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Legal and environmental aspects of authorizing edible insects in the European Union

Nicole GRMELOVA[1]*, Tomas SEDMIDUBSKY[2]

[1]*Department of Business and European Laws, Faculty of International Relations, University of Economics Prague, Prague, Czech Republic*
[2]*Department of Applied Ecology, Faculty of Environmental Sciences, Czech University of Life Sciences, Prague, Czech Republic*

*Corresponding author: grmelova@vse.cz

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Abstract: Nutritional values of different foodstuffs have been examined in various studies on a number of occasions. However, so far, little attention has been paid to the legal aspects of introducing edible insects in the European Union. Yet, the rearing of this mini-livestock for food and feed has a potential of developing into a new agricultural sector, which is sustainable, unlike the breeding of the traditional livestock. The aim of this paper is to provide a comprehensive overview of the legal background of authorizing edible insects in the European Union, taking into account the environmental impacts thereof. At present, the Member States are free to regulate this field, however, only until the transitional period established by the European Union (EU) rules has expired, since the EU wide regulation for authorizing edible insects is to be introduced as of 1st January 2018.

Keywords: environment, European Food Safety Authority (EFSA), food safety, mini-livestock, Novel Food Regulation, regulatory framework

Nutritional values of different foodstuffs have been examined on a number of occasions (see e.g. Skibniewska 2013; Kocková and Valík 2014; Vrbiková 2014). However, so far, little attention has been paid to the legal aspects of introducing edible insects. The existing studies on legal aspects of food security refer to the old EU legislation on the so-called novel foods, but they do not reflect its updated wording adopted in late 2015 (Belluco 2013; Rumpold 2013; van der Spiegel 2013). Food security has been addressed particularly with respect to developing countries (Jeníček and Grófová 2015a, b). Nevertheless, in developing countries a manual collection of edible insects in the wild is more likely (Morales-Ramos et al. 2014) than a mass farming of mini-livestock under controlled conditions that may emerge into a growing sector of the agricultural economy. The aim of this paper is to provide a comprehensive overview of the legal background of authorizing edible insects in the European Union, taking into account the environmental impacts thereof.

Whereas many non-EU countries display a continued tradition of consuming insects and in some developing countries, the consumption of insects appears to be a solution to overcoming protein shortage in human diet, the EU's position on promoting the breeding of edible insects has been reserved so far and seems to address different issues: firstly, the food safety, and secondly, the environmental benefits of breeding edible insects compared to breeding livestock (Mlcek et al. 2014). Some authors argue that the EU's approach to promoting edible insects is inconsistent insofar as there is a conflict between the stress on research and development on the hand, and high safety standards for food and feed on the other hand, which hamper a fast development of a new agricultural industry sector (De-Magistris et al. 2015).

Food safety raises a number of issues aimed at providing for a high level of protection of human health. Researchers tend to distinguish different kinds of food safety hazards: allergies, chemical risks, microbiological risks, parasitical risks and some food

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Table 1. Health risks requiring regulatory framework

Type of health risks	Regulatory response
Allergies	Obligatory labelling of allergens
Chemical risks	Selection of species of edible insects posing no chemical risks and introducing strict farming conditions
Macro-biological and parasitical risks	Stipulating the processing mechanisms, such as the heat treatment of edible insects prior to their consumption
Physical risks	Labelling – instructing the consumer to remove certain sharp parts of insects before consuming them

Source: Own compilation based on the information contained in Belluco (2015) and FASFC (2014)

safety assessment studies also include physical risks (FASFC 2014).

Table 1 summarizes the manner of responding to different health hazards related to edible insects by the means of legislation.

All of these issues require a regulatory framework to comply with the EU's precautionary principle well established in the general EU Food Law[1]. Regulation 178/2002[2] is often referred to as the EU's General Food Law. It codifies for the first time the risk analysis, which is based on a methodology consisting of three steps: first, it is the scientific risk assessment, second, it is the risk management, and third, it is the risk communication. This methodology reflects the "farm to fork" principle which should provide for a traceability of the origin and distribution of foodstuffs used in the EU including a network for sharing the possible health risks (such as salmonella found in frozen chicken) called the RASFF (Rapid Alert System for Food and Feed). As Szajkowska puts it, "on the basis of scientific risk assessment, decision makers define political objectives to determine the level of risk acceptable for the society" (2012). Since the scientific risk assessment is carried out by the European Food Safety Agency (EFSA), the food safety regulation will depend on its opinions to a large extent (Chalmers 2003).

With respect to the mutual relations between the EFSA and the national food safety authorities, the EFSA's scientific opinions are not supposed to prevail over similar opinions issued by the national authorities (Gabbi and Alemanno 2014). The General Food Law establishes procedures to deal with such a conflict. A joint document drafted by both the EFSA and the national food safety authority concerned shall explain why these opinions do not coincide (Szajkowska 2012).

Some of the EU Member States regulate or tolerate the breeding and marketing of edible insects within their territory. This is particularly the case of Belgium, and the Netherlands (van der Meulen 2014). However, once the Novel Food Law recast regulation has become effective, Member States may no longer adopt the national measures.

Legal Regulation of edible insects in Belgium

Before looking at the new EU legislation on breeding edible insects, let us concentrate on the regulation of bugs for human consumption in Belgium.

The Belgian federal food safety agency (the so-called FASFC, standing for the Federal Agency for the Safety of the Food Chain) approved a list of twelve edible insects to be found in Table 2. Prior to releasing this list, the FASFC elaborated a scientific study addressing the possible health risks of insects, following a similar structure to the report drafted for the purpose of the 2014 conference on "Insects to feed the world" held in Wageningen (the Netherlands), organized jointly by the United Nations Food and Agricultural

[1]In the case-law of the Court of Justice of the European Union see e.g. judgments in cases T-13/99, Pfizer Animal Health v. Council (2002) ECR II-3305, T-70/99, Alpharma v. Council (2002) ECR II-3495, and C-221/10P Artedogan GmbH v. European Commission (2012) published in the electronic Reports of Cases. In the EU legislation, the precautionary principle was codified in Article 7 of the General Food Law to read as follows: "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."

[2]The Regulation (EC) No. 178/2002 of the European Parliament and the Council of 28 January 2002.

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Table 2. List of edible insects authorized in Belgium

Latin name	English name	Stage of development at the time of consumption
Acheta domesticus	House cricket	Adult
Achroia grisella	Lesser wax moth > wax moth worm	Caterpillar
Alphitobius diaperinus	Litter beetle > lesser mealworm	Larva
Alphitobius leavigutua	Buffalo worm > lesser mealworm	Larva
Bombyx mori	Silkmoth > silkworm	Pupa (without cocoon) and caterpillar
Galleria sigillatus	Banded cricket	Adult (imago)
Gryllus assimilis	Field cricket	Adult (imago)
Locusta migratoria	African migratory locust	Larva and adult (nymph and imago)
Schistocerca Americana	American desert locust	Adult
Tenebrio molitor	Yellow meal beetle > yellow mealworm	Larva
Zophobas atratus	Morio beetle > morio worm	Larva

Source: Belgium Federal Agency for the Safety of the Food Chain – FASFC (2014)

Organization and the Wageningen University and Research Center.

The Belgian food business operators marketing edible insects require a prior registration with the FASFC and they are obliged to abide by the applicable rules on the hygiene, traceability, labelling as well as the HACCP[3] principles concerning the organization of a self-checking system.

The need for an EU wide binding regulatory framework

The United Nations Food and Agricultural Organization believes that "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" (FAO 2014). In this context, the Food and Agricultural Organization calls for a clear regulatory framework to promote the farming of edible insects, since the absence of clear regulation deters the possible food business operators from entering the market. Legal insecurity discourages the growth of the edible insects business. To this end, the Food and Agricultural Organization also encourages the environmental non-governmental organizations to promote the EU wide lobbying for a specific regulation on edible insects, stressing the importance of this issue for the sustainable development and lowering the amount of greenhouse gasses compared to breeding livestock (FAO 2014).

It is not only the EU based farmers of edible insects that would benefit from an EU regulatory framework, but also those who wish to import edible insects to the EU. The EU regulatory framework of authorizing and marketing edible insects may also be relevant with respect to the ratification of the Comprehensive Economic and Trade (CETA) Agreement which is likely to expand the volume of trade between Canada and the European Union. Lähteenmäki-Uutela maintains that restrictions on the international trade in insects persist, even though they have been traditionally consumed outside of the EU for a long period of time (2007). Since the same tradition of consuming insects does not go for the EU, the Commission considers edible insects as a novel food, which requires a previous authorization. The recast wording of the EU Novel Food Regulation[4] to become effective as of 1st January 2018 finally covers insects as a whole. Since the revision of the Novel Food Regulation is very recent, some Member States, such as Belgium, have introduced a creative solution, tolerating the breeding of edible insects under certain conditions which

[3]The Hazard Analysis and Critical Control Point System (HACCP) was introduced by the Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.

[4]Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001.

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guarantee the food safety and consumer protection. Also, the Czech Republic tolerates the farming of edible insects without any specific regulation covering this nascent agricultural business. The long transitional period for the application of the recast Novel Food Regulation is due to the missing implementing acts to be adopted by the European Commission by that deadline.

The need for an EU-wide regulation has also been stressed by different administrative practices as to the possibility of importing edible insects from outside the EU both in bulk and for the personal use. These practices vary among different Member States significantly. Business imports of edible insects have been withdrawn from Denmark, the media report, due to a lack of the regulatory environment surrounding this issue (The Local 2015). Other sources indicate, for instance, that while importing up to 2 kg of edible insects per person is permitted in the United Kingdom, a prohibition on importing bugs intended for human consumption persists in Germany and Italy (Belluco et al. 2014). The review of the EU Novel Food Regulation is likely to simplify the trade in edible insects by having included them into the scope of the Novel Food Regulation explicitly and by changing the current pre-authorization regime to a notification procedure, which is less bureaucratic for the prospective food business operators in this field.

The new European Union legislation governing edible insects

Within the structure of the EU bodies and institutions, it is the European Commission who holds the monopoly on drafting legislation in the EU law. Since the European Commission itself does not have the scientific resources to evaluate the possible health hazards of introducing edible insects to the EU market, it commissioned the European Food Safety Agency (EFSA) to elaborate a risk assessment of using bugs for the human consumption.

The mandate received by the EFSA included the evaluation of a number of issues concerning food safety. The EFSA adopted its scientific opinion on 5 October 2015 in line with its mandate (EFSA 2014). The EFSA assessment was based on a risk profile approach. Its scope of assessment has been delimited both in the positive and in the negative way. The EFSA was asked to evaluate the hazards associated to edible insects identified in the context of comparing these to other sources of protein. Its task included expressing its opinion on the imports of insects and products thereof, however, it was not supposed to deal with the imports of live insects (EFSA 2015).

In its scientific opinion of 5 October 2015 entitled "Risk profile related to production and consumption of insects as food and feed", the EFSA draws no clear conclusions as to the safety of breeding animal insects. On the contrary, it identifies a number of areas which require further research. These issues include the occurrence of human and animal bacterial pathogens in insects processed for food and feed; the likelihood of human viruses such as the norovirus, rotavirus, Hepatitis E and A being passively transferred from the feedstock through the residual insect gut contents; and the extent to which insects act as mechanical vectors of prions (EFSA Scientific Committee 2015).

The EFSA working group on edible insects meets regularly and publishes the minutes of its meetings, including the list of external experts comprising the insect food businesses operating in the EU and academics from Asian countries where the consumption of edible insects has a long standing tradition (such as Thailand and China) (EFSA 2015). The above EFSA scientific opinion coincided with the review of the Novel Food Regulation which is discussed below.

Review of the Novel Food Regulation

The original Novel Food Regulation (Regulation (EC) No. 258/97) established the year 1997 as a year of reference for assessing the novelty of foods introduced to the EU market. If a food was not commonly marketed in a Member State before 1997, it required a risk assessment before being placed on the EU market. Whereas the original Novel Food Regulation did not cover insects as a whole, the recast Novel Food Regulation has included insects as a whole into the scope of its regulatory framework. The new Novel Food Regulation shall repeal and replace the original one.

The draft of the new novel food regulation was published by the European Commission in December 2013, approved by the European Parliament in October 2015 and by the Council of the EU in November 2015. The summary of the updated Novel Food Regulation available at the official webpage of the European Parliament says that the aim of the new legislation is to simplify the authorization procedures for the

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novel food in order to improve its efficiency and transparency. With respect to edible insects, the Commission proposal shall subject novel foods to the safety evaluation and authorization through a fully harmonized procedure (thus precluding Member States from adopting divergent national measures), and it shall introduce a simplified procedure for marketing traditional foods from third countries. This last category of novel foods to the EU market shall undoubtedly cover also insects imported from non-EU countries with a long standing tradition of consuming edible insects (European Parliament 2015).

The simplified procedure consists in the obligation of the applicant to show a history of safe food use in a third country for a period of at least 25 years. This burden of proof is not self-sufficient, since the Member States or the EFSA may present reasoned safety objections based on scientific evidence, in which case an EFSA assessment is required. Nevertheless, the EFSA should deliver its scientific opinion within a shorter deadline than that applicable for the standard authorization procedure (European Parliament 2015).

The notification procedure applicable to edible insects

The notification procedure for obtaining the authorization for marketing edible insects in the EU market is described in detail in Articles 15 to 18 of the recast Novel Food Regulation. This Article stipulates the procedure for applicants to follow in case a Member State has raised objections as to the safety of the edible insect to be authorized. In that case the Commission rejects the authorization of the mini-livestock and the applicant may submit a new application in which it addresses the food safety objections raised by a Member State providing further documentation of their safety. Such a new application is subsequently forwarded by the Commission to the Member States and to the European Food Safety Authority for further evaluation. The European Food Safety Authority shall adopt its opinion within six months from the date of the receipt of a valid application. This period, however, may be extended, if the European Food Safety Authority requires the applicant to submit further information. Once it has drafted its opinion, the European Food Safety Authority shall forward it to the Commission and to the Member States. Within three months of the date of the publication of the European Food Safety Authority's opinion, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed[5] a draft implementing act authorizing the placing on the market within the Union of the traditional food from a third country. Where the above Committee delivers a positive opinion, the Commission shall adopt the draft implementing act and vice versa, if the committee delivers a negative opinion, the Commission shall not adopt the draft implementing act (Article 5 of Regulation (EU) No. 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers). It is obvious that such a procedure is very bureaucratic and time consuming for the food business operators whose first application to market edible insects has been rejected.

Environmental aspects of farming edible insects

The European Parliament made use of its prerogative to adopt amendments to the original Commission proposal to recast the Novel Food Regulation. In total, the Members of European Parliament adopted over one hundred pages of changes to the original wording of the document. The first set of amendments concerned the objectives of the new novel food regulation. Whereas the European Commission only included the high level of protection of human health and that of the consumer interests, the European Parliament Environment Committee also added environmental concerns, the animal welfare (relevant to farming edible insects), and the precautionary principle to the aims pursued by the new regulatory framework. Also, the Environment Committee stressed the need for the products imported from the third countries to comply with the requirements of those made in the EU (European Parliament 2014).

Environmental aspects of farming mini-livestock will also have a direct impact on the land use. The statistics provided by the United Nations Food and Agricultural Organization show that the breeding of traditional livestock requires 68% of the world

[5]This Committe was established by Article 58(1) of Regulation (EC) No. 178/2002. It is composed of representatives of all Member States and presided by a European Commission representative.

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agricultural land, comprising both pastures and the land area for growing feed (van Huis 2015). Farming mini-livestock will require considerably less agricultural land. Further environmental aspects of rearing edible insects contributing to a more sustainable agriculture also include lower greenhouse gas emissions (FAO 2013) as well as a potential to grow edible insects on the organic by-products, including manure. Morales-Ramos recalls that using organic manure for feeding edible insects may not be completely safe, but it would be safe enough for using insects as feed (Morales-Ramos et al. 2014).

Since the European Parliament is supposed to represent the interests of the EU citizens, it is clear that it endeavours to stress environmental advantages of breeding edible insects to farming livestock. Surveys carried out by the Eurobarometer, the department of the European Commission conducting opinion polls, have noted that the EU citizens are becoming ever more aware of and sensitive to the environmental issues, which have acquired a significant role in the legislative policy (Vogel 2012).

Possible shortcomings of the reviewed Novel Food Regulation

The new legal framework for farming edible insects in the EU will undoubtedly contribute to a better environment. This has not been criticized by any researchers. On the other hand, criticism has been voiced as to the level of the transparency of the approval process, which may impede a smooth functioning of the procedures, deterring small and medium-sized enterprises from entering this field of business (Bartl 2015). Also, unequal legal conditions will persist during the transitional period between the adoption of the recast Novel Food Regulation (November 2015) and the date when it becomes fully applicable (January 2018), since the existing food business operators farming edible insects may continue to pursue their activities under the national and often more relaxed legal rules, whereas those who wish to initiate their activities in farming mini-livestock will be obliged to adhere to the more stringent EU rules.

CONCLUSION

The lack of any EU-wide regulatory environment of authorizing edible insects has provided for the legal insecurity for the prospective food business operators who wished to breed or import and subsequently market bugs aimed at human consumption for a long time. The legislative vacuum discouraged the food business operators from introducing innovative products which may be more environment friendly than traditional sources of protein obtained from the livestock. The review of the Novel Food Regulation has introduced more clear and uniform rules for authorizing and marketing edible insects across the EU. The recast wording of the Novel Food Regulation is not perfect, featuring a number of shortcomings in terms of the transparency of the authorization procedure, in particular; yet, it will be a step forward in the promotion of a new agricultural industry in farming mini-livestock in the European Union.

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