

United States Department of Agriculture Foreign Agricultural Service

Global Agricultural Information Network GAIN REPORT

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 3/19/2019 GAIN Report Number:

Poland

Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report

Approved By: Jonn Slette, Agricultural Attaché Prepared By: Piotr Rucinski, Mira Kobuszynska, Agricultural Specialists, Jolanta Figurska, Marketing Specialist

Report Highlights:

Poland is a European Union (EU) Member State and applies EU food and agricultural import regulations, with few exceptions. U.S. food and agricultural suppliers to Poland should verify with local importers and appropriate U.S. regulatory agencies for the most current local requirements prior to shipping.

Table of Contents

Section I. General Food Laws Section II. Food Additives Regulations Section III. Pesticides and Other Contaminants Section IV. Packaging and Container Regulations Section V. Labeling Requirements Section VI. Other Specific Standards Section VII. Facility and Product Registration Requirements Section VIII. Other Regulations and Requirements Section IX. Import Procedures Section X. Copyright and/or Trademark Laws Appendix I: Government Regulatory Agency Contacts Appendix II: Other Import Specialist Contacts

Disclaimer

This report was prepared by U.S. Embassy Warsaw's Office of Agricultural Affairs (OAA) for exporters of U.S.-origin food and agricultural products. While every effort was taken to ensure accuracy, some information may have changed since publication or was not fully available while drafting. Post recommends that U.S. exporters verify all import requirements with their international customers before any goods are shipped. Final import approval of any product is subject to the importing country's rules and regulations, as interpreted by border officials at the point of entry and/or the time the product enters into commerce. The following Food and Agricultural Import Regulations and Standards (FAIRS) Report should also read in conjunction with the <u>FAIRS Report</u> prepared by the U.S. Mission to the EU's OAA.

Section I. Food Laws:

Poland follows EU regulations governing agricultural imports, as per the EU's single market principle. Regulation EC/178/2002 (General Food Law) establishes general principles and requirements for the EU's harmonized food law. Although some variations exist between Member States vis-à-vis applying EU regulations, Poland's food and agricultural import regulations are consistent with the EU requirements. In January 2018, the Commission finalized its "<u>fitness check</u>" of the General Food Law and found that ineffective risk communication negatively affects consumer confidence regarding regulatory decisions. In April 2018, the Commission <u>proposed</u> to improve risk communication by amending the General Food Law to create a public register of studies by businesses seeking approvals for genetically-engineered products, novel foods, food and feed additives, plant protection products, and food contact materials. This proposal is still under review and may be finalized by mid-2019.

Poland is responsible for enforcing compliance with EU food law requirements. A new regulation on harmonized food controls, <u>Regulation 2017/625</u>, will be applied on December 14, 2019, repealing the current <u>Regulation 882/2004</u>. A "rapid alert system" for food and feed (RASSF) shares cross-border information when public health risks threaten the food chain. Foods products determined to be

dangerous and/or unfit for human consumption cannot be sold on the market. To determine whether a food product is dangerous, the following criteria are considered:

- Normal conditions of use;
- Information provided to the consumer;
- Probable immediate or delayed effect on health;
- Cumulative toxic effects; and
- Specific sensitivities for certain consumers

Whenever a food product is determined to be unsafe and is part of a batch, lot, or consignment, it is assumed that the whole batch, lot, or consignment is also unsafe. Animal feed deemed to be unsafe cannot be sold on the market or fed to any food-producing animals. Producers must apply the food legislation throughout the value chain, from the production, processing, transport and distribution stages through to the supply of food. Furthermore, producers are responsible for ensuring traceability at all stages of the production, processing, and distribution, including substances and/or ingredients used.

The General Food Law also established the European Food Safety Authority (EFSA), an independent body that provides scientific advice to the European Commission (EC). EFSA provides scientific expertise and scientific and technical support in all areas regarding food safety. EFSA is also responsible for coordinating risk assessments and identifying emerging risks, providing scientific and technical advice to the EC, including crisis management, collecting and publishing scientific and technical data in areas relating to food safety, and establishing European networks of organizations operating in the field of food safety. EFSA resources are available to EU Member States and to other countries which apply EU food safety standards. Additional detailed information on the EU procedures can be found in FAS USEU's <u>How the EU Works Report</u> (updated September 2017).

Current Polish Food Laws

On August 10, 2018, Poland published an update (Polish Journal of Law 2018, pos. 1541) to its 2006 Consolidated Act on Food Safety and Nutrition. The 2006 Act (and subsequent amendments) is Poland's legal framework to regulate food safety and nutrition, including sanitation and hygiene, conditions applicable to food products, packaging and materials and products which come into contact with food, and others. The Act is composed of the following Sections:

- (1) General provisions and definitions
- (2) Sanitary and labeling requirements for food
- (3) Materials and products intended to come into contact with food
- (4) Hygienic requirements
- (5) Official inspection on food
- (6) Institutions and cooperation in the area of food safety
- (7) Liability for harms caused by foods
- (8) Criminal provisions and penalties
- (9) Amendments to provisions in force, transitional, and final provisions

Food Authorities in Poland

Poland's primary food regulators include the following (see Appendix for contact information):

<u>The State Sanitary Inspection</u> or *Państwowa Inspekcja Sanitarna* (PIS) is responsible for supervising food quality, materials, or products intended to come in contact with food. Food control (not including meat) is conducted appropriately by inspectors from Sanitary-Epidemiological Stations in their respective districts of coverage.

The State Veterinary Inspection or *Państwowa Inspekcja Weterynaryjna* (PIW) regulates animal health and products of animal origin.

<u>The Main Inspectorate of Plant Health and Seed Inspection</u> or *Państwowa Inspekcja Ochrony Roślin i Nasiennictwa* (PIORIN) regulates plant health, international trade, the application and production of agrochemicals and other plant-protection inputs, and regulates trade of seeds.

<u>The Agricultural and Food Quality Inspection</u> or *Inspekcja Jakości Handlowej Artykułów Rolno-Spożywczych* (IJHARS) reports to the Minister of Agriculture and performs all tasks specified in the Act of Commercial Quality of Agricultural Food Products, and other national and EU regulations including:

- Quality control of food in production and sales, including exported products
- Quality control of imported food products, including border control of these articles
- Evaluation and issuance of certificates in terms of quality of food articles
- Controlling conditions of storage and transport of food
- Cooperating with officiala in other countries, exchange of information and food samples
- Coordination with the Office of Competition and Consumer Protection which also supervises the quality of food products in the retail trade
- Reporting infringements of EU food and feed legislation through the Rapid Alert System on Food and Feeds (RASFF)

<u>The Office of Competition and Consumer Protection</u> or *Urząd Ochrony Konkurencji i Konsumentów* (UOKiK) is the central authority responsible for antitrust policies and consumer protection laws. UOKiK is authorized to control mergers to prevent monopolistic situations or similarly, dissolve cartels that negatively affect consumers.

Section II. Food Additives Regulations:

The EU's "Package on Food Improvement Agents" includes four Regulations: <u>Regulation 1331/2008</u> which establishes a common approval process for food additives, food enzymes and food flavorings, <u>Regulation 1332/2008 on food enzymes</u>, <u>Regulation 1333/2008 on food additives</u> and <u>Regulation 1334/2008 on flavorings</u>. Only additives included in the EU's positive list may be used in food products marketed in the EU. Inclusion in the EU positive list is based on a risk assessment by the EFSA. <u>Commission Implementing Regulation 234/2011</u> explains how to requests updates to the positive lists (*e.g.* content, data requirements and presentation). EFSA will then review and determine the suitability of the data.

Regulation on Permitted Additives

Annex II to Food Additives Regulation 1333/2008 lists additives approved for use in foods and conditions of use. The authorized additives and uses are listed according to the food category to which

they may be added. An important difference from U.S. legislation is that the EU does not allow chlorine, bromates, and peroxides to be used as flour-bleaching agents. Annex I to regulation 1333/2088 defines 26 different categories of food additives. Annex III contains a second list of food additives approved for use in food ingredients such as other food additives, food enzymes, food flavoring, and nutrients. <u>Commission Regulation 231/2012</u> sets out specifications for food additives listed in Annexes II and III.

Regulation on Specifications and Criteria of Purity of Additives

The Polish Ministry of Health (MOH) issued a regulation on specifications and criteria of purity of additives, namely, Regulation of the Minister of Health of 12 October 2007. This regulation specifies purity criteria of additional substances (Regulation of the Minister of Health of 12 October 2007, Polish Journal of Law 2011, No. 2, pos. 3). It was amended on December 23, 2010 and changed again on April 22, 2011 in "Regulation of the Minister of Health of 22 April 2011, which amended specifications and purity criteria of additional substances (Polish Journal of Law 2011, No. 91, pos. 526).

Solvents

The MOH issued a regulation on solvent extractions for use in food products in February 18, 2011. The Regulation of the Minister of Health of 22 April 2011 amended specifications and purity criteria of additional substances (Regulation of the Minister of Health of 18 February 2011) (Polish Journal of Law 2011, No 52, pos.272).

Flavorings

The EU regulates flavorings and certain ingredients with flavoring properties via EC Regulation No. 1334/2008. An <u>online database</u> allows consumers, food businesses, and food control authorities to verify which flavoring substances are authorized in food with the EU.

Enriching Agents

The MOH issued a regulation regarding enriching agents, namely, Regulation of the Minister of Health of 19 December 2002, which limits enriching agents as well as conditions of use (Polish Journal of Law No. 27, pos. 237). The Regulation was amended on September 16, 2010 (Polish Journal of Law 2010, No. 174, pos. 1184).

Dietary Supplements

EU Regulation (EC) No 1925/2006 of the European Parliament and the EC established standards for vitamins, minerals, and other substances to foods was published on December 20, 2006.

The Regulation applies without prejudice to provisions related to:

- Foods for particular nutritional uses
- Novel foods and novel food ingredients
- <u>Genetically modified foods</u>
- <u>Food additives</u> and <u>flavorings</u>
- <u>Wine and certain other wine sector products</u>

Section III. Pesticides and Other Contaminants:

European Parliament and Council Regulation 1107/2009 establishes rules for the authorization of plant protection products (PPPs). PPPs (also referred to as 'pesticides') contain at least one approved active substance. Only PPPs containing active substances included in the list of approved active substances as established in Commission Implementing Regulation (EU) No 540/2011 of May 25, 2011 may be authorized for use in the EU.

Rules for the marketing and using pesticides in Poland are regulated by Law on Plant Protection Products (Journal of Laws of 2013, pos. 455, Law on Plant Protection Products on 8 March 2013). Basic rules for the protection of plants against harmful organisms are available in Law on Plant Protection of 18 December 2003 (Journal of Laws of 2004 No. 11, pos. 94), Act on plant protection of 18 December 2003. A consolidated text of the law was published on June 14, 2018 (Dz.U.2018 pos. 1310).

Endocrine Disruptors

"Endocrine disruptors" refer to substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. Both the Plant Protection Products Regulation 1107/2009 (pesticides) and the Biocidal Products Regulation 528/2012 (biocides) introduced "endocrine disrupting properties" as one of the categories of hazard-based cut-off criteria. This allows the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking exposure into account. <u>Commission Regulation 2018/605</u>, identifying endocrine disrupting properties under Regulation 1107/2009 on plant protection products, in the Official Journal. The criteria to identify endocrine disruptors was applied as of November 10, 2018, to all ongoing and future evaluations of active substances used in plant protection products. In June 2018, the European Chemicals Agency and the EFSA published a <u>technical guidance document</u> to implement the criteria for both biocides and pesticides.

Section IV. Packaging and Container Regulations:

Size and Content

The maximum margin of error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC, as amended. Directive 2007/45/EC abolished regulations on mandatory pack sizes at both EU and national levels for all prepackaged products except wine, spirits, and coffee. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC. Detailed information on "Legal Metrology" is available on the EC's website.

Packaging Waste Management

Member States are required to reduce packaging waste and must introduce systems for reuse, recovery, and recycling of packaging materials. Council Directive 94/62/EC harmonizes national measures concerning the management of packaging and packaging waste and its impact on the environment. To facilitate collection, reuse and recovery, including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. An overview of current EU legislation applicable to packaging and related waste is available on the EC's <u>website</u>.

Materials in Contact with Foodstuffs

European Parliament and Council Regulation 1935/2004 specifies the main requirements for all materials that come into contact with foodstuffs. It also establishes labeling and traceability

requirements and the procedure for the authorization of substances through the EFSA. Annex I to regulation 1935/2004 lists the group of materials which may be covered by specific measures. Specific measures set out additional requirements and include lists of authorized substances and materials. To date, specific directives have been developed for plastic materials (Commission Regulation 10/2011), recycled plastic materials (Commission Regulation 282/2008), regenerated cellulose film (Commission Directive 2007/42/EC) and ceramics (Council Directive 84/500/EC). In the case of ceramics, migration limits have been established for lead and cadmium. Materials must indicate "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

Commission Implementing Regulation 321/2011, amending Regulation 10/2011 on plastic materials, bans the use of Bisphenol A in plastic infant feeding bottles. A summary of EU and national legislation as well as guidance documents and contact information with regard to the submission of applications for authorization can be downloaded from the EC website.

Plastic Materials

The MOH regulation concerning the list of substances intended for food contact and permitted in manufacturing or processing of plastic materials and the methods of checking of compliance of those products within the set limits was published on June 22, 2007 (Polish Journal of Law 2007, No 129, pos. 904). It was nullified and replaced on December 4, 2013, ("Regulation of the Minister of Health of 15 October 2013) with an updated list of substances permitted in the manufacture or processing of materials and plastic products, as well as compatibility of these materials and articles within established limits.

Commission Regulation EU/558/2010 concerning specific hygiene rules for food of animal origin was published on June 24, 2009. The Regulation specifies requirements in terms of temperature and microbiological criteria in the production of *foie gras*, meat from poultry and lagomorphs, frozen fish in brine. In addition, sea snails are excluded from the legislation of classifying production areas. This classification is necessary for bivalve mollusks, live echinoderms, and tunicates. Requirements to transport of live bivalve mollusks in containers and the specification of raw materials used for gelatin production are updated.

Materials other than Plastics

The MOH regulation concerning the list of substances intended for food contact and permitted in manufacturing or processing of materials and products from materials other than plastics ("Regulation of the Minister of Health of 15 January 2008) regarding the list of substances whose use is permitted in the manufacture or processing of materials and products from other materials than plastics intended to come into contact with food was published on January 15, 2008 (Polish Journal of Law 2008, No. 17, pos. 113).

Section V. Labeling Requirements:

General Requirements

The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU's <u>"Food Information to Consumers (FIC)" regulation 1169/2011</u> became applicable to all pre-packaged food and drink products marketed in the EU, including those imported from third countries.

The mandatory nutrition declaration requirement introduced by the FIC regulation became applicable on December 13, 2016.

Detailed information on food labeling requirements set out in the FIC regulation is available in <u>GAIN</u> report "New EU Food Labeling Rules Published", supplemented by <u>GAIN report "How to Comply with</u> the EU's New Food Labeling Rules". These reports and other updates on labeling rules can be found on FAS USEU's <u>website</u>.

To assist food business operators complying with the EU's food labeling rules, the EC as well as several Member State authorities and EU food federations have published guidance documents.

- EC: Questions and Answers on the Application of Regulation 1169/2011 on the Provisions of Food Information to Consumers (January 2013)
- EC: Notice on questions and answers on the application of Regulation 1169/2011 on the Provision of Food Information to Consumers (June 2018)
- EC: Infographic on the new labeling rules
- Food Drink Europe (EU Food and Drink Industry Confederation): <u>Guidance on the Provision of</u> <u>Food Information</u>
- U.K.: Food Labeling Giving food information to consumers

The objective of a "regulation" is to set harmonized rules that apply throughout the EU. However, the FIC regulation allows Member States to deviate from EU rules. Article 39 of the FIC regulation sets conditions for Member States to adopt additional mandatory national measures, including measures for country of origin labeling. The FIC regulation exempts alcoholic beverages from mandatory nutrition labeling and ingredient listing but Article 41 allows Member States to maintain national rules on the listing of ingredients until EU-harmonized provisions are adopted. U.S. exporters are strongly advised to check for additional national requirements with their importers.

Article 9 of FIC regulation 1169/2011 sets out the list of mandatory declarations on food and drink labels:

- Name of the food
- List of ingredients
- Allergens
- Quantity of certain ingredients or category of ingredients
- Net quantity of the food
- Date of minimum durability or "use by date"
- Any special storage conditions and/or conditions of use
- Name of business name and address of the food business operator under whose name the food is marketed. If that operator is not established in the EU, the name and address of the importer
- Country of origin or place of provenance
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- Alcoholic strength by volume for beverages containing more than 1.2 percent by volume of alcohol
- Nutrition declaration

Basic Laws on Food Labeling in Poland

Ministry of Agriculture and Rural Development regulates labeling in Poland. On July 31, 2007, the basic law on food labeling, Regulation of the Minister of Agriculture and Rural Development dated July 10, 2007, regarding labeling of foodstuffs was published (Polish Journal of Law 2007, No. 137, pos. 966). It was amended on January 8, 2015 (Polish Journal of Law 2015, pos. 29).

Food labeling is also regulated by the Polish Food Safety Law (Polish Journal of Law 2006, No. 171, pos. 1225). EU Law was also amended to reflect European Council Regulation 1169/2011 on consumer information relating to food products.

Compulsory Information on Labels

The standard U.S. label fails to comply with Polish labeling requirements as it is not in Polish. Compulsory information must appear in the Polish language on the pre-packaging or on a label attached to it with a sticker. The information is in line with Article 9 of FIC regulation 1169/2011 which sets out the list of mandatory declarations must be marked in such a way that it is easily visible and clearly legible. Article 13 of the FIC regulations specifies that the minimum font size for printing mandatory information on food and drink labels is 1.2 millimeters.

As of January 1, 2017, a new regulations on voluntary marking of foodstuffs with the words "*Produkt polski*" (Made in Poland) went into effect in Poland. Manufacturers are able to place logo "*Produkt Polski*" on products produced in Poland with the use of Polish raw materials and containing no more than 25 percent of components derived from imported ingredients (this percent does not include water content). Meat used in products marked with logo "*Produkt Polski*" should be derived from animals born on the Polish territory and whose breeding and slaughter took place on Polish territory.

Labeling Irregularities

The most frequent and common irregularities, found during store inspections, in labeling found by Polish inspections include:

- Lack of complete identification of the manufacturer, *i.e.* no address, no contact information
- Providing incorrect information on the composition of the foodstuff, such as incomplete list of ingredients (lack of information on allergenic ingredients, food additives, overstatements in meat content) or the ingredients are not indicated in descending order
- No percentage of ingredients specification used in production, such as lack of hazelnuts content in "milk chocolate with hazelnuts"
- Providing misleading information in the matter of composition, nature and source of the foodstuff, such as inscription: "Bio ..." on non-organic product, suggesting that the product is environmentally friendly
- Using graphic signs suggesting that the product is a different product than it is, for example, the image of ham and sausages on the offal packaging
- No additional substance and no technological function provided in description, such as lack of technological features used in citric acid
- Improper use of the product name, such as "wine" in relation to fermented wine
- In the case of fruit and vegetables lack of qualitative characteristics of products (grade, size, if sorted by plurality) as well as type name
- Another type of incompatibility related to physical and chemical parameters or sensory

evaluation.

Food Traceability

Throughout the EU, traceability is compulsory by Regulation EC/178/2002. Traceability is defined as the ability to track food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution. Traceability allows immediate response to potential risks that can arise in food and feed, to ensure that all food products in the EU are safe for consumption. It is vital that when national authorities or food businesses identify a risk they can trace it back to its source in order to swiftly isolate the problem and prevent contaminated products from reaching consumers. In addition, traceability allows targeted withdrawals and the provision of accurate information to the public, thereby minimizing disruption to trade.

All food and feed operators implement special traceability systems. The EU has published guidelines, which require business operators to document the names and addresses of the supplier and customer in each case, as well as the nature of the product and date of delivery. Operators are also encouraged to keep information on the volume or quantity of a product, the batch number if there is one, and a more detailed description of the product, such as whether it is raw or processed.

Medical/Health/Nutrition Claims

Commission Regulation (EC) No. 1924/2006 concerning the nutrition and health claims in foodstuffs was published on December 20, 2006. The following Regulation (EC) No 109/2008 was released on January 15, 2008.

In December 2011, the EC proposed a list of 222 functional health claims for substances other than botanicals. More than two years after the due date set by Regulation 1924/2006, the list of EU-approved functional health claims and their conditions of use was finally adopted on May 25, 2012. Regulation 432/2012 establishing the EU positive list became applicable on December 14, 2012. Anyone is able to use the permitted health claims provided the conditions set out in Regulation 432/2012 are met. The EU's online "Register of Nutrition and Health Claims" has been updated not only with the 222 authorized health claims referring to botanical substances have been put on hold because the Commission and the Member States are discussing the potential conflict of the Health Claims Regulation with the Traditional Herbal Medicinal Products Directive. All claims that are not authorized and not on hold or under consideration are prohibited as of December 14, 2012. Food products carrying claims must comply with the provisions of nutritional labeling are set out in Nutrition & Health Claims Regulation 1924/2006 and Regulation 432/2012.

Food Labeling for Dietary Supplements and Special Nutritional Products

Poland takes a much stricter approach regarding dietary supplement labeling than other EU countries. Polish regulations require the wording "dietary supplement" ("suplement diety") to be used with the product brand name wherever the brand name is mentioned on the product label.

An amendment to Regulation of the Minister of Health dated May 18, 2010 (Polish Journal of Law, No. 91, pos. 596) changed the composition and labeling of dietary supplements. On September 16, 2010, a new regulation on foodstuffs for special nutritional diets was issued, Regulation of the Minister of

Health of dated September 16, 2010 (Polish Journal of Law 2010, No. 180, pos. 1214).

Marketing Quality of Agricultural Food Products

The basic law on market quality of agricultural food products the Act of October 24, 2008 amending the Act on the commercial quality of agri-food products and some other acts were published on October 24, 2008 (Polish Journal of Law 2008, No. 214, pos. 1346).

Section VI. Other Specific Standards:

Bovine Genetics

Imports of bovine genetics to Poland are based on requirements outlined in the Commission Decision 2008/120/EC dated February 7, 2008, that amended Council Directive 88/407/EEC and Commission Decision 2004/639/EC laying down the importation conditions of semen of domestic animals of bovine species.

In addition to the EU regulations, exporters must follow Polish regulations on imported genetic material. The Polish regulation is based on the breeding law implemented in August 2007.

Bovine semen of U.S. origin must be accompanied by a veterinary health certificate, included in 2008/120/EC Regulation, and documents confirming the breeding value of the bull, from which the semen derives.

Genetically Engineered (GE) Foods

Since 2006, Poland has officially opposed approval of any event of biotechnology at the EU level, and has taken steps to become "GMO-free." In 2006, Poland passed legislation that banned the sale and registration of biotech seeds, restricted Polish representatives to the European Parliament from supporting pro-biotech legislation, and prohibited the importation, production, and use of animal feed containing ingredients enhanced through biotechnology. In practice, the ban on the use of GE feed ingredients was postponed by the Polish Parliament until January 1, 2019. Poland's lower and upper Chambers of Parliament (*Sejm and Senate*) approved a draft amendment to the 2006 Feed Act to postpone the Act's ban on GE feeds and GE-derived ingredients for another two years until January 1, 2021. After ratification by the Sejm and *Senat*, it is waiting for final approval from the President of Poland. For additional information regarding the GE foods please refer to FAS Warsaw Reports.

Novel Foods

For detail information on novel foods please refer to the website of the State Sanitary Inspection.

Traceability and Labeling of GE Foods

Labeling regulations for GE food products are established by Regulation 1829/2003 (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GE feed or treated with GE medicinal products do not require additional labeling. For more information please see the website <u>Labeling of GE Products</u>. The traceability rules require all business operators to transmit and retain information on GE products in order to identify both the supplier and the buyer of the GE product. Regulation (EC) No. 1829/2003 includes: all products which consist of or contain GE, including all products intended for human or

animal consumption, products destined for industrial processing for uses other than consumption (e.g. in the production of biofuel) or even products destined to be used ornamentally (*e.g.* in the production of cut flowers) and foodstuffs and animal feed products made from GE.

Operators must transmit the following information in writing: an indication that the products consist of or contain biotech-derived materials, and the unique identifiers of the events. If the product is a stacked biotech event, the industrial operator may submit a declaration of use of these products, together with a list of the unique traits of the stacked event. This information must also be saved for five years.

The operators who place pre-packaged products on the market consisting of or containing GE must, at all stages of the production and distribution chain, ensure that the words "This product contains genetically modified organisms" or "Product produced from GM (name of organism)" appear on a label of the product. In the case of products, including in large quantities, which are not packaged and if the use of a label is impossible, the operator must ensure that this information is transmitted with the product. When placing a product on the market the operator must transmit the following information in writing to the operator receiving the product: an indication of each food ingredient produced from GE, an indication of each raw material or additive for feeding stuffs produced from GE, and if there is no list of ingredients, the product must bear an indication that it is produced from GE.

Commission Regulation (EU) No. 619/2011 sets a tolerance of 0.1 percent for Low Level Presence (LLP) of non EU-authorized biotech events in feed imports.

Low-level Presence (LLP)

On June 24, 2011, the EU adopted Commission Regulation 619/2011 which established an LLP tolerance of 0.1 percent for adventitious traces of non-EU-authorized GEs in feed imports. The Regulation is laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material. For more information see the EC press release "Questions and Answers on the LLP of GEs in feed imports." The Commission may come forward with proposals dealing with LLP in food imports.

The EU sets out a framework for guaranteeing the traceability of GE throughout the food chain, including in processed foods in which the production methods have destroyed or altered the genetically modified DNA (e.g. in oils). These rules apply not only to GEs to be used in food, but also those intended to be used in crops (e.g. seeds). The EU has two main objectives: to inform consumers through compulsory labeling, giving them the freedom to choose, and to create a "safety net" based on the traceability of GEs at all stages of production and emergence on the market. This "safety net" will facilitate the monitoring of labeling, the surveillance of the potential effects on human health or the environment, and the withdrawal of products in cases of risk to human health or the environment and is similar to the system used for conventional food products. For meat, producers must tag each carcass with origin, slaughter date information, and the traceability code of the slaughter plant. Animal traceability methods, including ear tags, passports, or bar codes, vary across countries but must include the same information.

Section VII. Facility and Product Registration Requirements:

The EU approves establishments to ship products of animal origin based on submissions from U.S.

government agencies. Only products processed in approved establishments may enter the EU. Detailed information on approved U.S. establishments is available on our <u>website</u>. Third-country lists per sector and per country are published on the EC's <u>website</u>.

Section VIII. Other Regulations and Requirements:

Value Added Tax (VAT) Poland applies a VAT for agricultural and food products either imported or produced domestically and ranges from five to 23 percent depending on level of processing of the product.

- Five-percent VAT applies to unprocessed food like fruits, vegetables, milk, meat, fish, flavorings and also processed food like dairy products, fish products, floury products, fruit preserves, ready-to-cook meals.
- Eight-percent VAT applies to all remaining unprocessed foods.
- 23-percent VAT applies to highly processed food products.

Poland also applies an excise tax, which is an indirect tax levied on certain goods such as: beer, wine, liquor, tobacco products, fuel, electricity, and cars. In Poland, the excise tax is harmonized with the EU tax levied on each product. Excise tax rates on certain products can be determined by individual EU country but must not be lower than the levels found in EU directives.

Some excise products are subject to obligatory marking by excise strips, which need to be placed on individual product packaging. These regulations are obligatory for alcoholic beverages (except beer) and tobacco products. In case of bulk shipments of wine and alcoholic beverages (other than beer) the excise strips need to be placed on products prior to entering the EU. It is a standard procedure for the importer to supply the exporter with excise bands, to be put on products prior to shipping. Imported products must have excise tax stickers on them before entering Poland (based on a partial pre-payment). Once the product enters the country, the remainder of the tax must be paid.

A new law changing the Law on Excise Tax was published on October 29, 2010 (Polish Journal of Law 2010, No. 226, pos. 1477), which was amended and then published September 28, 2015 (Polish Journal of Law 2015, pos. 1479). The new law is in line with Council Directive 2010/12/EU from February 16, 2010 concerning the structure and tax values on tobacco products.

A list of VAT rates applicable in the different Member States can be found here.

A list of excise duties applicable on alcoholic beverages and tobacco can be found here.

Section IX. Import Procedures:

An importer of a product new to the Polish market can request pre-approval (i.e., prior to export) of a product by submitting a letter to health authorities requesting a permit for product entry (*"powiadomienie"*). The following documentations are required to request a pre-approval permit:

- Copy of invoice
- Any required certificates (e.g. Meat and Poultry Export Certificate of Wholesomeness)
- Producer's laboratory analysis, if available (to speed up the clearance process)

• Draft Polish language label that includes all product ingredients

On average, the pre-approval process takes about one month and can speed entry of a product to the Polish marketplace. If pre-approval clearance is not requested, full product testing may be implemented and the product held at the border until testing is completed. If pre-approved, a product can be cleared at the Polish border with the following routine trade documentation:

- Importer's request for sanitary inspection (3 copies)
- Invoice on its basis the customs value of goods is declared
- Specification of goods or the list of goods, if the invoice does not meet the role of specification
- Documents from which the tax determination on the goods can be ascertained, if the invoice or other document used to determine the customs value of goods does not contain the necessary data to determine the tax base
- Transportation document (i.e. airway bill)
- Certificate issued by the manufacturer or an authorized research facility containing the chemical composition of raw materials and goods (up to 100percent) and the information required in the notes to individual chapters of the Customs Tariff, if such document is necessary to determine the tariff classification of goods; Health Certificate/Phytosanitary Certificate/Microbiological Certificate
- Additional documentation from producer confirming products production standards (laboratory tests, certificates etc.) the license, permit or other documents, if required in connection with the import
- Official translation of all documents in the Polish language

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eightdigit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings; the two following digits represent the CN subheadings. The EU's on-line "Taric" customs database can be consulted to look up commodity codes and relevant import duties. Taric is a multilingual database covering all measures relating to tariff and trade legislation. The EU's 2017 Tariff Schedule was published on October 28, 2016 in Official Journal L 294. A list of Member State customs authorities can be found <u>here</u>.

Business operators can obtain Binding Tariff Information (BTI) from a member state's customs authority in order to get the proper product classification and relevant import duty. A BTI decision is legally binding in all the Member States. A BTI used to be valid for six years but the new UCC reduces the validity from six to three years. U.S. exporters should be aware that the new UCC makes the declaration of a BTI decision mandatory when completing customs formalities where before the BTI declaration was not legally required. All BTI decisions issued by the Member States' customs authorities are entered into an EBTI-database. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Novel food products must undergo a different registration procedure with health authorities (Main Sanitary Inspection). Novel foods are foods, and food ingredients, that were not used for human consumption to a significant degree within the EU prior to May 15, 1997.

Products Already in the EU Market

If an importer of a product already present in the EU provides a letter from the producer confirming this fact, the product can be allowed to enter Poland without additional clearance. The producer must provide the confirmation. There is no special format for such a letter, except that it must be in the Polish language.

Plant Products

Regulation of the Minister of Health dated February 14, 2007 regarding the application form for the border inspection and certificate of compliance with health requirements (Polish Journal of Law 2007, No 44, pos. 286) provides an example of application for the border sanitary control and for certificate of compliance with health requirements for Poland.

For a list of border crossings through which foodstuffs and materials meant to be in contact with food (subjected to the border sanitary control) may be introduced into the European Community see: Regulation of the Minister of Health of September 24, 2007 regarding the list of border crossings competent to carry out border sanitary control (Polish Journal of Law 2007, No 196, pos. 1423).

Products of Animal Origin

The <u>law</u> on Veterinary border inspection was published on February 20, 2014. General policies and procedures of veterinary border control in inspection posts are available <u>here</u>.

Chemical Substances and Preparations

The regulation concerning chemical substances and preparations introduced into Poland, changing regulations from 2001: Act amending the Act on chemical substances and preparations dated January 9, 2009, was published on January 9, 2009 (Polish Journal of Law 2009, No. 20, pos. 106).

Section X. Copyright and/or Trademark Laws:

In the EU, trademarks can be registered at the national, regional or EU level. Trademarks registered at the national level are protected in one EU Member State. Applications must be submitted directly to the relevant national Intellectual Property (IP) office. Currently, there is only one regional-level IP office in the EU, i.e. the Benelux Office, which registers trademarks for three Member States: Belgium, the Netherlands and Luxembourg. Applications for the protection of a trademark in all EU Member States must be submitted to the EU Intellectual Property Office (EUIPO). An online application costs 850 EUR. Full details on the registration process are available on the EUIPO website. Rules on the protection of trademarks in the EU are set in EU Directive 2015/2436.

Appendix I. Government Regulatory Agency Contacts:

Ministry of Agriculture and Rural Development Tel: (+48-22) 623 1510 <u>http://www.minrol.gov.pl/eng/content/view/full/5927</u> E-mail: <u>kancelaria@minrol.gov.pl</u>

General Veterinary Inspectorate Office of the Chief Veterinary Officer Tel.: (+48-22) 623 2203/2089 Fax: (+48-22) 623 1408 http://www.wetgiw.gov.pl/index.php?action=art&a_id=1931 E-mail: wet@wetgiw.gov.pl

Main Inspectorate of Plant Health and Seed Inspection Tel: (+48-22) 652 9290/620 2824 <u>http://piorin.gov.pl/</u> E-mail: gi@piorin.gov.pl

Inspectorate for Trade Quality Control of Agricultural Food Products Tel: (+48-22) 623 2900 <u>http://www.ijhars.gov.pl/</u> E-mail: <u>sekretariat@ijhars.gov.pl</u>

Main Sanitary Inspection Tel: (+48-22) 536 1302 <u>http://www.gis.gov.pl/?lang=en&go=news</u> E-mail: <u>inspektorat@gis.gov.pl</u>

Ministry of Environment Tel: (+48-22) 579 2723 <u>http://www.mos.gov.pl/?j=en</u> E-mail: info<u>@mos.gov.pl</u>

National Food and Nutrition Institute Tel. (+48-22) 842 2171 <u>http://www.izz.waw.pl/en/</u> E-mail:zbzz@izz.waw.pl

State Hygiene Office Tel: (+48-22) 542 1328 <u>http://www.pzh.gov.pl/en/</u> E-mail: <u>pzh@pzh.gov.pl</u> **Appendix II. Other Import Specialist Contacts:**

For additional information concerning market entry, other import requirements, and a current importer list, U.S. exporters of agricultural products and commodities can contact:

Embassy of the United States of America Office of Agricultural Affairs Warsaw, Poland Tel: (+48-22) 504 2336 E-mail: agwarsaw@fas.usda.gov