

General Introduction

1. Why is NACIA developing this best practices Guide?

The Guide aims to support North American food and feed safety regulation by producers active in the production of insects for food and/or feed. In turn, this will also help the insect producers to achieve a high level of consumer protection and animal health. The guide is developed in accordance with Canadian and US regulations governing the safe preparation of insect diets, rearing of insects, and processing insects into derived products, keeping in mind that the Guide does not aim to substitute or replace these national regulatory provisions.

2. Who is the author of this Guide?

This document has been drafted by a NACIA internal working group of experts representing companies active in the production of insects as food and feed. Based on input coming from producers, this document also reflects standards being followed by North American insect producers.

3. What does the Guide contain?

This guide contains general recommendations for operators to implement good practices in the area of food and feed safety, in accordance with applicable US and Canadian regulatory standards. To this end, it also comprises extensive references to the respective US and Canadian pieces of legislation.

Encompassing both food and feed applications of insect production, this guide discusses feedstock control, diet preparation, rearing, breeding, devitalization and post processing.

4. Does the Guide cover subjects such as animal health or welfare, environmental, or building standards?

No, the scope of the Guide is strictly limited to food and feed safety standards. However, references to those other relevant topics mentioned in the title are sometimes provided in the Guide (e.g. biosecurity, etc).

Furthermore, this document is not an “Instruction Manual” for insect production: indeed, the document is not intended to describe all possible techniques or methods for producing insects, nor does it present production building structures or equipment to be used in the framework of insect producing activities.

5. For whom is this Guide intended?

The document is mainly intended for insect producers in North America.

6. Is the Guide legally binding for insect producers and what is its legal status?

The document is a non-binding document, drafted under the sole initiative of the NACIA.

7. Will this Guide be reviewed in the future?

The Guide will be reviewed annually by the Regulatory Work Group. The Work Group will recommend amendments, when needed, to the NACIA Board for review and approval.

This document does not address the subject of insects for technical uses (e.g. biofuel production, cosmetics, biochemistry) since these activities do not fall within the scope of the present Guide (see introduction).

Contributing Authors (alpha order):

Alexx Blazzard, Chapul Farms
Aline Spindola, Enviroflight
Audrey Fleury, Entosystem
Barbara Campbell, NPC
Brenden Campbell, Planet Bugs
Erik Neff, Fluker Farms
Gabe Mott, Aspire
Gabriel Rubin, Entoboros™ LLC
Ian Banks, EnviroFlight

Jennifer Larouche, Université Laval
Kelly Hagen, Entomo Farms
Liz Koutsos, Enviroflight
Marie-Hélène Deschamps, Université Laval
Maye Walraven, Innovafeed
Muhammad Akhtar, Aspire
Trina Chiasson, Ovipost
Serena Harrington, Aspire
Virginia Emery, BetaHatch

Editors:

Aaron Hobbs
Sarah DeRaedt

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Table of Abbreviations

AAFCO	Association of American Feed Control Officials
ACIR	Agricultural Commodity Import Requirements
APHIS	Animal and Plant Health Inspection Service
BSFL	Black Soldier Fly Larvae
°C	Degrees Celsius
CFI	Common Food Index
CFIA	Canadian Food Inspection Agency
CFIT	Canadian Feed Ingredients Table
CFR	Code of Federal Regulations
cGMPs	Current Good Manufacturing Practices
CIP	Cleaning-In-Place
CO ₂	Carbon dioxide
COP	Cleaning-Out-of-Place
CVM	Center for Veterinary Medicine
EU	European Union
°F	Degrees Fahrenheit
FAP	Food Additive Petition
FCMs	Food Contact Materials
FD&C	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FEFO	First-Expired/First-Out
FIC	Food Information to Consumers
FIFO	First-In/First-Out
FSMA	Food Safety Modernization Act
GHPs	Good Hygiene Practices
GMPs	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis Critical Control Point
HARCP	Hazard analysis Risk-based Preventive Controls
IREGS	International Animal Product Export Regulations
NACIA	North American Coalition for Insect Agriculture
NH ₃	Anhydrous Ammonia
OP	Official Publication
PCB	Polychlorinated Biphenyls
PCQI	Preventive Controls Qualified Individual
PPE	Personal Protective Equipment
PRPs	PreRequisite Programs
QA	Quality Assurance
QC	Quality Control
RAC	Raw Agricultural Commodity
US	United States
USDA	United States Department of Agriculture
VS	Veterinary Services

CHAPTER 1 – *Food and Safety Management Systems: General Principles and North American Requirements*

1.1 Introduction

This chapter aims to capture and communicate best practices and regulatory requirements of North American food and feed safety standards for the insect industry. The recommendations and regulations shared focus on the two primary end-use paths, human food and animal feed, including pets. As a general recommendation, North American insect producers should be aware of the currently applicable rules and regulations at the country, state, and local levels.

Farming, food, and feed safety are generally regulated at the federal level, with assistance, including labeling and inspection, taking place at the state level. States and localities help enforce federal rules and regulations and are the primary regulators for activities such as site permitting and building.

1.2 United States Food and Feed Regulations and Recommendations

The Food and Drug Administration (FDA) is the primary regulatory authority in the United States (US) when insects are reared to be used in the food and feed supply chains. The intended use of insects and insect products impacts the specific regulations for individual farms and facilities.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Food Safety Modernization Act (FSMA) are essential laws impacting insect agriculture. These laws provide the guideposts for FDA actions referenced throughout this guideline.

Beginning with the FD&C Act, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with the FDA.

Specifically, owners, operators, or agents in charge of either a domestic or foreign facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States must register with the FDA, unless exempt under

[21 CFR 1.226](#) from the requirement to register. If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce. If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf. However, farms, as defined within US Federal law, are exempt, under certain circumstances, from registration as a food facility with the FDA.

The FDA [website](#) provides a link to a [Question and Answers](#) document regarding registration. The FDA website will provide the most up-to-date information and guidance.

Generally, every facility required to register with the FDA as a food facility must renew its registration every two years, and there is no fee associated with registration or renewal.

When identifying the facility type, it is notable that the FD&C Act defines “food” as “articles used for food or drink for man or other animals” ([21 US Code § 321\(f\) - Definitions](#)). Furthermore, the FD&C Act defines the term “raw agricultural commodity” to mean “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing” ([21 US Code § 321 \(r\) - Definitions](#)). Therefore, NACIA believes insects reared to enter the food and feed supply chains should be considered a “raw agricultural commodity” (RAC).

Considering the above, it is the responsibility of an insect farmer/producer to determine what kind of facility they operate and whether it requires registration based upon their due diligence:

[Here are some resources the FDA has published to assist in identifying the facility type:](#)

- [Questions and Answers Regarding Food Facility Registration](#)
- [Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities](#)

Any facility required to register with the FDA must have a food safety system that complies with FSMA, except for [Qualified Facilities](#). Registered facilities must follow current Good Manufacturing Practices (cGMPs) for animal food production. Covered facilities must also establish and implement a food safety system that includes an analysis of hazards and, if necessary, risk-based preventative controls. The rule sets requirements for a written food safety plan, including hazard analysis, preventative (process, sanitation, and other) controls, oversight and management of preventative controls, and recall plans. More details on cGMPs can be found in Chapter 2.

1.2.1 Animal Feed Ingredient Approval Process for Insect Feed

In the US, animal feed ingredients are regulated at the federal and state levels to ensure they are safe for animal consumption. This includes the feed ingredients in the diet of farmed insects raised for animal feed and pet food applications.

One of the three feed ingredient approval processes is managed by the Association of American Feed Control Officials (AAFCO), which publishes an Official Publication (OP) annually. Chapter 6 – Official Feed Terms, Common or Usual Ingredient Names, and Ingredient Definitions – of the AAFCO OP contains a comprehensive list of animal feed ingredients that can be fed to animals, including insects. Access to the entire AAFCO OP requires payment; however, Chapter 6 is available free of charge by AAFCO and can be found using the following [link](#) or by searching for the term “AAFCO Chapter 6 public access” using an internet search engine.

It is strongly recommended that insect producers familiarize themselves with the AAFCO OP feed ingredient definitions, restrictions, and requirements of the materials they intend to feed to their insects, as well as relevant state regulations.

If an insect producer intends to raise insects for animal feed and pet food applications on feed ingredients that are not listed in the AAFCO OP, it is recommended that they consult with a regulatory consultant or approach AAFCO for guidance.

Additional information regarding insect diets is presented in Chapter 3 of this guide.

1.2.2 Animal Feed & Pet Food

There are three ingredient definition approval processes in the US to approve the use of ingredients in animal feed and pet food. These processes are in place to establish the safety and utility of 1) new ingredients in a target animal or animals or 2) approved ingredients in a new target animal or animals.

The recognized processes for ingredient approvals include:

1. Generally Recognized as Safe (GRAS) for an intended use.
2. FDA Approved Food Additive Petition (FAP).
3. The AAFCO Ingredient Definition Process.

Each process is administered differently and has specific steps. However, all three share the fundamental step of preparing and submitting a dossier/petition. The aim of a dossier/petition is to demonstrate the safety and efficacy of a feed ingredient in a target

animal, and is achieved by summarizing relevant literature and research. The dossier/petition is then reviewed by the FDA Center for Veterinary Medicine (CVM) for processes #2 & 3, or in the case of a self-determined GRAS opinion (#1 process), reviewed by a panel of independent, expert scientists.

The different processes can take from 24-36 months, and it is recommended that any insect producer who intends to submit a new AAFCO or FAP dossier coordinates with NACIA before submission. This is because “overlapping” submissions of similar ingredients and target animals can slow down both applications, resulting in delays that impact the entire industry. NACIA strongly supports collaboration within the industry.

Lastly, all insect producers should check with relevant state authorities where they have operations or commercial activities to ensure they have the required licenses and product registrations.

1.2.3 Live Insects

Insects produced for live sales must be registered with the state when making and distributing to the state. The regulations around live animal sales follow what the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service states, and the distributor/producer must fill out a [PPQ 526 Permit](#) following the Regulated Organism and Soil Permits from the USDA. Each state has different allowances for insect production and live sale, along with insects considered invasive to each state. When growing and selling live insects, it is recommended that the producer keeps in mind the invasive status of the insects they are growing, and where these insects are considered invasive. Understanding the insects’ invasive status will aid in your permit application process.

1.2.4 Trade of Insects and Their Derived Ingredients

[The US Department of Agriculture \(USDA\) Animal and Plant Health Inspection Service \(APHIS\)](#) is the principal authority in the US that is responsible for the import and export of animals and animal products, including live insects and insect-derived animal feed or pet food ingredients ([link here](#)). The [Agricultural Commodity Import Requirements \(ACIR\)](#) list can help importers identify the required documentation for the importing process.

Although farmed insect species are typically exempt, it is recommended that importers verify the requirements for importing specific species with the US Fish and Wildlife Service ([link here](#)).

As a general rule, the FDA requires that food and feed imported into the US comply with the relevant requirements of food law. If applicable, importers must comply with the [Foreign Supplier Verification Program](#) ([link to decision tree](#)).

In addition to the federal requirements listed above, importers should reach out to each state that the product will be distributed into and ensure they meet state-specific licensing, registering, labeling, and reporting requirements.

Any products intended to be sold as animal food must be reviewed and approved for safety.

Additional information can be found here:

- <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda>
- <https://www.fda.gov/food/food-imports-exports/importing-food-products-united-states>
- <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/import-basics>

1.2.5 Exports

The USDA APHIS Veterinary Services (VS) is responsible for keeping existing export markets open and opening new export markets for American agricultural products by negotiating import protocols and certification language for US animal products. The USDA APHIS VS has created the International Animal Product Export Regulations (IREGS) to provide exporters with the best understanding of importing countries' requirements for certain animal-origin products. IREGS also contains information related to animal health export certification requirements for animal products.

As of the time of writing, only two countries have guidance that addresses explicitly insect-derived products: Canada and the European Union (EU). Canada allows the import of insect meal derived from the black soldier fly for pet and ornamental fish food or livestock feed. However, while the EU technically allows the importation of processed animal proteins derived from farmed insects, the required health certificate cannot be endorsed by APHIS VS, effectively blocking the export of insect protein from the US to the EU.

Several other countries may allow the import of insect meal under the description of animal feed ingredients containing animal products. However, insect producers/exporters must confirm prior to shipment that they have all the certifications required for their consignment.

CHAPTER 2 - *Good Manufacturing Practices for Insect Processing Facilities*

2.1 Introduction

This chapter aims to provide an overview of the regulatory requirements for processing facilities and outcome based best practices specific to insect processing facilities where appropriate.

Good Manufacturing Practices (GMPs) differ slightly based upon the destination of the final product, animal feed or food. The below GMPs are focused on national level laws and regulations, please note that local and state/provisional authorities likely maintain regulatory authority regarding facilities, site location, and similar building related topics, please check with your local jurisdiction. Section headings will clearly delineate between GMPs for feed or food. Further any general best practice recommendations will be shared at the beginning of each section with regulations by country, where applicable, to follow. Finally, this chapter focuses on processing and not farming. Please see Chapter 4 for farming.

Finally, given the importance and unique nature of pest control within insect rearing and processing facilities, Pest control is addressed separately, in addition to what is in the law, in section 2.4.

2.2 Current Good Manufacturing Practices for Producing Animal Feed

2.2.1 Law Governing GMPs in the United States

Below you will find an outline of the primary [Good Manufacturing Practices governed by US law](#).

Title 21 of the United States Code of Federal Regulations, deals with food and drugs. Chapter I, [Subchapter E, Part 507, Subpart B, Section 507](#) provides the current good manufacturing practice requirements for animal food processing facilities.

Subpart B includes the following sections:

- § 507.14 Personnel
- § 507.17 Plant and grounds.
- § 507.19 Sanitation.
- § 507.20 Water supply and plumbing.
- § 507.22 Equipment and utensils.
- § 507.25 Plant operations.
- § 507.27 Holding and distribution.
- § 507.28 Holding and distribution of human food by-products for use as animal food.

2.2.2 Law Governing GMPs in Canada

The Feeds Act and the Feeds Regulations of 1983 deal with animal food. So far, the Canadian government has not established GMPs for animal food processing facilities. However, The Canadian Food Inspection Agency (CFIA) is in the process of reviewing all of its regulations for food safety, plant and animal health. Amendments to the feed regulations will establish a feed framework that includes preventive controls, to be better aligned with international regulatory frameworks and best practices.

2.3 Current Good Manufacturing Practices for Producing Human Food

2.3.1 Law Governing GMPs in the United States

Title 21 of the United States Code of Federal Regulations, deals with food and drugs. [Chapter I, Subchapter B, Part 110](#) provides the current good manufacturing practice requirements for human food.

Part 110 includes the following:

Subpart A General Provisions

- § 110.3 Definitions.
- § 110.5 Current good manufacturing practice.
- § 110.10 Personnel.
- § 110.19 Exclusions.

Subpart B Buildings and Facilities

- § 110.20 Plant and grounds.
- § 110.35 Sanitary operations.
- § 110.37 Sanitary facilities and controls.

Subpart C Equipment

- § 110.40 Equipment and utensils.

Subpart E Production and Process Controls

- § 110.80 Processes and controls.
- § 110.93 Warehousing and distribution.

Subpart G Defect Action Levels

- § 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

2.3.2 Law Governing GMPs in Canada

The [Safe Food for Canadians Regulations SOE/2018-108, part 4](#) provides the current good manufacturing practice requirements for human food.

Part 4 - Preventives Controls includes the following:

DIVISION 1 - Interpretation and Application

DIVISION 2 - Biological, Chemical and Physical Hazards

DIVISION 3 - Treatments and Processes

DIVISION 4 - Maintenance and Operation of Establishment

SUBDIVISION A - Responsibility of Operator

SUBDIVISION B - Sanitation, Pest Control and Non-food Agents

SUBDIVISION C - Conveyances and Equipment

SUBDIVISION D - Conditions Respecting Establishments

SUBDIVISION E - Unloading, Loading and Storing

SUBDIVISION F - Competency

SUBDIVISION G - Hygiene

DIVISION 5 - Investigation, Notification, Complaints and Recall

DIVISION 6 - Preventive Control Plan

2.4 Pest Control

Pests (such as birds, insects, spiders, rodents and other small mammals) represent a hazard for the safety of food and feed derived from farmed insects, as well as a risk to their wellbeing. That is why a documented pest control program is recommended to prevent pest activity inside the facility. Incorporating the importance of pest control measures into the culture and practice of every team member is highly encouraged.

Five facets of pest control are recommended:

1. Intrusion limitation;
2. Zone control - Ensure that any pests are limited in their ability to move around the facility;
3. Make the space hostile to pest life cycle - Management/elimination of breeding conditions (nest sites, temperature and humidity), limiting access to food and water;
4. Capturing or killing of pests;
5. Monitoring Program to:
 - a. identify new pests

- b. measure the progression of an infestation
- c. determine the efficacy of control methods
- d. confirm the elimination of identified pests.

Preventing pest intrusion is difficult and highly valuable and should also include monitoring for penetrations. Sealing or hermetically blocking any holes, windows, doors, and air vents with appropriate devices is vital. Other structural barriers may also be considered during construction or retro-fitting such as floors being built with a curb edge, traps in floor drains preventing backflow into the facility, etc.

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

Usage and handling of pesticides and/or biocides must be done in accordance with applicable federal, state, and local regulations, such as [§ 205.271](#), and risks should be well understood and considered within a commercial insect rearing facility. Pest control as well as the risk of microbiological contamination to the products and facilities shall be part of the Hazard Analysis Critical Control Point (HACCP)/Hazard Analysis Risk-based Preventive Controls (HARPC) system and should be documented.

CHAPTER 3 – *Insect Diets*

3.1 Feed Ingredient Acquisition Background Information

Chapter 3 aims to highlight the different regulatory guidelines on insect diets, along with cGMPs for maintaining those feed stocks. Insect producers select insect diets and feed ingredients based on a number of criteria, including nutritional composition, expected effects on the targeted insect species (e.g. speed of growth, weight gain, feed conversion ratio, or fatty acid profile), absence of hazards to the target animals, or the ease of removal during harvesting.

Furthermore, the characteristics of the insect diet used are critical parameters for a suitable and safe growth of the insects: in general, diets used for flies (e.g. *Musca domestica* and *Hermetia illucens*) contain high levels of moisture, whereas mealworm (*Tenebrio molitor*), lesser mealworm (*Alphitobius diaperinus*), and crickets are usually raised on dry diets.

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

3.2 Current Regulations

While insects can feed on a variety of diets and can be used to upcycle agrifood byproducts, human food byproducts, or even residual matter, sourcing of insect diets must respect current regulatory requirements.

The sections below address the national regulations of animal feed ingredients for two countries: USA and Canada. However, due to the regulatory landscape in North America, it is recommended that insect producers familiarize themselves with their local, state/province, and federal regulations. Furthermore, if an insect producer intends to use feed ingredients that are not currently approved, they should consult with a regulatory consultant, and reach out to NACIA management for guidance/support.

3.2.1 Regulations in the USA

In the United States, the U.S. Food & Drug Administration (FDA) regulates animal feed to ensure that it is safe for consumption by animals. When insects are being raised for animal feed purposes, including pet foods, these regulations also apply to the insects.

If insect-derived products are intended to be fed to animals, including pets, they must be raised on a diet composed exclusively of approved animal feed ingredients. Any

ingredient used must have its nutritional or technical purpose established through a legally recognized process, and must be used within the limits of its established safety and utility. The Association of American Feed Control Officials (AAFCO) has no regulatory authority but is authorized to maintain a list of feed terms and ingredient definitions and works with the FDA to define and review new ingredients. Individual state regulatory agencies, most of whom are active within AAFCO, are ultimately responsible for regulating through registration, inspection, and enforcement.

The AAFCO Official Publication (OP) contains the most complete list of animal food ingredients with their definitions. It is divided into 101 sections, with sections 3-99 listing AAFCO approved ingredients, section 100 is a list of feed ingredients included in the US Code of Federal Regulations (CFR), and section 101 is a list of generally recognized as safe (GRAS)(21 CFR 570.30) notices that have been evaluated by the FDA and had no objections on the conclusion that the substances are GRAS for an intended use. While not all of the AAFCO OP ingredients have gone through federal regulatory approval, the FDA has accepted the listing of ingredients in the AAFCO OP for their marketing in interstate commerce, provided there were no apparent safety concerns about the use or composition of the ingredient. Public access to Feed Terms, Common or Usual ingredient Names, and Ingredient Definitions is provided free of charge by AAFCO and can be accessed through the following [link](#).

AAFCO also maintains a Common Food Index (CFI), which is a repository of common food items that may be appropriate for use in animal food, but are not defined by AAFCO. It was created as a tool for regulators and industry to use when reviewing labels. Common foods are defined by AAFCO as *“Food items commercially available and suitable for use in animal food but are not defined by AAFCO, including but not limited to certain whole seeds, vegetables, or fruits. Common food for animals may include common human foods that are known to be safe for the intended use in animal food. Manufacturers are responsible for determining whether a common food is safe and has utility for its intended use prior to commercial distribution as animal food.”* More details on how to submit food items for AAFCOs consideration can be found through the following [link](#).

As one example, currently, in the United States, AAFCO-approved black soldier fly larvae ingredients must come from insects that have been fed “feed grade material.” In the aforementioned definitions it states that organisms must be fed with feed grade materials as defined by AAFCO in which the “material that has been determined to be safe, functional, and suitable for its intended use in animal food, is handled and labeled appropriately, and conforms to the Federal Food, Drug, and Cosmetic Act unless otherwise expressly permitted by the appropriate state or federal agency.” Thus, insect producers must only source feed ingredients that are eligible as feed materials for farmed animals within the United States. See section 3.5 for further notes and tips on interpreting AAFCO definitions.

It is highly recommended that US-based insect producers familiarize themselves with the AAFCO OP feed ingredient definitions, restrictions, and requirements of the materials they intend to feed to their insects. If an insect producer intends to raise insects for animal

feed (including pet food) purposes, and would like to feed an ingredient that is not listed in the AAFCO OP, as an [FDA Approved Food Additive](#), [GRAS approved](#) for its intended use, or on the [CFI](#), it is recommended they consult with a regulatory consultant, or approach NACIA for guidance.

3.2.2 Regulations in Canada

As mentioned above, Canadian regulations regarding the feeding of insects differ according to the intended use of the insects.

3.2.2.1 Use as Pet Food

In Canada, the Foods Products Act and the Animal Health Protection act do not govern the manufacture of pet food. Then, there are no regulations applicable to the rearing of insects intended for pet food except that the insects must be safe for the animals. However, most Canadian Insect Farmers are following the guidelines of AAFCO. Insect producers must demonstrate the safety and security of the insects as a feed if it is intended to be used as such (see chapter 1 on food and feed regulations for more details).

Although the Canadian Food Inspection Authority (CFIA) does not regulate the diet used for rearing insects intended for the pet food industry, risk assessments should be conducted on ingredients. The assessments should be based on the type and the origin of the materials, diet storage conditions, usual inclusion rates, frequency of use, degradation/metabolization ability of the insect, and further processing steps (including insect-kill steps and pathogen elimination steps).

3.2.2.2 Use as Feed Ingredient

The CFIA regulates livestock feed to ensure that it is safe for consumption. If insects are reared to be used as an ingredient for livestock feed, they must be raised on and fed on a diet that is acceptable for the production of safe and nutritious livestock feeds. Insect-derived feed ingredients intended to be used as sources of macro-nutrients in livestock diets are listed in Schedule IV, Part II [{Canadian Feed Ingredients Table \(CFIT\)}](#) and do not meet the exemption from registration criteria as outlined in Section 5(2) of the Feeds Regulations. A pre-market assessment is required for each new ingredient as there may be inherent source related safety and/or efficacy variations associated with different insect species, growth diets, and/or manufacturing processes. Each source of these ingredients must be approved and registered prior to their importation, manufacture, or sale in Canada.

Regarding production of the insect-derived feed ingredient, insects must be raised on and fed a diet that is acceptable for the production of safe and nutritious livestock feeds. The producer must be able to describe to the CFIA the type and the origin of ingredients used including a detailed list of the sources/suppliers, storage conditions, usual inclusion rates, and frequency of use of the insect diet. Ingredients that come from packaged products can be used if foreign materials (e.g., plastic, glass, metal, polystyrene, or paper) are

removed before or during processing. Efficient measures must be in place to ensure removal of any harmful non-edible material in the final product. For any materials that come from packaged products, the producer must provide details on de-packaging and measures in place to ensure removal of non-edible portions that could result in foreign materials in the final product.

Producers must have records that identify any physical, chemical, or biological hazards that may be introduced by ingredients and chemicals used in the manufacturing process. Based on identified hazards, quality control measures should be in place to screen the ingredients and chemicals used during the feeding process. Insect producers should also record the insect diet supplier's name, its address, and delivery date for traceability purposes in case of major contamination. Depending on the sourcing, the producer may request a certificate of analysis to ensure that the ingredients meet pre-established physicochemical and microbiological specifications. However, this measure is not applicable when insects are fed with upcycled biological materials.

3.3 Current Good Manufacturing Practices

It is recommended that insect producers assess and select feed ingredients and/or insect diet suppliers (suppliers) before accepting new sources of feed ingredients or finished insect diets (materials). This assessment should consider quality and safety of the materials to the insect species as well as the target species the insect products are intended for, and a regulatory compliance check of the supplier, including any facility registrations and current good manufacturing practices (cGMPs) which may be legally required.

The quality and safety assessment of materials should include:

- Proximate analysis of the material (e.g., protein, fat, fiber, moisture, ash, etc.);
- Identification of any particular substances that would be a concern for the target species;
- Biological, chemical (including radiological), and physical hazards; and
- Introduction of other substances during processing (e.g., metals, preservatives, etc.).

The assessment should consider the entire process of the facility, including any processes which may reduce the risk of hazards (i.e., heat treatment steps). Insect producers should keep supplier assessments on file, and perform audits at a suitable frequency to keep records up-to-date and minimize risk.

Additionally when selecting feed ingredients, insect producers should consider the insects' nutrition and the quality of the materials ingested which may have a strong influence on its microflora (e.g. certain insects may be vectors of *Salmonella* spp., *Campylobacter* spp., or *Escherichia coli*) or on the presence of chemical contaminants, e.g. dioxin and PCB transferred via their diet - may accumulate in insects. Other materials of contamination to consider are from pests and/or rodents or other physical contaminants.

While North American regulations do not specify precise limits for many hazards, it is the insect producer's responsibility to perform risk assessments on their inbound-materials, process, and outbound-materials.

3.3.1 Receiving

Diet receiving and storage areas should be maintained in a manner that prevents access by vermin, birds, and other pests, and is protected from the elements. This may include roofs, walls, covers, or other containment systems, and will vary by diet component and geographical location. Producers should have receiving practices such that any diet components that are received and found to contain a hazard are sufficiently quarantined and not used until the hazard can be evaluated by appropriate personnel (e.g., area manager, QA/QC personnel, PCQI) and disposal is available, if needed. Upon receipt, ingredients and diets should be assessed and documented for quality. This may require having designated and trained staff at the point of receiving. Prior to storage, a brief inspection of the products should be performed to detect any suspicious odor or physical contaminants (e.g., unapproved ingredients or materials). When applicable, ingredient packaging and containers should be inspected for damage or evidence of tampering. When applicable, the Certificate of Analysis or Guaranteed Analysis should be compared to the agreed upon specification for that material. Non-conformity should be documented and records of any non-conforming diet components, and their disposition, should be maintained for at least two years according to the [Center for Veterinary Medicine Guidance for Industry Hazard Analysis and Risked-Based Preventative Controls](#).

3.3.2 Ingredient Processing

Insect diets may require additional physical, chemical, or biological processing to extend shelf stability or to increase digestibility for the insect. Some examples of such processing are depacking, addition of chemical preservatives and stabilizers, enzymatic digestion, or microbial transformation like fermentation. In the US, enzymes, chemical preservatives, chemical stabilizers, microorganisms, and additives are regulated and must be approved for adding into the insect diet (2023 AAFCO OP Section 73 73.001 Technical Additives Table Page 452). In Canada, these are regulated by CFIA and are found under Class 6. Non-nutritive ingredients of Canadian Feed Ingredients Table ([CFIT](#)). The CFIT lists and describes all single ingredient feeds approved for use in livestock feed in Canada up until August 2020. The CFIT will replace Schedules IV and V of the current regulations. All ingredients from Schedules IV and V have been transferred to the CFIT, but have been placed into new classes.

3.3.3 Storage

The storage vessel should be inspected regularly to ensure cleanliness of the interior of the vessel. The frequency of that inspection will be determined based on prior storage time as well as the material being stored.

In Canada and the United States, no specific physical storage conditions (e.g.

temperature, humidity, etc.) are provided for the storage of upcycled biological materials. However, ingredients must be stored in a way to prevent any internal and external contamination.

Ingredients should be stored in such a way to prevent adulteration, sanitation issues, and cross contamination with other ingredients or finished products. It is recommended that perishable ingredients (i.e., fresh produce) are received-staged-processed using a first-in/first-out (FIFO) system, and non-perishable ingredients (i.e., shelf-stable packaged goods) are received-staged-processed using a first-expired/first-out (FEFO) system. The physical integrity of the storage conditions should be assessed regularly, and climate-sensitive diet components should be stored and monitored in accordance with regulations. The insect producer should maintain a robust batch traceability system, and all ingredients should follow animal feed handling best practices.

3.4 Summary of Recommended Practices

Summary of recommended practices or ‘warning points’ in the management of incoming substrates:

1. Ensure that the insect diets and ingredients are provided by trusted suppliers;
2. Only source and use authorized insect diet ingredients which are eligible as feed for farmed animals, in accordance with applicable legislations;
3. Ensure that designated and trained staff are present at the point of receiving to detect damaged seals or packaging;
4. Appropriately document all ingredient lots;
5. Undertake your own testing/sampling of the ingredients following a risk-based approach, including assessing the potential contamination from biological, chemical, and physical hazards.

3.5 Notes on AAFCO Definitions

When describing different ingredient definitions, the AAFCO OP also defines specific restrictions on animal food ingredients:

Example:

40.28 (Old 60.28) Dried Potato Products is the dried residue of potato pieces, peeling, culls, etc., obtained from the manufacturer of processed potato products for human consumption. The residue **may contain up to 3% hydrate of lime** which may be added to aid in processing. (Proposed 1972, Adopted 1973).

Or contamination, storage, and sanitation requirements:

Example:

40.100 Recovered Retail Food is composed of edible human food products safe and suitable for livestock feed that are collected from retail food establishments, domestic holding facilities, and domestic packing facilities. Permitted recovered retail foods are products from overstocks, lacking consumer acceptance, or beyond their sell-by date that include items such as bruised, cut, or overly ripe produce (fruit and vegetables), bakery goods, eggs, and dairy products. It shall be safe and appropriately labeled for its intended use and shall be free of material harmful to animals. Materials excluded from this definition include pet foods and products containing beef, lamb, pork, poultry, fish, or shellfish. **It must not contain packaging materials (e.g., plastics, glass, metal, string, Styrofoam, cardboard, and similar materials), flowers, potted plants, or potting soil.** The recovered foods shall be **collected and intermixed in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests.** Egg and dairy products (and other products ordinarily held at refrigerator temperatures) must be kept in cold storage until the scheduled pick-up. To minimize spoilage, the recovered retail food shall be collected at least weekly, or more frequently if necessary. The establishment should have a **sanitation plan in place**, and the containers should be cleaned and sanitized as necessary. The collected material may be further processed or delivered as is to an animal feeding facility. The product must be handled to preserve its safety and nutritional value.

CHAPTER 4: *Insect Rearing Activities*

4.1 Introduction: Scope and Legal Framework

This chapter aims to give an overview of insect rearing, but insect rearing varies based upon species reared, processes used, and the rearing environment. Since each operation is different, we encourage each organization to undertake a risk assessment to properly manage risks at their facility. Rearing activities cover the following production steps:

1. Insect reproduction;
2. Administration of diet;
 - a. Traceability [[FSMA Proposed Rule for Food Traceability | FDA](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability), <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability> & ISO 9001:2005 Clause 8.5.2 also deals with traceability.]
 - b. Used container (materials)
 - c. Sanitation
3. Insect growth phases and abiotic requirements;
4. Feed ratios and feeding approach to minimize risks
5. Insect harvesting;
 - a. Collect Batches of Live Insects (Biosecurity)
 - b. Import and export of invertebrates (Biosecurity)

The activities described in this Chapter are considered the “farm operations” of a [Primary Production Farm](#). As per the [FSMA Final Rule for Preventive Controls for Animal Food](#), “An operation devoted to raising animals is not subject to the Preventive Controls for Animal Food rule.”. Simply put, the FSMA does not regulate the feeding or rearing of animals, including insects.

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

4.2 Insect Reproduction

4.2.1 Background Information

In this document, insect reproduction includes all steps required to promote mating, oviposition and egg eclosion. For several insect species, oviposition occurs within or close to a feed source. The substrate might also be used only as an attractant to promote mating. The first introduction of an insect on a diet can occur as an egg or as the first instar larva or nymph.

Eggs are usually introduced onto the diet manually, mechanically or by oviposition (directly from adult insects) while first instar insects can be introduced manually or

mechanically. When the oviposition substrate differs from the insect diet, eggs or first instar insects are harvested, and introduced on an insect diet directly or following density adjustment manipulations.

4.2.2 Recommended Practices

It is recommended to use breeding stocks of a known and traceable origin that can be traced back for at least 3 generations when introducing new genetics to your breeding stock. For companies that choose to import breeding stocks, import regulations can be found for Canada [here](#), and the United States [here](#) and [here](#). Companies within the United States should also be familiar with State regulations that govern live insect import/export. It is also recommended to keep records of all internal breeding programs for all insects produced.

In addition, during the rearing process, maintaining a consistent population density at each developmental stage can help prevent cannibalism, infections, wet diet deterioration, etc.

Insect producers should also consider whether perishable (i.e. insect diet, frass) and non perishable (i.e., sand) substrate used to promote mating and/or oviposition should be traceable.

4.3 Administration of Diet

4.3.1 Background Information

The administration of diets to insects constitutes an important component of the rearing and breeding processes. Such operations are designed to provide insects, specific to their species and consumption habits, with access to liquid and solid nutrients (i.e. wet and dry substrates) as a source of energy needed for their growth, as a medium for water, and/or as a material for laying their eggs.

The larvae or nymphs are maintained on the diet for a certain number of days or weeks depending on the insect species produced and the environmental conditions prior to harvesting.

4.3.2 Applicable Legislative Requirements

The activities described in this Chapter are considered the “farm operations” of a [Primary Production Farm](#). As per the [FSMA Final Rule for Preventive Controls for Animal Food](#), “An operation devoted to raising animals is not subject to the Preventive Controls for Animal Food rule.”. Simply put, the FSMA does not regulate the feeding or rearing of animals, including insects.

However, it is important that insect producers develop and implement “on-farm” practices

that ensure the safety of feed maintained and fed to insects on-farm. Therefore, it is recommended that insect producers are familiar with the [FDA's Guidance for Industry #203](#), Ensuring Safety of Animal Feed Maintained and Fed On-Farm to minimize risks of feed contaminants and unacceptable feed risks. The general principles and practices for animal feed safety on-farm include:

- A. Know what feed contaminants may be present in your animals' feed and the measures known to prevent such contaminants from becoming unacceptable feed risks;
- B. Obtain feed from safe and reliable sources;
- C. Recognize unexpected changes in the feed at your farm (e.g., changes in color, smell, texture, or appearance);
- D. Know where in your animal production system(s) unacceptable feed risks may occur;
- E. Monitor animal feed products for contaminants during receiving, holding, and handling; and,
- F. Be aware that other actions, such as limiting access to the premises to authorized personnel, following feed labeling directions, proper personnel training, and sampling and testing of feed, can help ensure feed safety.

4.3.3.1 Diet Management

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

- The diet used should be selected by taking into consideration the chosen insect species from the nutritional requirement standpoint;
- All diets delivered during the course of larvae growth (i.e. single or multiple feeding and/or and different diet profiles), should be traceable.

4.3.3.2 Equipment Management

The equipment destined to provide the nutrients/diet (or any other material which may enter into contact with the animals) should be adequately cleaned and sanitized to reduce the risks of biological and chemical contamination.

Additional guidance can be found in [CVM GFI #203 Ensuring Safety of Animal Feed Maintained and Fed On-Farm](#), which recommends:

“Maintain any buildings and equipment used for feeding animals in a manner permitting safe operation, maintenance, and cleaning, which will help prevent or significantly minimize the occurrence of feed contaminants. For example, make sure wood products that come in contact with animals or feed for such animals, are not treated with preservation products containing chemical contaminants such as dioxin. In addition, ensure feed troughs and other feed containers are cleaned routinely to prevent or significantly minimize the occurrence of feed contaminants in feed.”

Such principles should help to avoid or minimize any cross-contamination and errors. Any other technical or organizational measures that are deemed necessary by insect producers to prevent such risks should be taken (respective to the insect farming techniques, e.g. automated, manual, vertical stacking of breeding trays, movement of material, etc). These should include regular checks in the course of manufacture designation and training of staff at the point of distribution in order to prevent cross-contamination.

4.4 Insect Growth Phase

4.4.1 Background Information

During its growth, insects may display different metabolic states (i.e. catabolism vs anabolism), which may require an adequate environment and the application of tailor-made procedures that take into account their particular characteristics.

The key parameters to be controlled include:

1. **Temperature:** Insect growth rate is heavily influenced by environmental temperature. Overall, environmental temperatures between 25°C and 33°C (77°F to 91°F) are most beneficial in the majority of insect species and life stages. This range results in diet and bedding temperatures between 27°C and 45°C (80°F to 111°F). Moisture content of the diet and bedding can impact temperatures through mechanisms such as evaporative cooling.
2. **Relative Humidity:** Due to high or low moisture requirements for diets and beddings, the relative humidity must be calibrated to meet insect species recommended range in order to prevent water loss or retention. Moreover, relative humidity may be impacted by the environment temperature, therefore, those two parameters must be adjusted as needed for optimal growth;
3. **Ventilation:** The amount of air circulating and exchanged must be adjusted to provide oxygen for metabolism and to dilute/reduce/adjust temperature, moisture, odors, smoke, heat, dust, airborne bacteria, carbon dioxide, and other gasses (i.e., NH₃). Insects kept indoors must have a system in place to ensure optimal rearing conditions and avoid cross-contamination through the air.
4. **Enclosed space:** the insect colony should be enclosed and secured to facilitate pest control and prevent livestock escape. It is common to use multiple self-contained spaces, each with its own population, water supply, food sources, and space maximizers.

Understanding the main insect species and their life cycles used in production activities is necessary for the development of suitable rearing methods and further processing

steps.

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

Examples:

- Black soldier fly larvae are typically fed and grown on wet diets, whereas mealworms (e.g. Yellow Mealworm and Lesser Mealworm), or crickets are grown on dry materials;
- Intense light and certain wavelengths may affect both feed intake and pupation of certain insect species: e.g. bright light reduces the growth of black soldier fly species and to some extent affects the growth of other species;
- Production equipment used should be shaped and adapted to each species in order to prevent escape risks.

The responsibility lies with each producer to optimize and tailor the rearing conditions according to the specific insect species to ensure that these risks are minimized. Finally, the quality of the insect breeding stocks is an important parameter to take into consideration.

4.4.2 Recommended Practices

Farmed insects should be kept in a controlled environment where appropriate environmental conditions can be maintained to prevent the entry of pests and migrations between batches. Appropriate cleaning and sanitary measures should also be undertaken to avoid contamination or spread of diseases among the breeding stocks.

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

More details can be found in section 2.4. Pest Control.

4.5 Harvesting

4.5.1 Background Information

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

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

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

The harvesting method(s) used may therefore also differ from one species to another based on their breeding behavior. Current sector harvesting practices include:

- Sieving machines (for larvae) or 'sorters' (vertical devices like stackers, cardboard tubes or egg trays for crickets);
- Hand-selecting insects is also sometimes practiced.

4.5.2 Recommended Practices

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

- Sieve size (mesh) should enable effective separation of insects from frass and the remaining substrate;
- Clean the sieving equipment thoroughly (e.g. washing, use of appropriate cleaning and sanitation material, drying) and on a regular basis in order to limit microbiological exchange, the proliferation of larvae from unhatched eggs, or the spread of foreign bodies into breeding insects;
- Equipment, boxes, tools and nets should be cleaned consequently according to respective operators established safety management protocols to avoid contamination;
- In the particular case of volatile feces, operations should separate it from the larvae in a specific confined area, in order to avoid contamination of products in other production lines. Further, operators should be familiar with national, regional, and local air quality compliance, specifically occupational health and safety, and emission control requirements;
- Collected frass intended for use (e.g. land fertilizers or potentially feed) should be assessed using relevant quality control parameters (e.g. microbiological analysis, heavy metals) and stored in a dedicated area. Any frass deemed unusable (e.g. improper for land use/fertilizers) should be disposed of appropriately;
- If wet residual feeding substrate is to be reused, a drying step should ensure water activity suitable for storage. The insect producer should identify the acceptable

water activity for storage periods that would not encourage microbiological contamination of the substrates meant to be reused.

Besides or in addition to sieving, insect producers are encouraged to use sorting solutions enabling them to efficiently detect and remove foreign materials (e.g. metals or plastic coming from the equipment) or dead whole insects (e.g. black color larvae). If sorting solutions are not utilized to address the risk of foreign materials and dead insects, those risks should be considered and addressed alternatively.

4.6 Specific Case of Sourcing/Sub-contracting Practices

The acquisition of insect larvae, as well as part or in totality of the rearing process, can be outsourced or subcontracted. While working with subcontractors it is important to control risk of biological and chemical cross contamination.

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

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

All equipment, vehicles, boxes and tools used in the facilities of such subcontractors should be cleaned and thoroughly sanitized to reduce risk of contamination prior to reuse and handling of materials that come into contact with insect rearing activities and diets.

The admission of people to the facilities should be monitored and accompanied by trained personnel who know how to reduce risk to the insects within the insect rearing facilities. In certain facilities, movement between highly sensitive areas should be strictly prohibited to external personnel but is ultimately up to the facility personnel to decide.

Dedicated workers involved with different parts of insect rearing should limit movement between important areas, e.g. limited access to breeding areas to reduce risk to the insect colony, or prevent movement between diet preparation and product processing areas to reduce risk of cross-contamination.

Workers should use dedicated personal protective equipment (PPE), such as clothing, shoes, gloves, masks, and other necessary protective gear in certain areas of production to reduce risk to the worker and to the insect colony.

CHAPTER 5 – Overview of Current Processing Methods for Insects for Human and Animal Food

5.1 Introduction

The aim of this chapter is to provide an overview of the processing methods involved for insects which are applicable to the production of both animal feed, including pet food, and food for human consumption. The processing methods discussed in this chapter focus on the insect-kill step and post-killing steps resulting in insect products (e.g. whole insects, insect powder, and highly-processed ingredients). Also, good manufacturing processes should be used at all times.

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

Note that harvesting and shipping of live insects is not covered in this section, as this activity is considered exempt under 21 CFR 1.226.

5.2 Legislative Requirements for Insects as Feed

5.2.1 In the United States

Processing requirements and/or guidelines are defined during the ingredient approval process and included in the final ingredient definition. The AAFCO Official Publication (OP) and your state feed regulator will have the most current guidelines for insects to be sold as feed.

Below is one example of how processing methods are defined in the ingredient definition. Animal Feed Ingredient Definitions can be accessed free of charge at the AAFCO [website](#).

“Dried Black Soldier Fly Larvae is the dried Larvae of the Black Soldier Fly, *Hermetia illucens*, **with or without mechanical extraction of part of the oil**, that has been raised on feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is **dried by artificial means** to no more than 10% moisture. It is for use in salmonid, poultry, and swine feed and in adult dog food, as a source of protein and fat consistent with good feeding practices.”

Extracted, mechanical. (Process)
Having removed fat or oil from materials by heat and mechanical pressure.

Artificially dried. (Process) Moisture having been removed by other than natural means.

The highlighted text are the two processes (call-out boxes extracted from the AAFCO Official Feed Terms) which define how the product must be manufactured to be in compliance with the ingredient definition. Practically, this means that dried black soldier fly larvae can only be sold if a) the product has been artificially dried, not naturally dried, and b) can only be sold “defatted” if the oil has been mechanically extracted, not chemically.

5.2.2 In Canada

In Canada, feed given to livestock has to be authorized by the Feed act and its regulation. The feed ingredients are approved by the Canadian Food Inspection Agency (CFIA) after their safety and efficacy assessment. These authorized ingredients are defined in schedule IV of the regulation and include the dried whole BSFL, the defatted BSFL meal, and BSFL Oil. These definitions detail some of the required manufacturing processes.

Defatted Black Soldier Fly Larvae Meal (schedule IV, part II, section 5.21):

“is the product that consists of the defatted protein meal **mechanically extracted** from the whole larvae of the Black Soldier Fly, *Hermetia illucens*, raised on and fed a substrate that is acceptable for the production of safe and nutritious livestock feeds. Whole larvae are harvested and **cleaned to be free of the growth substrate**. Whole larvae are then **heat treated**, dried, **pressed** to extract the oil, and **then ground into meal**. It is approved as a source of protein for use in feeds for poultry, swine, tilapia and salmonid fish. It has a maximum inclusion rate of up to 10 percent of the total diet for tilapia and salmonid fish. This product **shall be processed in accordance with good manufacturing practices**. It shall be free of harmful microorganisms.

If an antioxidant is used, it must be approved for use in livestock feeds, it shall be used at the approved rate, and the common name or names shall be indicated on the label. It shall be labelled with guarantees for minimum percent crude protein, minimum percent crude fat and maximum percent moisture.”

It is worth noting that some states and/or provinces codify feed ingredients in their laws, therefore, it is important to check with your state or provincial regulator to make sure there are no additional processing requirements.

In general, it is up to the insect-derived product manufacturer to ensure whatever specific processing methods are used, within the defined processing requirements, result in a safe product. In the US this is achieved through the FDA Food Safety Modernization Act, which consists of seven major rules designed to prevent contamination of foods.

5.3 Legislative Requirements for Insects as Food

Producers of insects and products that are intended for human consumption must comply with the general principles and requirements outlined in the food manufacturing laws for each North American country (FDA's Code of Federal Regulations Title 21, and CFIA Feed Regulations, Schedule IV & V).

Insects are considered "food" in Canada and the United States, and thus must comply with the same rules that govern all food production. The insects must be specifically raised for human food following current Good Manufacturing Practices (cGMP, 21 CFR 110; CFIA Feed Regulations, Schedule IV & V). Insects raised for animal feed cannot be diverted to human food. In the U.S. and Canada, they cannot be "wildcrafted" (collected in the wild) and sold as food. Producers shall also comply with the food labeling specifications from each country (21 CFR 101, CFIA Feed Regulations, Schedule IV & V, NOM051 food labeling). Additionally, it has become best practice to include a statement on the label clearly identifying the potential risk for cross-reactivity with shellfish allergic individuals.

As an important note, the sale of live arthropods, excluding bees and certain agricultural pests, are exempt from regulation, in accordance with the registration exemption test outlined in [21 C.F.R. § 1.227](#). Importantly, many seemingly benign on-farm activities may trigger the definition of a Food Facility that requires FDA registration, so the registration exemption test must be followed closely and assessed regularly after process and product changes within the farm.

Under FSMA, all domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in the regulation, for human or animal consumption in the U.S. must be registered as a Food Facility with the FDA. The current opinion of the FDA states that if an insect-producer has an integrated model, the facility would be considered a farm-mixed type facility, and requires registration. An integrated model is a farm where they process raw materials into an animal food to provide only to insects they are raising, raising the insects which are processed into finished goods. Making the insect diet to feed their insects (and raising them) would fall under farm operations, and would be exempt from the Preventative Control for Animal Foods (PCAF) requirements, while processing finished goods (i.e., making insect meal) falls under facility operations and is subject to the PCAF requirement.

5.4 General Recommendations

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

To this end, insect producers shall refer to the requirements outlined in their country's food regulations for Good Manufacturing Practices (21 CFR 117/21 CFR 507, CFIA Feed Regulations, Schedule IV & V) and other food safety measures, including but not limited to establishing:

1. Written procedures identifying critical points in the manufacturing process;
2. Measures to monitor the presence of prohibited undesirable substances in the food;
3. Traceability measures and prevention of cross-contamination;
4. HACCP/HARPC procedures.

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

5.5 Insect-kill Step

5.5.1 Introduction

The insect-kill step can be performed through different methods, depending on the species reared. Farmed black soldier flies, mealworms and crickets in North America are most often killed via thermal and mechanical treatments (e.g hot water, steam, freezing, mincing).

This guide provides a non-exhaustive list and description of the techniques that are commonly used by North American insect producers.

5.5.2 Thermal Inactivation: Heat Treatments

5.5.2.1 Hot Water

Killing by heating may be done by plunging insects in hot water (i.e., 'blanching'). The high temperatures in this step often allow for an instant death of the insects and destroy the microbial flora, thereby mitigating microbiological hazards in the product. The insect-kill step temperatures vary from one insect species to another, and from their growth status. From an ethical standpoint, it is highly recommended to use a temperature that elicits near instant death.

Blanching times will depend on the end product. The following conditions should be considered:

1. Temperature;
2. Bacterial load and species, including spores, and their survival on the insects;
3. Risk assessment and hazard analysis of the product.

5.5.2.2 Other Heating Techniques Used

Other techniques resulting in near-instant deaths, such as high-temperature drying ovens, microwave, or infra-red tunnels, may also be used. Processing parameters such as time of exposure or thickness of products should be evaluated and adapted to the unique parameters of each insect reared (e.g. species, size, growth stage, etc.). An inadequate heat treatment, caused by not achieving the necessary time/temperature conditions, can lead to a bacterial survival and proliferation of pathogenic or spoilage organisms. The operator shall establish and follow safety standards (e.g. quick cooling methods, monitoring water activity, storage conditions) when preparing blanched insects for the next steps of manufacturing.

5.5.3 Thermal Inactivation: Cold Treatments

Operators freezing insects should set appropriate freezing times to validate the insect-kill step. The time varies from one species to another. If the insects are packaged before freezing, the time for the internal temperature (i.e., core of the package) to reach less than 40°F should be under two hours. This is to ensure insects are not starting to decompose at greater than 40°F for over two hours. Packaging should be as slim or flat as possible to ensure the fastest death from freezing.

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

5.5.4 Mechanical Inactivation

Operators using mechanical treatments should set appropriate processing techniques as an insect-kill step. Mincing or grinding in this step often allows for instant death of insects. Processing parameters should be evaluated and adapted to the unique parameters of each insect. The operator should establish and follow safety standards when preparing minced insects for the next steps of manufacturing.

5.6 Post Insect-kill Steps

5.6.1 Background Information

A number of processing methods may be applied to larvae and/or adult insects after the

insect-kill step. Referred to in the present guide as ‘post-killing steps’, these methods have specific purposes such as particle size reduction, pathogen elimination, or water, fat, or chitin extraction. These steps can be of thermal, chemical, or mechanical nature. And depending on the design of the process, the order of the specific operations could vary from process to process. The insect producer or processor should also be knowledgeable of any governmental guidelines or restrictions for processing (eg. the 2022 AAFCO OP definition for T33.29(A) Black Soldier Fly Larvae Oil does not permit chemical extraction of oil).

The guide provides a non-exhaustive list and description of the techniques that are commonly used by insect producers. Insect producers may therefore apply other techniques than the ones mentioned below so long as they follow all applicable regulations and comply with food safety protocols.

5.6.2 Pathogen Elimination

Pathogen elimination is a process in which foods are exposed to, typically, heat to eliminate pathogens and extend shelf life. If hot water is used as an insect-kill step, pathogen elimination may already happen in that step. However, if the insect-kill step uses another method, eg. freezing, a subsequent pathogen elimination step should be considered.

Thermal processing is well-known for reducing and eliminating bacteria. Some examples that may be considered are hot-water post insect-kill step or dry high temperature in an oven. The oven method is often also used for dehydration, and will be discussed in section 5.6.4.

If a pathogen elimination step is combined with the insect-kill step, the typical times and temperatures with hot water should follow cGMPs according to HACCP/HARPC specifications and Risk Management. For any material, it is key to identify the initial microbial load and the microorganisms of human and animal health concern. And for any pathogen elimination step, heating or otherwise, it’s important to have assurances of the targeted microbial elimination, either by process validation or documented industry reference data. It is important to note that not all possible time temperature combinations will result in a sufficient reduction of possible microbiological pathogens or eliminate any toxins that may have been produced by pathogens. The appropriate combinations must therefore be determined by the insect producer operator respective to the species and that particular environment. In addition, respective pathogen monitoring protocols should be conducted.

When hot water or boiling water treatments are applied, residual water post-treatment should be strictly monitored in order to avoid microbiological recontamination before further processing (e.g. before freeze drying, or mincing). In case unwanted contaminants are detected, insect producers should implement necessary corrective measures (as part of their HACCP/HARPC plan), in order to mitigate contamination further down in the process line. Furthermore, in accordance to (21CFR113.60(b), CFIA Feed Regulations,

Schedule IV & V), where heat treatment is applied to foodstuffs in hermetically sealed containers, it is to be ensured that water used to cool the container after heat treatment is not a source of contamination for the foodstuffs.

5.6.3 Freeze-drying

Freeze-drying is used to remove water from insects before they are ground or milled. This technique consists of maintaining a low temperature to dehydrate the insects using sublimation. The subsequent reduced water activity permits an extended shelf life for the product under the appropriate storage conditions.

Freeze-drying alone is not necessarily a sufficient pathogen elimination step. Careful consideration of the starting microbial load and target organisms should be considered. Freeze drying may need to be used in combination with a separate pathogen elimination step, such as blanching.

In order to ensure the safety of the product, insect producers should consider the following procedures:

1. Prior to placing the insects in the freeze dryer, the operator shall ensure that insects are kept away from any potential contamination sources (potential cross contamination during storage before freeze drying, transfer or handling);
2. Freeze-drying temperatures must be maintained throughout the process (the level of temperature required varies according to equipment and processes used);
3. The freeze-drying environment is thoroughly cleaned between two batches.
4. Freeze-dried products are very hygroscopic and 'attract water'. Therefore, must be stored in a closed container, or the water activity of the product may thus rise again and allow microbial growth.

5.6.4 Heat-based Dehydration Methods

Depending on the insect-kill step method used, larvae or adult insects might still have to be dried in order to remove the water and avoid microbiological contamination. This can be achieved with a batch oven process or continuous-type of dryer (eg. spray dryer or drum dryer), where high temperatures are maintained to allow moisture to be drawn off. Whatever method is used, the company should be aware of hazards associated with it (i.e., water condensing in dried products resulting in microbial activity), and are responsible for controlling the known or reasonably foreseeable hazards, and validating the process to ensure it is sufficient to reduce/eliminate pathogens.

Insects might need to be pre-processed before the drying phase. This means homogenization, dilution, pathogen elimination or anything else needed for complete control of the final product outcome. Insects can be powdered without compromising most of their valuable characteristics because of the very short time the nebulised products are heat treated.

In order to ensure the safety of the product, insect producers should consider the following

procedures:

1. Pressure, time, and temperatures should be maintained throughout the process (their levels can be different according to equipment and processes used). This ensures product safety and mitigates any potential microbiological contamination post-process. The temperature levels and time required may, however, vary between insect species or the treatment before the drying step (e.g. blanching time) and processes used (e.g. oven, microwave).
2. All equipment and the processing environment should be thoroughly cleaned between batches and during regularly scheduled shutdowns.

5.6.5 Grinding

Grinding or milling is a process that will reduce the particle size. Such particle size reduction can happen in a dry or a wet state before being dried. The ultimate resulting material would be a homogeneous powder. Considering the characteristics of the product (powder form), it is susceptible to potential microbiological contamination risk if hygiene practices are not maintained in production. Water activity and storage temperatures should be appropriately monitored. Additionally, appropriate packaging that is a good barrier to moisture and air should be used. The grinding/milling machinery should be cleaned regularly and thoroughly based on its installation (cleaning-in-place (CIP) and cleaning-out-of-place (COP) systems).

5.6.6 Fractionation

Like many multi-component food components, insect material can be separated into its various subcomponents through various methods. The foundational concept is to apply physical, chemical, and/or biochemical processes to extract protein, fat/oil, chitin, and derivatives (e.g. chitosan and glucosamine) at the end of the process. To obtain fat/oil, mechanical separation (pressing), heat treatment or organic solvents (e.g. supercritical CO₂ in low temperatures under high pressure) might be used. The latter method also preserves the nutritional values and bioactivity of the dry protein residues (fully defatted insect meal).

Chitin extraction might require chemical and/or enzymatic processing. Insect producers should identify possible hazards and/or contaminations during the aforementioned processes. Parameters such as mechanical errors, chemical hazards (residual from cleaning procedures or mechanical leaks), and efficient cleaning methods between batches should be considered, among others.

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