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STRATEGIC SAFETY CONCEPT FOR INSECTS AS FEED, UPDATED

1. INSECT PRODUCTION

Generally, Regulations (EC) No 178/2002¹ (General Food Law) and 183/2005² (Feed Hygiene) apply to all feed business operators and therefore also to those rearing insects. These acts ensure that general feed safety requirements, traceability and manufacturing requirements apply to insect farming. Producers of insects for feed use are feed business operators according to the Feed Hygiene Regulation as their activity is considered a primary production of feed. This implies hygiene requirements, safeguard measures and manufacturing standards to be respected by the insect farmers.

Moreover, Regulation (EC) No 1069/2009³ (Animal By-Products, ABP) establishes that insects kept in the EU for the production of food, feed or other purposes are "farmed animals". This status has repercussions on the animal health status of the farmed insects: Article 10 of the Animal Health Law⁴ establishes biosecurity measures for establishments keeping animals and establishes responsibilities for the operators in the area of animal health and biosecurity.

General requirements for feed hygiene and animal health apply to insect production

1.1. Insect species

The risk assessments related to insects as food or feed done by BE, NL, FR and EFSA identified the most relevant insect species which are currently –at small scale- reared in the EU.

Insects are currently listed as “Terrestrial invertebrates” in the EU-Catalogue of feed materials⁵. The insect species reared in the EU shall not be:

- **pathogenic**⁶ or have other **adverse effects** on **plant, animal** or **human health**,
- recognised as **vectors** of human, animal or plant pathogens⁷,

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1–24).

² Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1–22).

³ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁴ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (OJ L 84, 31.3.2016, p. 1–208).

⁵ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1–64).

⁶ For example, screwworms (*Cochliomyia hominivorax* and *Chrysomya bezziana*) are listed in <http://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2006/>

- protected or defined as an **invasive alien species**⁸.

In order to be more precise on the eligible insect species, when lifting the current ban on the use of insect Processed Animal Protein (PAP) in feed for aquaculture animals (see section 4.3), a **positive list** of insect species could be laid down in the Catalogue of feed materials (see section 4.1) and consistently of insect species intended for the production of PAP in a new Section of Annex X to Regulation (EU) No 142/2011. This first list would be drawn up based on the insect species currently farmed (at small industrial scale)⁹ in the EU scrutinised against the above mentioned criteria.

The subsequent addition of non-autochthonous insect species in the EU to the positive list would be based on a comprehensive EFSA opinion and will take into account environmental aspects.

Insect species reared in the EU must comply with environmental and health criteria. A short positive list based on the currently farmed species may be established

1.2. Substrates as feed for insects

Regulation (EC) No 767/2009¹⁰ (the Feed marketing Regulation) provides that animals in the EU may be only fed with safe feed. With respect to feed/substrate for insects, Annex III to the Feed marketing Regulation **prohibits the feeding of faeces and separated digestive tract content**.

Furthermore, the Animal By-products Regulation **prohibits the use of** certain materials such as **manure or catering waste**. Moreover, according to Regulation (EU) No 142/2011, unprocessed former foodstuffs¹¹ containing meat or fish are currently not authorised as feed for farmed animals.

Finally, as insects reared in the EU are farmed animals, Regulation (EC) No 999/2001¹² (the TSE Regulation) **prohibits to feed insects with any processed animal proteins (PAP)**, except fishmeal¹³.

⁷ Document on "Risk of Entry of Pathogens via Vectors" (23/10/2015, reviewed by EFSA and ECDC) lists certain insects species

⁸ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35–55) foresees in Article 4(1) a list of invasive alien species; the only insect species currently listed is the Asian predatory wasp (*vespa velutina*).

⁹ Mealworm (*Tenebrio Molitor*), Black Soldier Fly (*Hermetia Illucens*), Lesser Mealworm (*alphitobius diaperinus*), House Cricket (*Acheta domesticus*), Banded Crickets (*Grylloides sigillatus*) and Field Crickets (*Gryllus Assimilis*)

¹⁰ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1).

¹¹ Former foodstuffs are foods produced for human consumption but which is no longer intended for human consumption for reasons such as expired use-by date or due to problems of manufacturing or packaging defects; not to be confused with catering waste.

¹² Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

¹³ The TSE Regulation also prohibits to feed insects with blood products from ruminants, with gelatine from ruminants or with hydrolysed proteins other than those derived from non-ruminants or from ruminants hides and skins.

Insects may be produced in the EU exclusively with substrates eligible as feed materials for farmed animals

In its scientific opinion of 8 October 2015 on the "Risk profile related to production and consumption of insects as food and feed"¹⁴, EFSA concluded that, **when currently allowed feed materials are used** to feed insects, the microbiological hazards, including prions (TSE), are expected to be comparable to other sources of protein of animal origin; the substrate used as feed for the insects is considered to be one of the crucial elements with an impact on the occurrence and levels of biological and chemical contaminants. Thus, EFSA concluded that **new substrates** need to be specifically assessed.

Considering the EFSA risk profiling, any opening in this respect would require a **robust EFSA opinion** assessing the risk for human and animal health and recommending measures to ensure that such risk is negligible.

2. METHODS FOR PROCESSING OF INSECTS

In addition to the general feed hygiene requirements, insects intended for feed use have to be processed in establishments approved by the competent authority of the relevant Member State according to the ABP Regulation, addressing mainly biological risks.

When insects are rendered into PAP, operators currently producing insect meal with plant-based substrates must comply with processing methods 1-5 or processing method 7¹⁵ provided for by the ABP implementing Regulation. The processing is based on parameters such as the combination of reduction of particle size, heat treatment, time and pressure.

The mandatory HACCP system in insect farms includes also sampling during the production process and the checking of the final insect products against the microbiological criteria set out by the ABP implementing Regulation.

Establishments processing insects in the EU must be approved by the competent authority in the relevant Member State

Based on applications submitted by interested parties, Member States or the Commission would mandate EFSA to assess processing methods for establishments placing processed insect protein on the market to have EU methodologies in analogy with processing method 6 described in Chapter III (F) of Annex IV to Regulation (EU) No 142/2011 for aquatic animals including invertebrates.

3. CONTAMINANTS AND PLACING INSECTS ON THE MARKET

Regulation (EC) No 767/2009 on the marketing and use of feed requires that feed for and from insects is safe. In addition, Article 10(1) of Regulation (EC) No 1069/2009 lists "aquatic and terrestrial invertebrates other than species pathogenic to humans or animals" as **Category 3** materials, which can be used for the production of feed for farmed and pet animals (without prejudice to feed ban rules).

¹⁴ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4257.pdf

¹⁵ Processing methods as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011

Directive 2002/32/EC¹⁶ (the Undesirable Substances Directive) establishes maximum levels of undesirable substances in feed materials and compound feed. Feed materials for insects and insects used as feed material have to comply with these maximum levels.

The general feed safety requirements of Article 15 of the General Food Law apply to undesirable substances for which no maximum level has been established. Moreover, insects are covered (under "Other terrestrial animal products") by Regulation (EC) No 396/2005¹⁷ establishing pesticide residue limits.

<p style="text-align: center;">EU residue limits for contaminants apply to feed for insects and insects as feed materials</p>
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4. USE OF INSECTS AS A FEED

4.1. EU-Catalogue of feed materials

The EU Catalogue of feed materials lists feed materials together with a product description and the respective product properties in a non-exhaustive manner. Terrestrial invertebrates (entry 9.16.1) are in the current Catalogue described as "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". Live insects complying with this description can be fed to animals in the EU without prejudice to specific legislation (see chapter 4.2).

On top of the inclusion of the positive list of eligible insect species mentioned in chapter 1.1, a revision of the Catalogue should include the following aspects:

- "Processed animal protein" (9.4.1) would explicitly include insects;
- "Terrestrial invertebrates" (9.16.1) would consequently cover only insects not processed as referred to in the Animal by-products Regulation; and
- The footnote referring to insect products would require mandatory indication of the life stage of the insect.

4.2. Feed ban rules of the TSE Regulation

The feed ban rules laid down in Article 7 and Annex IV of the TSE Regulation prohibit the use in feed for farmed animals of PAP derived from insects. The only uses of insect PAP allowed are for pet food or for feed for fur animals. The feed ban does not apply to fats and oil derived from insects. Live insects may not be fed to ruminants¹⁸ but may be fed to non-ruminant animals if authorised by the competent authority of the Member State¹⁹. With respect to the ABP rules, insects treated but not processed according to Regulation (EC) No

¹⁶ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement (OJ L 140, 30.5.2002, p. 10).

¹⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1–16).

¹⁸ Article 7(1) of Regulation (EC) No 999/2001 prohibits the use of any animal proteins in feed for ruminants.

¹⁹ As live insects are not animal-by products, they are out of the scope of Regulation (EC) No 1069/2009, thus no conditions for the use of live insects as feed are laid down at EU level.

1069/2009, e.g. dry frozen insects, may be used for petfood²⁰ or technical uses but may not be used for feed for food producing animals.

The feeding of non-ruminant PAP to aquaculture animals was recently allowed by Regulation (EU) No 56/2013 amending the TSE Regulation. This opening, however, cannot be applied to insects due to the wording used, which refers to slaughterhouses, while insect larvae are not slaughtered before being processed into PAP.

PAP derived from insects cannot be fed to farmed animals, other than fur animals, in the EU

The EFSA scientific opinion of 8 October 2015 provides the basis for a revision of the feed ban in view of authorising the use of insect PAP, fed on substrates currently allowed by the legislation, in feed for non-ruminant animals.

The EU Reference Laboratory for Animal Proteins has investigated the implementation of analytical methods for feed ban official controls, laid down in Annex VI to Regulation (EC) No 152/2009²¹ (light microscopy and PCR), on 9 commercial samples of insect PAP. These investigations show that: 1/ the PCR method can be used on insect PAP (no problems of interferences were detected); 2/ certain particles can be identified by observations by light microscopy as being of insect origin, however, for certain muscle fibres, there is a risk of confusion with muscle fibres from other taxonomic PAP.

Based on this conclusion, the **revision of the feed ban can be envisaged** in a first stage to authorise the use of insect PAP in feed **for aquaculture** animals. More precisely, in analogy to Regulation (EU) No 56/2013, the revision of Annex IV would imply a new Section F in Chapter IV with **specific provisions for insect PAP**. In a second stage, once operational and validated analytical techniques are available, the use of insect PAP in feed for pigs and poultry could be authorised under the condition that the substrate and the processing of the insects ensure that there is no risk of transmission of pathogens to which those species are susceptible.

In line with the position expressed in the TSE Roadmap 2²², there is **no intention** to propose a revision of the feed ban in view of allowing the use of **insect PAP in feed for ruminants**.

4.3. Import rules for insect proteins

Within the existing legal framework, the import of insect PAP is allowed based on the following requirements:

- a. The insect PAP must be produced in line with the requirements laid down for category 3 material and for PAP;
- b. Only imports from the countries listed in Part I of Annex II to Regulation (EU) No 206/2010²³ are allowed;

²⁰ Point 3(iv) of Chapter II of Annex XIII to Regulation (EU) No 142/2011 provides that the competent authority may authorise a treatment such as drying or fermentation for the manufacturing of processed petfood provided that that the treatment ensures no unacceptable risks to public or animal health.

²¹ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

²² Communication from the Commission to the European Parliament and the Council of 16 July 2010 "The TSE Roadmap 2: A strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015" (COM(2010)384 final).

- c. The processing plant in the third country must be listed in accordance with the ABP Regulation;
- d. The insect PAP consignment must be accompanied by a health certificate in line with the model health certificate laid down in Chapter I of Annex XV to Regulation (EC) No 142/2011 and must undergo the veterinary checks at a Border Inspection Post;
- e. Before release into free circulation in the EU, the importer must ensure that each consignment is tested by light microscopy and/or PCR test, in line with the Standard Operating Procedure of the EURL for Animal Protein, to verify the absence of constituents of animal origin prohibited by EU feed ban rules²⁴.

The import of treated, but not processed according to Regulation (EC) No 1069/2009, insects (e.g. dry frozen insects) for petfood is currently allowed; however, in the absence of health import requirements laid down in the ABP Regulation, the import of treated but unprocessed insects for the manufacturing in the EU territory of processed animal protein for food producing animals is currently not permitted.

To date, the import of insect PAP into the EU, if any, is probably very limited, considering that currently insect PAP can only be used in pet food and in feed for fur animals. In order to ensure the **protection of animal and public health** with respect to **imported insect PAP** produced in third countries, new distinct **health requirements** for import into the EU could be laid down in Annex XIV to Regulation (EU) No 142/2011, which would require that the insect PAP does **not** come from insects fed with **feed materials prohibited in the EU**.

²³ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1)

²⁴ Section C of Chapter III of Annex IV to Regulation (EC) No 999/2001.