Natural Toxin and Scombrotoxin Fish Poisoning Illness in Fish Other Than Bivalve Molluscan Shellfish Annual Report for Calendar Years 2020 – 2023

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Introduction

This evaluation summarizes illness events of natural toxins (NT) in fish other than molluscan shellfish and scombrotoxin fish poisoning (SFP) for calendar years 2020 – 2023. Molluscan shellfish have a different reporting and tracking mechanism and will not be discussed in this summary. The Office of Food Safety/Division of Seafood Safety (DSS) and the Division of Seafood Science and Technology (DSST) relies on illness reporting from public health officials, healthcare providers, state and local agencies, and consumers to inform us of incidents that occur. These incidents and lessons learned inform DSS of potential changes which would impact policy, regulation, and guidance regarding FDA's managing of their seafood regulatory requirements.

While most foodborne outbreaks are tracked through FDA's Coordinated Outbreak Response and Evaluation (CORE) network, seafood related illnesses caused by NT and SFP have a unique reporting mechanism. NT and SFP illness incidents are reported directly to the Office of Food Safety (OFS) through several mechanisms. Incidents are received via a dedicated email account, CORE, Consumer Complaint Coordinators, medical community, state and local health departments, and individual consumer reporting. The incidents are reported to the Natural Toxin and SFP

Illness/Outbreak Workgroup (henceforth referred to as the Workgroup), whereby the Workgroup of subject matter experts from across the Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA) track and trend, monitor, and investigate illnesses to determine the root cause of the incident, levels of toxins that made the consumer ill, as well as the potential for regulatory action as deemed appropriate. Subject matter experts responsible for some part of work on each incident include a Medical Officer, biologists, microbiologists, chemists, Consumer Safety Officers, Consumer Complaint Coordinators (CCC), Emergency Response Coordinators (ERC), Compliance Officers, and Investigators.

Illnesses:

The Workgroup receives reports of illnesses associated with the consumption of specific types of fish. These illnesses may originate from the activity of certain bacteria, toxins produced by marine algae, or hazards inherent to the fish. The most commonly occurring illnesses are Ciguatera Poisoning (CP), Puffer Fish Poisoning (PFP), Scombrotoxin Fish Poisoning (SFP), and Seafood-associated Rhabdomyolysis (sometimes referred to as Haff disease) (Haff). Other less commonly occurring NT illnesses such as Gempylid Fish Poisoning (GFP), Paralytic Shellfish Poisoning (PSP) in fish other than bivalve molluscan shellfish, and Amnesic Shellfish Poisoning (ASP) in fish other than bivalve molluscan shellfish may occur and are also investigated and tracked through this program.

Ciguatera Poisoning:

FDA has changed the previous acronym from CFP (Ciguatera Fish Poisoning) to CP (Ciguatera Poisoning) to be more inclusive of additional seafood types associated with ciguatera globally as well as to reflect the "FAO and WHO 2020 Report of the Expert Meeting on Ciguatera Poisoning." For example, cone snails (*Conus* spp.), gastropods (*Tectus niloticus*), giant clams (*Tridacna maxima* and *Hippopus hippopus*), jellyfish (*Cnidaria* spp.), and lobster (*Panulirus penicillatus*) have been reported to bioaccumulate ciguatoxins. To date, no cases of CP from the consumption of these additional seafood types have been confirmed in the United States.

Ciguatera poisoning (CP) is commonly related to the consumption of subtropical and tropical reef fish which can bioaccumulate naturally occurring ciguatoxins through their diet. The highest incidences of ciguatoxins occur between latitudes 35° north to 35° south, to include the Caribbean Sea, Gulf of Mexico, and Atlantic, Pacific, and Indian Oceans.

Many fish species have been linked to illness incidents of CP including, but not limited to, barracuda; grouper; jacks and trevally; mackerel; moray eels; parrotfish; snapper; tang; and wrasse. Ciguatoxins have also been found in lionfish collected in waters surrounding the U.S. Virgin Islands. In 2023 the FDA investigated a CP illness directly related to the consumption of lionfish by assessing the symptomology; however, FDA was unable to confirm the diagnosis through laboratory analysis since meal remnants were not available.

CP results from human consumption of fish containing ciguatoxins. Reports of CP illnesses date back to the 1500s with a current global incident rate of 10,000 – 50,000 cases per year. However, these numbers could be low due to the underreporting by patients and health care professionals due to misdiagnosis from lack of knowledge of symptomology.

The illness onset typically occurs within 6 hours after consumption and may persist for several days to weeks. In severe cases the neurological symptoms may persist for months with potential recurrence for years. CP is usually not fatal; however, isolated fatalities have been reported. Symptoms of CP can include gastrointestinal (nausea, vomiting, and diarrhea); neurological (numbness and tingling of lips and extremities, itching hands and feet, joint pain, muscle pain, muscle weakness, reversal and sensitivity to temperatures, dizziness, and vertigo); and cardiovascular (irregular heartbeat and low blood pressure).

Puffer Fish Poisoning

Puffer fish poisoning (PFP) is typically caused by naturally occurring tetrodotoxin associated with the consumption of puffer fish from waters of the Indo-Pacific Ocean Regions, Gulf of Mexico, Gulf of California, and specific areas on the Atlantic coast of Florida. In addition, an accumulation of saxitoxins in the puffer fish, introduced through their diet, has also been referred to as PFP and should be reported accordingly.

The importation of all fish and fishery products containing all species of puffer fish is restricted. Import Alert 16-20 outlines the details of restrictions and permissible importation of puffer fish.

The illness onset typically develops within 3 hours post consumption of contaminated fish and may last from 24 – 48 hours. If sufficient toxin is consumed death can occur due to muscle paralysis resulting in respiratory failure when ventilatory support is not accessible. In non-lethal cases, symptoms include numbness of lips and tongue; tingling sensation in face and extremities; headache; abdominal pain; nausea; diarrhea; vomiting; difficulty in walking; paralysis; respiratory distress; difficulty in speech; shortness of breath; blue or purplish discoloration of the lips and skin; lowering of blood pressure; convulsions; mental impairment; and irregular heartbeat.

Scombrotoxin Fish Poisoning

Scombrotoxin (histamine) formation as a result of time and temperature abuse, such as improper storage/refrigeration, of certain types of fish that can cause consumer illness. SFP is closely linked to the development of histamine in these fish and is primarily associated with the consumption of tuna and mahi-mahi, among other species.

Symptoms usually occur within a few minutes to a few hours post consumption and last from 12 hours to a few days. Symptoms include tingling or burning in or around the mouth or throat; rash or hives on the upper body; drop in blood pressure; headache; dizziness; itching of the skin; nausea; vomiting; diarrhea; asthmatic-like constriction of the air passage; heart palpitations; and respiratory distress.

Seafood-associated Rhabdomyolysis (sometimes referred to as Haff disease)

Haff disease has primarily been linked to the consumption of buffalo fish in the U.S. although other species of fish such as burbot, eel, and pike have been associated with the disease worldwide. The majority of U.S. cases have been small, isolated outbreaks involving families or individuals consuming a single fish. In recent years, large outbreaks with symptoms consistent with Haff disease have been associated with crayfish and amberjack in China and Brazil, respectively. The cause(s) of Haff disease worldwide are unknown. Three

species of buffalo fish (*Ictiobus* sp.) are commercially harvested in the U.S. Most previous U.S. reports associated this illness with *Ictiobus cyprinellus* (bigmouth buffalo). However, through recent genomic sequencing we were able to associate Haff disease illnesses which have occurred in the U.S. from 2010 – 2020 as being most often associated with commercially harvested *Ictiobus bubalus* (smallmouth buffalo) and *Ictiobus niger* (black buffalo).

The FDA is currently collecting meal remnants from patients diagnosed with the disease to confirm the causative species and research the causative agent(s). Only species identification is reported for these incidents at this time.

Seafood-associated rhabdomyolysis results in the breakdown of skeletal muscle (rhabdomyolysis), with a risk of acute kidney failure that develops within 24 hours after consumption. Initial symptoms include muscle tenderness and weakness, sometimes with tea-colored urine. Blood testing is often used to diagnose seafood-associated rhabdomyolysis with elevated levels of creatine phosphokinase being one of the most common indicators.

Program Process:

Questionnaires:

The Workgroup has developed six different questionnaires with a specific questionnaire for each illness type (CP, PFP, SFP, Miscellaneous, Haff disease, and The Caribbean Public Health Agency (CARPHA-CP)). One illness specific questionnaire is completed for each complainant in the incident to assist with diagnosis, determination of follow up activities, and collection of additional epidemiological information. The questionnaires were designed to collect information in the following areas: General information (i.e., patient information not to include personal identifier information); fish and fish consumption information; clinical information (i.e., symptomology, long term effect(s) for the complainant); and knowledge of the illness. Minor differences exist with each questionnaire since the questionnaires are tailored for the specific illness type and information gathering needs. The Miscellaneous questionnaire was developed to include other NT illnesses that may occur in fish other than molluscan shellfish such as ASP, GFP, and PSP.

The CARPHA-CP questionnaire was specifically developed for a potential project with CARPHA. Although the project wasn't begun due to the COVID pandemic and resource constrictions. FDA has prepared the questionnaire and standard operating procedures (SOP) in the anticipation of the project being resurrected.

Website:

The How to Report Seafood-Related Toxin and Scombrotoxin Fish Poisoning Illnesses | FDA website was developed by the Workgroup and launched in 2021. The external site identifies pertinent information regarding the illnesses covered by the Workgroup to include the major illnesses, illness symptomology, email account for reporting purposes, incident table, and resources. The incident table is updated quarterly with closed incidents managed through the Workgroup. Only closed incidents are reported. In-process incidents are not reported since the complement of information for posting is unknown. The language on the site is managed and updated by the Workgroup as needed. Minor revisions have occurred to the

verbiage since 2021, with major revisions to launch January of 2024 including such information as the ciguatera poisoning (CP) name change and information to include in the email when reporting an incident.

Communication:

The Workgroup communicates with external stakeholders and the public through the website. Listserv notifications are issued each time the website is updated. In addition to the website, the Workgroup members have discussed the program in public forums such as seafood related conferences, the Seafood HACCP Alliance, and the Environmental Protection Agency's conference.

Analytical Testing:

FDA collects meal remnants for analysis when available for all illnesses reported to this Workgroup. The Workgroup has defined meal remnants as it pertains to this program as the edible portion of the fish (leftover), cooked or uncooked, from the exact fish consumed from the illness event associated with NT or SPF illnesses. We request meal remnants for analyses to confirm the illness and identify fish species as deemed appropriate. CP meal remnants are used to confirm the illness utilizing N2A cytotoxicity assay, and LC-MS/MS analysis, as well as DNA barcoding to identify the fish species. Tetrodotoxin is confirmed for PFP utilizing LC-MS/MS analysis. Decomposition (Sensory) and histamine analysis is conducted to confirm SFP. There is currently no causative agent identified for Haff disease. FDA is currently accumulating samples for research purposes. No analytical results are available for Haff disease. FDA is conducting genome skimming to identify the species of fish implicated in Haff disease incidents.

2020 Incidents:

General Information:

Calendar year 2020 was the first full year of this Workgroup tracking illnesses utilizing the numbering system. The program was still being developed for tracking and data collection purposes. SFP was added during this year, therefore, there may have been other SFP illnesses reported during this calendar year that are not captured.

The unclassified numbering system was not in place during the 2020 calendar year. Therefore, the total number of incidents reported to the Workgroup is unknown. We were, however, using classified numbers during this period. Ten (10) incidents were reported and pursued. The illness breakdown is listed in the Table immediately below.

Table 1. Illness Types:

	CP	PFP	SFP	Haff	Other	Unknown	Totals
Classified	7	0	1	2	0	0	10

The following tables identify overarching information about the incident to include the number of complainants, reported fish, month the incident was reported, the location of the incident (state or country), and how the incident was reported to the Workgroup.

Table 2: CP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Barramundi	January	Oregon	Oregon Department of Health
2	2	Hogfish	February	Puerto Rico	Ministry of Puerto Rico Regional Epidemiologist for Food and/or Water Communicable Diseases
3	1	Warsaw Grouper	March	Florida	Florida District Office
4	3	Barracuda	August	Maryland	Montgomery County Health Department
5	2	Barracuda	September	Chicago	Illinois Department of Health
6	5	Mackerel	September	Puerto Rico	Seafood Illness Mailbox
7	2	Snapper, One-Spot	October	Guam	CORE

Table 3: SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	4	Yellowfin Tuna	September	North Dakota	Reportable Food Registry

Table 4: Haff Disease demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Buffalo Fish	February	New Jersey	NJ Dept of Health: Foodborne Disease Program
2	2	Buffalo Fish	December	Missouri	CORE

Analytical Results:

Six (6) of the 10 incidents reported having meal remnants available for analytical testing. Five (5) of the 10 meal remnants were collected for ciguatera analyses and one was collected for Haff disease. DNA barcoding to identify the fish species is always conducted on CP, Haff disease, or other NT incidents when meal remnants are available to confirm the fish that was identified through the complaint. These analyses can also tell us if there are any emerging fish species accumulating toxins. The following table identifies the results of the analysis conducted. The DNA barcode confirmed the fish that was reported by the complainant for the CP and Haff diseases.

Table 5: CP analytical results

#	CP Type	N2a Cytotoxicity (ppb)	LC-MS/MS	Common Name	Scientific Name
1	C-CTX-1	1.1	Confirmed	Hogfish	*Lachnolaimus maximus*
2	CP	Not detected	Not present	Warsaw Grouper	*Hyporthodus nigritus*
3	C-CTX-1	0.45	Confirmed	Great Barracuda	*Sphyraena barracuda*
4	C-CTX-1	Raw: 0.090 Cooked: 0.298	Raw: Confirmed Cooked: Confirmed	Great Barracuda	*Sphyraena barracuda*
5	C-CTX-1	0.196	Confirmed	King Mackerel	*Scomberomorus cavalla*

Table 6: Haff Results

#	Common Name	Scientific Name
1	Smallmouth Buffalo	*Ictiobus bubalus*

2021 Incidents:

General Information:

The unclassified numbering system was not in place during the 2021 calendar year. Therefore, the total number of incidents reported to the Workgroup is unknown. Twelve (12) incidents were classified. The following table breaks down the type of illnesses tracked in the calendar year 2021.

Table 7: Illness types

	CP	PFP	SFP	Haff	Other	Unknown	Totals
Classified	4	0	7	0	0	1	12

The following tables identify overarching information about the incident to include the number of complainants, reported fish, month the incident was reported, the location of the incident (state or country), and how the incident was reported to the Workgroup.

The unknown illness was reported to FDA through CFSAN Adverse Event Reporting system (CAERS) and Center for Veterinary Medicine (CVM). The food consumed was lobster tail. The Workgroup pursued the incident as a potential paralytic shellfish poisoning (PSP) illness. PSP was not detected. The illness was not associated with natural toxins.

Table 8: CP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Salmon	May	Indiana	Emergency Response Coordinator – Detroit
2	5	Unknown	June	Puerto Rico	Seafood Illness Mailbox
3	2	Barracuda	June	New York	Emergency Response Coordinator
4	2	Grouper	September	Kentucky	Commonwealth of KY, DLS, Global Preparedness and Environmental Branch

Table 9: SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	3	Tuna	July	Indiana	Indiana Department of Health
2	2	Tuna	July	Ohio	Ohio Department of Ag. Food Safety Branch
3	3	Tuna	July	Massachusetts	MA Department of Public Health
4	2	Tuna	July	New Mexico	City of Albuquerque Env. Health Department
5	1	Yellowfin Tuna	September	Tennessee	U.S.D.A.
6	4	Ahi Tuna	October	Wisconsin	City of Wauwatosa Health Department
7	2	Albacore Tuna	November	California	Consumer Complaint

Table 10: Unknown demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Lobster tail	March	California	CAERS and CVM

Analytical Results:

Six (6) of the 12 incidents reported having meal remnants available for analytical testing. Three (3) meal remnants were collected for ciguatera analyses, 3 for SFP analysis, and 1 for the unknown illness. DNA barcoding to identify the fish species is always conducted on CP, Haff disease, or other NT illness such as PSP incidents when meal remnants are available to confirm the fish that was identified through the complaint. These analyses can also tell us if there are emerging fish species accumulating toxins. The following table identifies the results of the analysis conducted. The unknown illness was analyzed for domoic acid since the symptomology and fish (lobster tails) strongly suggested that illness. One CP incident reported the fish that was consumed as unknown. The DNA barcoding result identified the unknown fish consumed as dog snapper (*Lutjanus jocu*) for that incident. The DNA barcoding results confirmed the identification of the other fish consumed. DNA barcoding was not conducted on the lobster.

Table 11: CP analytical results

#	CP Type	N2a Cytotoxicity (ppb)	LC-MS/MS	Common Name	Scientific Name
1	N/A	None Detected	Not confirmed	Pink Salmon	*Oncorhynchus gorbuscha*
2	C-CTX-1	0.113	Confirmed	Dog Snapper	*Lutjanus jocu*
3	C-CTX-1	Raw: 0.200 Cooked: 0.097	Raw: Confirmed Cooked: Confirmed	Great Barracuda	*Sphyraena barracuda*

Table 12: SFP analytical results

#	Analysis Type	Actual Results	Check Results
1	Histamine	3,628 ppm	5,089 ppm
2	Histamine	Sub 1: 5680 ppm Sub 2: 318 ppm Sub 3: 201 ppm Sub 4: 140 ppm Sub 5: 6989 ppm	Sub 1: 6670 ppm Sub 5: 7320 ppm (report "Histamine: >5,700 ppm; SFP confirmed")
3	Histamine	Sub 1: 4193 ppm Sub 2: 55.06 ppm Sub 3: 2090 ppm Sub 4: 126.6 ppm Sub 5: 1420 ppm Sub 6: 387.2 ppm	Sub 1: 5400 ppm Sub 4: 2800 ppm (report "Histamine: >4,200 ppm; SFP confirmed")

Table 13: Unknown illness analytical results

#	Analysis	Actual Result
1	Domoic Acid	None detected

2022 Incidents:

General Information

Fifty-one (51) incidents were reported to the Workgroup. Of the 51 incidents 3 were not issued an unclassified number. Three (3) of the 51 incidents were received prior to the implementation of the unclassified numbering system being implemented. Forty-seven (47) unclassified numbers were issued by the Workgroup in calendar year 2022. Twenty-three (23) of the 47 incidents were transitioned to classified numbers. Table 1 breaks down the incidents by illness type. One illness reported symptomology that was consistent with CP and SFP. Meal remnants were not available for the CP/SFP incident. We were unable to determine the exact illness. The other incidents that were reported include: food poisoning, Gempylid fish poisoning (GFP), Ichthyohemotoxic fish poisoning (IHT), and neurotoxic shellfish poisoning (NSP.)

One (1) of the 51 was a referral for potential analytical testing only with no other work being accomplished. No work was conducted by the Workgroup except responding to emails from the reporting state. Since the Workgroup wasn't engaged and the work had been conducted outside this program no number was issued. This incident will only be included in Table 1 and will not be referenced in any other information.

Although the Workgroup has always collected HACCP plans and monitoring records to assess compliance with 21 CFR 123, it never captured when referrals for regulatory action were made. In 2022, the Workgroup began documenting referrals to CFSAN/Office of Compliance (OC) when deviations from 21 CFR 123 were identified. In 2022, the Workgroup began documenting referrals to CFSAN/OC in May. Seven (7) incidents were referred to CFSAN/OC for potential regulatory action in 2023. The 7 referrals were for SFP incidents. We are currently working to establish a system to track the regulatory action conducted post referral.

Table 14: Accounting of all incidents.

	CP	PFP	SFP	CP/SFP	Haff	Other	Unknown	Totals
No classification	1	0	2	0	0	0	0	3
Unclassified	11	0	21	1	1	4	9	47
Classified	9	0	11	1	0	2	0	23

From this point forward this evaluation will concentrate on incidents with classified numbers only. The following tables identify overarching information about the incident to include the number of complainants, reported fish, month the incident was reported, the location of the incident (state or country), and how the incident was reported to the Workgroup.

Table 15: CP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	3	African Pompano	March	Puerto Rico	PR Department of Health (PR DOH)
2	1	Red Porgy	March	Puerto Rico	PR DOH
3	6	Hogfish	April	Puerto Rico	PR DOH
4	1	Red Snapper	June	Illinois	Seafood Illness Mailbox
5	1	Unknown	July	Illinois	Seafood Illness Mailbox
6	3	Barracuda	July	Florida	FL Department of Health (FL DOH)
7	3	King Mackerel	June	Florida	Seafood Illness Mailbox
8	3	Rock Cod	August	California	Seafood Illness Mailbox
9	1	Barracuda	September	Puerto Rico	PR DOH

Table 16: SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Tuna	January	Florida	Seafood Illness Mailbox
2	1	Tuna	January	Washington	U.S.D.A.
3	1	Tuna	May	Alabama	Seafood Illness Mailbox
4	2	Tuna	June	Michigan	Seafood Illness Mailbox
5	2	Tuna	July	North Carolina	U.S.D.A.
6	2	Tuna	August	New Jersey	Seafood Illness Mailbox
7	1	Mahi Mahi	August	Virginia	Seafood Illness Mailbox
8	1	Tuna	September	Oregon	FDA/ State liaison
9	2	Tuna	September	New York	Seafood Illness Mailbox
10	1	Mahi Mahi	November	New Hampshire	NH Dept of Health and Human Services
11	2	Tuna	December	Massachusetts	Medical facility to the Seafood Illness Mailbox

Table 17: CP/SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Red Snapper	September	South Carolina	Seafood Illness Mailbox

Table 18: Other Incidents/ GFP

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Sea Bass	May	California	Seafood Illness Mailbox

Table 19: Unknown Incidents: Miscellaneous

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Lobsters & Scallops	October	California	Seafood Illness Mailbox

Analytical Results

Eight (8) of the 24 incidents reported having meal remnants available for analytical testing. Five (5) meal remnants were collected for ciguatera analyses, 1 for SFP analysis, and 2 for the miscellaneous NT [Gempylid Fish Poisoning (GFP) and Misc.] illness. DNA barcoding to identify the fish species is always conducted on CP, Haff disease, or other NT illness such as PSP incidents when meal remnants are available to confirm the fish identification. These analyses can also tell us if there is an emerging fish species accumulating toxins. DNA barcoding was only conducted on the first miscellaneous NT sample since the illness was potentially

reported as GFP. GFP is caused by wax esters naturally found in high concentrations in the meat of escolar (*Lepidocybium flavobrunneum*) and oilfish (*Ruvettus pretiosus*). Identifying the fish species would identify whether GFP is the likely illness. Mediterranean sea bass (*Dicentrarchus labrax*) is not a species which causes GFP. The following table identifies the results of the analysis conducted. DNA barcoding results confirmed the fish species reported by the complaint for CP. DNA barcoding was not conducted on the lobster that was analyzed for domoic acid.

Table 20: CP analytical results

#	CP Type	N2a Cytotoxicity (ppb)	LC-MS/MS	Common Name	Scientific Name
1	C-CTX-1	0.212	Confirmed	Hogfish	*Lachnolaimus maximus*
2	C-CTX-1	0.038	Confirmed	Great Barracuda	*Sphyraena barracuda*
3	C-CTX-1	0.065	Confirmed	King Mackerel	*Scomberomorus cavalla*
4	C-CTX-1	1.578	Confirmed	Great Barracuda	*Sphyraena barracuda*
5	C-CTX-1	0.08	Confirmed	African Pompano	*Alectis ciliaris*

Table 21: SFP analytical results

#	Analysis Type	Actual Results	Check Results
1	Decomposition Histamine	No decomposition detected. No histamine detected	N/A

Table 22: Miscellaneous illness analytical results

#	Analysis	Actual Result	Common Name	Scientific Name
1	N/A	N/A	Mediterranean Sea Bass	*Dicentrarchus labrax*
2	Domoic acid	None detected	N/A	N/A

2023 Incidents:

General Information:

Fifty-one (51) illnesses were reported to FDA in calendar year 2023. Thirty-six (36) of the 51 illnesses were converted to classified illnesses and followed by the Workgroup. Thirteen (13) of the illnesses were CP, 22 were SFP, and 1 was an unknown illness. The illness demographics are as follows. The initial request for the Unknown illness was to test meal remnants for ciguatoxins and histamine. Based on the information received to include the questionnaires, the Workgroup was unable to confirm either illness. The symptomology proved inconclusive. Although the incident transitioned, no additional work was conducted.

HACCP plans and monitoring records are collected by the Workgroup to assess compliance with 21 CFR 123. The HACCP plans and monitoring records are reviewed accordingly. When deficiencies are identified, the closed incident is referred to CFSAN/Office of Compliance for potential regulatory action. In 2023, 13

incidents were referred to CFSAN/OC. The referrals were for 1 CP and 12 SFP incidents. We are currently working to establish a system to track the regulatory action conducted post referral.

Table 23: Accounting of all incidents.

	CP	PFP	SFP	SFP?	Haff	Other	Unknown	Totals
Unclassified	14	0	33	1	0	0	3	51
Classified	13	0	22	0	0	0	1	36

The following tables identify overarching information about the incident to include the number of complainants, reported fish, month the incident was reported, the location of the incident (state or country), and how the incident was reported to the Workgroup.

Table 24: CP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	3	Whiting	February	South Carolina	ATL – DO
2	3	Red Snapper	May	Puerto Rico	Seafood Illness Mailbox
3	1	Snapper	June	Florida	Seafood Illness Mailbox
4	3	Lionfish	July	U.S. Virgin Islands	Seafood Illness Mailbox
5	2	Barracuda	September	Pennsylvania	FDA and State
6	5	Amberjack	October	Florida	Seafood Illness Mailbox
7	8	Jack	October	Hawaii	HI State Department of Health
8	1	Grouper	November	Puerto Rico	PR Department of Health
9	4	Salmon, aquaculture	November	Virginia	Seafood Illness Mailbox
10	3	Almaco Jack	November	Florida	Florida Department of Health
11	4	Kingfish, Sierra	November	Puerto Rico	PR Department of Health
12	3	Hogfish	December	Puerto Rico	PR Department of Health
13	2	Hogfish	December	Puerto Rico	PR Department of Health

Table 25: SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Tuna	January	Illinois	Seafood Illness Mailbox
2	1	Tuna	March	California	Seafood Illness Mailbox
3	2	Tuna	April	Maryland	Seafood Illness Mailbox
4	4	Tuna	May	Nebraska	Seafood Illness Mailbox
5	1	Tuna Ahi Poke	May	Rhode Island	RI department of Health to NEW – DO
6	2	Tuna	May	Massachusetts	Seafood_NT_Illness_Contact email
7	2	Yellowfin Tuna	June	New York	Consumer Complaint Coordinator

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
8	1	Tuna	June	California	Seafood Illness Mailbox
9	2	Ahi Tuna	July	California	Seafood Illness Mailbox
10	1	Sea Bass	July	Nevada	Seafood Illness Mailbox
11	1	Yellowfin Tuna	August	Texas	Seafood Illness Mailbox
12	1	Ahi Tuna	September	Maryland	Seafood Illness Mailbox
13	1	Mahi Mahi	August	Texas	Seafood Illness Mailbox
14	1	Sushi (Mango Crunch Roll)	September	California	Seafood Illness Mailbox
15	1	Tuna	October	New York	NYC Department of Health & NY District Office
16	1	Mahi Mahi	August	New York	Seafood Illness Mailbox
17	1	Tuna	October	Washington	King County Public Health Department, WA
18	1	Tuna	November	Colorado	Consumer Complaint Coordinator
19	1	Ahi Tuna	November	New Hampshire	NH Department of Health and Human Services
20	1	Salmon	November	Alabama	Seafood Illness Mailbox
21	UK	Herring	October	Washington	Seattle District
22	3	Tuna	December	Tennessee	TN Department of Health

Table 26: Unknown demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	6	Flounder, Shrimp, Clams, Oysters	July	S. Carolina	SC Department of Health and Environmental Control to the Seafood Illness Mailbox

Analytical Results:

Eleven (11) of the 36 incidents reported having meal remnants available for analytical testing. Six (6) meal remnants were collected for ciguatera analyses, and 5 for SFP analysis. SPF sample number 3 in the table below was not conducted by FDA laboratory but rather by the state Department of Health (DOH). SFP sample number 5 in the below table contained 6 different laboratory samples. Of the 6 samples one contained 11 sub samples. An analytical value range was utilized to capture the significant difference in the results. DNA barcoding to identify the fish species is always conducted on CP, Haff disease, or other NT illness. It was determined there was no fish tissue in one of the CP samples; therefore, only 5 analyses were conducted. The following table identifies the results of the analysis conducted. DNA barcoding results confirmed the fish species reported by the complaint for CP. DNA barcoding confirmed the reported species as accurate except for one sample. The reported Almaco jack was actually Greater Amberjack (*Seriola dumerili*).

Table 27: CP analytical results

#	CP Type	N2a Cytotoxicity (ppb)	LC-MS/MS	Common Name	Scientific Name
1	C-CTX-1	A: 0.159 B: 0.148	Confirmed	Greater Barracuda	*Sphyraena barracuda*
2	P-CTX-1	A: 0.107 B: 0.161	See note	Jack/Trevally or Giant Trevally	*Caranx ignobilis*
3	CTX	None Detected	N/A	Atlantic Salmon	*Salmo salar*
4	C-CTX-1	0.184	Confirmed	Greater Amberjack	*Seriola dumerili*
5	C-CTX-1	A: 0.192 B: 0.231	Confirmed	Hogfish	*Lachnolaimus maximus*

Note: The sample portions tested positive for sodium channel activity by the N2a cytotoxicity assay. Pacific ciguatoxin-1 was not confirmed in either portion by LC-MS/MS analysis. However, another unidentified Pacific ciguatoxin congener could be responsible for the sodium channel activity detected. The FDA guidance level for Pacific ciguatoxins is 0.01 ppb P-CTX-1 equivalents.

Table 28: SFP analytical results

#	Analysis Type	Actual Results	Check Results
1	Histamine	Below LOQ of 2.5 ppm	N/A
2	Histamine	Below LOQ of 2.5 ppm	N/A
3	Histamine	1: >800 ppm 2: ~2,000 ppm	N/A Conducted by State DOH
4	Histamine	None Detected	N/A
5	Histamine	Range: 48.4 ppm – 4186 ppm	Range: 537.82 – 3182 ppm

Conclusion:

The NT and SFP illness reporting program has grown significantly over the years. The Workgroup has been diligently working since 2019 to expand and standardize the program to include foundational output and documents such as website launch, SOPs, protocols, questionnaires, standardize language, and now writing annual evaluations documenting the program's progress. This is the first report that reflects the illnesses tracked as well as documents the efforts of the program to outside stakeholders. As time and resources allow, this will be an annual report henceforth. Since the program was stood up independently, it has expanded, which is reflected in the number of incidents covered by the program. The number of incidents has steadily increased since 2020. We attribute this to website availability and public activities with which the Workgroup has engaged. These include several presentations at conferences where the program was articulated to the public.

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