

# FDA UPDATE TO THE ISSC

## CFSAN UPDATE

International Partnerships, Federal waters, training and evaluation of Chapter II were discussed during the virtual meeting.

- The Molluscan Shellfish Compliance Program will be published soon. It will be available on the FDA.gov internet site.
- While COVID has had some impact on our foreign evaluation schedule, FDA is working to reschedule activities as soon as possible.

### LAB TEAM:

- The CFSAN LEOs have continued to perform NSSP Quality System and technical evaluations for domestic and foreign laboratories currently supporting the NSSP that needed to expand their scope of services.
- The Team has continued to provide technical assistance for several NSSP laboratories that are performing method verifications and for new State and private laboratories that are seeking conformance with NSSP requirements.
- LEOs have remained engaged in ISSC Lab Committee and Subcommittee work and have continued to support various OTED shellfish course creation and maintenance needs, such as the new We Storage/Depuration online course.
- The DSP checklist for LC-MS/MS was recently accepted by the ISSC Lab Committee.
- The NSSP Method Portal went live on the ISSC website; CFSAN LEOs maintain oversight of Method Portal updates and ensure content is complete and useful to current and prospective NSSP partners.

- Continued involvement in the IFPTI Lab Curriculum Framework Development Workgroup, to develop training competencies for shellfish specific and general laboratory content areas.
- Will shortly be hiring a new LEO position. We will keep the conference apprised of this development.

### ELEMENTS TEAM:

- We are lucky enough to have hired an epidemiologist/microbiologist willing to take on the illness monitoring responsibilities for our group, Dr. Elisa Elliot. Elisa will be involved in the VvIR, advise on the VMC, and will be managing illnesses for other programs in DSS, not just shellfish. We are VERY happy to have her on board.

### Shellfish International Policy (SIP) TEAM:

- Arrangements with Korea, Mexico, New Zealand and Canada are all still in place. The equivalence arrangement with the EU should allow trade to begin soon.
- At the request of Japan, FDA has begun work on a documentation review of their shellfish sanitation program. An outdated MOU exists that Japan still uses to accept exports from the US, but the US does not currently accept exports from Japan.

## ISSC VIRTUAL INFORMATION MEETING

Thank you to all who attended the ISSC Virtual Information Meeting on November 3, 2021. We also appreciate the feedback from those of you who completed the survey at the end of the meeting.

# OSCP DIVISION OF SHELLFISH SANITATION UPDATE

- During FY20/21 OSCP DSS completed all required program element evaluations through desk audit. Due to COVID travel restrictions, no field work was conducted. We thank all of the state partners who provided records and documents to the Shellfish Specialists for review that made the evaluations possible.
- Several PEERs and APERs are in final review and will be issued soon to state partners.
- The five Shellfish Specialists hired in 2020 completed their basic new hire training and assisted with record review and writing PEERs and APERs. They are getting out into the field to prepare for their standardization and to conduct independent program element evaluations.
- Shellfish Specialists have been instrumental in working with OTED to update all course materials and presentations and change face-to-face training to virtual format.
- The first session of FD342, Advanced Sanitary Survey of Shellfish Growing Areas was offered in July 2021. The CAG and Cadre worked extensively to develop the course and to improve it after an internal technical review. The course was well received by participants.

## OCSP CURRENT PRIORITIES

OSCP DSS is anxious to get back out into the field and work with our state partners! FDA is still limiting field work to mission critical activities. Therefore, our current work is focused on scheduling SSO standardization exercises for those that were extended due to COVID. During the COVID-19 'pause' over 20 SSO standardizations expired and were extended based on the NSSP Strategies document. We are working hard to get caught up and standardize new SSOs at state's request. We are also focusing on scheduling program element evaluations. We remain sensitive to health and safety concerns of our staff and state partners and the status of the industry.



## OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT UPDATE

OTED reports that all FY22 courses will be offered as Virtual Instructor Led Training (VILT). No information is yet available as to whether face-to-face courses will be offered in FY23.

The 2022 Shellfish Course Schedule:

FD245 Shellfish Plant Standardization: January 24 – 27, 2022

FD342 Advanced Sanitary Survey of Shellfish Growing Areas: July 25 – 28, 2022

OTED plans to offer FD245, FD242 and FD246 in FY23

OTED took significant steps to help states meet the new training requirements in Chapter I of the MO. To ensure staff were trained, OTED increased the required course offerings. Specifically, OTED offered 2 sessions of FD245 in both 2019 and 2020 and 1 session of FD242 Sanitary Survey of Shellfish Growing Areas in both 2020 and 2021.

The following courses are currently available online:

FD8001W: Intro to the NSSP

FD242W100: Intro to Shellfish Growing Areas

FD245W199: Intro to Shellfish Plant Sanitation

FD243200: Control of Shellfish Harvest

The registration process for future shellfish courses is as follows:

- Course announcement distributed via e-mail
- Attachment A will be a fillable PDF format
- Those wishing to register will forward their nominees to the shellfish email box: [oraotedshellfish@fda.hhs.gov](mailto:oraotedshellfish@fda.hhs.gov)
- OTED and shellfish management will evaluate training needs and assign slots as appropriate.

The new process can be found at: <https://www.fda.gov/training-and-continuous-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners>

Two new shellfish courses are currently under development:

- Wet Storage and Depuration online module
- Shellfish Risk Assessment and Risk Management

We are interested in hearing from you about future training needs. Is there a need to bring back the Basic Shellfish Plant Sanitation Course? Are there other areas of need or interest? Contact your Shellfish Specialist with your ideas!

## OFFICE OF PARTNERSHIPS UPDATE

### 1. Voluntary National Shellfish Regulatory Program Standards (VNSRPS)

- Provide:
  - a guide to design and manage a regulatory program
  - tools to evaluate the effectiveness of food safety interventions
- Standards for Plant and Shipping Element can be found at:
  - 2019 NSSP Guide – Section XVII. Full Plant Evaluation Standards

### 2. Milk Shellfish Cooperative Agreement

- More than \$2.4 Million is expected to be awarded for 2022 Training and Equipment Projects
- Training must be completed, and equipment purchased during CY 2022.
- If you have any other ideas or would like to submit an official subaward change request, please send an email to [msgrants@afdo.org](mailto:msgrants@afdo.org)
- Remember that any changes to your subaward must be approved in writing by AFDO in advance of any expenditure
- Important dates are:**
  - Training grant portal opens Sept. 27, 2021.**
  - Training grant portal closes Oct. 29, 2021**
  - Tentative Award letters sent early Dec. 2021**
  - Tentative Equipment grant portal opens early 2022**
- Recommend working with shellfish specialists for questions, ideas, and training opportunities
- PLEASE inform AFDO as soon as possible on any under used awards
- Also, if your state has a Federal Government Indirect costs agreement, may apply for this in the award application
- And finally, this funding is not available for developing or implementing the Voluntary National Shellfish Regulatory Program Standards BUT it can be used for travel to training that is required under Standard 2 or your program equipment needs after your program resource assessment conducted for Standard 8 of the VNSRPS .

### CONTACT:

Michael Antee, MS, RS

Shellfish Sanitation Program Specialist

Office of Partnerships (OP) | Division of Standards Implementation | Cooperative Programs

Office: 206-715-3481

Email: [michael.antee@fda.hhs.gov](mailto:michael.antee@fda.hhs.gov)

## OSCP DSS Welcomes New Branch Director

Michael Lombardi was selected as the new Branch Director for Branch II in the Office of State Cooperative Programs Division of Shellfish Sanitation and began his new position on Tuesday, October 12, 2021.

Michael has extensive Federal and State program management, HACCP and preventive controls expertise. Educated in environmental health, he has worked in FDA as an Investigator and Supervisor in HAFE4, in the Florida Department of Agriculture as the Director of Field Operations/Environmental Administrator and supervisor and he has worked at the NY Department of Agriculture and Markets as an inspector.

He has been part of several key leadership and technical development programs, Partnership for Food Protection (PFP), Seafood Investigator Level 2 Certification, Preventive Controls Training Cadre, and served as a State Food and Seafood Products Performance auditor. Michael is a big picture thinker who is a true collaborator who embraces the



cooperative program model.

Michael is located in Miami, FL and can be contacted at [michael.lombardi@fda.hhs.gov](mailto:michael.lombardi@fda.hhs.gov). We are happy to welcome Michael to the OSCP DSS family!