Deep-Sea Research II ▮ (▮▮▮▮) ▮▮▮–▮▮▮

Contents lists available at SciVerse ScienceDirect

Deep-Sea Research II

journal homepage: www.elsevier.com/locate/dsr2

Onboard screening dockside testing as a new means of managing paralytic shellfish poisoning risks in federally closed waters

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ARTICLE INFO

Keywords:
Field kits
Georges Bank
Management
Offshore waters
Paralytic shellfish poisoning
Quahogs
Saxitoxin
Surfclams

ABSTRACT

Paralytic shellfish poisoning (PSP) is the foodborne intoxication associated with the consumption of seafood contaminated with naturally occurring neurotoxins known as paralytic shellfish toxins. To protect public health from this potentially fatal syndrome, harvesting closures are implemented when toxins exceed the regulatory action level. Traditional monitoring programs established by state shellfish authorities allow for timely closures in state waters with minimal negative impacts on industry. However, such monitoring programs are not feasible in federal offshore waters given their distance from shore and the range of their spatial coverage. Thus innovative management strategies were investigated for these offshore resources. Georges Bank, an offshore resource with an estimated market value of more than $3 billion in Atlantic surfclams and ocean quahogs, has been closed to harvesting following a temporary ban in 1989 and a subsequent indefinite closure in 1990 due to the risk of PSP. As a means of managing this risk and allowing harvest of safe shellfish from this important resource, the Onboard Screening Dockside Testing Protocol (referred to as the Protocol) was developed by the US Food and Drug Administration (FDA), National Marine Fisheries Service (NMFS), state shellfish control authorities, and industry. The Protocol, which sets forth control measures to ensure product safety and public health protection, was endorsed by the Interstate Shellfish Sanitation Conference (ISSC) for pilot testing. Briefly, the pilot study Protocol required that (1) the fishing vessel receive a permit from NMFS to harvest in closed waters, (2) a minimum of five shellfish samples per intended harvest lot be tested for PSP toxins onboard, and (3) harvesting only occur when the samples tested from the intended fishing area are negative using the Jellett Rapid Tests or Abraxis Shipboard ELISA kits. Finally, product landed under the Protocol was confirmed to be safe for consumption using the mouse bioassay (MBA) prior to its introduction into commerce. This paper presents data from the pilot study, with primary focus on the advantages and challenges of the field kits employed onboard compared to the dockside MBA, which has served as the longstanding regulatory method for PSP toxins. In 2010 alone, the successful pilot study resulted in the safe harvest of over $2.7 million worth of surfclams in an area that has otherwise been unavailable for decades. Due to the success of this pilot study, the Protocol was adopted into the National Shellfish Sanitation Program Model Ordinance as an approved marine biotoxin control strategy for use in federal waters at the 2011 ISSC Biennial Meeting. In January 2013 a portion of Georges Bank was reopened for the harvest of Atlantic surfclams and ocean quahogs to fishermen following the Protocol.

1. Introduction

Paralytic shellfish poisoning (PSP) is a well-known intoxication that may manifest when seafood that is contaminated with neurotoxins, known as saxitoxin congeners or PSP toxins, is

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0967-0645/$ - see front matter © 2013 Published by Elsevier Ltd.
http://dx.doi.org/10.1016/j.dsr2.2013.01.036

consumed (e.g., Deeds et al., 2008; Etheridge, 2010; Hall et al., 1990; Schantz, 1984). Congeners belonging to this toxin family bind to voltage-gated sodium (Na^+) channels, attenuate action potentials, and prevent the passage of Na^+ ions across the channel membranes, resulting in paralysis. Patient treatment includes respiratory support, and on occasion fluid therapy to enhance toxin excretion. In general, prognosis is considered good for those surviving the first 24 h (Schantz, 1969). When fatalities occur, the cause of death is typically asphyxiation. Given the recurrent, yet ephemeral nature of these algal derived toxins, public health protection relies on successful monitoring and management strategies to keep contaminated seafood products from reaching the consumer. In the United States, individual states are responsible for managing PSP risks and implementing harvesting bans when necessary to prevent the harvest of contaminated products from state waters, nominally within three nautical miles offshore. State shellfish authorities have long established effective monitoring programs that allow for timely closures in state waters with minimal negative impacts on industry (Bean et al., 2005). Such programs are not feasible in federal offshore waters given the distance from shore (typically from 3 to 200 nautical miles) and the extent of spatial coverage when considering all waters included in federal jurisdiction (DeGrasse and Martinez-Diaz, 2011; Etheridge, 2010).

Georges Bank, located more than 50 nautical miles offshore in the North Atlantic Ocean, serves as a highly productive region, especially for bivalve molluscs. According to Thouzeau et al. (1991), 71% of the total megafaunal biomass is composed of Atlantic surfclams (*Spisula solidissima*), ocean quahogs (*Arctica islandica*), and sea scallops (*Placopecten magellanicus*). This region is valued at more than $3 billion in Atlantic surfclams and ocean quahogs alone (D. Wallace, Wallace & Associates, unpublished data). Moreover, the annual sustainable Georges Bank fishery for Atlantic surfclams, ocean quahogs, and roe-on sea scallops has an estimated value of $60–70 million (D. Wallace, Wallace and Associates, personal communication). Yet, this rich resource has largely been unavailable for more than two decades due to the risks of PSP toxins. While the US Food and Drug Administration (FDA) is responsible for the safety of seafood collected from federal waters, the agency does not have the statutory authority to close a fishery. Therefore, FDA works closely with the National Marine Fisheries Service (NMFS), which uses its authority granted under the Magnuson-Stevens Fishery Conservation and Management Act (Public Law 94–265) to open or close shellfish beds accordingly.

Reports of PSP toxins on Georges Bank date back to the early 1960s when Bourne (1965) observed low levels in the digestive glands of sea scallops. After toxin levels rose in the late 1980s, coordination between FDA, NMFS, and state shellfish authorities led to the implementation of closures on Georges Bank. Specifically, the initial closure began after PSP levels in Atlantic surfclams were found to be in excess of the regulatory action level of 80 μg saxitoxin equivalents (STX eq) per 100 g shellfish tissue. The Federal Register reported that values between 384–533 μg STX eq 100 g^{-1} were measured in surfclams collected at that time on Georges Shoals, a traditional fishing ground on Georges Bank. The resulting 90-day ban (emergency interim rule) on surfclam harvests from Georges Bank (east of 69°W) went into effect August 11, 1989 (54 FR 33700, August 16, 1989). In November 1989, the harvesting closure for surfclams was extended (emergency interim rule, extension) through February 7, 1990 as toxin levels remained above the action level (54 FR 47364, November 14, 1989).

Following a brief reopening in early 1990, a fisherman and his wife experienced PSP symptoms after consuming blue mussels (*Mytilus edulis*) collected as bycatch from Georges Bank on May 22, 1990 (White et al., 1993a). Shellfish testing at that time resulted in another 90-day harvesting ban on Georges Bank, which was implemented on May 25, 1990 as an emergency interim rule not only for surfclams, but this time it also included ocean quahogs, whole sea scallops, and blue mussels (55 FR 22336, June 1, 1990). The closure notice stated that PSP values measured 1527 μg STX eq 100 g^{-1} in surfclams at the time. Despite the harvesting ban, six more fishermen were poisoned after consuming contaminated blue mussels collected on Georges Bank on June 5, 1990 (Sharifzadeh et al., 1991; White et al., 1993a). The fishermen indicated that they were unaware of the ban. Two of the men became severely ill and were hospitalized for days. According to Sharifzadeh et al. (1991), toxin levels in the raw uneaten mussels that caused this event were 24,400 μg STX eq 100 g^{-1}. Subsequently, an emergency interim rule extension of 90 days was granted from August 23, 1990 (55 FR 35435, August 30, 1990). At this time, the Federal Register reported toxicity from July surveys ranging between 1666 and 4396 μg STX eq 100 g^{-1} in surfclams and up to 537 μg STX eq 100 g^{-1} in ocean quahogs. Two minor clarifications were made in this extension: (1) while the previous emergency interim rule stated that sea scallops could not be landed unshucked, this extension specifically stated that only sea scallop adductor muscle may be landed, and (2) the closure area was further defined with a northern boundary of 42° 20′N. Given the continued presence of PSP toxins in the region, another notice was published in the Federal Register in September 1990 that resulted in closure of the area indefinitely (55 FR 37500, September 12, 1990).

With a vast resource unavailable, fishermen were forced to move into other regions. For example, many fishermen focused efforts nearshore in the Nantucket Shoals area, which led to an early seasonal closure of surfclam fishing in this region in November 1989 when landing quotas were reached (54 FR 49298, November 30, 1989). Then in 2005 another widespread PSP event impacted this fishery when ~15,000 mi^2 of additional offshore waters were closed to the harvest of bivalves, except for sea scallop adductors (70 FR 35047, June 16, 2005). An amendment was made to this ruling in July 2005 to ensure that shellfish sample collection would be allowed in this region for the purpose of determining when PSP toxins were no longer a threat (70 FR 39192, July 7, 2005). In September 2005, the closure area was divided into northern and southern components (70 FR 53580, September 9, 2005) with the southern area designated as reopened (although the limitation of only harvesting sea scallop adductor muscles at sea was retained). Since June 2006, the northern area has remained closed (71 FR 37505, June 30, 2006). Recent harvesting closures for bivalve molluscs in federal waters are shown in Fig. 1. As a result of these widespread closures, fishermen have been pushed further south to harvest in the Mid-Atlantic Bight, an area that has been experiencing declines in surfclam populations due to natural mortalities (Marzec et al., 2010).

Stakeholders, which included FDA, NMFS, EPA, industry, and state shellfish authorities, met in the early 1990s and created an initial version of an alternative strategy for managing PSP risks in offshore waters. Mounting pressures on industry and the declining available resources in 2005 prompted the shellfish industry and federal/state agencies to develop a management plan rather than continuing to rely on temporary or indefinite closures. By 2007 the stakeholders had developed and agreed upon the Onboard Screening Dockside Testing Protocol (referred to hereafter as the Protocol), which was published in the Federal Register for comment (72 FR 70823, December 13, 2007). The actual pilot phase of the Protocol, allowing one fishing vessel to receive an exempt fishing permit (EFP) to harvest on Georges Bank, began in 2008 and continued through 2011. This paper describes the

Please cite this article as: DeGrasse, S., et al., Onboard screening dockside testing as a new means of managing paralytic shellfish poisoning risks in federally closed waters. Deep-Sea Res. II (2013), http://dx.doi.org/10.1016/j.dsr2.2013.01.036