August 26, 2026

Mark Abdoo
Associate Commissioner
Office of Global Policy and Strategy
The United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
United States of America

Dear Mr. Abdoo,

I write in reference to your letter dated August 11, 2026 which reads as follows:

"The United States Food and Drug Administration (FDA) is pleased to cooperate with the Department of Agriculture, Fisheries and Forestry (DAFF) of the Commonwealth of Australia concerning certification requirements for bivalve molluscs and bivalve mollusc products exported from the United States of America to Australia. FDA intends to support the certification requirements with the following arrangement with DAFF.

FDA and DAFF intend to strengthen existing collaboration in areas of mutual interest and establish certification requirements for the export from the U.S to Australia of bivalve molluscs and bivalve mollusc products from a U.S. FDA registered establishment[1]. Bivalve molluscs include clams, cockles, mussels, oysters, pipis and scallops (including adductor meat of shucked scallops). Bivalve mollusc products are food that contains 50% or more bivalve mollusc meat, such as seafood mixes. This includes bivalve molluscs that have been grown and harvested in the U.S.; bivalve molluscs that have been grown and harvested in countries other than the U.S.[2]; and bivalve mollusc products that have been made from these bivalve molluscs but excludes bivalve molluscs that are dried or retorted and shelf stable.

To meet biosecurity import conditions[3] for bivalve molluscs, currently only nonviable[4] molluscs are expected to be permitted entry. Oysters are expected to be flesh only (no shell) and other bivalve molluscs are expected to only include shell if they are frozen.

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[1] That includes bivalve molluscs that have been grown and harvested in the U.S. or in countries other than the U.S., and bivalve mollusc products that have been made from such bivalve molluscs. Australia's assessment of the U.S. regulatory system provides assurance that the FDA or its regulatory partners conduct routine inspections of foreign bivalve mollusc processors to verify compliance with U.S. requirements, which provides an equivalent food safety outcome to Australia's.

[2] Australia's assessment of the U.S. regulatory system provides assurance that the FDA or its regulatory partners conduct routine inspections of foreign bivalve mollusc processors to verify compliance with U.S. requirements, which provides an equivalent food safety outcome to Australia's.

[3] Details on biosecurity import conditions for bivalve molluscs can be found in the Department's Biosecurity Import Conditions system (BICON) under the biosecurity case for seafood (excluding finfish) for human consumption.

[4] Non-viable refers to bivalve molluscs that are dead, i.e. those that have undergone processing including shucking, chilling, freezing, cooking, marinating and smoking.

FDA understands that DAFF intends to, in its operation of the Australian *Imported Food Control Act of 1992:*

1. Recognize FDA as the government competent authority empowered to provide certification for these products and to conduct sampling and testing as necessary.

2. Notify the FDA where non-compliance is detected with bivalve mollusc and bivalve mollusc products.

3. Check the validity of certification that accompanies consignments.

4. Conduct sampling and testing of bivalve molluscs and bivalve molluscs products exported from the U.S.

To discharge FDA's responsibilities regarding bivalve molluscs and bivalve mollusc products, FDA intends to:

1. Provide certification for each consignment of bivalve molluscs and bivalve mollusc products exported to Australia. Consignments are expected to be accompanied by certificates issued by the FDA. An example of this certificate is enclosed as an attachment.

2. Certify that bivalve mollusc and bivalve mollusc products covered by this letter meet applicable food standards and food safety requirements as outlined in the "Report supporting foreign government certification arrangements for bivalve molluscs exported from the United States of America" enclosed as an attachment.

3. Inform DAFF of any changes to existing regulations regarding bivalve molluscs and bivalve mollusc products, or the competent authorities involved in regulating bivalve molluscs and bivalve mollusc products.

4. Immediately notify DAFF when there is an identified serious public health risk related to bivalve molluscs and bivalve mollusc products exported to Australia.

FDA and DAFF intend to cooperate and communicate, as appropriate, on export certification for bivalve molluscs and bivalve mollusc products, including, but not limited to:

1. Communication about legislation, policies, procedures and guidelines concerning enforcement and inspection; and

2. Exchanging specific information to facilitate the operation of areas of cooperation under this arrangement such as adverse findings during inspections, adverse findings during compliance checks and the measures taken regarding the product in question, any follow up information or assurances requested by DAFF of FDA where product fails during compliance checks, and evidence located by either DAFF or the FDA of falsification of certificates.

Information exchanged between FDA and DAFF may be provided in a form appropriate for public dissemination under applicable domestic and international laws and regulations. The exchange of any non-public information is expected to be done in accordance with established confidentiality commitments and any applicable laws and regulations.

This arrangement is not intended to, and does not, create rights or obligations under international or domestic law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. FDA and DAFF each intend to bear their own expenses associated with this cooperation. Operation is expected to be in accordance with the Codex Alimentarius: Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) of the Food and Agriculture Organization (FAO).

Either FDA or DAFF may request to modify this arrangement. Either FDA or DAFF may discontinue the areas of cooperation outlined in this arrangement at any time but is expected to provide sixty (60) calendar days' written notice to the other. FDA and DAFF intend to discuss reassessments, reviews, or audits of the arrangement at least once every five years.

If the foregoing is acceptable, then this letter, together with your letter of acceptance in reply, constitutes an arrangement between FDA and DAFF, which commences on the date of your reply."

The DAFF confirms its acceptance of the above letter, and that your letter and this letter in reply confirms this collaboration between the FDA and DAFF, which commences on the date of this letter.

Sincerely,

-/s/-

Dr. Joffrid Mackett
Assistant Secretary
Residues and Food Branch
Department of Agriculture, Fisheries and Forestry
Agriculture House
70 Northbourne Avenue, Canberra 2601
Commonwealth of Australia

8/26/26

Date