

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: 12/24/2013

GAIN Report Number: PL1341

Poland

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Michael Henney - Agricultural Attaché

Prepared By:

Pawel Flakiewicz and Brian D. Healy – Agricultural Interns Jolanta Figurska, Mira Kobuszynska, and Piotr Rucinski – Agricultural Specialists

Report Highlights:

Poland applies EU directives and regulations to agricultural imports with but a few exceptions. U.S. suppliers should verify with the respective AMS, FDA, FSIS or APHIS Inspection offices and importer for the most current EU/Poland import requirements prior to export. The EU Food and Agricultural Import Regulations and Standards (FAIRS) report prepared by the U.S. Mission to the EU in Brussels should be consulted simultaneously with this report.

Table of Contents

Section I. Food Laws:	2
Section II. Labeling Requirements:	5
Section III. Packaging and Container Regulations:	10
Section IV. Food Additives Regulations:	11
Section V. Pesticides and Other Contaminants:	18
Section VI. Other Regulations and Requirements:	19
Section VII. Other Specific Standards:	19
Section VIII. Copyright and/or Trademark Laws:	22
Section IX. Import Procedures:	23
Appendix I. Government Regulatory Agency Contacts:	25
Appendix II. Other Import Specialist Contacts:	26

Disclaimer

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Warsaw, Poland for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign 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 TIME OF PRODUCT ENTRY.

Section I. Food Laws:

Based on the EU single market principle, Poland, as a member of the EU, mostly adheres to EU regulations governing agricultural imports. <u>Regulation EC/178/2002</u> (General Food Law) is the harmonized regulation which sets out the general principles and requirements of EU harmonized food law. Exporters should be aware that there may also be some variation among Member States in applying EU harmonized legislation, however, most of the regulations relevant to food and agricultural imports into Poland have been harmonized with EU regulations.

In addition, <u>Regulation EC/178/2002</u> protects consumers against fraudulent or deceptive commercial practices. This legislation also aims to protect animal health and welfare, plant health, and the environment. No foodstuff dangerous to health and/or unfit for consumption may be placed on the market. To determine whether a foodstuff is dangerous, the following are considered:

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

Where any food which is unsafe is part of a batch, lot or consignment, it is assumed that the whole batch, lot, or consignment is unsafe. Animal feed deemed to be unsafe cannot be placed on the market or fed to any food-producing animals. Producers must apply the food legislation at all stages of the food chain, from the production, processing, transport and distribution stages through to the supply of food. Furthermore, producers are responsible for ensuring the traceability of products at all stages of the production, processing, and distribution, including with regard to substances incorporated into the foodstuffs.

Exceptions can occur when a member state can substantiate a health concern about a product; a member state can apply leeway (actual or perceived) in how to interpret an EU directive; and when harmonized EU legislation is lacking, for example, for vitamins, minerals, and pesticide residues. Wide variations in inspection fees, in registration fees and in the time required to evaluate ingredients also exist between member countries. For these reasons, exporters are strongly encouraged to work closely with local importers.

The European Food Safety Authority (EFSA) provides scientific expertise and scientific and technical

support in all areas impacting food safety. It constitutes an independent source of information on all matters in this field to build an integrated and effective food safety system across all member states, and disseminates changes in regulations to the general public. Participation in EFSA is open to EU Member States and to other countries applying EU food safety law.

EFSA is also responsible for coordinating risk assessments and identifying emerging risks, providing scientific and technical advice to the EU Commission, 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. More information about EFSA can be found at: http://www.efsa.europa.eu/.

Current Polish Food Laws

On August 25, 2006, the law governing food products contained in the Act on Food Safety and Nutrition (*Ustawa o bezpieczeństwie żywności i żywienia*) was published (Polish Journal of Law 2006, No 171, pos. 1225). The consolidated version of the law was published on June 29, 2010 (Journal of Laws 2010 No. 136, pos.914) (in Polish) and can be found at:

http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101360914. This Act sets out the legislative framework on safety of food and nutrition. It establishes: sanitary requirements applicable to food, hygienic conditions to be fulfilled by foodstuffs as well as materials and products intended to come into contact with food, properties of institutions responsible for the official control of food, pursuant to Regulation (EC) No. 882/2004, provisions on food inspection.

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 foodstuffs;
- (8) Criminal provisions and penalties;
- (9) Amendments to provisions in force, transitional and final provisions.

(source; http://faolex.fao.org/cgi-

 $bin/faolex.exe?rec_id=058135\&database=faolex\&search_type=link\&table=result\&lang=eng\&format_name=@ERALL)$

On January 8, 2010, modifications to the 2006 Act on Food Safety and Nutrition were published (Polish Journal of Law 2010, No 21, pos 105).

Regulation <u>EC/1334/2008</u> applies to flavorings used to impart odor and/or taste to food, but it does not apply to substances which have exclusively a sweet, sour or salty taste, raw foods, smoke flavorings or mixtures of spices and/or fresh, dried or frozen herbs, mixtures of teas and mixtures for infusion, as long as they have not been used as food ingredients. The marketing or use of flavorings which do not satisfy purity criteria and maximum levels for dangerous or undesirable elements or substances is prohibited. Some flavorings or food ingredients with flavoring proprieties may be used in or on food

without being subject to an assessment and an authorization as long as they present no risk for human health and their use does not mislead the consumer.

In 2011, a new regulation from the Minister of Health on products entering the Polish market for the first time was introduced: "Rozporządzenie Ministra Zdrowia z dnia 23 marca 2011 r. w sprawie wzoru formularza powiadomienia o produktach wprowadzonych po raz pierwszy do obrotu na terytorium Rzeczypospolitej Polskiej, rejestru produktów objętych powiadomieniem oraz wykazu krajowych jednostek naukowych właściwych do wydawania opinii" (Polish Journal of Law 2011, No. 80, pos. 437) was published on March 23, 2011. The text of that law (link in Polish only) can be found at: http://isip.sejm.gov.pl/DetailsServlet?id=WDU20110800437+2011%2404%2430&min=1

Once imported into Poland, food products are subject to quality control based on regulations on "Trade Quality of Food Products" and their minimum amounts. <u>Ustawa z dnia 21 grudnia 2000 r. o jakości handlowej artykułów rolno-spożywczych.</u> The newest regulation was released on 18th of January 2013: *Rozporządzenie Ministra Rolnictwa i Rozwoju Wsi z dnia 18 stycznia 2013 r. w sprawie wykazu artykułów rolno-spożywczych przywożonych z zagranicy oraz ich minimalnych ilości podlegających kontroli jakości handlowej*, (Polish Journal of Law 2013, No. 0, pos. 174).—
The text of that law as well as the list of products and their control amounts (link in Polish only) can be found at: -http://isap.sejm.gov.pl/DetailsServlet?id=WDU20130000174

In July 2010, Regulation (EC) No 258/97 was amended to prohibit use of nanotechnology in food production until the new technology's safeness could be fully confirmed. On December 18th 2013, European Commission tabled a proposal on regulation on novel foods. It revises the existing Novel Food Regulation with a view to improving access of new and innovative food to the EU market, while still maintaining a high level of consumer protection.

http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-cloning_com2013-894_final_en.pdf

Food Control in Poland

The official food control in Poland is conducted by the following authorities; see Appendix for contact information of the respective organizations:

State Sanitary Inspection – *Państwowa Inspekcja Sanitarna* (PIS) holds responsibility for supervising the quality of food, materials, or products intended to come in contact with food. Food control (no meat included) is conducted appropriately by inspectors from Sanitary-Epidemiological Stations in districts of coverage.

State Veterinary Inspection – *Państwowa Inspekcja Weterynaryjna* (PIW) is the authority that conducts controls of animal health and products of animal origin.

Main Inspectorate of Plant Health and Seed Inspection – *Państwowa Inspekcja Ochrony Roślin i Nasiennictwa* (PIORIN) is responsible for monitoring plant health conditions, trade and use of plant protection remedies and their production, and verification and trade of seed material.

Agricultural and Food Quality Inspection – 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 national and European Community 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 official control units 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)

Office of Competition and Consumer Protection – *Urząd Ochrony Konkurencji i Konsumentów* (UOKiK) is the central authority responsible for shaping the antitrust policy and consumer protection policy of the state administration. UOKiK is authorized to control mergers to prevent monopolistic situations, where a single entity may dominate the market effectively reducing consumer surplus, or similarly, dissolves cartels that negatively impact consumers.

For detailed information on structure of Polish food safety system please refer to the EC country profile: http://ec.europa.eu/food/fvo/country_profiles/CP_poland.pdf

Section II. Labeling Requirements:

General Requirements

The EU new regulation on food labeling <u>Regulation EU/1169/2011</u> will become effective from December 13, 2014. Regulation EU/1169/2011 is an amendment to the current <u>Directive 2000/13/EC</u>, and it is recommended that exporters be in compliance with the new Regulation. Review the full scope of the EU Food and Feed Safety regulations:

http://ec.europa.eu/food/food/foodlaw/guidance/index en.htm.

The legislation update deals with the issues of label visibility, font size; font and background contrast, and regulates the obligation to inform about allergens, such as peanuts or dairy on product packaging. According to the new Regulation, the obligation of country of origin labeling is extended to fresh meat: pork, poultry, goat, and sheep. The Regulation additionally requires nutrition information for processed foodstuffs. The new Regulation will allow consumers to more easily distinguish products that are similar to other products but that are produced from different ingredients, e.g. cheese-like products.

Foodstuffs intended for sale to the final consumer, for restaurants, hospitals and other mass caterers must comply with the labeling legislation. The labeling, presentation, and advertising of foodstuffs must not mislead the consumer about the foodstuff's characteristics or effects, or attribute properties for the prevention, treatment, or cure of a human illness to a foodstuff.

Flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of

ingredients. Specific requirements for the use of the term "natural" to describe a flavoring are set out in Article 16 of European Parliament and Council Regulation 1334/2008. For more information see Section IV "Food Additive Regulations."

Basic Laws on Food Labeling in Poland

Polish labeling is regulated by the Ministry of Agriculture and Rural Development. On July 31, 2007, the basic law on food labeling: *Rozporządzenie Ministra Rolnictwa i Rozwoju Wsi z dnia 10 lipca 2007 r. w sprawie znakowania środków spożywczych* was published (Polish Journal of Law 2007, No. 137, pos. 966). Its amendment was released on 15th of March 2013. (Polish Journal of Law 2013, No. 0, pos. 414). Food labeling is also regulated by the Polish Food Safety Law (Polish Journal of Law 2006, No 171, pos. 1225), which was amended on January 8, 2010: Modification to the Polish Food Safety Law of 2006: (Polish Journal of Law 2010, No 21, pos. 105). 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 Polish language on the pre-packaging or on a label attached to it with a sticker. The information must be marked in such a way that it is easily visible, clearly legible, and indelible.

- **Product Name** Clearly inform the buyer about the type of foodstuff, should clearly differentiate it from other similar foods, and should clearly contain information on the form of food or processes used in production.
- **List of Ingredients**, in descending order of weight Include permitted additional substances and allergenic ingredients present in the product, even in modified form (i.e., soy lecithin). The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, certain food colorings, aspartame and polyols, quinine and caffeine, phytosterols and phyostanols and licorice. Additionally, EU/1169/2011 requires listing the presence of nanoingredients.
- Nutritive Value Information must include: energy value, fat, saturated fatty acids, carbohydrates, sugars, protein, and salt. The information must be presented as calculated per 100 g or 100 ml and additionally it can be presented as a Recommended Daily Intake (RDI). The obligation to inform abort nutritive value does not apply to some products, e.g. unprocessed food or foodstuffs containing low energy value (e.g. spices tea or coffee). On July 25, 2007, the Polish law on food labeling by nutritive value: Rozporządzenie Ministra Zdrowia z dnia 25 lipca 2007 r. w sprawie znakowania żywności wartością odżywczą was published (Polish Journal of Law 2007, No 137, pos. 967) and was amended on January 8, 2010 (Polish Journal of Law 2010, No 9, pos. 63).
- Allergens Annex IIIa to Directive 2000/13/EC lists the groups of potential allergenic ingredients which must be clearly indicated on food labels: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products (including lactose), nuts and nut products, sesame seeds, lupine and products thereof, mollusks and products thereof and sulfite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages and bulk goods. EU wine labeling Regulation EU/1266/2010 amends Directive 2007/68/EC, wines found with egg and milk derivatives must

be labeled for allergens. EU Commission <u>Directive 2007/68/EC</u>, amended by <u>Commission Regulation EU/415/2009</u>, establish a list of ingredients and substances which are permanently exempted from the mandatory allergen labeling requirement.

Other Labeling Requirements

- Certain ingredients may be designated by the name of the category rather than the specific name (Annex I to Directive 2000/13/EC). These include fats, oils (note that peanut oil is also subject to the new allergen rules), starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine.
- Date of minimum durability: Poland strictly enforces the EU date format requirement of: dd/mm/yyyy. The shelf life is indicated by words "Best before..." ("Najlepiej spożyć przed dd/mm/yyyy") when the date includes an indication of the day; "Best before end of..." ("Należy spożyc do dd/mm/yyyy") in other cases. Storage and use instructions must also appear on the label, as necessary.
- Name or business name and address of the manufacturer, packager, or the seller established within the EU Community.
- Details of the place of origin.
- Net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram, or gram).
- Special storage conditions or conditions of use if the food label contains information about the date and shelf-life and also when the quality of the food significantly depends on the conditions of storage.
- The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.
- A mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU, for traceability. The marking must be preceded by the letter "L," except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in un-coded form on the label.
- Treatments undergone, with specific indications for irradiated foods and deep-frozen foods.
- Description how to prepare or use, if there is no information here, it could result in inappropriate conduct with the foodstuff, such as "eat cooked".
- Batch designation information about the batch, certain quantity of the products manufactured, processed, or packaged having a uniform quality.
- Quality grade if it was fixed in the regulations on the detailed requirements for the quality of food products or their groups.

In addition, it is permitted to label the packaged foodstuff, with a surface area of less than 10 cm, by giving, at the minimum, the following information:

- Name of food product
- Date of minimum durability
- Net quantity or a number of foodstuff pieces packed

Note: the use of the EAN (**European Article Number** - renamed **International Article Number**) product coding system is not regulated by EU law. However, this bar code system is commonly used in

the EU to fulfill the traceability requirement, mandatory since January 1, 2005.

General principles of marketing and labeling of **organic products** are determined in The Law on Organic Agriculture on 25 June 2009 (Journal of Laws No. 116, pos. 975). The Law is implementing the rules of the Council Regulation (EC) No 834/2007 of 28 June 2007 on the production and labeling of organic products.

http://isap.sejm.gov.pl/DetailsServlet?id=WDU20091160975.

Labeling Derogations

Guidelines concerning labeling derogations can be found on the EU Commission's website: http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf. These guidelines specify in which cases derogations may be accepted:

- Foodstuffs for which no ingredients list is required, because they comprise a single ingredient, or are almost exclusively derived from a single basic product
- Sub ingredients of certain compound ingredients
- Ingredients which belong to well defined categories
- Substances that are not regarded as ingredients

The guidelines describe the indication or repetition of an ingredient and/or of the source of that ingredient, according to the Subparagraph 1 of Paragraph 10, which requests in substance that, unlike "normal" ingredients, ingredients listed in Annex IIIa shall not be admitted to derogations. As a result, these ingredients shall be indicated on the label with a clear reference to the name of the ingredient from which they originate.

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, for example: 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

Changes in Labeling Regulations Following EU Regulations

The regulation from 2003 (Polish Journal of Law 2003, No 177, pos. 1735) concerning labeling of juices produced wholly or partly from concentrated juices was amended in 2010 by the "Rozporządzenie Ministra Rolnictwa i Rozwoju Wsi z dnia 21 kwietnia 2010 r. zmieniające rozporządzenie w sprawie szczegółowych wymagań w zakresie jakości handlowej soków i nektarów owocowych" (Polish Journal of Law 2010, No 88, pos. 579).

Food Traceability

Under EU law traceability is compulsory by <u>Regulation EC/178/2002</u>. Traceability is 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. A food traceability factsheet can be found here.

B. 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 15 January 2008.

In December 2011, the European Commission 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 becomes applicable on December 14, 2012. Anyone will be 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 but also with the more than 1600 rejected claims and the reasons for their non-authorization. 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 <u>Directive 90/496/EC</u>.

Food Labeling of Supplements and Foodstuffs for Particular, Nutritional Use

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

On May 18, 2010, the regulation changing the composition and labeling of dietary supplements: <u>Rozporządzenie Ministra Zdrowia z dnia 18 maja 2010 r. zmieniające rozporządzenie w sprawie składu oraz oznakowania suplementów diety</u> was published (Polish Journal of Law, No. 91, pos. 596).

On September 16, 2010, a new regulation on foodstuffs for special nutritional diet: <u>Rozporządzenie Ministra Zdrowia z dnia 16 września 2010 r. w sprawie środków spożywczych specjalnego</u> przeznaczenia żywieniowego (Polish Journal of Law 2010, No. 180, pos. 1214) was published.

Marketing Quality of Agricultural Food Products

The basic law on market quality of agricultural food products ("<u>Ustawa z dnia 24 października 2008 r. o zmianie ustawy o jakości handlowej artykułów rolno-spożywczych oraz niektórych innych ustaw</u>") was published October 24, 2008 (Polish Journal of Law 2008, Nr. 214, pos. 1346).

Section III. Packaging and Container Regulations:

Plastic Materials

The Polish Minister of Health 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) was nullified and replaced on December 4, 2013 ("Rozporządzenie Ministra Zdrowia z dnia 15 października 2013 r. w sprawie wykazu substancji, których stosowanie jest dozwolone w procesie wytwarzania lub przetwarzania materiałów i wyrobów z tworzyw sztucznych, a także sposobu sprawdzania zgodności tych materiałów i wyrobów z ustalonymi limitami")

A comprehensive list of EU regulations regarding plastic for foodstuffs can be found here.

Commission Regulation EU/558/2010 concerning specific hygiene rules for food of animal origin was published on June 24, 2009. The Regulation specifies new 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. The requirements for the transport of live bivalve mollusks in containers are tightened and the specification of raw materials used for gelatin production is changed.

Materials Other Than Plastics

The Polish Minister of Health 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 ("Rozporządzenie Ministra Zdrowia z dnia 15 stycznia 2008 r. w sprawie wykazu substancji, których stosowanie jest dozwolone w procesie wytwarzania lub przetwarzania materiałów i wyrobów z innych tworzyw niż tworzywa sztuczne przeznaczonych do kontaktu z żywnością") was published on January 15, 2008 (Polish Journal of Law 2008, No. 17, pos. 113).

Section IV. Food Additives Regulations:

The "Package on Food Improvement Agents" includes four Regulations: Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings, Regulation 1332/2008 on food enzymes, Regulation 1333/2008 on food additives and Regulation 1334/2008 on flavorings.

The common authorization procedure for food additives, food enzymes and food flavorings, established by Regulation 1331/2008 is introducing a single common procedure for the approval of food additives, flavorings and enzymes. The benefits of this common approach include simplified legislation and more consistency in the procedures used to approve additives, flavorings and enzymes with an emphasis on the safety evaluations by EFSA on which the approval procedure is based.

The implementing rules are laid down in Commission Regulation 234/2011, Commission implementing Regulation 562/2012, explaining the content of an application and all the data both administrative and technical that have to be submitted to the Commission. The Commission will then request EFSA to verify the suitability of the data. An application consists of a letter, a technical dossier and a summary of the dossier.

Regulation on Permitted Additives

The Polish Minister of Health regulation on permitted additives was published on April 22, 2011 (*Rozporządzenie Ministra Zdrowia z dnia 22 kwietnia 2011 r. zmieniające rozporządzenie w sprawie dozwolonych substancji dodatkowych*) in the Polish Journal of Law 2011, No. 91, pos. 525.

Regulation on Specifications and Criteria of Purity of Additives

The Polish Minister of Health regulation on specifications and criteria of purity of additives: <u>Rozporządzenie Ministra Zdrowia z dnia 12 października 2007 r. w sprawie specyfikacji i kryteriów</u> <u>czystości substancji dodatkowych</u> (Polish Journal of Law 2011, No. 2, pos. 3) which was published on October 12, 2007, was amended on December 23, 2010 and changed on April 22, 2011 ("<u>Rozporządzenie Ministra Zdrowia z dnia 22 kwietnia 2011 r. zmieniające rozporządzenie w sprawie</u> <u>specyfikacji i kryteriów czystości substancji dodatkowych</u>") (Polish Journal of Law 2011, No. 91, pos. 526).

Solvents

The Polish Minister of Health regulation on solvent extraction, which can be used in the production of food: February 18, 2011 "*Rozporządzenie Ministra Zdrowia z dnia 18 lutego 2011 r. zmieniające rozporządzenie w sprawie rozpuszczalników ekstrakcyjnych, które mogą być stosowane w produkcji żywności*") (Polish Journal of Law 2011, No 52, pos.272).

Aromas

Regulation of the European Parliament and of the Council (EC) No 1334/2008 on flavorings and certain food ingredients with flavoring properties for use in and on foods was published on December 16, 2008.

Enriching Substances

The Polish Minister of Health regulation on enriching substances added to food: Rozporządzenia *Ministra Zdrowia z dnia 19 grudnia 2002 r. w sprawie substancji wzbogacających dodawanych do żywności i warunków ich stosowania* was published on December 19, 2002 (Polish Journal of Law No. 27, pos. 237). The Regulation was <u>amended</u> on September 16, 2010 (Polish Journal of Law 2010, No. 174, pos. 1184).

Dietary Supplements

<u>Regulation (EC) No 1925/2006</u> of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods was published on December 20, 2006.

The Regulation applies without prejudice to the provisions relating to:

- Foods for particular nutritional uses
- Novel foods and novel food ingredients
- Genetically modified foods
- Food additives and flavorings
- Oenological practices and processes

The nutrition labeling of products which vitamins and minerals have been added to and which are covered by the Regulation is compulsory. It must contain the following information: the total amounts of vitamins and minerals where they are added to a food, the amount of protein, carbohydrate, sugars, fat, saturates, fiber and sodium, and the energy value of the product in accordance with <u>Directive 90/496/EEC</u>.

The Regulation specifies that excessive intakes of vitamins and minerals may result in adverse health effects and sets maximum quantities of vitamins and minerals added to foods. The maximum amounts take account of the upper safe levels for vitamins and minerals following a scientific risk assessment,

the potential intake of vitamins and minerals from other foods, and the reference intakes of vitamins and minerals recommended for the population. Furthermore, if necessary, it also takes account of the contribution of individual products to the overall diet of the population and of the nutrient profile established in accordance with Regulation (EC) No. 1924/2006.

Commission Regulation (EC) No. 1170/2009 of November 30, 2009, an amendment of <u>Directive</u> 2002/46/EC, lists the vitamins, minerals and their chemical forms that can be used in the manufacture of dietary supplements, as well as the chemical forms of vitamins and minerals that can be added to food.

Specific Nutritional Purposes

Commission Regulation (EC) No. 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses was published on October 13, 2009.

Additives

The Polish Minister of Health regulation of September 18, 2008 concerning the allowed additives ("Rozporządzenie Ministra Zdrowia z dnia 14 stycznia 2009 r. w sprawie wprowadzenia do obrotu i stosowania w żywności na terytorium Rzeczypospolitej Polskiej określonych substancji dodatkowych") (Journal of Laws 2009, No. 17, Item 96) with amendment from August 9, 2010 specifies the list of additives which can be used in Poland under other conditions than in the EU.

To see the full list of regulations concerning additives please view:

https://webgate.ec.europa.eu/sanco_foods/main/?event=substances.search&substances.pagination=1. The following tables are included due to most recent issues regarding additive regulations.

Conditions of using or introducing dyes for maturing cheese analogues and fermented wine in the territory of Poland

Foodstuff	Substance number according to the European Union coding system		Maximum acceptable levels
Ripened cheese	E160a	Carotenes	quantum satis
analogues (cheese-like	E 160c	Paprika extract	
products)	E 160b	Annatto, bixin, norbixin	15 mg/kg
Flavored Polish wine,	E 100	Curcumin	200 mg/1
Wine-like fruit drinks,	E 102	Tartrazine	
including flavored	E 104	Quinoline yellow	
wine-like fruit drinks, Low-alcohol content	E 110	Sunset yellow FCF, Sunset yellow F	
drinks, including flavored low-alcohol	E 120	Cochineal, Carminic acid, Carmines	
content drinks	E 122	Carmoisine, Azorubine	

E	124	Cochineal Red A, Ponceau 4R	
E	129	Allura red AC	
E	131	Patent Blue V	
E	132	Indigotine, Indigo carmine	
E	133	Brilliant Blue FCF	
E	142	Green S	
E	151	Brilliant Black BN, Black PN	
E	155	Brown HT	
E	160d	Lycopene	
E	160e	Beta-apo-8'-carotenal	
E	LAUT	Ethyl ester of beta-apo-8'-carotenic acid	
E	161b	Lutein	

Conditions (other than those in the EU) for using sweeteners to certain fermented wine:

Foodstuff	Substance number according to the European Union coding system	Substance name	Maximum acceptable levels
1177 1'1 C '. 1 ' 1	E 950	Acesulfame potassium	350 mg/l
including flavored wine-	E 951	Aspartame	600 mg/l
	E 054	Saccharin and its sodium, potassium and calcium salts	80 mg/l
including flavored low-	E 959	Neohesperidine DC	20 mg/l
alcohol content drinks	E 955		50 mg/l
diconor content drinks	E 962 1)	Aspartame-acesulfame salt	350 mg/l ²⁾

¹⁾ Specific maximum acceptable levels of aspartame-acesulfame salts are derived from specific maximum acceptable levels of its components: aspartame (E 951) and acesulfame K (E 950). The maximum acceptable levels specified for aspartame (E 951) and acesulfame K (E 950) may not be exceed as a result of the use of aspartame and acesulfame salts individually or combined with E 950 or with E 951.

²⁾ Maximum acceptable level as per acesulfame K.

Conditions (other than those in the EU) for using certain food additives other than those in EU:

Foodstuff	Substance number according to the European Union coding system	Substance name	Maximum acceptable levels	
	E 170 Calcium carbonate		quantum satis	
Ripened cheese analogues (cheese-like products)	E 500ii	Sodium bicarbonate	quantum satis (applicable only to cheese from sour milk)	
	E 504 Magnesium carbonates			
	E 509	Calcium chloride	quantum satis	
	E 575 Glucono delta-lactone			
	E 170	Calcium carbonate		
Sliced and grated ripened	E 460	Cellulose	quantum satis	
cheese analogues (cheese-like products)	E 504	Magnesium carbonates		
	E 509	Calcium chloride		
	E 575	Glucono delta-lactone]	
Ripened cheese analogues (cheese-like products)	E 234	Nisin ¹⁾	12.5 mg/kg	

Ripened cheese analogues (cheese-like products), onto the surface only	E235	Natamycin	1 mg/dm ² surface (none in the 5 mm surface product layer)
Ripened cheese analogues (cheese-like products)	E 1105	Lysosyme	quantum satis
Fermented wine products with sugar content not lower than 5 g/l	E 242	Dimethyl dicarbonate	200 mg/l, quantity added to the drink, residue: not detectable
Polish wine, Flavored Polish wine, Wine-like fruit drinks, including flavored wine-like fruit drinks, Low-alcohol content drinks, including flavored low-alcohol content drinks, Alcohol-free fruit wine, Flavored fruit wine	E 220	Sulfurous acid anhydride (Sulfur dioxide)	
	E 221	Sodium sulfite	
	E 222	Sodium bisulphite	
	E 223	Sodium metabisulphite	200 mg/l
	E 224	Potassium metabisulphite	
	E 226	Calcium sulphite	
	E 227	Calcium hydrogen sulphite	
	E 228	Potassium hydrogen sulphite	
Polish wine, Flavored Polish wine	E 353	Metatartaric acid	100mg/l

Nisin may be naturally present in certain cheese products as a result of fermentation processes.

Conditions (other than those in the EU) for using preservatives:

Foodstuff	Maximum level (mg/kg or mg/l, respectively)					
	Sa ¹⁾	$Ba^{1)}$	PHB ¹⁾	Sa+Ba	Sa + PHB	Sa + Ba + PHB
Packaged, sliced ripened cheese analogues (cheese-like products)	1000					
Ripened cheese analogues (cheese-like products), sandwiched and with foodstuffs added	1000					
Polish wine, Flavored Polish wine, Wine-like fruit drinks, including flavored wine-like fruit	200					

drinks, Low-alcohol			
content drinks, including			
flavored low-alcohol			
content drinks			
Flavored fruit wine			

¹⁾ Acronyms according to table 3 of Appendix 4 to the Regulation of the Minister of Health of 18 September 2008 concerning the allowed additives (Journal of Laws No. 177, Item 1094).

Notes:

Maximum levels of all the aforementioned substances are given as per the free acid.

The acronyms used in the table have the following meaning:

Sa + Ba: Sa and Ba used individually or combined.

Sa and PHB used individually or combined.

Sa + Ba + PHB: Sa, Ba and PHB used individually or combined.

3) Maximum levels of the use indicated refer to foodstuffs ready for consumption, prepared according to manufacturers' instructions.

Commonly Used Colorants Approved in the EU and Poland

- E100 Curcumin/Turmeric
- E102 Yellow # Tartrazine
- E110 Yellow #6 Sunset Yellow
- E129 Red #40 Allura Red
- E132 Blue #2 Indigo Carmine
- E133 Blue #1 Brilliant Blue
- E150 Caramel color Caramel
- E171 Titanium Dioxide Titanium Dioxide

Approved/Disapproved Additives

Erythritol sweetener (E 968) is currently approved for use in foods in the EU, with exception for use in drinks.

Commission's Decision (2010/228/EU) authorizes introduction of concentrate of the morinda citrifolia fruits. It can be in the market in the EU as a new food ingredient in certain types of foods, including dietary supplements.

Monometylsilanetriol (MSS) - organic silica - in specific nutritional purposes for food supplements remains still prohibited.

EFSA decided to reduce up to half of the current ADI (acceptable daily intake) for the bronze HT (E

155) - (up to 1.5 mg/kilo m. c). The ADI for the BN (E 151) has not changed (5 mg/kilo).

A breakthrough in the market of sweeteners in EU - Stevia extracts received positive opinion by the EFSA. The evaluation was made for the whole family of steviol glycosides derived from stevia, except for Rebaudiozyd A, which was recently approved by the U.S. FDA (Food and Drug Administration) as a positive. Steviol glycosides extracted from the stevia plant have been approved for use as non-caloric sweeteners in the European Union, according to the Official Journal of the European Union on November 12, 2011. As a result, products sweetened by steviol glycosides may be available to European consumers since December 2, 2011, according to the International Stevia Council.

The specifications and criteria changing for such additives: mannitol sweetener, riboflavin, nisin, sodium and potassium alginate, carrageenan, guar gum, beeswax. In addition, the criteria for the biphenyl and thiabendazole were repealed - these are no longer permitted. Polish Journal of Law No. 23 of 12 February 2010, Pos no. 120, in accordance with Community directives - (No 2008/60/EC, 2008/84/EC, 2008/128/EC, 2009/10/EC).

Regulation of the Minister of Health - according to <u>Directive 2009/39/EC</u> – on the adding requirements in terms of quality protein used in preparations for the infant and to extend the list of nutrients used in preparations for the initial and continued feeding of infants with L-arginine and its hydrochloride. The regulation entered into force on February 17, 2010.

Complete information concerning additives can be located <a href="https://example.com/here.co

Section V. Pesticides and Other Contaminants:

The European Union (EU) is setting maximum levels for certain contaminants with a view to reducing their presence in foodstuffs. In Poland the basic law regulating the level of contaminants in foodstuffs is the EU Commission Regulations (EC) which is directly applicable. The basic law is the EC regulation No 1881/2006 of December 19, 2006 (OJ L 364, 20.12.2006, pos.5) with amendments.

Rules for the marketing and use of the pesticides in Poland are regulated by Law on Plant Protection Products of 8 March 2013 (Journal of Laws of 2013, pos. 455) (Ustawa o środkach ochrony roślin z dnia 8 marca 2013 roku (Dz.U. z 2013 r., poz. 455)) The Polish language text of the regulation can be found at: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20130000455

Basic rules for the **protection of plants against harmful organisms** are available in Law on Plant Protection (text consolidated) of 18 December 2003 (Journal of Laws of 2008 No. 133, pos. 849), (Ustawa o ochronie roślin (tekst scalony) z dnia 18 grudnia 2003 r (Dz.U. z 2008 r. Nr 133, poz. 849)). Text of the law can be found at the following link: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20081330849

Section VI. Other Regulations and Requirements:

Directive <u>2006/112/EC</u> has provided EU Value Added Tax (VAT) legislation since January 1, 2007. Poland applies a VAT for agricultural and food products either imported or produced domestically and ranges from 5 to 23 percent depending on level of processing of the product. The quoted below rates were applicable from January 1, 2011 until December 31, 2013.

5 percent VAT - applied 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

8 percent VAT - applied to all remaining unprocessed foods 23 percent VAT - applied to highly processed food products

VAT rates for individual products can be found at:

http://www.epodatnik.pl/index.php/klasyfikacje/polska-klasyfikacja-wyrobow-i-uslug

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 bands, 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 bands 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 prepayment). 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 April 29, 2011 (Polish Journal of Law 2011, No. 108, pos. 626). 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. The excise duty rates for the EU current as of 1 July 2013 can be found here. As of January 1, 2014 excise tax for alcohol and tobacco in Poland is expected to increase by 15 percent and 5 percent, respectively.

Section VII. Other Specific Standards:

Imports of Bovine Genetics

Imports of bovine genetics to Poland are based on requirements outlined in the Commission <u>Decision 2008/120/EC</u> 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

(http://dokumenty.rcl.gov.pl/D2013001085601.pdf).

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

The breeding value of the bull is based on the European system of bull evaluation, "Interbull" published by the Animal Breeding Institute in Balice near Krakow. Poland does not support the European Commission interpretation on Decision 2006/427/EC that suggests member states accept valuation of breeding bull genetics based on genomic evaluation as equal to traditional evaluation based on progeny testing. Absent recognition of genomic evaluation, offspring resulting from imported genetic material is ineligible to be registered in national herd books thus diminishing the value of importing genetic material from genomic ally evaluated U.S. origin young bulls.

Imports of Eggs and Egg Products

Poland does not recognize certification by either USDA's Food Safety and Inspection Service (FSIS) or Agricultural Marketing Service (AMS) of U.S. facilities as eligible for export of eggs for processing or processed to the European Union. Polish law requires in absence of formal recognition by European Commission regulation or EU law, third country meat and egg related facility eligibility must be established by the General Veterinary Inspectorate prior to export (per Article 24 of the Polish Law on Products of Animal Origin (Polish Law Paper 2006 No 17 position 127 with amendments, dated December 16, 2005). The absence of EU law/regulation recognizing U.S. meat and egg suppliers as eligible to export to the European Union and the lack of the General Veterinary Inspectorate recognition of U.S. facility prevents access to this market which in 2012 experienced a spike in market prices when Class A, Class B and further processed eggs were in short supply.

Genetically Modified 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-biotechnology legislative proposals, and prohibited the importation, production, and use of animal feed containing ingredients enhanced through biotechnology beginning in August 2008. Two Polish Presidents have authorized continuation of a delay in implementation of provisions of the law governing animal feed. The first continuation went through January 1, 2013. The second is now through January 1, 2017.

On December 21, 2012, President Komorowski signed amendments into the Law of the Seed to bring Polish law closer to compliance with EU legislation related to market access of registered seeds. The signed amendment permitted registration of seeds of any origin in the national seed bank, a prerequisite for commercial activity in Poland. On January 2, 2013 the Polish Council of Ministers, at the request of the Minister of Agriculture, re-authorized its 2008 framework position on biotechnology and permitted the Ministry to ban cultivation of seeds enhanced through biotechnology through application of the EU safeguard clause. On January 28, 2013, the ban on cultivation of seed enhanced through biotechnology

entered into force in tandem with implementation of the amended Law of the Seed.

On September 24, 2013 Polish Minister of Agriculture stated that Poland is currently free from "GE" crop cultivation based on over 9,000 checks on corn farms conducted in 2013.

For more information about biotechnology in Poland refer to the most recent FAS/Warsaw <u>GAIN</u> Report on plant and animal biotechnology available at <u>www.fas.usda/gov</u> Attaché Reports link.

Novel Foods

For detail information on novel foods please refer to the website of the State Sanitary Inspection (http://gis.gov.pl/dep/?lang=en&dep=14&id=29).

Traceability and Labeling of Genetically Modified Foods

Labeling regulations for genetically modified (GM) 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 GM feed or treated with GM medicinal products do not require GM labeling.

The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

"Low Level Presence" (LLP)

On June 24 2011, the EU adopted Commission Regulation 619/2011 setting a tolerance of 0.1 percent - "Low Level Presence" (LLP) - for adventitious traces of non EU-authorized GMOs in feed imports. For more information see the European Commission press release "Questions and Answers on the low level presence (LLP) of GMOs in feed imports." The Commission may come forward with proposals dealing with LLP in food imports.

For more information on biotechnology and biotech products consult the <u>EU-27 2013</u> Agricultural Biotechnology Annual GAIN Report.

Regulation (EC) No 1829/2003 (articles 12-13) of the European Parliament and of the Council of September 22, 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amends <u>Directive 2001/18/EC</u>.

The European Union sets out a framework for guaranteeing the traceability of GMOs 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 GMOs to be used in food, but also those intended to be used in crops (e.g. seeds). The European Union 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 GMOs 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 animals, producers must tag each animal with origin details and when animals are taken for slaughter, the must be stamped with the traceability code of the abattoir. The traceability methods, ear tags, passports, or bar codes, vary across countries but must include the same information.

Regulation (EC) No. 1829/2003 includes:

- All products which consist of GMOs or which contain them (this includes fields as diverse as the products, which are intended for entry into the human or animal food chain, 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)
- Foodstuffs and animal feed products made from GMOs

Operators must transmit the following information in writing: an indication that the products consist of or contain GMOs, and the unique identifiers assigned to the GMOs. If the product is a mixture of GMOs, the industrial operator may submit a declaration of use of these products, together with a list of the unique identifiers assigned to all the GMOs used to constitute the mixture. This information must also be held for five years.

The operators who place pre-packaged products on the market consisting of or containing GMOs 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. It may take the form of accompanying documents, for example. When placing a product on the market, the operator must transmit the following information in writing to the operator receiving the product. Firstly, an indication of each food ingredient produced from GMOs. Secondly, an indication of each raw material or additive for feeding stuffs produced from GMOs, and finally - if there is no list of ingredients, the product must bear an indication that it is produced from GMOs.

Commission <u>Regulation (EU) No. 619/2011</u> sets a tolerance of 0.1 percent - "Low Level Presence" (LLP) - for adventitious traces of non EU-authorized GMOs in feed imports.

For more information on biotechnology and biotech products consult the <u>EU-27 2013</u> Agricultural Biotechnology Annual GAIN Report.

Section VIII. Copyright and/or Trademark Laws:

Council <u>Regulation (EC) No. 207/2009</u> of February 26, 2009 is the legislation for the registration of Community trademarks and creates a single, unitary registration system covering the entire Community.

A Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company, and is valid for 10 years. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to fees defined under Commission Regulation (EC) No. 2869/95, or at a national

industrial property office in a Member State of the EU. On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

The Community Trademark did not replace the existing trademark laws of the member states but co-exists alongside national trademarks. <u>Directive 2008/95/EC</u> approximates the laws of the Member States relating to trademarks. The range of registered names protection of regional products in Poland is enclosed in EU Community law Article 13 of Council <u>Regulation (EC) No. 510/2006</u>: published March 20, 2006.

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 100%) 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

On the matter of the customs application, authorities may require transport documents or, documents relating to the preceding customs procedure. Where a single item is presented in two or more packages, they may also require the packing list or equivalent document indicating the contents of each package. A product not pre-approved for import requires the same documentation, but also will likely be subject to laboratory analysis and certification verification, which could take several weeks or longer. During this time, the product will be held by border officials and subject to storage fees, which could be significant. Once an importer starts to import a product on a regular basis, not every shipment will need

to be tested. Products of producers/importers with a clean record with local health authorities will be tested once a year or less frequently. Other products could be tested every 6 months after the first border control.

Novel food products must undergo a different registration procedure with health authorities (Main Sanitary Inspection). Note: Novel foods are foods, and food ingredients, that have not

been used for human consumption to a significant degree within the Community before 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.

Vegetable Products

<u>Rozporządzenie Ministra Zdrowia z dnia 14 lutego 2007 r. w sprawie wzorów wniosku o dokonanie granicznej kontroli sanitarnej oraz świadectwa spełniania wymagań zdrowotnych</u> (Polish Journal of Law 2007, No 44, pos. 286) provides an example of the border control inspection for food and the certificate of compliance with health requirements for Poland.

For the list of goods under border sanitary control see: <u>Rozporządzenie Ministra Zdrowia z dnia 4</u> września 2008 r. zmieniające rozporządzenie w sprawie wykazu towarów, które podlegają granicznej kontroli sanitarnej (Polish Journal of Law 2008, No 169, pos. 1048)

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: <u>Rozporządzenie Ministra Zdrowia z dnia 24 września 2007 r. w sprawie wykazu przejść granicznych właściwych dla przeprowadzania granicznej kontroli sanitarnej</u> (Polish Journal of Law 2007, No 196, pos. 1423)

Products of Animal Origin

The <u>basic regulation</u> of the Polish Ministry of Agriculture on the detailed terms and procedures of veterinary border shipments and consignments of animal products control was published on February 2, 2004. General regulation <u>GLW Nr GIWbip.600-2/2010</u> on the policies and procedures for veterinary border control in inspection posts was published on January 19, 2010. Current information on Veterinary Border Inspection Points is available at:

http://www.wetgiw.gov.pl/files/1611_wykaz%20posterunkow%20weterynaryjnej%20kontroli%20granicznej%20w%20Polsce.pdf

General regulation GIWbip-600/3/2010 on the scope and mean of the national screening program of

prohibited substances, chemical residues in products of animal origin imported from third countries, was published on January 19, 2010.

General regulation <u>GIWbip-601/1b/09</u> on the approval and supervision of bonded warehouses destined for products of animal origin, which not meet import requirements of the EU, was published on April 29, 2009.

Chemical Substances and Preparations

The regulation concerning chemical substances and preparations introduced into Poland, changing regulations from 2001: <u>Ustawa o zmianie ustawy o substancjach i preparatach chemicznych z dnia 9 stycznia</u>, was published on January 9, 2009 (Polish Journal of Law 2009, No. 20, pos. 106)

Appendix I. Government Regulatory Agency Contacts:

Ministry of Agriculture and Rural Development Stanislaw Kałemba – Minister ul. Wspólna 30 00-930 Warsaw

Tel: (+48-22) 623 1510 Fax: (+48-22) 623 1788 http://www.minrol.gov.pl/eng/content/view/full/5927

Ministry of Agriculture and Rural Development Department of Plant Breeding and Protection Małgorzata Surawska – Director Email: malgorzata.surawska@minrol.gov.pl

Tel: (+48-22) 623 1837 Fax: (+48-22) 623 1781 http://www.minrol.gov.pl/eng/content/view/full/11477

Ministry of Agriculture and Rural Development Department of Plant Breeding and Protection Małgorzata Woźniak – GMO Specialist Email: malgorzata.wozniak@minrol.gov.pl

Tel: (+48-22) 623 2336 Fax: (+48-22) 628 8784

http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=579&LangId=0

General Veterinary Inspector Office of the Chief Veterinary Officer Mr. Janusz Związek – CVO

E-mail: janusz.zwiazek@wetgiw.gov.pl

Tel.: (+48-22) 623 2203/2089Fax: (+48-22) 623 1408

http://www.wetgiw.gov.pl/index.php?action=art&a_id=1931

Main Inspectorate of Plant Health And Seed Inspection (Państwowa Inspekcja Ochrony Roslin i Nasiennictwa) Mr. Tadeusz Kłos – Main Inspector

Email: t.klos@piorin.gov.pl

11 Jana Pawła II 00-828 Warsaw

Tel: (+48-22) 652 9290/620 2824 Fax: (+48-22) 654 5221

http://piorin.gov.pl/index.php?pid=102

Deputy Chief Inspector for Trade Quality Control of Agricultural Food Products (Z-ca Głównego Inspektora Jakości Handlowej Artykułów Rolno-Spożywczych)

Ms. Dorota Krzyżanowska

Email: dkrzyzanowska@ijhars.gov.pl

ul. Wspólna 30 00-930 Warsaw

Tel: (+48-22) 623 2900 Fax: (+48-22) 623 2998

Email: sekretariat@ijhars.gov.pl http://www.ijhars.gov.pl/

Main Sanitary Inspection

(Główny Inspektorat Sanitarny - GIS)

Mr. Marek Chodkiewicz – Temporary Chief Sanitary Inspector

ul. Targowa 65

03-729 Warsaw

Tel: (+48-22) 536 1302 Fax: (+48-22) 635 9290

Email: inspektorat@gis.gov.pl http://www.gis.gov.pl/?lang=en&go=news

Ministry of Environment

Department of Environmental Protection

Senior specialist for GMO – Joanna Rybak

Tel: (+48-22) 579 2723 Fax: (+48-22) 579 2730

E-mail: joanna.rybak@mos.gov.pl http://www.mos.gov.pl/?j=en

Appendix II. Other Import Specialist Contacts:

National Food and Nutrition Institute

(Instytut Zywnosci i Zywienia)

Dr. Mirosław Jarosz – Director

ul. Powsińska 61/63

02-903 Warsaw

Tel. (+48-22) 842 2171/550 9677

E-mail: jarosz@izz.waw.pl http://www.izz.waw.pl/en/

State Hygiene Office (Państwowy Zakład Higieny – PZH)

Prof. Jan Krzysztof Ludwicki – Vice Director of Environmental Health

ul. Chocimska 24

00-971 Warsaw

Tel: (+48-22) 542 1328 Fax: (+48-22) 849 7441

E-mail: k.ludwicki@pzh.gov.pl http://www.pzh.gov.pl/page/

Voivodship Sanitary Station in Warsaw (SANEPID) - actual tests & check ups

Małgorzata Czerniawska-Ankiersztejn

ul. Żelazna 79 00-875 Warsaw

Tel: (+48-22) 620 3719 Fax: (+48-22) 624 1423

E-mail: sekretariat@wsse.waw.pl http://www.wsse.waw.pl/

Polish Center for Research and Certification (Polskie Centrum Badan i Certyfikacji)

Dr Wojciech Henrykowski - Main Director

ul. Klobucka 23A 02-699 Warsaw

Tel: (+48-22) 464 5201 Fax: (+48-22) 647 1222

Email: pcbp@pcbp.gov.pl http://www.pcbc.gov.pl/english/

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

Embassy of the United States of America

Office of Agricultural Affairs

Warsaw, Poland

Michael Henney, Agricultural Attaché

Dr. Piotr Rucinski, Senior Agricultural Specialist

Ms. Jolanta Figurska, Senior Agricultural Marketing Specialist

Tel: (+48-22) 504 2336 Fax: (+48-22) 504 2320

E-mail: agwarsaw@usda.gov