a beneficiary currently purchasing Medicare premium Part A coverage, is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan is subsidizing the individual's Part A premium.

Form CMS–R–285 provides the necessary information regarding the prior state or local government employment to process the individual's request for premium Part A reduction based on their employment by a state or local government.

The form is completed by the state or local government employer on behalf of the individual seeking the Medicare premium reduction. The SSA—CMS' agent for processing Medicare enrollments and premium amount determinations will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. The form is owned by CMS but not completed by CMS staff. *Form Number:* CMS–R–285 (OMB control number: 0938–0769); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations (EFIOs) that submit National Provider Identifier (NPI) data to the National Plan and Provider Enumeration System (NPPES); *Use:* The EFI process allows organizations to submit NPI application information on large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO can electronically submit the file to NPPES for processing. As each file can contain up to approximately 25,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers. It is essential to collect this information from the EFIO to ensure that the EFIO understands its legal responsibilities as an EFIO and attests that it has the authority to act on behalf of the providers for whom it is submitting data. In short, the certification statement, which must be signed by an authorized official of the EFIO, serves as a safeguard against EFIOs attempting to obtain NPIs for illicit or inappropriate purposes. *Form Number:* CMS–10175 (OMB control number 0938–0984); *Frequency:* Once, Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 32; *Number of Responses:* 32; *Total Annual Hours:* 8. For questions regarding this collection contact DaVona Boyd at 410–786–7483.

Dated: September 21, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–21095 Filed 9–23–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0810]

Food and Drug Administration Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish With Additional Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a final determination that the adoption and implementation by Spain and the Netherlands of the European Union's (EU's) system of food safety control measures for raw bivalve molluscan shellfish (''shellfish''), along with their application of additional measures specifically adopted for this purpose, *i.e.,* for export to the United States, provides at least the same level of sanitary protection as comparable food safety measures in the United States and is therefore equivalent. This final equivalence determination will permit the importation of raw shellfish harvested from certain production areas in Spain and the Netherlands from establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List (ICSSL).

DATES: The determination becomes final on September 24, 2020.

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

A. Introduction

FDA is responsible for protecting public health by ensuring, among other things, the safety of our nation's food supply, including imported foods. This includes raw bivalve molluscan shellfish (oysters, clams, mussels, roe-on scallops, and whole scallops, referred to as ''shellfish'' throughout this notice) imported into the United States. In the **Federal Register** of March 9, 2018 (83 FR 10487), we published a notice that announced and explained the basis for our proposed equivalence determination that the EU system of food safety control measures for shellfish, along with the application of additional measures specifically adopted for this purpose, *i.e.,* for export to the United States, as adopted and implemented in Spain and the Netherlands, provides at least a level of sanitary protection as comparable food safety measures in the United States. This notice announces that, after considering comments we received on the proposed equivalence determination, we are finalizing the equivalence determination as proposed, except that we are narrowing the scope of this final equivalence determination so that it only encompasses two EU Member States, Spain and the Netherlands. FDA will use this determination as a basis to evaluate additional EU Member States that adopt and implement these measures.

In the future, we will evaluate and recognize as equivalent, as appropriate, other EU Member States in separate determinations. In addition, we further clarify and explain our basis for the final equivalence determination in response to the comments. We note that, in the March 9, 2018, notice, we used both ''production area'' and ''growing area'' in referring to beds or sites that support or could support the propagation of bivalve molluscan shellfish. For purposes of this notice, we continue to use the same terminology.

B. Basis for Equivalence Determination

Under section 432 of the Uruguay Round Agreements Act (URAA), Public Law 103–465, U.S. Agencies may not find foreign sanitary and phytosanitary measures (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)). The URAA also provides that FDA publish a notice in the **Federal Register** and consider public comment before finalizing an equivalence determination when the determination is based on domestic SPS measures that FDA is not required to issue as a rule under the Federal Food, Drug, and Cosmetic Act or other statute we administer (19 U.S.C. 2578a(c)). In accordance with these procedures specified in the URAA, we are finalizing this equivalence determination.

As explained in the March 9, 2018, notice, our equivalence assessment focused on whether the EU's food safety control measures for shellfish, along with the application of additional measures specifically required for export to the United States, which have been adopted and implemented by Spain and the Netherlands, provide at least the same level of sanitary protection as comparable food safety measures in the United States applied through the National Shellfish Sanitation Program (NSSP) (83 FR 10487 at 10488). The NSSP is a Federal-State cooperative program that provides a broad framework of shellfish sanitation standards through its ''Guide for the Control of Molluscan Shellfish'' (NSSP Guide) (Ref. 1). The NSSP Guide functions as a model ordinance incorporated into State law by participating States but is not itself a Federal regulation. The NSSP Guide incorporates Federal regulations specific to fish and fishery products, which are found at part 123 (21 CFR part 123) and § 1240.60 (21 CFR 1240.60). We explained in the March 9, 2018, notice that the NSSP, which governs how U.S. growing areas are managed and classified for shellfish harvest, is implemented and enforced by U.S. States, and 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 (83 FR 10487 at 10488). Because the NSSP incorporates relevant Federal food safety measures, we determined that the NSSP standards are the appropriate SPS measures to use in determining whether the EU's food safety control measures for shellfish, along with the application of additional measures specifically adopted for export to the United States, which have been adopted and implemented by Spain and the Netherlands, are equivalent to comparable U.S. food safety control measures.

We also explained in the March 9, 2018, notice the process by which we conducted our equivalence assessment (83 FR 10487 at 10489). In the EU, the European Commission (EC) establishes food safety measures that the EU Member States adopt and implement. Our proposed determination was predicated on an indepth evaluation of the EC and certain Member States' regulatory approach, including a comprehensive document review, technical consultations, expert analysis, and onsite evaluations in Spain and the Netherlands to verify their adoption and implementation of relevant EU measures (id.).

In the course of our assessment, FDA's technical experts identified sanitary measures in the EU system that differed from those in the U.S. regulatory approach and determined that further evaluation was needed. As explained in our March 9, 2018, notice, our technical experts completed indepth quantitative and qualitative analyses and determined that in most areas, despite differing regulatory approaches of certain sanitary measures, such measures provided at least the same level of sanitary protection as comparable food safety measures in the United States. However, FDA's technical experts identified some gaps in the EU's system of control measures that provided less sanitary protection than is provided by U.S. measures. To address these gaps, the EC amended and re-issued two Guides to include additional controls that EU Member States must adopt and implement in Class A growing areas to achieve equivalence with the U.S. system of food safety measures: 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) (Ref. 2); and the ''Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application'' (Technical Application Guide) (Ref. 3). The Community Guide specifically prescribes additional controls that EU Member States exporting shellfish to the United States will have to adopt and implement, while the Technical Application Guide sets specific sampling methodologies that must be followed as part of implementation. For purposes of FDA's equivalence evaluation, the EC-identified Class A production areas within Spain and the Netherlands where the EU food safety control measures and the additional controls in the Community Guide and the Technical Application Guide (Guides) are being applied. (Class ''A'' is an EU shellfish production area from which live bivalve molluscs may be harvested for direct human consumption.) (Ref. 5)

We note that since the publication of our proposed equivalence determination the EU has implemented two new regulations for official food and feed controls. These new regulations reorganize and incorporate several existing laws into a comprehensive regulation for the safe handling of food and feed. However, the EU's regulatory amendments do not change our determination of equivalence. Specifically, Regulation (EU) 2017/625, applicable as of December 14, 2019, repeals and replaces Regulations (EC) No 854/2004 and (EC) No 882/2004, which FDA previously identified and assessed as part of our proposed shellfish equivalence determination (Ref. 4). Relatedly, the EU also adopted Regulation (EU) 2019/627, which harmonizes procedures to verify compliance with the rules set forth in Regulation (EU) 2017/625 and related EU legislation for the safe handling of products of animal origin. Regulation (EU) 2019/627, applicable as of December 14, 2019, repeals and replaces procedures formerly contained within Regulation (EC) No 854/2004 (Ref. 5). Importantly, FDA has reviewed Regulations (EU) 2017/625 and (EU) 2019/627 and has confirmed that there is no impact on FDA's technical findings that support this final shellfish equivalence determination because the new regulations include the relevant controls from Regulations (EC) No 854/2004 and (EC) No 882/2004 that were the basis of FDA's technical evaluation for the proposed equivalence determination. Since the relevant controls of Regulation (EU) 2017/625 and (EU) 2019/627 are now being applied as of December 14, 2019, this final equivalence determination cites to these new regulations instead of Regulations (EC) No 854/2004 and (EC) No 882/2004, among other applicable requirements that have not changed, when describing EU food safety control measures for shellfish.

Based on our extensive review of relevant EU measures, the adoption and implementation by Spain and the Netherlands of those measures with additional controls contained in the Guides, and onsite evaluations in Spain and the Netherlands, we conclude that EU food safety control measures for raw bivalve shellfish, along with the Guides, when successfully adopted and

implemented, provide at least the same level of sanitary protection as comparable food safety measures in the United States, as contained in the NSSP; currently these controls have been adopted and implemented in certain production areas in Spain and the Netherlands. Therefore, we are finalizing our equivalence determination for EC-identified Class A production areas in Spain and the Netherlands.

After considering comments received on the proposed equivalence determination, as discussed in section C, the scope of this final equivalence determination only encompasses two EU Member States, Spain and the Netherlands. We will evaluate and recognize as equivalent, as appropriate, other EU Member States in the future in separate determinations. In addition, the scope of the final equivalence determination applies to raw bivalve molluscan shellfish harvested from EC-identified Class A production areas in the EU where additional controls specified in the Guides have been adopted and implemented, and then verified by competent authorities, which currently applies only to raw bivalve shellfish harvested from EC-identified Class A production areas in Spain and the Netherlands. To ensure that equivalence is maintained, FDA intends to engage in technical consultations with relevant competent authorities, conduct surveillance of imported product, and perform audits of EU Member States, as appropriate.

As a result of this determination, only raw bivalve shellfish harvested from EC-identified Class A production areas in Spain and the Netherlands are eligible to be exported to the United States at this time. Shippers of shellfish harvested from these areas must be listed on the ICSSL before they are permitted to export product to the United States (Refs. 6 and 7).

Additionally, certain sanitary measures are not covered by the scope of our equivalence determination. For example, measures related to food and color additives, processing aids, flavors, pesticide and chemical residues, animal drug residues, physical contaminants, and labeling (including nutrition labeling) are not part of this equivalence determination pertaining to raw bivalve molluscan shellfish because the equivalence evaluation did not include these measures and because these measures are excluded from the Agreement between the United States of America and the European Community on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products (Ref. 8). For measures not covered by the scope of our equivalence determination, raw bivalve shellfish exported from EC-identified Class A production areas in Spain and the Netherlands to the United States, must comply with applicable U.S. requirements.

C. Consideration of Comments Received

In the March 9, 2018, notice, we gave interested parties an opportunity to submit comments and any supporting information by May 23, 2018. We received approximately 25 comments. Most comments generally supported the proposed equivalence determination and did not take specific issue with the technical basis for our conclusion that the EU system of food safety control measures for shellfish, along with the application of additional measures specifically adopted for this purpose, *i.e.,* for export to the United States, as adopted and implemented in Spain and the Netherlands, provides at least a level of sanitary protection as comparable food safety measures in the United States. Several comments questioned the procedural steps by which FDA reached the proposed equivalence determination, the respective roles of the EC and competent authorities in Spain and the Netherlands, and the process FDA will follow when considering additional EU Member States in the future. Some comments asked about whether processed shellfish are included in the present determination.

Other comments pertained to the EC's equivalence determination of the U.S. system of food safety control measures for shellfish, the process the EC will follow for assessing additional U.S. States, the classification of growing areas eligible for export, and other matters associated with the export of shellfish from the United States to the EU. These comments are outside the scope of this equivalence determination.

One comment questioned whether importing live bivalve molluscan shellfish from the EU would present an animal disease risk for native U.S. shellfish wild stocks. Animal disease risks are beyond the scope of this equivalence determination, which is based on an assessment of safety for human consumption. Importers of raw molluscan shellfish must also comply with any applicable U.S. requirements that fall outside the scope of this final equivalence determination, including any regulatory requirements governing the importation of animal products that are implemented by other U.S. Agencies.

D. Clarifications

In response to comments to the March 9, 2018, notice regarding our proposed equivalence determination, we make the following clarifications. On the respective roles and authority of the EC and competent authorities in the individual EU Member States (including Spain and the Netherlands) in the equivalence determination process, we note that the EC is responsible for establishing harmonized food safety measures that the EU Member States adopt and implement. The EC audits EU Member States to ensure that they have adopted and are implementing harmonized measures, and competent authorities in the EU Member States provide oversight of food business operators to enforce compliance with the measures. The scope of this equivalence determination applies to EC measures for raw bivalve molluscan shellfish in EC-identified Class A production areas and implementation of additional controls in the Guides, as adopted and implemented by Spain and the Netherlands. We did not include processed shellfish in this equivalence determination because we currently permit the importation of processed shellfish that comply with U.S. seafood HACCP regulations (part 123 and § 1240.60) from all EU Member States. This determination does not extend to the implementation of EU food safety control measures for shellfish by other EU Member States. We have revised the title of this notice and the scope of our final equivalence determination to clarify this point. In summary, we have determined that the adoption and implementation by Spain and the Netherlands of the EU's system of food safety control measures for shellfish, along with their application of additional control measures provided in the Guides, is equivalent to the comparable U.S. measures because the adoption and implementation by Spain and the Netherlands of the EU measures and additional controls achieves at least the same level of sanitary protection as comparable food safety measures in the United States.

On the matter of recognizing additional EU Member States in the future, we stated in the March 9, 2018, notice that we would update the ICSSL with the names of the establishments in recognized EU Member States intending to export to the United States (83 FR 10487 at 10492). In order for FDA to recognize additional EU Member States as equivalent, the competent authority in the EU Member State would need to demonstrate that it has adopted and implemented EU shellfish safety control

measures, along with the additional control measures provided in the Guides. The process for seeking such recognition is identified in the Administrative Arrangement between 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 (Ref. 9). In the future, FDA will publish in the **Federal Register** any proposal to recognize additional EU Member States as equivalent and accept comments on the proposal before finalizing the Agency's determination.

Regarding the maintenance of equivalence, both FDA and the EC will carry out periodic onsite evaluations or audits to ensure that equivalence is maintained. In addition, the EC will notify FDA of any plan to adopt, modify or repeal a food safety control measure applicable to molluscan shellfish so that FDA can determine whether the new, modified or repealed measure affects its equivalence determination (Ref. 9).

After considering the comments, we are finalizing the equivalence determination for Spain and the Netherlands.

II. Equivalence Determination

We are announcing that we recognize the adoption and implementation by Spain and the Netherlands of the EU system of food safety control measures for raw bivalve molluscan shellfish, along with their application of additional control measures described in the Guides, as equivalent because the adoption and implementation of these measures by Spain and the Netherlands provide at least the same level of sanitary protection as comparable food safety measures in the United States (19 U.S.C. 2578a(a)).

Because FDA recognizes these control measures have been successfully adopted and implemented by Spain and the Netherlands, this final equivalence determination allows FDA, the competent authorities in Spain and the Netherlands, and the EC to implement procedures for resuming trade in accordance with the final equivalence determination. For the export of raw bivalve shellfish from Spain and the Netherlands to the United States, these procedures include the subsequent listing of eligible establishments in Spain and the Netherlands on the ICSSL once the EC has been notified of our final equivalence determination.

III. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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. National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. Food and Drug Administration and Interstate Shellfish Sanitation Conference. 2007 through 2017 revisions (web page last updated October 2018). Accessed online at *https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm.*
2. ''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://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_community_guide_bivalve_mollusc_monitoring_en.pdf.*
3. ''Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application (Technical Application Guide).'' 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://www.cefas.co.uk/media/jyzhl1si/good-practice-guide-issue-6.pdf.*
4. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 repeals Regulations (EC) No 854/2004 and (EC) No 882/2004. Accessed online at *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625&from=EN.*
5. Commission Implementing Regulation (EU) 2019/627 of 15 March 2019, lays down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls. Accessed online at *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0627&from=EN.*
6. National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. Food and Drug Administration and Interstate Shellfish Sanitation Conference. 2007 through 2017 revisions (web page last updated October 2018). See Section II, Chapter 1 @.02, page 13 and Section IV, Chapter III, .03, page 363. Accessed online at *https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm.*
7. Meeting Summary and Attachment from the U.S.-EU Bivalve Molluscan Shellfish Equivalence Project. November 19 to 20, 2015. FDA Hillandale Building, Silver Spring, MD.
8. Agreement between the United States of America and the European Community on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products dated July 20, 1999.
9. Administrative Arrangement between 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.

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20755 Filed 9–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS–3378–N]

Secretarial Review and Publication of the 2019 Annual Report to Congress and the Secretary Submitted by the Consensus-Based Entity Regarding Performance Measurement

AGENCY: Office of the Secretary of Health and Human Services, HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the Secretary of the Department of Health and Human Services' (the Secretary) receipt and review of the National Quality Forum 2019 Annual Activities Report to Congress and the Secretary submitted by the consensus-based entity under a contract with the Secretary as mandated by the Social Security Act (the Act). The Secretary has reviewed and is publishing the report in the **Federal Register** together with the Secretary's comments on the report not later than 6 months after receiving the report in accordance with the Act. This notice fulfills the statutory requirements.

FOR FURTHER INFORMATION CONTACT: Michelle Geppi, (410) 786–4844.

SUPPLEMENTARY INFORMATION:

I. Background

The United States Department of Health and Human Services (HHS) has long recognized that a high functioning health care system that provides higher quality care requires accurate, valid, and reliable measurement of quality and efficiency. The Medicare Improvements for Patients and Providers Act of 2008