DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

[Docket No. FSIS-2015-0002]

National Residue Program: Monitoring Chemical Hazards

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS; also Agency) is clarifying its approach within the National Residue Program’s (NRP’s) Tier 2 exploratory program when it tests tissue samples collected from livestock and poultry carcasses and detects chemicals that do not have established tolerances or other regulatory levels. This approach applies to potentially hazardous chemicals that are not animal drugs or pesticide chemicals with established tolerances. The Agency also intends to apply this approach to egg products should these products become subject to chemical testing and to products from fish of the order Siluriformes when the final rule to make these species amenable to the Federal Meat Inspection Act (FMIA) is fully implemented. FSIS requests comments on the approach discussed in this document, and on how FSIS can further improve its management
of environmental contaminants and other chemical hazards in meat and poultry products.

DATES: To receive full consideration, comments must be received on [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the online instructions at that site for submitting comments.


Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2015-0002.
Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriot Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Patty Bennett, Humane Handling Enforcement Coordinator, Office of Field Operations, FSIS, USDA; Telephone (202) 720-5397.

SUPPLEMENTARY INFORMATION

Background

To protect consumers and to verify the safety of meat, poultry, and egg products in the United States, FSIS collects samples and analyzes them for a number of potentially harmful chemicals. Historically, the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP), administered by FSIS, has primarily monitored

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1 Products that meet USDA’s definition of ‘egg product’ are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.
livestock and poultry carcasses for animal drugs and pesticide chemicals, which are regulated and approved for use by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), respectively.

However, in addition to animal drugs and pesticide chemicals, there are other chemicals, including metals, mycotoxins, dioxins, and other environmental and industrial contaminants, that may on occasion be found in FSIS-regulated products. The NRP systematically addresses animal drugs and pesticide chemicals, but it has not covered other chemicals in a structured manner. The fact that it has not done so led the USDA Office of the Inspector General (OIG) to recommend, in a March 2010 report on FSIS’s chemical residue program, that FSIS “establish policies and procedures for handling hazardous substances with no tolerances.” While the OIG report concentrated on cattle, FSIS believes this concern applies to poultry and the other amenable livestock species (e.g., hogs, sheep) because issues associated with chemicals without a regulatory tolerance often are associated with sources that could involve more than one establishment and production class, such as contaminated feed. It is common practice for feed

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mills to produce feed for multiple species, and thus, a single contamination event may become an issue for several livestock and poultry production industries. In addition, FSIS does not limit testing for chemicals without tolerances to cattle. In a contamination event, the Agency would conduct testing on all exposed species.

In this notice, FSIS is announcing that it has taken significant steps to enhance its ability to address all types of chemical hazards and is clarifying its approach within the NRP for addressing hazardous chemicals without established tolerances.

Recent Improvements to the National Residue Program

On July 6, 2012, FSIS announced that it was restructuring the NRP with respect to how samples are collected and analyzed for chemical compounds (New Analytical Methods and Sampling Procedures for the United States National Residue Program for Meat, Poultry, and Egg Products, 77 FR 39895). The new methods and procedures that FSIS has adopted have strengthened the NRP by making it into an integrated chemical hazard identification, prioritization, and management program that supports the Agency’s efforts to ensure that the U.S. supply of meat, poultry, and egg products is safe. FSIS has implemented new,
more efficient analytical methods in its laboratories that enable the Agency to detect a greater number of chemicals than had been the case, and, at the same time, FSIS has streamlined its process for collecting samples for analysis.

The restructured NRP consists of three tiers of sampling. Tier 1 is the scheduled sampling program that functions as an exposure assessment and includes sampling of both domestic and imported product. Production classes representing the majority of the annual volume of animals slaughtered in the United States (e.g., beef cows, market hogs, and young chickens) are tested under Tier 1. When a tissue sample from a livestock carcass is collected for residue testing under Tier 1, FSIS withholds the mark of inspection from the livestock carcass until all test results that bear on the determination as to whether the carcass is not adulterated have been received. On the other hand, poultry carcasses are not held pending test results (Not Applying the Mark of Inspection Pending Certain Test Results, 77 FR 73401, Dec. 10, 2012).

Samples tested under Tier 1 are analyzed for a set of chemicals that currently includes animal drugs and pesticide chemicals. When any level of a chemical subject to Tier 1 testing is detected in a livestock carcass muscle sample,
FSIS inspection program personnel are instructed to condemn the carcass and all parts, unless a tolerance level has been set for the chemical in the tissue and production class in question, and the detected level does not exceed this tolerance (Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products, FSIS Directive 10,800.1). As mentioned above, poultry carcasses are generally not held pending the availability of test results, but any FSIS follow-up actions in response to violative results are the same for both poultry and livestock, including consultation with FDA and EPA. In recent years, egg products have not been a focus of the NRP. However, FSIS intends to apply the approach discussed in this notice to all FSIS-regulated products, including egg products, at which time egg products become subject to chemical testing. Thus, this notice generally refers to “carcasses,” even though analogous actions may be taken with respect to FSIS-regulated egg products.

Tier 2 testing encompasses two separate programs. The first, known as the inspector-generated program, is a targeted testing program in which field public health veterinarians (PHVs) decide to perform in-plant screens because they suspect that animals or carcasses contain
higher than allowable levels of chemical residues. FSIS inspectors will collect and submit samples for inspector-generated residue testing if a screen test is positive, or if a PHV has reason to believe that a carcass or its parts may contain violative levels of one or more chemical residues, even if the screen test is negative (Residue Sampling, Testing and Other Verification Procedures under the National Residue Program, FSIS Directive 10,800.1, Rev. 1).

The second, Tier 2 testing program, known as the exploratory assessment program, includes sampling plans designed in response to information gained from previous exposure assessments, from the chemical hazard identification process, or from other agencies. Unlike livestock carcasses selected for sampling under Tier 1 or under the inspector-generated program, carcasses selected for sampling under the exploratory assessment program can be released into commerce before exploratory sampling results are available. Essentially the exploratory assessment program is designed to investigate animal populations when the compounds in question have no established tolerances; respond to intelligence regarding use of veterinary drugs, pesticides, and environmental contaminants reported from the
field; determine the prevalence and concentration of residues; and evaluate residue trends.\(^3\) FSIS uses the results from these exploratory assessments to identify potential chemical hazards of concern and to inform FSIS and NRP priorities. The exploratory assessment program includes testing for veterinary drugs, pesticides, and several metals.\(^4\)

Tier 3 testing occurs in response to indications of chemical exposure to more than a single animal and encompasses targeted testing at the herd or flock level. Events triggering this type of testing are rare and usually involve extensive coordination between federal and state agencies at both the local and headquarters levels.

This notice provides clarification to the Tier 2 exploratory assessment program.

Current Regulatory Framework

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Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.), FSIS inspection personnel apply the mark of inspection to meat, poultry, and egg products only if they find upon inspection that these articles are not adulterated (21 U.S.C. 455, 457, 604, 606, 607, 1034, 1036). Under the Acts, meat, poultry, and egg products that do not bear an official mark of inspection are misbranded (21 U.S.C. 601(n)(12), 453(h)(12), and 1034). The Acts prohibit the sale or transportation in commerce of meat, poultry, and egg products capable of use as human food that are adulterated or misbranded or that have not been inspected and passed (21 U.S.C. 458(a)(2), 610(c), 1037(b)).

Under the FMIA, “any carcass, part thereof, meat or meat food product” is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in the case the substance is not an added substance, such article shall not be considered adulterated ... if the quantity of such substance in or on such article does not ordinarily render it injurious to health” (21 U.S.C. 601(m)(1)). Under the FMIA, a product is also adulterated “if it bears or contains by reason of
administration of any substance to the live animal or otherwise any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity, (ii) a food additive, or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food” (21 U.S.C. 601(m)(2)(A)). In addition, a product is adulterated under the FMIA if it bears or contains any pesticide chemical, color additives, or food additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetics Act (FFDCA) (21 U.S.C. 601(m)(2)(B)-(D)). Both the PPIA and EPIA contain similar provisions (21 U.S.C. 453(g)(1)-(2) and 1033(a)(1)-(2)).

As mentioned above, because FSIS has primarily monitored livestock and poultry carcasses for animal drugs and pesticide chemicals, the approach described in this notice is initially intended to apply to livestock and poultry carcasses. FDA and EPA have statutory authority to establish residue tolerances that allow certain chemicals to remain in food products in non-harmful quantities, without causing these products to be adulterated. Under the FFDCA, the FDA may establish tolerances regulatory limits, and other limitations or specifications for animal drugs,
approve food additives including conditions under which they may be used, and establish tolerances and regulatory limits for added or naturally occurring poisonous or deleterious substances, and the EPA may establish tolerance levels for registered pesticides. Title 21 of the Code of Federal Regulations (CFR) sets out tolerances and regulatory limits established by FDA, while Title 40 of the CFR sets out the tolerance levels established by EPA. In addition, FDA may also establish non-binding action levels that provide guidance for levels of contamination at which a food may be regarded as adulterated.

Many of the tolerances and regulatory limits applicable to meat, poultry, or egg products have only been established for chemicals that are either animal drugs or pesticide chemicals. Yet other hazardous chemicals exist that do not have established tolerances, regulatory limits, or action levels but that could nonetheless be present in FSIS-regulated products at levels that may cause consumers to exceed a risk level for human consumption.\(^5,6\) This group of

chemicals includes, but is not limited to, environmental contaminants, heavy metals, industrial chemicals, and mycotoxins. Unlike animal drugs or pesticide chemicals, these chemicals are usually not intentionally administered to food-producing animals or feed crops as part of accepted husbandry and agricultural practices. As such, they may not usually be reviewed by FDA or EPA as part of an approval process and hence may not have tolerances like animal drugs and pesticide chemicals and may not be subject to other regulatory limits. In most cases, the presence of these chemicals in edible animal tissue results from the food-producing animal’s ante-mortem exposure to the chemical through feed, water, air, soil, or direct application.

When a livestock or poultry carcass tested under the Tier 1 or the Tier 2 inspector-generated program is determined to contain a level of an animal drug or pesticide chemical that exceeds the applicable tolerance set by FDA or EPA, the carcass and parts are adulterated under the FMIA or PPIA and as such must be condemned.\footnote{For example, for dioxin-like compounds, see results from FSIS dioxin surveys at: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry.}

\footnote{If there is no tolerance for an identified animal drug or pesticide subject to Tier 1 testing, carcasses or parts containing any amount of the substance are condemned.}
provides instructions to FSIS personnel on the disposition of carcasses containing violative residues and on other procedures related to residue sampling under the Tier 1 and inspector-generated programs.

In contrast, although FSIS has detected, and continues to detect, environmental contaminants and other potential hazardous chemicals without established tolerances or regulatory levels through its exploratory assessment program, the Agency does not have a consistent and structured procedure for addressing these exploratory assessment results. Therefore, to better address the potential human health risks that may be associated with the presence of environmental contaminants and other potential chemical hazards without tolerances in meat and poultry products, FSIS is providing information regarding its approach to responding to findings from its exploratory sampling program. This information is intended to clarify how the Agency will respond to sampling results that reveal the presence of contaminants and chemicals of this type.

FSIS is publishing this Federal Register document to inform the public of approach and to request public comments.

Structured Approach for Chemicals without Established Tolerances
FSIS intends to proceed as follows when chemicals without established tolerances or other applicable regulatory levels are detected in livestock or poultry carcasses. For chemicals designated for testing in the Tier 2 exploratory assessment program, FSIS will derive a de minimis level (DML) for the chemical in samples collected from a given production class or species below which FSIS is confident that any public health concern is nonexistent or negligible (next section describes the derivation of the DML). If the concentrations of the chemical detected in Tier 2 exploratory testing are consistently at or below the DML, FSIS will likely discontinue the exploratory testing for that chemical.

If, based on FSIS testing results, carcasses in Tier 2 testing are found to contain levels of a chemical above the de minimis level, FSIS will take certain actions, including notifying the slaughter or processing establishment or other affected entities, such as suppliers of the source animals, if needed, of the presence of the chemical and notifying the appropriate federal partners for possible trace-back investigations and consideration of potential mitigation actions. This approach is one that FSIS has historically taken on an ad hoc basis for chemical exposure incidents and
in its dioxin surveys, and one that the Agency will continue to apply in this more structured approach for the exploratory chemicals in Tier 2 that are detected above the DML. Carcasses subject to Tier 2 exploratory sampling are typically not held pending the exploratory testing results. As discussed below, the Agency intends to assess levels of chemicals subject to exploratory sampling over time to evaluate the need to revise this policy.

If the levels of the chemical are found to be above the DML on more than an occasional basis, FSIS will consider adding the chemical to the Tier 1 scheduled sampling program. FSIS will consult with the appropriate federal agency (FDA or EPA) regarding such an action and will issue a notice in the Federal Register to request public comments before placing such a chemical into Tier 1. If the chemical without a tolerance or other regulatory level is placed in Tier 1, FSIS will not apply the mark of inspection to livestock carcasses that have been sampled for testing until results at or under the DML are available and received for any testing conducted by the Agency. In the further absence of a tolerance or other regulatory level, the detection of

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any chemical levels over the DML would preclude FSIS from determining that the carcass or its parts are not adulterated.

Deriving De Minimis Levels (DMLs)

The DML is a concentration of the chemical in a particular edible tissue below which any risk to public health is negligible (de minimis risk). FSIS intends to use the DML as a guide to help ascertain whether a test result from the Tier 2 exploratory assessment program needs follow-up actions or not. The derivation of a DML follows standard and routinely accepted risk assessment approaches. The DML is derived from a health-based guidance value for the given chemical, which is usually a human intake value (e.g., oral dose exposure) that is likely to be without an appreciable risk of deleterious effects during a lifetime, like a reference dose (RfD) or an acceptable daily intake (ADI). Health-based guidance values for many chemicals are published by agencies such as the EPA, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). If

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significant exposure routes other than meat or poultry products exist for the chemical hazard, an appropriate fraction of the health-based guidance value will be allocated to these other exposure routes. To arrive at the DML, the health-based guidance value — or the fraction thereof allocated to the meat or poultry products in question — will be used together with consumption estimates taken from the What We Eat in America (the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES)) or other appropriate consumption data.\textsuperscript{10,11}

For almost all chemicals being considered for Tier 2 exploratory testing, a health-based guidance value exists, and the DML will be derived as described above. In the extremely rare instance where there is not a health-based guidance value, FSIS will work its federal partners to decide on a course of action to develop one. In other instances however, a DML equivalent, such as a maximum level determination by the Codex Alimentarius, is available for

\textsuperscript{10} http://www.cdc.gov/nchs/nhanes.htm

specific chemicals in specific food commodities (e.g., for lead in meat of cattle, pigs and sheep\textsuperscript{12}). In these instances, FSIS will use such values as the DML.

**Identifying Chemicals of Concern**

FSIS may identify potential chemicals of concern for testing and the possible presence of chemical hazards in meat and poultry products through scientific literature reviews, expert elicitations, attendance at scientific meetings, collaboration with Federal, State, and international partners, and communication with stakeholders and trade partners. FSIS will also consult with its NRP collaboration body, the interagency Surveillance Advisory Team (SAT)\textsuperscript{13}, for guidance on which chemicals to pursue in the Tier 2 exploratory program and for derivation of DMLs.

Moreover, the multi-residue methods recently adopted by FSIS laboratories not only enable the Agency to test for a greater number of animal drug and pesticide chemical

\textsuperscript{12} Found in: Codex General Standard For Contaminants And Toxins In Food And Feed. At: http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1?provide=standards&orderField=ccshort&sort=asc&num=.

\textsuperscript{13} The Surveillance Advisory Team (SAT), is an interagency committee comprised of representatives from FSIS, FDA, EPA, AMS, ARS, and CDC. It consists of experts in veterinary medicine, toxicology, chemistry, and public health who provide professional advice, as well as information on veterinary drug and pesticide use in animal husbandry. The purpose of the SAT is to enhance communication, which includes obtaining and evaluating relevant toxicity and exposure information for each compound that supports the NRP.
residues than in the past but also allow detection of a greater number of other potentially harmful chemicals, most of which do not have regulatory tolerances. As mentioned, FSIS has already been collecting data on certain environmental contaminants, including several metals, through its Tier 2 exploratory sampling.

As a result of these efforts, FSIS may identify a chemical in meat or poultry products that is not being monitored by the Agency, and for which no applicable tolerance exists. In most such cases, FSIS will seek to empirically confirm the chemical’s presence in FSIS-regulated product through a Tier 2 exploratory assessment, which may be run for a period of time (e.g., one year) and will record baseline levels of the chemical.

Cost-Benefit Analysis

No significant costs to establishments, regardless of size, are expected as a result of the Tier 2 exploratory assessment program. The purpose of this sampling is to determine prevalence and levels of various hazardous chemicals in meat and poultry carcasses. Exploratory testing is being conducted under the NRP at little or no additional cost to the establishment or to the Agency. Once a DML is established, and FSIS is confident that these
products are not adulterated based on the results from the exploratory testing, FSIS will then be able to limit the scope of this testing in the future. As mentioned, establishments will receive notification if any results of those tests are above the DML. There is no requirement for establishments to hold carcasses until acceptable results are available (as for Tier 1 and Tier 2 inspector-generated samples) under Tier 2 exploratory sampling, so there is no establishment cost associated with Tier 2 exploratory assessment program.

In most instances, FSIS does not expect establishments to take significant mitigating actions as a result of Tier 2 exploratory sampling since the purpose of this sampling is to inform the Agency on general prevalence, and not the performance of a particular establishment. However, if an establishment has received multiple test results that are above the DML or if it receives a test result well above the DML, FSIS will consult and work with its federal, state and local partners to determine the cause of the positive test results at little or no additional expense to establishments. Once a cause has been discovered, the establishment may receive a letter from FSIS or its partner agencies (which could include any test results, possible
leads of sources of contamination to evaluate, and provide opportunities to consult with the appropriate agencies), at which time the establishment may voluntarily choose to incur the additional costs of certain mitigating actions, such as discarding feed or replacing feed troughs. Given its experience under the dioxin survey program and the ongoing Tier 2 exploratory program for veterinary drugs and pesticides, FSIS expects these follow-up letters and mitigating actions to be a rare occurrence while products from an establishment are tested in the Tier 2 exploratory assessment program.

If a chemical is moved into Tier 1 sampling, the Agency will inform the public and will conduct a cost-benefit analysis for the specific chemicals and products involved. The public will then have the opportunity to comment on the cost-benefit analysis.

Request for Comments

The approach discussed in this notice is intended to provide more structure and consistency for existing FSIS procedures and practices for addressing chemicals in livestock and poultry carcasses that do not have established tolerances or other regulatory levels. The approach is designed to cover most chemical hazards that do not derive
from animal drugs or pesticide chemicals. As part of an integrated chemical hazard identification, prioritization, and management system operating under the NRP, FSIS intends to use the risk-based procedures described in this document to efficiently and effectively address public health concerns associated with chemical hazards that may be detected in livestock and poultry carcasses. FSIS requests comments on the approach discussed in this document, and on how FSIS can further improve its management of environmental contaminants and other chemical hazards in meat and poultry products.

**USDA Non-Discrimination Statement**

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accessed online at:
http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

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U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410
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E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at:
FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done in Washington, DC: December 18, 2015.

Alfred V. Almanza,

Acting Administrator.

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