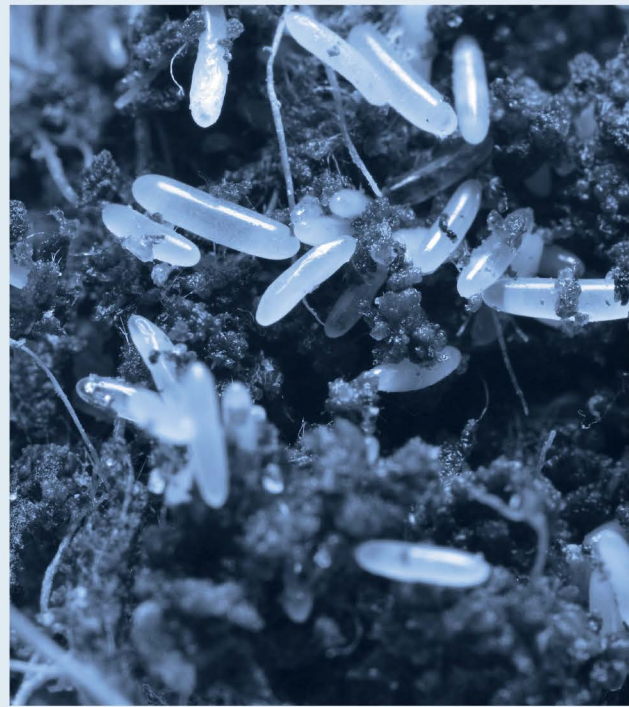




IPIFF
Guide on
Good Hygiene
Practices



for European Union (EU)
producers of insects as food
and feed

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PREFACE

The industry to farm insects as food and feed started only about a decade ago. In tropical countries eating insects was based on harvesting from nature. Sometimes that occurred at a very large scale such as the harvesting, processing and marketing of the mopane caterpillar in southern Africa. However, efforts to rear or farm edible insects in large numbers was never the case, although there were examples of semi-domestication by indigenous people such as providing egg laying sites for aquatic Hemiptera in lakes of Mexico, manipulating the habitat to increase edible caterpillars in Africa, and cutting palm trees deliberately to encourage palm weevils to lay their eggs in South America. There are only sporadic examples that insects were used as feed, such as luring termites to devices which were then emptied to feed the chicks.

Rearing of insects at a large scale occurred in pest management. The Sterile Insect Technique needed enormous numbers of reared sterile insects to be released into the wild to control fruit flies or flesh-eating screwworms. Biological control needed large numbers of predators and parasitoids to be released to control pests. Edible insects were reared but mainly for customers with house pets like reptiles and amphibians. When the idea of using insects for food or feed emerged, some of those insect rearing companies set up special production lines to rear mealworms, crickets and locusts for human consumption. Those special production lines were necessary because it was realised that society needed safeguards with respect to food safety. Strict hygienic measures and track and tracing systems were self-imposed. The knowledge that insect consumption could trigger allergic reactions prompted the industry to put warnings on the label. However, because it was all new, the insect industry was not sure how to deal legally with all food safety issues.

During the last ten years, the worldwide interest in using insects as food and feed surged, both in the public and private domain. Hundreds of start-ups in the world are now engaging in this activity. Some very large industrial insect rearing companies have emerged capable of producing tons of insects a day. The interest of the academic world in this topic is growing exponentially, especially during the last three years. The environmental benefits of using insects as food and feed by the public media is often highlighted. National and international authorities are becoming increasingly supportive as they also discover the benefits of this new agricultural sector. But how to ensure food and feed safety?

I happened to be present at the first meeting in 2013 of the European Union (EU) insect producing companies in Brussels when the International Platform of Insects for Food and Feed (IPIFF) was created. The main concern was legislation. Since then IPIFF has done a tremendous job of promoting edible insects towards the European Union. This Guide shows that the association also wants to support its members in the effective implementation of EU food and feed safety legislation. As such, the Guide contributes to underline the critical importance of food and feed safety (procedures) in insect production activities as concluded by the European Food Safety Authority (EFSA) in recent opinion¹ dealing with risks associated with insects as food and feed and acknowledged by EU public authorities (e.g., European Commission, Directorate-General for Health and Food Safety²). This Guide by IPIFF is an excellent guideline for everyone engaging in the business of how to produce, process and market insects safe for human consumption and for animals to feed. It is very complete and gives a profound overview of all relevant EU regulations and how to deal with it.

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GENERAL INTRODUCTION

An initiative by the International Platform of Insects for Food and Feed (IPIFF)

The International Platform of Insects for Food and Feed (IPIFF) is a not-for-profit organisation which represents the interests of the insect production sector. With 54 members from 20 different countries across Europe and worldwide, IPIFF is the voice of European insect producers towards the European Union and the wider public.

The prime objective of the European insect production sector is to produce safe products suitable for both human consumption and animal feed. Against this background, in November 2016, the IPIFF members decided to launch a Task Force on Good Hygiene Principles aimed at preparing and developing a Guide on Good Hygiene Practices (GHP) for insect production (hereafter referred to as 'the Guide').

Objectives of the Guide:

The overarching objective of the Guide is to help insect producers for food and/or animal feed purposes (hereafter referred to as 'insect producers') to achieve a high level of consumer protection and animal health through the production of safe products. To this end, the Guide provides guidance to insect producers to effectively apply EU food and feed safety legislation, while providing an incentive for them to develop a robust food and feed safety management system.

In addition, this Guide specifies requirements enabling to:

1. ensure that insect producers conform to their stated food and feed safety policy and demonstrate their commitments in this regard;
2. help the insect producers to effectively communicate food and feed safety issues to the regulatory authorities, and when needed, to their suppliers, customers and relevant interested parties (i.e., consumers) in the food and feed chains.

To achieve the above objectives, the Guide has drawn on the skills and expertise of companies directly involved in the production of insects, either for human consumption or for animal feed purposes. Annex III lists all insect producing companies that have been active in the development of the present document – i.e. Members of the 'IPIFF Task Force on Good Hygiene Principles'.

Furthermore, IPIFF has consulted several European representative organisations of the food and feed business sectors and other interested parties – i.e. the Members of the Advisory Group on the Food Chain and Animal and Plant Health - during the preparation of the present Guide. The consulted organisations are listed in Annex IV.

Scope of the Guide and Legal framework

The Guide covers the following activities:

1. the production of insects destined for **human consumption** (e.g. whole insects and processed insect meals, including when incorporated into processed products, or parts of insects and their derived products);
2. the production of insects as **feed** for food **producing animals**, including terrestrial livestock (e.g. poultry and pig species) or farmed fish, as well as feed for **pet food animals**.

Insect products destined for animal feed may concern:

- **live insects** (sections in the Guide addressing steps following the breeding of insects fall out of scope for live insects);
- **dead whole insects** if subject to light treatment steps (i.e. drying);
- **ground and further** processed insects (e.g. insect-derived hydrolysates, oils or processed insect proteins such as in the form of fat meals, defatted or partially defatted meals).

The Guide is in line with **Regulation (EC) No 183/2005** and **Regulation (EC) No 852/2004** which encourage the development of Guides of Good Hygiene Practices and the **application of HACCP principles** in order to attain a high standard of food and feed safety. It does not aim to substitute these regulations nor to replace national regulatory provisions: for legal compliance purposes, operators should always refer to applicable regulatory requirements.

In addition to the above-mentioned EU requirements, several of them must comply with **specific limits and/or standards as set out in frameworks of food and feed safety assurance systems** (e.g. see section 6.6 regarding 'microbiological limits') established by national authorities or private organisations. Such systems may serve as a point of reference for IPIFF and its members to complement and update, in the future, the recommendations that are provided in this Guide.

Similarly, the present Guide may serve as a point of reference for establishing supplementary guides or for developing food and feed safety assurance systems that apply to insect production activities. Yet, it should not serve the purpose of establishing standards falling subject to third party certification.

The Guide encompasses **all production steps**, from the feeding of the insects, their breeding, the killing and other processing steps, storage, transport or retail activities, to the final delivery of the product to consumers, feed manufacturers or livestock producers.

In respect of the above activities, insect producers must **comply with the same general safety requirements** and Good Hygiene Practices (GHP) **as Food or Feed Business Operators** that are active in other food or feed sectors. Thus, the present Guide covers:

1. the operations referred to in article **4.1** and **4.2** of **Regulation (EC) No 852/2004**, concerning respectively primary production (and associated operations), processing and distribution of food.
2. the operations referred to in article **5.1** and **5.2** of **Regulation (EC) No 183/2005**, which concern respectively primary production of feed and other activities.

Therefore, it follows that the recommendations provided for in annex I, part B of Regulation (EC) No 852/2004 and of Regulation (EC) No 183/2005 concerning the control of hazards in primary production of both food (and associated operations) and feed products.

Furthermore, the Guide **identifies** the **elements** that **require particular attention from insect producers**, as previously identified by the European Food Safety Authority (i.e. '*the specific production methods, substrates used, stage of harvest, insect species and development stage and methods for further processing, environmental effects*')¹, in order to **achieve compliance with food and feed safety objectives**, as defined in the applicable EU Regulations (see above).

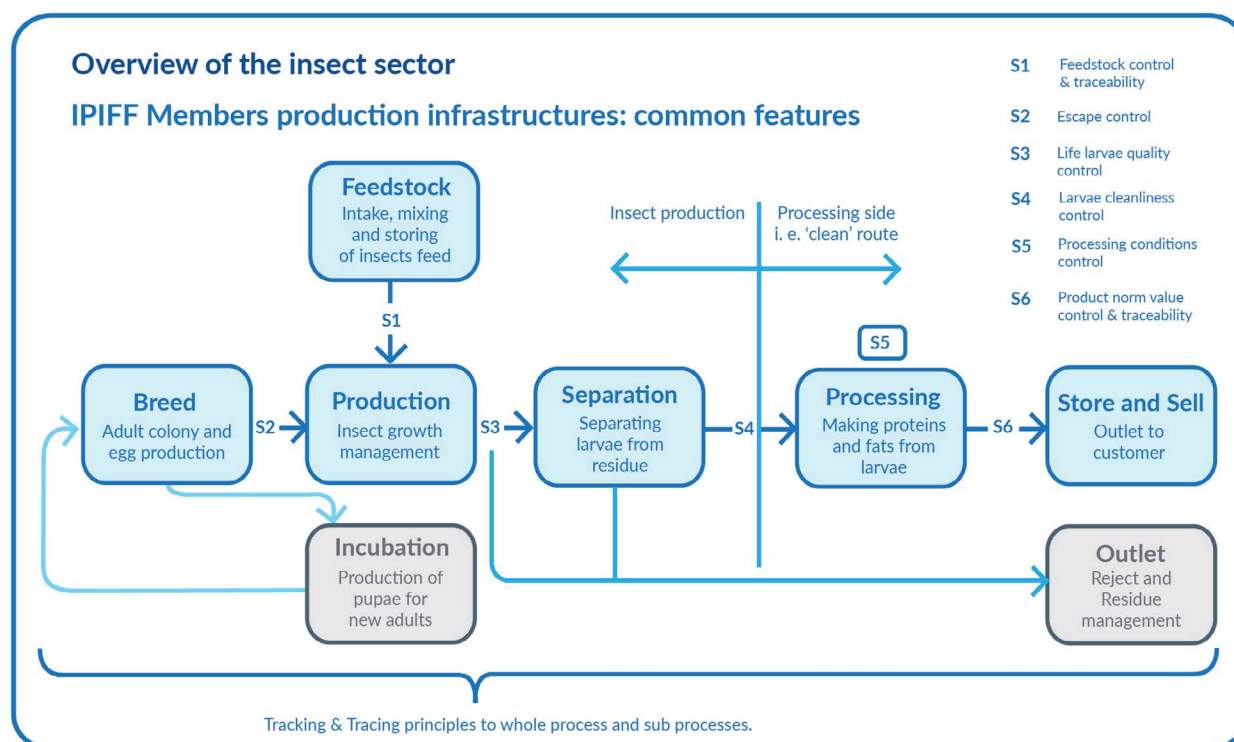
To this end, it makes a series of concrete recommendations aimed at addressing and managing safety hazards identified along the production chain, including on the application of **hazard analysis and critical control points (HACCP) principles**, whenever applicable (for more details, see chapter 7 - 'Implementation of HACCP principles by insect producers').

¹ EFSA scientific opinion 'Risk Profile related to production and consumption of insects as food and feed' (8 October 2015).

Although **biosecurity, environment or quality measures** do not fall within the scope of EU food and feed safety legislation, the present Guide includes several recommendations concerning the safety of personnel, visitors and/or neighbourhoods. It also includes recommendations on the prevention of environmental adverse effects and practices to ensure good and stable quality products.

It may be consulted as a useful **reference for production activities taking place outside the EU**, without prejudice to the national legislation². In addition, the Guide also applies to subsequent activities (e.g. packaging, transport, retail) if they take place in the European Union, from the EU importer up to the final distribution stage.

The use and effective implementation of all recommendations contained in the present Guide remains, however, **voluntary** and is based on full self-responsibility of the insect producer.



Applicable EU Regulations and other reference texts

Besides the General EU Food and Feed Hygiene Regulations - Regulation (EC) No 853/2004 on the hygiene of foodstuffs and Regulation (EC) No 1831/2003 laying down requirements for feed hygiene - and the EFSA's scientific opinion from 8 October 2015, insect producers may refer, for compliance with EU food and feed safety objectives, to the following EU legal acts:

1. Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (better known as 'General Food Law' Regulation);
2. Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law;
3. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules;
4. Regulation (EC) No 854/2004 laying down specific hygiene rules for food of animal origin;
5. Regulation (EC) No 853/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;

² Pursuant to the 'non-territorial effect' of EU provisions, these operations do not fall within the scope of EU food and feed safety requirements.

6. Regulation (EU) 2015/2283 on novel food of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001;
7. Commission Implementing Regulation (EU) 2017/2469 of December 2017 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;
8. Commission Regulation 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs;
9. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers;
10. Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;
11. Regulation (EC) No 142/2011 implementing Regulation (EC) 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;
12. Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies;
13. Regulation (EC) No 767/2009 on the placing on the market and use of feed;
14. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in feed;
15. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

The following documents may also be regarded as essential tools for insect producers to ensure compliance with General Food Law Principles.

1. European Food Safety scientific opinion 'risk profile related to production and consumption of insects as food and feed' (8 October 2015);
2. Report on 'novel foods': a risk profile opinion for the house cricket (*Acheta domesticus*) by the Swedish University of Agricultural Sciences (EFSA funded report, adopted on 6 July 2018);
3. Commission Notice – Guidelines for the feed use of food no longer intended for human consumption (OFJEU, 16 April 2018);
4. Hazard Analysis and Critical Control Points (HACCP) system and Guidelines for its application (Codex Alimentarius);
5. EN ISO 22000:2018 on Food Safety management systems;
6. The Codex code of practice on good animal feeding;
7. IPIFF Briefing Paper on Regulation (EU) 2015/2283 (28 May 2018) on novel foods.

Overall structure of the document

The Guide is divided into seven parts:

Chapter 1: Food and feed management safety systems: general principles and EU requirements

Chapter 2: Prerequisite programs: management of insects' substrates

Chapter 3: Prerequisite programs: insect rearing activities

Chapter 4: Overview of processing methods applied to insects intended for human consumption and animal nutrition

Chapter 5: Prerequisite programs: storage, packaging, labelling and transport operations

Chapter 6: Prerequisite programs: infrastructures and general conditions of production

Chapter 7: Implementation of HACCP principles by insect producers

Each chapter sets out a series of recommendations aimed at addressing and managing safety hazards identified along the entire production chain. Referred to as 'recommended practices' - see the last subchapter at the end of each chapter - and/or encapsulated in summary frames, these recommendations are presented with references to applicable EU regulatory provisions or illustrations whenever deemed appropriate.

These recommendations **are applicable** to insect production activities for **both food or feed** purposes, with the **exception of chapter 4** which contain elements specific to these operative branches³.

The Guide is complemented by the following **four annexes**:

Annex I contains a glossary of definitions, mainly extracted from EU regulatory provisions;

Annex II provides the list of 'insects authorised in feed for aquaculture animals within the EU';

Annex III lists all insect producing companies who contributed to the development of the present document – i.e. the Members of the IPIFF Task Force on 'Good Hygiene Principles';

Annex IV lists the European representative organisations of food and feed business sectors and other interested parties – i.e. Members of the Advisory Group on the Food Chain and Animal and Plant Health – which were consulted during the development of the present Guide.

Future updates

Any future changes to the current Guide will be made by IPIFF in consultation with stakeholders and subject to endorsement by the Standing Committee on Plants, Animals, Food and Feed. The Guide will be reviewed as required to take into account technological or scientific advances, as well as legislative developments on the topic of safe insect production.

³ However, insect food producers should refer to section 4.1., section 4.2. (killing methods) and 4.2.3. (post killing methods) as those practices and/or techniques reflect, to a large extent, the standards being followed by those operators, similarly to insect feed producers. As EU standards may differ as result of the 'first' novel food authorisations covering insects as food, and owing to potential future updates of EU hygiene standards in this field (e.g. setting of specific microbiological criteria for processed insects for human consumption), **section 4.1.3. Applicable legislative requirements insects as food**, will have to be complemented accordingly.

CHAPTER 1 – FOOD AND FEED MANAGEMENT SAFETY SYSTEMS: GENERAL PRINCIPLES AND EU REQUIREMENTS

Introduction

The purpose of this Guide is to ensure the achievement of EU food and feed safety standards by insect producers. To this end, food and feed safety management systems must be established, documented, implemented and maintained.

The structure of the systems must include policies, requirements and documented procedures that reflect best practices.

Furthermore, a formal risk assessment must be carried out with the aim of identifying and controlling hazards that might adversely affect the safety of insect products along the production chain. Risk assessments must be carried out in accordance with HACCP principles, whenever feasible and/or applicable (see Chapter 7 for more details).

This chapter contains general recommendations which should be followed by any insect producer - before starting their activities - in the setting up of the above systems. Whenever relevant, references to EU food and feed hygiene requirements are indicated.

1.1. Applicable EU Regulations

1.1.1. 'General' EU food and feed hygiene requirements

Regulation (EC) No 178/2002 (i.e. 'General Food Law'), Regulation (EC) No 852/2004 (Food hygiene) and Regulation (EC) No 183/2005 apply to all insect producers rearing, processing, handling (e.g., transport, storage) or distributing insects along the food or feed chain.

As a general rule, **operators active in the rearing of insects**, and/or in other handling operations that are directly associated with these activities (including storage and transport) are considered as '**primary producers**', according to EU food and feed legislation⁴:

1. Operators producing insects for animal feed **must be registered** before the national competent authorities – pursuant to article 9 of Regulation (EC) No 183/2005 - and **comply with the general requirements** contained in **Annex I**, Part A of the text. Part B of the same annex includes several recommendations for the development of guides to good practices covering primary production activities, while **Annex III** describes general practices regarding the **feeding of their insects** (including storage and distribution operations);
2. Operators producing insects for human consumption must register with and notify national competent authorities of **operations** under their control – pursuant to article 6.2 of Regulation (EC) No 852/2004 - in view of **their registration**, and comply with general requirements contained in **Annex I**, Part A of the text. Part B of the same Regulation specifies recommendations for the development

⁴ According to article 3 f. of Regulation (EC) No 183/2005, 'primary production of feed' means the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter) or fishing resulting exclusively in products which do not undergo any other operation following their harvest, collection or capture, apart from simple physical treatment (Chapter 1, article 4, point f). Insect breeding can therefore be considered as primary production within the meaning of the EU feed hygiene legislation. Likewise, pursuant to article 3 17. of Regulation (EC) No 178/2002 - which defines 'primary production' similarly to article 3. f. of Regulation (EC) No 183/2005 - the breeding of insects intended for human consumption should be regarded as 'primary production' activities.

of guides to good practices covering the above activities. This recruitment applies without prejudice

to the obligations of insects producers to obtain or benefit from a novel food authorisation in order to produce and market their products, pursuant to Regulation (EU) 2015/2283 on novel foods⁵.

The killing of insects and other processing activities - including the handling operations directly associated with these activities - are **not considered 'primary production'**, since these steps lead to a change in the nature of the primary product. Thus, the above activities fall subject to **different hygiene requirements**, under EU food and feed safety legislation:

1. Operators producing insects for animal feed, at 'other stages than primary production' - i.e. from the killing stage up to further processing stages - must **comply with specific hygiene requirements** laid down in **Annex II** of Regulation (EC) 1831/2003 (these requirements concern the facilities and equipment, personnel, storage and transport operations, compulsory sampling plans, record keeping measures, complaints and product recall);
2. Operators producing insects for human consumption, at 'other stages than primary production' - i.e. from the killing stage up to further processing stages including distribution - shall also refer to Annex II of Regulation (EC) 853/2004, which contains specific hygiene requirements applying to these activities. (These concern facilities and equipment, personnel, storage and transport operations, compulsory sampling plans, record keeping measures, complaints and product recall).
3. **Producers of processed animal proteins** derived from insects or insect derived fat intended for animal feed **must be approved before national competent authorities** (see chapter 4.1.2.).

⁵ See IPIFF Briefing Paper on Regulation (EU) 2015/2283 (28 May 2018) for more details.

Stages of production covered	'Regulatory status' (e.g. primary production or processing activities) and applicable EU requirements	
<p>Management of substrates and rearing of insects for <u>food</u> and <u>feed</u></p> <p><i>see chapter 2 and 3 of the Guide</i></p>	Producers of insects for human consumption	Producers of insects for animal feed
	<p>Regulation (EC) No 852/2004 on food hygiene.</p> <p>Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin.</p>	<p>Regulation (EC) No 183/2005 on feed hygiene.</p>
	Considered as 'Primary production' activities	
	<p>Are not required to implement HACCP based procedures (article 5.3 of Reg. No 852/2004).</p> <p>Yet, their use is highly recommended.</p>	<p>Are not required to implement HACCP based procedures (article 6.1 of Reg. No 183/2005).</p> <p>Yet, their use is highly recommended.</p> <p>Yet, insect breeders are no longer considered as 'primary producers' when using additives or premixtures of additives (article 5.2 of Reg. 183/2005) and must consequently implement a HACCP plan.</p>
	Operators must ' register ' their activities	
	<p>Registration as 'food business establishment' provided for by article 6.2 of Reg. 852/2004.</p>	<p>Registration as 'feed business establishment' provided for by article 9 of Reg. 183/2005.</p>
	Applicable hygiene requirements	
	<p>Must comply with <u>Annex I, Part A. of Reg. 852/2004</u> (contains requirements for operators active in primary production of food, incl. hygiene provisions and record keeping).</p>	<p>Must comply with <u>Annex I part A of Reg. 183/2005</u> (contains requirements for operators active in primary production of feed incl. hygiene provisions and record keeping).</p> <p>Must comply with <u>Annex III of Reg. 183/2005</u>, which refers to 'good animal feeding practices' (contains requirements regarding feeding equipment, feeding practices, water and personnel).</p>

Killing and further processing of insects for food and feed

See Chapter 4 to 7 of the Guide

Producers of insects for human consumption

1. Regulation (EC) No 852/2004 on **food hygiene**.
2. Regulation (EC) No 853/2004 laying down hygiene rules for **products of animal origin**.

Producers of insects for animal feed

3. Regulation (EC) No 1831/2003 on **feed hygiene**.
4. EU **Animal-by-products** legislation (i.e. Reg. 1069/2009 and Reg. 142/2011).
5. EU **'TSE' legislation** (Reg. 999/2001).

Being considered as **'non-primary production'** activities (e.g. processing), operators must comply with **specific hygiene requirements**

Must comply with Annex II of Reg. 852/2004 (i.e. contains requirements regarding all food premises, transport, equipment requirement, food waste, water supply, personal hygiene, heat treatment, training).

Must comply with the general provisions of Annex II of Reg. 1831/2003 (i.e. contains requirements regarding facilities and equipment, personnel, production, quality control, storage and transport, record keeping and complaints and product recall).

As category 3 material (i.e. article art. 3(l) of Regulation 1069/2009 insect-derived products (e.g. insect processed protein, insect fat) must be treated in accordance with **validated processing** standards, as defined in Annex IV, chapter III of Reg. 142/2011 (method 1-5 or method 7) see *chapter 4.2.1 of the present Guide*.

Must be produced in **processing plant dedicated** exclusively to the production of products derived from **insects**, pursuant to Annex IV, chapter IV, section F of Reg. 999/2001.

Activities subject to **'registration'**

Registration as **'food business establishment'**, provided for by article 6.2 of Reg. 852/2004.

Activities subject to **'approval'** and **'registration'**

Registration as establishment **producing 'category 3' animal byproducts** (C3) provided for by Regulation (EC) No 1069/2009.

Registration as **'feed business establishment'** under article 9 of Reg. 1831/2003.

Approval as **'establishment handling animal by products'** and complying with processing methods authorised under article 24. 1a of Regulation 1069/2009.

1.1.2. Requirements on substrates as feed for insects

Insects reared within the European Union fall within the category of 'farmed animals' according to the EU animal by-products legislation (i.e. article 3 6. of Regulation (EC) 1069/2009). Consequently, these animals may only be fed with eligible materials for farmed animals: i.e. **materials of vegetal origin** and/or animal origin that are listed in Annex IV of Regulation (EU) No 142/2011 **and** Annex XIV Chapter 1 Section 2, 5.b of Regulation (EC) No 999/2001 (Annex IV)⁶, namely:

- fishmeal;
- blood products from non-ruminants;
- di and tricalcium phosphate of animal origin;
- hydrolysed proteins from non-ruminants;
- hydrolysed proteins from hides and skins of ruminants;
- gelatine and collagen from non-ruminants;
- eggs and egg products;
- milk, milk based-products, milk-derived products and colostrum;
- honey;
- rendered fat.

However, the feeding of **catering waste** (i.e. Regulation 1069/2009 - article 11 (b)), **'former foodstuffs' containing meat and fish** (i.e. Regulation (EC) No 142/2011, Annex X, chapter 2, section 10) or **manure/animal faeces** (Annex III of Regulation (EC) 767/2009) to insects is **prohibited** on EU territory.

Furthermore, **suppliers** of insect producers must comply with the requirements of **EU feed hygiene legislation** (i.e. Regulation (EC) 1831/2003). This includes being **registered as a feed business operator** before their national competent authorities and having implemented a HACCP plan, if not covered by Article 5(1) of Regulation (EC) No 1831/2003 (primary producers)^{7 8}.

Feed additives approved in the EU in accordance with Regulation (EC) No 1831/2003 can be used in feed for insects: the list of authorised additives is provided within the EU Register of Feed Additives. Only generic feed additives (i.e. additives for which the approval is not specific to certain animal species) may be used as feed for insects (at the time of drafting this Guide, no feed additive has been specifically approved for insects).

Finally, **contaminants or harmful substances** may not exceed the **maximum limits** foreseen by the Directive 2002/32/EC on undesirable substances in animal feed.

1.1.3. Animal health and environmental requirements

Insects intended for food and/or feed have the legal status of 'farmed animal' (see section 1.1.2. above). The general requirements of animal health, therefore, also apply to insects. Insect producers shall therefore, consider the following: they must comply with animal health and biosecurity measures on transmissible animal diseases, as foreseen in the Animal Health Law - i.e. Article 10 of Regulation (EU) 2016/429.

⁶ See footnote 4 for more details;

⁷ Food manufacturers, wholesalers or retailers supplying insect producers with substrates of vegetal origin (i.e. food no longer intended for human consumption but destined for feed use, either arising from the food manufacturing process or constituting the final food product – most commonly known as 'former foodstuffs') are bound by the EU feed hygiene obligations (see EC Guidelines for the feed use of former foodstuffs), unless insect producers further process the product, in accordance with EU feed hygiene standards (e.g. implementation of an HACCP plan).

⁸ Pursuant to section 10 of annex X of Regulation (EC) No 142/2011, former foodstuffs containing milk milk-based products, milk-derived products, eggs, egg products, honey, rendered fats, collagen and/or gelatine may be used directly by insect producers (i.e. without further processing) provided that those products have undergone processing according to the food hygiene legislation and originate from the European Union.

Insect species and products thereof shall not:

1. **be pathogenic** or have other adverse effects on plant, animal or human health (see entry 9.4.1 'terrestrial invertebrates' and entry 9.16.1 'processed animal proteins' of the Catalogue of feed materials – Regulation (EC) 2017/1017);
2. be protected or defined as an **invasive alien** species in accordance with Regulation (EU) 1143/2014.

Insects are, however, **exempted** from the application of the EU animal welfare legislation, which only concerns vertebrate animals (see article 1 d. of Directive 98/58 concerning the protection of animals kept for farming purposes).

1.2. Management of responsibilities, organisational structure and employees

1.2.1. GHP policy and Management responsibility

The Management of an insect producing undertaking shall set the objectives related to GHP and HACCP principles (later referred to as 'the GHP policy') for the operating staff, rearing, killing, processing, storage and transport operations as well as visitors and subcontractors.

The GHP policy states the expectations management has on hygiene practices to ensure the safe production, storage and delivery of insects and related products.

Management shall inform staff about the practices being followed in the organisational and is committed to ensuring the implementation of the Guide within the company.

The policy should be reviewed and updated, when necessary, based on the outcomes of the internal and external audits. Employees are kept informed accordingly.

1.2.2. Employees' appointment and structure

Annex II of Regulation 183/2005 (EC) on feed hygiene states that:

'Where appropriate a qualified person responsible for quality control must be designated'.

Annex II, chapter XII of Regulation (EC) No 853/2004 on food hygiene provides:

'Those responsible for the development and maintenance of (...) (HACCP based procedures) or for the operation of relevant guides have received adequate training in the application of the HACCP principles'.

Management could appoint a Hygiene, Security, Environment and Quality (HSEQ) manager, who could, amongst other things, be responsible for the HSEQ principles. The HSEQ manager could organise the work of the team and has the authority/responsibility to:

1. Ensure that a critical control point system is established, implemented, maintained and updated;
2. Develop and maintain GHP within the company;
3. Report to Management about issues and to suggest appropriate measures to remediate or control problems when they occur;
4. Prepare for and train the HSEQ team, should it exist, in developing and maintaining the HACCP system and implementing GHP, and;
5. Train company employees in GHP.

The Management shall ensure that adequate communication channels are in place to inform the HSEQ manager of significant changes in products or processes.

1.2.3. Employees' skills

Staff is required to have the skills and the qualifications necessary for the manufacture of the products concerned.

Annex II of the Regulation (EC) 1831/2003 on feed hygiene states:

1. *'Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organisation chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection (...).'*

Annex II, Chapter XII of Regulation (EC) No 853/2004 states:

1. *'Food business operators are to ensure (...) that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity'.*

Among the minimal employees' skills required for insect production activities are the following:

1. The behavior of insects;
2. Feed and food safety principles;
3. Ability to identify species of insects;
4. Farmed insect species life cycle;
5. Handling of live insects and how to prevent them from escaping.

1.3. Traceability and record keeping

1.3.1. General requirements

Traceability is a risk management instrument to be used to identify and contain a possible food and feed safety problem more easily and efficiently. Relying on the 'one step back – one step forward' approach as well as on record keeping measures, insect producers must have systems and procedures in place that enable them to send traceability information to the relevant authorities upon request. This ensures that product withdrawals and recalls are precise and targeted.

Such system should enable, at all times, to trace any raw materials, ingredients, additives and primary packaging materials backward (one step upstream in the food chain) and to trace any finished products that have left the manufacturer forwards (one step downstream in the food chain).

Article 18 of Regulation (EC) No 178/2002 specifies the main principles and obligations implied by traceability.

Article 18 Regulation (EC) 178/2002 on 'General Food Law' states:

'1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.'

Furthermore, Regulation (EC) No 852/2004 as well as Regulation (EC) No 1831/2003 recommend guides on good hygiene practices to contain recommendations to ensure the traceability of food and feed products or of hazardous inputs such as plant protection, biocides, veterinary products or feed additives (e.g. Regulation 852/2004 annex I, part B c., d. and e.).

Traceability is also ensured through the recording of all measures aimed at controlling hazards (e.g. Regulation 852/2004 annex I part A chapter III on 'record keeping').

1.3.2. Product traceability records

In accordance with EU legislation and/or national provisions, insect producers must record and keep the following information in order to ensure product traceability:

1. The name and address of the substrate (e.g. feed materials, compound feed products, feed additives and premixtures) suppliers, the batch number, the quantity and delivery date of the products;

2. The name and address of the insect breeding flock providers, the main characteristics of the flock and its delivery date;
3. The nature, formulation and quantity of the products manufactured, along with their manufacturing date and batch number. Samples and records of each batch must be retained in accordance with EU food and feed hygiene Regulations;
4. Food allergens (e.g. gluten) which the substrate given to the insects may contain when the latter are intended for human consumption (and those made into semi-finished and finished products, including non-conforming products reprocessed to match treatment requirements or microbiologic criteria);
5. The name and address of the buyer(s) and of the site where the batch of semi-finished or finished products are delivered to.

In addition, insect producers are highly recommended to keep records of the following information:

1. The point of loading and unloading of the products;
2. The transport company and the means of transport used, such as boats (in hold or tank), vehicles (with reference to the trailer), etc;
3. If relevant, the storage company and the means of storage used, such as warehouses, silos or tanks and the number or distinguishing mark of the store or silo;
4. Temperature levels, information on processing control points, origin, processing equipment used, heat and freezing treatment, the substrates used, sample results and staff involved in regard to each product batch;
5. All finished products should be labelled to ensure traceability of the batch ('first in first out strategy').

National legislation or EU Regulations generally specify the amount of time documents should be retained to ensure traceability. By default, a two-year period is recommended.

1.3.3. Other documentation requirements

Product release procedures shall be in place to ensure that the traceability system is maintained: each producer shall be able to ensure that products leaving the control of the business are traceable to the customers. A system shall also be in place to deal with products that are rejected by customers for food safety reasons.

Operators must have systems and procedures in place that allow the sharing of information with national food and feed safety authorities whenever deemed necessary.

Relevant data needs to be registered and maintained for potential later use. The identification can, for instance, be a product production code and/or, its best before date and/or its batch number/code.

1.4. External communication

External communication among the different parties of the value chain (the food or feed chain) and control authorities is key to ensure the safety of the food and feed products. To this end, 32 communication channels and efficient processes are established to ensure a smooth exchange of

information.

1. All operators along the value chain should provide all relevant contact points/ details to their direct suppliers and customers (e.g. email address and phone number in order to ensure rapid and efficient communication during recall activities).
2. A procedure for notifying control authorities and operators both upstream and downstream, of any non-conformity with food and feed safety requirements and other specifications should be established. This procedure shall include provisions for the management of recalls when needed.

1.5. Emergency and product recall strategy

1.5.1. Background information

Crises are emergency situations and potential accidents which can be of very different natures (e.g. presence of unacceptable levels of contaminants, a break in the supply of raw materials, breakdowns or accidents, strikes by personnel, natural disasters, etc.).

1.5.2. Recall obligations under EU legislation

Article 19 of Regulation (EC) No 178/2002 on 'General Food Law' states

Responsibilities for food: food business operators

'1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.'

Regulation (EC) No 178/2002, Article 20 indicates:

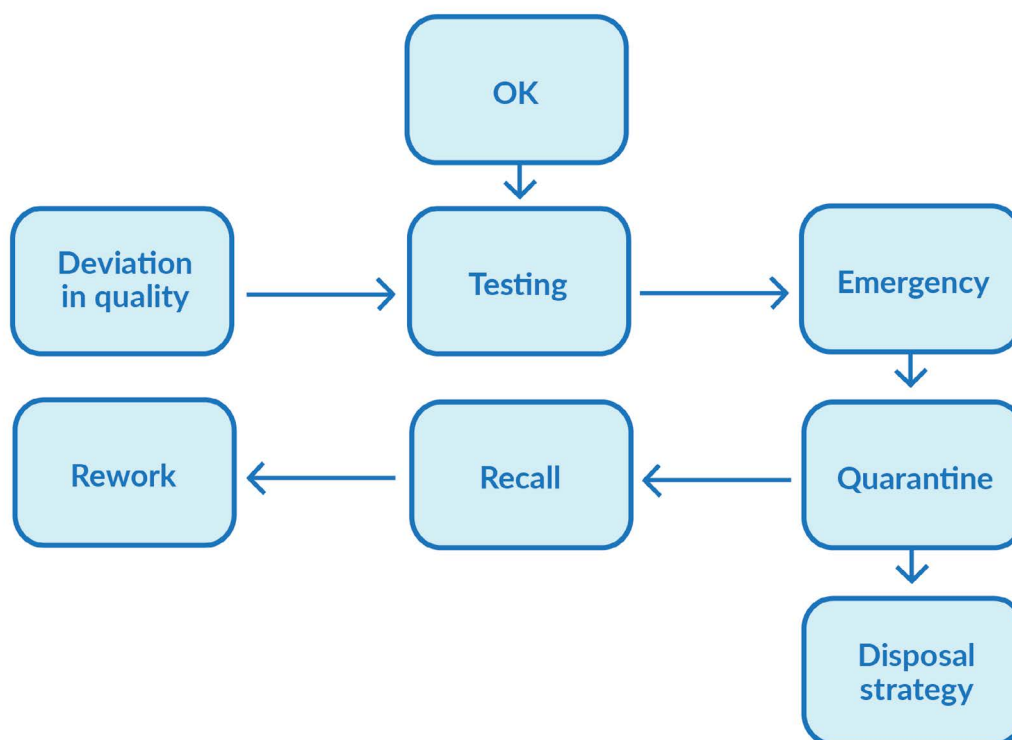
Responsibilities for feed: feed business operators

'1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.'

1.5.3. Recommended practices

Insect producers should formulate a definition of an 'emergency' situation. A clear strategy linked to the emergency should be defined by the manufacturer, who should follow the proposed mentioned scheme in case of such situations.

A written crisis management procedure available in line with regulation EU 178/2002 should be established to assist the personnel confronted with emergency situations and potential accidents to act effectively and consistently, thereby avoiding improvisation.



Annex II of Regulation (CE) No 1831/2003 on feed hygiene indicates:

Complaints and products recall

'1. Feed business operators shall implement a system for registering and processing complaints.

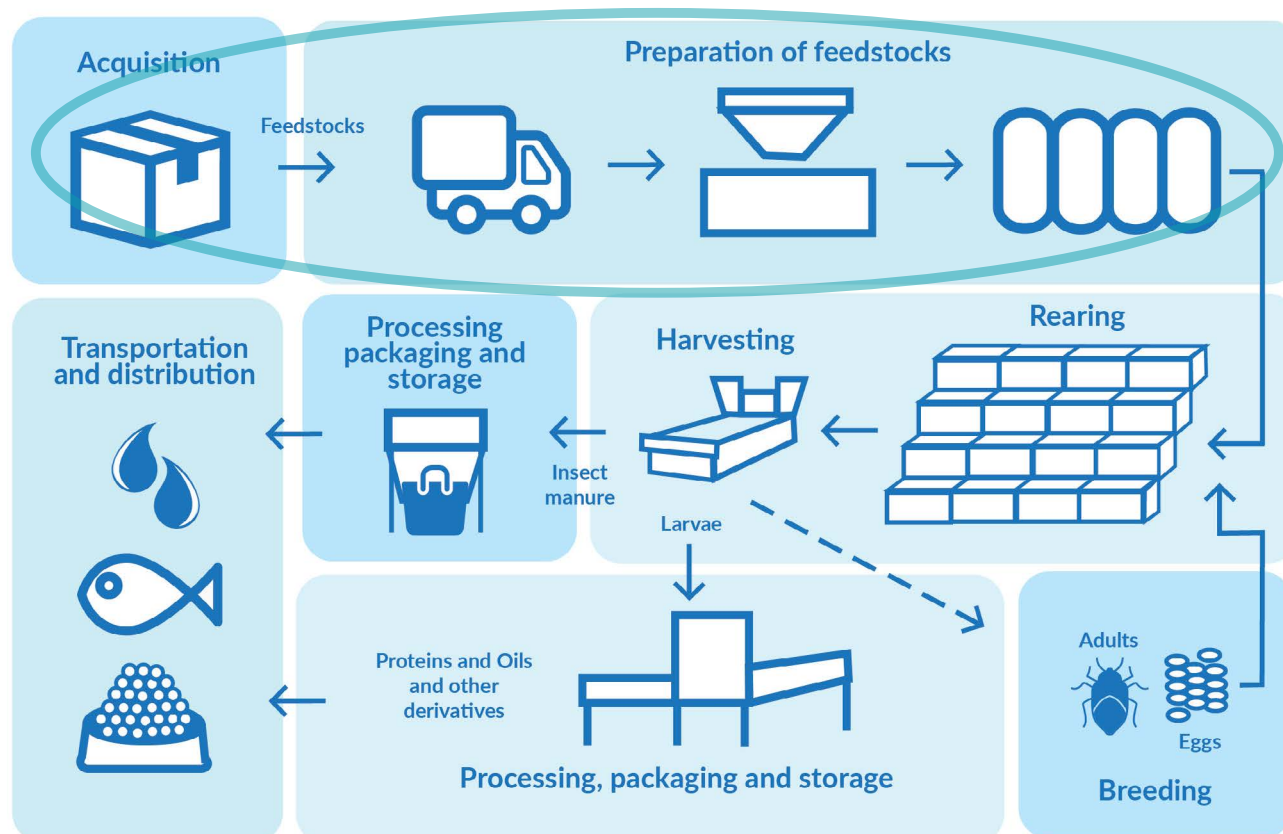
2. They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation, they must undergo a quality-control reassessment.'

The procedure should include the following information and measures and be tested beforehand:

- Contact details of relevant staff with allocated responsibilities for decision making;
- Contact details of external organisations (e.g. authorities, fire services) as per the emergency plan;
- How to identify the product/area that is affected by the emergency situation, e.g. potential contamination from the activities of the first responders e.g. fire-fighter, rescue team;
- Handling procedures for potentially unsafe food products;
- How to evaluate and restore the affected area through correction and corrective action processes.

CHAPTER 2 – PREREQUISITE PROGRAMS: MANAGEMENT OF INSECTS' SUBSTRATES

2.1. Substrates supply and insect producers sourcing activities



2.1.1. Background information

Insect producers select substrates based on a number of criteria, including the nutritional composition, the expected effects on the targeted insect species (e.g. speed of growth, weight gain, feed conversion ratio or fatty acid profile), the absence of hazards on the targeted animals or the ease of removal during harvesting (see Chapter 3.4. below).

Furthermore, the characteristics of the substrates used are critical parameters for a suitable and safe growth of the animal: in general substrates used for flies (e.g. *Musca domestica* and *Hermetia illucens*) contain higher levels of moisture (sometimes referred to as 'xiroculture'), whereas mealworm (*Tenebrio molitor*) and lesser mealworm (*Alphitobius diaperinus*) species are usually raised on dry substrates (sometimes referred to as 'hygroculture').

The origin of the substrate is an important factor with respect to product traceability. When procuring the substrate, it is important to consider the reliability of suppliers and their management systems put in place.

2.1.2. Applicable legislative requirements

Insect producers must only source substrates that are legally authorised as feed for insects within the European Union - rules as defined under the EU Animal-By-Products legislation (i.e. Reg. 1069/2009 & Reg. 142/2011) and Regulation (EC) No 767/2009 (on the placing on the market and use of feed) - Annex III (prohibition to use manure/animal faeces).

Non-exhaustive list of substrates commonly used by EU insect producers⁹

1. Cereal-based materials (e.g. wheat bran, chaff bran, bruised rye, oatmeal, grass, brewery/distillery grains);
2. Fruits and vegetables and their derived products;
3. Commercial feed¹⁰;
4. Unsold products (due to 'technical defects') from supermarkets, food industry or bakery establishments (the so-called 'former foodstuffs' in accordance with EU legislation) if containing materials of vegetal origin, eggs and/or milk products¹¹.

Non-exhaustive list of non-authorised substrates within the EU

1. Livestock manure and/or slurry or other products derived from animal digestive tract content;
2. Human excrements;
3. Water treatment (e.g. industrial sludges) or solid waste streams (urban industrial or domestic);
4. Packaging and parts thereof (e.g. plastic, PET, paper);
5. Seeds treated with plant protection products;
6. Treated wood;
7. Animal by-products originating from slaughterhouses or rendering establishments (e.g. processed animal proteins)¹²;
8. Food waste originating from restaurants, catering establishments and household;
9. 'Former foodstuffs' containing materials of animal origin (excluding eggs, milk and their derived products -see above).

⁹ Answers collected through IPIFF questionnaire addressed to its members (9 March 2018). 27 answers collected.

¹⁰ When using commercial compound feed, insect producers must comply with applicable restrictions and/or prohibitions - e.g. insect producers must ask guarantees to their suppliers as to the absence of feed additives whose use in insect feed is prohibited - e.g. coccidiostat.

¹¹ Provided that these are free from packaging residues, in accordance with EU legislation.

¹² Several exceptions apply (e.g. blood products from non-ruminant, rendered fat or hydrolyzed proteins).

Furthermore, insect producers must conform to the general provisions of Regulation (EC) No 183/2005 on feed hygiene (for more information about EU authorised substrates as feed for insects, please refer to chapter 1.1.2.)

2.1.3. Specifications and checking measures

Substrates sourced outside the production facility must be obtained from a registered feed business operator, or from an approved establishment if feed additives, premixtures or compound feeding stuffs are produced, in accordance with the EU feed hygiene legislation¹³. Pursuant to the 'European Commission Guidelines for the feed use of food no longer intended for human consumption' (16 April 2018), suppliers of former foodstuffs must have been registered or approved under the EU food hygiene legislation (i.e. for products of non-animal origin)¹⁴ and/or the animal by-products legislation (i.e. for products of animal origin)¹⁵.

It is also recommended that substrate suppliers are selected and audited through internal approval guidance, taking into account the safety of the product, registration of the production sites, the safety management system in place and implementation of good hygiene practices and/or the implementation of HACCP procedures when applicable.

Insect producers must also register the substrate provider's name, its address and delivery date¹⁶, in accordance with EU specific requirements on traceability and record keeping, as in Article 18 of Regulation (EC) No 178/2002.

Insect producers must keep up-to-date information listing the prerequisites for substrates to be safely used as feed for insects intended for food or feed purposes (the so-called 'specifications'). The specifications also indicate when and to what extent deviations may be accepted.

The specifications must at least cover:

1. The analytical characteristics of the incoming substrate;
2. The results of the risk analysis carried out for each incoming substrate, e.g. the product specification and monitoring results;
3. The list of approved geographic origins and sources;
4. The animal species for which their use is approved;
5. Notes on any hazards or limitations on their use and any other special characteristics;
6. Conditions of usage (e.g. pH, temperature).

Insects' nutrition and the quality of the substrates ingested may have a strong influence on its microflora (e.g. certain insects may be vectors of Salmonella, Campylobacter or Escherichia Coli) or on the presence of chemical contaminants (e.g. dioxin and PCB transferred via the substrate may accumulate in insects). Furthermore, the substrate may have been contaminated with pests/rodents or other physical contaminants.

In light of the above hazards, insect producers should carry out regular checks of incoming materials through sampling measures to verify compliance with parameters as defined in the specifications (e.g. test against the presence of unauthorised substances and/or applicable limits for contaminants

¹³ Article 9 and 10 of Regulation (EC) No 183/2005

¹⁴ See section 3.2 of the EC Guidelines for the feed use of food no longer intended for human consumption.

¹⁵ See section 4.2 of the above-mentioned EC Guidelines.

¹⁶ Annex III on Record-Keeping (b) (iv) Regulation (EC) No 183/2005.

present in the substrate). Samples and results of the analysis shall be made available to the competent authorities upon request at any time.

While EU legislation does not foresee specific regulatory provisions regarding (microbiological or chemical) analyses and pathogen agents in substrates destined for insects, operators may implement own sampling measures/protocols:

- Sampling measures must always be conducted if there is any doubt about the quality of the substrate and/or in the absence of analyses conducted by the supplier;
- Although the substrates are delivered by trusted suppliers with full traceability ensured and/or accompanied by analytical results, sampling measures must be randomly conducted to detect the presence/levels of mycotoxins, heavy metals and residues of pesticides and the samples should be stored at least until the end of the production cycle of the batch being fed with;
- If the substrate(s) undergo(es) chemical/biochemical (acidification/enzymatic hydrolysis etc.) or any fermentation processes, the analysis should be conducted, based on the producer's assessment of possible resulting hazards on insects).

2.2. Storage of substrates

Insect producers must pay attention to the physical conditions (storage technology, storage atmospheric characteristics) and biosecurity levels to prevent the introduction of organisms from the environment surrounding the storage facilities of the substrate.

To this end, insect producers must follow these principles:

1. Incoming materials must be stored in dry (i.e. for dried substrates) and hygienic conditions;
2. Installations must be free from vermin, birds and any form of pests. Storage facilities must have roofs, walls or other protection systems, and be regularly checked in order to avoid leaks or rodent infestation;
3. Damaged or corrupted substrates must be contained and evaluated for an exemption to be reintroduced as substrate or disposal.

Furthermore, there must be a system of **site allocation for safe storage** (e.g. easily identifiable, intake identification easily visible). In case of any doubt about the identity of a product during storage (i.e., damaged packaging), a 'non- conformity procedure' must be established whereby the HSEQ Manager or any other competent and/or designated person must decide on the destination of the product (re-identification, clearance for use, disposal, etc.). Records must be kept at all times about the actions taken. The substrates that have been rejected by the HSEQ Manager must be clearly identified and segregated from other materials in a manner which precludes their unauthorised used.

Finally, insect producers must pre-treat, whenever deemed necessary (i.e. should risks of contamination be identified), the substrates before feeding them to insects, including through shredding, grinding, milling, mixing or acidification.

Summary of recommended practices or 'warning points' in the management of incoming substrates

1. Only source your substrate from registered or approved Feed Business Operators or Food Business Operators or animal by-product producers (when sourcing products of animal origin);
2. Only source and use legally authorised substrates, pursuant to EU legislation;
3. Ensure that designated and trained staff are present at the point of delivery;
4. Visually control the truck before unloading and accepting the delivery to detect damaged seals or packaging;
5. Register all batches of substrate;
6. Ensure that the substrates are provided by trusted suppliers;
7. Undertake your own testing/sampling of the substrate following a risk-based approach, after assessing the potential contamination of the feed (notably, you should pay attention to the development of *Salmonella* spp., *Campylobacter* and *Enterobacteria*);
8. Pre-treat the substrate whenever necessary.

CHAPTER 3 – PREREQUISITE PROGRAMS: INSECT REARING ACTIVITIES

3.1. Introduction: scope and legal framework

Insect rearing activities cover the following production steps:

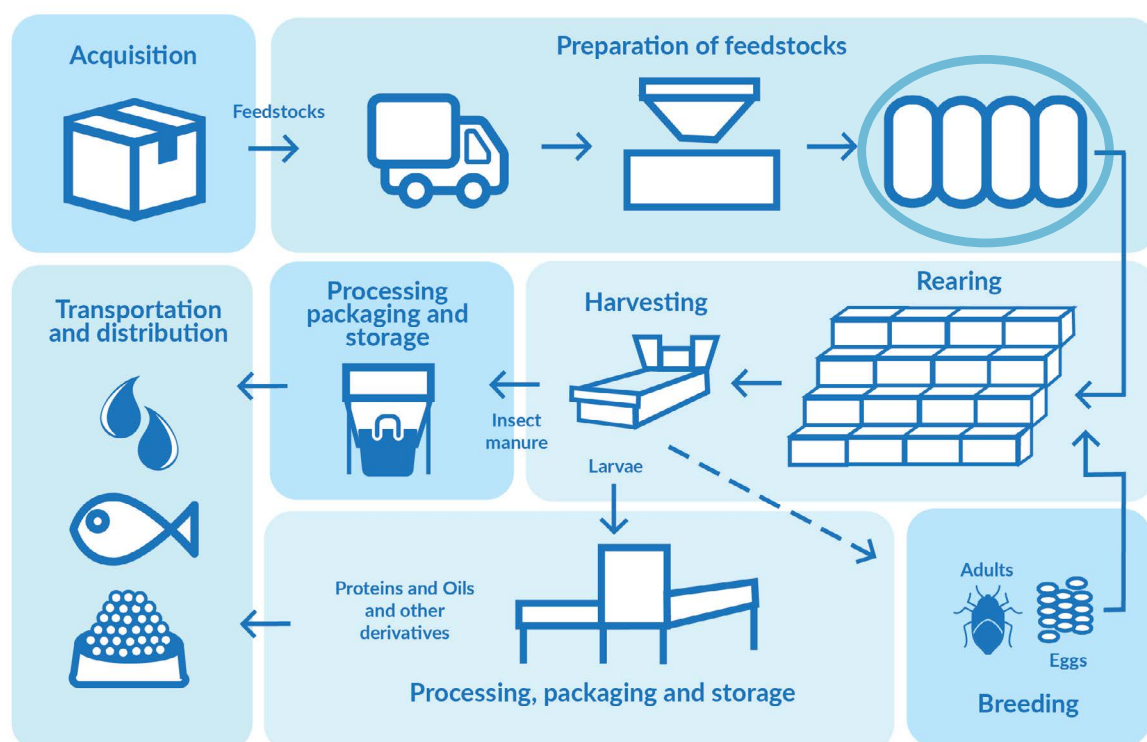
1. Administration of feed/substrates to insects;
2. Insect growth phase;
3. Insect harvesting;
4. Pre-treatment step.

All the above-mentioned steps are considered 'primary production' activities¹⁷ under EU food and feed safety legislation. Consequently, insect producers that are active in these fields fall subject to distinct hygiene requirements. In practice, those operations often take place in the same establishment of processing activities, therefore limiting the risks for contamination (e.g. may arise from transport from one establishment to another). However, insect producers may decide to outsource certain stages for the rearing activities. In that case, operators should refer to the recommendations provided in section 3.6 below.

For more information about applicable requirements, you may refer to subchapter 1.1.

This chapter applies to insect products intended for human consumption and animal feed. However, should insect producers produce both food and feed, a strict separation between these two production activities should be implemented – e.g. distinct producing establishments or segregation between production lines for food vs feed if those operations take place in the same building.

3.2. Administration of feed/substrates



3.2.1. Background information

Feed/substrate administration constitutes an important component of the breeding process. Such operations are designed to provide insects with access to liquid and solid nutrients (i.e. wet and dry substrates) as a source of energy needed for their growth.

Eggs are usually introduced onto the substrate manually, mechanically or by natural oviposition (directly from adult insects). The larvae are maintained on the substrate for a certain number of days or weeks depending on the species produced and the temperature and humidity levels within the building.

3.2.2. Applicable legislative requirements

Insect producers should follow the specific hygiene requirements, as foreseen in Annex III of Regulation (EC) No 183/2005.

Annex III of Regulation (EC) No 183/2005 on feed hygiene indicates:

'Feeding'

2. Distribution

'The on-farm feed distribution system shall ensure that the right feed is sent to the right destination. During distribution and feeding, feed shall be handled in such a way as to ensure that contamination does not occur from contaminated storage areas and equipment (...).'

3.2.3. Recommended practices

In order to prevent the risks of contamination – which may originate from the introduction of pathogens, chemical contaminations, cross-contamination - the administration of the substrate to the animals should be done according to the following principles:

- The substrate used should be selected by taking into consideration the chosen insect species, based on its mycotic, bacterial and viral disease resistance;
- Each batch of substrate delivered to the animal must be traceable;
- The equipment destined to provide the nutrients/substrates (or any other material which may enter into contact with the animals) should be certified as 'food contact' material (avoid chemical contamination) and equally thoroughly cleaned;
- Insect producers should thoroughly clean boxes/cages containing insects and equipment destined to provide the substrate and/or the water to the animal between each batch of production.

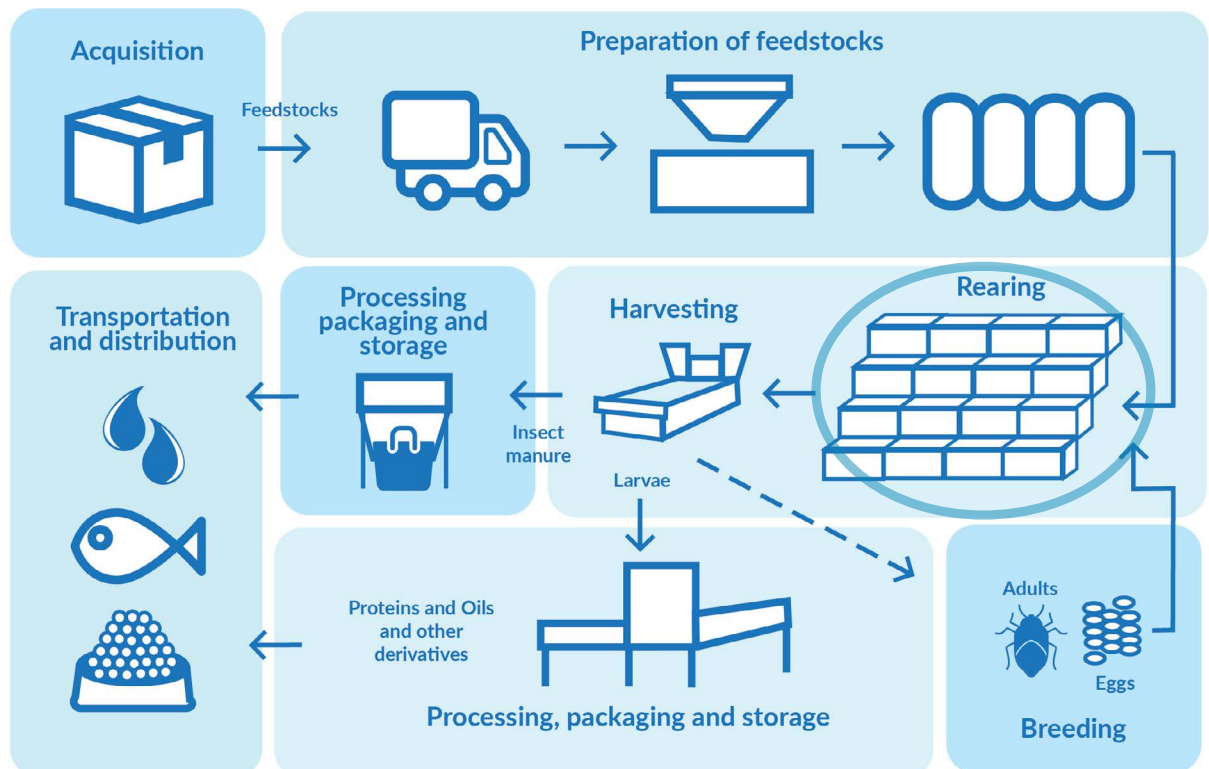
Such principles should help to avoid or minimise any cross-contamination and errors. Any other technical or organisational measures that are deemed necessary by insect producers to prevent such risks must be taken. These should include regular checks in the course of manufacture¹⁸ designation and training of staff at the point of distribution in order to prevent cross-contamination.

¹⁸ Annex II chapter on 'production' of Regulation (EC) No 183/2005.



Photo: Feeding insects at Kreca. Courtesy of Protifarm.

3.3. Insect growth phase



3.3.1. Background information

Besides the composition of the substrate, insect rearing conditions may also contribute to the development of microbiota (naturally or accidentally) and/or to the presence of chemical contaminants (e.g. transferred via the growing medium) in the final product. Farmed insects, therefore, require an adequate environment and the application of tailor-made techniques that take into account their particular characteristics.

The key parameters to be controlled include:

1. **The temperature:** insect growth rate is indeed heavily influenced by temperature levels. Temperatures between 25°C to 45°C are most beneficial in the majority of cases.
2. **Humidity:** temperatures must correlate with a specific level of relative humidity, depending on the phase of development (e.g. approx. 70% of humidity for *Tenebrio Molitor*, 50-70 % for Black Soldier Fly and house fly, 90% for crickets and 50% after hatchings).
3. **Enclosed space:** the insect colony must be enclosed and secured to facilitate pest control and prevent livestock escape. It is common to use multiple self-contained spaces, each with its own population, water supply food sources, and space maximisers.
4. **Ventilation:** proper ventilation of the premises is required and must be suited to the species characteristics and projected temperature/humidity levels. This ensures clean rearing conditions and avoids cross-contamination through the air.

Generally speaking, a good understanding of the main insect species (including their different life cycles) used in production activities is necessary for the development of suitable rearing methods and further processing steps.

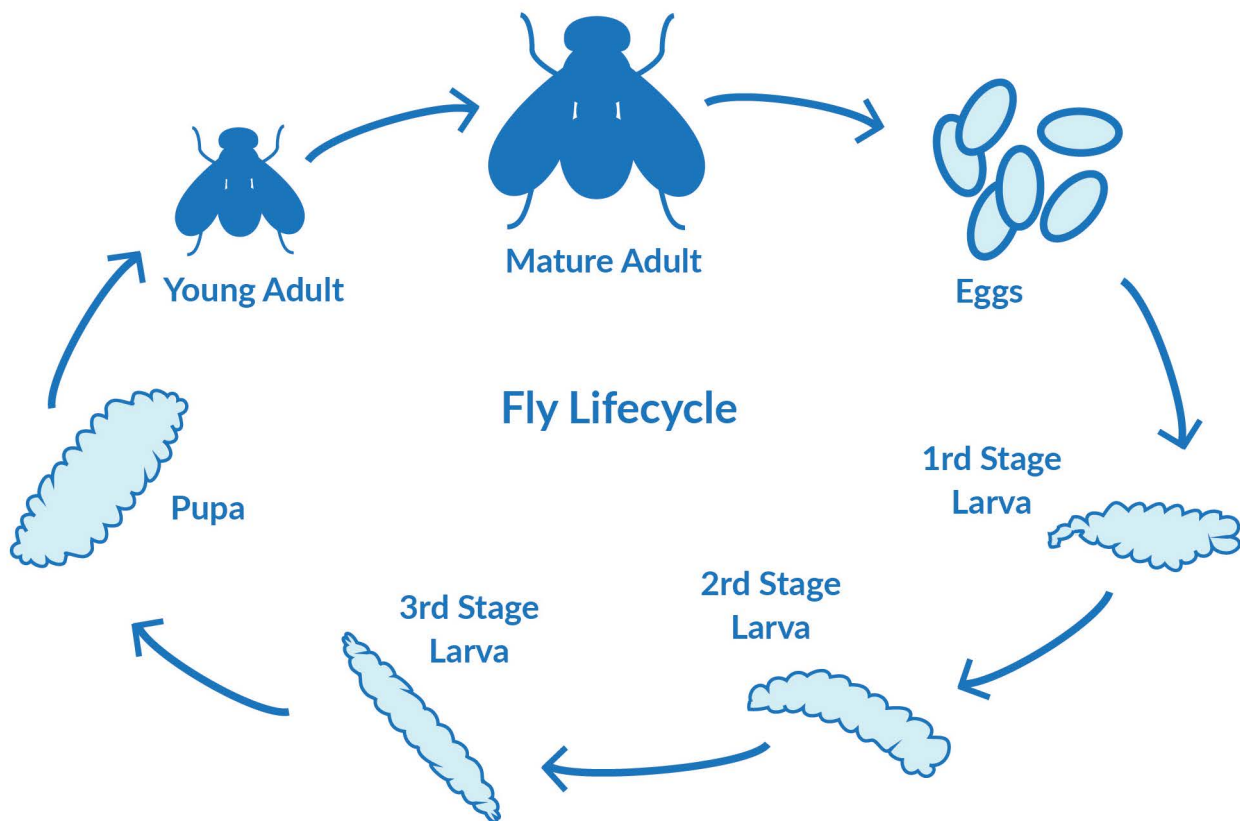


Illustration of House Fly life cycles

Owing to the differences that exist between insect species (e.g. in terms of nutritional needs), the chosen substrate or growing environment may differ substantially.

Examples:

- Black soldier flies are typically fed and grown on wet substrates, whereas mealworms (e.g. yellow mealworm and lesser mealworm), or crickets are grown on dry materials;
- Intense light and certain wavelengths may affect both feed intake and pupation of certain insect species: e.g. bright light inhibits the growth of black soldier fly species, and to some extent affects the growth of other allowed species;
- Production equipment used must be shaped and adapted to each species in order to prevent escape risks: e.g. mealworms can be safely raised in open containers, while Black Soldier Fly or Housefly must be stored in closed containers specifically designed to prevent any escapes.

The responsibility lies with each producer to optimise and tailor the rearing conditions according to the specific insect species to ensure that these risks are minimised. Finally, the quality of the insect breeding flocks is an important parameter to take into consideration (see Chapter 3.3.3 for more details).

3.3.2. Applicable legislative requirements

All operations associated with the growth phase of the animal are considered 'primary production' activities. Therefore, they are subject to the specific requirements contained in Annex I of Regulation (EC) No 1831/2003 as well as in Annex I of Regulation (EC) No 853/2004.

See subchapter 1.1. for more information.

3.3.3. Recommended practices

1. Insect breeding flock management:

First of all, it is recommended to use breeding flocks of a known and traceable origin, that can be traced back for at least 3 generations.

During the rearing process, insect producers should also maintain consistent population density at each developmental stage and register all breeding flocks (e.g. via a traceability report).

2. Control of overall growing environment:

Farmed insects must be kept in a closed environment, whether in vessels, containers, boxes or cages, where the supply of air and substrate can be well controlled.

Insect producers should set up a pest control plan in the growing rooms (e.g. check the absence of pests in the breeding rooms and good conditions of the fixtures).

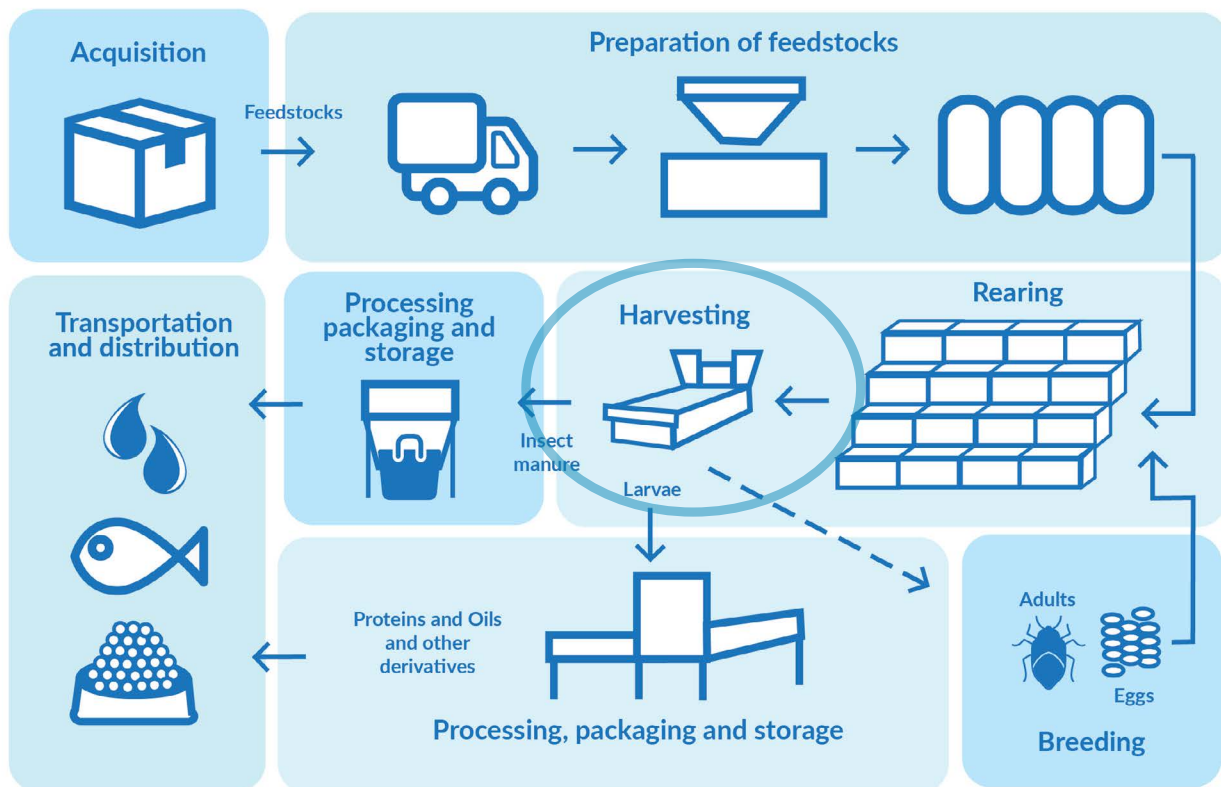
3. Separation of the insect from its feeding substrate before harvesting:

Different practices are used depending on the species reared, the farming system used or the substrates given to the insects. However, as a general rule, no fresh substrate should be added prior to harvesting: in some cases, insects are being removed from the growing substrate several hours before harvesting.

Examples of practices followed by insect producers are provided below:

1. Mealworms and crickets usually go through a specific diet for intestine cleaning before harvesting (e.g. mealworms can be left 12-24 hours after separation from the substrate to empty intestines before killing);
2. Housefly larvae are often isolated from the substrates by lowering oxygen concentration in a closed container.

3.4. Harvesting



3.4.1. Background information

Harvesting operations consist of collecting larvae or adults at the end of the rearing cycle. Insects are removed from the rearing containers or chambers and then separated from the growing substrate and frass.

For holometabolic insects (i.e. mealworms, black soldier fly, housefly) fully grown larvae are harvested, whereas in hemimetabolous insects (e.g. crickets and grasshoppers) animals are harvested at young nymphaea or adult stage.

The harvesting method(s) used may, therefore, also differ from one species to another:

1. Usually, **mealworm larvae** remain in their growing substrate until they are mechanically separated (sieving);
2. **Black soldier fly** larvae may naturally (at a mature level) migrate from the moist substrate to a dry environment, where they can be easily sieved manually or mechanically.

In practice:

1. **Mealworm and black soldier fly** larvae are often collected by a sieving procedure (manual or automated);
2. **Cricket adults** are often collected by sieving from the growing substrate or by insect collecting nets.

The responsibility lies with each insect producer to take account of the characteristics of each insect species reared and to design a harvesting process, which enables the effective separation of the larvae or adult insects from their frass, dead individuals and remaining substrates before killing:

1. Most insect producers use **sieving machines** (for larvae) or '**sorters**' (vertical devices like stackers, cardboard tubes or egg trays for crickets);
2. Hand-selecting insects is also sometimes practiced.

3.4.2. Applicable legislative requirements

Like the insect growth phase, harvesting operations are subject to the requirements contained in **Annex I of Regulation (EC) No 183/2005** and in **Annex I of Regulation (EC) No 852/2004**.

See Chapter 1.1.1 for more details.

3.4.3. Recommended practices

In case the sieving technique is used, the following specific measures are recommended:

- Sieve size (mesh) should enable effective one or two-step separation of insects from frass and the remaining substrate;
- Clean the sieving equipment thoroughly on a regular basis in order to limit microbiological exchange, the proliferation of larvae from unhatched eggs, or the spread of foreign bodies into conforming insects;
- Equipment, boxes, tools and nets should be cleaned consequently according to HESQ principles to avoid contamination;
- In the particular case of volatile feces, operations should separate it from the larvae in a specific confined area, in order to avoid contamination of products in other production lines;
- Collected frass intended for reuse (e.g. land use/fertilisers) must be controlled (e.g. microbiological analysis, heavy metals) and stored in a dedicated area. Non-reused frass (e.g. improper for land use/fertilisers) must be disposed of;
- If wet residual feeding substrate is reused, a drying step should ensure adequate moisture residual contents/water activity suitable for storage.

Besides or in addition to sieving, insect producers are encouraged to use sorting solutions enabling them to efficiently detect and remove foreign materials (e.g. metals or plastic coming from the equipment) or dead insects (e.g. black color larvae).



Photo: Solids Processing.

3.5. Pre-treatment step

Pre-treatment steps generally refer to the cleaning and storage of insect post-harvest to prepare or keep them in hygienic and appropriate conditions before killing and processing.

Different methods may be used to this end. Chilling is commonly used by producers: chilling is a pretreatment step which makes it possible to keep the insects alive while also immobilising them. For example, cold temperatures of 0°C-5°C are often used for black soldier larvae and mealworm, while temperatures between 5°C-10°C are typically applied for crickets. The operator ensures that the temperature remains consistent throughout the process.

Chilling can be used prior to freeze-drying the insects. Chilled insects can be stored/transported in containers. The insects have to form a layer of a certain thickness.

3.6. Specific case of sourcing/sub-contracting practices

The acquisition of insect larvae, as well as part or totality of the rearing process, can be outsourced or subcontracted.

Suppliers or subcontractors responsible for such activities shall fulfill the same legislative requirements and good hygiene practices as described throughout this chapter (i.e. compliance with Annex I of Regulation 183/2005 and in Annex I of Regulation (EC) 852/2004). Their activities should be monitored through an appropriate vendor/supplier approval system. They should demonstrate their commitment to GHP, the safety of the feed substrates and the delivered products (e.g. 'in-house' inspections).

In the case of multi-species facilities (insect rearing and other animal husbandry activities), rooms dedicated to rearing activities and those in which incoming substrates have been sorted must be physically separated from each other to avoid all risks of cross-contamination.

All equipment, vehicles, boxes and tools must be dedicated solely to insect rearing activities. They must be thoroughly cleaned between batches and not circulated outside of the insect rearing perimeter.

The admission of people to the facilities must be strictly controlled. Workers involved with different animals must not enter the rearing perimeter without clean and dedicated clothing, shoes, gloves and other necessary protective gear.

Summary of 'recommended practices or 'warning points' associated with insect rearing activities

Administration of feed/substrates (Chapter 3.2.)

1. The traceability of the substrates given to the animals must be ensured;
2. Only use certified food contact equipment to provide the nutrients/substrates to the animal;
3. Comply with feed preparation formulas;
4. Visually control the truck before unloading and accepting the delivery to detect damaged seals or packaging;
5. Between each batch of production, thoroughly clean the equipment destined to host the insects and/or to provide the substrate to the animal.

During the insects' growth phase (Chapter 3.3.)

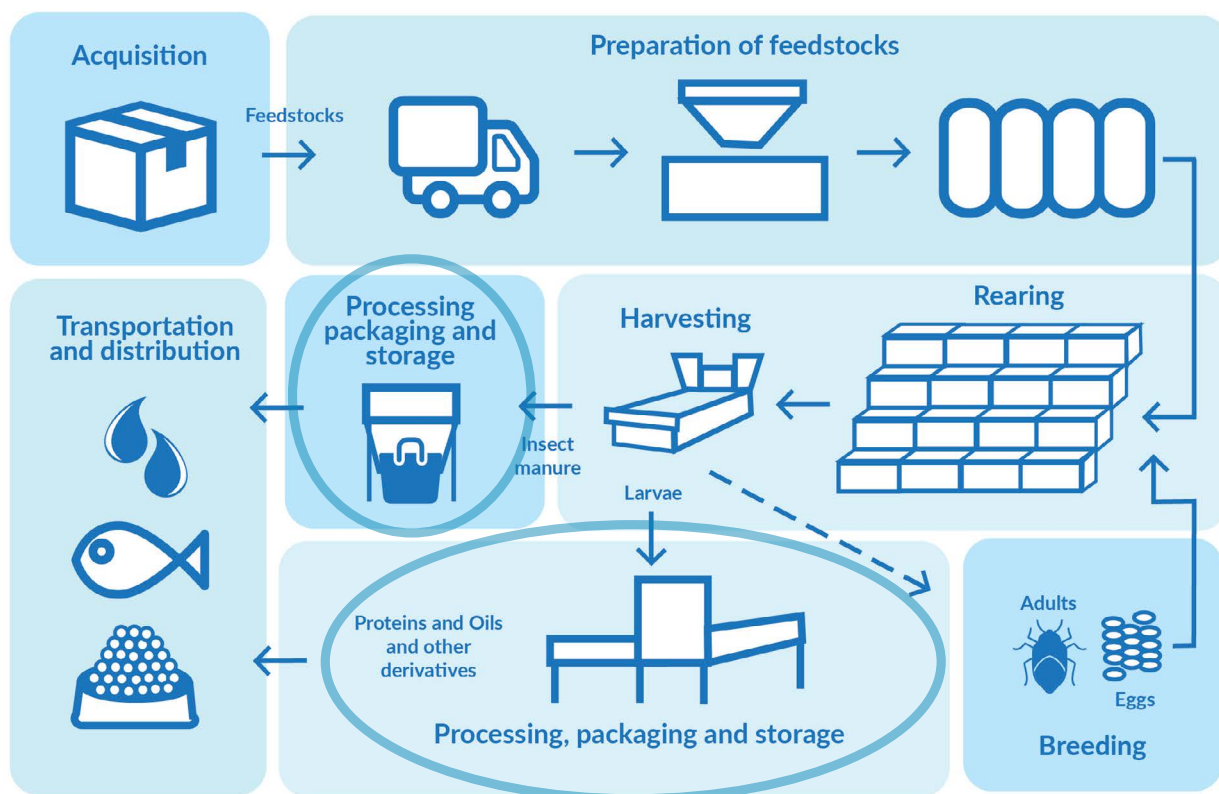
1. Maintain adequate abiotic conditions, especially temperature, light and moisture (taking into consideration the needs of the species);
2. Register all breeding flocks (e.g. traceability report) and ensure they come from a traceable source;
3. Check overall environmental conditions to ensure the absence of pests in the breeding rooms.

Harvesting (Chapter 3.4.)

1. Ensure safe and efficient separation of insects from remaining substrates, frass, dead insects and other foreign bodies;
2. Ensure safe disposal of dead insects, growing substrate and unused frass;
3. Clean thoroughly and regularly the equipment used for harvesting operations;
4. Implement and record analyses on collected frass.

CHAPTER 4 – OVERVIEW OF PROCESSING METHODS APPLIED TO INSECTS INTENDED FOR HUMAN CONSUMPTION AND ANIMAL NUTRITION

4.1. Introduction: scope, legal framework and general recommendations



4.1.1. Background information

This chapter provides an overview of the processing methods involved for insects which are applicable to the production of both animal feed/ food for human consumption. The processing methods discussed in this chapter focus on the killing and post-killing steps resulting in insect-derived ingredients (e.g. processed proteins or insect fat).

To this end, this chapter is divided into three subchapters:

1. The killing of the animal (various methods are used);
2. The 'post-killing steps' (e.g. freeze-drying/heating);
3. The fat extraction steps (mechanical, chemical).

The different steps or techniques described throughout this chapter are not an exhaustive list of all methods that may be used by operators on the ground.

However, this chapter does not cover the following situations, as these fall outside the scope of the EU animal by-products legislation – i.e. Regulation (EC) No 1069/2009 (see section 4.1.2 for further details):

1. The production of live insects (notably used as feed for zoo, circus, reptiles and birds as well as for farmed poultry);
2. Unprocessed (dead) or slightly processed whole insects – that are intended for certain categories of non-food producing animals (e.g. fur animals, reptiles and birds, zoo and circus animals or fishing bait in accordance with article 18 of Regulation 1069/2009).

4.1.2. Applicable legislative requirements for insects as feed

The killing of insects and the further processing steps required to produce animal feed are covered by the **EU legislation on animal by-products** (i.e. Regulation (EC) No 1069/2009 and its implementing Regulation (EU) No 142/2011). Pursuant to Regulation (EC) No 1069/2009, insects and their derived products are treated as ‘category 3’ materials, and are thus authorised for use in feed for food-producing animals and pet food. The ‘TSE legislation’ (Regulation (EC) No 999/2001 – *see below for more details*) should be kept in mind.

Their categorisation as ‘category 3 materials’ implies a number of consequences as to the legal obligations and safety requirements imposed on producers, including the following:

1. Insect processing establishments must be **specifically approved** for the processing of dead animals into insect-based ingredients;
2. Insect producers must conform with **common processing standards and/or criteria** as defined in Regulation (EC) No 142/2011 (Annex IV – Chapter II, Section 4).
3. General standards applying to the processing of insects
See section 4.3 for an overview of the most commonly used methods.

Insect producers of feed must comply with the methods provided for in Regulation (EC) 142/2011. Insect operators must choose between methods 1 to 5 or method 7, as referred to in Annex IV of the above Regulation:

1. If opting for methods 1 to 5, producers must comply with specific parameters (e.g. reduction of particle size, heat treatment, time and pressure) as defined in Annex IV, Chapter 3, points A to E;
2. If opting for Method 7 operators shall comply with the following conditions (defined in Annex IV, Chapter 3, point G).

Processing method 1 (pressure sterilisation)

Reduction

1. 'If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.'

Time, temperature and pressure

2. 'The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.'

3. 'The processing may be carried out in batch or continuous systems.'

Processing method 2 (pressure sterilisation)

Reduction

1. 'If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.'

Time, temperature and pressure

2. 'The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.'

3. 'The processing may be carried out in batch or continuous systems.'

Processing method 3

Reduction

1. *'If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.'*

Time, temperature and pressure

2. *'After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater than 120 °C is achieved for at least 13 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.'*

3. *'The processing may be carried out in batch or continuous systems.'*

Processing method 4

Reduction

1. *'If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.'*

Time, temperature and pressure

2. *'After reduction the animal by-products must be placed in a vessel with added fat and heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight minutes and a core temperature greater than 130 °C is achieved for at least three minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.'*

3. *'The processing may be carried out in batch or continuous systems.'*

Processing method 5

Reduction

1. 'If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.'

Time, temperature and pressure

2. 'After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater than 100 °C is achieved for at least 60 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.'

3. 'The processing may be carried out in batch or continuous systems.'

3. 'The processing may be carried out in batch or continuous systems.'

Processing method 7 (refers to) any processing method authorised by the competent authority where the following have been demonstrated by the operator to that authority:

(a) 'The identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the member states or the area or zone where the method is to be used;

(b) 'The capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health';

(c) 'the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards.

1. Samples of material taken directly after the treatment:
Clostridium perfringens absent in 1 g of the products

2. Samples of material taken during or upon withdrawal from storage:
Salmonella: absence in 25 g: $n=5$, $c=0$, $m=0$, $M=0$
Enterobacteriaceae: $n=5$, $c=2$; $m=10$; $M=300$ in 1 g

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m ;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the

number of bacteria in one or more samples is M or more; and,
c = number of samples the bacterial count of which may be between m and M, the samples still being considered acceptable if the bacterial count of the other samples is m or less.

Details of the critical points under which each processing plant satisfactorily complies with the microbiological standards indicated above must be recorded and maintained so the operator and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, and, as appropriate the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.'

3. Target species allowed, microbiological standards and feed ban rules

Pursuant to Regulation (EU) No 142/2011, insect by-products processed in accordance with the above-mentioned standards may then be used either as insect Processed animal proteins (PAPs), as hydrolyzed proteins or as fat.

If so, Annex X of the above Regulation imposes microbiological targets for the derived products.

Annex X, Chapter I Regulation (EC) No 142/2011

The following microbiological standards shall apply to derived products: samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:

Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g

where: n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.




Furthermore, the options and conditions for using insect-derived products in animal feed are strictly regulated by the EU legislator: **these limitations**, which result from Regulation (EC) No 999/2001 (the so called 'TSE legislation') concern both the target species to which **the insect products** are intended to as well as the **categories of animal by-products used**.

A short overview of the regulatory possibilities for using insects and/or their derived products in animal feed is provided below:

Insects PAPs:

1. Insects PAPs are prohibited as feed for farmed livestock animals (i.e. ruminant and monogastric animals) pursuant to article 7 and Annex IV, Chapter I and II of Regulation 999/2001.
2. However, since 1st July 2017¹⁹, Regulation (EC) No 999/2001 allows **the use of insect PAPs in feed for aquaculture animals**. This authorisation is limited to seven insect species (i.e. black soldier fly, house fly, yellow mealworm, lesser mealworm, house cricket, banded cricket and Field Cricket) based on the insect species that are currently farmed at small industrial scale.
3. Insect PAPs are authorised in feed for pet food without any specific restrictions on insect species that may be used (unlike for aquaculture animals).
4. Insect fats and hydrolysed proteins are authorised in feed for farmed animals (i.e. aquaculture and monogastric livestock animals) and pet food animals, without restrictions as to the insect species.
5. The feeding of live insects to farmed and pet food animals are not subject to limitations at EU level but are often regulated at the national level (such products are traditionally used as feed for niche markets such as birds, reptiles or zoo animals).

¹⁹ Modifications introduced through Regulation 2017/893 (adopted by the European Commission on 24 May 2017)

Substrates			Insect production	Target species			
✓	Vegetal-origin substrates, fishmeal, blood products from non-ruminants, di and tricalcium phosphate of animal origin, hydrolysed proteins from non-ruminants, hydrolysed proteins from hides and skins of ruminants, gelatine and collagen from non-ruminants, eggs and egg products, milk, milk based-products, milk-derived products and colostrum, honey, rendered fats.	Regulation (EU) No 142/2011; Annex XIV Chapter 1 Section 2, 5b			Processed animal proteins	Insect fats and hydrolysed proteins	Live
				Pets and fur animals	✓	✓	✓
				Aquaculture	✓	✓	✓
				Poultry	X	✓	✓
				Pigs	X	✓	✓
✓	Unprocessed former food stuff: milk, eggs and their derived products, honey, rendered fats, collagen, gelatine;	Regulation (EC) No 142/2011; Annex X, chapter 2, section 10	 				
X	Unprocessed former food stuff meat and fish	Regulation (EC) No 142/2011; Annex X, chapter 2, section 10		Authorised list of insect species which are authorised for the production of processed animal proteins (for pet food and aquaculture animals)		REGULATION (EU) No 142/2011; Annex X Chapter 2 section 1A.2.	
X	Catering waste	Regulation (EC) No 1069/2009, article 11 (b)		No restriction as to the insect species		REGULATION (EU) 2017/1017 on the catalogue of feed materials covers:	
						Entry: 9.2.1 for 'insect fat'	
						Entry 9.6.1 for 'hydrolysed proteins of insects'	
X	Animal manure	Regulation (EC) No 767/2009, Annex III chapter 1 (1)				Entry 9.16.1 for 'terrestrial invertebrates live'	
						Entry 9.16.2 for 'terrestrial invertebrates, dead'	

4.1.3. Applicable legislative requirements for insects as food

Producers of insects and products thereof that are intended for human consumption must comply with the 'general' requirements contained in Regulation (EC) 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin.

- Furthermore, this chapter will be complemented, based on the expected new EU standards covering insects for human consumption. Notably the following:

Future authorisations of insects as food at EU level - under [Regulation \(EU\) 2015/2283](#) on novel foods are expected.

Operators processing insects for food purposes may refer to the general provisions contained in Chapter 4. Food production follows similar production techniques and conforms, to a large extent, to the same 'general' safety requirement standards as operators active in the feed sector. Consequently, operators that are active in those fields should refer to section 4.1.1., section 4.2 (killing methods) and 4.2.3 (post killing methods), pending the completion of the present section. They may also refer to the recommendations contained in the other **chapters of the Guide** regarding food and feed safety management systems.

Finally, operators should refer to chapter 6.6.2. on Food safety requirements and recommended practices and the Chapter 7 recommendations on HACCP principles.

4.1.4. General recommendations

The implementation of GHP throughout the manufacturing process is crucial for the production of food/feed products, to prevent biosecurity as well as health-associated risks.

To this end, insect producers for feed shall refer to the general requirements provided for in Annex II of Regulation (EU) No 183/2005. This Annex sets out the following obligations:

1. Written procedures identifying critical points in the manufacturing process must be established;
2. Measures to monitor the presence of prohibited undesirable substances in the feed are in place;
3. Waste materials must be eliminated;
4. Traceability measures and prevention of cross-contamination;
5. Setting up of HACCP procedures (article 6 of Regulation (EU) No 183/2005).

The main duty lies with insect producers to ensure that the processing method(s) implemented are adequate to achieve the general requirements foreseen in the EU legislation (e.g. processing methods used may differ substantially from one operator to another and/or according to the species reared).

Furthermore Regulation 853/2004 on specific hygienic rules on hygiene of foodstuffs, requires food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on HACCP principles. Insect based food operators shall refer to the respective requirements.

4.1.4.1. Recommendations for implementing HACCP principles

Recommendations on implementing HACCP principles at both primary and non-primary insect production and processing stages are outlined in further detail in Chapter 7. A detailed discussion to implement HACCP principles can be found in there.

4.2. Killing step

4.2.1. Introduction

The killing of insects can be performed through different methods, depending on the species reared:

1. Farmed mealworms and crickets are often killed with **hot water** or **boiling vapour**.
2. Farmed black soldier flies are often subject to **mincing** and **heating up**.

The present Guide provides a non-exhaustive list and description of the techniques that are commonly used by European insect producers.

4.2.2. Heating

Killing by hot water

Killing by heating may be done by plunging insects in **hot water** (i.e. 'blanching'). This step allows for an instant death of the insects. The killing temperatures vary from one insect species to another, and from their growth status (e.g. for black soldier fly, the temperature applied is usually of minimum 80° C or a larvae status of 4-5).

Blanching times will depend on the end product and legislative requirements.

1. The levels of temperatures used;
2. Bacterial spores and their survival on the insects;
3. Any other insects reared in the manufacturing environment.

In case hot water or boiling water treatments are applied, residual water post-treatment should be strictly monitored in order to avoid microbiological contamination before further processing. Larvae or insects are then packaged to avoid external contamination and stored in dry conditions.

[Other heating techniques used](#)

Other techniques resulting in near-instant deaths, such as microwave, or infra-red tunnels, may also be used. Processing parameters such as time of exposure or thickness of products should be adapted to the species reared. The operator shall follow safety and security-oriented standards when preparing blanched insects for the next steps (e.g. packaging or grinding) of the manufacturing.



Photo: Example of a thermal step. Courtesy of Protifarm.

4.2.3. Freezing

Through freezing the nutritional value of the insects can be maintained until they are further processed. Insects must be killed at temperatures below 5°C, however, most freezers operate at -20°C. Operators using such techniques freeze insects in bulk and set appropriate freezing times to kill the animals. The time varies from one species to another.

Various methods of industrial tunnel freezing are available such as cryogenic, fluidisation, and impingement, using liquid nitrogen/CO₂ or cooled air.

Before freezing, insects are chilled and deactivated (see chapter 3.5. for more details), as these methods ensure a consistently high quality of the product.

Frozen insects could be stored in sealed boxes or bags (at -20°C) in order to minimise the loss of mass, prior to further processing.



4.3. Post killing steps

4.3.1. Background information

A number of processing methods may be applied on larvae and/or on adult insects after the killing steps. Referred to in the present Guide as 'post-killing steps', these methods have specific purposes in terms of water, fat or chitin extraction. These steps can be of thermal, chemical or mechanical nature.

The Guide provides a non-exhaustive list and description of the techniques that are commonly used by European insect producers.

4.3.2. Freeze-drying

Freeze-drying is used to remove water from insects before they are ground or milled. This technique consists of maintaining a low temperature to dehydrate the insects using sublimation. Blanching times will depend on the end product and legislative requirements.

In order to ensure the safety of the product, insect producers must conform with the following procedures:

1. Prior to placing the insects in the freeze dryer, the operator shall ensure that insects are kept away from any potential contamination sources;
2. Freeze-drying temperatures must be maintained throughout the process (the level of temperature required varies according to equipment and processes used);
3. The freeze-drying environment is thoroughly cleaned between two batches.



Photo: Freezer-dryer. Courtesy of Protifarm.

4.3.3. Heat-based dehydration methods

Depending on the killing method used, larvae or adult insects might still have to be dried in order to remove the water and avoid microbiological contamination. This can be achieved with an oven, where high temperatures are maintained to allow moisture to draw off.

In order to ensure the safety of the product, insect producers must conform to the following procedures:

1. Drying temperatures must be maintained throughout the process (the temperature levels required may, however, vary between insect species or the processes used);
1. The oven is thoroughly to be cleaned between batches and the residues of dead insects are taken away and disposed of with insect waste.



Photo: Union Microwave property.

4.3.4. Grinding

The majority of insect applications in animal feed require a grinding/milling process which transforms the insects into fine particles and a homogeneous powder.

The grinding/milling machinery should be cleaned regularly. The equipment used for grinding purposes shall not be subject to disassembled.



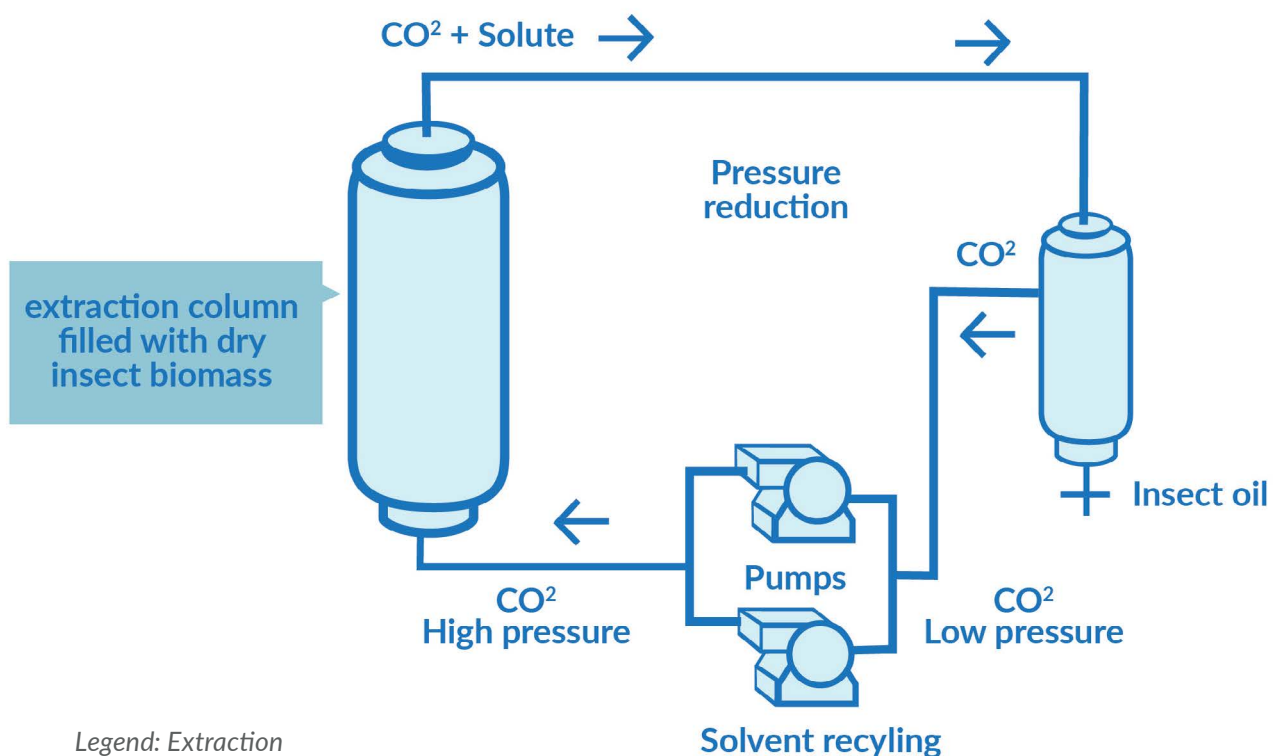
Photo: Grinding, Vercella.

4.3.5. Fractioning

Fractioning consists of applying physical, chemical and biochemical processes to extract protein, fat/oil, chitin and derivatives (e.g. chitosan and glucosamine) at the end of the process. To obtain fat/oil mechanical separation (pressing), heat treatment or organic solvents (e.g. supercritical CO₂ in low temperatures under high pressure) might be used. The latter method also preserves the nutritional values and bioactivity of the dry protein residues (fully defatted insect meal).

Mechanical separation (pressing) and/or heat treatment is used for oil/fat extraction.

Chitin extraction requires chemical and/or enzymatic processing.

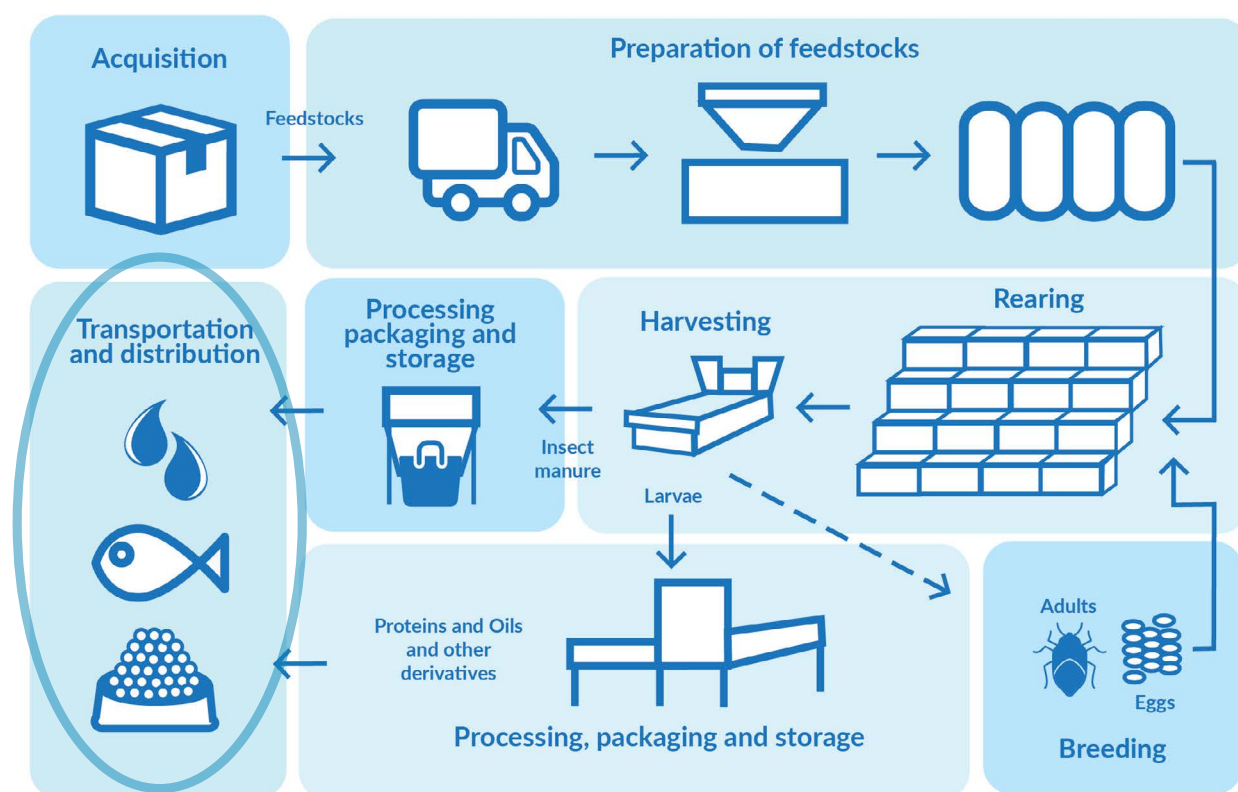


Legend: Extraction



Photo: Mechanical Pressing, Ecolea Technologie

CHAPTER 5 – PREREQUISITE PROGRAMS: STORAGE, PACKAGING, LABELLING AND TRANSPORT OPERATIONS



5.1. Introduction: applicable legislative requirements

Producers of insect products for feed use shall refer to the EU feed hygiene provisions regarding storage and transport contained in the EU feed hygiene legislation (i.e. annex II Regulation (EC) No 1831/2003). The same legislation applies to them as to any other 'feed business operator that is active in stages other than primary production'.

Regulations and relevant annexes	Aspects operators must cover
Regulation (EC) 1831/2003 – other levels than primary production	1. Facilities and equipment
	2. Personnel
	3. Production
	4. Quality control, audit
	5. Storage and transport
	6. Record-keeping
	7. Complaints and product recall

Similar requirements are foreseen in EU food hygiene legislation for food business producers (Regulation (EC) No 852/2004, annex II²⁰): these should, therefore, serve as relevant source of information for producers of insects intended for food use.

Regulations and relevant	Aspects operators must cover
Regulation (EC) 852/2004 – general hygiene requirements for all food business operators, others than in primary production	1. General requirements for food premises
	2. Specific requirements in rooms where foodstuffs are prepared, treated or processed
	3. Transport
	4. Equipment requirements
	5. Food waste
	6. Water supply
	7. Personal hygiene
	8. Provisions applicable to the wrapping and packaging of foodstuffs
	9. Heat treatment
	10. Training

The following sections outline a set of concrete recommendations for translating these general requirements into practice.

Furthermore, specifically for food business operators, Commission Regulation (EC) No 1935/2004²⁰ provides a harmonised legal EU framework on the general principles of safety and inertness for all Food Contact Materials (FCMs). The Regulation revolves around the following core principles that require materials to not: release their constituents into food at levels harmful to human health, change food composition, taste and odour in an unacceptable way. FCMs include direct or indirect contact of materials during the production process of insect-based food products (e.g. containers for transporting final insect-based food products, machinery to process food, packaging materials, etc.). Furthermore, specific FCMs could be subject to requirement on import for non-EU countries (e.g. Products originating or consigned from China or Hong Kong). Furthermore, ERegulation (EC) 2023/2006 on Good Manufacturing Practices for materials and articles intended to come into contact with food, ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation.

²⁰ REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC)

5.2. Recommended practices for storage operations

5.2.1. Premises layout

The layout of the premises is designed to ensure a safe environment and prevent contamination, allow maintenance and minimise deterioration.

Live insects (e.g. often destined to pet food animals or farmed poultry species), should be stored in premises that are designed to avoid any release of the insects into the environment. They should also be kept in a different room from processed insects, in case the company produces both types of products.

Storage areas shall also be designed or arranged to allow **segregation** of raw materials (processed), other ingredients (salt, oil, etc.), flavoring ingredients (relevant for insects as food), packaging, chemicals (e.g. cleaning materials), waste and processed insects.

A separate area for storing materials identified as potentially unsafe shall be provided. Furthermore, producers should prevent non-dedicated vehicles from parking (e.g. fork-lift trucks, lorries) or circulating in storage areas, where possible.

Dry storage facilities (e.g. used to store dry ingredients, packaging) shall provide protection from dust, condensation, drains, waste and other sources of contamination. They shall be kept dry and well ventilated.

The monitoring and control of **temperature** and **humidity** shall be applied as required by product or storage specifications.

All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.

When necessary and appropriate, the operator shall renovate the storage premises and/or ensures premises comply with new standards.

5.2.2. Premises maintenance and cleaning

The storage premises are checked and maintained in accordance with the evaluation procedures detailed in the monitoring programme (see chapter 6.6. for more details on the monitoring programme). Maintenance operations are undertaken by certified and/or qualified agents: E.g. to check that humidity levels correspond to the safety standards applicable to the production activities.

The storage premises **are kept clean** under any circumstances (e.g. to ensure that pests do not spread). Each cleaning employee is required to indicate at what time the storage room or storage equipment was cleaned. The employee signs the document when finished with the cleaning operations. The storage handler keeps a book with the number of cleaning operations per day or per week, depending on the needs. It is important to establish a procedure including cleaning and disinfection activities, monitoring of hygiene and prevention of contamination by cleaning (agents). A documented cleaning and disinfection program is recommended to include the following elements: cleaning method, standards, frequency, chemicals used, equipment used, time and temperature specifications. Records of cleaning and disinfection procedures must be kept. The cleaning and disinfection agents used must be in accordance with the user instructions of the manufacturer and product safety data (information on the potential hazards: health, fire, reactivity and environmental). If cleaning and disinfection agents come into contact with feed/food material, then the responsible personnel must ensure that the control systems always ensure correct and effective levels of dilution of the agents. Cleaning and disinfection agents and other chemicals which are used for hygienic purposes must, if applicable, be stored separately in clearly identified areas. This is to avoid the risk of unintentional contamination or contamination due to negligence. Only permitted cleaning and disinfection agents must be in contact with food/feed materials. These activities should not

form any risk under any circumstances to food/ feed safety. It is to be ensured that objects used for cleaning, cleaning agents themselves, do not remain behind without need on/ in the cleaned equipment or areas.

A **proper ventilation system** equips the storage premises to make sure air-flow is constantly renewed in the premises. The storage premises must be ventilated to prevent excess humidity or heat.

5.2.3. Control of storage conditions

If insects are intended for food use, raw materials and ingredients shall be stored at the temperatures specified by the food establishment responsible for their manufacture. Storage management of non-insect material should follow the principle of first expired – first out (FEFO).

Material that requires cold storage shall be placed under chilled conditions without any unnecessary delay.

Finished products must be clearly identified and appropriately handled and stored.

Placement of finished products in the warehouse shall be managed according to the principle of first in – first out (FIFO).

A thermometer must be fitted in a prominent position on a wall of the warehouse. Temperature readings must be taken regularly.

Traffic arrangements shall be put in place to ensure the safety of the area. Pedestrianised areas should be clearly marked.

Producers of insects intended for food should declare the proper storage conditions that are required depending upon the intended shelf life and use of the product on the label.

Some typical examples of the storage conditions are listed below:

1. Dry, cool and closed;
2. Avoid direct sunlight;
3. Frozen.

Producers of insects intended for food use should periodically check the stability of their product during the shelf life period. In case of deviations, there should be a strategic analysis to identify root causes and the appropriate actions to be taken. Any deviation during the shelf life period should be properly documented.

Summary recommendations of control measures in respect to storage operations for insect-based products

- (Locked) closed storage;
- (Locked) closed transport;
- Cleaning and disinfection procedures;
- Prevention accumulation of organic material;
- Visual check on objects foreign to the product;
- First in First Out (FIFO) strategy;
- Sampling plan for analysis of hazards for incoming raw materials and outgoing products;
- Adequate storage conditions with respect to product specifications;
- Documentation.

5.3. Packaging

Sealing and packaging of insects is a crucial part of the manufacturing process as it contributes to the condition the products will be in when they reach the end-user. Good hygiene, environment, security and quality practices must, therefore, be respected throughout the packaging process to ensure safe food or feed is delivered. To this end, several measures are recommended.

1. The producer using packaging ensures it is clean before insects are placed inside. Where necessary it should be disinfected.
2. The producer ensures the packaging is closed immediately.
3. Storage rooms and recipients/containers/vessels are kept clean to avoid development of non-desired pests. Levels of humidity and lights are monitored and maintained in accordance with the end-product needs.
4. When sealing the final product, the operator ensures that no external source of contamination (e.g. pests, waste...) is included in the sealed bag.
5. Packaging is also labelled according to existing legislation. The operator labels the sealed package on the basis of the intended use.
6. The packaging material used (i.e. FCMs) must come from a certified supplier in order to mitigate chemical, physical and microbiological hazards which could compromise the food/feed safety.

Summary recommendations of hygiene control measures in respect to packaging of insect-based products:

- Have certified suppliers for packaging materials receiving records of packaging materials to avoid packaging material contamination;
- Maintain staff hygiene and attire;
- Set up a cleaning and disinfection plan to avoid chemical residues and microbiological contaminations;
- Develop a quality control plan and preventive maintenance from physical hazards;
- Develop production planning and control to avoid labelling and packaging errors;
- Document the above measures.

5.4. Labelling

End products shall be labelled with the legislative 'mandatory labelling particulars', and insect-based food business operators should emphasise on the following:

Insect as food:

1. Identification mark (see Regulation (EC) 853/2004);
2. Origin of the product (name and address of manufacturer, packer or distributor);
3. Shelf life, date of minimum durability or use-by date (Regulation (EU) No 1169/2011 on the provision of food information to consumers);
4. Recommended storage conditions;
5. List of ingredients (a label reconciliation programme shall be developed to ensure that the labelling of allergens is in full conformity with product recipes and any allergenic substances in the recipe must be highlighted).

Please refer to the IPIFF guidance document on food information to consumers for detailed labelling guidance for insect-based food products²¹.

²¹ IPIFF Guidance the provision of food information to consumers Edible insect-based products.
<http://ipiff.org/publications-position-papers/>

Insects as feed:

1. The rules on the marketing of feed materials and compound feed are established in Regulation (EC) No 767/2009 on the placing on the market and use of feed.
2. End products shall be labelled with the legislative 'mandatory labelling particulars', and insect-based food business operators should emphasise on the following:
 - Traceability information (e.g. type of feed, batch or lot number, net quantity, etc.);
 - Instructions for use (e.g. general instructions for use, species and category of target animals, restrictions for certain species, etc.);
 - Feed specifications (e.g. mandatory nutritional constituent, etc).

5.5. Release of end products

A finished Product Specification document (often referred to as 'birth certificate') should be issued for each batch, specifying all the following requirements:

1. Product description and composition;
2. Ingredient list to be put on the label;
3. Chemical, physical and sensory requirements and characteristics;
4. Microbiological criteria applied to verify microbial controls;
5. Any allergenic contents;
6. Product packaging (including traceability data and information to be put on the pack);
7. Shelf life and corresponding storage and transport conditions (temperature, humidity and lighting conditions and all other applicable elements which can affect product quality and food safety);
8. Any conditions of use.

5.6. Transport operations

This section only concerns transport operations of insect end-products (i.e. dead insects); therefore, it excludes transport of live animals (e.g. breeding stocks or live insects intended for pet food).

5.6.1. General requirements and recommended practices

Manufacturers or handlers, whose mission is to transport food and feed products derived from insects, should maintain the same hygiene standards applied throughout the production chain. These operators are, therefore, compliant with legal requirements set in Regulation (CE) No 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 183/2005 laying down requirements on feedstuff (*see section 5.1 above for more details*).

A few examples of recommended practices are provided below:

- The selection of transports and their activities should be monitored through an appropriate vendor/supplier approval system, demonstrating their commitment to good hygiene practices, especially with their transportation units and workers;
- The transporter shall provide information of the previous shipment and proof of disinfection before insect ingredients are loaded.

Food and Feed business operators shall notify the appropriate competent authority of any establishments under their control, active in transport as laid down by Regulation (EC) No 183/2005 (see Chapter 'Facilities and Equipment' and 'Storage') and Regulation (EC) No 852/2004 as amended (see annex II - Chapter IV transport: Point 4, 5 and 6).

5.6.2. Transport units

Any mode of transport used for transporting food and feed products derived from insects, should be designed appropriately to avoid cross-contamination due to simultaneous or consecutive transport. Transport means must be cleanable and must be made of appropriate material or should be appropriately coated. Appropriate measures to prevent.

The design and manufacture of the transportation units should facilitate inspection, cleaning, disinfection, and when appropriate enable temperature and cooling control. Sanitary requirements are as important in the transport operations as they are in the manufacturing activities.

Upon request by the competent authorities, evidence may be requested to demonstrate that the heating media or cooling system employed has been properly cleaned, evaluated and safely used. Before compartments are loaded, they must be inspected by staff authorised by the operator, the owner or the receiver of the goods (e.g. the truck driver in case of self-service truck stations). An inspection of the loading compartment will be carried out to establish that the loading compartment:

1. Is clean, dry, odorless and correctly maintained;
2. Is compatible with the loading and transport of the specific products;
3. Is suited to the transport needs and forms a closed whole;
4. Does not contain pests and rodents in the widest sense of the term;
5. Does not contain residues or remains from previous loads and/or from cleaning products.

Appropriate measures must be taken to prevent any harmful influence from other products that could arise during loading and transport. This must include consideration of other operations when transporting within a port complex.

Compartments that have been used to transport products regarded as 'high-risk' during the previous load must undergo a risk analysis and may be refused. Construction materials shall be selected to prevent contamination of reared insects and of the stored products. Floors, walls and ceilings shall be washable or covered/painted with a washable protective layer. Technologies used for livestock building construction are recommended, including 'sandwich panel' etc. Raw timber, and materials with rough surfaces should be generally avoided. The operator should prevent non-dedicated vehicles from parking (e.g. fork lift trucks, lorries) or circulating in storage areas, where possible.

Summary of 'recommended practices or 'warning points' associated with storing or delivery operations

Food and feed storing temperatures:

1. Freeze-dried: unchilled
2. Fresh: 0-7°C
3. Frozen: -18°C or colder

Food and feed storing temperatures:

1. Freeze-dried: unchilled
2. Fresh: 0-7°C
3. Frozen: -15°C or colder
4. 4. Dried: ambient temperatures

If the temperature is warmer than above-mentioned limits, the product must be rejected, or Q/A must prove that no damage occurred to the product due to the fact that was exceeding the above thresholds for a very short period only.

Example of elements a Load Compartment Inspection (LCI) module should include:

General Information	Product Batch Reference number / Instructing Company representative and Name of personnel / Name of the transporter / telephone number of the transporter
Place of inspection	(e.g. Storage unit 1/2/3)
Load in Kg	
Temperature (if applicable)	
Destination	
Procedure Information	Date / Start time / End time
Previous cargo in compartment	Last /second last / third last cargo compliant to standards predetermined
Cleaning	Dry / With water / With water+ detergent / With water+ detergent + disinfection
Inspection	Empty Clean Dry Free from pests Free from remnants from previous cargo Visual: completely intact and fully closing
Final result	Accepted: Yes/No
Remarks	
Signatures	Surveyor and transporter

Summary recommendations of hygiene control measures in respect to transport of insect-based products:

- Specifications carrier loads to ensure carrier cleanliness and avoid hazard contaminations;
- Specifications carrier loads to ensure adequate product conditions to avoid hazard contaminations;
- Shipping control to ensure package integrity to avoid hazard contaminations;
- Shipping control to ensure presence of harmful pests;
- Document the above measures.

CHAPTER 6 – PREREQUISITE PROGRAMS: INFRASTRUCTURES AND GENERAL CONDITIONS OF PRODUCTION

6.1. Introduction

This annex provides an overview of the main requirements or recommendations, which may serve as guidance to insect producers, in the designing and/or maintenance of their infrastructures (e.g. the premises, production equipment) and in the general management of their production operations.

6.2. Building and Premises

6.2.1. Building and premises location

Insect producers shall provide and maintain the resources (i.e. buildings, equipment, staff, infrastructure and facilities) that are adequate to the operations involved. When selecting the location for a new production site, at least the following shall be taken into consideration:

1. Availability of services, such as electricity, gas, potable water, drainage and waste collection;
2. The Site should be protected from:
 - neighboring facilities and activities creating possible contamination sources, e.g. farms, heavy chemical industries, etc;
 - areas where waste cannot be removed effectively;
 - rivers, canals, ponds, marshes and other waterways;
 - areas subject to flooding;
 - areas prone to infestations of pests;
 - areas prone to excessive levels of airborne bacteria, yeasts and molds;
 - loud external noise that could disturb the rearing of specific insect species.

Ideally, the local authorities should be consulted from the planning stage.

6.2.2. Building and premises: design principles

Annex II and relevant articles of Regulation (EC) 1831/2003 on feed hygiene indicate:

'2. The lay-out, design, construction and size of the facilities and equipment shall: (a) permit adequate cleaning and/or disinfection; (b) be such as to minimise the risk of error and to avoid cross-contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.

4. Facilities must have adequate natural and/or artificial lighting.

9. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.'

Annex II Chapter I of Regulation (EC) 852/2004 on food hygiene indicates:

'1. Food premises are to be kept clean and maintained in good repair and condition. (...)'

The design and construction of the premises and the process flow shall take into account the relevant hygienic and safety standards. The purpose of a hygienic layout is to facilitate good hygienic practices, to avoid contamination and to enable effective cleaning. Zoning is a widely used principle in the hygienic lay-out of food businesses. Zoning of rooms and areas consists of visual and/or physical barriers that control the movement of staff, products, and utensils between the zones.

The layout, design, construction, siting, and size of the premises shall:

1. Permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
2. Protect goods from damage and contamination. Production units in which insects are reared must stay closed or fitted with nets or grids or any other appropriate means to exclude other pests, or the contamination with other insects, and prevent the presence of rodents. Premises should be built in order to avoid cross-contamination with and from other animal production premises;
3. Have adequate natural and/or artificial light and a controlled environment if necessary;
4. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed;
5. Sewage and waste shall be disposed of in a responsible manner, ensuring that the equipment as well as the safety and quality of food and feed is not affected;
6. The facility should be closed so that dust, rain water and pest invasion is controlled;
7. The premises are also designed to avoid accidental release of insects from the production facilities (e.g. the premises might be surrounded by a shallow moat);
8. Hazardous substances are kept away from rearing environments and from the storage facilities and only used when appropriate (e.g. cleaning process between two batches). Substances considered dangerous are labelled to prevent confusion and misuse by employees;
9. Access to the storage, breeding and rearing areas is restricted to the authorised staff.

In addition, the suggestions below can be integrated into the facility:

1. Foreign substances are prevented from contaminating the substrates or the environment where insects are reared by falling or dropping down (this is particularly crucial when designing new equipment or affecting repairs to existing structures);
2. The building structure could be higher than the surrounding ground to protect it from demolition and contamination;
3. The premises are kept in a good state of repair: the roofing, in particular, should be kept watertight to prevent the substrates, the environment where insects are reared and the storage areas from being affected by water leaks, which can cause mold and attract unwanted insects; Consideration is given to the design and layout of new buildings to minimise roosting and nesting areas for birds/rodents and other areas that will harbor and attract pests.
4. The site is recommended to have:
 - clearly defined boundaries to keep out animals, pests or unauthorised persons;
 - no open water ways that attract birds, insects, rodents etc.;
 - minimal vegetation and foliage. When present, shrubs and plants should be located at minimum distance respective to recommended legislative or certification standards from the buildings;
 - an area of minimum distance respective to recommended legislative or certification standards

around the building, i.e. a gravel walk, which is free of grass, weed, flowers, plants, and other vegetation;

- weed control to reduce harborage for insects and rodents but also to prevent air-borne seeds getting into the factory;
- general facilities designed to meet security and pest control strategies and if needed separate utility buildings, trailers, garages, wastewater treatment facilities, storage sheds, and guard shacks;
- boundaries enough to effectively prevent intrusion.

6. Building design for good hygienic operations should include the followings:

- measures to prevent entry of contaminants from doors, windows, etc., by keeping them closed or using insect proof screens;
- the airflow systems should be adequately adapted to insect production specifications. Excess of heat and/or humidity should be optimised and can even be used for other production activities;
- all facilities should have maintenance for the roof, wall and foundations to prevent leakage;
- measures to prevent entry and harboring of pests, birds and wild insects;
- there should not be structures or equipments, which could provide places for microbial contamination or provide an environment for invasion. E.g. lightings with horizontal parts or fixed to walls which could accumulate dust and residues;
- measures should be taken to reduce cross contamination by planned segregation of flow of air, personnel, materials, products and waste;
- there should be separate storage areas for raw materials, packing materials, chilled or frozen products as well as cleaning tools and agents etc. Furthermore, these areas should fulfil other EU legislative requirements e.g. cleaning agents should be kept in locked cupboards;
- operators should maintain raw materials, products and insects at appropriate temperatures and allow monitoring of these temperatures;
- there should be few personnel entries or openings acknowledging security and fire escape requirements to prevent contamination from people.

7. Hygienic rooms where microbiologically decontaminated ingredients of insect-based products or formulations are sampled, handled or further processed should:

- protect against accumulation of dirt and shredding of particles into food;
- protect against contact with toxic materials, dirt, dust, fumes, smoke and other contaminants;
- protect against condensation and undesirable growth of mold, yeast and bacteria (or microbial growth) on surfaces;
- permit sufficient cleaning and/or disinfection and maintenance;
- allow immediate drying after cleaning and disinfection methods;
- provide enough lightning and ventilation.

Finally, cross-contamination shall be prevented. An assessment of potential contamination sources shall be conducted, in particular, to identify the susceptibility of the product and activities taking place along the processing line. Areas where the potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and segregation (zoning) plan implemented. More specifically, the following measures shall be considered:

1. physical barriers, walls or separate structures;
2. access controls with requirements to change into work clothes;
3. restricted traffic patterns or equipment segregation;
4. separating wet areas from dry areas;
5. separating high-risk areas from other areas, e.g. that the filling area is separated from the handling of raw materials and other food processing;
6. forward moving flow of product (by pipes, conveyors, trucks etc.), from the reception of raw material to the release of the final products to reduce distances traveled by material and staff;
7. areas in which steam is used or aerosols are formed should be separated from areas where products are exposed/freely accessible;
8. adequate and separate location of facilities for staff (cloak rooms, toilets, cafeterias, etc.);
9. have a designed plan in order to move insects personnel and waste without cross contamination.

Construction materials shall be selected to prevent contamination of reared insects and of the stored products. Floors, walls and ceilings shall be washable or covered/painted with a washable protective layer. Technologies used for the construction of livestock buildings are recommended i.e., 'sandwich panel'. Raw timber and materials with rough surfaces should be generally avoided.

All surfaces in contact or close to the product shall be made with smooth, impermeable, corrosion resistant and non-toxic material. All such surfaces shall also be designed to:

1. be easily cleaned and disinfected;
2. protect the product from external contamination;
3. not present any 'dead space', that is space which is not easily accessible for cleaning;
4. be resistant to the cleaning systems applied.

Ceilings and walls shall be made of non-toxic materials which do not flake which are impervious to water and steam. Walls shall be covered with materials which are impervious, non-absorbent, lightcolored, washable and non-toxic. Their surfaces should be smooth, without cracks or flakes and easy to clean and to sanitise. Wall-floor junctions and corners shall be designed to facilitate cleaning. In processing areas, wall-floor junctions shall be rounded.

Doors should be made from smooth and non-absorbent materials which are easy to clean.

Floors should be made of impervious and non-absorbing materials. They should be washable, slip resistant, non-toxic and without cracks.

6.2.3. Building and premises: ventilation

Annex II, Chapter I, of the Regulation (EC) 853/2004 on food hygiene indicates:

'5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. Sanitary conveniences are to have adequate natural or mechanical ventilation.'

A proper ventilation system (mechanical or natural) ensures that the airflow on the insect farming premises is constantly renewed. Excess of heat and/or humidity is transferred under certain circumstances for other rearing environments. For example, excess metabolic heat might be used to heat incubation chambers and breeding chambers, where insects are kept in lower population densities.

Odours should be extracted so that they can disperse in the atmosphere without causing a nuisance to the employees or occupants of the building or any surrounding buildings.

6.2.4. Water supply

The supply of potable water shall be sufficient to meet the needs of the production process(es). A large water supply, under pressure and at an adequate temperature, is required as well as adequate facilities and equipment for its storage and distribution. Potable water shall be protected against contamination.

The processing establishment shall have a supply of potable water, which prior to its first use (including ice), shall meet all applicable local and national regulatory requirements. Plant water including cooling and process water shall meet quality and microbiological requirements appropriate to the intended usage.

6.2.5. Sanitary facilities, staff rooms and laboratories

Annex II, Chapter, Regulation (EC) 852/2004 indicates:

'3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.

4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.'

Management must ensure that sanitary facilities are available to any staff. The sanitary area is equipped with sinks and toilets, has soap or cleaning solution at disposal and is supplied with running water.

Staff facilities shall be well lit, ventilated and kept clean. When necessary, Management makes **cloakrooms** or private closets available to staff so that they can change their clothes before and after performing work-related duties.

These facilities shall be made available to any person frequenting the processing, packaging and storage areas, including visitors. Personnel may only access a high-risk zone through a cloakroom, specially fitted for the purpose, and must observe procedures for putting on working clothes which are clean and visually identifiable. Working clothes and normal clothes shall be stored separately.

Facilities to wash and disinfect hands and shoes shall be available at the entry to the processing areas. Alternatively, shoes must be changed to footwear dedicated to the processing area. The washbasins must be located in highly visible spots before entering the process areas, ensuring that staff have passed them. Washbasins shall be equipped with hands-free operated taps dispensing warm water, with adequate soap dispensers and with hygienic hand drying equipment. When paper napkins are used, there shall be an adequate number of dispensers and waste bins close to each washbasin. The drainage of the washbasins shall be linked directly to the general drainage network.

In-line and on-line **testing facilities** shall be designed in a manner that sampling practices do not increase the risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production area.

6.3. Production equipment

Annex II of the Regulation (EC) 1831/2003 on feed hygiene indicates:

'2. The lay-out, design, construction and size of the facilities and equipment shall: (a) permit adequate cleaning and/or disinfection; (b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.

3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products. (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for

accuracy regularly. (b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.'

Annex II, Chapter V, of the Regulation (EC) 853/2004 on food hygiene indicates:

'1. All articles, fittings and equipment with which food comes into contact are to: (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination; (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination.'

General (design, CIP and installation)

All machines and equipment used for manufacture shall be designed so as to:

1. be easily cleaned and disinfected following validated cleaning procedures and facilitate maintenance;
2. not increase the likelihood of contaminating the product from external sources;
3. prevent that the goods are altered by sludge, water, rain, and other potential contaminants;
4. minimise contact between the operator's hands and the products;
5. not present any 'dead space', that is space which is not easily accessible for cleaning;
6. use food grade lubricants;
7. allow easy disassembling for inspection with tools normally used by the operating and the cleaning personnel if not designed specifically for CIP (cleaning – in place).

All elements including those within a 'Cleaning-in-Place' (CIP) circuit shall be designed and dimensioned to ensure efficient cleaning. All equipment surfaces in contact or close to the product shall be made with smooth, impermeable, corrosion resistant and non-toxic material.

Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

They shall meet current EU regulations on materials in contact with food²². Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

Machinery should be placed in a way that allows adequate maintenance and cleaning to be carried out. The operation of machinery must correspond with its intended purpose and its location must allow it to work according to good operational practice. The location of machinery shall also allow its operation to be monitored, where needed.

If items of equipment are not sealed to the floor, they shall be raised from the floor by a sufficient space to allow easy cleaning and inspection. Ingress of contaminants such as undesirable insects, dust and condensate shall be prevented by ensuring that all the equipment is fitted with appropriate lids. The openings shall also be protected by raised edges so as to prevent the entry of surface drainage.

All joints should be smooth and finished close to the adjoining surfaces, be free from crevices and have smooth rounded corners. Where standing water cannot be removed and may result in contamination of food, the surfaces shall be sloped in order to allow self-drainage.

The fitting of shafts shall be such that leakage of lubricant into the product or leakage of product into the lubricant is prevented. It is recommended to use a seal for the shafts on the product side and another seal on the lubricant side. Any leakage on either side shall flow into an open area without pressure.

²² See https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

Design: equipment specific rules

Vessels shall be designed in such a way as to allow their cleaning with a CIP system wherever possible.

Pipelines shall be designed so as to be cleanable with CIP whenever possible. All product and cleaning pipelines shall be rigid, self-draining and fixed. Pipelines shall preferably be welded or equipped with hygienic joints. Use of plug- cocks shall be avoided if they must be manually disassembled, cleaned and disinfected.

The use of flexible pipelines shall be limited to a minimum, because of their unhygienic junctions. The internal surface shall be regularly inspected. Permanent junctions which are hygienic shall be used.

In order to prevent cross-contamination, there shall not be any piping which connects directly between areas where raw materials are stored and handled and areas where pasteurised products are processed, handled and packed. The same principle shall apply to CIP circuits.

Pumps shall be of a hygienic design and preferably cleanable in place. All pipes shall be designed and equipped to avoid contamination by condensation. The insulation used on the various pipelines shall have an outer layer which is of non-absorbent and cleanable material.

Equipment for CIP shall be designed and installed with no empty spaces that may trap product and prevent cleaning effectiveness. CIP systems shall be separated from active product lines.

Heat treatment equipment shall be designed and installed to ensure that all particles reach the required temperature within the stipulated time. Heat treatment equipment which is linked to a Critical Control Point (CCP) must be equipped with time and temperature control and monitoring devices. A system which prevents non-conforming products (i.e. not treated as intended) from moving forward in the process flow should also be linked. Non-conforming products must be sent back to be heat treated again.

All parts of the **freezing equipment** in contact with the product shall be easily accessible for inspection. The mechanical parts and the framework of the freezing equipment shall be designed so as to avoid inaccessible crevices.

Containers for waste and inedible or hazardous substances shall be:

1. clearly identified for their intended purpose;
2. constructed of impervious material which can be readily cleaned and disinfected;
3. closed, when not in immediate use;
4. preferably fitted with a foot-operated lid or other suitable means to minimise contamination of hands.

This equipment shall be designed in such a way as to prevent rodents from having access and avoid any contamination of the food or feed, the potable water, the equipment, the premises and passages.

Safe food is achieved through adequately designed and effective food safety management systems that include good hygienic practices and HACCP. Adequate traceability and recall procedures are further important tools in case of an undetected loss of control or a problem has been detected after the product has left the control of the food business operator.

Cleaning of production equipment

Equipment must be **maintained in a sufficiently clean** and hygienically acceptable condition in order to avoid pest damages and microbiological contamination. Technical maintenance/service is to be done by qualified staff.

Cleaning could be done both manually or automatically. However, it is important to standardise and validate protocols.

Cleaning programmes shall be established to ensure that the equipment and environment are maintained in a good hygienic condition. The effectiveness and suitability of those programmes shall be monitored on a regular basis.

The equipment is to be cleaned on a regular basis, by means of sweeping and collecting dust or equivalent procedures. This should also be performed prior to a change in products should the products not be compatible.

Records of the cleaning measures must be kept. The record is a part of the internal quality management system. If vehicles (such as pay loaders, etc.) are used, they are to be cleaned on a regular basis.

Regular checks and audits

Annex II of the Regulation (EC) 1831/2003 on feed hygiene indicates

'3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products. (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly. (b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.'

Annex II, Chapter V, of the Regulation (EC) 853/2004 on food hygiene indicates:

'2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfillment of this Regulation's objectives.'

Appropriate hygiene, quality and safety controls are undertaken on the premises, and on machinery and equipment used throughout the production chain. Controls aim to identify issues and correct them, where and when necessary: equipment is regularly checked, maintained and cleaned by qualified staff at fixed and pre-defined intervals.

Maintenance inspections are performed and **recorded** on all equipment. Maintenance inspections at predefined intervals shall be performed and recorded on all equipment where corrosion or failure to operate correctly will result in product degradation or cross-contamination. Records are to be kept about the service and maintenance of the equipment used in the operations. These records are a part of the internal management system.

Each room and machinery have their own cleaning specifications. The effectiveness and suitability of these procedures and instructions shall be monitored on a regular basis. The cleaning materials are also made available in case of emergency or specific punctual needs.

The equipment is replaced when necessary for hygiene, environment, safety, quality or security reasons.

6.4. Pest control measures

Pests (such as birds, insects, spiders, rodents and other small mammals) represent a hazard for the safety of food and feedstuffs derived from insects. That is why a documented **pest control programme** shall be in place to prevent pest activity inside the facility and within the boundaries of the outer grounds.

Potential breeding sites must be removed, any orifices sealed off or hermetically blocked, and windows, doors and air vents fitted with appropriate devices.

The most effective contribution towards infestation control is maintaining good housekeeping and standards (e.g. controlling the accumulation of food and paper debris, keeping gangways and passages clear, removing redundant equipment and materials from production areas, good stock rotation, keeping organic and soiled waste containers covered, etc. (the presence of foodstuffs and water, even as mere trails, unprotected from contact with ambient air is liable to attract pests and shall be always avoided to prevent attracting pests).

The presence of infestation must be checked regularly and the monitoring plan must be reviewed according to the results of the inspections. If rodent baits are used in the factory for the control of rats and mice, they shall be based on fatty and waxy substrates and shall be placed in a solid box. The use of poison baits for rodents shall be limited along the external walls of the facility (unsecured bait stations). Electric flying insect killers must not attract outside insects and must be placed more than three meters away from unprotected products. No domestic animals should be allowed to gain entrance in production or storage areas.

When rodent activity demands, programmes may be set up to utilise poison within the manufacturing site. In this case, the programme shall be controlled in respect of authorised handling of poison bait and great care is taken to prevent any bait spillage and subsequent food safety risks:

1. All bait stations must be clearly identified/coded at the point of use;
2. The bait station must be contained in a secure metal trap;
3. The poison must be of a solid block type (not loose granulates).

Usage and handling of pesticides and/or biocides must be done in accordance with applicable regulations²³. Pest control as well as the risk of microbiological contamination to the products and facilities shall be part of the HACCP system and should be documented. Special attention should be taken for processed feed material such as oilseeds meals, fish meal, maize products.

6.5. Waste management

Annex II of the Regulation (EC) 1831/2003 on feed hygiene states:

'5. Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.'

Annex II, Chapter VI, of the Regulation (EC) 853/2004 on food hygiene indicates:

'1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.

2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.

3. Adequate provision is to be made for the storage and disposal of food waste, non-edible byproducts and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.

4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.'

²³ REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the making available on the market and the use of biocidal products.

Waste²⁴ generated from production or insects or their products, containing hazardous levels of contaminants such as mycotoxins, heavy metals, pesticide residues, chemicals, or other hazards (physical) must be controlled. These must be disposed of in an appropriate way to prevent the contamination of the rearing environment, the substrates used to feed the insects and the insects themselves. These products are to be labelled and stored in a dedicated area with clear zoning points for authorized access.

By-products from insect rearing could include parts from insects, insects that have died naturally insect eggs, and pupas, together with excrement, frass, or substrate if to be discarded must be properly heated before throwing it away or burnt, to prevent any potential remaining eggs from hatching in nature. Other wastes generated from the production process such as discarded packaging material, wastewater, etc. should be managed appropriately through their respective means.

Examples of waste materials expected from insect production:

1. Substrates discarded due to non-conformity;
2. Packaging used for transport of substrates (e.g. paper sacks, big-bags and disposable containers);
3. Plastic foil wrapping used to protect bulk packed substrates.

6.6. Monitoring (sampling and analyses)

6.6.1. General requirements

Insect producers are responsible for demonstrating the safety of the products leaving their production facilities. Official sampling procedures should be put in place to verify that such conditions are met: e.g. to verify that their own product safety sampling systems work properly. Such sampling obligations are often associated with the fulfillment of compulsory microbiological criteria/targets (e.g. for processed insect proteins intended for animal feed use) and maximum limits for contaminants (food contaminants and undesirable substances and products for feed).

While most of the microbiological criteria that are provided for in the EU legislation (e.g. criteria for food products) concern animal species other than insects²⁵ (see below), insect producers are advised to test their finished products periodically against those pathogens, as these could have been transmitted to the animal through the feeding substrate or the production process. This recommendation is in line with the conclusions from the EFSA released on 8 October 2015.

Besides the above-mentioned EU microbiological criteria, insect producers must comply with specific limits and/or standards as set out in food and feed safety assurance systems, established by national authorities or private organisations. Such systems may serve as a point of reference for IPIFF and its members to complement and update the recommendations that are presented in this Guide, in the future.

6.6.2. Food safety requirements and recommended practices

Regulation (EC) No 2073/2005 foresees that *Listeria monocytogens* must be controlled in ready-to-eat foods (e.g. limit of 100 cfu/g for ready-to-eat foods other than those intended for infants that are already placed on the market). These limits, therefore, also apply to food made from insects.

In addition, microbiological limits have been set for raw materials used in meat preparation, for minced meat and meat preparation (e.g. absence of *Salmonella* in 10 g for minced meat and meat

²⁴ Waste: any substance which constitutes scrap material, an effluent, unwanted surplus substance, article which requires disposing of as being broken, worn out, contaminated or otherwise spoiled.)

²⁵ contrary to warm blooded animals, mass-reared insects are not likely to contain substantial number of typical pathogen agents – e.g. *Salmonella*, *Listeria Monocytogenes*.

preparation made from other species than poultry intended to be eaten cooked, 500 cfu/g for **E. Coli** in minced meat at the end of the manufacturing process), or for cooked crustaceans and molluscan shellfish (i.e. Salmonella absence in 25 g of product) under Regulation 2073/2005.

Although these limits are not binding for insect products, insect producers shall assess these risks by testing their finished products periodically against the above. Proposed applications, shelf life and further processing should be taken into consideration when considering microbiological limits; referring to Regulation 2073/2005.

If deemed necessary, insects should also be periodically tested for the presence of other specific pathogens, and for chemicals (e.g. pesticides or heavy metals and mycotoxins following the limits foreseen in Directive 2002/32/EC on undesirable substances in animal feed) and physical agents (e.g. a w).

An overview of microbiological, physical and chemical parameters commonly monitored by producers of insects and insect-based products intended for human consumption (prior to being incorporated as an ingredient in food end-product or to be used as an end-product) are listed below. The 'identification' of hazards does not indicate a contaminated product, but rather direct control measures to be taken using good hygiene/manufacturing practices to fulfil legal/product specific monitoring requirements in order to avoid the identified hazards to impact on food safety. The hazards identified for insect-based products can be controlled by prerequisite programs and HACCP procedures, which also include several hazards 'commonly controlled' under mandatory EU legal requirements. The hazards are identified, and limits developed based on practices by IPIFF members. The criterion in the table are subject to products sampled at the end of the manufacturing process. The frequencies for monitoring these pathogens depend on the respective insect species, production methodology and specification of the insect-based product(s).

Microbiological parameters to be monitored:

Hazards	Main origins	Severity	Management	Target	Limit	Reference
Aerobic flora 30°C	Hygiene indicator Manipulations	Low	Good Hygiene Practices	10.000 cfu/g	500.000 cfu/g	REG EU 2073/2005 Section dry fruits
E. coli	Health indicator Manipulations	Low	Good Hygiene Practices	10 cfu/g	500 cfu/g	REG EU 2073/2005 Section dry fruits
Staphylococcus coagulase + (S. aureus)	Hygiene indicator Manipulations (raw materials or processing operations)	Medium	Good Hygiene Practices	10 cfu/g	100 cfu/g	REG EU 2073/2005 Section dry fruits and Minced meat
Listeria monocytogenes		High	Sourcing/ breeding management	Absence in 25g	Absence in 25g	REG EU 2073/2005 Section ready to eat foods
Salmonella	Insects intestinal tractus	High		Absence in 25g	Absence in 25g	REG EU 2073/2005 Section shellfish
Cronobacter spp. (Enterobacter sakazakii)	Insects	Medium	Sourcing/ breeding management	Absence in 10g	Absence in 10g	REG EU 2073/2005 Section baby powder

Bacillus cereus	Feed	Medium	Feedstock management	10 cfu/g	100 cfu/g	
Monitoring Campylobacter	Insect guts	Medium	Sourcing/ breeding management	Absence in 25g	Absence in 25g	
Moulds and Yeast	Hygiene indicator Manipulations	Medium	Good Hygiene Practices	100 cfu/g	1000 cfu/g	

Chemical parameters to be monitored:

- Pesticides (Organochlorine pesticides, organophosphorus pesticides, other pesticides);
- Heavy metals (lead, cadmium);
- Cleaning and disinfection residues;
- Contamination through material contact.

Physical parameters to be monitored:

- Metal pieces;
- Foreign particles, glass and plastic pieces;
- Insect parts such as wings or legs (if applicable).

Allergens

Considering the existence of scientific evidence showing allergic cross-reactivity between insects and crustaceans, and/or unprocessed or processed insects that may contain allergens(s) originating from the feed materials which were ingested by the insects, allergen residue and cross contamination among products must be monitored. Monitoring for the presence of one or more of the 14 EU listed food allergens and or the insect itself linked to the listed allergen crustaceans is recommended to be included in the 'monitoring plan'.

6.6.3. Feed safety requirements and recommended practices

Samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:

1. Salmonella: absence in 25 g: $n = 5$, $c = 0$, $m = 0$, $M = 0$
2. Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 300$ in 1 g

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m ;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more;

and c = number of samples the bacterial count of which may be between m and M , the sample still being considered acceptable if the bacterial count of the other samples is m or less.

Operators applying the so-called 'method 7' (annex IV, Chapter 3, point G. of Regulation (EC) No 142/2011) must demonstrate the absence of *Clostridium perfringens* in 1 g of the product. The sample must be taken directly after treatment, on a daily basis, over a period of 30 production days.

If deemed necessary, insects should also be periodically tested for the presence of other specific pathogens, including chemicals (e.g. pesticides or heavy metals and mycotoxins following the limits foreseen in Directive 2002/32/EC on undesirable substances in animal feed) and physical agents (a w).

Some possible chemical and physical parameters identified regarding insect production for feed are listed below:

- Pesticide residues;
- Mycotoxins (Aflatoxin, Ochratoxins, Deoxynivalenol, Zearalenone, Fuminosin);
- Heavy metals (As, Cd, Cr, Cu, Hg, Pb, Ni, Zn);
- Polycyclic aromatic hydrocarbons;
- Dioxins;
- Animal proteins;
- GMOs;
- Metal, plastic, stone pieces;
- Foreign objects.

6.6.4. Creating a monitoring programme

Sampling and testing measures implemented by insect producers must be specifically foreseen in the monitoring programme in Chapter 7 on HACCP.

General remarks regarding sampling for insect products as food and feed:

- It may be necessary to intensify or reduce sampling based on the results;
- In the case of a positive detection of microbial contamination, it is advisable to test for contamination afterwards;
- Moisture content percentage measurements are of great importance because it is the final step in the production process to guarantee food safety. Registration of moisture percentage measurements must be recorded on the 'product registration' form.

6.7. Personnel

6.7.1. Information flow and training

The employees, including temporary, recently hired staff, maintenance and transport staff as well as suppliers, are informed about and trained in their duties and areas of responsibilities. They are aware of hygiene requirements. The purpose of training employees is to ensure that they have the competencies needed to meet the corporate objectives on food safety.

The Management and the HSEQ manager make sure all type of staff is made aware of hygiene issues along the insect food and feed production chains.

Training of all staff - whether permanent, temporary or sub-contractor - shall at least address the following:

1. GHP and HACCP standards;
2. Food safety, including carrying out monitoring, corrections and corrective actions;
3. Safety of people, particularly with regard to the potential allergenic properties of the insect species reared;
4. Specific competencies related to the operations carried out;
5. Basic first aid skills;
6. Principles and conditions for rearing;
7. Principles and conditions for processing;
8. Required documentation;
9. Pathogens and pests that could grow in an insect farm to enable early recognition of disease symptoms.

Newcomers to the organisation shall receive specific training according to a hygiene training schedule adapted to the competences of the person engaged. The main objective of the frequent (annual) training scheduled is to ensure that every employee has the skills necessary to evaluate and interpret the results from the annual HACCP review. Frequent performance reviews shall ensure that each member of staff has the competencies required to meet the company objectives (particularly on food safety) and tasks and to successfully complete the tasks their role profile requires. Opportunities for improvement and expansion of their skill-set shall be provided. The effectiveness of staff training shall be regularly evaluated.

For internal staff, training also addresses internal management, recording procedures, commercial uses and when appropriate legislative aspects. There should be personnel on-site who are specifically trained for emergency situations.

For external visitors, a HSEQ presentation should be done covering for example:

10. the main factory risks;
11. forbidden behaviors (smoking, running etc.);
12. emergency exits and emergency procedures;
13. individual protection equipment.

6.7.2. Clothing and personal behaviour

Annex II of the Regulation (EC) 853/2004 on food hygiene indicates:

'14. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean, and where necessary, protective clothing.'

Management ensures staff has access to and is using appropriate clean clothing and protective wear (e.g., helmet, safety shoes, gloves when required, apron, protective glasses, dust masks) when operating within the production facilities. A list of necessary clothing should be elaborated and communicated to the staff and updated when necessary.

Examples of appropriate clothing in insect production facilities:

1. Ear plugs should for people working in high noise environment;
2. Helmet and glasses should be used by maintenance staff;
3. Gloves for people with direct product contact;
4. Mask for people working in breeding chambers;
5. When dealing with insect frass, which is a potential allergen, the staff responsible for harvesting should make sure to use appropriate protective tools (e.g., protective glasses, dust mask with filters, and aprons).

Furthermore, the staff is required to avoid any behavior that could impact the safety of the food and feed produces and comply with the following minimum requirements: in particular any form of smoking, eating, chewing and spitting is prohibited inside the production area. Signs and instructions should clearly indicate prohibited behavior and staff must comply with it.

6.7.3. Personal health

Annex II of the Regulation (EC) 853/2004 on food hygiene indicates:

'2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come in contact with food is to report immediately the illness or symptoms, and if possible, their causes, to the food business operator.'

Operators who may come in contact with foodstuffs must always be in good health: no person who suffers from or is a carrier of a disease likely to be transmitted through food or feed is to be permitted to handle insect products (e.g. whole animals, killed animals, processed products), food and feed, or enter any food/feed handling area.

Personnel shall be instructed by their supervisors to report poor health conditions such as all communicable diseases, illness, open lesions or any other abnormal source of microbiological contamination to avoid contaminating food, food-contact surfaces or food packaging materials.

Management will, in turn, submit a declaration in case of health problems e.g. gastroenteritis; vomiting; carrying Salmonella; high temperature; a sore throat with fever; infected skin lesions; nose, eye or ear discharges.

Supervisors shall verify that the staff have understood the instructions. People who report or are shown to have the above symptoms shall be excluded from any operations involving food handling until they have recovered. Personnel must be aware of the diseases which must be reported to management.

Subject to legal restrictions in the country of operation, employees shall undergo a medical examination prior to employment in food contact operations, unless documented hazard or medical assessment indicates otherwise.

Summary: the implementation of the above mentioned PRPs are summarised here. If the PRPs are properly implemented, maintained and verified, risks for food/feed safety are reduced.

6.2.	Building and Premises
Aim	Lay-out, design and maintenance of company premises must be as such that risks of contamination of insect food/feed stuff is minimised.
Action	Risk assessment on environment/company premises and implementing hygiene practices <ul style="list-style-type: none"> • Plan on facility site map • Plan on access, outlets, physical and organisation separation plans
6.3.	Production equipment
Aim	<ul style="list-style-type: none"> • Prevent contamination of insect food/feed products due to unsuitable equipment design, leading to inefficiency in cleaning and disinfection procedures. Develop, implement and maintain a cleaning and disinfection program. • Prevent contamination of insect food/feed products due to maintenance, lack of maintenance or not well calibrated equipment. Develop, implement and maintain a maintenance program
Action	<ul style="list-style-type: none"> • Compliant Equipment design to hygiene requirements and cleaning and disinfection programs. • Maintenance and calibration procedure, program and records.
6.4.	Pest control measures
Aim	<ul style="list-style-type: none"> • Prevent pest (including insects, birds) and increments from contaminating insect food/feed products. • Make a pest control program, implement and maintain it.
Action	<ul style="list-style-type: none"> • Pest control procedure, program and records.
6.5.	Waste management
Aim	<ul style="list-style-type: none"> • Identify waste and minimise the risk of unintended introduction into insect food/feed ingredients.
Action	<ul style="list-style-type: none"> • Waste management procedure, program and records.
6.6.	Monitoring (sampling and analyses)
Aim	<ul style="list-style-type: none"> • To demonstrate and ensure the safety of the insects food/feed product.
Action	<ul style="list-style-type: none"> • Risk assessment and develop monitoring plan • Maintain records
6.7.	Personnel
Aim	<ul style="list-style-type: none"> • Establish hygiene policy and access control and communicate these to all personnel and subcontractors.
Action	<ul style="list-style-type: none"> • Communication of hygiene policy (instruction agreed by employees and subcontractors) • Access regulation (instruction)

CHAPTER 7

IMPLEMENTATION OF HACCP PRINCIPLES BY INSECT PRODUCERS

7.1. Introduction

Food and feed producers use the HACCP (Hazard Analysis and Critical Control Points) approach to anticipate, prevent, eliminate or reduce to acceptable levels physical, biological and chemicals hazards in the food and feed production chain.

Instead of relying on end-product testing, HACCP offers a preventative approach that can be applied to the food chain, from primary production – although not required by EU food and feed hygiene legislation - to the final consumption of the insects irrespective of whether they are intended for food or feed.

A wide variety of modern preservation methods are available. However, specific measures to ensure high quality and food safety may be required for different insect species depending on their biological makeup.

It is important to stress that HACCP systems are company-specific and are based on respective farming, rearing and production techniques followed within the identified company.

Although no significant health problems have arisen from the consumption of edible insects, consumer confidence is arguably strongly correlated with the perceived safety of a given product. The HACCP is, therefore, crucial to ensure edible insects are subject to the highest safety standards possible.

The HACCP elements underlined in the following pages aim to provide a basic guide for HACCP aspects that shall be covered by the industry.

Reminder: The implementation of the GHPs described in the first chapters of this Guide is a mandatory prerequisite to the HACCP plan.

7.2. HACCP principles

HACCP is designed to prevent problems before they occur, correct deviations when they are detected and provide all the records for further analysis. It relies on seven principles:

1. Conduct a hazard analysis;
2. Determine the Critical Control Points (CCP) and Operational Prerequisite Programmes (OPRP);
3. Establish critical limits;
4. Establish a system to monitor the CCP and the OPRP;
5. Establish corrective actions to be taken when monitoring indicates that a particular CCP is not under control;
6. Establish procedures of verification to confirm that a HACCP System is working effectively;

7. Establish documentation concerning all procedures and records appropriate to these principles and their applications.

7.3. HACCP in 12 points

Implementing a robust HACCP system can be achieved with twelve sequenced steps:

1. Assemble the HACCP team;
2. Describe the food and its distribution
3. Identify the intended use and consumers;
4. Develop a flow diagram describing the process;
5. Verify the flow diagram;
6. Conduct hazard analysis (Principle 1);
7. Determine critical control points (CCPs) (Principle 2);
8. Establish critical limits (Principle 3);
9. Establish monitoring procedures (Principle 4);
10. Establish corrective actions (Principle 5);
11. Establish verification procedures (Principle 6);
12. Establish record-keeping and documentation procedures (Principle 7).

The first five steps are preparatory phases to the application of the classical seven HACCP principles.

7.3.1. Assemble the HACCP team

The HACCP team consists of a group of people responsible for applying the HACCP method. They are identified within the company and properly trained to implement, review and maintain the HACCP plan.

In cases where the formation of the company consists of few personnel (e.g. startups), the HACCP team participant could be outsourced or if within the company, undertake multiple responsibilities whilst fulfilling the required competence of the position.

The team should include multidisciplinary specialists of different levels (field staff and management), related to the insect sector and have the following skills:

1. Understanding of the biological, chemical or physical hazards connected to products for feed and food in the insect sector;
2. Having responsibility for, or being closely involved with engineering/producing/controlling activities;
3. Having sufficient knowledge of the hygiene and safety operations applied to the process plant and equipment;
4. The team lead - HACCP team leader- must be a management representative or have direct access to management.

A representation of a HACCP team for an insect producing company as food and feed is portrayed below.

Name	Role HACCP Team	Job title	Organisation	Contribution	Contact email	Approved By
XXX XXX	HACCP Lead	Chief Operations Officer	XXXX	Select HACCP team, chair HACCP meetings, manage HACCP process	XXX@xxx.com	XXX XXX
XXX XXX	Product specialist	Technical Manager	XXXX	Product specifications	XXX@xxx.com	XXX XXX
XXX XXX	QMS Team	QHSE Specialist	XXXX	Quality and Hygiene design and implementation	XXX@xxx.com	XXX XXX
XXX XXX	Process specialists	Process Operator	XXXX	Operations, working practices specifications	XXX@xxx.com	XXX XXX
XXX XXX	Insect rearing expert	Insect rearing expert	XXXX	Insect rearing specifications	XXX@xxx.com	XXX XXX
XXX XXX	Entomologist	Entomologist	XXXX	Insect health and characteristic specifications	XXX@xxx.com	XXX XXX
XXX XXX	Additional specialists	Consultant in the food/feed production chain	XXXX	Knowledge in regulations	XXX@xxx.com	XXX XXX

7.3.2. Describe the product and its distribution

A detailed description of the products must be done to provide a relevant basis for the hazard analysis and ensure a proper assessment of food safety. The following elements should be covered:

1. A description of the feed/food range of products (e.g. Whole insects, protein meal, fat, hydrolyzed proteins);
2. The origin and description of the intakes at rearing or processing level, ingredients, additives as well as their prominent physical properties (Aw, pH, etc.);
3. Processing methods involved (freezing, refrigerating, heating, drying, etc.);
4. Microbiological or chemical criteria applicable;
5. Packaging (e.g. carton, plastic-based materials, vacuum, etc.);
6. The storage conditions, shelf life, delivery methods.

A non-exhaustive example of a product description is illustrated below

Name of Product	'Name of insect species'
Life Stage	
Product description	'insect meal, powder,etc'
Processing method used	
Category of product	Raw/Semi-finished/Finished product
Packaging	

**Storage
conditions**

Intended use

Destination 'Intended user'

7.3.3. Identify the intended use and consumers

Considering the applicable regulations for the insect in food or feed, the HACCP team should describe the normal/expected use of the product by customers, and the targeted consumers (humans, pets, farmed fishes, etc.).

1. Describe the expected use;
E.g. 'Name of product' 'powder/meal' is a natural balanced source of protein, fat and fibers, obtained by processing 'name and life stage of insect species' reared on feed material. The product is a powder/meal typically used at 'XX %' for wet/dry pet food/animal feed/fish feed/edible food formulations as a source of proteins and fats.
2. Identify the consumers;
E.g. Local and International pet food/ animal feed/fish feed/edible food market
3. Identify possible misuses.
E.g. Improper storage conditions, preparation of formulations.

7.3.4. Develop a flow diagram describing the process

The flow diagram acts as a key element for the comprehension of the steps associated with insect processing activities.

Preceding, following or sub-contracted steps might also be considered.

The flow diagram must list the consecutive processes and does not need to be complex (block type flow diagram).

Representation of a flow diagram applicable to insects as food/feed producers and processors based on IPIFF member activities.

Legend:

Primary Production: Rearing of insects: ■
Processing 1: Processing of insects: ■
Processing 2: Integration of processed insects as an ingredient: ■



It could be supported or annotated with the following technical data, for a better understanding.

1. Segregation of clean and dirty routes;
2. Equipment layout and characteristics;
3. Sequence of process steps (including the incorporation of feed/ingredients/additives, delays between steps, etc.);
4. Technical parameters of operations (time/temperature at processing or storage of insect ingredients);
5. Flow of semi-finished/finished products, wastes (including potential cross-contamination).

7.3.5. Verify the flow diagram

An on-site review shall be conducted to demonstrate the accuracy of the diagram. All process routes including interactions between the personnel, wastes and the product must be investigated.

Evidence of the verification by the food safety team must be documented and recorded.

7.3.6. Conduct Hazard analysis (Principle 1)

Hazard analysis consists on the consecutive implementation of the following activities

1. Hazard identification;
2. Hazard evaluation and preventive measures;

Hazard identification results in creating the most comprehensive list of hazards which are reasonably likely to occur and cause injury or disease if not effectively controlled.

Different tools can be used by the HACCP team to properly sort hazards at each step of the process (Ishikawa diagram, histories of non-compliances in the company /sector or a list of predefined questions – Appendix A).

An example of using 5 Ms method for the process step (Step 15 in the process diagram portrayed above) on storage of insect sourced raw materials.

Material	Insect powder quality, specifications
'Milieu' - Environment	Atmosphere, surrounding areas, pests
Man	Staff hygiene
Method	Operating method, cleaning and disinfection plan
Machine	Installations, transport equipment

Hazards are usually divided into the following categories:

1. Biological

- pathogenic microorganisms (Listeria, Salmonella, Bacillus Cereus, Staphylococcus aureus, E. coli), These may originate from
 - contaminated goods
 - water/air used in processing
 - accumulation of biofilms in equipment;

A representation of a HACCP team for an insect producing company as food and feed is portrayed below.

- Viruses, parasites
These may originate from contaminated goods;
- Yeast and moulds
These may originate from contaminated goods;
- Mycotoxins
These may originate from
 - contaminated goods
 - long storage and/or bad storage conditions of the goods.

2. Chemical:

- pesticides (Organochlorine, Organophosphorus, Carbamate) residues on goods;
- cleaning and disinfection product residues on equipment's;
- heavy metals traces on goods;
- equipment maintenance residues.

3. Physical: contaminants such as broken glass, plastic or metal fragments, dead or other types of insect pests, stones.

4. Allergens (food): Allergens from the insect (allergic cross-reactivity between insects and crustaceans) themselves and/or unprocessed or processed insects that may contain allergens(s) originating from the feed materials which were ingested by the insects. Other sources can include products containing allergens used to formulate final product.

These hazards can be introduced, controlled or enhanced (e.g. introduction, survival or multiplication of organisms in the case of microbiological hazards).

The second step of the **hazard analysis**, involves a risk assessment and the definition of preventive measures.

In the risk assessment identified hazard are rated according to:

1. Their severity of harm for the end user of insect-based products;
2. Their probability of occurrence without suitable control measures.

Even though no hierarchy is imposed, severity and occurrence can be rated from 1 to 5. Their multiplication provides an estimation of the overall risk as well as possible responsive actions.

Example of a risk assessment matrix:

RISK RATING							
SEVERITY	Catastrophic (5)	5	10	15	20	25	
	Significant (4)	4	8	12	16	20	
	Moderate (3)	3	6	9	12	15	
	Low (2)	2	4	6	8	10	
	Negligible (1)	1	2	3	4	5	
	(1) Improbable	(2) Unlikely	(3) Occasional	(4) Probable	(5) Frequent		
OCCURRENCE							
						Severe Unacceptable Undesirable Acceptable Normal	<div></div> <div></div> <div></div> <div></div> <div></div>
							Interruption Urgent action Action Monitoring No action

Finally, the HACCP team shall describe the control measures required to prevent the occurrence of the hazard, eliminate it or reduce it to an acceptable level. When necessary, an action plan should be set up, details of people in charge and lead-times to implement the control measure (see 3.10 – corrective actions).

Outputs of the analysis can be documented and recorded within a table identifying the potential types of hazards, their causes, the risk of occurrence and proposed control measures for each processing step.

Example of a risk assessment table:

Process Stage:	Hazard	Reference number in process diagram	Causes		Risk			Preventive measures	Decision			
			Source	Description	Frequency (F)	Gravity (G)	F*G=Risk		PrP	oPrP	CCP	
Reception of raw material	Microbiological											
	Enterobacteriaceae	1	Material	Contaminated goods	1	5	5	Cleaning and disinfection procedures - Closed production system - Use only feed materials and feed additives according to feed legislation and/or 'private standards' requirements for feeding of food-producing animals.	x			
	Salmonella	1	Material	Contaminated goods	1	5	5					
	Moulds and yeasts	1	Material	Contaminated goods	2	5	10					
	Microbiological pathogens	1	Man	Staff hygiene	2	4	8	Instruction / training for reception	x			
	Microbiological pathogens	1	Method	Cleanliness of the reception area	1	4	4	Cleaning and disinfection plan	x			
	Chemical											
	Heavy metals and Pesticides in raw material	1	Material	Contaminated goods	2	5	10	Controlled reception,Supplier Management (analysis, audits), Testing for pesticides and heavy metal residues.	x			
	Physical											
	Metal, plastic, stone pieces in raw material	1	Material	Contaminated goods	1	4	4	Controlled reception,Supplier Management (analysis, audits), raw material analysis	x			
	Pests	1	Environment	Infested goods	1	5	5	Designated closed storehouse for raw material,Implementation of a pest control program, visual control at reception	x			
	Allergens											
	Allergen cross contamination	1	Method	Poor storage and mixing raw materials	1	4	4	The organisation and procedure on storage of raw material	x			

7.3.7. Determine critical control points (CCPs) (Principle 2)

A **CCP (Critical Control Point)** is a step at which **control can be applied** and **is essential** to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

All CCPs require control measures, monitoring procedures, responsible staff and records. In addition, CCPs require that **measurable critical limits be identified** to determine safe and unsafe conditions.

Examples of CCPs may include:

1. Chilling;
2. Thermal processing;
3. Testing product for metal contaminants.

The determination of **CCPs** can be done with a decision tree (see Appendix B, which indicates a logical reasoning approach).

Other significant hazards not identified as a CCP, are defined as **oPRP (Operational Prerequisite Program)**.

oPRPs are essential to reduce the likelihood of introducing food safety hazards and/or contamination to the products or the processing environments as well as limiting the proliferation of hazards.

oPRPs require control measures, monitoring procedures, responsible staff and records. They **do not require that critical limits be set**.

As a comparison, **CCP** must be monitored on a permanent basis (continuously or not continuously), while **oPRP** are monitored on a regular basis (non-frequent monitoring) but not necessarily on a permanent basis.

Reminder: **PrP (prerequisite programs) or GHP (Good Hygiene Practice) are basic food safety conditions**, necessary to implement or maintain a hygienic environment throughout the feed/food chain, suitable for the production, handling and provision of safe end-products. They are the first step to implement before considering a HACCP analysis.

An example of a CCP determination regarding insect as food/feed processing using thermal treatment (Blanching, Thermal treatment, drying) – corresponding to process step 8, 9, 11 in the process chart portrayed above. One or all the thermal treatment steps could be determined as a CCP depending on the processing method used for the specific insect species. For this example, step 8- blanching is considered as a CCP.

Description of the CCP: Blanching

Description of risk	Unsafe end products by the presence of microbiological contamination
Process step	Blanching
Reference number in process diagram	8
Type of risk	Temperature and/or time too low with as a result insufficient killing microbiological population
Control measure	
Measure	Heating of the 'product' above 'XX' ° C for a minimum of 'X' minutes to guarantee microbiological killing.
Control	<ul style="list-style-type: none"> • Equipment temperature log • Alarm signal in case of temperatures below parameters • Insects sampling after blanching treatment for postmortem inspection: color verification (visual control) • End products sampling for bacteriological analysis (Salmonella and Enterobacteriaceae) • Equipment surface examination to ensure efficiency of cleaning and disinfection measures
Frequency	<ul style="list-style-type: none"> • Continuous measurement during production for postmortem inspection, • Continuous monitoring of the log data for equipment time/temperature efficiency,
Responsible person	Operator
Referral document Control measure	Sr.no.xx. Procedures production: control measure
Recording	Paper and/or electronical documentation (quality department document)

Corrective Actions in the event of deviations

Corrective action	<ul style="list-style-type: none"> • Action on equipment deviations (time/temperature) and check product temperature • After consultation, reheat or dispose
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Responsible person	Production Manager
Referral document corrective action	Sr.no.xx. Procedures production: corrective action
Recording	Paper and/or electronical documentation (quality department document)
Verification	Paper and/or electronical documentation (quality department document)
Method	Calibration equipment
Frequency	Minimum once a year or when in doubt
Referral document corrective action	Sr.no.xx. Calibration report
Responsible person	Production manager

Comments

7.3.8. Establish critical limits (Principle 3)

For each **CCP**, the HACCP team must determine critical limits and tolerances for monitoring purposes. These limits must be established to ensure that the hazard never exceeds the acceptable level in the finished product. Limits must be measurable, clearly documented and validated.

Example of criteria:

1. Temperature, time or pressure according to processing methods (e.g.: annex 4, chapter 3 of Regulation EC 142/2011)
2. Moisture level, Aw
3. pH

Example of management of process monitoring during blanching of edible insects

Operating limit: Blanching time and temperature is adequate

Critical Limit:

Process parameters

- Blanching temperature: more than XX°C;
- Blanching time: more than X min;

Insect's postmortem inspection:

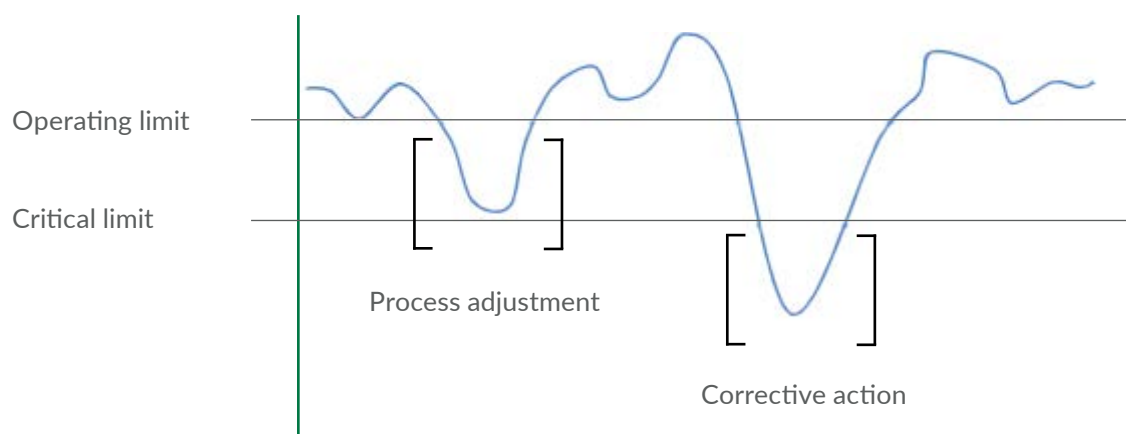
- 100 % of dead insects;
- 0 % of black insects;

Process adjustment:

Implementation of verification procedures on equipment efficiency and or staff competency

Corrective action:

Implementation of corrective actions on equipment deviation and product quality.



7.3.9. Establish monitoring procedures (Principle 4)

Monitoring procedures are essential to demonstrate product compliance with specified critical limits and feed/food safety requirements. Respective food/feed business operator, who produces, trades, processes or stores the feed/food material must set up, implement and carry out a monitoring plan, based on the operators own risk assessment for the undertaken activities. Monitoring procedures also facilitate CCP tracking. This enables immediate corrective actions to be taken when a loss of control is noticed and before a critical limit is reached. Observations or measurements of each CCP provide accurate records and written evidence to justify the possible retirement of insect PAPs before they are placed on the market. Each company has its own responsibility and specifies the critical points for its own business situation and determines a minimum sampling plan. A sampling process diagram should be part of the sampling plan. This shows the critical points for the process control.

For Each CCP, the monitoring procedure should include:

1. The description of monitoring methods;
2. Parameters for hazards;
3. Corrective actions if trends indicate a loss of control;
4. When, how and who is performing monitoring and checking.

Staff responsible for the monitoring process must be trained and fully aware of the monitoring techniques for which they are responsible.

An example of monitoring procedures for batches (see definition of 'batch' in Annex I) of materials used in production of insect based products.

Insects as Feed:

A batch, subject to the following monitoring plan, may comprise maximum **100** tons. For batches of up to 100 tons, at least 1 sample is taken and for batches of more than 100 tons at least 5 samples are taken. For the latter a mix of the sample may be made for the analysis. Sampling and analysis of Salmonella and Enterobacteriaceae in feeds: The critical control points must be examined for Salmonella. The frequency of inspection must be once per month and if this is negative for a half year then the frequency can be reduced to once per two months. In the event of a positive finding analysis must be done again once per month for at least half a year. The positive samples must be classified for corrective measures.

For incoming raw materials (substrate) for breeding of insects as feed:

Product	Analysis	Frequency	Number of subsamples	When	Responsibility	Storage locations
Incoming raw materials	Chemical Residue	Every batch	1	Arrival	Internal / External qualified laboratory	All
	Moisture content percentage	Every batch	1	Arrival	Internal / External qualified laboratory	All
	Ph	Every batch	1	Arrival	Internal / External qualified laboratory	All
	Mycotoxins, heavy metals, PAHs, PAs	1 time per year/ or when suspicion	1	Arrival	Internal / External qualified laboratory	All

Microbiological analysis for raw materials frequency minimum once a year. In case deviations are recorded in the breeding facility testing protocols should be amplified accordingly. Physical hazards should be determined and monitored accordingly in every batch.

For out going feed products

Product	Analysis	Frequency	Number of subsamples	When	Responsibility	Storage locations
Insect-based feed product	Chemical (all), microbiological (all)	1 time per year	1	1 month after production batch	Internal / External qualified laboratory	All
	Clostridium Perfringens	30 days (Method 7 Plan)	1	Directly after the treatment	Internal / External qualified laboratory	All
	Salmonella	30 days (Method 7 Plan)	5	During the filling of packaging	Internal / External qualified laboratory	All
	Enterobacteriaceae	30 days (Method 7 Plan)	5	During the filling of packaging	Internal / External qualified laboratory	All
	Moisture content percentage	3x a day	1	During production	Internal / External qualified laboratory	All

Microbiological (all) analysis frequency of the end product can be increased to one time/month if requested. Physical hazards should be determined and monitored accordingly in every batch.

For insects as food activities

Number of subsamples and frequencies for sampling of insect-based food products should be increased/ decreased, Specific chemical and microbiological hazards should be monitored, respective to the conducted risk assessments on the products (depending on insect species and/or product form-flour, whole insect, etc) and the weights of each batch. Minimum sampling frequencies are illustrated below follow the start up phase.

Product	Analysis	Frequency	Number of subsamples	When	Responsibility	Storage locations
Insect- based product as raw material	Microbiological (all)	Once a month when >1 batch is produced per month/ every batch if <1 batch is produced in 1 month/ if suspicion	1	Arrival	Internal / External qualified laboratory	All
	Microbiological (specific)*	Every batch	1	Arrival	Internal / External qualified laboratory	All
	Chemical (all)	Once a year	1	Arrival	Internal / External qualified laboratory	All
	Chemical specific	Every batch	1	Arrival	Internal / External qualified laboratory	All
During production and raw material	Moisture content percentage	Every batch	1	During production and arrival	Internal / External qualified laboratory	All
Insect based product final product**	Microbiological (all)	Once per month	1	Process end	Internal / External qualified laboratory	All
	Chemical (all)	Twice per year	1	Process end	Internal / External qualified laboratory	All
	Chemical specific	Per quarter	1	Process end	Internal / External qualified laboratory	All

* Yeast/Moulds, *Listeria monocytogenes*, *Bacillus cereus*, *Enterobacteriaceae*, *Salmonella*.

** Parameters are to be defined based on the products in which insects are incorporated (e.g. insect-based pastas, granola bars, etc).

Physical hazards should be determined and monitored accordingly in every batch.

7.3.10. Establish corrective actions (Principle 5)

For each **CCP**, a pre-established set of corrective actions should be planned to avoid hazardous feed/food from reaching customers.

Corrective actions should include:

1. The identification of people in charge of implementing the corrective actions;
2. The means and methods required to correct the cause of the deviation;
3. The disposition to be taken with the non-compliant product (finished or semi-finished) manufactured during the process deviation;
4. Recording of all context information about the non-compliance and verification checks.

Please refer to the example provided on CCP determination and description - 3.7. Determine critical control points (CCPs) (Principle 2).

7.3.11. Establish procedures of verification to confirm that a HACCP System is working effectively (Principle 6)

Verifications determine the validity of the HACCP system and its ability to operate according to the plan. They can take place on a daily basis, or periodically as part of the reassessment of the plan (annual or after significant changes).

Verifications may include the following scope of documents or methods:

4. Audits, in-plant observations, measurements, and evaluations;
5. Random sampling and testing;
6. Records of the CCPs and oPRPs;
7. Deviations history;
8. Initial validation of the HACCP plan (including scientifically and/or technical evidences);
9. Customer complaints.

Verifications are handled by persons with appropriate and sufficient expertise. When necessary, this review might result in the amendment of existing procedures. The changes should be incorporated into the documentation and recordkeeping system, to ensure that up-to-date information is available.

7.3.12. Establish documentation concerning all procedures and records appropriate to these principles and their applications (Principle 7)

The records kept for HACCP system should include:

1. A summary of the hazard analysis, including the rationale for determining hazards and control measures.

2. The HACCP Plan, including:

- a. A list of the HACCP team and assigned responsibilities;
- b. A description of the finished product, including its distribution, intended use and target consumer;
- c. A list of product ingredients and incoming materials;
- d. A plant schematic;
- e. A Verified flow diagram;
- f. A List of hazards identified;
- g. Critical control point determination - decision tree;g.
- h. A HACCP Plan Summary Table that includes information for:
 - Steps in the process that are critical control points;
 - The hazard(s) of concern;
 - Critical limits;
 - Monitoring;
 - Corrective actions;
 - Verification procedures and schedule;
 - Record keeping procedures.

3. Support documentation such as HACCP plan review, verification and validation records.

4. Records that are generated during the operation of the HACCP system.

ANNEX I

GLOSSARY OF DEFINITIONS

The following glossary provides the most relevant EU regulatory and non-regulatory definitions applicable to the insect food and feed sectors in the context of good hygiene, security, environment and quality practices.

This section is subject to change, according to the regulatory developments occurring in the food and feed sectors which might impact the insect sector.

1. EU regulatory and non-regulatory definitions

1. **Batch²⁶**: an identifiable quantity of feed/raw material/material/product determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labeling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together.
2. **Biosecurity**: proven procedures and practices to prevent or limit the exposition of the flocks to external biological factors and to minimise farm influence on surroundings.
3. **Critical Control Point (CCP)**: a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
4. **Cleaning**: the removal of soil, dust, food residue, dirt, grease or other objectionable matter.
5. **CIP**: Clean-In-Place
6. **Competent authority²⁷**: the central authority of a Member State competent to ensure compliance with the requirements of the applicable regulation or any other authority to which that central authority has delegated that competence.
7. **Contamination²⁸**: the presence or introduction of a hazard.
8. **Environment**: the natural world, as a whole or in a particular geographical area, especially as affected by human activity.
9. **Equipment**: any items, machinery used for the purpose of the treating, processing, manufacturing or packing insects for food and feed.
10. **Establishment**: any unit of a feed or food business.
11. **Established breeding lines**: farmed insects have to be kept as established breeding lines in captivity for at least three generations, with traceable well documented origin.
12. **Farmed insect²⁹**: any insect species kept deliberately in established culture, maintained in a controlled environment on a mass scale.
13. **Feed hygiene³⁰**: the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use.

²⁶ Art 3 2. (r) of Regulation (EC) No 767/2009

²⁷ Art 2 1. (d) of Regulation (EC) 852/2004

²⁸ Art 2 1. (c) of Regulation (EC) 852/2004

²⁹ Art 3(6) of Regulation (EC) No 1069/2009

³⁰ Art 3 (a) of Regulation (EC) 1831/2003

- 14. Food Contact Materials:** Food Contact Materials (FCMs) are all materials and articles intended to come into contact with food, such as packaging and containers, kitchen equipment, cutlery and dishes. These can be made from a variety of materials including plastics, rubber, paper and metal.
- 15. Food safety:** assurance that food is acceptable for human consumption according to its intended use.
- 16. Feedingstuff³¹:** means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.
- 17. Foodstuff³²:** 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
- 18. Former foodstuffs³³:** means foodstuffs, other than catering reflux, which were manufactured for human consumption in full compliance with the EU food law but which are no longer intended for human consumption for practical or logistical reasons or due to problems of manufacturing or packaging defects or other defects and which do not present any health risks when used as feed.
- 19. Good Hygiene Practices (GHP)³⁴:** essential conditions and activities that are necessary to maintain a hygienic environment throughout the food (and feed) chain(s) suitable for the production, handling and provision of safe end-products.
- 20. Good quality products:** products which have reached higher quality standards from a safety perspective according to the GHP outlined in this Guide.
- 21. HACCP (Hazard Analysis and Critical Control Points):** a system which identifies, evaluates and controls hazards which are significant for food safety.
- 22. HACCP system/plan³⁵:** a document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.
- 23. Hazard³⁶:** a (micro)biological, chemical, physical or allergen agent in, or condition of, food or feed with the potential to cause an adverse health effect.
- 24. HESQ:** Health, Environment, Safety and Quality
- 25. Insect frass:** Mixture of insect feces with by products from insect farming activities (under discussion at a legislative level)
- 26. oPRP:** an oPRP is identified during the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment. oPRPs are defined as a PRP that has a control measure that controls a significant hazard—ISO 22000.
- 27. Packaging³⁷:** the placing of one or more wrapped foodstuffs in a second container, and the latter container itself which protects the quality of the product.
- 28. Prerequisite programme (PRP):** an identifiable quantity of feed/raw material/material/product determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labeling, and, in the case of a production process, a unit of production from a

³¹ Art 3 4. of Regulation (EC)178/2002

³² Art 2 of Regulation (EC) 178/2002

³³ Annex, Part A (3) of Commission Regulation (EU) No 68/2013

³⁴ ISO22000:2005

³⁵ FAO, Hazard analysis and critical control point (HACCP) system and guidelines for its application

³⁶ Art 3 14. of Regulation (EC) 178/2002

³⁷ Art 2 1. (k) of Regulation (EC) 852/2004 31 Art 2 1. (k) of Regulation (EC) 852/2004

single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together.

- 29. Primary products³⁸:** products of primary production including products of the soil, of stock farming, of hunting and fishing.
- 30. Primary production of feed³⁹:** the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter), or fishing resulting exclusively in products which do not undergo any other operation following their harvest, collection or capture, apart from simple physical treatment.
- 31. Processing⁴⁰:** any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.
- 32. Processed animal protein (PAP)⁴¹:** animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including pet food, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.
- 33. Processed products⁴²:** foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.
- 34. Potable water⁴³:** water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- 35. Quarantine:** temporary retirement of breeding flocks in order to eliminate potential risks of contagious factors, parasites transmission or other factors (e.g. risk of inbreeding). This is an important element of biosecurity.
- 36. Traceability⁴⁴:** the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

38 Art 2 1. (f) of Regulation (EC) 852/2004

39 Art 3 (f) of Regulation (EC) 1831/2003

40 Art 2 1. (m) of Regulation (EC) 853/2004

41 Annex I 5 of Regulation (EC) 142/2011

42 Art 2 1. (o) of Regulation (EC) 853/2004

43 Art 2 1. (g) of Regulation (EC) 853/2004

44 Art 3 15. Regulation (EC) 178/2002

ANNEX II

LIST OF INSECTS AUTHORISED FOR THE PRODUCTION OF PROCESSED ANIMAL PROTEINS INTENDED AS FEED FOR FARMED ANIMALS (OTHER THAN FUR ANIMALS) WITHIN THE EU⁴⁵

1. *Gryllodes sigillatus* (Walker, 1869)



Order: Orthoptera; Family Gryllidae

Tropical house cricket, Indian house cricket or banded cricket, native to Southwest Asia, widespread in tropical regions around the world. Due to its high thermal optimum, this species is considered non-invasive in temperate zones.

Adults grow up to 20-22 mm, both male and female have reduced wings, in females only a small scale is visible behind the thorax. Tropical house crickets are light yellow in colour and can be easily distinguished from house crickets by two thick, black bands on the thorax and upper abdomen.

Figure 1. *Gryllodes sigillatus*

Incubation period (days from egg-laying to hatching)	12 _a
Time to maturity (days from hatch to max body weight)	33-40 _b

a = Ivy and Sakaluk (2005) b = McFarlane (1964)

1. Species are extremely resistant to environmental conditions, and is very productive in mass culture, tolerating the high population density.
2. Protein content in larvae and imagines varies from 60 to 70% (d.m.), with fat content of 20-25 % (d.m.) and generally lower chitin content than average crickets.
3. Species is immune to the Cricket Paralysis Virus.

⁴⁵ In accordance with point 2 of Part A of Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011

2. *Gryllus assimilis* (Fabricius, 1775)

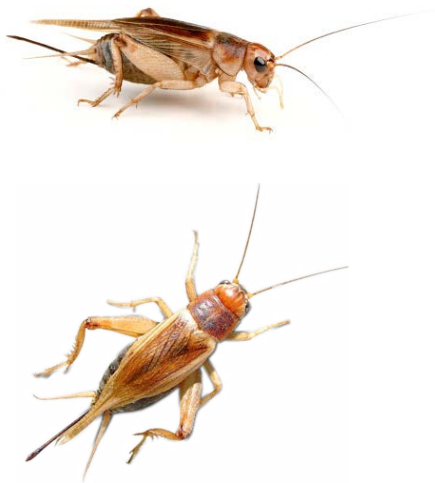


Figure 2. *Gryllus assimilis*

Order: Orthoptera; Family Gryllidae

Jamaican field cricket, tropical species of cricket native to West Indies and Southern part of North America. Due to its high thermal optimum, this species is considered non-invasive in temperate zones.

Adults grow up to 25-28 mm, both sexes are fully winged. Adult females are slightly bigger with prominent ovipositor protruding from the abdomen. Crickets are greyish yellow in color, more robust than house crickets.

Incubation period (days from egg-laying to hatching)	12
Time to maturity (days from hatch to max body weight)	42-49

1. Species is relatively resistant to environmental conditions, and is productive in mass culture, however under high population density it shows a tendency towards cannibalism.
2. Protein content in larvae and imagines varies from 50 to 65 % (d.m.), with a fat content of 25-30 %
3. (d.m.). Contains a high level of chitin.

3. *Acheta domesticus* (Linnaeus, 1758)



Figure 3. *Acheta domesticus*

Order: Orthoptera; Family Gryllidae

House cricket, native to Southwest Asia, widespread in tropical and temperate zones. Species are native to most of the European countries.

Adults grow up to 20-22 mm, both sexes are fully winged. Adult females are slightly bigger with prominent ovipositor protruding from the abdomen. Crickets are greyish yellow in color.

Incubation period (days from egg-laying to hatch)	11 _a
Time to maturity (days from hatch to max body weight)	32-49 _b

a = Nowosielski and Patton (1965) *b* = Ghouri and McFarlane (1958)

1. Species are resistant to environmental conditions, and is very productive in mass culture, tolerating high population densities. The species is however very susceptible to the Cricket Paralysis Virus
2. Protein content in larvae and imagines varies from 60 to 70% (d.m.), with a fat content of 20-25 % (d.m.).

4. *Tenebrio molitor* (Linnaeus, 1758)

Order: Coleoptera; Family: Tenebrionidae.



Figure 4. *Tenebrio molitor* Adult, larva, pupae respectively. Photos courtesy of HiProMine.

Lesser Mealworm
Alphitobius diaperinus
1-1,2 cm

Mealworm
Tenebrio molitor
1-2 cm



Figure 5. Mealworm species, credits Protifarm

Known as mealworm, species of the darkling beetles. It has a cosmopolitan distribution, being common in Europe, as a pest of the grain storages.

The adult beetles are up to 15-18 millimeters long. It is shiny black or brown with reddish brown elytra. The eggs are oval, whitish, about 1.5 millimeters long. The larvae resemble larvae of other mealworms, at the final stage measuring up to 25 millimeters in length.

Incubation period (days from egg-laying to hatching)	10-12
Time to maturity (days from hatch to adult)	280-400

1. Species is resistant to environmental conditions, and is very productive in mass culture, tolerating high population densities.
2. Protein content in larvae varies from 50 to 65% (d.m.), with a fat content of 30-40 % (d.m.) highly depending on the feed and rearing conditions.

5. *Alphitobius diaperinus* (Panzer, 1797)

Order: Coleoptera; Family: Tenebrionidae

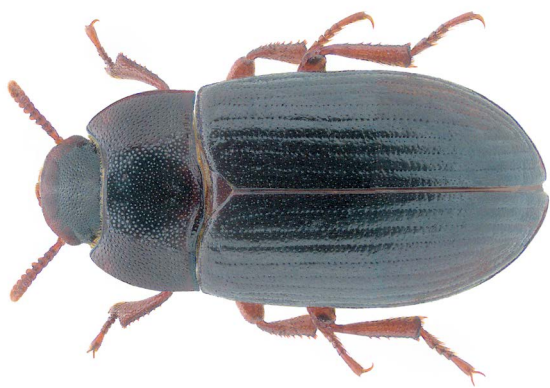


Figure 6. *Alphitobius diaperinus*,

Known as lesser mealworm or litter beetle, species of the darkling beetles. It has a cosmopolitan distribution, being common in Europe, as a pest of the grain storages and poultry farms.

The adult beetles are 6 millimeters long, oval in shape. It is shiny black or brown with reddish brown elytra. Color is variable among individuals and subpopulations and changing with age. The antennae are paler at the tips and are covered in tiny, yellowish hairs. The elytra have shallow longitudinal grooves. The eggs are narrow, whitish, about 1.5 millimeters long. The larvae resemble larvae of other mealworms, at the final stage measuring up to 11 millimeters in length.

Incubation period (days from egg-laying to hatching)	10-12
Time to maturity (days from hatch to adult)	280-400

1. Species are resistant to environmental conditions and is very productive in mass culture.
2. Protein content in larvae varies from 50 to 65% (d.m.), with fat content of 30-40 % (d.m.) highly depending on the feed and rearing conditions.

6. *Hermetia illucens* (Linnaeus, 1758)

Order: Diptera; Family: Stratiomyidae



Figure 7. *Hermetia illucens* adult, larva, pupa. Photos courtesy of HiProMine

Black soldier fly, composting fly belonging to the soldier fly family. It is supposedly native to South America but is currently widespread in tropic and temporal zones worldwide. As it requires a high level of UV irradiation and temperatures above 24 °C to mate it must be considered as noninvasive species in colder zones.

The adult flies reach up to 15-18 millimeters in length. Adults are black, showing mimicry to wasps. The eggs are round, yellow and about 0.5 millimeters in diameter. The whitish larvae grow up to 25 millimeters in length, going through six instars to reach the brown prepupa stage. Prepupae leave the moist compost environment to seek for a dry place to pupate, that enables efficient separation of the larvae from the substrate. Larvae of the BSF are very efficient composters, being able to digest a whole variety of organic products.

Incubation period (days from egg-laying to hatching)	4 _a
Time to maturity (days from hatch to max body weight)	12-60

a = Tomberlin et al., 2002

1. Species grow in a wide range of environmental conditions, and is very efficient in mass culture, tolerating high population densities and being able to complete the life-cycle within 3 weeks.
2. Protein content in larvae varies from 40 to 50% (d.m.), with a fat content of 35-45 % (d.m.) with high lauric acid content. Exact composition highly depends on the feed and rearing conditions.

7. *Musca domestica* (Linnaeus, 1758)

Order: Diptera; Family: Muscidae

House fly, most common fly species, with a cosmopolitan distribution, therefore it is a native species in Europe.



Figure 8. *Musca domestica* adult and larvae respectively. Photos courtesy of Amusca.

The adult flies reach up to 10-12 millimeters in length. Adults are grey to black with four longitudinal dark lines on the back, and the body covered with hair-like protrusions. Eggs are usually laid on decaying organic matter, yellow in color and about 0.5 millimeters in diameter. After few days of incubation, they hatch into legless white maggots which after two to five days of development transform into reddishbrown pupae of ca. 8 mm in length.

Incubation period (days from egg-laying to hatching)	1
Time to maturity (days from hatch to max larval body weight)	2-30

1. Species are resistant to a wide range of environmental conditions, and is very efficient in mass culture, tolerating high population densities.
2. Protein content in larvae varies from 40 to 65 %(d.m.), with a fat content of 20-45 % (d.m.). The amino acid profile composition highly depends on the feed and rearing conditions.

ANNEX III

IPIFF CONTRIBUTORS TO THE GUIDE

As members of the IPIFF Task Force on 'Good Hygiene Principles', the following companies contributed actively to the development of the present Guide:

HiProMine

Entomo Farm

NextAlim

Protix

Ynsect

Protifarm

Jimini's

Koppert

Andromeda

NextProtein

Innovafeed

BioBee

Micronutris

Danish Technnological Institute

Mutatec

Agriprotien

Hermetia

Amusca

Next-Generation Network

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ANNEX IV

LIST OF CONSULTED EUROPEAN FOOD AND FEED BUSINESS SECTORS

The Members of the **Advisory Group on the Food Chain and Animal and Plant Health** - based on the revised membership established by the European Commission in 2017- are being consulted on the present Guide. Namely the following stakeholder organisations

AESGP : Association of the European Self-Medication Industry

AIPCE-CEP : European Fish Processors and Traders Association

ANIMALHEALTH EUROPE

AVEC : Association de l'Aviculture, de l'Industrie et du Commerce de Volailles dans les Pays de l'Union Européenne

BEUC: Bureau Européen des Unions de Consommateurs

CEFIC: European Chemical Industry Council

CELCAA: European Liaison Committee for Agriculture and agri-food trade

CLITRAVI : Centre de liaison des industries transformatrices de viande de l'UE

COCERAL : Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'UE

COGECA: European agri-cooperatives

COPA: European farmers

ECPA: European Crop Protection Association

ECSLA: European Cold Storage and Logistics Association

EFFAT: European Federation of Food, Agriculture and Tourism Trade Unions

EFPR: European Fat Processors and Renderers Association

EHPM: European Federation of Associations of Health Product Manufacturers

ELO: European Landowners' Organisation asbl

ENA: European Nurserystock Association

EOCC: European Organic Certifiers Council

EPBA: European Professional Beekeepers Association

EU specialty food ingredients Federation of European Specialty Food Ingredients Industries (previously known as ELC)

EUROCOMMERCE

EUROCOOP: European Community of Consumer Co-operatives

EUROGROUP FOR ANIMALS

FACE: Federation of Associations for Hunting and Conservation of the EU

EU FEAP: Federation of European Aquaculture Producers

FEDIAF : Fédération européenne des industries des aliments pour animaux familiers

FEFAC : Fédération Européenne des Fabricants d'Aliments Composés

FEFANA: EU Association of Specialty Feed Ingredients and their Mixtures

FESASS Fédération Européenne pour la Santé Animale et la Sécurité Sanitaire

FoEE: Friends of the Earth Europe

FOODDRINKEUROPE

FOODSERVICE EUROPE

FRESHFEL Europe: the forum for the European fresh fruits and vegetables chain

FVE: Federation of Veterinarians of Europe

HOTREC: Hotels, Restaurants and Cafés in Europe

IFOAM EU GROUP: International Federation of Organic Agriculture Movements EU Regional Group

INDEPENDENT RETAIL EUROPE Independent Retail Europe (formerly UGAL) - Union of Groups of Independent Retailers of Europe

PAN EUROPE : Pesticide Action Network Europe

PFP: Primary Food Processors SLOW FOOD Slow Food (NA)

SNE : Specialised Nutrition Europe

UEAPME : Union européenne de l'Artisanat et des petites et moyennes entreprises

UECBV : Union Européenne du Commerce du Bétail et de la Viande

APPENDIX A

EXAMPLES OF QUESTIONS TO BE CONSIDERED WHEN CONDUCTING A HAZARD ANALYSIS.

As outlined by the FDA in the 'HACCP Principles and Application Guidelines' source (<https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#impl>)

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

1. Ingredients:

- Does the feed/food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g. aflatoxin, antibiotic or pesticide residues); physical hazards (stones, glass, metal, packaging material) or prohibited constituents (e.g. prohibited animal proteins)?
- Are potable water, ice and steam used in formulating or in handling the feed/food product?
- What are the sources (e.g. geographical region, specific supplier)?

2. Intrinsic Factors - Physical characteristics and composition (e.g. pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food/feed during and after processing.

- What hazards may result if the food composition is not controlled?
- Does the food permit survival or multiplication of pathogens and/or toxin formation in the feed/food during processing?
- Will the feed/food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
- Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

3. Procedures used for processing.

- Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
- If the product is subject to recontamination between processing (e.g. cooking, pasteurising) and packaging which biological, chemical or physical hazards are likely to occur?

4. Microbial content of the food

- What is the normal microbial content of the feed/food?

- Does the microbial population change during the normal time the feed/food is stored prior to consumption?
- Does the subsequent change in microbial population alter the safety of the feed/food?
- Do the answers to the above questions indicate a high likelihood of certain biological hazards?

5. Facility design

- Does the layout of the facility provide an adequate separation of the dirty route from the clean route?
- Is the traffic pattern for people and moving equipment a significant source of contamination?

6. Equipment design and use

- Will the equipment provide the time-temperature control that is necessary for safe feed/food?
- Is the equipment properly sized for the volume of feed/food that will be processed?
- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe feed/food?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be easily cleaned and sanitised?
- Is there a chance for product contamination with hazardous substances (e.g. glass, metal pieces)?
- What product safety devices are used to enhance consumer safety?
 - metal detectors
 - magnets
 - sifters
 - filters
 - screens
 - thermometers
- To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
- Are allergen protocols needed in using equipment for different products?

7. Packaging

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Does the package include instructions for the safe handling and preparation of the feed/food by the end user?
- Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
- Are tamper-evident packaging features used?
- Is each package and case legibly and accurately coded?
- Does each package contain the proper label?
- Are potential allergens in the ingredients included in the list of ingredients on the label?

8. Sanitation

- Can sanitation have an impact on the safety of the feed/food that is being processed?
- Can the facility and equipment be easily cleaned and sanitised to permit the safe handling of feed/food?
- Is it possible to provide sanitary conditions consistently and adequately to assure safe feed/foods?

9. Employee health, hygiene and education

- Can employee health or personal hygiene practices impact upon the safety of the food being processed?
- Do the employees understand the process and the factors they must control to assure the preparation of safe feed/food?
- Will the employees inform management of a problem which could impact upon the safety of feed/food?

10. Conditions of storage between packaging and the end user

- What is the likelihood that the feed/food will be improperly stored at the wrong temperature?
- Would an error in improper storage lead to a microbiologically unsafe feed/food?

11. Intended use

- Will the food be heated by the consumer?
- Will there likely be leftovers?

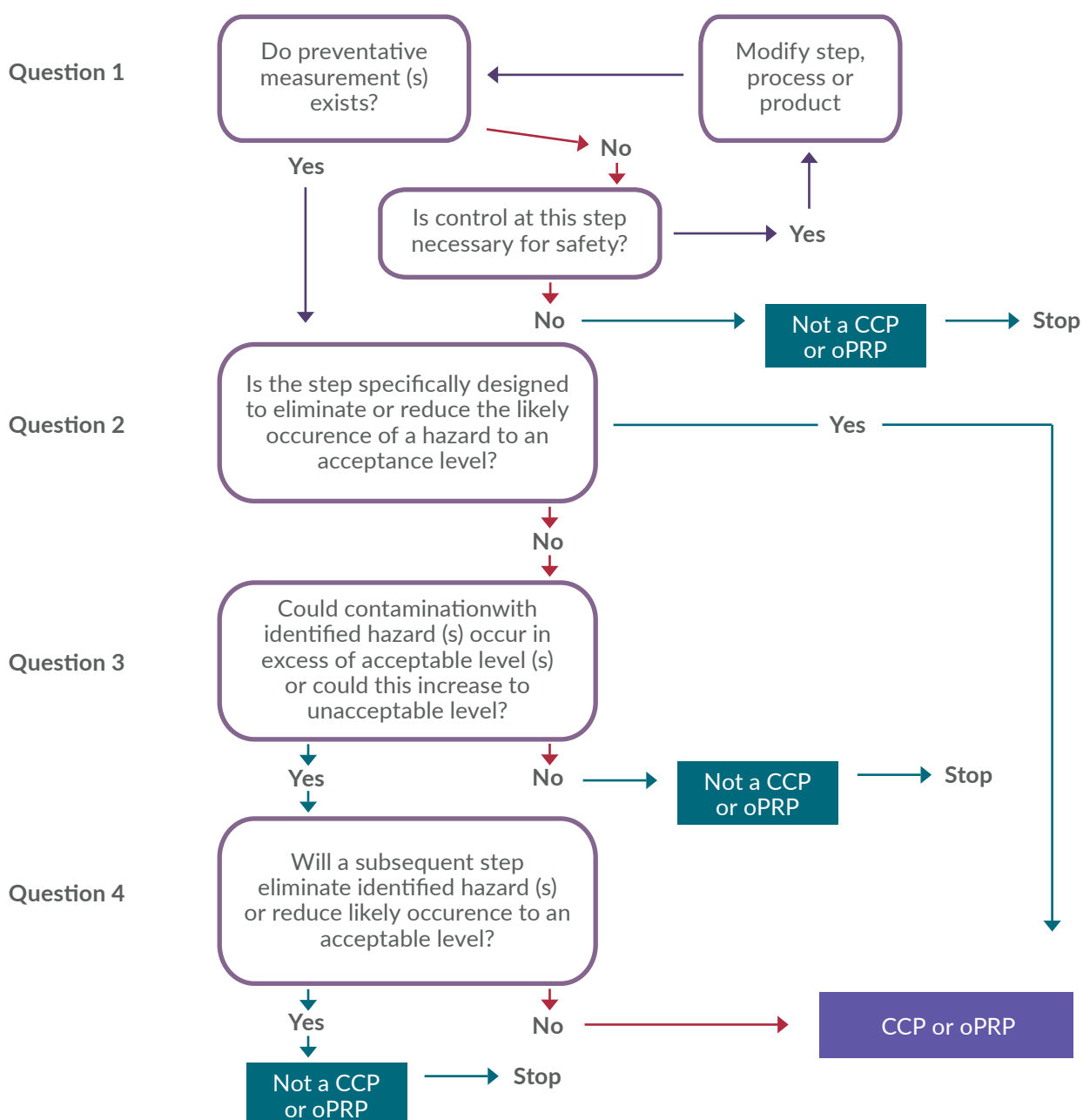
12. Intended consumer

- Is the food intended for the general public?
- Is the food intended for consumption by a population with increased susceptibility to illness (e.g. infants, the aged, the infirmed, immunocompromised individuals)?

APPENDIX B

DECISION TREE FOR CRITICAL CONTROL POINT (CCP) DETERMINATION

SOURCE : ADAPTED FROM CODEX ALIMENTARIUS



Question 5

Does monitoring of control measure allows to detect a loss of control?

Yes

No

Question 6

Is it possible to apply a critical limit to the control measure?

Yes

No

oPRP

CCP

