

## Analysis

The following contains Food & Water Watch (FWW)'s analysis of some of the information received from a Freedom of Information Act (FOIA) request seeking records related to the agency's evaluation of the Hazard Analysis and Critical Control Point (HACCP) Based Inspection Models Project for market hogs—an inspection system that is supposed to serve as a model for the proposed New Swine Inspection System (NSIS) rules. FWW's analysis particularly focuses on the ability of Food Safety and Inspection Service (FSIS) Inspection Program Personnel (IPP) to segregate those animals suspected of being diseased at antemortem inspection, their ability to perform critical offline Public Health Regulation (PHR) verification checks during postmortem inspection, and plants' Noncompliance Records.

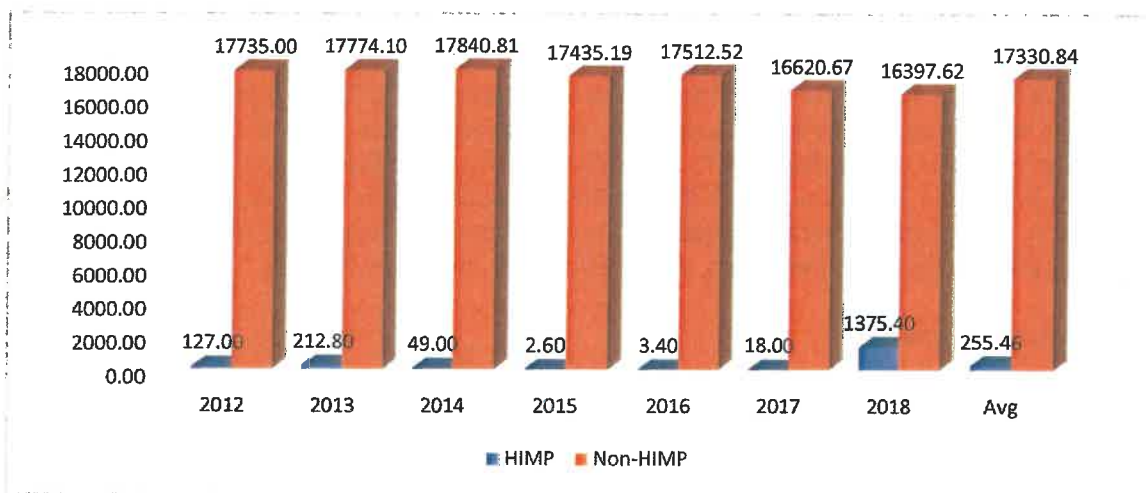
### **Antemortem Inspection**

FSIS has contended that antemortem inspection under the proposed NSIS rules will resemble the present system, as most plants have adopted a voluntary segregation program that allows them to segregate and remove animals that have health problems prior to presenting them for antemortem inspection. Under NSIS, such segregation will be mandatory and will resemble that of HIMP plants, where plant personnel remove and dispose of dead and moribund animals and animals suspected of having central nervous system disorders or pyrexia prior to antemortem inspection.

To evaluate whether HIMP-plant employees are effectively removing potentially diseased animals prior to antemortem inspection, FWW analyzed records from Fiscal Year (FY) 2012 to 2018 detailing the number of carcasses "sorted" by employees, condemned by inspectors, and deemed "U.S. Suspect," which according to FSIS regulations means "the livestock so identified is suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, when slaughtered, and is subject to further examination by an inspector to determine its disposal." 9 C.F.R. § 301.2 (2019).

While companies do identify and remove animals prior to antemortem inspection, FWW has uncovered that this comes at the cost of agency IPP being able to identify and inspect animals suspected of disease. From FY 2012 to 2018, the five HIMP plants had an average of 3.4 million market hogs arrive at each plant annually, while a comparator set of 21 plants had an average of more than 4 million per plant. Of those, HIMP-plant personnel were able to sort and remove slightly more than 8,000 animals per year on average per plant. But because this is only 0.2 percent of all animals, agency IPP were still charged with inspecting more than 99 percent of all animals that they would have without sorting. What's more, in the HIMP plants, very few animals were deemed as "U.S. Suspect." An average of 255 animals per year per plant were tagged as U.S. Suspect in these plants annually, *compared to an average of more 67 times more at 17,330 animals per plant in traditional plants*, including in those that have voluntary segregation programs. As a result, an average of 0.25 percent of hogs were segregated in this process and removed through plant employee "sorting," while twice the number of animals (0.43 percent) were isolated as suspect prior to and during antemortem inspection in traditional plants. This means that far more animals suspected of disease, about 9,000 per plant, were isolated for

potential and actual removal in these plants. In the end, HIMP-plant personnel end up “sorting” an average of 6.6 times more animals than inspectors are able to condemn in these plants.



This failure to segregate animals as “U.S. Suspect” is not a mere formality, akin to renaming disease-suspected-animal-holding pens as “Subject” pens, as the agency has suggested. The Federal Meat Inspection Act (FMIA) requires that “all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other amenable species[] and . . . shall be subject to a careful examination and inspection . . .” 21 U.S.C. § 603 (2012). FSIS’ regulations require that such suspected animals be slaughtered separately from other livestock unless they are condemned and disposed. 9 C.F.R. § 309.2(n) (2019), and livestock suspected of being affected with any disease or condition that would cause the carcass or parts to be condemned must be tagged as suspect until it is given a postmortem inspection. *Id.*, § 309.2(a). The data demonstrate that the agency’s HIMP and NSIS systems effectively preclude the tagging of animals as “U.S. Suspect,” preventing potentially diseased animals from being slaughtered separately from others and from receiving the “careful examination and inspection,” including postmortem inspection, required under the law. This is a violation of the FMIA that endangers public health.

### Postmortem Inspection

The proposed NPIS rules are predicated on the agency removing inspectors from the slaughter lines to perform “more offline activities [that] will be more effective in ensuring food safety.” 83 Fed. Reg. 4780, 4781 (Feb. 1, 2018). A key part of this is for offline inspectors to maintain or increase the number of verification tasks they do, particularly Public Health Regulation (PHR) verifications. *Id.* at 4789. FSIS designates PHRs as a “transparent and data-driven approach that identifies regulations with which there is an elevated rate of noncompliance during the three months before a *Salmonella*, *E. coli* O157: H7, or *Listeria monocytogenes* (Lm) positive.” USDA, “Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs,” at 22 (2014).

In assessing the HIMP plants, the agency evaluated the ability of inspectors to conduct these PHR verifications. Inspectors' performance of these verifications varied greatly between HIMP and non-HIMP plants (with HIMP plants ranging from less than 11 percent of the non HIMP facilities, to close to 400 percent *more* than the non-HIMP plants, depending on the particular PHR). Inspectors performed fewer than 85 percent of the total verifications in HIMP plants than they did in non-HIMP plants for a large proportion of the regulations (more than 50 percent of them). Despite both of these facts, the agency concluded that because it found in CY 2010 to 2013 an equivalent number of PHR verifications between HIMP and non-HIMP plants (although it only reported CY 2012 to 2013), when aggregated, this shows an "equivalent scrutiny of compliance with sanitary dressing and process controls." *Id.* at 20.

FWW sought to evaluate whether inspectors in HIMP plants performed an equivalent number of PHR verifications in more recent years from FY 2014 to 2017. Because many of the applicable PHRs changed at the end of June of each of those years, but the agency tracks its verification activities for the entire fiscal year beginning October 1, the data provided by the agency containing the number of verifications and applicable PHR in each year did not completely overlap—*i.e.*, if a regulation changed in June, it was impossible to determine how many of the verifications conducted for that regulation for the entire year occurred when it was a PHR. To get around this, FWW performed three analyses, one that only evaluated the PHRs that stayed constant and in effect from 2014 through 2017, one that only looked at the PHRs that did not change within each fiscal year (excluding those that did), and one that reasonably assumed that for any PHR that changed during the fiscal year, the number of verifications performed for that regulation as a PHR was proportional to the amount of time that the regulation was a PHR during that year (*e.g.*, if there were 120 verifications of the particular regulation for the entire fiscal year, but the regulation was only a PHR for only 9 months, or three quarters of the year, it was assumed that there were 90 verifications when the regulation was a PHR.) The first method examined those regulations which have been consistently deemed PHR over time. The second method includes a greater number of PHR data points each year and involved no imputation, and the third allows the greatest number of PHRs to be evaluated, as none were excluded, but includes some estimation of the likely number of verifications during years that the PHR changed during the year.

Regardless of how it looked at the data, FWW's analysis shows that there are deficiencies in how the agency has directed inspection verification tasks to be performed in HIMP plants, and this could have serious public health ramifications for its proposed NSIS rules. Like the agency's data showed, inspectors in HIMP plants consistently performed *fewer* PHR verifications than in non-HIMP plants for a substantial portion of these regulations (from 33 to 62 percent of the PHR regulations verified depending on the year and set of PHRs evaluated). (*See* Appendix A).

Moreover, FWW's analysis shows that any notion that inspectors conducted more PHR verifications in HIMP plants may be a statistical mirage. There were very few statistically significant differences in verifications between HIMP and non-HIMP plants. As summarized in Appendices B and C, where such differences existed, it was primarily for those PHRs where inspectors conducted a *greater number of verifications in non-HIMP plants* than in HIMP plants:

- For example, for those PHRs that did not change from 2014 through 2017, there were only six (6) instances (involving four (4) regulations) out of 84 total (21 PHR verified each year), where there was a statistically significant difference in PHR verifications between HIMP and non-HIMP plants. In two-thirds (4) of these instances, there were *more PHR verifications in non-HIMP plants*. Per plant, inspectors in non-HIMP plants conducted more than 57 net additional verifications of these PHRs per plant over four years than in HIMP plants, a 3.8 percent increase.
- Likewise, for PHRs that stayed the same within each year, there were only 14 instances (involving 9 regulations) out of 153 PHRs, where there was a statistically significant difference in PHR verifications between HIMP and non-HIMP plants. In close to two-thirds (nine (9) out of 14 instances), there were *more verifications of these regulations in non-HIMP plants*. The average non-HIMP plant had more than 55 net additional verifications of these PHRs than did HIMP plants over the four years, a 2 percent increase.
- Finally, for those regulations that were not excluded when they changed on June 30 of each year, but where FWW estimated how many verifications likely took place for those regulations based on the amount of time the regulation was a PHR, there were only 18 instances (involving 12 PHRs) out of 249 where there was a statistically significant difference in PHR verifications between HIMP and non-HIMP plants each year, and in more than three-fifths (11) of these instances, there were more verifications of these regulations in non-HIMP than HIMP plants. Per plant, inspectors in non-HIMP plants conducted more than 35 net additional verifications of these regulations over four years than in HIMP plants, an increase of one percent.
- Some of the PHRs for which there were greater verifications in non-HIMP plants were critically important, including checking that plants' critical control points (CCP) are under control and ensuring that carcasses are not reprocessed when they are accidentally contaminated with digestive tract contents. The statistically significantly greater verifications in HIMP plants were also very important, but primarily occurred in 2017 and focused on whether the plant had a written hazard analysis plan.

In sum, FWW's data shows that one cannot say that there is an equivalent number of PHR verifications in HIMP and non-HIMP plants and that there was "equivalent scrutiny of compliance with sanitary dressing and process control[]" as the agency contends in its 2014 evaluation of HIMP plants. While there were similar totals between the types of plants, for those regulations where there were statistically significant differences, the agency conducted more verifications of PHR in non-HIMP than HIMP plants. For the rest of the regulations where the differences were not statistically significant, under conventional statistical analyses, it cannot be determined whether any such differences were merely a product of sampling error in the data.

Finally, the data show that the agency likely committed a fallacy in evaluating the number of PHR verifications per plant in HIMP and non-HIMP plants in CY 2010 to 2013 (only CY 2012 to 2013 reported), if the data is comparable to that which FWW analyzed in FY 2014 to

2017. (See Appendix D.) FWW found that differences in the *total* number of PHR verifications performed per plant were primarily driven by differences in the particular PHR verified at the plant level. That is, whether any given type of plant, HIMP or non-HIMP, had more PHR verifications than the other type was primarily dependent on differences between the allocations of verifications for the particular PHR, rather than the type of plant. Comparing the pooled differences in the number of verifications for all PHRs, between HIMP and non-HIMP plants, as the agency did in its 2014 evaluation of its HIMP pilot, therefore, mathematically masks the differences between the two type of plants when evaluated by the individual PHR, so that the differences appear larger when pooled. To suggest that inspectors performed an equivalent amount of scrutiny in HIMP plants as in non-HIMP plants simply because, on aggregate across all regulations, there were equivalent numbers of verifications in these types of plants is to commit an ecological fallacy, assuming that individual regulations perform the same as they did in aggregate over all regulations. To draw an analogy, the agency's conclusion is like saying that a baseball team that has all-star players with high batting averages hitting at the top of the batting order is about the same as a middle-of-the-road team, based on both teams' batting averages, which include not only those of the batting order's lower spots, but also those of all of the pitchers—even those that rarely bat.

### **Noncompliance Records**

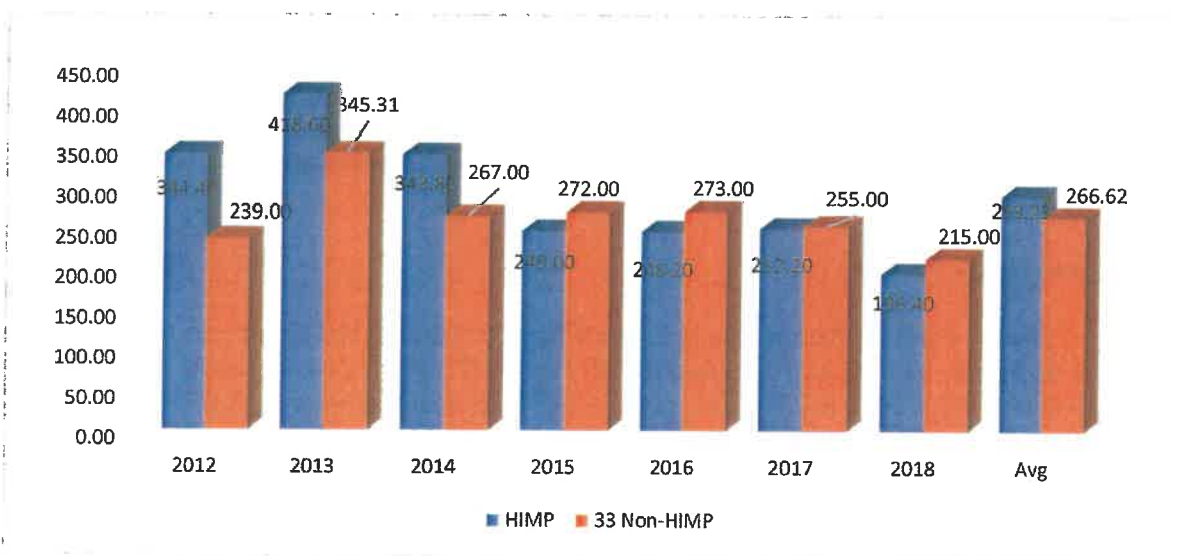
Finally, FWW looked at Noncompliance Record (NRs) in HIMP and non-HIMP plants. While the agency had focused on rates for PHRs in HIMP and the 21-comparator set of non-HIMP plants in CY 2012 to 2013, the agency's risk assessment indicates that all NRs in a study of 159 establishments had the strongest correlation with observed *Salmonella* prevalence. USDA, "Public Health-Based Market Hog Slaughter Inspection Risk Assessment" at 47 (2018). It states that NRs "are expected to be linked to illness rates because the frequency of noncompliance records is a known indicator of establishment performance at achieving public health standards." *Id.* at 65. The risk assessment then used the correlations to model the possible reductions in *Salmonella* illness in 35 plants likely to adopt NPIS, although it excluded NRs in this modeling as a non-decisional variable. *Id.*

FWW examined the total numbers of NRs per plant in 33 of the plants that the agency contends are likely to adopt NSIS from FY 2012 to 2018. Two plants of the 35 likely to switch, M44844 and M51241, were excluded because they did not have any NRs over the relevant time period and were not in the agency's directory of establishments (possibly because they have not yet come online). Also excluded are other plants that the agency analyzed in its risk assessment as likely to switch over, including M20917, M34078, M363, and M9880, as the agency has not included the data from these plants.

On average, HIMP plants had more NRs than non-HIMP plants during this time period. The annual differences are largest in 2012 through 2014 (from 21 to 44 percent more NRs in HIMP plants) while in later years HIMP plants have slightly fewer NRs than traditional plants (from 4 to 11 percent). Overall, HIMP plants had 10 percent more NRs than did traditional plants. While this 33-plant comparator set includes some smaller plants not included in the agency's 21-comparator set, the agency has never provided any justification for selecting these 21 plants, and the agency's set excludes at least one very large high-volume plant that is as big as

any HIMP plant. The agency's set also excludes a number of small high-volume plants that the agency indicates are likely to adopt NSIS.

The agency has provided little to no analysis of how these 35 plants are likely to perform under NSIS. The agency must provide more analysis to determine whether the reported differences are statistically significant by regulation to avoid the same ecological fallacy that the agency has likely committed elsewhere. Regardless, this evidence does indicate that HIMP plants pose a greater risk of producing contaminated pork than non-HIMP plants over this time period. The proposed NSIS rules are very likely to increase the risk of adulterated pork coming from the plants that the agency projects will adopt the inspection scheme.



## Conclusion

FWW's analysis shows that there are serious problems with the HIMP plants that serve as a model for the proposed NSIS rules. Under HIMP, far fewer animals suspected of disease, about 9,000 per plant are sorted and isolated for potential and actual removal as "U.S. Suspect." Inspectors in HIMP plants consistently performed fewer PHR verifications than in non-HIMP plants for a substantial portion of these regulations. For those regulations where the differences between HIMP and non-HIMP plants were statistically significant, inspectors in traditional plants performed more verifications than in HIMP plants. For the rest of the regulations where the differences were not statistically significant, under conventional statistical analyses, it cannot be determined whether any such differences were merely a product of sampling error in the data. Finally, on average, HIMP plants had more NRs than 33 of the non-HIMP plants that the agency believes are likely to adopt NSIS from FY 2012 to 2018.