Natural Toxin and Scombrotoxin Fish Poisoning Illness in Fish Other Than Bivalve Molluscan Shellfish Annual Report for Calendar Year 2024

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Introduction

This evaluation summarizes illness events of natural toxins (NT) in fish other than bivalve molluscan shellfish and scombrotoxin fish poisoning (SFP) for calendar year 2024. Bivalve molluscan shellfish have a different reporting and

tracking mechanism and will not be discussed in this summary. The Human Foods Program Office of Microbiological Food Safety/Division of Seafood Safety (DSS) with the Office of Laboratory Operations and Applied Science/Division of Seafood Science and Technology (DSST) receives illness reports from public health officials, healthcare providers, state and local agencies, and consumers. 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 incidents (henceforth referred to as incidents) caused by NT and SFP have a unique reporting mechanism. NT and SFP incidents are reported directly to the Division of Seafood Safety through several mechanisms such as a dedicated email account, CORE, Consumer Complaint Coordinators, medical community, state and local health departments, and the individual consumer. The incidents are reported to the Natural Toxin and SFP Illness Response Workgroup (henceforth referred to as the Workgroup), whereby the Workgroup made up of subject matter experts from across the Human Foods Program (HFP), 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 follow-up as deemed appropriate. The Workgroup is made up of subject matter experts representing the following areas of expertise a Medical Officer, biologists, microbiologists, chemists, Consumer Safety Officers, Consumer Complaint Coordinators (CCC), 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.

The Workgroup has also followed incidents that resemble known illnesses such as CP and SFP. We consider those illnesses CP- and SFP-like. The symptomology usually aligns with the respected illnesses; however, the fish are not consistent with those that cause these illnesses. We are trying to understand the similarities between the fish and symptomology as well as potentially understand whether there are emerging fish for these types of illnesses. We will continue to collect and analyze meal remnants as well as conduct tracebacks to the primary processor for these incidents and analyze the information to determine how to proceed with them in the future be it new guidance or modification to the existing guidance.

Ciguatera Poisoning:

Ciguatera Poisoning 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.

Ciguatera poisoning 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 conducted follow-up activities regarding 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.

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 fish and fishery products containing any species of puffer fish is restricted. Import Alert 16-20 identifies the 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 is the result of time and temperature abuse, such as improper storage/refrigeration, of certain types of fish and can subsequently 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. Previously illnesses in the U.S. were mostly associated with *Ictiobus cyprinellus* (bigmouth buffalo). However, through recent genomic sequencing we were able retest the fish associated with the Haff disease illnesses in the US 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 of fish and research the causative agent(s). Only fish 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 regulatory 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 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.

Numbering system:

The Workgroup has developed a two-tiered numbering system for reported incidents, Unclassified and Classified numbers. incidents are first assigned an unclassified number until a determination is made whether the incident falls within the purview of the Workgroup. The numbering system format for an unclassified number is as follows: UYY-##. The U identifies the incident as being an unclassified incident. The YY corresponds to the calendar year of the incident. The ## is the next consecutive number beginning with 01 for the first incident received in that calendar year. Once information is received such as the questionnaire and other pertinent information, a determination is made to either pursue the incident as part of the program or forward the incident on for follow-up utilizing their normal protocols since it doesn't fall within our purview.

A classified number is assigned to incidents that fall within the Workgroup's purview as identified through the assessment of the questionnaires. The number format is YY-MM-## with YY corresponding to the calendar year of the incident, MM corresponding to the month the incident was reported, and ## is the consecutive number beginning with 01 for the first incident received in that calendar year. Each incident is tracked utilizing this numbering system. A file is maintained for each tracked incident which houses all information collected for that specific incident.

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, reporting mechanism, incident table, and resources. The incident table is updated quarterly with closed incidents managed through the Workgroup. 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 full Workgroup meets annually to discuss the program and subsequent improvement options. Standard operating procedures, protocols, questionnaires, the website, etc. are discussed. Decisions for updates are made, such as, in 2023 the decision was made to update the webpage to include initial reporting information to be launched in January 2024. The Workgroup also communicates outside of the annual meetings and incidents regarding issues that arise. A training program was developed for CCCs. Training by the Workgroup leads was conducted and recorded for the CCCs. As new CCCs are on-boarded, the recorded training session is used. The Workgroup is in constant contact to ensure program continuity and amendments as issues arise

throughout the year. The Workgroup incident point of contacts are in constant communication with each other and collaborate throughout each incident.

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 incidents reported to this Workgroup. The Workgroup has defined meal remnants as it pertains to this program only as "the edible portion of the fish (leftover), cooked or uncooked, from the exact fish consumed from the illness event associated with the NT or SPF illnesses." We request meal remnants for analyses to confirm the illness and identify the 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 involved. Tetrodotoxin is confirmed for PFP utilizing LC-MS/MS analysis. Decomposition (Sensory) and histamine (AOAC Official Method 997.13 – Histamine in Seafood) analysis is conducted to confirm SFP. There is currently no causative agent identified for Haff disease. FDA is currently accumulating samples from Haff disease incidents 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.

2024 Incidents:

General Information:

Fifty-nine (59) incidents were reported to FDA in calendar year 2024. Forty-one (41) of the 59 incidents were converted to classified incidents and followed by the Workgroup. Table 1 is a breakdown of the incidents identifying the specific illness from unclassified to their conversion to classified numbers. The other incidents that did not transition were initially reported as PSP; however, the fish involved in the incidents were bivalve molluscan shellfish. The incidents did not fall within the purview of this Workgroup and were referred to the Shellfish team for follow-up activities as deemed appropriate. The individual incident demographics for the classified incidents are captured in Table 2 through Table 7 to include the fish species, number of ill and location of the incident.

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.

Table 1: Accounting of all incidents.

Number type	CP	CP-Like	Haff	PFP	SFP	SFP-Like	Other	Totals
Unclassified	13	1	1	2	38	2	2	59
Classified	12	1	1	2	24	1	0	41

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	2	Red Snapper	January	Puerto Rico	PR Department of Health
2	3	Hogfish & Red Snapper	January	Puerto Rico	PR Department of Health
3	3	African Pompano	February	Puerto Rico	PR Department of Health
4	2	Snapper & Parrotfish	April	Puerto Rico	PR Department of Health
5	3	Peacock Grouper	May	Hawaii	HI State Department of Health
6	7	Sea Bass	May	Puerto Rico	FDA – Puerto Rico
7	2	Sierra (Mackerel)	June	Puerto Rico	FDA – Puerto Rico
8	3	Barracuda	June	Puerto Rico	FDA – Puerto Rico
9	1	Barracuda	June	Florida	Seafood Illness Mailbox
10	1	Trevally	July	Hawaii	HI State Department of Health
11	2	Barracuda	December	Hawaii	HI State Department of Health
12	2	Hogfish	December	Puerto Rico	Seafood Illness Mailbox

Table 3: CP-Like demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Salmon	August	Utah	Seafood HACCP Mailbox

Table 4: Haff disease demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Buffalo Fish	May	Illinois	Seafood Illness Mailbox

Table 5: PFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	1	Blowfish (puffer fish)	June	New Jersey	NJ Department of Health
2	1	Puffer Fish	October	New York	NYC Department of Health

Table 6: SFP demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Wahoo	April	Indiana	Boone County Indiana Department of Health
2	1	Tuna	April	Michigan	MI Department of Health
3	2	Tuna	April	Tennessee	Seafood Illness Mailbox
4	4	Tuna	April	Rhode Island	Seafood Illness Mailbox
5	1	Tuna	May	California	CA Environmental Protection Agency
6	1	Yellowtail & Salmon	May	Washington	Seattle – King County Public Health Department
7	2	Sardines	May	California	Seafood Illness Mailbox
8	1	Yellowtail	May	California	Seafood Illness Mailbox
9	2	Yellow Fin Tuna	June	California	CA Department of Community Health
10	1	Ahi Tuna	June	New York	Seafood Illness Mailbox
11	2	Tuna	June	Pennsylvania	Seafood Illness Mailbox
12	1	Yellowtail	June	Maryland	Seafood Illness Mailbox
13	2	Tuna	June	Florida	Seafood Illness Mailbox
14	1	Ahi Tuna	July	Washington	FDA – Washington
15	2	Yellowfin Tuna	August	New York	Seafood Illness Mailbox
16	1	Tuna	August	California	Seafood Illness Mailbox
17	1	Anchovy	August	North Carolina	Seafood Illness Mailbox
18	1	Tuna	September	Florida	Seafood Illness Mailbox
19	1	Mackerel | Tuna | Salmon	September	Connecticut	Seafood Illness Mailbox
20	2	Tuna	September	New York	Seafood Illness Mailbox
21	3	Tuna	October	Colorado	Seafood NT Illness Contacts email address
22	3	Tuna	October	Texas	Seafood Illness Mailbox
23	3	Tuna	October	North Carolina	Seafood Illness Mailbox
24	1	Sardines	November	New York	Seafood Illness Mailbox

Table 7: SFP-Like demographics

#	# Ill	Reported Fish	Month Reported	Location	Reporting Source
1	2	Salmon	October	Washington	Seattle – King County Public Health Department

Analytical Results:

Eighteen (18) of the 41 incidents reported having meal remnants available and one incident had fish available from the same lot of fish (Puffer Fish) for analytical testing. Our protocols identify testing meal remnants only; however, since the fish were identified as Puffer Fish, we thought it prudent to determine if the fish contained toxins since 2 separate illnesses were reported from the mid-Atlantic region of the U.S. This area has typically not shown PFP in the northern puffer fish. Tables 8 through 10 describe the analytical results reported for the different incidents according to the illness type. Nine (9) samples were collected for ciguatera analyses; 1 collected for PFP analysis; and 8 collected for SFP analysis.

CP sample 7 tested positive for sodium channel activity by the N2a cytotoxicity assay; however, Pacific-ciguatoxin-1 was not confirmed by LC-MS/MS analysis. Another unidentified Pacific ciguatoxin congener could be responsible for the sodium channel activity detected.

PFP sample number 1 detected very low concentrations of STX which are unlikely to cause the illness.

The traceback for SFP sample number 2 identified the restaurant prepared mackerel in the same preparation area as the yellowtail. It was proposed that the histamine in the yellowtail is a result of cross-contamination between the two fish species. The complainant did not consume mackerel.

Table 8: CP analytical results

#	CP Type	N2a Cytotoxicity (ppb)	LC-MS/MS	Common Name	Scientific Name
1	C-CTX-1	0.074	Confirmed	Hogfish	*Lachnolaimus maximus*
2	C-CTX-1	2.581	Confirmed	African Pompano	*Alectis ciliaris*
3	C-CTX-1	A. 0.511 ppb B. None Detected	A. Confirmed B. None Detected	A. Cubera Snapper B. NA	A. *Lutjanus cyanopterus* B. NA
4	P-CTX-1	0.155	Confirmed	Purplespotted Grouper	*Cephalopholus argus*
5	C-CTX-1	None Detected	None Detected	Snook	*Centropomus undecimalis*
6	C-CTX-1	0.110	Confirmed	Barracuda	*Sphyraena barracuda*
7	P-CTX-1	0.115	See above text	Jack | Trevally	*Caranx ignobilis*
8	P-CTX-1	1.014	Confirmed	Barracuda	*Sphyraena barracuda*
9	C-CTX-1	Raw: 1.991 ppb Cooked: 2.222 ppb	Raw: Confirmed; Cooked: Confirmed	Hogfish	*Lachnolaimus maximus*

Table 9: PFP analytical results

#	Analysis Type	Actual Results	Common Name	Scientific Name
1	PFP | STX	65 µg STX-diHCL equiv/kg	Northern Puffer or Southern Puffer	*Sphoeroides maculatus* *Sphoeroides nephelus*

Table 10: SFP analytical results

#	Analysis Type	Actual Results	Check Results
1	Histamine	4,660 ppm (4.66g/kg)	N/A -only enough sample to perform one analysis
2	Histamine	No histamine detected in the samples	NA
3	Histamine	1.100 ppm (1.1 g/kg)	1,200 ppm (1.2 g/kg)
4	Histamine	Raw – 3,900 ppm Cooked – 1,800 ppm	Raw – 3,900 ppm Cooked – 1,800 ppm
5	Histamine	3,412 ppm (3.4g/kg)	3,571 ppm (3.6 g/kg)
6	Histamine	Sub 1 – 2,234.5 ppm Sub 2 – 2,483.3 ppm Sub 3 – 2,361.0 ppm Sub 4 – 67.9 ppm	Sub 1 – 2,302.7 ppm Sub 2 – 2,517.0 ppm Sub 3 – 2,321.1 ppm Sub 4 – 71.0 ppm
7	Histamine	8,132 ppm	8,201 ppm
8	Histamine	5,237 ppm	5,192 ppm

Referral for follow-up regulatory activities:

The Workgroup does not conduct follow-up regulatory activities beyond the traceback to identify the primary processor and laboratory analysis. FDA collects HACCP plans, monitoring records, and identify the harvest locations to assess whether the manufacturing facilities are in compliance with eCFR :: 21 CFR Part 123 -- Fish and Fishery Products. The Workgroup's point of contact for the incident conducts a high-level assessment of the HACCP plan and monitoring records to identify deviations. Incidents that meet specific criteria such as the product was sold in interstate commerce; deviations with the HACCP plan and monitoring records were identified; and/or high analytical levels are found in the fish are referred for potential follow-up regulatory activities. Regulatory activities include inspection of the primary processor and/or a targeted sampling assignment. Warning letters are not distributed to facilities based on HACCP plans and monitoring records obtained by this Workgroup since the documents are not collected through official channels, for example an inspection. Since inspections aren't conducted in the same calendar or fiscal year, there is a lag time with reporting.

2022, the Workgroup began referring incidents to the Center for Food Safety and Applied Nutrition/Office of Compliance (CFSAN/OC) for regulatory activities. Referrals began in May 2022. Seven referrals were made. One inspection and one FRRA were conducted which resulted in two warning letters (WL) with one of the firms being placed on Import Alert 16-120– Detention Without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP. The other 2

inspections/RFFA resulted in VAI designations for the firms. The Workgroup is currently pursuing the remaining work to ensure it has been accomplished.

In 2023, 13 incidents were referred to the Center for Food Safety and Applied Nutrition/Office of Compliance (CFSAN/OC). Five inspections or foreign Remote Regulatory Assessment's (FRRA) were conducted. 3 of the 5 were classified as 1 voluntary action indicated (VAI) and 3 no action indicated (NAI). The Workgroup is currently pursuing the remaining activities to ensure it has been accomplished.

In 2024, 15 incidents were referred to the Human Foods Program/Office of Compliance and Enforcement [Formerly: The Center for Food Safety and Applied Nutrition/Office of Compliance (CFSAN/OC)] The referrals were for 14 SFP and 1 SFP-Like incidents. We are currently working to establish a system to obtain regulatory action conducted post referral. The SFP referrals were either for HACCP plan deviations and/or high histamine levels. Inspections of foreign facilities are not scheduled to be immediately conducted due to logistics; however, they are placed on a list for inspection for the upcoming fiscal years. The following activities occurred regarding the referrals.

With the reorganization of CFSAN and the Office of Regulatory Affairs to the new Human Foods Program, the Workgroup in conjunction with new internal partners in the Office of Investigation and Inspection are in the process of re-establishing our relationship with regard to referrals for follow-up regulatory activities.

The following tables break down the regulatory activities that were accomplished for the incidents referred to them. The Workgroup and OCE are still working through updating the process to ensure those referrals are managed appropriately. None of the inspections have resulted in official action indicated (OAI); however, there have been VAI and NAI designations associated with the primary processors. Table 13 has been reserved for incidents referred for targeted sampling assignments; however, there have been no referrals for a sampling assignment thus far.

Table 11 – Incidents referred:

Year	Referrals	CP	SFP	SFP-Like	Comments
2022	7	0	7	0	
2023	13	1	12	0	
2024	15	0	14	1	

Table 12 – Referral for regulatory action

Year	Referrals	Number of Insp/RFFAs Conducted	WL	OAI	VAI	NAI	Comments
2022	7	4	2	0	2	0	Unknown designations for those firms receiving WLs. Follow-up to be conducted.
2023	13	3	0	0	1	2	Follow-up to be conducted
2024	15	0	0	0	0	0	No inspections/FRRA's conducted thus far.

Table 13 – Referral for Sampling assignments

Year	Referrals	Illness	
2022	0		
2023	0		
2024	0		

Annual Incident Reflection:

The following tables identify the number of incidents that have been investigated through the NT/SFP Illness Response Workgroup. The incidents have been documented either through the How to Report Seafood-Related Toxin and Scombrotoxin Fish Poisoning Illnesses | FDA and/or through the current or previously published Annual Program Evaluations. Table 16 is a work in progress since information is evolving for this section. As the Workgroup continues with the developing the program and streamlining the regulatory activities, the information will be expanded.

Table 14 – Unclassified number

NOTE: Unclassified numbers were not assigned during calendar years 2020 and 2021. The numbers were first initiated in 2022.

Years	CP	CP-Like	CP/SFP	Haff	PFP	SFP	SFP-Like	Other	Unknown	Total
2022	11	0	1	1	0	21	0	4	9	47
2023	14	0	0	0	0	33	1	0	3	52
2024	13	1	0	1	2	38	2	2	0	59

Table 15 – Classified numbers

Years	CP	CP-Like	CP/SFP	Haff	PFP	SFP	SFP-Like	Other	Unknown	Total
2020	7	0	0	2	0	1	0	0	0	10
2021	4	0	0	0	0	7	0	0	1	12
2022	9	0	1	0	0	11	0	0	2	21
2023	13	0	0	0	0	22	0	0	1	36
2024	12	1	0	1	2	24	1	0	0	41

Table 16 – Regulatory Referrals

Years	Referrals
2022	7
2023	13
2024	15

Conclusion:

The NT and SFP Illness Response 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 continuously updating the website; updating SOPs, protocols, and questionnaires; standardizing language, and crafting the annual program evaluations. This is the second program evaluation that defines and examines the incidents tracked as well as documents the efforts of the program to outside stakeholders. As time and resources allow, this will be an annual evaluation published henceforth. The NT and SFP Illness Response Program has become more visible to the public and the illness associated with these incidents are being recognized which directly correlates to the increased number of incidents reported annually especially for the SFP illnesses since 2020. We attribute this to transparency of the program with the availability of the website 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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