



MEMORANDUM TO: Seafood Inspection Program Users and Personnel

FROM: Steven Wilson, Chief, Seafood Inspection Program
Office of International Affairs, Trade, and Commerce

SUBJECT: Certifications for Fish Oil Dietary Supplements
Update and Label Approval Procedures

This memo serves as an official notification from the National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program (SIP) to update stakeholders on the certification of encapsulated fishery product oils identified as dietary supplements or intended for human consumption. SIP had previously limited certification to only products using trace amounts of oils other than fish oil. To continue our plan to avoid further trade disruption, SIP will certify all dietary supplements characterized as fish oil, including those with other oil ingredients. NOAA continues to consult with other agencies with relevant authorities related to certification of dietary supplements.

NOAA seeks to support the continued trade in legitimate products to support industry stakeholders and consumers, while also ensuring that SIP has adequate information to make accurate attestations and is able to maintain continued integrity in certification processes for trade with other countries. SIP is the competent authority to certify the fish oil ingredient as a fishery product. To ensure consistency and clarity on this process, SIP will certify products using the approval process outlined below:

- Fish oil must be traceable to the harvest location. Firms requesting certification will be required to maintain documentation that demonstrates this traceability and will be required to provide that documentation to SIP immediately upon request during routine audits.
- For product going to the EU, all facilities involved in the process, including the encapsulator, must be on the EU Approved Establishments List.
- The primary label must prominently identify the product as a fish oil, and the species of the fish oil ingredient must be declared.
- Labels must be pre-approved prior to certification. To gain label approval, please send an electronic copy of the label and the formulation of the product to sip.fishoil@noaa.gov
- Once the label is approved, it will be logged into our system and a notice sent back that the label is approved for certification, whether any changes are necessary, and

the details of the approval. The applicant will then need to contact their servicing SIP Region for the certificate. The SIP Region will consult our system to verify approval and will then issue the certificate.

SIP is preparing information to be placed into the online Seafood Inspection Manual, which will state all the requirements for the certification of this product, including any requirements that have been sent out through our communications in order to have all the Program policies and procedures in one place. A notice will be sent out once the manual is updated.

SIP will continue to communicate with users and personnel as requirements evolve, interagency roles and responsibilities are clarified, and if it becomes necessary to change certification processes or suspend certification. SIP may consider future requirements to ensure integrity in the certification process, such as whether oils sourced entirely from foreign countries should be eligible to receive SIP certification for export; whether firms involved in this process should become SIP approved establishments in the Seafood Inspection Program, especially U.S. based encapsulation plants; end-item product testing by SIP; and the language to be used regarding the certification of the oil or the entire capsule.

Approved Establishments under the Seafood Inspection Program will continue to be able to gain certification for bulk shipments when product lots are identified as processed under the SIP controls. SIP continues to enhance the certification process of encapsulated fish oils and will continue discussions with other federal agencies and trading partners to support trade and compliance with related requirements.

Please contact your local SIP Regional Office for updates on product exports and certification requests.