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Finland

Food and Agricultural Import Regulations and Standards

Country Report

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Report Highlights:

This report outlines the requirements for food and agricultural imports into Finland. The report aims to assist U.S. exporters by providing information on labeling, packaging, permitted ingredients and other relevant information. It also provides points of contact for Finnish government authorities.

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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Stockholm, Sweden 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.**

SECTION I. FOOD LAWS

Finland is one of 25 member states of the European Union and Finnish food legislation is, to a large extent, harmonized with the EU's food legislation. The Finnish Food act (23/2006), which came into force on 1 March 2006, governs production, processing, distribution, sales and marketing of food. The provisions on food laid down in this act also apply as appropriate to materials and articles intended to come into contact with food. The objectives of the Food Act are, among other things:

- to ensure the safety and quality of food,
- to ensure truthful, sufficient and not misleading information about food,
- to protect the consumer from health hazards and financial losses caused by foods,
- to ensure traceability of food, and
- to secure high-quality food control system.

Food or foodstuff in this Food Act means any substance or product, whether processed, partially processed or unprocessed, intended to be ingested by humans. The Food Act does not cover feed, live animals (unless they are prepared for placing on the market for human consumption), plants prior to harvesting, medicinal products, cosmetics, tobacco products, narcotic or psychotropic substances, or residues and contaminants. These products are regulated by other laws. Unofficial translations of the Food Act and some other Finnish laws can be found on the website www.finlex.fi/en/laki/

The Finnish Food Act implements EU regulations, such as:

- General Food Regulation (EC No 178/2002)
- Control Regulation (EC No 882/2004)
- General Food Hygiene Regulation (EC No 852/2004)
- Foodstuffs of Animal Origin Hygiene Regulation (EC No 853/2004)
- Foodstuffs of Animal Origin Control Regulation (EC No 854/2004)
- GMO Regulation (EC No 1829/2003)
- Traceability and Marking of GMO food and feed (EC No 1830/2003)
- Novel Foods Regulation (EC No 258/1997)
- Procedures for Contaminants in Food (EC No 315/93)
- Materials and Articles Intended to Come into Contact with Food (EC No 1935/2004)
- TSE Regulation (EC No 999/2001)
- Control of Salmonella and Other Food-borne Zoonotic Agents (EC No 2160/2003)
- Maximum Residue Levels of Pesticides in or on Food and Feed of Plant and Animal Origin (EC No 396/2005)

Another important act concerning Finnish import policies for agricultural products is the Act on Veterinary Border Inspections (1192/1996). This act applies to animals and foodstuff of

animal origin. The purpose of the act is to prevent the spread of infections from animals to humans and to ensure the hygienic quality of imported foodstuffs of animal origin, which originate outside the EU.

Other important acts concerning agricultural products are:

- Communicable Diseases Act (583/1986) (Provisions on requirements concerning the health status of persons who handle food)
- Health Protection Act (763/1994) (Provisions on the quality of drinking water and on the prevention of waterborne diseases)
- Animal Disease Act (55/1980) (Provisions on combating animal diseases with an impact on food safety)
- Radiation Act (592/1991) (Provisions on criteria for assessing the radiation safety of food)

Although Finnish food legislation is harmonized with the EU's food legislation, it is important to note that there can be some exceptions. For example, Finland is allowed (in addition to Sweden) to apply stricter salmonella controls than the other EU member countries. Finland is granted additional salmonella guarantees covering trade in fresh meat from bovine and porcine animals, fresh poultry meat, table eggs and minced meat.

The Ministry of Agriculture and Forestry in Finland (www.mmm.fi/en) is responsible for the preparation of legislation concerning food and agriculture and is also responsible for the monitoring of its implementation. The Ministry of Agriculture and Forestry has thirteen agencies and institutes within its administrative sector. The most important one concerning enforcement practices and import policies for agricultural products is the Finnish Food Safety Authority EVIRA (www.evira.fi/portal/en/). The Food Safety Authority implements control duties and steers control, carries out research and risk assessment, provides communication services and engages in international cooperation, in order to ensure the quality and safety of food products as well as of the production input of agriculture and forestry, the health and well being of animals, and plant health. The objective of the Authority is to create prerequisites for the safeguarding of human and animal health as well as the environment, for agriculture, forestry and food economy, and for high consumer protection.

SECTION II. LABELING REQUIREMENTS

A. General Requirements

In Finland, the general provisions applying to the labeling of foodstuffs are prescribed in the Decree of the Ministry of Trade and Industry on the Labeling of Foodstuffs (1084/2004 and 888/2005). The labeling Directives of EU (2000/13/EC, 2003/89/EC and 2005/63/EC) are implemented in Finland by this Decree. These Decrees and Directives concern the labeling of foodstuffs to be delivered to the ultimate consumer. They also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. The standard U.S. label fails to comply with these regulations.

Labeling information should be clear and understandable and also easy to distinguish from other package text. In addition, the label text should be made with adequate large letters in permanent way.

Languages that are required in labeling information are Finnish and Swedish. Instead of Swedish, it is possible to use Norwegian or Danish language. However, the country and place of origin can be informed in another general language such as English.

Stick-on labels are allowed. Stick-on labels in Finnish and in Swedish can be affixed next to or over to the standard U.S. label. Finnish legislation does not contain any exemptions or special requirements for labeling sample-size products. The Finnish Food Safety Authority EVIRA can be consulted about this issue.

There are no major exemptions in Finnish labeling regulations. Those that exist are described in the Decree of the Labeling of Foodstuffs (1084/2004). One exemption worth mentioning is that simpler labeling requirements apply for small packages (largest surface less than 10 cm²).

Information Needed in the Label

The label on foodstuff shall contain at least the following mandatory items:

- the name under which the product is sold,
- the list of ingredients, in descending order of weight,
- the quantity of certain ingredients,
- the net quantity in metric units,
- the date of minimum durability or the "use by" date (shelf life),
- the name and address of the manufacturer, packager, or a seller established within the EU,
- the country and place of origin (information on the place of origin must only be indicated if the lack of such information could mislead the consumer.)
- a mark to identify the lot to which a foodstuff belongs,
- any special storage conditions or conditions of use,
- instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions, and
- the actual alcoholic strength by volume, when beverages contain more than 1.2 % by volume of alcohol or when solid food contains more than 1.8 % by weight of alcohol.

In addition to preceding requirements, the following information is usually required on the label of the foodstuff:

- the salt content of the foodstuff,
- the use of sweetener,
- the use of packing gas, and
- nutritional value.

Various product specific laws exist concerning labeling requirements. Therefore, it is advised to find out the product specific requirements before entering the market.

The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored. The date shall be preceded by the words "Best before ..." ("Parasta ennen ..." in Finnish) and consist of the day, month and year (in this order). For foodstuffs that keep for more than three months but not more than 18 months, an indication of the month and year is sufficient. For highly perishable foodstuffs that, from a microbiological point of view, are likely to after a short period constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "use by" date or "last date of use" ("viimeinen käyttöpäivä" in Finnish). The shelf life information should be followed by a description of the storage conditions that must be observed.

B. Requirements Specific to Nutritional Labeling

The standard U.S. nutritional fact panel is not acceptable in EU. Basically, the use of nutritional labeling is voluntary. Nutritional labeling can be used as additional information to

the customer. Nutritional labeling means any information relating to energy value and the following nutrients that appears on a label: protein, carbohydrate, fat, fiber, sodium, vitamins and minerals. When nutritional labeling is provided, the information should contain at least energy value and the amounts of protein, carbohydrate and fat in this order ("Short marking"). Another way to give nutritional information is to include energy value and the amounts of protein, carbohydrate, sugars, fat, saturates, fiber and sodium in this order ("Long marking").

The energy value and the proportion of nutrients should be numerical and given with following units:

- energy – kJ and kcal
- protein, carbohydrate, and fat – grams (g)
- fiber, sodium, and cholesterol – milligrams (mg)
- vitamins and minerals – the specific units (μg or mg depending on substance)

The information should be expressed per 100 g or per 100 ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated.

Ingredients that may cause allergic reactions, including carriers, solvents or other aid material, must be stated on the label.

Nutrient Content Claims

Nutritional labeling is mandatory when a nutrition content claim appears on labeling, presentation or in advertising. Nutrition claim means any message that states, suggests or implies that a foodstuff has particular nutrition properties due to the energy and/or due to the nutrients. The only nutrition claims permitted are related to energy, protein, carbohydrate, fat, fiber, sodium, vitamins and minerals, which foodstuff

- provides/contains,
- provides/contains in reduced or increased proportions, or
- does not provide/contain.

When a nutrition claim is made for sugars, fats, fiber or sodium, the information must be given in longer marking form.

Two ways exist to express the nutrient content claims. Nutrient content claim can be a nutrition claim that describes the level of a nutrient contained in a food (examples: "source of calcium"; "high in fiber and low in fat") or nutrient comparative claim, which compares the nutrient levels and/or energy value of two or more foods (examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

The conditions using nutrient content claims in Finland are partly based on Codex Alimentarius guideline concerning nutrition claims (CAC/GL 23-1997).

Examples of allowed nutrient content claims (Finnish translations in parenthesis):

- no lactose (laktoositon/ ei laktoosia)
- light (kevyt/ light)
- rich in fibre (runsaskuituinen)
- non-gluten (gluteiiniton)
- added C-vitamin (lisätty C-vitamiinia)
- rich in polyunsaturated fatty acids (sisältää runsaasti monitydyttymättömiä rasvahappoja)
- contains C-vitamin (C-vitamiinipitoinen)

- no sugar (sokeriton)
- energy only 20 kcal (energiaa vain 20 kcal)
- no cholesterol (kolesteroliton)
- low-fat (vähärasvainen)
- contains fructose (sisältää fruktoosia)

Finland does not follow Codex with regard to light products. The claim light or reduced in fat or other similar claim are allowed only when the energy content in the product amounts to at most 70 % of the energy in similar ordinary product. (KTMP 1496/1993).

Health Claims

Medical claims related to a foodstuff such as preventing, treating, or curing diseases are prohibited in Finland. The legislation concerning health claims is currently changing in the EU. Therefore, it is advised to contact Finnish authorities for further information.

Health claim means any information that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims must be based on current relevant scientific information and the level of proof must be sufficient. In many cases clinical studies are needed. At this moment, possible health claims include the following:

- Nutritional claim (see before)
- Nutrient Function Claims: a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body
 - o Example: "Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."
 - o Allowed claims in Finland include for example
 - Xylitol is good for your teeth.
 - Fiber promotes your gut health.
 - Replacing hard fats with soft fats helps to control the blood cholesterol. Product X is rich in soft fats.
 - Low salt diet has positive effect in regulating blood pressure. Product X is low in salt. It contains salt x grams.
 - Bacterial strain X promotes your gut health.
- Reduction of disease risk claims: Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.
 - o Examples:
 - "A healthy diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A"
 - "A healthy diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A"

It is prohibited to use health claims related to specific diseases and their treatment or care in Finland. It is also prohibited to give any direct reference to any diseases. In addition, general claims such as "eating plenty of fruits reduces cancer" are prohibited.

The Finnish Food Safety Authority, EVIRA, controls the use of nutrition and health claims.

New legislation in the pipeline: In October 2006, the proposal for a regulation on nutrition and health claims was finally adopted and will likely enter into force on January 1, 2007. The new regulation will set EU-wide conditions for the use of nutrition claims such as "low

fat" or "reduced sugar". In addition, the Commission will compile an EU positive list of well-established health claims such as "calcium is good for your bones", based on member states' lists of claims already approved at national level. For more information, please see GAIN Report [E36086](#)

SECTION III. PACKAGING AND CONTAINER REGULATIONS

Finland has no special regulations for packaging or container size. It is preferred, however, to use metric units such as liters, kilograms, grams etc.

Recycling Regulations

Finnish rules for waste disposal are laid down in the Waste Act 1072/1993, amended by Waste Act 452/2004. Finland has also implemented EU directives 94/62/EC and 2004/12/EC on packaging and packaging waste by Council of State decision no. 962/1997 and decree 817/2005, respectively. The aim of the Finnish legislation is to reduce the quantity of packaging waste while at the same time increase the reuse of packaging and recover the waste that has been generated.

According to the Waste Act, firms with a turnover of EUR 1 million or more that place packaging on the Finnish market together with its products, are obliged to attend to the recovery of packaging system. In addition, the firms are obliged to provide information and report on matters pertaining to recovery. This also applies to firms that import packed products into Finland. Importers of packed products comprise all firms that import any product whatsoever where some packaging material has been used to pack the product. An importer is considered to be the owner of the product at the instance of import when the product crosses the border.

The easiest way for a firm to fulfill the packaging recovery requirements is to make a contract with the Environmental Register of Packaging PYR Ltd (www.pyr.fi/en). PYR assists its member firms, as well as the authorities, in fulfilling the packaging recovery requirements as economically and as smoothly as possible. When a firm makes a contract with PYR, it is released from these requirements and does not need to organize recovery of the packaging or report on the effectiveness of recovery to the authorities. In practice, making a contract with PYR means filling in and signing a contract form. The firm has to pay a registration and an annual fee. The amount depends on the size of the firm's turnover the previous year.

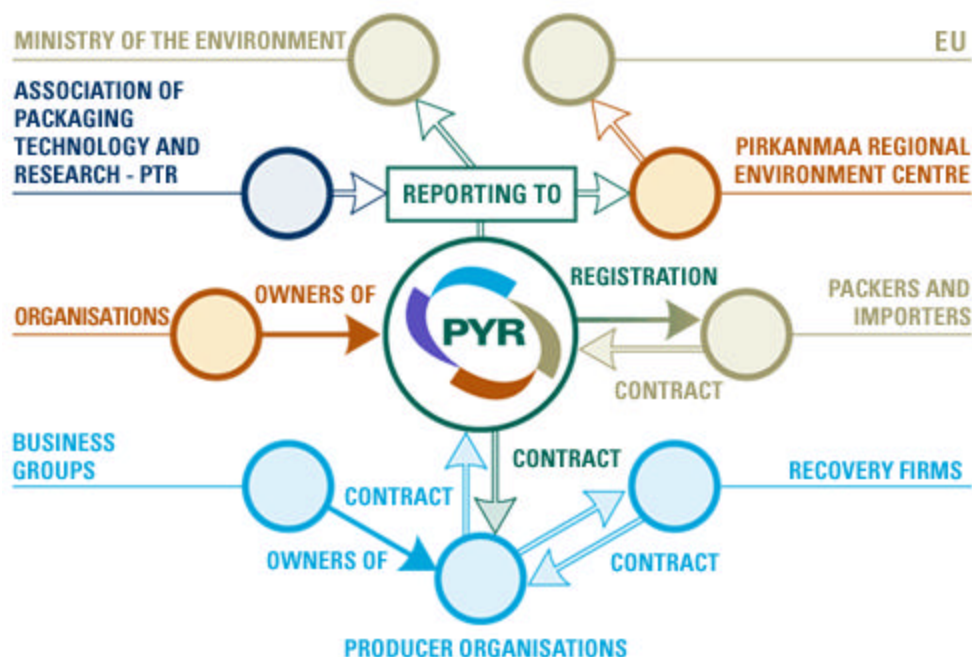


Figure 1 Organization of recovery of packaging (www.pyr.fi/en)

Packaging Material Requirements (materials in contact with food)

Food packaging materials are governed by several laws. All of the EU's directives related to plastic materials have been enforced in Finland by decrees and decisions of the Ministry of Trade and Industry. EU regulation 1935/2004 specifies the main requirements for materials that come into contact with foodstuff. EU Directive 72/2002 concerns plastic materials that come into contact with food. This directive contains, for example, lists of allowed monomers, other raw material, and additives. The National Food Safety Authority has drawn up a declaration form (the suitability of packing material for food contact use), which can be used to indicate the food-grade quality of the packaging. This form is also available in Swedish and English.

Specific limitations for vinyl monomer in PVC have been set in EU Directives 78/142/ETY, 80/766/ETY and 81/432/ETY. The maximum allowed amount of vinylchloride in the end plastic product is 1 mg/kg. It must not be detected in the foodstuff. The limit of analysis in foodstuffs is 0.01 mg/kg.

The manufacturer has the main responsibility for the suitability of material for food use. Materials must bear an indication "for food contact" or the corresponding symbol (see regulation 1935/2004).

SECTION IV. FOOD ADDITIVE REGULATIONS

Legislation concerning food additives in Finland is completely harmonized with EU legislation. Directive 89/107/EEC provides positive lists (lists of what is permitted) of food additives. Additives not included in the list are prohibited. The lists of authorized food additives and their conditions for use are published in three specific Directives

- colors (94/36/EC),

- sweeteners (94/35EC),
- the remaining food additives (95/2/EC).

Legislation related to additives and additive lists can be found on the EU website http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm

Most food additives may only be used in limited quantities in certain foodstuffs. For these additives, ADI-values (Acceptable Daily Intake) are set. If no quantitative limits are mentioned for the use of a food additive, it must be used according to good manufacturing practice, i.e., only as much as necessary to achieve the desired technological effect. Food additives may only be authorized if:

- there is a technological need for their use;
- they do not mislead the consumer;
- they present no health hazard to the consumer.

Prior to their authorization, food additives are evaluated for their safety by the Scientific Committee on Food, an expert panel that advises the European Commission in questions relating to food. In principle, EU recognizes the positive additive list of JECFA (Joint FAO/WHO Expert Committee on Food Additives) and therefore, the "Codex General Standard for Food Additives." It is recommended, however, to check the positive list of the EU authorities in order to get the correct information.

Finland has two exemptions from the EU level additive regulation:

- traditional Finnish fruit juices are not allowed to contain colors
- in traditional Finnish Easter pudding, it is not allowed to use any additives except preservative

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

The most important regulations concerning pesticides and pesticide residues in foodstuff are the Pesticide Act (327/69) and the Pesticide Decree (792/95). A new pesticide act is, however, coming into force in the beginning of the year 2007. The aim of the new law is to modernize the control of the pesticide regulations. The supervisory authority will be the Finnish Food Safety Authority EVIRA.

Regulations concerning the pesticide residues in Finland contain several Decrees and Decisions of the Ministry of Trade and Industry. These regulations are based on EU Directives. Maximum levels of allowed pesticides in food can be found on the EU website concerning pesticide residues:

http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm

This information can also be found in Finnish at the website of the Finnish Food Safety Authority, EVIRA. EU maximum residue levels take into account the work done by Codex Alimentarius, but exemptions exist.

Registration of pesticides is compulsory and it is not allowed to import pesticides to Finland without registration. Application for registration shall be submitted to the Finnish Food Safety Authority, EVIRA. The applicant must, however, be from an EU- or ETA-country. Pesticides manufactured outside the EU can be registered only by the Finnish pesticide manufacturer or importer. The physical and chemical properties and the active ingredient of the product, as well as the effects on health and the environment, must be tested according to the OECD Guidelines for Testing of Chemicals. The efficacy and usefulness of the pesticide

should be tested, if possible, according to the recommendations of the European and Mediterranean Plant Protection Organization (EPPO).

A list of approved and registered pesticides and their components is maintained by the Finnish Food Safety Authority EVIRA and can be found at www.evira.fi Most of the information is in Finnish, but extended information in English is due.

The maximum levels of other contaminants such as heavy metals, mycotoxins etc. are set in the EU Regulation 466/2001, which is harmonized EU wide.

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

Food regulations and requirements are applied equally for all food products at retail and wholesale distribution levels. The Finnish Food Safety Authority EVIRA is responsible for the monitoring of foodstuffs.

Product Samples

Product samples make an exception. Small amounts of food products, which are intended to be used as commercial samples, for exhibition purposes or for special research purposes, can be imported without being subject to import regulations. However, a written announcement to Finnish Food Safety Authority EVIRA at least two days before shipping is required. Food product samples must not be offered for sale or consumption.

Product Inspection and Registration

Generally, there is no requirement to register common imported food products. However, the food products that require registration and authorization includes at least

- novel food,
- organic food,
- dietetic or special use food,
- vitamin-enriched food,
- food supplement, and
- GMO food. (See section VII. OTHER SPECIFIC STANDARDS).

Importers of these products must register at the Finnish Food Safety Authority. Exporters must provide required certificates and product information to demonstrate that products are according to Finnish legislation (See also section VII. OTHER SPECIFIC STANDARDS).

In general, inspections of food products can be done at import or at all further stages of the distribution chain. The Finnish Food Safety Authority EVIRA carries out the inspections. Animals and food of animal origin are, however, subject to veterinary border inspection upon entry before released to market. Fresh fruits and vegetables are subject to phytosanitary controls. (See SECTION IX. IMPORT PROCEDURES).

Products Requiring Laboratory Testing

Finland (and Sweden) has received extensions of the derogations approved in its EU accession agreement. This allows Finland to continue to enforce stricter salmonella control than that of other EU Member States. Imports of fresh or frozen beef, pork, poultry and eggs from other EU countries and third countries must be certified to be free from salmonella in accordance with directive 1688/2005. Live animals and food of animal origin requires

laboratory testing concerning salmonella and other specific food-borne zoonotic agents (EU Regulation 2160/2003).

Organic Food needs to be certified and the certifier of the product needs to be accredited to EN 45011 or ISO 65 by an authority recognized by Finland.

Documentation and Certification Requirements

The list of import documents required for Finland market is presented in the Export Certification FAIRS Report Finland 2006.

SECTION VII. OTHER SPECIFIC STANDARDS

GMO

Genetically Modified Foods (GMOs) are regulated in EU Directives 1829/2003 and 1830/2003. These regulations are fully enforced in Finland. Finland has established a national control program for GMOs, which is executed by the Finnish Food Safety Authority EVIRA. Information concerning GMOs in English can be found on the EU website http://ec.europa.eu/food/food/biotechnology/gmfood/index_en.htm

All food and feed products containing GMOs must be granted approval authorization before entering the market. Applications for approval shall be sent to the national authority of a Member State, which in Finland is the Finnish Food Safety Authority EVIRA.

All food products that contain GMOs, are produced from GMOs, or contain ingredients produced from GMOs must be labeled. The labeling regulation of GMOs does not concern processing aids or milk, eggs or meat obtained from animals fed with GM feed. All GMO products should also be traceable. Traceability means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains.

Ionizing Irradiation of Food

Finland has harmonized the EU Directives 1999/2/EC and 1999/3/EC concerning the food irradiation with Decree of the Ministry of Trade and Industry of the Treatment of the Food with Ionizing Radiation (852/2000). It is only allowed to irradiate spices, aromatic herbs, or other aromatic plants. If these are packed and sold as such, the labels must contain marking "irradiated" (säteilytetty) or "treated with ionizing radiation" (käsitelty ionisoivalla säteilyllä). When irradiated product is used as ingredients, the corresponding marking is needed in the ingredients list of the end product.

Organic Food

The use of the term "organic" (luomu or luonnonmukaisesti tuotettu in Finnish) on a label requires certain production and processing methods, labeling and marketing, and inspection and import procedures. These requirements are stated in the EU Council Directive 2091/91, which is enforced in Finland. Organic food is not allowed to contain any GMO ingredients. The implementation and control of the directive is the responsibility of Finnish Food Safety Authority.

Importers of organic food from the United States or other countries outside the EU need to prove that products are produced and controlled according to EU legislation. Importers need

to apply for import authorization from the Finnish Food Safety Authority EVIRA. In addition, importers have to prove that the certifier of the product has been accredited to EN 45011 or ISO 65 by an organization recognized by Finland.

The customs of Finland requires a certificate of inspection before they release products for free circulation. Certifiers of U.S. organic products must use the EU certificate format presented in the EU Regulation 1788/2001. The certification should be in Finnish or Swedish. Every batch that will be imported must be reported beforehand to the Finnish Food Safety Authority EVIRA.

Novel Foods

The Novel Food Regulation 258/97 has been enforced in Finland by the decision of the Ministry of Trade and Industry (No 427). Novel foods are foods that were not used to a significant degree in the EU before May 15th, 1997. Novel foods must undergo a safety assessment before being placed on the EU market. Only those products considered to be safe for human consumption are authorized for marketing.

Companies that want to place a novel food on the EU market need to submit their application in accordance with Commission Recommendation 97/618/EC that concerns the scientific information and the safety assessment report required. Novel foods or novel food ingredients may follow a simplified procedure, which only requires notifications from the company, if they are considered by a national food assessment body as "substantially equivalent" to existing foods or food ingredients (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein). More information can be found on the EU website

http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm

The Finnish Food Safety Authority is the competent authority concerning novel foods in Finland.

Dietetic or Special Use Foods

Foodstuffs for particular nutritional uses are foodstuffs that, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption. They must be suitable for their claimed nutritional purposes and marketed in such a way as to indicate such suitability.

Several regulations cover the dietetic and special use of foods:

- Decree on the Special Use Foods (662/2000)
- Decision on the Dietetic Products (904/1997)
- Decree on the Clinical Food Supplements (406/2000)
- Decision on the Baby Food (789/1997)
- Decision on the Infant Formula and Follow-on Formula (485/1997)
- Decree on the Labeling the Foodstuff (1084/2004)
- Decision on the Nutritional Labeling of Foodstuff (1496/1993)
- The Food Act 23/2006

The importer must inform Finnish Food Safety Authority of imports of dietetic foods of foods for special use. The products that must be registered include

- low lactose and non-lactose milk products
- non-gluten food
- clinical food supplements

- other products excluding infant formula, follow-up formula, sport formula

A model of the label text is attached to the registration form (available at the Finnish Food Safety Authority EVIRA). EVIRA confirms the registration by letter. It is worth to notice, however, that clinical food supplements and their legality will be evaluated separately. An official decision is sent to the applicant. For products already registered in another EU country, the decision of the country in question should be attached to the registration form.

Vitamin-Enrichment Requirements

Foodstuffs may be enriched with vitamins or some other substances (minerals, amino acid, fatty acids etc.) in the following cases:

- if enrichment is generally allowed by the Decree of the Ministry of Trade and Industry (917/2002)
 - o example: addition of C-vitamin to juices
- if the product is a special use food (Decree 662/2000)
- if product is a food supplement that belongs to Annex 2 in Decree 571/2003

Otherwise, the permission to enrichment is needed. This is based on Decree of Enrichment of Foodstuff (281/1972), which has been amended several times (585/1979, 975/1985, 350/1989, 845/1992, 1272/1992, 1159/1994). The permission can be granted for five years at a time.

In order to import enriched foods to Finland, an application has to be filed at Finnish Food Safety Authority, where the application form is available. The application must include information concerning

- the name and product name of the foodstuff
- the name and quantity of the added nutrient (commonly known names of nutrients, e.g. the commonly known name of vitamin B1 is thiamine)
- the chemical compound form in which the nutrient is added (e.g. thiamine can be added as thiamine mono chloride or thiamine mono nitrate)
- an laboratory analysis certificate issued by a reliable laboratory that employs accredited methods, indicating the amount of the added nutrient in finished product
- the manufacturing method of the foodstuff, indicating also the manner in which and the stage at which the nutrients are added (e.g. manufacturing diagram)
- a proposal for the labeling of the package in Finnish or Swedish
- the reasons for which nutrients are added, indicating also whether the product is on the market in other EU countries
- the quantity of the added substance in the final foodstuff per unit of weight or volume
- type of packaging (package size and type)

Food Supplements

Food supplement means a pre-packed product in the form of briquette, capsule, pastille, tablet, pill, powder, concentrate, extract, liquid or in some other equivalent dose form. Food supplements are marketed as a foodstuff to be taken in measured small unit quantities so that the amount of energy received has no relevance for the diet as a whole. EU Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements is implemented in Finland by the decree of the Ministry of Trade and Industry on Food Supplements (571/2003) (English version in website www.finlex.fi/en).

A food supplement may contain vitamins and minerals listed in Annex 1 of the Decree and shall be in one of the forms listed in Annex 2 of the Decree. Vitamins and minerals that have not been mentioned in these annexes can be used, if they were used in food supplements

already before 12 July 2002 in one or several Member States of the European Community. Those vitamins and minerals under unfavorable opinion by the European Food Safety Authority are not allowed to be used in food supplements.

The compounds used in food supplements must meet the purity criteria defined in Directives 95/45/EY (amended 1999/75EY, 2001/50/EY) and 96/77/EY amended 98/86/EY, 2000/63/EY, 2001/30/EY and 2002/82/EY). If specification of a certain substance is absent, the Codex Alimentarius recommendations can be used.

The labeling of the product must include at least

- the names of the categories of nutrients or substances that characterize the product, or indication of the nature of these nutrients or substances;
- the recommended daily dose of the product;
- a warning not to exceed the recommended daily dose;
- a statement that food supplements should not be used as a substitute for a varied diet;
- a warning stating that the products shall be stored out of reach of children.

The labeling, presentation and advertising of food supplements may not include any information stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general or claims concerning or references to properties of preventing, treating or curing diseases.

Manufacturers and importers of food supplements must at least one month before starting their operations submit a written notification to the Finnish Food Safety Authority. A notification must also be made every time the manufacturer or importer changes. The Finnish Food Safety Authority considers that the notification obligation is fulfilled when the notification has arrived at the Agency with the required information and appendices. Appendices required include the model of the product label and the certificate of analysis.

The responsibility for the compliance of products with the Food Supplement Decree and with other relevant regulations lies with the traders themselves. They are also required to practice self-monitoring under the Act on Foods. The Finnish Food Safety Authority does not evaluate the legality of product composition or labeling. The fact that the Finnish Food Safety Authority has received a notification does not mean that it has approved the supplement as complying with the relevant regulations on foodstuffs.

Food of Animal Origin and Seafood

The Foodstuff of Animal Origin Hygiene Decree (37/EEO/2006) came into force 1st October 2006. This decree covers the following EU regulations:

- General Food Hygiene Regulation (EC No 852/2004)
- Foodstuffs of Animal Origin Hygiene Regulation (EC No 853/2004)
- Regulation of Health rules concerning animal by-products not intended for human consumption (EC No 1774/2002)
- Regulation of additional rules on the common organization of the market in milk and milk products for drinking milk (EC No 2597/97)
- Directive of detailed procedures for carrying out checks to ensure that the freezing point of untreated milk (89/384/EEC)

The decree regulates the production and transportation of all food of animal origin including seafood. All imported food products of animal origin have to fulfill the requirements in this decree.

Other relevant regulations concerning the import of food of animal origin and seafood include

- Regulation on microbiological criteria for foodstuffs (EC No 2073/2005)
- Compulsory beef labeling (EU Regulations 1760/2000 and 1825/2000, the Decree of Beef Labeling 1203/2001)
- Handling and labeling of eggs (EU Directive 1907/1990 and EU Regulation 2295/2003)
- Common organization of the markets in fishery and aquaculture products (EC No 104/2000) and informing consumers about fishery and aquaculture products (EC No 2065/2001)

The import of animals and products of animal origin is regulated by the Act on Veterinary Border Inspections (1192/1996) and the Decree on Veterinary Border Inspections of Products of Animal Origin. The regulations state that veterinary border inspections are required to import animals or products of animal origin. Foodstuffs derived from animals (meat, fish, milk, eggs and products thereof) must be accompanied by a health certificate (for meat, a veterinary certificate) and come from an EU-approved export facility. In addition, animals and products of animal origin require guarantees concerning salmonella and other specific food-borne zoonotic agents for consignments imported to Finland.

Wine, Beer and Other Alcoholic Beverages

According to Alcohol Act (1143/1994), importers of beer and other alcoholic beverages do not need import permission, but must have a license from the National Product Control Agency (STTV) (www.sttv.fi) to sell alcohol. STTV steers the implementation of the Alcohol Act at the regional and local level. STTV also supervises the State Alcohol Monopoly in Finland (ALKO) and ensures that it treats the producers of alcoholic beverages equally.

Imports of wine products from non-EU countries require import certificates. Import certificates can be applied for with AGRIM form (form 561023). Applications shall be sent to the Intervention Unit of the Ministry of Agriculture and Forestry (www.mmm.fi) Application of import certificate requires also the payment of securities. The application of import certificate and the payment of securities are the responsibilities of importer – not the US exporter. The importer delivers the certificate to Finnish customs with other documents required in customs declaration."

SECTION VIII. COPYRIGHT AND TRADEMARK LAWS

Copyright Laws

In Finland, copyright is governed by national legislation, EU directives and international conventions. The Finnish Copyright Act (404/1961), which was amended in 2005 and 2006 in order to implement the Copyright Directive of EU, protects basically works of Finnish origin. Works of foreign origin are protected under international treaties. International copyright treaties signed by Finland have been implemented nationally by separate Acts and Decrees.

In Finland, copyright matters come under the Ministry of Education, including:

- The development of copyright legislation
- Negotiations concerning international copyright treaties
- Copyright issues in the remit of the World Intellectual Property Organization WIPO and other international organizations (WTO, OECD, Unesco, Council of Europe)
- Participation in the preparation of EU legislation

The Copyright Council, appointed by the Ministry of Education, assists the Finnish government in copyright matters. It also gives its opinion on the application of the Copyright Act. Anyone can request an opinion from the Copyright Council. The opinions are given either in Finnish or in Swedish.

More information about the copyright laws can be found on the website of the Ministry of Education www.minedu.fi/OPM/Tekijaenoikeus/?lang=en

Trademark Laws

Industrial property rights, such as patents and trade marks, come under the Ministry of Trade and Industry. The National Board of Patents and Registration (www.prh.fi/en.html) provides information and advice regarding questions about industrial property rights.

Legislation

Finnish trademark legislation is regulated in the Trademarks Act, Trademarks Decree and Act on Collective Marks. The unofficial English translations can be found on the website www.prh.fi/en/tavaramerkit/lainsaadanto.html

A trademark or a brand mark can be registered at the National Board of Patents and Registration (NBPR). Registration gives the exclusive right to use the mark as a symbol for goods or services in Finland. An exclusive right means that only the registration holders may use the trademark in their business and may also, when necessary, prohibit others from using their mark or some other mark liable to be confused with it.

The trademark can, for example, be a word or a figure or a combination of these. It can also be a slogan, a combination of letters, a sound or some other mark that can be represented graphically. The purpose of a trademark is to distinguish the products of one trader from those of another trader on the market.

Registration

In order to register a trademark, the applicant has to file an application in writing to the National Board of Patents and Registration (NBPR). A separate application has to be filed in respect of each mark and the applicant or his representative signs the application. A foreign applicant not residing in Finland has to appoint a representative resident in Finland to represent him in all matters concerning the trademark. If the applicant has appointed a representative, the application must contain the representative's name, domicile, and address. The application can be made on a form available from NBPR (www.prh.fi/en/tavaramerkit/lomakkeet.html). It is not, however, obligatory to use this form.

A trademark cannot be altered after filing the application. Only minor changes that do not alter the overall impression of the trademark are allowed. The application is considered filed when the application fee has been paid. A copy of the receipt has to be attached to the application.

The protection of a registered trademark begins on the date when the application is filed. The registration is in force ten years from the date of registration, and can be renewed for a further ten years to begin after the previous term of registration has expired. If the applicant does not wish to alter any of the particulars entered into the Register, the renewal can simply be made by paying the renewal fee into the Trademarks Unit's bank account. The

renewal application has to be made in writing when the applicant wishes to make changes to his register entries.

Limitations on Trademarks

According to the Trademarks Act, the trademark has to be distinctive in order to be registered. The distinctive character is an absolute condition for registration. A mark is not distinctive if it denotes, either alone or with only a few alterations or additions, the kind, quality, use, price, origin, or time of manufacture of the goods or services. The distinctive character is examined in Finnish, Swedish, English, and in some other languages. Some words cannot be registered because no exclusive rights can be granted to them owing to the freedom of advertising.

More information about the trademark issues can be found from the website of National Board of Patents and Registration of Finland www.prh.fi/en/tavaramerkit.html

SECTION IX. IMPORT PROCEDURES

General Import Procedure

When Finland became a member of the EU in 1995, it also joined the customs and fiscal territories of the European Community. The Community's basic customs legislation is contained in the Customs Code (Council Regulation (EEC) No 2913/92) and the Code's implementing provisions (Commission Regulation (EEC) No 2454/93), which Finland has also implemented.

The regulation requires traders to supply customs authorities with advance information on goods brought into the customs territory of the European Community. This will provide for quicker process and release upon arrival, resulting in a benefit for traders. The custom declaration is performed by the owner of the goods or a person acting on his behalf (a representative). It may also be performed by the person having control over the goods. These persons may be individuals or companies and, in certain cases, associations of persons. As a general rule, these persons and companies (= importer) should be established in the European Union. Responsibilities of the U.S. exporter are limited to providing products manufactured according to the laws and regulations of Finland, providing required export certificates, and providing required commercial documents.

The custom declaration is to be lodged with the customs office where the goods were or will shortly be presented. In the EU, the single administrative document (SAD) is used within the framework of trade with third countries and for the movement of non-EU goods within the EU.

Several Customs Clearance procedures exist, but the most significant is the release of the goods for free circulation. For the sake of the clarity, it is the only procedure mentioned in this report. The release of the imported goods for free circulation requires payment of the import duties to which they are liable. The term "customs debt" means the obligation for a person to pay the amount of the import duties (customs debt on importation), which apply to specific goods. Such duties are laid down in the Community Customs Tariff (CCT). The purpose of release for free circulation is to fulfill all import formalities so that the goods can be sold within the EU. Release for free circulation thus confers on non-Community goods the status of Community goods.

Finland, as well as other European Union countries, uses the Combined Nomenclature (CN) for the customs classification of goods. This classification code determines relevant import duties and taxes as well as the other responsible authorities (e.g. Finnish Food Safety Authority) in addition to Customs. The EU's databases can be consulted to look up commodity codes and import duties http://ec.europa.eu/taxation_customs/dds/en/home.htm

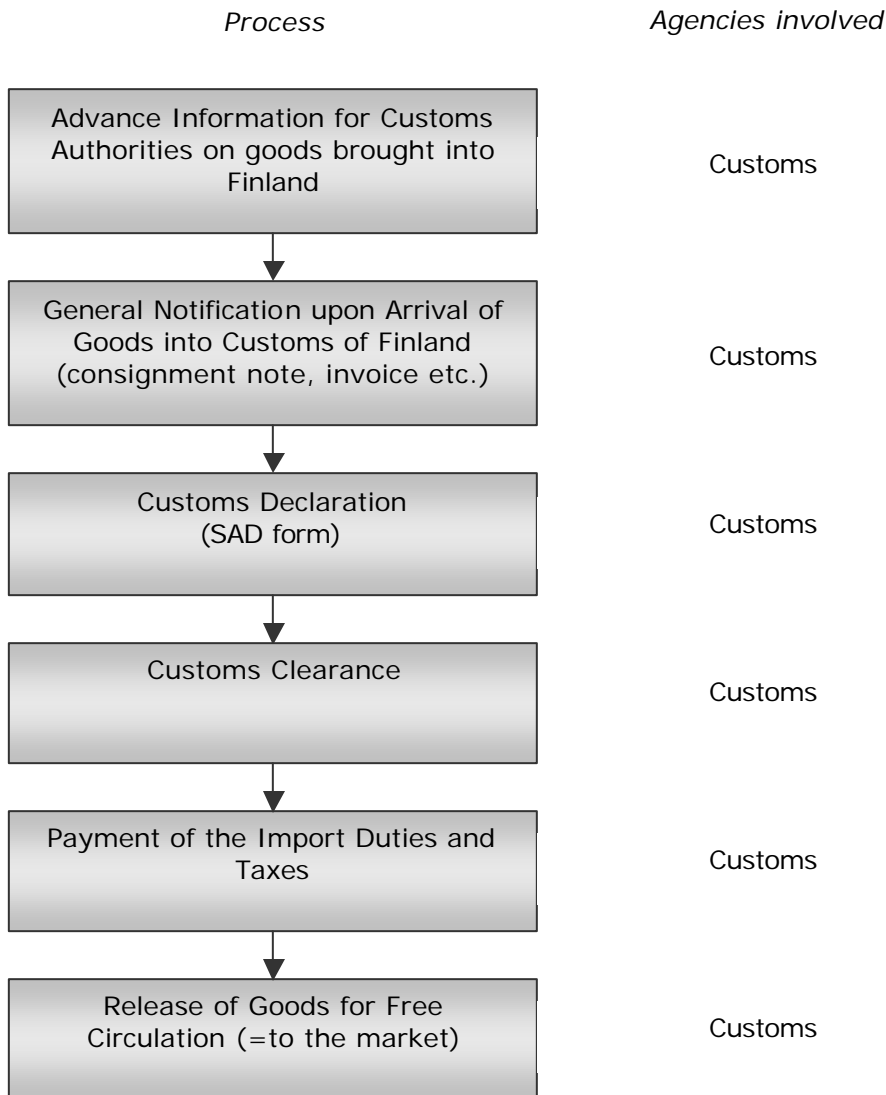
The value added tax (VAT) in Finland is 22 % and it will be paid at the same time with other duties and taxes.

Finnish Customs may require the translation of some documents to Finnish or Swedish. The length of the customs clearance procedure will depend on the products. Also the requirements for import depend on the products. For example, imports of organic foods require import licenses from the Finnish Food Safety Authority EVIRA. Various plants, seeds, cereal requires international phytosanitary certificate in order to be released on the Finnish market.

More information in English can be found on the EU website www.ec.europa.eu/taxation_customs/customs/index_en.htm

The website of the Finnish Customs in English is www.tulli.fi/en/index.jsp?language=en
Currently, there is no information on import procedures in English available on this website.

GENERAL IMPORT PROCEDURE



General Import Procedures for Agricultural Products

Finland applies the European Union system of import certificates for agricultural products. Commission Regulation (EC) No 1291/2000 lays down common detailed rules for the application of the system of import and export licenses and advance fixing certificates for agricultural products. For example, following products need import certificates:

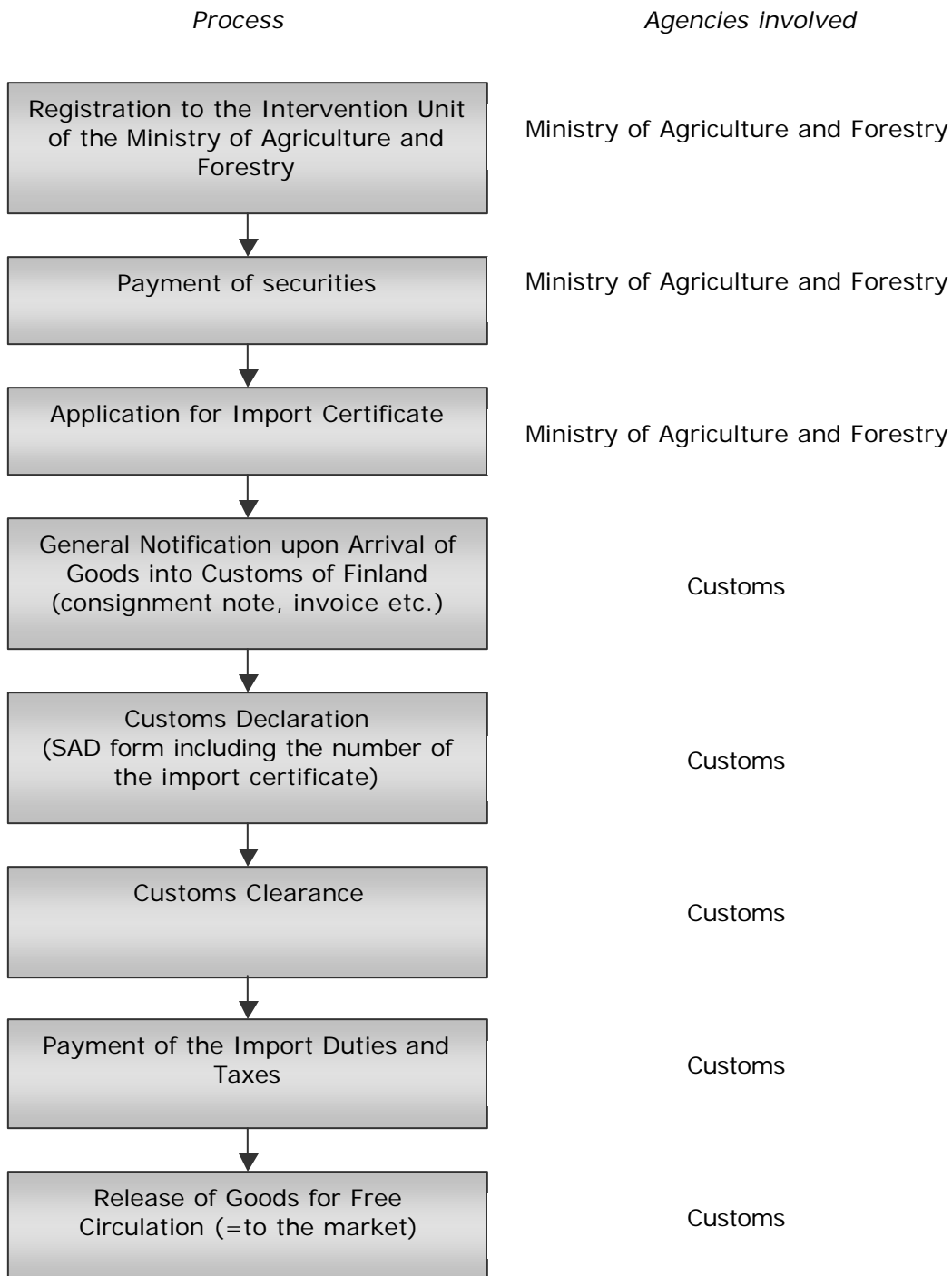
- oils and fats (Regulation No 136/66/EEC),
- live plants and cut flowers (Regulation (EEC) No 234/68),
- seeds (Regulation (EEC) No 2358/71),
- pig meat (Regulation (EEC) No 2759/75),
- eggs (Regulation (EEC) No 2771/75),
- poultry meat (Regulation (EEC) No 2777/75),
- ovalbumin and lactalbumin (Regulation (EEC) No 2783/75),
- cereals (Regulation (EEC) No 1766/92),

- bananas (Regulation (EEC) No 404/93),
- rice (Regulation (EC) No 3072/95),
- fruit and vegetables (Regulation (EC) No 2200/96),
- processed fruit and vegetable products (Regulation (EC) No 2201/96),
- sheep meat and goat meat (Regulation (EC) No 2467/98),
- beef and veal (Regulation (EC) No 1254/1999),
- milk and milk products (Regulation (EC) No 1255/1999),
- wine (Regulation (EC) No 1493/1999),
- sugar, isoglucose and inulin syrup (Regulation (EC) No 2038/1999).

Commission Regulation (EEC) No 2220/85 lays down common detailed rules for the application of the system of securities for agricultural products. When importers apply for import certificates, the obligation to import the products mentioned is formed. Securities guarantee that the import obligations will be fulfilled during the period of certificate validity.

Import certificates to Finland can be applied for from the Intervention Unit of the Ministry of Forestry and Agriculture. Before application, the importer must register in the Intervention Unit of the Ministry of Forestry and Agriculture as an importer of certain products. Registration can be made with a special form available from the Ministry.

GENERAL IMPORT PROCEDURE FOR AGRICULTURAL PRODUCTS, WHICH REQUIRE IMPORT CERTIFICATE



Import Procedures for Animals and Food Products

The import of animals and products of animal origin is regulated by the Act on Veterinary Border Inspections (1192/1996) and the Decree on Veterinary Border Inspections of Products of Animal Origin. These regulations state that veterinary border inspections are required to import animals or products of animal origin. Five veterinary border inspection posts, which operate under Ministry of Agriculture and Forestry, hold the responsibility for veterinary border inspection in Finland.

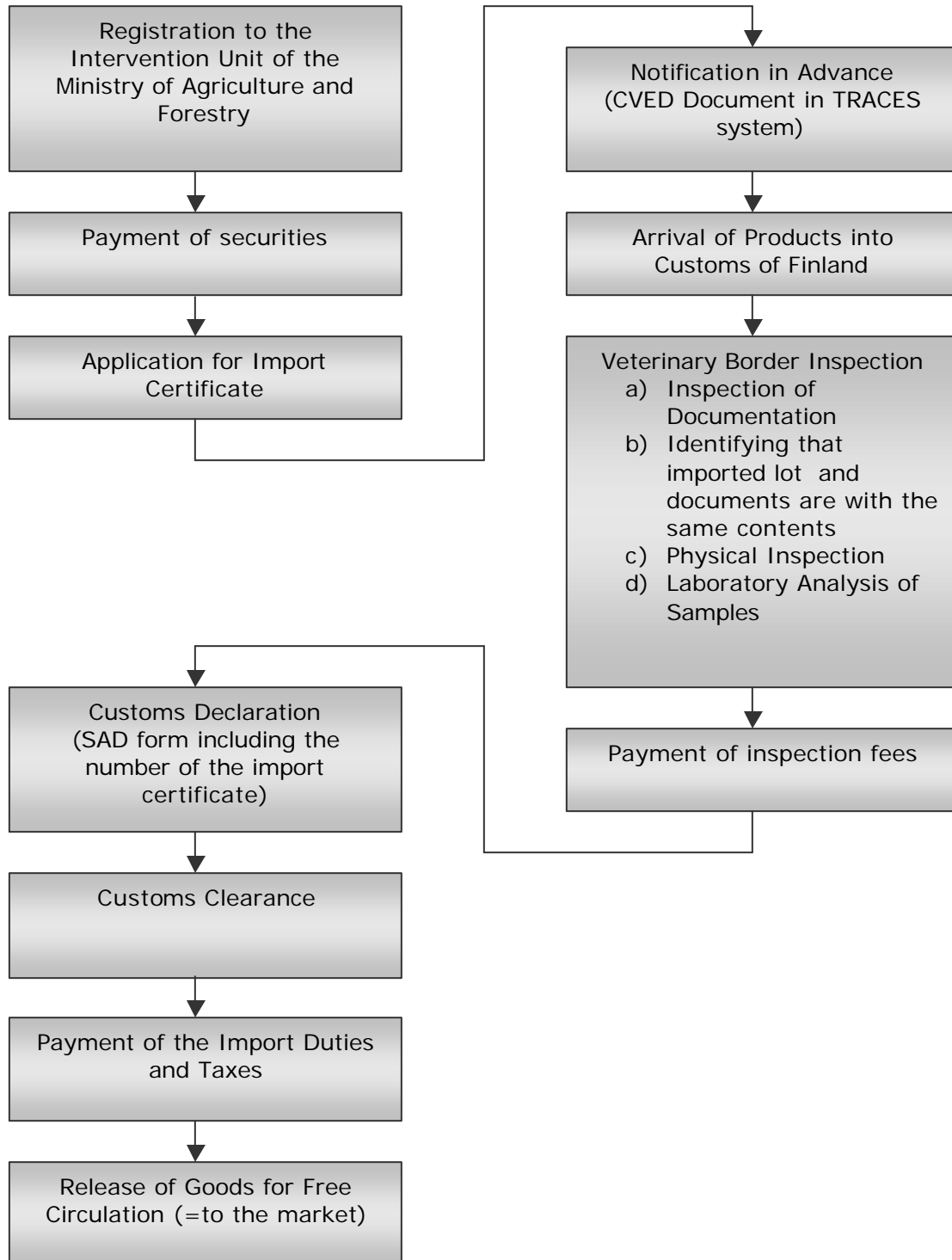
Before the physical arrival of the consignment on Finnish territory, the notification of the arrival of the products must be made to the veterinary staff of the border inspection post to which the products are to be submitted. This notification is made using the Common Veterinary Entry Document (CVED).

Common Veterinary Entry Document (CVED) can be filed in TRACES –system. TRACES, which stands for 'TRAde Control and Expert System', is a web-based system networking veterinary authorities in all Member States and economic operators (companies). The system allows, among other things, the company to introduce its requests on line to speed up all the administrative procedures for import (or for intra trade). The registration to the TRACES and logging in to the system occur on the website <https://sanco.cec.eu.int/traces/>

Veterinary Border Inspection includes the inspection of documentation, verifying that imported lot and documents are with the same contents, physical inspection and possible laboratory analysis of taken samples. The inspection is made by the veterinarians of the Finnish Food Safety Authority.

After completion of the veterinary checks, the CVED is completed and signed by the official veterinarian responsible for the border inspection post in order to give veterinary clearance to the consignment. After the veterinary clearance, the consignment is ready for custom declaration and clearance. In addition, health certificates and guarantees concerning salmonella and other specific food-borne zoonotic agents for consignments imported to Finland are required.

GENERAL IMPORT PROCEDURE FOR PRODUCTS OF ANIMAL ORIGIN, WHICH REQUIRE ALSO IMPORT CERTIFICATE



APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS**Ministry of Agriculture and Forestry**

PO Box 30,
FI-00023 GOVERNMENT
FINLAND

Tel: +358-9-16001
Fax +358-9-160 54202
Website: www.mmm.fi

Legislation concerning food and agriculture and monitoring of its implementation

Finnish Food Safety Authority EVIRA

Mustialankatu 3
FI-00790 HELSINKI
FINLAND

Tel: +358 20 77 2003 (exchange)
Fax: +358 20 77 24350
E-mail: info@evira.fi
Website: www.evira.fi

Implementation and control of regulations concerning the quality and safety of food products, agriculture and forestry, animals and plants health

Agency operates under Ministry of Agriculture and Forestry

National Board of Patents and Registration of Finland

P.O.Box 1170,
FI-00101 HELSINKI
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Fax: +358 9 6939 5328
E-mail: registry@prh.fi
Website: www.prh.fi

Trademarks

Ministry of Education

P.O. Box 29
FI - 00023 GOVERNMENT
FINLAND

Tel: +358 9160 04 or +358 9 578 14
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E-mail: opmkirjaamo@minedu.fi
Website: www.minedu.fi

Copyright matters

National Board of Customs

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FI-00530 HELSINKI
FINLAND

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Fax +358 20 492 2852
E-mail: kirmo@tulli.fi (to the registry)
Website: www.tulli.fi

Finnish Customs Laboratory

P.O. Box 53
02151 Espoo
Tel. +358 9 6141
Fax +358 9 463 383

National Product Control Agency for

Alcoholic products, tobacco and

Welfare and Health

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FINLAND
Tel. +358 9 3967 270
Fax +358 9 67 2797
e-mail: sttv@sttv.fi
Website: www.sttv.fi

chemicals

Agency operates under the Ministry of
Social Affairs and Health.