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WASHINGTON, DC

Public Interest Comment<sup>1</sup> on  
The Food Safety and Inspection Service's proposed rule

Egg Products Inspection Regulations

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The George Washington University Regulatory Studies Center

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food Safety Inspection Service's (FSIS's) proposed "Egg Products Inspection Regulations" does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of FSIS's proposal on overall consumer welfare.

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<sup>1</sup> This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

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## Introduction

The Food Safety Inspection Service (FSIS) is proposing to require *official plants*<sup>3</sup> that process *egg products*<sup>4</sup> to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (Sanitation SOPs). At the same time, FSIS would eliminate certain existing regulatory requirements that it considers inconsistent with HACCP, Sanitation SOPs, and other new regulatory requirements, but add new labeling requirements. Official plants would be subject to the regulation, and all manufacturing facilities that process egg products must be official plants.

*HAACP* is a process management system that includes the identification of *food safety hazards*, the identification of *critical control points* for managing hazards using *process monitoring equipment*, and the conduct of a *hazard analysis*, all combined into a *HACCP plan* that includes prescribed *preventive measures* and *corrective actions* taken in response to exceedances of a *critical limit*.<sup>5</sup> A key feature of HACCP-style regulation is extensive recordkeeping used for validation, verification, and reassessment with a focus on continuous improvement toward zero risk.<sup>6</sup>

FSIS characterizes the proposed rule as deregulatory, with an estimated cost saving of \$1.29 million (\$2016) per year.<sup>7</sup>

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<sup>3</sup> *Official plant* means “any plant in which the plant facilities, methods of operation and sanitary procedures have been found suitable and adequate by the Administrator for the continuous inspection of egg products in accordance with this part and in which inspection service is carried on.” 9 C.F.R. § 590.5.

<sup>4</sup> *Egg products* means “any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following products, among others, are exempted as not being egg products: Freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing eggs or egg products, provided, such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Balut and other similar ethnic delicacies are also exempted from inspection under this part.” 9 C.F.R. § 590.5.

<sup>5</sup> All definitions are found in 9 C.F.R. § 417.1-2.

<sup>6</sup> See 9 C.F.R. Part 417 generally. As indicated below, another purpose is to convert risk-based regulation into paperwork-based compliance.

<sup>7</sup> USDA Food Safety and Inspection Service (2018, p. 6343).

## Is the proposed rule Needed?

FSIS gives three justifications for the proposed rule.

### Justification #1: The proposed rule Overcomes a Government Failure

First, FSIS says the Rule would “increase efficiency from complying with less burdensome regulations”:

FSIS is proposing that the current “command and control” egg products inspection regulations be changed to more flexible regulatory requirements.<sup>8</sup>

Simplified, this argument is primarily a recognition of a prior government failure.<sup>9</sup> Existing regulations are overly burdensome and do not cost-effectively accomplish their risk-reduction objectives.

### Justification #2: The proposed rule Would Lead to More Efficient Business Operations

Second, FSIS says the proposed rule would improve the productive efficiency of egg product plants in ways that are separate and distinct from any efficiencies gained by the repeal of existing, inefficient regulations or the internalization of externalities:<sup>10</sup>

Under this proposed rule, egg products plants would be required to develop and maintain HACCP systems. A HACCP system allows greater flexibility for producers to realize increased production efficiency. In addition, the proposed rule will allow plants to use different pasteurization methods. With 93 percent of egg products plants already under a HACCP system, many have incurred additional unnecessary costs from complying with FSIS requirements in terms of “command and control” regulations and by processing under their own HACCP systems. By operating under the HACCP system alone, egg products plants can use plant resources in a more efficient manner while controlling for hazards in innovative ways in their HACCP plans.<sup>11</sup>

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<sup>8</sup> 83 FR 6334

<sup>9</sup> 83 FR 6334. For a clear exposition of the difference between *market* failure and *government* failure, see Wolf Jr. (1988, 1997). Executive Order 12,866 § (b)(2) directs agencies to “examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.” See Clinton (1993pp. 51735-51736).

<sup>10</sup> USDA Food Safety and Inspection Service (2018, p. 6333).

<sup>11</sup> USDA Food Safety and Inspection Service (2018, pp. 6333-6334).

This implies that those who own and/or manage eggs products plants are not as well-informed as FSIS concerning how best to maximize profits; firm behavior is irrational and cannot maximize profits without FSIS regulation.

### Justification #3: The proposed rule Materially Reduces Foodborne Illness Risk

Third, FSIS asserts that “regulatory action is warranted by the non-negligible public health risks associated with pasteurized egg products.”<sup>12</sup> These “non-negligible” risks consist of an estimated 5,500 cases of *Salmonella* infection per year due to pasteurized liquid egg products, or 0.5% of the approximately 1.03 million annual domestically-acquired foodborne illnesses that FSIS says are caused by *Salmonella*.<sup>13</sup>

In 2014, the industry produced 1.8 billion pounds of dried, frozen, and liquid egg products for distribution in commerce plus another 4 billion pounds of liquid unpasteurized product for further processing.<sup>14</sup> Taking FSIS’s estimate of 5,000 *Salmonella* cases as given, and assuming (1) one ounce is the bolus dose of egg product sufficient to induce foodborne illness, (2) all serotypes have the same risk and (3) are proportionally found in egg products covered by the proposed rule, the average number of cases per ounce of egg product ranged from  $1.7 \times 10^{-7}$  (5.8 million ounces of egg products per *Salmonella* case) to  $7.8 \times 10^{-8}$  (12.8 million ounces of liquid unpasteurized product per *Salmonella* case). In 2014, USDA’s Economic Research Service (ERS) estimated the expected social cost of a random *Salmonella* case at \$3,568.<sup>15</sup> Therefore, the expected social value of preventing a random ounce from being contaminated ranges from \$0.0006 (if all cases are attributed to dried, frozen, and liquid egg products)<sup>16</sup> to \$0.0003 (if all cases are attributed to liquid unpasteurized product).<sup>17</sup> As “non-negligible” risks go, this one is quite small, and it would be much smaller if cases were simultaneously allocated to both product types, the estimate were

<sup>12</sup> See USDA Food Safety and Inspection Service (2018, p. 6344), attributing the estimates to Scallan et al. (2011). However, nothing in Scallan et al. (2011) or Gurtler et al. (2013) — the two references cited — allocates *Salmonella* cases to specific foods such as egg products. FSIS is required by government-wide information quality guidelines (Office of Management and Budget 2002) to transparently document how it obtained this estimate of *Salmonella* cases.

<sup>13</sup> This estimate is from Scallan et al. (2011). Centers for Disease Control and Prevention (CDC) surveillance reports indicate a 2006 incidence rate of 14.6 per 100,000 for *Salmonella*. CDC recognizes that its sample, which comprises 15% of the U.S. population, may not be representative. If the true number is 1 million cases, as estimated by Scallan et al. (2011), then either the CDC surveillance program severely oversamples from jurisdictions with very low incidence or it misses 20 cases for each one it records.

<sup>14</sup> USDA Food Safety and Inspection Service (2018, p. 6334). Cost savings are annualized over 10 years at 3% and 7%, and for some reason are identical or both discount rates.

<sup>15</sup> USDA Economic Research Service (2017 [Cost of foodborne illness estimates for *Salmonella* (non-typhoidal)]). While this may be a lower-bound for total willingness-to-pay, it uses WTP estimates for premature mortality risk, and premature mortality risk comprises 92% of the total valuation.

<sup>16</sup>  $5,000 \text{ cases} \div 1.8E^9 \text{ lbs} \div \frac{16 \text{ oz}}{1 \text{ lb}} \times \frac{\$3,568}{\text{case}} = \frac{\$0.0006}{\text{oz}}$ .

<sup>17</sup>  $5,000 \text{ cases} \div 4.0E^9 \text{ lbs} \div \frac{16 \text{ oz}}{1 \text{ lb}} \times \frac{\$3,568}{\text{case}} = \frac{\$0.0003}{\text{oz}}$ .

restricted to the *S. Enteritidis* serotype (the presumptive target of the proposed rule), or the minimum bolus dose were smaller than one ounce.

## Compliance with Executive Order 12866 and OMB Circular A-4

The standard of review for proposed rules under Executive Order 12866 is found in Section 1:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.<sup>18</sup>

FSIS's identification of its basis for regulation is summarized in the following subsections.

### Would the Rule Overcome Regulatory Failure Caused by Past Regulation?

In the preamble FSIS acknowledges that its longstanding command-and-control regulation of the egg products industry is overly burdensome. This is not surprising. Command-and-control regulation is inherently inefficient because, among other things, it imposes one-size-fits-all requirements on entities that are diverse on multiple dimensions. The ineffectiveness of historic regulation is, among other things, a product of an outdated and arguably pre-scientific view of health risks embodied in the 1957 Poultry Products Inspection Act (PPIA), which does not even mention foodborne pathogens.<sup>19</sup>

FSIS estimates the annualized savings resulting from the repeal of inefficient command-and-control regulations at \$5,388,000,<sup>20</sup> or an average of \$70,000 across 77 egg products plants.<sup>21</sup> These savings are incidental fractions of FSIS's estimate of average plant revenue (\$104.4 million). Therefore, the gross reduction in regulatory burden that FSIS claims would be provided by the proposed rule is quite small.

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<sup>18</sup> Clinton (1993, Section 1(a)).

<sup>19</sup> Pub. L. 85-172, Aug. 28, 1957. The purpose of the PPIA was to ensure that poultry products were “wholesome” and not “adulterated.” *Wholesome* was defined as “sound, healthful, clean, and otherwise fit for human food. See PPIA § 4(f). *Adulterated* was generally defined as (1) bearing or containing “any poisonous or deleterious substance which may render them injurious to health,” except insofar as “the quantity of such substance in such poultry and poultry products does not ordinarily render them injurious to health,” or (2) bearing or containing an additive triggering (1). PPIA § 4(h)(1)-(2). FSIS has by regulation defined *adulterated* to include the presence of pathogens in any quantity that are naturally or routinely present in poultry — i.e., they never were added.

<sup>20</sup> USDA Food Safety and Inspection Service (2018, p. 6341 [Table 18]).

<sup>21</sup> For the 31 plants FSIS believes are small entities, average cost savings are on average \$9,200 per plant. See USDA Food Safety and Inspection Service (2018, p. 6344).

These meager cost-savings come at a price. FSIS estimates that the proposed new HACCP regulations will cost \$4,235,200, or \$55,000 per plant.<sup>22</sup> Given myriad uncertainties in FSIS's cost estimation methodology, the absence of any analysis of variability and uncertainty, and evidence that FSIS has historically underestimated costs,<sup>23</sup> a reasonable first-order approximation is that there will be no net deregulatory savings.<sup>24</sup>

Whether FSIS is proposing to replace one government failure with another depends on the risks posed by egg products and how much of these risks the new HACCP regulations eliminate. This question is addressed later, in the section asking whether the proposed rule would materially reduce foodborne illness risks posed by egg products.

### Would the Rule Help Egg Product Plants Maximize Profits?

Skepticism is justified when regulatory agencies claim to know more about the industry they propose to regulate than the industry itself. When an agency also says it knows how to make the industry operate more efficiently, skepticism is mandatory. Yet this is a longstanding feature of FSIS regulation. In the 1996 regulation that began the HACCPification of meat and poultry production, FSIS made similarly grandiose claims:

[T]here are other benefits to this rule that have not been quantified. Examples include increased public protection from physical hazards and *the increased production efficiency that accompanies improved process control* (emphasis added).<sup>25</sup>

In the proposed rule, FSIS displays remarkable confidence in the proposition that regulation will improve profit maximization:

USDA's process control strategy will educate industry management about the need and methodology for development of a consistent, preventive, problem-solving approach to safety hazards, which can be expanded to other business objectives such as product quality and production efficiency. There is considerable evidence of how process control has improved worldwide industrial productivity in the past

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<sup>22</sup> USDA Food Safety and Inspection Service (2018, p. 6343 [Table 19]) (annualized at 7% over 10 years), range = \$2,195,000 to \$6,287,800.

<sup>23</sup> In its 1996 HACCP rule, (USDA Food Safety and Inspection Service 1996, p. 38858), FSIS estimated annualized costs at \$968 to \$1,156 million. Roberts et al. (1996) cite cost estimates by Knutson et al. (1995) (no longer in print) that are 36 times higher for HACCP planning and training, 4.8 times higher for HACCP data recording, and 33 times higher for HACCP testing. For a critical review of FSIS's 1996 cost estimates, see Antle (2000). For a critical review of the quality of 1996 FSIS's regulatory impact analysis, see Belzer (2000).

<sup>24</sup> This inference is supported by FSIS's claim that *net savings* are only \$1.3 million. See USDA Food Safety and Inspection Service (2018, p. 6343).

<sup>25</sup> USDA Food Safety and Inspection Service (1996, p. 38948).

40 years. This proposal will extend process control principles to parts of the meat and poultry industry that have not formerly used them.<sup>26</sup>

However, this claim is inconsistent with elementary economic theory. Clear and convincing evidence, obtained over many studies using different data sets and analytic methods, must be marshaled before abandoning the bedrock Economics 101 principle that firms strive to maximize profits. Yet, despite more than 20 years of experience with HACCP regulation, the proposed rule includes no evidence that firms (in this case, managers of egg products plants) make irrational decisions with respect to production technology. FSIS claims that “[a] HACCP system allows greater flexibility for producers to realize increased production efficiency,” and because “93 percent of egg products plants already [operate] under a HACCP system”<sup>27</sup> it is necessary to mandate that the other 7 percent also do so in order to capture the private benefits earned by the 93%. It is more plausible that HACCP is not cost-effective for some egg products plants, or that some firms among the 93% have adopted HACCP for purposes other than improved production efficiency, such as compliance with other regulations.

In the proposed rule, FSIS does not attempt to estimate the private benefits that it suggests its HACCP regulation will enable managers of egg products plants to obtain. In the Final Rule, FSIS should focus instead on analyzing whether imposing HACCP on egg products plants that currently do not use it will produce substantial and sustained reductions in health risk from foodborne pathogens, most notably *Salmonella* and especially its serotype *S. Enteritidis*.

### Would the Rule Materially Reduce Foodborne Illness Risks?

FSIS began imposing HACCP regulations on meat and poultry plants in 1996.<sup>28</sup> *Salmonella* was one of eight pathogens FSIS wanted HACCP to control<sup>29</sup> and eggs products were specifically identified as ingredients that posed risks which plant managers (though not *egg products* plants) were now required to directly manage.<sup>30</sup> In its Regulatory Impact Analysis, FSIS reported a range of 0.8–4 million cases of *Salmonella* infection per year, 87–99% of which were foodborne, which the agency said caused 800–4,000 deaths per year.<sup>31</sup> The agency further estimated that *Salmonella* in meat and poultry products was responsible for 0.4–2.9 million foodborne illness cases and 384–

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<sup>26</sup> USDA Food Safety and Inspection Service (1996, p. 38952).

<sup>27</sup> USDA Food Safety and Inspection Service (2018).

<sup>28</sup> USDA Food Safety and Inspection Service (1996).

<sup>29</sup> USDA Food Safety and Inspection Service (1996, 38907 [Table 4]).

<sup>30</sup> USDA Food Safety and Inspection Service (1996, p. 38912 [Table 11]).

<sup>31</sup> USDA Food Safety and Inspection Service (1996, p. 38964 [Table 4]).

2,880 deaths per year,<sup>32</sup> that meat and poultry establishments were the source of 90% of these cases, and the 1996 HACCP Rule would reduce 100% of the 90%.<sup>33</sup>

Since 1997, the Centers for Disease Control and Prevention (CDC) has conducted an annual surveillance program for estimating the incidence of illness and death from foodborne pathogens.<sup>34</sup> Figure 1 shows that the reported infection rate from *Salmonella* has been fairly constant, at about 14 per 100,000 population (shown by the blue columns). Similarly, the fraction of all reported foodborne illness cases caused by *Salmonella* has been fairly constant at about 40% (shown by the red line). Figure 2 shows the number of reported deaths caused by *Salmonella* (blue columns) and its share of all foodborne illness deaths (red line).<sup>35</sup> Neither statistic shows any decrease in reported cases or deaths.

Surveillance reports are necessarily incomplete, so baseline incidence must be obtained by extrapolation. Scallan et al. (2011) obtains figures that differ significantly. Whereas CDC surveillance reports attribute about 70 deaths per year to foodborne pathogens (and about 26 to *Salmonella*), Scallan et al. (2011, Tables 2 and 3) estimate 1,351 total deaths (and 378 to *Salmonella*). Thus, the accuracy of the extrapolated figures depends less on the reported surveillance data than the validity of the extrapolation methodology. Extrapolation was based on multipliers derived from statistical models that relied on, among other things, numerous assumptions and hypothesized probability distributions.<sup>36</sup>

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<sup>32</sup> USDA Food Safety and Inspection Service (1996, p. 38964 [Table 5]). The lower-bound for deaths is identical to the estimate by Scallan et al. (2011) published five years later.

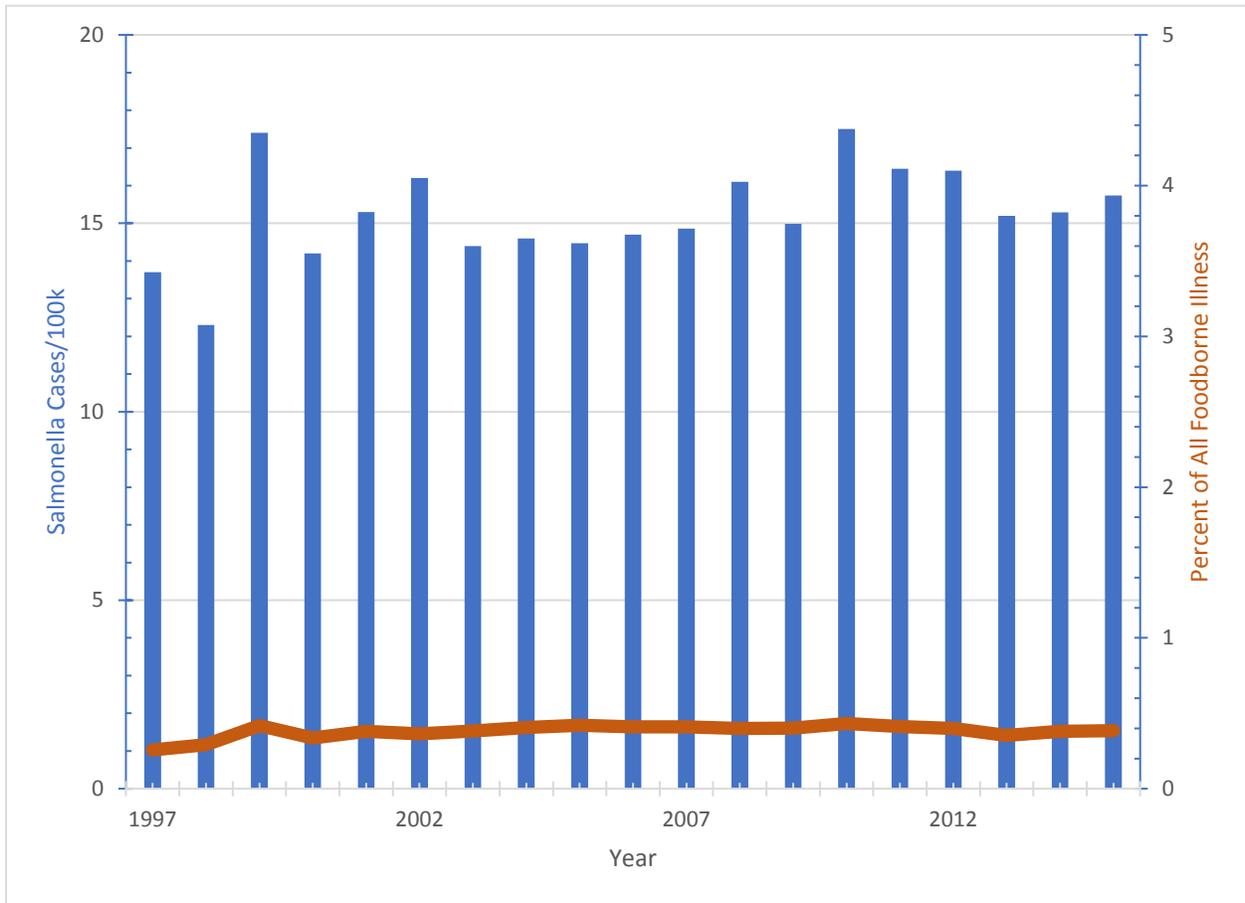
<sup>33</sup> USDA Food Safety and Inspection Service (1996, p. 38967). The RIA admits that FSIS simply assumed these benefit estimates without a scientific basis: “The link between regulatory effectiveness and health benefits is the assumption that a reduction in pathogens leads to a proportional reduction in foodborne illness. FSIS has presented the proportional reduction calculation as a mathematical expression that facilitates the calculation of a quantified benefit estimate for the purposes of this final RIA. FSIS has not viewed proportional reduction as a risk model that would have important underlying assumptions that merit discussion or explanation. For a mathematical expression to be a risk model, it must have some basis or credence in the scientific community. That is not the case here” (p. 38945).

<sup>34</sup> Centers for Disease Control and Prevention (2000a, 2000b, 2000c, 2002, 2003, 2004, 2005, 2006, 2008, 2009a, 2009b, 2010, 2011a, 2011b, 2012, 2014, 2016a, 2016b, 2017).

<sup>35</sup> Note that the annual number of deaths from *Salmonella* (average = 26; coefficient of variation = 0.32) is 0.9–6.8% of FSIS’s 1996 estimate. The 1996 risk estimates were based on the “expert judgment of FSIS microbiologists” (USDA Food Safety and Inspection Service 1996, p. 38966). FSIS retained them because “[t]he comments have not provided any basis for changing” them (p. 38967).

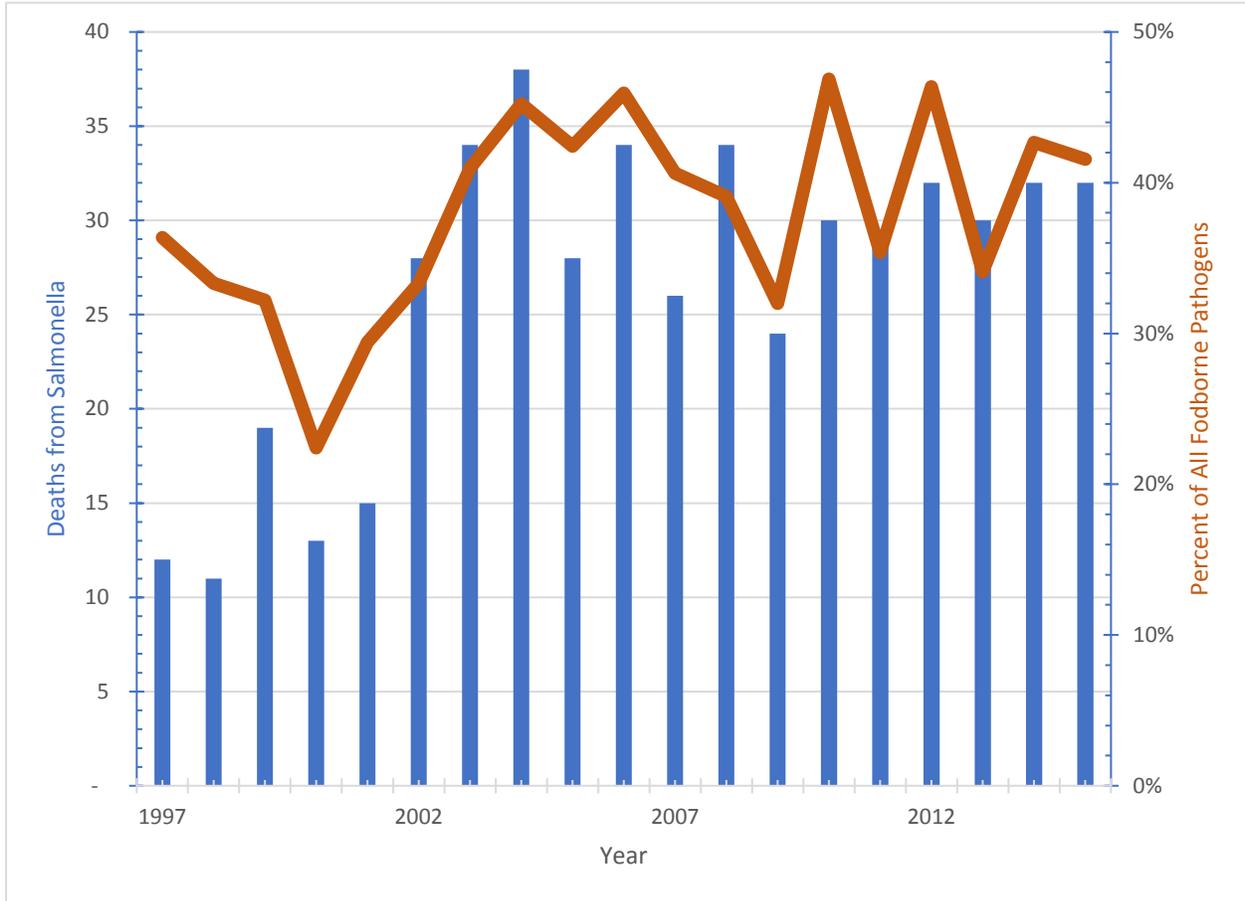
<sup>36</sup> See Scallan et al. (2011) Technical Appendix 1 for assumptions and Technical Appendix 2 for hypothesized probability distributions. One key assumption is reported hospitalizations and deaths were *doubled* to account for under-diagnosis. For *Salmonella*, a multiplier of 29.3 was used in lieu of hypothesized probability distributions “because of a lack of data on under-diagnosis factors.” See Scallan et al. (2011 Technical Appendix 3 and Table 3.5). This multiplier is described as an “[a]djustment for under-diagnosis due to variations in medical care seeking, specimen submission, laboratory testing, and test sensitivity” and is reported with both a mean and 90% credible confidence intervals, but without any other foundation.

**Figure 1. Reported *Salmonella* Infection Rates**



Derived from Centers for Disease Control and Prevention (2000a, 2000b, 2000c, 2002, 2003, 2004, 2005, 2006, 2008, 2009a, 2009b, 2010, 2011a, 2011b, 2012, 2014, 2016a, 2016b, 2017).

**Figure 1. Number and Share of *Salmonella* Deaths**



Derived from Centers for Disease Control and Prevention (2000a, 2000b, 2000c, 2002, 2003, 2004, 2005, 2006, 2008, 2009a, 2009b, 2010, 2011a, 2011b, 2012, 2014, 2016a, 2016b, 2017).

The proposed rule relies on Scallan et al. (2011) for baseline estimates, a critical review of which is beyond the scope of this comment. Nonetheless, it is self-evident that the estimates in Scallan et al. (2011) are far more precise than the authors’ methods justify. They report estimated number of *Salmonella* cases and deaths to the nearest case—seven significant digits for illnesses and four significant figures for deaths.

A key question is whether 20 years of HACCP regulation has reduced incidence and mortality. Unfortunately, neither Scallan et al. (2011) nor an earlier estimate by Mead et al. (1999) can be used to derive such estimates.<sup>37</sup> Moreover, for the CDC surveillance program to have failed to detect reductions in reported illnesses and deaths due to HACCP, the program in its early years

<sup>37</sup> Neither estimate concerns HACCP, and the most recently published of the two estimates specifically says they are not comparable because they are derived using different methodologies. See Scallan et al. (2011, p. 7). For the record, the earlier estimates by Mead et al. (1999, Table 3) are higher and just as overly precise: 1,412,498 cases and 582 deaths.

must have systematically missed the very cases that HACCP *would have* prevented and in its later years systematically missed the cases that HACCP *did* prevent. These assumptions are too heroic to be reasonable.

More likely, the CDC surveillance data show a decades-long record of HACCP ineffectiveness. Further, no credible evidence is presented in the proposed rule suggesting that *this* HACCP Rule would succeed even though all previous HACCP regulations apparently did not. Therefore, a reasonable first-order approximation of the health-risk reduction benefits from the proposed rule is zero. And there are additional facts, reported in and referenced by the CDC surveillance record, that reinforce this preliminary conclusion. First, about 10% of *Salmonella* cases appear to result from foreign exposure within seven days of entry to the U.S.<sup>38</sup> No HACCP rule targeting domestic plants can prevent these infections. Second, only 6% of *Salmonella* cases were associated with outbreaks, and it is outbreaks that would be expected from systematic failures at the plant level. The rest appear to be isolated events occurring after product distribution that cannot be prevented at an official plant.<sup>39</sup> This means the proximate cause of most *Salmonella* infection is temperature abuse, cross-contamination, or some other post-production error. The proposed rule cannot prevent these cases unless egg products leave a plant free of *Salmonella* and are somehow immune to infection throughout their distribution to the consumer, and beyond.

### What else might the proposed rule accomplish?

HACCP would reallocate inspection resources away from conventional activities that may have been reasonable decades ago, before knowledge that pathogenic organisms were the proximate cause of foodborne illness.<sup>40</sup> This is probably a good thing, because it reduces burdensome and ineffective application of inspection resources. But HACCP itself creates an alternative and potentially perverse use of these inspection resources—the identification and penalization of paperwork violations. Transforming inspection resources this way creates the appearance of social value, especially if FSIS inspectors are able to use paperwork violations to require corrective action or impose substantial financial penalties. Conversely, the social benefit of FSIS inspection becomes transparently suspect if firms do not commit the paperwork violations that inspectors need to mandate corrective action and impose financial penalties. Thus, HACCP *as a regulatory*

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<sup>38</sup> Centers for Disease Control and Prevention (2008, p. 20, 2009b, p. 3). Scallan et al. (2011, Table 2) estimate this fraction at 11%.

<sup>39</sup> See, e.g., Centers for Disease Control and Prevention (2000c, Table 4), Lee et al. (2004), Angulo et al. (2006), Centers for Disease Control and Prevention (2006, p. 10, 2007). CDC implicitly admits that HACCP is irrelevant. See Centers for Disease Control and Prevention (2009b, p. 34): “Enhanced measures are needed to understand the complex ecologies that link pathogens to animals and plants; to control or eliminate pathogens in food sources; to reduce or prevent contamination during food growing, harvesting, and processing; and to educate restaurant workers and consumers about infection risks and prevention measures.”

<sup>40</sup> The PPIA makes clear that its focus is on “filthy, putrid, or decomposed substances” See § 4(f)(2).

*tool* creates perverse incentives for FSIS to maximize violations in order to justify its continuous inspection regime, which dates from the Egg Products Inspection Act of 1970.<sup>41</sup>

That the rate of reported *Salmonella* infection has not measurably declined over the past 20 years, as shown in Figures 1 and 2, indicates that paperwork violations of the kind the proposed rule would generate are almost certainly uncorrelated with foodborne illness risk. They are either costs that are not matched by benefits or transfers to FSIS inspectors.

Before finalizing the proposed rule, FSIS should analyze the existing record of HACCP regulation and show clear, causal relationships between HACCP violations and foodborne illness risk and HACCP regulation and foodborne illness risk reduction.<sup>42</sup> If causal relationships cannot be documented, then FSIS should acknowledge that mandating HACCP in the egg products industry may be similarly ineffective.

## **Compliance with Executive Order 13771 and Applicable OMB Guidance**

Executive Order 13771 amends EO 12866 several ways, but most importantly by establishing an incremental regulatory budget.<sup>43</sup> Agencies are limited with respect to the costs they can impose and must promulgate deregulatory actions that reduce costs to create headroom for imposing new regulatory burdens. USDA states that it hopes to capture deregulatory cost savings from the proposed rule, but any such savings would be minimal even if FSIS's estimate (\$1.3 million<sup>44</sup>) is accurate.

As noted above, however, a first-order approximation of net cost savings is zero. Industry commenters on the proposed rule are better equipped to offer insight concerning the accuracy of FSIS's estimates of the costs eliminated by the rule's deregulatory provisions and the new costs added by the rule's HACCP provisions. Before granting USDA any cost-savings from deregulation, the Office of Management and Budget (OMB) should require FSIS to provide (and publish for public comment) clear and convincing evidence that the savings from deregulation are not exceeded by the additional costs of HACCP. This should include a rigorous estimate of the rule's predictable indirect costs resulting from corrective actions driven by paperwork violations.<sup>45</sup> Because FSIS's cost-savings estimate is so small, it is plausible (if not likely) that the proposed rule has net social costs. If so, USDA should be granted no credit toward its regulatory budget and required to find cost-savings from other deregulatory actions before finalizing the proposed rule.

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<sup>41</sup> Egg Products Inspection Act. Pub. L. 91-597. 84 Stat. 1620. (1970). In 2016, FSIS employed 3,123 inspectors to oversee eggs products plants. The President's FY 2019 budget would increase the number of inspectors at egg products plants by 5.7%, to 3,300. See Office of Management and Budget (2018, p. 81).

<sup>42</sup> In the preamble to the proposed rule, FSIS asserts several times that HACCP is known to reduce foodborne illness risks. None of these assertions is supported by evidence.

<sup>43</sup> Trump (2017, p. 9339 [Section 3]) and Office of Management and Budget (2017).

<sup>44</sup> USDA Food Safety and Inspection Service (2018, p. 6343).

<sup>45</sup> Fines imposed on egg products plants for HACCP violations are transfers and should be counted separately.

Moreover, OMB should not credit USDA with a deregulatory action pursuant to the 2-for-1 provisions in E.O. 13771 §§ 1, 2(a) and (c).

## Retrospective Review

Executive Order 13563 and OMB implementing guidance direct agencies to establish plans for the retrospective review of regulations for efficiency and effectiveness after they have been in place a reasonable period of time.<sup>46</sup> This responsibility cannot be fulfilled if new regulations do not include mechanisms sufficient to ensure that retrospective review can be performed.

The proposed rule does not include any retrospective review mechanisms, however. If the proposed rule is finalized without provisions for retrospective review, it will be impossible for FSIS to ever evaluate whether the rule accomplished its stated objectives and achieved them cost-effectively.<sup>47</sup>

## Conclusion

FSIS does not expect the proposed rule extending HACCP to egg products to result in any material reduction in regulatory burden. Because FSIS proposes to *replace* certain existing regulations with new regulations, it is plausible if not likely that the net effect is either a wash or a net *increase* in regulatory burden. It is therefore misleading for FSIS to characterize the proposed rule as deregulatory. Public comments from those more knowledgeable about the costs of HACCP plans and programs are needed to determine if FSIS's cost estimates are reliable, and if not, how they should be modified to be accurate.

FSIS claims three types of benefits from the proposed rule, but skepticism is due for two of these claims and the third is unsupported by empirical evidence. The proposed rule would not overcome the government failure caused by past regulation because it appears to supplant it with a different government failure. The proposed rule will not improve the operational efficiency of egg products plants unless, for some unexplained reason, FSIS employees are better managers of these plants despite the absence of expertise or experience. The baseline health risks posed by foodborne pathogens are so small that if any market failure exists it is minor and primarily caused by actions taken by entities and persons after egg products are distributed in commerce. Finally, there is sufficient evidence from the surveillance record that the reported incidence of infections and deaths caused by *Salmonella*, including serotype *Enteritidis*, have not declined since FSIS began its HACCPification of meat and poultry regulation in 1996. If two decades of HACCP have failed to

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<sup>46</sup> Obama (2011, Section 6(b) [directing agencies to submit retrospective review plans]) and Sunstein (2011, pp. 4-6 ["Retrospective Analysis of Existing Rules"]).

<sup>47</sup> HACCP regulations are excellent candidates for retrospective review under Executive Order 13563. USDA did not list any HACCP rules in its January 2012 or July 2015 retrospective review plans. See U.S. Department of Agriculture (2012, 2015).

materially reduce risks from *Salmonella*, the likelihood that extending it to egg products plants is essentially zero.

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