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SCIENTIFIC OPINION

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# Safety of HelixComplex snail mucus (HSM) 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 HelixComplex Snail Mucus (HSM) as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF consists of snail mucus collected from *Helix aspersa maxima* and is proposed to be used by adults as a food supplement. The data provided by the applicant about the composition and stability of the NF together with the report of the subchronic toxicity study were overall considered unsatisfactory. The Panel noted inconsistencies in the reporting of the certificates of analysis and of the data on the subchronic toxicity provided by the applicant. Owing to these deficiencies, the Panel cannot establish a safe intake level of the NF. The Panel concludes that the safety of the NF has not been established.

**KEYWORDS**

food supplement, novel foods, snail, snail mucus

# CONTENTS

# 1 | INTRODUCTION

## 1.1 | Background and terms of Reference as provided by the requestor

On 2 May 2019, the company HelixPharma Srl submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise the placing on the market of HelixComplex Snail Mucus (HSM) as a novel food (NF).

The application requests to authorise the use of HSM in food supplements, excluding food supplements for infants and young children.

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 HSM.

# 2 | DATA AND METHODOLOGIES

## 2.1 | Data

The safety assessment of this NF is based on data supplied and information submitted by the applicant following EFSA's request for supplementary information.

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.[2]

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.

## 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.

No additional information was retrieved by literature search following a search strategy and standard operating procedure as described by Dibusz and Vejvodova (2020).

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 snail mucus collected from *Helix aspersa maxima*. The NF is produced by collecting the snail mucus via a patent-controlled supply chain and consists mainly of proteins, mucopolysaccharides and minerals. The NF is proposed to be used as food supplement supplied in a liquid form. The target population is the general adult population, excluding pregnant women.

The NF falls under Article 3(2)(a)(v): food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union, as defined in Regulation (EU) 2015/2283.

## 3.2 | Identity of the NF

The NF is an aqueous solution (97%) containing snail mucus collected from *Helix aspersa maxima*. The NF contains proteins, glycosaminoglycans, hyaluronic acid, polyphenols, sugars and minerals.

[1]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.

[2]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.

## 3.3 | Production process

According to the information provided, the NF is produced in line with the Hazard Analysis and Critical Control Points (HACCP) principles and the applicant provided accreditation from the 'Emilia Romagna Regional Sanitary Service', but no good manufacturing practice (GMP) accreditation has been provided.

The NF is produced through a patent-controlled production (Patent n. FE102017000117547 and WO 2013/011371).

The livestock is provided by the 'Istituto Internazionale di Elicicoltura di Cherasco (CN), Italy'. Snails are grown outdoors in enclosures where selected vegetables are planted in order to enhance the characteristics of the produced secretion, and to minimise the organoleptic variability of the mucus. Snails conduct their entire life cycle in the enclosures, where they are placed back after each extraction session, to be used for successive sessions or to be sold for food purposes.

The extraction takes place in well-defined time windows according to the biological cycle of snails (generally spring and autumn). The snails are collected manually in the morning and placed in ventilated boxes.

After the collection from the field, snails are washed and placed in metal or plastic boxes which are positioned in an automatic machine and moved in a series of chambers where either a heated saline solution (5% NaCl), or water (tap water) is nebulised (depending on in which chamber the box is), in order to irritate the snails and to cause the release of the secretion. During the cycles, the mucus released from the snails is collected in a special container for liquid foodstuffs.

After treatment, the animals pass under another shower in order to rehydrate and to recover the excreted fluids. At the end of the cycle, they are re-introduced into the field.

The extracted secretion is pre-filtered, before being collected in the container for food use, on 40-μm porosity membranes, in order to remove gross impurities and then microfiltered in a sterile environment on 0.22-μm membranes. After and during bottling, some samples are collected for subsequent analyses.

The NF is then stored at 4°C and applicant claims that no additional preservatives are used.

The Panel considers that the production process is sufficiently described.

## 3.4 | Compositional data

The NF consists of 97% of water and 3% of proteins, glycosaminoglycans, hyaluronic acid and minerals.

In order to confirm that the manufacturing process is reproducible and adequate to produce on a commercial scale a product with certain characteristics, the applicant provided analytical information for five independent batches of the NF. The first certificates of analysis (CoAs) submitted by the applicant were incomplete, inconsistent and with discrepancies. Therefore, following EFSA's request dated 16 March 2020 and a clarification request on 12 June 2020, the applicant provided additional data on 21 May 2020 and clarification on 2 July 2020. Discrepancies were still detected in the reported values for some parameters in the CoAs submitted for identical batches. These data were therefore deemed unsatisfactory with respect to the composition of the NF triggering the need to ask for additional toxicological data.

On 19 June 2023, the applicant submitted additional CoAs for five new batches which replaced the ones previously provided. A clarification (sent by EFSA on 7 July 2023) was requested and the applicant replied on 3 August 2023. The final compositional data submitted by the applicant for the five new batches are presented in Table 1.

**TABLE 1** Batch to batch analysis of the NF.

| | Batches | | | | | |
|---|---|---|---|---|---|---|
| **Parameter** | **1** | **2** | **3** | **4** | **5** | **Method of analysis** |
| Appearance | Clear | Clear | Clear | Clear | Clear | Visual |
| Colour | Light yellow | Intense yellow | Light yellow | Light yellow | Light yellow | Visual |
| Odour | Odourless | Odourless | Odourless | Odourless | Odourless | |
| pH | 7.54 | 7.34 | 7.89 | 7.59 | 7.32 | pH meter |
| Viscosity (mPa/s) | 1.10 | 1.09 | 1.00 | 1.11 | 1.04 | Viscosimetry |
| Dry matter (g/100 g) | 1.6 | 2.2 | 2.0 | 1.7 | 1.8 | Gravimetry |
| Water (g/100 g) | 98.4 | 97.8 | 98.0 | 98.3 | 98.2 | Gravimetry |
| Sodium (mg/kg) | 4597 | 4593 | 4460 | 4776 | 4316 | Atomic Absorption |
| Protein (mg/L) | 189 | 257 | 149 | 266 | 159 | Bradford Assay |
| Glycosaminoglycan, sulfated (mg/L) | 49 | 82 | 39 | 59 | 65 | Colorimetric method (DMMB) |
| Glycosaminoglycans, non-sulfated/ mucopolysaccharides (Hyaluronic acid equivalents) (mg/L) | 70 | 74 | 71 | 73 | 75 | Turbidimetric method (CTAB) |
| Glycolic acid (mg/L) | 100 | 107 | 68 | 87 | 78 | HPLC/UV |

**TABLE 1** (Continued)

| Parameter | Batches 1 | 2 | 3 | 4 | 5 | Method of analysis |
|---|---|---|---|---|---|---|
| Allantoin (mg/L) | 13 | 16 | 16 | 18 | 13 | HPLC/UV |
| Total polyphenols (mg/L) | 74 | 78 | 78 | 78 | 73 | Folin–Ciocalteu method |
| D-glucose/D-fructose (mg/L) | 20 | 9 | 24 | 20 | 17 | Enzymatic assay |
| **Minerals and heavy metals** | | | | | | ICP-MS analysis |
| Cadmium (mg/kg) | < 0.002 | < 0.002 | < 0.002 | < 0.002 | < 0.002 | MP 1288 rev 22 2022 |
| Calcium (mg/kg) | 64 ± 19 | 65 ± 19 | 52 ± 18 | 45 ± 18 | 35 ± 17 | MP 1289 rev 17 2022 |
| Chromium (mg/kg) | < 0.008 | < 0.008 | < 0.008 | < 0.008 | < 0.008 | MP 1288 rev 22 2022 |
| Iron (mg/kg) | < 1.0 | < 1.0 | < 0.33 | < 0.33 | < 0.33 | MP 1288 rev 22 2022 |
| Magnesium (mg/kg) | < 25 | < 25 | < 25 | < 25 | < 25 | MP 1289 rev 17 2022 |
| Manganese (mg/kg) | 0.070 ± 0.020 | 0.072 ± 0.021 | 0.043 ± 0.016 | 0.058 ± 0.019 | 0.041 ± 0.016 | MP 1288 rev 22 2022 |
| Mercury (mg/kg) | < 0.002 | < 0.002 | < 0.005 | < 0.002 | < 0.002 | MP 1288 rev 22 2022 |
| Nickel (mg/kg) | < 0.02 | < 0.02 | < 0.008 | < 0.02 | < 0.02 | MP 1288 rev 22 2022 |
| Lead (mg/kg) | < 0.002 | < 0.002 | < 0.005 | < 0.005 | < 0.002 | MP 1288 rev 22 2022 |
| Potassium (mg/kg) | 57 ± 20 | 62 ± 20 | 51 ± 19 | 43 ± 18 | 37 ± 18 | MP 1289 rev 17 2022 |
| Copper (mg/kg) | 0.052 ± 0.034 | 0.064 ± 0.035 | 0.071 ± 0.035 | < 0.05 | < 0.05 | MP 1288 rev 22 2022 |
| Zinc (mg/kg) | < 0.5 | < 0.2 | < 0.2 | < 0.2 | < 0.2 | MP 1288 rev 22 2022 |
| **Microbials** | | | | | | |
| Coliforms (CFU/mL) | < 1 | < 1 | < 1 | < 1 | < 1 | ISO 4832:2006 |
| *E. coli* (CFU/mL) | < 1 | < 1 | < 1 | < 1 | < 1 | ISO 16649-2:2001 |
| *Salmonella*/25 mL | Absent | Absent | Absent | Absent | Absent | ISO 6579:2002 |
| Staphylococci (CFU/mL) | < 1 | < 1 | < 1 | < 1 | < 1 | ISO 6888-2:1999 |
| *L. monocytogenes* (CFU/mL) | < 1 | < 1 | < 1 | < 1 | < 1 | ISO 11290-2:2017 |
| Total plate count (CFU/mL) | Not reported | Not reported | Not reported | Not reported | Not reported | ISO 4833-2:2013 |
| Yeast and mould (CFU/mL) | Not reported | Not reported | Not reported | Not reported | Not reported | ISO 21527-1:2008 |
| **Aflatoxins** | | | | | | |
| Total aflatoxin (μg/kg) | < 2 | < 2 | < 2 | < 2 | < 2 | MP 2287 rev 12,021 HPLC/MS |
| Aflatoxin B1 (μg/kg) | < 0.5 | < 0.5 | < 0.5 | < 0.5 | < 0.5 | MP 2287 rev 12,021 HPLC/MS |
| Aflatoxin B2 (μg/kg) | < 0.5 | < 0.5 | < 0.5 | < 0.5 | < 0.5 | MP 2287 rev 12,021 HPLC/MS |
| Aflatoxin G1 (μg/kg) | < 0.5 | < 0.5 | < 0.5 | < 0.5 | < 0.5 | MP 2287 rev 12,021 HPLC/MS |
| Aflatoxin G2 (μg/kg) | < 0.5 | < 0.5 | < 0.5 | < 0.5 | < 0.5 | MP 2287 rev 12,021 HPLC/MS |

The Panel noted that no data on total bacterial, yeast and moulds counts have been provided for the new batches.

Information was provided on the accreditation of the laboratories that conducted the analyses presented in the application.

The Panel notes that the CoAs provided for different batches were inconsistent, the variability of most parameters (e.g. proteins) is high as well as the standard deviations for calcium, copper, manganese and potassium, and data on the total bacterial, yeast and moulds counts have not been provided for the final batches.

Considering the repeated alterations made in the CoAs of the NF over the course of the risk assessment, and considering the reporting discrepancies herein described, and the missing information the Panel considers that the information provided on the composition is not sufficient to characterise the NF.

### 3.4.1 | Stability

The applicant performed stability tests with five independently produced batches of the NF. The tests were carried out at normal storage conditions at room temperature for periods of 6, 12 and 24 months. The batches were analysed for viscosity, appearance and precipitate. No information regarding stability of the chemical components was provided.

The applicant provided a microbiological analysis for which EFSA requested additional information on 16 March 2020, 12 June 2020 and 23 September 2022. The replies provided by the applicant on 21 May 2020, 2 July 2020 and 19 June 2023 did not entirely address EFSA's requests.

At 24 months, formation of an unidentified precipitate was observed. Based on these data, the physical stability has been demonstrated up to 12 months at room temperature whereas the microbiological stability cannot be fully assessed.

The Panel considers that the data provided are insufficient to draw conclusions on the stability of the NF.

## 3.5 | Specifications

Owing to the shortcomings about the composition (Section 3.4) and stability (Section 3.4.1) of the NF, the Panel decided not to report specifications for the NF.

## 3.6 | History of use of the NF and/or of its source

There is no history of use of the NF; however, snails and snail products do have a history of consumption.

The species *Helix pomatia*, *Helix aspersa maxima*, *Helix aspersa Muller* and *Cornu aspersum* are some of the most common snail species used as food.

Helicidine®, an extract from *Helix pomatia L*. has been authorised by the French National Authority for Health as anti-tussive medicinal product. Helix Med (snail mucus) and Alsiroyal (snail syrup) are commercialised for wet and dry cough and fluidification of airway mucus.

## 3.7 | Proposed uses and use levels and anticipated intake

The applicant intends to market the NF for use as food supplements in form of syrup, at a maximum dose of three table spoons a day corresponding to ca. 45 mL/day, which corresponds to c.a. 0.64 mL/kg bw per day for adults.

### 3.7.1 | Target population

The target population proposed by the applicant is adult population excluding pregnant women.

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

The applicant provided a permeability assay performed *in vitro* with Caco2 cells to predict the *in vivo* absorption. The Panel considered this study not relevant to assess the ADME of the NF.

## 3.9 | Nutritional information

The Panel considers, taking into account the composition of the NF (water > 97%) and the proposed conditions of use with a maximum daily intake of 45 mL/day, that the consumption of the NF is not nutritionally disadvantageous.

## 3.10 | Toxicological information

The applicant provided one *in vitro* toxicological study, two genotoxicity studies and two animal studies performed not in compliance with the respective OECD guidelines and not in accordance with the OECD principles of good laboratory practice (GLP) (OECD, 1998).

Additionally, the applicant provided one bacterial mutation test and one *in vitro* micronucleus test in compliance with the respective OECD guidelines (TG 471 and 487) and following the OECD principles of GLP (OECD, 1998) (Table 2).

**TABLE 2** List of toxicological studies with the NF.

| Reference | Type of study | Test system | Dose |
|---|---|---|---|
| Study No. not specified; results are reported in the dossier under toxicological information | Cytotoxicity study at 24, 48, 72 h (Trypan blue and MTT) | MRC-5 human dermal fibroblasts | 4 µg–20 mg |
| Study No 250/2021 (Unpublished, 2021a) | *In vitro* mammalian cells micronucleus test (no-GLP, no-OECD TG 487) | Human lymphoblast TK6 cells | 60, 80 and 100 µL/mL |
| Study No. 12406-21en Lab4LIFE (Unpublished, 2021b) | Mutagenicity Ames test (no-GLP, no-OECD TG 471) | Salmonella typhimurium TA98, TA100, TA102, TA1535 and TA1537 | 250–5000 µg/plate |
| Study No. VBPL-GTX-340-G-U-2023 Vipragen (Unpublished, 2023b) | *In vitro* Micronucleus Test (GLP, OECD TG 487) | Chinese Hamster Ovary (CHO-K1) cells | 500, 1000 and 2000 µg/mL |
| Study No. VBPL-GTX-339-G-U-2023 Vipragen (Unpublished, 2023a) | Bacterial Reverse Mutation (GLP, OECD TG 471) | Salmonella typhimurium TA98, TA100, TA1535, TA1537 and E. coli uvrA pKM101 | 125–5000 µg/plate |
| Study from LTTA (Laboratorio per le tecnologie delle terapie avanzate) (Unpublished, 2021) | Acute, subacute and subchronic oral toxicity study (no-GLP, no-OECD TG 408) | Male mice CD-1 | Limit test at 2000 mg/kg bw per day |
| Study from LTTA (Laboratorio per le tecnologie delle terapie avanzate) (Unpublished, 2022) | Subchronic oral toxicity study (no-GLP, no-OECD TG 408) | Male and female mice CD-1 | 0, 500, 1000 and 2000 mg/kg bw per day |

### 3.10.1 | Genotoxicity

In their original submission, the applicant did not provide genotoxicity data on the NF. In response to EFSA's request (20 July 2020 and clarification on 9 August 2021) to comply with the EFSA scientific opinion on genotoxicity testing strategy (EFSA Scientific Committee, 2011), the applicant submitted on 20 July 2021 and 5 September 2022 two genotoxicity studies (Unpublished, 2021a, 2021b) not performed according to GLP and OECD guidelines. These data were therefore deemed unsatisfactory to assess the potential genotoxicity of the NF.

After EFSA's clarification request on 23 September 2022, the applicant submitted (on 19 June 2023) a bacterial reverse mutation and an *in vitro* micronuclei (MN) test in accordance with GLP and with the respective OECD guidelines (TG 471 and 487).

The bacterial reverse mutation test was performed with the NF in four histidine dependent strains of Salmonella typhimurium TA98, TA100, TA1535, TA1537 and one tryptophan-dependent strain of *E. coli* in the presence and absence of a metabolic activation (S9) (Unpublished, 2023a). A preliminary experiment and two main experiments were conducted. The preliminary test did not show precipitation of the test items or cytotoxicity up to a dose of 5000 µg/plate. Based on these data, one main experiment was performed using the plate incorporation treatment and one using the pre-incubation treatment with the NF at concentrations of 50, 150, 500, 1500 and 5000 µg/plate, in the presence and absence of S9. The NF did not cause an increase in the mean number of revertant colonies compared to the negative control (water) in any strains tested, both in the absence and in the presence of metabolic activation.

The NF was also evaluated for its potential to induce MN in Chinese Hamster Ovary (CHO-K1) cells. A main experiment was performed in duplicate and concentrations of 500, 1000 and 2000 µg/mL were selected on the basis of a preliminary cytotoxicity test where toxicity and precipitation were not detected up to the highest concentration tested. The cells were incubated with the NF at concentrations up to 2000 µg/mL for either 3 h and further incubated for 20 h in fresh medium with and without metabolic activation (short-term treatment), or for 20 h without metabolic activation (long-term treatment). No precipitation of the test material and cytotoxicity were detected up to the highest doses in any of the conditions applied. The positive control substances induced statistically significant increases in MN frequency compared to the negative control, although the values were slightly below the historical controls. The NF did not induce a statistically significant increase in the micronucleated cell frequency in Chinese Hamster Ovary-K1 (CHO-K1) cells compared to the control at any tested conditions.

Based on the results of these studies, the Panel considers that there are no concerns regarding genotoxicity for the NF.

### 3.10.2 | Acute and subacute toxicity

The applicant provided an acute and a subacute toxicity study in CD-1 mice, not performed according to GLP and OECD guidelines. The Panel considers that, in general, acute toxicity studies are not pertinent for the safety assessment of NFs.

### 3.10.3 | Subchronic toxicity

In the original submission, the applicant did not provide a subchronic toxicity study with the NF. Because of the incomplete and inconsistent compositional data, on 20 July 2020, EFSA requested to submit a 90-day study. In response, on 20 July 2021, the applicant submitted an acute, subacute and a 90-day toxicity study in male CD-1 mice as limit test at 2 g/kg per day oral gavage for 13 weeks (20 controls and 40 treated animals). The scope of the study did not correspond to the OECD TG 408 and it has not been performed according to GLP standards.

In response to EFSA's clarification request sent on 9 August 2021, the applicant submitted a new subchronic toxicity study on 5 September 2022 in ICR (CD-1) male and female mice, which again did not comply with the OECD guideline 408. The study was not performed in a GLP-certified facility, and thus was not compliant with GLP as required by Commission Implementing Regulation (EU) 2017/2469.

In addition, due to missing data, discrepancies and limitations in reporting the data, and poor quality of the study report, the applicant was asked to submit clarification on 23 September 2022 and on 7 July 2023 to which the applicant replied on 19 June 2023 and 3 August 2023, respectively. The final amended study provided by the applicant was performed in male and female ICR (CD-1) mice that received 0, 500, 1000 and 2000 mg/kg bw per day of the NF dissolved in water via gavage for 105 days.

No differences were detected between controls and treated animals for all reported parameters. However, there were inconsistency in the data for which no conclusion can be drawn.

The Panel noted that after all the clarification requests, there was still insufficient reporting (e.g. insufficient description of the methods and results, summary tables provided averaging male and female values, insufficient and limitation of histopathological evaluation, limitation in historical data).

Considering the lack of GLP certification of the laboratory in which the subchronic toxicity study was performed and the discrepancies in the reporting of the results, the Panel considers that the study cannot be a reliable source of information, hence cannot be used to assess the safety of the NF.

## 3.11 | Allergenicity

The Panel notes that the NF is composed of snail mucus (≤ 3%) with a protein content of ≤ 0.03%. However, according to the EFSA opinion on the evaluation of allergenic foods and food ingredients for labelling purposes (EFSA NDA Panel, 2014), land snails (including *Helix aspersa maxima*) belong to molluscs (*Mollusca phylum)*, which are included in Annex II of the Regulation (EU) No 1169/2011 and require mandatory labelling.

# 4 | DISCUSSION

The NF which is the subject of the application consists of snail mucus. It is proposed to be used by adults, excluding pregnant women, as a food supplement. The NF is produced from *Helix aspersa maxima* through a patent-controlled production process. Considering that the description of the composition of the NF has changed several times over the course of the risk assessment period as well as the shortcomings in reporting of the toxicological data, the Panel has concerns regarding the robustness, consistency of the data submitted by the applicant and their appropriateness for a safety assessment. Therefore, the Panel could not establish the safety of the NF.

# 5 | CONCLUSIONS

The Panel concludes that the safety of the NF has not been established.

# 6 | STEPS TAKEN BY EFSA

1. On 16 October 2019 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of HelixComplex Snail Mucus. Ref. Ares(2019)6405674.
2. On 16 October 2019, a valid application on HelixComplex Snail Mucus, which was submitted by Helixpharma S.r.l., was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2019/1077) and the scientific evaluation procedure was initiated.
3. On 16 March 2020, 4 May 2020, 20 May 2020, 12 June 2020, 20 July 2020, 9 August 2021, 23 September 2022, 7 July 2023, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4. On 1 May 2020, 4 May 2020, 21 May 2020, 2 July 2020, 20 July 2021, 5 September 2022, 19 June 2023, 3 August 2023 and 28 August 2023, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.

5. During its meeting on 29 November 2023, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of HelixComplex Snail Mucus as a NF pursuant to Regulation (EU) 2015/2283.

## ABBREVIATIONS

| | |
|---|---|
| ADME | Absorption, Distribution, Metabolism And Excretion |
| bw | body weight |
| CFU | Colony Forming Unit |
| CHO-K1 | Chinese Hamster Ovary-K1 |
| CoAs | Certificates of analysis |
| CTAB | Cetyltrimethylammonium Bromide Turbidimetric Method |
| DMMB | Dimethyl Methylene Blue |
| GLP | Good Laboratory Practice |
| GMP | Good Manufacturing Practice |
| HACCP | Hazard Analysis and Critical Control Points |
| HPLC/UV | High-Performance Liquid Chromatography-Ultraviolet |
| HSM | HelixComplex Snail Mucus |
| ICP-MS | Inductively Coupled Plasma-Mass Spectrometry |
| ICR | Institute of Cancer Research |
| ISO | International Organization For Standardization |
| MN | Micronucleus |
| MRC-5 | Medical Research Council cell strain 5 |
| MTT | 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide |
| NDA | Scientific Panel On Dietetic Products, Nutrition And Allergies |
| NF | Novel Food |
| OECD | Organisation For Economic Co-Operation and Development |
| OECD TG | OECD Guidelines for the Testing of Chemicals |
| S9 | Rat liver postmitochondrial fraction |
| UV | ultra-violet |

## 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

EFSA-Q-2019-00388

## COPYRIGHT FOR NON-EFSA CONTENT



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