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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2015-0042]

RIN:0583-ZA11

Eligibility of the Republic of Poland to Export Poultry Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed Rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to add the Republic of Poland (Poland) to the list of countries in the regulations eligible to export poultry products to the United States. FSIS has reviewed Poland's poultry laws, regulations, and inspection system as implemented and has tentatively determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the U.S. food safety system for poultry.

Should this rule become final, slaughtered poultry, or parts or other products thereof, processed in certified Polish establishments, would be eligible for export to the United States. Although Poland may be listed in FSIS's regulations as eligible to export poultry products to the United States, the products must also comply with all other applicable requirements

of the United States, including those of USDA's Animal and Plant Health Inspection Service (APHIS), before any products can enter the United States. All such products would be subject to re-inspection at U.S. ports-of-entry by FSIS inspectors.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW, Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2015-0042. Comments received in response to this docket will be made

available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend its poultry products inspection regulations to add Poland to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). Poland is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Section 17 of the PPIA (21 U.S.C 466) prohibits importation into the United States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food.

Under the PPIA and the regulations that implement it, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

Section 381.196(a) requires a foreign country's poultry inspection system to include standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering of poultry and processing of poultry products by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6)

requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) assignment of qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

The foreign country's inspection system must ensure that establishments preparing poultry or poultry products for export to the United States, and their products, comply with requirements equivalent to those of the PPIA and the regulations promulgated by FSIS under the authority of that statute. The foreign country certifies the appropriate establishments as having met the required standards and advises FSIS of those

establishments that are certified or removed from certification. Before FSIS will grant approval to the country to export poultry or poultry products to the United States, FSIS must first determine that reliance can be placed on the certification of establishments by the foreign country.

As indicated above, a foreign country's inspection system must be evaluated by FSIS before eligibility to export poultry products to the United States can be granted. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. To help the country in organizing its materials, FSIS provides the country with a series of questions asking for detailed information about the country's inspection practices and procedures in six areas or equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an onsite review is scheduled using a multidisciplinary team to evaluate all aspects of the

country's inspection program. This comprehensive process is described more fully on the FSIS Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview>.

The PPIA and implementing regulations require that foreign countries determined by the Administrator to have acceptable inspection systems be listed in the regulations as eligible to export poultry products to the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to export poultry or poultry products to the United States are listed in the poultry inspection regulations at 9 CFR 381.196(b). Once listed, the government of an eligible country must certify to FSIS that establishments that wish to export poultry products to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)(3)). Countries must renew certifications of establishments annually (9 CFR 381.196(a)(3)). To verify that products imported into the United States are not adulterated or misbranded, FSIS re-inspects and randomly samples those products at ports-of-entry before they enter U.S. commerce.

#### Evaluation of the Polish Poultry Inspection System

In 2004, the government of Poland requested approval to export raw, ready-to-eat (RTE), and canned poultry to the United

States. Poland stated that, if approved, its immediate intent was to export chicken, turkey, and goose meat to the United States. FSIS conducted a document review of Poland's poultry (slaughter and processing) inspection system to determine whether that system was equivalent to the United States poultry inspection system. FSIS concluded, on the basis of that review, that Poland's laws, regulations, control programs, and procedures were sufficient to achieve the level of public health protection required by FSIS.

Accordingly, FSIS proceeded with an on-site audit of Poland's poultry inspection system from May 10 to June 1, 2011, to verify whether Poland's General Veterinary Inspectorate (GVI), which is Poland's central competent authority (CCA) in charge of food inspection, has effectively implemented a poultry inspection system equivalent to that of the United States. FSIS reviewed two processing and one cold storage establishment intending to export to the United States. From the on-site audit, FSIS concluded that Poland's poultry inspection system did not meet the Government Oversight, Sanitation, HACCP Systems, and Microbiological Testing Programs equivalence components. For example, FSIS found that there was inconsistency in the enforcement of corrective action requirements in response to non-compliances. In addition, FSIS found that the CCA was lacking current policy or regulations that specifically require

establishments to develop and implement written Sanitation Standard Operating Procedures and HACCP plans as conditions for gaining certification for export of poultry products to the United States. FSIS also found that the GVI did not possess evidence of staff participation in training, did not maintain tracked records of training at all levels of the CCA, and that the GVI did not have a mechanism to assess the effectiveness of the training programs.

In addition, FSIS was not able to audit the poultry slaughter inspection in operation because the GVI withdrew the poultry slaughter establishment scheduled for the FSIS audit. FSIS's report discussing the findings of the 2011 on-site audit and the initial corrective actions proffered by GVI is available at the following web address:

[http://www.fsis.usda.gov/wps/wcm/connect/18fc607d-9511-4cc8-8e4c-bc9f6b90cb0c/Poland\\_Poultry\\_2011\\_FAR.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/18fc607d-9511-4cc8-8e4c-bc9f6b90cb0c/Poland_Poultry_2011_FAR.pdf?MOD=AJPERES)

Following the 2011 on-site audit, Poland addressed the FSIS audit findings through corrective action plans presented to FSIS on September 5, 2012, October 11, 2012, and March 20, 2013. FSIS evaluated the corrective action plans and, based on the information Poland submitted, determined that Poland had addressed FSIS's findings.

In July 2014, FSIS conducted a follow-up initial equivalence on-site audit. During the follow-up audit, the FSIS

auditor reviewed the inspection operations at two chicken slaughter and three chicken processing establishments intending to export raw, ready-to-eat (RTE), and thermally processed commercially sterile (canned) products to the United States. Based on the results of the follow-up audit, FSIS concluded that Poland had satisfactorily addressed all initial audit findings and was able to meet FSIS requirements and equivalence criteria related to all six components. The final audit report on Poland's poultry inspection system (slaughter and processing) can be found on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/wcm/connect/33c2d71a-6d5c-4224-b64d-fd7725b8282f/Poland-FAR-2011-2014.pdf?MOD=AJPERES>

In summary, FSIS has completed the document review, on-site audits, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has tentatively determined that, as implemented, Poland's poultry inspection system (slaughter and processing) is equivalent to the United States poultry inspection system pending issuance of a final rule.

Following the FSIS audit of Poland's poultry inspection system, on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule implemented new U.S. regulatory requirements including (1) the New Poultry Inspection System (NPIS), an optional post-mortem

inspection system, and (2) regulatory changes that apply to all poultry slaughter establishments. FSIS expects Poland to submit sufficient evidence to demonstrate how the Polish poultry inspection system achieves an equivalent outcome to the revised U.S. regulations. Before issuing a final rule to add Poland to the list of equivalent countries, and before any product is shipped to the United States, FSIS must verify whether the Polish poultry inspection system is equivalent with the new U.S. regulatory requirements in the August 21, 2014 final rule.

Should this rule become final, Poland will be eligible to export raw, RTE, and thermally processed commercially sterile (canned) poultry products to the United States. The government of Poland must certify to FSIS those establishments that wish to export poultry products to the United States are operating in accordance with requirements equivalent to those of the United States. FSIS will verify that the establishments certified by Poland's government meet the U.S. requirements through periodic and regularly scheduled audits of Poland's poultry inspection system.

Although a foreign country may be listed in FSIS regulations as eligible to export poultry to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR Part 94 of the

United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulations, which also regulate the importation of poultry products from foreign countries into the United States. APHIS has recognized Poland as part of the EU Poultry Trade Region and considers them not affected with either HPAI or Newcastle disease. There are specific certification statements required for poultry product imports to address the animal health issues, and these are defined under 9 CFR 94.28. Any poultry product imports from Poland would be required to meet these requirements.

If this proposed rule is adopted, all slaughtered poultry, or parts and products thereof, exported to the United States from Poland will be subject to re-inspection at the U.S. ports-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS will conduct other types of re-inspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition. Products that pass re-inspection will be stamped with the official U.S. mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days must be exported to the country

of origin, destroyed, or converted to animal food (subject to approval of the U.S. Food and Drug Administration (FDA)), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures/fsis-import-reinspection>.

FSIS has found Poland eligible to export all poultry and poultry products to the United States. Currently, Poland has elected to only certify chicken establishments for export to the United States. In order to export turkey or goose product, Poland will need to notify FSIS and certify any new establishments. FSIS will review information provided by Poland and may decide to audit based on additional product. Poland would not be allowed to export additional products to the United States until FSIS determines that the country's requirements and inspection program for the products are equivalent to FSIS's system.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866.

Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

#### Expected Cost of the Proposed Rule

Poland intends to certify seven establishments that would export chicken to the United States. Within the European Union (EU), Poland is a major poultry producer. According to a 2014 report, the EU listed Poland as the top poultry producer.<sup>1</sup> Over the past 10 years, Poland has doubled its poultry production (2.2 million metric tons in 2014). Poland's poultry production consists of 81% chicken broilers, 14% turkey broilers, and 5% other poultry broilers such as duck and geese. Poland's poultry production uses mostly locally produced grain.<sup>2</sup> Lower feed costs and continuing export demand has helped Poland double its poultry exports within the last five years (741 thousand metric tons in 2014.)<sup>3</sup> Currently, Poland's primary export markets are Germany, the United Kingdom, and France.

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<sup>1</sup> [http://ec.europa.eu/agriculture/poultry/index\\_en.htm](http://ec.europa.eu/agriculture/poultry/index_en.htm) Accessed: September 18, 2015.

<sup>2</sup> Correspondence with the Foreign Agricultural Service (FAS), USDA, May 2015.

<sup>3</sup> Ibid.

Poland exports chicken, turkey, duck and geese products to other countries. Table 1 provides unit values for Poland's poultry product exports and shows Poland's price competitiveness in the poultry export market. Poland is price competitive for most poultry products that the United States imports from other countries, primarily Canada and Chile.

Commodity Description	Poland Export Unit price U.S.\$ /MT		U.S. Import Price U.S.\$ /MT	
	2014	3-Year Average	2014	3-Year Average
Meat & Edible Offal Of Poultry, Fresh, Chill Or Frozen	\$ 2,713	\$2,701	\$3,207	\$3,188
Chicken Cuts And Edible Offal (Including Livers), Frozen	\$ 1,892	\$1,885	\$3,021	\$3,022
Turkey Cuts And Edible Offal (Including Liver) Frozen	\$ 2,744	\$2,616	\$3,015	\$2,475
Chicken Cuts & Edible Offal (Including Liver) Fresh/Chilled	\$ 3,184	\$3,144	\$4,331	\$4,158
Meat & Offal Of Chickens, Not Cut Fresh Or Chilled	\$ 1,979	\$1,992	\$3,588	\$3,511
Cuts And Offal Of Ducks, Frozen	\$ 2,924	\$2,677	\$3,834	\$4,320
Turkey Cuts & Edible Offal (Including Liver) Fresh/Chilled	\$ 4,500	\$4,326	\$2,897	\$4,729
Meat Of Ducks, Frozen, Not Cut In Pieces	\$ 2,870	\$3,041	\$4,277	\$4,185
Meat & Offal Of Chickens, Not Cut In Pieces, Frozen	\$ 1,818	\$1,870	\$4,133	\$4,483
Cuts And Offal Of Ducks, Excluding Livers, Fresh/Chilled	\$ 5,057	\$5,480	\$13,628	\$12,764
Turkeys, Not Cut In Pieces, Fresh Or Chilled	\$ 3,217	\$3,154	\$3,820	\$4,015
Fatty Livers Of Ducks, Fresh Or Chilled	\$20,324	\$8,493	\$54,021	\$54,157
Turkeys, Not Cut In Pieces, Frozen	\$ 3,187	\$3,159	\$2,123	\$4,052
Meat, Offal Of Guinea Fowls, Fresh, Chilled Frozen	\$ 2,154	\$2,039	\$2,270	\$2,495
Meat Of Ducks, Fresh Or Chilled, Not Cut In Pieces	\$ 3,278	\$2,908	\$9,715	\$7,411

Source: U.S. Department of Commerce, and Global Trade Atlas at

<http://www.gtis.com/gta/secure/gateway.cfm>

Both the low cost of poultry production and low export unit price are why the United States is a top poultry exporter.

In total, poultry imports account for only 0.3% of the U.S. poultry supply.<sup>4</sup> In 2014, the United States produced 17.3 million Metric Tons (MT) of poultry, exported 3.3 million MT of poultry, consumed 14 million MT of poultry, and imported only 0.053 million MT of poultry.<sup>5</sup> U.S. poultry imports have remained relatively unchanged in recent years<sup>6</sup>, and there is no reason to believe the amount will change substantially in the future. For Poland to export poultry to the United States, it must be export-eligible, export-capable, and price-competitive. After comparing Poland's price competitiveness with the United States, Chile, and Canada, FSIS estimates that the maximum potential Polish poultry products exports to the United States is expected to be between 29,500 MT and 44,300 MT. This means that the total U.S. poultry supply will increase only between 0.15% and 0.22% due to Poland's projected export volume to the United States, leaving the total U.S. poultry supply almost unchanged. Thus, Poland's projected poultry export volume to the United States would only minimally change U.S. poultry prices, not enough to alter the U.S. poultry market. Currently, however,

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4 USDA, Foreign Agricultural Service, <https://apps.fas.usda.gov/psdonline/psdQuery.aspx>

5 Ibid.

6 Ibid

Poland only intends to certify as eligible seven establishments to export raw, RTE, and thermally processed commercially sterile (canned) chicken products to the United States. The total processing capacity of these seven establishments is less than Poland's total poultry export capacity. With minimal price change expected in the U.S. poultry markets, adopting this proposed rule would not have a negative effect on U.S. consumers.

Companies that export products from Poland to the United States will incur the standard costs associated with exporting products to the United States, such as export fees and freight or insurance costs. They will be willing to bear these costs, however, because of the anticipated financial benefits associated with marketing their products in the United States.

#### Expected Benefits of the Proposed Rule

Adoption of this proposed rule will increase trade between the United States and Poland. The volume of trade stimulated by the proposed rule is likely to be small and is expected to have little or no effect on U.S. poultry supplies or poultry prices. U.S. consumers, however, are expected to enjoy more choices when purchasing poultry products. The proposed rule would, therefore, expand choices for U.S. consumers and promote economic competition.

#### Effect on Small Entities

The FSIS Administrator has made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The expected trade volume will be small, with little or no effect on U.S. establishments, regardless of size.

#### Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Poland with questionnaires asking for detailed information about the country's inspection practices and

procedures to assist that country in organizing its materials. This information collection was approved under OMB control number 0583-0094. The proposed rule contains no other paperwork requirements.

#### E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

#### Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this proposal and will announce it on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules>. FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the

FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

<http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

#### USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

#### How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at

<http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain>

[combined 6 8 12.pdf](#), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture  
Director, Office of Adjudication  
1400 Independence Avenue, SW  
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: [program.intake@usda.gov](mailto:program.intake@usda.gov)

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR Part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR  
2.7, 2.18, 2.53.

§ 381.196 [Amended]

2. Amend §381.196(b) by adding "Poland" in alphabetical  
order to the list of countries.

Done at Washington, DC, on: April 15, 2016.

Alfred V. Almanza

Acting Administrator.

[FR Doc. 2016-09185 Filed: 4/19/2016 8:45 am; Publication Date: 4/20/2016]