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Abbreviations

ABP	Animal By-Products
BSA	Bovine Spongiform Encephalopathy
Insect-PAP	"processed animal protein derived from farmed insects and compound feed containing such processed animal protein"
PAP	Processed Animal Protein
TSEs	Transmissible Spongiform Encephalopathies

1 INDIRECT: INSECT BIOCONVERSION AND THE LAW

1.1 INTRODUCTION: INDIRECT AND WORK PACKAGE 1

The InDirect project targets biorefinery of under-spent side streams as feedstock, aiming at 'closing loops' and 'producing more with less'. One of the value chains considered is the InDIRECT biorefinery, which converts side streams into crude extracts via a two-step process. The aim of the first step is to convert heterogenic feedstock into a homogenous biomass via insects. Insects are able to convert a variety of feedstock into a more homogenous biomass, being their own biomass. Even manure can be used as substrate. The second step is biorefinery of the insect biomass. The InDIRECT approach is expected to have potential for a year-round relatively stable production of mainly chitin, proteins, lipids and N-light compost.

Although the potential of insects is considerable and an increasing number of pioneers is attracted by the subject, there are still a number of barriers to reduce before insect based new value chains can be implemented. These barriers are related with aspects like legislation and acceptability of the generated products in terms of safety and perception. In Europe, the use of insects for feed and other applications is currently restricted to legislations that were put in place for classical agricultural approaches and not for new farming types, such as insect bio conversion.

One major potential barrier to the utilisation of insects as food and feed, or as waste bio convertors, is the lack of precise and insect-inclusive legislation, standards, labelling and other regulatory instruments governing the production, use and trade of insects along the food and feed value chains. So far, there has been relatively little international dialogue regarding the incorporation of insects as food and feed into international standards like the Codex.

Most, if not all legislation regarding the use of insects in Food, Feed or as a source of bio materials is regulated at a European level. This document aims at providing an overview of all relevant European legislation.

Currently, due to the demands from the nascent insect industry and from feed operators, the European Commission (EC) is elaborating a comprehensive framework that would cover all aspects of breeding and rearing insects for Food and Feed purposes. On these matters, the EC is in constant discussion, in several working groups, with the representatives of the member states (MS). This paper will summarize the main tracks the EC is working on. This paper also includes the relevant EU directives.

Legislation to be taken into account is numerous, comprising:

- Regulation (EU) No 68/2013 on the Catalogue of feed materials
- Council Directive 98/58/EC on the protection of animals kept for farming purposes
- (EC) 178/2002 on General Food Law
- Regulation (EC) 2283/2015 on Novel Foods
- Regulation (EC) 183/2005 on Feed Hygiene
- Regulation (EC) 999/2001 on rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
- Regulation (EC) 1069/2009 on Animal By-Products (ABP), and Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption

- Regulation (EC) No 1099/2009 on the protection of animals at the time of killing
- Regulation (EU) 893/2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein

And most recently:

- Regulation (EU) 2018/848 of the European Parliament and of the Council on detailed production rules of organic products
- Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers

Document purpose and scope:
The aim of DL1.3 is (1) to provide an inventory of legal aspects related to growth and use of insects, and (2) to list current bottlenecks, "easy" short-term goals and "harder" long-term legal issues. These barriers are being considered in the other work packages, and where possible, information will be collected to lower the identified barriers. The current document is an updated version of deliverable 1.2. The most recent legislations (see above) and interpretations of legislations are taken into account.

Since the legislation on several issues is in rapid evolution, this document is a snapshot of the current situation, and it aims at providing clear pathways as to where legislation should be taken, and what actions can contribute in that direction.

Intended Audience:

- InDIRECT consortium, to target the research in the InDIRECT-project towards the identified barriers
- Other parties involved in the insect biomass value chain.

1.2 INTRODUCTION: INSECT REARING AND THE LAW

Insects are attracting a lot of interest, both from the general public and from stakeholders in the industry, as a new source of more sustainable protein and lipids, for human consumption (Food), for livestock feed or pet food (Feed) or for technical applications (Non-feed). Insects are even being considered as a way of treating organic waste, in an analogy to worm-composting.

The use of insects for Food and Feed was analysed in "Edible insects: Future prospects for food and feed security", published by the FAO and Wageningen University in 2013.

This document covers all aspects of insect farming and consumption and is one of the most frequently downloaded publications in the history of FAO. It has created a strong momentum for the insect industry.

It states in the Executive Summary: "Insects as food and feed emerge as an especially relevant issue in the twenty-first century due to the rising cost of animal protein, food and feed insecurity, environmental pressures, population growth and increasing demand for protein among the middle classes. Thus, alternative solutions to conventional livestock and feed sources urgently need to be found. The consumption of insects, or entomophagy, therefore, contributes positively to the environment and to health and livelihoods[1]."

Chapter 14, "*Regulatory frameworks governing the use of insects for food security*", however is one of the shortest, and poses as many new questions as it provides answers. This is mainly due to the global scope of the document, since it is published by the Food & Agricultural Organisation of the United Nations, and to the pioneering character of the document at the time of publication (2013).

"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. 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." "At most, legislative references to insects in the context of food prescribe maximum limits of insect traces in foodstuffs, where this is unavoidable. 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."

In this document, we will fill the gap identified by the FAO, and provide an analysis of the legal framework in the European Union for insect rearing for different purposes.

We will touch upon many questions, around which confusion exist. Are insects "farm animals"? Which regulation on "farm animal welfare" applies? What feedstock is allowed for insects? Is there a difference between insects reared for food and insects reared for feed? Should there be a difference? Is it possible to rear insects as a waste management agent? Or for technical applications, a bit like fur animals? Should we

[1] http://www.fao.org/docrep/018/i3253e/i3253e.pdf ; page 15

make that possible, and if so, how? What pieces of legislation do apply now “by default”, and how do we create a comprehensive “insect rearing” legal framework? What is the status of the rest fraction, and can we use this as a soil improver, and under what conditions?

The fact that insects can have applications in multiple sectors offers optionality to business operators, but also creates confusion regarding the legal framework. The use of insect products on an industrial scale in the markets of food, animal feed and technical applications, is rapidly growing into a fully-fledged business sector. 360°-clarity on the legal framework is a prerequisite for this industry to live up to its potential.

2 INSECTS AS FARMED ANIMALS?

2.1 COUNCIL DIRECTIVE 58/1998 ON THE PROTECTION OF FARMED ANIMALS

Well describe under 3.1 that Regulation 1069 on animal by-products clearly defines insects as farmed animals. That has implications on the authorised feedstocks, but should also have repercussions on animal welfare, another field where the EU has created a level playing-field for all operators across the Union.

The first EU rules on animals kept on the farm were adopted in 1986 and concerned the protection of laying hens. Council Directives followed in 1991, first on the protection of calves then of pigs.

In 1998, Council Directive 98/58/EC[2] on the protection of animals kept for farming purposes, gave general rules for the protection of animals of all species kept for the production of food, wool, skin or fur or for other farming purposes, including fish, reptiles of amphibians. These rules are based on the European Convention for the Protection of Animals kept for Farming Purposes.

The farm animal welfare legislation is designed to cover all stages of a farm-animal's life whilst on the farm, during transport and at the time of killing.

In the EU, the enforcement of this legislation falls within the principle of subsidiarity, which means that Member States are responsible for day to day enforcement through their national legislation and controlling activities; transposition of directives into national legislation and the implementation of EU rules at national level. The European Commission is responsible for providing appropriate information and where necessary training on EU legislative requirements; ensuring that EU legislation is properly implemented and enforced; in extreme cases acting against Member States that have failed to implement legal requirements

Legislation has been further developed since to progressively improve the welfare status of farmed animals and to set standards for their transport and conditions at the time of stunning and slaughter.

2.1.1 Definition of farmed animals under Directive 58/1998

There is no specific EU legislation concerning *other farmed animals* such as ducks, geese and those raised for fur: here the general rules apply, as laid down in Council Directive 98/58/EC **on the Protection of farmed animals**, *irrespective of the species*.

The end of the phrase, "*irrespective of the species",* makes the scope of the Council Directive to be all-encompassing, seemingly to also include insects.

The directive then stipulates that these rules apply to farmed animals destined for the production of foodstuffs, wool, skin or fur, or *for other agricultural purposes*, including fish, reptiles and amphibians.

The "*other agricultural purposes"* is another comprehensive part of the definition and seems intended to make sure no practice of farming animals could fall outside of the scope. As it stands, that would mean insects are included, but just not mentioned (for example because of an omission at the time of drafting).

[2] http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:31998L0058

The directive even specifically mentions fish, reptiles and amphibians, to make it clear that the Directive is not limited to the most common farm animals, which are mammals (cattle, pigs, rabbits, etc.) or birds (poultry, pigeons, ostrich, etc.), but also includes the 3 main other Classes of Vertebrata[3].

This Directive, however, then specifically stipulates it does **not** apply to:

- wild animals;
- animals intended for use in sporting or cultural events (shows);
- experimental or laboratory animals;
- *invertebrate animals*.

This last specification is important: insects are not specifically mentioned, but it is without any doubt that insects are invertebrate animals. So, this Directive does not apply to rearing insects.

2.1.2 Consequences within the framework of the Directive

The Directive contains clear instruction for the Member States to adopt provisions to ensure that the owners or keepers of animals look after the welfare of their animals and see that they are not caused any unnecessary pain, suffering or injury. The rearing conditions relate to the following, with our own emphasis added on aspects which could be of impact when applied to insect rearing:

- **staff:** animals must be looked after by a sufficient number of staff who have the appropriate professional skills, knowledge and competence;
- **inspections:** all animals kept in husbandry systems *must be inspected at least once a day*. Injured or *ill animals must be treated immediately* and isolated if necessary in suitable premises;
- **maintaining records:** the owner or keeper of the animals must keep a record of any medical treatment for at least three years;
- **freedom of movement:** all animals, even if tethered, chained or confined, must be given *enough space to move* without unnecessary suffering or injury;
- **buildings and accommodation:** materials used in the construction of buildings must be capable of being cleaned and disinfected. Air circulation, dust levels, temperature and relative humidity should be kept within acceptable limits. Animals kept in buildings must *not be kept in permanent darkness* or constantly exposed to artificial lighting;
- **automatic or mechanical equipment:** automatic or mechanical equipment essential for the health and well-being of the animals *must be inspected at least once a day*. Where an artificial ventilation system is in use, *an appropriate backup system* must be in place to guarantee sufficient air renewal;
- **feed, water and other substances:** the animals must be given a wholesome and appropriate diet, fed to them in sufficient quantities and at regular intervals. All other substances are prohibited, unless given for therapeutic or prophylactic reasons or for the purposes of zootechnical treatment. In addition, the feeding and watering equipment must minimise the risks of contamination;
- **mutilations:** national rules on mutilation apply;
- **rearing methods**: rearing methods that cause suffering or injury must not be used unless their impact is minimal, brief or expressly allowed by the national authorities. No animal should be kept on a farm if it is harmful to its health or welfare.

Inspections

Member States must take the necessary steps to ensure that the competent national authorities *carry out inspections*. They must report on these inspections to the Commission, which will use the reports to formulate proposals on harmonising inspections.

[3] This is a legal analysis, without any ambition regarding the taxonomical system.

The fact that this Directive specifically excludes invertebrates (and thus also insects), means an insect breeding operation does not have the obligation to - for example - daily inspect all insects or its mechanical equipment; have a back-up system for the ventilation system; be inspected by the competent national authorities, etc.

This conclusion invalidates several obligations that seems logical in a regular livestock farming operation but are not applicable when it comes to insects.

It improves the odds to get insect bioconversion approved as an alternative technology for disposal of animal by-products under Regulation 1069/2009, as elaborated above.

2.2 REGULATION 1099/2009 ON THE PROTECTION OF ANIMALS AT THE TIME OF KILLING

Closely linked to the theme of the welfare of farmed animals, is the issue of protection of animals at the time of killing, under Regulation 1099/2009. [4]

This Regulation introduces welfare rules for the killing or slaughter of animals kept for the production of food and products such as fur and leather. It also covers the killing of animals on farms in other contexts such as disease control situations. The regulation does not apply to animals killed in the wild, or as part of scientific experiments, hunting, cultural or sporting events and euthanasia practiced by a veterinarian, nor to poultry, rabbits or hares for private domestic consumption.

Animals must be spared any avoidable pain, distress or suffering during their killing. Businesses, such as slaughterhouse operators, must ensure that animals:

- are provided physical comfort and protection, kept clean, protected from injury and handled and housed considering their normal behaviour;
- do not show signs of avoidable pain or fear or abnormal behaviour;
- do not suffer from prolonged withdrawal of feed or water;
- are protected from avoidable interaction with other animals that could harm their welfare.

Facilities used for killing must fulfil all these conditions at all times.

The Regulation is quite detailed concerning Restraining and stunning methods, certificates of competence and the rules for the construction, the equipment and operations of slaughterhouses.

It refers explicitly to Article 13 of the Treaty on the Functioning of the European Union, which introduced the recognition that animals are sentient beings*.

This could be an important piece of legislation regarding insect bioconversion, and the subsequent killings of insects. So, let's have a look at the applicable definitions:

> *Article 2*
> **Definitions**
> For the purposes of this Regulation, the following definitions shall apply:
> (a) 'killing' means any intentionally induced process which causes the death of an animal;
> (b)'related operations' means operations such as handling, lairaging, restraining, stunning and bleeding of animals taking place in the context and at the location where they are to be killed;
> (c) 'animal' means any **vertebrate** animal, excluding reptiles and amphibians;

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:303:0001:0030:EN:PDF

This definition excludes all invertebrates (and even the vertebrate reptiles and amphibians), so insects clearly do not fall under the scope of this Regulation.

So, the two main pieces of legislation that cover the act of insect farming itself, do NOT consider insects as farmed animals. What gives rise to the notion that insects are farmed animals? The Regulations covering the front-door (what you can feed to insects), and the backdoor (where farmed insects can be used for).

3 EU LEGISLATION ON INSECT REARING FEEDSTOCK

3.1 THE ANIMAL BY-PRODUCTS REGULATION 1069/2009

The Animal By-products Regulation[5] 1069/2009 has its own definition of "farmed animal" under Article 3:

> *"For the purposes of this Regulation, the following definitions shall apply:*
> *1. 'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;*
> *2. 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;*
> *3. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;*
> *4. 'carcase' means carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;*
> *5. 'animal' means any **invertebrate** or vertebrate animal;*
> *6. 'farmed animal' means: (a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes;"*

This definition clearly includes insects when they are farmed. So: farmed insects are "farmed animals".

Then, we need to look at the purpose of this Regulation, to correctly assess the impact of this divergent definition of insects as "farmed animals".

What is Regulation 1069 about?

> *TITLE I: GENERAL PROVISIONS*
>
> *CHAPTER I: Common provisions*
>
> *Section 1: Subject matter , scope and definitions*
>
> *Article 1: Subject matter*
> *This Regulation lays down public health and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain.*

Article 1 of 1069/2009 is an interesting one, as it determines the two areas in which it has severe implications on the insect bioconversion industry.

First, we need to take a thorough look at the impact this Regulation 1069 has on which "animal by-products" can be used as animal feed. This sounds like a repetition of the first point, but here we will examine which

[5] 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

side streams we can use as a feedstock for our insects! Indeed, any limitation Regulation 1069 imposes on the use of animal by-products in animal feed, will have a direct impact on the side streams that we can bioconvert using insects.

Article 11 of Regulation 1069/2009 prohibits the feeding of terrestrial animals of a given species other than fur animals with processed animal protein (PAP) from the bodies or parts of bodies of animals of the same species: in legal jargon this is dubbed “intra-species recycling”, for colloquially it is known as the “cannibalism clause”. In short, pigs should not be fed pig protein, chicken should not be fed chicken protein.

This is the DNA-question. Elaborate here that DNA is checked at the level of compound feed, not at the level of individual ingredients.

If insect meal producers could use a test to prove there is no pig-DNA in their insect meal, it could be allowed for pigs, but this is not the case.

Check the problem with the list of Animal By-Products that are allowed as feed: if we feed these products to the insects, there is a risk of a positive DNA-test on the insect meal for another species protein. If we use milk products, this could raise a red flag for ruminant DNA!

The Animal By-products Regulation prohibits, in particular, the use of **manure, catering waste** and **unprocessed former foodstuff** containing meat or fish as feed for farmed animals.

Secondly, we’ll see that the insect biomass resulting from insect bioconversion is without any doubt an “animal by-product” and need to follow the rules laid down under this regulation. This will have an impact on the markets where we can use insect products, especially in the feed market. We’ll come back on this in Chapter 4.

Before we can do this, however, we need to have a close look at other Regulations that have an impact on the feedstock allowed for insects.

3.2 REGULATION 999/2001 ON TSE[6]

Bovine Spongiform Encephalopathy (BSE) is a Transmissible Spongiform Encephalopathies (TSE) of cattle. BSE was first diagnosed in the UK in 1986, and reached epidemic proportions with over 20.000 cases per year at its peak. It was considered a result of cattle being fed with processed animal protein, produced from infected ruminant carcasses.

BSE is considered to be transmissible to humans, with severe health risks: Variant Creutzfeldt-Jacob Disease (vCJD) is a TSE disease in humans, assumed to be caused by the transmission of the BSE agent to humans by the oral route. vCJD was first diagnosed in 1996.

The fight against TSE and BSE quickly became a policy priority. Regulation (EC) No 999/2001 laid down rules for the prevention, control and eradication of certain Transmissible Spongiform Encephalopathies (TSE). Regulation 999 is also known as the “Mad Cow Disease”-regulation.

Reg 999/2001 gathered together all BSE measures adopted over the years into a single, comprehensive framework consolidating and updating them in line with scientific evidence and international standards. It

[6] https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse_en

has been amended many times in response to the evolution of the BSE situation, new or updated scientific advice and/or technological developments. In addition, according to the EU hygiene legislation (Regulation (EC) No 854/2004), all animals presented for slaughter must undergo a veterinary inspection (ante mortem) to ensure that suspected cases do not enter the food and feed chain.

Although it sounds rather technical and focussed on a disease that has very little to do with insects, the Regulation has a strong impact on what happens in the EU with all sorts of processed animal protein (PAP), mainly through an instrument called the "feed ban".

The feed ban was established as the basic preventive measure against TSE and consisted of a ban on the use of processed animal protein (PAP) in feed for farmed animals.

Findings by the scientific committees linked the spread of BSE to the consumption of feed contaminated by the infected ruminant protein in the form of PAP. The 1994 ban on the feeding of mammalian processed animal protein to cattle, sheep and goats was expanded in 2001 with the feeding of all processed animal proteins to all farmed animals being prohibited, with certain limited exceptions. The legislators wanted to prevent any cross-contamination between feed containing PAP intended for species other than ruminants and feed intended for ruminants. Only certain animal proteins considered to be safe (such as fishmeal) could be used, and even then under very strict conditions.

Official controls must be carried out by the Member States' competent authority to verify the correct application of the feed ban, based on laboratory analytical methods, as laid down in Annex I and Annex VI to Regulation (EC) No 152/2009. The validation of analytical methods for the official controls of the feed ban is carried out by the **EU Reference Laboratory (EURL) for Animal Proteins in Feedingstuffs**, which also organizes interlaboratory studies to ensure the excellence of performance of National Reference Laboratories (NRL).

The EU feed ban provisions are reviewed regularly based on EFSA opinions and the development of new analytical methods for official controls.

By doing so, and by the same mechanism as Regulation 1069/2009 above, it impacts insect bioconversion at the front door and at the back door: it regulates what protein containing side streams can be fed to insects, and it regulates where insect-derived protein can be used for.

In short, regarding the front-door: as part of its risk reduction measures, feeding animal protein to ruminants is prohibited, as is *feeding processed animal protein (such as gelatin and blood products) to any farm animal* (except for fur-producing carnivores such as mink). Since insects are considered to be farm animals, feeding processed animal protein to insects was prohibited under this regulation.

Article 11 of 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,[7] prohibits the feeding of terrestrial animals of a given species other than fur animals with processed animal protein from the bodies or parts of bodies of animals of the same species (intra-species recycling).

The Communication from the Commission to the European Parliament and the Council of a Strategy paper on TSEs for 2010-2015 (the TSE Road Map 2) was adopted on 16 July 2010[8]. It outlines possible amendments to Union legislation to align the TSE's prevention, control and eradication measures with the evolution of the

7 OJ L 300, 14.11.2009, p. 1.

8 COM/2010/0384.

epidemiological situation on Bovine Spongiform Encephalopathy (BSE). It also emphasises that any review of the TSE rules should be primarily driven by scientific advice.

The TSE Road Map 2 addresses, *inter alia*, the revision of the current feed ban provisions for non-ruminant animals laid down in Union legislation. It acknowledges that no TSE have been identified as occurring in non-ruminant farmed animals under natural conditions and that the transmission risk of BSE from non- ruminants to non-ruminants is negligible as long as intra- species recycling is avoided. Consequently, it concludes that a lifting of the ban on the use of processed animal protein from non-ruminants in non-ruminant feed could be considered respecting the existing prohibition on intra-species recycling.

On 29 November 2010, the Council adopted conclusions on the TSE Road Map 2[9]. Those conclusions consider that it should be a prerequisite of any possible reintroduction of the use of non-ruminant processed animal protein to feed for other non-ruminant species that effective and validated analytical techniques are available to distinguish between processed animal protein originating from different species and also that there has been an analysis of the risks of relaxation, regarding animal and public health.

On 9 March 2012, the European Union Reference Laboratory for Animal Proteins in feeding stuffs (EURL- AP) validated a new diagnostic DNA-based method (PCR) which is able to detect ruminant material that may be present in feed. The validation of this method permitted the re-authorisation in 2013 of the use of non-ruminant processed animal protein in feed for aquaculture animals[10]. Subsequently, in 2015 and 2017, PCR methods, able to detect the presence of porcine or poultry material in feed, were validated by the EURL-AP. These analytical techniques allow determining the species origin of processed animal proteins in feed. Therefore, they enable the control of the correct implementation of the prohibition on intra-species recycling.

On 7 June 2018, the European Food Safety Authority (EFSA) adopted a scientific opinion[11] on the revision of the quantitative risk assessment of the BSE risk posed by processed animal proteins. The quantitative risk assessment estimated a total BSE infectivity four times lower than that estimated in 2011, with less than one new case of BSE expected to arise each year.

This assessment has opened the door for the rehabilitation of some PAPs as a feed ingredient for some livestock species.

3.3 Regulation 893/2017: Feedstock for Insects for Insect PAP's?

Regulation 893/2017 will be discussed in detail under 4.3, as it regulates where "farmed insect processed animal proteins" can be used in the feed chain. In this chapter, we'll have a look at the impact of this brand-new Regulation on the definition of insects as farmed animals and on the authorised feedstocks to rear insects on.

The Farmed Insect PAP-Regulation reinstates that insects bred for the production of processed animal protein derived from insects are to be considered as **farmed animals**, and are therefore subject to the **feed**

[9] http://register.consilium.europa.eu/pdf/en/10/st13/st13889- ad01re01.en10.pdf

[10] Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. OJ L 21, 24.1.2013, p. 3

[11] http://www.efsa.europa.eu/en/efsajournal/pub/5314

ban rules laid down in Article 7 and Annex IV to Regulation (EC) No 999/2001 as well as to the rules of animal feeding laid down in Regulation (EC) No 1069/2009.

Thus, the use of ruminant proteins, catering waste, meat-and-bone meal and manure as a feed for insects is prohibited. Furthermore, in accordance with Annex III to Regulation (EC) No 767/2009 of the European Parliament and of the Council (4), the use of faeces for animal nutritional purposes is prohibited.

The amended Annex stipulates that the substrate for the feeding of insects may only contain products of non-animal origin and the following products of animal origin of Category 3 material: fishmeal; blood products from non-ruminants; di and tricalcium phosphate of animal origin; hydrolysed proteins from non-ruminants; hydrolysed proteins from hides and skins of ruminants; gelatine and collagen from non-ruminants; eggs and egg products; milk, milk based-products, milk-derived products and colostrum; honey; rendered fats.

Furthermore, the substrate for the feeding of insects and the insects or their larvae must not have been in contact with any other materials of animal origin than those mentioned above, and the substrate did not contain manure, catering waste or other waste.

3.4 LINK BETWEEN FEEDSTOCK AND FINAL APPLICATION OF INSECT-DERIVED PRODUCTS

Careful inspection of the full text of Regulation 893 gives a better view of the intentions of the European Commission when laying down the provisions.

Regarding insect bioconversion of waste streams, paragraph 6 of the Preamble is particularly interesting:
As per the definition of 'farmed animals' laid down in Article 3(6) of Regulation (EC) No 1069/2009, insects bred for the production of processed animal protein derived from insects are to be considered as farmed animals, and are therefore subject to the feed ban rules laid down in Article 7 and Annex IV to Regulation (EC) No 999/2001 as well as to the rules of animal feeding laid down in Regulation (EC) No 1069/2009.

This creates considerable room for interpretation.

Does it mean that "insects NOT bred for the production of processed animal protein derived from insects are NOT to be considered as farmed animals, and are therefore NOT subject to the feed ban rules laid down in Article 7 and Annex IV to Regulation (EC) No 999/2001 as well as to the rules of animal feeding laid down in Regulation (EC) No 1069/2009"?

This would create a serious opportunity for rearing insects as waste-management agents: if the business case can be made on waste tipping fees and the sales of the derived products for technical applications, it would be an interesting market.

Part of the answer is probably in Regulation 893 itself, as it adds its own definition of "farmed insects" to the legal framework, by amending Annexes I of Regulation (EC) No 999/2001 to include:
'(m): "farmed insects" means farmed animals, as defined in Article 3(6)(a) of Regulation (EC) No 1069/2009, of those insect species which are authorised for the production of processed animal protein in accordance with < the Animal By-Product Regulations >'

One question we should focus on in the framework of insect bioconversion of waste, is whether this definition of "farmed insects" closes the option of legally rearing any other insect species than the seven listed in Regulation 893, or whether it actually loosens the legal framework for rearing them?

A cautious analysis would say they do, because they may not be “farmed insects”, but they remain “farmed animals”, so 1069 still applies.

Regulation 893 has only been applicable for a couple of days, and both operators and authorities still need to come to terms with the exact implications of all the provisions in this fast-changing industry, but it is clear what the European Commission were aiming for when drafting this Regulation 893: making this possible for the insect products in feed whilst safeguarding public and animal health.

The insect operators that do not aim for the Insect-PAP’s market should build on this to make new progress.

3.5 Special Feeding Purposes under Regulation 1069

Regulation 893 creates a considerable market for Insect-PAP in European aquaculture, and we’ve analysed the limits Regulation 1069 imposes regarding the feedstock that can be used for rearing insects.

Now, when we step away completely from “insects for feed or food”, we should have a look at Regulation 1069/2009, and more specifically at the Derogations sections.

Under Article 18, a number of “Special feeding purposes” have been outlined, under which Category 3 and even specific Category 2 Animal By-Products are authorised for feeding to:

(a) zoo animals;
(b) circus animals;
(c) reptiles and birds of prey other than zoo or circus animals;
(d) fur animals;
(e) wild animals;
(f) dogs from recognised kennels or packs of hounds;
(g) dogs and cats in shelters;
(h) maggots and worms for fishing bait.

It is of course the last category that draws our attention, as it creates a certain category of insects that are not considered “farmed insects” under the Regulation 893 on Insect PAP’s. Indeed, fishing bait, servicing the recreational angler, is clearly distinct from use in commercial aquaculture-feed. And these “maggots and worms for fishing bait” seem to be exempted from being considered “farmed animals”.

The legislator has clearly tried to create the possibility to rear maggots (without specifying the species) and worms for an application that is not linked to human consumption of the insect, or the use as feed.

If the legislator would want to make a similar effort to allow for insect bioconversion of Category 3 Animal By-Products (or even Category 2), it only needed to extend the clause (h) to read “maggots and worms for fishing bait and/or other technical applications”.

Although this might seem, to an outsider, like a fairly easy amendment, it would entail a serious workload, because it would undoubtedly be reinforced with clauses making clear that the insect biomass generated would have to be treated as an animal by-product of the same category, and that operators should not be active in this market and the Insect-PAP’s market at the same time, etc. The legislators will want full guarantees that there can be no contamination from a waste-management insect rearing operation to an Insect-PAP’s-producing insect rearing operator and will include provisions to that effect.

The lead author of this analysis is currently preparing with the Belgian authorities a review of all local and European regulations that would be affected by such an amendment, in order to map this workload and define a strategy if the amendment is deemed sufficiently feasible. It will also be taken up by the author in the framework of the IPIFF industry federation.

3.6 ALTERNATIVE METHODS OF USE OR DISPOSAL OF ANIMAL BY-PRODUCTS UNDER REGULATION 1069

We have seen earlier that Regulation 1069 is quite strict on its definition of farmed animals, and on its categorization of animal by-products, and on what ABP can be used in animal feed and which certainly cannot. This is of course a direct result of several food crises, after which a clear "precautionary attitude" was taken in legislative action.

However, the European Commission states explicitly and repeatedly that the current legal framework is not cast in iron, but open for amendments when sufficient data is provided and positively evaluated. The preamble of Regulation 1069 states:

> (30) Progress in science and technology may lead to the *development of processes which eliminate or minimise the risks to public and animal health*. Amendments to the lists of animal by-products set out in this Regulation should be possible, in order to take account of such progress. Prior to any such amendments, and in accordance with the general principles of Community legislation aimed at ensuring a high level of protection of public and animal health, a risk assessment should be carried out by the appropriate scientific institution, such as EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of animal by-products for which risks are to be assessed. However, it should be clear that once animal by-products of different categories are mixed, the mixture should be handled in accordance with the standards laid down for the proportion of the mixture belonging to the highest risk category.

> (44) Novel technologies which are being developed offer advantageous ways of generating energy on the basis of animal by-products or of *providing for the safe disposal of such products*. Safe disposal may take place through a combination of methods for the safe containment of animal by-products on site with established disposal methods, and through a combination of authorised processing parameters with new standards which have been favourably assessed. In order to take account of the related progress in science and technology, *such technologies should be authorised as alternative methods for the disposal or use of animal by-products* throughout the Community.

The Commission comes back to this issue of new technologies in the body of the Regulation, and to the minimisation of health risks they could pose:

Article (4) New technologies have widened the possible use of animal by-products or derived products to a large number of productive sectors, in particular for the generation of energy. However, the use of those new technologies might pose health risks that must also be minimised.
Article (5) Community health rules for collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use or disposal of animal by-products should be laid down in a coherent and comprehensive framework.
Article (6) Those general rules should be *proportionate to the risk to public and animal health* which animal by-products pose when they are dealt with by operators at different stages of the chain from collection to their use or disposal. The rules should also take into account the risks for the environment posed during those operations. The Community framework should include health rules on the placing on the market, including intra-Community trade and import, of animal by-products, where appropriate.

This Article 6 introduces the interesting concept of *proportionality* between rules and risks: if a novel technology poses (little or) no risk, the rules should not obstruct it. This mechanism can be used when elaborating an application file for EFSA examination of a novel technology.

Secondly, Article 6 refers to the risks for the environment: if a novel technology poses no risk to human health, but is environmentally unsound, the authorities will find here a reason to evaluate it negatively. This does, however, not mean that an environmentally positive novel technology will be accepted, whatever the risk to human or animal health. Public health safety will always be number one priority.

The application will be checked by the competent national authority and examined by EFSA before such authorisation is granted, in order to ensure that an assessment of the risk reduction potential of the process is carried out and that the rights of individuals, including the confidentiality of business information, is preserved.

This clearly opens the path for operators to apply for European approval for a novel technology for bioconverting side streams, containing animal by-products, as long as the resulting insect products are kept out of the feed and food chain.

That means Animal By-Products could be fed to insects, if the EU approves, under Regulation 1069. There are, however, some more general Regulations on Animal Feed, that we need to take a long, hard look at.

3.7 REGULATION 767/2009 ON THE PLACING ON THE MARKET AND USE OF FEED

The Regulations 1069 and 999 have an impact on both the front door of insect bioconversion and on the back door at the same time. Now we should have a closer look at Regulation 767/2009[12], that regulates the placing on the market and the use of different kinds of animal feed. That's the front door: what can we use as a feedstock to rear insects on?

Again, definition is important, so let's have a look at what Regulation 767 has to say:

[12] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1458144587916&uri=CELEX:02009R0767-20100901

Article 3: **Definitions**
(c) 'food-producing animal' means any animal that is fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption, but that belong to a species that is normally used for human consumption in the Community;
(d) 'non-food producing animals' means any animal that is fed, bred or kept but that is not used for human consumption, such as fur animals, pets and animals kept in laboratories, zoos or circuses;

Insects that would be reared for use as animal-feed might strictly speaking not fall under "food-producing animal", but since they are intended for the food chain, they would be most definitely, under the spirit of the law, be considered as such.

Insects reared as a waste disposal method, for technical applications, could be considered as "non-food producing animals".

But that does not really matter much, since the Preamble clearly states that it is appropriate that this Regulation apply, given the risk of contamination of the feed and food chain, to *feed for both food and non-food producing animals*, including wild animals.

Article 4
Safety and marketing requirements
1. Feed may only be placed on the market and used if:
(a) it is safe; and
(b) it does not have a direct adverse effect on the environment or animal welfare.
The requirements set out in Article 15 of Regulation (EC) No 178/2002 shall apply, *mutatis mutandis*, to feed for non-food producing animals.
2. In addition to the requirements set out in paragraph 1 of this Article, feed business operators placing feed on the market shall ensure that the feed:
(a) is sound, genuine, unadulterated, fit for its purpose and of merchantable quality; and
(b) is labelled, packaged and presented in accordance with the provisions laid down in this Regulation and other applicable Community legislation.
The requirements set out in Article 16 of Regulation (EC) No 178/2002 shall apply, *mutatis mutandis*, to feed for non-food producing animals.
3. Feed shall comply with the technical provisions on impurities and other chemical determinants set out in Annex I to this Regulation.

This seems to deal a heavy blow to the possibility of bioconverting waste streams with insects, since food-producing and non-food-producing animals are treated equal under this Regulation.
Let's have a short look at the requirements of Article 15 of Regulation (EC) No 178/2002, to which Regulation 767 refers in this respect:

Regulation 178/2002

Article 15 Feed safety requirements

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.
2. Feed shall be deemed to be unsafe for its intended use if it is considered to:
— have an adverse effect on human or animal health;
— make the food derived from food-producing animals unsafe for human consumption.
3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.
4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.
6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

These are rather general principle of common sense, regarding feed safety, that do not necessarily block the approval of insect bioconversion of waste streams, as long as the derived products do not end up in the food chain.

However, Regulation 767 gets more specific than that:

Regulation 767
Article 6
Restriction and prohibition
1. Feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited. The list of such materials is set out in Annex III.

This forces us to have a look at the Annexes, what the sting of many European Regulations really is:

ANNEX III
Chapter 1: Prohibited materials
1. ***Faeces, urine*** *and separated digestive tract content resulting from the emptying or removal of digestive tract, irrespective of any form of treatment or admixture.*
2. Hide treated with tanning substances, including its waste.
3. Seeds and other plant-propagating materials which, after harvest, have undergone specific treatment with plant-protection products for their intended use (propagation), and any by-products derived therefrom.
4. ***Wood****, including sawdust or other materials derived from wood, which has been* ***treated with wood preservatives*** *as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.*
5. ***All waste obtained from the various phases of the treatment of the urban, domestic and industrial waste water****, as defined in Article 2 of Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment, irrespective of any further processing of that waste and irrespective of the origin of the waste waters.*
6. ***Solid urban waste****, such as household waste.*
7. ***Packaging*** *from the use of products from the agri-food industry,* ***and parts thereof****.*
8. Protein products obtained from yeasts of the Candida variety cultivated on n-alkanes.

This list eliminates quite a few side-streams that could benefit from insect-bioconversion.

1. ***Faeces, urine:*** we should check whether this is an alternative definition for manure, or not. It could also be read as "***Faeces, urine*** *<>resulting from the emptying or removal of digestive tract".* Notwithstanding the scope of the definition, it is clear that the EU does not allow for manure to be placed on the market as feed. When insect operators go for a derogation to this rule, they should read this in conjunction with Regulation 1069 on Animal By-Products, which manure clearly is.
2. ***Wood:*** although not extensively researched yet, insect bioconversion of wood and derived products could become an alternative to the production of energy, for example by rearing termites. Question here is also on definition: is untreated wood allowed for as feed, or not?
3. ***Waste water treatment waste:*** this could include a variety of sludges, especially from the food-processing industry, which are very suitable to insect bioconversion, and of which the disposal using current technologies places a heavy financial burden on the industry.
4. ***Solid urban waste:*** especially in countries where the separation of organic waste from plastic, PET, and paper is not yet fully implemented at household-level, Solid Urban Waste contains up to 35-50% of organic matter, which could benefit from insect bioconversion. Of course, the risk of contamination from other waste (medication, dyes, batteries, plastics, pesticides etc.) is very high, so it is clear that this type of insect bioconversion is not without risk for the insects themselves, but also that the insect-derived products will never be suitable for the food chain.
5. ***Packaging and parts thereof:*** this prohibition on the feeding of packaging material, and parts thereof, to insects creates a problem regarding the bioconversion of former foodstuffs. Currently, the retail sector is looking for sustainable ways to reduce the environmental cost of their unsold food products. Most of these products are packaged in some way or another, and the current technologies to separate organic fraction from the packaging is not 100% effective, resulting in minor parts of packaging material still ending up in the organic fraction. This poses a technical problem for the bio-gas installations where these streams are currently headed but would create a legal problem in the case of insect bioconversion.

Again, this list is not cast in stone, as the Regulation states that the Commission shall amend the list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited taking into account in particular scientific evidence, technological developments, notifications under the Rapid Alert System for Food and Feed (RASFF) or results of official controls pursuant to Regulation (EC) No 882/2004.

CHAPTER 6
GENERAL AND FINAL PROVISIONS
Article 27
Implementing measures
1. The Commission may amend the Annexes in order to adapt them in light of scientific and technological developments.
Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).

The room for derogations under this Regulation is fairly limited:

Article 21
8. By way of derogation from the provisions of this Regulation, Member States may apply national provisions for feed intended for animals kept for scientific or experimental purposes on condition that such purpose is clearly indicated on the label. The Member States shall notify those provisions to the Commission without delay.

3.8 REGULATION 183/2005 ON REQUIREMENTS FOR FEED HYGIENE

Whenever we look at European legislation regarding animal feed, we need to combine Regulation 767 with REGULATION 183/2005.

Regulation 183 lays down general rules on feed hygiene; conditions and arrangements ensuring traceability of feed; conditions and arrangements for registration and approval of establishments; and creates a framework of control mechanisms and auto-control schemes, following the "hazard analysis and critical control points" (HACCP) methodology.

Again, let's have a look at the definition regarding insects:

> 2. This Regulation shall not apply to:
> (a) the private domestic production of feed:
> (i) for food-producing animals kept for private domestic consumption; and
> (ii) for animals not kept for food production;
> (b) the feeding of food-producing animals kept for private domestic consumption or for the activities mentioned in Article 1(2)(c) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (2);
> (c) the feeding of animals not kept for food production;
> (d) the direct supply of small quantities of primary production of feed at local level by the producer to local farms for use on those farms;
> (e) the retailing of pet food.

In short, when insects are reared with the intention to bring them to the feed market under the "Farmed Insect-PAP"-regulation 893/2017, Regulation 183/2005 applies, and operators must implement and adhere to a system of auto-control and external control.

When insects are reared as a waste management technique, of which the resulting insect biomass is to be kept out of the food chain, this Regulation would not apply.

Regarding the precise implementation of the above-mentioned clause, the Regulation allows the Member States to establish rules and guidance governing these activities to ensure the achievement of the objectives of this Regulation.

3.9 EFSA OPINION ON THE RISKS OF INSECTS AS FOOD AND FEED

It is clear that any change in the rules regarding the feedstock allowed for insects, will be made only after careful evaluation of sufficient and solid scientific data. The European Food Safety Authority [13] will play a crucial role in such a breakthrough.

EFSA has already drawn the outlines of the possibilities of insect bioconversion and the associated risks in 2015. 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 the **substrate used as feed for the insects is considered**

[13] http://www.efsa.europa.eu/
[14] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4257/full

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.

The risk profile presented potential biological and chemical hazards as well as allergenicity and environmental hazards associated with farmed insects used as food and feed, considering of the entire chain, from farming to the final product.

The opinion also addressed the occurrence of these hazards in non-processed insects, grown on different substrate categories, in comparison to the occurrence of these hazards in other non-processed sources of protein of animal origin. When currently allowed feed materials are used as substrate to feed insects, the possible occurrence of microbiological hazards is expected to be comparable to their occurrence in other non-processed sources of protein of animal origin.

The possible occurrence of prions in non-processed insects will depend on whether the substrate includes protein of human or ruminant origin. Data on transfer of chemical contaminants from different substrates to the insects are very limited. Substrates like kitchen waste, human and animal manure are also considered and hazards from insects fed on these substrates need to be specifically assessed. It is concluded that for both biological and chemical hazards, the specific production methods, the substrate used, the stage of harvest, the insect species and developmental stage, as well as the methods for further processing will all have an impact on the occurrence and levels of biological and chemical contaminants in food and feed products derived from insects.

Hazards related to the environment are expected to be comparable to other animal production systems.

The opinion also identifies the uncertainties (lack of knowledge) related to possible hazards when insects are used as food and feed and notes that there are no systematically collected data on animal and human consumption of insects.

4 EU LEGISLATION ON INSECT DERIVED PRODUCTS

The Commission Report of 22 November 2018[15] on the development of plant proteins in the EU highlighted again the need to reduce the EU dependency from third countries for its protein supply.

It stated that "nutritionally speaking, processed animal proteins are an excellent feed material, with high concentration of highly digestible nutrients such as amino acids and phosphorous, a high content in vitamins. Reauthorisation of processed animal proteins from non-ruminant origin in non-ruminant animals would reduce this dependence on third countries' protein."

Although in theory, the European authorities are all in favour of insect protein, they are quick to point out that between theory and practice, there's regulation that needs to be adapted…

4.1 REGULATION 1069/2009 AND 142/2011 ON ANIMAL BY-PRODUCTS[16]

In chapter 3, we've seen that the "Animal By-Products Regulation" impacts the insect bioconversion at the front door (feedstock going to insects), but it impacts insect bioconversion *a fortiori* at the back door: what can we use insect derived products for?

Now, let's have a look at how Regulation 1069 impacts insect products.

Article 4 defines the "Starting point" in the manufacturing chain and the obligations that arise for operators when they create "animal by-products" and Article 5 defines the "End point in the manufacturing chain", determining when "animal by-products" stop being ABP's and become another products, regulated by other directives. This applies to all "ABP's" and is not of particular importance to insect bioconversion.

The main mechanism of Regulation 1069, which it inherited from the earlier Regulation (EC) No 1774/2002 it replaces, is categorizing, in Article 7, the different types of Animal By-Product "into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10."

We can jump straight to Article 10, which defines the "Category 3 material", to comprise the following animal by-products:
< a – k > **(l) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;** < m – p >

This clearly includes insects, as long as they are not pathogenic to humans and animals.[17]

This categorization in Category 3 is clearly good news for insect bioconversion, because Category 1 is highest risk, and Category 3 is lowest risk. Logically, Cat. 3 animal by-products, which pose the smallest risk to human and animal health, has the broadest scope of possible "disposal and use" methods.

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[15] https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/plants_and_plant_products/documents/report-plant-proteins-com2018-757-final_en.pdf

[16] For the sake of clarity: content-wise, 1069 and 142/2011 are similar, the latter being an implementation regulation for the former; in later documents, references are made to both

[17] Clarification needs to be sought regarding the definition of "pathogenic", to verify whether this includes poisonous insects, and/or insects capable of transmitting diseases rather than "producing disease", the strictest definition of "pathogenic"

Those "Disposal and use"-methods for Category 3 material are stipulated in Article 14 of Regulation 1069:

Article 14
Disposal and use of Category 3 material
Category 3 material shall be:
(a) disposed of as waste by incineration, with or without prior processing;
(b) recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;
(c) disposed of in an authorised landfill, following processing;
(d) processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:
*(i) for the **manufacturing of feed for farmed animals** other than fur animals, to be placed on the market in accordance with Article 31, except in the case of material referred to in Article 10(n), (o) and (p);*
*(ii) for the **manufacturing of feed for fur animals**, to be placed on the market in accordance with Article 36;*
*(iii) for the **manufacturing of pet food**, to be placed on the market in accordance with Article 35; or*
*(iv) for the **manufacturing of organic fertilisers or soil improvers**, to be placed on the market in accordance with Article 32;*
(e) used for the production of raw pet food, to be placed on the market in accordance with Article 35;
(f) composted or transformed into biogas;
(g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
(h) in the case of shells from shellfish, other than those referred to in Article 2(2)(f), and egg shells, used under conditions determined by the competent authority which prevent risks arising to public and animal health;
(i) used as a fuel for combustion with or without prior processing;
*(j) used for the **manufacture of derived products** referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles;*
(k) in the case of catering waste referred to in Article 10(p) processed by pressure sterilisation or by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or composted or transformed into biogas; or
(l) applied to land without processing, in the case of raw milk, colostrum and products derived therefrom, which the competent authority does not consider to present a risk of any disease communicable through those products to humans or animals.

This article paints a very broad scope of potential uses for insect-derived "animal by-products", going from feed for farmed animals, pet food and fur animals to derived products, all being legally possible under Regulation 1069. So, if all of these markets are open for insect-derived products, what is the problem, then?

The 1069/2009 Regulation on Animal By-Products also stipulates how these products can be place in the market:

CHAPTER II : Placing on the market
Section 1
Animal by-products and derived products for feeding to farmed animals excluding fur animals

Article 31 Placing on the market
1. Animal by-products and derived products destined for feeding to farmed animals, excluding fur animals, may only be placed on the market provided:
(a) they are or they are derived from Category 3 material other than material referred to in Article 10(n), (o) and (p);
(b) they have been collected or processed, as applicable, in accordance with the conditions for pressure sterilisation or other conditions to prevent risks arising to public and animal health in accordance with measures adopted pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 2 of this Article; and
(c) they come from approved or registered establishments or plants, as applicable for the animal by-product or derived product concerned.

These stipulations seem rather harmless, but have, in the case of insects, created a significant obstacle. One of the reasons why insects have attracted so much attention the last years, was their perceived role as a source of high-quality protein, to help fill the so-called protein gap.

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 7** 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.

So, one of the products derived from insects, is protein. (The others are lipids and chitin, more about those later.) Now, under sub-paragraph c) of article 31 of 1069/2009, we need to look at the" approved or registered establishments or plants, as applicable for the animal by-product or derived product concerned", in this case protein.

4.2 TSE REGULATION 999/2001

Regarding the back-door for insect bioconversion, Regulation 999 also provided clear instruction on the operators authorized to place Processed Animal Protein on the market. Annex IV to Regulation (EC) No 999/2001 initially extended the prohibition provided for in Article 7(1) to the feeding of, inter alia, processed animal protein to non-ruminant farmed animals. This means the entire feed market was blocked, except for pet food and carnivorous fur producing animals.

There was however, under specific conditions, a derogation (Chapter II of Annex IV) authorising the feeding of non-ruminant processed animal protein to aquaculture animals only.

This was allowed for processed animal protein produced in slaughterhouses or cutting plants in compliance with Section D of Chapter IV of Annex IV to Regulation (EC) No 999/2001. Given the production process of processed animal protein derived from insects, this requirement cannot be met in the case of insects, since

no slaughterhouse wants to take on insect-slaughtering, since it cannot be combined with other animal species and since it is legally unclear how insect slaughtering should be executed. Thus, the use of processed animal protein derived from insects in feed for aquaculture animals was not allowed under this Regulation.

4.3 INSECT PAP-REGULATION 893/2017

4.3.1 Farmed Insects PAP for Aquaculture

Recently, both Regulations were amended by **COMMISSION REGULATION (EU) 2017/893** of 24 May 2017, amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 about the provisions on processed animal protein[18].

Regulation 893 entered into force on **1st July 2017**.

This amendment was introduced **specifically with insects in mind**. In the introductory remarks of the text, the Commission noted that *"In several Member States, the rearing of insects for the production of processed animal protein derived from them and other insect derivatives destined for pet food has started. This production is carried out under the national control schemes of the competent authorities of the Member States. Studies have shown that farmed insects could represent an alternative and sustainable solution to conventional sources of animal proteins destined for feed for non-ruminant farmed animals."*

In short, Regulation 893/2017 allows "Processed animal protein derived from insects and compound feed containing such processed animal protein" for feeding aquaculture animals.

Regulation 893 is an enormous step forward for the insect breeding sector, as it opens an enormous market: aquaculture. Not only in size is this market very large, the feed requirements of several species such as salmon and trout are very high and can only be met using high-value protein sources such as fishmeal. The authorization to bring insect-derived proteins to this market, is a major breakthrough.

4.3.2 Insect PAPs beyond aquaculture: poultry and pigs

With insect meals considered safe for the aquaculture market, the logical question is: why are insect meals not yet allowed in the other main markets, like poultry and pig feed?

It turns out this is not a question of the suitability of insect products as feedstuff for chicken and pigs, or even of the safety of insect meals. It is 100% a question of detection techniques. Control authorities need to be able to check for the absence of prohibited material in compound feed, for example, ruminant proteins in aquafeed.

In 2012, the European Union Reference Laboratory for Animal Proteins in feeding stuffs (EURL- AP) validated a new diagnostic DNA-based method (PCR) which is able to detect ruminant material in feed. This permitted the re-authorisation in 2013 of the use of non-ruminant PAP in aquafeed.

[18] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0893

This “only ruminant Polymerase Chain Reaction (“PCR”)” is a technically fairly well-established test, that also covers the now authorized insect meal. Remember: this DNA-test is not to verify the insect nature of the meals, but to guarantee the absence of ruminant materials in aquafeed. In aquafeed, other non-ruminant PAP are also authorised, so the authorities only need to check for ruminant prohibited materials.

It becomes more complicated for other feeds, since the absence of ruminant materials needs to be checked, but also the absence of “intra-species material” (cfr cannibalism). In 2015 and 2017, PCR methods, able to detect the presence of porcine or poultry material in feed, were validated by the EURL-AP. These analytical techniques allow determining the species origin of processed animal proteins in feed. Therefore, they enable the control of the correct implementation of the prohibition on intra-species recycling.

Following these validations and the Updated Quantitative Risk Assessment of the BSE risks of PAP’s and its assessment by EFSA in June 2018, the legislators have opened the door for pig PAP in feed for poultry, and have stated that insect PAP’s will be authorized in that market at the same time.

In a draft “Non-paper in view of a possible revision of Regulation (EC) No 999/2001 as regards prohibitions concerning animal feeding”, it was formulated as follows: “*Considering the structure of the feed industry, the use of processed protein of porcine origin in poultry feed should be reauthorized as a first step. Strict requirements during the collection, transport and processing of those products should apply in order to avoid any risk of cross-contamination with ruminant protein. In addition, regular sampling and analysis of the processed animal proteins and the compound feed containing these processed animal proteins should be performed in order to verify the absence of cross-contamination with ruminant proteins and intra-species recycling. Authorisation of poultry processed protein in porcine feed is not considered yet, as there are still control difficulties due to the complex formulation of pig feed.”* The draft text further recognizes that “poultry are insectivorous animals and there are no concerns extending the authorisation of processed animal protein derived from insects, fulfilling the same conditions required for feeding aquaculture animals to feeding poultry.”

When (and if) this draft is approved, it will enter into force and apply very rapidly: on the twentieth day following that of its publication in the *Official Journal of the European Union.* This is significantly different to the delay for the entry into force of Reg 893/2017, which took around 18 months after approval, because it was a new Regulation. The Regulation needed to open the poultry market for insect meal is an amendment to an Annex, i.e. Annex IV of Reg (EC) 999/2001.

From the perspective of the insect breeding sector, access to the poultry would be a huge step forward as it opens doors to another huge market potential globally, but also for insect breeding in countries that do not have a strong aquaculture sector.

If the technical analysis problems can be overcome, the use of insect meal in the pig feed market will also be authorized sooner or later. This would be another major breakthrough for insect breeders, since a significant portion of the global fishmeal production, up to a million tons of fishmeal per year, is now absorbed by the pig industry. Especially weening piglets benefit from a high-quality protein source like fishmeal, albeit as a minor component, in their diet. Substitution tests with insect meal instead of fishmeal have given satisfactory preliminary results.

Currently, the Commission has, in line with the position expressed in the TSE Roadmap 218, no intention to propose a revision of the feed ban in view of allowing the use of insect PAP in feed for ruminants.

The EURL-AP is in the meantime also working on the validation of an adapted light microscopy method, with a double sedimentation, which would be more suitable for the detection of insect particles in order to control that such particles are absent from feed in which insect PAP are not authorised.

In parallel, an amendment to Annex VI of Regulation (EC) No 152/2009 is being prepared in order to insert a new category, "particles from invertebrates", in addition to the two existing ones (particles from fish and particles from terrestrial animals).

4.4 WHICH PROCESSING PLANTS CAN PRODUCE INSECT-PAP'S?

Regulation 893 comes, however, with a couple of complicating factors. A number of specific conditions apply to the production and use of Insect-PAP intended to be used for feeding aquaculture animals.

Regulation 893 stipulates that Insect-PAP must be produced in processing plants approved in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009 and dedicated **exclusively** to the production of products derived from farmed insects.

Compound feed containing processed animal protein derived from farmed insects must be produced in establishments authorised for that purpose by the competent authority and which are dedicated **exclusively to the production of feed for aquaculture animals**.

If the establishment is not dedicated to producing compound feed for aquaculture animals, it must, in order to produce compound feed containing insect PAP, meet a series of requirements laid down in the TSE Regulation (separate production lines, regular laboratory analysis, etc.) which must be checked on-the-spot by the competent authority. The competent authority must maintain a list of compound feed establishments authorised to produce compound feed for aquaculture animals containing insect PAP.

By way of derogation from this last specific condition, the production of compound feed, containing processed animal protein derived from farmed insects, for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, except fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

- compound feed destined for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminant animals are manufactured and kept,
- compound feed destined for aquaculture animals must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for other non-ruminant animals are manufactured and kept,
- records detailing the purchases and uses of processed animal protein derived from farmed insects and the sales of compound feed containing such protein must be kept available to the competent authority for a period of at least five years,
- regular sampling and analysis of the compound feed destined for farmed animals other than aquaculture animals in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;
- a specific authorisation to produce complete feed from compound feed containing processed animal protein derived from farmed insects shall not be required for *home compounders* that comply with the following conditions:

- ✓ they are registered by the competent authority as producing complete feed from compound feed containing processed animal protein derived from farmed insects,
- ✓ they keep only aquaculture animals, and
- ✓ the compound feed containing processed animal protein derived from farmed insects used in their production contains less than 50 % crude protein.

In short: this means the insect producing companies must most probably process their insects themselves, since it will require an investment in machinery that can only be used for insect processing. Secondly, it means insect-PAP's will most probably only go to aquaculture-feed producers, because of the extra administrative burden, but at least it is clear what conditions must be met by feed producers that also produce for other markets.

4.5 How to label Insect-PAP's

The accompanying commercial document or health certificate[19], as appropriate, of processed animal protein derived from farmed insects and the label thereof shall be clearly marked with the following words: "*processed insect protein — shall not be used in feed for farmed animals except aquaculture and fur animals*".

The following words shall be clearly indicated on the label of *compound feed* containing processed animal protein derived from insects: "*contains non-ruminant processed animal protein — shall not be fed to farmed animals except aquaculture and fur animals*".'

4.6 Insect allowed for Insect-PAP's

Under Regulation 893, insect-PAP, intended for the production of feed for farmed animals other than fur animals, may only be obtained from the following insect species:

- Black Soldier Fly (*Hermetia illucens*)
- Common Housefly (*Musca domestica*)
- Yellow Mealworm (*Tenebrio molitor*)
- Lesser Mealworm (*Alphitobius diaperinus*)
- House cricket (*Acheta domesticus*)
- Banded cricket (*Gryllodes sigillatus*)
- Field Cricket (*Gryllus assimilis*)

This list is explicitly based on national risk assessments of species already reared commercially, as well as the EFSA opinion of 8 October 2015. With respect to the insect species reared in the European Union, these should not be pathogenic or have other adverse effects on plant, animal or human health; they should not be recognised as vectors of human, animal or plant pathogens and they should not be protected or defined as invasive alien species.

The Regulation stipulates that this list may be amended in the future based on an assessment of the risks posed by the insect species concerned to animal health, public health, plant health or the environment.

In short, the current regulation limits the production of Insect PAP's to seven species, which are currently already reared at commercial level. This, however, will soon turn out to be quite restrictive, given the number

[19] under Article 21(2) of Regulation (EC) No 1069/2009

of available insect species and the growing knowledge about rearing them commercially. A notable absentee from the list is the Migratory Locust (*Locusta Migratoria*).

4.7 IMPORT INTO THE EU OF INSECT-PAP'S

Regulation 893 retains the conditions for EU-produced Insect-PAP's for the import of Insect-PAP's from outside the EU. This is logical when it comes to creating a level playing field, but might also turn out to place an unnecessary obstacle for insect-producers in third countries, rearing other insects that are banned in the EU but are locally - in those Third countries - not considered a risk to animal health, public health, plant health or the environment.

Given the large numbers of insects already being reared for human consumption and for local use as livestock feed, it is only a matter of time before operators of third countries request permission to import Insect-PAP's of these species for use in European aquaculture.

4.8 EXPORT FROM THE EU OF INSECT-PAP'S

EU legislation does not only regulate the use of insect PAP on the European market, but also contains clear instructions on the way operators are allowed to export these products outside of the EU. This information is contained in Annex IV "Animal Feeding"; Chapter V "General Requirements"; in Section E "Export of processed animal protein and products containing such protein".

Paragraph 3. of this section lists a series of conditions to which the export of processed animal protein derived from non-ruminants, or compound feed containing such protein, shall be subject to compliance, in matters of processing plants, storage, transport, packaging and labelling, etc.

However, the section continues with paragraph 4.: "By way of derogation from point 3, the conditions laid down in that point shall not apply to:

< >

(c) processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;

(d) compound feed containing no other processed animal protein than fishmeal and processed animal protein derived from farmed insects, provided that it is produced in accordance with this Annex;

(e) processed animal protein derived from non-ruminants destined for the manufacturing of pet food or of organic fertilisers and soil improvers in the third country of destination, provided that, before export, the exporter ensures that each consignment of processed animal protein is analysed in accordance with the method of analysis set out in point 2.2 of Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of constituents of ruminant origin."

The European legislators are also reviewing the modalities for the export of processed animal proteins, from both ruminants and non-ruminants. This has implications for insect-products that are produced within the EU and exported abroad.

A draft document was circulated, that contained a draft Annex to a Regulation, that amends Annex IV to Regulation (EC) 999/2001 as regards the requirements for export of products containing processed animal protein derived from ruminants and non-ruminants.

4.9 WHAT DOES REGULATION 893 SAY ABOUT LIVE INSECTS AND DRIED INSECTS?

The Regulation specifically mentions that the provisions set out in Annex X do **not** cover live insects and dried insects in feed for **farmed** animals. This means that they can still be used in that form for feeding other farmed animals than aquaculture, such as poultry and pigs.

This underlines the specification in **COMMISSION REGULATION (EU) No 68/2013 on the Catalogue of feed materials[20], which includes:**

9.16.1	**Terrestrial invertebrates** ([27])	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.	

This is quite strange, since the use of dried insects in or as **pet** food is subject to the provisions set out in Annex XIII to the aforementioned Regulation 893.

4.10 ORGANIC INSECT PRODUCTS

The European Commission has drafted a proposal to amend Regulation (EU) 2018/848 on the detailed production rules of organic products, to consider the production of insects. This would bring "organic" or "bio" insect farming in line with other organic livestock production systems, but in a perfect world also take into consideration the specificities of insect farming. Regulation 848/2018 contains specifications with regards to the origin of animals, nutrition, housing and husbandry practices, health care and animal welfare, for all conventional livestock species, including bees, but didn't cover any other insect species. The Commission now wants to add other insect species to the Regulation.

It has to be kept in mind that the rules for "organic" farming of cows, pigs and chicken are very strict, and have adopted a holistic 360°-approach: the objective is to cover the full production circle. This creates a pretty high barrier for farmers to convert their farm from regular to "organic" farming.

The Regulation would cover the production of insects for both food and feed. For small-scale farm-level insect farming for food, the rules don't contain much surprises, given the parallels with other organic livestock farming. We can, however, safely assume that it will be pretty hard to get large-scale insect farming for feed, waste management or technical applications certified as "organic".

The proposal contains a number of interesting clauses, including:
"With regard to nutrition, the following rules shall apply:

(a) at least 20 % of the feed shall come from the production unit itself or, if this is not feasible or such feed is not available, shall be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material produced or mixed or processed in the same region. The feed shall preferably be constituted of by-products that cannot be used for food;
(b) up to 30 % on average of the feed formula of rations may comprise in-conversion feed from the second year of conversion. This percentage may be increased to 100 % if this in-conversion feed comes from the holding where insects are kept."

[20] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R0068&qid=1458145153829#ntr27-L_2013029EN.01000301-E0027

"With regard to housing and husbandry practices, the following rules shall apply:

(a) used organic substrates, including frass, uneaten or spilt feed and egg laying material, shall be removed as often as necessary and disposed of in a secure manner in accordance with Article 13 of Regulation (EC) No 1069/2009[21], either by returning them to the holding where insects are kept or by processing them into 'products produced by insects' to be purchased and used by third parties [only by organic operators]; [an exemption regarding Regulation (EC) No 1069/2009 for frass of insects is being prepared by DG SANTE]

(b) housing materials used shall not cause injuries to insects; in particular, grid floors in which insects can lose their legs or sharp materials. Materials associated to a high risk of the presence of contaminants or unauthorised products and substances according to this Regulation, such as recycled paper or board, or egg cartons, shall not be used as structural elements or for housing. Structural elements shall be either made of raw materials that cannot be used by insects as a feed source or consist exclusively of raw materials that can be used by insects as a feed source provided those materials meet the requirements of this Regulation on feed;

(c) appropriate husbandry practices shall ensure the expression of natural behavior and the prevention of cannibalism at different life stages between insects as much as possible;

(d) dark phases and light supply shall be provided for all insects species, especially in the corresponding development phases."

Several national delegations have proposed amendments to the Commission draft. The Strategic Platform on Insects from Flanders and the Belgian Insect Industry Federation have provided input to adapt the clauses, that seemed to have been copy-pasted from the existing livestock to the realities of insect farming. Most of these proposed amendments have been taken into account.

The insect industry federation IPIFF has also tried to weigh in on the debate, with a Contribution paper[22]. These proposals were not yet incorporated in the draft text that is currently available.

Interestingly, the draft text mentions that "an exemption regarding Regulation (EC) No 1069/2009 for frass of insects is being prepared by DG SANTE. Currently, insect frass is eligible as soil amendment for organic farms, and we need to keep an eye on the way this would be amended, because this is an interesting market for the frass, even if it is not produced according to the full "organic" specifications.

[21] 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).

[22] http://ipiff.org/wp-content/uploads/2019/03/IPIFF_Contribution_Paper_on_EU_organic_certification_of_insect_production_activities_29-03-2019.pdf

5 FRASS:

5.1 A NEW FERTILISER REGULATION?

We have analysed what can be fed to the insects as feedstocks, and what the insects can be used for, in both feed and food. One big question that still needs to be looked at, is the legal status of the rest fraction: the remainder of the feedstock that the insects have either not eaten, have only partially eaten, or have secreted out themselves. The physical nature of the rest fraction, dubbed "frass", depends entirely on the insect species, the feedstock used, and the rearing conditions. Also, the quantities can vary from virtually nothing, to amounts equivalent to the insect biomass produced or more.

In the absence of a defining European framework, local legislators have tried to give insect operators some clarity on the matter. This was not necessarily at step in the right direction, since the nature of the components of the "frass" brought confusion: there is insect poop, which could be regarded as manure, there is inevitably a small quantity of insect material itself, and there is in many cases some bedding material as well. This could mean that insect frass ends up as Category II Animal By-Products, as in the Belgian example[23].

At a European level, the status of insect frass remains unclear. It is generally expected that the upcoming "Fertilizing Products Regulation"[24] provides clarity, if not on the status of frass, at least on the procedure under which it could be considered as a soil amendment / fertilizer.

Under current rules, ie. Regulation 2003/2003, [25] only conventional, non-organic fertilizers, typically extracted from mines or produced chemically, can freely be traded across the EU. Innovative fertilizing products produced from organic materials are outside the scope of the current Fertilizers Regulation. It was estimated that this Regulation didn't cover around half of the fertilizers on the EU market. The revised text has the ambition to have a more holistic view than the existing Regulation 2003/2003 and to include all types of fertilizers – mineral, organic, bio stimulants, growing matters, industry by-products, etc, and also provide the procedures for new types of fertilizers. It was even suggested that the term "fertilizer" would even be replaced by "plant nutrition" in the title of the regulation, to symbolize the new approach to the matter, but it seems not to have made it into the final text.

Under the 2015 Circular Economy Action Plan, the Commission called for a revision of the EU regulation on fertilizers to facilitate the EU-wide recognition of organic and waste-based fertilizers, to dampen the competitive disadvantage which hampers innovation and investment in the circular economy.

The Commission aimed to reduce the need for mineral-based fertilizers, the production of which has negative environmental impacts, and depends on imports of phosphate rock through the sustainable use of fertilizers made from organic waste material in agriculture.

The agreement on the Fertilizing Products Regulation will open the Single Market for new and innovative organic fertilizers by defining the access conditions, with common rules on safety, quality and labelling

23 http://www.afsca.be/dierlijkeproductie/dierenvoeding/insekten/_documents/20171207_Nota_substraat_insecten_NL.pdf

24 http://europa.eu/rapid/press-release_IP-18-6161_en.htm

25 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02003R2003-20170701&qid=1543595416544&from=EN

requirements for all fertilizers to be traded freely across the EU. Producers will need to demonstrate that their products meet those requirements before affixing the CE mark.

The Regulation also offers the possibility to opt for optional harmonization. A fertilizer/plant nutrition product has to meet the requirements of the new regulation in order to be CE marked (sold between member States), but member States will still have the possibility to set specific rules for their internal market. Furthermore, a manufacturer who does not wish to CE-mark the product can choose to comply with national standards and sell the product to other EU countries based on the principle of mutual recognition.

The 279-page draft text for a "REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009" contains a number of interesting general principles:

- Definition of primary and secondary macro-nutrients, and the distinction between straight and compound fertilizers
- Assignment of responsibility regarding product quality, conformity assessment procedures, market surveillance authorities' obligations, and general subsidiarity competence clauses
- A list of "product function categories" (PFC) and the product requirements (in Annex I):

Product Function Categories

1. Fertiliser
    - A. Organic fertiliser
        - I. Solid organic fertiliser
        - II. Liquid organic fertiliser
    - B. Organo-mineral fertiliser
        - I. Solid organo-mineral fertiliser
        - II. Liquid organo-mineral fertiliser
    - C. Inorganic fertiliser
        - I. Inorganic macronutrient fertiliser
            - a) Solid inorganic macronutrient fertiliser
                - i) Straight solid inorganic macronutrient fertiliser
                - ii) Compound solid inorganic macronutrient fertiliser
            - b) Liquid inorganic macronutrient fertiliser
                - i) Straight liquid inorganic macronutrient fertiliser
                - ii) Compound liquid inorganic macronutrient fertiliser
        - II. Inorganic micronutrient fertiliser
            - a) Straight inorganic micronutrient fertiliser
            - b) Compound inorganic micronutrient fertiliser
2. Liming material
3. Soil improver
    - A. Organic soil improver
    - B. Inorganic soil improver
4. Growing medium
5 Inhibitor
    - A. Nitrification inhibitor
    - B. Denitrification inhibitor
    - C. Urease inhibitor
6. Plant biostimulant
    - A. Microbial plant biostimulant
    - B. Non-microbial plant biostimulant
7. Fertilising product blend

- A list of relevant “component material category” (CMC) or categories and the requirements (in Annex II) a fertilizing product has to meet
- And the labelling requirements (in Annex III) for access to the market for these products

A number of clauses are of immediate interest for the insect industry, because they have direct impact on how other Regulations are to be implemented.

- Directive 2008/98/EC on waste: Article 18 of this new Regulation defines the “End-of-waste status”, by laying down criteria according to which material that constitutes waste as defined in Directive 2008/98/EC can cease to be waste, if contained in a compliant EU fertilising product. In such cases, the material shall be considered as having ceased to be waste from the moment the EU declaration of conformity is drawn up.
- Regulation (EC) No 1069/2009 on Animal By-Products: Derived ABP-products referred to in Article 3(2) of Reg 1069/2009 which are already placed on the market and used in the Union as organic fertilisers and soil improvers <> constitute promising raw materials for the production of innovative fertilisers in a circular economy. As soon as an end-point in the manufacturing chain has been determined for the respective derived product, the fertilising products containing such derived products in accordance with this Regulation should be granted free movement on the single market without being subject to the requirements of Regulation (EC) No 1069/2009. For this purpose, the European Commission should, without undue delay, carry out a first assessment to check whether an end-point in the manufacturing chain can be determined. (ref: 10a)

This could provide an elegant solution for the situation whereby insect frass is considered a combination of insect manure, dead insect Animal By-Products and bedding material, and would therefor be treated as Category II ABP under 1069/2009: if an end-point in the manufacturing chain can be determined, an End-of-Waste status would be possible for frass, that could then be marketed as a fertilizer according to this new Regulation.

The draft Regulation creates clear opportunities for the insect industry to get “insect frass” recognized as a type of fertilizer, or insect bioconversion as a way to bioconvert waste streams into soil improvers. The industry should in that regard look at paragraph (13), which stipulates that “*for certain recovered wastes, such as struvite, biochar, and ash-based products, < >, a market demand for their use as 39fertilizing products has been identified. < > For EU f39ertilizing products, those requirements should be laid down in this Regulation. Therefore, as of the moment of compliance with all the requirements of this Regulation, such products should cease to be regarded as waste within the meaning of Directive 2008/98/EC , and accordingly it should be possible for products containing or consisting of such recovered waste materials to access the internal market. To ensure legal clarity, take advantage of technical developments, and further stimulate the incentive among producers to make more use of valuable waste streams, the scientific analyses and the setting of recovery requirements at Union level for such products should start immediately after the entry into force of this Regulation.*

If the insect industry manages to get "frass" into the same wave as struvite, biochar, and ash-based products, the Commission could define a new category of component materials in a relatively short delay. We should in that context note that this is deemed urgent, and that “a*ccordingly, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of defining, without unnecessary delay, larger or additional categories of component materials eligible for use in the production of EU 39fertilizing products.”*

Article 42 of the draft Regulation also stipulates that the Commission has broad competences regarding the "Amendments of Annexes" for the purposes of adapting them to technical progress and of facilitating internal market access and free movement for EU fertilising products (a) which have the potential to be subject of significant trade on the internal market, and (b) for which there is scientific evidence that the they do not present an unacceptable risk to human, animal or plant health, to safety or to the environment, and that they are sufficiently effective ensure agronomic efficiency.

The text specifically mentions that "*when adopting those delegated acts, the Commission shall prioritise in particular animal by-products, by-products within the meaning of Directive 2008/98/EC, and recovered waste, in particular from the agricultural sector and the agro-food industry, as well as materials and products already lawfully placed on the market in one or more Member States*." Thi obviously creates serious potential for the insect industry to get its frass recognized in one of the existing product function categories.

Although a political agreement has been reached on the text, the Regulation has not been adopted yet, since the negotiated text still needs to be translated to all official EU languages, and each linguistic version needs to be vetted by the jurislinguists from each member States. Only after this formality, can the text be officially adopted, after which the Regulation will then be directly enter into force in all Member States and will become applicable three years after its entry into force for some clauses, and immediately for others.

5.2 INSECT FRASS AS "ORGANIC" ORGANIC FERTILIZER?

It is in this context noteworthy that "Regulation 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control" contains a specific mention to insect rest fraction.

In TITLE II: "RULES ON PRODUCTION, PROCESSING, PACKAGING, TRANSPORT AND STORAGE OF ORGANIC PRODUCTS"; CHAPTER 1: "Plant Production"; Article 3 "Soil management and fertilization" states clearly that "1. Where the nutritional needs of plants cannot be met by measures provided for in Article 12(1)(a), (b) and (c) of Regulation (EC) No 834/2007, only fertilizers and soil conditioners referred to in Annex I to this Regulation may be used in organic production and only to the extent necessary."

And in that *ANNEX I:* "Fertilisers and soil conditioners referred to in Article 3(1)", it states in the category A (authorised under Reg 2092/91 and carried over by Art16(3)(c) of Reg 834/2007: "Dejecta of worms (vermicompost) and insects", without any further description, compositional requirements, and/or conditions for use.

A first analysis of the draft Fertilizer Regulation 2003/2003 seems to indicate that no major amendment are made to the Regulation (EC) No 834/2007, so it seems this approval to use insect dejecta (= frass) as organic fertilizer in organic farming will continue to stand.

6 REGULATION ON PRODUCING INSECTS FOR HUMAN CONSUMPTION

The European Regulation (EU) 2015/2283 repeals Regulation (EC) No 258 from 1997 and has been applicable since 1 January 2018. It states that all products based on insects (not only parts of insects or extracts, but also complete insects and their preparations) are considered Novel Food, due to the lack of evidence of a significant history of use in the European Union before 15 May 1997.

When insects are destined for use in food applications, they automatically fall under all legislation covering food items:

- REGULATION 178/2002 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[i]
- REGULATION 852/2004 on the hygiene of foodstuffs[ii]

As insect products are correctly considered to be of animal origin, the Regulation with specific hygiene rules for food items of animal origins also applies:

6.1 REGULATIONS 853/2004 AND 854/2004 ON THE HYGIENE OF FOOD OF ANIMAL ORIGIN

Regulation (EC) No. 853/2004[26] lays down specific rules on the hygiene of food of animal origin for food business operators. They shall apply to unprocessed and processed products of animal origin. It is complemented by Regulation (EC) No. 854/2004[27] which lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Both Regulations are important for insect rearing, specifically for human consumption.

This EU legislation was implemented and often complemented by local legislation, regarding traceability, reporting obligations and sectoral autocontrol systems; the local food safety authorities also have a system of certifications, permits and registrations.

However, the current EU legislation has no specific stipulations regarding the farming, transformation and distribution of insects.

The insect sector federation IPIFF has drafted a Handbook for Good Hygiene Practices[28] for insect farmers, which "aims to support the effective implementation of EU food and feed safety legislation 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 document is a non-binding document, drafted by the IPIFF Working Group after consultations with EU representative organisations from the food and feed chain. IPIFF has officially transmitted the Guide to the European Commission services in view of its assessment by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) in accordance with EU procedures, but the Guide has not yet been officially recognized by the European Institutions.

[26] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0853R(01)
[27] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0083:0127:EN:PDF
[28] http://ipiff.org/good-hygiene-practices/

6.2 REGULATION 258/97 CONCERNING NOVEL FOODS

The fact that no specific regulation on the farming or transformation of insects for human consumption was in place, did not mean, however, that the road was wide open. The national authorities in charge of food safety quickly pointed out to the insect snack start-ups that this innovative food product quite possibly constituted a "novel food", also when only "whole insects" are used and not the extracted components of these insects. In that case, the procedures for submitting an application file for each insect species and its products as outlined in Reg 258/97 would be applicable.

The situation of insects was unclear due to the fact that extractions from insects where described in regulation 258/97[29], but not the insects as a whole. The interpretation made by most local Safety Authorities in the different EU countries was that the legislator's intention was clear: insects (also as a whole) are Novel Foods. Others though interpreted the implicit distinction between "extractions" and "insects as a whole" and the absence of the explicit mentionning of "insect as a whole" being a Novel Food, as the legislator's intention to "not forbit" insects as Novel Food. Every local safety authority has the obligation and the right to implement and apply EU regulations on its own territory. Several countries have taken national initiatives regarding these matters, resulting in different shades of acceptance/tolerance of insect farming and entomophagy. So, Novel Food or not Novel Food, that was the question. Given the heavy burden that this status of Novel Food inflicts on market operators who have to prove the safety of their new products before they can be brought to the market and given the philosophy of one single market; this situation was not to be continued indefinitely, and the European authorities have chosen to include insect food products under the amended Regulation: 2283/2015[30] on Novel Food, which repeals and replaces Regulation 258/97

6.3 REGULATION 2283/2015 ON NOVEL FOODS

Regulation 2283/2015 lays down rules for the placing of novel foods on the market in the European Union (EU). These are designed to provide a high level of protection for human health and consumers' interest.

According to the Commission website[31], *"Novel Food" is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force. 'Novel Food' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.*

Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from Euphausia superba), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast).

The underlying principles underpinning Novel Food in the European Union are that Novel Foods must be:

- *Safe for consumers*
- *Properly labelled, so as not to mislead consumers*

[29] http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:31997R0258
[30] http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=celex:32015R2283
[31] https://ec.europa.eu/food/safety/novel_food_en

- *If novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer.*

Pre-market authorisation of Novel Foods on the basis of an evaluation in line with the above principles is necessary.

Food business operators must determine whether the product they wish to place on the market is covered by the legislation. If they are unsure:

- they may consult the national authorities of the market concerned by providing all the necessary information;
- those national authorities may consult colleagues in other EU countries and the European Commission.

The Commission has established a positive **list of authorised novel foods**[32] (on 1 January 2018) and updates it regularly.

An **authorised product must not**:

- pose a risk to human health, based on scientific evidence;
- mislead consumers, especially when it is intended to replace another food and there is a significant change in nutritional value;
- be nutritionally disadvantageous when replacing another food under normal consumption.

The **authorisation procedure** for the placing of a novel food on the market can be triggered either by an applicant (EU country, a non-EU country or an interested party) or by the Commission. The **application** must include details, such as the name and description of the novel food, its detailed composition, production processes and scientific evidence, confirming that it does not pose any danger to human health.

The Commission may ask the European Food Safety Authority to give its opinion on the safety of the novel food. The Commission presents its final opinion on whether to authorise a novel food to the Standing Committee on Plants, Animals, Food and Feed. Its endorsement is necessary before the new product can be added to the positive list.

Specific rules apply to traditional foods from non-EU countries which their food business operators or importers wish to sell in the EU, a rule that will be applicable for several "customary" insect food products, from Third countries.

This brings clarity to the situation of new insect products for human consumption as from its date of entering into action, 1st January 2018: if there is no clear History of Consumption (HOC) of a specific insect species or product based on this specific insect species in the EU in the recent history (since 1945), this insect species or product containing this insects species, is a Novel Food.

The countries that had tolerated insects and insect food products on their national markets had the possibility to specify the terms their local operators had to adhere to during the current transition phase, whilst preparing their "Novel Food application"

Only the Belgian authorities have conducted a far-reaching and transparent tolerance policy over the last few years. Due to constructive cooperation between Belgian operators (united in the Belgian Insect Industry

[32] https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en

Federation) and local authorities, a transitional period will be applicable after 1th January 2018. Only operators who submitted a novel food dossier for a specific insect species before January 1, 2018 may continue to place this insect on the market, until (dis)approved by the European Commission for this insect species and it's applications.

Current novel food applications for insect products include:

- Acheta domesticus (house cricket)
- Alphitobius diaperinus (lesser mealworm) larvae products*
- Dried Gryllodes sigillatus (crickets)*
- Honey bee drone brood (Apis mellifera male pupae
- Migratory locust (Locusta migratoria)
- Dried Tenebrio molitor (mealworms)*
- Tenebrio molitor (mealworm)

The up-to-date list of applications and notifications can be found on the Commission website[33] as well, including details regarding each application. Applicants can choose to keep a certain amount of information confidential.

The sector federation IPIFF also provides information regarding novel food applications on its website[34].

6.4 REGULATION 2073/2005 ON MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.

This Regulation refers to problematic contamination with *Listeria*, *E. Coli* and other pathogens, that could be harmful or lethal to the consumer.

Although the Annexes to the Regulation contain specifications regarding echinoderms, tunicates and gastropods (snails and slugs), no mention of insect products can be found.

[33] https://ec.europa.eu/food/safety/novel_food/authorisations/summary-applications-and-notifications_en
[34] http://ipiff.org/insects-novel-food-eu-legislation/

7 CONCLUSION

On a biological level, the use of insects as feed for livestock animals is a natural thing to do, since several of the most popular livestock animals, such as chicken, pigs, turkey and several fish species, are omnivorous by nature where insects are a part of their daily diet.

On an economic level, rearing a type of animals specifically as a source of feed for other farm animals, adds a trophic level to the agricultural chain. This is quite uncommon in traditional livestock farming, where plant-based fodder is fed to animals, which are in turn aimed for human consumption. Fishmeal might be the closest analogy to animal-based feed, but these small fish that form the basis of fishmeal are not reared but caught in the wild.

Another analogy could be the use of Processed Animal Protein (PAP's) in livestock feed, but the PAP's themselves are a side stream of the meat industry, as it mostly consists of slaughterhouse offal.

A perfect analogy would be rearing zooplankton as fish feed, but very few examples are known, and very few people consider zooplankton to be animals, although biologically, they are.

So, insect bioconversion creates a new concept, of rearing animals as feed for other animals, and it would be an understatement to say that the existing legislation was not written down with room for such an innovation to easily fit in.

The example of Processed Animal Protein also takes us to the underlying problem with "insects as feed": the use of slaughterhouse waste (in PAP's) led to the "mad cow disease" (TSE) problem, with severe consequences for animal welfare and consumer safety. The legislators subsequently tackled the problem, by banning the use of PAP's in most feedstock applications. This decision, taken around the turn of the century, turned out to be a serious barrier for insect-breeding start-ups aiming for the animal feed market in the past couple of years.

As in most markets, cost price of the new products will be a determining factor of success. And as for most types of livestock farming, one of the determining cost factors is the price of feedstock. An important aspect of breeding insects is their ability to grow on relatively low value side streams. This means that in principle large quantities of cheap feedstock are available, creating the possibility of cheap insect farming. This use of side streams also offers an additional advantage, as it adds to the sustainability appeal of insects.

The use of side streams, however, can seriously complicate matters on the legal level. Some side streams are on feed-grade level, and pose no additional legal challenge, but a lot of side streams are currently considered as waste, i.e. excluded for use as livestock feed. This prohibition is understandable when the insects would end up in the food chain, either directly as insect food products or indirectly as livestock feed.

The logic is not so clear if the insects are reared specifically as a waste treatment agent, or as a source of raw materials for use outside the food chain (for example in industrial detergents, lubricants, coatings or glues).

It has become clear for all parties concerned that the current legislative framework was not written with insect bioconversion in mind, and that it contains numerous stipulations that make perfect sense in traditional livestock farming, but are actually counterproductive in the development of an insect industry, playing a role in the circular economy the authorities have set as our common objective.

Currently, the legislative stipulations on a certain aspect are completely disconnected from what happens further down the value chain: for example, a number of side streams are forbidden for use as insect feed, full stop. They are forbidden for reasons of food safety, even when the insects will be kept out of the food chain altogether.

The European legislative framework is currently being adapted to the possibilities of insect bioconversion of sidestreams into feed and food. During the INDIRECT-project, we have seen major changes, to the industries

where insect products could be used, to how insect can be farmed “organically”, to how innovative products can be marketed as fertilisers, to how insect products can be sold as Novel Food items in the EU, and many more. This analysis has also identified a number of potential changes, that could further expand the scope of waste streams legally available for insect bioconversion, new markets for insect products, and ways to get insect frass approved as a fertiliser, a soil improver or a plant bio-stimulant.

Our earlier conclusion still stands: insects can play a role of cross-sectoral bridge, and turn organic waste into bio based building blocks for the chemical industry. Legislative packages in several sectors must be examined and adapted. Now that minor clauses in a specific Regulations have been adapted and the industry has a viable but minimal legal framework to operate in, it should now be time for a broad review of all relevant legislative packages and the integration of the relevant measures in a comprehensive Regulation on insect breeding and rearing for the different possible purposes.

	Farmed animals other than fur animals			Pets and fur animals
	Ruminants	Non-ruminants (except fish)	Fish	
Ruminant Processed Animal Proteins, except blood meal and fish meal	NA	NA	NA	A
Non-ruminant Processed Animal Proteins, except fish meal	NA	NA	A	A
Blood meal from ruminants	NA	NA	NA	A
Blood products from ruminants	NA	NA	NA	A
Gelatine from ruminants	NA	NA	NA	A
Hydrolysed proteins other than those derived from non-ruminants or from ruminant hides and skins	NA	NA	NA	A
Blood meal from non-ruminants	NA	NA	A	A
Fishmeal	NA*	A	A	A
Blood products from non-ruminants	NA	A	A	A
Di and tricalcium phosphate of animal origin	NA	A	A	A
Hydrolysed proteins from non-ruminants or from ruminant hides and skins	A	A	A	A
Gelatine from non-ruminants	A	A	A	A
Egg, egg products, milk, milk products, colostrum	A	A	A	A
Animal proteins other than the above- mentioned ones	NA	A	A	A

Farmed Insect Processed Animal Protein

Figure 1: Overview of animal fractions and their authorisation for different feed applications. * Milk replacers containing fishmeal and intended only for unweaned ruminants are authorised.

A = authorised NA = not authorised

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
Rearing insects						
Protection of farmed animals	Council directives 58/1998, 98/58/EC Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009	Protection of farmed animals irrespective of the species: does not apply for insects. Describes health rules as regards Animal By-Products and derived products not intended for human consumption - "Insects" are "farmed animals". - "Farmed insects" are "farmed animals"	Invalidation of obligations that are applicable on regular livestock farming (e.g. Staffing, inspection, records, accommodation, rearing method …) Insects are to be treated under the regulations as "farmed animals"	Insect bioconversion for disposal of Animal By-Product is possible under this directive: it simplifies the operational organization of insect bioconversion	Keep insects (non-feed and non-food) as non-farmed animals If Feed- or Food-insects are considered as Farmed animals, have specific clauses regarding their welfare Specifically exclude non-feed and non-food insects from 1069, from definition as "farmed animals".	Provide scientific data and analysis regarding insect welfare when used as bioconvertors
Side streams/ Feedstock	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009	Which "animal by-products" can be used as animal feedstock	Prohibits the use of manure, catering waste and unprocessed former foodstuff (containing meat or fish)	New regulation (cf. regulation 893/2017) amending annexes in regulation 999/2001 to use catering waste and unprocessed former	Specifically exclude non-feed and non-food insects from 1069, as waste treatment agents, or bioconvertors of waste into technical raw	Select raw materials that are widely available and relevant for insect rearing Provide scientific data and analysis regarding insect

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001	Rules for prevention, control and eradication of TSE (mad cow, Creutzfeldt-Jakob). Covers production and placing on the market	Prohibits Processed Animal Protein as feedstock for farmed animals e.g. insects Limitation in substrate for rearing insect	foodstuff as feedstock for insects Use of approved GMP raw materials	materials outside the foodchain New regulation (cf. regulation 893/2017) amending annexes in regulation 999/2001 to increase legal applications to use PAP as feedstock for insects as farmed animals	bioconversion, showing the economic and ecological potential
Frass (excrement of insect larvae)		Frass is an "animal by-product"	Limitation on the use of frass as e.g. fertiliser	Clarification on the legal use of frass, would open new applications ans markets		Provide scientific data and analysis regarding insect frass' biosafety and potential and soil improver
Animal well-fare	Regulation (EC) No 1099/2009 of the European Parliament and of the Council of 24 September 2009	During their killing: animals must be spared pain, distress or suffering. By definition, insects are excluded.	Invalidation of obligations during killing that are applicable on regular livestock farming (e.g. restraining and stunning methods, protection, accommodation …)	Most applied methods are blanching and freezing, which are fast in execution, easy to use and cost efficient.	Use most (scientifically) accepted methodology for killing insects	Evaluation different killing methods: frying, cooking, grinding (alive), …
Transport and storage of insects						
	Animal welfare legislation	Covers all stages of all farm animals: on				

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	Regulation (EC) No 893/2017 24 May 2017 of the European Parliament and of the Council	the farm, during transport and at time of killing Describes amendments of annexes of Regulation 999/2001 as regards on transport and storage of feedstock for non-ruminants including feedstock from farmed insects	Transport and storage of feed materials and compound feed derived from Insect-PAP intended for aquaculture need to be separated from feed intended for non-ruminants other than aquaculture and for ruminants,	Clear description on storage and transport, helps building momentum that supports insect operators aiming on insect-PAP, to make progress in organising their operations. Use of GMP approved raw materials		Provide scientific data and analysis regarding insect welfare during transport and storage
Applications						
Insect-products in general	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009	Describes health rules as regards Animal By-Products and derived products not intended for human consumption.	Animal By-Products are considered Category 3 material – which poses the smallest risk to human and animal health.	Enabling operators to use insects in a very broad scope: because they are considered category 3 material		Provide scientific data and analysis regarding safety of insect-derived products in technical applications
Application in feed						
Market	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of	Describes health rules as regards Animal By-Products and derived products not	ABP for feeding farmed animals, are derived from category 3 material via processing	Enabling operators to use insects in a very broad scope		Provide scientific data and analysis regarding insect PAP's, lipids and chitin for use in animal feed

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	21 October 2009. Chapter II	intended for human consumption.	methods 1-5 or 7 and under HACCP conditions:			
	Regulation (EC) No 893/2017 24 May 2017 of the European Parliament and of the Council	Describes amendments of annexes of Regulation 999/2001 as regards the provisions on PAP	Supporting insect-products in Feed and creating a market for insect-PAP in aquaculture whilst safeguarding public and animal health	Both operators and authorities still need to come to terms with the exact implications of all provisions. Insect operators aiming on insect-PAP, can build in this momentum to make progress.	Possibility of insect bioconversion of waste stream, under conditions and after approval.	Provide scientific data and analysis regarding insect PAP's, for use in animal feed, including nutritional data and possibly health benefits
	Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009.	Regulates the placing on the market and the use of (animal) Feed; Food-producing and non-food-producing animals are treated equal	No explicit block on an approval of insect bioconversion of waste streams (excluding faeces, urine, wood, waste water, solid urban waste, packaging), as long as those insects are not used in food chain, but derogations are limited.	Need for the possibility of insect bioconversion of waste stream, under conditions and after approval.		Provide scientific data and analysis regarding safety of insect products, when fed on sidestreams that are currently excluded, or contain packaging material
New technologies	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001	Rules for prevention, control and eradication of TSE (mad cow, Creutzfeldt-Jakob).	Prohibits Processed Animal Protein as	This blocks the entire feed market, except for petfood and carnivorous fur producing animals.		

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
Hygiene Aquaculture Other Feed applications	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009, article 6 Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 Regulation (EC) No 893/2017 24 May 2017 of the European Parliament and of the Council	Covers production, placing on the market…) Article 6 introduces the concept of proportionality between rules and risks General rules on feed hygiene; traceability of feed; framework of control mechanisms and auto-control schemes (HACCP) Describes amendments of annexes of	feedstock for farmed animals e.g. insects Insect-PAP cannot be authorised as feed for aquaculture, because of its production process. If a novel technology poses (little or) no risk to public health safety, the rules should not obstruct it. This supports the elaboration of an application file for EFSA of a novel technology. Mandatory implementation of auto-control system and external control if insects are used in feed market as "farmed insect-PAP"	Opens a path for operators to apply for European approval for a new technology. No auto-control or external control applies if insect bioconversion is used as waste management facilitates operational organisation of operators. It is clear what conditions must be met by feed producers to include insect-PAP as feed(component), therefore this is an enormous step forward	Opens a path for operators to apply for European approval for a new technology.	Provide scientific data and analysis that will support the application of insect bioconversion as a new technology for ABP-treatment Provide scientific data and analysis regarding an auto-control system/handbook for the insect breeders/rearers Provide scientific data and analysis regarding other insects than the species currently mentioned

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	Regulation (EC) No 893/2017 24 May 2017 of the European Parliament and of the Council	Regulation 999/2001 as regards the provisions on PAP Describes amendments of annexes of Regulation 999/2001 as regards the provisions on PAP	Allows "PAP derived from insects and compound feed containing such processed animal protein" for feeding aquaculture animals, if the complete insect-PAP process is kept separated from the processes destined for feed for ruminants and non-ruminants (except aquaculture). Does not allows "PAP derived from insects and compound feed containing such processed animal protein" for feeding pigs and poultry. In line with TSE roadmap 218, there is no intention to make insect-PAP	for the insect breeding sector, as it opens an enormous market: aquaculture Once reg. 893/2017 is operational, 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. non Restriction of 7 species can be amended.	non Restriction of 7 species can be amended.	Provide scientific data and analysis regarding insect PAP's, for use in poultry and pigs, as the next step after aquaculture

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	Regulation (EU) No 68/2013 on the Catalogue of feed materials	Described feed catalogue: Includes whole (or parts) of insects in all their life stages.	usable as feed for ruminants Insect-PAP intended for feed for farmed animals" (e.g. insect) may only be obtained for 7 described species. But 893/2017 doesn't cover live and dried insect as feed for farmed animals Potential use of live and dried insects as petfood			Provide scientific data and analysis supporting the inclusion of specific insect derived products in the Catalogue of Feed materials
Application in technical solutions						
	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009; article 18	Derogations described in article 18, creates a category of insects to be used in an application (fishing bait) that is not linked to food or feed.	This derogations of the "fishing bait"-application, can be supplemented by a description "technical applications"	non	Allowing insect bioconvertion of Category 3 and/or 2 Animal By-Products	

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
Safety			Bioaccumulation of chemical substances (heavy metals, veterinary medicine, pesticides, antibiotics, mycotoxins) and pathogens	Use of GMP approved raw materials	Define strategies for avoiding risks	Detect and quantify risks
Safety/impact	N.A.		Antinutritional effects of co-extracted chitin	Use chitin free protein fractions.	Use well defined chitin fractions	Qualify and quantify chitin in insects
Safety	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002		Bioaccumulation of chemical substances (heavy metals, veterinary medicine, pesticides, antibiotics, mycotoxins) and pathogens Allergens (type tropomyosins)	Use of GMP approved raw materials Create awareness among people handling and eating insects. Labelling of insect-based products for possible allergenic reactions	Define strategies for avoiding risks Labelling of insect-based concepts for possible allergenic reactions	Detect and quantify risks Qualify and quantify allergenic potential in insects
Processing	Regulation (EC) No 893/2017 24 May 2017 of the European	Describes amendments of annexes of Regulation	Allows "PAP derived from insects and compound feed containing such	A clear description of the conditions that must be met by feed producers to include		Evaluation of potential processing methodologies (physical, chemical and biotechnological)

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	Parliament and of the Council	999/2001 as regards the provisions on PAP	processed animal protein" for feeding aquaculture animals, if the complete insect-PAP process is kept separated from the processes destined for feed for ruminants and non-ruminants (except aquaculture).	insect-PAP as a feed (component). Most probably, (1) only insect producing companies will process their insects, (2) only aquaculture feed producers will use insect-PAP		
			Scale of production		Match scale insect production and downstreamprocessing to relevant raw materials	Select raw materials that are widely available
	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 Regulation (EC) No 178/2002 of the European Parliament		Residual processing aids (solvents, …)	Investment in scalable insect rearing, and downstream-processing solutions are viable Use feed grade solvents	Avoid solvents	Evaluation of potential processing methodologies (physical, chemical and biotechnological) Selection of relevant feeding strategies

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
	and of the Council of 28 January 2002 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 N.A.		Residual substrates in gastrointestinal tract of insect Presence of parasites during cultivation of insects, and possibly harming livestock	Use of GMP approved raw materials Use hygienic rearing conditions	Use of GMP approved raw materials or suitable feeding strategy (including fasting of insects) Prevent parasite contamination	Make an inventory of parasites and prevention methodologies
labelling	Regulation (EC) No 893/2017 24 May 2017 of the European Parliament and of the Council	Describes amendments of annexes of Regulation 999/2001 as regards the provisions on PAP	Label for PAP derived from farmed insects and for compound feed containing PAP derived from insects shall be clearly marked.	Labelling of insect-based products for possible allergenic reactions	Use of GMP approved raw materials or suitable feeding strategy (including fasting of insects)	Selection of relevant feeding strategies
Application in food						

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
Hygiene Novel Foods	Regulation (EC) No 853/2004 of the European Parliament and of the Council Regulation (EC) No 854/2004 of the European Parliament and of the Council Regulation (EC) No 2283/2015 of the European Parliament and of the Council	Specific rules on the hygiene of food of animal origin for food business operators. Specific rules for the organisation of official controls on products of animal origin intended for human consumption Placing of Novel Foods on the market. Need for a granted application if an absence by a significant degree of use for human consumption within the EU before 15 May 1997, occurs	Local food safety authorities have a system of certifications, permits and registrations of the operators. Creating different local regulations for insect rearing and transformation of insect into products From the 1st of January 2018, this new Regulation will be in force: declaring that insects are Novel Food. If no granted application on the applied insect species and its products exist; the species and products thereof cannot be placed on the market	Possibilities for local operators to establish an agreement with local safety authorities concerning rearing, transforming and placing on the market of insects. Possibilities for local operators to establish a transitional arrangement from the 1st of January 2018 onwards and continue rearing, transformation and placing on the market of insects and their products.	Need for an alignment of the application of regulations 853, 854, 2283, in order to establish one general EU market for insects and products thereof. Generating one EU market is the only way to create a viable market for insects as human food.	Provide scientific data and analysis regarding hygiene of insect farms and farming procedures
Safety	Regulation (EC) No 2073/2005 of the European Parliament and of the Council	Microbiological criteria for certain micro-organisms and the	No mention of insect products can be found This void in regulation on food	Need for an amendment of regulation 2073/2005 on the microbiological		Provide scientific data and analysis regarding microbiological load of

Topic	Related legislation	Description of the legislation	Barrier / advantage	Potential solution/opportunity short term	Potential solution/opportunity longer term	Possible contribution of InDIRECT to lower the barrier
		implementing rules to be complied with by food business operators	safety and thereby the void in controlling possibilities of food products, based on insects, creates a more severe control than scientifically needed.	criteria for foodstuff base on insects.		insect products for human consumption

[i] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF
[ii] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0001:0054:en:PDF