



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE/AB/D3/AA/es(2020) 4520400

Dear Mme Abram,

**Subject: Reply to your letter on “EU-U.S. Shellfish Cooperation”
(ref. Ares(2020)3915938)**

Thank you for your note of 13 July 2020, referring to the preparatory steps already taken to commence trade in bivalve molluscs. We share the understandings described in your note and the intended further actions described in the Administrative Arrangement between the US Food and Drug Administration (FDA) and the Directorate General for Health and Food Safety (SANTE) of the European Commission.

In this respect, I would like to kindly let you know that DG SANTE intends to apply the Administrative Arrangement to ensure the smooth running of the evaluation procedure for additional U.S. NSSP participants seeking to be listed on the EU “List of third countries and territories from which imports of live, chilled, frozen or processed bivalve molluscs for human consumption are permitted” (EU List), and to list NSSP participants on the EU List without regard to the volume of trade between us.

In addition, DG SANTE intends to jointly establish a Technical Working Group with the FDA which will provide a forum to address scientific and technical issues related to the safe trade of bivalve molluscs and undertake an equivalence evaluation of the U.S. food safety control systems in place for *processed* molluscan shellfish, which FDA applies and is seeking recognition on a national basis. DG SANTE launched the equivalence exercise in January 2020 and, up to date, the following steps are completed:

- End of January 2020: Launch of the EU-US equivalence assessment exercise on processed shellfish. Request to FDA for further information/updates needed on relevant documentation.
- February – April 2020: Information gathering and comparative analysis of the regulatory requirements.
- July 2020: Final consolidated comparative table on the control systems’ requirements.

Mme Anna K. Abram
Deputy Commissioner for Policy, Legislation and International Affairs
U.S. Food and Drug Administration

The assessment shall continue with the on-site equivalence audit of the U.S food safety control systems in place for processed molluscan shellfish, which the FDA applies and is seeking recognition on a national basis. However, given that the pandemic has resulted in many audits either being cancelled or postponed, and that there is still a doubt about the planning for the onsite equivalence audit, the following remaining steps will be carried out within a timeline to be decided depending on the evolution of the situation:

- Exchanges with the FDA in relation to the audit preparation.
- Equivalence audit of the U.S. food safety control systems in place for processed molluscan shellfish, which FDA applies and is seeking recognition on a national basis. The extent of the scope, duration, teams and location of establishments will be defined once the desk analysis finalised but will cover the full production chain.
- Audit report and if there are sufficient grounds, the preparation of the proposal for a Decision of the equivalence determination and certificate.
- Planned adoption and subsequent publication of the Decision.

We understand that FDA is proceeding with its publication in the Federal Register of the final equivalence determination for live bivalve molluscs from Spain and the Netherlands and DG SANTE is proceeding with the administrative steps to commence trade in bivalve molluscs.

Yours sincerely,

(e-signed)

Anne BUCHER

Enclosure: Administrative arrangement between the US Food and Drug Administration and DG SANTE regarding trade in bivalve molluscan shellfish