

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0810]

Equivalence Determination Regarding the European Union Food Safety Control System for Raw Bivalve Molluscan Shellfish

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is inviting public comment on a proposed determination that the European Union (EU) food safety control system for raw bivalve molluscan shellfish (“shellfish”) intended for export into the United States, as administered by the European Commission (EC), provides at least the same level of sanitary protection as the United States’ system and is therefore equivalent. If finalized, this determination would permit the importation of shellfish harvested from certain production areas and processed by establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List (ICSSL). This notice also briefly describes the processes whereby other EU Member States (EUMS) may be approved in the future.

DATES: Comments must be received on or before May 23, 2018 to ensure consideration before the equivalence determination is finalized.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-0810 for “Equivalence Determination Regarding the European Union Food Safety Control System for Raw Bivalve Molluscan Shellfish.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80

FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Abbott, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1401 or Robert Tuverson, Center for Food Safety and Applied Nutrition (HFS-550), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1586.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible for protecting public health by ensuring the safety of our nation’s food supply, including imported foods. This includes raw bivalve molluscan shellfish (oysters, clams, mussels, and roe-on and whole scallops, referred to as “shellfish” throughout this notice) imported into the United States. This notice announces and explains the basis for our proposed determination that the EU food safety control system for shellfish intended for export to the United States, which is currently being implemented in certain growing areas in the Netherlands and Spain, provides a level of sanitary protection equivalent to the relevant elements of the U.S. system. FDA is seeking comment on this proposed determination.

A. What is an equivalence determination?

Under the 1995 World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), WTO Member States are required to enter into consultation with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures (SPS Agreement, Article 4.2) (Ref. 1). When a WTO Member State requests an equivalence determination from another WTO Member State, the requesting WTO Member State must objectively demonstrate that its measures achieve the other WTO Member State’s

appropriate level of sanitary or phytosanitary protection (SPS Agreement, Article 4.2) (Ref. 1).

Equivalence is evaluated by an examination of the sanitary and phytosanitary measures (SPS measures) in use in the country, which include all relevant laws, decrees, regulations, requirements and procedures, including end-product criteria, processes and production methods, testing, inspection, and certification and approval procedures. In addition, equivalence is evaluated by how the country implements those SPS measures. In this case, equivalence is evaluated by an examination of sanitary measures relating to shellfish safety.

The United States implemented the SPS Agreement requirement relating to equivalence in section 432 of the Uruguay Round Agreements Act (URAA), Public Law 103–465, which amended section 492 of the Trade Agreements Act of 1979 (Pub. L. 96–39). Under the URAA's section 432(a), U.S. agencies may not find foreign SPS measures equivalent to comparable SPS measures in the United States unless the agency determines that the foreign measures provide at least the same level of sanitary or phytosanitary protection as the comparable SPS measures established under Federal law (19 U.S.C. 2578a(a)).

Also under the URAA, where the comparable domestic SPS measures corresponding to an equivalence determination are not required to be issued as a rule under the Federal Food, Drug, and Cosmetic Act (FD&C Act) or other statute that we administer, we must publish a notice in the **Federal Register** and consider public comment before finalizing the equivalence determination (19 U.S.C. 2578a(c)). Once an equivalence determination is made final, we intend to engage in technical consultations and ongoing verification, including appropriate checking of imports, to ensure that equivalence continues to exist.

B. How are domestic and imported shellfish regulated in the United States?

FDA regulates the safety of fish and fishery products, including shellfish, under the FD&C Act, the Public Health Service Act (PHS Act), and our regulations (21 CFR part 123 *Fish and Fishery Products* and 21 CFR 1240.60 *Molluscan Shellfish*). To satisfy those regulatory requirements, shellfish in interstate commerce is regulated by the States of the United States (States or State) through the National Shellfish Sanitation Program (NSSP) and its *Guide for the Control of Molluscan Shellfish* (NSSP *Guide*) (Ref. 2), which

together constitute the broad framework of sanitation standards adopted by each participating State. While the NSSP *Guide* functions as a model ordinance incorporated into State law by participating States, it is not itself a Federal regulation.

The NSSP, which is authorized under section 702 of the FD&C Act (21 U.S.C. 372) and section 311 of the PHS Act (42 U.S.C. 243), is a Federal-State cooperative program supported collaboratively by FDA and the Interstate Shellfish Sanitation Conference (ISSC). The ISSC is a voluntary national organization of Federal and State regulatory officials and the shellfish industry that is engaged in the sanitary control of shellfish. The ISSC provides a formal structure for State regulatory authorities to create legal requirements, guidelines, and procedures for managing the safety of shellfish intended for human consumption. The ISSC passed a resolution in 2011 recognizing FDA as the U.S. authority responsible for considering equivalence with the NSSP if so requested by foreign countries (Ref. 3).

C. What is the history of requests for equivalence determinations by the United States and the EU with respect to shellfish?

The Veterinary Equivalency Agreement of 1998 (VEA) established a framework for the United States and the EU to pursue equivalence determinations for food of animal origin, including shellfish (Ref. 4). For FDA-regulated products, FDA is the competent authority for the United States. For the EU, the EC's Directorate-General for Health and Food Safety (DG SANTE, formerly known as DG SANCO), is the competent authority and represents EUMS with respect to equivalence determinations.

In June 2008, DG SANCO formally requested that the United States undertake an equivalence determination under the VEA with respect to shellfish to allow the EU to export to the United States (Ref. 5). In March 2009, DG SANCO audited the U.S. food safety control system for shellfish, concluding that certain aspects of the U.S. control system were not equivalent to those in the EU (Ref. 6). As a result, in October 2009 the EC determined that the U.S. eligibility to ship shellfish to the EU would end on December 31, 2009 (this date was later moved to July 1, 2010). In 2010, FDA and DG SANCO agreed to engage in equivalence determinations and agreed on a process to evaluate one another's shellfish safety systems to determine whether they provide an

equivalent level of food safety protection (Refs. 7 and 8). This process involved expert technical consultations, together with documentary and onsite evaluations and audits, conducted between 2010 and 2016 by both the United States and the EC. This **Federal Register** notice provides the basis for FDA's proposed determination that the EU food safety control system for shellfish is equivalent to the NSSP. As a result of its own assessment of the United States' system, the EC also has made a determination that the United States' system is equivalent to its own, and as a result of that determination has stated its intent to accept shellfish from certain growing areas in the States. For information about the EC's evaluation of the U.S. food safety control system for shellfish, including its onsite visits to production and processing facilities, see Refs. 9 and 10.

II. What is FDA's proposed determination concerning the equivalence of the EU shellfish safety system to the system in the United States?

A. What U.S. SPS measures for shellfish did FDA compare to comparable EU SPS measures?

FDA's assessment focused on whether the EU food safety control system for shellfish contains measures that provide the same level of protection as the food safety measures of the NSSP, which has incorporated Federal regulations specific to fish and fishery products (these are found at part 123 and § 1240.60). Thus, the NSSP, which is implemented and enforced by the States, contains within it all relevant Federal requirements concerning, among other things, current good manufacturing practices, hazard analysis and Hazard Analysis Critical Control Point (HACCP) plans, recordkeeping, sanitation control procedures, and the restriction of interstate transport of shellfish in an insanitary manner. The NSSP provisions, similar to the incorporated Federal requirements, apply to both imported and domestic products (Ref. 2). Because of the incorporation in the NSSP of the relevant Federal requirements, we have determined that the NSSP standards are the appropriate SPS measures to use in determining whether the EC regulations are equivalent to U.S. shellfish safety safeguards.

B. What was the scope and process of our assessment of the EU's food safety control system for shellfish?

FDA's proposed determination of equivalence is predicated on an in-depth evaluation of the EC's food safety controls for shellfish and their implementation by EUMS. FDA focused its review on Class A growing areas in the Netherlands and Spain, based on selections made by the EC.

We began our consultation regarding shellfish equivalence by comparing sanitary measures applied by the States through the NSSP with those shellfish sanitary measures applied by the EUMS in accordance with EC legislation. This documentary review included the regulatory framework; training programs; inspection programs; program assessment and audit; food-related illness and outbreaks; compliance and enforcement; industry and community relations; program resources; international communication and harmonization; and laboratory support.

For sanitary measures related to growing area controls, enforcement, and biotoxins, FDA technical experts determined that further evaluation was needed. In conducting this further review, FDA technical experts relied on technical consultations and observations from onsite evaluations, as well as appropriate data analysis and risk assessments. In addition to documentary review, technical consultations, and expert analysis, we performed onsite evaluations as well as appropriate data and risk assessments to verify EUMS implementation of the EU food safety control system for shellfish (Ref. 11).

The FDA expert evaluation combined both quantitative and qualitative considerations, such as the statistical analysis of shellfish meat versus water standards and the review of legal systems. Whether considering quantitative or qualitative factors, we relied on the knowledge and experience of our technical experts and their understanding of known or reasonably foreseeable hazards in shellfish. Our technical experts used their extensive scientific knowledge and experience with shellfish control systems to evaluate and determine whether different control measures were equivalent in controlling identified hazards.

C. What did FDA tentatively conclude based on its evaluation?

FDA technical experts concluded, based on their extensive review of relevant EU measures and onsite evaluations, that the EU's food safety

control system for shellfish provides an equivalent level of sanitary protection as the NSSP. Specifically, FDA technical experts concluded that:

- The documentary review demonstrated that most of the shellfish sanitary measures applied by the EUMS in accordance with EC legislation, including certain additional controls negotiated with FDA, are equivalent to the sanitary measures applied by the States through the NSSP (Refs. 7, 8, 11, and 12);

- EC procedures and enforcement criteria for assessing the safety of shellfish using shellfish meat are equivalent to the sanitary measures applied by the States through the NSSP, which rely on assessing growing water quality and classification of waters (Ref. 13); and

- With respect to identifying and responding to emerging pathogens of public health concern, including *Vibrio spp.*, the EU food safety systems provide the same level of public health protection as U.S. systems (Ref. 14).

In reaching these conclusions, FDA technical experts relied on their documentary review, technical consultations with counterparts with the EC, observations from onsite evaluations, as well as appropriate data and risk assessments, described more fully in sections II.E. and II.F.

D. To what growing areas and processing facilities in the EU does this proposed determination apply?

This proposed determination only applies to EC Class A growing areas where additional controls have been implemented to satisfy specific U.S. food safety concerns ("Class A" means approved for the harvesting of shellfish for direct consumption). For purposes of this notice, we use the term "growing area," by which we mean any site which supports or could support the propagation of shellstock by natural or artificial means. (The EC uses the term "production area" and defines it as "any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken" (Regulation (EC) No 853/2004, Annex I, 2.5).) Currently, the only shellfish growing areas in the EU that have been determined to be implementing these additional controls are in the Netherlands and Spain. This notice describes the process whereby we may recognize additional EUMS growing areas and list additional EUMS processing facilities on the ICSSL in the future.

E. What is the basis for the FDA's tentative conclusion that procedures and enforcement for assessing shellfish growing area controls in the EU are equivalent to those in the United States?

1. Growing Area Controls

In the United States, the microbiological quality and safety of shellfish is determined through extensive sanitary surveys of shellfish growing areas, which include microbiological testing of the water. Sanitary surveys are "the written evaluation report[s] of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area" (NSSP *Guide* at page 9) (Ref. 2). The EC, in contrast, historically has determined the safety of shellfish and classified shellfish growing areas based on the levels of indicator bacteria found in shellfish meats.

In January 2012, the EC stated that an effort was underway to develop a set of guidelines on how to interpret and implement EU Food Hygiene Regulation (EC) No. 854/2004 (basic food hygiene regulation) as it related to shellfish growing areas, including through the use of sanitary surveys. These new guidelines were contained in a document entitled the *Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with Regard to Regulation 854/2004* (*Community Guide*). In April 2012, the EC provided the *Community Guide* to FDA for review (Refs. 5 and 15).

The *Community Guide* incorporated growing area controls that provided for the assessment of pollution sources in sanitary surveys, the selection of representative monitoring points, the creation of sampling plans, the classification of growing areas, and ongoing monitoring. The EC also provided the associated *Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application* (*Technical Application Guide*) (Ref. 16), which provides implementation guidance for the *Community Guide*. FDA technical experts indicated that the *Community Guide* and the *Technical Application Guide* ("Guides") would be satisfactory if they included additional controls specific for products coming to the United States. To address the U.S. proposal for more detailed guidance covering pollution source identification and the implementation of buffer zones around pollution sources, FDA and the EC formed a working group. In September 2013, this working group

presented annexes addressing buffer zones to be added to the *Guides* (Refs. 5, 15, and 16).

On the basis of this consultation, and on the agreement of the EC to add additional provisions to the *Guides*, we decided that the two *Guides* provided additional controls that would, if properly implemented, provide the same level of public health protection as U.S. controls. While the EC said that these *Guides* would be voluntary for EUMS, it affirmed that it would require their application in growing areas that would be authorized to export shellfish to the United States under a finding of equivalence and that it planned ultimately to require the use of the *Guides* by EUMS, including the additional growing area controls (Ref. 5).

The *Community Guide* specifically prescribes additional guarantees that shellfish exported to the United States from the EU will have to meet. EUMS must ensure that shellfish originate from a specifically listed growing area; the listed growing area will be of permanent Class A status; and all aspects of the guidance set out in both *Guides*, including a full sanitary survey and the buffer zone requirements, will have been implemented for the listed growing areas prior to export to the United States. The *Technical Application Guide* sets specific sampling methodologies that must be followed. FDA and the EC identified priority growing areas within the Netherlands and Spain that would implement the two *Guides'* provisions and form the basis for FDA's onsite evaluation. FDA and the EC technical experts concluded that only growing areas fully implementing the two *Guides* would be permitted to export shellfish to the United States as a part of the equivalence determination (Ref. 17).

2. Classification of Growing Areas Using Water Versus Shellfish Meat Testing

In the United States, growing areas are classified as U.S. Approved, U.S. Conditionally Approved, U.S. Restricted, U.S. Conditionally Restricted, or U.S. Prohibited. Growing areas that are U.S. Approved include those areas where harvesting is permitted for direct marketing. Areas that are U.S. Conditionally Approved meet the criteria for the U.S. Approved classification, except under certain conditions (e.g., excessive rainfall) described in a management plan, in which case they are either closed to harvest or classified as U.S. Restricted. Management plans are formulated by State shellfish authorities and establish the criteria that must be met for growing

areas to remain U.S. Approved (NSSP *Guide*, Section IV, Chapter II .05) (Ref. 2). Areas that are U.S. Restricted allow harvesting by special license only of shellstock that are subjected to a suitable and effective post-harvest treatment process through depuration or relaying. Depuration is the process of reducing pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as a treatment process. Relaying means transferring shellstock from a growing area classified as U.S. Restricted to a growing area classified as U.S. Approved or U.S. Conditionally Approved for the purpose of reducing pathogens. Areas that are U.S. Conditionally Restricted are considered U.S. Restricted except under certain conditions described in a management plan, in which case they are closed to harvest. Areas that are U.S. Prohibited are closed to all harvest.

In contrast to FDA's approach of classifying shellfish growing waters based primarily on indicator levels of microorganisms measured in growing waters, the EC classifies its growing areas primarily based on the indicator levels measured in shellfish meats. The EC separates shellfish growing areas into Classes A, B, and C. Class A growing areas are approved for the harvesting of shellfish for direct human consumption. Shellfish harvested from Class B and Class C growing areas are treated in a purification center or relayed so as to meet EU health standards. Shellfish from unclassified areas may not be harvested for human consumption (Ref. 18). Although the classification approach is different, both systems use complex decisional rules based on levels of indicator microorganisms to determine how shellfish from the growing area may be used.

In September 2010, FDA provided initial results of a statistical analysis and model relating to the comparison of shellfish meat versus water testing as the means for providing assurances as to the safety of shellfish (Ref. 13), after which the EC provided additional microbiological and site information data. Following further statistical analysis, FDA's technical experts concluded that the EU's system of growing area classification provided a level of protection equivalent to that of the United States, as long as the shellfish was from EC Class A growing areas. The report of the statistical analysis, entitled *FDA Evaluation of EU and US Microbiological Standards Used for Classifying Shellfish Growing Areas*, concluded that, "For comparisons made using *E. coli* [*Escherichia coli*] standards

prescribed by the EC for shellfish and fecal coliform standards prescribed by the US for waters, no statistically significant level of disagreement can be established between failure and approval outcomes using EU Category A criteria and US Approved criteria ($p > 0.05$). However, a statistically significant level of disagreement between outcomes is demonstrated for comparison using EU Category B criteria and US Restricted criteria ($p < 0.001$)" (Ref. 13). Based on this statistical analysis, FDA technical experts concluded that EC Class A growing areas were equivalent to U.S. Approved growing areas and that, despite different regulatory approaches and testing methods, restricting shellfish harvesting to EC Class A areas provides the same level of public health protection (Refs. 13 and 17).

Following completion of the statistical analysis, the EC adopted a new regulation in December 2015 (Commission Regulation (EU) 2015/2285) (Ref. 18), establishing a new *E. coli* standard for molluscan shellfish which required further analysis to ensure the adoption of this new *E. coli* standard did not impact the conclusion that EC Class A growing areas are equivalent to U.S. Approved growing areas. To evaluate the impact of this new standard, FDA technical experts compared statistical assessments of the new sampling methodology and concluded that the EC's requirement for monitoring shellfish to maintain Class A growing area status remained equivalent to the U.S. standard (Ref. 19). Further, the EC committed to clarify requirements contained in Annex II (Additional Requirements for Production Areas from which Live Bivalve Molluscs are Harvested for Export to the USA) of the *Community Guide* to specify that "the listed production area will be of permanent Class A status with a minimum data set of 24 samples to establish classification." Based on this understanding, the FDA technical experts concluded that the revised EU *E. coli* standard contained in Commission Regulation (EU) 2015/2285 (Ref. 18), in conjunction with instructions for its application contained in the *Community Guide* and the *Technical Application Guide* (*Guides*), provides the same level of public health protection between the EC Class A molluscan shellfish standard and U.S. Approved growing areas (Refs. 15 and 16).

F. What did FDA conclude regarding the EU food safety system's approach to marine Vibrio spp.?

Differing approaches to control pathogenic strains of *Vibrio spp.* were identified as an area that required further analysis as to whether FDA's and the EU's control programs were equivalent. Specifically, approaches to controlling for two species of pathogenic *Vibrio* bacteria, *Vibrio vulnificus* (*V. vulnificus*) and *Vibrio parahaemolyticus* (*V. parahaemolyticus*), were considered. Filter feeding by shellfish can cause *V. vulnificus* and *V. parahaemolyticus* to concentrate in their tissues. Consuming raw or undercooked shellfish can lead to illness from these pathogens. *V. vulnificus* is found in estuarine environments throughout coastal waters of the continental United States (Ref. 20). Optimal temperatures for *V. vulnificus* growth are between 20 °C to 35 °C, and therefore it appears most often in warm waters. Ninety percent of *V. vulnificus* illnesses linked to shellfish in the United States are associated with the consumption of raw oysters from the Gulf of Mexico. While illnesses associated with *V. vulnificus* are less common than other *Vibrio* species in shellfish, the mortality rate is high. *V. parahaemolyticus* appears in tropical and temperate coastal areas worldwide, including in the United States and the EU. Pathogenic strains of *V. parahaemolyticus* cause more illnesses than *V. vulnificus*, but usually result in only mild or moderately severe gastrointestinal symptoms (Ref. 20).

In December 2012, the FDA and EU technical experts decided to form a working group to discuss differing approaches to address pathogenic strains of *Vibrio spp.* in order to determine whether their control programs were equivalent. Coming out of this working group, the EU's Centre for Environment, Fisheries & Aquaculture Science (CEFAS), as chair of the working group, produced a summary in April 2013 that discussed the occurrence of *V. vulnificus* and *V. parahaemolyticus* illnesses in both the United States and EU (Ref. 10). The summary reported that while the United States has experienced significant public health problems with marine *Vibrios* following consumption of products from at risk areas, currently *Vibrio* infection associated with consumption of shellfish produced in the EU was rarely documented.

Both parties recognized that *V. vulnificus* poses a significant public health concern. As environmental conditions in the EU (e.g. growing water

temperature) do not present the same level of risk, FDA's technical experts concluded that the EU is able to achieve the same or better public health outcomes as the U.S. system (Ref. 21).

With regard to *V. parahaemolyticus*, both the United States and the EC recognized that the pathogen poses a growing public health concern and recognized the need to engage specific controls when appropriate, given the environmental changes that could impact growing conditions for this organism (Refs. 22 and 23). Given that currently *Vibrio* infection associated with consumption of shellfish produced in the EU was rarely documented, FDA technical experts evaluated the EU food safety system for identifying and responding to pathogens of growing public health concern and illness events, and the EU's underlying systems for controlling pathogens in shellfish to determine whether those systems offered the same level of public health protection as systems in use in the United States. Through this evaluation, FDA technical experts concluded that the EU and the United States have equivalent systems in place to identify and respond to emerging pathogens, including those involving *V. parahaemolyticus* (Ref. 14).

Specifically, FDA technical experts determined that both the United States and EU food safety systems for shellfish are designed and operate to identify and control risks associated with emerging public health threats, including *V. parahaemolyticus*. While the EC does not currently consider *V. parahaemolyticus* nationally notifiable, the Rapid Alert System for Food and Feed (RASFF) is designed to capture adverse events and has included *V. parahaemolyticus* related notifications, which, to date, are from shellfish harvested outside the EU. The RASFF ensures that information is shared and urgent notifications are responded to in order to ensure food safety for consumers within and outside of the EU. In an event, such as a shellfish-related illness outbreak, the EUMS are required to report and investigate the event in order to take appropriate action. The evidence from RASFF alerts (relating to notifications of products presenting a serious health risk or to products tested at border entry and found to present a risk) indicates that *Vibrio* contamination of bivalve mollusc on the EU market is an uncommon occurrence (Ref. 14).

In addition to the EC requiring adverse event reporting through RASFF, FDA technical experts concluded that the EU has significant controls in place to minimize exposure to hazards

generally, including foodborne pathogens, that contribute to *V. parahaemolyticus* control:

- The EC mandates that EUMS have systems to ensure that shellfish is harvested from classified growing waters;
- It mandates additional post-harvest controls through mandatory HACCP systems that require business operators to identify and control hazards in their products before they are marketed to consumers; and
- Finally it mandates harvested shellfish are subject to tagging and labeling so that contaminated lots are identified and recalled rapidly (Ref. 14).

Therefore, FDA technical experts have concluded that the EU food safety systems for identifying and responding to emerging pathogens and illness events, together with their underlying systems for controlling pathogens in shellfish, provide that same level of public health protection as the United States to identify and respond to emerging pathogens, including *Vibrio spp.*

G. What was the outcome of FDA's June 2015 onsite evaluation of the EU food safety control system for shellfish?

Finally, FDA performed an onsite evaluation of the EU food safety control system for shellfish in June 2015 to verify EUMS implementation of the EU food safety system, including the additional controls specified in the *Guides*. FDA's onsite evaluation, conducted in the Netherlands and Spain, focused on the procedures for classifying shellfish growing areas; testing of shellfish growing area waters and shellfish meats; preventing harvest of shellfish from growing areas that would not meet the EC Class A or U.S. Approved criteria; assessing and controlling post-harvest processing, handling, labeling, and traceback activities; and assessing and controlling the risk from marine biotoxins (Ref. 11). We identified several issues regarding the implementation of EC controls by the competent authorities of the EUMS evaluated and made recommendations for corrective action. The EC and FDA agreed these recommended corrective actions in the Netherlands and Spain would be implemented before trade could commence under equivalence. The issues identified during our onsite evaluations, and our recommendations for corrective action, are summarized in our 2015 onsite assessment report of Spain and the Netherlands (Ref. 11).

III. Recommended Determination of Equivalence With Conditions

Based on the evaluation described in section II, FDA technical experts conclude that the EU food safety control system for shellfish intended for export to the United States, including implementation of the EC regulations, directives, and the *Guides* (see Refs. 12, 15, and 16), provides at least the same level of public health protection as the U.S. system, as contained in the NSSP sanitation standards adopted and implemented as law by the States.

While recognizing the equivalence of the food safety control systems for raw bivalve molluscan shellfish under the conditions described in this notice, and while FDA and the EC understand that eligibility to export under equivalence would initially apply to growing areas and processing facilities meeting applicable standards in the evaluated EUMS, FDA, and the EC also discussed and established the following steps for adding growing areas and processing facilities in the EUMS:

- EUMS seeking to export shellfish into the United States will notify the EC;
- The EC will confirm that the growing areas to be used for harvesting product intended for export to the United States have a Class A designation;
- The EC will confirm that the growing area controls, including those specified in the *Guides*, are in place, including assessment of the risk related to marine biotoxins and other hazards in shellfish;
- The EC will notify FDA of the EUMS notification, including the location of the growing areas, and the names of the shellfish processing facilities intending to export to the United States; and
- FDA will update the ICSSL as appropriate.

FDA has concluded that it would evaluate exporting EUMS on a periodic basis as part of our routine evaluation program as is done under the NSSP, but would not require prior onsite evaluations before allowing new EUMS or growing areas to export into the United States.

After consideration of public comment submitted in response to this notice, FDA will issue a final determination. FDA and the EC confirmed that the following subjects were excluded from the equivalence finding, as stated in the VEA: Food labeling requirements; food additive maximum levels (MLs); pesticide maximum residue limits (MRLs); drug MRLs; and contaminant MLs. Exported shellfish must comply with the

importing country's requirements for these items. FDA and the EC committed to negotiate a bilateral equivalence arrangement that documents the understandings reached during the equivalence process.

IV. Additional Issues for Consideration and Comment

FDA seeks comment on this **Federal Register** notice, including comments and any supporting data or other information, addressing whether this proposed equivalence determination for shellfish coming from the EU, subject to the limitations added by FDA, meets the standard that the EU measures provide at least the same level of sanitary protection as our domestic program's measures (19 U.S.C. 2578a(a)).

V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), World Trade Organization (WTO), 1995. Accessed online at https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.
2. National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. Food and Drug Administration and Interstate Shellfish Sanitation Conference. 2007 through 2015 revisions. Accessed online at <https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm>.
3. Guidance on Equivalence Criteria for Food, Interstate Shellfish Sanitation Conference Resolution 11–003, at p. 376 in National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. Food and Drug Administration and Interstate Shellfish Sanitation Conference. 2011 Revision. Accessed online at <https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm>.
4. Veterinary Equivalency Agreement of 1998. Accessed online at https://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111716.pdf.
5. EU-U.S. Molluscan Shellfish Project Major Event Timeline. Food and Drug Administration. 2016.
6. Final Report of a Mission Carried Out in the United States From 02 March to 16 March 2009 in Order to Evaluate the Control Systems in Place Governing the Production of Bivalve Molluscs Intended

for Export to the European Union. European Commission, Health & Consumers Directorate-General, Directorate F—Food and Veterinary Office. DG (SANCO)/2009–8055–MR—FINAL.

7. Meeting Summary and Attachments from the U.S.-EU Molluscan Shellfish Equivalence Project. January 27–28, 2010. Brussels, Belgium.
8. Meeting Summary and Attachments from the U.S.-EU Molluscan Shellfish Equivalence Project. September 21–22, 2010. College Park, MD.
9. Final Report of an Audit Carried Out in the United States from 17 March 2015 to 27 March 2015 in Order to Evaluate the Control Systems in Place Governing the Production of Bivalve Molluscs and Fishery Products Derived Therefrom Intended for Export to the European Union. European Commission, Directorate-General for Health and Food Safety, Directorate F—Food and Veterinary Office. December 2015. Accessed online at http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3585.
10. Marine vibrio's—Summary of Food Safety Concerns Regarding Trade of Bivalve Molluscs from USA to EU. The Center for Environment, Fisheries & Aquaculture Science (CEFAS). April 2013. Accessed online at https://eur.cefass.org/media/13641/ws12_13.pdf.
11. EU-U.S. Molluscan Shellfish Equivalence Project Report of the U.S. Food and Drug Administration's On-site Assessment of Spain and the Netherlands, 15 June–26 June, 2015. FDA. December 9, 2015.
12. Comparison Chart of FDA–NSSP–EC Provisions That Achieve the Same Shellfish Safety Outcomes. FDA, Center for Food Safety and Applied Nutrition. 2016.
13. FDA Evaluation of EU and U.S. Microbiological Standards Used for Classifying Shellfish Growing Areas. Food and Drug Administration. February 2011.
14. FDA Technical Memo to File on EU safety systems for identifying and responding to emerging pathogens and illness events associated with shellfish. Food and Drug Administration. November 8, 2017.
15. Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with Regard to Regulation 854/2004. European Commission. June 2012, updated January 2014 and January 2017. Accessed online at https://eur.cefass.org/media/13972/cg_issue-3_final-170117.pdf.
16. Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application. EU Working Group on the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas. Issue 4, August 2010, updated June 2014 (Issue 5) and January 2017 (Issue 6). Accessed online at https://eur.cefass.org/media/13973/gpg_issue-6-final-170117.pdf.

17. Meeting Summary and Attachment from the U.S.-EU Bivalve Molluscan Shellfish Equivalence Project. November 19–20, 2015. FDA Hillandale Building, Silver Spring, MD.
18. Commission Regulation (EU) 2015/2285 of 8 December 2015 Amending Annex II to Regulation (EC) No. 854/2004 of the European Parliament. Accessed online at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2285&from=EN>.
19. Meeting Summary and Attachment from the U.S.-EU Bivalve Molluscan Shellfish Equivalence Project. September 19–20, 2016. FDA Center for Food Safety and Applied Nutrition, College Park, MD.
20. Bad Bug Book, *Foodborne Pathogenic Microorganisms and Natural Toxins*. Second Edition. FDA. 2012. Accessed online at <https://www.fda.gov/food/foodborneillnesscontaminants/causesofillnessbadbugbook/>.
21. Risk Assessment of *Vibrio vulnificus* in Raw Oysters, Interpretive Summary and Technical Report. World Health Organization/Food and Agriculture Organization of the United Nations. 2005. Accessed online at <http://www.who.int/foodsafety/publications/micro/mra8.pdf>.
22. Meeting Summary and Attachments from the U.S.-EU Molluscan Shellfish Equivalence Project. September 5–6, 2013. FDA White Oak Campus, Silver Spring, MD.
23. On-going Activities on Emerging Risks in the SCER Unit. Presentation at European Food Safety Authority (EFSA) 56th Advisory Forum Meeting. June 11–12, 2015. Accessed online at <https://www.efsa.europa.eu/sites/default/files/assets/af150611a-p9d.pdf>.

Dated: March 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04772 Filed 3–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0410]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Peripheral and Central Nervous System Drugs Advisory

Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments” that appeared in the **Federal Register** of February 22, 2018. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, February 22, 2018 (83 FR 7727), in FR Doc. 2018–03603, on page 7727, the following correction is made:

1. On page 7727, in the first column, in the header of the document, the docket number is corrected to read “FDA–2018–N–0410.”

Dated: March 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04774 Filed 3–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–5946]

Determination That DORYX MPC (Doxycycline Hyclate), Delayed-Release Tablets, 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Aaron Young, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 301–796–8083.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term

Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, are the subject of NDA 50–795, held by Mayne Pharma International Pty Ltd., and initially approved on May 6, 2005. DORYX MPC is indicated for rickettsial infections; sexually transmitted infections; respiratory tract infections; specific bacterial infections; ophthalmic infections; anthrax, including inhalational anthrax (post-exposure); alternative treatment for selected infections when penicillin is contraindicated; adjunctive therapy in acute intestinal amebiasis and severe acne; and prophylaxis of malaria.

Mayne Pharma International Pty Ltd. has never marketed DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg. In previous instances (see, e.g., 72 FR 9763 (March 5, 2007) and 61 FR 25497 (May 21, 1996)), the Agency has determined that, for