

Insects as food



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1 INTRODUCTION

Consumer and business interest in the rearing and consumption of insects has increased over the last few years. Insects offer a new source of protein for both food and feed uses. The diverse nutritional content of insects has also become a focus for interest and research.

This guide is intended for food control authorities, primary producers of insects and businesses producing food from insects. The guide will be updated as needed, for example in case of changes in interpretation or legislation or after the transitional period specified in the regulation on novel foods has ended. The changes to the previous version of the guideline will be listed at the end of the guide

This instruction clarifies the requirements of the EU and national food legislation and the responsibilities of both the operators in the food chain and the control authorities. The guide also contains some of the requirements related to animal welfare and the control of feed and by-products. In addition to this guide the operator has to take into account any other legislation that applies to their operation, such as protection of the environment and wildlife, waste management and construction.

The guide only covers whole, reared insects intended for human consumption and the related activities within the food sector which are subjected to food controls. Insects gathered in the wild are not to be sold, marketed or presented as food.

2 VALIDITY OF THE GUIDE

The actions of an authority must be based on the powers granted to it by legislation, and the laws must be strictly adhered to in the activities performed as a public authority. By their legal nature, instructions issued by authorities are not binding on other authorities or operators. Issues concerning application of legislation are ultimately settled in a court of law.

This instruction includes both direct quotations from the legislation and interpretations of the application of the legislation. Direct quotations from a legislative text are written in *italics*. The interpretations presented in this guide are Evira's opinion of how the legislation should be applied.

3 LEGISLATION ON NOVEL FOODS

3.1 Whole Insects as Food

The wording "food ingredients isolated from animals" in article 1 of the former regulation on novel foods (EC) No 258/97 was considered to be open to interpretation. In some member states the wording was interpreted to mean that whole animals were not covered by the leg-

isolation on novel foods. In these countries it was therefore possible to produce, sell and market whole insects as food.

In September 2017 the Ministry of Agriculture and Forestry made representation to Evira that the interpretation of the regulation on novel foods ((EC) No 258/97) should be changed so that whole insects are not considered to be covered by the regulation. With the change of the interpretation, insect production was legally considered as food production and insects as legal foods, and therefore all of the requirements and controls according to the food legislation apply. The interpretation applies to whole insects only (definition in section 5).

3.2 The Regulation on Novel Foods (EU) 2015/2283 (fully applicable from 1.1.2018)

The regulation on novel foods has been revised. The new regulation of the European Parliament and of the Council on novel foods (EU) 2015/2283 entered into force at the end of 2015 and will be implemented in full as from 1.1.2018. It replaces the current regulation on novel foods (EC) No 258/97.

Foods which consist of, are isolated or produced from animals, and which have not been used for human consumption to a significant degree within the Community before 15.5.1997, are covered by the regulation on novel foods. Therefore, insects as they are defined in section 5 in this guideline and foods containing insects are novel foods as from 1.1.2018 and the entry into the market requires authorisation. After 1.1.2019 only such insect species and food produced from those species for which an application for novel food has been submitted to the European Commission by that date can be marketed.

The new regulation has taken into account the problem with the non-uniform interpretation regarding insects within the member states. According to article 35 of the regulation, so called transitional measures will be applied for foods not falling within the scope of Regulation (EC) No 258/97, and which are lawfully placed on the market by 1 January 2018 and fall within the scope of regulation (EU) 2015/2283 (such as whole insects).

3.2.1 Transitional Measures

All whole, reared insects or foods containing such, which are placed legally on the market by 1.1.2018 (definition in section 5) may remain on the market after 1.1.2018 provided that a request in accordance with the regulation on novel foods has been submitted to the Commission by 1.1.2019. The marketing of these insect species can continue until the Commission makes a decision on the matter. The authorisation for sales and marketing is valid for the transitional period (2.1.2018–1.1.2019). The authorisation is made for a specific insect species and all operators can use it.

The application can be made for a certain insect species and for all foods containing that insect or only the insect in question or only a particular food containing that insect. The object of the application is defined by the operator who files the application. A separate application does not have to be filed by every operator if the product is already covered in an applica-

tion. Applications can also be compiled in co-operation between several operators. The application does not have to be filed by a Finnish operator.

Evira is the authority to contact in Finland. Evira puts information on the filed applications on the Authority's home pages as it becomes available. Evira also compiles the information on which insect species are legally on the market by 1.1.2018.

The Commission has issued implementing regulations on the information required for the applications and on notifications of traditional foods of third countries. The guidelines compiled by the Commission on how to file applications as necessary are found on the pages of the Commission https://ec.europa.eu/food/safety/novel_food/e-submission_en.

3.2.2 List of Species

All insect species which have been legally placed on the market as food in Finland or another EU country before 1.1.2018 can be marketed in Finland between 1.1.2018 and 1.1. 2019. The register maintained by Evira on the approved insect species is found on Evira's pages <https://www.evira.fi/en/foodstuff/manufacture-and-sales/food-categories/insects-as-food/list-of-permitted-species/>. All operators may sell and market these insect species and products produced from them as foodstuffs. An application for use as novel food has to be submitted also for these insect species to the Commission by 1.1.2019 so that they can remain on the market after 1.1.2019.

4 RESPONSIBILITY OF THE OPERATOR

The national or the EU food legislation does not currently cover the requirements specifically for insects. The general requirements of the food legislation and the controls are applied to insect production. The operators are responsible for the safety of their products in accordance with the Food Act and for the correctness of the information given. The responsibility of the operator is emphasized especially when there is no specific legislation applying to insects. Animal welfare, hygiene practices and the information given to consumers are central to the operation.

5 DEFINITIONS

Primary production means the production, rearing or growing of primary products including harvesting, milking and all stages of animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products. Also transport, storage and handling of primary products at the place of production are considered to be part of primary production, provided that this does not substantially alter their nature. Transport of live animals is also considered to be primary production.

Animal by-products means dead animals or parts thereof and other products obtained from animals which are not intended for human consumption.

Former foodstuffs means former foodstuffs of animal origin or foodstuffs containing products of animal origin which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects (e.g. the package gets broken, the date is exceeded, labelling errors, the cold chain is broken) which do not represent any risk to humans or animals.

Food made from insects means food which contains an insect/insects.

Insects in this guide means only whole, reared insects intended for human consumption. Whole insects can be crushed, ground or dried but no parts are to be removed from them (e.g. wings, legs, heads or intestines). It is not permitted to isolate or extract for example protein or lipid fractions. Such products are novel foods which require authorisation.

Placing insects on the market means the holding of food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves ((EC) No 178/2002). Whole, cultivated insects are to be placed on the market by 1.1.2018. If the insects are placed on the market in an EU country where they are considered to be legal foods and their cultivation has been submitted to food controls, the species on these markets are included in the list for the transitional period. The operator has to be able to demonstrate that the insects used for food were placed on the market by 1.1.2018.

Freezing means a less regulated method than deep-freezing, which depending on the capacity of the equipment used for freezing can be considerably slower than deep-freezing. Freezing is carried out for example in a freezer intended for the home kitchen.

Fasting means to stop feeding the insects before they are killed.

Feed means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding of animals.

Feed additives means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water to for example favourably affect the characteristics of feed or animal products and the environmental consequences of animal production with the aim of meeting the nutritional needs of the animals in order to enhance animal production.

Catering waste means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

Transitional period means the period 2.1.2018–1.1.2019, during which only insect species on Evira's list can be used as food or as ingredients in food.

Trend monitoring means continual monitoring, assessment and comparison with previous results of the analyses of the operator's own-checks.

Novel foods mean foods that have not been used for human consumption to a significant degree within the EU before 15.5.1997. It must be ensured that foods of which there is no previous experience within the EU are safe to use before they are approved. Insects, for example, are novel foods, as there is no significant history on the use of insects as food in the EU prior to 1997.

Composite foods and **composite products** mean foods which contain ingredients from both plants and processed ingredients of animal origin and in which both ingredients are used also for other purposes than for flavouring food. For example, pizzas and protein bars containing insects are composite products and not foods of animal origin.

6 PRIMARY PRODUCTION

The definition of primary production in article 3(17) of regulation (EC) No 178/2002 is as follows: *"Primary production" means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.* Also transport, storage and handling of primary products at the place of production are considered to be part of primary production, provided that this does not substantially alter their nature. Transport of live animals is also considered to be primary production.

In insect production, primary production means rearing of insects, possible transports of live insects and other measures until the termination of the insects. The actual termination of the insects is also considered as primary production when they are killed by way of freezing or deep-freezing.

Further processing of insects into products is no longer considered to be primary production as boiling, roasting, grinding and other processing changes the nature of the primary product.

If methods such as boiling, steaming or chopping are used to kill the insects, the nature of the primary product changes considerably and the operation is no longer primary production. A notification for food premises will then be required for the operation.

The primary producer can also sell killed insects as food directly to the consumer, for example from the farm or at the market. If the primary producer sells the killed insects and the value of the sale is no more than 10 000 euros a year, a notification for food premises is not necessary, as the small scale sales in conjunction with the primary production is not then considered to be a means of livelihood.

As the microbiological food safety risks with insects are not yet completely known, the insects used for food have to be heated at some stage of the processing. If the insects are to be sold unheated, frozen, there has to be instructions on the package, for example "heat the insects to at least 75 °C throughout before consumption".

Insects that have died naturally or other by-products shall be prevented from being included as foodstuffs as much as possible.

Rearing and sale/release of whole live, frozen, dried or ground insects for feed is primary production of feed which is feed business operation. Insects that have died naturally are not permitted to be used for feed.

The rearing containers and similar used for the insects have to be manufactured using chemically safe materials. Even though rearing boxes for live insects are not actual packaging and food contact materials, good practice to care for their safety is to acquire containers for insect rearing that are made from materials suited for food contact. The marketing name of the container (such as a storage carton for food) can inform of its intended use for food purposes or the bowl-and-fork symbol on the container itself or on the label. When requested, it is also the duty of the seller of the container to inform whether it is intended to come into contact with food.

6.1 Notifications and Registrations

An operator who rears insects for food uses, that is the primary producer, has to notify the municipal food control authority of the place of primary production before any activities are undertaken. If the producer is already involved in primary production, for example rearing of pigs or greenhouse production, the producer has to make an addendum to their existing notification of place of primary production, where the producer notifies that they are going to start production of insects as food. The addendum can be made as a written notification in free format to the municipal food safety authority.

Honey producers also have to add production of bees for food to their notification of place of primary production even though they already have filed a notification of primary production for the production of honey. Bee production has, though, been covered by the controls of primary production and therefore for example drone larvae which have been stored frozen can be sold from the beginning of November 2017 and processed into food.

Notification of the new activity has to be filed in good time in writing or electronically before the activities are undertaken. The operator also has to notify any substantial changes to the information mentioned above, suspension of the operation for more than a year or closure of the operation. The notification has to be filed at the latest when the changes come into force. Insects that were reared before filing the notification for primary production cannot be used as food.

The operator has to supply the following information in their notification (Government Decree on food controls 420/2011, section 2):

- name and address of the operator and other necessary contact details;
- the operator's business ID, the ID of the holding or customer ID or, if these are not available, personal identity code;
- the address of the place of primary production and name if needed; and

- information on the nature of the operation, that is the primary production operation carried out at the place of primary production and the scale of the operation.

The notification can be made on a form supplied by the municipality or on Evira's form. The notification can be written in free format, but the information mentioned above has to be included. The notification has to be supplied to the municipal food control authority. There is more information in Finnish on filing a notification of a place of primary production on Evira's pages <https://www.evira.fi/elintarvikkeet/alkutuotanto/alkutuotantopaikasta-ilmoittaminen/>.

An operator in primary production does not have to file a separate notification on the transport from the place of primary production when the products are produced by the operator.

An operator within the food sector who transports products from primary production away from the place of primary production to the first food premises has to notify the authorities of the transport operation (notification of primary production; transport operation) unless the municipal food control authority has been notified of the transport operation in conjunction with the notification of another activity (e.g. notification of food premises). The transport of products of primary production to the first premises is transport of products from primary production even if the transporter or another operator would buy the products at the place of primary production.

Even if insects are reared solely for use as food, the primary producer has to register as an operator in primary production within the feed sector. This is because insects are fed with feed, and the use of feed and their safety are covered by feed legislation. The registration as a feed business operator in primary production is carried out with so-called F form, which is found in Finnish on Evira's pages at the address <https://www.evira.fi/elaimet/rehut/rehualan-toiminta/lomakkeet/>. Feed business operators are registered as well as controlled by Evira. The requirement to register is related to the rearing of insects for food and feed uses.

6.2 Hygiene Requirements for Primary Production

The operator has to ensure that the place of primary production, the activities there and the foods produced fulfil the legal requirements. The operator also has to ensure that food safety is not compromised.

The hygiene requirements for primary production are found in the regulation on the hygiene of foodstuffs ((EC) No 852/2004) and in the decree of the Ministry of Agriculture and Forestry on the food hygiene of foods from primary production (1368/2011, the so-called decree on primary production). In addition to these, primary production is also covered by the EU and national legislation for the food sector (e.g. the general food regulation (EC) No 178/2002 and the Food Act 23/2006). This legislation also applies to the primary production of insects.

Description of the own-check

Own-check means the operator's own control system which is used by the operator to ensure that the foods fulfil the set requirements and that the products from primary production are safe.

The description of the own-check is the producer's description of how the hygiene requirements laid down in II, part A of Annex I to the regulation on the hygiene on foodstuffs are realised in the operation. The description should give a clear picture of the hygiene practices in use in the operation. This description of the own-check is used by the producer to demonstrate how they control the hazards of the operation. The description does not require recording of tasks performed on a regular basis. The description can be an oral summary of the practices in the operation, but if necessary the producer can also be required to give a written description of their own-check.

The contents of the description of the own-check of animal production (incl. insect production) to the parts that relate to the activities at the place of primary production (see examples below):

1. Cleaning and disinfection of the premises as needed
 - production, processing and storage premises for the insects
 - storage and processing premises for feed
2. Cleaning and disinfection of equipment, containers, cages, fishing vessels and vehicles as needed
 - cleaning of the rearing boxes at least between each batch
 - regular cleaning of drinking equipment
3. Ensuring as much as possible that the production animals are clean
 - removal of decaying material from the rearing substrates during rearing
4. Usage of clean water or water intended for human consumption always when needed in order to avoid contamination
 - drinking water for the insects
 - water used for cleaning
 - see further down in this section
5. Ensuring good health of the staff and training staff on health hazards
 - instructions for the staff, such as:
 - the staff must not work in food production when unwell (e.g. upset stomach)
 - hands should be washed carefully before starting work and when needed during work and between different stages of work, always after using the toilet, after smoking or coughing, sneezing or blowing one's nose
6. Preventing contamination caused by animals and pests
 - see further down in this section
7. Storage and correct handling of waste and hazardous agents (e.g. disinfectants)
 - contamination of food as well as accidents have to be prevented
8. Prevention of the introduction and spread of contagious diseases
 - when bringing new insects to the premises where insects are reared
 - by reporting suspected infectious diseases to the local food control authority
9. Taking into consideration of the results of samples taken from animals and other samples of significance for human health

- taking action based on the results of the analyses when necessary
10. Using feed additives and veterinary medicinal products correctly in accordance with the relevant legislation.

If the operation has both primary production and food processing, the own-check can be partly shared by both activities.

Only clean water can be used at the place of primary production as drinking water for the insects, for irrigating, cleaning and cooling products in primary production and for cleaning and rinsing of the surfaces, floors and equipment of the place of primary production. The water is not to have an odd smell or taste or micro-organisms, parasites or contaminants so that the water could risk the safety of the products of primary production or the foods originating from them.

Pests and other animals, such as pets, must be prevented from contaminating food. The primary means of prevention is solid constructions and nets on the windows and vents. Section 6.6 of this instruction deals with how to prevent the reared insects from escaping from the premises where they are reared and processed.

The rearing platforms or other materials used for rearing are not to be a risk for food safety. Used chicken egg containers are for example not to be used as rearing platforms.

Insects that have been frozen in primary production have to be stored and transported at a temperature of -12 °C or colder.

Traceability and record keeping

In order to ensure traceability, the primary producer of the insects has to keep the records of the insects received and of the insects despatched from the place of primary production for use as food.

At least the following information has to be recorded for insects despatched from the place of primary production for use as food:

1. the name and address of the customer (is not required when sold directly to the consumer)
2. the name of the product (incl. the scientific name of the insects species)
3. date of dispatch and time if needed
4. quantity delivered.

The requirement can be fulfilled by for example keeping the receipts of sale and purchase, which is supplemented with the information mentioned above when needed. The records must be kept for a minimum of one year.

In primary production, records have to be kept on the following in accordance with the general regulation on the hygiene of foodstuffs:

1. the nature and quantity of feed fed to the insects
2. veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods (for example medication of bees)

3. the occurrence of diseases that may affect the safety of products of animal origin
4. the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health (for example samples taken from insects in primary production and any water analyses)
5. all relevant reports on checks carried out on animals or products of animal origin (for example inspection protocols carried out by the food control authority)

The records are to be made available to the control authority on request. As a rule, the records have to be retained for at least three years, but the records on feed and medication have to be retained for five years.

Cultivation of insects in conjunction with other primary production

In principle, it is not possible to cultivate insects and plants side by side in the same greenhouse as it is difficult to organise the operation so that food safety is not endangered. Dust from feed and straw formed in conjunction with the cultivation of crickets will inevitably spread over plants grown on the same premises and any pesticides/insect sprays used during the cultivation of the plants are a food safety risk when cultivating insects. The possible escape of insects from the cultivation boxes to the cultivated plants will also cause problems. If the greenhouse is on soil, there will inevitably also be other insects on the premises which will easily mix with the cultivated insects. They may also potentially transfer disease to the cultivated insects.

Seasonal cultivation could potentially come into question. In this case for example crickets and plants could be grown during different seasons without actual risks involved, if the premises are otherwise suited for both of these.

6.3 Feed for Insects

Feed materials of vegetable origin, mineral compounds, milk and egg products, hydrolysed protein and gelatine derived from animals other than ruminants, fish meal and former food-stuffs which do not contain meat or fish as mentioned in the Catalogue of feed materials (EU/2017/1017) can be used in feeding of insects. It is not permitted to rear insects for use as food or feed using for example with food waste/bio waste, other waste (including slaughterhouse waste and fish scraps) or manure. Food waste/bio waste does not mean products of vegetable origin specified to be used as feed, for example vegetables from institutional kitchens or restaurants that have not been served as food, or parts of vegetables that have been gathered separately in the industry.

Feed additives approved in the EU can be used in feeding for insects (the European Union Register of Feed Additives) https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en. In some categories of feed additives the approval is specific for certain animal species, such as the additives category which affects animal production (for example enzymes and micro-organisms) and for example colouring agents. At this time, not one feed additive has been approved specifically for insects. However, there are plenty of so called generic feed additives, such as technological additives and additives intended for the feeding

of all animal species, such as nutritional additives like vitamins and trace elements, which can be used to feed insects.

Salmonella or forbidden substances are not allowed to occur in feed for insects. The amount of harmful substances in feed cannot exceed the maximum limits determined in the legislation. Feed has to be of good quality and suitable for feeding insects. Nothing spoiled (for example mouldy vegetables) is suitable as feed. The insects' drinking water also has to be of good quality. There is more information on feed legislation in Finnish on Evira's pages <https://www.evira.fi/elaimet/rehut/lainsaadanto/>.

Feed for the insects grown for food or feed has to be obtained from a registered feed business operator. Foods (such as vegetables) suited for feed can also be used as feed. An operator who supplies food for feed use has to register as a feed business operator, as the operation is covered by the feed legislation, and feed for food producing animals can only be obtained from a registered food business operator. The lists of the registered feed business operators in primary production and other operators are available on Evira's pages <https://www.evira.fi/en/animals/feed/>. Records have to be kept on the purchased supply and use of feed (a model form for record keeping for primary production in the feed sector in Finnish <https://www.evira.fi/elaimet/rehut/rehualan-toiminta/lomakkeet/>).

Insects can be used as feed. There is more information on the use of insects as feed and on the other feed business operations than primary production on Evira's internet pages in Finnish https://www.evira.fi/globalassets/elaimet/rehut/tiedotteet/tied2017/tiedote_3740_0405_2017.pdf.

6.4 Animal Welfare

The keeping and killing of insects is regulated by the Animal Welfare Act (247/1996) and the Animal Welfare Decree (396/1996). In addition, the Animal Transport Act (1429/2006) applies as appropriate to transports of live invertebrate animals. Because there are no detailed requirements in the legislation on animal protection on the keeping and treatment of different insect species, it has to be assessed on a case-by-case basis whether the operation is in accordance with the law. The hygiene requirements for primary production sets out the requirements for the conditions in the place where the insects are kept. These will also affect the welfare of the animals.

The legislation on animal welfare does not contain detailed requirements on the keeping, care or treatment of bees, so the requirements come from the general requirements. Animals have to be treated well and it is not permitted to cause them unnecessary distress, pain or suffering. In addition, maintaining the health of the animals must be promoted when keeping animals and the physiological and behavioural needs of the animals must be taken into account.

The keeping, care and treatment of the animal has to be organised in such a way that the needs of the species in question are taken into account. The animal premises must have sufficient space and lighting and it must be protective, clean and safe as well as appropriate in other respects taking into account the needs of each animal species. The risk of escape from the premises must be as low as possible. An animal may not be left without care or abandoned. It must obtain suitable feed, drink and other necessary care in sufficient quantities. The welfare and conditions of the animal must be checked often enough.

The killing of an animal must be performed as quickly and painlessly as possible using a method and techniques suited for the killing of that animal. An animal can only be killed by a person who has sufficient knowledge and skills for the killing of the species in question. The competency of the person who kills the animal is assessed on a case-by-case basis. The operator has to ensure that the method of killing is suited for the animal species in question and that it causes as little suffering as possible for the animals that are to be killed. When killing animals it also has to be ensured that the efficiency of the method used remains at a high level all the time and that too many animals are not put into the killing equipment at once.

It is recommended that the welfare of the animals is documented as a part of the plan for own-checks and that it describes how the welfare of the animals is ensured during the different stages of the cultivation and especially when the animals are killed.

6.5 Animal Health and Animal Diseases

The keeping of insects is also subject to the Animal Diseases Act (441/2013). The legislation on animal diseases mainly only concerns diseases which are classified as animal diseases which must be combated or animal diseases which must be reported as specified in the degree of the Ministry of Agriculture and Forestry (843/2013). So far, no diseases of any insects other than bees (*Apis mellifera* and *Bombus spp.*) are classified as animal diseases that must be combated or that must be reported.

The keeper of insects is obliged to notify the municipal veterinary officer if they suspect that the animals have a serious animal disease. In practice, a disease has to be notified in case of a major disease event or mass death amongst the insects that cannot be explained by environmental factors. When it comes to bees, the duty to notify also pertains to the small hive beetle (*Aethina tumida*), Tropilaelaps mites or American foulbrood (*Paenibacillus larvae*). On the autonomous province of Åland, a notification also has to be made in case of suspected infection with Varroa mite.

An operator responsible for insects who suspects that their animals have a serious animal disease also has to keep the diseased insects separate from the other animals on the holding, and avoid moving animals, products, goods and substances that might be spreading the disease until the Regional State Administrative Agency has decided on which further measures to take.

6.6 Invasive Alien Species

Insect producers shall ensure that the insects they cultivate cannot be released into the wild or into the environment elsewhere. According to the Act on Managing the Risks Caused by Invasive Alien Species (1709/2015) an invasive alien species shall not be kept, bred, planted or sown or otherwise handled in a way that it may be released into the environment (Section 3). The ELY Centres (Centres for Economic Development, Transport and the Environment) supervise the compliance with the Act. The ELY Centres can also order someone who intentionally or through negligence releases into the environment an invasive alien species to eradicate the species released into the environment (Section 17). If the escaped individuals cause damage or harm, to for example buildings or cultivations, the operator may also be liable to pay damages in accordance with the Tort Liability Act (412/1974).

The rearing and handling of live insects requires that care be taken and that safety measures are adhered to in order to ensure that no live insects spread outside the premises where the insects are reared and handled.

6.7 Organic Production

At the moment, food and feed produced from insects in Finland cannot be marketed as organic.

No common provisions for organic rearing of insects have been defined for the European Union at this stage. Therefore, the production of insects cannot yet be in this connection and no claims referring to organic production can be used for the end products.

It may be possible to buy organic food and feed made from insects or raw materials from other countries, if the country in question has established a standard for the insect species cultivated. These foods and feeds can be marketed also in Finland as organic.

6.8 Processing Requirements for Animal by-products

In insect production, animal by-products are parts of insects reared as production animals, insects that have died naturally, insect eggs, skins of larvae, pupae and excrements (manure). Manure means the excrements of insects which also can contain rearing platform, uneaten feed, parts of insects or insects that have died naturally. Animal by-products are classified according to the risk for animal diseases. Parts of insects, insect eggs, skins of larvae, pupae and insects that have died naturally and are not suspected to have died from an animal disease are considered to be category 3 material. Insects that have died from or been killed due to an animal disease are category 2 material. Manure is always category 2 material.

Extra care has to be taken when processing animal by-products from insect production in order to avoid live insects or individuals at the different stages of development or their eggs from ending up in the environment. The animal by-products have to be inactivated, that is

processed in order to destroy viable individuals and eggs. They can be inactivated for example by freezing, in the same way as insects intended to be used as food are killed. They can be frozen in a separate freezer or in the same freezer as insects that can be used as food. If the by-products are inactivated in the same freezer as insects to be used as food, there must be separate compartments or drawers for the animal by-products and the insects to be used as food. The animal by-product category and the mention “not for human consumption” must be noted on the animal by-product. The animal by-products are not to be mixed with insects intended to be used as food.

Animal by-products from insect production that are category 2 and category 3 material can be sent for disposal to a waste incineration plant or to a co-incineration plant that are approved under the environmental legislation. Category 2 manure can be sent to a plant approved in accordance with the legislation on animal by-products which incinerates manure from farmed animals. Category 3 animal by-products and manure of category 2 can also be processed in an approved biogas or composting plant. There is a list of approved plants on Evira’s pages in Finnish <https://www.evira.fi/yhteiset/elaimista-saatavat-sivutuotteet/laitosten-ja-toimijoiden-hyvaksynta-ja-rekisterointi/sivutuoteasetuksen-mukaisesti-hyvaksytyjen-tai-rekisteroitujen-laitosten-luettelo/>.

Foodstuffs containing insects which are no longer intended for human consumption for commercial reasons can be disposed of in the same way as the retailers other former foodstuffs. There is a guideline on the processing of former foodstuffs on Evira's pages in Finnish https://www.evira.fi/globalassets/tietoa-evirasta/lomakkeet-ja-ohjeet/elintarvikkeet/elintarvikehuoneistot/eviran_ohje_16088_7.pdf.

Manure from insects reared as farmed animals can be applied on the fields as such or composted, for example, if the manure does not constitute a risk of spreading a serious transmissible disease. The manure has to be stored and applied in accordance with the requirements in the environmental legislation.

After being inactivated, the animal by-products to be sent to an incineration plant as energy waste or to a biogas or composting plant can be put into the same receptacles as similar waste fractions to be forwarded on. Records have to be kept of quantities, animal by-product categories, times of delivery and the place of processing the animal by-products that are sent to incineration, composting or biogas plants.

7 ACTIVITIES ON REGISTERED FOOD PREMISES

The processing of insects into food and selling foods made from insects is a registered activity on food premises. This is preparation of food of animal origin, but approved establishments are not required for the activity, as there are no legislated specific requirements for insects in Annex III to Regulation (EC) No 853/2004.

As the insect sector is new and all of the risks related to the production of food made from insects are not yet known, neither the production and/or sales of food made with insects cannot be seen as a low risk operation. Therefore, all production and sales of food made from insects is an operation on food premises which requires approval and it is also monitored as an operation on food premises.

Food premises means any building or premises or a part of them or other outdoor or indoor space in which food meant for sale or conveyance is prepared, stored, transported, marketed, served or otherwise handled, but not a place of primary production.

In insect production, activities on registered food premises include all activity that significantly changes the nature of a product from primary production. Such activities are for example boiling, roasting, grinding and other processing. Killing is also considered as an activity on registered food premises when it is carried out by boiling, steaming or chopping.

There is more information on activities on registered food premises on Evira's pages in Finnish

<https://www.evira.fi/elintarvikkeet/valmistus-ja-myynti/elintarvikehuoneistot/ilmoitetut-elintarvikehuoneistot/>.

7.1 Notifications and Registrations

Operators processing and producing foods made from insects have to notify the municipal food control authority of the activities on the registered food premises before starting the operation.

Products that are made into something other than food (e.g. kitchen decorations) cannot be sold as food, as the cultivation of the insects and the processing of the products have not been subjected to food controls.

If food made from insects is processed or produced on existing, registered food premises, a new notification of the food premises or a notification of significant changes of the operation does not have to be made. Insects are simply raw materials such as for example eggs or milk. Here it is sufficient that the use of the new raw material is noted in the own-check plan.

7.2. Central Structural and Operational Requirements

The requirements set for registered food premises and the activities on those premises are laid down in Chapter II and Annex II to Regulation (EC) No 852/2004 and in the decree of the Ministry of Agriculture and Forestry on the food hygiene on food premises (1367/2011). This guideline contains the essential requirements.

Evira's guideline on food hygiene on registered food premises is found on Evira's pages in Finnish <https://www.evira.fi/globalassets/elintarvikkeet/elintarvikehuoneisto/ohje-ilmoitettujen-elintarvikehuoneistojen-elintarvikehygieniasta.pdf>.

7.2.1 Structural Requirements

Food premises have to be adequately separated from premises or operations that can risk or lessen the hygienic quality of foods that are processed on the food premises. For example boiling or roasting insects has to be structurally separated from the operations in primary production, as the dust caused during the cultivation of insects can contaminate the finished food.

The surface materials of the food premises and the materials of the working utensils and equipment have to be easy to keep clean and when necessary withstand washing with water and mechanical cleaning.

The staff must have facilities available for changing and keeping work clothing and they must also have toilets. The toilet door must not open directly into the production premises. With a small scale operation, the staff facilities and the toilet may be in a building other than the production premises, as long as this does not jeopardise food safety.

There has to be an adequate space for storing cleaning equipment, detergents and disinfectants and for cleaning and drying the cleaning equipment.

Premises where insects are processed into food have to have a sufficient number of water supplies including an adequately equipped spot for handwashing.

The production facilities are to have sufficient ventilation in order to remove steam.

If boiled insects are not put directly into the oven while they are still hot, there has to be sufficiently large cold stores for chilling and storing the boiled insects. Cold stores can be used also for chilling, but only if the storage and chilling can be separated by time or if the number of products to be chilled is so low that it doesn't cause a rise in temperature for the products that already are in the cold store.

7.2.2 Operational Requirements

Frozen insects have to be defrosted in a controlled manner without jeopardising food safety.

Frozen insects are not to be defrosted for storage. They are to be defrosted just before they are processed further.

Bacteria that form spores are a risk for foods made from insects. If boiled insects are not put hot into an oven directly after boiling, they have to be chilled in 4 hours to a temperature below +6 °C and stored at a temperature below +6 °C.

If there is a retail establishment in conjunction with the production facilities, the production facilities have to be kept separate from the retail establishment. The retail operation can be separated either structurally or temporally from the production, for example by carrying out production on the premises in the morning and sales in the afternoon. After the sales, the premises have to be cleaned and also disinfected if needed. They are to be dry before production begins.

7.3 Own-check Plan

The Food Act requires food business operators to prepare an own-check plan which contains a procedure for assessing and controlling the food safety hazards of the operation. Food business operators must possess sufficient and accurate information about the food they produce, process and distribute. In the own-check plan the operator clarifies how they supervise and comply with the rules related to the safety and quality of the foodstuffs they process.

The important stages in the acquisition, preparation, handling and storing of food from a food safety point-of-view and the measures to be taken to control the risks in these areas have to be presented in the own-check plan. It is the duty of the operator to adhere to the procedures recorded in their own-check plan for ensuring food safety.

Considering the nature of the operation, the own-check plan has to be sufficient and it has to be developed regularly as needed, for example when there is a change of activities.

The own-check plan and related record keeping can be fully or partly electronic documents. They are to be presented to the food control authority on request. The records of the own-checks have to be kept for a minimum of one year after the food was processed or after the indicated date of minimum durability has expired.

There is more information on own-checks on Evira's pages <https://www.evira.fi/en/shared-topics/own-checkown-check/>.

7.3.1 Labelling of Insects and Products Containing Insects

Only whole, reared and killed insects and products prepared from these can be marketed as food. Whole insects can be sold for example chilled, frozen or dried (for example freeze dried). Whole insects have to be easily identifiable. If the insects are sold unheated, there has to be instructions on the packaging advising the insects to be heated thoroughly before use. There is little information available on allergies and symptoms of hypersensitivity caused by insects. They can cause allergies and cross-reactions. Therefore, Evira recommends the following warning on packaging containing insects: *“Insects may cause allergic reactions. Cross-reactivity is possible if you are allergic to crustaceans, molluscs and/or dust mites.”* In addition, when needed, the packages should be labelled with the residual agents related to allergens and intolerances: *“may contain small quantities of xxxx”*. There is more information on the subject below in the section on the labelling of insects.

The food business operator responsible for the food information is the operator under whose name or business name the food is marketed. If that operator is not based in the Union, it is the operator who imports the products into the EU market.

Legislation

Labelling is compulsory for foods that are sold *to consumers or mass caterers*. Article 9 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council (the food information regulation) lists the mandatory general information that has to be written *on the packaging or the labelling of the food*. *The national legislation dictates* in which languages the mandatory labelling has to be written and how to assign the lot number (sections 4 and 5 to the Decree by the Ministry of Agriculture and Forestry 834/2014). Compulsory information on packaged food for sale or food being released otherwise in Finland has to be written in both Finnish and Swedish. Food that is sold or otherwise released in monolingual municipalities only needs to be labelled in the language of that municipality. If insects or products made from insects are sold frozen, the information listed in section 7 to the Decree by the Ministry of Agriculture and Forestry (818/2012) has to be displayed in addition to the general information on the label. Foods that are significant as to the intake of salt and are listed in the Decree by the Ministry of Agriculture and Forestry (1010/2014) have to be labelled as heavily salted. When foods are sold unpackaged, the decrees by the Ministry of Agriculture and Forestry should be adhered to (834/2014, 1010/2014).

In addition to the overall legislation, specific legislation has to be adhered to when needed, such as the Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (EC) No 1924/2006 and the legislation on food improvers (additives, aromas and enzymes) (for example the Regulation of the European Parliament and of the Council on food additives (EC) No 1333/2008).

The food business operators who deliver food to other food business operators which are not meant for the end consumer or for mass caterers, have to ensure that these other food business operators have sufficient information to fulfil their obligations.

Finnish Food Safety Authority Evira has published a guideline on information to be given on the food: Evira’s guideline 17068 Food information guide for food control authorities and

food business operators (“Pakkausmerkintäopas”, only in Finnish) <https://www.evira.fi/tietoa-evirasta/julkaisut/elintarvikkeet/opaat/>.

The following information has to be displayed on packaging which is intended for the consumer or mass caterers:

- the name of the food (e.g. “House Cricket” and in addition detailed information on the characteristics of the food, such as specific treatment, freeze-dried, pre-cooked etc. In addition, see Evira’s recommendation below)
- the net quantity
- the date of minimum durability or the ‘use by’ date
- the name and address of the responsible food business operator, trade name or auxiliary business name
- country of origin or point of departure whenever its absence is likely to mislead consumers
- storage instructions
- instructions for use (including a warning label, see below)
- identification of the food lot (expressions related to minimum durability such as “best before” and the date or the “use by” date instead of labelling the lot can be used provided that it is accompanied by at least the day and the month)
- nutrition labelling when needed, for example when whole insects are sold processed, boiled, dried or when they are turned into various products. If the insects are solely frozen or if they are sold defrosted, no nutrition labelling is required.
- use of packaging gas (when needed)
- heavily salted products (when needed).

Evira instructs that in addition to the information above, the following should be displayed on packaging containing insects:

- the *scientific name* of the insect species (for example “*Acheta domesticus*” for house cricket) and the indication “cultivated” or another similar expression in conjunction with the name of the food.
- instructions for use, which contain
 - a warning label which informs the consumer that “*Insects may cause allergic reactions. Cross-reactivity is possible if you are allergic to crustaceans, molluscs and/or dust mites.*”
 - advice on how whole insects are to be used, for example that insects are to be consumed fully cooked.
- Labelling regarding allergens “*may contain small amounts of xxxx*” when needed, for example when the intestines of the insects are not emptied of allergens or if the insects are contaminated otherwise by ingredients that are not part of the recipe. (Substances or products causing allergies or intolerances are listed in Annex II to the regulation on the provision of food information to consumers).

When it comes to *frozen insects*, the packaging of frozen products must be labelled with the following in addition to the general labelling:

Food Safety

Insects as food

- The word “frozen” or “frozen food”
- date of minimum durability (best before)
- a description of the storage conditions which indicates the storage temperature (e.g. - 18 °C or colder).
- The label “*Do not refreeze after thawing*”.

Evira also advises that if insects are used as one ingredient in the food preparation, the following has to be mentioned in addition to the general information on the label:

- in conjunction with the name of the food, complementing additional information stating that the product contains cultivated insects, in order to avoid the buyer being taken by surprise.
- in addition to the name of the insect, the scientific name of the species has to be listed in the list of ingredients.
- a warning label regarding the use of insects.

Example 1. Labelling of insects


KASVATETTUJA JAUHOMATOJA / ODLADE MJÖLMASKAR (*Tenebrio molitor*)

Pakaste / Djupfryst 200 g Pakattu vakuumiin / Förpackad i vakuum

Ei saa jäädyttää uudelleen sulatuksen jälkeen / Får inte frysas ner igen efter upptining

Alkuperämaa / Ursprungsland: Suomi

Säilytysohje / Förvaringsanvisning: - 18 °C tai kylmemmässä / -18 °C eller kallare

Käyttöohje / Bruksanvisning: Sulata tuote jääkaapissa tai huoneenlämmössä X tuntia ennen niiden valmistamista. Kypsennä jauhomadot kypsäksi (X °C ja X aika) ennen niiden käyttöä. / Uptina produkten i kylskåp eller vid rumstemperatur i X timmar innan beredning. Koka mjölmaskarna tills de är färdiga (X °C och X tid) före användning.

Hyönteiset voivat aiheuttaa allergisia reaktioita. Ristiallergia on mahdollinen henkilöillä, jotka ovat allergisia äyriäisille, nilviäisille ja / tai pölypunkeille. / Insekter kan förorsaka allergiska reaktioner. Korsallergi är möjlig hos personer som är allergiska mot kräftdjur, blötdjur och / eller husdammskvalster.

Erä / Parti: 1212 Parasta ennen 12.2018 loppua / Bäst före utgången av 12.2018

Valmistaja / Tillverkare: Yritys Oy, Yritystie 6, 00000 Paikkakunta

Example 2. Labelling of food containing insects

Pehmeä mustikkakeksi hyönteisillä 140 g / Mjuk blåbärskex med insekter 140 g

Ainekset: Mustikka (34%), **vehnä jauho**, hedelmäsokeri, kasvimargariini (kovetettu kasvirasva (rypsi), aromi), **kananmuna**, vesi, kuivattu kotisirkkajauhe (*Acheta domesticus*) 5,2%, **ohratärkkelys**, **kauralese**, suola, nostatusaine (E500), happamuuden säätöaineet (E330, E336) ja säilöntäaine (E202). Laktoositon.

Ingredienser: Blåbär (34%), **vetemjöl**, fruktsocker, vegetabiliskt margarin (härdat vegetabiliskt fett (ryps), arom), **ägg**, vatten, torkat hussyrsa (*Acheta domesticus*) -pulver, **kornstärkelse**, **havrekli**, salt, jäsningsmedel (E500), surhetsreglerande medel (E330, E336) och konserveringsmedel (E202). Laktosfri.

Hyönteiset voivat aiheuttaa allergisia reaktioita. Ristiallergia on mahdollinen henkilöillä, jotka ovat allergisia äyriäisille, nilviäisille ja / tai pölypunkeille. / Insekter kan förorsaka allergiska reaktioner. Korsallergi är möjlig hos personer som är allergiska mot kräftdjur, blötdjur och / eller husdammskvalster.

Parasta ennen: 12.12.2017 /
 Bäst före: 12.12.2017

Valmistaja / Tillverkare:
 Leipomo Oy,
 Osoitetie 1, 0000 Paikkakunta

Ravintosisältö / Näringsinnehåll / 100 g	
Energiaa / Energi	1450 kJ (340 kcal)
Rasvaa / Fett	16 g
josta tyydyttyneitä rasvahappoja / varav mättade fettsyror	
	7,3 g
Hiilihydraatteja / Kolhydrater	
	43 g
josta sokereita / varav sockerarter	
	23 g
Proteiinia / Protein	6,0 g
Suolaa / Salt	0,74 g

7.3.2 Allergens

Food made from insects may cause allergic reactions. Food allergens are proteins that trigger an immune response in the body. The symptoms of food allergy vary from a harmless itch in the mouth to life-threatening anaphylaxis. Food allergies can also cause skin symptoms and stomach pain. A food allergy can be caused by any food if a person is sensitive to it.

As with any food, you can also become sensitized to insect proteins and the use of insect proteins as food can lead to new allergies being developed. At the cultivation site it has to be ensured that individuals of one insect species cannot mix with another species, as a person can be allergic to one species but not another.

An allergic reaction to food made from insects may be caused if a person is sensitized to insects or as a result of cross reactivity. Cross reactivity means allergy symptoms that are caused by plants, animals or invertebrates belonging to different genera after a person has become sensitised to one of them. It is unclear how for example the food of the mealworm affects the potential for allergies (the intestine of the mealworm is not emptied). This may increase the risk for an allergic reaction for those who are allergic to the proteins that occur in the food of the mealworm. General allergens such as for example grain containing gluten, fish meal, milk and egg products can be used for the cultivation of insects. It is not known what the potential additional risks (depending on what food it consumes) are with the feeding of mealworms (or insects) when it comes to people with allergies, and research would be required.

Earlier laboratory research has established cross-reactivity between dust mites and crustaceans in 80 % of those who are allergic to crustaceans. The allergen causing the cross-reaction has been identified as tropomyosin which, in addition to crustaceans, is found in for example dust mites and cockroaches. The same types of allergens are found in molluscs and insects, and may lead to cross-reactions. The same general allergens are found in crustaceans and insects, arthropods and arachnids. That is why food made from insects may cause an allergic reaction in people who are allergic to for example dust mites or shrimps.

It is not known how the processing of insects/food made from insects affects allergenicity. It has to be noted, though, that for example heat treatment does not remove allergenicity, even though some proteins may be inactivated. On the other hand, heat treatment or any other processing may also cause an increase in allergenicity, or a concentration of allergens.

The current knowledge of the potential for allergies and risks from insects used as food is very insufficient. In the light of the information we have available it can be said that food made from insects can cause strong anaphylactic reactions in people with allergies. **It is therefore critically important that the potential for allergies is labelled very clearly on all foods made from insects and foods containing insects.**

There is more detailed information on labelling in section 7.3.1 “Labelling of insects and products containing insects”.

7.3.3 Nutrition Claims, Health Claims and Marketing

A nutrition claim means any claim which implies that a food has beneficial nutritional properties due to the calorific value it provides, or the nutrients and other substances it contains, contains in reduced or increased proportions, or does not contain. A nutrition claim means that a relationship exists between a food and health.

If nutrition claims (such as *source of iron* or *contains protein*) or health claims (such as *iron contributes to the normal function of the immune system* or *protein contributes to the maintenance of muscle mass*) are used in the labelling, presentation or advertising of foods made from insects, the claims used must be approved and the products must fulfil the requirements for the use of the claims. Only nutrition and health claims approved in accordance with the regulation on nutrition and health claims made on foods (EU) No 1924/2006 can be used. Approved nutrition claims are listed in the annex to the regulation and approved health claims are listed in a register maintained by the Commission http://ec.europa.eu/food/safety/labelling_nutrition/claims/register. No health claims pertaining directly to insects have been assessed or approved, but nutrition or health claims can be made regarding the nutrients in insect products, if the conditions for use of the claims are fulfilled. A food business operator who makes a nutrition claim or a health claim always has to justify the use of the claim and establish the compliance with the requirements in the regulation on nutrition and health claims made on foods.

Because insects are very light, it is worth noting the requirement in article 5(1)(d) according to which the **quantity of the product that can reasonably be expected to be consumed** provides a significant quantity of the nutrient to which the claim relates. A quantity that can be reasonably expected to be consumed is for example one glass, a couple of slices of bread or 2-3 tbsp. of powder.

Example 1. Source of iron

If it is claimed that an insect product is a good “source of iron” or another similar claim is made, which has the same meaning to the consumer, the product in question must contain a significant quantity of iron. A significant quantity means that the insect product must contain iron at a minimum of 15 % of the daily reference intakes for vitamins and minerals specified in annex XIII to regulation (EU) No 1169/2011 on the provision of food information to consumers. The daily reference intake for iron is 14 mg. This means in practice that an insect product has to contain iron at a minimum of $14 \text{ mg} \times 15 \% = 2.1 \text{ mg}/100 \text{ g}$. This quantity has to be obtained from a reasonable serving size of insects. If the consumer has to consume a large quantity of the product in order to get a significant quantity, the serving cannot reasonably be expected to be consumed. The lightness of insects can mean that large quantities of insects have to be consumed in order for the quantity to be significant and this can mean that the claim cannot be used. The situation is the same with herbs, such as dill, for example. But if an insect product does contain a significant quantity of iron in a reasonably sized serving, an approved health claim as to iron can also be made for the insect product.

Example 2. Good source of protein

If a nutrition claim such as “*good source of protein*” or another similar claim of the same significance to the consumer is made, the product in question has to contain the quantity of protein required for the use of that claim. If a minimum of 12 per cent of the energy content of the food made from insects consists of protein, the claim can be used. Though again it has to be assessed what the recommended serving is for the insect product, and how much protein the consumer gets from this serving. If the quantity of protein obtained from this serving is very small, the usage of a claim related to protein can be misleading as the consumer only gets a rather small quantity of protein from the insect product. If the recommended serving size is increased considerably, the serving can no longer be considered to reasonably be expected to be consumed. If, however, the nutrition claim *source of protein* can be made for the product, the health claim approved for protein can also be made for the product.

There is more information on nutrition claims and health claim on Evira’s pages <https://www.evira.fi/en/foodstuff/manufacture-and-sales/food-information/nutrition-and-health-claims/>.

Other matters to be taken into account when marketing insect products

Insects must not be presented as having properties related to prevention, treatment or curing of diseases or refer to such properties as such claims are medicinal and prohibited for food under section 9 of the Food Act.

It cannot either be claimed that insects have effects or properties that they do not have or as to where they do not differ from other similar products. The information given has to be correct, clear and easy to understand for the consumer. The consumer must not be misled.

There is more information on marketing on Evira’s page in Finnish <https://www.evira.fi/elintarvikkeet/valmistus-ja-myynti/elintarvikkeista-annettavat-tiedot/markkinointi/>.

7.3.4 Chemical Risk Management

Just as with other foods of animal origin, there can be many kinds of chemical risks with foods made from insects. The processing method, the composition of the feed and the insect species affect the chemical composition of the foods. The management of chemical risks is covered by the operator’s own-checks. Official controls related to the chemical safety of food are part of the Oiva system and samples also have to be taken when needed.

Chemical hazards that do not intentionally end up in food are for example toxic compounds that occur naturally in insects, contaminants from feed or from the environment or contaminants formed during food preparation. The occurrence of these compounds in food are to be avoided and/or minimised as much as possible by for example correct cultivation and handling of the insects and by preparing the food correctly.

Insects that contain contaminants (e.g. heavy metals or mycotoxins) of such quantities that the food becomes harmful to human health or otherwise unfit for human consumption cannot be marketed and shall not be used as an ingredient in food. The risk management of contaminants is carried out by e.g. the use of safe feed (see section 6.3), maintaining good production hygiene (see section 6.2) or by ensuring that the contaminants are not transferred to the insects from their environment etc. When necessary, the safety of the products has to be proven by way of chemical analyses carried out as own-checks.

Some chemical compounds, such as veterinary medicinal products or nutrients added to food, additives, food processing aids, aromas and enzymes are used intentionally in the food chain. The chemical compounds used shall be permitted for the purpose in question and the regulatory requirements related to their use have to be adhered to. Antimicrobials for example, can only be used for the treatment of diseases diagnosed in the animals and for example the withdrawal period for the medication prescribed by the veterinarian has to be adhered to. It is not permitted to use antimicrobials in order to improve the production conditions.

When these compounds are used correctly and in accordance with the regulations they are not harmful to health. If the regulations are not adhered to, large concentrations of these compounds can risk the chemical safety of the food.

Also the use of packaging and food contact materials under the wrong conditions can cause a risk for foods made from insects. A food business operator who handles insects and processes food from them, must ensure that all dishes, utensils and equipment used for food preparation and the packaging materials are intended to be used with food and are suited for their purpose.

When acquiring the materials and products in question from for example a wholesaler, the marketing name can inform of the intended use for food (such as a storage box for food) or the bowl-and-fork symbol on the dish itself or on the label. The labelling of these materials and products should also state what kind of contact (e.g. temperature, characteristics of the food) they are suited for. When the suitability of the material is not displayed adequately on the label, the issue has to be ascertained with the salesperson. Because the risk of migration of chemical agents from the contact material is higher for greasy, acidic and warm foods, it is especially important to ascertain, by asking additional questions, that the materials and supplies are suited for their intended use, if the conditions for use are not displayed on the label.

When acquiring materials and products directly from the manufacturer or importer, the supplier has to be asked for the documents showing that they fulfil the requirements. The documents should, amongst other things, contain the conditions for use. These documents have to be kept as part of the records on the own-checks.

When using packaging and other food contact materials it has to be ensured that they are used in accordance with the instructions given for them, while observing possible limitations for use, for example as to the temperature and composition of the food.

7.3.5 Traceability

The basic requirement for the traceability of foods relies on the 'one-step back'-'one-step forward' approach which is legislated for in Article 18 of the general regulation on foodstuffs. The traceability requirements for food of animal origin are also provided for in the Commission Implementing Regulation (EU) No 931/2011.

The operator has to have systems and procedures in place that enable them to forward the required information on traceability to the authorities on request. The traceability system means that the operator has a planned and organised procedure in place for receiving, supplying, storing and managing data on traceability. The system is not defined by legislation.

When foods are sent from food premises, the information required by legislation is to be supplied to the consignee of the food.

A specific format is not required for the documents by law. The supplier of the food can choose in which format to make the information available. A document can also be available in electronic format only. It is important to describe in the own-check plan how paper and electronic documents are handled and which systems are being used. The operator shall also have a systematic method in place (for example a systematic system and itemized number codes), with which they can connect the information in the electronic system and the document stored in the system with the lot and the product. It should also be noted that it must be possible to connect the products to be dispatched to the information supplied in electronic format.

The consignee has to have the information on the lot already when the consignment is being received. If the information is in electronic format and the date is not directly visible in the system or it cannot be connected to the electronic document or corresponding information, the date has to be recorded separately, and if there are several deliveries on a certain day, a more specific time.

Food business operators shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

- a) an accurate description of the food (also includes the country of origin and the scientific name of the insect species);
- b) the volume or quantity of the food;
- c) the name and address of the food business operator from which the food has been dispatched;
- d) the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched;
- e) the name and address of the food business operator to whom the food has been sent;
- f) the name and address of the consignee (owner), if different from the food business operator to whom the food has been sent;
- g) a reference identifying the lot, batch or consignment, as appropriate; and
- h) the date of dispatch.

The appropriate format in which the information a-h must be made available is up to the choice of the supplier of the food, as long as the information requested

- is clearly and unequivocally available to the business operator to whom the food is supplied when the food is received
- is clearly and unequivocally available to the authority within a reasonable period of time, if the authority so requests
- can be clearly and unequivocally connected with the delivery and the food lot.

It is recommended that the information related to the foods (documents) can be checked on the food premises during a control visit. The recommended storage period for the documents is one year after the transaction.

7.4 Hygiene Passport

A person has to have a hygiene passport if

- they work on food premises and
- handle unpackaged perishable foodstuffs.

A hygiene passport has to be acquired within 3 months at the latest after starting work. The 3 months are calculated retrospectively and also include previous work within the food sector for which a hygiene passport is required (section 27 of the Food Act).

Food premises are for example cafés, restaurants, fast food restaurants, institutional kitchens, food shops, bakeries and factories producing foodstuffs. Examples of perishable foodstuffs are milk, meat and fish. A hygiene passport is required from staff that process insects into food on food premises, who handle insects before they are in a form that keeps well, for example after drying. Hence, a hygiene passport is required for example when frozen insects are defrosted or when defrosted insects are boiled.

There is more information on hygiene passports on Evira's pages <https://www.evira.fi/en/foodstuff/hygiene-passport/>. Matters related to hygiene passports are also covered in section 3 to Evira's guideline 16044 on risk-based controls of food premises which is mainly intended for food control authorities.

8 MICROBIOLOGICAL AND CHEMICAL ANALYSES

8.1 The Microbiology of Insects

As a class, insects cover very different types of species and foodstuffs made from insects can be very variable as products. Dead insects form a good growing medium for different microbes, as they have high water content and contain many different nutrients. Insects that are used whole as food include the intestinal microflora of the insect. The insect's nutrition and the quality of the feed has a strong influence on its microflora. The microflora on the external surface of the insects is affected by the excrements, dead insects, insect shells and feed residues via the rearing platform.

Fasting the insects, that is withholding their feed before the insects are killed has not been observed to have much effect on the microflora of the insects. Despite fasting, intestines of insects contain a large quantity of different microbes and the microbes on the rearing platform can contaminate the. Therefore, it is not necessary for the insects to fast, provided that the operator can demonstrate that the products are safe based on their own procedures. Insects can be flavoured by feeding them for example herbs, such as rosemary, before they are killed.

Insects are a new research matrix, and it would be recommended that the laboratories analysing samples should verify their methods for insect products. As a research matrix they resemble vegetables to some degree. The analyses shall also be planned in accordance with the nature of the product to be analysed, depending on whether it is a question of a ready-to-eat food or whether it is intended to be heated.

The food business operator is responsible for the microbiological quality and for determining the shelf life of the foodstuffs they produce. In this guide we give the recommendations for a microbiological analyses package for samples taken by the authorities, and examples of analyses to be included in the own-checks.

8.1.1 Microbiological Own-check Analyses

Food safety requirements

- *Listeria monocytogenes*¹

Based on the food legislation, the points covering the *Listeria monocytogenes* in the regulation on microbiological criteria for foodstuffs (EC) No 2073/2005 is applied to foods made from insects (Chapter 1, food categories 1.2 and 1.3 to Annex I). In addition, on food premises where foods are produced that can be consumed as such, where listeria can grow, listeria has to be analysed for on the surfaces that come into contact with the foods.

Recommendations for sampling frequencies on food premises and instructions on how to determine shelf life are found in Evira's guideline 10501 (only in Finnish).

Recommended safety analyses

- *Salmonella* spp.¹⁾

In addition to listeria, the presence of salmonella can be analysed in the samples to evaluate the safety of the product. A number of EU countries allowing insects to be used as food have instructed that the safety criteria for salmonella for crustaceans and molluscs in the regulation on microbiological criteria to be used with insects. In addition, the presence of STEC bacteria¹⁾ can be checked at one's discretion for example for insects that have been fed fresh feed of vegetable origin.

Analyses for ensuring process hygiene and monitoring trends

- The aerobic colony count 30 °C¹⁾
- The *Bacillus cereus* group¹⁾
- *Enterobacteriaceae*¹⁾
- *Escherichia coli*¹⁾²⁾
- Yeasts and moulds³⁾
- Coagulase positive Staphylococci¹⁾
- *Listeria monocytogenes*¹⁾
- Sulphite-reducing clostridia⁴⁾
- Hygiene samples of the surfaces

- 1) Evira has published a recommendation for microbiological methods to be used for food analyses (only in Finnish): https://www.evira.fi/globalassets/tietoa-evirasta/esittely/toiminta/vertailulaboratoritoiminta/suosittelavat-menetelmat/elintarvikemikrobiologia_menetelma_luettelo_fi_2017.pdf
- 2) Other EU countries allowing insects to be used as food have a recommended MPN method suited for determination of small concentrations of *E. coli*, which is used for crustaceans, for example. In Finland the MPN method for *E. coli* is not in general use by many laboratories and other methods for the determination of the *E. coli* can be used instead
- 3) ISO 21527-1 and -2, NMKL 98
- 4) NMKL Nr 56, 5th edition, 2015, ISO 15213: 2003.

For example, the colony count of aerobic micro-organisms at 30 °C, *Enterobacteriaceae* and the determination of the group *B. cereus* are suited for monitoring the trends as to the quality of food made from insects. These determinations are also economical to perform. The colony count of aerobic micro-organisms gives an overview of the normal level of microbes in the products. A determination of *Enterobacteriaceae* is well suited as an indicator for monitoring the success of the heating process, as it should be sufficient in order to significantly decrease the concentrations of *Enterobacteriaceae*. Spore-forming bacteria, such as bacteria of the group *B. cereus*, are common in insects. An increased quantity of bacteria of the group *B. cereus* over the normal level in the end product can be due to problems with the production and the quantity can be monitored in the finished product. For example determinations of *E. coli* and coagulase positive staphylococci are suited for the assessment of secondary contamination after heat treatment. The damp and warm rearing conditions for insects are favourable for growth of yeasts and moulds in rearing environment and may enable the formation of mycotoxins. The effects of the rearing conditions on insects intended for

food can be assessed by carrying out determinations of yeasts and moulds. Evira also recommends that the food business operators include hygiene samples of the surfaces surfaces (that come into contact with food) in their own-check plan.

The Food business operator makes a sampling plan for the own-checks and determines the sampling frequency. Recommendations for sampling frequencies on food premises where food is produced are found in annex 8 of Evira's guideline 10501.

The Finnish Food and Drink Industries' Federation has published recommendations for maximum microbe concentrations in foods on the expiry date (only in Finnish) <http://www.etl.fi/media/aineistot/suositukset-ja-ohjeet/suositus-2017-elintarvikkeiden-mikrobiologisia-ohjausarvoja-viimeisena-kayttopaivana-id-41101.pdf>. These recommendations can be used for the own-checks when the durability and the date of durability for the food business operator's products are determined. The food business operators are recommended to carry out microbiological analyses of shelf-life for the foodstuffs made from insects, as there is no extensive published information available on the shelf-life of these new products.

As a new food category the foodstuffs made from insects present a challenge also for the own-check sampling, as there is not sufficient research data available on the product category, and the operator is responsible for the safety of the products. The operator must specify the critical points from a product safety point-of-view in their own-check plan and allocate the sampling based on these. Different products such as dried and roasted crickets and ready-made meals or salads prepared from insects are very different when it comes to microbiological shelf life and safety. Ensuring efficient food safety using good hygiene practices also goes for foodstuffs made from insects, but due to the lack of microbiological background information there may be a greater need for the operators to monitor the processing hygiene and their products also by way of sampling. The food business operator is responsible for planning sufficient own-checks and for ensuring that the own-check monitoring works. The operator is also responsible for the assessment of how the product safety is ensured by way of own-checks, for example by taking surface samples, such as hygiene samples and listeria samples.

When assessing product safety, it is good that the food business operators are aware of and analyse also potential safety risks related to parasites of the insects. The operators need to clarify the potential of commercial laboratories for parasite analysis, and possibly include these analyses in their own-checks. An example of such analyses related to parasites could be the determination of *Toxocara* in mealworm.

8.1.2 Recommendation for Microbiological Analyses of Official Samples

No microbiological requirements are set out in the EU legislation specifically for insects intended for food. Official sampling of this new food category can verify that the own-check sampling regarding the microbiological safety functions properly, and supply information on the microbiological quality of the products on the market. Analyses of official samples also inform of potential risks related to the new food group as there is a lack of background in-

formation. The food business operator is however always responsible for demonstrating the safety of the foodstuffs.

Analyses of official samples comparable with the microbiological analyses mentioned in section 8.1.1 can be made. The best way to get information on the identification of the characteristics and potential risks of the new food group is to carry out your own investigation of insects to be used for food and of products of which insects form a considerable part.

The microbiological methods of analysis recommended by Evira are presented in section 8.1.1.

Isolated bacterial strains and food samples containing high concentrations of group *B. cereus* bacteria or of coagulase positive staphylococci shall be sent to Evira in accordance with Evira's instruction LAB009 for possible analyses of toxins.

8.2 Chemical Analyses

At this stage, very little is known about the chemical risks related to the use of insects for food and feed. According to EFSA's report (2015), heavy metals (cadmium, lead, mercury and arsenic) may accumulate in insects. Insects may also contain toxic compounds produced by the insects themselves, and mycotoxins, residues of medicinal products, hormones and pesticides depending on their feed and rearing conditions.

Once it is known to what degree insects are being used as food and what harmful substances may be accumulating in the insects, limits may be imposed for these compounds and then it may become necessary to analyse for them. The basic composition of the insects has to be clarified for the sake of labelling.

9 IMPORTS

Live animals and food of animal origin have to be imported via veterinary border inspection posts if the operator imports live animals or food of animal origin directly from countries outside the EU. If the intention is to import foods of animal origin from other member countries, the operator has to register as a first destination operator with Evira. Customs and Evira are responsible for the controls of the imports of composite products. More information on controls of import of composite products is found in Finnish on Evira's <https://www.evira.fi/elintarvikkeet/tuonti-ja-vienti/eun-jasenmaat-norja-ja-sveitsi/ensisaapumisvalvonta/yhdistelma--ja-elaimista-saatavat-elintarvikkeet/> ja <https://www.evira.fi/elintarvikkeet/tuonti-ja-vienti/tuonti-eun-ulkopuolelta/elaimista-ja-kasveista-koostuvat-elintarvikesekeitukset-ent.-yhdistelmatuotteet/>. If the operator intends to import food into the country as part of their operations, this must be included in the notification for food premises and taken into account in the own-checks.

The operator has to know and be able to show where the foods destined for sale were acquired from. According to the general food regulation (EC) No 178/2002, food and feed business operators shall be able to identify any person from whom they have been supplied with a food (article 18(2)).

9.1 The EU countries, Norway and Switzerland

9.1.1 Live Animals

There are no requirements related to animal health for the movements of insects other than bees and bumble bees (*Apis mellifera* and *Bombus spp.*) between the EU countries, Norway and Switzerland, and there is no prerequisite to be registered as an operator on the internal market.

There can be limitations as to the keeping or importing of certain animals based on legislation, e.g. the legislation on alien species or environmental legislation.

It is prohibited within the EU to trade, rear, sell, hold or release invasive alien species. The EU member countries have approved a list of invasive alien species. The Government Decree (1725/2015) regulates for national invasive alien species.

The significant invasive alien species for the European Union and the nationally significant invasive alien species are listed on the pages <http://vieraslajit.fi/fi/content/welcome-invasive-alien-species-portal>.

When importing rare or otherwise endangered species, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which requires an export or import permit or an import declaration for certain species, should always be taken into consideration.

The Finnish Environment Institute will provide more information, phone 0295 251 000, cites@ymparisto.fi or <http://www.syke.fi/en-US>.

The Nature Conservation Act regulates the use of insects when the insects are a nationally protected species. Import of these species requires a permit which is granted by the ELY-Centres.

9.1.2 Food of Animal Origin

An operator who brings food of animal origin to Finland from within the internal market, must register with Evira as a first destination operator (Decree by the Ministry of Agriculture and Forestry 118/2006, section 8). The registration is done by filling in Evira's form "Commencing, significantly altering and terminating activities at place of first arrivals". If the operator has already registered as a first destination operator, they have to update the notification they made previously if they intend to import food made from insects from within the

internal market to Finland. The form “Commencing, significantly altering and terminating activities at places of first arrival” and the updates are to be sent to Evira’s first destination control (ensisaapumisvalvonta@evira.fi) at least 14 days before the operation is begun. For the classification of foods made from insects, the main category 4 and subcategory 123 are to be used.

The first destination operator has to send a monthly summary to Evira’s first destination control on what foods of animal origin the operator has received (ensisaapumisvalvonta@evira.fi) (Decree by the Ministry of Agriculture and Forestry 118/2006, section 10 and Decree by the Ministry of Agriculture and Forestry 353/2008, section 10). A monthly summary is done by using Evira’s form “Monthly Report”. The name/names of the supplier can be written on the form in the points 13 and 15, as food made from insects can also be processed on premises other than an approved plant.

Within the internal market, foods made from insects can only be brought to Finland from countries in the internal market that permit the use of insects as food, and where processing and sale of food made from insects are covered by food controls. Such countries are Belgium, the Netherlands, Great Britain, Austria, Switzerland and Denmark. In this context, Switzerland is considered to be a country within the internal market. If the food made from insects originates from a third country, the food has to come to Finland via a country within the internal market that approves of the use of insects as food. All food made from insects which originates from a third country must undergo a veterinary border control before it is released onto the internal market.

It is permitted to bring foods made from insects and raw materials from insects for further processing from the countries mentioned above, provided that the countries have approved the insect species in question for food uses. These can be fresh or further processed and, based on how they are processed, they can be chilled, frozen or stored at room temperature. There is information on insect species that are approved as food on Evira’s pages at <https://www.evira.fi/en/foodstuff/import-and-export/eu-member-countries-norway-and-switzerland/controlling-the-places-of-first-arrivals/> and on EviraNet, which is intended for inspectors.

The first destination operator has to observe the rules for imports of foods made from insects and a plan for sampling and analysis has to be added to the own-check plan related to these foods. The own-check analyses adhere to the instructions and lay-out set out in section 8 to this guideline based on risk assessment. The operator shall ensure during the own-checks that the foods made from insects or raw materials that are to be processed further are intended for human consumption and are safe for the consumer and are sent from a country in the internal market where the use of insects as food is permitted and the production and sales are covered by food controls. The operator must be able to demonstrate that the foods made from insects are subjected to controls in the country where they were produced or are resold, by for example presenting a document or control report drawn up by the food control authority in the country in question. The operator also has to present a document indicating that the product is intended to be used as food (for example through labelling), if that information is not evident on the control document. It is recommended that these documents be written in Finnish, Swedish or English. Should the documents in question not be available in one of the languages mentioned above, the operator can have the

documents translated. The documents mentioned above have to be delivered to Evira's first destination control in conjunction with handing in the notification for commencement of the operation or when updating it.

There is more information on controls at the places of first arrival on Evira's pages <https://www.evira.fi/en/about-evira/forms-and-instructions/food/control-of-places-of-first-arrivals/> and <https://www.evira.fi/en/foodstuff/import-and-export/eu-member-countries-norway-and-switzerland/controlling-the-places-of-first-arrivals/>.

9.1.3 Composite foods

Foods that contain products both of plant origin and processed products of animal origin are not products of animal origin as intended in Annex I, point 8.1 of Regulation 853/2004, but these foods are called composite foods in this context. These composite products are not covered by the controls at the place of first arrival. Customs control the composite foods brought to Finland in the internal market.

The definitions of composite products and foods from animal origin are found in Finnish on Evira's pages <https://www.evira.fi/elintarvikkeet/tuonti-ja-vienti/eun-jasenmaat-norja-ja-sveitsi/ensisaapumisvalvonta/yhdistelma-ja-elaimista-saatavat-elintarvikkeet/>

9.2 Imports from Countries outside the European Union

Live insects, food made from insects and insect products can only be imported into the EU via approved veterinary border inspection posts.

The importer notifies the veterinary border inspection post in advance of the arrival of the lots to be imported using the TRACES system. The information on the lot is entered in the system, which is the first page of the CVED document (Common Veterinary Entry Document). This has to be done either for live animals or products, depending on the nature of the lot. The notification has to be done on the last working day before the arrival of the lot, at the latest. After the check, the border veterinarian fills in the second page of the CVED document. A CVED document that has been signed and stamped by a border veterinarian serves as proof that the lot has been checked. A CVED certificate is issued regardless of the result of the check. The lot can be either accepted or refused. The CVED certificate granted by the border veterinarian will accompany the lot until the first destination. After the veterinary border control, a lot approved during the import control can, with a few exceptions, enter the market in the entire EU.

In conjunction with the veterinary border control, the documents of every imported lot are checked, and these documents must match the lots. A physical check is carried out on 1–100 per cent of the lots regardless of the origin and the nature of the products. Samples for laboratory analyses can also be taken of the lots in accordance with a programme authorised by Evira. The information on the samples is recorded in the TRACES system.

The importer is responsible for all of the costs related to the lot, including the costs of storage and keeping of the lots for which the veterinary border control is not completed, or for which the investigation into the border control obligation is incomplete. Lots such as the lots mentioned above will be stored at the border inspection post if necessary.

9.2.1 Live Animals

The conditions for import of live bees (*Apis mellifera* and *Bombus* spp.) are laid down in Commission Regulation (EU) No 206/2010. It is only permitted to import bees of certain species from countries outside the EU. Import is only permitted from certain countries outside the EU and the consignment has to be accompanied by a veterinary certificate in accordance with the regulation in question.

Import of live insects other than bees is permitted from all third countries. It is not permitted to import invasive alien species.

When importing rare or otherwise endangered species, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which requires an export or import permit or an import declaration for certain species, should always be taken into consideration. More information on CITES: <http://www.syke.fi/en-US>.

The Nature Conservation Act provides for the use of insects when the insects are a nationally protected species and the import of these species requires a permit which is granted by the ELY-centre.

9.2.2 Food Made from Insects

The import of food made from insects is permitted from all third countries (countries outside the EU) provided that the food is manufactured from whole insects. The insects can be dried, crushed, chopped, smoked or ground, but no parts can be removed (e.g. wings, legs, intestines) and protein or lipid fractions have not been isolated or extracted from them. Food made from insects has to fulfil the general hygiene requirements, that is it has to be produced hygienically, approved as food and it has to be safe for the consumer.

At this stage there are no common provisions within the EU for the import of foods made from insects. During the transitional period in the EU legislation which lasts until the end of 2020, foods made from insects may be imported into the EU without requirements on a country approved for import, an establishment of origin approved for import or a veterinary certificate approved for import.

Once the transitional period has expired, as from 1.1.2021, foods made from insects that are imported into the EU have to fulfil the basic requirements set out in article 6 of regulation (EC) No 853/2004 to the European Parliament and the Council of the European Union (a country approved for import into the EU, the establishment and the veterinary certificate).

In order to be able to market foods in Finland made from insects imported from third countries as foods, they have to fulfil the same requirements as the foods that are produced from insects in Finland. The food business operator is responsible for the safety of the foods they produce and market and for the accuracy of the information provided, also in conjunction with imports.

10 EXPORTS

10.1 The EU Countries, Norway and Switzerland

There are no requirements related to animal health for the transportation of insects other than bees (*Apis mellifera* and *Bombus* spp.) between the EU countries, Norway and Switzerland, and there is no prerequisite to be registered as an operator on the internal market.

There can be limitations as to the keeping or exporting of certain animals based on e.g. the legislation on alien species or the environmental legislation.

It is prohibited within the EU to trade, rear, sell, hold or release invasive alien species. The EU member countries have approved a list of invasive alien species. The Government Decree on Invasive Alien Species of National Concern (1725/2015) regulates for national invasive alien species.

The significant invasive alien species for the European Union and the nationally significant invasive alien species are listed on the pages <http://vieraslajit.fi/fi/content/welcome-invasive-alien-species-portal>.

When exporting rare or otherwise endangered animal species, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which requires export and import permits for certain animal species, should always be taken into consideration. The Finnish Environment Institute will provide more information, phone 0295 251 000, cites@ymparisto.fi or <http://www.syke.fi/en-US>.

10.2 Countries other than EU Countries

The starting point for the export of foods made from insects is that the exporting company and the product exported have to fulfil the requirements stipulated in the EU and national legislation. The company also has to clarify and fulfil the requirements set by the authorities in the countries of destination. It is a prerequisite that the country of destination approve of the entry of the foods made from insects onto their market.

The conditions set by the countries of destination for imported foods vary, and consequently they have to be clarified for each country separately. For some of the countries it may be sufficient that the certificate needed for the export (for example a veterinary certificate or a

health certificate) and the conditions for it are agreed upon with the country of destination. Market access can also be a longer process which requires for example replying to a market entry enquiry sent by the country of destination, a registration of the food premises by the country of destination and in some cases audits by the authorities of the country of destination to be carried out in Finland.

Exporters of live bees and honey, royal jelly and other bee products intended to be used as food, such as drone larvae, have to be entered on Evira's export register before the export. There is a link to the export register on Evira's pages (only in Finnish) www.evira.fi/vienti/viejarekisteri.

At this stage there are no registering requirements for exporters of other insects or foods made from insects. However, it is recommended that all businesses exporting or planning to export insects or foods made from insects register with Evira as exporters of insects. This makes it easier for Evira to promote the export of insect products and to share current information on the matter. The voluntary registration is to be sent to the address pk-vienti@evira.fi. The notification should contain the exporter's contact details, place of primary production and information on the food premises, place of loading, country/countries of destination for the export and whether the products are meant to be transported via another EU country or via a country that is not part of the EU to the country of destination.

It is the duty of the food business operator to clarify which requirements the country of destination has set for the imported foods, and that these requirements are fulfilled. Likewise, if the lot is transported via another country, the requirements regarding transit set by that country have to be clarified and fulfilled.

It is important to carefully clarify the requirements for the export beforehand. We recommend that you contact Evira at the stage of planning the export pk-vienti@evira.fi.

11 CONTROLS

Both primary production and the activities on food premises are subject to the municipal food control. The control frequency is determined based on the risks of the operation, both in primary production and in the activities on food premises. The insect sector is new and still in its infancy, and the risks have not yet been assessed extensively. Evira recommends that primary production and the food premises where insect products from primary production are processed (for example by boiling or roasting) shall be controlled annually. The recommended control frequency will be reassessed when the operations in the insect sector are more established. If the activities are on a rather small scale and quite simple, the time used for the control visit can be short.

11.1 Recording the Data in KUTI

At the moment there is no activity type for insect production in KUTI. The primary production of insects is recorded under the activity type “meat production” and “frogs” and the processing of insects into food is recorded under the activity category “processing of foods” for the activity type “other production, e.g. coffee roasting”. Even though the KUTI classification mentioned above is not correct for insect production, it is the most suitable classification at this stage, until the activity types for insects are created when the VATI system is taken into use.

Place of primary production

The data for the place of primary production is recorded in the centralised municipal data system as follows:

Activity category “Primary production”

Activity type “Meat production”

Detail “Frogs”

The production volume is recorded as insects kg/year (at least 1), even though the unit is item per year

Description of the own-check Y

A description of the own-check is required Y

By-products Y

Transport of animal by-products Y/N

Novel foods N

Is subjected to the notification procedure Y

Activity on food premises

The data for the food premises is recorded in the centralised municipal data system as follows:

Activity category “Food production”

Activity type “Other production, for example coffee roasting etc.”

The production volume is recorded as insects kg/year

Own-check plan Y

Novel foods Y/N

Is subjected to the notification procedure Y

11.2 Control of Primary Production

For the time being, Evira recommends that primary production of insects for food should be controlled annually. It is recommended that the first control at a place of primary production of insects should be carried out within approximately three months after notification of the place of primary production has been made.

Controls are carried out on the farms producing insects to check that the requirements are fulfilled using the guidelines 1.1–1.7. and 2.1–2.8 for food control of primary production when applicable. The guidelines for the food controls of primary production are found in

Finnish on Evira's pages <https://www.evira.fi/tietoa-evirasta/lomakkeet-ja-ohjeet/elintarvikkeet/alkutuotanto/>

Office holders performing food control duties related to insect production must have a higher education degree that is suitable for the duties at hand (Section 35 of the Food Act). The municipality can, on the whole, decide which office holder performing food control duties will carry out the control.

Evira is the authority responsible for the controls of feed (rehukyselyt@evira.fi).

11.3 Controls of Activities on Food Premises

The nature, scale and control history of the operation are the starting point for assessing how significant the risks related to the operation are. The need for controls of the food premises are assessed based on this. When the risks affecting food safety grow, the need for controls also grows. The food business operators are responsible for their own operation and for the safety of the foods they handle. It is the task of the official control authority to ensure that the legal requirements are adhered to and that correct and sufficient methods are used to control the risks. The more complicated and extensive the operation is, the more there is to check and at the more frequent intervals the control authority has to check the matters mentioned above.

At this stage, the risk category for processing insects to food has not been determined. It is recommended that the first control of food premises processing insects into food should be carried out within 1–3 months after the operation on the food premises has begun.

Evira's guide on risk rating of food premises and on how to determine the need for controls is found on Evira's pages (only in Finnish) https://www.evira.fi/globalassets/tietoa-evirasta/julkaisut/oppaat/eviran_ohje_10503_2_fi.pdf.

The applicable parts of the Oiva assessment guidelines are used during the controls.

12 LEGISLATION AND GUIDES

Legislation:

- The Regulation of the European Parliament and of the Council concerning novel foods and novel food ingredients (EC) No 258/97
- The Regulation of the European Parliament and of the Council on novel foods (EU) 2015/2283, will be implemented in full as from 1.1.2018
- The general EU regulation on foodstuffs 178/2002
- The general EU regulation on food hygiene 852/2004
- Commission regulation on microbiological criteria for foodstuffs (EC) No 2073/2005
- Regulation (EU) NO 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
- Regulation (EC) No 1334/2008 of the European Parliament and of the Council on food flavourings
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes
- Regulations on materials intended to come into contact with food (EU regulations 1935/2004 and 10/2011)
- Regulation (EC) No 1069/2009 on animal by-products, implementing regulation (EU) No 142/2011
- Regulation (EC) No 183/2005 on feed hygiene and other EU feed legislation
- Regulation (EC) No 999/2001 on TSEs
- Commission regulation (EU) No 206/2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
- Commission implementing regulation (EU) 2017/2469, laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
- Commission implementing regulation (EU) 2017/2468, laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
- Commission implementing regulation (EU) 2017/2470, establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
- Commission implementing regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin
- Council Directive 97/78/EC laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
- Food Act (23/2006)
- Decree of the Ministry of Agriculture and Forestry on the activities at the place of first destination (118/2006, not translated into English)

- Decree of the Ministry of Agriculture and Forestry on the amendment of the decree on the activities at the place of first destination (353/2008, not translated into English)
- Government Decree on food controls (420/2011, not translated into English)
- Decree of the Ministry of Agriculture and Forestry on food hygiene of food in primary production (1368/2011, not translated into English)
- Decree of the Ministry of Agriculture and Forestry on the supply of food information for the consumer (834/2014, not translated into English)
- Decree of the Ministry of Agriculture and Forestry on frozen foods (818/2102, not translated into English)
- Decree of the Ministry of Agriculture and Forestry on the labelling of certain foods as heavily salted (1010/2014, not translated into English)
- Decree of the Ministry of Agriculture and Forestry on processing aids (1020/2011, not translated into English)
- Feed Act (86/2008) and other national feed legislation
- Animal Welfare Act (247/1996)
- Animal Welfare Decree (396/1996)
- Animal Transport Act (1429/2006)
- Animal Diseases Act (441/2013)
- Decree of the Ministry of Agriculture and Forestry on animal diseases to be combated and their classification (843/2013, not translated into English)
- Act on Managing the Risk Caused by Alien Species (1709/2015)
- Government Decree on Invasive Alien Species of National Concern (1725/2015)
- Decree of the Ministry of Agriculture and Forestry on requirements related to animal diseases for animals and animal products that are exported to countries outside the EU and on inspections of these (832/2013, not translated into English)
- Act on veterinary medicinal products for animals (387/2014, not translated into English)

Guides:

- Evira's guide 10002: HACCP-system, principles and application (not translated into English)
- Evira's guide 10501: Microbiological requirements for food, the application of Commission regulation (EC) No 2073/2005 and general guidelines for microbiological analyses of food – Guide for Food Business Operators (not translated into English)
- Evira's guide 10502: Microbiological sampling and analyses of foods – Guide for food control authorities (not translated into English)
- Evira's guide 10503: Risk classification of food premises and determination of the need for controls (not translated into English)
- Evira's guide 10507: Food controls and risk assessment of primary production (not translated into English)
- Evira's guide 16025: Guide on the food hygiene of notified food premises (not translated into English)
- Evira's guide 16043: Risk based own-checks of food premises (not translated into English)
- Evira's guide 16044: Risk based controls of food premises (not translated into English)
- Evira's guide 16049: Freezing and deep-freezing foods on food premises (not translated into English)
- Evira's guide 17018: Control guide for materials and equipment that come into contact with food (not translated into English)

- Evira's guide 17068: Food information guide for food control authorities and food business operators (not translated into English)
- Evira's guide 18400: Guide for the local authority on controls at the place of first destination (not translated into English)
- Evira's guide 18401: Guide on controls at the place of first destination (not translated into English)
- Evira's guide 18402: Sampling by the authorities at the place of first destination and sampling for the purpose of own-checks carried out by the operators at the place of first destination (not translated into English)
- Evira's guide 18403: Guide for the local control authority at the place of first destination – Control checklist (not translated into English)
- Evira's instruction LAB009: Sending of bacterial strains and food samples to Evira, instruction for laboratories
- Oiva evaluation guidelines
- Evaluation guidelines for food control authorities in primary production
- European Commission guidance document: Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs

13 UPDATES TO THE GUIDELINE

This guideline shall be updated as necessary and whenever changes are made to the legislation. The updates and amendments are listed in this section.

- The contents of section 3 has been updated in accordance with the changes in the legislation on novel foods (Regulation (EC) No 258/97 replaced by Regulation (EU) 2015/2283). The numbering of the sections and subsections has also been changed.
- The definitions of foods made from insects and novel foods have been added to section 5 and the definitions of insects and composite foods have been specified.
- A new section has been added at the end of subsection 6.2 on the cultivation on insects in conjunction with other primary production
- Subsection 8.1.1 has been clarified
- A new subsection 9.1.3 on the import of composite products on the internal market has been added to subsection 9.1

Furthermore, some amendments which do not significantly affect the content of the guideline have been made.

