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Direção Geral
de Alimentação
e Veterinária

Code of Good Practices

Insect Production, Processing and Use in Animal Feeding

“Insects as food and feed emerge as an especially relevant issue in the twenty-first century due to the rising cost of animal protein, food and feed insecurity, environmental pressures, population growth and increasing demand for protein among the middle classes. Thus, alternative solutions to conventional livestock and feed sources urgently need to be found. The consumption of insects, or entomophagy, therefore contributes positively to the environment and to health and livelihoods.”

Edible Insects: Future Prospects for Food and Feed safety, FAO, 2013

Manual of Good Practices for Insect Production, Processing and Use in Animal Feeding

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ACRONYMS AND ABBREVIATIONS

BSF - Black Soldier Fly (*Hermetia illucens*)

OFC - Official Feed Control

CRDC - Coordination and Rural Development Commission

EC - European Commission

CJD - Creutzfeldt Jakob

LU - Livestock Units

CWD - Chronic Wasting Disease in Cervids

DL - Decree-law

DGFVA - Directorate General of Food and Veterinary Affairs (DGAV - Direção Geral de Alimentação e Veterinária)

DRARD - Directorate General of Agriculture and Rural Development (DGADR - Direção Geral de Agricultura e Desenvolvimento Rural)

RDAF - Regional Directorate of Agriculture and Fisheries (DRAP - Direção Regional de Agricultura e Pescas)

CVED - Common Veterinary Entry Document

BSE - Bovine Spongiform Encephalopathy

TSE - Transmissible Spongiform Encephalopathies

EFSA - European Agency for Food safety

MS - Member State

FSE - Feline Spongiform Encephalopathy

NSLF WG - Working Group on the New Scheme of Livestock Farming (GT NREAP - Grupo de Trabalho sobre o Novo Regime do Exercício de Atividade Agropecuária)

HACCP - Hazard Analysis and Critical Control Point

IB - Identification of Beneficiary

ICNF - Institute for the Conservation of Nature and the Forests (Instituto da Conservação da Natureza e das Florestas)

IFAP - Institute for the Financing of Agriculture and Fisheries (IFAP - Instituto de Financiamento da Agricultura e Pescas)

SRM- Specific Risk Material

VCN - Veterinary Control Number

IIN - Individual Identification Number

UPOS - Unit of Production of Other Species (NPOE - Núcleo de Produção de Outras Espécies)

NSLF - New Scheme of Livestock farming

PACE - Plan of Approval and Control of Establishments

PAP - Processed Animal Protein

MMP - Municipal Master Plan (PDM - Plan Diretor Municipal)

BIP - Border Inspection Post

PVC - Vinyl Polychloride

LSAECSCI - Legal Status of Access to the Exercise of Commercial, Services and Catering Industries (RJACSR - Regime Jurídico de Access e Exercício de Activities de Comércio, Serviços e Restauração)

RIS - Responsible Industry System

CNS - Central Nervous System

MTE - Mink Transmissible Encephalopathy

TRACES - Trade Control and Expert Systems

EU - European Union

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1. INTRODUCTION

1.1 Setting the context

In view of its livestock production needs, the EU needs protein sources that enable making available compound feedingstuffs in the necessary quantity, quality and safety to provide adequate nutrition to food-producing animals, ensuring high standards of animal health and welfare and safeguarding consumer health. Scarcity of protein sources, dependency on international markets, price fluctuations, climate change, environmental, social and political issues related to the use of genetically modified organisms in the food chain in Europe require finding alternatives to traditional protein raw materials. Among various strategies, resorting to protein sources that are new or originate from advanced technologies is one of the more viable options.

Insects are an alternative nutritional source, inasmuch as they are produced in a relatively simple and sustainable way, have high conversion rates and comprise several edible species. One of their greatest advantages is their capacity to promote a circular agri-industrial economy, inasmuch as nutrients existing in by-products of the agrifood industry, which would otherwise be lost, can be re-introduced in the value chain as secondary raw materials.

However, as products of animal origin, insects fall within the scope of measures for the prevention, eradication and monitoring of certain Transmissible Spongiform Encephalopathies (TSE).

TSE are progressive, transmissible and fatal diseases that affect the Central Nervous System (CNS) of both animals and humans. TSE are diseases without treatment and immune response, characterized by a long incubation period, followed by a symptomatic stage with neurological, sensorial and behavioural disturbances.

The ethiological agent of all TSEs is a infectious protein particle known as the prion, which was one of the main discoveries made in the 20th century by Prusiner. This agent is highly resistant to heat, UV rays, chemical agents and ionizing radiations.

There are several known TSE that affect animals, such as scrapie, which affects small ruminants and has been referenced since the 18th century in sheep and goats. Other rare diseases have also been detected, such as the Transmissible Encephalopathy of the Mink (TEM) and, in the second half of the 20th Century, the Chronic Wasting Disease in Cervids (CWD) affecting cervids in North America, and the Feline Spongiform Encephalopathy (FSE). In 1986 Bovine Spongiform Encephalopathy (BSE) was identified for the first time in the UK. In humans, there is the Creutzfeldt Jakob (CJD) disease, the kuru related with cannibalism practices in tribal regions of Papua New Guinea, the Fatal Familial Insomnia Insónia, and, more recently (1996), a new variant of CJD.

The origin of BSE was investigated in great depth and scientific opinion points to the use of meat and bone meal of infected animals, very popular as a raw material of animal origin due to its high protein and mineral content (namely calcium and phosphorus). It is believed that the changes in processing methods that took place starting in the '80s, shifting from a discontinuous process using organic solvents in three heating stages, to a continuous process, which had a positive economic impact and improved the quality and palatability of the final product, enabled the survival of the infectious agent, which in turn led to spreading of the disease and possibly the crossing of the species barrier at a later stage (Figure 1).

BOVINE SPONGIFORM ENCEPHALOPATHY

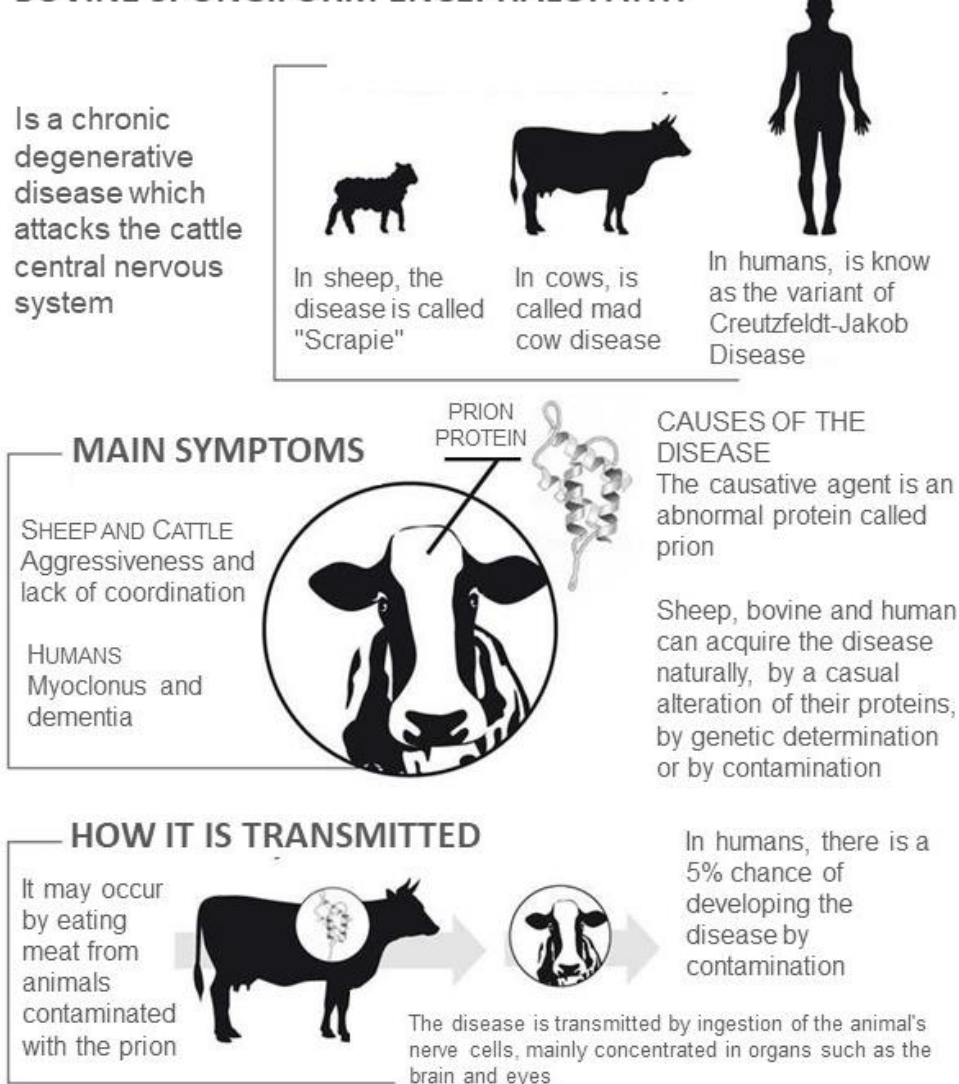


Figure 1 - Origin and transmission of Bovine Spongiform Encephalopathy (BSE).
(Image adapted from: osaogoncalo.com.br/geral/21367/four-persons-are-interned-with-suspicious-of-mad-cow-disease-in-rj)

In view of the fact that BSE has a food origin, the European Commission adopted measures for the prevention, eradication and monitoring of certain TSE, namely by requiring the removal from the food chain of specific risk material (SRM) and prohibiting animal protein in feed (feed-ban).

However, by-products of animal origin and derived products, originating in the food chain, pose a problem for the circular economy, besides the unsustainable costs of their elimination from production and the risk of environmental contamination. Considering that by-products of animal origin and derived products obtained during animal slaughter, production of foodstuffs of animal origin, disposal of dead animals and treatment of animal diseases pose risks for humans and animals, depending on its nature and origin, a safe destination must be found, either by proper disposal or by use for other purposes under restricted conditions.

1.2. Prohibition of animal protein in feed and derogations

The feed-ban was based on the fact that the infectious agent of BSE is conveyed through the use of processed animal protein (PAPs) originating from infected animals. This prohibition began in 1994 as a ban on processed animal proteins originating from mammals in ruminant feed and later, in 2001, with the total prohibition of animal protein in the feed of all farmed animals in order to ensure that there was no cross contamination between compound feedingstuffs for species other than non-ruminants containing PAP and compound feedingstuffs for ruminants.

Some exceptions do however exist, based on recognition that some raw materials of animal origin are safe for certain animal species/categories of destination and on the need to ensure sustainability of the sector in terms of the circular economy and environmental preservation, if certain conditions are fulfilled as regards production, transport, placing on the market, storage and use.

Currently the prohibition on animal protein in feed, under Article 7 and derogations thereof laid down in Annex IV, both to Regulation (EC) No. 999/2001 is indicated in Table 1:

Whereas Regulation (EC) No. 999/2001 lays down what feed of animal origin may be given to food-producing animals, Regulation (EC) No. 1069/2009, implemented by Regulation (EU) No. 142/2011, on by-products and products from animal origin not intended for human consumption, lays down which materials/products are approved for feed and how these materials/products must be produced/processed and placed on the market.

There is a clear connection between these pieces of legislation on production, processing, placing on the market and use of safe feed that consists in or contains proteins of animal origin.

Table 1 - Current prohibition of animal protein in feed and derogations thereof (Regulation (EC) No. 999/2001).

	BOVINE	SMALL RUMINANTS	SWINE	POULTRY	EQUINE	AQUATIC ANIMALS	PETS	FUR ANIMALS	ZOO ANIMALS
PAP (Ruminants)									
PAP (non-ruminants, except fish meal and blood meal)						ONLY IN MONOGASTRIC			
PAP (Insects)									
GELATIN & COLAGEN (Ruminants)									
GELATIN & COLAGEN (Non-ruminants)									
BP (Ruminants)									
BP (Non-ruminants)									
Blood Meal (Non-ruminants)						NO RECYCLING INTRASPECIES			
Hydrolyzed Proteins (Non-ruminants)									
Hydrolyzed Proteins (Ruminant leathers and skins)									
Hydrolyzed Proteins (Others)									
Fish Meal	ONLY MILK REPLACEMENT	ONLY MILK REPLACEMENT				NO RECYCLING INTRASPECIES			
Di and tricalcium phosphate									
Milks and derivatives									
Eggs and egg products									
<div> <div>PAP – Processed Animal Proteins</div> <div>BP – Blood Products</div> </div>									
		FORBIDDEN			AUTHORIZED		AUTHORIZED WITH RESTRICTIONS		

1.3. Insects as feedstock

In June 2013 an important amendment was made to the provisions then in force on the prohibition of animal protein in feed, namely the approval of processed animal protein originating from poultry or swine in feed for aquaculture animals.

Amendments to EU measures on TSE, keeping food safety and consumers protection as the maximum priority, were only possible because of the prevention, eradication and monitoring measures taken, the gradual approach based on sound scientific evidence with advice provided by the European Authority for Food Safety (EFSA) playing a crucial role in weighing political options, and the development and validation of new analytical methods able to identify ruminant DNA in feed.

More recently, in June 2017, a new amendment made it possible to use processed animal proteins originating from insects in feed for aquaculture animals.

This approval resulted from EFSA's own scientific evaluation on using insects as a nutritional source according to their risk profile. This evaluation also compared potential risks with those of conventional animal protein production.

It was concluded that the occurrence of hazards in non-processed insects in the food chain is expected to be comparable to those of any other source of protein of animal origin and that the use of insects as a protein source is beneficial to the environment, the economy and food safety.

In view of the above, and considering that insects or their products may have impact in the occurrence and accumulation of contaminants in feed, it is important to ensure approval of the appropriate insect species, type of substrate used for growing larvae, stage of life cycle for their separation, as well as the appropriate processing methods.

On the basis of EFSA's scientific opinion, that considers that insect species cannot be pathogenic or have adverse effects on plants, animal or human health, must not be recognized as vectors of human, animal or plant pathogens, cannot be protected species or classified as invasive species and must have the potential for large scale production, seven species of insects for aquaculture feed were approved, which do not pose risks for animal health and welfare, consumer health and the environment, and which are already commercially produced in the EU and third countries.

2. LEGAL FRAMEWORK

- ✓ D.L. No. 555/99 of 16 December 1999 - Establishing the legal basis of urban planning and building;
- ✓ D.L. No. 76/2003 of 19 April 2003 - Adopting additional measures against spongiform encephalopathy in feed;
- ✓ D.L. No. 81/2013 of 14 June 2013- Approving the new scheme of livestock farming (NREAP) in livestock holdings, warehouses and collection points, and amends Decrees-Laws nos. 202/2004 of 18 August 2013, and 142/2006 of 27 July 2006;
- ✓ D.L. No. 169/2013 of 1 August 2013 - Approving the System of Responsible Industry (SIR);
- ✓ D.L. No. 33/2017 of 23 March 2017- Enacting the provisions of Regulation (EC) no. 1069/2009 of 21 October 2009 that lays down health rules on animal by-products and derived products not intended for human consumption, as well as the respective implementing provisions, Commission Regulation (EU) No. 142/2011 of 25 February 2011;
- ✓ Decree no. 8442/2017 of 26 September 2017- establishing the consignment notes of animal by-products and derived products which, under no. 3 of article 4 of D.L. no. 33/2017 of 23 March 2017, must complete the transport document.
- ✓ Council Directive 97/78/EC of 18 December 1997 - Laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries;
- ✓ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 - On undesirable substances in feed;
- ✓ Ministerial order no. 635/2009 of 9 June 2009- Establishing rules on livestock keeping or complementary activities as regards the Leporidae order (rabbits and hares), as well as of animals of other species;
- ✓ 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;
- ✓ 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;
- ✓ Commission Regulation (EC) No. 136/2004 of 22 January 2004 - Laying down procedures for veterinary checks at Community Border Inspection Posts on products imported from third countries;
- ✓ Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 - on official controls performed to ensure the verification of compliance of feed and food law, animal health and animal welfare rules;
- ✓ Regulation (EC) No. 183/2005 of the European Parliament and of the Council of 12 January 2005 - laying down requirements for feed hygiene;
- ✓ Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005 - On maximum residues levels of pesticides in or on food and feed of plant or animal origin;

- ✓ 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;
- ✓ 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;
- ✓ Commission Regulation (EC) No. 206/2010 of 12 March 2010 - laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat, and the veterinary certification requirements;
- ✓ Regulation (EU) No. 142/2011 of 25 February 2011 - implementing Regulation (EC) No. 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing to Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive;
- ✓ Commission Regulation (EU) No. 691/2013, 19 June - Amending Regulation (EC) No. 152/2009 as regards methods of sampling and analysis;
- ✓ Commission Regulation (EC) No. 68/2013 of 16 January 2013 - On the EU Catalogue of Feed Materials;
- ✓ Regulation (EU) no. 2016/429 of the European Parliament and Council of 9 March 2016 - On transmissible animal diseases and amending and repealing certain acts in the area of animal health;
- ✓ Regulation (EU) no. 2017/625 of the European Parliament and 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;
- ✓ Commission Regulation (EU) No. 2017/893 of 24 May 2017 - Amending annexes I and IV to Regulation (EC) no. 999/2001 of the European Parliament and Council and Annexes X, XIV and XV to Commission Regulation (EU) No. 142/2011 as regards the provisions on processed animal protein;
- ✓ Commission Regulation (EC) No. 2017/1017 of 15 June 2017 - Amending Regulation (EU) No. 68/2013 on the Catalogue of feed materials.

3. OBJECTIVE

This Manual of Good Practices seeks to provide guidance to insect feed operators on the principles, conditions and criteria that must be followed in order to fulfil legal requirements as regards insect production, processing and use in feed of food producing animals. The safety and quality of processed animal proteins from insects as a raw material of animal origin for animal nutrition must be ensured in order to safeguard animal health and welfare, human health and protection of the environment, as well as consumer confidence in products of animal origin. Whenever relevant this manual also makes reference to insect production, processing and use in feed of other animals or intended for other purposes.

4. FIELD OF APPLICATION

This manual is applicable to insect production, processing, placing on the market and use in animal feeding.

5. DEFINITIONS

“Additives for use in animal nutrition”: substances, micro-organisms or preparations other than feed materials and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions:

- a) favourably affect the characteristics of feed;
- b) favourably affect the characteristics of animal products;
- c) favourably affect the colour of ornamental fish and birds;
- d) satisfy the nutritional needs of the animals or improve animal production;
- e) favourably influence the environmental consequences of animal production;
- f) favourably affect animal production, performance or welfare, particularly by affecting the gastrointestinal flora or digestibility of feedingstuffs;
- g) have a coccidiostatic or histomonostatic effect.

“Complementary feed”: compound feed with at least one feed material that has a high content of certain substances but which, by reason of its composition, is enough as a daily feed only if used in combination with other feed.

“Complete feed”: compound feed which, by reason of its composition, is enough for a daily ration.

“Compound feed”: a mixture of at least two feed materials for animal nutrition, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed.

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

“petfood”: feed for pets and dogchews: which

(a) contain Category 3 material, other than material indicated in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, and

(b) may contain imported Category 1 material comprising animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC, and which for this reason are classified as Category 1 in the case of imports

“Canned petfood”: heat-processed petfood contained within a hermetically sealed container.

‘processed pet food’: pet food, other than raw pet food, which has been processed in accordance with point 3 of Chapter II of Annex XIII to Regulation (EU) No. 142/2011

“Animals”: any invertebrate or vertebrate animal.

“Pet”: any non-food producing animal that belongs to a species normally fed and kept, but not consumed, by humans for purposes other than livestock breeding.

“Farmed animals”: any animal kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins, or any other product obtained from animals or for other farming purposes; and equidae.

“non-food producing animals”: any non-food producing animal kept, fed or bred, but that is not used for human consumption, such fur animals, pets and animals kept in laboratories, zoos or circuses.

“fur animal”: animals kept or reared for the production of fur and not used for human consumption;

“food producing animal”: any animal fed, bred or kept for production of food for human consumption, including animals that are not used for human consumption but that belong to a species that is normally used for human consumption in the Community.

“Competent authority”: the General-Directorate of Feed and Veterinary Affairs (DGAV), that is the national animal and plant health authority responsible for the food and feed safety systems.

“Putting in circulation” or “circulation”: the holding of products to be used in animal nutrition for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, as well as the sale itself or any other form of transmission.

“Placing on the market”: holding of feedstuffs for purposes of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

“Check”: checks performed by the competent authority to verify on the conformity with legal provisions in force on the feed sector.

“Untreated hides and skins”: all cutaneous and subcutaneous tissues that have not undergone any treatment, other than cutting, chilling or freezing.

“Establishment”: any unit of the feed business.

“Feed business”: any undertaking, whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding.

“Food business”: any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any of the stages of production, processing and distribution of food.

“Carrier”: a substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself.

“Meat and bonemeal”: animal protein derived from processing of Categories 1 and 2 materials, in accordance with any of the processing methods established in Chapter III of Annex IV to Regulation (EU) no. 142/2011.

“Fishmeal”: processed animal protein derived from aquatic animals, except sea mammals including farmed aquatic invertebrate and starfish of the *Asterias rubens* species harvested in mollusc-producing areas.

“Blood meal”: processed animal protein derived from the heat treatment of blood or fractions of blood, in accordance with Section 1, Chapter II of Annex X to Regulation (EU) no. 142/2011.

“Gelatine”: natural, soluble proteins, gelling or non-gelling, obtained from the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.

“Foodstuffs or (food for human consumption)”: a processed, partially processed or unprocessed substance or product intended for ingestion by humans or with reasonable expectations of being ingested.

“Rendered fat”: fats derived from processing: a) animal by-products; or b) products for human consumption that the operator intended for purposes other than human consumption.

“Imports”: free circulation of feed and the intention to release feed for free circulation within the meaning of Article 201 of Regulation (EU) No. 952/2013, that establishes the Union Customs Code.

“Farmed insects”: farmed animals, as defined in Article 3(6)(a) of Regulation (EC) No. 1069/2009, of the insect species that are approved for the production of processed animal proteins in compliance with A

nnex X to Chapter II(1)(A)(2) to Regulation (EC) No. 142/2011.

“Intermediary importer”: a feed business that, in accordance with customs provisions under the Union Customs Code, is responsible for the release for free circulation or intention of release for free circulation of feed in the customs territory of the Union and subsequently for purposes of placement under customs procedure, as well as its use and/or putting in circulation of said feed, in full compliance with customs and veterinary measures in force.

“Release for free circulation and consumption”: customs procedure that confers on non-Community goods the custom status of the Community goods.

“Batch”: an identifiable quantity of feed 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.

“Feed materials”: products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures.

“Raw materials of animal origin for animal nutrition”: raw materials for feed of animal origin, including processed animal protein, products derived from blood, rendered fat, eggproducts, fish oil, fat derivatives, collagen, gelatine and hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, milk, milk products, dairy products, colostrum, colostrum-based products and centrifuge or separator sludge.

“Category 3 Materials”: comprise the following animal by-products listed in Article 10 of Regulation (EC) No. 1069/2009:

- a) Carcasses and parts of animals slaughtered, or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;
- b) Carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an antemortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation:
 - i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption, but which did not show any signs of disease communicable to humans or animals;
 - ii) heads of poultry;
 - iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones of:
 - animals, other than ruminants requiring TSE testing, and
 - ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No. 999/2001,
 - iv) pig bristles,
 - v) feathers;
- c) entire animal by-products from poultry and lagomorphs, slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) no. 853/2004, which did not show any signs of disease communicable to humans or animals;
- d) blood of animals that did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation:
 - i) animals, other than ruminants requiring TSE testing, and
 - ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No. 999/2001;
- e) animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and centrifuge or separator sludge from milk processing;
- f) 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;
- g) petfood and feedstuffs of animal origin or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding 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;

- h) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of disease communicable through that product to humans or animals;
- i) aquatic animals and parts of such animals, except sea mammals, that did not show any signs of disease communicable to humans or animals;
- j) animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;
- k) the following materials originating from animals that did not show any signs of disease communicable through that material to humans or to animals:
 - i) shells from shellfish and shells of crustaceans with soft tissue or flesh,
 - ii) the following originating from terrestrial animals:
 - Hatchery by-products,
 - Eggs,
 - Egg by-products, including egg shells,
 - iii) Day-old chicks killed for commercial reasons;
- l) aquatic and terrestrial Invertebrate other than species pathogenic to humans or animals;
- m) animals and parts of thereof of the zoological order Rodentia and Lagomorpha, except Category 1 material, as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material, as referred to in Article 9 (a) to (g) of Regulation (EC) No. 1069/2009;
- n) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals, that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point b);
- o) Adipose tissue from animals that did not show any signs of disease communicable through this material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation;
- p) catering waste, other than catering waste from means of transport operating internationally.

“Feed business operator”: the natural or legal person responsible for ensuring that the requirements of food law are met within the feed business under their control or in any undertaking, whether or not for profit, and whether public or private, carrying out any of the activities related to the production, manufacture, processing, storage, transport or distribution of feedstuffs, including any operator that produces, processes or stores foods intended for animal feeding in his own holding.

“Food business operator”: the natural or legal person responsible for ensuring that the requirements of food legislation are met within the food undertaking under their control.

“Dogchews”: products for pet animals to chew, produced from untanned hides and skins of ungulates or from other material of animal origin

“Border Control Posts”: the site and the facilities that pertain to it, designated by a Member State (MS) to conduct official controls.

“Border Inspection Post (BIP)”: any inspection post designated and approved in accordance with article 6 of Council Directive 97/78/EC, for the carrying out of veterinary checks on products arriving from third countries at the border of one of the territories listed in Annex I and in accordance with article 8 of Decree-law No. 210/2000.

“Product intended for feed” or “product”: food for animals or any substance used in feed.

“Premixtures”: mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals.

“Derived products”: products obtained from one or more treatments, processing or processing stages of animal by-products.

“Products derived from blood”: products derived from blood or from blood fractions, with the exception of bloodmeal; including dry/frozen/liquid plasma, total dry blood, dry/frozen/liquid red blood cells or the respective fractions and mixtures.

“Products of animal origin”: products of animal origin within the meaning of Point 8.1. of Annex I to Regulation (EC) No. 853/2004.

“Processed Animal Protein”: animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X to Regulation (EU) No. 142/2011 (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 petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-based products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins, dicalcium/tricalcium phosphate, eggs and egg-products, including eggshell, tricalcium phosphate and collagen.

“Hydrolysed proteins”: polypeptides, peptides and aminoacids and mixtures thereof, obtained by the hydrolysis of animal by-products.

“Consignment”: considered for purposes of imports control as the quantity of any feed of the same type, covered by same veterinary certificate(s) or veterinary document(s) or other document(s) provided for by veterinary legislation, conveyed by the same means of transport and coming from the same third country or part of such country.

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

“Blood”: fresh whole blood.

“Apiculture by-products”: honey, beeswax, royal jelly, propolis or pollen not intended for human consumption.

“Animal by-products”: entire bodies or parts of animals, products of animal origin or other products obtained from animals which are not intended for human consumption, including oocytes, embryos and semen.

“Pet feed plant”: premises or facilities for the production of petfood or flavouring innards, as referred to in Article 24 (1)(e) of Regulation (EC) No. 1069/2009.

“Processing plant”: premises of facilities the processing of animal by-products, as referred to in Article 24 (1) (a), of Regulation (EC) No. 1069/2009, where animal by-products are processed in accordance with Annex IV and/or X.

6. GENERAL PRINCIPLES AND REQUIREMENTS

Regulation (EC) No. 767/2009 establishes that feed may only be placed in the market and used if it is safe and does not have a direct adverse effect on the environment or on animal health and welfare.

Additionally, Article 10(i) of Regulation (EC) No. 1069/2009 lays down that aquatic or terrestrial invertebrates, with the exception of the species that are pathogenic for humans or animals, are considered as Category 3 materials. Category 3 materials may be used in feed production for production animals or for pets.

On this basis, EU regulatory provision on insects use in farmed animal feed, with the exception of fur producing animals, laid down by Regulation (EC) No. 999/2001, as well as the use of Category 3 materials and the special feeding purpose under Regulation (EC) No. 1069/2009 implemented by Regulation (EU) No. 142/2011, are essentially connected with the insect species that can be used, the life cycle stage to consider, the substrates where they are produced, the microbiological criteria to be complied with, as well as the appropriate processing methods to obtain processed animal proteins originating from insects.

To these are added the feed provisions under Regulation (EC) No. 183/2005, as well as the maximum permitted levels for certain chemical contaminants laid down in Directive 2002/32/EC. The same maximum levels for many of the undesirable substances listed in the Annex to this Directive are applicable to all raw materials, but in some cases specific limits are set for certain raw materials/additives or compound feedingstuffs according to the species/category animal of destination. No exceptions have been made so far to raw materials consisting in or produced from insects.

Insects are further covered by Regulation (EC) No. 306/2005 that sets maximum levels for pesticides residues in and on foodstuffs and feed of vegetable or animal origin.

All previously stated requirements have to be complied with in producing, processing, placing on the market and using processed animal proteins originating from farm insects and/ or compound feedingstuffs containing them.

7. DESIGN OF THE HOLDING

The general structure of the insect production chain is set out in figure 3 for the various insect species approved under Regulation (EU) No. 2017/893, including sampling stages, processing and products obtained with the indication of the possible final uses.

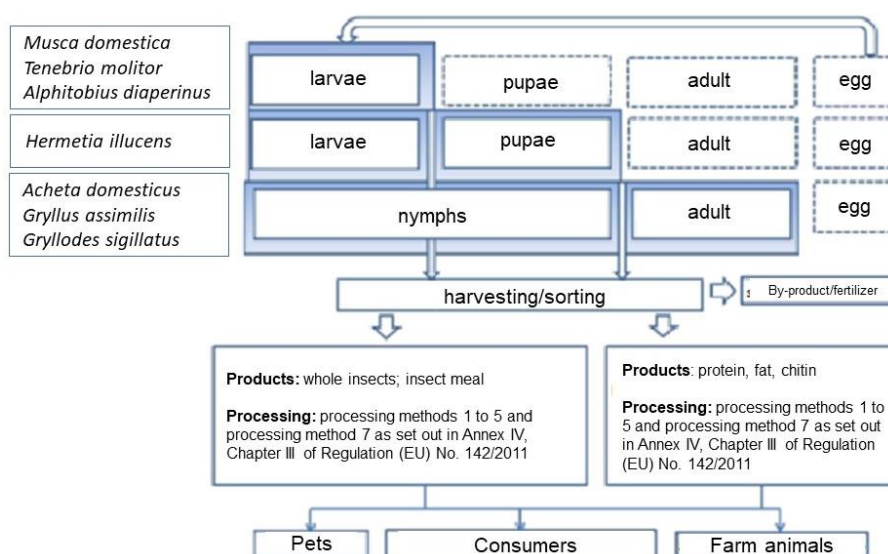


Figure 2 - overview of the chain of insects production.
production and sampling stages and possible final destinations (adapted from: EFSA's scientific opinion, October 2015).

7.1. Livestock Holding - NSLF

Insects production is a form of livestock farming which falls within the new scheme of livestock farming (NSLF) established by Decree-law No. 81/2013 of 14 June, which requires full compliance with animal welfare and health standards, human health and safety, property and environmental preservation and land use planning, as part of sustainable livestock production. Additionally, under ministerial order no. 635/2009 of 14 June, insect production is a form of animal production considered as a production nucleus for other species (PNOS).

Consequently, insects production as a form of livestock farming requires licensing, which depends on the classification of the holding, and is calculated on the basis of the livestock units (LU) and production area.

The licensing process requires:

- Submitting the land registry (holding Identification by means of the title certificate and/or aerial photograph and/or plot identification for registration of the production site, as well as evidence that the production site is owned or leased by the operator and the intended area for insect production);
- Obtaining the beneficiary identification number (BIN) by means of registration with the Institute of Financing of Agriculture and Fisheries (IFAP). A land registry will then be issued indicating the exact location and intended purpose of the holding. The holding form, the descriptive documents and the production plan must then be submitted to the Directorate General of Agriculture and Rural Development (DGADR) as provided for in Decree-law no. 81/2013, annex III;
- Holding identification number according to LU, species and herd intended to be bred, as well as the projected greater plant area.

Note: If an urban approval by the Municipality is required under Decree-law no. 555/99 of 16 December, the licensing process is initiated in the Municipality where the holding is located, with a formal application for previous Information with the intended location (regardless of whether a new building is envisaged or merely renovation of existing buildings), depending on the respective Municipal Master Plan (MMP). This procedure may be facilitated if the area in question is already licensed for agricultural production.

7.2. Holding Registration NSLF

Under NSLF livestock holdings with a capacity of up to 15 LU are Class 3, livestock holdings with a capacity of 15 <LU <260 are Class 2 and intensive livestock holdings with a capacity of more than 260 LU are Class 1.

Licensing procedures for livestock holdings depend on their classification. Class 1 requires the approval application for installation of new livestock holdings, Class 2 the procedure of Previous Declaration for livestock holdings and Class 3 the registration for livestock holdings. Class 1 and Class 2 livestock holdings are subject to a global revision 7 years on from the date of issue of the Holding License/Title". The decision on whether to conduct a study on the environmental

impact is taken by the Commission of Coordination and Rural Development (CCDR) of the region where it is located.

Interpretative Note No. 2/2013 of the NSLF Working Group (NSLF WG) establishes that insect production is conducted in closed facilities under an intensive scheme, with LU equivalence not exceeding 0.2LU / m², in other words 5m² / LU of the productive site area. This interpretative note further establishes that as animal byproducts may be used as insect feed, an evaluation by DGAV is necessary and consequently facilities must always be subject to at least Previous Declaration procedures, in other words, Class 2 procedures.

Note: In view of the entry into force of Regulation (EU) No. 2017/893, the NSLF WG is revising Interpretative Note No. 2/2013 in view of its probable repeal

In view of the above, a potential insect producer that wishes to initiate livestock farming must lodge the application with the Coordinating Entity of the licensing procedures for livestock breeding, namely the Regional Directorate of Agriculture and Fisheries (DRAP) of his geographical location. Forms and annexes which, according to the Class of livestock holding that the activity falls under, have to be filled in are available on the websites of the respective territorially competent coordinating entities.

Note: Additional Information on licencing procedures for livestock farming can be requested from the respective coordinating entities.

7.3. Production of exotic species

With the exception of the species currently listed in Regulation (EU) No. 2017/893, exotic insects production must be previously approved by the Instituto de Conservação da Natureza e Florestas (ICNF).

8. INSECT PRODUCTION

8.1. LIFE CYCLE, EGG LAYING AND HATCHING, PRODUCTION AND BIOCONVERSION

This Manual only covers insect species that, in light of legislation currently in force, may be used in producing processed animal protein originating from farmed insects, with a view to its use in farmed animal feed. The list of species may be amended in the future on the basis of an evaluation of the hazards that the insect species at stake pose for animal, public and plant health and the environment.

Regulation (EU) no. 2017/893 approves rearing of the following insect species in the EU for feed use (Figure 3):

Flies

- Black-soldier-Fly (*Hermetia illucens*);
- Common HouseFly (*Musca domestica*);

Mealworms

- Yellow Mealworm (*Tenebrio molitor*);
- Lesser Mealworm (*Alphitobius diaperinus*);

Crickets

- House cricket (*Acheta domesticus*);
- Banded cricket (*Gryllodes sigillatus*);
- Field cricket (*Gryllus thusilis*).

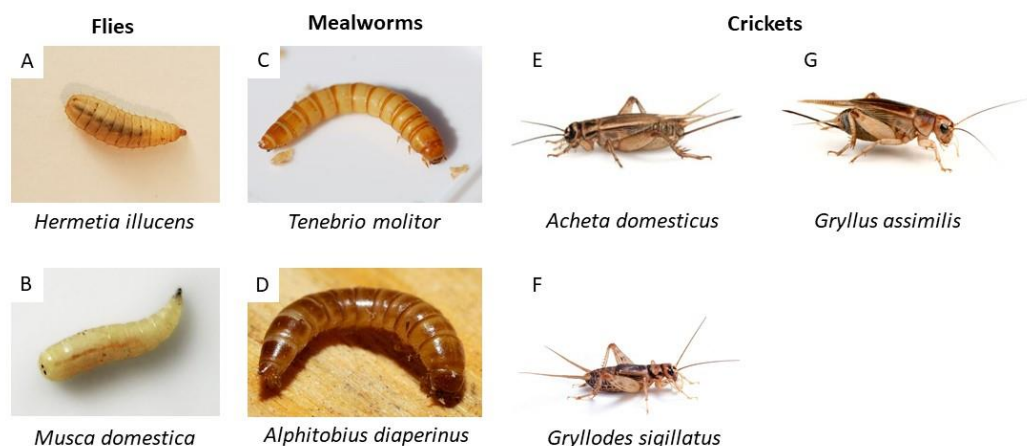


Figure 3 - Species currently allowed for rearing for production of insect PAP for farmed animal feed. Individuals, presented in the ready for harvesting stage. A - Black Soldier Fly larvae (EntoGreen original), B - Common house fly larva (adapted from feedipedia.org), C - Mealworm Larvae (adapted from blog.growingwithscience.com), D - Lesser mealworm larvae (adapted from biolib.cz), E - Adult stage of the house cricket (adapted from food-insects.com), F - Adult stage of the banded cricket (adapted from warrenphotographic.co.uk) and G - Adult stage of the field cricket (adapted from bat-rodents.eu).

Industrial insect production is designed in such a way as to control the life cycle of the species being produced. As in other livestock production, stages of reproduction, raising and fattening (production) are kept separate. However, insect breeding opens the door to the reuse of by-products and other generally undervalued raw-materials, favouring its use and reintroduction back into the value-chain, providing the opportunity to produce new nutritional sources with a potentially lower environmental impact (Figure 4).

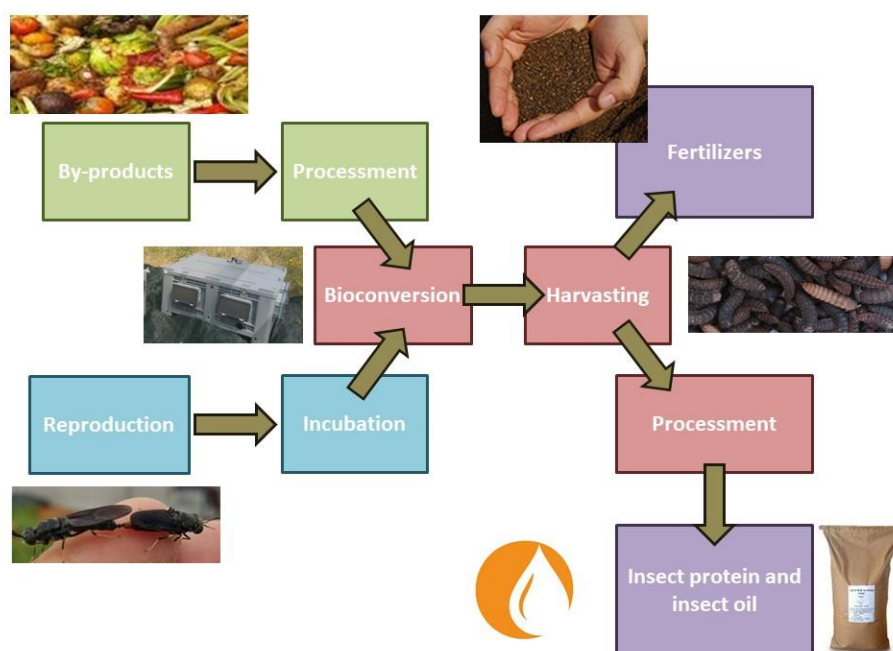


Figure 4 - basic layout of industrial scale insect production. Green - stage of reception and processing of by-products/substrate, blue - reproduction of juveniles, red - production/fattening, purple - final products (original layout)

Thus, the basic layout of insect production includes the use of by-products which must be prepared for inoculation by juveniles, bioconversion of by-products by insects, and finally, separation and processing of final products (Figure 5).

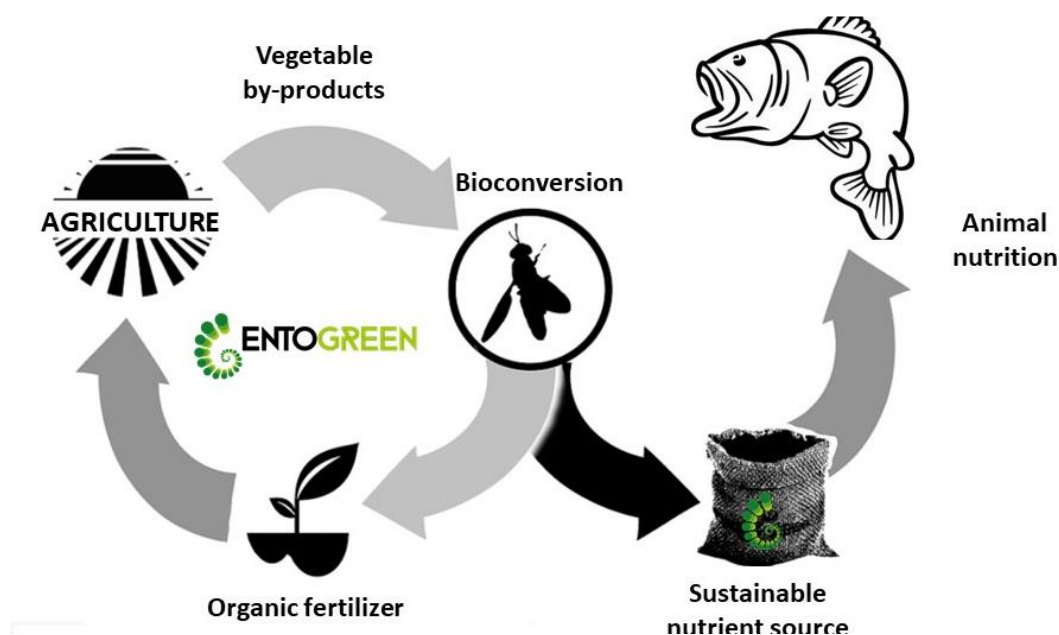


Figure 5 - Circular economy in insect production. Example of the production of the black soldier fly. (EntoGreen original)

8.1.1. Production of Flies (*Hermetia illucens*, *Musca domestica*)

Information on life cycle: *Hermetia illucens*, usually known as Black Soldier Fly - BSF - has a short life cycle of about one to two months, which may however be extended by several months under unfavourable environmental conditions (Figure 6). Its life cycle comprises four key stages, egg, larvae, pre-pupae, pupae and fly (adult).

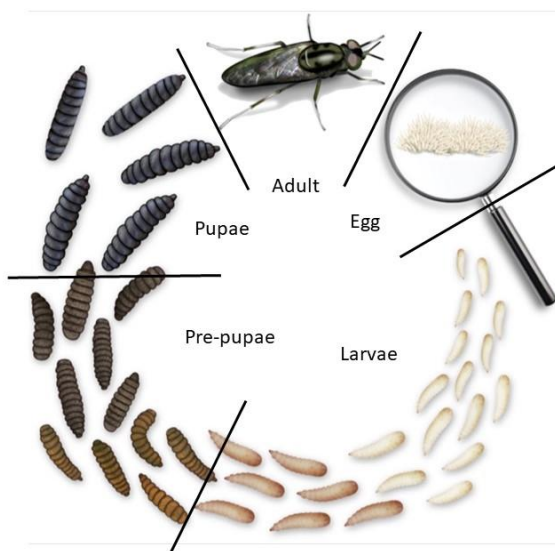


Figure 6 - close-up of the different stages of the life cycle da Black Soldier Fly (adapted from youtube.com).

The common house fly (*Musca domestica*) in turn has a very short life cycle of about 7 to 10 days, which, as in the case of BSF, may be extended for some months under unfavourable conditions. Its life cycle stages may be divided in egg, larvae, pupae and fly (adult) (Figure 7).

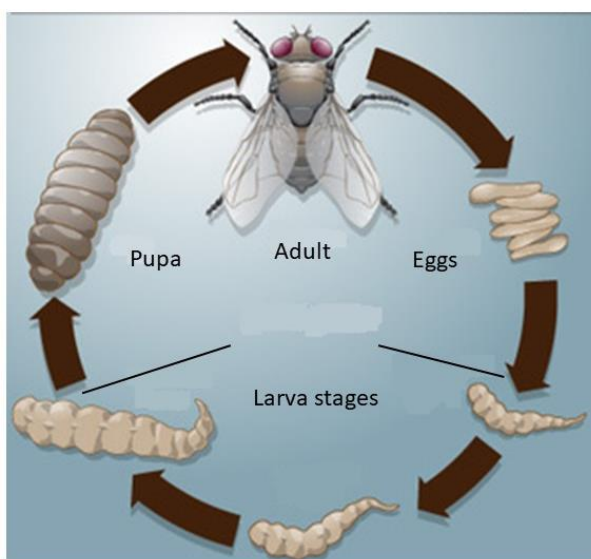


Figure 7 - close-up of the life cycle of the common house fly (adapted from thelifeoffly-mitton.wBSEly.com)

In general, both species may be produced by separating the different life cycle stages. Thus, the production unit may be divided in egg production area (reproduction) and larvae production or bioconversion area (Figure 8).

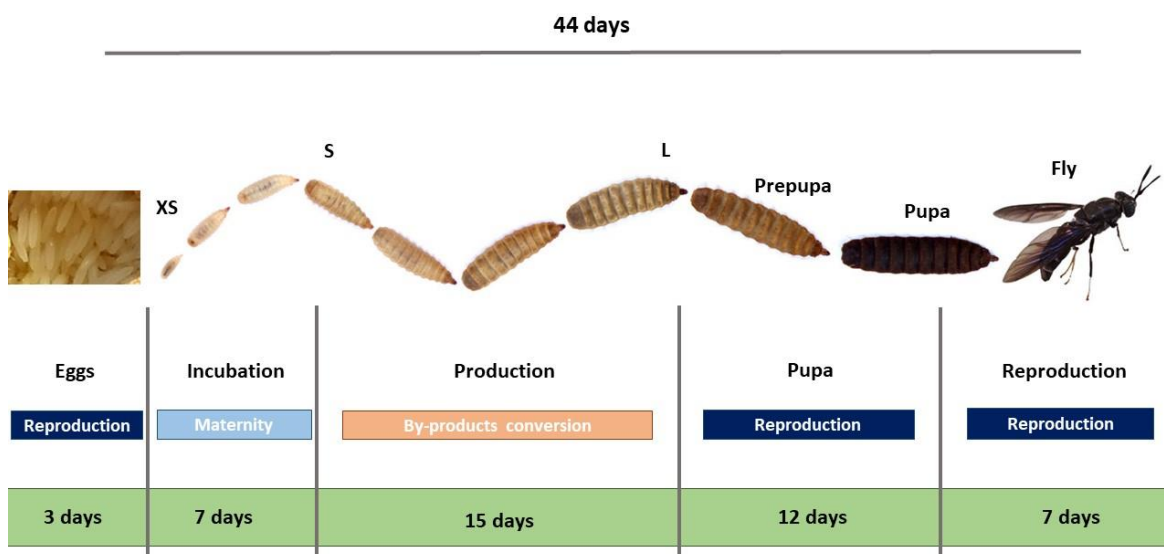


Figure 8 - Life cycle of the black soldier fly suitable for controlled production. Life cycle stages are adapted to the physical areas and stages of the production of this species. Production stages - Reproduction (dark blue), Maternity/raising (light blue), Production or bioconversion (salmon) approximate duration of each stage in days. (original layout, images adapted from the internet).

Egg laying and hatching: In both species pupae are placed in closed environments (rooms, nets, boxes, amongst others) (Figure 9). After hatching adults will reproduce themselves and lay eggs (Figure 10 and Figure 11 A). Adults are housed in an area where flight and mating are permitted, with ideal environmental conditions for mating (Figure 9 D and F) and egg laying (Figure 10). Egg laying must take place in specific sites that respect the natural behaviour of the animals and optimize egg laying and its easy collection. Eggs must be collected regularly in order to avoid larvae hatching in this area, otherwise they must be captured or contained (Figure 10 and Figure 11 B).



Figure 9 - Various forms of contentment of adult flies in the reproduction stage. Mating in the three different systems presented. A - system of nets in the interior, B - system of nets in greenhouses, C - inner room, D - mating in the internal net, E - mating in room, F - mating in greenhouse. Notes: The system shown in A and C enables the control of luminosity, ambient temperature and relative humidity, the system shown in B enables the use of sunlight and the climate conditions of the region, with the disadvantage of seasonality, however, it may enable a greater efficiency in egg production. Note: in both systems stacked boxes with pupae can be seen. In both cases of interiors there is a direct window to the exterior, however a completely closed system can be obtained. (EntoGreen images)

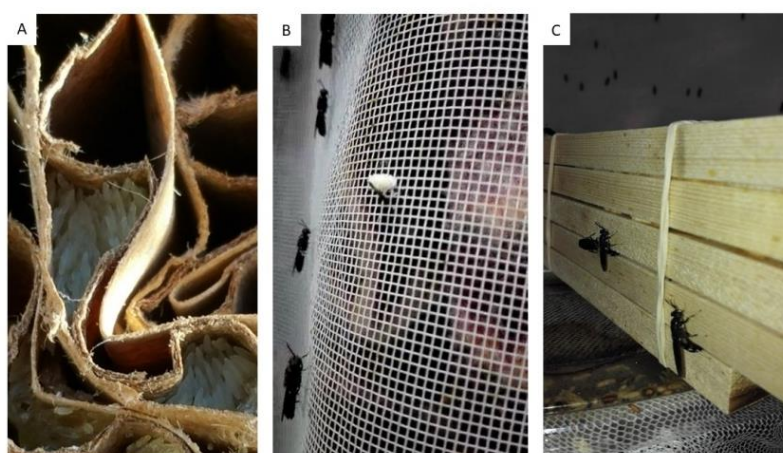


Figure 10 - Different forms of egg collection of the black soldier fly. A - collection in carton box, B - collection in net, C - collection in wooden slats. Note: adults during laying are shown in images B and C. (EntoGreen images)



Figure 11 - production stages of the black soldier fly. A - reproduction room (adult), B - black soldier fly eggs, C - example of mobile biodigester, prototype of EntoGreen, D - black soldier fly larvae, E - black soldier fly dehydrated larvae. Note: the mobile biodigester shown in image C is a prototype developed as part of the EntoValor project that permits automous separation of the larvae, and can be used in a domestic or semi-industrial environment. (EntoGreen images).

Production/bioconversion: After collection of the eggs produced, these, or the resulting larvae, are innoculated in the selected substrate during the period of time and under the conditions that ensure the effective development of larvae and full conversion of the substrate. Ideally the system used should allow the process to be carefully controlled as regards space and time, in order to attain a balanced production pace and greater homogeneity of insects produced. It is therefore advisable that each holding divides its production site in specific areas for each development/production stage of the insects. Besides physically separating production areas from each other, preventing contamination between different stages and facilitating traceability, bioconversion containers must have the appropriate conditions to facilitate production of each species and prevent any leaks (Figure 11 C and figure 12). Containers used may range from stackable small boxes, that allow handling by a single operator, to pallet boxes or architectural structures that enable the conversion of large amounts of by-products at a time. There are also mobile structures that can be used domestically or in holdings for larvae production for poultry (Figure 11 C). These models usually have larvae collection systems that use the capacity of the larvae to separate themselves from the substrate on their own, however this model and its uses are not covered by this manual.

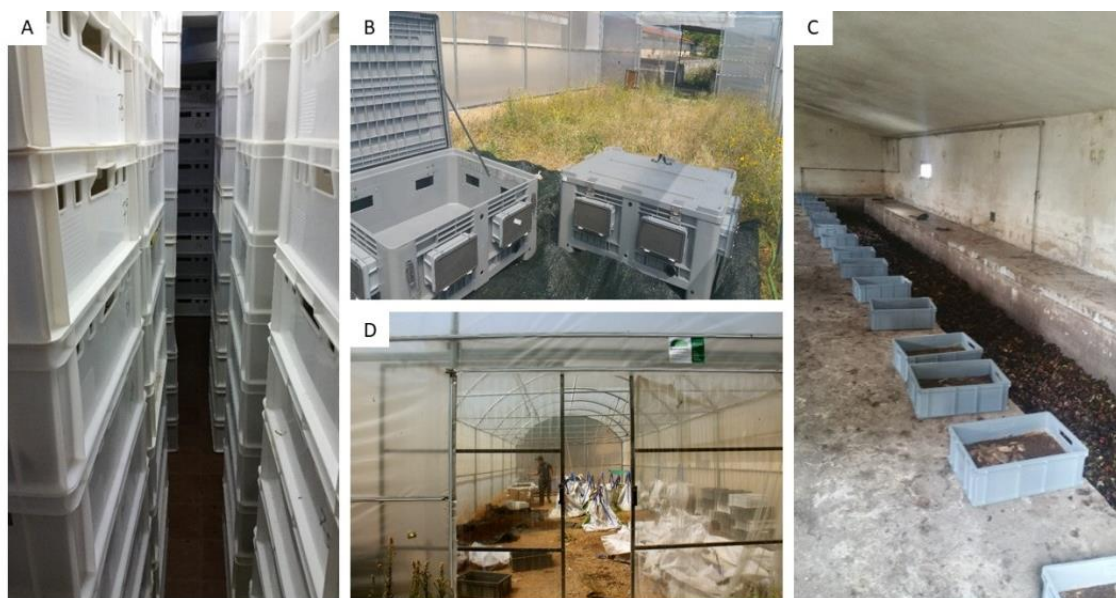


Figure 12 - Examples of bioconversion containers used in fly larvae production. A - stackable boxes, B - pallet boxes, C - biodigestion in ditches, D - pallet boxes, stackable boxes and big bags in greenhouses. (EntoGreen images)

Larvae produced is separated from the substrate that must be totally converted by the end of the process (Figure 11 D and Figure 13 A). For the process of separation of the larvae an efficient equipment must be selected that reduces to a minimum the permanence of larvae in the converted substrate (examples of equipment in Figure 13 B to D).

In order to avoid any environmental contamination it is advisable that the fertilizer complies with biosafety procedures ensuring the elimination of any existing larvae before it is spread in the environment. It is therefore advisable to apply chemical or physical processes that ensure the elimination of all forms of existing insects, being their eggs, larvae or adults.

Larvae separated from the substrate are sent for processing (Figure 11 E).



Figure 13 - Substrate converted into organic fertilizer and the separation process. A - converted substrate/organic fertilizer, B - semi-industrial vibratory sieve, C - rotational drum sieve, D - detail of vibratory sieve. (EntoGreen images)

8.1.2. Mealworm production (*Tenebrio molitor*, *Alphitobius diaperinus*)

Information on the life cycle: the life cycle of the *Tenebrio molitor* consists in four stages, egg, larva, pupae and adult, and can last between 280 to 630 days. Duration of the life cycle and of each stage depends on environmental conditions, such as temperature, relative humidity, nutrition and water source. In general however, larvae hatch after 10-12 days (at 18-20 °C) and become mature after undergoing a variable number of stages (8 to 20), typically after 3-4 months (at ambient temperature), but the larvae stage may last up to 18 months. Mature larva is yellowish-brown in colour, its length is between 20 to 32 mm, and weighs between 130 to 160 mg. The pupae stage lasts between 7 to 9 days at 25 °C and up to 20 days at lower temperatures. The adult *Tenebrio molitor* lives between 2 to 3 months (Figure 14).

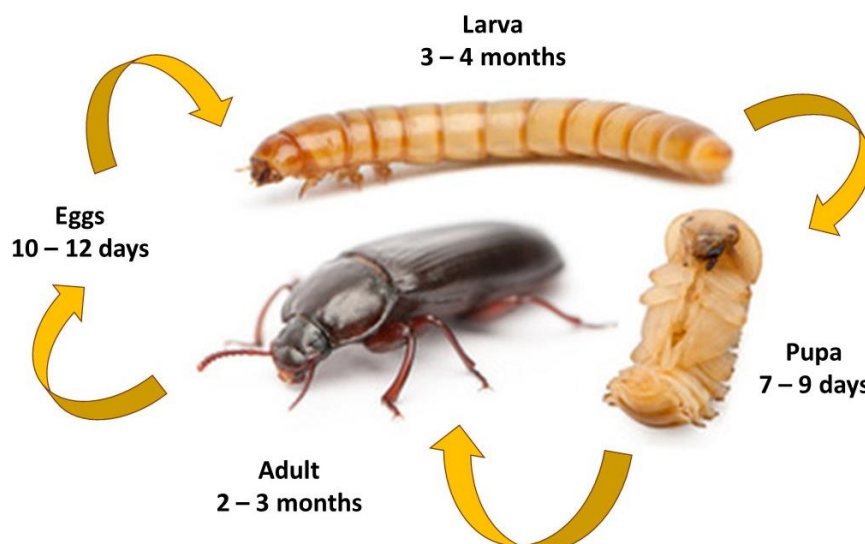


Figure 14 - Close-up of the life cycle of the *Tenebrio molitor* with the approximate duration of each stage stage. (original layout, image adapted from epicmealworms.wBSEly.com)

During the larvae stage individuals undergo several moults as they grow and remains of the exoskeleton can be found in the production boxes after some moults (Figure 15). At the end of the larvae stage individuals seek appropriate sites to become pupae, where this transition can take place without the risk of being swallowed by other insects of the same species (Figure 16).

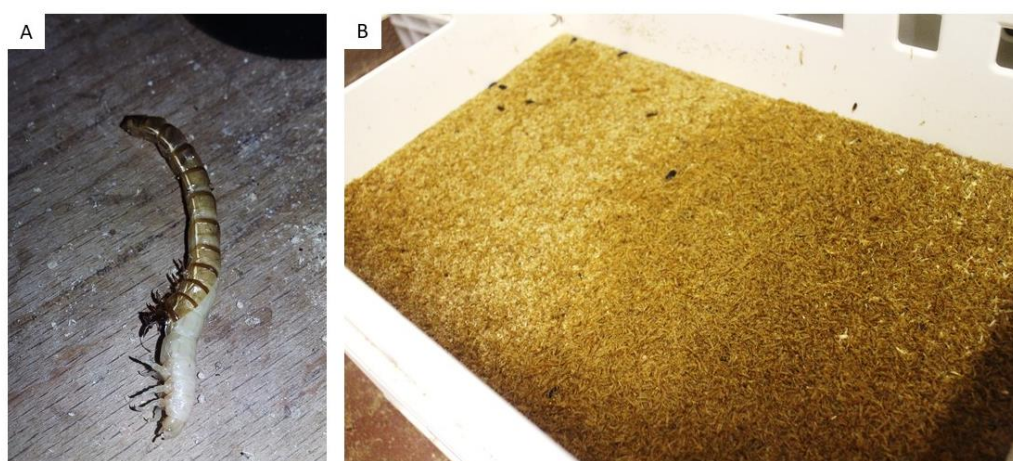


Figure 15 - Mealworms exoskeleton. A - mealworm larvae moult. B - production box of the mealworm with young larvae; the exoskeleton layer accumulated on the substrate is visible. (Aki à Bixo and EntoGreen images)



Figure 16 - Structure with mealworm pupae and young adults. (Aki à Bixo images)

Alphitobius diaperinus is generally found in flour infestations and other cereal products, especially in poorly maintained cereal processing plants. Because of its tropical origin, it is adapted to hot and humid conditions, and it is a significant and frequent inhabitant in poultry holdings, where both adults and larvae are abundant in the substrate used as poultry litter (Figure 17).



Figure 17 - *Alphitobius diaperinus* in production poultry litter.
(image adapted from mwiah.com)

After mating, an adult female has the potential for lay more than 2.000 eggs (the average is closer to 200 to 400). Adults lay eggs in cracks and fissures in henhouses, in manure or litter, in grains husks and under feed and water lines. Adults live between three to twelve months, with females continuing to lay eggs for most of their lives at 5-days intervals. Larvae hatch in between four to seven days and develop until the adult stage in 40 to 100 days, depending on temperature and feed quality (Figure 18).

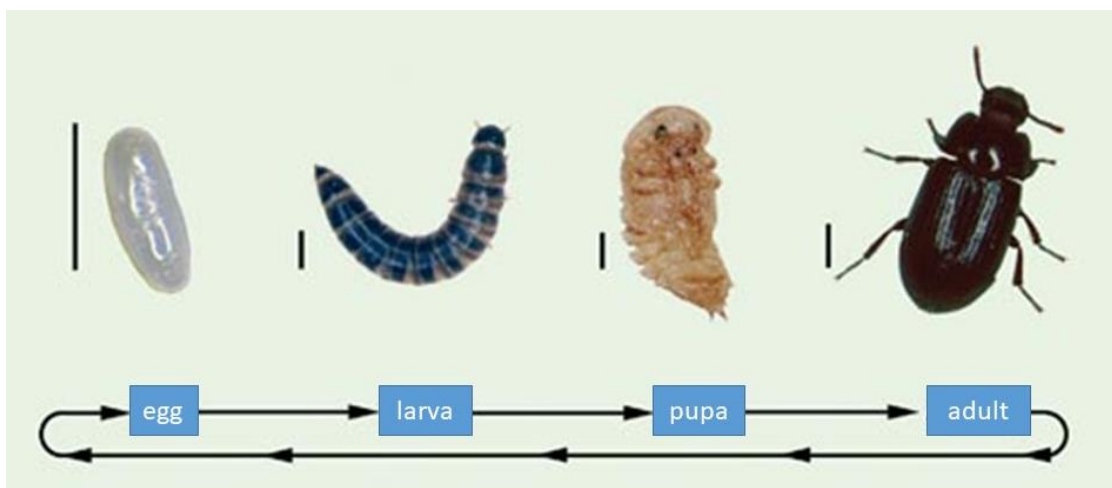


Figure 18 - Close-up of the life cycle de *Alphitobius diaperinus*.
(adapted from poultryhub.org)

Temperatures of 30° to 33°C with approximately 90% relative humidity are required for optimal development. Both stages, larvae and adult, are essentially nocturnal, with greater activity occurring in the evening. Mealworms are very active and rapidly bury themselves in the litter when disturbed. Adults live for long periods, usually for over one year and under experimental conditions they have survived for over two years.

Both *T. molitor* and of *A. diaperinus* production may be organized by stages, dividing the production site in reproduction, hatching and production/bioconversion areas.

Egg Laying and hatching: The reproduction area may consist in boxes with adults where a solid substrate and a source of humidity is supplied, such as greenery or other forms of water supply (Figure 19). Boxes containing adults may have bottoms of fine mesh or other forms of autonomous separation of eggs. There can also be boxes where substrate replacement by sieving is done often.



Figure 19 - adult mealworm with different sources of moisture.
(Aki à Bixo, Ricardo Victor e EntoGreen images)

In either case, the eggs produced are incubated under appropriate conditions for larvae hatching, with feed being supplied in the necessary quantities and favourable environmental conditions maintained. After some weeks of development the larvae produced are separated and either selected for reproduction, where they can finalize their life cycle, or sent for production.

In batches selected for reproduction, larvae are allowed to reach the pupae stage. However, since at this stage there is the risk of being swallowed by other individuals, great care must be taken in keeping separate the different stages (Figure 20).



Figure 20 - mealworms boxes where larvae reach the pupae stage. (EntoGreen images)

Production/bioconversion: Larvae obtained in the previous stage may be kept in the original substrate or inoculated in new substrates. When seeking to add value to vegetable by-products larvae may be inoculated at this stage in these substrates, and attention must be paid to the relative humidity of these by-products. However, in most cases, producers use purpose-made substrates, compound feedingstuffs for animals, or a simple mixture of cereals or bran. Mealworms may be produced in stackable boxes, generally with a size and weight such that allows individual handling, with lateral walls preventing insects from escaping. It is advisable to organize the rooms containing the boxes in such a way as to ensure traceability between production batches and physical separation between production stages (Figure 21).



Figure 21 - Boxes with mealworm production in a room (Portugal Bugs and EntoGreen images)

At the end of the production/bioconversion period, which may vary according to the substrate used and environmental conditions, insects, still at the larvae stage, are separated and sent for processing (Figure 22 A). The result of substrate bioconversion is a fertilizer with a very small particle size that easily turns to dust, and it is advisable that workers who separate or handle these insects use protective material over their mouths and noses (Figure 22 B).

In order to avoid environmental contamination, fertilizer must comply with biosafety norms that ensure the elimination of any larvae before it is spread in the environment. It is therefore advisable to apply chemical or physical processes which ensure the elimination of all forms of existing insects, being their eggs, larvae or adults.



Figure 22 - Mealworms sieving. A - mechanical sieve, B - manual sieve. Note: see the fine particle size of the substrate digested by the insects, visible in image B.

(Aki à Bixo and EntoGreen images)

8.1.3. Cricket Production (*Acheta domesticus*, *Gryllus thusilis* and *Gryllodes sigillatus*)

Information on life cycle: the three species of crickets undergo three stages in their life cycle: egg, nymph and adult. House crickets (*Acheta domesticus*) take between two to three months to complete their life cycle when bred at temperatures between 26° to 32° C. Eggs are laid in any humid substrate supplied - sand or turf for example. The cricket begins its life in an egg which, after about 14 days, evolves into a nymph. Juveniles /nymphs are similar to adults, except for being smaller, wingless and females lack ovipositors. These young crickets generally become game for bigger crickets and other insects. In order to grow, nymphs have to shed their hard exoskeleton, a process called moulting which happens 8 to 10 times. The new exoskeleton is milky white and soft and hardens within a few hours. Nymphs will start growing wings after about one month. Once a cricket reaches maturity, its wings are totally developed and it only has two objectives: to eat and to mate. Males will seek to attract fertile females. Once mating has taken place, females will look for suitable places where they will lay eggs almost continuously. Females use their ovipositor, a tube-like organ, to lay eggs in any available humid substrate. Over their lifetime females may easily lay 100 eggs and, sometimes, up to 200 (Figure 23).

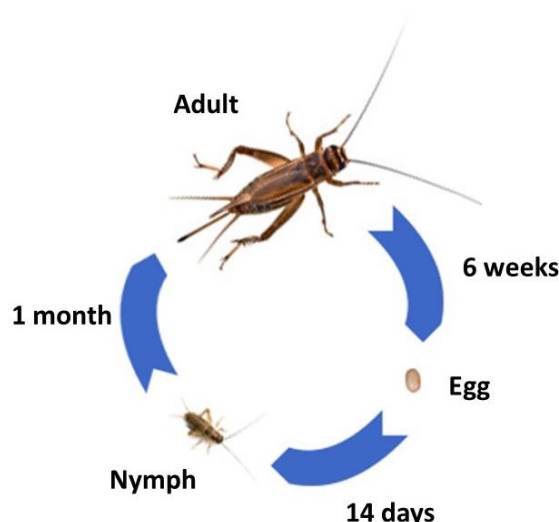


Figure 23 - Life cycle of the house cricket (*Acheta domestica*).
(image adapted from cricketcare.org)

Females of the field cricket (*Gryllus thusilis*) lay up to 400 eggs by means of a ovipositor in humid soil and generally in appropriate temperatures (between 25 °C and 30 °C). Eggs hatch in about eleven days, and the nymph stage lasts six to seven weeks, when the insect reaches sexual maturity and males start calling females. Eggs may be consumed by adults looking for food on the soil, for which reason precautions must be taken to keep adults from egg laying sites. Banded crickets (*gryllodes sigillatus*) have a life cycle of 50 to 70 days and their production/reproduction conditions are similar to the other two species.

Egg Laying and hatching: An “universal substrate” for plants is used as substrate for laying eggs, as it provides an appropriate humid environment. Even in large-scale industrial production the amount of substrate needed for this purpose is minor, and substrate may therefore be purchased from specialized producers. Substrate is used in several cycles and only disposed of when it shows signs of fungal contamination (although fungi do not affect the efficiency of the procedure). Between cycles small portions of substrate, used in the containers where eggs are hatched, are mixed, revolved and humidified for the new cycle. In egg laying a net is used to prevent substrate from being ingested by adults.

Raising: Substrate where the eggs were laid and hatched is placed in a nursery on the day before the expected hatching day. When nymphs hatch in the nursery they fall into a clean area from where they cannot escape. In this way clean nymphs are obtained, easy to harvest and to count, in order to stock with the exact quantity the final captivity site where they will complete their life cycle. Because of the natural mortality rate, there will be a lower number of individuals at the end than that at the outset. Thus, after hatching, nymphs are separated and placed in containers with high walls or a net that prevents their exit.

In cricket breeding (*Acheta domesticus*, *Gryllus assimilis* and *Gryllodes sigillatus*), each breeding is dated from the moment of the last hatching with a difference between individuals of 48h. There are however breedings with 10 day intervals. Each breeding is kept physically separate from the other. Each breeding sector has a panel indicating the last hatching date as well as records of any interventions performed so as to allow the identification of each production batch and ensure traceability.

Production takes place in a closed insulated compartment with separate areas for each breeding stage. Crickets are housed in carton boxes in a dry and ventilated environment. Feed, entirely of vegetable origin, is dry and separated at least 20 cm from the trough. During breeding it is imperative to maintain the troughs. If the troughs are of the running water variety cleaning must be performed at least 5 times per breeding, if they are of the still water variety (ex. syphon troughs for poultry) water must be changed at least once every 3 days. Plastic materials used in the insectarium (such as as troughs and feeders) must be rigid, and/or without hard edges, otherwise crickets will chew on and ingest the plastic.

Carton containers are equally used to increase the breeding area of the insects and foster their natural behaviour. This paper structure is also ingested specially by adults, although in residual quantities. This material deteriorates so it has to be discarded and replaced at the end of several breeding cycles (on average 5). In the future other containers may be used, such as washable and non-disposable pickled PVC boxes (Figure 24).

In order to avoid possible environmental contamination it is advisable that any type of substrate used in cricket breeding complies with biosafety processes that ensure elimination of possible insects existing in it before it is disposed of in the environment. It is therefore advisable to use chemical or physical processes to ensure the elimination of all forms of insects existing in the substrate, whether as eggs, nymphs or adults.



Figure 24 - House crickets in different developmental stages and with different substrates. A - Two females, B a C - crickets with vegetable substrate, D - carton structure. (Nutrix and Aki à Bixo images)

8.2 Contention methods of individuals

One of the main concerns of the breeding holding is the contention of individuals, preventing them from leaving the facilities where they are confined, in order to avoid damages to both the operator and the environment. This holds true for any animal production, insects included, but in this last case concern with contention is not only as regards preventing individuals from leaving but also with preventing entry of other insects from the environment or even the installation of pests, that sometimes may even become mixed up with the species being produced and thereby difficult to eliminate.

Consequently it is advisable that individuals be housed in appropriate containers, from where they cannot leave, for which reason they must be built in material that is not digestible nor degradable by the insects, with sufficiently high walls as to prevent insects from leaping, flying ou climbing over them, have a lid allowing air to pass in and out or contention nets. It is equally advisable that these containers prevent individuals from passing from one container to the other, ensuring batch identification, homogeneity and traceability. It it also advisable that, depending on the production methods, containers are placed in specific areas according to the productive stage for which they are intended. In the case of flying insects, such as flies, mating

areas (rooms, nets, boxes or others) must be physically separated from the others and prevent individuals from leaving, whether by flight or on the ground, and measures must be taken that prevent egg laying in inappropriate areas and hatching and larvae from exiting this area.

Despite the existence of appropriate contention of individuals in the different stages of the life cycle, several physical barriers must exist between the productive areas, preventing insects from passing from one area to the other, whether by flying or on the ground. These barriers may range from air, net or plastic curtains, to retention grids or other devices that ensure the capture and contention of crawling individuals, insect-o-cutors, sticky traps or other types of traps to eliminate individuals that may have abandoned the production site. Insecticide use is unadvisable because of the toxic hazards it poses for production.

In all insect species production, it is advisable that the different productive areas be subject to stamping-outs with variable regularity according to the duration of the life cycle of each species. This practice will enable cleaning and disinfection of the production area and ensure elimination of insects potentially existing outside the appropriate production sites. Furthermore, despite the fact that there are no known diseases in some of these species, stamping-out aims to prevent outbreaks of diseases in production.

8.3. Substrate processing techniques

Substrates that can be used in insect feed with a view to the nutrition of production animals may be composed of several products/ingredients, as long as they are in compliance with feed hygiene, production and placing on the market requirements laid down by Regulation (EC) No. 183/2005 and Regulation (EC) No. 767/2009, combined with rules for prevention, control and eradication of certain transmissible spongiform encephalopathies established by Regulation (EC) No. 999/2001 and health rules on animal by-products and derived products not intended for human consumption laid down by Regulation (EC) No. 1069/2009.

Ingredients of both vegetable and approved animal origin require prior processing to their use, whether in order to comply with legal requirements or in order to facilitate insect production. Ingredients can therefore be crushed, mixed, compressed, dehydrated or fermented, and also be submitted to controlled temperature and pressure conditions during a variable period of time, in order to condition their characteristics and ensure the quality and safety of the final substrate.

If there are ingredients that need storing, they must be stored separately and always ensuring the appropriate entry and exit system, traceability and safety. Ingredients with a low humidity content (less than 5%) must be stored in dry sites and away from ingredients with higher humidity levels. Perishable ingredients stored in open areas (co-products of agrindustrial activities) must be protected from direct sunlight and steps taken to prevent their

contamination by insects or rain water. Their storage time before admission to the processing/innoculation lines must be kept as short as possible. It is therefore advisable that packaging of vegetable co-products outside the buildings be done in sealed or tarp-covered containers or containers, silos, hoppers, or box pallets or special plastic big boxes.

It is also advisable that dry ingredients be stored in silos, containers or bags that are kept under cover and that liquid ingredients be stored in silos, drums or sealed containers.

8.4. Substrate used

Emerging interest in insect production, other than the need of new protein sources and promoting the circular economy, is very much based on the potential of insects to convert organic material of low nutritional quality into high protein quality feed.

This bioconversion potential is very high and the natural characteristics of some approved species allow the efficient conversion of a much wider range of substrates than that which is currently permitted by legislation. Expectations are therefore that in the future, with the development of production process and control of potential chemical and microbiological hazards of these substrates, the range of approved substrates will significantly increase.

Interest in the increased range of substrates that have the potential to be used in insect production is based on two principles, the greater production capacity of processing plants, due to the increase of raw materials available (substrate), and the role that bioconversion by insects can play in the circular economy and the lower environmental impact of such substrates. The nature of these species is such that we are given the opportunity to use substrates that are currently deemed to be harmful to the environment.

However, since according to Regulation (EC) No. 1069/2009, insects are considered as production animals, the use of certain substances in feed is restricted.

EU regulations only allow the use in feed of products that are safe and do not have a direct adverse effect on the environment or animal health and welfare. Annex III to Regulation (EC) No. 767/2009 further establishes which raw materials are prohibited in feed.

In order to be used in insect production, substrates must be sound, genuine, unadulterated, fit for purpose and of merchantable quality (Figure 25).



Figure 25 - Vegetable by-products used in insect production. A - by-products crushed in pallet box, B - whole by-products in ditch, C - By-products in biodigestion by black soldier fly larvae. (EntoGreen images)

Therefore, and considering that under existing legal provisions insect use in feed for food-producing animals is only approved for aquaculture animals, substrate for their feed may only contain products of non animal origin, including co-products from primary production of food of non-animal origin, or the following products of animal origin, as long as originating from Category 3 material:

- Fishmeal;
- Products derived from blood of non-ruminants;
- Dicalcic phosphate and tricalcic phosphate of animal origin;
- Hydrolysed proteins derived from non-ruminants;
- Hydrolysed proteins derived from ruminant hides and skins;
- Gelatin and collagen derived from non-ruminants;
- Eggs and eggproducts;
- Milk, milk-based products, milk-derived products and colostrum;
- Honey;
- Rendered fat.

Substrate for insect feed and insects or their larvae must not have been in contact with any other material of animal origin, with the exception of those indicated in the previous list, and substrate cannot contain slurry, catering waste or other waste.

NOTE: In the case of insect production for pet food, fur animals or bait, other ingredients/ products/substrates used must be always object of a previous legal-technical opinion by the competent authority.

8.5. Good health and management practices

Insects production requires fulfilling the specific conditions of holdings or PNOS, and specific health and welfare requirements for each animal species as laid down by DGAV.

In insect production, it is advisable that, as stated above, principles of animal contention be complied with and stamping-outs conducted in the various production areas on a regular basis depending on the life cycle and productive potential of each species. Favourable environmental conditions for the normal development of individuals in each of the productive stages must be ensured, respecting their natural behaviour and preventing whenever possible, except in events that are part of the productive process itself, said individuals from being subject to extreme conditions.

Appropriate environmental conditions for normal development of insects must be maintained by means of environmental control systems or, in their absence, by preventing the production site from direct influence of natural environmental conditions, which may sometimes provoke significant changes in production conditions, which in turn may cause losses or deterioration of insect colonies.

Keeping conditions that respect the natural behaviour of each species increases the effectiveness of insect production, such as providing sufficient flight area for mating, in the case of flies, or allowing insects to find refuge from direct sunlight exposure, in the case of mealworms.

In the case of insect productions that use co-products from agricultural production, it is advisable to perform regular controls by randomly selecting batches, origins and types of products in order to rule out any chemical and microbiological hazards. It is equally advisable to regularly test these products to ascertain their characteristics and quality, thereby ensuring the success and effectiveness of their production.

Structures used in production and all material used in processing and handling, either of the substrate or of the insects, must be regularly cleaned and disinfected.

Furthermore, good practices for feed as laid down by Annex III to Regulation (EC) No. 183/2005 must be followed, namely:

Health Provisions

- Adopt, amongst others, appropriate measures for the control of hazardous agents, regardless of their physical, chemical or biological origin;
- Ensure the hygiene of the substrates and/or their ingredients intended for insect feed, at any stage of the production process;
- Keep facilities and equipments clean, and whenever necessary, disinfected;

- Store hazardous substances and dispose of their residues and their packagings materials in such a way as to ensure that they are not a source of hazardous contamination for insects or their products;
- Take account of the results of any relevant analyses carried out, so as to ensure the safety of substrates and/or their ingredients intended for insect feed;

Conservation of records

Proper records must be filled in and kept as regards measures adopted for control of hazardous agents, specifically in what concerns:

- Presence of pests or diseases liable to affect the safety of the products to be obtained;
- Results of all testing conducted on samples collected from the products obtained, or from other samples collected for diagnosis purposes, important for the safety of the feed produced;
- Filling-in and conservation of proper records on the origin and quantity at entry of substrates and/or their ingredients for insect feed, as well as on the destination and quantity at exit of processed animal proteins derived from breeding, or others products obtained.

Good feed practices

- facilities and equipments must be designed in such a way that they are easily cleaned;
- chemical products used in cleaning and disinfection, besides being duly approved, must be used in accordance with the instructions and stored away from any production areas and insect nutrition;
- an effective pest control system must be put in place;
- systems for regularly removing residual material and other potential sources of insect contamination or their products must be put in place;
- Substrates and/or their ingredients intended for insect feed must be labelled and stored away from the chemical products and other products prohibited for animal consumption;
- Storage areas and containers must be kept clean and dry, and whenever necessary, appropriate measures must be taken on pest control and preventing cross contamination;
- staff responsible for insect production and handling must possess the necessary skills and qualifications.

8.6. Insect slaughter

Invertebrates are excluded from the scope of application of Council Directive 98/58/EC of 20 July 1998, concerning welfare of animals kept for farming purposes. In the absence of welfare standards and legal provisions on their slaughter, good practices for killing must be applied. Although it is unlikely that suffering, fear or tension exist during insect slaughter, the precautionary principle must nevertheless be observed and procedures that ensure a speedy and effective death must be followed.

The method used depends on breeding conditions and the desired final product.

It is nevertheless advisable to apply some internationally acknowledged procedures as appropriate slaughter methods for insects, such as freezing, heating (cooking or rapid dehydration) and crushing, notwithstanding other slaughter methods which may be deemed appropriate.

9. INSECT PROCESSING

9.1. Insect Processing

Processed animal protein derived from farmed insects must be produced in processing plants approved by DGAV in compliance with Article 24(1)(a) of Regulation (EC) No. 1069/2009 on by-products of animal origin not intended for human consumption and derived products which are exclusively dedicated to the production of products derived from farmed insects.

Processing plants must apply procedures based on the principles of risk analysis and critical control points (HACCP) and keep written records of them as laid down in Article 29 of said regulation.

Operators must also be registered with DGAV as producers of derivatives and by-products of the feed sector as provided for in Article 9 of Regulation (EC) No. 1831/2003 and in full compliance of obligations under Article 5.

Processed animal protein produced must comply with the microbiological standards of Chapter I of Annex X to Regulation (EU) No. 1831/2003.

9.2. Production of processed animal protein derived from farmed insects

The following specific conditions are applicable to the production of processed animal protein derived from farmed insects intended for feed:

- a) Processed animal protein derived from farmed insects must be produced in compliance with requirements laid down in Section 1, Chapter II, Annex X to Regulation (EU) No. 1831/2003;

b) Processed animal protein derived from farmed insects intended for production of feed for farmed animals, with the exception of fur animals, may only be obtained from the following insect species (Figure 26):

- i) Black-soldier-fly (*hermetia illucens*) and common house fly (*musca domestica*),
- ii) mealworm (*mealworm molitor*) and lesser mealworm (*alphitobius diaperinus*),
- iii) House cricket (*acheta domestica*), banded cricket (*gryllodes sigillatus*) and field cricket (*gryllus thusilis*).

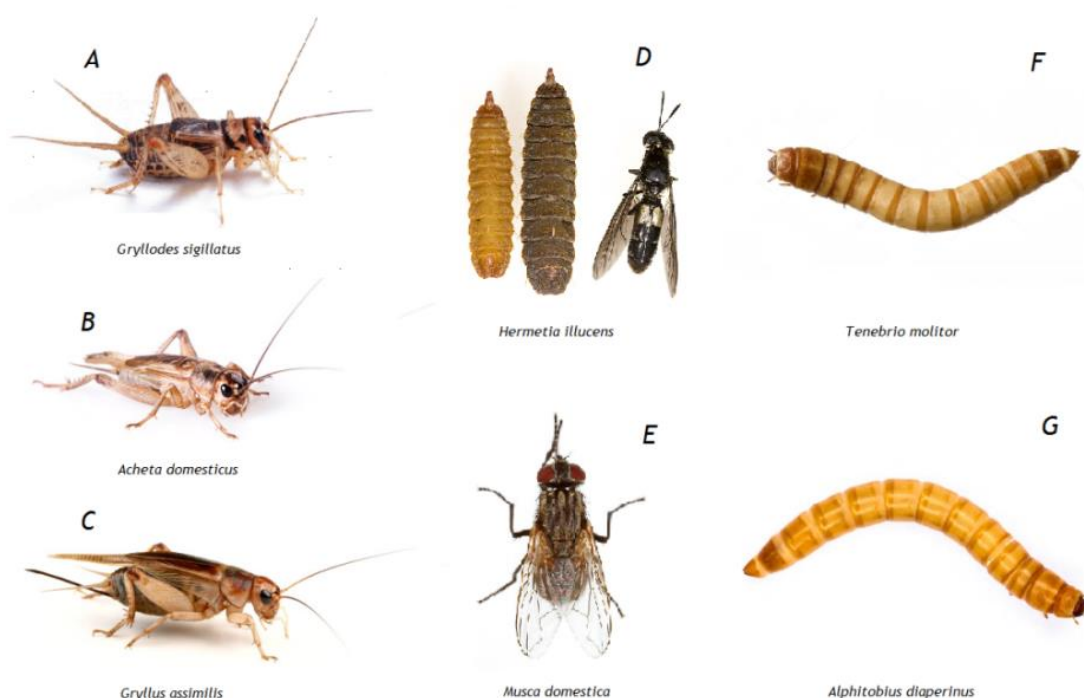


Figure 26 - Insect species allowed according to Regulation (EU) No. 2017/893
A - Adult stage of the banded cricket(adapted from warrenphotographic.co.uk), B - Adult stage of the house cricket(adapted from bat-rodents.eu), C - Adult stage of the field cricket(adapted from bat-rodents.eu), D Larva of the black soldier Fly (adapted from bugguide.net), E - Adult stage of the common house fly(adapted from bugguide.net), F - Mealworm Larvae (adapted from dreamstime.com) and G - Lesser mealworm larvae (adapted from shutterstock.com)

Processed animal protein derived from farmed insects must have been submitted to one of processing methods 1 to 5 or processing method 7, established in Annex IV, chapter III to Regulation (EU) No. 142/2011 whose main characteristics are listed in table 2:

Table 2. Specifications of the treatments applied during processing according to methods 1 to 5 (Adapted from Regulation (EU) No. 142/2011)

Processing method	Particle size	Duration	Central Temperature	Pressure	Observations
Method 1	<50 mm	20 minutes	133 ° C	> 3 bar	discontinuous or continuous system
Method 2	<150 mm	125 minutes	>100 ° C		discontinuous system
		120 minutes	>110 ° C		
		50 minutes	>120 ° C		
Method 3	<30 mm	95 minutes	>100 ° C		discontinuous or continuous system
		55 minutes	>110 ° C		
		13 minutes	>120 ° C		
Method 4 ¹	<30 mm	16 minutes	>100 ° C		discontinuous or continuous system.
		13 minutes	>110 ° C		
		8 minutes	>120 ° C		
		3 minutes	>130 ° C		
Method 5 ²	<20 mm	120 minutes	>80 ° C		discontinuous or continuous system.
		60 minutes	>100 ° C		

1. After being reduced and before heating animal by-products must be placed in a container with added fat.
2. After being reduced and before heating for the second time, animal by-products must be heated until they coagulate and then submitted to pressing until fat and water are removed from the protein materials.

Processing method 7

Any processing method where the following have been demonstrated:

- 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 State or the area 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:

Samples of material taken directly after treatment:

- i) *Clostridium perfringens* absent in 1 gram of the products

Samples of materials 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 em 1 g

Where

n = the 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 bacteria number; the result is considered unsatisfactory if the bacteria count 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.

- d. Registration and monitoring of particles size and, if necessary, critical temperature, absolute time, pressure profile, feed flow of raw materials and fat recycling rate.

9.3. Other products

Breeding insects may result in products of interest for other areas, namely:

Insect oil

Chitin

Fertilizer

Insect oil is used in areas that range from feed to cosmetics and to pharmaceuticals and biofuels. Insects may be very rich in fat and their lipid component can be efficiently extracted. They are also rich in fatty acids with significant nutritional and pharmacological characteristics, and can be submitted to a purification process. Thus, new technologies may give rise to innovative business lines that resort to fine processing of products generated in insect breeding.

Chitin, on the other hand, is a significant part of insects, as it constitutes their exoskeleton. However, despite its presence being more abundant in the adult stages, insects produced can be submitted to an extraction process of this component, which may be commercialized for various industrial purposes (Table 3).

Table 3 - Industrial applications of insect-derived products (Adopted from: Dossey, A. T., Morales-Ramos, J. A, Rojas, M.G. Insects As Sustainable Food Ingredients: Production, Processing And Food Applications. Chippenham: Elsevier, 2016)

Cosmetics	Lipstick, soap, nail polish
Pharmaceuticals	Antibiotics, toothpaste, cough syrup, nasal solutions
Food Industry	Hamburgers, soups, sausages, ice-cream
Textiles	Wool, textiles, carpets
Wine	Aromatized fortified wines and alcoholic liqueurs
Beverages	Light beverages

Whether compound feedingstuffs or whether by-products bioconversion are used, the productive process of insects will produce a very large quantity of digested substrate. This substrate entirely digested by insects is a stable product that can be directly used on agricultural land and has a very wide field of applications, from fruit and vegetable and flower production, to pastures and forages. Organic fertilizer generated by the process of byproduct

bioconversion can be one of the main products resulting from large-scale production of insects, with significant financial gains. Great care must be taken to ensure the quality and safety of the final product.

Current legislation on the application of this type of products on the soil and quality standards must be complied with. This product, inasmuch as it is insect-based, must be submitted to a process that totally eliminates live insects, ensuring that spreading these fertilizers on the land does not contribute to the dissemination in nature of these species. It is therefore advisable to resort to chemical or physical processes that ensure complete elimination of live insects in the fertilizer, regardless of their developmental stage.

10. PLACING ON THE MARKET OF ANIMAL PRODUCTS DERIVED FROM INSECTS

10.1. Packaging

Regulation (EC) No. 767/2009 packaging requirements must be complied with, complemented by provisions under Regulation (EC) No. 142/2011.

Feed materials and compound feed may be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that, when the package or container is opened, the seal is damaged and cannot be reused.

Compound feedingstuffs containing processed animal protein derived from farmed insects may however be marketed in bulk (in containers or covered vehicles), or in unsealed packaging or containers, in the case of:

- deliveries between producers of compound feed;
- deliveries of compound feed directly from the producer to the feed user;
- deliveries from producers of compound feed to packaging firms;
- quantities of compound feed not exceeding 50 kilograms in weight which are intended for the final user and are taken directly from a sealed package or container.

10.2. Labelling

Without prejudice to mandatory labelling requirements whether general, specific or additional laid down in Regulation (EC) No. 767/2009, placing on the market of raw materials of animal origin consisting in processed animal protein, including those originating from insects, as well as feed containing them, must also comply with provisions laid down in D.L. No. 76/2003, Regulation (EC) No. 2017/1017 and/or Annex IV to Regulation (EC) No. 999/2001 as amended by Regulation (EU) No. 2017/893, namely:

10.2.1. Raw materials of animal origin consisting in processed animal protein derived from farmed insects, or the insects themselves dead or alive.

Marketing of raw materials that consist in processed animal protein originating from farmed insects, or dead or alive insects, must comply with general mandatory labelling requirements and specific mandatory labelling requirements of raw materials for feed, as laid down in Articles 15 and 16, respectively of Regulation (EC) No. 767/2009, complemented by the mandatory declarations established for each raw materials of the category at stake, according to paragraphs 9.4.1., 9.16.1. and 9.16.2. of the list of raw materials in Part C of the EU Catalogue of Feed Materials, whose latest version is published in Regulation (EC) No. 2017/1017.

Note: There must also be compliance with provisions under footnotes 33 and 34 on complementing the designation of raw materials as appropriate, such as: by animal species of the insect, by life stage (for example, larva), and/or by the naming of the animal species not used in respect of the ban on intra-species recycling.

In the case of processed animal proteins originating from farmed insects, Regulation (EC) No. 999/2001, Annex IV, Chapter IV(F)(c) also applies:

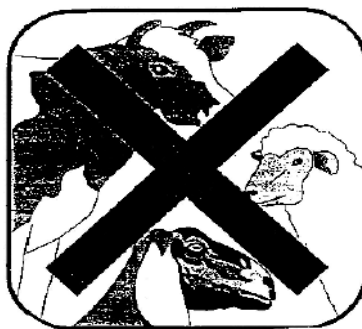
“Processed proteins derived from insects – do not use in farmed animal feed, except aquaculture animals intended for fur production”

10.2.2. Compound feedingstuffs containing processed animal proteins derived from farmed insects

Marketing of compound feedingstuffs containing processed animal protein derived from farmed insects must observe general and specific labelling requirements for compound feedingstuffs, as laid down in Articles 15 and 17 of Regulation (EC) No. 767/2009. And additionally provisions under Regulation (EC) No. 999/2001, Annex IV, Chapter IV(F)(c):

“Contains processed animal protein of non-ruminant origin – do not use in farmed animals feed, except aquaculture animals and animals intended for fur production”

Besides this mention, as a reinforcement measure of the labelling provisions, packaging material or the packaging container must bear the pictorial indication in red, by means of direct printing or by stamping, of the animal species for which compound feed is prohibited, according to the form established in D.L. No. 76/2003 Article 14(3):



Note: In the case of compound feedingstuffs for pets additional mandatory labelling requirements applicable to pet food must be observed, according to Article 19 of Regulation (EC) No. 767/2009.

10.3. Transport Documents (commercial document)

During transportation from the producer to the place of destination, processed animal protein derived from farmed insects must be accompanied by a commercial document.

The commercial document must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.

For transport within the European Union, the commercial document must be in accordance with the model set out in Chapter III, Annex VIII to Regulation (EU) No. 142/2011. Arrival of the consignment must be confirmed via the TRACES system.

In national transport, the commercial document must be in accordance with Form 376/DGV adopted under Regulation (EC) No. 142/2011, Annex VIII, Chapter III (4)(2) and transposed by Decree no. 8442/2017 of 26 September.

Records and related commercial documents or health certificates shall be kept for a period of at least two years for presentation to the competent authority.

10.4. Storage and Transport

Storage and transport of raw materials of animal origin consisting in processed animal protein, including those originating from farmed insects, as well as feed containing them, must comply with provisions under Regulation (EC) No. 183/2005, complemented by Regulation (EC) No. 1069/2009, implemented by Regulation (EU) No. 142/2011 in conjunction with those of Annex IV to Regulation (EC) No. 999/2001.

The following minimum conditions must be observed:

- Processed feed must be separated from raw materials for non processed feed and additives, in order to avoid cross contamination of processed food;
- Feed must be stored and transported in appropriate containers. Containers must be stored in designated sites, adapted and maintained in such a way as to ensure good storage conditions, and accessible only to approved personnel;
- Feed must be stored and transported in such a way that they are easily identified, in order to avoid confusions, cross- contamination and deteriorations;
- Reusable containers must be dedicated to the carriage of a particular animal by-product or derived product to the extent necessary to avoid cross-contamination.
- Containers and equipment used for transportation, storage, displacement, handling and weighing must be maintained in a clean state. There must be cleaning and disinfection programmes and minimized all traces of detergents and desinfetants. All storage units must be emptied and cleaned on a regular basis, as often as necessary to prevent contamination;
- Deterioration must be kept to a minimum and under control at all times, in order to reduce pest invasion or other contaminations, including environmental contamination;
- Temperatures must be kept as low as possible to avoid condensation and deterioration. All necessary measures must be taken to minimize condensation inside silos, other storage sites, conveyor systems or elevators.

All operators working exclusively in transportation or storage, namely hauliers or storekeepers without commercial activities as regards raw materials of animal origin consisting in processed animal protein, including those originating from farmed insects, as well as the feed containing them, must be registered under Article 9 of Regulation (EC) No. 183/2005. Transportation or storage conducted by operators already registered or approved under Regulation (EC) No. 183/2005 (manufacturers or intermediaries with establishments), or operators producers of products derived from animal origin, namely rendering plants, do not require additional registration as a transporter or storekeeper. (This last derogation is provided by Article 23(4) of Regulation (EC) No. 1069/2009, namely Article 24(1)(j)(iii).

Raw materials consisting in processed animal protein originating from farmed insects, or the compound feedingstuffs containing them, must be kept as dry as possible.

10.4.1. Bulk storage and transport

According to Regulation (EC) No. 999/2001, Annex IV (III)(A) transport and storage of bulk processed animal protein originating from non-ruminants, including processed animal protein originating from farmed insects, as well as bulk compound feedingstuffs containing them, must be transported in vehicles and containers and stored in storage facilities that are not used for, respectively, transport or storage of feed for ruminants, or of feed intended for farmed non-ruminants, with the exception of aquaculture animals. Detailed records on the type of products that were transported or stored in a storage unit must be kept at the disposal of the competent authority during a period of, at least, two years.

By way of derogation to the provisions of the paragraph above, vehicles, containers and storage facilities that were previously used in transportation or storage of said products, may be subsequently used in transportation or storage of ruminants feed, or of feed intended for farmed non-ruminants, with the exception of aquaculture animals, as long as they are previously cleaned in order to avoid cross-contamination, in compliance with a documented procedure previously approved by DGAV. A formal approval application must be sent using a standardized form (Form 1253/DGAV), with the respective cleaning procedure set out in the annex.

The cleaning procedure must comply with the following requirements:

- In the case of loads with a high protein or fat content a (semi) strong alkaline detergent must be used, in the dosage prescribed by the manufacturer;
- A higher water temperature is required to remove fats more easily. However, temperature must not exceed 60°C to prevent protein coagulation and its consequent adherence to surfaces;
- In open loads it is advisable to use foam fat-removing detergent. However, in wagons or closed compartments, foam detergent cannot be used, and it is preferable to use a “Clean in Place” (CIP) system as an alternative to high temperature detergent;
- During cleaning, wastewater run-off must be ensured;
- Depending on the nature of the subsequent load, the vehicle must be allowed to dry by means of sufficient natural ventilation or using a hot air pistol;
- It is further advisable to regularly test surfaces after cleaning after bulk transportation of products with biological contamination, for detection of constituents of animal origin.

Whenever this procedure is used, a documented record must be kept at the disposal of the competent authority during a period of at least two years.

10.4.2. Storage and transport of packaged goods

Raw materials of animal origin consisting in processed animal protein, including those originating from farmed insects as well as compound feedingstuffs containing them, must be packed and stored in new or sterilised bags and duly sealed so that its opening makes re-use impossible.

Storage and transport of raw materials of animal origin consisting in processed animal protein, including those originating from farmed insects as well as compound feedingstuffs containing them, must be stored and transported in such a way as to be easily identified, in order to avoid confusions, cross contamination and/or any deteriorations.

Re-usable vehicles and containers, equipments or tools, as well as storage areas, must be kept in good hygiene conditions.

10.5. Distribution

Feed business operators, other than manufacturers, who hold or put into circulation processed animal proteins originating from farmed insects, or compound feedingstuffs containing them, in an intermediate stage between production and use, including packing, must register as an intermediary distributor in the feed sector, under Article 9 of Regulation (EC) No. 183/2005.

10.6. Intracommunity trade

In intracommunity trade, consignments of processed animal proteins originating from farmed insects must be accompanied by the commercial document set out in Chapter III of Annex VIII to Regulation (EU) No. 142/201. For purposes of prior notification, the competent authority of the Member State (MS) of origin must notify DGAV, via TRACES, on the dispatch of each consignment.

Note: In intracommunity trade labelling provisions laid down in Chapter 10.2 must be complied with.

Feed business operators responsible for intracommunity trade of processed animal proteins intended for feed and originating from farmed insects, or of compound feedingstuffs containing them must register as a intermediary distributor in the feed sector, under Article 9 of Regulation (EC) No. 183/2005.

10.7. Imports from third countries

In the case of imports of processed animal proteins originating from farmed insects being constituted as raw materials for feed, as well as any feed containing them, feed business operators responsible for the consignment, or their legal representative, must fulfill the responsibilities and the legal requirements applicable to imports and subsequent placing on the market or use of feed originating from third countries.

More information is available in the Manual of Good Practices “Feed Imports originating from Third countries: Obligations of the sector operators”.

Considering the nature of the product, the feed business operator responsible for the consignment, or his legal representative, is required to proceed to prior notification by means of filling in Part I of the Common Veterinary Entry Document (CVED). To the CVED must always be attached the specific health certificate according to the nature and destination of the product to be imported, or others that legal provisions in force require, besides the relevant commercial documents.

Imports of processed animal proteins originating from farmed insects may only be approved if requirements laid down in Regulation (EU) No. 142/2011 are met, which implements Regulation (EC) No. 1069/2009, namely provisions in the first line of table 1 of Section I and number 5 of Section 2, both from Chapter I of its Annex XIV, namely:

a) they must consist of or have been produced from, as applicable, Category 3 materials referred to in Article 10 of Regulation (EC) No. 1069/2009 (a), (b), (d), (e), (f), (h), (i), (j), (k), (l) and (m);

b) they must comply with the import and transit conditions established;

c) they must come from a third country and establishments indicated on the lists approved according to the type of product and sector at stake, made available on the COM link:

http://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en

c) they must be accompanied by a health certificate in compliance with the model adopted for “Processed animal protein derived from farmed insects not intended for human consumption, including mixtures and products other than petfood containing such proteins, for dispatch to or for transit through the European Union”, stated in Chapter 1-A of Annex XV to Regulation (EU) No. 142/2011.

Note: In the case of imports originating from third countries, labelling provisions laid down in Chapter 10.2. are applicable

Feed sector operators responsible for third country imports of processed animal proteins intended for feed and derived from farmed insects, or of compound feedingstuffs containing them, are required to register as a intermediary distribuidor in the feed sector, under Article 9 of Regulation (EC) No. 183/2005.

10.8. Exports to third countries

Insect-derived PAP are currently approved in the EU for use in aquaculture, pet food and fur producing animals, as well as for purposes other than the food chain.

PAP referred to in the preceding paragraph may only be produced from Category 3 materials indicated in Regulation (EC) No. 1069/2009 Article 10(a) to (m), in by-products processing plants approved by the competent authority of the Member State of origin.

These PAP are listed in the Catalogue of feed materials, and their placing on the market as feed requires fulfilling legally applicable safety and labelling requirements.

Exports of PAP derived from insects or of compound feedingstuffs containing such proteins, are subject to the fulfilment of the following conditions:

- a) PAP derived from insect production must be produced in approved rendering plants exclusively dedicated to the production of products derived from farmed insects. The list of national establishments authorized to supply PAP from non-ruminants, including those from farmed insects, for the manufacture of aquaculture feed may be consulted at:

<https://sipace.dgv.min-agriculture.pt/Establishments/OtherListas?s.Lista=4>

Note: For purposes of exports approval, the rendering plant of origin must demonstrate a compliance degree of at least 2 in the scope of the last check under the Plan of Approval and Control of the Establishments (PACE).

- b) Compound feedingstuffs containing PAP derived from non-ruminants, including those of farmed insects, must be produced in establishments approved by the competent authority that are dedicated exclusively to aquaculture feed production. Such national establishments may be consulted at:

<http://www.dgv.min-agriculture.pt/portal/page/portal/DGV/genericos?generico=201155&cboui=201155>

Note: For purposes of export approvals, the food business operator of origin of compound feedingstuffs containing PAP derived from non-ruminants must demonstrate a compliance degree of at least 2 in the last check under the National Official Control Plan (NOCP).

- c) By way of derogation from the condition laid down in (b), the competent authority may approve the production of compound feedingstuffs for aquaculture animals in establishments that also produce compound feedingstuffs intended for other farmed

animals, except animals intended for fur production, as long as during the on-the-spot control the following conditions are complied with:

- Compound feedingstuffs for ruminants must be processed and kept, during storage, transportation and packaging, in facilities physically separated from the facilities where the compound feedingstuffs for non-ruminants are processed and stored;
 - Compound feedingstuffs for aquaculture animals must be processed and kept, during storage, transportation and packing, in facilities physically separated from the facilities where the compound feedingstuffs for non-ruminants are processed and stored;
 - Detailed records of purchases and uses of PAP, as well as of the sales of compound feedingstuffs containing these proteins must be kept at the disposal of the competent authority during at least five years;
 - Implementing a detailed documented plan of regular PAP sampling and testing so as to evidence the lack of ruminant protein, whose records must be kept during at least five years. Sampling and testing frequency is determined by the the operator on the basis of risk assessment, as part of procedures based on HACCP principles. Methods of analysis established in Annex IV to Commission Regulation (EC) No. 152/2009 of 27 January 2009 shall be used.
- d) When leaving EU territory, processed animal protein derived from non-ruminants, including compound feedingstuffs containing them, must be accompanied by the health certificate applicable to the nature of the consignment at stake and issued by the veterinary competent authority of the region where the rendering plant is located, of the compound feed operator of origin, as well as of the appropriate commercial documents.
- e) For purposes of exports of processed animal protein intended for feed and originating from farmed insects, or of the compound feedingstuffs containing them, the operators must establish themselves as feed business operators and be registered in accordance with their main business, under Article 9 of Regulation (EC) No. 183/2005.

Note: For purposes of issuing the appropriate health certificate, the operator must previously contact DGAV to request issuance of a proper health certificate according to the third country of destination.

11. USE OF PROCESSED ANIMAL PROTEINS DERIVED FROM FARMED INSECTS AND PRODUCTS DERIVED FROM INSECTS

Under current legislation, use in food-producing animals of compound feed containing processed animal protein derived from farmed insects is only allowed in aquaculture animals feed, as long as produced, marketed and used in compliance with the general conditions laid out in Chapter III and with the specific conditions laid out in Section F, Chapter IV of Annex IV to Regulation (EU) No. 2017/893.

Use of insect oil in feed is not subject to any health or biosafety restrictions, so its use in all species/categories animals is as of now possible, as long as the organoleptic characteristics of the final products are ensured, maintaining compound feed palatability and aroma, as well as their proper nutritional content as regards crude fat.

Use of dead or alive insects in feed of food-producing animals is not currently legislated, and is therefore not approved.

NOTE: there are no restrictions as regards the use of processed animal protein derived from farmed insects in pet food and fur animals producers.

11.1. Manufacture of compound feedingstuffs containing processed animal proteins derived from farmed insects

For the production of compound feedingstuffs containing processed animal protein derived from farmed insects, and intended for aquaculture animal feed, the following specific conditions shall apply:

Compound feedingstuffs containing processed animal protein derived from farmed insects must be produced in establishments approved for this purpose by the competent authority and that are dedicated to the production of aquaculture feed. For this purpose they require registration/approval by DGAV as compound feedingstuffs business operator, according to Article 9 or 10, respectively, of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council, of 17 September 2003, laying requirements for feed hygiene. As processed animal proteins originating from farmed insects they must comply with the requirements laid down in Chapter 9 of this Manual.

Note: Manufacture of compound feedingstuff for pets or fur animals containing processed animal protein derived from farmed insects must be carried out in establishments approved for this purpose by the competent authority, by means of registration under Article 9 of Regulation (EC) No. 1831/2003 as compound feed business operator. These operators also require approval under Regulation (EC) No. 1069/2009 Article 24(e) on by-products of animal origin not intended for human consumption and derived products.

Production of compound feedstuffs containing processed animal protein derived from farmed insects, and intended for aquaculture animals in establishments that also produce compound feedingstuffs intended for other farmed animals, except animals intended for fur production, must be approved by the competent authority. For this purpose a formal approval application for appropriate use must be submitted, which shall be followed by an in situ inspection of the site to check on the following conditions:

- Compound feedingstuffs for ruminants must be processed and kept, during storage, transport and packaging, in facilities physically separated from the facilities in which are processed and kept compound feedingstuffs for non-ruminants;
- Compound feedingstuffs for aquaculture animals must be processed and kept, during storage, transport and packaging, in facilities physically separated from the facilities in which are processed and kept compound feedingstuffs for other non-ruminants;
- Detailed records of purchases and of uses of processed animal protein originating from farmed insects, as well as the sales of compound feedingstuffs containing these proteins must be kept at the disposal of the competent authority for at least five years;
- Sampling and testing of the compound feedingstuffs for farmed animals, with the exception of aquaculture animals, must be performed regularly, in order to establish the absence of non-approved constituents of animal origin and determine the constituents of animal origin in the scope of feed control laid down in Annex VI to Regulation (EC) No. 152/2009; sampling and testing frequency is established by the the operator on the basis of risk assessment, as part of procedures based on HACCP principles; results must be kept at the disposal of the competent authority for at least five years.

Specific approval for the production of complete feedingstuffs from compound feedingstuffs containing processed animal protein derived from farmed insects shall not be required from home compounders that comply with following conditions:

- Are registered with the competent authority as producing complete feed from compound feedingstuffs containing processed animal protein originating from farmed insects;
- Only keep aquaculture animals, and
- Use in production compound feedingstuffs containing processed animal protein derived from farmed insects, with less than 50 % of gross protein.

11.2. Distribution in the fish farms of compound feedingstuffs containing processed animal protein derived from farmed insects

Aquacultures must ensure that they only purchase feed in establishments duly registered or approved by DGAV. When purchasing products, these must be accompanied by the respective documents, such as notes of consignment and/or invoices, label/sign/ tag, in order to ensure proper traceability.

Compound feedingstuffs for aquaculture animals containing processed animal protein derived from farmed insects must comply with labelling provisions established by Regulations (EC) No.767/2009, No. 2017/1017, No. 2017/893 and D.L. No. 76/2003, as described in Chapter 10.2. Storage and use of processed animal protein derived from farmed insects and of compound feedingstuffs containing them, are prohibited in holdings that keep species of farmed animals for which these feeds are not intended. However DGAV may approve the use and the storage of compound feedingstuffs containing processed animal protein derived from farmed insects in holdings that keep species of farmed animals for which these compound feedingstuffs are not intended, as long as the appropriate measures are implemented in the holding to prevent such feedingstuffs from being consumed by the animal species for which they are not intended.

The feed distribution system in the fish farm must be such that the feed used is appropriate for the animal species and developmental stage for which they are intended. During distribution and feeding of the fish, feed must be handled in such a way as to avoid any spoiling originating from storage areas or from equipments which may not be properly cleaned. Handling and distribution of medicated feedingstuff must be kept separate from other feed, in order to avoid any contamination. Vehicles used for food transport in holdings as well as the equipment for its distribution must be maintained in a good state of conservation.

12.REGISTRATION/APPROVAL OF ESTABLISHMENTS

Any undertaking, for profit or not, public or private, that engages in any feed production, manufacture, processing, storage, transportation or distribution activities, including any operator that produces, processes or stores feedstuffs in its own holding, is considered as a feed business operator under Regulation (EC) No. 183/2005.

For purposes of, and considering Article 11 of that regulation, feed business operators must not exercise their activity:

- a) Without the registration indicated in Article 9;
- b) Without the approval, when required under Article 10.

Registration or approval is awarded by DGAV, as the National Competent Authority, considering all stages of the chain, from primary feed production to its placing on the market. Registration or approval entails awarding an Individual Identification Number (IIN) to the feed business establishment, according to the its main activity.

Regulation (EC) No. 1069/2009 may also be applicable, namely the concomittant approval under Article 24 for any activities that in the scope of this Manual pertain to processing of farmed insects and to manufacture of pet food, with award of a Veterinary Control Number (VCN).

Registration or approval under Regulation (EC) No. 183/2005 is performed by means of formal approval application to the Director-General of Feed and Veterinary Affairs that, together with the other required documents, must be sent to the e-mail address establishmentsaa@dgav.pt.

Table 4 - Models for formal approval applications or other legally required documents, according to the activity developed in the scope of insect processing and use in feed

ACTIVITIES OF THE ANIMAL FEED SECTOR	TEMPLATES			OTHERS DOCUMENTS
	Approval	Registration	Responsible entities	
Producer of derived and by-products of animal origin		667/DGAV	557/DGAV 558/DGAV	<ul style="list-style-type: none"> • Proof of the industrial licensing ⁽¹⁾ • Proof of the VCN ⁽²⁾
Feed Storekeeper without trade		572/DGAV		<ul style="list-style-type: none"> • Proof of the updated tax register ⁽³⁾
animal feed transporter		567/DGAV 1253/DGAV ^(*)		<ul style="list-style-type: none"> • Proof of the updated tax register ⁽³⁾
Manufacturer of compound feedingstuffs for aquaculture animals containing animal protein derived from farmed insects	560/DGAV 754/DGAV ^(**)	563/DGAV 754/DGAV ^(**)	557/DGAV 558/DGAV	<ul style="list-style-type: none"> • Proof of the industrial licensing ⁽¹⁾
Compound feedingstuffs for pets and fur animals producers	560/DGAV	563/DGAV	557/DGAV 558/DGAV	<ul style="list-style-type: none"> • Proof of the industrial licensing ⁽¹⁾ • Proof of VCN ⁽²⁾
Intermediary distribuidor	562/DGAV	565/DGAV	559/DGAV	<ul style="list-style-type: none"> • Proof of the updated tax register⁽³⁾ • Proof of the municipal use license of the establishment ⁽⁴⁾
The operator/Receiver UE		565/DGAV	559/DGAV	
Importer from third countries		565/DGAV	559/DGAV	

⁽¹⁾ Industrial Licensing in the scope of the System of Responsible Industry (SIR) under D.L. No. 169/2012 of 01 August;

⁽²⁾ Approval under Article 24 of Regulation (EC) No. 1069/2009, with award of VCN, for the activities that in the scope of this manual are dedicated to processing of farmed insects and to manufacture of pet food;

⁽³⁾ Copy of the electronic declaration obtained in the portal of the Tax Authority in the feed sector or similar updated tax document. Anyone wishing to engage in intracommunity trade and/or imports from third countries must state it in the tax document;

⁽⁴⁾ Access and exercise of trade, services and catering activities (LSAECSCI). Exception is made to feed businesses that only engage in trade without storage facilities ("broker");

^(*) Specific approval for use of same vehicles or containers in bulk transport of feed that consists in or contains raw materials of animal origin;

^(**) Use of raw materials of animal origin and approval for production in the same establishment of feed for ruminants or other feed for farmed animals that do not contain processed animal proteins and other processed products of animal origin.

Note: Additional Information on registration/approval of feed business operators may be consulted via the link to DGAV's website: <http://www.dgav.min-agriculture.pt/portal/page/portal/DGAV/genericos?generico=1166810&cboui=1166810>

13. PLACING ON THE MARKET AND INSECTS USE (DEAD OR ALIVE)

Non-processed insects cannot be used in farmed animals feeding, in view of the requirements of the animal protein ban in feed laid down in Regulation (EC) No. 999/2001. Insect feed with insects is prohibited by the intra-species recycling provisions laid down in Regulation (EC) No. 1069/2009, as well as the potential composition of substrate for insect feed under Regulation (EC) No. 2017/893.

If previously approved by the competent authority, provisions in Regulation (EU) No. 142/2011 Annex XIII, (II)(3)(v) allow the treatment of insects intended for pet food production that ensures that said insects do not pose unacceptable risks for public and animal health. However the pet market does place on the market non-processed insects packed in boxes for certain animal species, such as reptiles, in relatively limited distribution chains.

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