SAFE FOOD COALITION

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March 30, 2016

Docket Clerk
U.S Department of Agriculture, FSIS
Patriots Plaza 3
355 E Street SW
Mailstop 3782, Room 8-163B
Washington, DC 20250-3700
Re: Docket No. FSIS-2015-0002

Comments of the Safe Food Coalition on the Food Safety and Inspection Service's Approach to testing livestock and poultry carcasses for chemicals that do not have established tolerances or other regulatory levels. Docket No. FSIS–2015–0002

The undersigned members of the Safe Food Coalition appreciate the opportunity to comment on the Food Safety and Inspection Service's (FSIS) Federal Register notice regarding the National Residue Program and Monitoring Chemical Hazards pursuant to the Federal Meat Inspection Act (FMIA) (Docket No. FSIS-2015-0002). The Safe Food Coalition strongly supports efforts to establish formal mechanisms for addressing contamination of FSIS-overseen products by all hazardous chemicals that may find their way into the food supply and threaten consumers' health.

As FSIS points out in its Federal Register notice, the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP) does not effectively or uniformly address heavy metals, dioxins, and many other potential contaminants that fall outside the categories of animal drugs or pesticide chemicals. This regulatory disorder affects consumers. As a recent report from the Pew Charitable Trusts points out, "compounds excluded from the NRP's scheduled sampling clearly do pose an important public health risk."[1] We therefore applaud the agency's decision to set *de minimis* levels for contaminants that will guide agency personnel's actions in the absence of tolerance levels. However, in addition to *de minimis* levels, we urge FSIS to set action levels for such contaminants, beyond which the meat and poultry products would be recalled or removed from the market.

The agency's notice explains that FSIS can refer to established health-based standards to set these *de minimis* levels for all of the chemicals under consideration. Setting the levels therefore falls well within the agency's expertise. It also falls well within the agency's authority. Indeed, FSIS's duty to prevent

[1] The Pew Charitable Trusts. "The National Residue Program for Meat, Poultry, and Egg Products: An evaluation." (March 2016), at p.16 *available at*: http://www.pewtrusts.org/~/media/assets/2016/03/the_national_residue_program_for_meat_poultry_and_egg_products.pdf

"adulterated" products from entering the stream of commerce arguably requires such a threshold determination, particularly in the absence of action from the Environmental Protection Agency or the Food and Drug Administration to set maximum residue limits for these substances. The most straightforward way FSIS could fulfill this duty would be to set an action level for contaminants, beyond which a product would be considered "adulterated," in addition to setting a *de minimis* level.

Going forward, we encourage the agency to document and make transparent its process for setting *de minimis* levels and action levels, to publish data on residues exceeding the *de minimis* levels and action levels in the agency "Red Book," and to elaborate on how the agency will address ongoing contamination by these chemicals. Beyond setting *de minimis* levels and action levels for contaminants in meat and poultry, the agency should put in place clear, scientifically sound criteria to determine which chemicals it tests for in the National Residue Program, and it should disclose this criteria and its evaluation of the health risks associated with chemicals to the public. Pew's recent analysis of the NRP finds that the current criteria for whether to test for a given substance are not transparent, they do not consistently prioritize public health, they rely on questionable scientific studies, and they are internally inconsistent.[2] We encourage FSIS to address these deficiencies when developing *de minimis* levels and action levels.

FSIS acknowledges in its notice that this action responds to concerns raised in a March 2010 USDA Office of Inspector General (OIG) Report.[3] In its report, the OIG recommended that FSIS work with EPA and FDA "to develop a formal plan with reasonable timeframes to establish policies and procedures for handling hazardous substances with no tolerances," and that the agency "develop and implement detailed procedures that specify the actions agency personnel are to take regarding the disposition of carcasses that contain potentially hazardous substance(s), when there are no formal tolerances established by EPA or FDA." The OIG made these recommendations because "there are no established tolerances for heavy metals, such as lead, cadmium, copper, or arsenic in meat," or for "persistent organic pollutants, such as dioxin, polybrominated diphenylethers (fire retardants), and pesticides with cancelled registrations." In interviews with OIG, one FSIS official indicated that without a tolerance level, the agency lacked any authority to act in response to finding unacceptable levels of residues from these chemicals in meat and poultry. Another FSIS official indicated that the absence of a tolerance level created a zero tolerance situation. Both agreed that the agency needed some sort of threshold reference levels to assess these substances. The OIG report notes that the National Academy of Sciences recommended setting thresholds for these chemicals back in 1985, and that other countries have had standards in place for years.[4]

The internal confusion documented in the OIG report demonstrates that, without standards, harmful residues pose a significant danger to consumers. These dangers are not hypothetical. As early as 1997,

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[2] *Id.* at 18.
[3] *See* "FSIS National Residue Program for Cattle." USDA, Office of the Inspector General Audit Report 24601-08-KC, March 2010.
[4] *Id.* at 17.

FSIS inspectors have discovered high levels of dioxins in products headed to the market, with dioxin contamination in Mississippi chicken meat eventually traced back to a soybean feed processed with clay "naturally contaminated by dioxins."[5] These products should not have been permitted to be sold to consumers. Dioxins are highly toxic and can cause reproductive and developmental problems, damage the immune system, interfere with hormones and also cause cancer. The World Health Organization estimates that over 90% of the average human exposure to dioxins results from dietary intake, mainly meat and dairy products, fish and shellfish.[6] Yet FSIS inspectors do not currently test for dioxins with adequate regularity, in part because no tolerance levels, or any other threshold values, are established for these substances.

This treatment of dioxins is in stark contrast to the testing protocols of many U.S. trading partners. In Europe, widespread dioxin contamination in Belgian chicken and eggs in 1999 led to recalls, international trade restrictions, and more stringent regulations.[7] Recently, the European Food Safety Authority ranked "dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) . . . as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels (MLs) and in consideration of their toxicological profile;" whereas "all other substances were ranked as of medium or lower concern."[8] These risk factors apply in the U.S. as well, even though the absence of tolerance levels for dioxins in the National Residue Program suggests otherwise. Establishing a *de minimis* level for dioxin contamination is a necessary, albeit not sufficient, condition for more effective testing. An action level should also be set for dioxins, so that meat and poultry products that exceed such levels can be removed from the market to protect American consumers, much like the Belgian chicken and eggs recalled in 1999. Notably, recent research suggests that European authorities' efforts, which have included recalls, have led to a drop in Europeans' dietary exposure to dioxins over the last decade. Similar efforts should protect American consumers from dioxins.[9]

Heavy metals also pose significant risks. Industry experts recognize, for example, that lead poisoning commonly affects cattle, who "will readily drink crankcase oil, lick grease from machinery and chew on lead plumbing and batteries."[10] No one disputes that cattle with lead poisoning are not fit for human consumption. Without a readily accessible standard, however, FSIS personnel must make an *ad hoc* determination of every positive lead residue result, and decide whether the agency is justified in

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[5] *See* United States Department of Agriculture. "Monitoring Dioxins" in *AgResearch Magazine available at*: http://agresearchmag.ars.usda.gov/2001/jan/dioxin.

[6] World Health Organization. "Fact Sheet No. 225: Dioxins and their effects on human health." (June 2014) *available at*: http://www.who.int/mediacentre/factsheets/fs225/en/

[7] Rainer Malisch and Alexander Kotz. "Dioxins and PCBs in feed and food — Review from European perspective." *Science of The Total Environment* Vol. 491–492, (Sept. 1, 2014), pp. 2–10 *available at*: http://www.sciencedirect.com/science/article/pii/S0048969714003520

[8] EFSA Panel on Biological Hazards, "Scientific Opinion on the Public Health Hazards to Be Covered by Inspection of Meat (Bovine Animals)," EFSA Journal 11, no. 6 (2013): 3266.

[9] European Food Safety Authority. "Dioxins and PCBs report shows drop in dietary exposure over last decade." (July 2012) *available at*: http://www.efsa.europa.eu/en/press/news/120718

[10] *See* The Beef Site. "Lead Poisoning" *available at*: http://www.thebeefsite.com/diseaseinfo/217/lead-poisoning/

taking further action, or even whether further documentation is warranted. A threshold *de minimis* value and an action level would eliminate the need for many of those decisions and would better protect consumers as it would allow for the removal or recall of those products from the market.

FSIS staff have the expertise to determine these values. The agency is proposing that it will establish *de minimis* levels for certain "chemicals of concern," based on health-based guidance values. As the agency points out, for most chemicals, these guidance values are defined already in one or more sources. Where a health-based guidance value is not defined, other sources, such as the Codex Alimentarius, may provide guidance on an appropriate *de minimis* level and action level. We support this approach to defining threshold values for contaminants and encourage FSIS to undertake the development of these values expeditiously for all chemicals that may pose a hazard to consumers.

FSIS indicates that where it finds residues of a certain chemical exceeding the *de minimis* level "on more than an occasional basis," the agency "will consider adding the chemical to the Tier 1 scheduled sampling program." In order to inform that consideration, the agency should publish the results of its Tier 2 exploratory testing in a similar fashion to the residue violations reported in the residue sample results "Red Book."[11] In other words, the agency should disclose how often its testing reveals residues exceeding the *de minimis* level for a given chemical. That information will better enable the public to participate in the agency's decision of whether to elevate a chemical to the Tier 1 program.

Setting *de minimis* levels and action levels for hazardous chemicals lies well within FSIS's authority. The Federal Meat Inspection Act (FMIA) defines a food as "adulterated" if it "contains any poisonous or deleterious substance" in a quantity that ordinarily "render[s] it injurious to health." 21 U.S.C. § 601(m). Moreover, inspectors "shall" condemn any food "found to be adulterated." *Id.* at § 604. Setting *de minimis* levels and action levels for dioxins, heavy metals, and other contaminants is essential to enabling inspectors to fulfill this statutory duty. Similar authority exists under the Poultry Products Inspection Act (PPIA) and the Egg Products Inspection Act (EPIA), as FSIS has recognized.[12]

In some cases, FSIS may need to exercise its authority to protect the public health before elevating a chemical to the Tier 1 program. FSIS explains that it does not expect its Tier 2 exploratory assessment program to cause establishments to take significant mitigating actions "in most instances." However, where an establishment "has received multiple test results that are above the [*de minimis* level] or . . . a test result well above" that level, the agency will work with public partners to determine the cause of the violation "at little or no additional expense to establishments," and the agency suggests that it will rely on voluntary actions from establishments to mitigate the source of the contamination. We agree with FSIS's assessment that setting these de minimis levels should not be expected to result in significant costs to producers, and that voluntary actions may be appropriate. However, FSIS should

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[11] *See* U.S. National Residue Program: 2014 Residue Sample Results *available at*: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/red-books/red-book

[12] *See, e.g.* USDA Food Safety and Inspection Service. "Advisory to Owners and Custodians of Poultry, Livestock and Eggs." (July 8, 1997) *available at*: http://www.fsis.usda.gov/Oa/topics/dioxinlt.htm

also use its current statutory authority to establish action levels that trigger mandatory removal from the market. Moreover, even where no such action level exists, the agency's statutory duty to prevent adulterated products from entering commerce provides it with the authority, and the obligation, to prohibit sales from an establishment that declines to take voluntary mitigation action after receiving multiple positive test results or a result "well above" the de minimis levels.

Thank you for the opportunity to submit these comments.

Sincerely,

Center for Foodborne Illness Research & Prevention

Center for Science in the Public Interest

Consumer Federation of America

Consumers Union

Food & Water Watch