

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

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# PREFACE

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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 opinion 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 Safety). 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

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## 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 over 87 members from 24 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 operators producing insects 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 and other related EU requirements (e.g. food and feed labelling requirements, EU animal-by-products and TSE legislations), 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 insect producers to effectively communicate food and feed safety issues to the national competent authorities, and when needed, to their suppliers, customers and relevant interested parties (i.e. consumers) in the food and feed chain.

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.

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 production of insects destined for human consumption or animal feed (i.e. including feed for food producing animals, pet food and fur animals) and 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 farmers.

Yet, it does not address the specific steps and/or measures to be applied by operators when handling insects/insect products and/or their by-products (e.g. insect frass) which are intended for 'technical uses' (i.e. non-food and/or feed use) (e.g. use of insect fat as biofuel, valorisation of insect frass as organic fertiliser).

Insect products destined for human consumption include the followings:

- killed whole insects which have been subject to post treatment steps i.e. steps which do not change the shape and/or structure of the product (e.g. drying step);
- ground and further processed insects (e.g. insect meals, including when incorporated into processed products, or parts of insects and their derived products).

N.B: At the time of the present document's writing, 'only' dried *Tenebrio molitor* larva and frozen, dried formulations from *Locusta migratoria* and of *Acheta domesticus* can be legally placed on the EU market. **Indeed, insects as food in the EU require pre market authorisation, based on novel food applications, pursuant to Regulation (EU) 2015/2283. These EU novel food authorisations being a prerequisite for placing those products on the EU market as food**<sup>1</sup>.

The authorisation for placing on the EU market of dried *Tenebrio molitor* larva was granted the company SAS EAP Group Agronutris<sup>2</sup>. The company Fair Insects BV (Protix group) obtained the same authorisation for the EU commercialisation of frozen and dried formulations of *Locusta migratoria*, *Acheta domesticus* and *Tenebrio molitor*<sup>3</sup>.

As of this writing, several novel food applications have been submitted to the European Commission and are currently being assessed by the European Food Safety Authority. A few formed the basis of an EFSA's opinion and should soon pave the way to 'new' EU novel food authorisations<sup>4</sup>.

Although the Guide is only applicable for products authorised on the EU market (e.g. some specific national regulatory provisions may apply in EU Member States implementing the novel food transitional measure), the recommendations provided in the document are also relevant for insect producers (i.e. producers of insect as food) in the aforementioned countries.

Different types of products may be commercialised for animal feed. The related production steps are addressed in this document. These concern the followings:

- live farmed insects. The Guide does not however specifically address the steps and/or measures which should be applied by operators following the breeding/growing phase of the live insects intended for animal feed (the latter being covered through chapter 3 and 4);
- killed whole insects if subject to post treatment steps, i.e. steps which do not change the shape and/or the structure of the product (e.g. 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 provides specific recommendations and guidelines for the insect sector how to concretely implement the requirements on food and feed safety in **Regulations (EC) No 183/2005, Regulation (EC) No 852/2004, Regulation (EC) No 178/2002 (i.e. 'General Food Law')** and other related EU requirements.

In respect of the above activities, insect producers must **comply with the same 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**.
3. the specific provisions referred to in Article **5(5) of Regulation (EC) No 183/2005** which apply to the **feeding of food producing animals. The latter article refers to Annex III of the legal text, which sets out a number of requirements as regards the feeding of food producing animals**.

Therefore, it follows the requirements provided for in Annex I (primary production) and II (processing and distribution) 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. It is also in line with the requirements provided in Annex III of Regulation (EC) No 183/2005 concerning good animal feeding practice.

<sup>1</sup> For further information about the applicable procedures for placing insect food products on the EU market, operators may refer to the **Questions and Answers** document from the European Commission, which is available through the following link : [https://ec.europa.eu/food/safety/novel-food/authorisations/approval-insect-novel-food\\_en](https://ec.europa.eu/food/safety/novel-food/authorisations/approval-insect-novel-food_en). Further information can be found in the briefing paper document developed by IPIFF. See document through the following link: [https://ipiff.org/wp-content/uploads/2019/08/ipiff\\_briefing\\_update\\_03.pdf](https://ipiff.org/wp-content/uploads/2019/08/ipiff_briefing_update_03.pdf). These authorisations apply without prejudice to the possibly open by several EU Member States to market insect food products within their territory, pursuant to the transitional measure foreseen in Article 35 (2) of Regulation 2015/2283. For further details, see IPIFF briefing paper on novel food - document available on the IPIFF website

<sup>2</sup> For further details, see Commission Implementing Regulation (EU) 2021/882 of 1 June 2021 authorising the placing on the market of dried *Tenebrio molitor* larva as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

<sup>3</sup> For further details, about these authorisations, see Commission Implementing Regulation (EU) 2021/1975 Commission Implementing Regulation (EU) 2022/188 and Commission Implementing Regulation (EU) 2022/169 respectively

<sup>4</sup> At the time of writing this document, the European Food Safety Authority (EFSA) had recently published opinions concluding on the safety of frozen and freeze-dried formulations of the lesser mealworm (opinion published on 4 July 2022 following a dossier submitted by the company Proti-Farm B.V.) and of partially defatted house cricket (opinion published on 13 May 2022 following a dossier submitted by the company Cricket One Co.). For further information about this subject, see dedicated [webpage](#) of EFSA and of the European Commission.

The guidelines provided in the Guide revolve around good hygiene practices including prerequisite programs and procedures based on the HACCP principles, when applicable.

Furthermore, the Guide identifies 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'*)<sup>5</sup>, in order to achieve compliance with food and feed safety objectives, as defined in the applicable EU regulations.

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'). Notably, HACCP principles do not apply to primary production and associated activities.

The development of such sector specific hygiene guides is encouraged by the above-mentioned Regulations. Yet, their use and effective implementation by insect producers remains voluntary and is based on their full self-responsibility. Furthermore, the Guide does not aim to substitute these Regulations nor to replace national regulatory provisions which may apply to their activities: therefore, for legal compliance purposes, operators should always refer to applicable regulatory requirements.

In addition to the above-mentioned requirements, several insect producers may have to comply with standards as set out in the framework of food and/or feed assurance systems (e.g. see section 2.6.2. regarding 'microbiological limits'). Such schemes 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/or feed assurance schemes that apply to insect production activities. Yet, it should not serve the purpose of establishing standards falling subject to third party certification.

Furthermore, it may be consulted as a useful reference for production activities taking place outside the EU, without prejudice to the applicable legislative standards in these countries<sup>6</sup>.

Notably, the recommendations contained in the document should be used by third country operators intending to sell their products on the EU market: compliance with EU requirements is indeed mandatory for imported insect products intended as food or feed.

- In the case of import of insect food products, only third countries that are listed in Annex XV of Commission Implementing Regulation (EU) 2021/405 at the time of writing this document (i.e. Canada, Switzerland, South Korea, Thailand, Vietnam and the United Kingdom) can legally import<sup>7</sup> such products into the EU. Each consignment shall be accompanied by an official certificate as required by Article 26 of Commission Implementing Regulation (EU) 2020/2235 (this official certificate shall correspond to the model set out in Chapter 48 of Annex III to the aforementioned Regulation).
- The import in the EU of processed insects, 'treated' but not 'processed' (in view of their use as feed) is allowed, only if originating from countries listed in the EU legislation, in accordance with the provisions from Commission Delegated Regulation (EU) 2020/692<sup>8</sup> and Commission Implementing Regulation 2021/404 and accompanied by a health certificate, in line with the model health certificate laid down in Chapter Ia of Annex XV to Regulation (EU) No 142/2011. (See chapter 1.2.4 for further details)

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.

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<sup>5</sup> EFSA scientific opinion 'Risk Profile related to production and consumption of insects as food and feed' (8 October 2015).

<sup>6</sup> Pursuant to the 'non-territorial effect' of EU provisions, these operations do not fall within the scope of EU food and feed safety requirements.

<sup>7</sup> Imports would be only possible on the approval of the product as a novel food; or in EU Member States applying the EU novel food transitional measure laid down by Article 35(2) of Regulation (EU) 2015/2283 and allowing imports of insect food products from non EU countries.

for further information please refer to the [information note on imports of insects as food](#).

<sup>8</sup> This Regulation repealed and replaced Regulation (EU) No 206/2010

## Applicable EU regulations and other reference texts

Besides the General EU food and feed hygiene regulations - i.e. Regulation (EC) No 853/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 laying down specific hygiene rules for products of animal origin, Regulation (EC) No 1831/2003 laying down requirements for feed hygiene as well as Regulation (EU) 2015/2283 (novel food authorisations are a pre-condition for operators to be entitled to place insect food products on the EU market and thereby a prerequisite to the implementation of the food hygiene regulations), producers may refer, for compliance with EU food and feed safety objectives, to the following EU legal acts:

1. **Regulation (EC) No 178/2002** of the European Parliament and of the Council of 28 January 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. European Commission 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 (EU) 2017/625** of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;
4. **Regulation (EU) 2016/429** of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law');
5. **Regulation (EU) No 1143/2014** of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species;
6. Commission Implementing **Regulation (EU) 2016/1141** of 13 July 2016 adopting a list of invasive alien species of Union concern pursuant to Regulation (EU) No 1143/2014;
7. Commission Delegated **Regulation (EU) 2019/625** supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption;
8. Council **Directive 98/58/EC** of 20 July 1998 concerning the protection of animals kept for farming purposes;

9. Commission Implementing **Regulation (EU) 2020/2235** of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates;
10. Commission Implementing **Regulation (EU) 2021/404** of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council
11. Commission Implementing **Regulation (EU) 2021/405** of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625;
12. Commission Delegated **Regulation (EU) 2020/692** of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin;
13. **Regulation (EU) 2015/2283** of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 and repealing Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001;
14. Commission Implementing **Regulation (EU) 2017/2469** of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods;
15. Commission Implementing **Regulation (UE) 2017/2470** of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (UE) 2015/2283 of the European Parliament and of the Council on novel foods
16. Commission Implementing **Regulation (EU) 2021/882** of 1 June 2021 authorising the placing on the market of dried *Tenebrio molitor* larva as a novel food under Regulation (EU) 2015/2283;
17. Commission Implementing **Regulation (EU) 2021/1975** of 12 November 2021 authorising the placing on the market of frozen, dried and powder forms of *Locusta migratoria* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470
18. Commission Implementing **Regulation (EU) 2022/169** of 8 February 2022 authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.
19. Commission **Regulation (EC) No 2073/2005** of 15 November 2005 on microbiological criteria for foodstuffs;
20. Commission **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;
21. Commission **Regulation (EC) No 37/2005** of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption;
22. Commission **Regulation (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food;
23. Commission **Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food;
24. **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;
25. **Regulation (EC) No 1069/2009** of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;
26. Commission **Regulation (EU) No 142/2011** of 25 February 2011 implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;
27. **Regulation (EC) No 999/2001** of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies;
28. **Regulation (EC) No 767/2009** of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed;
29. **Directive 2002/32/EC** of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed;
30. **Regulation (EC) No 396/2005** of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
31. **Regulation (EC) No 1831/2003** of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition;
32. Commission **Regulation (EU) No 68/2013** of 16 January 2013 on the catalogue of feed materials;
33. Commission **Regulation (EU) 2017/893** of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein;
34. Commission **Regulation (EU) 2021/1372** of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non ruminant farmed animals, other than fur animals, with protein derived from animals.
35. Commission **Regulation (EU) 2021/1925** of 5 November 2021 amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method.

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 Authority (EFSA) 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 domestica*) by the Swedish University of Agricultural Sciences (EFSA funded report, adopted on 6 July 2018);
3. EFSA scientific opinion on the safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283 (published on 13 January 2021)
4. EFSA scientific opinion on the safety of frozen and dried formulations from migratory locust (*Locusta migratoria*) as a Novel food pursuant to Regulation (EU) 2015/2283 (published on 2 July 2021)
5. EFSA scientific opinion on the safety of frozen and dried formulations from whole house crickets (*Acheta domestica*) as a Novel food pursuant to Regulation (EU) 2015/2283' (published on 17 August 2021)
6. EFSA scientific opinion on the safety of frozen and dried formulations from whole yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283 (published on 25 August 2021)
7. EFSA scientific opinion on the safety of partially defatted house cricket (*Acheta domestica*) powder as a novel food pursuant to Regulation (EU) 2015/2283 (published on 13 May 2022)
8. EFSA scientific opinion on the safety of frozen and freeze-dried formulations of the lesser mealworm (*Alphitobius diaperinus* larvae) as a Novel food pursuant to Regulation (EU) 2015/2283 (published on 4 July 2022)
9. Commission Notice – Guidelines for the feed use of food no longer intended for human consumption (OJEU, 16 April 2018);
10. Commission notice – Guidance document on the implementation of certain provisions of Regulation (EC) No 1831/2003 laying down requirements for feed hygiene (OJEU, 5 July 2019);
11. Commission notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (OJEU, 16 September 2022) (2022/C 355/01);
12. Hazard Analysis and Critical Control Points (HACCP) system and Guidelines for its application (Codex Alimentarius);
13. EN ISO 22000:2018 on Food Safety management systems;
14. The Codex code of practice on good animal feeding;
15. Strategy safety concept for Insects as Feed (Updated);
16. IPIFF Policy priorities towards 2025 (IPIFF's Regulatory Brochure) (20 May 2020);
17. IPIFF Briefing Paper on Regulation (EU) 2015/2283 (September 2021) on novel foods.

## Overall structure of the document

The Guide is divided into seven chapters:

- Chapter 1: Food and feed safety management systems: general principles and EU requirements
- Chapter 2: Prerequisite programs: infrastructures and general conditions of production
- Chapter 3: Prerequisite programs: management of insects' substrates
- Chapter 4: Prerequisite programs: insect rearing activities
- Chapter 5: Overview of processing methods applied to insects intended for human consumption and animal nutrition
- Chapter 6: Prerequisite programs: storage, packaging, labelling and transport operations
- 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' and/or encapsulated in summary frames - see at the end of chapter 3 as well as in sections 4.2.4, 4.3.2, 4.3.5., 5.1.4, and 6.4.4., 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 5** which contains elements specific to these operative branches<sup>9</sup>.

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 insect species authorised for use as processed proteins 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 – who were consulted during the development of the present Guide.

## Future updates

Any future change(s) to the present Guide will be made by IPIFF in consultation with relevant stakeholders. The Guide is currently pending the official 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. The current version of the Guide was updated in November 2022.

<sup>9</sup> However, insect food producers should refer to section 5.1., section 5.2. (killing methods) and section 5.2.3. (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. In the wake of the 'first' novel food authorisations covering insects as food, and anticipating potential future updates of EU regulatory standards for insect food products, reference to applicable legislative requirements will be inserted

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

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## 1.1. 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, insect producers should implement the necessary good hygiene practices, traceability systems and recall requirements. These operators should also be aware of hazards that might adversely affect the safety of insect products along the production chain. Whenever feasible and/or applicable (e.g. at insect processing stage) hazard analysis must be carried out in accordance with HACCP principles (see chapter 7 for more details).

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

## 1.2. Applicable EU regulations

### 1.2.1. '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 (feed hygiene) apply to all insect producers rearing, processing, handling (e.g. transport, storage) or distributing insects along the food or feed chain. In practice, the requirements contained in Regulation (EC) No 852/2004 and Regulation (EC) No 183/2005 for producing insects for food and feed are closely related, in particular as regards '**primary production**' activities. Due to the nature of **insect production** activities which remain very **similar regardless of insect products intended use (food or feed)**, the recommendations contained in the present Guide therefore combine both production activities (except for operations which are subsequent to processing activities - see chapter 5). However, these **production activities should be registered respectively** to the competent authorities.

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 at the rearing plant and transport from the rearing plant) are considered as '**primary producers**', according to EU food and feed hygiene legislation<sup>10</sup>:

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<sup>10</sup> 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)(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 a 'primary production' activity.

1. **Operators active in any of the stages of processing, storage, transport or distribution of insects intended for animal feed must be registered<sup>11</sup>** with 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 rearing insects for human consumption, once being granted a novel food authorisation for the insect products they wish to place on the EU market (see page 7 for further details), must register** and notify national competent authorities of operations under their control – pursuant to [Article 6.2 of Regulation \(EC\) No 852/2004](#) - including the handling operations directly - 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 of Guides to good practices covering the above activities<sup>12</sup>.

**The killing of insects and other processing activities** - including handling operations directly associated with these activities - are **not** considered as ‘**primary production**’ activities, even if carried out in the same rearing plant, since these steps lead to a change in the shape and/or structure of the product. Thus, those fall subject to different hygiene requirements, under EU food feed hygiene legislation and are governed by the ‘EU Animal By-Products (ABP) Regulations’ (i.e. Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011) in case of insect products intended for animal feed.

1. **Whenever processing<sup>13</sup>** killed insects (e.g. in view of producing processed animal proteins derived from farmed insects), **insect producers must be approved<sup>14</sup>** before national competent authorities in accordance with Regulation (EC) No 1069/2009 (Article 24 (1)(a)) (see chapter 4.1.2.);
2. Operators active in the production of insect products intended for animal feed, but 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 \(EC\) No 183/2005](#) (these requirements concern the facilities and equipment, personnel, storage and transport operations, compulsory sampling plans, record keeping measures, complaints and product recall) and **notify the competent authorities about the concerned activities**, in accordance with the registration procedure laid down in Article 9 of this legal text;
3. Operators active in the production of insect products intended for **human consumption**, but **in ‘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 \(EC\) No 852/2004](#), 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) and **notify the competent authorities about the concerned activities**, in accordance with the registration procedure laid down in Article 6 (2) of this legal text.

**The handling of insect by-products** generated through the production process (e.g. processing of insect frass as organic fertiliser) is subject to ‘separate’ hygiene standards in accordance with [Regulation \(EC\) No 1069/2009](#) (e.g. a new categorisation is foreseen by Article 9, and a separate approval procedure before the national competent authority applies, pursuant to Article 24 (1)(a))<sup>15</sup>. Those by-products are classified as ‘category 2 materials’ under the aforementioned legislation and are therefore prohibited for use as food and animal feed. Animals which died under abnormal conditions during the breeding phase (e.g. exceeding mortality) may be similarly classified as category 2 materials by the national competent authorities. Furthermore, [Regulation \(EU\) No 142/2011](#) defines some specific processing conditions for the placing on the market of insect frass as organic fertiliser and soil improver (e.g. a minimum heat treatment process of 70 °C for at least 60 minutes and specific microbiological criteria are being defined in Chapter I, Section 2 (f) to Annex XI of the legal text).

<sup>11</sup> Registration involves the placing of establishments on a list which will be used to develop a programme of official controls. Approval requires a prior inspection visit by the national competent authorities before a feed business operator is allowed to carry out its production activities.

<sup>12</sup> This requirement applies without prejudice to the obligations of insect 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 foods (see introduction for more details).

<sup>13</sup> Processing does not include treatment steps such as drying or freezing. The latter treatments have not been officially recognised as ‘processing methods’ under Regulation (EU) No 142/2011 or under Regulation (EC) No 999/2001.

<sup>14</sup> The approval procedure is defined in Article 44(1). of Regulation (EC) No 1069/2009 as the procedure by which the national competent authority shall approve establishments or plants only where an on-site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements of the animal by-products legislation.

<sup>15</sup> As previously indicated, these activities are not directly covered in this Guide.

Stages of production covered	General principles, main obligations and legislative requirements for insect producing activities: overview of main EU provisions in the areas of food and feed safety ‘	
Supply of substrates and rearing of insects for food and feed – see chapter 3 and 4 of the Guide	Applicable EU legislative provisions	
	Producers of insects for human consumption	Producers of insects for animal feed
	Regulation (EC) No 178/2002 ( <b>‘General Food Law’</b> ) lays down the general principles governing food and feed safety. The most relevant provisions include Article 6 (‘risk analysis’), Article 14 (‘food safety requirements’), Article 15 (‘feed safety requirements’), Article 17 (‘responsibilities’), Article 18 (‘traceability’), Article 19 (‘responsibilities for food: food business operators’) and Article 20 (‘responsibilities for feed: feed business operators’)	
	Regulation (EC) No 852/2004 on <b>food hygiene</b> . Regulation (EC) No 853/2004 laying down <b>specific hygiene rules for food of animal origin</b> .	Regulation (EC) No 183/2005 laying down requirements for <b>feed hygiene</b> .
	Considered as <b>‘primary production’</b> activities	
	Are <b>not required</b> to implement <b>HACCP</b> based procedures (Article 5 (3) of Regulation (EC) No 852/2004).	<b>Are not required</b> to implement <b>HACCP</b> based procedures (Article 6(1) of Regulation (EC) No 183/2005). Yet, insect breeders are no longer considered as ‘primary producers’ when using additives or premixtures of and must consequently implement a procedures based on HACCP principles (Article 6(2) of Regulation (EC) No 183/2005).
	Operators must <b>‘register’</b> their activities	
	Registration as <b>‘food business establishment’</b> provided for by Article 6 (2) of Regulation (EC) No 852/2004.	Registration as <b>‘feed business establishment’ (if active in the processing, storage, transport or distribution of insects)</b> provided for by Article 9 of Regulation (EC) No 183/2005.
	Applicable hygiene requirements	
	Must comply with <b>Annex I, Part A. of Regulation (EC) No 852/2004</b> (contains requirements for operators active in primary production of food, incl. hygiene provisions and record keeping).  Insect frass being considered as a by-product pursuant to Regulation (EC) No 1069/2009, insect producers fall subject to the requirements of the above legislation when it comes to the management of these materials (e.g. sorting obligations, approval before national competent authorities in accordance Article 4 and article 24 of Regulation (EC) No 1069/ 2009 and compliance with heat treatment processes and microbiological standards defined in Regulation No 142/2011) Yet, these steps fall outside the scope of the present Guide.	Must comply with <b>Annex I Part A of Regulation (EC) No 183/2005</b> (contains requirements for operators active in primary production of feed incl. hygiene provisions and record keeping).  Must comply with <b>Annex III of Regulation (EC) No 183/2005</b> , which refers to ‘good animal feeding practices’ (contains requirements regarding feeding equipment, feeding practices, water and personnel).  Insect frass being considered as a by-product pursuant to Regulation (EC) No 1069/2009, insect producers fall subject to the requirements of the above legislation when it comes to the management of these materials (e.g. sorting obligations, approval before national competent authorities in accordance with Article 4 and Article 24 of Regulation (EC) No 1069/2009 and compliance with heat treatment processes and microbiological standards defined in Regulation (EU) No 142/2011) Yet, these steps fall outside the scope of the present Guide.

Killing and further processing of insects for food and feed

See Chapter 5 to 7 of the Guide

Producers of insect products for human consumption

1. Regulation (EC) No 852/2004 on **food hygiene**.

Producers of insect products for animal feed

1. EU **Animal-By-Products** legislation (Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011)<sup>16</sup>.
2. EU **'TSE' legislation** (Regulation (EC) No 999/2001).

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

Article 5 of Regulation (EC) No 852/2004 requires that food business operators 'shall put in place, implement and maintain a permanent procedure or procedures based on **the HACCP principles**'

Insect producers shall comply with **Annex II of Regulation (EC) No 852/2004** (i.e. contains requirements regarding all food premises, transport, equipment requirement, food

Article 29 of Regulation (EC) No 1069/2009 provides that operators handling or managing animal by-products shall 'maintain a permanent written procedure or procedures based on **HACCP principles**'

Insect producers shall comply with the general provisions of **Annex II of Regulation (EC) No 183/2005** (i.e. contains requirements regarding facilities and equipment, personnel, production, quality control, dioxin monitoring for oils, fats and derived products, storage and transport, record keeping and complains and product recall).

'Terrestrial invertebrates other than species pathogenic to humans or animals' are classified **category 3 materials** (Article 10 (I) of Regulation (EC) No 1069/2009). Therefore, insect-derived ingredients intended for animal feed (e.g. insect processed protein, insect fat, hydrolysed proteins) must be treated in accordance with **validated processing methods** (Article 31 (1) (b) of Regulation).

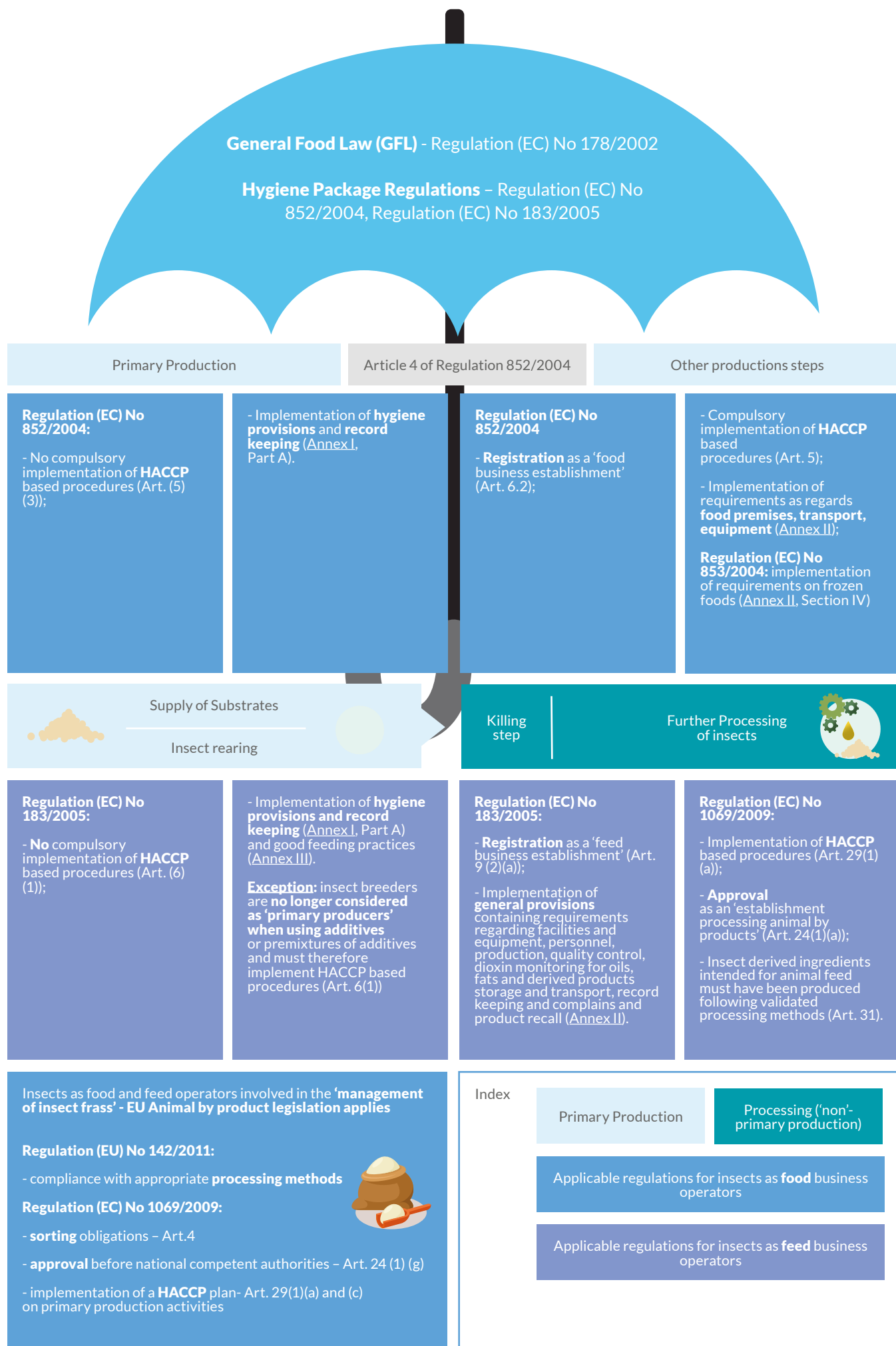
Activities subject to **'registration'**

Registration as **'food business establishment'**, provided for by article 6 (2) of Regulation (EC) No 852/2004.

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

Registration as **'feed business establishment'** under Article 9 (2)(a) of Regulation (EC) No 183/2005.

Approval as 'establishment handling animal by products' and complying with processing methods as required under Article 24. of Regulation (EC) No 1069/2009 (including for the manufacture of pet and other activities such as the processing of insect frass).



## 1.2.2.Requirements on substrates of animal origin as feed for insect

### Introduction

Insects reared within the European Union fall within the category of ‘farmed animals’ as defined in the EU Animal By-Products’ (ABP) legislation (i.e. Article 3(6)<sup>16</sup> of [Regulation \(EC\) No 1069/2009](#)). Consequently, these may only be fed with feed materials which are eligible for the above category of animals. These ‘**restrictions**’ **apply, no matter the destination of the insect derived products**, including if those are intended e.g. as feed for pet food, fur animal or for technical uses (e.g. biofuel production, cosmetic, biochemistry).

The only exception concerns **maggots and worms intended for fishing bait**, which may notably be fed with catering waste or with animal manure (category 2 materials under the ABP legislation), if authorised by the national competent authority of the EU country where the product is being commercialised, pursuant to Article 18 of [Regulation \(EC\) No 1069/2009](#).

The present chapter aims to provide a comprehensive overview of the **EU restrictions applying to the feeding of insects with products of animal origin**. Furthermore, it outlines the specific EU requirements relating to the **presence of contaminants** in the selected substrate (of vegetal or animal origin) and the regulatory provisions applying to the use of **feed additives** (see below ‘where to find the applicable EU requirements’).

*Yet, requirements relating to feed suppliers’ obligations (e.g. compliance with HACCP standards, registration obligations) are being addressed in chapter 3.1.2.*

For ease of reading and in order to better illustrate the above-mentioned regulatory possibilities, this chapter includes examples of substrates that are expressly prohibited. Yet, for legal compliance purposes, operators should always refer to applicable regulatory requirements.

#### Where to find the applicable EU requirements?

Applicable EU rules revolve around the following sets of legislation:

- Those feed materials that are expressly prohibited in animal feed (including for pet food and fur animals or for food and feed producing animals only) are listed in the **EU ‘Feed Marketing’ and ABP Regulations**;
- The ‘**TSE Regulation**’ foresees a series of restrictions on the feeding of farmed species with proteins derived from animals;
- **The EU ABP legislation** sets out a list of animal products of animal origin that are authorised as feed for farmed animals;
- EU contaminants and pesticide residue limits applying to feed materials when used as substrate for insects can be found in **Directive 2002/32/EC** and in **Regulation (EC) No 396/2005**. As regards feed additives, the general provisions are in **Regulation (EC) No 1831/2003**, and the specific applicable requirements are laid down in the **authorising act** of each concerned feed additive.

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<sup>16</sup> Article 3(6) of Regulation (EC) No 1069/2009 defines ‘farmed animal’ as any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hide, hides and skins, or any other product obtained from animals or from other farming practices’.

N.B: the EU **Catalogue of feed materials** contained in [Regulation \(EU\) No 68/2013](#) provides a comprehensive list (above 1000 entries) of feed materials (together with a product description) which are being commonly used on the EU market. Yet, the mere fact that a product is listed in this Catalogue or in the accompanying register of feed materials does not necessarily mean that the product is authorised as feed material for farmed insects. Indeed, the Catalogue of feed materials is 'non-exhaustive' instrument. Furthermore, the use of several entries included in the Catalogue is subject to restrictions, in accordance with relevant EU legislation. This is notably the case for certain feed materials consisting of or containing animal by-products which are only allowed as feed for non-farmed animals, including fur animals.

### Prohibited materials as substrate for insects

Annex III to [Regulation \(EC\) No 767/2009](#) (the '**Feed Marketing Regulation**') prohibits the use of the following substances for use as animal feed:

- **Faeces** and **separated digestive tract** content (in that context, the substrate being mixed with frass from insects or dead insects cannot be used for further rearing processes);
- **hide** treated with tanning substances;
- **seeds** and other plant-propagating materials (treated with plant protection products);
- **wood and materials derived from wood** which have been **treated with wood preservatives** as defined in Annex V to [Regulation \(EU\) No 528/2012](#) concerning the making available on the market and use of biocidal products;
- waste derived from **urban, domestic and industrial waste treatment**;
- solid urban waste (e.g. household waste);
- **packaging** from agri-food products and parts thereof;
- protein products obtained from **yeasts of the Candida variety** cultivated on n-alkanes.

The **ABP legislation** (i.e. [Regulation \(EC\) No 1069/2009](#)) prohibits the use of certain materials of animal origin, including notably:

- **manure** (being classified as 'category 2' material under Article 9 (a) of [Regulation \(EC\) No 1069/2009](#), manure is therefore not eligible for use as feed material (see article 13 of the above-mentioned Regulation);
- **catering waste**<sup>17</sup> (Article 11 (1)(b) of [Regulation \(EC\) No 1069/2009](#) prohibits its use as feed for food and feed producing animals).

### Restrictions stemming from the 'TSE' Regulation

According to the ABP legislation, **processed animal proteins (PAPs)** (i.e. protein entirely derived from 'category 3' materials, as listed in Article 10 of [Regulation \(EC\) No 1069/2009](#) – see annex I 5. of [Regulation \(EU\) No 142/2011](#)) are authorised for use in animal feed, including for food and feed producing animals, if complying with the requirements (e.g. processing methods) provided in Section 1 of Chapter II of Annex X to [Regulation \(EU\) No 142/2011](#).

However, the EU legislator, at the beginning of the year 2000, reduced to a large extent the possibilities for using PAPs as feed materials for farmed animals. Indeed, the 'TSE' Regulation (i.e. [Regulation \(EC\) No 999/2001](#)) prohibits their use as feed for ruminants and non-ruminant farmed animals (excluding fur animals but including insects), except in the case of fish meal (and compound feed containing fish meal)<sup>18</sup>.

Yet, swine and poultry PAPs as well as insect PAPs have been (re)authorised as feed for farmed fish, respectively in 2013 and in 2017.

Subsequently, on 17 August 2021, the European Commission adopted a new regulation, i.e. [Regulation \(EU\) 2021/1372](#) amending Annex IV of [Regulation \(EC\) No 999/2001](#). The legal text provides that insect and poultry PAPs are authorised for feeding to pig animals while insect and pig PAPs are allowed for feeding to poultry.

Furthermore, the TSE Regulation prohibits to feed insects (as well as other non-ruminant farmed animals) with **blood products, derived from ruminants**, as well as with **hydrolysed proteins of animal origin and derived from ruminants** (Annex IV, Chapter I to [Regulation \(EC\) No 999/2001](#))<sup>19</sup>.

<sup>17</sup> Annex I 22. to [Regulation \(EU\) No 142/2011](#) defines catering waste as 'all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens'

<sup>18</sup> Provided that it has been produced and placed on the market in accordance with the specific conditions laid down in Section A of Chapter IV to annex IV of [Regulation \(EC\) No 999/2001](#).

<sup>19</sup> A contrario, the use of hydrolysed proteins and blood products derived from non-ruminants or parts of non-ruminants is therefore authorised, provided that these products have been produced and placed on the market in accordance with the specific conditions laid down in Annex IV of [Regulation \(EC\) No 999/2001](#). Likewise, hydrolysed proteins from ruminant hide and skins as well as for di and tricalcium phosphate (including compound feed containing such products), can be used as feed for insects (pursuant to Annex IV, Chapter II b. of [Regulation \(EC\) No 999/2001](#)).

However, the TSE legislation does not prevent to feed farmed animals (therefore including farmed insects) with rendered fat, including fats delivered from ruminant animals.

### **Restrictions applying to former foodstuffs containing products of animal origin under the ABP legislation**

Article 10(f) of Regulation (EC) No 1069/2009 refers to 'products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise' (the later are being referred as 'former foodstuffs containing products of animal origin').

Annex X, Chapter II, Section 10 of Regulation (EU) No 142/2011 **restricts** the possibilities for using these materials in feed for food producing animals to '**non-containing meat or fish**' **former foodstuffs products**.

Although former foodstuffs containing products of animal origin may be used as feed for insects, only those containing following ingredients are authorised;

- eggs and egg products;
- milk, milk based-products and milk-derived products;
- honey;
- rendered fat;
- collagen;
- gelatine.

*A contrario*, the following products **are prohibited** for use as feed for insects (this list is non exhaustive, as the products highlighted below are provided for illustrative purposes only).

- Meat and meat derived products originating from butcher shops or food processing establishments;
- Quiches containing pork meat (e.g. ham and/or smoked bacon) or other meat products;
- Pizzas containing meat products (e.g. ham or poultry meat);
- Sandwiches (ex: if containing meat products);
- Cans of sardines;
- Catering meals containing meat and/or fish.

Moreover, former foodstuffs containing products of animal origin must have been **previously processed** (either prior their intended use as food product or after being requalified as animal by product) and comply with the microbiological criteria as defined in Annex X, Chapter 1 of Regulation (EU) No 142/2011 (thresholds are set for enterobacteria, salmonella).

► Only products which have been previously pasteurized (e.g. milk) or cooked (e.g. eggs) are eligible as feed for food producing animals, thereby including farmed insects

Moreover, Annex X, Chapter II, section 10 (iv) to Regulation (EU) No 142/2011 provides that 'all precautions must have been taken to prevent the contamination of the material' whereas Annex III, Chapter 1 of Regulation (EC) No 767/2009 prescribes that these products must be free from packaging residues.

► Unwrapped products or products with 'apparent' moulds (or any 'similar' defects) shall be discarded.

### **EU residue limits for contaminants, pesticides and requirements applying to feed additives**

The '**Feed Marketing**' Regulation (i.e. Regulation (EC) No 767/2009) provides that animals (including therefore insects) bred in the EU may be only be fed with safe feed.

The **Undesirable Substances Directive** (i.e. Directive 2002/32/EC) establishes maximum levels of undesirable substances in feed materials and compound feed, while Regulation (EC) No 396/2005 sets out maximum residue levels of **pesticides in feed**.

Feed materials and compound feed intended as feed for farmed insects therefore have to comply with the limits established in the aforementioned pieces of legislation.

Only 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](#). Since at the time of drafting this Guide no feed additive has been specifically approved for used as feed for insects yet, only the feed additives which are authorised for all animal species may be used as feed ingredient for farmed insects.

### **EU legislation on the use of veterinary medicinal products**

Although the addition of veterinary medicinal products, including through feed or water, is not a common practice in the insect industry today, insect producers should refer to the applicable EU legislation, i.e. [Regulation \(EU\) No 2019/6](#) on **veterinary medicinal products** and [Regulation \(EU\) No 2019/4](#), which regulates the conditions for manufacturing, placing on the market and use of **medicated feed**.








### **Requirements on water quality**

Insect producers are using water from the regular water network, on a regular basis in addition to the water naturally included in some substrates. The requirements are defined according to the EU member states or local rules, in accordance with applicable EU legislation.

### **Authorised and non-authorised substrates as feed for insects: a few examples<sup>24</sup>**

#### **Non-authorised substrates**

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)
4. Solid urban waste (e.g. household waste);
5. Aquaculture sludges;
6. Products containing packaging residues (e.g. plastic, PET, paper);
7. Animal by-products originating from slaughterhouses or rendering establishments, except those that are expressly authorised (see above);
8. Processed Animal Proteins (PAPs) referred to in Annex IV to Regulation (EC) No 999/2011 are prohibited: PAPs from ruminants, PAPs from non-ruminants, PAPs from poultry animals; PAPs from swine animals and PAPs from farmed insects.
9. Food waste originating from restaurants, catering establishments, household and international transport;
10. Unsold products from supermarkets or food producing establishment containing meat or fish products and/or residues of packaging materials.

Authorised		Prohibited
Feed materials of vegetal origin 		<b>‘Feed Marketing’ Regulation - Regulation (EC) No 767/2009 Annex III:</b> <ul style="list-style-type: none"> <li>- Faeces and separated digestive tract content</li> <li>- hide treated with tanning substances</li> <li>- seeds and other plant-propagating materials (treated with plant protection products)</li> <li>- wood or other materials derived from wood, which have been treated with wood preservatives</li> <li>- waste derived from urban, domestic and industrial waste treatment</li> <li>- packaging from agri-food products and parts thereof</li> <li>- protein products obtained from yeasts of the <i>Candida</i> variety cultivated on n-alkanes.</li> </ul>   
Feed materials of animal origin 	<b>TSE Regulation (EU) No 999/2001, Article 7 and Annex IV, Chapter 1 and 2:</b> <ul style="list-style-type: none"> <li>- Hydrolysed proteins, collagen and gelatine or blood products derived from non-ruminants (or parts of non-ruminants) (including compound feed containing such products)</li> <li>- Hydrolysed proteins from ruminant hide and skins</li> <li>- Dicalcium phosphate and tricalcium phosphate of animal origin (including compound feed containing such phosphates)</li> <li>- Fishmeal</li> </ul>	
Former Foodstuffs 	<b>TSE legislation - Regulation (EC) No 999/2001 Annex IV, Chapter II:</b> <ul style="list-style-type: none"> <li>- Without meat and/or fish</li> <li>- only products containing the following ingredients of animal origin: eggs and egg products; milk, milk based-products and milk-derived products; honey; rendered fat; collagen; gelatine</li> <li>- <i>*these ingredients must have been previously processed (either prior their intended use as food product or after being requalified as animal-by-product).</i></li> </ul>	<b>EU Animal By-Products (ABP) Regulation (EC) No 1069/2009:</b> <ul style="list-style-type: none"> <li>- catering waste (Art. 11 (1) (b))</li> </ul>    <b>TSE legislation - Regulation (EC) No 999/2001 (Annex IV, Chapter 1 and 2)</b> <ul style="list-style-type: none"> <li>- Processed Animal Proteins (PAPs) referred to in Annex IV are prohibited: PAPs from ruminants, PAPs from poultry animals; PAPs from swine animals and PAPs from farmed insects and PAPs from other non-ruminants except fishmeal.</li> <li>- Blood products from ruminant animals</li> <li>- hydrolysed proteins of animal origin and derived from ruminants</li> </ul> 
Residue limits for contaminants and requirements applying to feed additives		The ‘ <b>Feed Marketing’ Regulation</b> (i.e. Regulation (EC) No 767/2009) provides that animals (including therefore insects) bred in the EU may be only be fed with <b>safe feed</b> .  <b>Regulation (EC) No 396/2005</b> - maximum residue levels of <b>pesticides in feed</b>  <b>Undesirable Substances Directive (i.e. Directive 2002/32/EC)</b>
Feed additives 		Only the feed additives which are authorised for all animal species may be used as feed ingredient for insects. - <b>Regulation (EC) No 1831/2003</b> . No specific additives for insects have been defined.

### 1.2.3. Overview of the EU regulatory possibilities for using insect products as food and feed

#### ► General remarks

As general recommendation, EU insect producers should be well aware of the applicable EU requirements since the possibilities for commercialising insects and insect products for food or feed purposes differ, depending on the type of product (e.g. whole insects, processed animal proteins, insect facts) and on the market targeted (e.g. food vs. feed). Notably, these operators should be aware about the currently applicable EU restrictions (e.g. restrictions applying to processed animal proteins or to whole insects intended as feed for farmed animals) and/or of the legislation applying at national level whenever the subject falls under EU Member States’ competence (e.g. use of live insects as animal feed, commercialisation of whole insects and their derived products for human consumption).

**N.B:** This chapter does **not** address the subject of the use of insects for technical uses (e.g. biofuel production, cosmetic, biochemistry) since these activities do not fall within the scope of the present Guide (see introduction). As general rule, whenever authorised for animal feed in accordance with the EU ABP legislation, animal by-products derived from insects (e.g. insect PAPs, hydrolysed proteins, rendered fat) may be commercialised for those technical uses provided that applicable requirements of the ABP legislation (i.e. Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011) or specific legislations concerning these uses (when they exist) are being complied with.

#### ► Use of insects for human consumption

Producers of insects and products thereof that are intended for human consumption and which have been granted a novel food authorisation for the placing on the EU market of these products (see page 7 for further details) must comply with the ‘general’ requirements contained in Regulation (EC) No 178/2002, which lays down the general principles and requirements of ‘Food Law’ and of Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

At the time of the present document’s writing, **‘only’ dried *Tenebrio molitor* larva** as well as frozen and dried formulations of ***Locusta migratoria*, *Acheta domesticus* and *Tenebrio molitor*** can be legally placed on the EU market, following their authorisation as ‘novel food’ pursuant to Commission Implementing Regulation (EU) 2021/882, Commission Implementing Regulation (EU) 2021/1975, Commission Implementing Regulation (EU) 2022/188 and Commission Implementing Regulation (EU) 2022/169 respectively.

The conditions under which these products may be commercialised (e.g. the forms under which these may be marketed, the food categories in which they may be incorporated as an ingredient, the applicable maximum limits, the labelling requirements, the maximum thresholds for chemical and microbial contaminants) are being defined in the above Regulations, and have been integrated into the so called 'Union list of novel foods' (i.e. Commission Implementing Regulation (EU) 2017/2470).

These 'first' novel food authorisations covering an insect product are granted to the company SAS EAP Group Agronutris and Fair Insects BV (Protix group) respectively, for a five years period following the date of application of the authorising regulation. These may however be extended to another/other producer(s) if expressly agreed by the aforementioned companies. Today, the EU commercialisation of other insect species and products remains therefore prohibited, pending their authorisation as novel food pursuant to Regulation (EU) 2015/2283<sup>20</sup>.

Yet, such prohibition applies without prejudice to the possibility open by several EU Member States to market insect food products within their territory, pursuant to the transitional measure foreseen in Article 35(2), of Regulation (EU) 2015/2283<sup>21</sup>.

## ► Use of insects as animal feed

### Where to find the applicable EU requirements?

Several pieces of legislation regulate the conditions for producing and placing insects and derived feed products on the EU market. These include notably:

- The **EU Catalogue of feed materials** (Regulation (EU) No 68/2013), which enumerates insects in their various forms, that may be used as animal feed;
- The **TSE Regulation** (or 'feed ban' rules), which foresees several restrictions for using processed animal proteins derived from farmed insects (insect PAPs) in animal feed;
- The **ABP legislation** (i.e. Regulation (EC) No 1069/2009) which elaborates on the contours for live and whole insects (dead 'untreated' and 'treated' animals) to be used in animal feed;
- Furthermore, specific methods for the processing of animal by products derived from insects (e.g. insect PAPs, insect fat) are included in Regulation (EU) No 142/2011 (these provisions are further described in chapter 1.4.1);
- Finally, the **Feed Marketing Regulation** (i.e. Regulation (EC) No 767/2009) and **feed hygiene legislation** (Regulation (EC) No 1831/2003) do also regulate the conditions for producing and placing insects and their derived products (as feed) on the EU market (on the latter, see chapter 1.2.1 for more details).

### Provisions of the EU Catalogue of feed materials

Terrestrial invertebrates are listed in the EU Catalogue of feed materials (i.e. Regulation (EU) No 68/2013)<sup>22</sup> under entry 9.16.1, (i.e. 'terrestrial invertebrates live') and 9.16.2 ('terrestrial invertebrates, dead'), thereby encompassing **live insects** and **whole insects** (untreated or treated but not processed/ground-into insect meal). Entries 9.4.1 titled 'Processed animal proteins' and 9.2.1 'animal fat' also include invertebrates ('other than species pathogenic to humans and animals') in their description. Insect PAPs as well as fat/oil derived from insects are therefore also authorised for use in animal feed, but excluding 'species having adverse effects on plant, animals and human health'.

N.B: The fact that such feed materials are listed in the EU Catalogue or in the accompanying Register of feed materials does not however mean that such products are authorised for all animal species (see chapter 2.1.1 for more details). Notably a distinction must be drawn between insect products intended for food producing animals, other farmed animals (i.e. fur animals) pet animals and other feeding purposes (e.g. feed for birds of prey, reptiles or zoo animals).

Indeed, the EU ABP and TSE legislations further define those 'targeted species' to which feed materials derived from farmed animals (including therefore farmed insects) may be intended. Furthermore, the TSE Regulation sets out a list of '**authorised insect farmed species**' which may be used as processed animal protein (PAP) for aquaculture, pig and poultry animals (see below for more details).

### Restrictions imposed under the TSE legislation

A clear **distinction** must be made between **insects PAPs, other ingredients** derived from insects (e.g. fat) and **whole insects** (either live, dead, with or without treatment) as different rules apply.

- Restrictions are imposed to insect PAPs when used as feed for food producing animals:

Processed animal proteins are defined in Annex I of Regulation (EU) No 142/2011 as 'animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X of the present Regulation (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feeding stuffs, including pet food, or for use in organic fertilisers or soil improvers'. These therefore include meal/proteins derived from farmed insects (insect PAPs).

As general rule (as laid in Article 7 and Annex IV of Regulation (EC) No 999/2001), the TSE Regulation prohibits the use of any PAP when intended as feed for non-ruminant farmed animals (excluding fur animals). This prohibition therefore **also applies to insect PAPs**. However, this feed ban was partially lifted on the 1st of July 2017 in the case of insects PAPs intended for **aquaculture animals**. **This relaxation was recently extended to insect PAPs destined to poultry and swine species** (see above and below for more details).

20 As of this writing, several novel food applications have been submitted to the European Commission and are currently being assessed by the European Food Safety Authority. A few formed the basis of an EFSA's opinion which soon pave the way to 'new EU novel food authorisations. The latest updates on these above can be consulted on [the IPIFF website](#) (see notably the document 'Insects as Novel Foods in the European Union: Frequently Asked Questions') as well as on the dedicated webpage of the European Commission.

21 For further details about these subjects, see IPIFF briefing paper on novel foods (see link) or the dedicated webpages from national competent authorities

22 For more details about the objectives and content of the Catalogue of feed materials, see above in the document.

Today insect PAPs are 'only' allowed for use as feed for farmed fish, poultry and pig species as well as for pet, fur animals and other non-food producing animals (e.g. reptiles, birds of prey, zoo and circus animals) as listed in Article 18 of Regulation (EC) No 1069/2009.

On 17 August 2021, the European Commission adopted a new regulation, i.e. Regulation (EU) 2021/1372 amending Annex IV of Regulation (EC) No 999/2001 authorising insect, poultry and pig PAPs as feed for poultry and swine feed. The aforementioned Regulation entered into force on 7 September 2021.

The authorisation for use of insect PAPs in aqua feed materialised through the adoption of Regulation (EU) 2017/893. This text defined specific standards for the production and use of processed animal protein derived from farmed insects. The latter provisions were integrated in Annex IV, Chapter IV, Section F of Regulation (EC) No 999/2001 and subsequently amended by the aforementioned Regulation (EU) 2021/1372 in order to cover insect PAPs intended for pig and poultry feed (see above)<sup>23</sup>.

In order for insect producers to benefit from the above authorisation, killed insects (insect by-products) must be processed in **establishments that are specifically approved and dedicated for the production of insect PAPs** (e.g. these establishments shall not be dedicated to the production of other animal species) in accordance with Article 7 and Annex IV, Chapter IV, Section F (a) (i) of Regulation (EC) No 999/2001. Regulation (EU) No 142/2011 (Annex X, Chapter II, Section 1, B(2)) requires operators to follow one of the processing methods (1 to 5 or 7) as described in Chapter III of Annex IV of that Regulation.

The authorisation for using insect PAPs as feed for farmed fish, poultry and pig species is **limited to eight insect species** namely to the followings: black soldier fly (*Hermetia illucens*), house fly (*Musca domestica*), yellow mealworm (*Tenebrio molitor*), lesser mealworm (*Alphitobius diaperinus*), house cricket (*Acheta domesticus*), banded cricket (*Gryllodes sigillatus*), field cricket (*Gryllus assimilis*) and **Silkworm** (*Bombyx mori*) (see Chapter II, section 1 of Annex X to Regulation (EU) No 142/2011).

The aforementioned '**positive list**' does **not** apply to insect PAPs intended for pet food animals, fur animals or other non-food producing animals. Consequently, any species that is not pathogenic to humans or animals may be used as feed for such animals, provided that the obligations foreseen under of Regulation (EC) No 1069/2009 (e.g. approval required under Article 24 (1)(b), and adherence to an HACCP plan pursuant Article 29) and hygiene and processing requirements laid down in Regulation (EU) No 142/2011 (i.e. annexes X and annex XIII for pet food) are being respected. (See chapter 5.1.2 of the Guide for more details)

- Insect derived ingredients (i.e. hydrolysed proteins and insect fat/oil)

Defined in Annex I (definition 14) to Regulation (EU) No 142/2011 as 'polypeptides, peptides and amino acids, and mixtures thereof, obtained by the hydrolysis of animal by-products', **hydrolysed proteins** are specifically authorised for use as feed for non-ruminant and ruminant animals (see Annex IV to Regulation (EC) No 999/2001). Classified as 'hydrolysed proteins derived from parts of non-ruminants', **hydrolysed proteins derived from farmed insects are therefore allowed for use as feed for ruminant and non-ruminant animals**, in accordance with Annex IV, Chapter II (a)(iv) and (b)(i) of Regulation (EC) No 999/2001 (for more details about the required conditions, see Section 5.1.2).

The **TSE Regulation does not either apply to fats and oil derived from insects, (those must be free from insect PAPs if intended as feed for ruminant farmed species)** as listed in Section 3, of Chapter II to Annex X of Regulation (EU) No 142/2011. These products may therefore be fed to **ruminant and non-ruminant farmed species**<sup>24</sup> as well as to **pet animals and other non-food producing animals** (including fur animals and other animals listed in Article 18 of Regulation (EC) No 1069/2009 – see above for further details).

<sup>23</sup> With this revision, the EU legislator also created, for the first time, 'EU dedicated standards' for insect production intended as animal feed. These standards complement the other pieces of legislation whose 'general' provisions are also applicable to insects as food and/or feed (e.g. Regulation (EC) No. 178/2002, Regulation (EC) No. 852/2004, Regulation (EC) No. 183/2005, Regulation (EC) No. 1069/2009 and Regulation (EC) No. 999/2001 etc) as listed in the previous section.

<sup>24</sup> Article 7 of Regulation (EC) No. 999/2001 prohibits to feed ruminant animals with any protein of animal origin, except these mentioned in chapter II to Annex IV of Regulation (EC) No 999/2001.

Specific hygiene requirements and processing standards applying to the above-mentioned feed materials derived from farmed insects are provided in Regulation (EU) No 142/2011 (i.e. in Annex X, Chapter II Section 3, 5 and 8). *These are described in chapter 5.1.2 of the Guide which outlines the applicable hygiene and processing methods.*

- Live and killed whole insects

Regulation (EC) No 999/2001 prohibits the use of live insects in feed for ruminant animals<sup>25</sup>.

- **Restrictions imposed under the ABP legislation and prohibitions and/or derogations under national law**

The possibilities for feeding of live and killed whole insects to non-ruminant animals have to be assessed in accordance with the provisions of the ABP legislation as well as of national legislation.

- Firstly, the EU ABP legislation limits or prohibits (i.e. in the case of 'untreated' whole insects) the use of killed whole insects as feeding ingredients;
- Moreover, the use of live insects as feed falls subject to national legislation;
- Finally, national authorities are competent to define the conditions under which killed whole insects (incl. 'treated' and 'untreated' animals) may be used as feed for non-food producing animals, in accordance with the derogatory provisions included in the EU ABP legislation. *See below for more details*

However, the use of killed **whole insects, live insects** and of ingredients derived from farmed insects (e.g. **insect fat, hydrolysed proteins** from insects) - is **not limited to those eight insect species** which are included in the aforementioned 'positive list' (*see above*).

- Live insects are excluded from the scope of Regulation (EC) No 1069/2009

Being classified as 'non-animal-by products', live insects fall outside the scope of Regulation (EC) No 1069/2009. Hence, the EU legislator has not regulated their conditions of use in animal feed (except Regulation (EC) No 999/2001 which prohibits their use as feed for ruminant as above mentioned). Their commercialisation remains however governed by the provisions stemming from the EU feed safety legislation (incl. feed marketing or labelling and contaminants).

The **possible use of live insects in animal feed remains at the discretion of EU Member States**. National competent authorities may therefore decide to allow their use as feed for farmed non-ruminant animals, pet animals as well as for other feeding purposes (as listed in Article 18 of Regulation (EC) No 1069/2009 – see above).

- The ABP legislation restricts the possibilities for using killed whole insects in feed for farmed animals

Both **killed 'untreated' whole insects** and **killed whole 'treated' insects** (e.g. dry frozen insects' but not 'processed' to the extent of altering the physical characteristics of the product, according to Regulation (EC) No 1069/2009) **are not authorised for use as feed for food producing animals** (feed for farmed animals other than fur animals). Furthermore, **the manufacture of pet food (e.g. dog and cat food) with whole untreated dead insects is prohibited**.


















































However, national competent authorities may, in accordance with Article 18 and 35 of Regulation (EC) No 1069/2009 authorise the use of treated and untreated whole dead insects (on their territory) in processed pet food, as feed for fur animals or for other feeding purposes (including zoo and circus animals, reptile, birds of prey, wild animals and fur animals, as well as for fishing bait) provided that the absence of health risks is guaranteed. To this end, these products must have been produced in accordance with the provisions foreseen in Annex XIII of Regulation (EC) No 142/2011 (the latter defines e.g. specific treatment methods<sup>26</sup> and microbiological standards applying to these products)<sup>27</sup>.

- Processing methods for insect products used in animal feed  
See section 5.1.2 of the Guide for more details

<sup>25</sup> Article 7(1) of Regulation (EC) No 999/2001 prohibits the use of any animal proteins in feed for ruminants including if originating from live insects. The text does not indeed distinguish as to whether the protein(s) come(s) from live or killed animals.

<sup>26</sup> Point 3(iv) of Chapter II of Annex XIII to Regulation (EU) 142/2011 provides that the national competent authority may authorise a treatment such as drying or fermentation for the manufacturing of processed pet food provided that the treatment 'ensures no unacceptable risks to public or animal health'.

<sup>27</sup> Furthermore, the company shall be approved in accordance with Article 24 (1) (e) and Article 35 of Regulation (EC) No 1069/2009.

Insects as feed - <b>Regulation (EU) No 68/2013</b> on the Catalogue of feed materials and in accordance with <b>Regulation (EC) No 999/2001</b> and <b>Regulation (EC) No 1069/2009</b>	Ruminant animals 	Aquaculture 	Poultry 	Pigs 	Pets 	Fur and other animals (e.g. zoo) 	Technical uses (e.g. cosmetic industry, bio-based fuels, production of other bio-based materials such as bioplastics) 
<b>Insect proteins</b> (under entry 9.4.1. 'Processed animal protein')		 **	 **	 **			
<b>Insect fats</b> (under entry 9.2.1 'animal fat')							
<b>Whole insects (untreated)</b> (under entry 9.16.2. 'terrestrial invertebrates, dead')					 ***	 ***	
<b>Whole insects (treated- e.g. Freeze drying)</b> (under entry 9.16.2. 'terrestrial invertebrates, dead')					 ***	 ***	
<b>Live insects</b> (under entry 9.16.1 'terrestrial invertebrates, live')		 *	 *	 *	 ***	 ***	
<b>Hydrolysed insect proteins</b> (under entry 9.6.1. 'Hydrolysed animal proteins')							

\* if authorised by the national competent authority of the Member State where the product is being commercialised

\*\* Limited to Black Soldier Fly (*Hermetia illucens*), Common Housefly (*Musca domestica*), Lesser Mealworm (*Alphitobius diaperinus*), House cricket (*Acheta domestica*), Banded cricket (*Grylodes sigillatus*), Field Cricket (*Gryllus assimilis*) and Silkworm (*Bombyx mori*).

\*\*\* if authorised by the national competent authority of the Member State where the product is being commercialised, under the specific conditions applicable to processed pet food (in case the product is intended for use as processed pet food)

Restriction to insect species (insect PAPs for aqua feed)- Regulation (EU) No 142/2011; Annex X Chapter 2 Section 1, A.(2). - Insect PAPs must be produced in <b>processing plants approved</b> in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009 and <b>dedicated exclusively</b> to the production of products derived from farmed insects <b>Regulation (EC) No 999/2001; annex IV, chapter IV, Section F, 1 (a)</b> . - Insect PAPs must be produced according to <b>processing methods 1 to 5</b> or <b>processing method 7</b> (Regulation (EU) No 142/2011, Annex X, Chapter II, Section 1, B (2)).	
No restriction as to the insect species (provided that these are not pathogenic to humans and animals)	

## 1.2.4. Imports of insects and their derived ingredients

As general rule, Article 11 of Regulation (EC) No 178/2002 ('General Food Law') provides that **'food and feed** imported into the EU shall comply with **the relevant requirements of food law or conditions** recognised by the Community to be at least **equivalent** thereto'.

Several sets of regulations are applicable in the case of insects intended as food and feed. This section is divided in two parts respectively:

### ► Imports of insects as food

#### General conditions

**The EU Official Controls (OCR) Regulation** - (i.e. Regulation (EU) 2017/625) provides the framework for the EU Member States (MS) to verify that Agri-food businesses comply with European food and feed safety standards. European food and feed safety standards also encompass the import conditions on animals and goods entering the EU from 'third countries' (countries outside the EU). As general rule, Article 11 of Regulation (EC) No 178/2002 ('General Food Law') provides that 'food and feed imported into the EU shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto'. **Imports of insects intended for human consumption may only be of those products authorised under the Novel Food Regulation** (i.e. Regulation (EU) 2015/2283) and listed in the Union List of novel foods (i.e. Implementing Regulation (EU) 2017/2470). Furthermore, the imported products must comply with the conditions of use, additional specific labelling requirements, other requirements and specifications (e.g. definition, physical-chemical properties, heavy metal and microbiological criteria, etc.) as established in the Union List of novel foods (Annex, Table 1)

## Rules applicable for insects and their derived products intended for human consumption<sup>28</sup>.

- Commission Delegated Regulation (EU) 2019/625 (Article (3)(a)) foresees that imported insects and insect products intended as food must originate from a **country** which has been included in a **list of authorised countries**.
- Commission Implementing Regulation (EU) 2020/2235 (Article 26) establishes a **model official certificate** (Annex III, Chapter 48) for insects as food imported into the EU.
- Commission Implementing Regulation (EU) 2021/405 (Article 24) draws a list of third countries (Annex XV) authorised to export insects and insect derived products into the EU. EU Member States benefiting from the so-called 'novel food transitional measure' and allowing imports of insects (as food) from EU third countries, will only permit authorised and listed countries to do so. Currently (on 15 October 2021) imports of insects as food are only authorised if originating from **Canada, South Korea, Switzerland, Thailand, Vietnam and the United Kingdom**.

## Imports of insects as feed

### General conditions

Most requirements applicable to animals and animal by products (therefore including insects) can be found in Annex XIV and Annex XV of Regulation (EU) No 142/2011.

### Rules applicable to processed animal proteins derived from farmed insects (insect PAPs)

Where to find the applicable EU requirements?

- Annex XIV, Chapter I, Section 1 and Section 2 to Regulation (EU) No 142/2011
- Annex XIV, Chapter I, Section 1, Table 1 (entry 1 (a)) which concerns processed animal proteins derived from farmed insects (insect PAPs) for **farmed animals**
- Annex XIV, Chapter II, Section 1, Table 2 (entry 12 (b)) which concerns processed animal proteins (PAPs) (including PAPs derived from farmed insects) intended for use in **processed pet food**

Applicable **health certificate models** can be found in Annex XV to Regulation (EU) No 142/2011:

- Annex XV Chapter 1a for insect PAPs as feed for **farmed animals**
- Annex XV, Chapter 3(A) In the case of canned petfood, Chapter 3(B) In the case of processed petfood other than canned petfood and in Chapter 3(C) in the case of dogchews

### Overview of main requirements

- The insect PAP must originate **from a species authorised for use as insect PAP in feed for farmed fish, poultry and pig species**, namely back soldier fly, common house fly, yellow mealworm, lesser mealworm, house cricket, banded cricket, field cricket or silk worm (annex XIV, Chapter I, Section 2, point 5. (a) of Regulation (EU) No 142/2011). N.B. this restriction only applies in the case the imported PAP is intended for use as feed for farmed animals (not applicable for pet food and fur animals). Furthermore Regulation (EU) No 142/2011 requires that the insect PAP does **not come from insects fed with feed materials which are not eligible as feed for farmed animals** (e.g. manure, treated wood, catering waste, former containing meat and fish, etc) (annex XIV, Section 2 5. (b) of Regulation (EU) No 142/2011).
- **The insect PAP must be produced in line with the requirements laid down in Regulation (EC) No 1069/2009 for category 3 materials;**
- Article 14 (a)(d)(i) and (iii) of Regulation (EC) No 1069/2009 requires that category 3 materials intended as feed for farmed animals or for the manufacture of pet food are being processed) **Article 31** defines the conditions under which animal by-products may be placed on the EU market as feed for farmed animals (e.g. these must be processed according to method 1 to 7) Article 35 in the case of pet food.
- **Article 35** regulates the conditions for marketing animal by-products intended as feed for pet food animals.
- In the case of **insect PAPs** intended as feed for **farmed animals**, only imports originating from the countries listed in Part 1 of Annex XIII or in Part 1, Section A, of Annex XV of Reg. (EU) 2021/404<sup>29</sup> as well as from Albania, Algeria and El Salvador are allowed.
- Only the countries listed in Part 1 of Annex XIII, Part 1 of Annex XIV or Part 1, Section A, of Annex XV of Reg. (EU) 2021/404<sup>30</sup>, as well as Albania, Ecuador, Algeria, Georgia, Sri Lanka, El Salvador and Taiwan can legally export to the European Union **insect PAPs** intended for use in **processed pet food**.
- The **processing plant** in the third country must be **approved in accordance with the requirements included in the ABP legislation**. See Traces system which defines the procedure to request such authorisation (e.g. once the country is approved for export in the EU based on previous controls performed by the EU competent authorities). The third country authorities are responsible for

<sup>28</sup> for further information on this subject see 'IPIFF information note on EU import conditions for insects intended for human consumption (see [link](#))

<sup>29</sup> Argentina, Australia, Bosnia Herzegovina, Bahrain, Brazil, Botswana, Belarus, Belize, Canada, Switzerland, Chile, China, Colombia, Costa Rica, Cuba, Ethiopia, Falkland Islands, United Kingdom, Greenland, Guernsey, Guatemala, Hong Kong, Honduras, Isle of Man, Israel, India, Japan, Jersey, Kenya, Morocco, Montenegro, Madagascar, Republic of North Macedonia, Mauritius, Mexico, Malaysia, Namibia, New Caledonia, New Zealand, Panama, Paraguay, Serbia, Russia, Singapore, Eswatini, Saint Pierre et Miquelon, Thailand, Tunisia, Turkey, Ukraine, United States, Uruguay, South Korea, South Africa, Zimbabwe and Kosovo.

<sup>30</sup> Argentina, Australia, Bosnia Herzegovina, Bahrain, Brazil, Botswana, Belarus, Belize, Canada, Switzerland, Chile, China, Colombia, Costa Rica, Cuba, Ethiopia, Falkland Islands, United Kingdom, Greenland, Guernsey, Guatemala, Hong Kong, Honduras, Isle of Man, Israel, India, Japan, Jersey, Kenya, Morocco, Montenegro, Madagascar, Republic of North Macedonia, Mauritius, Mexico, Malaysia, Namibia, New Caledonia, New Zealand, Panama, Paraguay, Serbia, Russia, Singapore, Eswatini, Saint Pierre et Miquelon, Thailand, Tunisia, Turkey, Ukraine, United States, Uruguay, South Korea, South Africa, Zimbabwe and Kosovo.

selecting the authorised establishments after ensuring these comply with EU requirements. (See **annex XIV, Section 1(d) of Regulation (EU) No 142/2011** for more details)

- The insect PAP consignment must undergo **veterinary checks** at a **EU Border Inspection Post**. To this end, the consignment must be accompanied by a **health certificate** delivered by the exporting country, in line with the model health certificate laid down in **Chapter I of Annex XV to Regulation (EU) No 142/2011** (for further details, see the paragraph on 'applicable health certificates models' on page 26)
- Before free circulation into the EU market, the importer must ensure that each consignment is **tested by light microscopy and/or PCR test**, in line with the Standard Operating Procedure of the EURL for Animal Protein, to verify the absence of constituents of animal origin prohibited by EU feed ban rules (for more details see **Section C of Chapter III of Annex IV to Regulation (EC) No 999/2001**).

### Import of whole (frozen or dried) insects

#### Where to find' the applicable requirements?

- Annex XIV, Chapter II, Section 1, Table 2 (entry 12(b)) which concerns animal by-products intended for use in processed pet food

The model certificate is provided in Annex XV, Chapter 3(A) in the case of canned petfood, Chapter 3(B) in the case of processed petfood other than canned petfood and Chapter 3(C) in the case of dogchews

#### Overview of main requirements

**The import into the EU of treated** (e.g. dried or frozen insects) **but not 'processed'** insects according to Regulation (EC) No 1069/2009 is currently allowed, **but only for the manufacture of pet food** (including for reptiles, birds of prey, circus or zoo animals) and **if approved by the importing national competent authority** in accordance with Article 18 of Regulation (EC) No 1069/2009.

**The same general requirements as for insect PAPs do apply** (e.g. the products must come from a country which is included in the list of authorised countries', they must come from an establishment which is approved by competent authority of the third country and the consignment must be accompanied with a health certificate). Yet, no light microscopy and/or PCR test is required.

If intended for pet animals, the subsequent pet animals manufacturer must be approved in accordance with Article 24 (1)(e) of Regulation (EC) No 1069/2009.

#### **Import of whole 'untreated' insects**

**Imports of non-treated (dead) insects** (for pet animals, reptiles, birds of prey, circus or zoo animals, etc) **should theoretically be possible** - in accordance with Article 18 of Regulation (EC) No 1069/2009 - **if authorised** by the **competent authorities of the importing country**.

#### **Import of insect fat as feed for farmed animals**

**Insect fats** are **not specifically regulated** but should theoretically be allowed under the same **conditions as for rendered fat intended as feed for farmed animals** (see Annex XIV, Chapter I, Section 1, table 1 (entry 3 (a)) of Regulation (EU) No 142/2011) The same list of authorised countries as for PAPs and whole insects should therefore apply, while the model of health certificate provided in Annex XV, Chapter 10 (A) should be used by operators.

## 1.2.5. Animal health and environmental requirements

The general requirements relating to animal health, apply to farmed insects since these are considered as 'farmed animals' (see section 1.2.2. of the Guide). 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. They shall also comply with related provisions provided in Regulation 852/2004 (Annex I, part A, Chapter II 3. (b), Chapter III, 8. (b) and (c) and Part B. 2. (d)) and in Regulation 183/2005 (Annex I, part A, Chapter I 3. (i) and (ii)) as well as in Regulation (EC) No 470/2009 and Commission Regulation (EU) No 37/2010.

Insect producers should also refer to Regulation (EU) No 2019/6 on **veterinary medicinal products** and Regulation (EU) No 2019/4 on **medicated feed** (see chapter 1.2.2. for more details)

Insects and their derived products intended for food and feed purposes shall not:

1. **be pathogenic** or have other adverse effects on plant, animal or human health (see article 15 (1) and 15(2) of Regulation (EC) No 178/2002 and requirements applicable to category 3 materials in accordance with the ABP legislation or for 'terrestrial invertebrates' in the EU Catalogue of feed materials (i.e. Regulation (EC) No 68/2013).

2. **be protected or defined as an invasive alien species** in accordance with Regulation (EU) No 1143/2014<sup>31</sup>.

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

## 1.3. Management of responsibilities, organisational structure and employees

### 1.3.1. Food and feed safety management system responsibility

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

The respective safety management system states the expectations the Management has on hygiene practices to ensure the safe production (primary production and processed products), storage and delivery of insects and related products.

The Management shall inform the operating staff about the hygiene practices and protocols being followed in the company and is committed to ensuring their implementation within the company.

The safety management system in place should be reviewed and updated, when necessary, based on the outcomes of internal and external audits. Employees are kept informed accordingly.

#### **Annex II, Chapter XIa of Regulation (EC) No 852/2004 on food the hygiene of foodstuffs** *'Food Safety Culture'*

'1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:

- (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food;
- (b) leadership towards the production of safe food and to engage all employees in food safety practices;
- (c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business;
- (d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations;
- (e) availability of sufficient resources to ensure the safe and hygienic handling of food'.

### 1.3.2. Employees' appointment and structure

#### **Annex II of Regulation (EC) No 183/2005 laying down requirements for feed hygiene**

'A qualified person responsible for production must be designated (...) Where appropriate a qualified person responsible for quality control must be designated'

#### **Annex II, Chapter XII of Regulation (EC) No 852/2004:**

'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'.

The Management could appoint a qualified person responsible for supervising the quality control of the production and/or process lines, and ensuring product safety parameters. The responsible person could organise the work of the team and has the authority/responsibility to:

1. Develop and maintain GHP within the company;
2. Report to the Management about issues and to suggest appropriate measures to remediate or control problems when they occur;
3. Prepare for and train the Health, Safety, Environment and Quality (HSEQ) team, should it exist, in developing and maintaining the HACCP system and implementing GHP, and;
4. Train company employees in GHP.

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

### 1.3.3. Employees' skills

The operating staff is required to have the skills and the qualifications necessary for the manufacture of the products concerned.

#### **Annex I, Part A, II, point 4(e) of Regulation (EC) No 852/2004**

'4. 'Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are (...) to ensure that staff handling foodstuffs are in good health and undergo training on health risks'

#### **Annex II of Regulation (EC) No 183/2005**

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 (...)'.  
'The person responsible for the feeding and handling of animals shall possess the requisite ability, knowledge and competence.'

#### **Annex III of Regulation (EC) No 183/2005**

'The person responsible for the feeding and handling of animals shall possess the requisite ability, knowledge and competence.'

#### **Annex II, Chapter XII of Regulation (EC) No 852/2004**

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, feature the followings:

1. Knowledge about the behaviour of insects;
2. Ability to identify species of insects;
3. Knowledge about farmed insect species life cycle;
4. Handling of live insects.
5. Knowledge and/or ability to detect insect diseases symptoms and capacity to adopt appropriate management measures.

## 1.4. Traceability and record keeping

### 1.4.1. 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 of Regulation (EC) No 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 183/2005 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 (EC) No 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 (EC) No 852/2004, annex I, Part A, 'III record keeping').

### 1.4.2. 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, providing it immediately and as necessary to the competent authorities on their request:

1. The name and address of the substrate provider(s) (e.g. feed materials or compound feed products, suppliers, the batch number, the quantity and delivery date of the products, etc);
2. The name and address of the insect breeding flock provider(s), 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 hygiene<sup>32</sup> and feed<sup>33</sup> 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)<sup>34</sup> and of the site where the batch of semi-finished or finished products are delivered to.

<sup>32</sup> Regulation (EC) No 852/2004, Article 5(5); Annex I, III Record-keeping, 7.

<sup>33</sup> Regulation (EC) No 183/2005, Annex II, Quality Control .4. Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability.

<sup>34</sup> Regulation (EU) No 931/2011, Article 3 'Traceability requirements'

In addition, insect producers could 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').
6. A system shall also be in place to deal with products that are rejected by customers for food or feed safety reasons.

EU regulations and/or national legislations state that documents should be retained to ensure traceability at least until it can be reasonably assumed that the food has been consumed<sup>35</sup>. By default, a two-year period is recommended. Operators must have systems and procedures in place that allow the sharing of information with national food and feed safety authorities whenever deemed necessary.

## 1.5. 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, 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.

## 1.6. Emergency and product recall strategy

### 1.6.1. 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.). The aforementioned situations can affect the production process itself (e.g. delay in supplying raw materials can halt the production line, delay in feeding substrates for insects could lead perishable raw material to degrade over time).

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<sup>35</sup> Commission implementing Regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin

substrates for insects, perishable raw material could degrade over time on delayed delivery or use) or cause contamination in the product (contaminated raw materials, human or equipment error). Potentially, such crises could impact the product, compromising its safety and quality.

## 1.6.2. Withdrawal and recall obligations under EU legislation

### **Article 19 of Regulation (EC) No 178/2002**

#### ***'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.'*

### **Article 20 of Regulation (EC) No 178/2002**

#### ***'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.'*

### **Annex II of Regulation (EC) No 183/2005**

#### ***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.'*

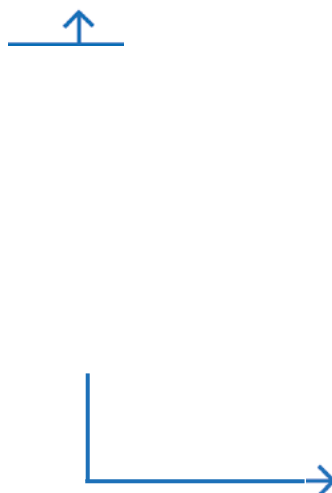
The procedure should include the following information and measures and should be tested beforehand:

- Contact details of relevant staff with allocated responsibilities for decision making;
- Contact details of external organisations (e.g. national competent authorities) as per the emergency plan;
- How to identify the product/area that is affected by the emergency situation such as fires, and potential contamination from the activities of the first responders (e.g. fire-fighter, rescue team);
- Handling procedures for potentially unsafe products (e.g. waste or allergen cross contamination) ;
- How to evaluate and restore the affected area through corrective action processes. (e.g. allergen cross contamination in insect-based food products production line, evaluation on area of contamination in production line, potential cleaning protocols before restarting the production line).

### 1.6.3. Recommended practices

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

A written crisis management procedure available in line with Regulation (EC) No 178/2002 should be established to assist the personnel confronted with emergency situations and potential accidents to act effectively and consistently, thereby avoiding improvisation.



The above is an indicative diagram regarding a crisis management procedure to be established by the respective operator. In case of deviation in quality during production, it should be determined by testing the product safety parameters. If the product is 'OK' in its safety parameters, the product may re-enter the production line. In case of deviation in safety parameters compromising the product, quarantining the product must be the immediate action subsequently its appropriate disposal should be implemented. In case the product has proceeded in the production line or supply chain, respective 'product recall' measure should be activated. Subsequently its appropriate disposal should be implemented.

# CHAPTER 2 – PREREQUISITE PROGRAMS: INFRASTRUCTURES AND GENERAL CONDITIONS OF PRODUCTION

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## 2.1. 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.

## 2.2. Building and Premises

### 2.2.1. 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:
  - neighbouring 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 moulds;
  - loud external noise that could disturb the rearing of specific insect species.

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

### 2.2.2. Building and premises: design principles

#### **Annex I, Part A, II, point 4(a) of Regulation (EC) No 852/2004**

*'Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:*

*(a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner'.*

#### **Annex II and relevant articles of Regulation (EC) No 183/2005:**

*'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 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.'*

*'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. Those shall also be specifically designed to prevent insects from escaping. 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;
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 mould and attract unwanted insects;
4. 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 harbour and attract pests.
5. 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 harbourage 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, or other openings, 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 harbouring of pests, birds and wild insects;
  - there should not be structures or equipment's, which could provide places for microbial contamination or provide an environment 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 mould, 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. ensure that the filling area is separated from the handling of raw materials and other food processing activities;
6. forward moving flow of products (by pipes, conveyors, trucks etc.), from the reception of raw material to the release of the final products to reduce distances travelled 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 and which are impervious to water and steam. Walls shall be covered with materials which are impervious, non-absorbent, light coloured, 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.

### 2.2.3. Building and premises: ventilation

#### Annex II, Chapter I of Regulation (EC) No 852/2004

*'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.'*

### 2.2.4. 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. The necessary monitoring protocols should be in place.

## 2.2.5. Sanitary facilities, staff rooms and laboratories

### Annex II, Chapter I of Regulation (EC) No 853/2004

*'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.'*

The 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, the 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.

## 2.3. Production equipment

### Annex II of Regulation (EC) No 183/2005

*'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 Regulation (EC) No 852/2004

*'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, 'Cleaning-in-Place'-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 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 food**<sup>36</sup>. 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.

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<sup>36</sup> See EC safety guideline for Food contact materials [https://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials\\_en](https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en)

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 pests, 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.

#### 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 Regulation (EC) No 183/2005**

*'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 Regulation (EC) 852/2004**

*'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.

## 2.4. Pest control measures

Pests (such as birds, insects, spiders, rodents and other small mammals) represent a hazard for the safety of food and feed 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 regulations<sup>37</sup>. 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 or maize products.

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<sup>37</sup> 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.

## 2.5. Waste management

### Annex II of Regulation (EC) No 183/2005

*'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 Regulation (EC) No 852/2004

*'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.'*

Waste<sup>38</sup> generated from production of insects or their derived 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.

Waste could also include parts from insects, insects that have died naturally insect eggs, and pupas, together with excrement, 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 such as discarded packaging material, wastewater, etc. must be taken care of. Those materials shall be kept and discarded in the "unclean" part of the production plant which is separated from the "clean part" of the facility where the processing of the larvae takes place.

When managing such by-products, insect producers shall comply with obligations derived from the EU ABP legislation (e.g. Article 13 and 14 of Regulation (EC) No 1069/2009 depending on their 'categorisation' according to the ABP legislation).

#### 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.

<sup>38</sup> 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.)

## 2.6. Monitoring (sampling and analyses)

### 2.6.1. 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 fulfilment 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 insects<sup>39</sup> (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's opinion 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.

### 2.6.2. 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 ready-to-eat food made from insects. Those requirements might include sampling of the processing area and equipment.

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 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 (EC) No 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; by referring to Regulation (EC) No 2073/2005. The microbiological criteria in the table mentioned below refer to Annex I (Microbiological criteria for foodstuffs) to Regulation (EC) No 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. water activity).

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<sup>39</sup> Contrary to warm blooded animals, mass-reared insects are not likely to contain substantial number of typical pathogen agents – e.g. *Salmonella*, *Listeria Monocytogenes*.

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, in addition to legal obligations by operators. The following listed potential hazards are recommended to be monitored in start-up phases (during initial risk analysis and determining monitoring plan). Identification of hazards, are 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 criteria in the table are subject to products sampled at the end of the manufacturing process of the production of whole/ground insects, ready to eat or as a food ingredient. The frequencies for monitoring these pathogens depend on the respective insect species, production methodology and specification of the insect-based product(s).

Last but not least, authorised insects as food products must fulfil the **microbiological criteria** as defined in the '**Union List of Novel foods**' – Commission Implementing Regulation (EU) 2017/2470 for the concerned product.

### Microbiological parameters recommended to be monitored:

Hazards	Main origins	Severity	Management	Target	Limit
<b>Aerobic flora 30°C</b>	Hygiene indicator-Process Manipulations	Low	Good Hygiene Practices (GHP)	10,000 cfu/g	500,000 cfu/g
<b>E. coli</b>	Hygiene indicator-Process Manipulations	Low	Good Hygiene Practices (GHP)	10 cfu/g	500 cfu/g
<b>Staphylococcus coagulase + (S. aureus)</b>	Hygiene indicator Manipulations (raw materials or processing operations)	Medium	Good Hygiene Practices (GHP)	10 cfu/g	100 cfu/g
<b>Listeria monocytogenes</b>		High	Sourcing/ breeding management (GHP)	Absence in 25g	Absence in 25g
<b>Salmonella</b>	Insects intestinal tractus, feed	High		Absence in 25g	Absence in 25g
<b>Cronobacter spp. (Enterobacter sakazakii)</b>	Insects, feed	Medium	Sourcing/ breeding management (GHP)	Absence in 10g	Absence in 10g
<b>Bacillus cereus</b>	Feed	Medium	Feedstock/ breeding management (GHP)	10 cfu/g	100 cfu/g
<b>Monitoring Campylobacter</b>	Insect guts	Medium	Sourcing/ breeding management	Absence in 25g	Absence in 25g
<b>Moulds and Yeast</b>	Hygiene indicator-Process Manipulations, feed	Medium	Good Hygiene Practices (GHP)	100 cfu/g	1000 cfu/g

### Chemical parameters recommended to be monitored:

- Pesticides (e.g. organophosphorus pesticides, other pesticides) in accordance with the limits set out in Regulation (EC) No 396/2005;
- Heavy metals (lead, cadmium), organochlorine pesticides, based on the thresholds provided under Directive 2002/32/EC;
- Cleaning and disinfection residues;
- Contamination through material contact.

### Physical parameters recommended 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 allergen(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 of the insect itself linked to the listed allergen crustaceans is recommended to be included in the 'monitoring plan'.

On authorisation of the respective insects as novel food, operators should refer and must mandatorily follow the specifications on hazards to be monitored, as indicated in the Union list of novel foods.

### 2.6.3. 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 III, point G. of Regulation (EU) 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, Fumonisin);
- Heavy metals (As, Cd, Cr, Cu, Hg, Pb, Ni, Zn);
- Polycyclic aromatic hydrocarbons;
- Dioxins;
- Animal proteins;
- GMOs;
- Metal, plastic, stone pieces;
- Foreign objects.

### 2.6.4. Creating a monitoring programme

Sampling and testing measures implemented by insect producers must be specifically foreseen in the monitoring programme in chapter 7.3.9. on HACCP.

Some general recommendations regarding sampling for insect products as food and feed are provided below:

- Sampling based on the results could be intensify or reduced;
- In the case of a positive detection of microbial contamination, it is advisable to test for contamination afterwards;
- Water activity ( microbial growth does not take place any more, below 0.60 a.w. whatever the matrix) and pH measurements are of great importance because these constitute the final

step in the production process to guarantee food safety. Registration of water activity must be recorded on the 'product registration' form.

An example of monitoring procedures for batches (see definition of 'batch' in Annex I) of materials used in production of insect-based products. Operators are recommended to perform analysis on fresh samples (or in case stored in freezers not more than 24 hrs) in order to have accurate results on microbiological colonies.

### Insects as Feed:

**A batch**, subject to the following monitoring plan, **may comprise a maximum of 100 tons**. For batches of up to 100 tons, at least 1 sample is taken while 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. In the context of 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 half a 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. Minimum sampling frequencies are illustrated below for a start-up phase.

### 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	1 time per year/ or when suspicion	1	Arrival	Internal / External qualified laboratory	All

The frequency of microbiological analysis for raw materials is 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 outgoing 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) Regular sampling following the 30 days' period (e.g. once a month)	1	Directly after the treatment	Internal / External qualified laboratory	All
	Salmonella	30 days (Method 7 Plan) Regular sampling following the 30 days' period (e.g. once a month)	5	During or upon withdrawal from storage.	Internal / External qualified laboratory	All
	Enterobacteriaceae	30 days (Method 7 Plan) Regular sampling following the 30 days' period (e.g. once a month)	5	During or upon withdrawal from storage.	Internal / External qualified laboratory	All

Moisture content percentage	3x a day	1	During production	Internal / External qualified laboratory	All
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The frequency of microbiological analysis (all) of the end product can be increased to one time/month if requested. Physical hazards should be determined and monitored accordingly in every batch.

## Production of insects as food

The number of subsamples and frequencies for sampling of insect-based food products should be increased or decreased when necessary. 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) and the weights of each batch. Minimum sampling frequencies are illustrated below for a 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* group, *Enterobacteriaceae*, *Salmonella*, criterion to be maintained according to the risk analysis especially for the monitoring of raw material flours used for the production of insect based food products.**

\*\* 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.

## 2.7. Personnel

### 2.7.1. 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 procedures;
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.
10. Capacity to manage insect diseases outbreaks in an effective way, notably through adherence to appropriate biosecurity measures (e.g. elimination of flocks or implementation of quarantine measures whenever deemed appropriate).

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 behaviour (smoking, running etc.);
12. emergency exits and emergency procedures;
13. individual protection equipment.

#### **Annex II of Regulation (EC) No 853/2004**

*'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.'*

The 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. People working in high noise environment should wear ear plugs
2. Helmet and glasses should be used by maintenance staff;
3. People with direct product contact should wear gloves;
4. People working in breeding chambers should wear a mask;
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 behaviour 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 behaviour and staff must comply with it.

### 2.7.3. Personal health

**Annex II of Regulation (EC) No 853/2004**

*'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 supervisors to report poor health conditions such as specific communicable diseases transmissible onto the food/feed products, illness, open lesions or any other abnormal source of microbiological contamination to avoid contaminating food, food-contact surfaces or food packaging materials.

The Management will, in turn, submit a declaration to support medical examination in case health problems are discovered/encountered during operator activities 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 the 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.

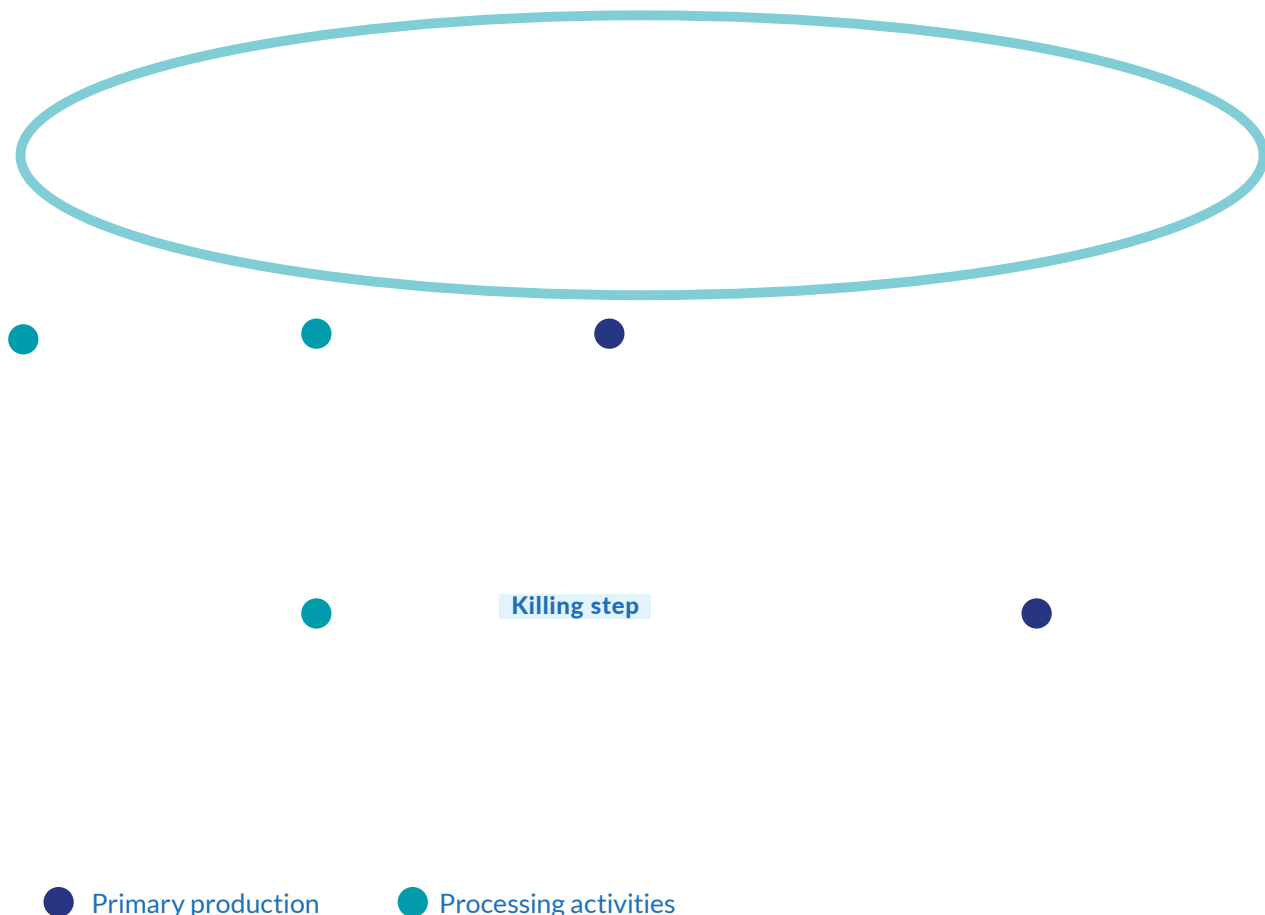
**Summary:** the implementation of the above mentioned PrPs is summarised here. If the PRPs are properly implemented, maintained and verified, risks for food/feed safety are reduced.

<b>2.2.</b>	<b>Building and Premises</b>
Aim	Lay-out, design and maintenance of company premises must be as such that risks of contamination of insect food/feed is minimised.
Action	Risk assessment on environment/company premises and implementing hygiene practices <ul style="list-style-type: none"> <li>• Plan on facility site map</li> <li>• Plan on access, outlets, physical and organisation separation plans</li> </ul>
<b>2.3.</b>	<b>Production equipment</b>
Aim	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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</li> </ul>
Action	<ul style="list-style-type: none"> <li>• Compliant equipment design to hygiene requirements and cleaning and disinfection programs.</li> <li>• Maintenance and calibration procedure, program and records.</li> </ul>
<b>2.4.</b>	<b>Pest control measures</b>
Aim	<ul style="list-style-type: none"> <li>• Prevent pest (including insects, birds) and excrements from contaminating insect food/feed products.</li> <li>• Make a pest control program, implement and maintain it.</li> </ul>
Action	<ul style="list-style-type: none"> <li>• Pest control procedure, program and records.</li> </ul>
<b>2.5.</b>	<b>Waste management</b>
Aim	<ul style="list-style-type: none"> <li>• Identify waste and minimise the risk of unintended introduction into insect food/feed ingredients.</li> </ul>
Action	<ul style="list-style-type: none"> <li>• Waste management procedure, program and records.</li> </ul>
<b>2.6.</b>	<b>Monitoring (sampling and analyses)</b>
Aim	<ul style="list-style-type: none"> <li>• To demonstrate and ensure the safety of the insects food/feed product.</li> </ul>
Action	<ul style="list-style-type: none"> <li>• Risk assessment and develop monitoring plan</li> <li>• Maintain records</li> </ul>
<b>2.7.</b>	<b>Personnel</b>
Aim	<ul style="list-style-type: none"> <li>• Establish hygiene policy and access control and communicate these to all personnel and subcontractors.</li> </ul>
Action	<ul style="list-style-type: none"> <li>• Communication of hygiene policy (instruction agreed by employees and subcontractors)</li> <li>• Access regulation (instruction)</li> </ul>

# CHAPTER 3 – PREREQUISITE PROGRAMS: MANAGEMENT OF INSECTS' SUBSTRATES

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## 3.1. Substrates supply and insect producers sourcing activities



### 3.1.1. 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.

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 high levels of moisture (sometimes referred to as 'hygroculture'), whereas mealworm (*Tenebrio molitor*) and lesser mealworm (*Alphitobius diaperinus*) are usually raised on dry substrates (sometimes referred to as 'xiroculture').

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 of their management systems.

### 3.1.2. Applicable legislative requirements

Insect producers must only source substrates that are eligible as feed materials for farmed animals within the European Union - rules as defined under the EU Animal-By-Products legislation (i.e. Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011) and not being forbidden by the Feed Marketing Regulation (i.e. Regulation (EC) No 767/2009 - Annex III, e.g. manure and animal faeces, feed containing packaging residues) (see the full list of prohibited materials in section 1.2.2.).

Furthermore, any **substrate which has been mixed with insect frass** (e.g. during the production cycle) may **not be reused in further production cycles**. Insect frass is indeed regarded as a category 2 material, so its mixture with substrates ('category 3 materials') shall be classified as **'category 2 materials'**, in accordance with article 9(g) of Regulation (EC) No 1069/2009

Finally, insect producers must conform to the general provisions of Regulation (EC) No 183/2005 on feed hygiene. Notably, the substrates sourced outside the insect production facility must be obtained from a registered or approved feed business operator, in accordance with the aforementioned Regulation (EC) No 183/2005 (Article 5(6)).

- Substrates' suppliers producing or placing on the market certain feed additives, premixtures and/or compound feed prepared using feed additives shall be approved in accordance with Article 10(1) of the above Regulation;
- 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<sup>40</sup> and/or the EU animal by-products legislation if these products contain materials of animal origin<sup>41</sup>.

Finally, substrates suppliers must have implemented a HACCP plan, if not covered by Article 5 (1) of Regulation (EC) No 183/2005 (applicable to 'primary producers').

### 3.1.3. Specifications and checking measures

Substrates sourced outside the insect production facility must be obtained from a registered or approved feed business operator in accordance with Regulation (EC) No 183/2005 (Article 5(6)).

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 the implementation of good hygiene practices and/or of HACCP procedures when applicable.

Insect producers must also register the substrate supplier's name, its address and delivery date<sup>42</sup>, 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).

<sup>40</sup> See Section 3.2 of the EC Guidelines for the feed use of food no longer intended for human consumption.

<sup>41</sup> See Section 4.2 of the above-mentioned EC Guidelines.

<sup>42</sup> Annex III on Record-Keeping (b) (iv) Regulation (EC) No 183/2005

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 present in the substrate). Samples and results of the analysis shall be made available to the national 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 their 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 substrates undergo 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.

## 3.2. 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 the following principles:

1. Incoming materials must be stored in dry (i.e. for dried substrates), appropriate temperature 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. Ensure that the substrates are provided by trusted suppliers;
2. Only source your substrate from registered or approved Feed Business Operators
3. Only source and use authorised substrates which are eligible as feed for farmed animals, in accordance with EU legislation;
4. Ensure that designated and trained staff are present at the point of delivery;
5. Visually control the truck before unloading and accepting the delivery to detect damaged seals or packaging;
6. Register all batches of substrate;
7. Undertake your own testing/sampling of the substrate following a risk-based approach, after assessing its potential contamination (notably, you should pay attention to the development of *Salmonella* spp., *Campylobacter* and *Enterobacteria*);
8. Pre-treat the substrate whenever necessary (see above).
9. Take all the necessary measures in order to prevent the risks of cross contamination.

# CHAPTER 4 – PREREQUISITE PROGRAMS: INSECT REARING ACTIVITIES

## 4.1. Introduction: scope and legal framework

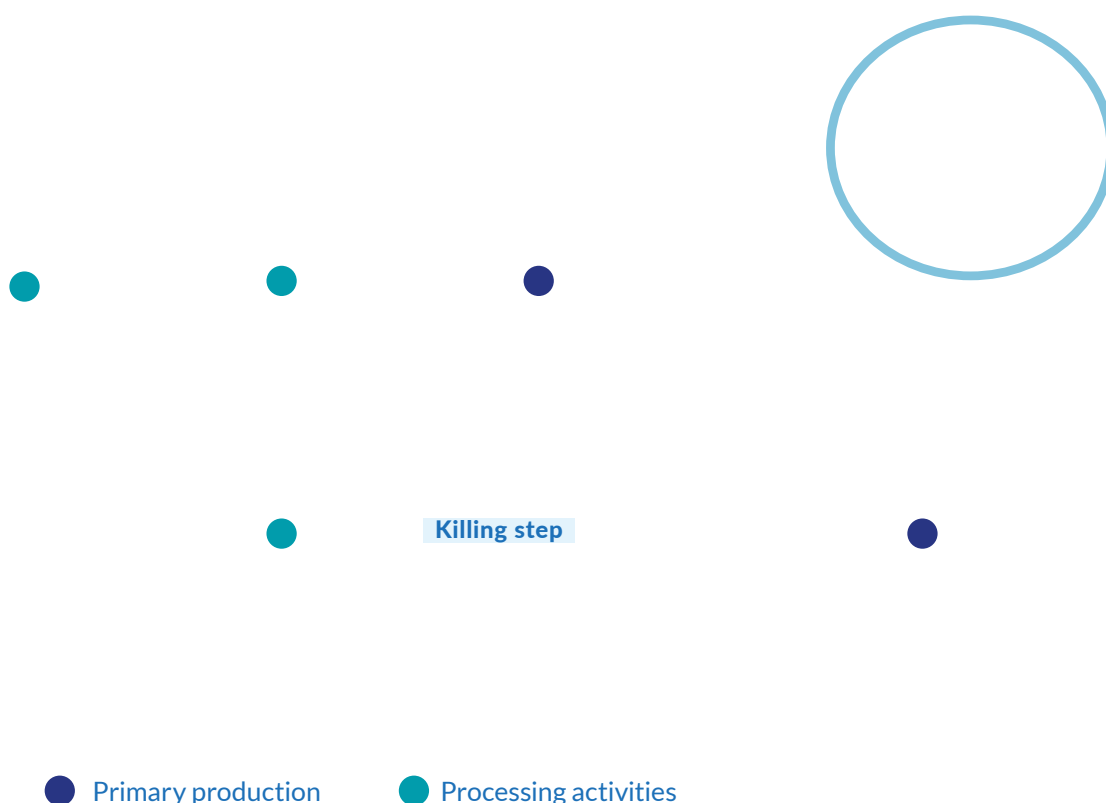
Insect rearing activities cover the following production steps:

1. Administration of substrates to insects;
2. Insect growth phase;
3. insect harvesting;
4. pre-treatment step.

All the above-mentioned steps are **regarded as ‘primary production’ activities**<sup>43</sup> 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 as of processing activities, therefore limiting the risks for contamination which 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 4.6. of the Guide.

This chapter applies to insect products intended for human consumption and animal feed.

## 4.2. Administration of substrates



<sup>43</sup> Unless when mixing feed additives (see section 1.2.1. for more details).

### 4.2.1. Background information

The administration of substrates to insects constitutes an important component of the breeding process. Such operations are designed to provide insects, specific to their species and consumption habits, 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.

### 4.2.2. Applicable legislative requirements

All operations associated with the feeding of the animals are considered as ‘**primary production**’ activities (unless when mixing feed additives). Therefore, they are subject to the specific requirements contained in **Annex I and III of Regulation (EC) No 183/2005 and Annex I of Regulation (EC) No 852/2004.**

*For further information, see section 1.2.1. of the present Guide*

#### **Annex III of Regulation (EC) No 183/2005**

##### **‘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 (...).’*

### 4.2.3. 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:

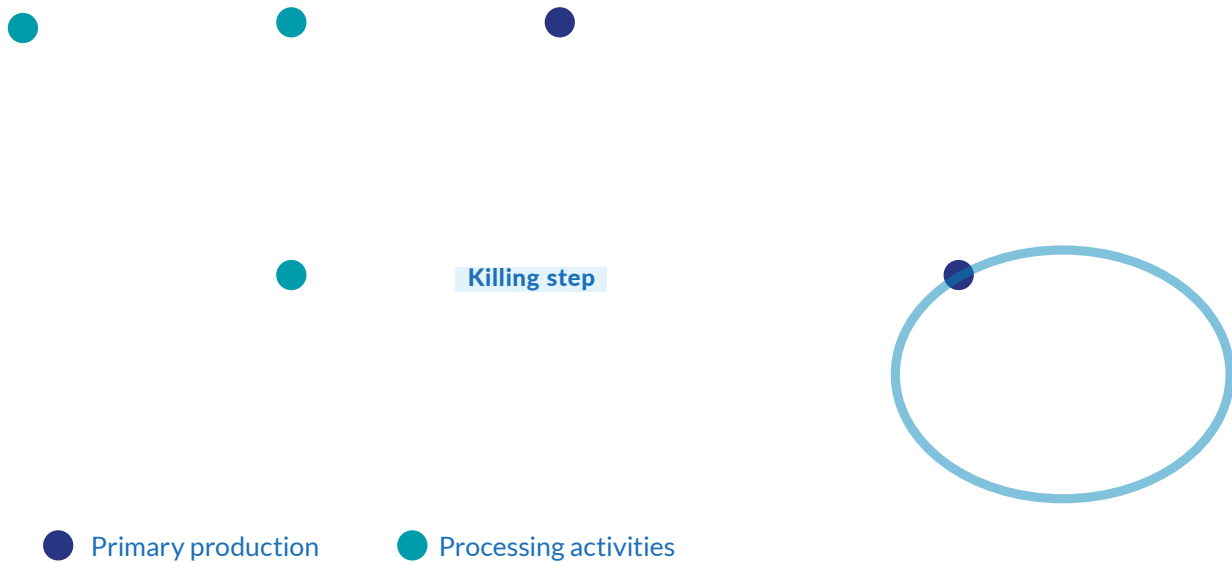
- The substrate used should be selected by taking into consideration the chosen insect species, based on its mycotic, bacterial and viral disease resistance;
- Each batch of substrate delivered to the animal must be traceable;
- The equipment destined to provide the nutrients/substrates (or any other material which may enter into contact with the animals) should be certified as ‘food contact’ material (in order to 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 (respective to the insect farming techniques, e.g. automated, manual, vertical stacking of breeding trays, movement of material, etc). These should include regular checks in the course of manufacture<sup>44</sup> designation and training of staff at the point of distribution in order to prevent cross-contamination.

<sup>44</sup> Annex II, Chapter ‘PRODUCTION’ of Regulation (EC) No 183/2005.

*Photo: Courtesy of Protifarm.*

### 4.3. Insect growth phase



### 4.3.1. Background information

Besides the composition of the substrate, insect rearing conditions may also contribute to the development of microorganisms (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 hatching).
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 Common 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 section 4.3.2. below for more details).

### 4.3.2. 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 keep records of 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. Appropriate cleaning and sanitary measures should also be undertaken to avoid contamination or spread to diseases among the breeding flocks.

Insect producers should set up a pest control plan in the growing rooms (e.g. check the absence of pests in the breeding rooms such as protection from invasion of external insects or rodent control, and good conditions of the fixtures). Respective operators and breeders should consider the location of the production site (e.g. close to marshlands, swamps, etc) to identify potential pest invasion.

*more details can be found in section 2.4. 'Pest control measures' of the Guide*

Having a register on rearing conditions and supplied raw materials will help to control and monitor that production is between the established limits, to optimise the yield and to guarantee the survival of the livestock (e.g. Conditions temperature, moisture, substrate quantities, conditions of water - pH, hardness). Furthermore, if applicable, the correct and appropriate use as well as traceability, of veterinary medicinal products and feed additives should be maintained.

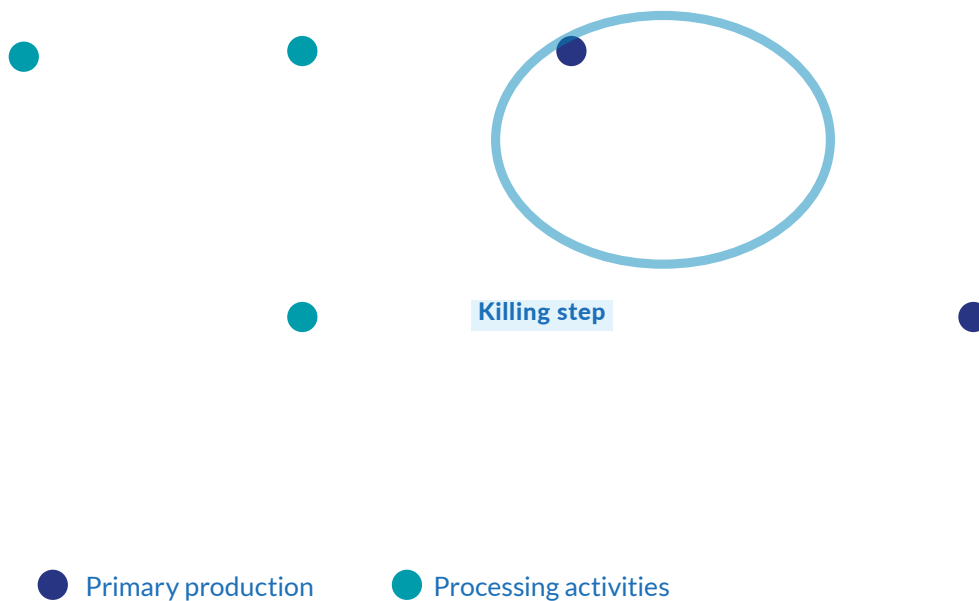
### 3. Separation of the insect from its feeding substrate before harvesting:

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 practice in the breeding process 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. House Fly larvae to be harvested are often isolated from the substrates by lowering oxygen concentration in a closed container, creating an avoidance of substrate intake by the larvae.

## 4.4. Harvesting



### 4.4.1. 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, House Fly) fully grown larvae are harvested, whereas in hemimetabolous insects (e.g. crickets and grasshoppers) animals are harvested at young nymphae or adult stage.

The harvesting method(s) used may therefore also differ from one species to another based on their breeding behaviour:

1. Usually, Yellow 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.

Current sector harvesting practices include:

1. Yellow 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 **eventual residues of 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.

#### 4.4.2. 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;
- 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 whole insects (e.g. black colour larvae).
- Clean the sieving equipment thoroughly (e.g. washing, use of appropriate cleaning and sanitation material, drying) and on a regular basis (once between each harvest) in order to limit microbiological exchange, the proliferation of larvae from unhatched eggs, or the spread of foreign bodies into breeding insects;
- Equipment, boxes, tools and nets should be cleaned consequently according to respective operators established safety management protocols (GHPs, PRPs, HACCP 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 use (e.g. land 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 appropriately;
- Eventual residues of substrates separated from the larvae or adult insects (before killing) must be disposed of as well;
- Feeding substrates left overs are disposed of too. Insect producers may decide to reuse these left-overs for another production slot. In such a case, operators should devise clear and strict procedures, notably by defining criteria under which those substrates may be reused and ensure the absence of larvae and frass residues. Operators may monitor the microbiological status of these substrates through sampling measures and should foresee appropriate treatment of the concerned materials, notably to prevent the multiplication of micro-organisms contained therein.

*Photo: Solids Processing.*

## 4.5. Pre-treatment step

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

Chilling is commonly used by producers, i.e. a pre-treatment 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 mealworms, while temperatures between 5°C-10°C are typically applied for crickets. The operator ensures that the temperature remains consistent throughout the process. Such measures provide adequate storage periods to maintain the product properties and avoid microbiological contamination.

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.

## 4.6. 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 fulfil the same legislative requirements and good hygiene practices as described throughout this chapter (i.e. compliance with Annex I of Regulation (EC) No 1831/2003 and in Annex I of Regulation (EC) No 853/2004). 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 used in the facilities of such subcontractors 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 substrates (Chapter 4.2.)**

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 4.3.)**

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.

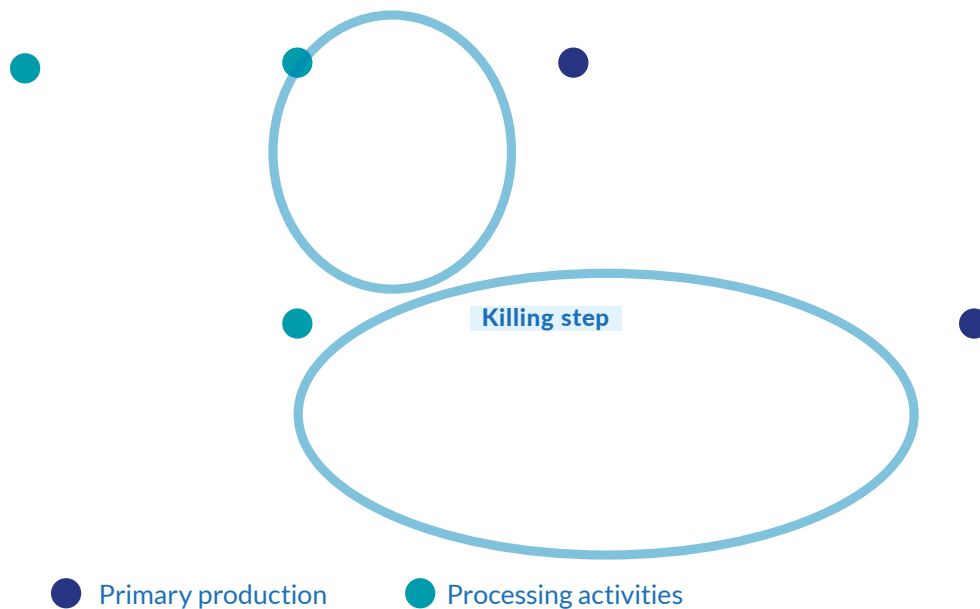
#### **Harvesting (Chapter 4.4.)**

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

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## 5.1. Introduction: scope, legal framework and general recommendations



### 5.1.1. Background information

This chapter provides an overview of the processing methods involved for insects which are applicable to the production of both animal feed and 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). Chapter 7. provides a detailed description to implement HACCP principles for the following processing methods discussed below.

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

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).

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

## 5.1.2. 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 ABP legislation** (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 (other than species pathogenic to humans or animals) are treated as 'category 3' materials (article 10(l) of Regulation (EC) No 1069/2009, and are thus authorised for use in feed for food producing animals, if being previously processed. The possibilities apply without prejudice to the restrictions which may derive from the 'TSE legislation' (Regulation (EC) No 999/2001). (See section 1.2.3 for further details on this subject)

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 killed insects into insect-based ingredients; (see chapter 1.2.1. for more details on this subject);
2. Insect processing establishments shall comply with a set of **general requirements** (see below);
3. Insect producers must conform with common processing standards and/or criteria as defined in Regulation (EU) No 142/2011 (Annex X, Chapter II, Section, Part 1, point B) (see below).

Insect producers of feed must comply with the methods provided for in Regulation (EU) No 142/2011. Insect producers 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 III, 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).

### • **General requirements**

The decision of the operator to destine killed insects (e.g. whole insects, insect PAPs or fat derived from insects) for other purposes than human consumption (e.g. feed or for technical uses) should be considered **as an irreversible decision**, in accordance the provisions of the ABP legislation, i.e. Article 2. 1 (b) of Regulation (EC) No 1069/2009.

Furthermore, the operator shall issue an **accompanying commercial document** and a **health certificate** indicating the destination of the product, in accordance with Article 21(3). of Regulation (EC) No 1069/2009. The latter document shall at least include information on the origin, the destination and the quantity of such products, and a description of the animal by-products or derived products. Article 26 of the above Regulation provides that the treatment, processing or storage of animal by-products (e.g. insect PAPs) shall be done **under conditions which prevent cross contamination** and if appropriate in a dedicated part of the establishment or plant (e.g. unprocessed materials shall not mixed with insect PAPs).

### • **Applicable processing methods**

#### **General**

'Terrestrial invertebrates other than species pathogenic to humans or animals' are classified as category 3 materials, pursuant to Article 10(l) of Regulation (EU) No 1069/2009. As consequence of this qualification, insect derived ingredients intended for animal feed (e.g. insect PAPs, insect fat, hydrolysed proteins) must be treated in accordance with **validated processing methods** (Article 31(1)(b) of Regulation (EC) No 1069/2009).

- These methods are defined in Annex IV, Chapter III to Regulation (EU) No 142/2011 (method 1-5 or method 7);

- **Some specific requirements** and/or other processing methods are defined in that same Regulation, notably in the case of **fat derivatives** (i.e. Annex X, Chapter II, Section 3) **and hydrolysed proteins** (i.e. Annex X, Chapter II, Section V)

- Required processing methods for insect PAPs

Insect PAPs must be produced in line with the requirements laid down in Regulation (EC) No 1069/2009 for category 3 materials (i.e. Article 13 of Regulation (EC) No 1069/2009 requires that category 3 materials intended as feed for farmed animals or for the manufacturing of pet food are being processed), e.g. Article 31 which applies to PAPs to be placed on the EU market as feed for farmed animals, or Article 35 which concerns the feeding of pet animals.

According to Annex X, Chapter II, Section 1, B(2), PAPs with the exception of fishmeal, must have been submitted to any **of processing methods 1 to 5 or processing method 7** (as set out in Chapter III of Annex IV).

- Required processing methods for fat and oil derived from insects

Defined in Annex I (definition 8) to Regulation (EU) No 142/2011 under the terminology of 'rendered fat', fat and oil derived from insects must come from insects which have been processed as required for category 3 materials (Article 14 of Regulation (EC) No 1069/2009) and follow the production and processing methods **1 to 5 or processing method 7** (as defined in Annex X, Chapter II, Section 3 to Regulation (EU) No 142/2011).

- Required processing methods for hydrolysed proteins from insects

In the case of hydrolysed proteins, the processing facility must be approved as it normally applies for actors processing animal by products in accordance Regulation (EC) No 1069/2009 (Article 24 (1)(a)). Although specific conditions are foreseen in annexes X (Chapter II, Section 5) of Regulation (EU) No 142/2011, no specific method has been defined for the processing of non-ruminant animal by-products.

The responsibility therefore lies with the operator to demonstrate that the chosen methods allow to prevent risks of contamination.

### **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**

#### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 150 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 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 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 125 minutes, a core temperature greater than 110 °C is achieved for at least 120 minutes and a core temperature greater than 120 °C is achieved for at least 50 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing must be carried out in a batch system.

### **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.'*

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

#### **Annex X, Chapter I of Regulation (EU) 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.*

### 5.1.3. 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) No 178/2002 which lays down the general principles and requirements of food Law ('General Food Law'), Regulation (EC) 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 853/2004<sup>45</sup> (definitions in Annex I point 8 and Section IV on requirements applicable to frozen food of animal origin laying down specific hygiene rules for food of animal origin).

Insects are considered as novel food in the EU and are covered under [Regulation \(EU\) 2015/2283](#) requiring pre-market authorisations before commercialising these products on the EU market<sup>46</sup>. Authorised operators shall also comply with the specifications for the authorised edible insects (labelling, hazard limits) as defined in the Regulation (EU) 2017/2470 establishing the Union list of novel foods (for more details on this subject, see section 1.2.3)<sup>47</sup>.

### 5.1.4. 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 feed producers shall refer to the general requirements provided for in [Annex II](#) of [Regulation \(EC\) 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 (EC) 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).

**Insect food producers** must follow the requirements laid down in [Regulation \(EC\) No 852/2004](#), e.g. [Article 4\(2\)](#). Furthermore, [Article 5](#) of the aforementioned Regulation, requires food business operators to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Recommendations on implementing HACCP principles for insect as food and feed activities are outlined in further detail in chapter 7.

**For further information on the above subjects, see section 1.2.1.**

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<sup>45</sup> Article 6 (import conditions)

<sup>46</sup> A non-exhaustive list of applications which have been submitted under Regulation (EU) 2015/2283 can be found on the DG SANTE (European Commission) website, through the following [link](#)

<sup>47</sup> The Union list of authorised novel food can be found on the DG SANTE (European Commission) website, through the following [link](#)

## 5.2. Killing step

### 5.2.1. 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, boiling vapour or via freezing**.
2. Farmed black soldier flies are often subject to **mincing** and **hot water**.

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

### 5.2.2. Heating

#### Killing by hot water

Killing by heating may be done by plunging insects in hot water (i.e. 'blanching'). The high temperatures in this step allow for an instant death of the insects and destroy the microbial flora, thereby mitigating microbiological hazards in the product. 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 for about 4-6 minutes whereas for mealworms it goes above 90°C for about 5-7 minutes). It is important to note that not all possible time temperature combinations will result in a sufficient reduction of possible microbiological pathogens. The appropriate combinations must therefore be determined by the operator respective to the species. In addition, respective pathogen monitoring protocols should be conducted.

Blanching times will depend on the end product and legislative requirements (see above sections 5.1.2. and 5.1.3.). The following conditions should also be considered:

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 (e.g. before freeze drying, or mincing). In case of unwanted contaminants detected, insect producers should implement necessary corrective measures, in order to mitigate contamination further down in the process line. Furthermore, in accordance to Regulation (EC) No 853/2004, where heat treatment is applied to foodstuffs in hermetically sealed containers, it is to be ensured that water used to cool the container after heat treatment is not a source of contamination for the foodstuff.

### 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. An inadequate heat treatment caused by non-compliance of time/temperature conditions can lead to a bacterial proliferation. The operator shall follow safety standards (e.g. quick cooling methods, monitoring water activity, storage conditions) when preparing blanched insects for the next steps (e.g. packaging or grinding) of manufacturing.

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

### 5.2.3. 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, (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/CO<sub>2</sub> or cooled air.

Before freezing, insects are chilled and deactivated (see section 4.5. 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.

## 5.3. Post killing steps

### 5.3.1. Background information

A number of processing methods may be applied on larvae and/or on adult insects after the killing step. 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. Insect producers may therefore apply other techniques than the ones mentioned below (e.g. spray drying<sup>48</sup>).

### 5.3.2. 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. The subsequent reduced water activity as well as lower temperatures ensure the low survival and growth microbial flora. This permits an extended shelf life and mitigates microbiological contamination risks for the product under the appropriate storage conditions.

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 (potential cross contamination during storage before freeze drying, transfer or handling);
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.
4. Freeze-dried products are very hygroscopic and 'attract water'. If not stored in a closed container, the water activity of the product may thus rise again and allow microbial growth.

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<sup>48</sup> Spray Drying is a technique largely applied in various food processing since decades to remove water from products. The insect end product is a fine insect powder, and no grinding or milling is needed. High temperature air flow meets product droplets in a vacuum chamber where the drying occurs in very few seconds, according to the equipment and process used. Insects might need to be pre processed before the drying phase, which means homogenization, dilution, pasteurization or anything else needed for a complete control of the final product outcome. Insect can be powdered without compromising most of their valuable characteristics because of the very short time the nebulised products are heat treated. Pressure and temperatures must be maintained throughout the process (their levels can be different according to equipment and processes used). All equipment environment is thoroughly cleaned between batches.

*Photo: Freezer-dryer. Courtesy of Protifarm.*

### 5.3.3. 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 to ensure product safety and mitigate any potential microbiological contamination post process (the temperature levels and time required may, however, vary between insect species or the treatment before drying step (e.g. blanching time) and processes used (e.g. oven, microwave).
2. The oven is thoroughly to be cleaned between batches and the residues of killed insects are taken away and disposed of with insect waste.

*Photo: Union Microwave property.*

### 5.3.4. 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**. Considering the characteristics of the product (powder form), It is susceptible to potential microbiological contamination risk if hygiene practices are not maintained in production. Water activity and storage temperatures should be appropriately monitored (see chapter 7.2.9. Establish monitoring procedures (Principle 4)).

The grinding/milling machinery should be cleaned regularly and thoroughly based on its installation (cleaning-in-place (CIP) and cleaning-out-of-place (COP) systems).

*Photo: Grinding, Vercella.*

### 5.3.5. Fractioning

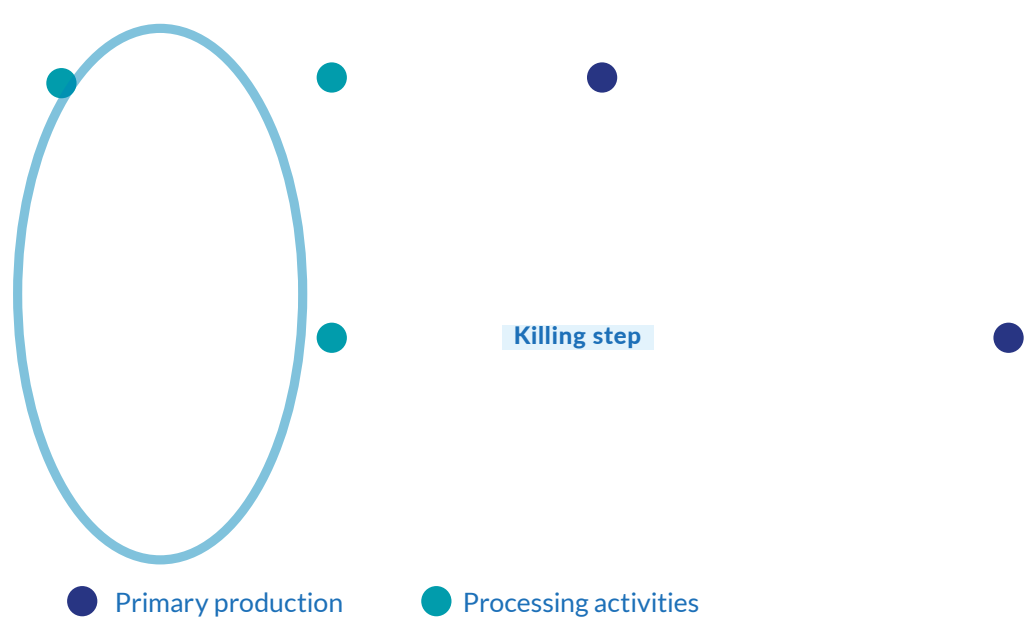
Without prejudice to the application of the EU legislation on novel food, fractioning consists of applying physical, chemical and biochemical processes to **extract protein, fat/oil, chitin and derivatives** (e.g. chitosan and glucosamine) at the end of the process. To obtain fat/oil mechanical separation (pressing), heat treatment or organic solvents (e.g. supercritical CO<sub>2</sub> 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. Insect producers should identify possible hazards and/or contaminations during the aforementioned processes. Parameters such as mechanical errors, chemicals hazards (residual from cleaning procedures or mechanical leaks) and efficient cleaning methods between batches should be considered among others.

*Photo: Mechanical Pressing, Ecolea Technologie*

# CHAPTER 6 – PREREQUISITE PROGRAMS: STORAGE, PACKAGING, LABELLING AND TRANSPORT OPERATIONS



## 6.1. Introduction: applicable legislative requirements

**Producers of insect products for feed** use shall refer to the EU feed hygiene provisions regarding storage and transport (i.e. Annex II of Regulation (EC) No 183/2005). The same legislation applies to them as to any other ‘feed business operator that is active in stages other than primary production’. **(For more details, see section 1.2.1).**

Regulations and relevant annexes	Aspects operators must cover
Annex II to Regulation (EC) No 183/2005 – other levels than primary production	1. Facilities and equipment
	2. Personnel
	3. Production
	4. Quality control, audit
	5. Dioxin monitoring for oils, fats and derived products
	6. Storage and transport
	7. Record-keeping
	8. Complaints and product recall

Similar requirements are foreseen in EU food hygiene legislation for food business producers ([Annex II to Regulation \(EC\) No 853/2004](#)): these should, therefore, serve as relevant source of information for **producers of insects intended for food use**.

Regulations and relevant annexes	Aspects operators must cover
Annex II to Regulation (EC) No 853/2004 – 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, [Regulation \(EC\) No 1831/2003](#) 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, [Regulation \(EC\) No 1825/2006](#) 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. Finally, [Regulation \(EU\) No 10/2011](#) establishes specific requirements for the manufacture and marketing of **plastic materials** and articles which are intended to come into contact with food.

## 6.2. Recommended practices for storage and transport operations

### 6.2.1. 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. Furthermore, distinctive storage arrangements should be in place to segregate between treated (slightly processed e.g. washing, freezing) and untreated live insects destined as feed. They should also be kept in a different storage arrangement to avoid cross contamination with processed insects in case the company produces both types of products.

Storage areas shall also be designed or arranged to allow **segregation to avoid cross-contamination** of raw materials (processed), other ingredients (salt, oil, etc.), flavouring ingredients (relevant for insects as food), packaging, chemicals (e.g. cleaning materials), waste, frass and processed insects. When operators produce both processed insect products and frass, a clear storage differentiation should be maintained.

A separate area for storing materials identified as potentially unsafe shall be provided (e.g. secure storage of cleaning and disinfecting materials). 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 storage areas shall be designed to minimize the risk of product contamination respective to the operator capacities and activity.

The monitoring and control of **temperature** and **humidity** shall be applied as required by product or storage specifications. Products should be kept at appropriate temperature (e.g. low temperature and humidity to inhibit microbiological growth), considering their composition and potential use, to avoid microbiological contamination.

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.

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.

### 6.2.2. Premises maintenance and cleaning

The storage premises are checked and maintained in accordance with the evaluation procedures detailed in the monitoring programme (see chapter 2.6. for more details on the monitoring programme). Maintenance operations are undertaken by certified and/or qualified agents to ensure adequate functioning of the premises: e.g. to check that humidity levels correspond to the safety standards applicable for storage, functioning of airflow systems.

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. 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.

### 6.2.3. Control of storage conditions

If insects and insect products 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). Furthermore, Regulation (EC) No 37/2005 defines the general conditions for the monitoring of the temperature in the means of transport, warehousing and storage used for quick-frozen foodstuff.

Material that requires cold storage shall be placed under appropriate chilled conditions (i.e. temperature between 0°C and 8°C) 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, in order to monitor and take corrective actions, on unwanted deviations in temperatures. A monitoring and maintenance plan should be in place. The latter shall foresee appropriate methods for measuring the temperature depending on the characteristics of the facilities.

Traffic and pedestrianised access arrangements shall be put in place to ensure the safety of the area in order to unintentionally or intentionally cause contaminations to the products. Pedestrianised areas should be clearly marked to avoid accidents and provide directions about restricted access. The traffic and pedestrian access should be for authorised personnel only. These arrangements should be in place where applicable depending on the capacities of the producers. Small holding producers may not directly need to apply traffic arrangements.

**Storage conditions are respective to insect-based products and their intended use, some typical examples of the storage conditions are listed below:**

- 1. Dry, cool and closed for insect powders:** These products would typically be further incorporated into food or feed formations. Considering their characteristics and potential use, such storage parameters are implemented.
- 2. Frozen storage for whole insects:** these products would typically be further used as feed or food. Although they could be further ground or used whole, very low temperatures allow longer shelf life, despite its higher water activity compared to powdered insects.

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. (See 7.3.8. Establish critical limits)

- (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.

## 6.2.4. Transport operations

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

### 6.2.4.1. 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 (EC) No 852/2004 on the hygiene of foodstuffs, in Regulation (EC) No 183/2005 laying down requirements on feedstuff (see chapter 6.1. above for more details) and in Regulation (EC) No 999/2001 which lays down specific requirements for insect PAPs intended as feed for non-ruminant farmed animals (see chapter 6.2.4.2. below for further 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.
- Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more EU languages, to show that they are used for the transport of foodstuffs or are to be marked 'for foodstuffs'.

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 entitled transport: points 4, 5 and 6).

### 6.2.4.2. 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.

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.

Furthermore, Regulation (EC) No 999/2001 (Annex IV, Chapter III, section A, (8) and (9)) foresees a series of specific obligations in the case of **transport and storage of insect PAPs** and compound feed containing such products intended to be used for feeding non-ruminant farmed animals:

- Bulk processed animal protein derived from farmed insects, and bulk compound feed containing such processed animal protein, shall be transported in **vehicles** and **containers** and stored in **storage facilities** which are **not used**, respectively, for the transport or storage of feed intended for **non-ruminant farmed animals other than aquaculture, poultry and porcine animals**.
- **By way of derogation** (...), vehicles, containers and storage facilities which have been previously used for the transport or storage of bulk processed animal protein derived from farmed insects and bulk compound feed containing such processed animal protein may be subsequently used for the transport or storage of feed intended for non-ruminant farmed animals other than aquaculture animals, poultry and porcine animals provided **that they are cleaned beforehand in order to avoid cross-contamination**, in accordance with a **documented procedure** which has been given prior **authorisation by the competent authority**.

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, odourless 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
4. Dried: ambient temperatures (room temperature)

Operators shall be capable of maintaining foodstuffs at appropriate temperature and allow those temperatures to be monitored.

If the temperature is warmer than above-mentioned limits, the product must be rejected, or Q/A must prove that no damage occurred (e.g. microbiological tests, in case of suspected contamination) to the product due to the fact that was exceeding the above thresholds for the respective period.

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.

## 6.3. Packaging

Sealing and packaging of insects and insect products 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 (such as recycled or reused material) 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 light exposure 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, physical hazards, etc) is included in the sealed bag. If potential risks are identified appropriate measures should be in place (e.g. use of metal detectors in the end of the process lines to detect possible physical hazards originating from the machinery).
5. The packaging material used (i.e. FCMs) must come from a reliable 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 (migration analysis of the materials);
- Packaging material conformity for appropriate storage conditions (e.g. frozen products);
- 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.

## 6.4. Labelling

**Edible insect-based food products** on authorisation as a novel food, are subject to all provisions of the Food Information to Consumers (FIC) Regulation (i.e. Regulation (EU) No 1169/2011). Producers of insects intended for food should indicate on the product label its proper storage conditions, shelf life and intended use of the product as well additional labelling requirements (e.g. designation of the product) as referred to in the authorising novel food Regulations (e.g. see Commission Implementing Regulation (EU) 2022/169 authorising the placing on the market of frozen, dried and powder forms of yellow mealworm).

Please refer to the IPIFF guidance document on food information to consumers for detailed labelling guidance for insect-based food products<sup>49</sup>.

### **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, and in compliance with the Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011 (e.g. labelling as Category 3 material);
2. End products shall be labelled with the legislative 'mandatory labelling particulars', and insect-based feed 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).
3. Chapter V section G of Annex IV to Regulation (EC) No 999/2001 defines the labelling conditions for processed animal protein derived from farmed insects (as well as porcine or poultry animals) and compound feed containing such processed animal protein.

The commercial document or, as appropriate, the accompanying health certificate (...) and the label of the processed animal protein derived from farmed insects, shall be clearly marked with the following words: '**Processed animal protein derived from farmed insects**' – '**shall not be used in feed for farmed animals except Aquaculture animals, fur animals, porcine animals, poultry**'.

The following words shall be clearly indicated on the label of compound feed containing processed animal protein derived from farmed insects, '**contains processed animal protein derived from farmed insects – shall not be fed to farmed animals except Aquaculture animals, fur animals, porcine animals, poultry**'.

<sup>49</sup> IPIFF Guidance the provision of food information to consumers Edible insect-based products. <http://ipiff.org/publications-position-papers/>

# CHAPTER 7

## IMPLEMENTATION OF HACCP PRINCIPLES BY INSECT PRODUCERS

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### 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 range of prerequisite measures are available, however, specific measures to ensure high quality and safety may be required respective to 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 food safety issues have not 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. The application of HACCP does not apply to primary producers (i.e. insect farming activities), however, they should be aware of the hazards associated with their activities and address them using GHP (see recommendations earlier in the document), which may include hazard monitoring activities. Those establishments that the HACCP applies (after primary production), hazard analysis is expected, subsequently to which Critical control Points (CCPs) should be determined and should be concluded that GHPs are sufficient. Operators are also recommended refer to the European Commission notice (2022/C355/01) on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses.

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 record-keeping and documentation procedures.

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. The team will be in charge of responding to every crisis circumstance encountered related to the respective product(s).

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, hydrolysed 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**

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**Storage  
conditions**

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**Intended use**

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**Destination**                      'Intended user'

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### 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 fibres, 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:** 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 9 in the process diagram portrayed above) on storage of insect sourced raw materials.

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

Hazards are usually divided into the following categories:

#### 1. Biological

- pathogenic bacteria (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 (e.g. 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).

Please refer to hazards to be monitored in chapter 2.6. 'Monitoring (sampling and analyses)'.

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	Severe	
	Significant (4)	4	8	12	16	20	Unacceptable	
	Moderate (3)	3	6	9	12	15	Undesirable	
	Low (2)	2	4	6	8	10	Acceptable	
	Negligible (1)	1	2	3	4	5	Normal	
		(1) Improbable	(2) Unlikely	(3) Occasional	(4) Probable	(5) Frequent		
		OCCURRENCE						

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
Killing step: Blanching/ mincing,etc (depending on product specifications)	Microbiological										
	Microbiological pathogens	1,2,3	Material	Contami- nated insects	5	4	20	MONITORING OF TEMP/TIME			X
	Microbiological pathogens	1,2,3	Man	Staff hygiene	1	1	1	Instruction / training for reception	X		
	Chemical										
	Heavy metals and Pesticides in material	1,2,3	Material	Contaminated insects	2	4	8	Controlled substrate Management (analysis, audits), Testing for pesticides and heavy metal residues.	X		
	Physical										
	Metal, plastic, stone pieces in material	1,2,3	Man	Contaminated insects	1	4	4	Instruction / training on handling	X		
	Metal, plastic, stone pieces in material	1,2,3	Material	Contaminated product	1	4	4	Instruction / training on monitoring	X		
	Pests	1,2,3	Environment	Infested goods	1	5	5	Designated closed storehouse for raw material, Implementation of a pest control programme, visual control at reception	X		
	Drying/freezing (depending on product specifications)*	Microbiological									
Microbiological pathogens		4	Method	Process errors	5	4	20	MONITORING OF TEMP/TIME			X
Microbiological pathogens		4	Man	Staff hygiene	1	1	1	Instruction / training for reception	X		
Chemical											
cleaning chemicals in material		4	Method	Cleanliness of the processing area	1	4	4	Cleaning and disinfection methods	X		
Physical											
Metal, plastic, stone pieces in material		4	Method	Contaminated product	1	4	4	Instruction / training on monitoring	X		
Packaging	Microbiological										
	Microbiological pathogens	5	Man	Staff hygiene	1	1	1	Instruction / training on reception	X		
	Chemical										
	cleaning chemicals in material	5	Method	Cleanliness of the processing area	1	4	4	Cleaning and disinfection methods	X		
	content-containing contamination (packaging film)	5	Material	Contaminated goods	1	1	1	Requires suppliers of packaging films migration certificates, protected packaging	X		

Packaging	Physical							Control at every stage of the manufacturing process, quality control plan preventive maintenance	X
	Metal, plastic, stone pieces in material	5	Method	Contaminated goods	2	4	8		
	Microbiological pathogens	5	Man	Staff hygiene	1	1	1		
	Metal, plastic, stone pieces in material	5	Man	Contaminated product	1	1	1	Visual inspection	X
	Microbiological								
Storage	Microbiological pathogens	6	Material	Contaminated product	1	4	4	FIFO, product monitoring	
	Chemical								
	Cleaning chemicals in material	6	Method	Cross contamination	1	4	4	storage design: separate for chemicals for cleaning and disinfection	X
	Physical								
	Foreign objects	6	Method	Contaminated product	1	4	4	Pest control programme. Warehouse and loading areas are dry, locked and secure, under supervision and properly sanitized.	X
Transport	Microbiological								
	Microbiological pathogens	7	Method	Contaminated product	1	4	4	Check transport conditions, visual inspections (audits, certificates)	X
	Physical								
	Foreign objects	7	Method	Contaminated product	1	4	4	Unsuitable transport conditions	X
	Microbiological								
	Enterobacteriaceae	8	Method	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	8	Material	Contaminated goods	1	5	5		X
	Moulds and yeasts	8	Material	Contaminated goods	2	5	10		X
	Microbiological pathogens	8	Man	Staff hygiene	2	4	8	Instruction / training for reception	X
	Microbiological pathogens	8	Method	Cleanliness of the reception area	1	4	4	Cleaning and disinfection plan	X
Reception of raw material	Chemical								
	Heavy metals and Pesticides in raw material	8	Man	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	8	Material	Contaminated goods	1	4	4	Controlled reception, Supplier Management (analysis, audits), raw material analysis	X
	Pests	8	Environment	Infested goods	1	5	5	Designated closed storehouse for raw material, Implementation of a pest control programme, visual control at reception	X
	Allergens								
	Allergen cross contamination	8	Method	Poor storage and mixing raw materials	1	4	4	The organisation and procedure on storage of raw material	X

\*It should be noted that freezing and drying processes do not necessarily result in the killing of all bacteria or other micro-organisms (depending on the time and/or temperature applied)

### 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. Metal detectors in process lines.

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. These are not part of HACCP rather GHPs to which more attention needs to be paid by monitoring.

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 1, 2, 4 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 1- 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	1
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. Also to be considered, that the coldest point of the product mass (which is not necessarily the centre) has been subjected to the required time-temperature combination
Control	<ul style="list-style-type: none"><li>• Equipment temperature log</li><li>• Alarm signal in case of temperatures below parameters</li><li>• Insects sampling after blanching treatment for post-mortem control: colour verification (visual control)</li><li>• End products sampling for bacteriological analysis (Salmonella and Enterobacteriaceae)</li><li>• Equipment surface examination to ensure efficiency of cleaning and disinfection measures</li></ul>
Frequency	<ul style="list-style-type: none"><li>• Continuous measurement during production for post-mortem inspection,</li><li>• Continuous monitoring of the log data for equipment time/temperature efficiency,</li></ul>
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"><li>• Action on equipment deviations (time/temperature) and check product temperature</li><li>• After consultation, reheat or dispose</li></ul>
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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)
<b>Verification</b>	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 IV, Chapter III of Regulation (EU) No 142/2011)
2. Moisture level (Water activity)
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 post-mortem inspection:

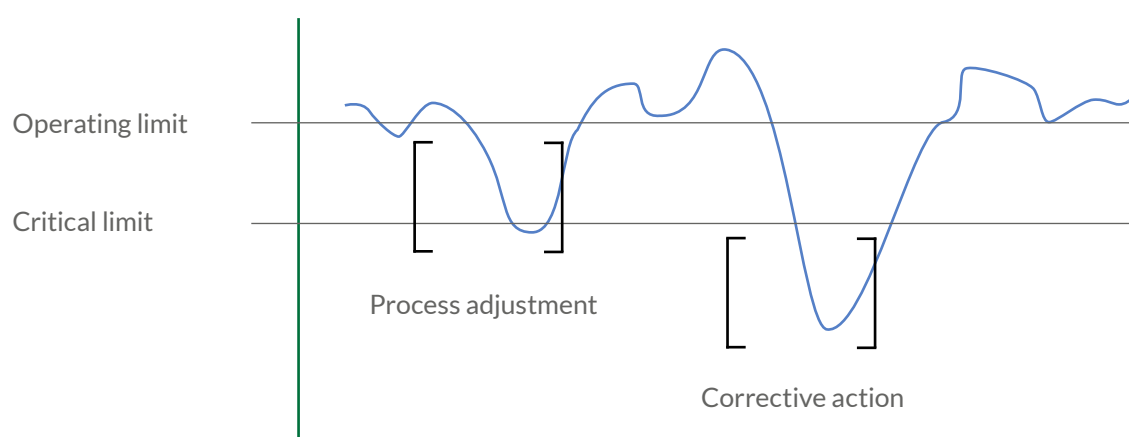
- 100 % of killed dead insects;
- 0 % of dead black insects;

### 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.

Refer to example in 7.3.7. Determine Critical Control Points (CCPs) - Description of the CCP: Blanching

### 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. The proper instituting of verification processes of HACCP plans should be undertaken during its development and implementation, maintenance and upon HACCP System change.

Procedures should be established for verification. Verifications should be handled by persons with appropriate and sufficient expertise. To determine if the HACCP system is working correctly, the verification methods can include random sampling and analysis. Verification frequencies should be enough to confirm that the HACCP system is working effectively. 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.

Examples of Verification activities include:

- Review of the HACCP system and its records, e.g. via audit and inspection;
- Review of incidents on product recall, complaints;

### 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. Records that are generated during the operation of the HACCP system.
2. A summary of the hazard analysis, including the rationale for determining hazards and control measures.
3. 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;
- h. A HACCP Plan Summary Table that includes information for:
  - Steps in the process that are Critical Control Points;
  - The hazard(s) of concern;
  - Monitoring;
  - Corrective actions;
  - Verification procedures and schedule;
  - Record keeping procedures.

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

# ANNEX I

## GLOSSARY OF DEFINITIONS

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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 annex 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. **Batch**<sup>50</sup>: an identifiable quantity of feed/raw material/material/product determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or **labelling**, 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 authority**<sup>51</sup>: 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. **Contamination**<sup>52</sup>: 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 insect**<sup>53</sup>: any insect species kept deliberately in established culture, maintained in a controlled environment on a mass scale.
13. **Feed hygiene**<sup>54</sup>: the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use.

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<sup>50</sup> Art 3 2. (r) of Regulation (EC) No 767/2009

<sup>51</sup> Art 2 1. (d) of Regulation (EC) No 852/2004

<sup>52</sup> Art 2 1. (c) of Regulation (EC) No 852/2004

<sup>53</sup> Art 3(6) of Regulation (EC) No 1069/2009

<sup>54</sup> Art 3 (a) of Regulation (EC) No 1831/2005

- 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. Feedingstuff<sup>55</sup>:** means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.
- 17. Foodstuff<sup>56</sup>:** ‘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 foodstuffs<sup>57</sup>:** 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)<sup>58</sup>:** 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/plan<sup>59</sup>:** 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. Hazard<sup>60</sup>:** 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. Frass<sup>61</sup>:** frass means a mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5 % in volume and not more than 3 % in weight.
- 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. Packaging<sup>62</sup>:** 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):** list of the measures to be undertaken in order to maintain full control of hygiene, biosecurity and quality of farmed insects.

<sup>55</sup> Art 3 4. of Regulation (EC) No 178/2002

<sup>56</sup> Art 2 of Regulation (EC) No 178/2002

<sup>57</sup> Annex, Part A (3) of Commission Regulation (EU) No 68/2013

<sup>58</sup> ISO22000:2005

<sup>59</sup> FAO, Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application

<sup>60</sup> Art 3 14. of Regulation (EC) No 178/2002

<sup>61</sup> Annex I of Regulation (EU) No 142/2011

<sup>62</sup> Art 2 1. (k) of Regulation (EC) No 852/2004 31 Art 2 1. (k) of Regulation (EC) No 852/2004

- 29. Primary products<sup>63</sup>:** products of primary production including products of the soil, of stock farming, of hunting and fishing.
- 30. Primary production of feed<sup>64</sup>:** 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. Processing<sup>65</sup>:** 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)<sup>66</sup>:** 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 products<sup>67</sup>:** 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 water<sup>68</sup>:** 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. Substrate for insects:** The feed material used to farm insects (including feed material(s), compound feed or feed additive(s)). 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. Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011), the Feed Marketing Regulation (i.e. Regulation (EC) No 767/2009), Annex III 'prohibition to use manure/ animal faeces') and Regulation (EC) No 1831/2003 as regards the authorisation of feed additives.
- 37. Traceability<sup>69</sup>:** 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. Treated insects:** these refer to insects that have undergone treatment after the killing step such as drying or freezing, without changing the nature of the insect as a product.
- 39. Processed insects:** these refer to insects that have undergone processing methods such as mincing or grinding that have changed the composition of the product.

<sup>63</sup> Art 2 1. (f) of Regulation (EC) No 852/2004

<sup>64</sup> Art 3 (f) of Regulation (EC) No 183/2005

<sup>65</sup> Art 2 1. (m) of Regulation (EC) No 852/2004

<sup>66</sup> Annex I 5 of Regulation (EU) No 142/2011

<sup>67</sup> Art 2 1. (o) of Regulation (EC) No 852/2004

<sup>68</sup> Art 2 1. (g) of Regulation (EC) No 852/2004

<sup>69</sup> Art 3 15. Regulation (EC) No 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 EU<sup>70</sup>

### 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 <sub>a</sub>
Time to maturity (days from hatch to max body weight)	33-40 <sub>b</sub>

*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.

<sup>70</sup> 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)

### 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 colour, more robust than house crickets.

Figure 2. *Gryllus assimilis*

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.

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## 3. *Acheta domesticus* (Linnaeus, 1758)

### 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 colour.

Figure 3. *Acheta domesticus*

Incubation period (days from egg-laying to hatch)	11 <sub>a</sub>
Time to maturity (days from hatch to max body weight)	32-49 <sub>b</sub>

*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

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. Colour 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.

Figure 6. *Alphitobius diaperinus*,

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 non invasive 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 <sub>a</sub>
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 colour 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 reddish brown 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.

## 8. *Bombyx mori* (Linnaeus, 1758)

### Order: Lepidoptera; Family: Bombycidae

Silkworm moth (adult) is the lepidopteran whose caterpillar has been used in silk production for thousands of years. Its closest relative is the wild silk moth (*Bombyx mandarina*). Although native to China, the silkworm has been introduced throughout the world and has undergone complete domestication.

An adult silkworm has a cream-coloured body with dark veined wings of 40 to 50 mm span. The female silkworm lays about 300 to 500 eggs, which their hatching period fluctuates based on the environmental conditions. The voracious larvae are monophagous, exclusively feed on mulberry (*Morus* sp.) leaves, and may grow up to 75 mm in length. Pupation occurs within a cocoon composed of two proteins: soluble sericin and insoluble fibroin. Fibroin is the component of silk fiber and is present in single strands of 900-1000 meters long. After 10-14 days of developing, the silkworm moth will emerge. It lives a very brief life of 5-10 days.

Incubation period (days from egg-laying to hatching)	7-14 days*
Time to maturity (days from hatch to max body weight)	24-33 days

\* temperature: 23-29 °C; relative humidity: 80%

Figure 9. *Bombyx mori* adult and larva respectively. Photos courtesy of Mori

1. The silkworm pupae is the remaining after reeling of silk and can serve as feed material. The dry pupae contain 50–82% (d.m.) crude protein and 23–34% crude lipid (d.m.). It has a rich and balanced content of essential amino acids such as valine, methionine and phenylalanine and is considered a good dietary source of protein for animal feed (poultry, cattle and all types of fish).
2. The silkworm cocoon is made of fibroin (≈75%) and sericin (≈25%), two nutritive proteins that are a source of essential amino acids.

## 9. *Locusta Migratoria* (Linnaeus, 1758)<sup>71</sup>

Order: Diptera; Family: Stratiomyidae

The common name is migratory locust and it is considered as a pest in many regions of the world. Through history, large swarms of migratory locusts have caused reductions in crops and vegetation. Migratory locust is the most abundant between the locust species and occur throughout Africa, Asia, Australia, New Zealand, and seldom in Europe.

Their size ranges between 32 to 80 mm and the development from egg deposit to adult is approximately 3 months depending on the environmental conditions. Currently the migratory locust can be mass produced in colonies and the adults can be harvested and consumed as human food.

Figure 10. *Locusta Migratoria*

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<sup>71</sup> *Locusta migratoria* species does not feature amongst the authorised species for use as PAP for farmed animals. Yet frozen and dried formulations of *Locusta migratoria* can be legally placed on the EU market for human consumption, following their authorisation as 'novel food' pursuant to Commission Implementing Regulation (EU) 2021/1975 (authorisation granted to the company Fair Insects BV (Protix group)) See section 'scope of the Guide' for more details.

## ANNEX III

# IPIFF CONTRIBUTORS TO THE GUIDE

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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  
Agronutris  
Danish Technnological Institute  
Mutatec  
Agriprotein  
Hermetia  
Amusca  
Entogourmet  
Invers  
KU Leuven  
Entoprotech  
Università di Pisa  
Entocycle  
Enterra  
Next-Generation Network  
Mori

## ANNEX IV

# LIST OF CONSULTED EUROPEAN FOOD AND FEED BUSINESS SECTORS

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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

EFPRA: 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.

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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 the 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?

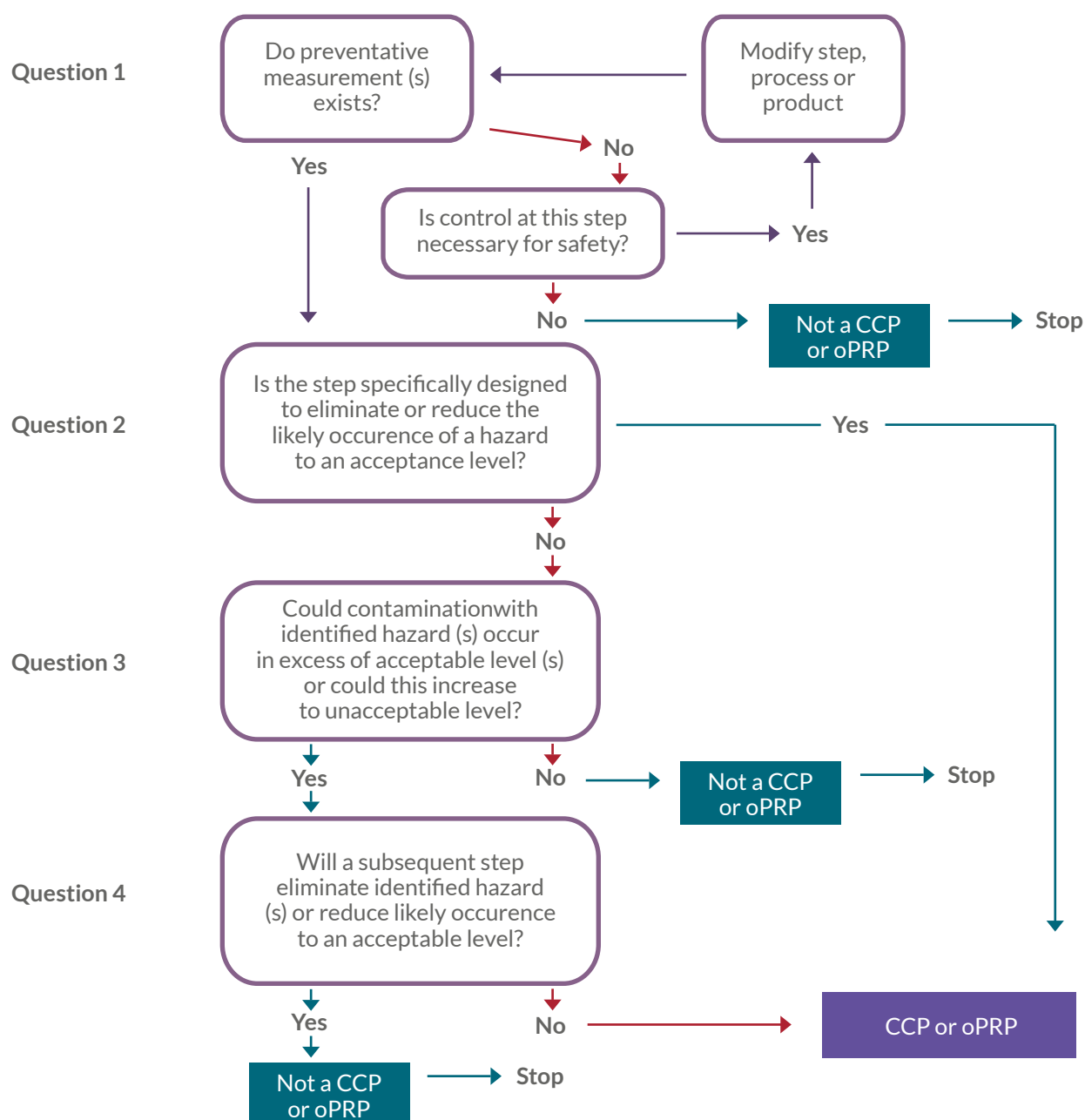
## 12. Intended consumer

- 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?

No

Yes

Question 6

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

No

Yes

CCP

oPRP

