Importing pre-packaged foods
Starting your business

This brochure provides important information for those who wish to import and sell pre-packaged foods.

Food safety is your responsibility

Anyone who serves or sells food is responsible for ensuring the food is safe to eat. It must not entail a risk to people’s health. This applies to both hygiene and labelling.

It is also the responsibility of anyone selling pre-packaged foods that the labelling is correct and does not mislead the consumer.

One example of a situation in which labelling is important for consumer safety is when the food contains allergens – i.e., ingredients that can cause an allergic reaction in people with allergies.

Register your business

When you start a business which involves importing and trading foods, you must be registered with a control authority. This is usually the environmental service at your local municipality authority.

You must be registered even if you do not have storage facilities of your own for your goods, but only an office. However, if your business is very limited, it may be the case that it does not need to be registered. Examples of such businesses can be found in the National Food Agency guidelines for approval and registration. It is the control authority (municipality) that evaluates whether registration is necessary or not in your specific case.

Regardless of whether the business needs to be registered or not, you are responsible for the consumer safety when selling the foodstuff.

NB: This brochure does not cover all regulations. The content is intended to provide an overview of legislation affecting you. At the back of this brochure you will find information about further guidelines and rules you may need to be aware of.
To apply for registration of your business, you will need the following:

- The food business operator’s name and address.
- The corporate identity number, the personal identity number, or the coordination number.
- Premises, or place, where your business will be conducted.
- A description of the type and scope of your business.
- Any other information requested by the local control authority.

Registration forms are available at your local authority.

Find out the rules that apply

Rules are there to protect the consumer
Legislation regarding food has two main aims:
- to protect the consumer from food that is unfit for human consumption or has negative health effects and
- to ensure that the labelling provides the consumer with sufficient information for making independent and safe choices. Labelling, advertisement and presentation of foods must not mislead the consumer.

Municipal fees
The control authority will charge a fee for registration and inspections. The size of your inspection fee is dependent on the complexity of your business and the work needed for the monitoring activities. The municipality will assess this need and provide information on when you will be inspected. Each municipality charges its own hourly rate for food inspections.

Your annual inspection fees are calculated by multiplying the duration of the inspection with the hourly rate. For example, 2 hours x SEK 1,000 = SEK 2,000 annual inspection fee.

Fees are paid annually, however, this does not necessarily mean that the municipality will perform inspections each year. The time stated in your decision is the time that the municipality will allocate for inspecting your operation. The time includes preparations, the inspection itself and any other follow-up work at the municipal office. Travel time is not included.

The following applies to all food companies

- Responsibility – as a business operator, you are responsible for all food you manufacture, transport, store or sell. For example, you are responsible for following the rules for safety and labelling.
- Traceability – Identification of suppliers and batches must be quick and accurate.
- Openness – You must immediately inform the appropriate authorities and consumers if there is any reason to suspect a foodstuff of being unsafe.
- Prevention – You must regularly assess the critical control points in your business and ensure that they are regularly inspected.
- Self-monitoring – You must have a system for self-monitoring your business
Labelling provides consumers with important information

Labelling regulations are there to make it easier for the consumers to make conscious and safe food choices.

The National Food Agency has published an information brochure about labelling of pre-packaged food. The brochure describes labelling regulations as per EU Regulation 1169/2011 regarding food information to customers, applicable as of 13 December 2014.

The main goal for this EU regulation is to ensure that the consumer information is clearly legible and easy to understand.

If you are running a food business, all pre-packaged foods you sell or give away for free must be correctly labelled.
How to label?

The food labelling brochure explains in short how the products must be labelled according to Regulation (EU) no. 1169/2011. The labelling must be written in Swedish and the letters must be legible. The brochure also states what information is mandatory in the labelling:

- a correctly stated name of the food
- ingredients provided in an ingredients list, in descending order of predominance by weight
- allergens shall be emphasised in the ingredients list
- the date of minimum durability or the ‘use by’ date; and any other storage information
- the net quantity
- the name and contact details of the food business operator
- country of origin where it applies
- preparation guidelines where appropriate
- alcohol content if it exceeds 1.2 % vol.
- a nutritional declaration in accordance with specific regulations

READ MORE
Read more about labelling in the National Food Agency information brochure “Labelling of pre-packaged foods” (in Swedish) or on www.livsmedelsverket.se.

Nutrition and health claims

There are strict regulations governing statements given on products concerning nutrition and health properties. Such statements are called nutrition and health claims. Health claims may only be stated on the label if they are approved by the European Commission.

Nutrition and health claims have special rules for labelling in addition to the regulation (EU) no 1169/2011 on food information.

READ MORE
Read more about nutrition and health claims at www.livsmedelsverket.se

Specific labelling rules apply to certain foods

Certain foods require specific labelling. These include for example:

- food supplements
- Infant formula and baby food
- foods for special medicinal purposes
- genetically modified organisms (GMO)

READ MORE
Read more about labelling in the National Food Agency information brochure “Labelling of pre-packaged foods” (in Swedish) or on www.livsmedelsverket.se.
It is important to be aware of whether a product contains allergens

Allergens are substances (often proteins) that cause allergic reactions amongst those who are allergic. Even very small amounts can trigger these allergies. Symptoms may vary, from itching to more serious symptoms such as anaphylaxis.

At worst, these symptoms can become so serious that they result in death. It is therefore extremely important that you know the composition of the foods you are importing and selling. You must also ensure that all allergens have been correctly highlighted in the ingredient list of the label.

When food additives or flavourings are included

Food additives are substances included in foods to affect their consistency, shelf life, flavour or colour. If you import and trade foods in Sweden, you are responsible for ensuring that all additives included in the products are approved.

Additives that are approved in one type of food is not necessarily approved in another. Regulation (EC) no. 1333/2008 on food additives states which additives are approved and may be used in different food types and under what conditions (e.g., permitted amount).

Flavourings and smoke flavourings added must also have approval by the EU. Regulation (EC) no. 1334/2008 states approved flavourings and (EC) no. 2065/2003 approved smoke flavourings.

READ MORE
Read more about additives at www.livsmedelsverket.se.
Genetically modified organisms – (GMO)

Genetic engineering is used in food production e.g. to help create crops that are resistant to insect attack or to provide better nutritional composition. The purpose of the GMO legislation is to guarantee that only safe genetically modified foods are available on the market.

There are rules for how food that consists of, contains or has been produced using GMO must be labelled so that the consumer is able to make an informed choice. An example of such labelling is “made from genetically modified soy”.

Foods containing no more than 0.9 per cent unavoidable residues of an approved GMO ingredient do not need this information in the labelling.

READ MORE
Read more about GMO at www.livsmedelsverket.se.

Food supplements

Food supplements are food products and are not to be confused with herbal medicinal products, which must be approved by the Medical Products Agency before they may be sold.

If you are going to import food supplements, you should contact the Medical Products Agency to find out whether the product is classed as a medicinal product or a food stuff (food supplement).

Certain food supplements containing animal products shall be inspected by National Food Agency border inspectors.

Novel foods must be approved

There are rules governing novel foods within the EU. According to the rules, foods that were unavailable on the EU market before May 15, 1997 are to be treated as ‘novel’. It may thus be the case that foods or ingredients that have been consumed outside the EU for centuries are not approved for use within the EU. Novel foods are approved by the EU Commission after their safety has been evaluated.

The EU Commission’s website provides a list of approved novel foods. It also provides descriptions of how the foodstuffs or ingredients may be used, for example in which foods and in what amounts.

There are a number of foodstuffs and ingredients that have been tested but not approved.

READ MORE
Read more about novel food on www.livsmedelsverket.se.
Controlling your business

As a food business operator, it is your responsibility to ensure that legislative requirements are met. If you import and trade pre-packaged foods, you must check that the labelling is correct and that the goods do not contain anything prohibited or that may harm the consumer. You may therefore need to check certain information with your supplier in order to, for example, provide the functional class for a food additive or to ensure that all allergens have been correctly labelled.

Storage space and premises
The space and premises where you will store your foods must be easy to clean and protect foods from pests. If there are special directions for the storage of your food, e.g. storage temperature, it must be possible to store the food at this temperature.

Traceability and recall
There are traceability requirements for all food businesses. If all of your customers are end consumers, you only need to be able to trace the food upstream. However, if you sell your products on to another food business operator you must also be able to trace the food one step downstream. You must document the supplier or customer name and address, what has been bought or sold, when and how much. For example, you can save receipts and any waybills for the foods you buy.

If you suspect that any of the food you sell is unsafe, you must inform your customers and the control authorities of this.

Thanks to efficient traceability, you are able to identify any sources and distribution of an unsafe product in case of a recall.

For certain foods such as beef, fish and foods containing GMO, there are more detailed requirements for their traceability. Read more in the brochure “Traceability information for food business operators” (in Swedish).
**Certain foods are inspected at the border**

**Import from EU countries**
Free trade rules apply within the EU and so no border controls are made when foods are transported over the border between two European countries. Sweden, however, has special requirements for salmonella testing in fresh meat from beef, pork and poultry. This is checked at the Swedish border before letting the foods in from another EU country.

**Import from non-EU countries**
To prevent infectious animal diseases or unsafe foods from entering the EU, there are regulations regarding the import of foods from countries outside the EU.

**Foods of animal origin**
Foods of animal origin include meat, fish, milk, eggs and honey.

All foods of animal origin that are imported from a non-EU country must first undergo a border inspection at one of the EU border inspection stations. Border inspection stations in Sweden may only handle foods of animal origin that are pre-packaged. A pre-notification of the goods must be made with a 24-hour notice before the goods reach Sweden's borders. Pre-notification is made via the web-based 'Traces' system.

A country outside the EU must be approved by the EU Commission to be allowed to ship foods of animal origin to the EU. The food must also come from an establishment approved in accordance with Regulation (EC) no. 853/2004 and accompanied by a health declaration for the goods. Lists of approved establishments can be found on the National Food Agency website. Specific rules apply to honey.

Certain foods of animal origin have special protective measures.

**Foods of non-animal origin**
Foods of non-animal origin derive from plants.

Most foods of plant origin which are imported to Sweden from countries outside the EU do not need to be controlled at the border. However, protective measures against certain foods of non-animal origin have been introduced by the EU Commission.

The National Food Agency border inspectors carry out the import control and pre-notification must be made via the web-based 'Traces' system.

Certain consignments, where traces of pesticides above the permitted limit value previously have been found, are not permitted on the Swedish market without the approval of the National Food Agency. These consignments are listed on the so-called “black list” and the National Food Agency has to be pre-notified before they are sold.

**Composite Products**
A composite product contains both ingredients of a non-animal origin and ingredients of animal origin that have undergone the process of heating. An accompanying trade document must arrive with the products and they must be clearly labelled with information regarding the product's type, quantity, country of origin and manufacturer. The production facilities and/or the country must be approved by the EU.

Composite products must be inspected at the border:
- if they include meat products,
- if at least half of the content is made up of milk, fish or egg,
- if less than half of the content is made up of milk, fish or egg, but it is not safe to store at room temperature.
The National Food Agency helps to assess whether or not a product should be inspected at the border.

**Protective measures**
The EU Commission sometimes makes decisions regarding special protective measures in order to protect both humans and animals from contagion or hazardous substances in foods of animal or plant origin.

These measures mean certain restrictions when importing to the EU. They often target a certain country or certain products from that country.

The Swedish Board of Agriculture have restricted the import of certain plants and there are rules against importing non-cultivated mushrooms from certain countries.