

## Ricerche

### Eating Insects: Crunching Legal Clues on Entomophagy

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#### 1.- Introduction

One could wonder about the reasons, but probably he or she will not find an immediate answer: what is certain is that over the last year – and mainly over the last months – «edible insects» have become a hot topic, better, a hot magazine topic. Lots of spot news have been published on newspapers, generalist journals, and on websites. A specialized review has however published its first issues<sup>1</sup> and this is the evidence that something is going on. A new awareness, and - why not – curiosity are spreading among scholars of different disciplines: can insects really be the food of the future?

The idea of eating insects is not something new. In great part of the world, insects are a common element of everyday diet or at least an ordinary food. In the rest of the globe, apart from some specific uses (for instance cochineal from which natural carmine dye is derived), insects are not even conside-

red as food.

Nevertheless, studies on edible bugs<sup>2</sup> have been carried on for more than fifty years<sup>3</sup> and even longer, if we consider that the pioneering theories on insects as a suitable source of proteins for human nutrition date back to the late nineteenth century<sup>4</sup>. So, why is entomophagy still struggling to become a generally accepted practice? On the one hand, it is obviously a matter of cultural habit: many consumers would probably turn their noses up at the idea of trying chocolate-covered silkworm pupae as snacks, or of starting their dinner with a dry roasted cricket appetizer.

And this is just because they are not accustomed to the idea<sup>5</sup>.

On the other hand, as we will shortly see, there are some legal issues at the origin of the missed spread: an unusual fact, indeed.

Generally, the evolution of law is strictly related to changes in practice. While customs progressively transform, new rules follow, in order to answer the new emerging issues, linked to such gradual development.

The case of edible insects, at least within the European Union, does not match the scheme: previous crystallized laws prevent entomophagy from increasing in «popularity» among consumers.

This paper neither supports nor disapproves the choice of eating insects: this is not its aim. It will just spot some clues from a law perspective<sup>6</sup>.

(<sup>1</sup>) *Journal of Insects as Food and Feed*, available at <http://www.wageningenacademic.com/loi/jiff> [last access January 9th 2016].

(<sup>2</sup>) The paper will use improperly the words «insects» and «bugs» as synonyms, though they do not have the same meaning and though they are not correct when referring to entomophagy (that can encompass also invertebrates other than insects).

(<sup>3</sup>) F.S. Bodenheimer, *Insects as Human Food*, The Hague, 1951.

(<sup>4</sup>) V.M. Holt, *Why Not Eat Insects*, London, 1885. Beyond the arguments used in favour of the suitability of insects to be treated as food, the Author considers entomophagy as the best weapon farmers could get to protect their crops from insects.

(<sup>5</sup>) On consumers' response to the opportunity of eating insects, M.A. Baker, Joungyoung Tiffany Shin, Young Wook Kim, *An Exploration and Investigation of Edible Insect Consumption: The Impacts of Image and Description on Risk Perceptions and Purchase Intent*, in *Psychology & Marketing*, 2016, 33, 2, pp. 94-112; G. Sogari, *Entomophagy and Italian consumers: an exploratory analysis*, in *Progress in Nutrition*, 2015, 17, 4, pp. 311-316; Hui Shan Grace Tan, Arnout R.H. Fischer, Patcharaporn Tinchan et al., *Insects as food: Exploring cultural exposure and individual experience as determinants of acceptance*, in *Food Quality and Preference*, 2015, 42, pp. 78-89; W. Verbeke, *Profiling consumers who are ready to adopt insects as a meat substitute in a Western society*, in *Food Quality and Preference*, 2015, 39, pp. 147-155; V.C. Materia, C. Cavallo, *Insetti per l'alimentazione umana: barrier e drivers per l'accettazione da parte dei consumatori*, in *Rivista di Economia Agraria*, LXX, 2015, 2, pp.139-161; R. Caparros Megido, L. Sablon, M. Geuens et al., *Edible Insects Acceptance by Belgian Consumers: Promising Attitude for Entomophagy Development*, in *Journal of Sensory Studies*, 2014,29,1, pp. 14-20.

Any substantive issue belongs to scientists.

## 2.- General problems: pros and cons

We could however wonder why one could be encouraged to eat insects, apart from being curious to try a new food.

There are at least two main theories that the supporters of entomophagy usually put forward.

The first motivation concerns nutritional profiles. Despite varying from a species to another one, in general, insects are deemed to be an inestimable source of proteins, vitamins, and minerals<sup>7</sup>.

The second motivation is an environmentalist reason<sup>8</sup>, linked to the high conversion efficiency<sup>9</sup> of bugs, that is to say the ratio of consumed feeding to produced edible material<sup>10</sup>. In other words, the part of energy wasted in converting the nourishment that insects eat into animal mass (let's inaccurately say «into meat») is less than that of traditional livestock. Further, farming of insects requires much less space than breeding «conventional» animals. Also the growth rate is very different: insects reproduce and grow up more rapidly than ordinary livestock<sup>11</sup>.

For all the mentioned reasons, bugs are acquiring the role of «food of the future», capable of answering the issues linked to the global increasing in population and to the need of producing enough healthy food in a sustainable way.

Despite such praiseworthy qualities, some cons may hinder the development of the «new» source of food, at least with regards to the Western Countries. First, some concerns arise with reference to the safety of insects intended for food. Since they have not been used in a significant way within the European Union as well as within the North America, there might be some doubts about their compliance with food safety standards: microbial hazards, allergy hazards but also parasitical and chemical hazards could derive from the ingestion of insects<sup>12</sup>.

Further, modifying nutritional habits and breeding new species of animals is something that, like it or not, might affect the environment: up till now, while scholars have been investigating safety and nutritional aspects, little literature exists on the environmental impact of entomophagy<sup>13</sup>.

Before taking a conscious position on the topic, additional studies should be carried out, in order to

(6) The idea of writing a paper that takes stock of the legal issues deriving from the consumption of insects as food originated from a pleasant conversation on food and waste, had with Prof. B. van der Meulen of Wageningen University and Research Centre (that the Author hereby thanks), in August 2014. Besides being a possible source of food, insects can be a significant solution to reduce organic waste. On the topic, please refer to H.H.E. van Zanten, H. Mollenhorst et al., *From environmental nuisance to environmental opportunity: housefly larvae convert waste to livestock feed*, in *Journal of Cleaner Production*, 2015, 102, pp. 362-369. See also M. Casartelli, G. Tettamanti, *Utilizzo di insetti come biotrasformatori: dallo scarto alimentare alla produzione di proteine animali per la mangimistica*, in *Atti Accademia Nazionale Italiana di Entomologia*, LXIII, 2015, available online at [http://www.accademiaentomologia.it/pdf/Monografie/Monografia\\_XXVI.pdf](http://www.accademiaentomologia.it/pdf/Monografie/Monografia_XXVI.pdf) (last access 12 March 2016).

(7) G. Defoliart, *Edible insects as minilivestock*, in *Biodiversity and Conservation*, 1995, 4, p. 306; P. Vantomme, *Farming insects as a viable and global source of animal proteins*, in *Atti Accademia Nazionale Italiana di Entomologia*, cit., (last access 12 March 2016).

(8) To obtain some clues on environmental sustainability of intensive insect farming, please refer to A.M. Fausto, R. Fochetti et al., *Costi e benefici dell'entomofagia: sostenibilità ambientale dell'allevamento di insetti su larga scala*, in *Atti Accademia Nazionale Italiana di Entomologia*, 2015, cit. (last access 12 March 2016).

(9) Tabassum-Abbasi, Tasneem Abbasi, S.A. Abbasi, *Reducing the global environmental impact of livestock production: the minilivestock option*, in *Journal of Cleaner Production*, 2015, XXX, pp. 3-4.

(10) M. Shelomi, *Why we still don't eat insects: Assessing entomophagy promotion through a diffusion of innovations framework*, in *Trends in Food Science & Technology*, 2015, XXX, p. 1.

(11) M. Premalatha, Tasneem Abbasi, Tabassum-Abbasi, S.A. Abbasi, *Energy-efficient food production to reduce global warming and eco-degradation: the use of edible insects*, in *Renewable and Sustainable Energy Reviews*, 2011, 15, p. 4358.

(12) S. Bellucco, C. Losasso et al., *Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review*, in *Comprehensive reviews in food science and food safety*, 2013, 12, 3, pp. 296 ff. The Authors however consider also the concrete possibility that such hazards occur and the methods to limit their happening. See also S. Bellucco, A. Mantovani, A. Ricci, *Il consumo di insetti dal punto di vista della sicurezza alimentare: inquadramento normativo e valutazione dei rischi*, in *Atti Accademia Nazionale Italiana di Entomologia*, cit. (last access 12 March 2016).

(13) B.A. Rumpold, O.K. Schlüter, *Potential and challenges of insects as an innovative source for food and feed production*, in *Innovative Food Science and Emerging Technologies*, 2013, 17, pp. 1-11.

assess all the grey areas that remain unexplored. The only thing that the Author of this paper can do is trying to investigate «insects as food» *status* from a law perspective.

### 3.- International level

Before considering how the European Union is dealing with the issue of edible insects, we might wonder what is like at an international level. We know that in some cultures insects are part of everyday diet, while in some others consumers do not consider bugs as food.

Anyway insect trade for nutrition purposes does exist and we can investigate if it has found any regulation at a supranational level. Shall we explore the Codex Alimentarius Standards, for instance, we would not identify any rules on edible insects. It does not mean that the Codex has never worked on the topic. From the report of the Seventeenth Session of the FAO/WHO Coordinating Committee for Asia, LAO prepared and presented a «Proposal for New Work of Development of a Regional Standard for Edible Crickets and Their Products»<sup>14</sup>. The initiative to draft a standard for the Asiatic area depended on the significance that insects had, as food source, in the region: being bugs an important part of the diet, it was necessary to increase food safety for the protection of consumers' health. The adoption of a regional standard would have further ensured fair practice. The Coordinating Committee supported the proposal emphasizing the growing interest showed at a global level for the use of insects as source of food. It established therefore an electronic working group lead by Laos, to gather data on trade and production. Some of the comments made to the proposal focused on the lack of details on the nature of the products and on the volume of trade and production.

Two years later, in November 2012, the Eighteenth

Session of the FAO/WHO Coordinating Committee for Asia took place. In such occasion, the delegation of Laos underlined that the electronic working group had received only limited consumption data, while no information on trade was available. The chair of the group asked therefore FAO for support in collecting data. Following such results, the electronic working group, open to Members of the Region and observers, continued to perform its activities to revise the discussion paper<sup>15</sup>.

The last meeting, in November 2014, brought to the proposal to discontinue consideration of edible insects and their products<sup>16</sup>. Once again, Members of the Region provided only limited data, inadequate to draft a proposal under the Codex criteria. The Coordinating Committee agreed to suspend the work on the topic, postponing any consideration by the moment in which new data would have become available.

We could wonder about the reasons of the meagerness of such statistics. The answer comes from the same reports we have just mentioned. On the one hand, the consumption of insects often depends on wild harvesting rather than on farming. On the other hand, trade usually walks along informal paths.

Despite the efforts made under the Codex Committees, the adoption of a global standard is still far to be reached: if difficulties arose even just in collecting data on a regional basis, lot has still to be done to reach such an achievement.

As told in the premises, the present paper is not intended to offer any ethical perspective on the issue of insects as «food for the future». However this does not prevent us from throwing some ideas out for further discussion.

The first morsel of food for thought refers to the worthiness of the efforts to draft a standard for the trade of edible insects (or even for some limited species). As well as bringing about some positive elements, such as an increased protection for consumers' health, the adoption of an international

(<sup>14</sup>) Codex Alimentarius Commission, *REP11/ASIA, Report of the Seventeenth Session of the FAO/WHO Coordinating Committee for Asia*, held in Bali, Indonesia, 22-26 November 2010, p. 17, paragraph 140 ff.

(<sup>15</sup>) Codex Alimentarius Commission, *REP13/ASIA, Report of the Eighteenth Session of the FAO/WHO Coordinating Committee for Asia*, held in Tokyo, Japan, 5-6 November 2012, p. 21, paragraph 106 ff.

(<sup>16</sup>) Codex Alimentarius Commission, *REP15/ASIA, Report of the Nineteenth Session of the FAO/WHO Coordinating Committee for Asia*, held in Tokyo, Japan, 3-7 November 2014, p. 11, paragraph 79 ff.

standard may result in barriers to trade at the expense of developing countries<sup>17</sup>. Due to lack of adequate tools and techniques, meeting the requirements of standards is often much more complex in less developed countries than in the advanced ones. The work of committee sessions obviously aims to find a balance among different needs but, despite such efforts, standards often turn to be obstacles rather than incentives to trade. And this might be even more significant in the case of insects which, largely produced in developing countries, usually move on the informal market, where safety requirements might be disregarded<sup>18</sup>.

A case by case analysis that takes into account differences among countries, types of bred insects, technologies, systems of production and all the other factors that could influence the effective compliance with international standards shall be carried out, to predict the effects that the setting of a Codex norm on edible insects might have.

Further investigation may solve a second doubt on other side effects that the adoption of an international standard might bring about. Supposing that setting a norm on edible insects did not result in a barrier to trade, it would certainly facilitate trade of insects from production to consumption countries. The increasing in demand for the new food would lead to a rising in supply. Environmental issues might consequently arise, due both to the intensification of wild harvesting and to the conversion of

old - or growth of new - plants for insect production and processing<sup>19</sup>.

#### 4.- European Union

##### 4.1. Are insects food?

Insects are not food commonly consumed within the European Union. Well, we should first answer the question IF they are food. Let's consider the definition of Article 2, Regulation (EC) No 178/2002 according to which food is «*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*». Currently, the average EU consumer will not consider slaughtered insects as suitable for human consumption; he or she will not deem them as intended to be consumed and so insects are not reasonably expected to be ingested by humans.

This is a narrow, reductive, subjective view – one could argue. The fact that most part of EU consumers will not probably voluntarily eat insects does not imply that the remaining part rejects the idea of insects as food. Moreover, there are consumers coming from Asian countries who would probably look for bugs to eat, without finding them in supermarkets.

While, on the one hand, counting insects in the

(<sup>17</sup>) Besides what one could understand when taking part to some of the meetings of the Codex Committee, where difficulties to meet standards are often under discussion, several scholars investigated what international standards mean to developing countries. H. Hansen – N. Trifković, *Food Standards are Good – For Middle-Class Farmers*, in *World Development*, 2014, 56, pp. 226-242; J. Jongwanich, *The impact of food safety standards on processed food exports from developing countries*, in *Food Policy*, 2009, 34, 5, pp. 447-457; S.M. Anders – J.A. Caswell, *Standards as Barriers versus Standards as Catalysts: Assessing the Impact of HACCP Implementation on U.S. Seafood Imports*, in *American Journal of Agricultural Economics*, 2009, 91, 2 pp. 310-321; S. Henson – S. Jaffee, *Understanding Developing Country Strategic Responses to the Enhancement of Food Safety Standards*, in *The World Economy*, 2008, 31, 4, pp. 548-568; T.W. Schillhorn van Veen, *International trade and food safety in developing countries*, in *Food Control*, 2005, 16, 6, pp. 491-496.

(<sup>18</sup>) The issue of food safety in informal market (also as a limit to trade) is a subject of considerable debate. S.K.P. Madete, et al., *Communicating food quality and safety standards in the informal market outlets of pastoral camel Suusa and Nyirinyiri products in Kenya*, in *African Crop Science Society Conference Proceedings*, Uganda, 2013, v. 11, pp. 432-426; K. Roesel – D. Grace, *Food safety and informal markets – Animal products in sub-Saharan Africa*, Routledge-ILRI, 2015.

(<sup>19</sup>) The quinoa case in Bolivia might be the example that an increasing in export of a local traditional product can result in destructive economic and environmental effects, through monopolising local activities and enlarging productive premises, at the expense of ecosystems. S.E. Jacobsen, *The Situation for Quinoa and Its Production in Southern Bolivia: From Economic Success to Environmental Disaster*, in *Journal of Agronomy and Crop Science*, 2011, 197, 5, pp. 390-399. Other scholars seem more cautious with such approach. See, for instance, T. Winkel, et al., *Calling for a reappraisal of the impact of quinoa expansion on agricultural sustainability in the Andean highlands*, in *IDESIA (CHILE)* 2014, September-November, 32, 4, pp. 95-100.

scope of the mentioned provision could nevertheless sound as a bold interpretation, on the other hand, the Regulation on organic farming expressly includes insects in the definition of 'livestock production', that is to say the production of domestic or domesticated terrestrial animals<sup>20</sup>. If the law thus assimilates insects to other farm animals, and if these are intended to become food, there are no good reasons to exclude bugs from the broad definition of food. Such statement, actually, is a false syllogism, the fallacy of which comes from considering all livestock as necessarily destined to turn into food. The scope of the regulation on organic farming is more comprehensive, since it applies throughout the production chain and includes also goods other than food. The organic method could for instance refer to textiles: so silk obtained from silkworms, bred according to the organic production scheme, will fall under the Regulation as well as the insects from which it comes from. Should we want to consider a «food» perspective, also bees reared for honey production are insects but this does not necessarily imply that they are considered «food» themselves.

The fact that the provisions on organic farming specifically mention insects among livestock, cannot ground in any circumstances their inclusion in the category of «legally recognized» food.

Up till now we have however thought to food just from the consumers' perspective, without considering the producer's point of view. The destination to human nutrition of any products is actually determined by the manufacturer or by the subject who decides to place it on the market. We could for instance have seeds intended for direct consumption, or for

food sprouting, or seeds sold for planting: it will be the producer that will determine their purpose and the way in which they will be presented to consumers. Similarly, the manufacturer could decide to use in its recipe some ingredients (let's think to some authorized additives) that people usually will not identify as food (for instance shellac, E904). A substance will fall into the category of «food» simply according to the use and the presentation that the producer will make. Should that substance be unauthorized, it will not lose the status of food, but it will merely constitute a non-permitted ingredient. In the light of what we said, insects will be food depending on how the subject who places them on the market decides to present them to consumers. We should now answer a further question: are insects authorised foods?

#### 4.2. The «old» Novel Food Regulation

Except for some very rare cases, insects have not been part of the diet of people living within the EU territory for centuries. Irrefutably, they were not used as food or food ingredients prior to 15 May 1997, that is to say prior to the date when the EC Regulation on Novel Foods crystallized the marketability of products for human consumption. What happened, then? Regulation (EC) No 258/97<sup>21</sup> submitted to an authorization procedure any food or food ingredient that had not been used «*for human consumption to a significant degree within the Community*» (meaning in any Member)<sup>22</sup> before May 15, 1997. Anyone wishing to market any product that was not meaningfully used in the everyday

<sup>(20)</sup> Article 2 (f), Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.

<sup>(21)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. For an overview on the «old» Novel Food Regulation, please refer to S. Rizzioli, *Novel Foods*, in L. Costato, F. Albisinni (eds.), *European Food Law*, 2012, pp. 393-400. Please refer also to L. Costato, *Organismi biologicamente modificati e Novel Foods*, in *RDA*, 1997, 2, I, pp. 137-164, for one of the first insights on Regulation (EC) No 258/97.

<sup>(22)</sup> In its judgment of 9 June 2005, *HLH Warenvertriebs GmbH and Orthica BV v Bundesrepublik Deutschland*, joined cases C-211/03, C-299/03 and C-316/03 to C-318/03, the EC Court interpreted Article 1(2) of Regulation (EC) No 258/97 «*as meaning that a food or a food ingredient has not been used for human consumption to a significant degree within the Community if, when all the circumstances of the case are taken into account, it is established that that food or that food ingredient has not been consumed in a significant quantity by humans in any of the Member States before the reference date. 15 May 1997 is the reference date for the purpose of determining the extent of human consumption of that food or food ingredient*».

diet had to submit a request to the Member State where the «novel food» had to be placed on the market for the first time, informing also the Commission. After an initial assessment carried out by a scientific body, and a final report forwarded to the EU Institution and to all Member States (with an additional assessment, where applicable), the EU Commission took a decision on the application.

Focusing only on the first words through which the Regulation described its scope, one could immediately conclude that since insects had not been used for human consumption to a significant degree before the identified date, they should then have undergone the authorization procedure.

The Regulation however required an additional condition for its application to a novel food or food ingredient: the product had to fall under one of the listed categories

- foods and food ingredients with a new or intentionally modified primary molecular structure;
  - foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
  - foods 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 use;
  - foods and food ingredients to which had been applied a production process that was not used at that time, where that process gave rise to significant changes in the composition or structure of the foods or food ingredients which affected their nutritional value, metabolism or level of undesirable substances.
- Insects neither relate to a change in molecular structure nor to microorganisms or similar. Also the production process is not relevant for the topic at issue. What about foods and food ingredients «isolated from animals»? Well, insects are themselves animals so the definition does not seem to apply. Focusing only on «bugs' meat», we could try to argue that it derives from animals, but the meaning of «isolation» contained in the Regulation looks more appropriate if related to food technology and its processes rather than to insects and their sla-

ughtering. In any case, the category would not include a single bug in its entirety, but just «a part isolated from it».

If insects do not fall under the list of Regulation (EC) No 258/97, the provisions on novel foods could not apply. Crickets, silkworm larvae, agave worms, etc. should therefore have freely circulated, provided that they were safe.

But we could consider a further possibility, that is to say interpreting the list as a non exhaustive one, being instead open to new entries.

Unfortunately, the EC Court of Justice had not had the opportunity to rule on the question; consequently, we still lack an official interpretation on the point. We could however hazard a legal reasoning. The Regulation on novel food imposed a condition on the free trade of certain products, requiring a prior authorization for their marketability. Being a restriction to one of the «fundamental freedoms», namely the free movement of goods, the authorization procedure should not have been anything but an exception to the general rule. And like any other exception, it had to be subject to a close reading, rather than to an extensive interpretation. The list of Regulation (EC) No 258/97 had therefore to be a closed one.

The scope of the EC Act, moreover, seemed to confirm that the provisions did not encompass insects or, at least, they were not expected to do so. The aim of the Regulation was to submit to the authorization procedures only those products reasonably requiring a safety assessment and it thus specified which food should fall under its provisions. It has been noticed that, despite such definite field of application, some Member States had been trying to broaden the scope to any new food or food ingredient, while some others interpreted it in a restrictive way<sup>23</sup>.

#### 4.3. The «new» Novel Food Regulation

Since its adoption, the scope of the Novel Food Regulation had been discussed, being the core

<sup>(23)</sup> P. Coppens, *The Revision of the Novel Foods Regulation – Forget about Cloning and Nanotechnology, Let's Focus on the Scope*, in *EFFL*, 2013, 4, p. 238.

issue of the previous attempts of amendments that occurred over time<sup>24</sup>.

Also the most recent proposal COM(2013)894 final operated in this direction, adding at the Regulation a procedure concerning «a faster and more proportionate safety assessment for traditional foods from third countries having a history of safe food use»<sup>25</sup>. When specifying the «general criteria» for the Novel Food definition, however, the proposal only referred to the historical data condition: novel foods and food ingredients were those products that were not consumed to a significant degree, in the EU, before May 15, 1997. If we stop to such definition, the list drawn by the Novel Food Regulation seems to be something additional, an explanation of the scope, lacking a binding nature. Indeed, when looking at the proposal, we realize that the wording of the provision on the field of application (under definitions of Article 2) is quite different from the previous version. The list does not match that of the «old» Regulation and, what is more, as already anticipated, there is a specific provision on traditional food from a third country, having a history of safe use. The proposal clarifies what such expression means (Article 2, para. 2): it refers to food, derived from primary production, the safety of which has «been confirmed with compositional data and from experienced of continued use for at least 25 years in the customary diet of a large part of the population of a third country», prior to the notification that opens the specific procedure for traditional foods from non EU countries (Article 13 and following).

According to the proposal, therefore, insects would definitely fall under the scope of the Novel Food Regulation and would undergo a faster authorization procedure.

On October 28, the European Parliament adopted at first reading the text of the proposal. The EP's position is significant. The eight «recital» in particular states that while the scope of the new regulation should remain the same as Regulation (EC) No.

258/97, it is necessary to «review, clarify and update the categories of food which constitute novel foods», covering also «insects and their parts». Recitals No (16) and (17) further recall the need to facilitate the placing on the market within the European Union of traditional food from third countries (and insects might fall into this category), provided that a history of safe use as food has been demonstrated. The attribute of «traditional» requires a food to have been used for at least 25 years «as a part of the customary diet of a significant number of people». Further, foods from third countries that would be regarded as Novel Foods in the European Union, will be considered as traditional foods only when they are derived from primary production, that is to say, according to the definition laid down in Regulation (EC) No 178/2002, the «production, rearing or growing of primary products, including harvesting, milking and farmed animal production prior to slaughter» and including «hunting and fishing and the harvesting of wild products».

Following the «Recital» wording, the new regulation on Novel Food will modify its scope including any food «consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union». As we told above, since insects had not been used as food before 1997 and since they do not have a history of safe food within the European Union, they will certainly fall under the Novel Food category.

Should they be traditional foods from third countries, with a history of safe food, they could however undergo a simplified procedure: this will though apply only to products derived from primary production. For what concerns processed products (let's think to food containing insect extracts), the «ordinary» procedure shall instead apply.

On Monday 16th November 2015, the Council of the

<sup>(24)</sup> See Commission proposal (2007) 872 final, which did not result in a Regulation because of some frictions on cloning of animals. On the topic, please refer to the text of the following proposal (2013)894 fin.. As for the history of the Novel Food Regulation and the debate on it, please refer to C. Ballke, *The New Novel Food Regulation – Reform 2.0*, in *EFFL*, 2014, 2, pp. 285-292.

<sup>(25)</sup> See the «Context of the proposal – Ground for and objectives of the proposal». For an insight on the proposal, please refer to A. Volpato, *La riforma del regolamento sui Novel Food: alla ricerca di un impossibile equilibrio*, in *q. Riv. www.rivistadirittoalimentare.it*, n. 4-2015, pp. 26-43.

European Union, Agriculture and Fishery Formation, voted on the text adopted by the European Parliament. Following the EU institutions agreement upon the definitive version on November 25th, on December 11th Regulation (EU) 2015/2283 was published in the EU Official Journal<sup>26</sup>.

For what concerns insects, the final text of the Regulation does not diverge much from the proposal: though the numbering of articles is slightly different and the provision on definitions underwent a significant restyling<sup>27</sup>, the substantive content on bugs remains unchanged<sup>28</sup>. Further, to ensure continuity with Regulation (EC) No 258/97, the new EU act maintains the same «cut-off date»: 15 May 1997 continues to be the dividing line to categorize a product as novel food or not.

#### 4.4. Insects in EU law: what is the Institutional trend, in the meanwhile?

Besides what we have just said about Novel Foods, the EU institutional approach to insects is pretty various and develops along several lines.

The first interest towards insects arises when the

EU Institutions focus on bugs as negative elements that threaten agriculture or the environment. Among the most recent acts adopted by the EU, we can for instance list the Commission Implementing Decision, concerning certain protective measures with regard to occurrences of the small hive beetle<sup>29</sup>, as amended by Commission Implementing Decision (EU) 2015/1943 of 27 October 2015<sup>30</sup>; the Commission Implementing Decision laying down provisional emergency measures to prevent the introduction into and the spread within the EU of the oriental chestnut gall wasp<sup>31</sup>; the Commission Implementing Decision to prevent the spread within the EU of the potato flea beetle<sup>32</sup>, etc.

The second ground of interest concerns pollinator insects, for the protection of which the EU Commission has been working for several years. Following, in particular, the 2009 report *Bee Mortality and Bee Surveillance in Europe*<sup>33</sup>, but continuing its previous policy, the EU Institution issued the Communication COM(2010)714 final on Honeybee Health, in which it recommended synergic initiatives among EU Institutions, Member States and stakeholders. In the following years several studies investigated the ways to protect bee health<sup>34</sup>, and actions were taken in a range of policy

<sup>(26)</sup> 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. For an insight on the new regulation, refer to G. Bonora, *I Novel Foods nel Reg. (UE) n. 2015/2283 e gli insetti: una possibile evoluzione dei costumi alimentari?*, in *q. Riv. [www.rivistadirittoalimentare.it](http://www.rivistadirittoalimentare.it)*, n. 1-2016.

<sup>(27)</sup> Definitions are now in Article 3, paragraph 2.

<sup>(28)</sup> The eight recital still suggests that we should interpret the definition of novel food as including also insects and their parts, while the provisions on food from third countries are the same as in the proposal.

<sup>(29)</sup> Commission Implementing Decision of 12 December 2014, concerning certain protective measures with regard to confirmed occurrences of the small hive beetle, OJ L 359, 16.12.2014, pp. 161-163.

<sup>(30)</sup> Commission Implementing Decision (EU) 2015/1943 of 27 October 2015 amending Implementing Decision 2014/909/EU by extending the period of application of the protective measures in relation to the small hive beetle in Italy (notified under document C(2015) 7330), in OJ L 283, 29.10.2015, pp. 11-12.

<sup>(31)</sup> Commission Implementing Decision 2014/690/EU of 30 September 2014 repealing Decision 2006/464/EC on provisional emergency measures to prevent the introduction into and the spread within the Community of *Dryocosmus kuriphilus* Yasumatsu, OJ L 288, 2.10.2014, p. 5.

<sup>(32)</sup> Commission Implementing Decision 2014/679/EU of 25 September 2014 amending Implementing Decision 2012/270/EU as regards its period of application and as regards the movement to packing facilities of potato tubers originating in areas demarcated in order to prevent the spread within the Union of *Epitrix cucumeris* (Harris), *Epitrix similaris* (Gentner), *Epitrix subcrinita* (Lec.) and *Epitrix tuberis* (Gentner), OJ L 283, 27.9.2014, p. 61-64.

<sup>(33)</sup> Aa. Vv., *Bee Mortality and Bee Surveillance in Europe – Scientific report submitted to EFSA*, 2009, [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/27e.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/27e.pdf) [last access January 9th 2016].

<sup>(34)</sup> EFSA Panel on Plant Protection Products and their Residues (PPR), *Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)*, in *EFSA Journal*, 2012; 10(5):2668; EFSA Pesticides Unit, *Statement on the findings in recent studies investigating sub-lethal effect in bees of some neonicotinoids in consideration of the uses currently authorised in Europe*, in *EFSA Journal*, 2012; 10(6):2752; EFSA, Conclusion on the



areas (agriculture, use of pesticides, environment...)<sup>35</sup>.

A third insect-related area where the European Union shows interest concerns the use of insects in organic production, and in particular in pest management. Being part to the International Plant Protection Convention (like all EU Member States), the European Union's action on biological control complies with the International principles and standards<sup>36</sup>. Provided that all environmental effects are taken into account, the European Union sustains the use of integrated pest management to reduce the dependency on pesticides<sup>37</sup>.

A fourth ground of interest covers a field that is very close to insects as source of food: bugs as feed. The need to produce enough food for a population increasing in number and the request for sustainable production methods are forcing the Policy Maker's attention to focus on new sources of proteins. Besides being a valuable source of nourishment for humans, insects can constitute also a

significant element to supplement the diet of traditional livestock. Their considerable nutritional profiles, the small spaces that their breeding requires, along with the fact that insects are naturally part of some animals' diet suggest focusing on bugs also as feed<sup>38</sup>. Once again, studies on insects date back in time<sup>39</sup> and show the suitability of these animals to the purpose. Anyway, as for food, also the use of bugs in feed can encounter some restrictions in law. Following the BSE crisis, the EC Institutions adopted a set of acts laying down provisions on food and feed safety and hygiene. The Council Decision 2000/766/EC<sup>40</sup> prohibited the feeding of any processed animal proteins<sup>41</sup> to farmed animals grown for food purposes (Article 2), except for a few cases. Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>42</sup>, in its original release, banned the feeding to ruminants and other animals of proteins derived from mammals. Commission Regulation (EC) No 1234/2003<sup>43</sup>

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peer review of the pesticide risk assessment for bees for the active substance clothianidin, *Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid and Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam*, in *EFSA Journal*, 2013; 11(1):3066 ff.; *Conclusion on the peer review of the pesticide risk assessment for bees for the active substance fipronil*, in *EFSA Journal*, 2013; 11(5):3158; *Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)*, in *EFSA Journal*, 2013; 11(7):3295; EPILOBEE consortium, *A pan-European epidemiological study on honeybee colony losses 2012-2014*, April 2015, available online at the following URL [ec.europa.eu/food/animals/live\\_animals/bees/docs/bee-report\\_2012\\_2014\\_en.pdf](http://ec.europa.eu/food/animals/live_animals/bees/docs/bee-report_2012_2014_en.pdf) [Last access January 9th 2016].

<sup>(35)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, listing also the EU Maximum Residue Limits in honey.

<sup>(36)</sup> FAO, *International Standards for Phytosanitary Measures*, 2005. See, for instance, ISPM No 3, *Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and other Beneficial Organisms*. Available at [www.fao.org/docrep/009/a0450e/a0450e00.htm](http://www.fao.org/docrep/009/a0450e/a0450e00.htm) [Last access January 9th 2016].

<sup>(37)</sup> Please refer to Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, and in particular to Recital No 5.

<sup>(38)</sup> B. A. Rumpold, O. K. Schlüter, *Potential and challenges of insects as an innovative source for food and feed production*, in *Innovative Food Science and Emerging Technologies*, 2013, 17, p. 7.

<sup>(39)</sup> G. De Foliart, *Edible insects as minilivestock*, in *Biodiversity and Conservation*, 1995, 4, pp. 306-321. The Author recalls the results of researches carried out in India and Sri Lanka on insects as «high-protein replacement» in feed, p. 307. Anyway, also EFSA Scientific Opinion on risks related to consumption of insects as food and feed makes a quick review of existing scientific literature on bugs as feed, cit., pp. 15 ff.

<sup>(40)</sup> Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein, in OJ L 306, 7 December 2000, pp. 32-33.

<sup>(41)</sup> The phrase «processed animal proteins» stands for «meat-and-bone meal, meat meal, bone meal, blood meal, dried plasma and other blood products, hydrolysed proteins, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatine and any other similar products including mixtures, feedingstuffs, feed additives and premixtures, containing these products».

<sup>(42)</sup> Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

<sup>(43)</sup> Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding.

merged the two acts, amending Annex IV of Regulation (EC) No 999/2001 so that the prohibition covered both the feeding of animal proteins to any farmed animals and the feeding of processed animal proteins to animals other than ruminants.

Since the new provision did not make any distinction on the animal origin of the processed proteins, the prohibition clearly applied also to proteins derived from insects.

Commission Regulation (EU) No 56/2013<sup>44</sup>, however, amended Annex IV of Regulation (EC) No 999/2001 reauthorising processed animal proteins from non-ruminant animals and feedingstuffs containing such proteins, for feeding aquaculture animals (fishmeal and compound feed containing fishmeal were already permitted for feeding non-ruminant animals) and other animal proteins for feeding non-ruminant animals. Feeding of animal proteins to ruminant animals is instead still prohibited (article 7, par. 1), with some exceptions (Annex IV, chapter II authorizes the feeding to ruminants of milk, milk-based products, milk-derived products, colostrum and colostrum products; eggs and egg products; collagen and gelatine derived from non-ruminants; hydrolysed proteins derived from parts of non-ruminants, or from ruminant hides and skins; compound feed containing these authorised products)<sup>45</sup>.

At least formally, insects could therefore be used as supplements for non-ruminant diets<sup>46</sup> and they are also included in the list of feed materials of Regulation (EU) No 68/2013<sup>47</sup>, as «terrestrial inver-

tebrates»<sup>48</sup>.

When feeding from insects is meant to animals for food production, operators must comply with Regulation (EC) No 183/2005, asking for registration of the establishment<sup>49</sup>. Further, operators involved in killing and slaughtering phases shall comply with relevant provisions. Regulation (EC) No 1099/2009 on the protection of animals at the time of killing<sup>50</sup> cannot however apply to insects: at the time in which the EC Council issued the regulation, the possibility that insect could become source of food or feed was not considered<sup>51</sup>. The lack of inclusive provisions therefore obviously hinders the possibility to use bugs for feeding animals<sup>52</sup>.

The few comments we made on the restrictions that the lack of provisions implies for the use of insects as feeding shall obviously extend also to bugs intended for human nutrition. Any phase of reared animals' life, from their birth (and, even before that, from the spawning) to their killing, shall be protected by provisions that ensure the animal welfare. If insects are meant to become the «food of the future», it will be essential a systemic regulatory activity in order to equalize the conditions of insects to those of all other animals intended for food or feeding purposes.

In order to revise the regulatory framework on feeding, the Commission asked the Expert Group for Technical Advice on Organic Production (EGTOP) to give advice on the use of earthworm and insects as protein source for animal nutrition. In its recent

<sup>(44)</sup> 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.

<sup>(45)</sup> The wording of the amended Annex is quite articulated: we have summarized, in few inaccurate lines, its very detailed text just to draw the limits to the use of insects in feed.

<sup>(46)</sup> EFSA's Scientific Opinion focused also on such topic, concluding that many of the possible risks linked to the employ of insects as feed depend on the substrate on and on the environment in which bugs are farmed and further research is necessary to solve some uncertainties still present also on this topic.

<sup>(47)</sup> Commission Regulation (EU) No 68/2013 of 16 January 2013, on the Catalogue of feed materials.

<sup>(48)</sup> Annex, part C, point 9.16.1: «Whole or parts of terrestrial invertebrates, in all their life stages, other than species pathogenic to humans and animals; with or without treatment such as fresh, frozen, dried».

<sup>(49)</sup> Recital no. 7 and Article 10

<sup>(50)</sup> Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.

<sup>(51)</sup> Such significant lack extends to reptiles, amphibians and any invertebrates (including crustaceans) as the Scottish public consultation issued on 29 August 2012 and closed on 26 October 2012 emphasised, Results are published at <http://www.gov.scot/Publications/2013/12/2502> [last access January 9th 2016].

<sup>(52)</sup> Scientists have however been studying the problem of insects' «welfare». For a comprehensive overview please refer to the students' report E. Jesse – S. Van Es – F. Haverkort – E. Kapsomenou – A. Luijben, *A Bug's Life. Large-scale insect rearing in relation to animal welfare*, Wageningen, 2012.

Final Report Feed Mandate II<sup>53</sup>, EGTOP confirms that «*terrestrial invertebrates, especially fly larvae and earthworms, constitute a considerable potential for production of high value certified organic protein (meal) for feeding of organic monogastrics*» and recommends removing legislative obstacles to the development of such new system. Specifically, the EGTOP Report makes a distinction between legal barriers for the use of earthworms and insect as protein feed, and legislation restricting the production and marketing of insects and earthworm as feed<sup>54</sup>. As for the former, it identifies two parts of regulatory obstacles: legislation on production, labelling and marketing of feed in general, but also legislation on animal products and legislation that lays down «*restrictions on the substrates used for the rearing of insects and earthworm*». For what concerns the latter, it pays attention to Regulation (EC) No 183/2005 on feed hygiene, on Regulation (EC) No 767/2009 on feed labelling, and on the relevant general provisions of the hygiene package, while emphasizing the limits originating from Regulation (EC) No 999/2001<sup>55</sup>.

For what concerns insects as food, there has not been a defined position until now. On the one hand, EU Institutions have just clarified that insects intended for food consumption should be regarded as Novel Foods. Accordingly, they cannot freely circulate within the Internal market without a prior authorisation. If at a regulatory level it has just tackled the problem in a prudential way, the European Union seems to support the idea of integrating insects in

everyday diet: on the one hand, it has already granted funding to research on this topic<sup>56</sup>. On the other hand, on May 2014, it asked the European Food Safety Authority to issue an initial scientific opinion, assessing the microbiological, chemical and environmental risks arising from production and consumption of insects as food and feed<sup>57</sup>. The EU Commission recognized both the general growing interests towards insects as source of food and feed, and the potential environmental, economic and food security benefits related to their consumption. In the mandate document, the DG Health and Consumers explains the ongoing evaluation of the possibility to develop the «*policy in the area of insects in the framework of legislation on novel foods* [A.N. this was a useful element to Member States in deciding how to deal with insects as food, before the adoption of Regulation (EU) 2015/2283], *animal feed and on the need for further risk/policy measures to ensure the safety of the food and feed chain*». Since the number of insects potentially suitable for nourishment is considerable, the European Commission provided the EFSA with a list of species with the highest prospective to be used for food and feed<sup>58</sup>.

#### 4.5. EFSA and insects as food and feed

Following the DG Health and Consumers' request, EFSA accepted the mandate<sup>59</sup> and identified some elements on which risk profiling (rather than risk

<sup>(53)</sup> Available at [http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/egtop-final-report-feed-ii\\_en.pdf](http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/egtop-final-report-feed-ii_en.pdf) [Last access January 9th 2016].

<sup>(54)</sup> EGTOP Report, Paragraph 4.4 *Use of earthworms or insects as a source of protein*, p. 42.

<sup>(55)</sup> To avoid an excessive digression, the paper will not analyse all the aspects that the EGTOP Report emphasizes on the limits to the use of insects as feed or source of proteins for feed. The full text is however worth reading for a comprehensive view of the number of provisions that could obstacle the development of alternative feeding.

<sup>(56)</sup> See for instance the ongoing project PROTEINSECT, Enabling the exploitation of Insects as a Sustainable Source of Protein for Animal Feed and Human Nutrition, 312084, funded under FP7-KBBE, the details of which are available at the CORDIS Community Research and Development Information Service webpage.

<sup>(57)</sup> EU Commission, Health and Consumer Directorate-General, ref. Ares(2104)173989-27/05/2014, Request for an initial scientific opinion on the safety risks arising from the production and consumption of insects as food and feed, sent to the EFSA and available at EFSA register of questions, with number EFSA-Q-2014-005708, Mandate No M-2014-0150.

<sup>(58)</sup> *Musca domestica* (Common housefly); *Hermetia illucens* (Black soldier fly); *Tenebrio molitor* (Mealworm); *Zophobas atratus* (Giant mealworm); *Alphitobus diaperinus* (Lesser mealworm); *Galleria mellonella* (Greater wax moth); *Achroia grisella* (Lesser wax moth); *Bombyx mori* (Silkworm); *Acheta domesticus* (House cricket); *Gryllodes sigillatus* (Banded cricket); *Locusta migratoria migratorioides* (African migratory locust); *Schistocerca Americana* (American grasshopper). The EU Commission provided the list only as a guidance tool for the assessment, without expecting it to be exhaustive or definite.

assessment) would have focused, and some others that would be excluded from the evaluation. September 2015<sup>60</sup> was negotiated as deadline to finalize the tasks. To draft its opinion, the Authority Working Group heard experts from the industry associations, research consortia and FAO, in order to obtain a shared view on farming, production and consumption of edible insects<sup>61</sup>.

We have just said that EFSA received the mandate from the EU Commission on May 2014: this should let us think that insects, at that time, were already representing a hot topic and that probably the European Food Safety Authority had already had the opportunity to discuss the theme. Indeed, just the previous month, in April 2014, EFSA issued its Technical Report on the activities carried out on emerging risks, for the period 2012-2013<sup>62</sup>. Among the questions discussed by the Stakeholder Consultative Group on Emerging Risk in 2012, the document listed the use of insects as food and feed and specifies that, although insects were already sold as «*novelty/niche foods*»<sup>63</sup>, they were not likely to be included in human diet. It added that potential safety issues could arise, as «*new hazards in terms of pathogens (for humans, plants and animals) or introduction of pests, animal and plant diseases into the EU, new or increased exposure to contaminants (e.g. pesticides, natural toxins like venoms and stings, heavy metals, processing/veterinary residues) and allergenicity (e.g. by the presence of chitin, which has been associated to asthma)*». Alleging however that bugs would not be likely to be used in the very next years as food (but also as feed, with the exception of pet food and feed in aquaculture), the document did not consider the issue of edible insects as a priority task for EFSA but acknowledged the need for further studies and

assessment (above all on the environmental field), in the event of future importation of insects for reproduction or consumption.

The growing rate on the topic shows thus in its whole magnitude: while in 2012 entomophagy in Europe was not considered as a key issue and while, until April 2014, at the time of publication of the Report, EFSA had not assessed the related risks yet, in May 2014 (just one month later) it received the request for a risk profiling in this subject. Further, in the first half of 2015 the number of initiatives on edible insects exponentially increased and the debate on the suitability of insects as source of food has now become a hot topic.

In October 2015, EFSA eventually published its scientific opinion «*Risk profile related to production and consumption of insects as food and feed*»<sup>64</sup>, collecting all the necessary data from peer reviewed literature, assessments carried out at a national level and from the information made available by experts invited to the working group meeting<sup>65</sup>. After a short introduction, the opinion briefly lists the sources of data and the methodologies used; then, before paying attention to the consumption aspects, it focuses on the description of the characteristics of the current situation of insect farming and processing (substrates, production chain, farming systems, manufacturing). The core part of the opinion relates to risk profiling. It analyzes all the possible sources of hazards linked to the use of bugs as food: microbiological hazards (bacteria, viruses, parasites, fungi, prions), chemical hazards (heavy metals and arsenic, toxins, veterinary drugs and hormones, and other contaminants such as pesticide residues, dioxins, dioxin-like polychlorinated biphenyl, polycyclic aromatic hydrocarbons and packaging migration contaminants), allergens, con-

<sup>(59)</sup> Please refer to EFSA acceptance letter of 07 August 2014, available at the Documents Section of the Register of Questions.

<sup>(60)</sup> The Scientific Committee Plenary Meeting would have been the place to discuss the draft scientific opinion.

<sup>(61)</sup> Scientific Committee and Emerging Risks Unit, Minutes of the 72nd Plenary Meeting Held on 22-23 April 2015, Parma (Agreed upon on 8 June 2015), paragraph 7.1.a.

<sup>(62)</sup> EFSA, *Update on EFSA's activities on Emerging Risks 2012-2013*, EFSA supporting publication, 2014:EN-585.

<sup>(63)</sup> This would exclude the «significant» use required by the Novel Food regulation to qualify a product as «non-novel».

<sup>(64)</sup> EFSA Scientific Committee, Risk profile related to production and consumption of insects as food and feed, EFSA Journal, 2015, 13(10):4257, doi:10.2903/j.efsa.2015.4257, adopted on October 5th, 2015 and published on October 8th, 2015.

<sup>(65)</sup> For a first short note on EFSA Opinion, please refer to M.D. Finke et al., *The European Food Safety Authority scientific opinion on a risk profile related to production and consumption of insects as food and feed*, in *Journal of Insects as Food and Feed*, 2015, 1, 4, pp. 245-247.

tamination linked to processing and storage activities, and environmental hazards associated with insect farming.

Following the identification of risks, the opinion draws some overall conclusions on hazards originating from insect farming and consumption, and lists the uncertainties that still persist due to lack of satisfactory information.

EFSA thus recommends starting research on these identified issues.

To all those people that – like the author of the paper – had been waiting with trepidation for EFSA's opinion the final document might appear slightly a letdown. Anyone who had thought that the opinion could represent an innovative view on the topic was indeed wrong.

The text is the condensation in organized form of the existing literature on insects, without any ground-breaking conclusion. Anyway, it might represent a milestone for entomophagy in the European Union.

It is certainly a starting point for future research on the safety of insects as food and feed and a necessary activity aimed at taking stock of what it has been done and what it will be required to answer this new challenge.

## 5.- Member States

Lacking any harmonised provisions on edible insects and without a clear unambiguous position of the European Institutions, how did Member States deal with the issue of edible insects, while waiting for EFSA risk profiling and for the new regulation on novel foods?

It is not hard to envisage that the scene was quite patchy, with a general choice to limit insects as they were Novel Food, and several spots that allowed their free movement or their marketability under certain conditions.

To understand fully what the situation was in EU Member States, a simple investigation was carried out: where official web pages did not provide infor-

mation, direct questions were asked to competent national authorities<sup>66</sup> on what the approach was about insects as food.

### 5.1. Austria

According to Austrian interpretation, any animal intended for human consumption, even insects, falls under the definition of Article 2 of Regulation (EC) No 178/2002.

This approach (that we could define as finalistic) answers the doubt we expressed above, on the possibility to qualify insects as food: where a product is «destined» to human ingestion, it will be «food».

We could say that «purpose qualifies the object». Since insects are food, better, food of animal origin and since the operators wish to put them on the market, they shall comply with EU food law and with national legislation.

In Austria, besides EU directly applicable acts (GFL, Hygiene Package, etc.), the Food Safety and Consumer Protection Law (Lebensmittelsicherheits- und Verbraucherschutzgesetz LMSVG) regulates the sector.

Austrian Special Goods, new Technologies and International Food Affairs officer who replied to the survey, underlined that insects would probably have those features of innovativeness required under the Novel Food Regulation.

The representative of the Ministry of Health emphasized that at EU expert level a discussion was ongoing to understand to which extent the mentioned regulation covered Arthropods (the officer specified that the word «insects» does not cover the whole scope of eligible species).

While processed animals could fall into the category of Novel Food, if matching the requirement «isolated from animals», the Regulation seems to exclude from its applicability «whole insects».

The Austrian officer, being confident that the new revised Novel Food Regulation would fill every gap at an EU level, communicated that, for what concer-

<sup>(66)</sup> The Author would like to express her sincere gratitude to all the officers of each national food safety authority who spent part of their time to answer the questions: their contribution is an essential element of this paper.

ned the International activities, a Working Group had been established within the Codex Alimentarius Austriacus Commission to draw up a guidance document on safety aspects for Arthropods as food.

## 5.2. Belgium

Belgium was one of the first EU Countries that adopted a clear policy on edible insects, while waiting for harmonised provisions or, at least, for the EU guidelines suggesting that insects should fall under «novel foods».

At the end of September 2014, the Federal Agency for the Safety of the Food Chain (AFSCA Agence Fédérale pour la Sécurité de la Chaîne Alimentaire) and the Health High Council issued an opinion on the safety of insects intended for human consumption, in which they assessed the microbial, chemical and physical hazards related to the use of insects in human diet<sup>67</sup>.

In May 2014 however, AFSCA had already approved a document aimed at clarifying the general rules applicable to production and trade of insects for human consumption (expressly excluding from its scope insects for animal feeding)<sup>68</sup>.

First, it set up a list of ten species of insects<sup>69</sup> accepted within the National market, without the need to start an authorisation procedure as novel foods. Such specific exceptions did not apply however to ingredients that had been isolated from insects, or to extracts (like isolated proteins).

Secondly, it specified that also insects intended for human consumption as well as business operators acting in insects-food chain should comply with the

general provisions of law. In particular, according to Regulation (EC) No 852/2004, all operators wishing to farm insects for human consumption, intended to be placed on the market, had to ask AFSCA for prior registration.

Business operators working in the processing and/or in the distribution phase wishing to put on the market insects or products with insects as ingredients should submit a request for authorization to AFSCA.

## 5.3. Croatia

In Croatia, there are not specific provisions regulating edible insects. Over the last year, Croatian Food Safety Agency has been carrying on a survey on this issue, in order to give its contribution to the EU project Proteinsect: the results, aimed at taking stock of the national perception of the possibilities to use insects as a source of proteins, were expected to be published by the end of 2015.

Currently, however, the issue of edible insects is not felt as a priority in the Country: should any instance related to food or feed safety arise, it would be sent to the Croatian Food Agency for assessment, while the Ministry of Agriculture would be entitled to adopt any regulatory provision on the subject<sup>70</sup>.

## 5.4. Denmark

The answer given by Denmark to the investigation is similar to those of several Member States. Without having a national specific provision on the

<sup>(67)</sup> Opinion of the Scientific Committee of the Federal Agency for the Safety of the Food Chain and of the Health High Council, SciCom 14-2014 and CSS No 9160, on «Sécurité alimentaire des insectes destinés à la consommation humaine» (food safety of insects intended for human consumption).

<sup>(68)</sup> AFSCA, *Circulaire relative à l'élevage et à la commercialisation d'insectes et de denrée à base d'insectes pour la consommation humaine*, available at AFSCA website [www.afsca.be/denreesalimentaires/circulaires/documents/2014-05-21\\_Circulaire\\_insectes\\_version11.pdf](http://www.afsca.be/denreesalimentaires/circulaires/documents/2014-05-21_Circulaire_insectes_version11.pdf) [Last access January 9th 2016]. *Asian Journal of WTO & International Health Law and Policy* 1/2013, p. 307.

<sup>(69)</sup> *Acheta domesticus*, *Locusta migratoria migratorioides*, *Zophobas atratus morio*, *Tenebrio molitor*, *Alphitobius diaperinus*, *Galleria mellonella*, *Schistocerca americana gregaria*, *Gryllodes sigillatus*, *Achroia grisella*, *Bombyx mori*. Most of the listed species are those contained in the EU Commission's request for scientific risk profiling to EFSA: this stems from the fact that the Belgian list was the result of a round table organized by the European Commission and focuses on the insects that had been proposed for human consumption by 2011.

<sup>(70)</sup> At the time when the Croatian Food Agency provided such information, the EFSA had not yet published its report on the issue of insects intended for human consumption.

topic, Denmark allowed trade of whole edible insects, grounding the decision on the wording of the Novel Food Regulation. Instead, it did not permit the marketing of processed insects.

## 5.5. Finland

As for Finland, the webpage of the Finnish Food Safety Authority<sup>71</sup> (EVIRA) displayed plain information on the status of insects intended for human food: since there had not been a significant use in the European Union, they should have undergone the authorization procedure as Novel Food. EVIRA specified that such interpretation was in line with the recommendation of the EU Commission and other Member States' general approach to the issue. It however recognized that in some EU Countries insects had already been authorized: it thus remarked the fact that to the extent that they were traded as products for human consumption, they had to comply with all the requirements provided for food.

## 5.6. France

For what concerns France, until the beginning of 2015 the legal status of «edible insects» was not definite. While it was possible finding some bugs as delicacies in large retail chains, or exotic menus in ethnic restaurants, as well in some of the first website selling insects for human consumption, there was not any explicit provision, either binding or not, on bugs as food. The legal status of edible insects was thus uncertain, to such a degree that some operators that formerly sold<sup>72</sup> their products had

suddenly to stop their businesses.

What was in other words officially tolerated swiftly became declaredly illegal. In February 2015, the French National Agency for Hygiene, Food, Environment and Work Safety adopted an opinion on the exploitation of insects as food and the state of scientific knowledge on risks linked to insect consumption<sup>73</sup>.

While reading the opinion (that is not a source of law, of course, but that might help in understanding the French point of view on the topic), a sentence catches the reader's eyes: it specified that since at the moment of the adoption no dossier had been validated yet, no insect or product thereof could be legally traded as food within the European Union<sup>74</sup>. This is actually the same information that the French Ministry for Agriculture displays on its website<sup>75</sup>.

## 5.7. Germany

To the Author's question, the German Federal Office for information to consumers of the Ministry for Food and Agriculture<sup>76</sup> replied with an articulated answer, starting from the statement that as far as the government knew, insects, both considered as food with high nutritional values and as delicacies, seemed to be of «no or only minor importance» in Germany.

Should have they be imported, the provisions of the Novel Food Regulation, the general rules on import of food of animal origin and those on animal diseases and food hygiene would apply. However, as we discussed above, according to a close interpretation, the «old» Novel Food Regulation applied only to food products «isolated» from insects, but not to

<sup>(71)</sup> [www.evira.fi/portal/en/food/manufacture+and+sales/novel+foods/insects+as+food/](http://www.evira.fi/portal/en/food/manufacture+and+sales/novel+foods/insects+as+food/) [last access January 9th 2016]].

<sup>(72)</sup> A. Malet, *A-t-on le droit de vendre des insectes comestibles en France?*, published online on August 9th 2014, at <http://www.lefigaro.fr/actualite-france/2014/08/09/01016-20140809ARTFIG00017-a-t-on-le-droit-de-vendre-des-insectes-comestibles-en-france.php> [last access January 9th 2016].

<sup>(73)</sup> ANSES, *Avis de l'Anses relatif à «la valorisation des insectes dans l'alimentation et l'état des lieux des connaissances scientifiques sur les risques sanitaires en lien avec la consommation des insectes»*, 12 February 2015, available at <https://www.anses.fr/fr/system/files/BIORISK2014sa0153.pdf> [Last access January 9th 2016].

<sup>(74)</sup> ANSES, *Avis, cit.*, p. 5.

<sup>(75)</sup> French Ministry for Agriculture, Agri-food and Forestry, *FAQ Insectes pour la consommation humaine*, <http://agriculture.gouv.fr/faq-insectes-pour-la-consommation-humaine> [last access January 9th 2016].

<sup>(76)</sup> Bundesministerium für Ernährung und Landwirtschaft.

whole bugs. In its answer, the German Office remarked this point, interpreting the EU provisions in the sense that they allowed the trade of whole insects (being outside the scope of the Novel Food Regulation) but not the sale of parts of insects.

For what concerns other provisions, the German officer specified that Council Directive 97/78/EC<sup>77</sup> applies to the import of dead insects, while Directive 92/65/EEC<sup>78</sup> shall be taken into consideration when importing live animals; also Commission Decision 2007/275/EC<sup>79</sup> is relevant.

This implies that as well as other food of animal origin, also insects will be subject to veterinary checks at the border inspection points.

The German Food Import Regulation requires that the import certification, officially stating that the product complies with the food safety and food hygiene requirements, issued by the inspector of the third country of origin, is to be presented to the responsible border inspection authority upon entry. For what concerns farming insects for human consumption, the general food safety, hygiene and animal welfare provisions apply.

Regional states authorities are responsible for monitoring the compliance with food regulations.

## 5.8. Hungary

According to what the Officer of the Hungary Directorate for Food Safety Risk Assessment replied to our questions, in Hungary there is no specific legislation for what concerns edible insects. Since insects had not been used as food to a significant extent before May 1997, Hungary has always considered them as «Novel Food».

## 5.9. Ireland

Also Ireland, as well as most EU Member States, considered insects for human consumption as Novel Food, while waiting for the «formalization» of such interpretation under the revised Novel Food Regulation.

## 5.10. Italy

For what concerns Italy, lacking any binding provision, in October 2013, as soon as it started receiving the first requests for opinions on the marketability of insects as food, the Ministry of Health issued a note<sup>80</sup> providing its interpretation on the theme. According to the note, being insects products of animal origin, and lacking a history of significant consumption as food within the European Union, they had to undergo the authorization procedure required for Novel Foods.

If a food business operator believed that a species did not fall into this category, he/she had to provide an official certification from the relevant Authority of a Member State, stating that such product had a evident history of safe and significant use in that country, or all data that proved the presence of that species on the EC market before 15 May 1997. Under this interpretation, during the Universal Exhibition EXPO2015, veterinary inspectors of Milan Health Unit who had detected insects ready to be offered to visitors as food tastings in Belgian and Dutch Pavilions, carried out a seizure of those products<sup>81</sup>, although in the EU States of provenance business operators could sell them without restrictions<sup>82</sup>.

<sup>(77)</sup> Council Directive 97/78/EC of 18 December 1997, laying down the principles governing the organization of veterinary checks on products entering the Community from third countries.

<sup>(78)</sup> Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A to Directive 90/495/EEC.

<sup>(79)</sup> Commission Decision of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directive 91/496/EEC and 97/78/EC in OJ L 116, 05 May 2007, p. 9.

<sup>(80)</sup> Italian Ministry of Health, *Controlli ufficiali in merito all'uso di insetti in campo alimentare con specifico riferimento all'applicabilità del reg. (CE) 258/97 sui «Novel Food»* (trans. Official controls on the use of insects for food purposes, with specific reference to Regulation (EC) No 258/97 on «Novel Foods»), 004430-P-29/10/2013.

<sup>(81)</sup> The webpage of the Local Health Office that carried out the seizure gives some details and explanations on the event [www.asl.milano.it/ita/Default.aspx?SEZ=10&PAG=88&NOT=6885](http://www.asl.milano.it/ita/Default.aspx?SEZ=10&PAG=88&NOT=6885) [Last access January 9th 2016].

<sup>(82)</sup> Please refer to paragraph 6 for further reasoning on the principle of mutual recognition.



## 5.11. Luxembourg

For what concerns Luxembourg, information is still available at the official webpage of the Food Safety Organism (OSQCA, Organisme pour la sécurité et la qualité de la chaîne alimentaire)<sup>83</sup>.

The first consideration that the source emphasized was the legal uncertainty underlying the theme of edible insects. Given that, it reported the decision of the Service for Food Safety of the Luxembourg Health Directorate to adopt a precautionary attitude, while a clear and harmonised solution had not been agreed upon at an EU level.

Grounding the choice on the fact that it had not been proved that all species of insects intended for human consumption were safe, Luxembourg preferred to consider insects as novel foods, thus requiring a safety assessment and an authorization according to Regulation (EC) No 258/97.

Through a press release, on 22 December 2014<sup>84</sup>, the Food Safety Service of the Health Ministry confirmed this approach, rejecting the possibility to adopt a more tolerant attitude and refusing to authorize the marketing of insects, unless respecting the provisions of the Novel Food Regulation.

## 5.12. The Netherlands

The Netherlands are often considered a spearhead for entomophagy in Europe<sup>85</sup>, aided by the fact that one of the world most famous universities<sup>86</sup> has been working on the topic for years and has cooperated with FAO<sup>87</sup> in carrying on relevant studies, and

by the presence of innovative companies operating in the sector.

Insects for human consumption had been already reared in the Netherlands, when the EFSA and the European Commission started investigating the problem.

Taking this circumstance into account, and considering the increasing interest on the topic, the Director of the Consumer & Safety Division of The Netherlands at the Food & Consumer Product Safety Authority asked the Director of the Office for Risk Assessment and Research to draft a report on the chemical, biological, parasitological risks of consuming heat-treated and non-heat-treated insects<sup>88</sup>. The assessment involved only those species that were reared in the Netherlands (the mealworm beetle, the lesser mealworm beetle, and the European migratory locust). To ensure the impartiality and credibility of the report, a team of independent experts evaluated it.

Scientists who worked on the assessment concluded that, to ensure safety, insects should be subject to same process hygiene criteria as raw materials used in meat preparation.

They affirmed that adequate production methods should be sufficient to control chemical, microbiological and parasitological risks, while it was not possible excluding allergic reactions from consumption of insects.

Experts emphasized also the need to reassess risks linked to chitin intake, if the intake of dried insects was expected to increase over 45g per day.

According to the Office for Risk Assessment and Research, bugs should be considered as all other

<sup>(83)</sup> <http://www.securite-alimentaire.public.lu/professionnel/Denrees-alimentaires/Nouveaux-aliments/Insectes/index.html?highlight=insectes%22nouveaux> [Last access January 9th 2016].

<sup>(84)</sup> The text of the communication is available at the following URL <http://www.securite-alimentaire.public.lu/professionnel/Denrees-alimentaires/Nouveaux-aliments/Insectes/Communique-SECUALIM-CS-584-2014.pdf> [Last access January 9th 2016].

<sup>(85)</sup> Most of the Food Safety Officers that replied to the Author's query identified in The Netherlands (and to some extent in Belgium) the country with the highest level of tolerance (rather than acceptance) of human entomophagy.

<sup>(86)</sup> Wageningen University and Research Centre has been working on the issue of edible insects for years. Some «practical» results of the research are included in A. Van Huis, H. Van Gurp, M. Dicke, *The Insect Cookbook – Food for a Sustainable Planet*, Columbia Press, New York, 2014. See also J. Erens, S. Van Es, F. Haverkort, E. Kapsomenou, A. Luijben, *A Bug's Life – Large-scale insect rearing in relation to animal welfare*, WUR, 2012 (Report from students).

<sup>(87)</sup> WUR-FAO, *Edible insects. Future prospects for food and feed security*, Rome, 2013.

<sup>(88)</sup> Netherlands Food and Consumer Product Safety Authority, Ministry of Economic Affairs, *Advisory Report on the risks associated with the consumption of mass-reared insects*, 15 October 2014, available in pdf at <https://www.nvwa.nl> [Last access January 9th 2016].

foods, being thus subject to the hygiene package provisions and to any other general rule on food.

As a consequence, it recommended also the adoption of a hygiene code with the identification of all critical points in the production process.

It finally emphasized the risks of allergic reactions, promoting further research on this topic and offering also some suggestions to the Inspector-General of the National Authority on microbiological risks.

### 5.13. Romania

The National Sanitary Veterinary and Food Safety Directorate General replied to our enquiry confirming that, till November 2015, in Romania there was not any authorized or registered food establishment for «*producing, processing, storing, transporting and trading insects intended for human consumption*», due to the fact that the use of insects as food was «*unknown to Romanian consumers*».

The answering office anyway underlined the need that the European Commission, following the EFSA's opinion, drew up any useful provision to harmonize the issues related to the trade and consumption of insects as food.

### 5.14. Sweden

In Sweden, even before EFSA's opinion and the new Novel Food Regulation, insect marketing was not allowed. As the National Control Division Officer specified, supervision on bug trade is up to local authorities that sometimes had to issue bans on the sale of insects, though no national explicit provision existed on the topic.

### 5.15. United Kingdom

For what concerns the United Kingdom, several

operators have been selling insects for human consumption for some years, so we could infer that, even though it does not explicitly allow it, the UK at least tolerates the sale of edible bugs. This is even more evident if we consider that in July 2015 the Food Standards Agency updated the information on its official website asserting that it was asking food business operators that had been selling insects for human consumption to get ready for the implementation of the new Novel Food Regulation<sup>89</sup>. Like in some other EU Countries, while whole insects were not considered novel, parts of bugs fell under the novel food discipline. Therefore the FSA was inviting all operators to provide information in order to demonstrate a history of safe consumption for insects, putting emphasis on the fact that where the record of secure exploitation could not be proved, products had to be considered as novel foods, according to the new provisions that the European Union was discussing. To such purpose, the FSA provided operators with some information and guidelines, useful to collect and send the Authority the correct and adequate data<sup>90</sup>. The first section of the guidance document, for instance, focuses on the quantities and uses of insects as food or food ingredients and clarifies that though to the purposes of the Novel Food Regulation is essential to verify the significant use of a product, it must be recognized that quantities may vary depending on the substance. It will be therefore necessary to carry on the assessment «*on typical level of consumptions for specific product categories*». Besides the quantity measured in weight, the document suggests that data on the availability on the market and on the nature of shops could be significant.

A noteworthy advice that comes out from one of the FSA's documents to operators, is the recommendation to be ready to submit the dossier for the authorisation of a product as novel food, in the event that, though traded and consumed within the UK, a history of significant use before May 1997 cannot be demonstrated.

<sup>(89)</sup> <https://www.food.gov.uk/news-updates/news/2015/14264/edible-insects> [Last access January 9th 2016].

<sup>(90)</sup> Information and guidelines are available at the following URL <https://www.food.gov.uk/sites/default/files/insectsinfo-guidance-companies.pdf> [last access January 9th 2016].

## 6.- Before and after Regulation (EU) no 2015/2283: mutual recognition and cut-off date

The situation originating from the ambiguous wording of Regulation (EC) no 258/97 and the new Regulation on novel foods is unique.

Since the old version of the EU provisions had received different interpretations, the approach to insects as food has been fragmentary. As we have just seen, some States have been deeming both whole insects and parts of bugs as novel foods, while some others have chosen a separate discipline, considering whole insects as falling outside the scope of the Novel Food Regulation.

According to such interpretation, both in the UK and in Belgium, for instance, operators have been trading whole insects for human consumption for years, even though they had not been consumed in a significant way, before May 1997. Following this fact, two questions may arise. First, one could wonder if the prohibition to the sale of insects for human consumption in force in some EU Members could represent an unlawful restriction to the free movement of goods, in breach of the principle of mutual recognition.

The second question is a doubt on the advisability of maintaining the same cut-off date (15th May 1997) as the previous regulation.

As for the first question, it is well-known that the principle of mutual recognition applies to products which are not subject to EU harmonised legislation, «or to aspects of products falling outside the scope of such legislation»<sup>91</sup>, and it implies that where a product is lawfully sold in a Member State, its circulation cannot be hindered in any other EU Country<sup>92</sup>. The case of insects is indeed curious: what might sound strange is the fact that actually there were no national provisions that expressly ruled in different

ways their marketability. It was just a matter of «interpretation» related to a single provision of an EU directly applicable act; an act that not only had been adopted in a time when no one was thinking to insects as possible food, but that was intended to regulate something very dissimilar (new types of food obtained through innovative technological methods).

According to the literal interpretation of the «old» Novel Food Regulation, while for food isolated from animals there was a uniform (not only harmonised) legislation, whole insects fell «outside the scope» of the provisions.

In such circumstances, there are two possible lines of thought.

On the one hand, we could suppose that if entire insects do not fall into the scope of the Novel Food Regulation, they are «ordinary» food: they must simply comply with the general provisions on food safety, controls, labelling and so on, such norms representing the harmonised legislation for food products. Provided that goods are safe, no one could lawfully hinder their free trade. Member States that prohibited the production and sale of edible insects would therefore have been acting in breach of the fundamental freedoms recognized by the European Union.

On the other hand, we could instead argue that since there had not been a significant consumption of insects, within the European Union, by May 15th 1997, they could not be subject simply to the general provisions on food safety. Some specific rules should be therefore necessary. The fact that the old Novel Food Regulation encompassed only products isolated from animals resulted in a lack of harmonisation for whole insects.

The principle of mutual recognition should thus have applied to their trade if bugs were lawfully sold

<sup>(91)</sup> Recital No 3, Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

<sup>(92)</sup> The principle of mutual recognition is a theme on which scholars have been debating since its statement by the EC Court of Justice, in judgment 20 February 1979, in case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, in *European Court Reports*, 1979, p. 649, ECLI:EU:C:1979:42. J. Rinze, *Free Movement of Goods: Art. 30 EEC Treaty and the Cassis-de-Dijon Case law*, in *Bracton Law Journal*, 1993, 25, 67, pp. 67-76; A. Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*, London, 2007, pp. 39 ff.; F. Albisinni, *The path to the European Food Law System*, in L. Costato – F. Albisinni eds., *European Food Law*, Padova, 2012, pp. 27 ff.; C. Janssens, *The Principle of Mutual Recognition in EU Law*, Oxford, 2013.

in some EU Member States. In other words, if an entire insect was legitimately present in the market of a Member Country, the Member State of destination could not forbid the sale of that product on its territory. No national legislative provision could prevent it from free movement. Possible limitations could originate from now Article 36 TFEU (ex Article 30 TEC).

In the United Kingdom, in Belgium and in the Netherlands, consumers could lawfully buy some species of insects that had to be safe as all other food products: the wording of Regulation (EC) No 258/97 allowed their trade, according to the mentioned interpretation.

The only way through which other Member States could forbid the sale of these products on their territory was to invoke Article 36 TFEU, and namely those exceptions based on the need to protect human health. At this point, we could wonder if such an exemption would indeed be justified. According to EU Court case law, lacking EU harmonisation, Member States can set the level of protection that «they wish to afford to public health and the way in which that level is to be achieved»<sup>93</sup>.

These discretionary powers find however their counterbalance in the compliance with proportionality<sup>94</sup>. In the case at issue, insects were obviously safe; otherwise, no operator could have put them on the market. The only element of concern could be the possible allergic reactions originated by the consumption of bugs. As some studies revealed, insects could cause some adverse impact on people that are sensitive to crustaceans and shellfish<sup>95</sup>.

If this is the only reason to ground Member States' opposition to the sale of edible insects lawfully sold in other Member Countries, we could argue that such bans barely comply with the principle of proportionality.

A simple indication on the label would answer the need to protect any interested consumer<sup>96</sup>. Nonetheless, the novelty of insects as food may justify the request for further scientific evidence on allergic response following the consumption of bug: on this assumption, Member States could have a suitable motivation on which to ground their measures.

The second doubt pertains to the appropriateness of the choice to maintain as dividing line between «ordinary» and «novel» foods, the 15th May 1997, also in Regulation (EU) 2015/2283. On the one hand, the solution may sound acceptable in order to ensure the continuity between the two acts (and this is what drove the EU Institutions' intention, according to the seventh recital of the new regulation). On the other hand, the effects of such choice are questionable.

The new EU regulation lays down various transitional measures. Since it shall generally apply from 01 January 2018 (see Article 36), except for some provisions, any request for placing on the market a novel food submitted by that date shall comply with Regulation (EC) no 258/97. For those foods that, falling outside the scope of the old regulation, had been lawfully placed on the market, but that would now answer the criteria for novel food set by the new regulation, there is a specific provision.

<sup>(93)</sup> Judgment of the Court (Grand Chamber) of 1 June 2010, *José Manuel Blanco Pérez and María del Pilar Chao Gómez v Consejería de Salud y Servicios Sanitarios and Principado de Asturias*, joined cases C-570/07 and C-571/07, in ECR, 2010, I-04629, ECLI identifier: ECLI:EU:C:2010:300, paragraph 44; Judgment of the Court (Fourth Chamber) of 11 September 2008, *Commission of the European Communities v Federal Republic of Germany*, Case C-141/07, in ECR, 2008, I-06935, ECLI identifier: ECLI:EU:C:2008:492, paragraph 51; Judgment of the Court (Grand Chamber) of 19 May 2009, *Apothekerkammer des Saarlandes and Others and Helga Neumann-Seiwert v Saarland and Ministerium für Justiz, Gesundheit und Soziales*, joined cases C-171/07 and C-172/07, in ECR, 2009, I-04171, ECLI identifier: ECLI:EU:C:2009:316, paragraph 19.

<sup>(94)</sup> Judgment of the Court of 25 July 1991, *Aragonesa de Publicidad Exterior SA and Publivia SAE v Departamento de Sanidad y Seguridad Social de la Generalitat de Cataluña*, joined cases C-1/90 and C-176/90, in ECR, 1991, I-04151, ECLI identifier: ECLI:EU:C:1991:327, paragraph 16.

<sup>(95)</sup> A. Barre, S. Caze-Subra et al., *Entomophagie et risque allergique*, in *Revue française d'allergologie*, 2014, 54 pp. 315-321; Bellucco, Losasso et al., *Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review*, in *Comprehensive Reviews in Food Science and Food Safety*, 2013, 12, pp. 296 ff. Please refer also to EFSA Scientific Opinion, *Risk profile related to production and consumption of insects as food and feed*, 2015, p. 31 ff.

<sup>(96)</sup> An amendment to Regulation (EU) No 1169/2011 could be appropriate, in order to include, for the future, also insects in the list of substances or products causing allergies or intolerances.

Article 35, paragraph 2 establishes that they could continue to be placed on the market, until a decision is taken, following an authorisation procedure (or notification procedure).

A Commission implementing act (that the Institution shall adopt by the 1 January 2018) will identify the date by which the authorisation request shall be submitted.

All the operators that had been legitimately selling their products (whole insects), in those countries that had adopted a literal interpretation of Regulation (EC) No 258/97, will have to ask for authorisation, under the new Novel Food Regulation, by an indefinite date.

The provisions of the latest act have not in fact laid down any exception for the bugs that were already present in the market of some EU Member States. We could consequently wonder whether such circumstance infringed the principles of legal certainty and of legitimate expectation. According to the EU Court's judgments, we should probably answer in the negative.

In line with EU settled case-law, under the principle of certainty, legal rules must be «*clear and precise*» and their consequences have to be «*foreseeable*»<sup>97</sup>, «*in particular where they may have unfavourable consequences for individuals and undertakings*»<sup>98</sup>. The new Regulation on Novel Food pursues precisely this goal: it clarifies its scope, by explicitly stating it, thus providing an answer to all the doubts arising from the previous wording. And we cannot even blame Regulation (EC) No 258/97 for being ambiguous since the EC Institutions, when voting on it, were approving some rules on innovative foods, far from thinking about insects for nutritional purposes.

The wording of the «old» Novel Food Regulation was thus clear, although the effect looked odd:

whole insects were «ordinary» food while parts of them fell into the category of Novel Foods.

The element of uncertainty instead relates to the time until which operators will be allowed to sell products that they had lawfully placed on the market. This is a very weak reasoning point indeed: the doubt is not on «if» and «when» they have to comply, but on «until when» they can benefit from an exception.

As soon as the Commission adopts the implementing act, they will know exactly the deadline. So, at least with regards to such element, there is not any breach of the principle of legal certainty.

The fact that a food business operator acted on the basis of a precise regulation that would have then undergone a radical, but necessary, change – at least with regards to insects - shifts our attention from the mentioned principle, to that of legitimate expectation<sup>99</sup>, that is certainly an additional aspect related to the former<sup>100</sup>.

In a judgment dating back to 1982, the Court of Justice recognized, as general rule, that no provisions (and measures) could be retroactive. It however identified an exception to that statement, in the event «*the purpose to be achieved so demands*», provided that due respect is ensured to legitimate expectations of concerned subjects<sup>101</sup>.

A further flow of questions thus follows: did the purpose of the new regulation on novel food really need its effects to be retroactive? Was there any other way to reach the same purpose? Was due respect really ensured to food business operators' legitimate expectations?

As we said above, the reason that led to the maintenance of 15 May 1997 as cut-off date was the intent to preserve continuity between the two regulations on novel foods, though the provision of Article 35 of the new act clearly reveals that the EU

<sup>(97)</sup> Judgment of the General Court (Eighth Chamber) of 12 June 2015, *The Health Food Manufacturers' Association and Others v European Commission*, Case T-296/12, para 86.

<sup>(98)</sup> Judgment of the General Court (Third Chamber) of 2 March 2010, *Arcelor SA v European Parliament and Council of the European Union*, Case T-16/04, para 198; Judgment of the Court of First Instance (Fourth Chamber) of 22 January 1997, *Opel Austria GmbH v Council of the European Union*, Case T-115/94, para 124.

<sup>(99)</sup> Please refer to P. Craig, *EU Administrative Law*, Oxford, 2006, chapter 16, pp. 607-654 for a comprehensive analysis of legal certainty and legitimate expectations in the EU.

<sup>(100)</sup> G. Tesaro, *Diritto dell'Unione europea*, Padova, 2012, p. 107.

<sup>(101)</sup> Judgment of the Court (Fifth Chamber) of 30 November 1983, *Ferriere San Carlo SpA v Commission of the European Communities*, case 235/82, para 9.

Legislator was aware that the scopes of the two acts did not match perfectly. This would be a sufficient reason to allow the rethinking of the cut-off date.

Such solution would have avoided the now undeniable retroactivity of Regulation (EU) 2015/2283.

Anyway, since entomophagy is still not significantly present within the European Union, any insects would necessarily undergo the required authorisation procedure.

The only way to preserve insects that had already been placed on the EU market was therefore the inclusion of an explicit provision to leave them out of the scope of the Regulation. This was not the case. The new EU Act plainly includes insects in those products that need to undergo an authorisation procedure, prior to their marketability.

We could therefore put forward the hypothesis that such provision infringes the legitimate expectations of all the EU food operators involved in the production and trade of edible insects.

The EU settled case-law does not support the supposition. The EU Judge specified that the protection of legitimate expectation applies also in the event that an EU authority drives a person to believe to have expectations which are justified, but only a precise assurance by the administration could ground a plea for infringement of the principle<sup>102</sup>. According to the Court judgment, proactive conduct on the part of the operator is necessary, if a cautious and attentive behaviour could foresee the adoption of the EU measure.

The Court finally acknowledged the possibility for a prevailing public interest to preclude transitional measures from being adopted, but at the same time underlined that the absence of an interest of that kind could represent an infringement of the rule of law<sup>103</sup>.

In the case at issue, the legitimate expectation originated from a provision of an EC act subject to conflicting interpretation (though the wording could

seem clear).

In the most recent years, any operators in the field of edible insects within the European Union was aware that something was going on and that the possible outcome of the EU legislative procedure could be the inclusion of bugs in the scope of the Novel Food Regulation.

Finally, for what concerns the new act, the EU Institutions adopted some transitional measures, to give the food business operators the opportunity to catch up with the new requirements.

So, though someone could still argue that the acquired juridical position had to be maintained and that the transitional period to ask for the authorisation does actually conflict with the rule of law, the new regulation on novel food definitely looks in compliance with both the principles of legal certainty and legitimate expectation.

## 7.- Farming insects: an «agricultural» issue?

In the wake of the latest debate, up till now we have been focusing on insects as food, wondering what the best applicable categorization could be, but without considering them other than «food» or «feed».

Let's step back and take a look to what these reared insects are, apart being food or feed. They are animals, of course, farmed for a very specific purpose. In other words, they become the result of a production process, or cycle, like any other living creature that humans destine to nutrition.

It might be however controversial whether insect rearing represents an agricultural activity or not (with the subsequent identification of the breeder as farmer or as a general business operator)<sup>104</sup>.

A similar reasoning had engaged Italian scholars for years<sup>105</sup>, till the adoption of the amended wording of Article 2135 of the national civil code, in 2001<sup>106</sup>. Before that modification, the national provision defi-

<sup>(102)</sup> Judgment of the Court (Second Chamber) of 22 June 2006, *Kingdom of Belgium and Forum 187 ASBL v Commission of the European Communities*, joined cases C-182/03 and C-217/03, para 147-149.

<sup>(103)</sup> For a short focus on the principle of legitimate expectation in relation to the «Rule of Law», please refer to M. Zuleeg, *The Advantages of the European Constitution*, in A. Von Bogdandy and J. Bast (eds.), *Principles of European Constitutional Law*, Oxford, 2009, pp. 773-774.

ned as agricultural entrepreneur anyone exercising an activity aimed at the cultivation of land, at forestry, at cattle breeding or any connected activity, including any activity aimed at processing or transferring agricultural products, when falling under the normal practice of agriculture.

Such definition could generally suit the characteristics of farming of the post-war period, but did not really represent all the possible conducts related to cultivation, nor could respond to the fast changes that agriculture would have been undergoing over years. In order to overcoming the constraints drawn by the legal obsolescence of the civil code wording, some scholars suggested investigating an extralegal view of the meaning of agriculture<sup>107</sup>. Emphasising the analysis on the content of the agricultural activities (what does agriculture pertain to?) rather than the involved good of such activities (what is the object, the product resulting from agricultural practices?) was the starting point of a new systemic approach to agriculture.

Indeed, to these questions the old Article 2135 c.c. could not answer in a satisfactory way. A close reading of the provision would have excluded several activities from the definition of agriculture: mushroom farming in caves, hydroponic cultivation, greenhouse flowers (because they do not strictly relate to land farming)<sup>108</sup>, or aviculture, fish farming<sup>109</sup> and fur animal rearing (since poultry, fish and fur animals are not cattles).

What was therefore the shared common element that could encompass all the different features of

possible agricultural activities? Some scholars answered the dilemma identifying the so called “agri-biological criterion” focused on the carrying out of the whole «*biological cycle relating to animal or plant farming, directly or indirectly linked to the exploitation of natural strengths and resources and that economically results in the production of out-growth (plants or animals)*»<sup>110</sup> intended for direct consumption.

The outcome of this reasoning is that agricultural activities are those actions resulting in providing the necessary care to ensure that those plants or animals can grow up, make fruits and reproduce<sup>111</sup>. Proving to be excessively wide, this theory was subject to further developments. Scholars tried to draw the confines, in order to avoid the inclusion of activities that, though involving the provision of adequate care to organisms aimed at their production and reproduction, had outcomes not even comparable to those usually considered as «agrarian» (for instance the microbiological cultures in laboratories).

The academic world sought therefore a remedial to the issue, focusing the distinction on the presence of the agricultural risk.

Where the biological cycle was totally controlled and it was thus free from the general agricultural risk, that activity would not fall under the notion of «agriculture», having clearly the features of the secondary sector<sup>112</sup>. Once again, the resulting theory could undergo some criticism since it left outside the definition all the products cultivated in

<sup>(104)</sup> A special thanks goes to prof. Ferdinando Albisinni who suggested that further investigation on this topic could offer a different perspective on insects, while strengthening the link between agricultural and food law.

<sup>(105)</sup> Attributing a certain activity to the discipline of agriculture or to that of general trade was not a merely academic disquisition but had also practical repercussions (having for instance fiscal and social security consequences). A. Carrozza, *Agrarietà ed impresa zootecnica*, in *Atti del Convegno* (proceedings), Pisa, 19-21 March 1987, Milano, 1989, pp. 345 ff. For a quick but comprehensive comparison of the old wording of Article 2135 c.c. and the text as amended in 2001, please refer to L. Costato, *Imprenditore agricolo, novità codicistiche e polemiche retro*, in *Riv. Dir. Civ.*, 2006, I, p. 89 ff. As for case law, please refer to Cass. Civ., sec. 1, 08 January 1966, no 150 on the distinction between agricultural and commercial enterprise; Cass. Civ., sec. 1, 17 May 1966, no 1245 on the definition of cattle breeding; Cass. Civ. Sec. 1, 16 November 1968, no 3742, on the concept of “activities aimed at cultivation”; Cass. Civ., sec. 1, 34 March 1969, no 946 on the meaning of “related agricultural activities”.

<sup>(106)</sup> D. Lgs. 18 May 2001, No 228, *Orientamento e modernizzazione del settore agricolo, a norma dell'articolo 7 della legge 5 marzo 2001*, n. 57, article 1.

<sup>(107)</sup> A. Carrozza, *Problemi generali e profili di qualificazione del diritto agrario*, v. I, Milano, 1975, p. 62.

<sup>(108)</sup> L. Costato (ed.), *Trattato breve di diritto agrario italiano e comunitario*, Padova, 1994, p. 3.

<sup>(109)</sup> A. Carrozza, *L'inquadramento giuridico della piscicoltura*, in *Giur. Agr. It.*, 1981, pp. 71 ff.

<sup>(110)</sup> A. Carrozza, *Problemi generali e profili di qualificazione del diritto agrario*, cit., p. 74. The original words of the Author are in Italian.

<sup>(111)</sup> L. Costato (ed.), *Trattato breve di diritto agrario italiano e comunitario*, cit., p. 3.

<sup>(112)</sup> A. Carrozza, *Problemi generali e profili di qualificazione del diritto agrario*, cit., p. 76.

highly technologic greenhouses. To overcome such weaknesses, scholars refined the agri-biological criterion, identifying as «agrarian» any animal and plant farming, whatever the used technology was, provided that it aimed at bringing into being plant or animal products that one could also obtain from land cultivation or breeding, carried out in strict connection with soil<sup>113</sup>.

What was just a theory became a provision with the civil code amendment in 2001<sup>114</sup>. The new Article 2135 provides that «*Agricultural entrepreneur is anyone carrying out any of the following activities: land cultivation, forestry, animal breeding and connected activities*». It then specifies that «*land cultivation, forestry and animal breeding mean any activities aimed at taking care and at the development of a biological cycle or of a necessary phase of the cycle, either of plant or animal character, that use or may use the land, the wood, or fresh, brackish, or marine water*».

The agri-biological criterion turned thus to be the core point of the new article, that gives emphasis to the fact of “taking care” – as some scholars noticed<sup>115</sup> – rather than to the general activities of plowing, sowing and so on.

As a consequence, any activity that involves “taking care” of plants or animals, despite their destination to food, shall be considered as «agricultural»<sup>116</sup>, while harvesting natural resources shall not fall into the agrarian concept (unless otherwise stated with a specific provision).

A corollary of this broadened perspective is that in the new text of Article 2135 cod.civ. the word «animal» replaced «cattle», so that, except for monera, protists, fungi and plants (about which we are not arguing now), any animal (needless to say, other than humans) could become the object of agriculture.

Let's decline now our thoughts on insects. They are noticeably animals and anyone could potentially rear them while developing their biological cycle. What can be questionable is their connection with land. On the one hand, they could be collected in the wild<sup>117</sup>, but we have just said that picking insects «in nature» is not an agricultural activity, unless expressly stated<sup>118</sup>.

On the other hand, rearing insects may require systems and techniques that are far from being referable to the land. Depending on the species, bug farming can necessitate the use of cages or boxes, kept in controlled light, temperature, humidity, and growth conditions<sup>119</sup> that could hardly be naturally found in land rearing. In these systems, the only connection with soil will probably be the farming substrate, thus missing the second requirement that Article 2135 c.c. adds in order to identify an activity as «agrarian».

Insects seem therefore to match perfectly the systemic structure of agri-food law<sup>120</sup>, as developed in the last decades: while losing the close *liaison* with agriculture (but maintaining some of its characteristics), farming insects for food and feed purposes drops

(<sup>113</sup>) L. Costato (ed.), *Trattato breve di diritto agrario italiano e comunitario*, cit., p. 4, and L. Costato, *Imprenditore agricolo, novità codicistiche e polemiche retro*, in *Riv. Dir. Civ.*, 2006, p. 93.

(<sup>114</sup>) For significant notes on the reform, please refer to L. Costato, *Il diritto agrario: rana di Esopo o diritto alimentare?*, in *Nuovo diritto agrario*, 2001, 2, p. 357; E. Casadei, *Commento agli articoli 1 e 2*, in L. Costato (ed.), *I tre «decreti orientamento»: della pesca e acquacoltura, forestale e agricolo*, in NLCC, 2001, 3-4, pp. 730 ff.; E. Casadei, *La nozione di impresa agricola dopo la riforma del 2001*, in *Riv. Dir. Agr.*, 2009 I, pp. 309 ff.

(<sup>115</sup>) A. Germanò, E. Rook Basile, *L'impresa Agricola – Le attività*, in L. Costato, A. Germanò, E. Rook Basile (eds.), *Trattato di diritto agrario*, Milano, 2011, p. 765.

(<sup>116</sup>) A. Germanò, E. Rook Basile, *L'impresa Agricola – Le attività*, cit., p. 766.

(<sup>117</sup>) B.A. Rumpold, O.K. Schlüter, *Potential and challenges of insects as an innovative source for food and feed production*, in *Innovative Food Science and Emerging Technologies*, 2013, 17, p. 3.

(<sup>118</sup>) Several scholars showed environmental concerns for the consequences of an intensive harvesting of wild insects Arnold van Huis et al., *Edible insects: future prospects for food and feed security*, FAO, 2013, pp. 45 ff.; B.A. Rumpold, O.K. Schlüter, *Potential and challenges of insects as an innovative source for food and feed production*, cit., p. 3.

(<sup>119</sup>) J.Erens et al., *A Bug's Life – Large-scale insect rearing in relation to animal welfare*, cit., pp. 13 ff.

(<sup>120</sup>) F. Albisinni, *Alimenti e salute: la prospettiva del diritto agroalimentare*, in *Riv. Dir. Agr.*, 2014, 4, I, p. 459 and 460.



the clear cut between agrarian and industrial activities. It summarises and shows plainly the ongoing process that turns food and feed production into a chain, with an undeniable commingling among traditional economic sectors.

## 8.- Conclusions

The final thoughts of this paper are actually the conclusions of one-year research spent on analyzing the quick development of the theme of entomophagy in the European Union. «Expo effect» and «passing fad»: these look to be the best expressions to portray the EU recent interests towards edible insects.

Apart from those research units and scholars that have been studying the issue for years, truly believing on the potential of entomophagy, most of the debate which arose on the theme will probably fade within few months. We could define it as the «Expo effect».

Following the 2015 leitmotiv «Feeding the Planet, Energy for Life», a number of interesting insights on many possible sustainable solutions have been put forward and «edible insects» are only one of those ideas.

Understanding if and when the transition from theory to practice will take place is something relying on the future. The feeling is that we are facing a passing fad, a phenomenon driven by curiosity rather than by an actual determination to achieve more sustainable habits.

Be that as it may, the need for specific provisions on edible insects is undeniable. The adoption of Regulation (EU) no 2015/2283 has certainly represented a required step but some further regulatory actions look indispensable to fill the outlined shortcomings.

Most of the appropriate measures shall depend on scientific support: EFSA's underpinning work will thus turn to be invaluable, being the authoritative source of scientific advice for EU institutional actions. In particular, further investigation on food

safety aspects is looked-for<sup>121</sup>, with the goal to assess the number of risks linked to the production and consumption of insects for food or feeding purposes. To reach this goal, the EU Commission shall provide detailed and clearly definite assignments, trying to avoid requesting broad and untargeted studies.

Besides these reflections on future possibilities, the «insect affair» brought out the inability of EU Member States to agree upon and adopt a single uniform policy on edible insects, while waiting for the approval of EU acts touching several different themes.

We could understand such incertitude and failure to find shared guidelines if the involved issues had significant political and economic repercussions but the theme of entomophagy looks to have consequences much less important than those of many other contemporary questions the European Union is facing.

And we shall probably look for the reasons of such lack of cohesion in the fact that edible insects were not indeed considered a theme to be treated as a priority. The subjects interested on their regulation were probably only those food operators wishing to expand their business activities.

This paper represents, of course, its author's point of view and perceptions; a perspective believing that the diffusion of entomophagy is not a matter of law. A regulatory action is certainly a pre-condition, but it is not the key of edible insect success: economic evaluations, consumers' acceptance of the new food and a steadfast promotional campaign are probably the most suitable means to reach the goal.

Nevertheless, some unexplored issues still remain, such as the qualification of insect farming as agricultural activity.

Though the similarities with livestock breeding suggest that we should consider it as falling under the notion of «agriculture», the systems and techniques of bug rearing do not match the requirements that scholars, first, and that legislation, then, identified to provide limits for the concept of «agricultural activity».

<sup>(121)</sup> H.C. Klunder et al., *Microbiological aspects of processing and storage of edible insects*, in *Food Control*, 2012, 26, pp. 628-631; S. Bellucco et al., *Edible insects: a food security solution or a food safety concern*, in *Animal Frontiers*, 2015, 5, 2, pp. 26-30.

## ABSTRACT

*Day after day, the interest in «edible insects» is gradually growing in Western countries. 2015 seemed to represent the turning point for entomophagy also within the European Union: EU Institutions offered solutions to some of the most significant uncertainties hindering the phenomenon diffusion.*

*The paper aims to take stock of the situation, while highlighting some legal concerns originating from the new trend.*

*Starting from a short summary of the pros and cons of the development of entomophagy, and considering what is happening at an international level, the paper will then focus on the regulatory approach that the European Union has been taking on the issue. It will provide an overview of the rules on*

*novel food, paying attention to the different interpretations that, under such provisions, EU Member States delivered on the marketability of edible insects, until the adoption of Regulation (EU) 2015/2283. The paper will quickly sum up the obstacles to entomophagy that the scientific opinion of the European Food Safety Authority on risks related to the consumption of insects as food and feed tried to answer.*

*While recognizing the importance of law as a precondition to the diffusion of entomophagy, but putting up the idea that «edible insects» can turn to be just a passing fad, the paper will conclude that the key for success is not in the regulatory framework. However, it will underline some grounds for further investigation, on the legal qualification of insect farming.*