



Circular concerning the breeding and marketing of insects and insect-based food for human consumption

| | | | |
|-----------------|---|-----------------|----------------------------|
| Reference | PCCB/S3/ENE/KBE/1158552 | Date | 26/04/2016 |
| Present version | 2 | Applicable from | Date of publication |
| Key words | Insects, insect-based food, human consumption, feed for animals; novel food | | |

| Written by | Approved of |
|---|---------------------------------|
| Ngonlong Ekendé Elisabeth, attaché Bergen Karolien, attaché Keppens Christophe, attaché | Lefevre Vicky, Director general |

1. Aim

This circular aims to clarify the general rules which apply for breeding and marketing of insects and insect-based food for human consumption while waiting at the European level for a legal clarification of the legal rules, especially the establishment of the status of “novel food” of insects.

2. Scope

This circular applies to all food businesses established in Belgium which breed insects and/or market insects and food-based insects for human consumption. This circular does not apply to insects for animal feeding, which are moreover not allowed in feed for food-producing animals, but are allowed in feed of pet food.

The regulation (EC) No 258/97 foresaw that foods or food ingredients which haven't been used for human consumption at a significant level in the European Union before 15 May 1997 are novel foods or novel food ingredients. According to this regulation, all novel foods or novel food ingredients must have been assessed and receive a European authorisation before they can be placed legally on the community market. This authorisation covers, amongst other things, the conditions of use, the designation of the novel ingredient or novel food as well as the specific labelling requirements. With regard to insects for human consumption, the European Commission has conducted a survey amongst all Member states in order to know which insects are placed on the food market. The Belgian authority has for this purpose submitted a list of insects proposed for human consumption in Belgium (see table).

There was legal uncertainty about including entire insects and their preparations (for example worm pasta) within the scope of the regulation No 258/97. This legal uncertainty has been lifted. Indeed, entire insects and their preparations fall within the scope of the new “novel food” regulation No 2015/2283. This regulation (EU) No 2015/2283 considers clearly all types and forms of insects as “novel food”, unless evidence can be provided that they have been used for human consumption at a significant level in the European Union before 15 May 1997. This new regulation has been published 11 December 2015. Its implementation is planned for 1 January 2018. This means that insects and insects-based food (that does not meet the scope of regulation (EC) No 258/97) but that is legally placed on the market, latest 1 January 2018 and that legally

fall under the scope of regulation (EU) No 2015/2283 can continue to be placed on the market until a decision is taken concerning their request for authorisation. Consequently, it is advisable for operators to undertake from now on the necessary steps at FPS HFCSE to obtain the authorisation placing on the market as "novel food" (see website of FPS HFCSE) While waiting for the implementation of the new regulation (EU) No 2015/2283 concerning "novel food", the placing on the market of insects which are indicated in the table below will still be allowed.

Keep in mind:

- However, this tolerance is not applicable for food ingredients isolated from insects, such as for example protein isolates for which an authorisation as "novel food" is needed before any placing on the market.
- This tolerance is also no longer applicable for insects intended for human consumption (included the 10 insects indicated in the table below) and which are imported from third countries for which an authorisation as "novel food" is necessary before any placing on the market.
- The operators who intend to place insects on the market and which are not indicated in the table below, must also obtain for these insects an authorisation as "novel food" before any placing on the market.

Additional information concerning the regulatory status of insects and the expected evolution in the following years is available on the website of the FPS HFCSE (questions & answers):

http://health.belgium.be/eportal/foodsafety/19105515?years=fr#.VqXU_E9zkI0

More information concerning the procedure for authorisation is available on the website of the FPS HFCSE:

<http://www.health.belgium.be/eportal/foodsafety/foodstuffs/novelfoods/index.htm#.VjnZxm5zIBI>

Additional information concerning the different submitted dossiers "novel food" and their status is available on the website of the European Commission:

http://ec.europa.eu/food/safety/novel_food/authorisations/index_en.htm (> Related Documents > Applications for authorisations and their status)

| | |
|--------------------------|--|
| House cricket | <i>Acheta domesticus</i> |
| African migratory locust | <i>Locusta migratoria migratorioides</i> |
| Giant mealworm | <i>Zophobas atratus morio</i> |
| Mealworm | <i>Tenebrio molitor</i> |
| Buffalo worm | <i>Alphitobius diaperinus</i> |
| Wax worm | <i>Galleria mellonella</i> |
| Desert locust of America | <i>Schistocerca americana gregaria</i> |
| Tropical house cricket | <i>Gryllodes sigillatus</i> |
| Lesser wax moth | <i>Achroia grisella</i> |
| Silkworm | <i>Bombyx mori</i> |

3. References

3.1. Legislation

Royal decree 13 September 1999 referring to labelling of prepacked foodstuffs

Royal decree 14 December 2006 referring to medicinal products for human or veterinary use

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

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 October 2003 laying down requirements for feed hygiene

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances of animal origin.

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending Regulation (EC) No 1831/2003 of the European Parliament and Council and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

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

Regulation (EU) No 37/2010 of the Commission 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 of the Commission.

Regulation (EU) No 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

3.2. Others

Joint opinion SciCom 14-2014 and CSS No 9160 concerning the food safety of insects intended for human consumption. (See www.afsca.be > Professionals > Scientific Committee > advice > 2014).

4. Definitions and abbreviations

ACT: Activity. The activities are characterized by a LAP combination: Place-Activity-Product: concerns a code that is used in the tree of activities of the FASFC for which a specific number is associated to for each place, activity and product. The combination of those three numbers builds a code that allows it to identify with precision "the activity" covered by the code in question.

FASFC Federal Agency for the Food Chain Safety

RD: Royal Decree

GHP: Good Hygiene Practices

CSS : Superior Health Council

Primary production: The production, breeding or the cultivation of primary products, including the harvesting, the milking and the production of farmed animals before slaughtering. It covers also hunting, fishing and gathering of wild products.

SciCom : Scientific Committee of the FASFC

FPS HFCSE: FPS Public Health, Food Chain Safety and Environment

5. Conditions for the marketing

5.1. Registration of activities

The activity "breeding of insects" is inserted into the activity tree of the FASFC. It refers to an activity of primary production. The operators who breed insects, must be registered at the FASFC as mentioned under point 5.1.1. Direct sales of living animals as well as the slaughtering of insects via methods which are not modifying significantly the insects such as refrigeration, freezing, deep-freezing or the use of gases (CO₂)¹are considered as implicit activities of breeding. The preparation and marketing of insect-based food are activities which need to be registered or authorised by the FASFC. Depending on the exercised activities, registrations or authorisations associated with the points 5.1.2. to 5.1.6. apply. This is a non-exhaustive list with the most pertinent activities. If insects are incorporated in special foodstuffs, other activities can apply. In this case, one has to refer to the activity tree of the FASFC.

5.1.1. Group of HOLDINGS WITH ANIMALS AND ANIMAL PRODUCTS/Registration

Place: PL42 Agricultural holding

Activity: AC28 Keeping

Product: PR220 Insects- other than bees/bumblebees

5.1.2. Group of RETAILERS/Registration

Place: PL29 Retailer

Activity: AC94 Itinerant retail sale

Product: PR57 Pre-packed foodstuffs with a shelf life of at the least 3 months at ambient temperature

¹If other type of slaughtering such as heat treatment (boiling,...) is used, a transformation of insects is happening and it's not linked to an implicit activity of breeding. The operator must put into place a HACCP system covering all dangers associated with this last step of transformation. The breeder of insects who is following this stage of transformation must also register a complementary activity at the FASFC (see point 5.1.4. et 5.1.6.)

Place: PL29 Retailer
Activity: AC94 Non itinerant retail sale
Product: PR57 Pre-packed foodstuffs with a shelf life of at the least 3 months at ambient temperature

Place: PL29 Retailer
Activity: AC95 Retail sale as a complementary activity
Product: PR57 Pre-packed foodstuffs with a shelf life of at the least 3 months at ambient temperature

5.1.3. Group HORECA/authorisation 1.1. Food retail trade

Place: PL88 Itinerant trade vehicle
Activity: AC66 Production and distribution
Product: PRI152 Meals

Place: PL92 Restaurant
Activity: AC66 Production and distribution
Product: PRI152 Meals

Place: PL83 Caterer
Activity: AC66 Production and distribution
Product: PRI152 Meals

5.1.4. Group of RETAILERS (sale of general foodstuffs without preparation)/authorisation 1.1. Food retail trade

Place: PL29 Retailer
Activity: AC68 Production and non itinerant retail trade
Product: PR52 Foodstuffs

Place: PL29 Retailer
Activity: AC94 Itinerant retail sale
Product: PR52 Foodstuffs

Place: PL29 Retailer
Activity: AC94 Non itinerant retail sale
Product: PR52 Foodstuffs

Place: PL29 Retailer
Activity: AC95 Retail sale as a complementary activity
Product: PR52 Foodstuffs

5.1.5. Group of WHOLESALERS (for foodstuffs)/authorisation 1.1. Food retail trade

Place: PL47 Wholesaler
Activity: AC97 Wholesaling
Product: PR52 Foodstuffs

5.1.6. Group of PRODUCTION UNITS/authorisation 1.2. Establishments for the preparation, processing and putting on the market of foodstuffs

Place: PL43 Manufacturer
Activity: AC39 Manufacture
Product: PR114 Prepared dishes

Place: PL43 Manufacturer
Activity: AC39 Manufacture
Product: PR26 Other foodstuffs

Place: PL43 Manufacturer
Activity: AC39 Manufacture
Product: PR45 Chocolate, confectionery

5.2. Main principles of food legislation

For the activities "breeding and placing on the market insects or insect based foodstuff for human consumption", the general rules of food legislation are in force and inter alia, in particular the application of the good hygiene practices, the traceability, the obligatory notification, the labelling,... and the implementation of HACCP based self-checking system.

1. All operators of the food chain are subject to the "General Food Law" (Regulation EC No 178/2002) which lay down the general requirements of the food legislation. The article 17 of the current regulation specifies that the operators must verify compliance with the regulatory requirements during all levels of the food chain which are placed under their control.
2. The operators of the food sector who breed and market living insects for human consumption are subject to the requirements of the regulation (EC) No 852/2004 which applies to operators of the primary production.
3. Food given to insects intended for human consumption is subject to the animal feed legislation and the general hygiene rules of animal feed as laid down in the regulation (EC) No 183/2005. Insects, which are raised for human consumption, are defined as breeding/farmed animals and more specifically as a 'food-producing animal'. Therefore, the feed rules for farmed animals such as swine, cattle and poultry do also apply for the insects mentioned in this current circular. More detailed information is available on the website of the FASFC: <http://www.favv-afsca.fgov.be/productionanimale/alimentation/>.
4. Operators who handle, prepare, process, store, expose and transport insects intended to be placed on the market for human consumption, must meet the requirements of the regulation (EC) No 852/2004 which applies for operators working in the food processing and food distribution chain.
5. There are no specific requirements for insects in the regulation (EC) No 853/2004.
6. The rules concerning the labelling of pre-packed foodstuffs are required by RD from 13 September 1999, The rules fixed in Regulation (EU) No 1169/2011 concerning pre-packed and not pre-packed foodstuffs do also apply.
7. All substances used during breeding of insects or the production of food-based insects (examples: veterinary drugs, biocides, food additives, additives for animal feed,...) must always be authorized for the intended use.

5.3. Specific aspects linked to food safety which must be taken into account for the insects and the insect-based food for human consumption

With regard to the feeding of insect species mentioned in the table and intended for human consumption, the following rules are particularly relevant in view of the natural diets of these species.

1. The feeding legislation authorises all feed materials for feedingstuffs, except if some of those are explicitly prohibited. Annex III of regulation (EC) No 767/2009 lists prohibited materials such as faecal matter, urine, wood which has been treated with wood preservatives, waste from waste water, solid urban waste, packagings and parts of packagings, etc.
2. Catering waste, food leftovers and non processed animal by-products can also not be used for feeding insects, and this based on regulation (EC) No 1069/2009. Likewise, adding fungicides and the use of pharmacological substances (such as antibiotics) in feed for insects is not allowed.

3. The legislation foresees also different restrictions with regard to the use of raw animal materials for feeding farmed animals. The main restriction concerns the prohibition to use animal proteins for feeding farmed animals such as specified in the regulation (EC) No 999/2001. A summary is available under:

http://www.afsca.be/productionanimale/alimentation/produits/documents/2013_11_Produits_animaux_autorises_et_non_autorises_999_2001_FR.pdf (column of non-ruminants). Animal fats can be used provided to be processed according to the regulation (EC) No 1069/2009.

The specific recommendations mentioned in the common advice of the SciCom 14-2014 and of the CSS 9160 must be taken into consideration for breeding insects as well as the marketing and the consumption of insects and insect-based food.

1. It is necessary to clean the breeding space, the breeding surfaces/layer and the material at least after each breeding cycle. If individuals of the same stage of development and of the same age are held in the same breeding space, cleaning must happen if the animals change breeding space or if they are collected for transformation. Moreover it is necessary to regularly clean if individuals from different stages of development are continuously maintained in the same breeding space. (Example: mealworm). Besides the cleaning one has also to carry out, if necessary, a disinfection (example: in case of an abnormal mortality).
2. The breeders of insects must, as far as possible, regularly eliminate faeces and dead insects (exception: *Galleria mellonella* - Greater wax worm of which the larvae/pupae are buried in the substrate because it is recommended in those cases to not manipulate them).
3. The breeders of insects must regularly renew food and water sources (exception: some stages of development of certain insects imply that those ones develop "in food" and it is recommended to not manipulate this one - example: *Galleria mellonella* - Greater wax worm).
4. If the breeders breed at the same time insects only intended for pet food (the insects are not authorized in food from other animals) and insects intended for human consumption, they have to maintain a clear separation (example: bulkhead) between the two types of production. The insects raised under the necessary conditions intended for human consumption can be placed on the market for animal feeding. However, the insects raised under the necessary conditions intended for animal consumption cannot be placed on the market for human food.
5. The administration of pharmacological substances for the purpose of veterinary treatment must respect the „cascade system" (RD 14 December 2006, Article 231). More precisely, the prescription and/or furniture and/or administration can only be carried out by a veterinarian. Moreover, the substance as referred to must be listed in table 1 of regulation (EU) No 37/2010. A proper waiting time must be respected before slaughtering insects intended for human consumption in such a way that the concentration of residues in insects at this moment meets at least the lowest maximum residue limit fixed for this substance in the regulation (EU) No 37/2010.
6. A processing step by heat (examples: bleaching, boiling or oven drying) is necessary as a germicidal treatment before placing the product on the market. The spore-forming bacteria presenting a potential risk during the consumption of insects, a treatment such as sterilisation and suitable storage conditions are also strongly recommended.
7. The products which are placed on the market must be tested periodically to detect the presence of pathogenic agents. For those periodical tests, one can base himself amongst other on criteria of food safety defined in Regulation (EC) No 2073/2005.

Salmonella :

The indicative value concerning food safety "not present in 10 grams" is applicable if the insects are actually consumed cooked (cfr. criteria 1.6 of Regulation CE No 2073/2005).

For insects that will not be cooked, it's the indicative value concerning food safety "not present in 25 grams" applies (cfr. criteria 1.17 of regulation (EC) No 2073/2005). "Not present in 25 grams" also applies for insects that underwent a heat treatment and products based upon insects (burgers, spreads,...)(cfr. Criteria 1.16 of Regulation (EC) No 2073/2005).

In terms of primary production, if one doesn't know beforehand if the insects underwent a heat treatment, the indicative value in terms of food safety "not present in 25 grams" applies.

Listeria monocytogenes :

The criteria of food safety that applies for *Listeria monocytogenes* in food based insects that are ready-to-eat allowing the development of this bacteria is (cfr. Criteria 1.2. of regulation (EC) No 2073/2005):

- < 100 cfu (colony-forming unit)/g for products that are placed on the market during their storage. This criteria is applicable if the manufacturer can prove to its competent authority that the product respects the limit of 100 ufc/g during all the shelf life;
- absence in 25 grams before the food has left the immediate control of the food business operator who has produced it. This criteria is applicable in cases where the producer cannot show that the product respects the limit of 100 cfu/g during all the shelf life.

If foodstuffs with/containing ready-to-eat insects do not allow the development of *Listeria monocytogenes*, it is possible to apply a limit of 100 cfu/g for all stages, for all products placed on the market during their shelf-life (cfr. Criteria 1.3. of Regulation (EC) No 2073/2005). The following products fall automatically under this category:

- The food based on ready-to-eat insects that has undergone a thermal treatment (via heat) or another efficient transformation to eliminate *L. monocytogenes* if the recontamination is no longer possible after this treatment, for example the products that are heat-treated in their final packaging;
- the products with a use-by date under 5 years;
- the frozen insects and the products based on frozen insects under the condition that those ones are not kept longer than 4 days in the thawed state before consumption (the time span before deep-freezing and the time span of thawing are included in the maximum storage life of 4 days.
- Products with $\text{pH} \leq 4,4$;
- Products with a $a_w \leq 0,92$ (a_w : water activity);
- Products whose $\text{pH} \leq 5,0$ and $a_w \leq 0,94$.

8. Considering the relatively long shelf life of dried or freeze-dried insects, the number of pathogenic agents which can develop in the product must also be taken into account until the end of life.
9. If the products are difficult to use without additional information, the instructions for use must be indicated on the label as well as the special and optimal conditions of storage and use.
10. If so, the label must mention that the legs and/or wings must be removed before consumption (crickets, grasshoppers).
11. The label must mention a warning: „the persons who are allergic against mollusc and crustacean(and/or mites)can have an allergic reaction to the consumption of insects.

7. Overview of revisions

| Inventory of revisions of the circular | | |
|--|----------------------------|---|
| Version | Applicable from | Reasons and extend of the revision |
| 1 | 21/05/2014 | Original version |
| 2 | Date of publication | Publication of the common advice of the SciCom and the CSS Clarification of the legal status of insects in the framework of the regulation of "novel food": publication of regulation (EU) No 2015/2283. |