

Seafood HACCP and Supplemental Training Protocol

This protocol has been developed to ensure a uniform and cost-effective delivery of the Seafood HACCP Alliance's HACCP training program for the processing and importing of fish and fishery products in the United States. The current protocol is reviewed at least annually by the Seafood HACCP Alliance (SHA) Executive Committee appointed by the Association of Food and Drug Officials (AFDO). Inquiries can be directed to haccp@afdo.org.

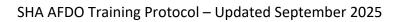
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1. Purpose

The purpose of the SHA/AFDO Seafood HACCP Training Protocol is to assist with the development and implementation of a uniform, cost-effective training program for the seafood industry. The Seafood HACCP Alliance (SHA) Seafood HACCP training is designed to satisfy the regulatory mandate that requires that certain HACCP activities must be completed by a "HACCP-trained individual" (FDA; Code of Federal Regulations Title 21 Part 123.10). The FDA Fish and Fishery Products Hazards and Controls Guidance (FDA Hazards Guide) specifically refers to the AFDO/Seafood HACCP Alliance training program. This SHA training program includes standardized courses, the training materials to be used in these courses, train-the-trainer (TTT) courses, instructors for TTT courses, and qualified trainers. Courses have been developed for training in seafood HACCP programs in addition to various supplemental trainings that complement the Seafood HACCP training program, such as the related Sanitation Control Procedures (SCP) training. The training is consistent with the regulatory mandates for processing and importing fish and fishery products for commerce in the United States. The primary audience is the seafood processing and importing industry, and regulatory officials based in the United States. This program may be provided for international audiences that need to meet U.S. regulations. Persons who complete the SHA/AFDO courses will receive Certificates of Course Completion from the Association of Food and Drug Officials (AFDO). The certificates for the seafood HACCP programs denote completion of a standard training program in the application of HACCP principles to fish and fishery processing as referenced by the U.S. Food and Drug Administration (FDA; 21 CFR Part 123) and the respective State HACCP regulations.

2. Organization and Process

The Seafood HACCP Alliance (SHA), or the "Alliance," is a collaborative training program involving representation from three federal agencies: the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture, and U.S. Department of Commerce – NOAA/Seafood Inspection Program; the Interstate Shellfish Sanitation Conference; and the seafood industry trade associations, e.g., National Fisheries Institute (NFI) and Seafood Products Association (SPA). Additional, pertinent expertise, programs, and associations can be progressively involved with this Alliance. These programs are linked in a cooperative partnership with expertise and trainers from numerous academic, Extension Service, and Sea Grant College programs across the nation. The Alliance includes the assigned SHA Executive Committee and the Seafood Community working jointly under the leadership of the Association of Food and Drug Officials (AFDO). The SHA Executive Committee is assigned by AFDO to provide timely advice needed to support and maintain the SHA/AFDO HACCP Training Program. Members of the executive



committee lead the management and maintenance of the training program and supplemental training through committee and workgroup activities supported by members of the Seafood Community. This collaborative effort is called the SHA/AFDO Seafood HACCP Training Program.

2.1. The Executive Committee

- 2.1.1. The Executive Committee shall be composed of:
 - 2.1.1.1. The Executive Director of AFDO,
 - 2.1.1.2. the Seafood HACCP Alliance (SHA) Director (hired contractor),
 - 2.1.1.3. a representative from the U.S. Food & Drug Administration [FDA],
 - 2.1.1.4. a representative from the U.S. Department of Commerce NOAA Fisheries,
 - 2.1.1.5. a representative from the U.S. Department of Agriculture
 - 2.1.1.6. a representative from the Interstate Shellfish Sanitation Conference [ISSC],
 - 2.1.1.7. a representative from the New York Sea Grant (NYSG)/Cornell University Segment One Training Program;
 - 2.1.1.8. a representative from the Florida Sea Grant training materials management team,
 - 2.1.1.9. The Train-the-Trainer (TTT) lead,
 - 2.1.1.10. Two representatives from industry organizations,
 - 2.1.1.11. Two representatives from state agencies,
 - 2.1.1.12. Two representatives from academia, and
 - 2.1.1.13. Three at-large members.
- 2.1.2. In the event of a vacancy on the Executive Committee, the Committee will continue to undertake its responsibilities, so long as the remaining Executive Committee members can satisfy the quorum requirement. The SHA director will work with the executive committee to identify and appoint new members to fill the vacancy.
 - 2.1.2.1. At-large members will serve staggered three-year terms with a new member elected annually. Any member of the seafood community is welcome to apply for the at-large position. Preference will be given to active trainers and those with expertise in seafood safety regulations and compliance.
- 2.1.3. Meetings Consistent with the purpose of the Committee, meetings of the Committee shall be called by the Director or designee. The Director or designee shall prepare an agenda in advance of any meeting.
- 2.1.4. Quorum A majority of the Executive Committee members shall constitute a quorum for the transaction of business.
- 2.1.5. Minutes and Reports The SHA director is responsible for ensuring that all



- actions taken by the Committee are reported to the Seafood Community. The Committee shall maintain the minutes of all Committee meetings and shall provide the Seafood Community with copies upon request.
- 2.1.6. Authority of the Director The Director of the Executive Committee may not act on behalf of the Committee.
- 2.1.7. Advisory Resources The Executive Committee may obtain such advice as it requires from time to time to address its responsibilities, whether through the appointment of one or more advisors to provide expert input, the engagement of consultants or other advisory resources, or through any other appropriate action.

2.2. The Seafood Community

- 2.2.1. The seafood community consists of all SHA trainers and any relevant trade associations or agencies with vested interest in seafood safety who wish to engage.
- 2.2.2. Community members can be involved in SHA activities by volunteering to serve on one or more active workgroups.
- 2.2.3. The SHA Community Engagement Workgroup will maintain regular avenues of communication between the executive committee and seafood community to support all SHA/AFDO qualified trainers.

2.3. The Association of Food and Drug Officials (AFDO)

- 2.3.1. AFDO fosters an integrated food safety system by proactively engaging with manufactured food, produce, and retail food safety programs and food safety stakeholders to identify their needs and implement targeted initiatives.
- 2.3.2. AFDO serves as the home and administrative arm of the Seafood HACCP Alliance. The SHA Administrator is an AFDO employee who supports the executive committee and activities of the Alliance as necessary.
- 2.3.3. The AFDO office will maintain records of registered courses, trainers, course evaluations, and course completions.

3. Qualified Trainers and Train-the-Trainer (TTT) Trainings

All SHA training courses must be supervised by a qualified trainer. A qualified trainer is one who has completed the appropriate Train-the-Trainer (TTT) training course as outlined below.

At least one Seafood HACCP TTT course will be taught annually in the United States with consideration to rotate the training location throughout the nation. Additional TTT courses may be taught depending on the demand in domestic, international, commercial, and regulatory settings and/or audiences that can meet course qualifications and provide the necessary support. Supplemental training TTT courses will be offered at the discretion of the SHA



executive committee based on need.

TTT Instructors will be appointed by the SHA Executive Committee with preference given to individuals involved in the development and maintenance of the SHA training materials and those used for TTT courses.

For the Seafood HACCP TTT, the participant's training certificate must be dated 2011 or later, as major revisions of the SHA training materials were released in 2011. U.S. Department of Commerce/NOAA-Seafood Inspection Program training certificates issued between 2011 and 2024 are also accepted.

To participate in a TTT, candidates must complete the required SHA/AFDO TTT application form that is subject to review and acceptance based on qualifications, experience, and intent to conduct SHA/AFDO training courses. The application form can be found online at https://www.afdo.org/training/sha/trainer/ttt/.

Within this protocol, assistant trainers are individuals who support a training session led by a Qualified Trainer. Assistant trainers are not required to be Qualified Trainers themselves; however, it is recommended that they have completed the training course they are assisting with. A *Technical Assistant* (TA) provides support to both Qualified Trainers and Assistant Trainers by managing the technical aspects of virtual training. An assistant trainer may also serve as the TA.

3.1. Seafood HACCP TTT Training Course

The required Seafood HACCP TTT training course must be at least 16 contact hours and will be taught by at least two qualified TTT instructors. Participants who complete the Seafood HACCP Train-the-Trainer are Qualified Trainers for the seafood HACCP training courses (Basic and Segment Two) consistent with this SHA/AFDO Training Protocol.

3.2. Sanitation Control Procedures (SCP) TTT Training Course

New Course Under Development, more information coming soon

3.3. Aquaculture HACCP TTT Training Course

Coming Soon

3.4. Importer TTT Training Course

Coming Soon

3.5. Other TTT Courses

Anyone who wishes to offer a non-Alliance organized TTT course must submit a formal



request, with relevant CV and credentials, to haccp@afdo.org and receive prior approval from the SHA Executive Committee.

4. SHA Training Materials

- 4.1. **HACCP Training Manual (English and Spanish):** The HACCP Training Manual is the core training manual for the HACCP Training Course. Chapters address implementation of HACCP programs consistent with recommendations by the National Advisory Committee on Microbiological Criteria for Foods and FDA's mandated HACCP Program for Fish and Fishery Products (21 CFR Part 123).
- 4.2. SCP Training Manual (English and Spanish): The Sanitation Control Procedures for Processing Fish and Fishery Products training manual was developed by the SHA/AFDO Alliance to address implementation of Sanitation Control Procedures (SCP) programs with recommendations consistent with FDA's mandated HACCP Program for Fish and Fishery Products (21 CFR Part 123) and Current Good Manufacturing Practice regulations (21 CFR Part 117).
- 4.3. **FDA's Fish and Fishery Products Hazards and Controls Guide (English and Spanish):** This guidance manual is prepared by the FDA to assist with hazard analysis and HACCP program development. This manual, referred to as "FDA Hazards Guide," can be viewed and downloaded at the FDA Seafood HACCP website. The latest editions are also available at the Florida Sea Grant section 4.6. All trainers and course participants are responsible for maintaining an awareness of changes and additions to the FDA Hazards Guide based on information, additions, and corrections posted on the respective FDA website. All participants, whether they attend a basic or Segment Two course, must have access to a copy of the FDA Hazards Guide during the training.
- 4.4. **Training Resources:** The SHA maintains standardized training resources to complement and support delivery of the curricula. The training slides reflect the required course content to be delivered and help ensure standard content delivery across training courses. The models and exercises were developed by the Alliance for training purposes and are used to conduct group exercises.
- 4.5. **Additional course materials** and content can be added and modified over time in accordance with SHA/AFDO protocol to assure compliance with regulatory mandates and commercial practice.
- 4.6. **Source:** The SHA training materials can be purchased or downloaded by qualified trainers at the Florida Sea Grant website, https://www.flseagrant.org/seafood/haccp/. (Most SHA training materials are available in both English and Spanish.)



5. General Training Requirements

The general training requirements outlined in this section apply to all SHA training courses.

- 5.1. Contact Hours: The contact hours are minimum time spent teaching, on class exercises, and on instruction/guidance. It does not include time spent on breaks and/or lunch. However, there is flexibility in the course design and agenda based on the nature of the audience (e.g., homogeneous audience by topic; very small class size; audience participants all using the same processing for similar products). If the Qualified Trainer can justify that they can accomplish all the objectives of the course and deviate from required contact hours, they must submit their justification in writing with the course registration application for consideration. Regardless of the format of the course, all topics need to be addressed; no sections can be deleted from a flexible course schedule.
- 5.2. Course Fees: The SHA/AFDO Seafood HACCP Training Program is intended to minimize the cost of the training. The Qualified Trainer should itemize any costs over \$600 per participant to justify the per-participant registration fee being charged. Registration fees should include the following items: certificate fees that will be paid to AFDO (see Table 1), refreshments, equipment and facility rentals, trainer fees, training manuals, and other costs for which participant registration fees will be collected. Incidental costs should be itemized on the course registration form.

Table 1: Summary of training materials costs and course fees. Any required training materials not listed in this table are available at no cost.

	Registration	Training Manuals ¹	AFDO Certificate Fee ²
Basic Seafood HACCP	Varies by Trainer	\$50 Hazards Guide	\$60
Training		\$40 HACCP Training	
		Manual	
Segment One Online	\$175	N/A	N/A
Course			
Segment Two Training	Varies by Trainer	\$50 Hazards Guide	\$0-\$60³
HACCP TTT	Varies by Year	\$50 Hazards Guide	Included in AFDO
	(AFDO)	\$40 HACCP Training	Registration
		Manual	
SCP Training	Varies by Trainer	SCP Training Manual	\$40
		(\$35)	

¹It is at the trainer's discretion to include this in the cost of their training or require participants to purchase directly OR allow digital access (not recommended for virtual training).

²This fee is necessary to reimburse AFDO for their services for registering HACCP courses, coordinating Qualified Trainers and Train-the-Trainer courses, maintaining the training protocol, and processing and



recording the Certificates of Training course completion.

³For participants who received a "Notice of Segment One Completion" PDF dated within 9 months, the \$60 certificate fee was collected at the time of enrollment in Segment One. Trainers do **not** need to submit an additional payment to AFDO for their certificate. Participants attending as a refresher – using a previously issued training certificate and **not** re-taking Segment One – will need to pay the \$60 certificate fee to have a new certificate issued.

- 5.3. **Virtual Trainings:** In a virtual learning space, there will be new administrative and electronic monitoring tools used to ensure participant activity and engagement. These should ensure that course content and structure is equivalent to any in-person training course.
 - 5.3.1. All participants must have internet connectivity and audio/video capabilities to participate.
 - 5.3.2. Participants must participate individually from a computer. Groups may NOT share a single computer.
 - 5.3.3. Participants may not access the virtual learning platform from a cell phone.
 - 5.3.4. It may be beneficial to record your training if there is a question regarding participants' participation as it relates to the issuance of their completion certificate. If you choose to record the virtual training, AFDO can request to review up to 45 days after completion of the course.
 - 5.3.5. Trainers should include the following language in their registration and confirmation emails to participants: "This training may be recorded for training and/or auditing purposes."
- 5.4.Training Course Evaluation: Trainers are responsible for sharing and requiring completion of the SHA standard training evaluation form for all training courses. The evaluation is available at bit.ly/SHAEvaluation. Digital is preferred. This URL and a QR code are provided in the training slides.
 - 5.4.1. When digital completion is not possible, hard copies of the forms can be completed and returned to AFDO with course closeout paperwork.
 - 5.4.2. Trainers interested in accessing their course evaluations can request the evaluations from haccp@afdo.org.
 - 5.4.3. Trainers who choose to do their own evaluation MUST include the questions in the SHA training evaluation and transfer the responses to the SHA Course Evaluation
 Spreadsheet to be submitted with the course closeout paperwork.

6. Basic Seafood HACCP Training

The Basic HACCP course is designed for persons working in commercial and regulatory settings or related professions who can influence and/or are involved with seafood and/or aquaculture



product safety. Course details and requirements are outlined in Table 2.

Table 2: Basic Seafood HACCP training requirements

	In Person	Virtual	
Minimum Contact Hours	16 hours	16 hours (an extra 30 minutes may be necessary for technical checks and remediation for some audiences)	
Required Training	Training Curriculum (Bl	ue Book) (SGR 137)	
Materials ¹	FDA Fish and Fishery Pr	oducts Hazards and Controls Guide	
	(Hazards Guide) (SGR 1	29)	
	SHA Basic Training Slide	es	
	 SHA Training Models/Ex 	xercise	
Certificate Fees	\$60/participant (paid to AF	DO with course closeout paperwork)	
Course Completion	Once course closeout pape	rwork is received (section 11.2) and	
Certificate	payment made, AFDO will issue training certificates to participants via email.		
Qualified Trainer	At least one qualified	At least one qualified trainer must be	
(section 3)	trainer must be present	present for the duration of the training.	
	for the duration of the	A technical assistant (TA) must also	
	training.	participate in virtual training. An	
	assistant trainer can serve as a TA.		
Qualified Trainer Register the training in advance of the training date.			
Responsibilities	Ensure ALL participants are: (1) actively engaged and learning		
	throughout the training course; (2) present for the training course; and (3) participating in group exe		
	Submit course closeout paperwork within 3 months of training		
	completion.		
Training Course		UST include all course content as	
Content	presented in Appendix I unless justification is provided and		
	approved for training modifications. It is important to allow at least		
Trainer: Darticinant	3 to 4 contact hours for the practical exercise. ant 1 trainer: 15 participants 1 trainer: 5 participants		
Trainer: Participant Ratio ²	1 trainer: 15 participants	T trainer: 5 participants	
Max Participants	None	20	
Group Size ² Max 5 participants per group			
Pre-requisites None			

¹ Trainers must possess/use the most recent editions of the required training materials listed above. All participants must have access to the current FDA Fish and Fishery Products Hazards and Controls Guidance Document (FDA Hazards Guide). The SHA training materials can be purchased or downloaded at the Florida Sea Grant website, https://www.flseagrant.org/seafood/haccp/. (Digital access is not recommended for virtual



trainings).

² If the ratio is lower or group size higher than what is stated above, the qualified trainer must provide additional justification on their application. This may require a course audit and auditing fees may apply.

7. Segmented Seafood HACCP Training

The segmented seafood HACCP training is a two-part training and an alternative to participating in the consecutive 16-contact-hour basic training course.

7.1. **Segment One:** The Segment One Online course is designed to teach participants the curriculum presented in the first two days of the SHA/AFDO Basic HACCP Course. The Cornell online course consists of 12 modules, each of which corresponds to the chapters in the Hazard Analysis and Critical Control Point Training Curriculum (most recent editions). Each participant's progress through the Online course will be tracked by course administrators. Twenty-four hours after completing Segment One, a "Notice of Segment One Completion (PDF)" will be available in the eCornell student portal (see image 1). This notice will serve as the participant's "ticket" to attend an SHA/AFDO Segment Two training course. All 12 Segment One course modules must be completed within 6 months of registration.

Image 1 – Example of Notice of Segment One Completion (PDF). This is the ONLY acceptable proof of completion for Segment One.



- 7.1.1. The registration fee for the Segment One Online course (Table 1) is paid by participants directly to the host organization for this course, the New York Sea Grant Program/Cornell University. Participants can register for the online course and pay the course fee online via credit card at http://seafoodhaccp.cornell.edu.
- 7.1.2. Trainers are responsible for ensuring that participants in their Segment Two training have successfully completed Segment One BEFORE their Segment Two.
- 7.2. **Segment Two:** Requirements for the live portion of the segmented training (Segment Two) taught by qualified trainers are outlined in Table 3 below.



Table 3: Segmented Seafood HACCP training requirements.

	In-Person	Virtual		
Minimum Contact Hours	6.5 hours	6.5 (an extra 30 minutes may be		
		necessary for technical checks and remediation for some audiences)		
Required Training	FDA Fish and Fishery Proc	ducts Hazards and Controls Guide		
Materials ¹	(Hazards Guide) (SGR 129			
	SHA Segment Two Trainir	•		
	 SHA Training Models/Exe 	_		
Certificate Fees	\$0-\$60 - For participants who	received a "Notice of Segment One		
	· ·	in 9 months, the \$60 certificate fee		
		enrollment in Segment One. Trainers		
		ditional payment to AFDO for their		
	certificate. Participants atten			
	1	rtificate and not re-taking Segment		
	certificate issued.	60 certificate fee to have a new		
Course Completion		vork is received (section 11.2), AFDO		
Certificate	will issue training certificates to participants via email within two			
	weeks.			
Qualified Trainer	At least one qualified	At least one qualified trainer must		
(Section 3)	trainer must be present for	be present for the duration of the		
	the duration of the	training. A technical assistant (TA)		
	training.	must also participate in virtual		
		training. An assistant trainer can serve as a TA.		
Qualified Trainer	Pogistor the training in adva			
Responsibilities	Register the training in advance of the training date. Ensure ALL participants are: (1) actively engaged and learning			
responsibilities	throughout the training course; (2) present for the duration of the			
	course; (3) participating in group exercises; and (4) in compliance			
	with training pre-requisites.			
	Submit course closeout paperwork within 3 months of training			
	completion.			
Training Course Content	Segment Two HACCP training courses must include all lectures			
	and activities in the agenda listed in Appendix II which includes at			
	least 2 hours for conducting practical exercises including hazard analysis and development of HACCP plans.			
, , , , , , , , , , , , , , , , , , , ,		1 trainer: 5 participants		
Trainer: Participant Ratio ²	1 trainer: 15 participants	T trainer. 3 participants		
Max Participants	None	20		
Group Size ²	Max 5 participants per group			



Pre-requisites	Participants must complete the Segment One online course
	within 9 months of the Segment Two training. Trainers are
	responsible for ensuring participants meet this requirement.

¹ Trainers must possess/use the most recent editions of the required training materials listed above. All participants must have access to the current FDA Fish and Fishery Products Hazards and Controls Guidance Document (FDA Hazards Guide). The SHA training materials can be purchased or downloaded at the Florida Sea Grant website,

https://www.flseagrant.org/seafood/haccp/. (Digital access is not recommended for virtual trainings.)

8. Sanitation Control Procedures (SCP) Training Course

The Basic SCP training course is designed for people working in commercial and regulatory settings or related professions that involve seafood and/or aquaculture product safety. The SCP course must use the SHA/AFDO training materials and follow the uniform course outline as presented in Appendix III. SCP training course requirements are outlined in Table 4.

Table 4: Sanitation Control Procedures (SCP) training requirements.

	In Person	Virtual		
Minimum Contact	6.5 hours	6.5 hours (An extra 30 minutes may		
Hours		be necessary for technical checks		
		and remediation for some		
		audiences.)		
Required Training	Sanitation Control Procedures (SCP) Training Manual			
Materials	SHA SCP Training Slides			
Certificate Fees	s \$40/participant due to AFDO with course closeout paperwork			
Course Completion	Once course closeout paperwork is received (section 11.2), AFDO			
Certificate	will issue training certificates to participants via email.			
Qualified Trainer	er At least one qualified trainer At least one qualifie			
	must be present for the	be present for the duration of the		
	duration of the training.	training. A technical assistant (TA)		
		must also participate in virtual		
		training. An assistant trainer can		
		serve as a TA.		
Qualified Trainer	Register the training in advance of the training date.			
Responsibilities	Ensure ALL participants are: (1) actively engaged and learning			
	throughout the training course; (2) present for the duration of the			

² If the ratio is lower or group size higher than what is stated above, the qualified trainer must provide additional justification on their application. This may require a course audit and auditing fees may apply.



	course; and (3) participating in group exercises.			
	Submit course closeout paperwork within 3 months of training			
	completion.			
Trainer: Participant	1 trainer: 15 participants 1 trainer: 15 participants			
Ratio				
Group Size	N/A			
Max Participants	None None			
Pre-requisites	None			

9. Aquaculture HACCP Training

Coming Soon!

10. Importer Training

Coming Soon!

11. Training Course Registration and Closeout

11.1. Course Registration

11.1.1. All SHA/AFDO training courses must be pre-registered to ensure they are approved in accordance with the established Training Protocol. A Basic HACCP, Segment Two HACCP, and SCP training may be registered by Qualified Trainers or their designated representatives. The periodic TTT courses are initiated and advanced through the SHA Executive Committee. All course registration applications MUST be submitted through the online registration portal,

https://www.afdo.org/training/sha/trainer/registration/, at least 20 business days before the scheduled training.

11.1.2. The SHA recommends all assistant trainers have successfully completed the training being taught.

11.2. Course Closeout

- 11.2.1. Upon completion of a training course, trainers should submit all course closeout paperwork described in the table below to AFDO (haccp@afdo.org) within 3 months of the training course end date to have certificates issued.
- 11.2.2. Certificates are sent via email within two weeks of receiving course closeout paperwork AND payment from the trainer, if necessary. Requests for re-issuing certificates or correcting mistakes on certificates will incur a \$15 fee if requested more



than 3 months after being issued.

Table 5: Course Closeout Paperwork.

	In Person and Virtual			
Basic Seafood	1. Trainer Worksheet			
HACCP	2. Participant Information Sheet			
	3. Certificate Invoice			
	Note: Participants should be strongly encouraged to complete the			
	digital evaluations before leaving (section 5.4).			
Segment Two	1. Trainer Worksheet			
Seafood HACCP	2. Participant Information Sheet			
	3. Certificate Invoice			
	4. Notice of Segment One Completion for each participant			
	Note: Participants should be strongly encouraged to complete the			
	digital evaluations before leaving (section 5.4).			
Sanitation	1. Trainer Worksheet			
Control	2. Participant Information Sheet			
Procedures	3. Certificate Invoice			
	Note: Participants should be strongly encouraged to complete the			
	<u>digital evaluations</u> before leaving (section 5.4).			

12. Revocation of Course or Trainer Credentials

- 12.1. **Course Revocations** The following items are just cause for AFDO to revoke any prior registered course:
 - 12.1.1. Failure to conduct training according to the SHA/AFDO Training Protocol and course registration requirements.
 - 12.1.2. Failure to pay the appropriate fees for any course.
 - 12.1.3. Submission of an intentionally false Course Completion Report (e.g., misidentified trainers, participants, dates, locations, or course outline).
 - 12.1.4. Responses indicating inappropriate instruction and/or failure to conduct training according to the SHA/AFDO course registration requirements. Inappropriate instruction can include concern for participants' listening and reading comprehension of the language used during instruction and in training materials.
 - 12.1.5. Failure to respond to violation notifications.
- 12.2. Certificates of course completion will not be issued if courses are taught without prior SHA/AFDO approval.
- 12.3. **Revocation of Trainer Qualifications:** Prior SHA/AFDO approved status as a Qualified Trainer can be revoked by the AFDO Executive Director in consultation with the



SHA Executive Committee depending on evidence from assigned audits of training courses, specific complaints from course participants, confounding factors involving compliance with required SHA/AFDO training protocols, mismanagement of registration fees or SHA/AFDO Certificates of Course Completion, misrepresentation of the SHA/AFDO courses and/or organization, and other related facts that compromise and/or taint the purpose and objectives of the SHA/AFDO Seafood HACCP Training Program.

13. Course Audits

13.1. Purpose

Per the SHA/AFDO Seafood HACCP and Supplemental Training Protocol, the Seafood HACCP Alliance reserves the right to arrange audits to monitor trainers and registered courses eligible for SHA/AFDO Certificates of Course Completion. The goal is to ensure that all trainers who are providing any SHA training courses adhere to the Training Protocols, which are intended to maintain a uniform and standard training format based on qualified trainers, current training materials, approved courses, and course audits for both domestic and international audiences.

13.2. Methodology

13.2.1. Training Violation Notification Letter

The first violation of the training protocol will initiate a written/email communication outlining the violation. The trainer will respond to violation(s) within five business days outlining justification or corrective action to the violation(s) identified. Failure to respond will result in a second notification and a pause in qualified trainer status and all scheduled courses.

13.2.2. Training Audit Initiation

An Audit may be initiated (1) based on failure to adequately address a violation notice, <u>OR</u> (2) Randomized virtual and in-person audit(s) may be conducted annually.

13.2.3. Audit Elements

Audit elements are outlined in the SHA/AFDO Audit Performance Form in section 13.6.



13.3. Audit Costs

13.3.1. Audit Compensation for Auditors

13.3.1.1. Randomized annual audit costs are paid by AFDO/SHA

13.3.1.2. Audit - Costs Compensation for Auditors

In-person Training Audits (\$850 per day for Audit; up to two travel days)

Segment Two - \$2,550 plus travel costs (1 day audit 2-day travel)

Basic Course - \$4,250 plus travel costs (3-days audit, 2-day travel)

<u>Virtual – Recording only</u>

\$125/hr 8hr cap for Segment two 16 hr cap for Basic

13.3.1.3. The cost of an audit is the responsibility of the trainer/auditee if an audit is initiated by a violation of the training protocol.

13.3.2. Audit Announcements

Auditees will be informed of an impending audit 48 hours before the auditor attends the course.

13.3.3. Multiple-Trainer Audit

If a course being audited has more than one trainer, all trainers will be included in that audit and will receive their own audit form.

13.4. Qualified Auditors

13.4.1. Definition

A **Qualified Auditor** is an active SHA Trainer on the SHA Executive Committee. **Active trainers** must lead or co-lead training at least annually. SHA may appoint an unbiased auditor familiar with the Alliance training protocols.

13.4.2. Unbiased Auditors

Qualified auditors will not be selected to audit a colleague or someone they work closely with and will always remain unbiased in their review.

13.4.3. Role of the Qualified Auditor



An auditor must be present for the duration of a course and is responsible for auditing the Qualified Trainer only and will not interfere with the course in any way.

13.5. Post-Audit Remediation

13.5.1. After the Audit

If the Qualified Auditor believes remediation is necessary for any area listed on the SHA/AFDO Audit Performance Form, the Alliance Trainer Audit Workgroup will determine the final remedy based on recommendations from the Qualified Auditor.

13.5.2. Status Definitions and Potential Next Steps

The Qualified Auditor will provide the Alliance with an overall evaluation of the Trainer in one of the following categories. The next steps based on the status are listed below.

Satisfactory - All sections are satisfactory

Definition: The auditor recommends Trainer status as "Satisfactory." Next Steps:

- The Auditor submits the Trainer's evaluation form.
- Reviews SHA/AFDO Auditor evaluation, and if it concurs, emails the Trainer and Alliance with a "Satisfactory" decision.

<u>Unsatisfactory – Three or fewer sections are evaluated as unsatisfactory</u>

Definition: The Auditor recommends additional instruction opportunities for the Trainer. Next Steps:

- The SHA Executive Committee discusses the <u>Unsatisfactory</u> evaluation with the Auditor and reviews the trainer course participant evaluations (if available).
- The SHA Executive Committee contacts the Trainer about the Unsatisfactory status and rationale to the trainer.
- The trainer must provide a written response for the unsatisfactory sections with a clear explanation and plan for how and when each area will be addressed and resolved.
- The trainer cannot conduct training until the unsatisfactory sections are addressed, and the SHA Executive Committee has verified that the Trainer has sufficiently corrected the deficiencies.

<u>Disapproved - Four or more of the sections are evaluated as unsatisfactory</u>

Definition: The Auditor recommends additional instruction opportunities for the Trainer.



Next Steps:

- The SHA Executive Committee discusses the <u>Disapproved</u> evaluation with the Auditor and reviews the trainer course participant evaluations (if available).
- The SHA Director or designee contacts the Trainer about the Disapproved status and rationale to the Trainer.
- A suspension/revocation of Trainer's certificate until remediation is taken and the SHA Executive Committee has verified that the suspended party has sufficiently corrected the instructional deficiencies. Re-audit is required at the trainer's expense.
- No certificates will be issued for participants in a training deemed unsatisfactory.
 Any participants in the unsatisfactory training will be reimbursed by the trainer and encouraged to participate in another SHA training.

13.6. Audit Form and Instructions

- 1) The Qualified Auditor reviews the evaluation form with the Qualified Trainer, prior to the start of the participant course, to help manage expectations. (For example, it is expected that the Trainer is actively engaged throughout the entire course.)
- 2) This performance audit is to be completed by the Qualified Auditor during the course.
- 3) At the conclusion of the course, the Qualified Auditor reviews the completed performance audit evaluation form with the Trainer.
- 4) The Qualified Auditor emails the completed evaluation form to AFDO and to the SHA Audit Committee no later than 72 hours after the completion of the course.





Seafood HACCP Alliance Association of Food and Drug Officials SHA/AFDO

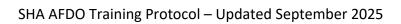
SHA/AFDO Audit Performance Form

Location	
Course Type	
Course Dates	
Course Hours	
Qualified Trainer Name	
Qualified Auditor Name	

In the tables provided below, please rate the Trainer's performance in the following areas. If you choose '0' or '1' for a given category, please provide an explanation in the comments section.

(S = Unsatisfactory, U = Satisfactory)

Sessions Delivered	Rating (S,U)	Duration of Session	Notes – Was there key curriculum content not delivered during the session?
ORIENTATION AND INTRODUCTION TO ALLIANCE COURSE AND HACCP			





PREREQUISITE PROGRAMS		
SEAFOOD SAFETY HAZARDS		
PRELIMINARY STEPS		
CONDUCTING A HAZARD ANALYSIS		
DETERMINING CRITICAL CONTROL POINTS		
ESTABLISHING CRITICAL LIMITS		
CRITICAL CONTROL POINTS MONITORING		
CORRECTIVE ACTIONS		
ESTABLISH VERIFICATION PROCEDURES		
RECORD-KEEPING PROCEDURES		
OVERVIEW OF FDA SEAFOOD HACCP REGULATION		
RESOURCES FOR PREPARING HACCP PLANS		
REVIEW AND INTRODUCTION OF		



PRACTICAL WORK SESSION		
GROUP WORK SESSIONS ON DEVELOPING HACCP PLANS		
GROUP PRESENTATIONS		
REVIEW, Q&A, AND ADJOURN		

Item No.	Evaluation Criteria	Rating (S,U)	Comments and Recommendations
1	Did the trainer discuss the layout of the guide?		
2	Were the learners required to demonstrate proper use of the guide?		
3	Did the trainer use SHA Material? (one point each)		
4	Approved slides		
5	Approved models		
6	Approved forms		
7	Proper representation of the Alliance (appropriate acknowledgment/attribution)		
8	Actively engaged with participants during the entire course		
9	Technical knowledge of course content		
10	Ability to answer questions		
11	Ability to provide relevant examples		



Item	Virtual and/or Blended Course		
No.	Elements	Rating (S,U)	
	Delivery methods (i.e., effective use		
12	of the virtual classroom to engage the group and deliver content)		
	Virtual/blended learning courses		
13	allow the interaction of participants		
14	Video and Audio communication		
	Monitors constant video and audio		
15	of learners		
	Monitors constant video and audio		
16	of learners		
	Use of required Technical Assistant		
17	(TA)		

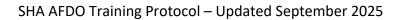
FOR INTERNAL USE ONLY

Qualified Auditor: Please complete the below information and email it to haccp@afdo.org. This information is not shared with the Trainer.

Location	
Course Type	
Course Dates	
Course Hours	
Name of Qualified Trainer	
Name of Qualified Auditor	

OVERALL TRAINER EVALUATION

Please indicate your overall evaluation level by placing an X next to the appropriate





status below and provide any additional comments on trainer and training that the executive committee should be aware of.

Satisfactory	
Unsatisfactory	
Disapproved	

Comments:



Appendix I Basic Seafood HACCP Training Curriculum (Agenda)

NOTE: The agenda below provides guidelines for time per topic. The standard agenda must be a minimum of 16 contact hours. Qualified Trainers must submit a course agenda with their Domestic or International Course Registration Form. When submitting the agenda with the course application, provide actual proposed times and show that the course is a minimum of 16 contact hours.

It is recommended but not required that the course be taught over a three-day period. The time allotted to each section allows for sufficient learning opportunities. However, there is flexibility in the design based on the nature of the audience (i.e., homogeneous audience by species or processing methods or very small class size). Regardless of the format of the course, allow three to four contact hours from the 16 hours, for the practical exercise. One useful alternative approach to stimulate participation is to arrange the work sessions following the respective instruction, e.g., work session on hazard analysis to follow the lecture on Determining Critical Control Points, and the work session on developing the HACCP Plan following the lecture on record-keeping. If using this format, indicate on the agenda submitted with the course application. Trainers may also elect to supplement information in Chapter 3 (Seafood Safety Hazards) with additional seafood-specific hazards unique to the audience, product types, or region.

Italicized blue text applies to virtual trainings.

Day 1	
Time	Topic
30 min	Virtual Trainings Only – May need to include a required 30-minute technology check and introduction.
15-20 min.	ORIENTATION AND INTRODUCTION TO ALLIANCE COURSE AND HACCP
	 Describe the purpose of the course. Explain the relationship of the Alliance and AFDO. Introduce the HACCP concept for food safety.
30-60 min.	PREREQUISITE PROGRAMS
	 Review programs that need to be in place before implementation of a HACCP program.
	 Describe the relationship between Good Manufacturing Practices (GMPs), sanitation control procedures (SCPs), and HACCP.

Describe monitoring, correction, and record-keeping requirements for 8



- areas of sanitation in the FDA Seafood HACCP regulation.
- Review examples of SCPs, monitoring, and records in curriculum manual.
- Review other relevant regulatory requirements that may apply to the audience.

60-75 SEAFOOD SAFETY HAZARDS min.

- Describe the general types of hazards, including species- and process-related hazards.
- Describe the species- and process-related seafood safety hazards found in the FDA Hazards Guide with emphasis on:
 - o What causes the seafood safety hazard
 - o What seafood products and processes are affected by the hazard
 - o How the hazard can be controlled (prevented, eliminated, or reduced to an acceptable level)

Knowledge Assessment 1

15-30 PRELIMINARY STEPS

min.

- Introduce preliminary steps that must be completed prior to applying HACCP principles.
- Introduce the XYZ Seafood Company model example to demonstrate preliminary steps.

90 min. CONDUCTING A HAZARD ANALYSIS

- Describe the steps in the Hazard Analysis process.
- Introduce and describe the Hazard Analysis form.
- Describe how to identify all potential species- and process-related hazards using the FDA Hazards Guide table in Chapter 3 of the Guide.
- Describe how to determine what hazards are significant using information from the Hazard chapter in the FDA Hazards Guide and justify the decision.
- Describe control measures for specific types of hazards.
- Use the XYZ seafood model to illustrate how to conduct a hazard analysis using the FDA Hazard Guide.

Knowledge Assessment 2

30-60

min. DETERMINING CRITICAL CONTROL POINTS



- Define critical control points (CCPs).
- Continue with teaching example to identify CCPs.
- Discuss tools to help identify CCP including the FDA Hazards Guide and the Decision Tree.

Optional – Conduct Practical Exercise of Hazard Analysis Here

Day 2	
Time	Topic
45-60 min.	ESTABLISHING CRITICAL LIMITS
	• Define and list typical critical limits (CLs) using examples from the curriculum manual.
	Introduce the HACCP Plan Form.
	 Describe control strategy options from the hazard chapters of the FDA's Hazards Guide.
	 Describe how to select one or more critical limits from a control strategy in Hazards Guide.
	Discuss use of operating limits.
	 Use the XYZ seafood model to illustrate how to set up HACCP plan form and select a critical limit using the FDA Hazards Guide.

Knowledge Assessment 3

45-60 CRITICAL CONTROL POINTS MONITORING min.

- Define and explain the purpose for monitoring.
- Describe the 4 elements of a complete monitoring procedure.
- Describe how to identify appropriate monitoring procedures for the critical limit option selected from the FDA Hazards Guide.
- Use the XYZ seafood model to illustrate how to identify monitoring procedures using the FDA Hazards Guide.

45-60 CORRECTIVE ACTIONS min.

- Define and explain need for predetermined corrective actions.
- Explain and identify the components required for a complete corrective action procedure.
- Describe how to identify appropriate corrective actions using the FDA Hazards Guide.
- Use the XYZ seafood model to illustrate how to identify corrective actions



using the FDA Hazards Guide.

45-60 min. ESTABLISH VERIFICATION PROCEDURES

- Define and explain the need for verification procedures.
- Explain types of verification procedures including validation, routine, and periodic verification.
- Give examples of typical verification procedures needed, including accuracy checks, calibration, and testing.
- Describe how to identify appropriate verification procedures using the FDA Hazards Guide.
- Use the XYZ seafood model to illustrate how to identify verification procedures using the FDA Hazards Guide.

45-60 min. RECORD-KEEPING PROCEDURES

- Define and explain the need for record-keeping procedures.
- Explain types of records needed and the record-keeping requirements in the FDA regulation.
- Review examples of types of records in the curriculum.
- Describe how to identify appropriate record-keeping procedures using the FDA Hazards Guide.
- Use the XYZ seafood model to illustrate how to identify record-keeping procedures using the FDA Hazards Guide.

Optional - Conduct Practical Exercise of HACCP Plan Development here

Day 3	
Time	Topic
90-120 min.	OVERVIEW OF FDA SEAFOOD HACCP REGULATION
	 Introduce the FDA seafood HACCP regulation and its format. Discuss each of the elements of the regulation using the curriculum manual format.
30 min.	RESOURCES FOR PREPARING HACCP PLANS
30-60 min.	REVIEW AND INTRODUCTION OF PRACTICAL WORK SESSION



- Divide participants into groups of 6 people or less and select a Teaching Model for each group to work on.
- Teaching models are available at https://www.flseagrant.org/seafood/haccp/.

180-240 GROUP WORK SESSIONS ON DEVELOPING HACCP PLANS min.

• Participants complete a Hazard Analysis and develop necessary HACCP Plans with trainer facilitation as necessary.

60 min.

GROUP PRESENTATIONS

• Each group presents the results of their Hazard Analysis and HACCP Plan with comments and discussion from participants and trainers.

30 min. REVIEW, Q&A, AND ADJOURN

RECOMMENDATIONS: The agenda must include numerous breaks and lunches to allow the participants to rest and concentrate better on the training. Although the required topics must be taught, they can be arranged to best suit the audience and situations. Experience has shown that the first portion should proceed through Critical Control Points, then conduct the practical exercises for completing the Hazard Analysis. This is followed by proceeding through the remainder of the curriculum and concluding with a final exercise for developing the HACCP plans. It is recommended that the course be taught over a 3-day period. Courses held within less than 2.5 days and/or less than 16 contact hours require written justification detailing mitigations and equivalency to the recommended protocol.

Knowledge Assessments (KA) can be used throughout the training to gauge participant understanding of the content and actively engage participants in the virtual setting. Example KAs are provided below and times for implementing them are suggested in the above example agenda.

Ex: Knowledge assessments (KA) 1: Seafood Hazards

- 1) Where in the hazards guide can you find more information on the hazard of allergens?
 - a) Chapter 7
 - b) Chapter 9
 - c) Chapter 12
 - d) Chapter 19



- 2) Where in the hazards guide can you find more information on the hazard of *Clostridium botulinum* toxin formation?
 - a) Chapter 7
 - b) Chapter 9
 - c) Chapter 13
 - d) Chapter 19

Ex: Knowledge assessment (KA) 2: Identifying Hazards

- 1) Which of the following hazards **IS** a concern in bluefish (*Pomatomus saltatrix*)?
 - a) Parasites
 - b) Natural toxins
 - c) Environmental chemicals
 - d) Aquaculture drugs
- 2) Which of the following hazards **IS** a concern in cod (*Gadus macrocephalus*)?
 - a) Environmental chemicals
 - b) Scombrotoxin (histamine)
 - c) Natural toxins
 - d) Parasites

Ex: Knowledge assessment (KA) 3: CCPs

- 1) On what page of the hazards guide can you find a table of potential control strategies for aquaculture drugs?
 - a) Page 11-18
 - b) Page 11-26
 - c) Page 11-22
 - d) Page 11-6
- 2) On what page of the hazards guide can you find a table of potential control strategies for glass inclusion?
 - a) Page 385
 - b) Page 398
 - c) Page 245
 - d) Page 297



Appendix II Segment Two Seafood HACCP Training Curriculum (Agenda)

The Cornell Online HACCP training course (Segment One) is designed to teach participants the information presented in the basic HACCP curriculum and assure that they understand how to use the FDA Hazards Guide. The SHA/AFDO Segment Two course provides additional instruction and Practical Work Sessions with oversight provided by a Qualified SHA/AFDO Trainer. To receive an AFDO "Certificate of Course Completion," participants who have completed the Segment One Cornell Online Course must then complete their training by attending a "live" (inperson or virtual) training course called Segment Two. The following Segment Two course format and agenda requires 6.5 contact hours. Individuals who previously attended an SHA/AFDO training course and want to attend a Segment Two course as a refresher, or to demonstrate that they have been updated or re-trained, must present a copy of their previous SHA/AFDO certificate to the Qualified Trainer, which is then forwarded to AFDO instead of a Notice of Segment One Completion.

Italicized blue text applies to virtual trainings.

Time	Topic
30 min	Introduction to (Zoom) and troubleshooting - REQUIRED for those not familiar with virtual learning and document sharing platforms (30 minutes)
30 min	Orientation, Course Objectives, and Introductions
30 min	Review of FDA Seafood HACCP Regulation (21CFR Part 123) Fish and Fishery Products, and the 7 Principles of HACCP
60 min	Identify species- and process-related food safety hazards and their associated control strategies using the FDA's <i>Fish and Fishery Products Hazards and Controls Guidance</i> (FDA Hazards Guide).
	• Explain how to use Chapter 3, using Tables 3-2, 3-3, and 3-4.
	 Discuss use of the "Understand the Potential Hazard" section of each chapter.
	 Participants should identify the food safety hazards for the provided commodities (e.g., model provided by SHA or based on participant's needs).
	Knowledge Assessment 1

90-120 Review Progressive Steps for Developing a HACCP Program min



• How to conduct a Hazard Analysis (e.g., product specification, flow diagram, and hazard analysis) using FDA's Hazards Guide (Chapter 2, Appendix 3, and a process model provided by SHA or based on a participant's needs).

Knowledge Assessment 2

- Developing a hazard analysis and identifying controls using the same model as bullet one and utilizing the individual chapters in the FDA's Hazards Guide to understand and develop a hazard analysis and identify CCPs
- Developing a HACCP Plan using individual chapters of the FDA's Hazards Guide and the same process model as per this section

Knowledge Assessment 3

- 120 180 Group Work Sessions using a new model(s) provided by the Alliance or model(s) min that are applicable to the participants' needs
 - Participants shall be divided appropriately into workgroups.
 - Each group shall develop a hazard analysis and HACCP plan as deemed appropriate by the Trainer.
 - 60 min Group Presentations Dependent on the number of groups presenting Team Presentations and Class Discussion of Group Work Session Results
 - 30 min Paperwork and Final Q&A
 - Participant information sheets
 - Digital SHA course evaluations

Ex: Knowledge assessment (KA) 1: Seafood Hazards (OPTIONAL)

- 1. Where in the hazards guide can you find more information on the hazard of allergens?
 - a. Chapter 7
 - b. Chapter 9
 - c. Chapter 12
 - d. Chapter 19
- 2. Where in the hazards guide can you find more information on the hazard of Clostridium botulinum toxin formation?
 - a. Chapter 7
 - b. Chapter 9
 - c. Chapter 13
 - d. Chapter 19



Ex: Knowledge assessment (KA) 2: Identifying Hazards (OPTIONAL)

- 1. Which of the following hazards IS a concern in bluefish (Pomatomus saltatrix)?
 - a. Parasites
 - b. Natural toxins
 - c. Environmental chemicals
 - d. Aquaculture drugs
- 2. Which of the following hazards IS a concern in cod (Gadus macrocephalus)?
 - a. Environmental chemicals
 - b. Scombrotoxin (histamine)
 - c. Natural toxins
 - d. Parasites

Ex: Knowledge assessment (KA) 3: CCPs

- 1) On what page of the hazards guide can you find the control strategies table for aquaculture drugs?
 - a) Page 11-18
 - b) Page 11-26
 - c) Page11-22
 - d) Page 11-6
- 2) On what page of the hazards guide can you find the control strategies table for glass inclusion?
 - a) Page 385
 - b) Page 398
 - c) Page 245
 - d) Page 297



Appendix III Sanitation Control Procedures Training Curriculum (Agenda)

Basic SCP Training Course Agenda

Italicized blue text applies to virtual trainings.

Time	Topic
30 min	Introduction to (Zoom) and troubleshooting - REQUIRED for those not familiar with virtual learning and document sharing platforms (30 minutes)
30 min	Registration and Welcome
60 min	Introduction
	Knowledge Assessment 1
30 min	Safety of Water*
90 min	Condition and Cleanliness of Food Contact Surfaces*
20 :	Knowledge Assessment 2
30 min	Prevention of Cross-Contamination*
30 min	Maintenance of Handwashing, Hand Sanitizing, and Toilet Facilities
30 min	Protection of Food from Adulterants and Proper Labeling, Storage, and Use of Toxic Compounds*
	Knowledge Assessment 3
30 min	Control of Employee Health Conditions
30 min	Exclusion of Pets
30 min	Example of SSOP Plan and Sanitation Control Procedures
	Knowledge Assessment 4

^{*}Discuss related concerns and controls for cross-contact with potential food allergens.

Ex: Knowledge assessment (KA) Questions:



1.	SCP re	cords shall be retained for at least for refrigerated products.
	a.	1 year
	b.	2 years
	с.	5 years
	d.	10 years
2.	The reg	gulation requires records for monitoring and corrections for key areas of tion.
	a.	10
	b.	6
	С.	_8
	d.	5
3.	Which	of these is not one of the nine common food allergens?
	a.	Milk
	b.	Fish
	C.	Wheat
	d.	Molluscan shellfish
4.	The re	gulation requires a written SSOP plan.
	a.	True
	b.	False