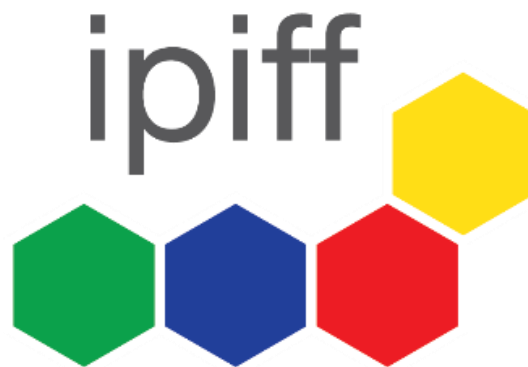


Insects

Food Safety First – First time Right

Regulatory roadmap for insect products in Feed and Food applications



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DISCLAIMER

The contents of this document are based on discussions with DG Sanco, Member state officials, legal and lobby advisors and has been read and communicated with various associated partners and knowledge institutes. The document depicts the best-at-our-effort knowledge on where the legal barriers are with respect to insect production and application in Feed and Food markets. No rights can be based on this document and for suggestions, questions and inputs related to the contents we would like to refer to the author(s).

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Introduction

Insects are of growing interest to many parties ranging from governments to knowledge institutions and industry. Insects play a pivotal role in nature in preservation of nutrients and can upgrade low-grad decaying matter into high quality biomass. With a growing population the pressure on agriculture and fisheries to provide in our nutrient needs is increasing. Insects offer one of many opportunities to feed the world.

With great opportunity comes great business. However, the regulatory frameworks currently don't provide in capturing the potential opportunities. Various parties and initiatives are working on clarifying the issues related to the business opportunities. This document is a summary of findings on where and how exactly EU Regulations are prohibiting us from going to market with insect derived products like insect protein meals. It is written to create an overview on where the current barriers are and offer an 'investable' picture for market players on where they believe the opportunities are now and in the future for innovative new products based on insects.

Main conclusions from our experiences and insights¹:

- Insects for Food application are allowed provided Novel Food Dossiers processes are followed
- Legislation with respect to insect proteins in Feed application should be considered as "unless explicitly allowed, all is forbidden", and therefore is currently forbidden as there is no specific mention of insect proteins as allowed ingredient.
- Legislation is specific for 'inputstream-market' combination implying we'll need a multi-phased approach for release of new inputstreams in combination with market applications.
- There's huge momentum created over the last 5 years from many interesting insect related initiatives across the EU and internationally. There's momentum and willingness both on the market side as well as on the regulatory side. Together with industry, knowledge institutions and governments an open relationship can be built to co-develop the roadmap towards a powerful and interesting new industry.

This document further details the underlying regulatory barriers and describes the strategy IPIFF proposes to create new market opportunities by managing a regulatory roadmap in collaboration with DG Sanco and member state governments. This document has left markets in Industry, chemicals and materials out of scope.

¹ General references:

- "Discussion paper: Regulatory frameworks influencing insects as feed and Food" – Afton Halloran; 18-12-2013
- "Pro-Insect platform in Europe" – Rhonda Smith and Rosie Pryor / Minerva; 31-07-2013

Rules and Regulations

There are several markets that can be served by insect based and derived products, main markets being the food and feed market.

Food industry

Insect consumption

It is widely accepted that by 2050 the world will host 9 billion people (FAO report, 2009). To cover this increase, current food production would need to almost double. Land is scarce and expanding the area devoted to farming is rarely a viable or sustainable option. Oceans are overfished, and climate change and related water shortages could have profound implications for food production. To meet the food and nutrition challenges of today – there are nearly 1 billion chronically hungry people worldwide – and tomorrow, what food we eat and how we produce it needs to be re-evaluated. Inefficiencies need to be fixed and food waste reduced. We need to find new ways of growing food.

Worldwide, nearly 1 900 insect species are reported to be used as human food. The practice of eating insects goes back thousands of years and has been documented in nearly every part of the world. Insects are indeed part of the food habits and culture of 2 billion people on Earth. Insects are mainly eaten in the inter-tropical areas, from Latin America, to South East Asia, and Central Africa. The consumption habits cover many different uses, either for subsistence consumption, or luxury dishes, like in Mexico.

Several scientific analysis confirm the balanced and healthy nutritional composition of some insects like *Tenebrio molitor* larvae or Crickets and Locust species, and several studies point to the potential to produce insects for food with far fewer negative environmental impacts than for many mainstream foods consumed today. Since 2008, Food and Agriculture Organization and Wageningen University have been very active to promote the use of insects in feed and food markets. They have compiled hundreds of worldwide publications presenting nutritive composition, rearing techniques, environmental advantages, etc. (See FAO reports 2008, 2010, 2012, 2013).

There is a real possibility that the mass production of beef, pork, chicken and fish (the standard protein sources for many millions) might not be possible indefinitely. This implies that entomophagy could become a very viable option for meals despite the general cultural resistance to the practice of eating insects.

Europe is part of the areas where insects are seen with a degree of distaste. There are though few traditional insect dish consumed, like the “maggot” cheese in Sardinia, or palm larvae in Reunion island. The consumption are allowed only in situ, and products cannot be exported out these places in other European places. Historically, Greeks and Romans have been used insects as delicacy meals.

Although the majority of edible insects in the world are gathered from forest habitats, innovation in mass-rearing systems has begun in many countries showing the way of a real agroindustry in Europe, that could create many jobs or diversification opportunities for farmers.

Insect products sales in European Food markets

With the increase of interest for insects as promising solution for more sustainable food systems, European regulatory institution took position on their use in feed and food European markets.

The decision of European Union and its Member States relied on the “Novel Food” regulation. The Novel Food directive 258/97 presents the guidelines for market authorization of products which have not history of human consumption before 1997 in European Union. It is required to show proofs of sales (e.g. bills) and sufficient volumes of sales and no effect on human health to be able to define an ingredient as not novel in that frame. The guidelines include a human health risk assessment. The appendix 618/97 describes how to conduct this risk assessment to prove that the new ingredient is safe for human consumption. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1997:253:0001:0036:EN:PDF>)

The situation has been quite blurry these last few years, with unaligned communications from different Member States. Belgium is the last example of this regulatory confusion, with the decision of its health agency AFSCA (<http://www.favv-afscab.be/denreesalimentaires/insectes/default.asp>) to authorize insect ingredients in food markets as long as European decision is not unified. On the other side, Italy has blocked *Bombyx mori* imported from South Korea (source : RASFF Portal, Ref : 2012.AMK) as unauthorized Novel Food ingredient from South Korean food supplement.

European Commission has indicated that Novel Food process will be modified, by taking into account in particular traditional human consumption in non-European countries, as long it is possible to prove that there has been a consumption longer than 25 years without health issues. Insects could be incorporated in that new Novel Food procedure. The agenda of this Novel Food directive update is unclear though.

Background on Novel Food process:

Specification of the origin and the composition of the novel food are needed to ensure the identity of the product tested/evaluated and the product to be marketed. In the design of the specification, parameters most relevant to characterize the product from a safety and nutritional point of view should be considered. Such parameters include species and taxon, as well as chemical composition relating particularity to nutritional properties. Taxonomic identity should be established according to referenced and internationally accepted principles should be explained (European Commission, 1997).

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed pertaining to the specifications of the novel food (European Commission 1997):

- “Depending on the derivation and composition of the Novel Food, is appropriate analytical information available on potentially toxic inherent constituents, external contaminants and nutrients?”
- “Is the information representative of the novel food when produced on a commercial scale?”
- “Is there an appropriate specification (including species, taxon, etc for living organisms) to ensure that the novel food marketed is the same as that evaluated?”

According to regulation No 258/97 of the European parliament and of the council of 27/01/1997 an insect compound like insect protein flour for example belongs to the category E: "Food and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food". It belongs to class 2: novel food complex which has an origin non GM. It belongs also to subclass 2.2 never used as food in community.

The following table (source: UE 618/97) shows the items that need to be fulfill by an ingredient in subclass 2.2.

Index to structured schemes to be followed for each class of NF

Structured scheme		Class of NF										
		1.1	1.2	2.1	2.2	3.1	3.2	4.1	4.2	5.1	5.2	6
I.	Specification of the NF	x	x	x	x	x	x	x	x	x	x	x
II.	Effect of the production process applied to the NF	x	x	x	x	x	x	x	x	x	x	x
III.	History of the organism used as the source of the NF	x	x	x	x	x	x	x	x	x	x	x
IV.	Effect of the genetic modification on the properties of the host organism					x	x	x	x	x	x	
V.	Genetic stability of the GMO					x	x	x	x	x	x	
VI.	Specificity of expression of novel genetic material					x	x	x	x	x	x	
VII.	Transfer of genetic material from GM microorganisms					x	x	x	x	x	x	
VIII.	Ability to survive in and colonize the human gut									x	x	
IX.	Anticipated intake/extent of use of the NF	x	x	x	x	x	x	x	x	x	x	x
X.	Information from previous human exposure to the NF or its source	x		x		x		x		x		x
XI.	Nutritional information on the NF	x	x	x	x	x	x	x	x	x	x	x
XII.	Microbiological information on the NF	x	x	x	x	x	x	x	x	x	x	x
XIII.	Toxicological information on the NF	x	x	x	x	x	x	x	x	x	x	x

Conclusions

Regarding these different EC member States positions, as long as there is no harmonized European definitive decision soon foreseen about whether or not insects are a Novel Food, IPIFF position is keep in line with regulation and follow Novel Food procedure in order to release insect ingredients on food markets, for the following reasons:

- **Respect of current regulation**
- **Protection of European consumers health**
- **Fair competition among European insects industry actors, for long terms European jobs opportunities in the insect industry**

In that frame, insect producers must furnish complete file with all data answering the 7 points of Novel Food dossier, in order to assess precisely the Health Risk Assessment (measure of potential hazard – i.e. toxicological, microbiological, allergical – and measure of European consumers exposure by defining precisely which kind of product are release and their markets of use).

Feed industry

Within the Catalogue of Feed Materials (EC 68/2013), there is no specific entry for 'insect meal' although there is a listing for 'whole or parts of terrestrial invertebrates' suggesting that the use of insect protein in animal feed may be possible. If they are to be used for feed, insects must meet the requirements of Directive EC 2002/32 on Undesirable Substances in Animal Feed. This sets the maximum permitted levels of contaminants such as heavy metals. Additionally, insects must be processed in accordance with the EU Animal By-Products Regulation 1069/2009 to become processed animal protein (PAP) before they can be fed to animals. Imported insect material from non-EU countries must also be processed in accordance with this regulation. Furthermore, under this regulation, non-pathogenic insects are classed as category 3 material and are therefore deemed suitable for feeding to farmed animals.

However, in response to the BSE outbreak, regulation EC 999/2001 prohibited all PAP, with the exception of hydrolysed proteins, from being used in animal feed. This ban has now been partly lifted and under regulation EC 56/2013, PAP derived from non-ruminants (including insects) is allowed to be fed to aquaculture species. However, there is still a prohibitory element on slaughterhouse registration for the processed product that prohibits the application in Aquaculture. Currently, this relaxation of the regulation cannot be extended to cover pig and poultry feed because there are no valid diagnostic methods able to detect the presence of pig or poultry material in animal feed. This means that there is no way of ensuring that the prohibition of intra-species recycling and forced cannibalism is being adhered to. Nevertheless, it is thought that once valid diagnostic tests become available, the use of PAP in pig and poultry feed will also be reauthorized (FAO, 2013).

Below a full map is made on what is currently allowed and not allowed with respect to insect derived products. This map is the basis for the industry strategy

What you feed the insects	Product made from insects	Target market of product	Permitted?	Permission / Restriction related to feeding het insect	Permission / Restriction related to marketing the product	Minimum requirements to start business	Proposed strategy for allowance in case of not permitted	
100% vegetable and/or including eggs and dairy	Life insects	Petfood	Yes			Admission based on article 24(1) sub a, Reg. 1069/2009		
	Derived insect fat	Petfood, Aquaculture, Livestock (excluding ruminants)	Yes	100% purely vegetable doesn't fall under restrictions mentioned in article 7, R 999/2001 Eggs and dairy are allowed based on Chapter II, article 10 R 142/2011	For pets: Article 35, R 1069/2009 For livestock including Aquaculture: Article 31, R 1069/2009	Admission based on article 24(1) sub a, Reg. 1069/2009		
	Hydrolyzed insect PAP	Petfood, Aquaculture, Livestock (excluding ruminants)	Yes	100% purely vegetable doesn't fall under restrictions mentioned in article 7, R 999/2001 Eggs and dairy are allowed based on Chapter II, article 10 R 142/2011	For pets: Article 35, R 1069/2009 For livestock including Aquaculture: Annex IV, chapter II, point b.i, R 999/2001	Admission based on article 24(1) sub a, Reg. 1069/2009		
	Non-hydrolyzed insect PAP	Petfood		Yes	100% purely vegetable doesn't fall under restrictions mentioned in article 7, R 999/2001 Eggs and dairy are allowed based on Chapter II, article 10 R 142/2011	Article 35, R 1069/2009	Admission based on article 24(1) sub a, Reg. 1069/2009	
		Aquaculture		No	100% purely vegetable doesn't fall under restrictions mentioned in article 7, R 999/2001 Eggs and dairy are allowed based on Chapter II, article 10 R 142/2011	Allowed under point c, chapter II, annex IV, R 999/2001 Under regulation 56/2013 insect PAPs are allowed as a product in feed for aquaculture when processed by registered slaughterhouse. This is technically not possible for insects.	Admission based on article 24(1) sub a, Reg. 1069/2009 Registration as slaughterhouse for processing of larvae based on Annex IV, R 999/2001	Currently in discussion with DG Sanco and member states for release. Collaborative strategy to be detailed.
	Livestock (excluding ruminants)		No	No	Yes, under regulation 56/2013 insect PAPs are allowed as a product, yet in article XXX, there is mention of the origin of the PAP being a certified slaughterhouse, which is technically impossible under ruling XXX/XXX in article XXX		Currently in discussion with DG Sanco and member states for release. Collaborative strategy to be detailed.	
100% vegetable and/or including eggs and dairy and meat and fish	Derived products like protein meal and fats	Petfood, Aquaculture, Livestock (excluding ruminants)	No	Falls under restriction article 7, R 999/2001			Develop general roadmap on risk assessment in collaboration with DG Sanco and EFSA	
	Hydrolyzed insect PAP	Petfood, Aquaculture, Livestock (excluding ruminants)	No	Falls under restriction article 7, R 999/2001			Develop risk analysis strategy to prove safety of hydrolyzed proteins derived from insects fed with these products	
All organic by-products and waste streams excluding manure, faeces and categorized material as prohibited to be fed to animals	Life insects	Life bait, circus animals and other markets mentioned in article XXX/XXX	Yes					
Manure	Derived products	Biodiesel, energy, Soil nutrients		Cannot be fed to animals in general under ruling 787/2003			Define process of growth of insects on manure as separate business process. NON-FOOD "Only for purpose of manure processing with use of insects in energy and/or soil nutrients"	

The Way Forward, a collaborative transparent approach

To facilitate the industry maturity, a market-driven approach is decided by the members of IPIFF. IPIFF will lay down and adhere to the following statements and proposed regulatory roadmap strategy.

- IPIFF will create market applications and products within industries that are currently allowed based on EU regulations for Food and Feed
- IPIFF will closely collaborate with EU and member state officials to open up new markets in Feed and Food
- IPIFF will propose a series of first potential products and target markets to regulatory bodies to create a transparent roadmap. See proposal for Feed and Food related products below.

Feed related products

Product	Target market	Strategy to tackle regulatory limitations
Insect PAP when insects are fed with 100% vegetable feedstock	Aquaculture / Livestock	Currently in discussion with DG Sanco
Insect PAP when insects are fed with Former Foodstuff including meat and fish	Petfood	Start open discussion with DG Sanco for release
Insect PAP when insects are fed with Former Foodstuffs including meat and fish	Aquaculture	Develop dossier strategy with DG Sanco and EFSA for risk analysis and strategy for allowance
Insect derived products when insects are fed with manure	Non-Feed markets, but application in other industries	To be discussed. Exclusion of manure as feedstock by co-developing other markets creates transparency to avoid risk averseness on manure as potential feedstock

Food related products

Product	Target market	Strategy to tackle regulatory limitations
Whole dried mealworms	Direct consumption	To be accepted as general food source
Processed products based on mealworms or other species	Direct consumption	To be accepted by notification dossiers