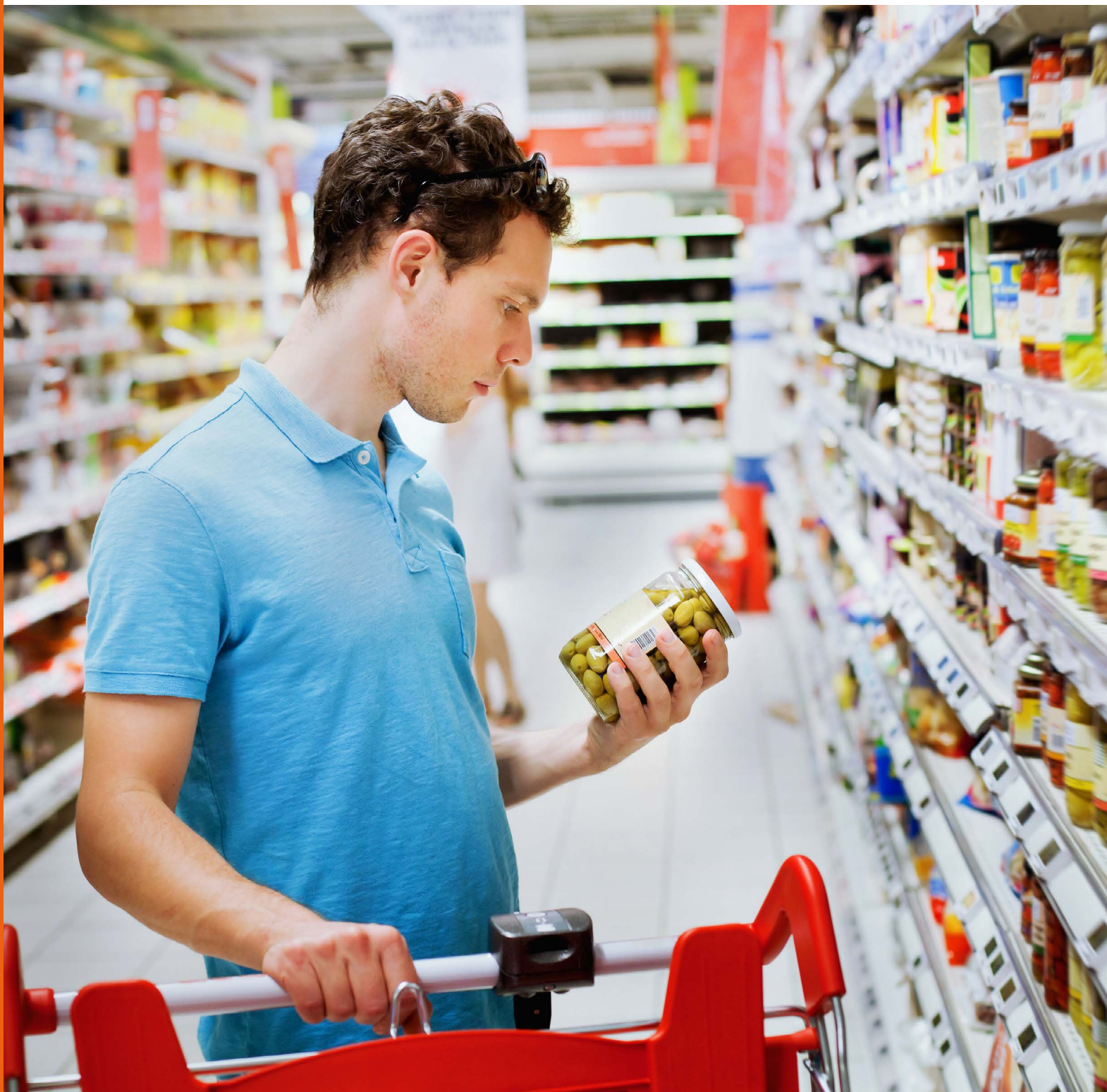


Information for those who wish to  
**Importing pre-packaged  
foods**







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# 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 on the Swedish Food Agency website. 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

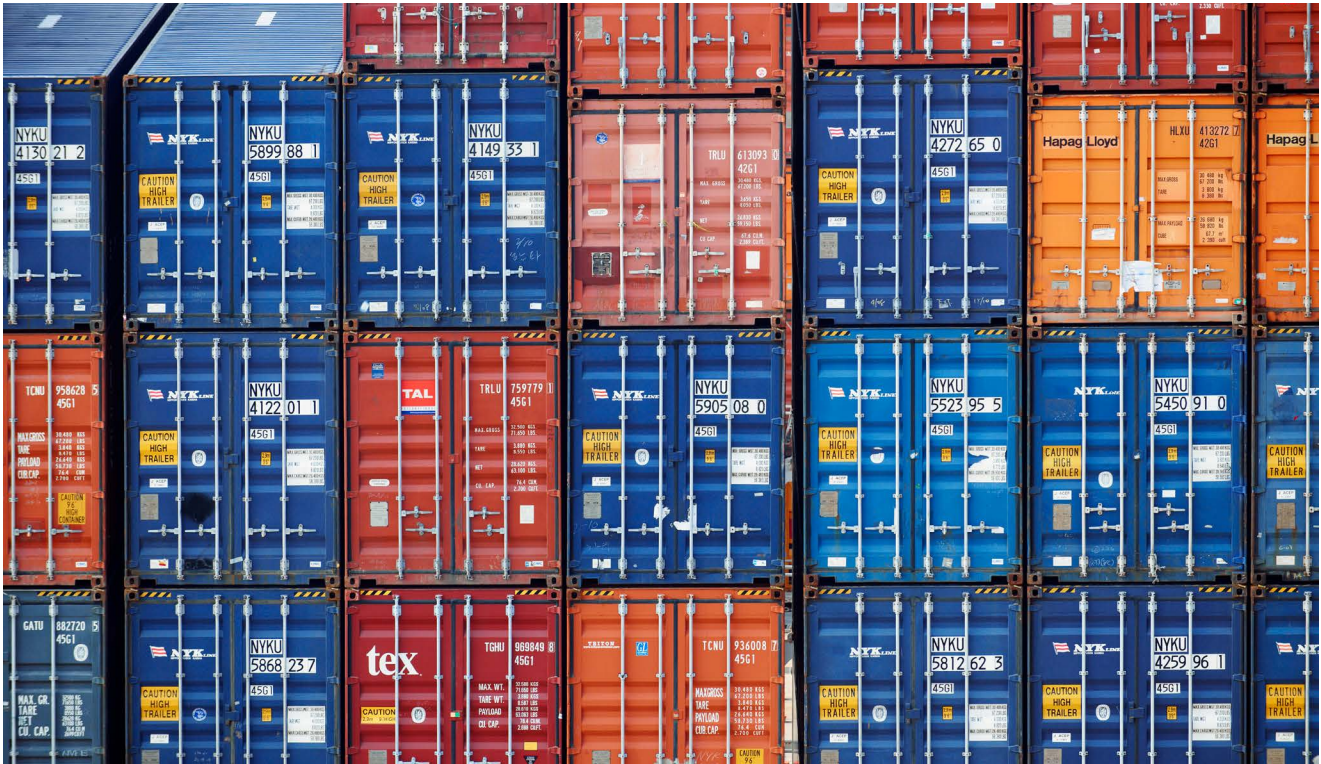
Legislation regarding food has two main aims:

- 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

**CHECKLIST FOR LABELLING OF FOOD**

Before you offer your goods for sale, go over the package’s labelling.

1. How should this particular product be labelled?
2. Has all mandatory information been included? It must be in Swedish. This shall be stated in Swedish.
3. Does the food contain any allergens? If so, ensure that they are correctly highlighted in the list of ingredients.
4. Are there any food additives, flavourings or smoke flavourings? Check that they are permitted within the EU and are correctly stated in the labelling.
5. Find out whether any of the product’s ingredients contain or have been produced using GMO and need to be labelled with information about this.
6. Are there any ingredients that can be considered to be novel foods?
7. Are there any ingredients that entail classification as a pharmaceutical?

# 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 Swedish 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
- quantitative indication
- 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 Swedish Food Agency information brochure "Labelling of pre-packaged foods" (in Swedish) or on [www.livsmedelsverket.se](http://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](http://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)





# The content of the products

## 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 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](http://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.livsmedelverket.se](http://www.livsmedelverket.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 Swedish Food Agency border inspectors.

### **Novel foods must be approved**

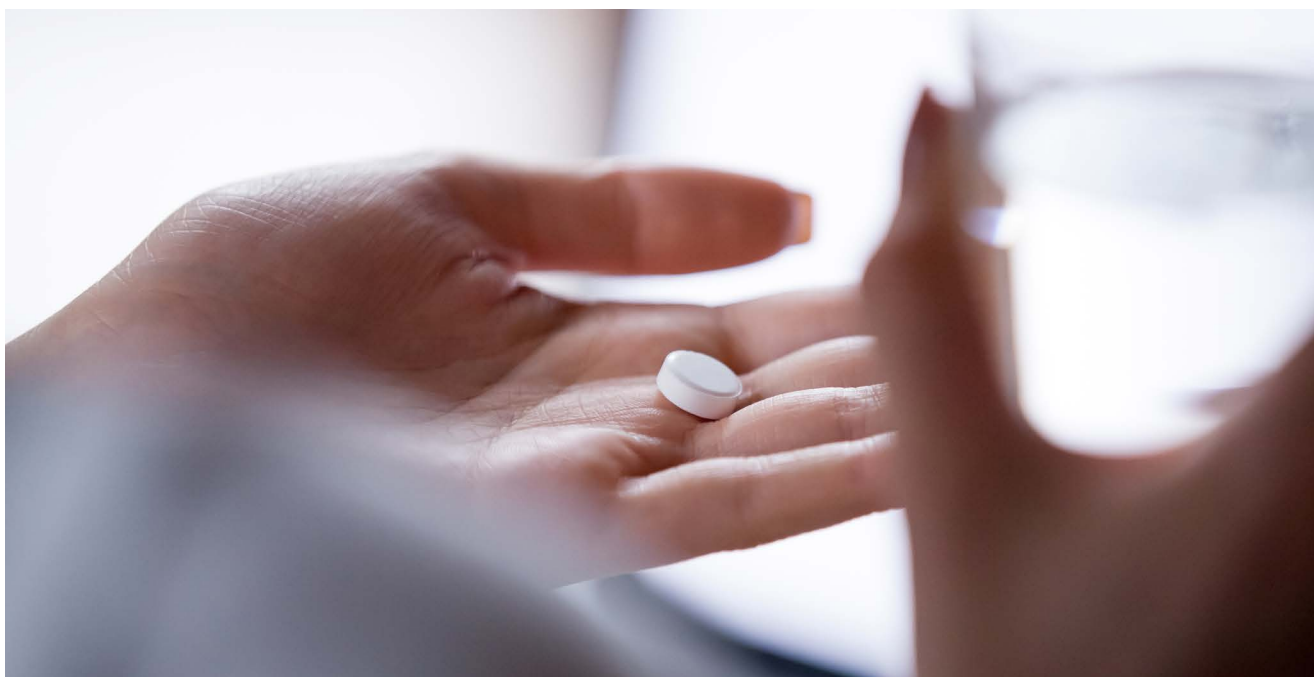
There are rules governing novel foods within the EU. According to the rules, foods that were unavailable on the EU market before May 15, 1997 are to be treated as 'novel'. It may thus be the case that foods or ingredients that have been consumed outside the EU for centuries are not approved for use within 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.livsmedelverket.se](http://www.livsmedelverket.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.

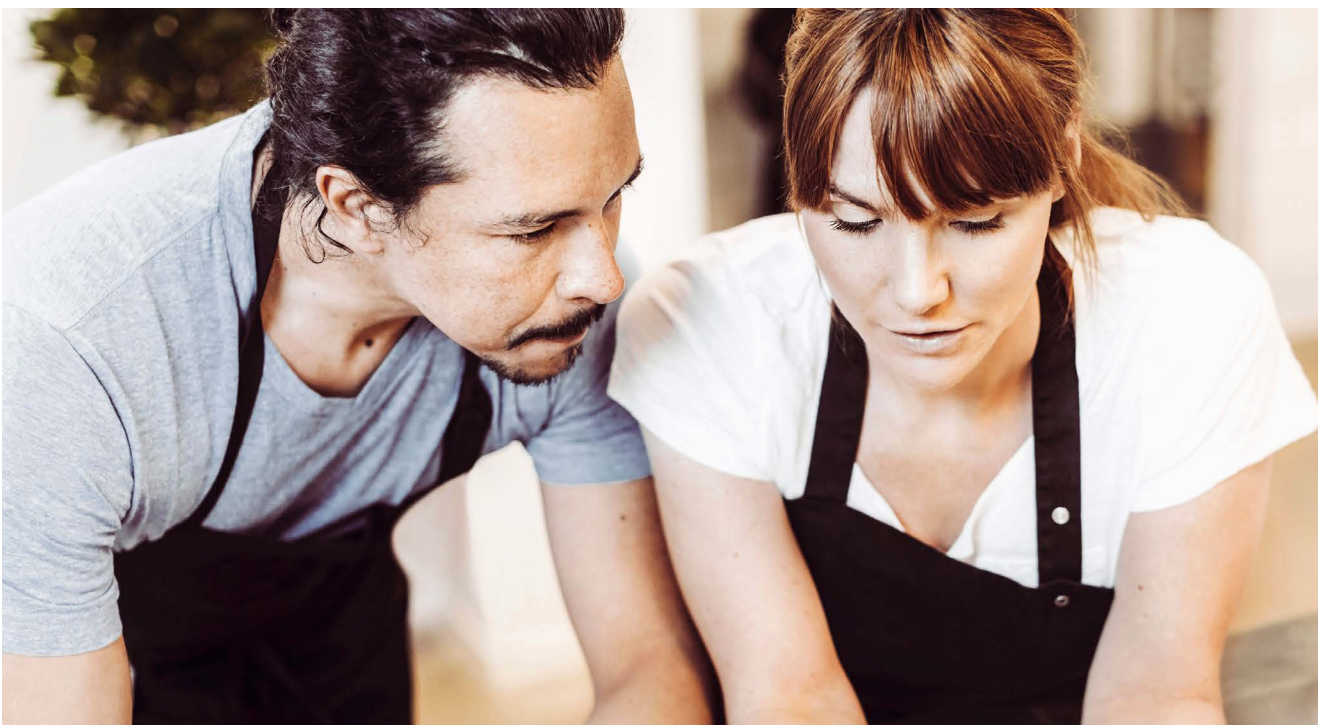
If you suspect that any of the food you sell is unsafe, you must inform your customers and the control authorities of this.

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).

### READ MORE

Read more about traceability and recall at [www.livsmedelsverket.se](http://www.livsmedelsverket.se).







# 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 by the competent local authority randomly.

## 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 control at one of the EU border control post. Border control posts in Sweden may only handle foods of animal origin that are pre-packaged. A pre-notification of the goods must be made one working day before the goods reach Sweden's borders.

Pre-notification is made via the web-based TRACES.NT (Trade Control and Expert System New Technology) 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 official certificate for the goods. Lists of approved establishments can be found on the Swedish 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 Swedish Food Agency border inspectors carry out the import control and pre-notification must be made via the web-based TRACES.NT (Trade Control and Expert System New Technology) system.

# 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.

All composite products need to be border controlled, except those that are listed on a so called exemption list, the annex in regulation (EU) 2021/630. But these composite products have to be accompanied by a so called private attestation, signed by the importer, and checked by the municipality when released for free circulation on the EU market. All composite products need to have ingredients of animal origin, that originate from establishments and countries outside EU, that are approved to export to EU. If this is not fulfilled the composite product is not allowed to enter the EU market.

The Swedish Food Agency helps to assess whether or not a product should be inspected at the border or if the product is banned to be imported.

Complete information about import of composite products you find in English on the website of the EU-Commission, linked to at the webpage of the Swedish Food Agency.

## Protective measures

The EU Commission sometimes makes decisions regarding special protective measures in order to protect both humans and animals from contagious 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.

### READ MORE

Read more about imports and other relevant areas on the Swedish Food Agency website (also available in English) [www.livsmedelsverket.se](http://www.livsmedelsverket.se) and [www.kontrollwiki.livsmedelsverket.se](http://www.kontrollwiki.livsmedelsverket.se) (Swedish only)

### In brochures

(in Swedish at [www.livsmedelsverket.se](http://www.livsmedelsverket.se))

- Labelling of pre-packaged foods (Okt 2017)
- Protected designations (May 2014)





## **In legislation, guidelines and other information (links may be found at [www.livsmedelsverket.se](http://www.livsmedelsverket.se))**

### **On foodstuffs and hygiene**

- Regulation (EC) No 178/2002 on general principles and requirements of food law concerns all food operators, even those that handle foodstuffs despite not running a food business.
- The Commission’s guidelines to Regulation (EC) no. 178/2002
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs. For those that sell pre-packaged food, it is good to know the content of this regulation in order to know what hygiene requirements are placed on the subsuppliers.
- The Commission’s guidelines to Regulation (EC) No 852/2002
- Regulation (EC) No 853/2004 on laying down specific hygiene rules for food of animal origin. For those that sell pre-packaged food of animal origin, it is good to know the content of this regulation in order to know what hygiene requirements are placed on the subsuppliers.
- The Commission’s guidelines to Regulation (EC) No 853/2002

### **On labelling**

- Regulation (EC) No 1169/2011 on the provision of food information to consumers
- The Swedish Food Agency’s provisions LIVSFS 2014:4 on food information
- Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

### **On food additives**

- Regulation (EC) No 1333/2008 on food additives

### **On flavourings**

- Regulation (EC) No 1334/2008 on flavourings
- Regulation (EC) No 2065/2003 on smoke flavourings

### **On nutrition and health claims**

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

### **On GMO**

Regulation (EC) No 1829/2003 on genetically modified food and feed

### **On food supplements**

The Swedish Food Agency’s regulations for food supplements LIVSFS 2003:9

### **On allergy**

Allergy and other intolerance – handling and labelling of foods. The industry organisation Swedish Food Federation (Li) has guidelines that describe how the label “may contain traces of” should be designed and under what conditions it can be used.



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