cracked eggs, whether or not piercing the membrane, those that are dirty, and those suffering from organic rot, amongst other problems, were all by law classified as rejected. Salmonella presence would not necessarily be included under any of these “rejection” categories but could be prevented through one of the categories qualifying an egg as “adulterated.”<sup>64</sup> A final key boundary line-drawing definition is that of “plant.” Even in parts of the EPIA that add regulatory restrictions to both eggs and egg products, many of these provisions are subsequently

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<sup>60</sup> See Irradiation in the Production, Processing, and Handling of Food, 65 Fed. Reg. 45280 (July 21, 2000).

<sup>61</sup> 21 U.S.C. § 1033(a)(7) (2006).

<sup>62</sup> For discussion of the difference between the two definitions, see, *infra*, text associated with notes 23 through 28.

<sup>63</sup> See 21 U.S.C. § 1033(g)(1) to (8) (2006).

<sup>64</sup> See 21 U.S.C. § 1033(a) (1) (2006) (applying adulteration those situations where an egg “bears or contains any poisonous or deleterious substance which may render it injurious to health”).

limited by having them apply only to production in “plants,” defined as a “place of business where egg products are processed” rather than any place of business where eggs are processed or produced.<sup>65</sup>

EPIA’s heart is its mandate of continuous inspection for safety and quality of all egg product processing facilities in the country.<sup>66</sup> By 1970, the USDA reported that roughly eighty percent of the gross egg product production in the U.S. was already under continuous inspection through voluntary USDA inspection.<sup>67</sup> The USDA also reported that twenty three million pounds of egg product, or four percent of the total egg product produced in a year, was segregated as “not fit for human food” by identification as such in the course of USDA continuous inspection.<sup>68</sup> Given this relatively substantial amount of rejected product, the clear inference was that those production facilities not participating in the voluntary inspection program were likely putting rejected product into the retail food market.<sup>69</sup> In that case, periodic spot inspections combined with retail regulation by state authorities might not be able to fully ensure the integrity of the egg market. Interestingly, analogous arguments have been made urging continuous or very frequent inspections, as opposed to occasional spot checks combined with outbreak response actions, for salmonella and other microbes.<sup>70</sup>

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<sup>65</sup> 21 U.S.C. § 1033(v) (2006).

<sup>66</sup> *See* 21 U.S.C. § 1034(a) (2006).

<sup>67</sup> *See* EGG PRODUCTS INSPECTION ACT, *supra*, note 24, at 2.

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

<sup>69</sup> *See id.* (“Manufacturers can use undesirable eggs and produce products that are difficult to distinguish from edible, wholesome products. This is done through the use of deodorants, filtering devices, flavoring ingredients, or pasteurization.”).

<sup>70</sup> *See, e.g.*, Elizabeth Dahl & Caroline Smith DeWaal, Center for Science in the Public Interest, *Scrambled Eggs: How a broken food safety system let contaminated eggs become a national food poisoning epidemic (1997)*, available at <http://www.cspinet.org/reports/eggs.html>.

Much of the Act continues to focus on egg product production plants, directing the USDA to set up an inspection regime for those facilities. Thus, it comes as a bit of a surprise when one reaches the prohibitions provision and finds language applying to all eggs and egg products.<sup>71</sup> The prohibitions section is again similar to broader provisions in the FDCA that supplement definitions and disfavored food characteristics by banning the parallel disfavored behavior leading to those characteristics (if Food Product A must not have X harmful characteristic, the prohibition bans Activity Leading to X). In the EPIA, it prohibits the buying, selling, or transport of “any restricted eggs” as well as the possession by an egg handler of “restricted eggs” for a purpose related to human food consumption.<sup>72</sup> On its face, this provision seems to cover all eggs in the U.S. market rather than just those destined for egg product facilities. On the other hand, since “restricted eggs” only possibly encompass eggs plagued by salmonella or other microbes, the expansive prohibition may still fall short of an even broader FDCA authority. Efforts to protect consumers from salmonella have found legal authority elsewhere, and not in this portion of the EPIA. But an alternative history could have been written, given that section 1037 prohibits trade or possession of restricted eggs and given that restricted eggs include “loss” eggs that are “unfit for human food” due to “contamination.”<sup>73</sup>

The section 1037 prohibition provisions in the EPIA are the strongest argument for refuting received wisdom that FDA has predominant legal authority over shell eggs. Additional support comes from EPIA implementing regulations promulgated by the

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<sup>71</sup> See 21 U.S.C. § 1037 (2006).

<sup>72</sup> 21 U.S.C. §§ 1037(a)(1) and (2) (2006).

<sup>73</sup> 21 U.S.C. § 1033(g)(7) (2006).

USDA Secretary and administered by the Agricultural Marketing Service (“AMS”).<sup>74</sup> In particular, USDA uses EPIA authority to promulgate periodic (quarterly) inspection authority of all businesses dealing with eggs for human consumption.<sup>75</sup> Consistent with the approach of all agencies involved in egg regulation, EPIA and AMS’ rules exempt certain categories from inspection and enforcement of the “restricted” eggs prohibition. Notable exemptions include: groups of eggs that have less than an accepted quantitative regulatory tolerance of “restricted” eggs; direct-to-consumer sales of eggs by poultry producers; very small producers (less than 3,000 hens); and wholesale businesses like bakeries and restaurants as long as they are using egg products that were inspected by the USDA.<sup>76</sup> Both the EPIA and its regulations also apply the same inspection requirement and “restricted” egg criteria to imported eggs and egg products.<sup>77</sup>

Today AMS’ Poultry Programs, Grading Branch operates the Shell Egg Surveillance Program, the actual program carrying out the EPIA regulations concerning shell eggs.<sup>78</sup> The above legal analysis clearly demonstrates that not only is there an existing specific regulatory program within USDA dealing with shell eggs but also that this program probably does not approach the full extend of possible authority to regulate shell eggs under the EPIA, including for salmonella. Perhaps it is a testament to its

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<sup>74</sup> See 7 C.F.R. §§ 57.1 to 57.1000 (2010).

<sup>75</sup> See 7 C.F.R. § 57.28 (2006) (“Periodic inspections shall be made of business premises, facilities, inventories, operations, transport vehicles, and records of egg handlers...In the case of shell egg packers packing eggs for the ultimate consumer, such inspections shall be made a minimum of once each calendar quarter.”).

<sup>76</sup> 7 C.F.R. §§ 57.100 (2010).

<sup>77</sup> See 21 U.S.C. § 1046 (2006); 7 C.F.R. § 57.900 (2010).

<sup>78</sup> See USDA AMS, *Fair Trading Regulations* (last accessed Apr. 25, 2011), <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&n avID=FairTradingRegulations&leftNav=FairTradingRegulations&page=PYShellEggSurveillance>.

lackluster budgetary, institutional, or political support but AMS is rarely even referred to in conversations about the federal regulatory universe for eggs. Instead materials dutifully note that FDA shares responsibility for egg safety with the Food Safety and Inspection Service (“FSIS”). A typical statement in reference materials within the agriculture industry runs: “The two agencies [FDA and FSIS]...both share authority in regard to egg safety because FSIS is in charge of inspecting plants processing liquid, frozen, and dried egg products, while FDA monitors fresh eggs.”<sup>79</sup> These statements seem to completely leave out the authority delegated to AMS for shell egg inspections. It is thus no wonder that, since the enactment of the EPIA in 1970, little specific preventive shell egg regulation has occurred and when it has, it has been through the FDA’s general authorities.

## **VII. Animal and Plant Health Inspection Service**

Yet another USDA agency typically ignored in sketches of federal egg regulation is the Animal and Plant Health Inspection Service (“APHIS”).<sup>80</sup> Congress passed the Animal Health Protection Act in 2002 to consolidate, clarify, and legally reiterate authority to monitor infectious diseases amongst livestock and quarantine animals if necessary.<sup>81</sup> Under that and other statutes dealing with livestock infectious diseases, the

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<sup>79</sup> Cornell University Cooperative Extension, *Who Are the Responsible Parties of the Tiered System?* (last accessed Apr. 25, 2011), available at <http://www.smallfarms.cornell.edu/pdfs/Livestock%20Processing%20Guide/Who%20are%20the%20Responsible%20Parties%20of%20the%20Tiered%20System.pdf>.

<sup>80</sup> See generally USDA APHIS, *Poultry Disease Information* (last accessed Apr. 25, 2011), [http://www.aphis.usda.gov/animal\\_health/animal\\_dis\\_spec/poultry/](http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/).

<sup>81</sup> Pub. L. No. 107-171 (2002) (codified at 7 U.S.C. §§ 8301-8317); USDA APHIS, *History of APHIS* (last accessed Apr. 25, 2011), [http://www.aphis.usda.gov/about\\_aphis/history.shtml](http://www.aphis.usda.gov/about_aphis/history.shtml); HENRY COHEN, CONG. RESEARCH SERV., RL 94731, BRIEF SUMMARIES OF FEDERAL ANIMAL PROTECTION STATUTES 4 (2008).



USDA Secretary delegated rulemaking and enforcement authority to APHIS, another modern USDA agency that is the product of much too many reorganizations to mention here.<sup>82</sup> APHIS in turn created the National Poultry Improvement Program (“NPIP”) for breeding and commercial poultry.<sup>83</sup> The NPIP is technically voluntary but APHIS has applied it as mandatory for any poultry moving in interstate commerce.<sup>84</sup> APHIS authority under the Animal Health Protection Act is broadly given, not unlike the relatively broad grants in parts of the FDCA and EPIA.

### **VIII. Modern Egg Regulation and Salmonella**

At this point, we have now sketched the outlines of three distinct lines of statutory and regulatory authority to administer an egg safety regime in the U.S. (putting aside for now the concurrent state authority to regulate). Two of these lines run through the USDA, one derived from the general mandate to prevent livestock disease in the Animal Health Control Act and the second derived from a specific mandate in the EPIA to protect eggs and egg products from “adulteration” and “misbranding.” The third line of authority runs through the FDA and derives from its general authority under the FDCA to, like the EPIA, protect the public from “adulteration” and “misbranding” of food products. Of the three lines of authority, none stands out as inherently more powerful or effective if one has as a goal more stringent regulation of egg safety. APHIS’ authority is

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<sup>82</sup> See USDA APHIS, *History of APHIS* (last accessed Apr. 25, 2011), [http://www.aphis.usda.gov/about\\_aphis/history.shtml](http://www.aphis.usda.gov/about_aphis/history.shtml).

<sup>83</sup> See 9 C.F.R. pts. 145-147 (2010).

<sup>84</sup> See 7 U.S.C. § 8305 (2006) (“The Secretary may prohibit or restrict the movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock; and the use of any means of conveyance or facility in connection with the movement in interstate commerce...”).

focused on contagious pests and disease so it would be inappropriate for regulation of general egg hygiene and quality concerns. This is a significant limitation. But if the regulatory challenge of the future is salmonella and other microbial diseases each statute seems to offer sufficient legal authority for confronting this problem through prospective regulation.

In fact, recent FDA actions have attempted just such a prospective solution. As early as the 1980s, the FDA and various USDA agencies were aware that salmonella seemed on the rise and posed a greater danger to egg consumers.<sup>85</sup> Most alarming was the discovery that salmonella was no longer confined to cracked or spoiled eggs but could infect consumers through intact shell eggs. FDA and FSIS generally took the lead in planned regulatory responses even though research demonstrated that salmonella could be passed to an intact egg during the incubation period<sup>86</sup>, a fact suggesting that APHIS' authority over livestock disease prevention might be the natural locus of prevention efforts.

In its responses to salmonella during the 1990s, FDA chose to rely on yet another statutory authority, so far not yet discussed. In 1999, FSIS engaged in a rulemaking that updated a provision in the EPIA concerning refrigeration of egg products.<sup>87</sup> The EPIA provision offered little discretion in implementing this rule: the Secretary was directed to conduct inspections of shell egg production facilities to ensure that already packed eggs

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<sup>85</sup> *Oversight of Egg Safety: Hearing Before the Subcomm. on Oversight of Government Management, Restructuring and the District of Columbia of the S. Comm. on Governmental Affairs*, 106th Cong. 1 (1999) (statement of Morris E. Potter, Dir. of Food Safety Initiatives, Center for Food Safety and Nutrition, FDA) [hereinafter *1999 FDA Egg Safety Testimony*].

<sup>86</sup> *Id.*

<sup>87</sup> See 21 U.S.C. § 1034(e) (2006).

are maintained in refrigeration of forty five degrees Fahrenheit or less.<sup>88</sup> At the time of this FSIS rulemaking, FDA chose to join FSIS in a food safety initiative. In doing so, it relied not solely on the FDCA but also on another federal statute, the Public Health Service Act (“PHSA”).<sup>89</sup> The PHSA grants broad power to the FDA<sup>90</sup> in order to:

[P]revent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.<sup>91</sup>

A close parsing of the above language shows that this provision is a powerful grant of power to regulate food and livestock involved in the production of food whenever communicable diseases are implicated. Salmonella is clearly a communicable disease; it is a microorganism passed from the poultry bird via the egg as disease vector to the human stomach, where it causes gastroenteritis.<sup>92</sup> While the PHSA could not regulate all

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<sup>88</sup> *Id.*

<sup>89</sup> Ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-300bbb

<sup>90</sup> The authority was originally given to the Office of the Surgeon General but that office was abolished as a distinct legal entity in 1966, with its powers transferred to the Secretary of Health and Human Services or his delegate (i.e. FDA Administrator). *See* 42 U.S.C.A. § 264 note (2006) (Transfer of Functions).

<sup>91</sup> 42 U.S.C. § 264(a) (2006).

<sup>92</sup> *See* Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56824 (proposed Sep. 22, 2004) (to be codified at 21 C.F.R. pts. 16 and 18).

aspects of egg inspection and quality control, it could powerfully shape any parts of the production process relating to salmonella transmission.

Initially, in 1999, FDA used its PHSa authority to engage in two modest rule-makings. First, it complemented the existing FSIS rule concerning egg refrigeration by issuing its own rule requiring refrigeration of all shell eggs in retail establishments at temperatures of forty five degrees Fahrenheit or less.<sup>93</sup> In this same rule-making, though, it also used its PHSa communicable disease prevention authority to require safe handling warning labels on *all* shell eggs in interstate or intrastate commerce.<sup>94</sup> The theory of legal authority in this case makes it analogous, although not perfectly, with the Surgeon General's tobacco warning labels issued under the PHSa. While eggs are not the only possible vector for pathogens, they remain the only food that FDA has required bear such labels.<sup>95</sup>

FDA returned to its authority under the PHSa, as well as the FDCA, in a much more substantial way with the long-planned Egg Safety Rule of 2009 ("FDA Egg Rule").<sup>96</sup> This rule represented a major expansion of FDA preventive oversight in egg safety as well as the most significant expansion of federal egg safety requirements since the enactment of EPIA in 1970. The final promulgation of the rule came five years after the proposed rule<sup>97</sup> but given its relatively large impact, including in the balance between

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<sup>93</sup> Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution, 65 Fed. Reg. 76092 (Dec. 5, 2000) (codified at 21 C.F.R. pts. 16, 101, and 115).

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

<sup>95</sup> PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 330 (3d ed. 2006).

<sup>96</sup> Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33030 (July 9, 2009) (codified at 21 C.F.R. pts. 16 and 118).

<sup>97</sup> *Id.*

the various regulatory agencies, this gap in time is not surprising. In the background information prior to the text of the FDA Egg Rule, FDA makes clear that it supports consensus scientific evidence showing salmonella is primarily transmitted to eggs “transoceanic” rather than through environmental contaminants.<sup>98</sup> This scientific basis for the spread of salmonella through shell eggs suggests future preventive regulation may continue to focus on the poultry animals rather than merely on storage and handling conditions for the eggs. FDA’s rationale for intervening most directly at the production stage entails two points: first, as just noted scientific consensus suggests transmission often occurs while the egg is incubating; and second, efforts to reduce illness severity and spread among consumer populations have slowed in effectiveness, suggesting any gains that can be made at the production stage should be taken.<sup>99</sup>

The FDA Egg Rule is a very, detailed programmatic intervention. However, a discussion of at least its highlights is appropriate here. First, the rule only applies to producers with greater than 3,000 egg-laying hens.<sup>100</sup> Second, producers, and transporter or handlers for certain provisions are required to undertake certain preventive requirements subject to enforcement inspections by the agency: a written salmonella prevention plan; producers must obtain chicks that have been monitored for salmonella (often requiring participation in the APHIS inspection service described above); operate a “biosecurity” program of limited access by humans and animals to production facilities; pest control; and disinfecting procedures when a salmonella-infected egg is found.<sup>101</sup>

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<sup>98</sup> *Id.* at 33031.

<sup>99</sup> *Id.* at 33033.

<sup>100</sup> *Id.* at 33034.

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

Producers are also now required, for the first time, to register with FDA, a procedure in place at AMS and FSIS but not at FDA.<sup>102</sup>

For most producers (except for very large ones with greater than 50,000 hens), the FDA Egg Rule goes into effect in July, 2012.<sup>103</sup> Ironically, only last summer media attention honed in on egg safety to an unprecedented degree. The egg beat became popular because of a salmonella outbreak in the spring and summer of 2010 centered on eggs produced at two large Iowa producers.<sup>104</sup> By the fall, than 500 million eggs had been recalled, making it the largest egg recall in U.S. history.<sup>105</sup> Both farms involved in the recall, Wright Farms and Hillandale Farms, used a chick supplier that was a participant in the APHIS NPIP monitoring regime.<sup>106</sup> The outbreak focused attention on two aspects of the salmonella concern: first that scientists still are not in agreement or certainty as to exactly how salmonella spreads or how it typically infects poultry; and second that one clear means it does so, and one easily regulated through preventive restrictions, is through rodent droppings and activity.<sup>107</sup>

Besides the recall and other outbreak tracking activities undertaken with the CDC, FDA also committed in the wake of the Iowa incident to inspect the 600 largest U.S. egg

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<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> See William Neuman, *Growing Concern About Tainted Eggs After Recall*, N.Y. TIMES, Aug. 20, 2010, at B1; FDA, *Salmonella* Enteritis Outbreak in Shell Eggs (last accessed Apr. 25, 2011), <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* (“F.D.A. officials said the chicks used by both farms came from a hatchery that participated in a national program meant to ensure that its chicks were free of salmonella infection.”).

<sup>107</sup> See William Neuman, *Fried, Scrambled, Infected*, N.Y. TIMES, Sep. 25, 2010, at WK5.

producers over the course of a year.<sup>108</sup> It conducted inspections over the course of 2010 and 2011 in two phases, first focusing on thirty five production firms “associated with previous outbreaks and/or poor compliance history.”<sup>109</sup> In reporting the results of these intensive inspections, FDA determined that most violations found were related to “failure to completely implement and/or consistently follow these [FDA Egg Safety Rule] plans and/or maintain all required documentation/records.”<sup>110</sup> Inspections are ongoing, and prioritized by likely risk, for the other large farms already subject to the FDA Egg Rule.<sup>111</sup> Also ongoing is a federal suit filed by parents of children made ill by the outbreak, claiming strict product liability, negligence, and negligence per se.<sup>112</sup>

The salmonella outbreak in the summer of 2010 raises intriguing questions both as to where our egg safety policy should head and also as to how federal legal authority will track that policy.<sup>113</sup> Most importantly a series of scientific studies present data showing that salmonella is less prevalent in eggs harvested from poultry raised cage-free than from caged poultry.<sup>114</sup> Critics of these studies argue that the relatively new condition of most cage-free facilities make them difficult to compare against older, caged facilities

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

<sup>109</sup> FDA, *Quarterly Summary on FDA Inspections Under the Egg Safety Rule: February 2011* (Mar. 2, 2011), <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/ucm241588.htm>.

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

<sup>111</sup> *Id.*

<sup>112</sup> *Dzinovic et al. v. Quality Eggs*, No. C 10-3055-MWB (N.D. Iowa filed Nov. 18, 2010).

<sup>113</sup> Special thanks to Natalie Prosin, a colleague and Boston College Law School Class of 2011, for help and ideas in thinking about agricultural practices in relation to our current egg safety regime.

<sup>114</sup> See, e.g., 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 (2010).

and thus clouds any argument of a lower risk for salmonella.<sup>115</sup> Still, there are signs that to cage or not may not be the only modern agricultural practice implicated in the recent higher prevalence of salmonella. Going back as far as the early 1990s, the respected government research agency, the Institute of Medicine, issued a study on the issue noting, “[T]he introduction of feedlots and large-scale poultry rearing and processing facilities has been implicated in the increasing incidence of human pathogens, such as Salmonella, in domestic animals over the past 30 years.”<sup>116</sup> Non-profit animal welfare, consumer advocacy, and environmental groups are advocating strongly for new laws dealing with so-called “factory farm” eggs and increasingly meeting with success in state capitals.<sup>117</sup>

This success holds out the possibility of a fundamental re-ordering in the nature of U.S. egg regulation. For much of the past century, federal agencies have regulated production and transport for safety while the states have concerned themselves with safety at the retail level and with quality control. State regulation of farm operations would mean state regulatory movement directly into the production sphere. However, the EPIA contains an explicit provision guaranteeing continued ability for state regulation, outside of egg processing plants.<sup>118</sup> Greater activity at the state level will likely increase political and institutional pressure at the USDA and FDA to more directly regulate

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<sup>115</sup> P.S. Holt et al. *The Impact of Different Housing Systems on Egg Safety and Quality*, 90 POULTRY SCI. 251 (2011).

<sup>116</sup> J. LEDERBERG ET AL., *EMERGING INFECTIONS: MICROBIAL THREATS TO HEALTH IN THE UNITED STATES* 64 (National Academies Press 1992).

<sup>117</sup> See, e.g., The Human Society of the United States, *Food Safety and Cage Egg Production* (last accessed May 1, 2011), [http://www.humanesociety.org/assets/pdfs/farm/report\\_food\\_safety\\_eggs.pdf](http://www.humanesociety.org/assets/pdfs/farm/report_food_safety_eggs.pdf).

<sup>118</sup> See 21 U.S.C. § 1052(b)(2) (2006) (“[A]ny State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products for the purpose of preventing the distribution for human food purposes of any such articles which are outside of such a plant and are in violation of any of said Federal Acts or any State or local law consistent therewith.”).



agricultural practices involved in egg production, using authority under the Animal Health Protection Act, EPIA, FDCA, and PHSA. As this paper has attempted to show, those legal authorities provide ample legal means to regulate practices such as cage-free birds. Any resistance to such regulation at the federal level should come from policy preferences or political will and not from worries about legal authority to do so.