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SCIENTIFIC OPINION

Safety of Acheta domesticus powder as a Novel food pursuant to Regulation (EU) 2015/2283

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on *Acheta (A.) domesticus* powder as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The main components of the NF are protein, fat and dietary fibre (chitin). The Panel notes that the concentration of contaminants in the NF depends on the occurrence levels of these substances in the insect feed. The Panel further notes that there are no safety concerns regarding the stability of the NF if the NF complies with the proposed specification limits during its entire shelf-life. The NF has a high protein content, although the true protein content is overestimated when using the nitrogen-to-protein conversion factor of 6.25 due to the presence of non-protein nitrogen from chitin. The applicant proposed to use the NF as food ingredient in a number of food products. The target population proposed by the applicant is the general population. Considering the composition of the NF and the proposed conditions of use, the consumption of the NF is not nutritionally disadvantageous. The panel notes that no safety concerns arise from the toxicological information of *A. domesticus*. The panel considers that the consumption of the NF might trigger primary sensitisation to *A. domesticus* proteins and may cause allergic reactions in subjects allergic to crustaceans, mites and molluscs. Additionally, allergens from the feed may end up in the NF. The panel concludes that the NF is safe under the proposed uses and use levels.

KEYWORDS

Acheta domesticus, food safety, house cricket, insect powder, novel food

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 11 June 2020, the company Società Agricola Italian Cricket Farm S.r.l. submitted an application to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283 to authorise the placing on the Union market of *Acheta domesticus* flour as a novel food.

The application requests to authorise use of *Acheta domesticus* flour as an ingredient in various food products.

The applicant has also requested data protection under Article 26 of Regulation (EU) 2015/2283.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion on *Acheta domesticus* flour as a novel food.

In addition, the European Food Safety Authority is requested to include in its scientific opinion a statement as to if, and if so to what extent, the proprietary data for which the applicant is requesting data protection was used in elaborating the opinion in line with the requirements of Article 26(2)(c) of Regulation (EU) 2015/2283.

In the process of the evaluation of this novel food, it became apparent that the Commission should amend the title of the mandate in relation to the term 'flour'. The term 'flour' is primarily used to describe powders of vegetable origins, therefore, as the concerned food is from animal origin, it is considered more appropriate to replace 'flour' by 'powder'. On that basis, the Commission amended the title to '*Acheta domesticus* powder as a novel food'.

1.2 | Additional information

On 07 July 2021, the NDA Panel adopted an opinion on the safety of frozen and dried formulations from whole house crickets (*Acheta domesticus*) as a novel food (NF) pursuant to Article 10 of Regulation (EU) 2015/2283. The Panel concluded that the NF is safe for human consumption under the proposed uses and use levels (EFSA NDA Panel, 2021). Following a positive vote of the Standing Committee on Plants, Animals, Food and Feed, the European Commission adopted on 10 February 2022 Commission Implementing Regulation (EU) 2022/188 authorising the placing on the market of frozen, dried and powder forms of *Acheta domesticus* as NF pursuant to Regulation (EU) 2015/2283.

On 23 March 2022, the NDA Panel adopted an opinion on the safety of partially defatted house cricket (*Acheta domesticus*) powder as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283. The Panel concluded that the NF is safe for human consumption under the proposed uses and use levels (EFSA NDA Panel, 2022).

2 | DATA AND METHODOLOGIES

2.1 | Data

The safety assessment of this NF is based on data supplied in the application and information submitted by the applicant following EFSA's requests for supplementary information. Additional information, which was not included in the application, was retrieved by literature search following a search strategy and standard operating procedure as described by UCT Prague (2020).

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469.[1]

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

This NF application includes a request for protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283. The data requested by the applicant to be protected comprise: study to identify the identity of the NF, production process and feed composition, batch-to-batch analyses of compositional data, nutritional information and digestibility study.

2.2 | Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469.

[1]Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

In the context of this opinion, EFSA's definition of dietary fibre (i.e. non-digestible carbohydrates plus lignin; EFSA NDA Panel, 2010a, 2010b) does not reflect the additional requirement of having a beneficial physiological effect demonstrated by generally accepted scientific evidence laid down in Annex I of Regulation (EC) 1169/2011[2] for:

a. edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means, and
b. edible synthetic carbohydrate polymers.

It is out of the scope of this opinion to establish whether the fraction of non-digestible carbohydrates present in the NF meets the legal definition of dietary fibre in the EU or not.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use, and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3 | ASSESSMENT

3.1 | Introduction

The NF which is the subject of the application is *Acheta (A.) domesticus* powder. The NF falls under the category of 'food consisting of, isolated from or produced from animals or their parts', as described in Article 3 (v) of Regulation (EU) 2015/2283.[3] The NF is produced by farming and processing of *A. domesticus* and consists mainly of protein, fat and dietary fibre (dry basis).

The NF is proposed to be marketed in the form of powder. The applicant proposed to use the NF as ingredient in various food products. Products with the NF can be consumed by the general population.

3.2 | Identity of the NF

The NF consists of powder of *Acheta domesticus*, also known as 'house cricket'. *A. domesticus* is an insect species that belongs to the family of Gryllidae, subfamily Gryllinae, genus *Acheta* (Linnaeus, 1758).

The species is living in the wild in various regions worldwide, including Australia, Asia, Africa, North America and Europe (GBIF, 2022). The identity of the species has been certified by an official attestation of species bred performed by the Animal Health Service of the Local Health Unit (Azienda Sanitaria Locale Torino 3 – ASLTO3).

3.3 | Production process

According to the information provided, the NF is produced in line with Hazard Analysis Critical Control Points (HACCP) principles. The production process can be divided into three distinctive parts: farming, harvesting and post-harvest processing.

Farming includes reproduction of the adult insect population and rearing of the nymphs into adults. All steps take place in separate sections of the breeding area. The eggs are separated from the adult insects so that nymphs can grow separately. After being hatched from the eggs, the nymphs grow under monitored temperature and humidity conditions, in containers made from polyethylene or cardboard, compliant with the relevant EU Food Contact Material Regulations [Regulation EC 1935/2004,[4] Regulation EC 1895/2005,[5] and in case of polyethylene, Regulation EU 10/2011[6]] and which are regularly disinfected. Water is provided through home-made starch gels. The applicant reported that no pesticides, antibiotics, solvents and growth hormones are used during farming.

The applicant reported that the feed administered to the insects is a mix of plant-derived material compliant with Regulation (EU) 2017/1017[7] and Regulation (EC) No 1831/2003.[8] The applicant reported the possible presence of GMO corn

[2] 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 Text with EEA relevance.

[3] 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.

[4] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

[5] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

[6] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

[7] Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials.

[8] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

in the feed mixture and commits to inform the consumers about the presence of GMO ingredients in the feed, according to Regulation (EC) No 1830/2003.[9]

During farming, *A. domesticus* can be affected by pathogens including cricket paralysis virus (CrPV) from the Dicistroviridae family, the cricket densovirus (AdDV) from the Parvoviridae family (Maciel-Vergara & Ros, 2017), the *Penaeus merguiensis* densovirus (PmergDNV) (La Fauce & Owens, 2008) and the nematode *Heterorhabditis georgiana* (Shapiro-Ilan et al., 2009). A literature review made by the applicant highlighted that these pathogens are mostly specific for insects, and non-pathogenic for humans or other vertebrates. Examples of foodborne bacteria that may be present in *A. domesticus* include *Citrobacter* spp., *Klebsiella* spp. and *Yersinia* spp. (Fernandez-Cassi et al., 2020). However, their potential presence in the NF is monitored by microbiological analysis of Enterobacteriaceae as reported in Section 3.4, Table 4. Insects and the breeding facility are visually inspected throughout rearing to monitor parasitic insects (e.g. *Tribolium confusum*).

Adult insects are harvested (5–9 weeks old) and undergo 24–48 h fasting to discard their bowel content. Finally, adult insects are sieved to eliminate debris and faeces, and cooled to 5°C within 1 h.

The post-harvesting process includes blanching in hot water (100°C for at least 10 min), drying in hot air oven (< 120°C for at least 75 min), and grinding. The powder obtained has a particle size between 0.18 and 1.5 mm.

Thermal treatment contributes to reducing the load of alive microorganisms in insects, potentially present viruses and parasites and reduction of enzymatic activity. Dehydration of the insects results in a final product with a moisture content < 6 g/100 g. The NF is stored in vacuum sealed packaging at room temperature.

The Panel considers that the production process is sufficiently described.

3.4 | Compositional data

The applicant provided qualitative and quantitative data on chemical and microbiological parameters for different batches of the NF. For all parameters, at least five independently produced batches were analysed. Certificates of accreditation for the laboratories that conducted the analyses were provided by the applicant. Analytical data were produced using methods validated for other types of matrices and a full description of the methods has been provided.

The results of the proximate analysis of the NF are presented in Table 1. The amino acid, fatty acid, vitamin and mineral compositions are reported in Section 3.9 Nutritional information.

TABLE 1 Proximate analysis of the NF.

	Batch number										
Parameter (unit)	**11/20**	**12/20**	**13/20**	**14/20**	**15/20**	**16/23**	**17/23**	**18/23**	**19/23**	**20/23**	**Analytical method**
Crude protein (g/100 g)	66.6	66.7	66.6	66.6	66.6	63.6	63.6	63.9	63.7	63.5	ISO 1871:2009, Kjeldahl (N × 6.25)
Fat (g/100 g)	16.6	16.8	16.7	16.6	16.6	19.0	18.3	19.4	18.1	20.0	ISTISAN Report 1996/34 Method A page 41, gravimetric method
Saturated fatty acids (g/ 100 g)	6.63	6.61	6.55	6.56	6.6	7.1	6.8	7.0	6.7	7.4	ISTISAN Report 1996/34 page 41 Method A + ISO 12966-2:2017 + ISO 12966-4:2015
Energy value (kcal/100 g)	416	418	417	416	416	–	–	–	–	–	Reg. (EU) No 1169/2011
	1/22	**2/22**	**3/22**	**4/22**	**5/22**	**16/23**	**17/23**	**18/23**	**19/23**	**20/23**	
Moisture (g/100 g)	4.1	4.2	4.1	4.2	4.2	–	–	–	–	–	Internal method, gravimetric method
Dietary fibre (g/100 g)	13.8	6.0	7.2	7.4	7.4	10.6	9.1	12.2	11.1	8.5	AOAC 985 29, enzymatic-gravimetric method
Ash (g/100 g)	3.8	3.9	3.5	4.2	4.5	–	–	–	–	–	Internal method, gravimetric method
Sugars (g/100 g)	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	–	–	–	–	–	Internal method, IC-AD
Digestible carbohydrates (g/100 g)	< 0.25	< 0.25	< 0.25	< 0.25	< 0.25	0.4	0.3	0.4	0.4	0.4	Calculation[a]

Abbreviations: AOAC, Association of Official Analytical Chemists; IC-AD, Ion chromatography with amperometric detection; ISO, International Organization for Standardization; ISTISAN: Istituto Superiore della Sanità.

[a]Sum of starch (internal method based on polarimetric analysis) and total sugars.

[9]Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Due to variability of proximate analyses among batches, the Panel requested further batch to batch analyses. The applicant provided analyses of protein, fat, carbohydrates and dietary fibres for further five batches of the NF as reported in Table 1 (#16/23 - #20/23).

Regarding the crude protein content of the NF, the Panel notes that literature (Boulos et al., 2020) suggested that it is likely overestimated when using the nitrogen-to-protein conversion factor of 6.25, mainly due to the presence of chitin. This issue will be addressed in detail in Section 3.9 Nutritional information.

Chitin is the main form of dietary fibre in *A. domesticus* (Hahn et al., 2018). It is a linear polysaccharide constituted by *β*-(1,4)-linked 2-amino-2-deoxy-*β*-D-glucopyranose and 2-acetamido-2-deoxy-*β*-D-glucopyranose residues (Roberts, 1992). After cellulose, chitin is the second most abundant natural biopolymer and occurs predominantly in the shells of crustaceans, the cell walls of fungi and the exoskeletons of insects (Muthukrishnan et al., 2016). The applicant provided chitin content of five independently produced batches of the NF (Table 2). The Panel notes that a nationally or internationally recognised reference method for the analytical determination of chitin does not exist. The chitin content in the NF was determined based on the protocol described by Hahn et al. (2018), in which chemical treatment based on acid detergent fibre–acid detergent lignin is used to estimate the chitin content in different insects. The Panel considers that the differences between the content of dietary fibres (Table 1) and chitin (Table 2) are due to different analytical methods utilised, and that no other source of dietary fibres is expected to be present in insects.

TABLE 2 Chitin content of the NF.

	Batch number				
Chitin (g/100 g NF)	**#1/22**	**#2/22**	**#3/22**	**#4/22**	**#5/22**
ADF (g/100 g)[a]	8.36	9.20	8.52	8.97	8.73
ADL (g/100 g)[b]	1.03	0.93	0.94	0.90	1.57
Chitin (g/100 g)[c]	7.33	8.38	7.58	8.06	7.15

[a]Acid detergent fibre (AOAC 973.18).
[b]Acid detergent lignin (AOAC 973.18).
[c]ADF-ADL.

Concentrations of heavy metals in the NF were provided by the applicant and reported in Table 3.

TABLE 3 Heavy metals in the NF.

Parameter	**Batch number**					
Heavy metals	**#11/20**	**#12/20**	**#13/20**	**#14/20**	**#15/20**	**Analytical method**
Mercury (Hg) (mg/kg)	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	EPA 7473:2007 (AAS)
Arsenic (As) (mg/kg)	0.21	0.19	0.2	0.2	0.2	EPA 3050B 1996 + EPA 6010D 2014 (ICP-AES)
Cadmium (Cd) (mg/kg)	0.05	0.07	0.07	0.07	0.06	EPA 3050B 1996 + EPA 6010D 2014 (ICP-AES)
Lead (Pb) (mg/kg)	0.26	0.26	0.26	0.27	0.27	EPA 3050B 1996 + EPA 6010D 2014 (ICP-AES)
New feed supplier	**#16/23**	**#17/23**	**#18/23**	**#19/23**	**#20/23**	
Lead (mg/kg)	0.09	0.09	0.09	0.09	0.10	UNI EN 13805:2014 + UNI EN 15763:2010 (F)

Abbreviations: AAS, atomic absorption spectrometry; EPA, U.S. Environmental Protection Agency; EN, Comité Européen de Normalisation; ICP-AES, inductively coupled Plasma-atomic emission spectroscopy; UNI, Ente nazionale italiano di unificazione.

EFSA observed a significant concentration of lead (Pb) in the NF (< 0.27 mg/kg). Upon requesting a decrease in the lead concentration, the applicant changed the feed supplier and provided new analytical data. By rearing *A. domesticus* on the new feed, the concentration of lead in the NF was reduced to < 0.096 mg/kg in five batches of the NF. The Panel considers that there are no safety concerns associated with the concentration of heavy metals in the NF, provided that these levels adhere to the specifications indicated.

The applicant analysed the proximate composition of the feed to be provided to *A. domesticus* before and after the change in feed supplier. Analyses showed no changes in crude protein, dietary fibre, ash and moisture of the feed.

The panel notes that the concentrations of heavy metals reported in the NF do not exceed maximum levels set for other foods, and that in the current EU legislation, no maximum levels are set for insects as food.

Analytical data on the concentrations of aflatoxins B1, B2, G1, G2, ochratoxin A, deoxynivalenol, fumonisins B1 and B2, and zearalenone in the NF have been provided (Table 4). The values reported are below the limit of quantification (LOQ) of the analytical methods implemented. The LOQ values are lower than the maximum limits (MLs) set for other foodstuffs in Regulation (EU) 2023/915.[10] The panel notes that, in the current EU legislation, no MLs of mycotoxins are set for insects as food.

TABLE 4 Mycotoxins in the NF.

Parameter	Batch number					
Mycotoxins (µg/kg)	**#1/21**	**#2/21**	**#3/21**	**#4/21**	**#5/21**	**Analytical method**
Aflatoxins B1	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	UNI EN ISO 16050:2011 (IAC RPLC/FD)
Aflatoxins B2	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	
Aflatoxins G1	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	
Aflatoxins G2	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2	
Aflatoxins (sum of B1, B2, G1, G2)	< 1.6	< 1.6	< 1.6	< 1.6	< 1.6	
Ochratoxin A	< 0.3	< 0.3	< 0.3	< 0.3	< 0.3	Internal method 135/002019 (IAC RPLC/FD)
Deoxynivalenol	< 10	< 10	< 10	< 10	< 10	4075 AGRI 2020 REV2 (LC–MS/MS)
Zearalenone	< 10	< 10	< 10	< 10	< 10	
Toxin HT2	< 10	< 10	< 10	< 10	< 10	
Toxin T2	< 10	< 10	< 10	< 10	< 10	
Fumonisin B1	< 40	< 40	< 40	< 40	< 40	4103 AGRI 2021 REV1 (LC–MS/MS)
Fumonisin B2	< 40	< 40	< 40	< 40	< 40	

Abbreviations: AGRI, Tentamus Agriparadigma S.r.l; EN, Comité Européen de Normalisation; IAC RPLC/FD, immunoaffinity chromatography reversed phase liquid chromatography/fluorescence detection; ISO, International Organisation for Standardisation; LC–MS/MS, liquid chromatography–tandem mass spectrometry; UNI, Ente nazionale italiano di unificazione.

Additionally, the concentrations of dioxins and dioxin-like PCBs in the NF were provided by the applicant (Table 5) and the values reported did not exceed MLs sets for other foodstuffs in Regulation (EC) No 2023/915. The Panel notes that, in the current EU legislation, no MLs of dioxins and dioxin-like compounds are set for insects and products thereof as food.

TABLE 5 Dioxins and dioxin-like PCBs in the NF.

	Batch number					
Dioxins and dioxin-like PCBs (pg/g fat)	**#1/21**	**#2/21**	**#3/21**	**#4/21**	**#5/21**	**Analytical method**
WHO (2005)[a] PCDD/F + PCB TEQ (upper bound)	2.85	3.44	2.80	3.33	2.57	GC/MS/MS

Note: WHO (2005). PCDD/F + PCB TEQ, sum of polychlorinated dibenzo-*p*-dioxins-polychlorinated dibenzofurans-polychlorinated biphenyls expressed as toxic equivalent.
[a]Van den Berg et al. (2006); GC/MS/MS, gas chromatography-tandem mass spectrometry.

Given the vegetable origin of the feed and the absence of prion or prion-related encoding genes in insects, no risk of developing prion diseases is associated with the consumption of the NF (EFSA Scientific Committee, 2015).

The applicant provided microbiological data on five independently produced batches of the NF (Table 6).

TABLE 6 Batch-to-batch microbiological analyses of the NF.

Parameter	**Unit**	**#11/20**	**#12/20**	**#13/20**	**#14/20**	**#15/20**	**Analytical method**
Total aerobic count	cfu/g	< 100	< 100	< 100	< 100	< 100	UNI EN ISO 4833-1:2013
Enterobacteriaceae	cfu/g	< 10	< 10	< 10	< 10	< 10	ISO 21528-2:2017
Escherichia coli	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI ISO 16649-2:2010
Listeria monocytogenes	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 11290-1:2017
Salmonella spp.	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 6579-1:2017
Bacillus cereus	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI EN ISO 7932:2005
Coagulase positive staphylococci	cfu/g	< 10	< 10	< 10	< 10	< 10	ISO 6888-2: 1999/Amd. 1:2003
Clostridium perfringens	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI EN ISO 7937:2005
Cronobacter spp.	in 10 g	ND	ND	ND	ND	ND	UNI EN ISO 22964:2017
Campylobacter spp.	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 10272-1:2017
Yeasts & moulds	cfu/g	< 40	< 40	< 40	< 40	< 40	ISO 21527-2:2008

Abbreviations: cfu, colony forming units; EN, Comité Européen de Normalisation; ISO, International Organization for Standardization; ND, not detected; UNI, Ente nazionale italiano di unificazione.

[10]Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006.

The applicant provided analytical data for biogenic amines for five independently produced batches of the NF (Table 7). Additional analyses have been performed on the NF batches at $t = 12$ months and the results are further discussed under Section 3.4.1 Stability.

TABLE 7 Biogenic amines in the NF.

Parameter (mg/kg)	Batch number #01/22	#02/22	#03/22	#04/22	#05/22	Analytical method
Histamine	5.2	< 1.0	< 1.0	< 1.0	< 1.0	Internal method, HPLC-DAD
Cadaverine	< 10	154	117	127	98.5	Internal method, HPLC-DAD
Putrescine	34.2	57.6	27.1	32.8	4.9	Internal method, HPLC-DAD
Spermidine	47.6	180	145	159	48.4	Internal method, HPLC-DAD
Spermine	36.5	116	98.2	114	14.4	Internal method, HPLC-DAD
Tyramine	< 10	125	107	116	72.3	Internal method, HPLC-DAD

Abbreviations: HPLC-DAD, high-performance liquid chromatography with diode array detection.

No MLs have been established for spermidine and spermine in foods. Higher concentrations have been reported in legumes/soybean products (up to 207 mg/kg and up to 69 mg/kg, respectively) and cereals (up to 353 mg/kg and up to 146 mg/kg, respectively), while lower values have been reported in fresh meat (13 and 69 mg/kg, respectively) and cheese (38 mg/kg and 3 mg/kg, respectively) (Muñoz-Esparza et al., 2019). The histamine values were much lower than the limit of 200 mg/kg for histamine in fishery products set in Regulation (EC) No 2073/2005.[11] The Panel notes the concentration of putrescine reported in the NF and that no legal limit has been established for putrescine in any food, although it may accumulate to very high concentrations in cheese (up to 1560 mg/kg), fermented sausages (up to 1550 mg/kg) and fish sauces (up to 1220 mg/kg) (EFSA BIOHAZ Panel, 2011). Tyramine concentration in the NF is similar to concentrations reported in other foods such as cheese (Andersen et al., 2019). Formation of biogenic amines can occur by endogenous biosynthesis, uptake from the feed source and by bacteria of the intestinal microbiota of insects. It can also occur during food processing and storage as result of bacterial contamination (EFSA BIOHAZ Panel, 2011). Upon EFSA's request, the applicant analysed the NF for *Pseudomonas aeruginosa* which belongs to the *Pseudomonas* genus and could have contributed to the occurrence of biogenic amines in the NF. This seemed not to be the case, as *P. aeruginosa* was reported at levels < 100 cfu/g in five independently produced batches of the NF.

The Panel considers that the information provided on the composition is sufficient for characterising the NF.

3.4.1 | Stability

The applicant provided data on the microbiological profile of five batches of the NF (Table 5). The NF has been analysed after 12 months under controlled conditions (25°C ± 2°C, relative humidity 60% ± 5%) in sealed packaging. The microbiological profile (Table 8) and the oxidative status of fat (Table 9) as well as biogenic amines (Table 10) were investigated.

TABLE 8 Microbiological status of the NF at 12 months of shelf-life.

Parameter	Unit	#05/19	#06/19	#07/19	#08/19	#09/19	Analytical method
Total aerobic count	cfu/g	< 100	< 100	< 100	< 100	< 100	UNI EN ISO 4833-1:2013
Enterobacteriaceae	cfu/g	< 10	< 10	< 10	< 10	< 10	ISO 21528-2:2017
Escherichia coli	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI ISO 16649-2:2010
Listeria monocytogenes	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 11290-1:2017
Salmonella spp.	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 6579-1:2017
Bacillus cereus	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI EN ISO 7932:2005
Coagulase positive staphylococci	cfu/g	< 10	< 10	< 10	< 10	< 10	ISO 6888-2: 1999/Amd. 1:2003
Clostridium perfringens	cfu/g	< 10	< 10	< 10	< 10	< 10	UNI EN ISO 7937:2005
Cronobacter spp.	in 10 g	ND	ND	ND	ND	ND	UNI EN ISO 22964:2017
Campylobacter spp.	in 25 g	ND	ND	ND	ND	ND	UNI EN ISO 10272-1:2017
Yeast & moulds	cfu/g	< 40	< 40	< 40	< 40	< 40	ISO 21527-2:2008

Abbreviations: cfu, colony forming units; EN, Comité Européen de Normalisation; ISO, International Organization for Standardization; ND, not detected; UNI, Ente nazionale italiano di unificazione.

[11]Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

The Panel notes that the microbiological values do not exceed the given specification limits.

The applicant provided analytical data on the oxidative status of five independently produced batches after 12 months of shelf-life, measuring peroxide and *p*-anisidine value (Table 9).

TABLE 9 Oxidative status of fat of the NF at 0 and 12 months of shelf-life.

Parameter	Unit	#01/22	#02/22	#03/22	#04/22	#05/22	Analytical method
0 months							
Peroxide value	meq O_2/kg fat	2.1	1.2	1.1	2.5	1.6	AOAC 965.331969
p-anisidine value	–	0.7	0.7	0.3	0.9	0.8	UNI EN ISO 6885:2016
12 months							
Peroxide value	meq O_2/kg fat	2.1	1.2	1.1	2.5	1.6	AOAC 965.331969
p-anisidine value	–	0.7	0.7	0.3	0.9	0.8	UNI EN ISO 6885:2016

Abbreviations: AOAC, Association of Official Analytical Chemists; EN, Comité Européen de Normalisation; ISO, International Organization for Standardization; UNI, Ente nazionale italiano di unificazione.

The Panel notes that the values do not exceed the respective specification limits.

TABLE 10 Biogenic amines in the NF at 12 months of shelf-life.

	Batch number					
Parameter (mg/kg)	#05/21	#06/21	#07/21	#08/21	#09/21	Analytical method
Histamine	1.1	1.0	1.0	1.0	< 1.0	Internal method, HPLC-DAD
Cadaverine	112	140	116	112	106	Internal method, HPLC-DAD
Putrescine	24	29.5	29.3	27.5	33	Internal method, HPLC-DAD
Spermidine	84	172	142	137	40.6	Internal method, HPLC-DAD
Spermine	105	115	95.4	95.5	49.2	Internal method, HPLC-DAD
Tyramine	112	126	96.8	105	67.9	Internal method, HPLC-DAD

Abbreviations: HPLC-DAD, high-performance liquid chromatography with diode array detection.

The panel considers that the data provided sufficient information with respect to the stability of the NF with a shelf-life of 12 months.

The applicant provided a measure of impurities or foreign bodies in the NF using the 'Filth Test'. In the test report, a few red and blue plastic wires from 0.5 to 4 mm were found in 50 g of NF. After EFSA's request, the applicant provided further measures of impurities or foreign bodies in the NF in five independently produced batches of the NF. After applying corrective measures, the test report showed no impurities.

Stability in the intended for use matrices

Since the NF is going to be used as an ingredient, EFSA asked the applicant to investigate the stability when used as an ingredient in the intended-for-use matrices (see Section 3.7.2). The applicant examined processing contaminants in pasta with the NF, lipid oxidation in biscuits with the NF and microbiological stability in cake with the NF. Analytical values were compared to those from foods processed without the NF (control) (Table 11).

TABLE 11 Stability of the NF in the intended for use matrices.

		0 months				12 months				
Parameter	Unit	Control	01/22	02/22	03/22	Control	01/23	02/23	03/23	Analytical method
Cricket pasta										
Water activity	–	0.52	0.53	0.49	0.48	0.48	0.50	0.48	0.48	ISO 18787:2017
pH	–	6.02	6.04	6.05	6.05	6.05	5.94	5.92	5.98	IM 7 rev. 5/2016
Moisture	g/100 g	10.3	9.7	9.7	9.7	9.6	9.8	9.9	9.7	ISTISAN Reports 1996/34 Page 7 Method B
Acrylamide	μg/kg	53.2	32.7	33.4	32.1	< 20	37.6	34.9	22.6	UNI EN 16618:2015
Furan	μg/kg	< 20	< 20	< 20	< 20	< 20	< 20	< 20	< 20	IM VA13.115 (2020–11)
2-methylfuran	μg/kg	< 20	< 20	< 20	< 20	< 20	< 20	< 20	< 20	
3-methylfuran	μg/kg	< 20	< 20	< 20	< 20	< 20	< 20	< 20	< 20	

(Continues)

TABLE 11 (Continued)

		0 months				12 months				
Parameter	**Unit**	**Control**	**01/22**	**02/22**	**03/22**	**Control**	**01/23**	**02/23**	**03/23**	**Analytical method**
Cricket biscuits										
Water activity	–	0.36	0.34	0.31	0.32	0.30	0.29	0.28	0.28	ISO 18787:2017
pH	–	7.40	6.32	6.16	6.28	6.08	6.27	6.22	6.18	IM 7 rev. 5/2016
Moisture	g/100 g	4.50	3.20	3.50	3.40	3.40	3.60	3.10	3.20	ISTISAN Reports 1996/34 Page 7 Method B
Peroxide value	Meq O_2/kg fat	8.40	20.30	8.70	17.40	8.80	13.20	9.40	9.80	Reg CEE 2568/1991 11/07/1991 GU CEE L248 05/09/1991
p-Anisidine value	–	30.20	25.90	30.40	31.10	28.90	30.10	31.20	29.90	Reg UE 1784/2016 30/09/2016 GU UE L273 08/10/2016
Acidity (as oleic acid)	% oleic acid	0.40	< 0.10	0.50	0.30	0.40	0.60	0.60	1.10	ISO 6885:2006
PAHs	µg/kg	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	NGD C10–1976
Cricket cake										
Water activity	–	0.63	0.64	0.63	0.6	0.6	0.52	0.51	0.56	ISO 18787:2017
pH	–	5.2	5.89	5.9	5.93	5.99	6.12	5.45	5.6	IM 7 rev. 5/2016
Moisture	%	4.5	11	11.4	10.2	11.2	12.8	12.3	10.23	ISTISAN Reports 1996/34 Page 7 Method B
Presumptive *Bacillus cereus* at 30°C – enumeration	CFU/g	< 100	< 100	< 100	< 100	< 100	< 100	< 100	< 100	ISO 7932:2004/Amd 1:2020
Beta-glucuronidase-positive *Escherichia coli* at 44°C – Count	CFU/g	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	AFNOR BIO 12/05–01/99
Coagulase positive staphylococci	CFU/g	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	ISO 6888-2:2021
Listeria monocytogenes – detection	CFU/25 g	ND	ND	ND	ND	ND	ND	ND	ND	AFNOR BKR 23/02–10/11
Salmonella spp.	CFU/25 g	ND	ND	ND	ND	ND	ND	ND	ND	AFNOR BKR 23/07–10/11
Yeasts at 25°C – enumeration	CFU/g	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	ISO 21527-2:2008
Moulds at 25°C – enumeration	CFU/g	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	ISO 21527-2:2008
Campylobacter spp. – detection	CFU/25 g	ND	ND	ND	ND	ND	ND	ND	ND	UNI EN ISO 10272-1:2017

Abbreviations: AFNOR, Association Française de Normalisation; CFU, colony forming units; EN, Comité Européen de Normalisation; IM, internal method; ISO, International Organization for Standardization; ISTISAN, Istituto Superiore della Sanità; ND, not detected; UNI, Ente nazionale italiano di unificazione.

Pasta – Cricket pasta was a mixture of durum wheat flour (85%), the NF (15%) and water. The production process employed followed the traditional method for producing dried pasta. After extruding/moulding, the pasta was dried in hot air oven at 52–54°C for 30 h until it reached a 12% relative humidity. Following drying, the pasta underwent a cooling step. A control sample was prepared by replacing the NF with durum wheat flour. The prepared pasta samples were stored in polypropylene bags at room temperature.

Biscuits – Biscuits were obtained by mixing wheat flour, pasteurised eggs, sunflower oil, yogurt, milk and glucose syrup (control biscuit). Samples containing the NF were obtained by replacing wheat flour and pasteurised eggs with 15% of the NF. After kneading, the dough was moulded and baked at 220°C for 8 min to reach a relative humidity of 4.5%. After cooling, samples were stored in polypropylene bags at room temperature.

Cake – The cricket cake was obtained by mixing wheat flour, sugar, pasteurised eggs, sunflower oil and milk. Samples containing the NF were obtained by replacing 10% of wheat flour with the NF. After mixing, the cake batter was transferred in baking tins and baked for 8 min at 220°C. After cooling, jam was added, and the samples were stored in polypropylene bags at room temperature.

The Panel notes that there are no reported alterations in the analytical data concerning potential formation of contaminants, lipid oxidation and microbiological spoilage when using the NF as an ingredient in the evaluated intended-for-use matrices, in comparison to the control. Nevertheless, the panel notes that the foods containing the NF have to comply with existing legislative limits, such as microbiological levels established by Regulation (EC) 2073/2005 and the benchmark concentrations of acrylamide in bakery products established by Regulation (EU) 2017/2158. Provided that the specifications are met also at the end of shelf-life, and that foods containing the NF are compliant with respective legislative limits on process-formed contaminants and microbiological criteria, the stability data do not raise safety concerns.

3.5 | Specifications

The specifications of the NF are indicated in Table 12.

TABLE 12 Specifications of the NF.

Description: Thermally processed, dried, *Acheta domesticus* powder		
Source: *Acheta domesticus*		
Parameter	**Unit**	**Specification**
Crude protein (N × 6.25)	% w/w	61–72
Fat	% w/w	11–22
Saturated fatty acids	% w/w	1.5–12
Dietary fibre	% w/w	4.0–14
Chitin*	% w/w	2.5–9.0
Moisture	% w/w	1.0–5.5
Digestible carbohydrates	% w/w	≤ 5.0
Manganese	mg/kg	≤ 7.0
Peroxide value	meq O_2/kg fat	≤ 2.5
p-anisidine	–	≤ 1.0
Heavy metals		
Lead	mg/kg	≤ 0.10
Cadmium	mg/kg	≤ 0.06
Mycotoxins		
Aflatoxins (sum of B1, B2, G1, G2)	µg/kg	≤ 1.6
Deoxynivalenol	µg/kg	≤ 10
Ochratoxins	µg/kg	≤ 0.3
Fumonisins B1 & B2	µg/kg	≤ 40
Ochratoxin A	µg/kg	≤ 0.3
Zearalenone	µg/kg	≤ 10
Sum of dioxins and dioxins-like PCBs (UB WHO_{2005} PCDD/F-PCB-TEQ)	pg/g fat	< 3.5
Microbiological		
TAMC	CFU/g	< 10^5
Enterobacteriaceae (presumptive)	CFU/g	≤ 100
Escherichia coli	CFU/g	≤ 50
Listeria monocytogenes	in 25 g	Not detected
Salmonella spp.	in 25 g	Not detected
Bacillus cereus (presumptive)	CFU/g	≤ 100
Coagulase positive – staphylococci	CFU/g	≤ 100
Clostridium perfringens	CFU/g	≤ 10
TYMC	CFU/g	≤ 100 (< 10)

Abbreviations: CFU, colony forming units; TAMC, total aerobic microbial count; TYMC, total yeast and mould count; UB, Upper Bound; w/w, weight per weight; WHO-PCDD/F-PBC-TEQ, sum of polychlorinated dibenzo-para-dioxins, polychlorinated dibenzofurans, –polychlorinated biphenyls expressed as World Health Organization toxic equivalent.

*Chitin calculated as the difference between the acid detergent fibre fraction and the acid detergent lignin fraction (ADF-ADL), as described by Hahn et al. (2018).

The Panel considers that the information provided on the specifications of the NF is sufficient and does not raise safety concerns.

3.6 | History of use of the NF and of its source

As per the information provided by the applicant, the NF has not been made available for consumption in European countries, nor in any other countries outside of Europe.

A. domesticus either collected from the wild or reared in farms is consumed as part of the customary diet in some non-EU countries. Their consumption by humans has been reported mainly in Thailand (Hanboonsong et al., 2013; Yen, 2015) and Lao PDR (Codex Alimentarius Commission, 2010; Durst & Hanboonsong, 2015), but also in Cambodia (FAO, 2013), Ghana (Anankware et al., 2016), Mexico (Ramos-Elorduy, 2009), Democratic Republic of Congo and Kenya (Halloran et al., 2018).

Hanboonsong et al. (2013) reported that around 20,000 *A. domesticus* small- and medium-sized farms are registered in Thailand. Products are distributed to wholesalers and local markets. Commercial chicken feed and vegetables are used as substrate and 7500 tons of crickets (including *A. domesticus*) a year are produced. In 2017, the Thai Agricultural Standards Committee established good agricultural farming practices for cricket farming including *A. domesticus* (ACFS, 2017).

A. domesticus is also farmed in Lao PDR (Hanboonsong & Durst, 2014), as well as at a lesser extent in Cambodia, Democratic Republic of Congo and Kenya (Halloran et al., 2018).

Additionally, in Australia and New Zealand, it is considered as non-traditional, not novel foodstuff and no safety concerns were identified with the exception of potential risk of allergenicity in crustacean-allergic or other sensitive individuals when consuming crickets or foods derived from crickets (FSANZ, 2021). Since 1 May 2017, *A. domesticus* in adult phase is among the insect species that can be legally introduced in the Swiss market as food (whole, chopped or ground). In Canada, it is considered non-novel for use as a food or food ingredient (Health Canada, 2021). *A. domesticus* also is marketed for human consumption in the EU, Australia and USA as a whole insect or as a food ingredient in several food products (e.g. nutritional bars, lollipops, flour, chocolate etc.).

The Commission Implementing Regulation (EU) 2022/188 of 10 February 2022 authorised the placing on the market of frozen, dried and powder forms of *A. domesticus*. The Commission Implementing Regulation (EU) (EU) 2023/5 of 3 January 2023 authorised the placing on the market of partially defatted powder of *A. domesticus* (house cricket).

3.7 | Proposed uses and use levels and anticipated intake

3.7.1 | Target population

As the NF is intended to be used as an ingredient in standard food categories, the NF can be consumed by any group of the population. Therefore, the safety data and the exposure assessment shall cover all population groups (Commission Implementing Regulation (EU) 2017/2469, article 5(6)).

3.7.2 | Proposed uses and use levels

The NF is proposed to be used as an ingredient in several food products. These food products are defined using the FoodEx2 hierarchy, and the maximum use levels are reported in Table 13.

TABLE 13 Food categories and maximum use levels intended by the applicant.

FoodEx2 level	FoodEx2 code	Food category	Max use level (g NF/100 g)
3	A00AN	Cakes	10
3	A009V	Biscuits	15
3	A007D	Pasta and similar products	15
4	A02PN	Whey powder	50
3	A03TE	Meat imitates	15
3	A03YY	Sandwiches, pizza and other stuffed bread-like cereal products	10
4	A0EQD	Chocolate and similar	15

3.7.3 | Anticipated intake of the NF

EFSA performed an intake assessment of the anticipated daily intake of the NF based on the applicant's proposed uses and maximum proposed use levels (Table 13), using individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The lowest and highest mean and 95th percentile anticipated daily intake of the NF (on a mg/kg body weight (bw) basis), among the EU dietary surveys, are presented in Table 14.

TABLE 14 Intake estimates of the NF resulting from its use as an ingredient in the intended food categories at the maximum proposed use levels.

		Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
Population group	**Age (years)**	**Lowest[a]**	**Highest[a]**	**Lowest[b]**	**Highest[b]**
Infants	< 1	14	152[e]	76	791[e]
Young children[c]	1 to < 3	138	354	326	1200
Other children	3 to < 10	122	598	319	1308
Adolescents	10 to < 18	52	305	149	677
Adults[d]	≥ 18	36	169	109	365

Abbreviations: bw, body weight; P95, 95th percentile.

[a]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 14 February 2022. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 14 February 2022. The lowest and the highest P95 observed among all EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).

[c]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[d]Includes elderly, very elderly, pregnant and lactating women.

[e]For infants the Finnish Diabetes Prediction and Prevention Nutrition Study (DIPP, 2001–2009) presented the highest means and 95th percentiles, with the main food contributor being 'whey powder'. However, this survey was not considered representative of the intended uses as the consumption of 'whey powder' derived from disaggregating the consumption of infant and follow-on formulae. Thus, the values from the surveys with the second highest means and 95th percentiles were reported in this table for infants.

The estimated daily intake of the NF for each population group from each EU dietary survey is available in the Excel file annexed to this scientific opinion (under supporting information).

3.7.4 | Estimate of exposure to undesirable substances

Based on the P95 intake estimate (Table 14), EFSA calculated the exposure to undesirable substances (heavy metals, mycotoxins), antinutritional factors, vitamins and minerals, for all population groups. The specification limits (Table 12) were used as maximum values for the concentrations of substances considered. When specification limits for a substance have not been proposed, the maximum values reported for the analysed batches were used. The Panel considers that the consumption of the NF under the proposed uses and use levels does not contribute substantially to the overall intake of the analysed substances through diet.

3.8 | Absorption, distribution, metabolism and excretion (ADME)

No ADME data are required for the NF.

3.9 | Nutritional information

The applicant provided nutritional analyses of the NF which consists mainly of protein, fat, dietary fibre (mainly chitin) and inorganic matter. The energy value of the NF is on average 416 kcal/100 g (Table 1). Analytical data on the amino acid composition (Appendix A), fatty acid content (Appendix B), minerals, vitamins (Table 15) and antinutritional factors (Table 16) in the NF have been provided for five independently produced batches of the NF.

3.9.1 | Protein content and protein quality

The NF contains on average 65.1 g crude protein per 100 g, calculated using a protein-conversion factor of 6.25. The Panel notes that the use of the conventional factor overestimates the true protein content in the NF due to the presence of non-protein nitrogen derived mainly from chitin (Janssen et al., 2017).

Boulos et al. (2020) determined an average conversion factor of 5.25 for whole *A. domesticus* as supported by literature data. Using this factor, the protein content of the NF amounts to 56.0 g/100 g, about 14% lower than considering a conversion factor of 6.25. For regulatory purposes with respect to nutritional labelling, protein is defined as the total nitrogen measured by Kjeldahl method multiplied by a nitrogen-to-protein conversion factor of 6.25 (Regulation (EU) No 1169/2011 on the provision of food information to consumers).

The applicant quantified the amino acids in five batches of the NF following an internal method (UHPLC–MS) in line with the method in Commission Regulation (EC) No 152/2009. Results for the amount of individual amino acids in 100 g of the NF crude protein are reported in Appendix A in comparison to the recommended amino acid scoring pattern for children aged 6 months to 3 years and for older children, adolescents and adults (FAO, 2013).

The applicant investigated the protein digestibility of the NF by means of in vitro digestibility test according to Reggi et al. (2020), of five independently produced batches of the NF. The test was conducted by a laboratory of the University of Milan (department of veterinary medicine and animal sciences). Whey protein was used as control. The digestibility was expressed as percentage of the digestible protein over total crude protein, including non-protein nitrogen. As a result, protein digestibility of the NF ranged from 66.5% to 77.9% (average 71.7%), with the protein digestibility of whey protein of 90.9%. The applicant determined the Protein Digestibility Corrected Amino Acid Score (PDCAAS), using the recommended amino acid scoring patterns as reference values (FAO, 2013). The resulting PDCAAS value for the NF was 0.53 for children aged 6 months to 3 years, with sulfur amino acids (methionine + cysteine) being the limiting amino acids. For other children, adolescents and adults, the estimated PDCAAS was 0.62, with sulfur amino acids (methionine + cysteine) being the limiting amino acids. The Panel notes that the applicant assessed protein quality of the NF by PDCAAS values calculated using digestibility of crude protein instead of true protein. The values provided may therefore not accurately reflect the protein quality of the NF.

Provided that the NF would not be the sole source of dietary protein, that it is integrated into a varied and mixed diet, and considering that the average protein intake in the EU population is high and frequently above the dietary reference values (DRVs) (EFSA NDA Panel, 2012), the consumption of the NF is not expected to negatively impact protein nutrition.

3.9.2 | Fatty acids, vitamins and minerals

The major fatty acids in the NF are linoleic acid, oleic acid and palmitic acid (Appendix B), accounting for on average 98% of all fatty acids in the NF. On average, saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids constitute 36%, 25% and 40% of the total fatty acids, respectively. The average *trans* fatty acid content is 0.5% of total fatty acids.

The applicant provided analytical data on the concentrations of some minerals and vitamins (Table 15).

TABLE 15 Concentration of micronutrients (minerals and vitamins) in the NF.

Parameter	Batch number					
Minerals (mg/ 100 g)	**#1/21**	**#2/21**	**#3/21**	**#4/21**	**#5/21**	**Analytical method**
Calcium	189	180	183	182	114	Internal, ICP-MS
Iron	6.6	7.9	6.7	7.3	5.5	Internal, ICP-MS
Magnesium	84	89	88	85	87	Internal, ICP-MS
Potassium	934	976	954	939	817	Internal, ICP-MS
Zinc	14.0	13.9	13.1	13.4	15.7	Internal, ICP-MS
Phosphorous	564	551	555	583	500	Internal, ICP-OES
	#1/22	**#2/22**	**#3/22**	**#4/22**	**#5/22**	
Sodium	216	391	407	386	403	Internal, ICP-MS
Iodine	0.16	0.05	0.06	0.01	0.07	UNI EN 15111–2007
Selenium	0.016	0.017	0.016	0.015	0.072	Internal, ICP-MS
Copper	0.70	0.70	0.70	0.66	2.8	Internal, ICP-MS
Manganese *	0.65	0.70	0.65	0.58	0.64	Internal, ICP-MS
Vitamins (units)	**#1/22**	**#2/22**	**#3/22**	**#4/22**	**#5/22**	
Thiamine (μg/100 g)	ND	25.4	21	25	25	Internal, LC–MS/MS
Riboflavin (μg/100 g)	0.28	0.44	0.46	0.46	0.46	Internal, LC–MS/MS
Retinol (μg/100 g)	ND	0.27	2.65	0.38	1.43	Internal, LC–MS/MS
Alpha-tocopherol (mg/100 g)	6.9	6.32	7.85	6.75	6.92	Internal, LC–MS/MS
Cobalamin (μg/100 g)	7.7	13.8	13.2	13.0	24.0	AOAC 95220/98623

Abbreviations: AOAC, Association of Official Analytical Chemists; EN, Comité Européen de Normalisation; ICP-MS, Inductively Coupled Plasma Mass Spectrometry; LC-MS/MS, Liquid Chromatography-Tandem Mass Spectrometry; UNI, Ente nazionale italiano di unificazione.

*Concentration of manganese in the NF obtained after a change in the insect feed supplier (NF batch n. 16/23; 17/23; 18/23; 19/23; 20/23).

The NDA Panel estimated the intake of Mn from the NF considering the product specification for Mn and the estimated daily intake of the NF for all population groups (Table 14). The highest estimated P95 intake of Mn (considering the highest Mn value in the NF of 7 mg/kg) from the NF ranges from 0.05 mg/day in infants, 0.1 mg/day in toddlers, 0.19 mg/day in other children, to 0.22 mg/day in adolescents and adults.

As compared to the highest P95 background dietary intake established by EFSA NDA Panel (2023), the maximum estimated intake of Mn from the NF would be 2.7% in infants, 2.6% in toddlers, 3.1% in other children and in adolescents and

2.6% in adults. The Panel considers that such intake of Mn (< 5% of the highest P95 background dietary intake[12]) from the NF is not of concern.

3.9.3 | Antinutritional factors

Insects may contain antinutritional factors (ANFs) such as tannins, oxalates, phytates, hydrogen cyanide (Meyer-Rochow et al., 2021; Shantibala et al., 2014), thiaminases (Nishimune et al., 2000) and protease inhibitors (Eguchi, 1993). The applicant determined the concentrations of total polyphenols, tannins, oxalates and hydrocyanic acid. The reported values for the NF are comparable to the occurrence concentration of these compounds in other foodstuffs (EFSA CONTAM Panel, 2019; Gupta, 1987; Holmes & Kennedy, 2000; Rao & Prabhavathi, 1982; Schlemmer et al., 2009) and to other published EFSA NF *A. domesticus* opinions (EFSA NDA Panel, 2021, 2022).

TABLE 16 Concentrations of antinutrients in the NF.

	Batch number					
Parameter	**#1**	**#2**	**#3**	**#4**	**#5**	**Analytical method**
Total polyphenols (as gallic acid) (mg/100 g)	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	Folin–Ciocalteu, spectrophotometry
Tannins (mg/100 g)	2.4	0.21	0.21	0.22	< 0.1	Spectrophotometry, based on Joslyn (1970)
Oxalates (mg/100 g)	0.49	0.5	0.5	0.68	1.2	Titration method, based on Day and Underwood (1986)
Hydrogen cyanide (mg/kg)	< 10	< 10	< 10	< 10	< 10	Titration method, ISO 2164:1975

Abbreviation: ISO, International Organization for Standardization.

The NF contains on average 7.7 g chitin in 100 g NF. The Panel considers that chitin is not expected to be digested in the small intestine of humans to any significant degree, although partial digestion in the human stomach has been suggested (Muzzarelli et al., 2012; Paoletti et al., 2009). It is also rather resistant to microbial fermentation and therefore assumed to be excreted mainly unchanged. Additionally, the panel notes that chitin can bind to bivalent minerals (Anastopoulos et al., 2017; Franco et al., 2004; Mwangi et al., 2022) possibly affecting their bioavailability, as reported for dietary fibres in general (Baye et al., 2017).

The panel considers that, taking into account the composition of the NF and the proposed conditions of use, consumption of the NF is not nutritionally disadvantageous.

3.10 | Toxicological information

No toxicological studies were provided with the NF under assessment. The applicant performed a literature search and no papers were found concerning the toxicity of *A. domesticus*.

The toxicological profile of *A. domesticus* has been previously assessed by the panel (EFSA NDA Panel, 2021, 2022). The panel concluded that no safety concerns arose from the history of use and compositional data of *A. domesticus*.

The Panel notes that the NF under assessment can be considered representative of the previously assessed *A. domesticus* (EFSA NDA Panel, 2021, 2022) only with regard to the profile of endogenously produced compounds of possible concerns, but not for compositional data and for any compound that can be present due to rearing conditions (e.g. feed) or processing.

The Panel identified and assessed a recently published toxicological study available in literature (in vitro and in vivo genotoxicity, 14- and 90-day subchronic toxicity study) with processed (dried and sterilised) *A. domesticus* powder as the testing material (Yasuki et al., 2022). All tests were reported to follow relevant OECD guidelines.

In vitro genotoxicity was examined using a mammalian chromosomal aberration test on Chinese hamster lung (CHL-IU) cells, and no genotoxic effects were observed at concentrations up to 5000 μg/mL with and without metabolic activation (S9 mix).

In vivo genotoxicity was assessed using the micronucleus test in ICR mice. The mice were administered 0, 500, 1000, and 2000 mg/kg body weight of cricket powder orally for two consecutive days. Cyclophosphamide monohydrate was used as a positive control. Bone marrow cells harvested 24-h post-treatment showed no increase in micronucleated polychromatic erythrocytes up to the highest tested dose.

[12]As reported by the published minutes of the 154th meeting of the working group on novel foods (WG NF, 2024), the WG considers that 'for the purpose of the assessment of NFs, intakes that lead to a significant increase of manganese (Mn) intake as compared to the safe levels set by the EFSA NDA Panel (2023) are considered of concern. In the absence of adequate data to establish an UL, the NDA Panel (2023) established the safe levels of intake of Mn based on observed background intake of Mn among high consumers from the general population (P95 estimates). Based on experts' judgement and criteria set by the WHO/FAO's Codex Alimentarius Commission (2015) for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin, the WG concluded that Mn intake from the NF exceeding 5% of the highest P95 background dietary intake is considered as a significant contribution.'

Toxicity was evaluated over 14-day and 90-day periods in mice. The mice received 300, 1000 and 3000 mg/kg bw *A. domesticus* in both studies. The evaluation included haematological analysis, blood biochemistry (limited parameters in the 90-day study) and relative organ weight measurements. Mice were also observed for any signs of toxicity or behavioural changes. No histopathological investigation was performed.

There were no relevant differences in body weight gain, blood biochemistry and haematological tests in the 300, 1000 and 3000 mg/kg *A. domesticus* powder groups compared with the control group for both males and females. Similarly, organ weights showed no significant deviations from control weights.

The panel concludes that since these studies were not performed with the NF, the outcomes can only be considered as supporting evidence for the safety of the NF.

Regarding the safety of chitin present in the NF, the applicant referred to the EFSA's scientific opinion on the safety of 'chitin-glucan' as an NF ingredient (EFSA NDA Panel, 2010a, 2010b). However, the panel is of the view that the polymer chitin-glucan cannot be considered as representative of the chitin derived from *A. domesticus*. After EFSA's request, the applicant provided a certified translation from Japanese of a 13-week subchronic toxicity study of purified chitin powder in F344 rats (Niho et al., 1999). No relevant effects were seen up to the highest dose of 5000 mg/kg bw. No information on the source of chitin was provided in the study.

Considering the history of consumption of *A. domesticus*, the toxicological studies, the compositional information and the production process, the Panel considers that there is no concern regarding the toxicity of the NF. Therefore, no additional toxicological studies are required.

3.11 | Allergenicity

The Panel has previously considered that the consumption of *A. domesticus* might induce primary sensitisation to *A. domesticus* proteins. The Panel also considered that allergic reactions may occur in subjects allergic to crustaceans, mites and molluscs (cross-reactivity) (EFSA NDA Panel, 2021, 2022).

Chitin has been shown to activate a variety of innate (eosinophils, macrophages) and adaptive immune cells (IL-4/IL-13 expressing T helper type-2 lymphocytes) after intranasal or intraperitoneal administration and this implies the potential to promote hypersensitivity (Komi et al., 2018).

From literature research, the panel has noted that additional allergens may end up in the NF, if these allergens are present in the substrate fed to the insects. This may include allergens listed in Annex II of Regulation (EU) No 1169/2011.

4 | DISCUSSION

The NF which is subject of the application is house cricket (*Acheta domesticus*), in the form of powder. The production process is sufficiently described and does not raise safety concerns. The panel considers that the NF is sufficiently characterised. The NF consists mainly of protein, fat, dietary fibre (mainly chitin) and inorganic matter. The concentration of contaminants in the NF depends on the occurrence of these substances in the insect feed. Provided that applicable EU legislation regarding feed is followed, the consumption of the NF does not raise safety concerns.

The panel notes that there are no safety concerns regarding stability if the NF complies with the proposed specification limits during its entire shelf-life.

The applicant intends to market the NF as an ingredient in several food products. The target population is the general population. The highest intake estimate per kg bw basis was calculated for other children (3 to < 10 years old) at 1308 mg NF/kg bw per day at the 95th percentile of the intake distribution.

The panel notes that consumption of the NF under the proposed uses and use levels does not contribute substantially to the total dietary exposure of analysed undesirable substances (heavy metals, toxins).

The protein from the NF has a PDCAAS value of 0.53 for children aged 6 months to 3 years, with sulfur amino acids (methionine + cysteine) being the limiting amino acids. The panel notes that the protein concentrations in the NF are overestimated due to the presence of non-protein nitrogen of chitin. The panel also notes that the applicant assessed protein quality of the NF by PDCAAS values calculated using digestibility of crude protein instead of true protein. The values provided may therefore not accurately reflect the protein quality of the NF. Provided that the NF would not be the sole source of dietary protein, that it is integrated into a varied and mixed diet, and considering that the average protein intake in the EU population is high and frequently above the DRVs (EFSA NDA Panel, 2012), the consumption of the NF is not expected to negatively impact protein nutrition.

None of the existing upper levels of the analysed micronutrients are expected to be exceeded considering the proposed uses and use levels.

The reported concentrations of the antinutritional factors in the NF are comparable to those in other foods. The panel considers that chitin is not expected to be digested in the small intestine of humans to any significant degree and is assumed to be excreted mainly unchanged. Taking into account the composition of the NF and the proposed conditions of use, the panel concludes that the consumption of the NF is not nutritionally disadvantageous. The panel notes that no genotoxicity and no subchronic toxicity studies were provided by the applicant. No safety concerns arise from the history of use and toxicological information of *A. domesticus*, or from the compositional data of the NF. The panel considers that the consumption of the NF might trigger primary sensitisation to *A. domesticus* protein. The Panel also considers that allergic reactions may occur in subjects allergic to crustaceans, mites and molluscs (cross-reactivity). Additionally, the panel notes that allergens from the feed (e.g. gluten) might be present in the NF.

5 | CONCLUSIONS

The Panel concludes that the NF is safe under the proposed uses and use levels. In addition, the Panel notes that allergic reactions may occur upon consumption.

5.1 | Protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283

The Panel could not have reached the conclusion on the safety of the NF under the proposed conditions of use without the data claimed as proprietary by the applicant (study to identify the identity of the NF, production process and feed composition, batch-to-batch analyses of compositional data, nutritional information and digestibility study).

6 | RECOMMENDATION

The Panel recommends that research should be undertaken on the allergenicity to *A. domesticus*, including cross-reactivity to other allergens.

7 | STEPS TAKEN BY EFSA

1. On 26/01/2022 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of *Acheta domesticus* flour as a Novel Food Ref. Ares (2022) 600833.
2. On 26/01/2022, a valid application on *Acheta domesticus* flour, which was submitted by Società Agricola Italian Cricket Farm S.r.l., was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2020/1860) and the scientific evaluation procedure was initiated.
3. On 16/05/2022, EFSA received a letter from the European Commission with the revised request for a scientific opinion on *Acheta domesticus* powder as a novel food Ref Ares (2022)3691415.
4. On 18/05/2022, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
5. On 05/05/2023, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
6. On 21/07/2023, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
7. On 09/01/2024, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
8. On 26/01/2024, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
9. On 21/04/2024, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
10. During its meeting on 26/06/2024, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of *Acheta domesticus* powder as a NF pursuant to Regulation (EU) 2015/2283.

ABBREVIATIONS

A.	*Acheta*
AAS	Atomic Absorption Spectrometry
ACFS	Thailand's National Bureau of Agricultural Commodity and Food Standards
AdDV	*Acheta domesticus* Densovirus
ADF	Acid Detergent Fibre
ADL	Acid Detergent Lignin
ADME	Absorption, distribution, metabolism and excretion
AFNOR	Association Française de Normalisation
AGRI	Tentamus Agriparadigma S.r.l.
ANFs	Antinutritional factors
AOAC	Association of Official Analytical Chemists
ASLTO3	Azienda Sanitaria Locale Torino 3

BIOHAZ	Panel on Biological Hazards
bw	body weight
CFU	Colony Forming Units
CHL-IU	Chinese Hamster Lung
CONTAM	Panel on Contaminants in the Food Chain
CrPV	Cricket Paralysis Virus
DRVs	Dietary Reference Values
DIPP	Diabetes Prediction and Prevention Nutrition Study
EN	Comité Européen de Normalisation
EPA	US Environmental Protection Agency
FAO	Food and Agriculture Organization
FSANZ	Food Standards Australia New Zealand
GBIF	Global Biodiversity Information Facility
GC/MS/MS	Gas Chromatography/tandem Mass Spectrometry
GMO	Genetically Modified Organism
HACCP	Hazard Analysis Critical Control Points
HPLC-DAD	High Performance Liquid Chromatography with Diode Array Detection
IAC-RPLC/FD	Immuno Affinity Chromatography Reversed Phase Liquid Chromatography with Fluorescence Detection
ICP-AES	Inductively Coupled Plasma-Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IC-AD	Ion Chromatography with Amperometric Detection
ICR	Institute for Cancer Research
IL-4	Interleukin-4
IL-13	Interleukin-13
IM	Internal Method
ISO	International Organization for Standardization
ISTISAN	Istituto Superiore di sanita
LOQ	Limit of Quantification
LC-MS-MS	Liquid Chromatography-tandem Mass Spectrometry
MLs	Maximum levels
Mn	Manganese
MUFA	Monounsaturated Fatty Acids
N	Nitrogen
NDA	Panel on Nutrition, Novel Foods and Food Allergens
ND	Not Detected
NF	Novel Food
NIF	Nutrition & Food Innovation Unit
OECD	Organisation for Economic Co-operation and Development
ORCID	Open Researcher and Contributor ID
P95	95th percentile
PCBs	Polychlorinated Biphenyls
PDCAAS	Protein Digestibility Corrected Amino Acid Score
PDR	People's democratic Republic
PmergDNV	Penaeus merguiensis densovirus
PUFA	Polyunsaturated Fatty Acids
SC	Scientific Committee
TAMC	Total Aerobic Microbial Count
TYMC	Total Yeast and Mould Count
UB	Upper Bound
UCT	University of Chemistry and Technology (of Prague)
UHPLC-MS	Ultra High Performance Liquid Chromatography - Mass Spectrometry
UNI	Ente nazionale italiano di unificazione
US	United States
WG	Working Group
w/w	weight per weight
WHO-PCDD/F-PBC-TEQ	Sum of Polychlorinated Dibenzodioxins, Polychlorinated Dibenzofurans, Polychlorinated Biphenyls expressed as World Health Organization toxic equivalent

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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REFERENCES

ACFS (Thailand's National Bureau of Agricultural Commodity and Food Standards). (2017). Good agricultural practices for cricket farm, Thai Agricultural Standard TAS 8202–2017.

Anankware, J. P., Osekre, E. A., Obeng-Ofori, D., & Khamala, C. (2016). Identification and classification of common edible insects in Ghana. *International Journal of Entomology Research*, *1*, 33–39.

Anastopoulos, I., Bhatnagar, A., Bikiaris, D. N., & Kyzas, G. Z. (2017). Chitin adsorbents for toxic metals: A review. *International Journal of Molecular Sciences*, *18*, 114.

Andersen, G., Marcinek, P., Sulzinger, N., Schieberle, P., & Krautwurst, D. (2019). Food sources and biomolecular targets of tyramine. *Nutrition Reviews*, *77*, 107–115.

Baye, K., Guyot, J. P., & Mouquet-Rivier, C. (2017). The unresolved role of dietary fibres on mineral absorption. *Critical Reviews in Food Science and Nutrition*, *57*, 949–957.

Boulos, S., Tännler, A., & Nyström, L. (2020). Nitrogen-to-protein conversion factors for edible insects on the swiss market: T. Molitor, A. Domesticus, and L. migratoria. *Frontiers in Nutrition*, *57*, 89.

Codex Alimentarius Commission. (2010). Development of regional standard for Edible Crickets and their products.17th CCASIA - CRD 8. Bali, Indonesia. 22–26 November 2010. https://www.fao.org/fao-who-codexalimentarius/meetings/detail?meeting=CCASIA&session=17

Durst, P. B., & Hanboonsong, Y. (2015). Small-scale production of edible insects for enhanced food security and rural livelihoods: Experience from Thailand and Lao People's Democratic Republic. *Journal of Insects as Food and Feed*, *1*, 25–31.

EFSA (European Food Safety Authority). (2011). Use of the EFSA comprehensive European food consumption database in exposure assessment. *EFSA Journal*, *9*(3), 2097. https://doi.org/10.2903/j.efsa.2011.2097

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards). (2011). Scientific opinion on scientific Opinion on risk-based control of biogenic amine formation in fermented foods. *EFSA Journal*, *9*(10), 2393. https://doi.org/10.2903/j.efsa.2011.2393

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain). (2019). Scientific opinion on the evaluation of the health risks related to the presence of cyanogenic glycosides in foods other than raw apricot kernels. *EFSA Journal*, *17*(4), 5662. https://doi.org/10.2903/j.efsa.2019.5662

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition, and Allergies). (2010a). Scientific opinion on the safety of chitin-glucan as a novel food ingredient. *EFSA Journal*, *8*(7), 1687. https://doi.org/10.2903/j.efsa.2010.1687

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition, and Allergies). (2010b). Scientific opinion on dietary reference values for carbohydrates and dietary fibre. *EFSA Journal*, *8*(3), 1462. https://doi.org/10.2903/j.efsa.2010.1462

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2012). Scientific opinion on dietary reference values for protein. *EFSA Journal*, *10*(2), 2557. https://doi.org/10.2903/j.efsa.2012.2557

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2016). Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. *EFSA Journal*, *14*(11), 4594. https://doi.org/10.2903/j.efsa.2016.4594

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2021). Scientific Opinion on the safety of frozen and dried formulations from whole house crickets (Acheta domesticus) as a Novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, *19*(8), 6779. https://doi.org/10.2903/j.efsa.2021.6779

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2022). Scientific Opinion on the safety of partially defatted house cricket (*Acheta domesticus*) powder as a Novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, *20*(5), 7258. https://doi.org/10.2903/j.efsa.2022.7258

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2023). Scientific opinion on the tolerable upper intake level for manganese. *EFSA Journal*, *21*(12), e8413. https://doi.org/10.2903/j.efsa.2023.8413

EFSA Scientific Committee. (2015). Risk profile related to production and consumption of insects as food and feed. *EFSA Journal*, *13*(10), 4257. https://doi.org/10.2903/j.efsa.2015.4257

Eguchi, M. (1993). Protein protease inhibitors in insects and comparison with mammalian inhibitors. *Comparative Biochemistry and Physiology Part B: Comparative Biochemistry*, *105*, 449–456.

FAO (Food and Agriculture Organization). (2013). Dietary protein quality evaluation in human nutrition: Report of an FAO expert consultation. In *Food and nutrition paper; 92*. FAO.

Fernandez-Cassi, X., Söderqvist, K., Bakeeva, A., Vaga, M., Dicksved, J., Vagsholm, I., Jansson, A., & Boqvist, S. (2020). Microbial communities and food safety aspects of crickets (Acheta domesticus) reared under controlled conditions. *Journal of Insects as Food and Feed*, *6*, 429–440.

Franco, L. D. O., Maia, R. D. C. C., Porto, A. L. F., Messias, A. S., Fukushima, K., & Campos-Takaki, G. M. D. (2004). Heavy metal biosorption by chitin and chitosan isolated from Cunninghamella elegans (IFM 46109). *Brazilian Journal of Microbiology*, *35*, 243–247.

FSANZ (Food Standards Australia New Zealand). (2021). Novel food - Record of views formed in response toinquiries. https://www.foodstandards.gov.au/industry/novel/novelrecs/Pages/default.aspx

GBIF Secretariat. (2022). *Acheta domesticus* (Linnaeus, 1758) in GBIF Secretariat (2022). GBIF Backbone Taxonomy. Checklist dataset. https://doi.org/10.15468/39omei, GBIF.org

Gupta, Y. P. (1987). Anti-nutritional and toxic factors in food legumes: A review. *Plant Foods for Human Nutrition*, *37*, 201–228.

Hahn, T., Roth, A., Febel, E., Fijalkowska, M., Schmitt, E., Arsiwalla, T., & Zibek, S. (2018). New methods for high-accuracy insect chitin measurement. *Journal of the Science of Food and Agriculture*, *98*, 5069–5073.

Halloran, A., Caparros, M. R., Oloo, J., Weigel, T., Nsevolo, M. P., & Francis, F. (2018). Comparative aspects of cricket farming in Thailand, Cambodia, Lao People's Democratic Republic, Democratic Republic of the Congo and Kenya. *Journal of Insects as Food and Feed*, *4*, 101–114.

Hanboonsong, Y., & Durst, P. B. (2014). *Edible insects in Lao PDR*. RAP PUBLICATION. Food and Agriculture Organization of the United Nations.

Hanboonsong, Y., Jamjanya, T., & Durst, P. B. (2013). *Six-legged livestock: Edible insect farming, collection and marketing in Thailand*. Food and Agriculture Organization of the United Nations. Regional Office for Asia and the Pacific, Bangkok.

Health Canada. (2021). List of non-novel determinations for food and food ingredients. https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/requesting-novelty-determination/list-non-novel-determinations.html

Holmes, R. P., & Kennedy, M. (2000). Estimation of the oxalate content of foods and daily oxalate intake. *Kidney International*, *57*, 1662–1667.

Janssen, R. H., Vincken, J. P., van den Broek, L. A., Fogliano, V., & Lakemond, C. M. (2017). Nitrogen-to-protein conversion factors for three edible insects: Tenebrio molitor, Alphitobius diaperinus, and Hermetia illucens. *Journal of Agricultural and Food Chemistry*, *65*, 2275–2278.

Komi, D. E. A., Sharma, L., & Cruz, C. S. D. (2018). Chitin and its effects on inflammatory and immune responses. *Clinical Reviews in Allergy and Immunology*, *54*, 213–223.

La Fauce, K. A., & Owens, L. (2008). The use of insects as a bioassay for Penaeus merguiensis densovirus (PmergDNV). *Journal of Invertebrate Pathology*, *98*, 1–6. https://doi.org/10.1016/j.jip.2007.11.006

Maciel-Vergara, G., & Ros, V. I. D. (2017). Viruses of insects reared for food and feed. *Journal of Invertebrate Pathology*, *147*, 60–75. https://doi.org/10.1016/j.jip.2017.01.013

Meyer-Rochow, V. B., Gahukar, R. T., Ghosh, S., & Jung, C. (2021). Chemical composition, nutrient quality and acceptability of edible insects are affected by species, developmental stage, gender, diet, and processing method. *Food*, *10*, 1036.

Muñoz-Esparza, N. C., Latorre-Moratalla, M. L., Comas-Basté, O., Toro-Funes, N., Veciana-Nogués, M. T., & Vidal-Carou, M. C. (2019). Polyamines in food. *Frontiers of Nutrition*, *11*, 108.

Muthukrishnan, S., Merzendorfer, H., Arakane, Y., & Yang, Q. (2016). Chitin metabolic pathways in insects and their regulation. In E. Cohen & B. Moussian (Eds.), *Extracellular composite matrices in arthropods*. Springer. https://doi.org/10.1007/978-3-319-40740-1_2

Muzzarelli, R. A. A., Boudrant, J., Meyer, D., Manno, N., DeMarchis, M., & Paoletti, M. G. (2012). Current views on fungal chitin/chitosan, human chitinases, food preservation, glucans, pectins and inulin: A tribute to Henri Braconnot, precursor of the carbohydrate polymers science, on the chitin bicentennial. *Carbohydrate Polymers*, *87*, 995–1012.

Mwangi, M. N., Oonincx, D. G. A. B., Hummel, M., Utami, D. A., Gunawan, L., Veenenbos, M., Zeder, C., Cercamondi, C. I., Zimmermann, M. B., van Loon, J. J. A., Dicke, M., & Melse-Boonstra, A. (2022). Absorption of iron from edible house crickets: A randomized crossover stable-isotope study in humans. *The American Journal of Clinical Nutrition*, *116*(4), 1146–1156. https://doi.org/10.1093/ajcn/nqac223

Niho, N., Tamura, T., Toyoda, K., & Hirose, M. (1999). A 13-week subchronic toxicity study of chitin in F344 rats. Kokuritsu Iyakuhin Shokuhin Eisei Kenkyujo Hokoku. *Bulletin of National Institute of Health Sciences*, *117*, 129–134.

Nishimune, T., Watanabe, Y., Okazaki, H., & Akai, H. (2000). Thiamin is decomposed due to Anaphe spp. entomophagy in seasonal ataxia patients in Nigeria. *The Journal of Nutrition*, *130*, 1625–1628.

Paoletti, M. G., Norberto, L., Cozzarini, E., & Musumeci, S. (2009). Role of chitinases in human stomach for chitin digestion: AMCase in the gastric digestion of chitin and chit in gastric pathologies.

Ramos-Elorduy, J. (2009). Anthropo-entomophagy: Cultures, evolution and sustainability. *Entomological Research*, *39*, 271–288.

Rao, B. S. N., & Prabhavathi, T. (1982). Tannin content of foods commonly consumed in India and its influence on ionizable iron. *Journal of the Science of Food and Agriculture*, *33*, 89–96.

Reggi, S., Giromini C., Dell'Anno M., Baldi A., Rebucci R., Rossi L., 2020. *In vitro digestion of chestnut and quebracho tannin extracts: Antimicrobial effect, antioxidant capacity and cytomodulatory activity in swine intestinal ipec-j2 cells animals*, *10*(2), 195.

Roberts, G. A. (1992). *Chitin chemistry*. Macmillan International Higher Education.

Schlemmer, U., Frølich, W., Prieto, R. M., & Grases, F. (2009). Phytate in foods and significance for humans: Food sources, intake, processing, bioavailability, protective role and analysis. *Molecular Nutrition & Food Research*, *53*(S2), S330–S375.

Shantibala, T., Lokeshwari, R. K., & Debaraj, H. (2014). Nutritional and antinutritional composition of the five species of aquatic edible insects consumed in Manipur, India. *Journal of Insect Science*, *14*, 14.

Shapiro-Ilan, D. I., Mbata, G. N., Nguyen, K. B., Peat, S. M., Blackburn, D., & Adams, B. J. (2009). Characterization of biocontrol traits in the entomopathogenic nematode Heterorhabditis georgiana (Kesha strain), and phylogenetic analysis of the nematode's symbiotic bacteria. *Biological Control*, *51*, 377–387.

UCT (University of Chemistry and Technology of) Prague, EcoMole, Dibusz, K., & Vejvodova, P. (2020). Systematic literature search to assist EFSA in the preparatory work for the safety assessment of novel food applications and traditional food notifications. *EFSA Supporting Publication*, EN-1774, 72 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1774

Van den Berg, M., Birnbaum, L. S., Denison, M., De Vito, M., Farland, W., Feeley, M., Fiedler, H., Hakansson, H., Hanberg, A., Haws, L., Rose, M., Safe, S., Schrenk, D., Tohyama, C., Tritscher, A., Tuomisto, J., Tysklind, M., Walker, N., & Peterson, R. E. (2006). The 2005 World Health Organization reevaluation of human and mammalian toxic equivalency factors for dioxins and dioxin-like compounds. *Toxicological Sciences*, 93, 223–241. https://doi.org/10.1093/toxsci/kfl055

WG NF. (2024). Minutes of the 154th working group on novel foods, 2024. https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/nda#working-groups

Yasuki, M., Kiyo, S., Yuuto, N., Kenta, N., Akira, M., Yuuki, M., Akane, Y., Nobuo, N., & Atsushi, O. (2022). Toxicity of house cricket (*Acheta domesticus*) in mice. *Clinical and Medical Biochemistry*, *8*, 128.

Yen, A. L. (2015). Insects as food and feed in the Asia pacific region: Current perspectives and future directions. *Journal of Insects as Food and Feed*, *1*, 33–55.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Detailed amino profile analysis of the NF

Amino acid (mg/g protein)	Batch number					Average	FAO (2013)[a]	FAO (2013)[b]
	#1	#2	#3	#4	#5			
Essential								
Histidine	23.57	23.57	23.87	23.57	23.12	23.54	20	16
Leucine	74.02	79.43	79.13	78.68	77.63	77.78	66	61
Isoleucine	42.64	45.05	44.89	44.89	44.44	44.38	32	30
Lysine	57.51	61.56	62.16	61.86	61.11	60.84	57	48
Methionine[c]	17.27	16.37	16.82	16.67	16.52	16.73	27	23
Phenylalanine[d]	35.89	35.59	37.24	36.19	35.14	36.01	52	41
Threonine	39.64	40.54	40.24	40.84	39.49	40.15	31	25
Tryptophan	7.21	8.86	9.31	9.01	9.01	8.68	8.5	6.6
Valine	58.71	60.96	60.81	63.81	60.06	60.87	43	40
Conditionally essential								
Arginine	63.81	67.42	67.72	67.72	65.77	66.49		
Cysteic acid	8.41	8.63	8.63	8.93	8.63	8.65		
Glycine	53.60	57.36	57.36	56.61	56.01	56.19		
Proline	57.36	60.66	60.21	59.46	58.56	59.25		
Tyrosine	54.35	57.06	56.46	57.51	57.06	56.49		
Non-essential								
Alanine	120.87	100.30	100.15	98.50	97.45	103.45		
Aspartic acid	88.14	94.74	94.74	94.44	92.64	92.94		
Glutamic acid	110.96	118.02	117.42	116.67	115.17	115.65		
Serine	46.40	49.10	49.55	49.85	48.80	48.74		

[a]Recommended amino acid scoring patterns for children (6 months to 3 years).

[b]Recommended amino acid scoring patterns for other child, adolescents and adults.

[c]Methionine + cysteine.

[d]Phenylalanine + tyrosine.

APPENDIX B

Fatty acid profile analysis of the NF

Fatty acids (g/100 g fatty acids)	Batch number				
	#1	#2	#3	#4	#5
Linoleic acid (C18:2)	37.00	37.80	37.50	38.00	37.80
Palmitic acid (C16:0)	27.10	23.70	23.90	23.80	23.80
Oleic acid (18:1)	24.10	24.00	24.00	24.10	23.80
Stearic acid (C18:0)	9.70	9.30	9.50	9.20	9.30
Gamma linolenic acid (C18:3)	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Saturated fatty acid	37.57	34.21	35.70	35.31	34.81
MUFA	24.38	24.55	24.50	24.65	24.33
PUFA	38.10	40.34	39.85	40.47	40.28
Trans fatty acid	< 0.10	0.55	0.49	0.55	0.52
Omega 3	0.11	1.48	1.72	1.48	1.82
Omega 6	37.00	38.16	37.50	38.30	37.80

Abbreviations: MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids.

ANNEX A

Dietary exposure estimates to the Novel Food for each population group from each EU dietary survey

Annex A is available under the Supporting Information section on the online version of the scientific output.