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**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 August 2012. 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.

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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 Designations of Origin, Geographical Indications (GI) and Traditional Specialty Logos for Agricultural Products and Foodstuffs
- The Law on the Organization of Agricultural Product Markets with amendments and regulations
- And other laws such as the Law on Special Conditions for Placing Flour on the Market and related regulations, and the Law on Sanitary and Health Inspection of Foodstuffs and Items of General Use and related regulations, etc.

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 Food Act published on the 7th of May, 2007 that went into effect on the 15th of May, 2007. Since then, Croatia's

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food legislation has been changing each year to further comply with EU legislation.

Scope of laws and regulations:

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

-- Regulation on grain, milling and bakery products, pasta, dough and dough products NN78/2005, NN135/2009, NN86/2010; NN72/2011

-- 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 the regulations on food and feed, and the regulations on the health and protection of animals NN99/2007, NN74/2008, NN118/2009 – a few of the articles in this regulation will only come into effect once Croatia becomes an EU member;

-- Regulation on hygiene of food originating from animals NN99/2007, NN28/2010, NN45/2011;

-- Regulation on official controls of food of animal origin NN99/2007, NN28/2010, NN94/2011, NN51/2012 - a few of the articles in this regulation will only come into effect once Croatia becomes an EU member

-- Regulation on food hygiene NN99/2007, NN27/2008, NN118/2009 - a few of the articles in this regulation will only come into effect once 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, NN152/2011 - article 8 line 6 and article 10 line 2 will come into 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 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 NN70/2008, NN86/2008; – article 3 line 2 will come into effect only after Croatia becomes an EU member;
- Regulation on microbiological criteria for food NN74/2008, NN156/2008, NN89/2010; NN153/2011;
- 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 come into effect only after Croatia becomes an EU member;
- Regulation on food for weight reduction NN89/2008;
- Regulation on food for special medical purposes NN 100/2008;
- Regulation on conditions and procedures for authorizing genetically modified food or feed products to be placed on the market and the requirements for traceability and special labeling of genetically modified food and feed NN 110/2008 NN72/02012;
- Regulation on measures used in practice for specific products (i.e. higher risk products) subject to the food law NN154/2008, NN78/2012;
- Regulation on maximum permitted amounts of specific contaminants in food NN154/2008, NN78/2011;
- Regulation on oils from olive fruit and crushed olive fruit 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 consumption 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 consumption NN39/2009, NN143/2010;
- Regulation on quality of products from tuna fish and Atlantic bonito NN56/2009;
- Regulation on strong alcoholic drinks NN 61/2009, NN141/2009, NN104/11;
- Regulation on market standards for specific products of fishing NN 67/2009;

- Regulation on alternative identification marks for some foods of animal origin NN75/2009 – this regulation will only come into effect once Croatia becomes an EU member
- 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 procedures for authorizing of novel food products to be placed on the market and the the specific requirements for the labeling of novel foods NN118/2009;
- Regulation on the quality of honey from one type of flower NN122/2009;
- Regulation on a rapid alert system for food and feed NN134/2009 -- article 6 will only come into effect once Croatia becomes an EU member;
- Regulation on authorizing a panel for the sensory analysis of virgin olive oils NN22/2010;
- Regulation on the frequency of sampling of carcasses, minced meat and meat preparations and conditions and methods for reducing the number of basic sample units in smaller production capacity facilities NN30/2010, NN38/2012;
- Regulation on food for special nutritional purposes NN41/2010;
- Regulation on the utilization list of feed for special nutritional purposes NN61/2010, NN68/2012;
- Regulation on food additives NN62/2010, NN62/2011, NN135/2011, NN79/2012;
- Regulation on nutritional and health claims NN 84/2010, NN113/2011;
- Regulation on coffee and chicory extracts NN81/2010;
- Regulation on maximum levels of coccidiostats and histomonostats in food, which is the consequence of using restricted substances in animal feed NN82/2010;
- Regulation banning the use of substances with hormone and thyrostatic effects and beta antagonists on farm animals NN82/2010;
- Regulation on food without gluten 83/2010;
- Regulation on food enzymes 86/2010 - article 4 will come into effect after the EU adopts a new list of

authorized enzymes and article 17 will no longer be in effect once Croatia becomes an EU member;

-- Regulation on flavorings 86/2010 – article 11 (line 3 and 4) and articles 12 and 28-32 will no longer be in effect once Croatia becomes an EU member;

-- Regulation on salt NN94/2010;

-- Regulation on increased official controls due to known or potential dangers from some foods and feeds of non-animal origin NN 119/2010, NN63/2011;

-- Regulation on special conditions for imports from third countries due to the risk of contamination with aflatoxins 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 25/2011;

-- 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;

-- Regulation on mineral and natural spring waters NN95/2011;

-- Regulation on food enriched with nutrients (addition of vitamins, minerals and other substances to food) NN112/2011;

-- Regulation on medicated feed NN120/2011

-- Regulation on beer NN142/2011;

-- Regulation on spreadable fats NN41/2012;

-- Regulation on edible oils and fats NN41/2012;

-- List of food and feed of non-animal origin, which are subject to increased official controls due to the known or potential danger these products represent NN 65/2012;

-- Regulation on feed catalogue NN76/2012; ...

The Food Act not only covers the operation of the Croatian Food Agency, crisis and emergency

management, and the general areas of responsibility for the various Government bodies relating to food for humans and animals, but also lays out the general requirements relating to food/feed hygiene and official controls, food/feed quality standards, the requirements for novel foods, and the requirements for food and feed resulting from genetic engineering. 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 Act on Cattle Breeding (NN 70/1997, NN 36/1998, NN 76/1999, NN 151/2003, NN 132/06):

-- Regulation on egg quality NN 115/2006, NN 69/2007, 76/2008;

-- Regulation on quality of bovine carcasses NN 40/2007, NN 68/2009;

-- Regulation on quality of sheep carcasses NN 30/2010;

-- Regulations on animal health requirements and veterinary certification for imports of animal casings from third countries NN 146/2010;

-- Regulation on procedure of veterinary checks at border inspection stations for products imported from third countries NN 32/2011, NN 101/2011 .

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

3. The Veterinary Act (NN 41/2007, NN 155/2008, NN 55/2011):

Some interesting regulations are as follows:

-- Regulation on the procedure of conducting Trichinae test in meat with amendments NN 62/2008, NN 74/2008, NN 102/2008, NN 78/2012;

-- Regulation on health conditions of animals and food of animal origin which are applied in the production, processing, import and placing on the market NN 75/2009;

-- Regulation on maximum levels of coccidiostats and histomonostats in food, which is the consequence of using restricted substances in animal feed NN 82/2010;

-- Regulation banning the use of substances with hormone and thyrostatic effects and beta antagonists on farm animals NN 82/2010;

The Veterinary Act regulates official inspections and inspection oversight in veterinary medicine, protection of human and animal health and welfare, including improving animal reproduction (e.g. procedures and measures to be followed during breeding and transport as well as during the holding and handling of animals and animal carcasses and by-products of animal origin)

4. The OLD Veterinary Act (NN 70/1997, NN 105/2001, NN 172/2003) is no longer in effect where new

legislation/regulations have been adopted, valid. However, until replaced the Regulation on Feed Additives published under the Old Veterinary Act is still valid.

5. The Wine Act (NN96/2003, NN55/2011 – articles 18, 20, 29-and31 are no longer in effect as they have been replaced by the Amendment to the Law on the Organization of Agricultural Product Markets NN 22/2011):

-- Regulation on wine NN96/1996, NN24/1997, NN117/1997, 57/2000 (articles 12 and 34 will no longer be in 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 once Croatia becomes an EU member);

-- 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 no longer be in 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 once Croatia becomes an EU member);

-- 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, NN52/2012;

-- Regulation on wine production with amendments NN 02/2005, NN 137/2008 (the following articles are no longer in effect 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 NN14/2010);

-- 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, NN8/2009, NN 88/2009, NN24/2011;

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

6. The old Act on Designations of Origin, Geographical Indications (GI) and Traditional Specialty Logos for Agricultural Products and Foodstuffs (NN84/2008, NN75/2009, NN107/2009, NN20/2010) is no longer in effect; however, until the regulations under the new Act are issued, the following regulations are still in effect:

-- Regulation on traditional agricultural and foodstuff products NN 82/2009, NN53/2010, NN46/2011;

-- Regulation on designations of origin, geographical indications (GI) and traditional specialty logos for agricultural products and foodstuffs NN88/2009, NN53/2010, NN46/2011;

-- Regulation on visual identity and application of authenticity mark, GI mark and marks for traditional agricultural and foodstuffs NN 23/2010

6.a. The new Act on Designations of Origin, Geographical Indications (GI) and Traditional Specialty Logos for Agricultural Products and Foodstuffs) (NN50/2012)

The Act on Designations of Origin, Geographical Indications (GI) and Traditional Specialty Logos for Agricultural Products and Foodstuffs regulates the following: procedures for the protection of GI and traditional specialty logos for agricultural and/or foodstuffs in Croatia, procedures for filing requests and filing complaints for GI and traditional specialty logos in the EU, procedures for the protection of traditional specialty logos in Croatia and the EU, official inspections and compliance with product specifications.

7. The Law on the Organization of Agricultural Product Markets (NN149/2009, NN22/2011) –some parts of this legislation will come into force only after EU accession:

-- 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 only after EU accession;

-- Regulation on control of product conformity in the wine sector in trade with third countries NN40/2011 - in force only after 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 only after EU accession;

-- Regulation on market standards for fruits and vegetables NN47/2012;

The Law on the Organization Agricultural Product Markets regulates the following: methods and measures of market regulation for certain agricultural products, (e.g. cereals, sugar, hops, pigmeat, wine, milk and milk products, fruits and vegetables, etc.) conditions for activating certain measures (e.g. production limitations, public interventions, private storage aid, special intervention measures, etc) of market regulation of these products, beneficiaries of the 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 and <http://www.hah.hr/zakonska.php>.

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 instructions such as , trademark, brand name, and/or picture or symbol referring to the food that is placed on the package, label, pendant,tag or accompanying documents/notifications accompanying or referring to the food. This information must be attached to the packaging in a way that removing it is difficult.

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 require it. 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 a minimum, the label must contain the 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 in descending order by weight of specific ingredients or, per a special annex to the regulation, the category of the ingredient;
- 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 origin of the food, if the 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 must have the true strength of the alcohol

Comment [m1]: To be able to sell food in Croatia company must have a representative that is a registered company in Croatia and the procedure and place for registration I can provide but FCS promotes that in their Commercial Guide Report as part of their service

We should provide. I have at the end of the document in Appendix.

Comment [s2]: Do we provide info about how/where to register to market food in Croatia?

by the volume 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 area on the label. This is valid for all other data required in other product specific regulations where the information must be clearly visible..

For food that is: ionized, packed using gasses, containing one or more artificial sweeteners; aromatized with quinine 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 the final product with the exception of products that point to the allergen in the name (e.g. chocolate with peanuts).

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 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 be labeled with an expiration date . Drinks from vending machines or beverages prepared in a similar way, such as non individually wrapped ice cream, 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 the species along 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 Section II A.1 above) as well as with other additional information needed for some specific food products (e.g. fishery products, long shelf life bakery

products, confectionary, perishable food, etc). In the case that a consumer asks for that documentation the document must be presented to the consumer.

On unpackaged food, irradiation or inclusion of one or more artificial sweeteners or aromatization with quinine 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 the final product with the exception being products that point to allergen in the name (e.g. chocolate with peanuts).

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 necessary to state the shelf life.

8. Croatian authorities do not grant exceptions to the labeling regulations.

9. Further details on labeling of food can be obtained from the FAS office in Zagreb. The following products have additional requirements:

-- The Regulation on Mineral Water and Natural Spring Waters (NN95/2011) covers special additions to the label for water.

-- The Regulation on Food for Babies, and Small Children and Grain Based Processed Foods 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 such products as 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,

Comment [s3]: Are you trying to say there are special conditions for the following and so they should contact you?

Comment [m4]: Yes

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 an advertising message, or for food with special nutritional purposes (e.g. food for infants and children, grain based processed food for infants and children, food without gluten, food for athletes, food for weight loss, etc).

-- The Regulation on Citing Nutritional Values of Food (NN29/2009) and the Regulation on Nutritional and Health Claims (NN84/2010, NN113/2011) describes nutritional value labeling and nutritional and health claim labeling for foods destined for consumers, foods destined for institutions, and foods destined for the service sector.

-- The Regulation on Nutritional and Health Claims (NN84/2010, NN113/2011) 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. When food with a health claim is first released on the market the Ministry of Health must be notified.

-- When EU Regulation 1169/2011 comes into effect with Croatia's accession, Croatia will also apply its provisions on food information for consumers.

-- Labeling of Foods Containing or Derived from Genetically Modified 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 Genetically Modified Organisms (GMO) Containing and/or Derived from GMOs and About Conditions of Labeling and Packaging of GMOs or Products Containing and/or Derived from GMOs (NN 106/2008) and The Regulation on Conditions and Procedure for Authorizing for the Placing on the Market of GMO Food or Feed and the Requirements for Traceability and Special Labeling of GMO Food and Feed (NN 110/2008, NN72/2012) must be labeled with additional, special information so that the consumer is informed about all the 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 amendments, the threshold for biotech content in food depends upon whether or not a GMO event is on the list of permitted GMO events created from the list of GMO events previously tested and licensed in the EU. For details see GAIN report HR1207.

-- Labeling of Novel Foods

The Regulation on conditions and procedures for authorizing of novel food products to be placed on the

Comment [m5]: Both

Comment [s6]: Genetically modified organism or genetically engineered products?

Comment [m7]: Government Ordinance with amendments regulates the labeling threshold for biotech content ("GMO Levels in Products Under Which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO") passed on July 31, 2008, (Governmental Gazette 92/2008); March 18, 2009 (Governmental Gazette 36/2009); March 11, 2010 (Governmental Gazette 33/2010); April 2, 2011 (Governmental Gazette 88/2011); and March 2012 (Governmental Gazette 39/2012)

market and the specific requirements for the labeling of novel foods NN118/2009 prescribes additional information that needs to be added to the label of novel food products. 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 Filling Packages and Bottles as Measuring Containers (NN90/2005, NN32/2006, 32/2009) 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, NN81/2011, and NN126/2011).

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 and **intelligent** materials.

Section IV. Food Additives Regulations:

A. Additives are regulated by the Regulation on Food Additives (NN62/2010, NN62/2011, NN135/2011, NN79/2012). 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 the Croatian FAS office (see appendix II). In addition, the EU Commission's food additives database which contains all necessary information on the different food additives allowed in the EU can be found at https://webgate.ec.europa.eu/sanco_foods/main/?event=display. 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

Comment [m8]: This is quotation from the regulation – Article 21...“c) the presence in the novel food of material which is not present in an existing equivalent food and which gives rise to ethical concerns.” See link - <http://www.mvep.hr/zakoni/pdf/768.pdf>

No explanation what they mean under ethical concerns.

Comment [s9]: How is this defined? We cant leave here without an explanation

Comment [m10]: I would think so but they do not mention nanomaterials per se in the regulation rather they give a definition of:

Intelligent material as a material that registers conditions in the package and environment.

Active material as material with a purpose of increasing durability of packaged food that contains components, which should give or absorb substances from or in the package or food surroundings.

Comment [s11]: Intelligent materials. Are nano particles and nano packaging covered here?

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 the Regulation on Active Pharmacological Substances and their Classification in Correlation with Maximal Permitted Levels of Residues in Food of Animal Origin (NN21/2011).

Croatia's 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. Thus any residue that is found that is not on the list regardless of quantity is deemed an adulterant. 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 an import tolerance. This request must be submitted 60 days before import. The request is submitted to the Ministry of Agriculture, Directorate for Food safety and Phytosanitary Policy, Department for Plant Protection (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 an 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
Directorate for Food Safety and Phytosanitary Policy
Department for Plant Protection
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.

The exception is the introduction of novel foods and biotech foods (see section II and gain report HR1207). In addition Regulation on Food for Special Nutritional Purposes (NN 41/2010) requires that food for special nutritional purposes also obtain approval from the Ministry of Health 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 if a notice is sent to the Ministry when placing a specific product on the market together with an application for that product to the responsible institution in the EU and an adequate explanation in the Croatian language. Moreover, Regulation on Food Supplements (NN 46/2011) requires that most food supplements (with some special exceptions) have a notification number from the Ministry of Health and The Regulation on Food Enriched with Nutrients (NN 112/2011) also asks for food enriched with nutrients to have a notification number from the Ministry of Health.

B. All shipments that contain food go through a quality and sanitary inspection. They are randomly tested for quality, health standards, and GMO content.

C. In October 2010, Croatia published special import conditions calling for mandatory testing of all U.S. almonds imports into Croatia. However, as of January 1, 2012, shipments accompanied with a Croatian Health Certificate (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) are now only subject to random testing.

USDA and the California almond industry have developed a “Voluntary Aflatoxin Sampling Plan (VASP)”. That procedure is considered to provide sufficient assurances so that almonds shipped under the VASP are only subject to random controls in Croatia under the following conditions:

- if the exporting company provides a Croatian Import Health Certificate or VASP (VASP must be signed and stamped by the USDA and the importing company must provide official VASP translation into Croatian language) then 5% of all almond shipments will be randomly tested for aflatoxin
- If the exporting company does not provide VASP nor Croatian, Import Health Certificate then that almond shipment will be tested on aflatoxin

Therefore, almonds not controlled under VASP continue to be subject to 100% border controls. 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 2012 for the latest information pertaining to these types of specific import documents needed for the Croatian market.

Section VII. Other Specific Standards:

A. Consumer 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 112/2011). In addition the product must receive a notification number from the Ministry of Health 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); Regulation on conditions and procedures for authorizing genetically modified food or feed products to be placed on the market and the requirements for traceability and special labeling of genetically modified food and feed (NN 110/2008 NN72/02012) 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, NN33/2010, 88/2011, 39/2012).

Novel foods are regulated by The Regulation on Conditions And Procedures for Authorizing Of Novel Food Products to be Placed On The Market and the Specific Requirements for the 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 Originating from Animals (NN99/2007, NN28/2010, NN45/2011), The Regulation on Microbiological Criteria for Food (NN74/2008, NN156/2008, NN89/2010, NN153/2011) 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, NN135/2011, NN79/2012). Only a small number of foods are authorized to 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, NN7/1997, 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), The Regulation on Fruit Wines (NN 73/2006, NN24/2011, NN28/2011, NN62/2011, NN82/2011), and some other regulations. The Regulation on Wine and Fruit Vinegar

(NN121/2005, NN53/2006, NN26/2011) regulates wine and fruit vinegars. After 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 (NN142/2011), and strong alcohol is regulated by The Regulation on Strong Alcohols Drinks (NN61/2009, NN141/2009, NN104/2011).

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. Regulation on Labeling of Food and Feed in Organic Production (NN25/2011) specifies details on labeling of organic products.

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/intellectual-property-protection/trademarks/>,

<http://www.dziv.hr/files/File/obrasci/zip/z-1.pdf>

C. Geographical Indications (GI), Designation of Origin, Traditional Specialty Logos for Agricultural Products and Foodstuffs

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, NN49/2011), The Act on Designations of Origin, Geographical Indications (GI) and Traditional Specialty Logos for Agricultural Products and Foodstuffs, the Wine Act (NN96/2003, NN55/2011) and regulations; however, 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 Ministry of Agriculture is responsible for regulating the protection of geographical indications and designations of origin for food and wine.

The State Intellectual Property Office of the Republic of Croatia is the competent authority governing the procedures of other products and services in compliance with the Act on Geographical Indications and Designations of Origin of Products and Services (NN173/2003, NN76/2007, NN49/2011), and Regulations on Geographical Indications and Designations of Origin of Products and Services

Comment [s12]: Sorry, but does that mean everything other than food and wine or does it mean MinAg does something else and then IPO enforces

Comment [m13]: Yes, everything except food and wine

(NN72/2004, NN117/2007, NN66/2011).

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: info@dziv.hr

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

Section IX. Import Procedures:

A. Incoming goods must go through customs storage at transport terminals or airports. After the goods arrive at the custom storage facility, the importer or freight forwarder starts the procedures for checking and clearing goods, which includes submitting the relevant documents to the Inspection Departments and the Customs Office. The procedure starts at the Sanitary Inspection Department of the Ministry of Health, which checks all products (except meat, which is checked by the Veterinary Inspection Department from the Ministry of Agriculture). Samples are taken for food safety check when an import first 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 the product is deemed wholesome. Custom clearance and removal from storage is carried out under the supervision of a customs officer who compares the documents with the commodities after they were checked for quality and a sanitary or veterinary inspector checked the goods for quality, ingredients and health standards.

Documents needed for importing meat products 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 afreight forwarding company to determine the proper rates.)

B. Customs import documents should be in the Croatian language, but documents in the English language are acceptable most of the time.

The average length of time to for food products to clear customs, if all documents are in order, is one day.

Comment [m14]: Yes and No because Croatia tends to make changes often, which might stop with EU accession

Comment [s15]: Also FSIS export library, no?

Comment [s16]: This seems extraordinarily fast to get vet/Agmin clearances?

Comment [m17]: If you have all the paperwork it is fast but that does not mean you company will not have a warehouse inspection or be randomly caught with a problematic product on the market shelf.

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
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
Planinska ulica 2a,
10000 Zagreb
Veterinary Directorate
Tel. +385 1 6443 540
Fax. +385 1 6443 899
E-mail: office@mps.hr
web page: www.mps.hr

Control over products that are regulated by the food law(all food except meat) and regulations and control over sanitary inspection:

Government of Republic of Croatia
Ministry of Health
Ksaver 200a
10 000 Zagreb
Tel. +385 1 4607 555
Fax. +385 1 4677 076
<http://www.zdravlje.hr/>

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

State Office for Metrology
Department for Metrology
Ibrisimoviceva bb
10 000 Zagreb
Tel: +385 1 563 52 22
Fax: +385 1 370 11 01
E-mail: mjeriteljstvo@dzm.hr

<http://www.dzm.hr/en/>

General trade legislation:

Government of Republic of Croatia
Ministry of Economy
Grada Vukovara 78
10000 Zagreb
Tel: +385 1 6106 111
Fax: +385 1 6109 110
web page: www.mingo.hr

Control over laws dealing with waste disposal:

Government of Republic of Croatia
Ministry of Environment and Nature Protection
Ulica Republike Austrije 14
10 000 Zagreb
Tel. +385 1 3717 109
Fax. +385 1 3717 135
web page: <http://www.mzoip.hr>

Appendix II. Other Import Specialist Contacts:

Useful contacts 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 can be found at:

<http://gain.fas.usda.gov/Pages/Default.aspx>

Quick information on establishing a Croatian company can be found at:

Hitro HR
Tel. 0800 0080
e-mail info@hitro.hr.
<http://www.hitro.hr/Default.aspx?sec=43>

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

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