Anne Bucher
Director-General
Directorate-General for Health and Food Safety
European Commission

Brussels, Belgium

Note to DG SANTE

Subject: EU– U.S. Shellfish Cooperation

Date: 13 July 2020

Dear Director-General Bucher,

FDA and DG SANTE (hereafter referred to as "the authorities") signed an Administrative Arrangement with respect to our individual determinations that the measures each authority applies to raw bivalve molluscan shellfish.[1] The Administrative Arrangement provides a mechanism for evaluating additional EU Member States and U.S. NSSP participants which, following a positive evaluation, will enable them to export raw and processed bivalve molluscan shellfish.

Importantly, the authorities do not intend to require an on-site audit as a condition of evaluating additional NSSP participants or EU Member States. However, the authorities recognize that they have the right to undertake on-site audits if a need is identified during the evaluation, and to verify that NSSP participants and EU Member States maintain equivalent controls in the years following their listing. To facilitate the evaluation of additional EU Member States by FDA and NSSP participants by DG SANTE, each authority intends to review the documentation specified in the Administrative Arrangement before submitting a request to the other authority.

The authorities do not intend to limit the number of NSSP participants or EU Member States seeking to be listed that the authorities will review in a single request. Additionally, the authorities do not intend to limit, on the basis of trade volume, the number of NSSP participants or EU Member States that the authorities will list.

To facilitate trade in bivalve molluscan shellfish, the authorities intend to establish a Technical Working Group, which will provide a forum for addressing scientific and technical issues related to the safe trade of bivalve mollusks, including:

- Sharing information about any planned, modified, or repealed measure or set of measures that have a bearing on the bivalve molluscan shellfish trade;
- Identifying and discussing problems associated with the import review and admission of bivalve molluscan shellfish shipments traded between the parties;

[1] *See* EC Annex I of Decision 2006/766/EC, amended on November 6, 2018. Also, see U.S. Federal Register Notice, dated [date].

- Adding NSSP participants to the EU List of third countries eligible to export animal products to the EU and EU Member States to the Interstate Certified Shellfish Shippers List (ICSSL) of shellfish processors and growing areas;
- Reviewing post-harvest processing options for U.S. raw molluscan shellfish harvested from growing areas operating under a *Vibro vulnificus* management plan;
- Discussing control of *Vibrio parahaemolyticus* and marine biotoxins in bivalve mollusk populations; and
- Engaging in technical discussion on other topics identified by DG SANTE and FDA.

To ensure the efficient use of time and resources, for each meeting of the Technical Working Group, the authorities intend to record minutes, identify action items and reach agreed timeframes for action. Furthermore, the authorities intend that all non-public information exchanged between them is to be exchanged in accordance with Confidentiality Commitments[2] between them.

Recognizing that DG SANTE's equivalence determination only addresses access to the EU market for raw and processed U.S. molluscan shellfish initially from "Approved growing areas" in Massachusetts and Washington, and that the United States does not require a determination of equivalence for processed shellfish exported from the EU to the United States, DG SANTE has agreed to undertake a separate equivalence evaluation of the food safety control systems in place for *processed* molluscan shellfish, which FDA applies and is seeking recognition on a national basis. FDA oversees the safety of processed shellfish in the United States through the enforcement of mandatory, national Seafood Hazard Analysis and Critical Control Point (Seafood HACCP) requirements governing the commercial sale of processed shellfish intended for human consumption. In conducting its evaluation of regulatory controls applied to U.S. processed molluscan shellfish, DG SANTE has agreed to rely also on information collected during its systems recognition reviews of FDA food safety controls, the evaluation of the U.S. system of controls applied to raw molluscan shellfish, and a long history of auditing Seafood HACCP controls applied to U.S. fish and fishery products.

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

Anna K. Abram

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

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[2] FDA-SANCO Confidentiality Commitment of June 2005
https://www.fda.gov/international-programs/confidentiality-commitments/dg-sanco-europe-fda-confidentiality-commitment