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ADMINISTRATIVE ARRANGEMENT BETWEEN THE THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THE DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY OF THE EUROPEAN COMMISSION REGARDING TRADE IN BIVALVE MOLLUSCAN SHELLFISH

1. This Administrative Arrangement aims to strengthen the cooperation and exchange of information between the United States Food and Drug Administration (FDA) and the Directorate-General for Health and Food Safety of the European Commission (DG SANTE) regarding trade in bivalve molluscan shellfish, including edible species of oysters, clams, cockles, mussels, and roe-on scallops, either shucked or in the shell, whole or in part. The procedures described in this Administrative Arrangement are intended to accord with applicable respective domestic legislation.

2. FDA and DG SANTE note that it is intended to commence trade regarding raw and processed bivalve molluscs harvested from Approved growing areas[1] in the United States by participants in the U.S. National Sanitation Program (NSSP participants[2]), initially from Massachusetts and Washington, which are officially listed by DG SANTE on the "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 raw bivalve molluscs harvested from eligible Class A production areas[3] in the European Union (EU), initially by the EU Member States of the Netherlands and Spain, which are officially listed by FDA on the U.S Interstate Certified Shellfish Shippers List (ICSSL).

3. In the context of handling the requests by NSSP participants to be added to the EU List:

   3.1. FDA intends to submit to DG SANTE requests from NSSP participants seeking to be added to the EU List.

   3.2. FDA intends to review the information referred to in points 3.3 and 3.4 and inform DG SANTE that, based on the information provided, NSSP participants seeking to be added to the EU List have applied relevant U.S. measures.

   3.3. FDA normally intends to submit the following documents and information with the requests referred to in points 3.1 and 3.2, unless a NSSP participant is seeking to be listed using point 3.4:
   a) List of Approved growing areas;
   b) List of firms/processors harvesting product in those Approved growing areas;
   c) Most recent FDA audit of the NSSP participant's implementation of the NSSP and any corrective actions taken after the audit;
   d) Most recent sanitary survey(s) for those Approved growing areas;

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[1] In the United States, "Approved growing area" under the NSSP means any site which supports or could support the propagation of shellstock by natural or artificial means where harvest for direct marketing is allowed.

[2] In the United States, the safety of raw molluscan shellfish is controlled by the application of measures in the U.S. National Shellfish Sanitation Program (NSSP). The NSSP is implemented in the United States at the sub-national State level, referred to as "NSSP participants."

[3] In the European Union, "Class A production area" is an area categorized according to the level of faecal contamination where harvesting of live bivalve molluscs for direct human consumption is permitted.

e) Most recent inspection reports for firms operating in those Approved growing areas and, in case of non-compliance, corrective actions taken by firms after the inspections;
f) List of laboratories performing official regulatory analysis of raw molluscan shellfish samples and the most recent NSSP evaluation report for each lab, including any resulting corrective actions; and
g) Summary description of applicable U.S. mechanisms for implementing and enforcing FDA regulations, plus enforcement of additional measures, if any, applied to those growing areas/processors.

3.4. For NSSP participants seeking to ship raw shellfish harvested from an Approved growing area in another NSSP participant that is already on the EU List, documentation normally consists of:
a) The most recent Plant and Shipping Element Program Evaluation Report; and
b) The most recent inspection report for each shellfish processing firm seeking to be listed for export to the EU.

3.5. Without limiting the number of NSSP participants to be considered, DG SANTE intends to evaluate promptly the documents referred to in point 3.3 or 3.4 and notify FDA of the results of its evaluation.

3.6. Following a positive evaluation, DG SANTE intends to promptly initiate its administrative procedures relevant to the context of handling the requests by NSSP participants to be added to the EU List, without prejudging the final outcome of such procedures.

4. In the context of handling the requests from EU Member States to be added to the ICSSL:

4.1. DG SANTE intends to submit to the FDA requests from EU Member States to be added to the ICSSL.

4.2. DG SANTE intends to review the information referred to in point 4.3 and inform FDA that, based on the information provided, EU Member States seeking to be added to the ICSSL have applied relevant EU measures, including additional agreed measures.

4.3. DG SANTE normally intends to submit the following documents and information with the requests referred to in points 4.1 and 4.2:
a) List of eligible Class A production areas;
b) List of firms/processors harvesting product in those Class A production areas;
c) Most recent EC audit of the EU Member State's implementation of EU measures, additional measures referenced in point 4.2, and the corrective actions taken, if any, after the audit;
d) Most recent sanitary survey(s) for those eligible Class A production areas;
e) Most recent inspection reports for firms operating in those Class A production areas and, in case of non-compliance, the corrective actions taken, if any, after the inspection;
f) List of laboratories performing official regulatory analysis of raw molluscan shellfish samples, and the most recent ISO 17025:2017 (or equivalent) audit report for each laboratory, including any resulting corrective actions; and

g) Summary description of EU Member State's mechanisms for implementing and enforcing: EU measures applied to raw bivalve molluscan shellfish; any additional national measures adopted by the EU Member State; and application of additional agreed measures referenced in point 4.2.

4.4. Without limiting the number of EU Member States to be considered, FDA intends to evaluate promptly the documents referred to in point 4.3 and notify DG SANTE of the results of its evaluation.

4.5. Following a positive evaluation, FDA intends to promptly initiate its administrative procedures relevant to the context of handling the requests by EU Member States to be added to the ICSSL, without prejudging the final outcome of such procedures.

5. Generally, DG SANTE and FDA each understand that an on-site audit is not required when evaluating requests referred to in point 3 from NSSP participants or point 4 from EU Member States, but each may determine that an on-site audit is necessary, including either during an evaluation or to ensure that a positive determination of equivalence is maintained.

6. DG SANTE and FDA each intend to promptly notify the other:
   a) of any listed Class A production area in the EU or Approved growing area in the United States that is reclassified;
   b) any food safety concern regarding bivalve molluscan shellfish exported to the other, including outbreaks, recalls, and foods that could cause acute or chronic deleterious human health consequences;
   c) of any product exported to the other that does not conform to the other's equivalence determination; and
   d) of any plan to adopt, modify or repeal a measure related to the production of bivalve molluscan shellfish.

7. DG SANTE and FDA each intend that for all non-public information exchanged between them is to be exchanged in accordance with the Confidentiality Commitments[4] between them.

8. For the purpose of implementing this Administrative Arrangement:
   a) The contact point for DG SANTE is Unit D3, Bilateral International Relations.
   b) The contact point for the FDA is from the Center for Food Safety and Applied Nutrition.
   c) The specific contact details are set out in the Annex to the present Administrative Arrangement.
   d) FDA and DG SANTE should notify each other of any changes to the contact persons.

9. DG SANTE and FDA intend to review periodically the present Administrative Arrangement and may jointly revise it.

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[4] FDA-SANCO Confidentiality Commitment of June 2005
https://www.fda.gov/international-programs/confidentiality-commitments/dg-sanco-europe-fda-confidentiality-commitment
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10. This Administrative Arrangement does not create any rights or obligations, nor does it constitute a legally binding agreement. DG SANTE and FDA intend to give each other six months' notice of an intent to discontinue using this arrangement.

11. DG SANTE and FDA intend for this Administrative Arrangement to commence when signed by both DG SANTE and FDA.

Signed in duplicate in the English language.

For the Directorate-General for Health and Food Safety of the European Commission:

Anne Bucher
Director-General

Place: Brussels
Date: July 31, 2020

For the U.S. Food and Drug Administration:

Anna K. Abram

Anna K. Abram
Deputy Commissioner for Policy, Legislation and International Affairs

Place: Silver Spring, MD
Date July 21, 2020

ANNEX

Specific contact point details

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY	UNITED STATES FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
Mr. Paolo Caricato Ms. Aikaterini Argiri European Commission DG Health and Food Safety Rue Froissart 101, Brussels, 1049, Belgium Telephone: (00322) 2993202, 2987448 e-mail: paolo.caricato@ec.europa.eu aikaterini.argiri@ec.europa.eu	Ms. Melissa Abbott U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition 5001 Campus Drive College Park, MD 20740 Telephone: 240-402-1401 Fax: 301-436-2601 e-mail: Melissa.Abbott@fda.hhs.gov

ADMINISTRATIVE ARRANGEMENT
BETWEEN THE
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
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Signed in duplicate in the English language.

For the Directorate-General for Health and Food Safety of the European Commission:

_____

Anne Bucher
Director-General

Place: Brussels

Date:_____

For the U.S. Food and Drug Administration:

_____

Mark Abdoo
Associate Commissioner for Global Policy and Strategy

Place: Silver Spring, MD

Date_____

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EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY	UNITED STATES FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
Mr. Paolo Caricato Ms. Aikaterini Argiri European Commission DG Health and Food Safety Rue Froissart 101, Brussels, 1049, Belgium Telephone: (00322) 2993202, 2987448 e-mail: paolo.caricato@ec.europa.eu aikaterini.argiri@ec.europa.eu	Ms. Melissa Abbott U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition 5001 Campus Drive College Park, MD 20740 Telephone: 240-402-1401 Fax: 301-436-2601 e-mail: Melissa.Abbott@fda.hhs.gov