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Croatia

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report provides information on food import rules for Croatia. It includes information on labeling, packaging, food additives and import procedures. Important points of contact for U.S. food exporters are listed in the appendices. All sections of this annual report were updated in July 2011. It should be noted that due to Croatia's rapid harmonization of food legislation with EU legislation, information in this report should be verified for accuracy with the USDA/FAS office in Croatia.

Section I. Food Laws:

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This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in (**Zagreb, Croatia**) 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, who are normally best equipped to research such matters with local authorities, 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.

Croatian food legislation consists of the following types of laws:

- -- The Food Act with amendments and regulations;
- -- The Act on Cattle Breeding with amendments and regulations;
- -- The Veterinary Act with amendments and regulations;
- -- The Wine Act with amendments and regulations;
- -- The Act on Marks of Authenticity, Geographical Indication (GI) and Marks of Traditional Agricultural and Foodstuff Product (Designations of Origin) with amendments and regulations.
- -- The Law on Market of Agricultural Products with amendments and regulations
- -- And some other laws like Law on Special Conditions on Placing Flour on the Market and regulations, some regulations that are still valid although they have been published under old versions of previously mentioned laws ...

Croatian food laws and regulations are valid both for domestic and imported products, and border inspections are regular and consistent. Since the first Food Act was published, Croatia has attempted to

harmonize its food legislation with EU food and labeling legislation. This resulted in the new Food Act which was published on the 7th of May, 2007 and came into effect on the 15th of May, 2007. Since then, Croatian food legislation has consistently changed (complying with EU legislation) almost every year.

Scope of laws and regulations:

1. The Food Act with amendments (Governmental Gazette NN46/2007, NN155/2008, NN55/2011) and regulations:

Some interesting regulations are as follows:

- -- Regulation on grain, milling and bakery products, pasta, dough and dough products NN78/2005, NN135/2009, NN86/2010;
- -- Amendments to the regulation on egg quality NN69/2007, NN76/2008;
- -- Regulation on edible casein and caseins NN80/2007, NN28/2011;
- -- Regulation on condense milk and powdered milk NN80/2007, NN34/2011;
- -- Regulation on official controls for verification of conduct in accordance with provisions of regulation on food, feed and regulations on health and protection of animals with amendments NN99/2007, NN74/2008, NN118/2009 few articles of this regulation will be in effect only after Croatia becomes an EU member;
- -- Regulation on hygiene of food originated from animals with amendments NN99/2007, NN28/2010, NN45/2011;
- -- Regulation on official controls of food of animal origin NN99/2007 few articles of this regulation will be in effect only after Croatia becomes an EU member;
- -- Regulation on food hygiene with amendments NN99/2007, NN27/2008, NN118/2009 few articles of this regulation will be in effect only after Croatia becomes an EU member;
- -- Regulation on methods of analysis of milk that is treated with heat and will be used for human consumption NN133/2007, NN55/2011;
- -- Regulation on secondary substances in the process of production (on processing aids) NN38/2008 article 8 line 6 and article 10 line 2 will be in effect only after Croatia becomes an EU member;
- -- Regulation of food that was treated with ionization radiation NN38/2008;
- -- Regulation on fast frozen food NN38/2008;
- -- Regulation on hygiene in feed NN41/2008; 28/2009;

- -- Regulation on health standards of drinking water NN47/2008;
- -- Amendment to the regulation on beer and beer with supplements NN69/2008;
- -- Amendment to the regulation on products similar to chocolates, cream-products and bonbon products NN69/2008;
- -- Amendment to the regulation on cookies and cookie related products NN69/2008;
- -- Regulation on permitted percentage of eruca acids in oils and fats with amendments NN70/2008, NN86/2008; article 3 line 2 will be in effect only after Croatia becomes an EU member;
- -- Regulation on microbiological criterions for food with amendments NN74/2008, NN156/2008, NN89/2010;
- -- Regulation on food for babies, and small children and processed food on a grain base for babies and small children NN74/2008 article 25 will be in effect only after Croatia becomes an EU member;
- -- Regulation on spreadable fats NN89/2008;
- -- Regulation on food for weight reduction NN89/2008;
- -- Regulation on food for special medical purposes NN 100/2008;
- -- Regulation on conditions and procedure of issuing permit for placing on the market of GMO food or feed and requirements for traceability and special labeling of GMO food and feed NN 110/2008;
- -- Regulation on food enriched with nutrients (addition of vitamins, minerals and other substances to food) NN148/2008;
- -- Regulation on measures used in practice for specific products for which are applied food regulations NN154/2008;
- -- Regulation on maximum permitted amounts of specific contaminants in food NN154/2008, NN78/2011;
- -- Regulation on oils from olive fruit and crushed olive fruit with amendments NN7/2009, NN112/2009;
- -- Regulation on frozen desserts NN 20/2009;
- -- Regulation on cheeses and products made from cheese NN20/2009;
- -- Regulation on milk and dairy products NN 20/2009;
- -- Regulation on fruit juices and related products intended for consummation NN 20/2009, NN27/2011;

- -- Regulation on citing nutritional value of food NN 29/2009;
- -- Regulation on sugar and methods of sugar analysis for sugars intended for consummation NN39/2009, NN144/2011:
- -- Regulation on quality of products from tuna fish and Atlantic bonito NN56/2009;
- -- Regulation on mineral and natural spring waters NN57/2009, NN85/2009, NN42/2011;
- -- Regulation on strong alcoholic drinks with amendment NN 61/2009, NN141/2009;
- -- Regulation on market standards for specific products of fishing NN 67/2009;
- -- Regulation on health conditions animals and food of animal origin that are applied in production, processing, import and placing on the market NN75/2009;
- -- Regulation on alternative identification mark for some foods of animal origin NN75/2009 this regulation comes into effect after Croatia becomes an EU member;
- -- Regulation on table waters NN92/2009, NN41/2011;
- -- Regulation on honey NN93/2009;
- -- Regulation on methods of sampling and analysis of condensed milk and powdered milk intended for consumption NN112/2009;
- -- Regulation on microbiological classification and procedure in the case of pollution of live shellfish NN118/2009;
- -- Regulation on the usage of milk, dairy products and products on the basis of dairy that are considered animal byproducts (category 3) that are not intended for human consumption NN118/2009;
- -- Regulation on conditions and procedure for issuing a permit for first time placing on the market of novel food products and conditions for special labeling of novel foods NN118/2009;
- -- Regulation on quality of honey from one type of flower NN122/2009;
- -- Regulation on System of rapid alert for food and feed NN134/2009 -- article 6 will be in effect only after Croatia becomes an EU member:
- -- Regulation on edible oils and fats NN22/2010;
- -- Regulation on authorizing panel for sensory analysis of virgin olive oils NN22/2010;
- -- Regulation on frequency of sampling of carcasses, minced meat and meat preparations and conditions

and method of reducing number of basic, sample units in facilities of smaller production capacity NN30/2010;

- -- Regulation on food for special nutritional purposes NN41/2010;
- -- Regulation on the list of utilization of feed for special nutritional purposes NN61/2010;
- -- Regulation on food additives NN62/2010, NN62/2011;
- -- Regulation on nutritional and health claims NN 80/2010;
- -- Regulation on coffee and chicory extracts NN81/2010;
- -- Regulation on maximum level of coccidiostats and histomonostats in food, which is the consequence of unavoidable feed pollution of feed fed to the animals for which addition of these substances in feed is not permitted NN82/2010;
- -- Regulation on ban on use of substances with hormone and thyrostatic effect and beta antagonists on farm animals NN82/2010;
- -- Regulation on food without gluten 83/2010;
- -- Regulation on food enzymes 86/2010 article 4 will be in effect after the EU adopts a new list of authorized enzymes and article 17 will be out of effect after Croatia becomes an EU member;
- -- Regulation on flavorings 86/2010 article, 11 line 3 and 4 and articles 12, 28 until 32 will be out of effect after Croatia becomes an EU member;
- -- Regulation on salt NN94/2010;
- -- List of recognized natural mineral water and natural spring water in Croatia NN116/2010, NN139/2010;
- -- Regulation on increased number of official controls due to known or potential danger that some food and feed of non-animal origin represents NN 119/2010;
- -- List of food and feed of non-animal origin, which are subject to increased number of official controls due to known or potential danger that these products represent NN 119/2010;
- -- Regulation on special conditions for import of specific food from third countries due to the risk of contamination with aflatoxicsins NN120/2010, NN63/2011;
- -- Regulation on sampling and analytical methods in official control of feed NN 146/2010;
- -- Regulation on active pharmacological substances and their classification in correlation with maximal permitted levels of residues in food of animal origin NN 21/2011;

- -- Regulation on feed catalogue NN 27/2011;
- -- Regulation on food supplements NN46/2011;
- -- Regulation on placing on the market and utilization of feed NN 72/2011;
- -- Regulation on quality control for soybeans, sunflower and rapeseed when traded NN 88/2010, NN 93/2010, NN 78/2011;
- -- Regulation on labeling, marketing and presenting of food NN63/2011; NN79/2011; ...

The Food Act regulates the following: general requirements relating to food, Croatian Food Agency, crisis and emergency management, food hygiene, feed hygiene, official controls, new (novel) food (not pertaining to GMO), food and feed that contains genetically modified organisms or consists of them, food and feed quality and areas of responsibility of responsible Government bodies. The Food Act applies to all stages of production, processing, storage and distribution of food and feed, except for primary production, preparation, handling and storage of food in households intended for personal consumption and feeding of household animals, which are not intended for sale on the market.

- 2. The OLD Food Act with amendments (Governmental Gazette NN117/2003, NN130/2003, NN48/2004, and NN85/2006) is out of effect but until replaced with new ones there still remain some interesting regulations that are in effect:
- -- Regulation on beer and beer with supplements with amendments NN42/2005, NN57/2005, NN69/2008 article 9 and tables 1 addendum 1 are out of effect;
- -- Regulation on products similar to chocolates, cream-products and bonbon products with amendments NN73/2005, NN69/2008;
- -- Regulation on cacao and chocolate products NN73/2005;
- -- Regulation on cookies and cookie related products with amendments NN73/2005, NN69/2008;
- -- Regulation on fruit jams, jellies, marmalades, and sweetened mashed chestnut NN76/2006; ...
- 3. The Act on Cattle Breeding with amendments (NN 70/1997 NN 36/1998, NN76/1999, NN151/2003, NN132/06) and regulations:

Some interesting regulations are as follows:

- -- Regulation on egg quality with amendments NN115/2006, NN69/2007, 76/2008;
- -- Regulation on quality of bovine carcasses with amendments NN 40/2007, NN68/2009;

- -- Regulation on quality of sheep carcasses NN30/2010;
- -- Regulations on animal health requirements and veterinary certification for imports of animal casings from third countries NN146/2010;
- -- Ordinance on the list of third countries and territories from which importation is permitted for bivalves, echinoderms, tunicates, marine gastropods and products of fisheries NN 3/2011;
- -- Regulation on procedure of veterinary checks at border inspection stations for products imported from third countries NN 32/2011...

The Act on Cattle Breeding regulates other items, including trade with animals, quality of animal feed and animal products and quality standards and labeling.

4. The Veterinary Act with amendments (NN 41/2007, NN155/2008, NN55/2011) and regulations:

Some interesting regulations are as follows:

- -- Regulation on the procedure of conducting Trichinae test in meat with amendments NN62/2008, NN74/2008, NN 102/2008;
- -- Regulation on health conditions of animals and food of animal origin which are applied in the production, processing, import and placing on the market NN75/2009;
- -- Regulation on maximum level of coccidiostats and histomonostats in food, which is the consequence of unavoidable feed pollution of feed fed to the animals for which addition of these substances in feed is not permitted 82/2010;
- -- Regulation on ban on use of substances with hormone and thyrostatic effect and beta antagonists on farm animals NN82/2010; ...

The Veterinary Act regulates the following: protection of animal health, conducting public veterinary medicine, improving animal reproduction, veterinary protection of environment, official inspections and inspection oversight in veterinary medicine.

- 5. The OLD Veterinary Act with amendments (NN 70/1997, NN105/2001, NN172/2003) is out of effect but, for example, until replaced the Regulation on Feed Additives (NN9/2007) is still valid.
- 6. The Wine Act with amendments (NN96/2003, NN55/2011 articles 18, 20, 29 and 31 are out of effect according to the Amendment to the Law on Market of Agricultural Products NN 22/2011) and regulations:

Some interesting regulations are as follows:

-- Regulation on wine NN96/1996, NN24/1997, NN117/1997, 57/2000 (articles 12 and 34 will be out of

effect according to the Regulation on protected designations of origin and protected geographical indications, traditional expressions and labeling wines NN141/2010, NN31/2011, NN78/2011 after Croatian EU accession);

- -- Regulation on advertising of wine with (GI) and fruit wine NN105/2004;
- -- Regulation on wine and fruit vinegar NN 121/2005, NN 53/2006, NN26/2011;
- -- Regulation on labeling wine with geographical indication (GI) NN7/2005, NN41/2008, NN32/2011 (articles 89-111 will be out of effect according to the Regulation on protected designations of origin and protected geographical indications, traditional expressions and labeling wines NN141/2010, NN31/2011, NN78/2011 after Croatian EU accession);
- -- Regulation on fruit wines NN 73/2006, NN24/2011, NN28/2011, NN62/2011, NN82/2011;
- -- List of traditional expressions for wine NN96/2007, NN62/2010, NN133/2010, NN14/2011;
- -- Regulation on wine production with amendments NN 02/2005, NN 137/2008 (out of effect articles 2 (just sections), 3-7, 14-17, 22, 23, 30-33, 35-38, 39 according to the Regulations on the categories of grape and wine, oenological practices and restrictions NN114/2010);
- -- Regulation on minimal technical conditions for the production of wines and fruit wines as well as for the selling of wines, other grape and wine products and fruit wines NN102/2004, NN91/2005, NN71/2006, NN73/2007, NN8/200/, NN 88/2009, NN24/2011; ...

The Wine Act regulates the following: production and trade with wines and other products from grapes and wines, distillation process, labeling, geographical indication (GI) protection, production and trade with fruit wines and other wines made from the base of fruit wines, etc.

7. The Act on Marks of Authenticity, Geographical Indication (GI) and Marks of Traditional Agricultural and Foodstuff Reputation (Designations of Origin) with amendments (NN84/2008, NN75/2009, NN107/2009, NN20/2010) and regulations:

Some interesting regulations are as follows:

- -- Regulation on traditional reputation of agricultural and foodstuff products with amendments NN 82/2009, NN53/2010, NN46/2011;
- -- Regulation on marks of authenticity and marks of geographical indication (GI) of agricultural and foodstuff products NN88/2009, NN53/2010, NN46/2011;
- -- Regulation on visual identity and application of authenticity mark, GI mark and mark of traditional reputation of agricultural and foodstuff products NN 23/2010; ...

The Law on Marks of Authenticity Geographical Indication (GI) and Marks of Traditional Agricultural and Foodstuff Reputation regulates the following: procedure for protection and procedure for filing

requests for GI and the mark of traditional agricultural and/or foodstuff reputation, procedures for the protection of traditional reputation and procedures for filing requests for agricultural products and/or foodstuff, official inspections and compliance with product specification.

- 8. The Law on Market of Agricultural Products with amendments (NN149/2009, NN22/2011) and regulations –some parts of this legislation will come in to force when Croatia accedes to the EU
- -- Regulation on market standards for fruit and vegetables NN77/2010, NN59/2011 in force until EU accession
- -- Regulation on import permits for agricultural goods NN74/2010, 106/2010;
- -- Regulation on the categories of grape and wine, oenological practices and restrictions NN114/2010;
- -- Regulation on protected designations of origin and protected geographical indications, traditional expressions and labeling wines NN141/2010, NN31/2011, NN78/2011 in force after Croatian EU accession;
- -- Regulation on control of conformity of products in the wine sector in trade with third countries NN40/2011 in force after Croatian EU accession;
- -- Regulation on market standards for poultry NN78/2011 in force from 1st of January 2012 except articles 14 line 9 and articles 18,19, 21 that will be in force after Croatian EU accession;...

The Law on Market of Agricultural Products regulates the following: methods and measures of market regulation for certain agricultural products, conditions for activating certain measures of market regulation, beneficiaries of applied measures, control of the beneficiaries, management and inspection of the application of the law.

Croatian laws and regulations can be found in the Croatian language at www.nn.hr.

Section II. Labeling Requirements:

A. General requirements

- 1. The Food Act (NN 46/2007, NN155/2008, and NN55/2011) provides general rules on product labeling, which require that labeling should not mislead the consumer. Furthermore, general labeling of packaged and unpackaged food is regulated by The Regulation on Labeling, Marketing and Presenting of Food (NN63/2011, NN79/2011).
- -- The requirements of the Regulation on Labeling, Marketing and Presenting of Food:

This regulation describes general labeling requirements for packaged and unpackaged food, as well as some rules for presenting and marketing of food. Food that is placed on the market of the Republic of Croatia must have a label. The labeling includes; all written indications, data, a market indication, trademark, brand name, and a picture or symbol referring to the food; that is placed on the packaging,

label, pendant, or the documents and all notifications that accompany or refer to that food. This information must be attached to the packaging in a way that taking it off is made very hard.

According to this regulation, food must be labeled in a way that the information on the label does not mislead the consumer and the retailer of food. This regulation specifies the details for every line statement on the label. It also demands that the label contain additional information if specific regulations for specific food products demand so. In cases of the list of ingredients and shelf life, if specific regulations for specific food products permit, some information can be omitted but only if the end consumer is fully aware of it. At minimum, the label must contain information listed below.

The declaration for packed food must contain the following information:

- Name of the food under which it is sold;
- List of ingredients;
- Quantity of specific ingredients or the category of the ingredients;
- Net quantity (in metric units: liter, centiliter, milliliter, kilogram or gram);
- Shelf life (The date of minimum durability);
- Storage conditions and when necessary, whether the storage conditions can influence the food's duration;
- Name and address of the producer or the person who packages the food and/or places it on the market and is registered in The Republic Croatia;
- Details about the place of origin, if absence of this information could be misleading to the consumer about the true origins of the product;
- Instructions and usage where necessary for proper handling;
- Beverages containing more than 1.2% vol. of alcohol, the true strength of the alcohol by the volume must be stated.
- Lot number (mark)

Information about the name of the food, net quantity, shelf life and the true strength of the alcohol content for beverages containing more than 1.2 percent volume of alcohol must be put on the packaging in a way that it is clearly visible in the same field of vision. This is valid for all other data that other regulations specific for some products specify as needed in the same field of vision.

For food that is: ionized, packed with usage of gasses, containing one or more artificial sweeteners; aromatized with kin in or caffeine; food with phytosterols; esters of phytosterols, phytostanols and esters of phytostanols; glycyrrhizin-acid or ammonium salts of glycyrrhizin acid and flavorings this

regulation requires additional information which needs to be added to the label. Furthermore, any potential presence of allergens must be clearly labeled even if there are only traces (leftovers from processing) present in final product with exemption of products that point to allergen with its name.

- 2. Food placed on the Croatian market must have a label written in the Croatian language in the Latin alphabet. Multi-language labeling is allowed.
- 3. Products are not allowed entry with only a standard U.S. label. A Croatian label must also accompany the product. In some special cases, products may be imported without a Croatian label, but the product cannot be sold until a trade inspection ensures that a Croatian label is attached to the product.
- 4. Stick-on labels, meeting local requirements, can be affixed in addition to the standard U.S. label.
- 5. Labels for the food service sector (that is for unpackaged food) must be in a visible place at the point of sale. If unpackaged food is kept in a special packaging at the point of sale than the label must be on that package. The retailer of the product is responsible for the labeling of unpackaged food. For most of the unpackaged food products the label must include a minimum of the following information:
- Name of the food under which it is being sold;
- Name of the producer or company that places the food on the market.

Unpackaged food that is microbiologically unstable needs to have expiration date labeled. Drinks from vending machines or beverages prepared in a similar way, ice cream sold unpackaged, bakery and confectionery products whose shelf life is longer than 24 hours, confectionery and snack products that are packaged in the presence of consumers, must also specify a list of ingredients. Moreover, the labeling of fishery products must also specify type of catch or breeding with the words "caught in the sea" or "caught in inland waters" or "grown".

Unpackaged food must be accompanied by a document that contains all of the information that is placed on the label of the packaged food (see IIA1) as well as with other additional information needed for some specific food products. In the case that a consumer asks for that documentation the document must be presented to the consumer.

On unpackaged food irradiation, content of one or more artificial sweeteners or aromatization with kinin or caffeine must, also, be clearly labeled. Furthermore, any potential presence of allergens must be clearly labeled even if there are only traces (leftovers from processing) present in final product with exemption of products that point to allergen with its name.

- 6. We are not aware of any products sold with only U.S. standard labeling.
- 7. The Regulation on Labeling, Marketing and Presenting of Food specifies the required language for stating shelf life the date of minimum durability, how the shelf life date should be marked, for which products the shelf life date is not required, and defines the product's shelf life. According to the regulation, the shelf life is a minimal period for food "life" duration. That is the date by which food

keeps its properties when properly stored. The shelf life is indicated by the words "Best before..." when the date includes an indication of the day or by "Best before end of... in other cases. The date has to be given in order of day-month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication. In the case of highly perishable foodstuffs the minimum durability date is replaced by the "use by" date consisting of the day, the month and possibly the year, or an indication of where the date is located on the packaging." For some products like salt, vinegar, sugar, chewing gums, fresh fruit, alcoholic drinks with more than 10% of alcohol, etc it is not needed to state shelf life.

- 8. Croatian authorities do not grant exceptions to their labeling regulations.
- 9. Further details on labeling of food can be obtained from the FAS office in Zagreb. Some of these details are pertinent for the following products:
- -- The Regulation on Mineral Water and Natural Spring Waters (NN57/2009, NN 85/2009, and NN 42/2011), Regulation on Table Waters (NN92/2009, NN41/2011) and Regulation on the Safety of Drinking Water (NN47/2008) covers special additions to the label for water.
- -- The Regulation on Food for Babies, and Small Children and Processed Food on a Grain Base for Babies and Small Children (NN74/2008, NN106/2010) prescribes special labeling for this kind of food.
- -- The Regulation on Food Supplements (NN46/2011) covers special additions to the label for food supplements.
- -- Additional labeling information is also need for some other products like: cocoa, coffee and chicory extracts, food without gluten, honey, etc...
- B. Other Specific Labeling Requirements

Nutritional Labeling Requirements and Nutritional/Health Claims

- -- The Food Act (NN46/2007, NN155/2008, and NN55/2011) and The Regulation on Labeling, Marketing and Presenting of Food (NN63/2011, NN79/2011) describes the basics for labeling.
- -- Nutritional labeling is not mandatory except for food that has a nutritional statement on the label or in advertising message, or for food with special nutritional purposes.
- -- The Regulation on Citing Nutritional Value of Food (NN29/2009) and the Regulation on Nutritional and Health Claims (NN84/2010) describes the nutritional value labeling and nutritional and health claims for end consumer foods and foods for institutions and the service sector.
- -- The Regulation on Nutritional and Health Claims (NN84/2010) and the Regulation on Food for Special Nutritional Purposes (NN 41/2010) covers special additions to the label for food for special nutritional purposes.

- -- Nutritional and health claims are permitted only if they can be scientifically substantiated. In addition only health claims and nutrition claims that are on the permitted health claims or nutrition claims list can be used on a product. If a health claim is not on the permitted list then a product can be placed on the market only if it has gone through a special procedure and received a notification number from the Ministry of Health and Social Welfare. When food with health claim is first released to the market Ministry of Health and Social Welfare must be notified.
- -- Labeling for Foods Containing or Consisting from GMO Substances

According to The Food Act (NN 46/2007, NN155/2008, NN55/2011), The Regulation on Contents and Technical Documentation for Placing on the Market of GMOs or Products Containing and/or Consisting from GMOs or Products that Originate from GMOs and About Conditions of Labeling and Packing of GMOs or Products Containing and/or Consisting of GMOs or Products Originating from GMOs (NN 106/2008) and The Regulation on Conditions and Procedure of Issuing Permit for Placing on the Market of GMO Food or Feed and Requirements for Traceability and Special Labeling of GMO Food and Feed (NN 110/2008) foods and feed containing, consisting or originating from GMO substances besides general label must be labeled with additional, special data so that consumers are informed about all characteristics that this kind of food or feed contains.

No biotech crops have been approved for food or feed use in Croatia, but there is a 0.9 percent threshold level for some biotech content in food and feed. Under a special ordinance from 2008 and its amendment in 2009 and 2010, the threshold for biotech content in food depends upon whether or not a GMO event is on the Ordinance's list of permitted GMO events (the list is created from the list of GMO events previously tested and licensed in the EU). For details see GAIN report HR1111.

-- Labeling of Novel Foods

The Regulation on Conditions and Procedure for Issuing a Permit for First Time Placing on the Market of Novel Food Products and Conditions for Special Labeling of Novel Foods (NN 118/2009) prescribes additional information that needs to be added to the label on the novel food product. In general that information should consist of the following: nutritional value, intended usage, how this food differs from conventional food, substances that are not present in the conventional food and can harm some groups of citizens or are morally doubtful.

Section III. Packaging and Container Regulations:

- A. Regulation on Metrological Requirements for Prepackages and Bottles as Measuring Containers (articles 12,16 and 17 line 1 are out of effect, NN90/2005, NN32/2006, 35/2009) prescribes package nominal fillings, marking of the quantities, etc.
- B. Packaging materials and packaging material waste is covered by The Regulation on Packaging Materials and Packaging Material Waste (NN97/2005, NN115/2005, NN81/2008, NN31/2009, NN156/2009, NN38/2010, NN10/2011, and NN81/2011).
- C. Limitations for each type of packaging material are described by The Regulation on Health Standards of Materials and Objects that are in Contact with Food (NN125/2009, NN31/2011).

This regulation describes in detail which types of packaging materials are allowed. The main requirement is that packaging materials do not negatively impact the organoleptic, chemical or physical characteristic of the food and cannot consist or release compounds that could be harmful to human health. In addition this regulation covers active materials, that is, intelligent materials.

Section IV. Food Additives Regulations:

A. Additives are regulated by the Regulation on Food Additives (NN62/2010, NN62/2011). Use of flavorings is covered by the Regulation on Flavorings (NN86/2010) and the use of secondary substances is covered by the Regulation on Secondary Substances in the Process of Production (Processing Aids) (NN38/2008). In addition Croatia has the Regulation on Food Enzymes (NN86/2010).

The Regulation on Food Additives covers all of the EU directives on sweeteners, artificial colors, etc. The Regulation on Flavorings and the Regulation on Processing Aids also are in compliance with the EU directives as well as the Regulation on Food Enzymes.

The list of approved food additives, flavorings and processing aids which is in compliance with the latest EU list can be found at www.nn.hr as well as at the Croatian FAS office (see appendix II). However, all of the lists are in Croatian language. List of approved enzymes will be available after the EU adopts a new list of authorized enzymes. Until then when dealing with enzymes producers should act in accordance with "good production practice".

B. If a certain additive is not on the Croatian list of food additives and if it is legally used by an exporting country, then the opinion about usage of that additive in Croatia is given by the Commission for Food Additives on the basis of a scientific opinion from the Croatian Food Agency. After the Commission on Food Additives gives its opinion, then, on the basis of that opinion, the Minister of Health and Social Welfare permits or denies usage of the new additive. The permission is granted for a period of two years and only for certain food products. For potential use of flavors that are not on the Croatian list, the Commission for Flavorings is the competent authority. For the potential use of processing aids which are not on the Croatian list, the Commission for Food Additives remains the competent authority. For the potential use of enzymes Commission for Enzymes, after its foundation, will be the competent authority. Until then producers should act in accordance with "good production practice".

Section V. Pesticides and Other Contaminants:

A. The maximum content of certain pesticide or pesticide residues in foodstuffs is governed by The Regulation on Maximum Level of Pesticide Residue in and on Food and Feed of Animal and Plant Origin (NN148/2008, NN 49/2009, NN118/2009, NN36/2010, and NN26/2011). Other contaminants in food are regulated by The Regulation on Maximum Permitted Amounts of Specific Contaminants in Food (NN154/2008, NN78/2011) and Regulation on Active Pharmacological Substances and their Classification in Correlation with Maximal Permitted Levels of Residues in Food of Animal Origin (NN 21/2011).

Croatian list of residues of pesticides on and in food is in full compliance with the EU lists. This regulation is enforced by municipal and customs sanitary and veterinary inspection officials.

B. The pesticide residue list is positive, i.e., stating what is permitted, versus, what is not permitted. When a product that is intended to be imported into Croatia does not meet the maximum permitted pesticide level defined by the European Union, the importer must submit a request for import tolerance. This request must be submitted 60 days before import. The request is submitted to the Ministry of Agriculture, Fisheries and Rural Development; Directorate for Agriculture and Food Industry; Phytosanitary Division (see VC). Phytosanitary Division transfers this request to the Croatian Food Agency for obtaining assessment of consumer health risk. On the basis of the consumer health risk assessment the request for import tolerance is either accepted or declined.

C. According to the Law on Plant Protection Chemicals (NN70/2005) and Regulation on Registration Procedure for Plant Protection Chemicals (NN57/2007, NN119/2009), all pesticides must be registered. The registration application should be sent to:

Ministry of Agriculture, Fisheries and Rural Development Directorate for Agriculture and Food Industry Phytosanitary Division Department for Plant Protection Chemicals Vukovarska 78 10 000 Zagreb Tel: +385 1 6109 566

D. U.S. exporters can obtain a list of approved pesticides at the USDA office in Zagreb (for contact information see appendix II).

Section VI. Other Regulations and Requirements:

A. Food products do not have to be registered for import into Croatia, but they have to comply with food-quality standards prescribed by Croatian laws and regulations.

Exception is the introduction of novel foods and biotech foods (see section II and gain report HR1111). In addition Regulation on Food for Special Nutritional Purposes (NN 41/2010) requires that food for special nutritional purposes obtain approval from the Ministry of Health and Social Welfare before being placed on the market. For details on the procedure contact the FAS Croatia office (for contact information see appendix II). However, food products for special nutritional purposes can be placed on the market without approval from the Ministry of Health and Social Welfare if a notice is send to the Ministry about placing a specific product on the market together with an application of that product to the responsible institution in the EU and adequate explanation in Croatian language. Moreover, Regulation on Food Supplements (NN 46/2011) requires that most of food supplements (with some special exceptions) have a notification number from the Ministry of Health and Social Welfare and The Regulation on Food Enriched with Nutrients (NN 148/2008) asks for food enriched with nutrients to have notification number from the Ministry of Health and Social Welfare.

B. All shipments that contain food will go to quality and sanitary inspection. Basically they will be randomly tested for quality, health standards, and GMO content...

- C. In October 2010, Croatia implemented special import conditions which call for mandatory testing of U.S. almonds imported into Croatia (Regulation on Special Conditions for Import of Specific Food from Third Countries Due to the Risk of Contamination with Aflatoxins NN120/2010, NN63/2011 in compliance with EU1152/2009). USDA and The California almond industry has developed a "Voluntary Aflatoxin Sampling Plan (VASP)" that procedure is considered to provide sufficient assurances which means that almonds shipped under VASP are subject to random controls. Almonds not controlled under VASP continue to be subject to 100% border controls. The Regulation covers almonds in shell or shelled, roasted almonds and mixtures of nuts or dried fruits containing almonds, and foodstuffs containing a significant amount of almonds (at least 20%). This regulation also introduces the use of a Common Entry Document (CED). Importers have to provide prior notification to the competent authorities at the designated port of entry for the goods covered by this regulation.
- D. Product samples shipped via express mail and food for fairs are treated like any other import therefore they will also be tested for quality, health standards and GMO content.
- E. It is viewed positively by the inspectors if an exporter/importer can provide additional certificates from the competent authorities of the exporting country such as producer specifications, certificate of origin, certificate of compliance with certain regulations, etc. Please refer to the FAIRS Export Certificate Report which is expected to be published in October 2011 for the latest information pertaining to these types of specific import documents needed for the Croatian market.

Section VII. Other Specific Standards:

- A. Consumers packaging or municipal waste disposal, see Section III, Item B.
- B. Only metric weights and measures are accepted.
- C. Fortification of foods with vitamins and minerals is permitted. In this case, labeling must be carried out according to The Regulation on Citing Nutritional Value of Food (29/2009) and The Regulation on Food Enriched with Nutrients (NN 148/2008). In addition the product must receive a notification number from the Ministry of Health and Social Welfare to be placed on the market.
- D. Food produced from substances originating from GMOs is regulated by The Food Act (NN46/2007, NN155/2008, NN55/2011) and The Ordinances on GMO Levels in Products Under which Products Placed on the Market Do Not Have to be labeled as Products Containing GMO (NN 92/2008, NN36/2009).

Novel foods are regulated by the Regulation on Conditions and Procedure for Issuing a Permit for First Time Placing on the Market of Novel Food Products and Conditions for Special Labeling of Novel Foods (NN118/2009).

E. Dietetic or special use foods fall under The Regulation on Food for Special Nutritional Purposes (NN 41/2010)

F. Food sanitation: This subject is covered by The Food Act (NN74/2007, NN155/2008, NN55/2011) – The Regulation on Food Hygiene (NN99/2007, NN27/2008, NN118/2009), The Regulation on Hygiene of Food Originated from Animals (NN99/2007, NN28/2010, NN45/2011), The Regulation on Microbiological Criterions for Food (NN74/2008, NN156/2008, 89/2010) and The Veterinary Act (NN41/2007, NN155/2008, NN55/2011)...

Allowed chemical preservatives are listed in The Regulation on Food Additives (NN62/2010, NN 62/2011). Only small number of foods can be preserved with ionizing radiation according to The Regulation on Food that was Treated with Ionization Radiation (NN 38/2008). Ionization of food needs to be stated on the food label.

- G. Animal quarantine: To import live animals, animals must pass through quarantine.
- H. Wine is regulated by The Wine Act (NN96/2003, NN 55/2011), The Regulation on Wine (NN96/1996, NN24/1997, NN117/1997, 57/2000), The Regulation on Wine Production (NN 02/2005, NN 137/2008), The Regulation on the Categories of Grape Wine, Oenological Practices and Restrictions (NN114/2010) and The Regulation on Fruit Wines (NN 73/2006, NN24/2011, NN28/2011, NN62/2011, NN82/2011). The Regulation on Wine and Fruit Vinegar (NN121/2005, NN53/2006, and NN26/2011) regulates wine and fruit vinegars. After Croatian EU accession The Regulation on the Control of Conformity of Products in the Wine Sector in Trade with Third Countries (NN 40/2011) will govern Croatian wine import from the US. Beer is regulated by The Regulation on Beer and Beer with Supplements (NN42/2005, NN57/2005; NN69/2008), and strong alcohol is regulated by The Regulation on Strong Alcohols Drinks (NN61/2009, NN141/2009).
- I. Organic products: According to the Law on Organic Production and Labeling of Organic Products (NN139/2010) imported, unprocessed product can be labeled as organic if its production was comparable to Croatian legislation on organic production; imported, processed product can be declared as organic if 95% of mass of product ingredients was produced from organic inputs (according to Croatian legislation on organic production) and if inputs comply with Croatian legislation of processed organic products. Croatian organic legislation does not recognize product as organic if product has traces of GMO, product is genetically modified or if product was irradiated.
- J. Product samples and mail order shipments are treated like any other import.

Section VIII. Copyright and/or Trademark Laws:

- A. Trademarks are legally protected in Croatia. A trademark is valid for a period of 10 years, and after ten years validity has to be renewed. The number of renewals is indefinite.
- B. Companies interested in registering trademarks or brand names must apply at the State Intellectual Property Office where all information and application forms are available. Some information and application forms can also be obtained at the State Intellectual Property Office web page: http://www.dziv.hr/en/default.aspx?pArtID=47&selection=1, http://www.dziv.hr/en/forms-and-publications/forms/

C. Geographical Indications (GI), Marks of Authenticity and Marks of Traditional Agricultural and Foodstuff Reputation (Designations of Origin)

In the Republic of Croatia the protection of geographical indications and designations of origin has been provided for under the Act on Geographical Indications and Designations of Origin of Products and Services (NN173/2003, NN76/2007), The Act on Marks of Authenticity Geographical Indications (GI) and Marks of Traditional Agricultural and Foodstuff Reputation (Designations of Origin) (NN84/2008, NN 75/2009, NN20/2010) and regulations, the Wine Act (NN96/2003, NN55/2011) and regulations but after Croatian EU accession The Regulation on Protected Designations of Origin and Protected Geographical Indications, Traditional Expressions and Labeling Wines (NN141/2010, NN31/2011, NN78/2011) will be pertinent for wine.

The proceedings on the protection of geographical indications and designations of origin for foodstuffs (food) and wine is carried on at the Ministry of Agriculture, Fisheries and Rural Development.

Ministry of Agriculture Fisheries and Rural Development

Directorate for Food Safety and Quality Division for Authentic Agricultural and Food Products

Address: Ulica grada Vukovara 78, 10000 Zagreb

tel: +35 1 6106 692 fax: +35 1 6109 189 web: http://www.mps.hr e-mail: office@mps.hr

The State Intellectual Property Office of the Republic of Croatia is competent to carry on procedures of other products and services in compliance with the <u>Act on Geographical Indications and Designations of Origin of Products and Services</u> and <u>Regulations on Geographical Indications and Designations of Origin (NN173/2003, NN76/2007) of Products and Services (NN72/2004, NN117/2007).</u>

Contact information for State Intellectual Property Office:

State Intellectual Property Office of The Republic of Croatia

Ulica grada Vukovara 78

HR - 10000 Zagreb

CROATIA

Director General's office Tel: +385 1 61 06 100 Fax: +385 1 61 12 017

INCENTIV - Information centre for intellectual property (information and customer services)

Tel: +385 1 61 09 825 Fax: +385 1 61 12 017 e-mail: <u>info@dziv.hr</u> Receiving office

Tel: +385 1 61 06 418 Fax: +385 1 61 12 017

Section IX. Import Procedures:

A. Incoming goods must go through custom storage at transport terminals or airports. After the goods arrive at the custom storage, the importer or freight forwarder should start procedures for checking and clearing goods, which includes special documents that should be sent to the Inspection Departments and the Customs Office. The procedure starts at the Sanitary Inspection Department of the Ministry of Health and Social Welfare, which checks all products (except meat, which is checked by Veterinary Inspection Department from the Ministry of Agriculture Fisheries and Rural Development). Samples are taken for food safety checking every time an import arrives. Products are also inspected for quality. The importer must pay for product examinations. If products are of suspicious quality and/or health standards their sales will be banned until analyses is conducted and proven otherwise. Custom clearance and removal from storage is carried out under the supervision of a custom officer who compares the documents with the commodities after they were checked for quality and a sanitary or veterinary inspector checks for quality, ingredients and health standards.

Documents needed for meat import can be found at:

USDA/FAS office in Croatia (see appendix II), http://www.mps.hr/default.aspx?id=3631

Custom rates and documents for imports can be found at:

http://www.carina.hr (This web site is only in Croatian language. For clarification, contact your Croatian partner or one of freight forwarding companies to determine the proper rates.)

- B. Custom import documents should be in Croatian language, but documents in English language are accepted most of the time.
- B. Average length of custom clearance for food products, if all documents are in order, is one day.

Appendix I. Government Regulatory Agency Contacts:

Control over the products that are regulated by the laws on food, cattle breeding and veterinary law and regulations, wine act and regulations, and coordination of inspections:

Government of Republic of Croatia Ministry of Agriculture, Fisheries and Rural Development Grada Vukovara 78 10000 Zagreb Tel. +385 1 6106 111 Fax. +385 1 6109 201

E-mail: office@mps.hr web page: www.mps.hr

Government of Republic of Croatia

Ministry of Agriculture, Fisheries and Rural Development

Miramarska 24 10000 Zagreb

Veterinary Directorate

Tel. +385 1 6106 207

Fax. +385 1 6109 207 E-mail: office@mps.hr

web page: www.mps.hr

Control over products that are regulated by the food law and regulations and control over sanitary inspection:

Government of Republic of Croatia Ministry of Health and Social Welfare Ksaver 200a 10 000 Zagreb Tel. +385 1 4607 623

Fax. +385 1 4607 631 web page: www.mzss.hr

Control over regulation on metrological requirements for prepackages and bottles as measuring containers:

State Office for Metrology Department for Metrology Ibrisimoviceva bb 10 000 Zagreb

Tel: +385 1 563 00 22 Fax: +385 1 563 00 01

E-mail: mjeriteljstvo@dzm.hr

web page: www.dzm.hr

General trade legislation:

Government of Republic of Croatia Ministry of Economy, Labor and Entrepreneurship Directorate for Trade Policy and International Relations Grada Vukovara 78 10000 Zagreb

Tel: +385 1 6106 114 Fax: +385 1 6109 114 web page: www.mingo.hr

Control over laws dealing with waste disposal:

Government of Republic of Croatia Ministry of Environmental Protection, Physical Planning and Construction Directorate for Waste Management Ulica Republike Austrije 14 10 000 Zagreb Tel. +385 1 3782 154

Fax. +385 1 3717 135

web page: www.mzopu.hr

Appendix II. Other Import Specialist Contacts:

Useful contact for all general advice on food trade in Croatia:

Croatian Chamber of Economy (Commerce) Agriculture, Food Industry and Forestry Department Rooseveltov trg 2 10000 Zagreb Tel. +385 1 4826 066 Fax. +385 1 4561 545

E-mail: poljoprivreda@hgk.hr

web page: www.hgk.hr

Information source for reports on Croatia and other countries is found at: http://gain.fas.usda.gov/Pages/Default.aspx

EMBASSY (USDA/FAS) POINT OF CONTACT

For questions regarding other issues not covered in this report, please contact:

Ms. Andreja Misir American Embassy Foreign Agricultural Service Thomas Jefferson St. 2 10000 Zagreb Tel. +385 1 665 8951 Mob. +385 91 455 2365

e-mail: andreja.misir@usda.gov