

## 14. Regulatory frameworks governing the use of insects for food security

The production, trade and use of edible insects as food and feed touch on a wide range of regulatory areas, from product quality assurance to the environmental impact of insect farming. Regulatory frameworks referred to in this chapter include legislation, standards and other regulatory instruments (legally binding or otherwise), at both the national and international levels, which would have a role in regulating the use of insects as food and feed. Regulatory frameworks on the use and conservation of insects in areas such as biodiversity conservation, disease control, IPM, sanitation, pest eradication and the health sector are not discussed here.

Globalization and growing consumer concern over food quality and production methods have dramatically changed consumption patterns in recent decades. Food chains have become longer and more complex due to the global trade in raw materials and food ingredients. As a result, food safety and the quality of traded food products have received increased attention and the regulatory frameworks governing food and feed have developed greatly in the last 20 years.

In many societies, insects are not perceived as a regular food/feed product and, as such, they rarely fall within the remit of food/feed regulators. At the national and international levels, standards and regulations acknowledging the use of insects as ingredients for food and feed are rare (Box 14.1).

### BOX 14.1

#### FAOLEX

FAOLEX is a comprehensive and up-to-date computerized legislative database that constitutes one of the world's largest electronic collections of national laws and regulations on food, agriculture and renewable natural resources. The resource is free and available online (<http://faolex.fao.org>). A search (conducted on 29 January 2013) in FAOLEX using the keyword "insects" generated 937 references to laws (in over 50 countries) dealing with insect-related issues, mainly concerning sanitation and pest control in the agricultural sector. Laws and regulations on beekeeping and silkworm-raising are well developed in several countries with significant honey and silk industries. A few countries have legislation that refers to insects in food as impurities and that prescribes maximum permissible levels. No reference could be found in the database to countries with laws or regulations governing the use of insects as food or feed ingredients. It seems, therefore, that specific legislation to regulate the use of insects in food and feed is yet to be developed.

At most, legislative references to insects in the context of food prescribe maximum limits of insect traces in foodstuffs, where this is unavoidable. Examples can be found in regulations governing the production of dried products such as grains, flour, peanut butter, fruits, spices and chocolate.

The absence of specific legislation is not because the risks are being neglected but because the quantities of insects in food and feed are, at present, negligible. If insects

were to become a more widely used ingredient in food and feed, a risk assessment would need to be carried out and an appropriate regulatory framework created.

For example, according to the United States Food and Drug Administration's (FDA) booklet, *Food Defect Action Levels*, average contamination levels below 150 insect fragments per 100 g of wheat flour pose no inherent health hazard. Table 14.1 gives other examples from the booklet of maximum permissible levels of insect contamination in food products for humans (below which such contamination is not considered to be hazardous to health).

TABLE 14.1

**Maximum permissible levels of insect contamination in food products**

Product	Type of insect contamination	Maximum permissible level
Canned sweet corn	Insect larvae (corn ear worms or corn borers)	Two or more 3 mm or longer larvae, cast skins, larval or cast skin fragments, the aggregate length of insects or insect parts exceeds 12 mm in 24 pounds
Canned citrus fruit juices	Insects and insect eggs	Five or more <i>Drosophila</i> and other fly eggs per 250 ml or 1 or more maggots per 250 ml
Frozen broccoli	Insects and mites	Average of 60 or more aphids and/or thrips and/or mites per 100 grams
Hops	Insects	Average of more than 2 500 aphids per 10 grams
Ground thyme	Insect filth	Average of 925 or more insect fragments per 10 grams
Ground nutmeg	Insect filth	Average of 100 or more insect fragments per 10 grams

Source: USFDA, 2011.

Insect "impurities" may actually be good for health. For example, people in rice-eating regions typically ingest significant numbers of rice weevil (*Sitophilus oryzae*) larvae, and this has been suggested as an important source of vitamins (Taylor, 1975).

For developed countries, the absence of specific legislation on the use of insects as food and feed ingredients is due to, among other factors, the very limited development of industrial insect farming to supply the food and feed sector and the insignificant quantities of insects currently consumed as food.

#### 14.1 MAJOR BARRIERS FACED

Investors, farmers and entrepreneurs willing to build up industrial-scale insect-rearing plants for food and feed have difficulty identifying the appropriate regulations and laws, if they exist at all. In many countries, the lack of a legal framework on insects for use as food and feed is considered by investors to be a major barrier (Box 14.2).

According to some producers of insects for food and feed, the barriers to establishing markets for insects and the implications for trade are a result of the following factors:

- Unclear regulations and legislation on farming and selling insects for human consumption and feed are an obstacle. For example, in the United States, the FDA's *Food Defect Action Levels* lists allowable percentages of insect fragments in food, yet insects as food do not seem to fall into any category. In the EU, the European Novel Food Regulation (Regulation (EC) No.258/97) (European Commission, 1997), which regulates food and ingredients that were not used for human consumption to a significant degree prior to 15 May 1997, restricts the trade of insects, even if they are consumed in other countries (Lähteenmäki-Uutela, 2007).
- Difficulty in understanding relevant national and international information regarding processing and quality, little networking among producers, and a lack of demand for large quantities for human consumption in developed countries represent additional obstacles.
- The lack of awareness among consumers and buyers about existing markets leads to low demand.
- It is difficult to market insects for human consumption because they are perceived to be inherently unsanitary.

## BOX 14.2

**Barriers to market establishment in the European Union**

Perceived major barriers to the farming of insects in the EU include:

- strict sanitary regulations for setting up farms;
- a lack of guidelines on the mass-rearing of insects;
- a lack of clarity on which insects are to be authorized for the market by EU Novel Food;
- limited information on species eaten prior to 15 May 1997, which is required for categorization as a Novel Food (Box 14.3);
- the recent restriction in the EU on the feeding of poultry, pig and farmed fish with processed animal proteins (PAPs), with no reference to insects.

Source: L. Giroud, personal communication, 2012.

Key EU legislation on the feeding of animals with insect meal can be summarized as follows:

- The catalogue of feed materials (Commission Regulation (EC) No.68/2013) is a non-exhaustive list. In principle, therefore, non-listed products can also be placed on the market. Feed producers are encouraged to have the important feed materials listed and thus described. Although “terrestrial invertebrates” are listed under entry 9.16.1 (“Whole or parts of terrestrial invertebrates, in all their life stages, other than species pathogenic to humans and animals; with or without treatment such as fresh, frozen, dried”), a specific entry for “insect meal”, for example, does not yet exist. Such a listing could be made at the initiative of a stakeholder via the EU Feed Chain Task Force.
- According to Regulation (EC) No. 1069/2009, insect meal is a PAP that has to be processed in line with the standards contained therein. Regulation (EC) No. 1069/2009 classifies insects and other invertebrates as Category 3 material (fit but not intended for human food chains). As such, they are suitable as feed for livestock, especially fish, poultry and pigs.

However, despite Regulation (EC) No. 1069/2009, Regulation (EC) No. 999/2001 prohibits the feeding of farmed animals with PAPs, with the exception of hydrolysed proteins;<sup>15</sup> proteins derived from insects fall within the definition of PAPs.<sup>16</sup> Thus, insect meal cannot currently be used as feed in the EU for food-producing animals, and may only be fed to pets. Referring to Regulation (EC) No. 999/2001 (the “BSE” regulation), authorities at various levels support a ban on feeding insect protein to farmed animals. However, in its original version, the BSE regulation only contained a ban on the use of protein from mammals as feed. This is still evident in the current version in the preamble and Article 7(4).

In July 2012, a relaxation of this ban was agreed to allow such PAPs to be fed to aquaculture species. This change will formally commence in early 2013 and will apply from 1 June 2013. Once certain conditions can be met, the EU also intends to re-authorize the use of such PAPs in pig and poultry feed (W. Trunk, personal communication, 2012).

The EU promotes free-range farming of pigs and poultry, in which the consumption of invertebrates is not merely tolerated but seen as correct procedure in terms of both animal welfare and feed intake, as free-roaming poultry and pigs eat insects as a natural feed. However, “natural feed” is not subject to checks for pollutants such as heavy metals, PCBs/dioxins or pesticides.

<sup>15</sup> Regulation (EC) No. 999/2001, Annex IV (as amended by Commission Regulation (EC) No. 1292/2005); Regulation (EC) No. 1923/2006; and Commission Regulation (EU) No. 56/2013).

<sup>16</sup> Commission Regulation (EU) No. 142/2011, Annex I(5) defines processed animal proteins as “animal protein derived entirely from Category 3 material, which have been treated ... 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”.

## 14.2 LEGAL FRAMEWORK AND STANDARDIZATION

International standards can serve as a useful basis for countries to set up their regulatory frameworks for food and feed. Aligning legislation with international standards, particularly Codex Standards (Box 14.3), facilitates their compliance with trade rules and enables and facilitates the trade of food and feed products.

### BOX 14.3

#### Codex Alimentarius

As the international reference standards for food and feed, a Codex Alimentarius standard on the use of insects as food and feed ingredients could serve as a reference for national legislation on insect production and use as food and feed, from both safety and quality viewpoints.

While the Codex Alimentarius does not contain specific standards on fresh or processed insects for use as food and feed, “insects” are included in the Codex Alimentarius standards as “impurities”. For example, Codex Standard 152-1985 stipulates that wheat flour shall be free of:

- abnormal flavours, odours and living insects;
- filth (impurities of animal origin, including dead insects) in amounts that may represent a health hazard to human health.

FAO and WHO established the Codex Alimentarius Commission in 1963 with the main objectives of protecting the health of consumers and ensuring fair trade practices in the food trade.<sup>17</sup> Presently, the Commission has 185 members – 184 member countries, 1 member organization (the EU) and 204 observers. The Codex Alimentarius Commission develops harmonized international food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of the international food trade. Codex standards are based on the best available science assisted by independent international risk assessment bodies and ad-hoc consultations organized by FAO and WHO. Although their implementation by members is voluntary, Codex standards serve in many cases as a basis for national legislation.

Under the World Trade Organization’s (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), national legislation that conforms with Codex standards is presumed to comply with international obligations resulting from the SPS Agreement. According to the SPS Agreement:

Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations ... Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be ... presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994 (Article 3, paragraphs 1 and 2).

These “international standards, guidelines or recommendations” for food safety are defined, in turn, as:

the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice (SPS Agreement, Annex A, Paragraph 3(a)).

WTO members that wish to apply stricter food-safety measures than those set by Codex may be required to justify these measures scientifically (WHO/FAO, 2012).

<sup>17</sup> See the homepage of Codex Alimentarius at: [www.codexalimentarius.org](http://www.codexalimentarius.org).

Specific legal provisions on the use of insects for food and feed production would serve to control and regulate the use of insects by industry processors and would guarantee consumer access to information. For this purpose, regulators would need to assess the potential risks associated with the use of insects, in terms of both species and quantities. Legal frameworks that are more protective of consumer interests may also focus on the information displayed on food packaging and the information made available to consumers on the results of risk assessments on the effects of insects on human health.

In 2010, the Government of the Lao People's Democratic Republic proposed to the FAO/WHO Codex Coordination Committee for Asia that standards for regional trade and food safety for house crickets be developed. This proposal was not accepted, however, as data indicated that there was no verifiable level of trade in insects to warrant such action (FAO, 2010a).

There is an increasing lobby in the feed sector for the development of specific legislation on the use of insects as feed. Lobbying is being conducted at a national level (including private sector-led actions by United States-based companies to obtain FDA approval on the use of insects in feed) and at a European level.

The farming of insects and edible arthropods for human food, referred to as minilivestock, is emerging as an ecologically sound form of animal husbandry. Recently, as a result of strong lobbying by the feed sector, initiatives have begun to emerge to create an enabling environment for the development of regulations and standards on the use of insects for aquaculture feed and to a lesser degree as human food. At the European level, for example, the quality and safety criteria for insect-based feed are currently undergoing review.

The production and consumption of insects should also be analysed from the viewpoint of their potential impact on health and biodiversity and the potential environmental hazards associated with insect production and release, including the accidental release of insect species not indigenous to the area of production. Risk assessments and containment measures should address potential outbreaks of disease that may be harmful to human or animal health and to plant protection. Other target areas for legislation could include regulation of the trade between countries of *living* insects as breeding stock.

As is often the case in an emerging industry, and as identified by the Expert Consultation Meeting on Assessing the Potential of Insects as Food and Feed in Assuring Food Security in Rome in January 2012, in addition to the development of public national and international standards, self-regulation by the insect producers/processors and other stakeholders in the sector can be useful in fostering harmonization and mutual recognition. This could include the development of standards, codes of practices/standards and product quality metrics to garner credibility.

The concept of novel food is guiding the development of rules and standards for insects as human food. The term novel food refers to food products that do not have a history of human consumption in the region or country in question. Examples of definitions of novel foods contained in national legislation are:

- “a food that does not have a history of human consumption in Australia or New Zealand” (Australia New Zealand Food Standards Code – Standard 1.5.1);
- “a substance, including a microorganism, that does not have a history of safe use as food” (Canada's Food and Drug Regulations (C.R.C., c.870) – B.28.001).

The term may include edible insects, oils, berries and foodstuffs that are the product of biotechnology (including genetically modified foods). Foods that are the product of biotechnology may be considered as novel globally, but foodstuffs derived from natural products, while novel in some countries, may represent a considerable portion of normal dietary intake in other countries. It has been suggested that a “long history of human use” implies that insects intentionally harvested for human use or consumption do not pose a significant risk (Banjo, Lawal and Songonuga, 2006b). However, in a number of developed countries, such as the United States, Canada and in the EU, some edible

insect species may require a premarket safety evaluation and authorization for sale as a novel food or ingredient (Box 14.3).

#### BOX 14.4

##### Definition of novel food by the European Commission

Regulation (EC) No. 258/97, Article 3(1), of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients considers foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997 to be “novel foods” and “novel food ingredients”.

According to this regulation, such novel foods and novel food ingredients must be, among other things (EC, 1997):

- safe for consumers; and
- properly labelled to not mislead consumers.

The EU obligates risk assessments (premarket safety assessments) on each individual species/product before it is placed on the market and can, in a second step, conduct an authorization (conditions of use, labeling and designation).

The European Food Safety Agency (EFSA), whose function is to ensure consumer protection and maintain food safety in Europe, carries out risk assessments for prospective novel foods. In 2011, the EFSA began to identify media agencies reporting on edible insects as a subject of the primary filter of the agency, which carries out data analysis and signal detection. During this process, EFSA started to collect more information on the subject. The EU is funding a project to investigate insects as a potential protein source in feed (KBBE 2012.2.3-05, see Chapter 13) and is also involved in a network of stakeholders in the field. To include insects in the diet as novel food, a premarket safety evaluation will need to be set up and the EFSA will be asked to perform a risk assessment.

The novel food concept may impose heavy administrative burdens and costs. Therefore, while it may protect consumer health, it may be out of reach of small-scale farmers wishing to farm a “novel” insect species. In the EU, a current proposal on the use of insects for human foods is to consider all insects as novel foods, except those 5–10 insect species (still to be defined) that were most commonly reared in Europe before 1997.

In a given country, a case could be made that an edible insect species is not novel and has a history of safe use. Most probably, the regulatory authority would need to conduct a risk assessment, and additional information such as pathogen/insect combinations would need to be available.

Much work still needs to be done and many issues taken into account when elaborating normative frameworks and adjusting for insect-inclusive food laws. At the Expert Consultation Meeting in January 2012, therefore, a working group developed the following proposals for elaborating regulatory frameworks (FAO, 2012f):

- Scientists, industry and regulators need to collaborate proactively and contribute to self-regulation in the sector. An analysis of existing policies and regulations on food and feed ingredients is necessary and can be achieved by:
  - communicating with the relevant regulatory bodies and their key contact persons;
  - identifying impediments and finding out where the existing framework needs to be improved.
- The development of new policies is inevitable. It will be necessary to listen to regulators to find out what can be expected, to be sensitive to consumers who might demand specific regulations, and to collaborate with retailers. An interesting example of a model to facilitate such a consultation is the Global Agricultural

Practice initiative. Examples of new regulations to be considered include quality standards, quality control and quality assurance guidelines on contaminants and nutritional compositions; label requirements; environmental impact assessments; and requirements for feed for animals (for example, can manure be used?).

- Public-sector and private-sector regulatory frameworks will need to be standardized at the national and international levels.

A defined degree of guaranteed safety is necessary for any product. Feasible practices for production (including sanitation measures) need to be developed, for which other industries can serve as role models. Private and public standards may establish the basis of harmonized regulatory practices on the use of insects as food and feed. Legal frameworks should be developed to consolidate and set binding provisions and to ensure the implementation and enforcement of such provisions throughout the sector. International harmonization through private or public standards would be positive for the sector but difficult to achieve because of the diversity of insect species and processing methods. Nevertheless, this dilemma needs to be addressed.

Recommendations for the regulatory framework on edible insects are as follows:

- Promote private and public standardization at the national and international levels for insects as food and feed, accompanied by a premarket safety evaluation (under Codex Alimentarius, among other standard-setting organizations).
- Promote the establishment of appropriate international and national standards and legal frameworks to facilitate the use of insects as food and feed and the development and formalization of the sector.
- Take into consideration the potential effects of insect production and rearing on the environment, and the environmental and trade implications of the international movement of insects, when drafting and implementing regulatory frameworks for insect production and use. This would oblige regulators to pay attention to a broad range of regulatory areas, including phytosanitary legislation, biodiversity, disease control and the environment.