

U.S. Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
Data Summary of Siluriformes Fish Testing:
A Five-Year Review, FY 2016-2020
March 29, 2022

Tracy Berutti
Randolph Duverna
Gurinder Saini
Wayne Schlosser
Erika Stapp-Kamotani

Contents

Executive Summary	4
Introduction	4
Purpose	4
Overall Findings	4
Recommendations	5
Background	6
History	6
2015 Risk Assessment	6
Salmonella	6
Salmonella Illness Estimates from 2015 Risk Assessment	7
Current Inspection/Testing Program Features	7
Domestic	7
Import.....	7
Domestic vs Import Volume.....	7
Methods/Approach.....	8
Microbiological Testing	8
Chemical Residue Testing.....	8
Literature Review	8
Contaminants in the Environment.....	8
Aquaculture.....	9
Salmonella in Siluriformes Fish Production	9
Outbreak Data	9
Data	10
Results	10
General Testing Results.....	10
Chemical Residues.....	11
Dyes.....	11
Multi-Residue Method (MRM).....	12
Nitrofurans	13
Pesticides	14
Metals	17
Arsenic.....	19

Siluriformes fish data summary 29 March 2022

Strontium	20
Lead	20
Nickel.....	21
Cadmium	21
Chromium.....	22
Salmonella.....	22
Risk Characterization for Salmonella	24
Salmonella Sampling for Siluriformes Fish Compared to Other Commodities	25
Conclusions	26
Recommendations	26
Appendix A: List of screened veterinary drug residues	29
Appendix B: List of screened pesticides.....	30
Appendix C: Determining proportion of Siluriformes fish servings	31

Executive Summary

Introduction

On December 2, 2015, FSIS published the final rule “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” (80 FR 75590) that establishes a mandatory inspection program for these fish and for products derived from these fish, including imported fish products. The risk assessment that informed this rule identified various hazards that could be present in Siluriformes fish such as pesticides, veterinary drugs, and other chemical residues. The risk assessment identified *Salmonella* as the primary microbial hazard likely to be present with an estimated 2,400 illnesses attributed per year. FSIS began testing raw Siluriformes products for chemical residues, speciation, and *Salmonella* in May 2016. Under the U.S. National Residue Program (NRP), FSIS conducts testing for approved and unapproved veterinary drugs, pesticides, and environmental contaminants known or suspected to be present in food animals. In addition, FSIS collects samples to monitor for the presence of *Salmonella* in raw Siluriformes fish.

Scope

This report includes five years of both domestic and import testing data for raw Siluriformes products for chemical residues (veterinary drugs, dyes, pesticides, and metals) and *Salmonella*. The years covered are fiscal years (FY) 2016 through 2020. Some recent developments related to Siluriformes testing for chemical residues are excluded from this report, namely, testing 16 per- and polyfluoroalkyl substances (PFAS) beginning in FY 2021, the results of the 2018 Dioxin Survey that include Siluriformes samples, and detections of semicarbazide (SEM) in imported Siluriformes. Additionally, in FY 2020, FSIS expanded National Antimicrobial Resistance Monitoring System (NARMS) testing to include Siluriformes fish. FSIS intends to publish additional results when sufficient data is collected to conduct a meaningful analysis of changes over time.

Purpose

In 2019, FSIS published the *Strategic Evaluation of Sampling Resources (SASR)*. The underlying premise of that evaluation was that FSIS sampling only fulfills its purpose when the data it generates is used by the Agency. As of the end of fiscal year (FY) 2020, FSIS has tested raw Siluriformes products for five consecutive years. To fulfill the premise of the SASR evaluation—and to routinely review FSIS testing data and utilize that data in Agency decision-making—this report summarizes those five years of Siluriformes testing and provides recommendations for future FSIS sampling activities related to raw Siluriformes products based on the data.

Overall Findings

By the end of FY 2020, 10,116 samples had been collected and analyzed since FSIS began Siluriformes testing in May 2016. Samples were submitted for either microbiological testing or chemical residue testing.

Chemical residue data analysis was divided into separate sections based on analytical methods: dyes, multi-class residue method, nitrofurans, pesticides, and metals.

The residue detection rate has declined since Siluriformes testing began. For example, at the beginning of the program over 7% of samples tested positive for dyes. That value fell to less than 1% after testing began and

has remained low. Other veterinary drugs were verified to have detection rates below 1% throughout the testing program. For contaminants such as pesticides and metals, a disproportionate number of positive tests come from wild-caught Siluriformes fish where exposure cannot be controlled. Nevertheless, less than 1% of tests were positive for pesticides. Of the metals detected, most positive tests were for metals not of toxicological concern. For metals of toxicological concern, tested samples had levels that were either below the Environmental Protection Agency (EPA) limits or below values set by other countries for their imports.

With regards to *Salmonella*, FSIS testing indicates that domestic Siluriformes fish have an average of 3.53 percent positive from FY 2016 to FY 2020. Imported Siluriformes fish have an average 0.32 percent positive from FY 2016 to FY 2020. This difference may be attributed to imported Siluriformes fish typically being frozen, whereas domestic Siluriformes fish are typically fresh. While *Salmonella* is present on Siluriformes fish, there is limited data to support Siluriformes fish attribution to any *Salmonella* illnesses or outbreaks, except for an outbreak identified 30 years ago. Most Siluriformes fish are consumed fully cooked, which could explain the limited illnesses and outbreaks associated with this commodity. Based on consumer cooking practices, lack of recent outbreaks attributed to Siluriformes fish, and low percent positives, Siluriformes fish appear to present a low risk to public health.

For the low number of estimated *Salmonella* illnesses attributed to Siluriformes fish, FSIS is greatly over-sampling Siluriformes fish compared to other products. Two different attribution models resulted in current estimates of 930 and 1,080 annual illnesses due to *Salmonella* in Siluriformes. Changes in consumer cooking practices or in the processing environment (to where Siluriformes fish have a higher *Salmonella* percent positive) may alter the public health significance.

Recommendations

The following recommendations are made with the intent to better understand the risk posed by possible contaminants in Siluriformes fish:

1. Develop a research priority for examining the effect of freezing on recovery of *Salmonella* from Siluriformes using FSIS methods. Different studies using different animal products yield different results. Knowing the \log_{10} reduction expected from freezing would allow FSIS to better evaluate results from imported frozen Siluriformes.
2. Consider suspending current FSIS *Salmonella* sampling in Siluriformes based on the updated illness estimates from the attribution-based risk assessment, the low overall occurrence of *Salmonella* in FSIS Siluriformes sampling results, and the absence of outbreaks attributable to Siluriformes.
3. Conduct further analysis (speciation) of positive arsenic samples to verify the presence of organic arsenic rather than inorganic arsenic. This would increase confidence in the safety of FSIS inspected product.

Background

History

On December 2, 2015, FSIS published the final rule “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” (80 FR 75590) that establishes a mandatory inspection program for Siluriformes fish and for products derived from these fish, including imported Siluriformes fish products. The final rule explains that because these fish are amenable species under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w)(2)), the inspection program for these fish is part of FSIS’ meat inspection program.

2015 Risk Assessment

FSIS published a risk assessment that informed this final rule in 2012. The assessment was updated in 2015. The risk assessment identified various chemical hazards that could be present in Siluriformes fish such as pesticides and veterinary drugs. The risk assessment also identified microbial hazards. The risk characterization focused on illnesses from *Salmonella*. The main objectives of the risk assessment were to estimate the annual numbers of human salmonellosis cases from Siluriformes with its accompanying uncertainty and to estimate the potential number of cases that might be avoided following implementation of an FSIS inspection program.

Salmonella

Regarding *Salmonella*, the 2015 risk assessment noted:

“Several bacterial pathogens have been associated with farmed-raised fish [1]. Because Siluriformes is typically cooked prior to consumption, Siluriformes-associated bacteria do not routinely present problems of public health concern [2]. Therefore, defining a specific pathogen as a microbiological hazard based on epidemiological data is a challenge.

Salmonella is a potential microbial hazard for aquatic environments and, thus, may be a concern with respect to fish products. Non-typhi *Salmonella* are regarded as one of the higher-priority hazards because the general burden of illness from this pathogen in the U.S. remains a concern. There is evidence that at least one outbreak of human salmonellosis may have been related to Siluriformes consumption. Specifically, the CDC surmised that an outbreak of 10 cases of salmonellosis (*Salmonella hadar*) at a restaurant in 1991 may have been caused by Siluriformes consumption [3]. Additional outbreaks or illnesses specifically attributed to *Salmonella* in Siluriformes were not identified in the literature review. No outbreaks or illnesses of *Salmonella* in Siluriformes have been reported to FSIS since 2016, when FSIS implemented mandatory inspection.

Salmonella was reported in 21% of 153 aquaculture catfish collected from aquaculture ponds and retail markets [4] and can be harbored within catfish for 30 days after exposure to high levels [5]. McCaskey et al. found *Salmonella* on 2.3% of 220 fillets sampled from three processing plants [6]. Heinitz et al. reported FDA *Salmonella* testing from imported (11,312 samples) and domestic (768) seafood samples tested from 1990 to 1998 [7]. They found that 10% of imported and 2.8% of domestic raw seafood was positive for *Salmonella*. For Fin Fish/Skin Fish in that study, the percent positive was 12.2% and 1.3% for imported and domestic, respectively. An examination of FDA seafood import

refusal data from 1998-2004 identified *Salmonella* contamination to be the most frequent violation in catfish (41.91% of violation categories) [8].”

Salmonella Illness Estimates from 2015 Risk Assessment

The 2015 risk assessment used two different methods to estimate illnesses from *Salmonella* in Siluriformes fish. One method was to develop a mechanistic model that considered *Salmonella* concentration on fish, methods of cooking, serving size, and dose response. This mechanistic model yielded an estimate of 2,308 illnesses annually. A boundary analysis of possible input ranges yielded a lower bound of 100 illnesses and an upper bound of 16,000 illnesses.

The other method used an attribution model. This model was based on how many *Salmonella* illnesses occur annually and how many of those could be attributed to Siluriformes based on reported outbreaks. This method yielded an estimate of 2,400 illnesses with a lower limit of 280 and an upper limit of 6,700.

Current Inspection/Testing Program Features

FSIS conducts testing on raw Siluriformes fish products for chemical residues, speciation, and *Salmonella*. This testing ensures that the product is not adulterated with violative chemical residues. It also ensures the product is not misbranded based on species testing. In addition, FSIS monitors for the presence of *Salmonella* in raw Siluriformes fish products. *Salmonella* is not considered an adulterant in raw products, but test results can be used to monitor the effectiveness of the inspection program.

Domestic

Domestic Siluriformes fish are sampled according to [FSIS Directive 14,010.1](#), *Speciation Residue and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments*. Eligible samples include single ingredient, intact samples. Multi-ingredient (including breaded products) and non-intact products (e.g., vacuum-tumbled, injected) are not eligible for testing.

Import

Imported Siluriformes fish are sampled according to [FSIS Directive 14,100.1](#), *Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments*. Eligible samples include intact samples. Non-intact products (e.g., vacuum-tumbled, injected) and breaded products are not eligible for testing.

Domestic vs Import Volume

For domestic samples FSIS collects estimated daily volume and production days per month when samples are collected. Monthly domestic volume is estimated by multiplying estimated daily volume (the midpoint of a selected range) by production days for unique month/establishment combinations. Information on whether the fish were wild-caught or farm-raised is usually available. For imported samples, product lot volumes are given. Using these values for FY 2019 and FY 2020, domestic Siluriformes fish represented about 70% of total volume (7% wild-caught) and imported Siluriformes fish about 30%. The National Agricultural Statistics Service

estimates domestic sales of about 348 million pounds in CY 2019 and 324 million pounds in CY 2020 ([Catfish Production 02/08/2021 \(usda.gov\)](#)). The National Oceanic and Atmospheric Administration estimates imports of 200 million pounds in 2019 and 209 million pounds in 2020 ([HOME \(noaa.gov\)](#)).

Methods/Approach

Microbiological Testing

Inspection program personnel collect Siluriformes fish samples at domestic establishments (per [FSIS Directive 14,010.1](#)) and at official import inspection establishments (per [FSIS Directive 14,100.1](#)). Samples are shipped overnight to one of three field service laboratories to be analyzed. Laboratory personnel analyze raw Siluriformes fish samples for *Salmonella* according to [Chapter 4 of the Microbiology Laboratory Guidebook](#). Analysts aseptically cut a 25 ± 6.5 g sample and combine it with 225 ± 4.5 mL of buffered peptone water (BPW) in a sterile bag. After hand stomaching, the sample is incubated at $35 \pm 2^\circ\text{C}$ for 22-26 hours. Enrichments are screened molecularly. *Salmonella* isolated from positive samples is confirmed phenotypically. The isolates are further characterized by antimicrobial susceptibility testing and whole genome sequencing. Serotype is then determined from the genomic data.

Chemical Residue Testing

An essential aspect of food safety in meat, poultry, and egg products is the control of residues that may result from the use of veterinary drugs and pesticides, or from exposure to environmental contaminants. Under the NRP, four analytical methods were used by FSIS to test for approximately 250 different veterinary drugs, pesticides, and environmental contaminants in Siluriformes fish. Testing includes drugs approved by the Food and Drug Administration (FDA) for use in fish as well as unapproved drugs that FSIS has a basis for believing, due to FSIS' familiarity with U.S. aquatic production, are available to and could be improperly used by U.S. Siluriformes fish producers. A violation occurs when an FSIS laboratory detects a chemical compound at a level that exceeds an established tolerance or action level for that compound, or if the specific type of chemical compound does not have an established tolerance. Violative residues render Siluriformes fish product adulterated under the [FMIA](#).

Literature Review

Contaminants in the Environment

Chemical contamination from manufacturing, runoff, effluent discharges, and other anthropogenic activities is a worldwide concern. Although some chemicals are transformed in the environment, chemicals or their metabolite residues may form persistent deposits in sediment [9, 10]. Siluriformes fish are benthic, or bottom-dwelling, feeders. As such, they are exposed to residues in both water and sediment. Residues can accumulate in the muscle tissue or fat and be potentially hazardous to wildlife and human health, depending on the amount of fish consumed [9, 11]. Watanabe et al. (2003) analyzed fish tissues for chemical contamination in the lower Mississippi River [10]. The resulting risk assessment named twelve species of concern; seven of them were benthic feeders, including three species of Siluriformes fish [12]. As residues increase in the environment, there is an increased risk of interference in biological processes by altering the composition of bacterial communities [13].

Aquaculture

Many fish belonging to the order Siluriformes are resilient and adaptable to harsh conditions, including low dissolved oxygen, that are common in aquaculture ponds. Their hardiness, growth rate, feed conversion efficiency, and ease of reproduction make them ideal candidates for aquaculture. Siluriformes fish constitute 60% of all aquaculture production in the U.S. [14]. However, farmed fish may still be exposed to contaminants through runoff, soil seepage, or wind [9].

Farmed fish may also be exposed to bacterial or chemical contaminants through feed [15, 16]. *Salmonella* has been found in multiple feed ingredients and in feed processing establishments. *Salmonella* strains in feed tend to be more heat resistant due to the drying process. However, if the dose is small, the risk of colonization in the fish is low [15].

Overuse of antibiotics and the resulting residues in the environment contribute to increases in antibiotic resistant bacteria. In aquaculture, several antibiotics are approved to treat disease. Triphenylmethane dyes, such as malachite green and crystal violet, have been used in aquaculture to prevent and control fungal growth, since the early 1900s [17]. Increased exposure to antibiotic resistant bacteria may lead to treatment failure in both animals and humans [18].

Schar et al. (2020) estimated that over 10,000 tons of antimicrobials were used in aquaculture globally in 2017 and that 8.3% of those compounds were applied to farmed Siluriformes fish [13]. Almost 90% of global aquaculture production is in Asia but it is expanding in developing nations. By 2030, it is possible that the number of antimicrobials used in aquaculture could increase by 33%. Advancements in husbandry and non-pharmaceutical interventions could reduce the potential environmental impacts [13].

Salmonella in Siluriformes Fish Production

As in all food processing, the proper implementation of Hazard Analysis and Critical Control Point (HACCP) is essential to reduce the risk of contamination, either directly or indirectly through cross-contamination. Once *Salmonella* forms a biofilm, it is difficult to eliminate from the processing environment. Although Siluriformes fish mucus has been shown to promote the growth of *Salmonella*, there are no published articles discussing persistent *Salmonella* in Siluriformes fish production [19]. Love et al. (2021) analyzed various hazards along the supply chain and showed that Siluriformes fish are safer across a broad category of risks including microbial risks than most other aquaculture species [20].

Outbreak Data

While *Salmonella* is present on Siluriformes fish, there is limited data to support Siluriformes fish attribution to any *Salmonella* illnesses or outbreaks, except for an outbreak identified 30 years ago [21]. The Interagency Food Safety Analytics Collaboration's (IFSAC) multi-year outbreak data model estimates that 2.1% of *Salmonella* can be attributed to fish of any kind. This model gives more weight to outbreaks that occurred in the last five years (IFSAC 2020). According to CDC's National Outbreak Reporting System (NORS), 655 foodborne outbreaks in the U.S. have been attributed to fish of any taxonomic order between 2000 and 2018. In all fish, 43% of attributed outbreaks were linked to scombroid fish poisoning, or a buildup of histamine in

fish tissues because of bacterial activity; poisoning of this type is due to temperature abuse of the product. Toxins produced by harmful algae blooms contributed 39.5% of the outbreaks. One outbreak was linked to heavy metal contamination. Nineteen of the outbreaks were linked to *Salmonella*. Of these, three were associated with tuna that may have been consumed raw. Eleven of the outbreaks could not specifically be linked to fish as the dish had multiple ingredients. For example, four were connected to gefilte fish, a prepared dish that also includes egg. The remaining outbreaks were associated with red snapper, smoked salmon, striped bass, flounder, codfish, tilapia, or an unspecified finfish species. There were four total outbreaks attributed to Siluriformes fish; two were of unknown etiology, one was linked to enterotoxigenic *Escherichia coli* and another was due to an unknown chemical or toxin. There were no known outbreaks of *Salmonella* attributed to Siluriformes fish.

Data

Laboratory test results for both chemical residue and pathogen testing are stored in the Public Health Information System. Data were summarized using Microsoft Excel and the results are provided below.

Results

General Testing Results

Since FSIS began Siluriformes fish testing, in May 2016, 10,116 samples were collected and analyzed. Of those, 4,253 samples were from domestic Siluriformes fish and 5,863 were from imports (Table 1). Samples were submitted for either microbiological testing or chemical residue testing.

Table 1. Types of samples collected for fish of the order Siluriformes fish in fiscal years 2016 through 2020.

Type of sample	Number
Domestic	4,253
Import	5,863
Total	10,116

As FSIS began incorporating testing of Siluriformes fish, relatively few samples were collected in the first two years of the program. Gradually, testing numbers increased in FY 2019 and FY 2020 (Table 2). By volume, proportionally more samples are collected for imported samples than for domestic samples, though it should be noted that samples from imported product represent only that specific lot while samples from domestic product are more representative of an ongoing process.

Table 2. Types of samples collected for fish of the order Siluriformes fish in fiscal years 2016 through 2020.

FY	Domestic		Import		Total
	Microbiological	Chemical residue	Microbiological	Chemical residue	
2016	77	78	42	84	281
2017	192	201	213	436	1,042
2018	613	636	221	580	2,050
2019	608	618	745	1,563	3,534
2020	607	623	652	1,327	3,209
Total	2,097	2,156	1,873	3,990	10,116

Chemical Residues

Analysis of chemical residue data was divided into separate sections based on analytical methods: dyes, multi-class residue method, nitrofurans, pesticides, and metals. For some domestic samples we could determine whether the source was farm-raised or wild-caught. Based on those samples, FSIS estimates that about 7% of domestic production comes from wild-caught Siluriformes fish. In cases where a violation is reported, FSIS shares the violation data with the EPA, as well as with the FDA when the FDA has on-farm jurisdiction. Because FSIS began testing for additional contaminants such as PFAS, semicarbazide, and dioxins in FY 2021, those results are not included in this report which covers only from FY 2016 to FY 2020. FSIS intends to publish these results when sufficient data is collected to conduct a meaningful analysis of changes over time.

Dyes

FSIS currently tests for the presence of the dyes crystal violet and malachite green. Both of these dyes have been used for their antimicrobial properties [22]. Due to their carcinogenicity, mutagenicity, and teratogenicity potentials, many countries, including the United States, have prohibited the use of these dyes in feed and aquaculture production [23]. Detection of crystal violet and malachite green, with their respective metabolites (leucocrystal violet and leucomalachite green), results in a residue violation in Siluriformes fish.

From FY 2016 to FY 2020, 3,147 Siluriformes fish samples were tested for dyes. Of these, 30 (0.95%) were violative. Samples of imported Siluriformes fish were twice as likely to have violative levels of dyes as domestic samples were (Table 3); although the difference was not statistically significant ($p=0.07$).

Table 3. Results of testing for dyes in domestic vs. imported Siluriformes fish.

	Violative	Non-Detect	Total	% Pos
Domestic	6	1,121	1,127	0.53%
Imported	24	1,996	2,020	1.19%
Total	30	3,117	3,147	0.95%

For some domestic samples, FSIS identified whether the source was farm-raised or wild-caught (Table 4). For those Siluriformes fish for which a source was identified as either farm-raised or wild-caught, there was no significant difference in the percentage of violative dye residues ($p=0.74$).

Table 4. Results of testing for dyes in farm-raised vs. wild-caught Siluriformes fish (domestic only).

Source	Violative	Non-Detect	Total	% Pos
Farm	2	525	527	0.38%
Wild	3	585	588	0.51%
Total	5	1,110	1,115	0.45%

Of the 30 dye violations, 22 were identified in the first two years (FY 2016 and FY 2017) of the testing program (Table 5). Another seven samples were found violative in 2018. Only one sample has been found violative since then.

Table 5. Results of testing for dyes in all Siluriformes fish by fiscal year (FY).

FY	Violative	Non-Detect	Total	% Pos
2016	4	69	73	5.48%
2017	18	269	287	6.27%
2018	7	798	805	0.87%
2019	1	1,033	1,034	0.10%
2020	0	948	948	0.00%
Total	30	3,117	3,147	0.95%

Table 6 and Table 7 show the yearly results for domestic and imported Siluriformes fish.

Table 6. Results of testing for dyes in domestic Siluriformes fish by fiscal year (FY).

FY	Violative	Non-Detect	Total	% Pos
2016	1	30	31	3.23%
2017	1	77	78	1.28%
2018	4	466	470	0.85%
2019	0	256	256	0.00%
2020	0	292	292	0.00%
Total	6	1,121	1,127	0.53%

Table 7. Results of testing for dyes in imported Siluriformes fish by fiscal year (FY).

FY	Violative	Non-Detect	Total	% Pos
2016	3	39	42	7.14%
2017	17	192	209	8.13%
2018	3	332	335	0.90%
2019	1	777	778	0.13%
2020	0	656	656	0.00%
Total	24	1,996	2,020	1.19%

Multi-Residue Method (MRM)

The Federal Food Drug and Cosmetics Act ([FFDCA](#)), 21 U.S.C. 301 *et seq.*, authorizes FDA to establish tolerances, regulatory limits, and other limitations or specifications for animal drugs. Under the NRP, FSIS conducts testing for more than 100 approved and unapproved veterinary drugs potentially present in food animals (Appendix A).

Siluriformes fish data summary 29 March 2022

Between the periods of FY2016 and FY 2020, 4,058 Siluriformes fish samples were analyzed for veterinary residues using the multi-residue method (MRM) (Table 8). Table 8 shows the number of samples analyzed by year.

Table 8. Number of tests using the multi-residue method for Siluriformes fish by fiscal year (FY)

FY	Tests
2016*	120
2017	414
2018	972
2019	1,343
2020*	1,209
Total	4,058

*Two violations were reported in 4,058 Siluriformes fish samples from 2016 thru 2020

Since implementation, FSIS has reported two veterinary drug violations (0.05%). In FY 2016, FSIS reported a finding of enrofloxacin in an imported Siluriformes fish product. In 2020, lasalocid was detected in a domestic farm-raised Siluriformes fish. Violations were reported to the FDA.

Nitrofurans

In 1991, the FDA prohibited the use of all nitrofurantoin antibiotics for use in food-animals, including aquaculture products. Nitrofurantoin antibiotics have been reported to initiate tumor growth, by the formation of hydroxylamine derivatives that cause oxidative damage to DNA [24]. Therefore, similar to the dyes, detection of nitrofurans (and metabolites) in Siluriformes fish product is considered violative. FSIS' current method can screen and confirm for parent compounds and metabolites of furazolidone, furaltadone, nitrofurantoin, and nitrofurazone.

Between the periods of FY 2016 and FY 2020, 2,658 Siluriformes fish samples were tested for nitrofurantoin antibiotics (Table 9). Table 9 shows the number of samples collected by year. Of these, there were only two violative samples (0.08%). Nitrofurazone and furazolidone were reported in product imported in FY 2016 and FY 2017, respectively.

Table 9. Number of tests for nitrofurans for Siluriformes fish by fiscal year (FY)

FY	Tests
2016*	89
2017*	350
2018	411
2019	1,094
2020	714
Total	2,658

*Two violations were reported in 2,658 Siluriformes fish samples from 2016 thru 2020.

Pesticides

Under the Acts, FSIS-regulated product is adulterated “if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a” of the [FFDCA](#). EPA establishes tolerance levels for many registered pesticides, which can be found in Title 40 of the Code of Federal Regulations (CFR). Similar to veterinary drugs, pesticide residues are considered violative if the detected level exceeds applicable EPA tolerance. Under the NRP, each sample is screened for more than 108 approved and unapproved pesticide residues (Appendix B).

From FY 2016 to FY 2020, 2,866 Siluriformes fish samples were tested for pesticides. Pesticide residues were detected in 45 (1.57%) domestic and imported Siluriformes fish products (Table 10). Of these, 19 (0.66%) Siluriformes fish samples contained pesticide residues that either exceeded an EPA tolerance or were detected in the absence of a tolerance (Table 11). Domestic Siluriformes fish samples were five times more likely to have pesticides detected as imported samples and nearly three times more likely to be violative. Both these differences were statistically significant ($p < 0.01$, $p < 0.05$, respectively).

Table 10. Non-violative or violative detections of pesticides in domestic vs. imported Siluriformes fish.

	Detect	Non-Detect	Total	% Pos
Domestic	32	870	902	3.55%
Import	13	1,951	1,964	0.66%
Total	45	2,821	2,866	1.57%

Table 11. Violative detections of pesticides in domestic vs. imported Siluriformes fish.

	Violative	Non-Detect	Total	% Pos
Domestic	11	891	902	1.22%
Import	8	1,956	1,964	0.41%
Total	19	2,847	2,866	0.66%

There were 55 total non-violative and violative detections of pesticides among 45 samples. Ten of the 45 samples had two different pesticides detected. Nineteen of the 45 samples had at least one result that was violative. In 3 of the samples there were 2 violative detections for a total of 22 violations among 19 samples. Thus, of the 55 detections, 33 represented non-violative detections and 22 violative detections. Table 12 shows pesticide non-violative detections alone and Table 13 shows pesticide violative detections alone. As noted above multiple pesticide residues may be associated with the same Siluriformes fish samples.

Table 12. Frequency of pesticide non-violative detections identified in all Siluriformes fish

Pesticide	Detections
DDT and Metabolites	14
Chlorpyrifos	10
Chlordane Cis and Trans	5
p DDE	1
Nonachlor Trans	1
Diuron	1
Dieldrin	1
Total	33

Table 13. Frequency of pesticide violative detections identified in all Siluriformes fish

Pesticide	Violative tests
Metolachlor	6
Atrazine and Metabolites	5
Fipronil	4
Chlorpyrifos	3
HCB	1
Profenofos	1
Fipronil sulfide	1
Fipronil desulfinyl	1
Total	22

For most domestic samples, FSIS identified whether the source was farm-raised or wild-caught (Table 14 and Table 15). The proportion of positive samples was about twice as high in wild-caught compared to farm-raised fish for both non-violative and violative detections ($p < 0.05$) and for violative detections alone, although the difference was not statistically significant for violative detections alone.

Table 14. Non-violative and violative pesticide detections in farm-raised vs. wild-caught Siluriformes fish (domestic only).

Source	Detect	Non-Detect	Total	% Pos
Farm	10	377	387	2.58%
Wild	23	408	431	5.34%
Total	33	785	818	4.03%

Table 15. Violative pesticide detections in farm-raised vs. wild-caught Siluriformes fish (domestic only).

Source	Violative	Non-Detect	Total	% Pos
Farm	3	384	387	0.78%
Wild	8	423	431	1.86%
Total	11	807	818	1.34%

When farm-raised and wild-caught were assessed together, there was no significant difference over time for the percentage of non-violative and violative detections (Table 16) or for violative detections alone (Table 17) for FY 2016 to FY 2020.

Table 16. Non-violative and violative detections of pesticides for all Siluriformes fish by fiscal year (FY).

FY	Detection	Non-Detect	Total	% Pos
2016	0	89	89	0.00%
2017	4	344	348	1.15%
2018	6	405	411	1.46%
2019	19	1,075	1,094	1.74%
2020	16	908	924	1.73%
Total	45	2,821	2,866	1.57%

Table 17. Violative pesticide detections in all Siluriformes fish by fiscal year (FY).

FY	Violative	Non-Detect	Total	% Pos
2016	0	89	89	0.00%
2017	4	344	348	1.15%
2018	1	410	411	0.24%
2019	7	1,087	1,094	0.64%
2020	7	917	924	0.76%
Total	19	2,847	2,866	0.66%

Figure 1 shows the geographic distribution of pesticide testing results for domestic samples. In general, positive tests occurred proportionally to testing. The differences among states were not statistically significant ($p > 0.40$).



Figure 1. Number of pesticide samples collected (middle value in each circle), number of total non-violative and violative detections (bottom value), and number of violative detections (top value) by state for both farm-raised and wild-caught Siluriformes fish.

Metals

As part of the NRP, FSIS analyzes Siluriformes fish samples for the presence of various essential (required for human health) and non-essential metals, which do not have discrete regulatory values to be enforced. Therefore, metal detections do not adulterate the product. The analyzed metals include aluminum, arsenic¹, barium, boron, cadmium, chromium, cobalt, copper, iron, lead, manganese, molybdenum, nickel, selenium, strontium, thallium, vanadium, and zinc.

From FY 2016 to FY 2020, 3,027 samples were tested for metals. Of these, 223 (7.37%) samples had detectable metals. Domestic samples were almost three times as likely to have detectable metals as imported samples (Table 18). This difference was statistically significant ($p < 0.01$).

Table 18. Non-violative detections of metals in domestic vs. imported Siluriformes fish

	Detect	Non-Detect	Total	% Pos
Domestic	136	958	1,094	12.43%
Import	87	1,846	1,933	4.50%
Total	223	2,804	3,027	7.37%

For many of the domestic samples, FSIS identified whether the source was farm-raised or wild-caught (Table 19).

Table 19. Non-violative detections of metals in farm-raised vs. wild-caught Siluriformes fish (domestic only).

Source	Detect	Non-Detect	Total	% Pos
Farm	16	377	393	4.07%
Wild	118	457	575	20.52%
Total	134	834	968	13.84%

The proportion of samples with detectable metal levels was five times higher in wild-caught compared to farm-raised fish ($p < 0.01$). Although domestic Siluriformes fish identified as wild-caught accounted for only 575 out of 3,027 samples (19.0%), they accounted for 118 out of 223 total positive tests (52.9%). Since FY 2016, the percentage of metal detection has been rising steadily (Table 20). Domestic sample detections account for that increase (Table 22 and Table 22).

¹ Arsenic as will be noted later is generally in an organic form and is of little toxicological concern.

Table 20. Non-violative detections of metals in all Siluriformes fish by fiscal year (FY).

FY	Detect	Non-Detect	Total	% Pos
2016	2	55	57	3.51%
2017	16	271	287	5.57%
2018	51	754	805	6.34%
2019	71	948	1,019	6.97%
2020	83	776	859	9.66%
Total	223	2,804	3,027	7.37%

Table 21. Non-violative detections of metals in domestic Siluriformes fish by fiscal year (FY).

FY	Detect	Non-Detect	Total	% Pos
2016	0	23	23	0.00%
2017	3	75	78	3.85%
2018	47	423	470	10.00%
2019	37	220	257	14.40%
2020	49	217	266	18.42%
Total	136	958	1,094	12.43%

Table 22. Non-violative detections of metals in imported Siluriformes fish samples by fiscal year (FY).

FY	Detect	Non-Detect	Total	% Pos
2016	2	32	34	5.88%
2017	13	196	209	6.22%
2018	4	331	335	1.19%
2019	34	728	762	4.46%
2020	34	559	593	5.73%
Total	87	1,846	1,933	4.50%

As noted in Table 19, wild-caught Siluriformes fish account for most samples that were detected for metals. Table 23 shows that the percentage of detected samples in wild-caught Siluriformes fish has increased since 2018.

Table 23. Non-violative detections of metals in wild-caught Siluriformes fish samples by fiscal year (FY).

FY	Zero	One	Two	Three	Total	% Pos
2017	3	1	--	--	4	25.0%
2018	208	38	1	--	247	15.8%
2019	119	26	5	1	151	21.2%
2020	127	35	11	--	173	26.6%
Total	457	100	17	1	575	20.5%

Metals detected in Siluriformes fish are shown in Table 24. The total number of metal detection (261) is higher than the total number of sample detections (223) because some samples may have multiple metal detections (Table 20). For both domestic and imported samples of Siluriformes fish, manganese accounts for nearly 47%

of the metal detection. As an essential metal, manganese is important in enzyme functions such as metabolism, regulation of cellular energy, reproduction, and bone and connective tissue growth [25].

Table 24. Frequency of metals identified in all Siluriformes fish

Metal	Positive tests
Manganese	124
Arsenic	45
Strontium	17
Zinc	17
Selenium	14
Iron	14
Lead	12
Nickel	7
Boron	4
Cadmium	2
Chromium	2
Copper	1
Aluminum	1
Molybdenum	1
Barium	0
Cobalt	0
Thallium	0
Vanadium	0
Total	261

Similar to manganese, aluminum [26], boron [27], copper [28], iron, molybdenum [25], selenium [29], and zinc [30], are all considered essential metals with important functions in the human body. Detection of essential metals does not warrant further analysis as they do not pose any potential public health concerns. Non-essential metals that may pose a concern to human health (arsenic, cadmium, chromium, lead, nickel, and strontium) do warrant further analysis. These are discussed individually below.

Arsenic

Second to manganese, arsenic was detected most frequently. From FY 2016 to FY 2020, FSIS reported 45 arsenic non-violative detections out of 1,747 Siluriformes fish samples, meaning more than 97.4% of samples had no detectable arsenic. As with other metals, arsenic was more likely to be found in domestic fish than in imported fish (Table 25 and Table 26). When the source was known, arsenic was only detected in wild-caught Siluriformes fish (Table 26). Domestic wild-caught Siluriformes fish accounted for 40 of the 45 total arsenic non-violative detections reported.

Table 25. Levels of arsenic detected in imported Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	1,196	39	--
100-200	4	--	--
200-300	1	--	--

Table 26. Levels of arsenic detected in domestic Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	8	182	277
100-200	--	--	29
200-300	--	--	9
300-400	--	--	2

Arsenic detection levels ranged from 100 to 322 ppb. FSIS’ analytical method quantifies total chromium and does not distinguish between organic and inorganic arsenic. Although inorganic arsenic is a known carcinogen it constitutes only a fraction of the total arsenic found in fish muscle [31]. The FDA has not set an acceptable limit for arsenic in Siluriformes fish. The U.S. Agency for Toxic Substance and Disease Registry (ATSDR) reported that levels of arsenic in fish, crustaceans, and seaweed are associated with the organic forms and are considered to be of little toxicological concern [32]. It should also be noted that the Australia New Zealand Food Standards Code includes a 2 ppm (2000 ppb) standard for arsenic in fish, which is six times higher than the highest level detected among these samples. Given the extremely low rate of detections, any exposure to arsenic in Siluriformes fish products would be short in duration. FSIS will continue to monitor arsenic data to identify trends and determine whether additional actions are necessary.

Strontium

From FY 2016 to FY 2020, FSIS reported 17 strontium non-violative detections out of 2,935 Siluriformes fish samples (0.58%). There are no regulatory levels for strontium.

Table 27. Levels of strontium detected in imported Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	1,769	117	--
0-100	4	--	--

Table 28. Levels of strontium detected in domestic Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	122	374	536
0-100	--	1	12

Lead

From FY 2016 to FY 2020, FSIS reported 12 lead non-violative detections in 2,941 Siluriformes fish samples (0.41%). Lead positives were detected in both imported (Table 29) and domestic (Table 30) samples. For imported fish, there were 8 samples with detectable lead levels out of 1,843 total samples (0.43%). For domestic fish, there were 4 detects for lead in 1,098 total samples (0.36%). When source information was available, there was no statistically significant difference between farm-raised and wild-caught lead detections.

Table 29. Levels of lead detected in imported Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	1,719	116	--
0-100	6	2	--

Table 30. Levels of lead detected in domestic Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	212	400	482
0-100	--	1	3

While no reference dose is available for lead, the FDA has published an Interim Reference Level (IRL). The IRL is a daily exposure level likely to be associated with increasing the consumer’s blood level of concern. The IRL for lead is set for 3 µg/day for children and 12.5 µg/day for adults (16). The European Union (EU) and the Australian government have established a maximum level of 100 ppb for lead in most meats. Lead detection levels ranged from 17 to 88 ppb, far below what would constitute a violation in exported product.

Nickel

From FY 2016 to FY 2020, FSIS reported 7 nickel non-violative detections (0.23%) out of 2,986 Siluriformes fish samples (Table 31).

Table 31. Results of testing for nickel in domestic vs. imported Siluriformes fish. Detection only, no violations

	Detect	Non-Detect	Total	% Pos
Domestic	2	1,803	1,805	0.18%
Import	5	1,903	1,908	0.26%
Total	7	2,986	2,993	0.23%

Food is the major source of nickel exposure, with an average intake for adults estimated to be approximately 100 to 300 µg per day [33, 34]. Nickel is an essential nutrient for some mammalian species and has been suggested to be essential for human nutrition. One animal study observed a significant decrease in the body and liver weights in rats when the animals were exposed to nickel at a concentration of 75 mg/kg/day [33].

Cadmium

From FY 2016 to FY 2020, 3,119 Siluriformes fish samples were analyzed for cadmium. Of those, two cadmium non-violative detections (0.06%) were reported in one imported fish (Table 32) and one domestic wild-caught fish (Table 33). Therefore, more than 99.9% of samples had no detectable cadmium.

Table 32. Levels of cadmium detected in imported Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	1,903	123	--
0-100	1	--	--

Table 33. Levels of cadmium detected in domestic Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	132	387	572
0-100	--	--	1

While the U.S. has not established regulatory levels for cadmium in meat, the European Union, Australia, and New Zealand have set a maximum level of 50 ppb. Only one of the samples tested (0.03 %) exceeded this level (imported sample at a level of 61.8 ppb).

Chromium

From FY 2016 to FY 2020, 3,088 Siluriformes fish samples were analyzed for chromium. Of those, two chromium positives (0.06%) were reported in one imported fish (Table 34) and one domestic wild-caught fish (Table 35). Therefore, more than 99.9% of samples had no detectable chromium.

Table 34. Levels of chromium detected in imported Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	1,903	123	--
0-100	1	--	--

Table 35. Levels of chromium detected in domestic Siluriformes fish for fiscal years 2016-2020.

Level (ppb)	Unknown	Farm-raised	Wild-caught
Not Detected	121	379	560
0-100	--	1	--

Chromium typically occurs in the environment as naturally occurring chromium III, which is an essential metal, or as chromium VI which is a relatively toxic industrial contaminant. FSIS’ analytical method quantifies total chromium and does not distinguish between the two forms of chromium. In the World Health Organization’s 2003 chromium review, the total chromium levels (both III and VI) of meat, fish, fruits, and vegetables ranged from < 10 to 1,300 ug/kg [35].

Salmonella

From FY 2016 to FY 2020 there were 3,970 tests for *Salmonella* and 80 positives. The percentage of domestic positive samples was about eleven times higher than in imported samples (p<0.01). Only six of the positive samples came from imported product.

Table 36. Results of testing for *Salmonella* in domestic vs. imported Siluriformes fish

	Positive	Negative	Total	% Pos
Domestic	74	2,023	2,097	3.53%
Import	6	1,867	1,873	0.32%
Total	80	3,890	3,970	2.02%

Imported samples are typically frozen. This may explain the lower percent of positive samples. DiGirolamo *et al.* (1970) showed a 2 log₁₀ decrease in *Salmonella* Derby and Typhimurium in frozen oysters [36]. Dominguez and Schaffner (2009), reported noting the survival of *Salmonella* Kentucky and Typhimurium in frozen cooked

chicken nuggets and frozen raw chicken strips, though the cells incurred structural damage and did not grow well on selective media [37]. Dykes and Moorhead (2001) reported no decrease in *Salmonella* Brandenburg, Dublin, or Typhimurium in frozen beef trim [38]. A study specific to frozen Siluriformes fish could help determine the reason for the low *Salmonella* prevalence in imported samples and, if necessary, could help identify a testing method to better detect *Salmonella* in frozen samples.

Of the 80 positive samples, serotype information was available for 27 (Table 37).

Table 37. *Salmonella* serotypes in positive samples from all Siluriformes fish

Serotype	Number
Hartford	6
Rubislaw	4
Senftenberg	3
Oranienburg	1
Minnesota	1
Pomona	1
Hvittingfoss	1
Newport	1
IIIb 17:z10:e,n,x,z15	1
Orion var. 15+,34+	1
Gaminara	1
Daytona	1
Urbana	1
Mbandaka	1
Agbeni	1
Virchow	1
Miami	1
Total	27

For domestic Siluriformes fish for which source information was available, there was no difference in the percentage of positive *Salmonella* samples in farm-raised compared with that in wild-caught fish.

Table 38. Results of testing for *Salmonella* in farm-raised vs. wild-caught Siluriformes fish (domestic only)

Source	Positive	Negative	Total	% Pos
Farm	25	717	742	3.37%
Wild	30	896	926	3.24%
Total	55	1,613	1,668	3.30%

There was a higher percentage of positive samples in the first year of testing than in subsequent years. Since FY 2017 there has been no significant difference in the percentage of positive samples between each year. This applies to total samples and for domestic and import samples (Table 39, Table 40, and Table 41).

Table 39. Results of testing for *Salmonella* for all Siluriformes fish by fiscal year (FY).

FY	Positive	Negative	Total	% Pos
2016	8	111	119	6.72%
2017	10	395	405	2.47%
2018	15	819	834	1.80%
2019	22	1,331	1,353	1.63%
2020	25	1,234	1,259	1.99%
Total	80	3,890	3,970	2.02%

Table 40. Results of testing for *Salmonella* in domestic Siluriformes fish by fiscal year (FY).

FY	Positive	Negative	Total	% Pos
2016	8	69	77	10.39%
2017	7	185	192	3.65%
2018	15	598	613	2.45%
2019	21	587	608	3.45%
2020	23	584	607	3.79%
Total	74	2,023	2,097	3.53%

Table 41. Results of testing for *Salmonella* in imported Siluriformes fish by fiscal year (FY).

FY	Positive	Negative	Total	% Pos
2016	0	42	42	0.00%
2017	3	210	213	1.41%
2018	0	221	221	0.00%
2019	1	744	745	0.13%
2020	2	650	652	0.31%
Total	6	1,867	1,873	0.32%

Risk Characterization for *Salmonella*

This report does not include an update of the mechanistic model found in the 2015 risk assessment. Such a model is beyond the scope of the current effort. That said, the attribution model in the 2015 risk assessment could be easily updated. This model was based on the number of *Salmonella* outbreaks reported to CDC from 1990 through 2007. Out of 1,159 outbreaks in which a foodborne vehicle was identified, there was one outbreak in which Siluriformes fish was the likely source. Using an estimate of about 1.4 million *Salmonella* illnesses annually [39], the model estimated 2,400 annual illnesses with a lower limit of 280 and an upper limit of 6,700.

To update this model, FSIS would add the number of outbreaks that have occurred since 2007 and apply the same equation applied in the 2015 risk assessment. FSIS would also use a new estimate of just over one million *Salmonella* illnesses annually [40]. This results in a new estimate of 1,080 illnesses with a lower limit of 130 and an upper limit of 3,000.

An alternative attribution model can be constructed using information from IFSAC.² IFSAC estimates that about 1.5% (0.7% lower bound, 2.6% upper bound) of the approximately one million annual *Salmonella* illnesses come from fish. Because there is no current attribution of *Salmonella* illnesses from Siluriformes fish, we use consumption data to help develop one. The National Health and Nutrition Examination Survey (NHANES) consumption data shows that about 6% of fin fish servings that are consumed in the United States are Siluriformes fish (Appendix C). Multiplying 1.5% by 6% by the 1,027,561 illnesses estimated by Scallan (2011) gives an estimate of 930 illnesses attributable to Siluriformes fish with a lower bound of 270 and an upper bound of 2,600. No adjustment is made for different cooking methods for Siluriformes fish compared to other types of fish (Appendix C).

It should not be surprising that these two estimates are so close to each other because both are based on the same set of reported outbreaks. Nevertheless, the 2015 risk assessment used the one outbreak attributable to Siluriformes fish in 1991 and the alternative model uses the IFSAC estimates with the assumption that all fish contribute equally to illness.

Salmonella Sampling for Siluriformes Fish Compared to Other Commodities

As noted in Table 39, there were 1,259 *Salmonella* samples from Siluriformes fish in FY 2020. Of these, 607 were from domestic samples (Table 40) and 652 were from imported samples (Table 41). The higher of the two estimates of the annual *Salmonella* illnesses in the United States is 1,080. Thus, for each sample taken there are 0.9 illnesses.

We can compare this to other categories of FSIS-inspected products by taking the number of illnesses estimated by using the IFSAC attribution fraction and dividing them by the number of samples reported by FSIS for other categories. The results are shown in Table 42.

Table 42. Estimated illnesses for different products subject to FSIS inspection compared to number of samples taken for FY 2020

Food category	Attribution fraction	Illnesses	Samples	Illnesses/sample
Beef	6.40%	65,764	17,328	3.8
Chicken	14.00%	143,859	25,942	5.5
Pork	10.30%	105,839	7,422	14.3
Turkey	6.20%	63,709	3,231	19.7
Siluriformes fish	0.09%	1,080*	1,259	0.9
Total		380,708	55,182	6.9

*The larger value of 1080 is used rather than the 930 using the attribution fraction

Table 42 shows that for each *Salmonella* sample that FSIS collects, there are about seven estimated *Salmonella* illnesses. Thus, Siluriformes fish would appear to be greatly over-sampled compared to other categories. If we limit our analysis to only domestic Siluriformes fish samples, then the illnesses per sample is 1.8, still well below the average for other FSIS inspected categories.

² Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2017 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. Atlanta, Georgia and Washington, District of Columbia: U.S. Department of Health and Human Services, CDC, FDA, USDA/FSIS, 2019, <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2017-report-TriAgency-508-revised.pdf>

Conclusions

FSIS residue testing appears to be having a measurable effect. For example, at the beginning of the program over 7% of samples tested positive for dyes. That value fell to less than 1%. Other veterinary drugs were verified to have detection rates below 1%. For contaminants such as pesticides and metals, a disproportionate number of positive tests come from wild-caught Siluriformes fish, where their exposure cannot be controlled. Nevertheless, less than 1% of tests were positive for pesticides. Of the metals detected, most positive tests were for metals that are not of toxicological concern. For metals that would be of concern, tested samples had levels that were either below EPA limits or below values set by other countries for their imports.

With regards to *Salmonella*, FSIS testing indicates that domestic Siluriformes fish have an average of 3.53 percent positive from FY 2016 to FY 2020. Imported Siluriformes fish have an average 0.32 percent positive from FY 2016 to FY 2020. This difference may be attributed to imported Siluriformes fish typically being frozen, whereas domestic Siluriformes fish are typically fresh. While *Salmonella* is present on Siluriformes fish, there is limited data to support Siluriformes fish attribution to any *Salmonella* illnesses or outbreaks, except for an outbreak identified 30 years ago. Most Siluriformes fish are consumed fully cooked, which could explain the limited number of illnesses and outbreaks associated with this product. Based on consumer cooking practices, lack of recent outbreaks attributed to Siluriformes fish, and low percent positives detected, FSIS concludes that *Salmonella* does not pose a significant health hazard in Siluriformes fish. Presently, for the number of estimated *Salmonella* illnesses attributed to Siluriformes fish, FSIS is over-sampling Siluriformes fish compared to other products. Changes in consumer cooking practices or in the processing environment (to where Siluriformes fish have a higher *Salmonella* percent positive) may alter the public health significance.

Recommendations

The following recommendations are made with the intent to better understand the risk posed by possible Siluriformes fish contaminants:

1. Develop a research priority for examining the effect of freezing on recovery of *Salmonella* from Siluriformes fish using FSIS methods. Different studies using different animal products yield different results. Knowing the log₁₀ reduction expected from freezing would allow FSIS to better evaluate results from imported frozen Siluriformes fish.
2. Consider suspending current FSIS *Salmonella* sampling in Siluriformes fish based on the updated illness estimates from the attribution-based risk assessment, the low overall occurrence of *Salmonella* in FSIS Siluriformes fish sampling results, and the absence of outbreaks attributable to Siluriformes fish.
3. Conduct further analysis (speciation) of positive arsenic samples to verify the presence of organic arsenic rather than inorganic arsenic. This would increase confidence in the safety of FSIS inspected product.

References

1. RAMOS, M. and W.J. LYON, *Reduction of Endogenous Bacteria Associated with Catfish Fillets Using the Grovac Process*. Journal of Food Protection, 2000. **63**(9): p. 1231-1239.
2. Kumar, G., C. Engle, and K. Quagraine, *Household Preferences and Consumption Patterns for Farm-Raised Catfish in the U.S.* 2008.
3. U.S. Department of Health and Human Services, Foodborne Disease Outbreak Line Listing. 1991. p. <https://www.cdc.gov/foodsafety/outbreaks/index.html>.
4. WYATT, L.E., R. NICKELSON, and C. VANDERZANT, *OCCURRENCE AND CONTROL OF Salmonella IN FRESHWATER CATFISH*. Journal of Food Science, 1979. **44**(4).
5. Ward, D.R., *Microbiology of Aquaculture Products*. Food Technology, 1989. **43**(11): p. 82.
6. Fernandes, C.F., et al., *Comparison of Quality in Aquacultured Fresh Catfish Fillets II. Pathogens E. coli O157:H7, Campylobacter, Vibrio, Plesiomonas, and Klebsiella (dagger)*. J Food Prot, 1997. **60**(10): p. 1182-1188.
7. Heinitz, M.L., et al., *Incidence of Salmonella in fish and seafood*. J Food Prot, 2000. **63**(5): p. 579-92.
8. Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports 2008. p. https://www.ers.usda.gov/webdocs/publications/44258/11766_eib39.pdf?v=9015.4.
9. Moraes, R., et al., *Pesticide residues in rivers of a Brazilian Rain Forest Reserve: assessing potential concern for effects on aquatic life and human health*. Ambio, 2003. **32**(4): p. 258-63.
10. Watanabe, K.H., et al., *Fish tissue quality in the lower Mississippi River and health risks from fish consumption*. Sci Total Environ, 2003. **302**(1-3): p. 109-26.
11. Pheiffer, W., et al., *Fish consumption from urban impoundments: What are the health risks associated with DDTs and other organochlorine pesticides in fish to township residents of a major inland city*. Sci Total Environ, 2018. **628-629**: p. 517-527.
12. Fair, P.A., et al., *Perfluoroalkyl substances (PFASs) in edible fish species from Charleston Harbor and tributaries, South Carolina, United States: Exposure and risk assessment*. Environ Res, 2019. **171**: p. 266-277.
13. Schar, D., et al., *Global trends in antimicrobial use in aquaculture*. Sci Rep, 2020. **10**(1): p. 21878.
14. Jin, Y., et al., *4 - Catfish genomic studies: progress and perspectives*, in *Genomics in Aquaculture*, S. MacKenzie and S. Jentoft, Editors. 2016, Academic Press: San Diego. p. 73-104.
15. Lunestad, B.T., et al., *Salmonella in fish feed; occurrence and implications for fish and human health in Norway*. Aquaculture, 2007. **265**(1-4): p. 1-8.
16. Xie, H., et al., *Pharmaceuticals and personal care products in water, sediments, aquatic organisms, and fish feeds in the Pearl River Delta: Occurrence, distribution, potential sources, and health risk assessment*. Sci Total Environ, 2019. **659**: p. 230-239.
17. Hurtaud-Pessel, D., P. Couedor, and E. Verdon, *Liquid chromatography-tandem mass spectrometry method for the determination of dye residues in aquaculture products: development and validation*. J Chromatogr A, 2011. **1218**(12): p. 1632-45.
18. Mesalhy Aly, S. and A. Albutti, *Antimicrobials Use in Aquaculture and their Public Health Impact*. Journal of Aquaculture Research & Development, 2014. **5**(4).
19. Dhowlaghar, N., et al., *Biofilm formation by Salmonella spp. in catfish mucus extract under industrial conditions*. Food Microbiol, 2018. **70**: p. 172-180.
20. Love, D.C., et al., *Risks shift along seafood supply chains*. Global Food Security, 2021. **28**: p. 100476.
21. McCoy, E., et al., *Foodborne agents associated with the consumption of aquaculture catfish*. J Food Prot, 2011. **74**(3): p. 500-16.
22. Alderman, D.J. and R.S. Clifton-Hadley, *Malachite green therapy of proliferative kidney disease in rainbow trout: field trials*. Vet Rec, 1988. **122**(5): p. 103-6.
23. Rao, K.V., *Inhibition of DNA synthesis in primary rat hepatocyte cultures by malachite green: a new liver tumor promoter*. Toxicol Lett, 1995. **81**(2-3): p. 107-13.

24. Morris, J.E., et al., *The carcinogenic activity of some 5-nitrofurans in the rat*. *Cancer Res*, 1969. **29**(12): p. 2145-56.
25. Zoroddu, M.A., et al., *The essential metals for humans: a brief overview*. *J Inorg Biochem*, 2019. **195**: p. 120-129.
26. Valković, V., *Is aluminum an essential element for life?* *Orig Life*, 1980. **10**(3): p. 301-5.
27. Lewis, D.H., *Boron: the essential element for vascular plants that never was*. *New Phytol*, 2019. **221**(4): p. 1685-1690.
28. Linder, M.C. and C.A. Goode, *Biochemistry of copper*. *Biochemistry of the elements*. 1991, New York: Plenum Press. xiv, 525 p.
29. Monsen, E.R., *Dietary reference intakes for the antioxidant nutrients: vitamin C, vitamin E, selenium, and carotenoids*. *J Am Diet Assoc*, 2000. **100**(6): p. 637-40.
30. Saper, R.B. and R. Rash, *Zinc: an essential micronutrient*. *Am Fam Physician*, 2009. **79**(9): p. 768-72.
31. Lewis, J., et al., *Stability of arsenic speciation in fish muscle samples, under different storage and sample preparation conditions*. *Microchemical Journal*, 2012. **105**: p. 56-59.
32. Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Arsenic*. 2007. p. <https://www.atsdr.cdc.gov/ToxProfiles/tp2.pdf>.
33. Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Nickel*. 2016. p. <https://www.atsdr.cdc.gov/toxprofiles/tp15.pdf>.
34. U.S. Environmental Protection Agency, Office of Research and Development, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, *Health Assessment Document for Nickel and Nickel Compounds*. 1986. p. <https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=30001ACC.PDF>.
35. WHO, *Chromium in drinking Water*, in *Guidelines for drinking-water quality*. 2003, World Health Organization.
36. DiGirolamo, R., J. Liston, and J.R. Matches, *Survival of virus in chilled, frozen, and processed oysters*. *Appl Microbiol*, 1970. **20**(1): p. 58-63.
37. Dominguez, S.A. and D.W. Schaffner, *Survival of salmonella in processed chicken products during frozen storage*. *J Food Prot*, 2009. **72**(10): p. 2088-92.
38. Dykes, G.A., S.M. Moorhead, and S.L. Roberts, *Survival of Escherichia coli O157:H7 and Salmonella on chill-stored vacuum or carbon dioxide packaged primal beef cuts*. *Int J Food Microbiol*, 2001. **64**(3): p. 401-5.
39. Mead, P.S., et al., *Food-related illness and death in the United States*. *Emerging infectious diseases*, 1999. **5**(5): p. 607-625.
40. Scallan, E., et al., *Foodborne illness acquired in the United States--major pathogens*. *Emerg Infect Dis*, 2011. **17**(1): p. 7-15.

Appendix A: List of screened veterinary drug residues

2 Amino Flubendazole	Eprinomectin	Prednisone
2 Aminosulfone Albendazole	Erythromycin	Propionylpromazine
2 Quinoxalinecarboxylic Acid	Fenbendazole	Ractopamine
Abamectin	Fenbendazole sulfone	Ronidazole
Acepromazine	Fenbendazole sulphone	Salbutamol
Albendazole	Florfenicol	Salinomycin
Amikacin	Florfenicol Amine	Sarafloxacin
Amoxicillin	Flubendazole	Selamectin
Ampicillin	Flunixin	Spectinomycin
Apramycin	Gamithromycin	Streptomycin
Azaperone	Gentamycin Sulfate	Sulfachlorpyridazine
Butorphanol	Haloperidol	Sulfadiazine
Carazolol	Hydroxydimetridazole	Sulfadimethoxine
Carbadox	Hydroxyipronidazole	Sulfadoxine
Cefazolin	Hydroxymetronidazole	Sulfaethoxypridazine
Chloramphenicol	Hygromycin	Sulfamerazine
Chlorpromazine	Ipronidazole	Sulfamethazine
Chlorpropham	Ivermectin	Sulfamethizole
Chlortetracycline	Kanamycin	Sulfamethoxazole
Cimaterol	Ketamine	Sulfamethoxypridazine
Ciprofloxacin	Ketoprofen	Sulfanilamide
Clenbuterol	Lasalocid	Sulfanitran
Clindamycin	Levamisole	Sulfapyridine
Clothianidin	Lincomycin	Sulfaquinoxaline
Cloxacillin	Melengestrol Acetate	Sulfathiazole
Cypermethrin	Meloxicam	Sulfisoxazole
Danofloxacin	Metronidazole	Taleranol
Deltamethrin	Monensin	Tetracycline
Desacetyl Cephapirin	Morantel tartrate	Tildipirosin
Desethylene Ciprofloxacin	Moxidectin	Tilmicosin
Desfuroylceftiofur	Nafcillin	Tolfenamic
Diclofenac	Narasin	Tolfenamic Acid
Dicloxacillin	Neomycin	Triflupromazine
Difloxacin	Norfloxacin	Tulathromycin
Dihydro Streptomycin	Orbifloxacin	Tylosin
Dimetridazole	Oxacillin	Tylvalosin
Dipyron	Oxyphenylbutazone	Virginiamycin
Doramectin	Oxytetracycline	Xylazine
Doxycycline	Penicillin	Zearalanol
Emamectin	Phenylbutazone	Zeranol
Enrofloxacin	Pirlimycin	Zilpaterol

Appendix B: List of screened pesticides

Acephate	Ethion	Norflurazuron
Acetamiprid	Ethofumesate	Omethoate
Alachlor	Fenoxaprop ethyl	P,P-DDE
Aldicarb	Fenpropathrin	Pentachloroaniline
Aldrin	Fenvalerate	Pentachlorobenzene
Atrazine and Metabolites	Fipronil	Permethrin Cis and Trans
Azinphos methyl	Fipronil desulfinyl	Piperonyl_Butoxide
Azoxystrobin	Fipronil sulfide	Pirimiphos methyl
Benoxacor	Fluridone	Prallethrin
Bifenthrin	Fluroxypyr-1-Methylheptyl Ester	Profenofos
Boscalid	Fluvalinate	Promethazine
Buprofezin	HCB	Propachlor
Carbaryl	Heptachlor and metabolites	Propanil
Carbofuran and 3-hydroxycarbofur	Hexachlorobenzene	Propetamphos
Carfentrazone Ethyl	Hexazinone	Propiconazole
Chlordane	Hexythiazox	Propyzamide Pronamide
Chlordane Cis and Trans	Imazalil	Pyraclostrobin
Chloroneb	Imidacloprid	Pyridaben
Chlorothalonil	Indoxacarb	Pyriproxyfen
Chlorpyrifos	Lindane	Resmethrin
Chlorpyrifos Methyl	Linuron	Simazine
Coumaphos and Oxygen Analog	Malathion	Sulprofos
Cyhalothrin	Metalaxyl	Tebufenozide
DDT and Metabolites	Methamidophos	Tefluthrin
Diazinon	Methomyl	Tetrachlorvinphos
Dichlorvos	Methoxyfenozide	Tetraconazole
Dieldrin	Metolachlor	Thiabendazole
Difenoconazole	Metribuzin	Thiamethoxam
Diflubenzuron	MGK 264	Thiobencarb
Dimethoate	Myclobutanil	Trifloxystrobin
Diuron	Natural_Pyrethrins	
Endosulfan I, II, and Sulfate	Nonachlor Trans	

Appendix C: Determining proportion of Siluriformes fish servings

Consumer dietary data for all finned fish was extracted from NHANES³. Different types of fish and different methods of preparation were identified by individual food codes. These 140 different codes gave an estimate of 7.4 billion servings annually. Catfish accounted for 10 codes and about 450 million servings, or about 6% of all finned fish servings.

We thus start with an assumption that, in the absence of specific attribution evidence, of all *Salmonella* illnesses from fish, about 6% would be attributable to catfish. This would certainly be reasonable if catfish were prepared the same as other fish. We find, however, that catfish preparation differs from other fish.

Possible preparation methods from NHANES included raw, unspecified cooking, canned, dried, pickled, smoked, steamed, baked or broiled, fried, or unspecified preparation at a fast-food establishment or restaurant. For servings that were baked or broiled the fish could be coated or uncoated. Fried servings were always coated.

Catfish were twice as likely to be coated and fried as other fish.

Percent of fish servings coated or fried

Preparation	Catfish	All other fish	Total
Coated, baked or broiled	35,845,010	450,040,470	485,885,480
Coated, fried	159,011,020	1,031,953,553	1,190,964,573
Not coated, baked or broiled	200,436,273	2,679,533,534	2,879,969,807
Total baked or broiled or fried	395,292,303	4,161,527,558	4,556,819,860
% fried	40.2%	24.8%	26.1%
% coated	49.3%	35.6%	36.8%
Total servings	447,247,485	6,963,821,666	7,411,069,151
% fried	35.6%	14.8%	16.1%
% coated	43.6%	21.3%	22.6%

Does this make catfish less likely to cause illness? The 2015 risk assessment developed a cooking model that concluded baking resulted in a median 7 log₁₀ reduction of *Salmonella*. Frying on the other hand, resulted in only a median 4.5 log₁₀ reduction. Thus, the larger percent of catfish that are fried means that catfish would be more likely to cause illness than other finned fish and there is no need to adjust illness estimates down.

³ Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2017-2018, <https://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Dietary&CycleBeginYear=2017>

Siluriformes fish data summary 29 March 2022

List of food codes used

26100100	Fish, NS as to type, raw	26131120	Pompano, baked or broiled, fat added
26100110	Fish, NS as to type, cooked, NS as to cooking method	26131121	Pompano, baked or broiled, no added fat
26100120	Fish, NS as to type, baked or broiled, made with oil	26131131	Pompano, coated, baked or broiled, no added fat
26100123	Fish, NS as to type, baked or broiled, no added fat	26131140	Pompano, coated, fried
26100130	Fish, NS as to type, coated, baked or broiled, made with oil	26131160	Pompano, steamed or poached
26100133	Fish, NS as to type, coated, baked or broiled, no added fat	26133110	Porgy, cooked, NS as to cooking method
26100140	Fish, NS as to type, coated, fried, made with oil	26133120	Porgy, baked or broiled, fat added
26100160	Fish, NS as to type, steamed	26133121	Porgy, baked or broiled, no added fat
26100170	Fish, NS as to type, dried	26133130	Porgy, coated, baked or broiled, fat added
26100200	Fish, NS as to type, from fast food	26133140	Porgy, coated, fried
26100260	Fish stick, patty or nugget from fast food	26133160	Porgy, steamed or poached
26100270	Fish stick, patty or nugget from restaurant, home, or other place	26137100	Salmon, raw
26101110	Anchovy, cooked, NS as to cooking method	26137110	Salmon, cooked, NS as to cooking method
26101180	Anchovy, canned	26137120	Salmon, baked or broiled, made with oil
26105140	Carp, coated, fried	26137121	Salmon, baked or broiled, made with butter
26107110	Catfish, cooked, NS as to cooking method	26137122	Salmon, baked or broiled, made with margarine
26107120	Catfish, baked or broiled, made with oil	26137123	Salmon, baked or broiled, no added fat
26107121	Catfish, baked or broiled, made with butter	26137124	Salmon, baked or broiled, made with cooking spray
26107123	Catfish, baked or broiled, no added fat	26137130	Salmon, coated, baked or broiled, made with oil
26107130	Catfish, coated, baked or broiled, made with oil	26137131	Salmon, coated, baked or broiled, made with butter
26107131	Catfish, coated, baked or broiled, made with butter	26137133	Salmon, coated, baked or broiled, no added fat
26107140	Catfish, coated, fried, made with oil	26137140	Salmon, coated, fried, made with oil
26107143	Catfish, coated, fried, no added fat	26137141	Salmon, coated, fried, made with butter
26107144	Catfish, coated, fried, made with cooking spray	26137142	Salmon, coated, fried, made with margarine
26107160	Catfish, steamed or poached	26137160	Salmon, steamed or poached
26109110	Cod, cooked, NS as to cooking method	26137180	Salmon, canned
26109120	Cod, baked or broiled, made with oil	26137190	Salmon, smoked
26109121	Cod, baked or broiled, made with butter	26139110	Sardines, cooked
26109122	Cod, baked or broiled, made with margarine	26139180	Sardines, canned in oil
26109123	Cod, baked or broiled, no added fat	26139190	Sardines, skinless, boneless, packed in water
26109130	Cod, coated, baked or broiled, made with oil	26141110	Sea bass, cooked, NS as to cooking method
26109133	Cod, coated, baked or broiled, no added fat	26141120	Sea bass, baked or broiled, fat added
26109140	Cod, coated, fried, made with oil	26141130	Sea bass, coated, baked or broiled, fat added
26109141	Cod, coated, fried, made with butter	26141140	Sea bass, coated, fried
26109160	Cod, steamed or poached	26141160	Sea bass, steamed or poached
26109180	Cod, dried, salted, salt removed in water	26143120	Shark, baked or broiled, fat added
26111120	Croaker, baked or broiled, fat added	26151110	Trout, cooked, NS as to cooking method
26111140	Croaker, coated, fried	26151120	Trout, baked or broiled, made with oil
26113110	Eel, cooked, NS as to cooking method	26151121	Trout, baked or broiled, made with butter
26115120	Flounder, baked or broiled, made with oil	26151130	Trout, coated, baked or broiled, made with oil
26115121	Flounder, baked or broiled, made with butter	26151133	Trout, coated, baked or broiled, no added fat
26115123	Flounder, baked or broiled, no added fat	26151140	Trout, coated, fried, made with oil
26115130	Flounder, coated, baked or broiled, made with oil	26151160	Trout, steamed or poached
26115140	Flounder, coated, fried, made with oil	26151190	Trout, smoked
26115160	Flounder, steamed or poached	26153100	Tuna, fresh, raw
26117120	Haddock, baked or broiled, fat added	26153120	Tuna, fresh, baked or broiled, fat added
26117121	Haddock, baked or broiled, no added fat	26153122	Tuna, fresh, baked or broiled, no added fat
26117130	Haddock, coated, baked or broiled, fat added	26153131	Tuna, fresh, coated, baked or broiled, no added fat
26117140	Haddock, coated, fried	26153160	Tuna, fresh, steamed or poached
26118020	Halibut, baked or broiled, made with oil	26153170	Tuna, fresh, dried
26118030	Halibut, coated, baked or broiled, made with oil	26155110	Tuna, canned, NS as to oil or water pack
26118050	Halibut, steamed or poached	26155180	Tuna, canned, oil pack
26119110	Herring, cooked, NS as to cooking method	26157110	Whiting, cooked, NS as to cooking method
26119120	Herring, baked or broiled, fat added	26157120	Whiting, baked or broiled, made with oil
26119140	Herring, coated, fried	26157123	Whiting, baked or broiled, no added fat

Siluriformes fish data summary 29 March 2022

26121110	Mackerel, cooked, NS as to cooking method	26157132	Whiting, coated, baked or broiled, made with margarine
26121120	Mackerel, baked or broiled, fat added	26157140	Whiting, coated, fried, made with oil
26121121	Mackerel, baked or broiled, no added fat	26157160	Whiting, steamed or poached
26121140	Mackerel, coated, fried	26158000	Tilapia, cooked, NS as to cooking method
26121160	Mackerel, pickled	26158010	Tilapia, baked or broiled, made with oil
26121180	Mackerel, canned	26158011	Tilapia, baked or broiled, made with butter
26123121	Mullet, baked or broiled, no added fat	26158012	Tilapia, baked or broiled, made with margarine
26125120	Ocean perch, baked or broiled, fat added	26158013	Tilapia, baked or broiled, no added fat
26127110	Perch, cooked, NS as to cooking method	26158014	Tilapia, baked or broiled, made with cooking spray
26127120	Perch, baked or broiled, made with oil	26158020	Tilapia, coated, baked or broiled, made with oil
26127121	Perch, baked or broiled, made with butter	26158021	Tilapia, coated, baked or broiled, made with butter
26127130	Perch, coated, baked or broiled, made with oil	26158023	Tilapia, coated, baked or broiled, no added fat
26127140	Perch, coated, fried, made with oil	26158024	Tilapia, coated, baked or broiled, made with cooking spray
26127143	Perch, coated, fried, no added fat	26158030	Tilapia, coated, fried, made with oil
26127160	Perch, steamed or poached	26158050	Tilapia, steamed or poached