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SCIENTIFIC OPINION

# Re-evaluation of argon (E 938) and helium (E 939) as food additives

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**Abstract**

The Panel on Food Additives and Flavourings (FAF) provides a scientific opinion re-evaluating the safety of the two food additives argon (E 938) and helium (E 939). Argon (Ar) and helium (He) are two noble gases, highly stable single atoms. Their chemical inertness is well known. Their physicochemical properties have served as a basis for their previous evaluations by SCF and JECFA, which have considered the use of these food additives safe even in the absence of a toxicological evaluation. No business operator or other interested party provided information in response to the call for data published by EFSA to support the re-evaluation of these two food additives with respect to their identity and specifications, manufacturing process (including the identification and quantification of potential impurities) and how they are applied to food to exert their technological function. One business operator replied to the call for data issued by EFSA reporting use levels of E 938 as a packaging gas in one food category. Based on their physicochemical properties, both gases are considered by the Panel to be of low toxicological concern when used as food additives. No information was available on the potential presence of impurities of toxicological concern resulting from the manufacturing process(es) applied to the production of the food additives E 938 and E 939. The Panel however noted that a minimum purity of 99.0% is required to comply with existing specifications. The Panel concluded that the use of argon (E 938) and helium (E 939) as food additives does not raise a safety concern. The Panel recommended an amendment of the existing EU specifications to introduce the respective CAS numbers.

**KEYWORDS**

argon, CAS No 7440-37-1, CAS No 7440-59-7, food additives, helium, noble gases, packaging gases

# CONTENTS

# 1 | INTRODUCTION

The present opinion deals with the re-evaluation of argon (E 938) and helium (E 939) when used as food additives.

## 1.1 | Background and Terms of Reference as provided by the European Commission

### 1.1.1 | Background

Regulation (EC) No 1333/2008[1] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union (EU). In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010.[2] This Regulation also foresees that food additives are re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee for Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU of 2001.[3] The report "Food additives in Europe 2000"[4] submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) No 257/2010 the 2003 Terms of References are replaced by those below.

### 1.1.2 | Terms of Reference

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

## 1.2 | Additional information

### 1.2.1 | Existing authorisations and evaluations

Argon (E 938) and helium (E 939) are authorised as food additives in the EU in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.[5]

The use of argon (E 938) as food additive has been previously evaluated by the EU Scientific Committee for Food (SCF) in 1990, jointly with other packaging gases and propellants. The SCF opinion states the following: '*This rare gas is an elemental constituent of air. It is completely inert chemically. The Committee considers the establishment of an ADI unnecessary. Its use as a packaging gas and propellant is* ***toxicologically acceptable*** *provided a food grade specification is available*'.

EFSA could not retrieve a previous evaluation by the SCF of helium (E 939), however the Panel assumed that similar considerations to those made for argon may have applied to its evaluation.

Specifications for both argon (INS No 938) and helium (INS No 939) were established at the 53rd JECFA meeting in 1999 (JECFA, 1999a, 1999b) but no toxicological monographs were prepared. JECFA specifications indicate that the functional use of argon is as a packaging gas whereas helium is reported as a processing aid.

[1]Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[2]Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

[3]European Commission, 2001. Report from the Commission on Dietary Food Additive Intake in the European Union. Brussels. COM(2001) 542 final.

[4]Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.

[5]Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p 1.

In addition to the authorised uses as food additive, in the EU, argon is also listed in Commission Delegated Regulation (EU) No 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013[6] on authorised oenological practices for use in the oenological process of bubbling and among the permitted gases and packaging gases.

Helium gas is listed among the substances Generally Recognised as Safe (GRAS) by the United States Food and Drug Administration (US FDA) after an opinion of the Select Committee on GRAS issued in 1979 (US FDA, online).

The Minister of Health, Labour and Welfare (MHLW) of Japan lists both argon and helium among the food additives permitted for use in Japan (MHLW, online).

In the EU, argon is permitted as an antioxidant in cosmetic products (European Commission database-CosIng[7]).

Both argon (EINECS No 231-147-0; CAS No 7440-37-1) and helium (EINECS No 231-168-5; CAS No 7440-59-7) are included in Annex IV to Regulation (EC) No 1907/2006[8] (REACH Regulation) among the substances that are exempted from registration with ECHA because they are considered to cause minimum risk to human health or the environment because of their intrinsic properties.

The EU Pharmacopoeia contains monographs for both argon (European Pharmacopoeia 11.6, 2024a) and helium intended for medicinal use (European Pharmacopoeia 11.6 , 2024b).

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The Panel was not provided with a newly submitted dossier. EFSA launched a public call for data to collect information from interested parties.[9] With respect to the data and information specified in Article 4 of Regulation (EU) No 257/2010, the Panel noted that for the re-evaluation of helium (E 939) no information falling under points (a)–(d) was made available to EFSA and no business operator nor other party have expressed an interest by replying to the calls for data issued by EFSA. For argon (E 938), a single use in Food Category (FC) 14.2.4 'Fruit wine and made wine' as packaging gas was reported (Documentation provided to EFSA No. 1).

The Panel conducted an extensive, open-ended literature search for the identification of any relevant literature published on the two gases as foreseen under point (e) of Article 4 of Regulation (EU) No 257/2010 (see Appendix A). For the present opinion, this task was limited to the review of selected publications that were deemed relevant by the Panel for the safety evaluation of these two gases when used as food additives.

The Mintel's Global New Products Database (GNPD) was used to check for the uses of argon (E 938) and helium (E 939) in food and beverage products and food supplements within the EU's market. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

### 2.2 | Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The FAF Panel assessed the safety of argon (E 938) and helium (E 939) as food additives in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001) and the Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

In the context of this re-evaluation, the Panel took into account the 'Conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EC) No 257/2010' (EFSA ANS Panel, 2014).

[6]Commission Delegated Regulation (EU) 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards wine-growing areas where the alcoholic strength may be increased, authorised oenological practices and restrictions applicable to the production and conservation of grapevine products, the minimum percentage of alcohol for by-products and their disposal, and publication of OIV files. OJ L 149, 7.6.2019, p. 1–52.

[7]Available online: http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple

[8]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30/12/2006, p. 1–849.

[9]Call for data for the re-evaluation of food additives in gaseous form. Published 28 June 2023. Available from: https://www.efsa.europa.eu/en/call/call-data-re-evaluation-food-additives-gaseous-form

# 3 | ASSESSMENT

## 3.1 | Technical data

### 3.1.1 | Identity of the substances and specifications

#### 3.1.1.1 | *Argon (E 938)*

Argon (Ar) is a noble gas with an atomic weight of 40 g/mol. The EU specifications describe argon as a colourless, odourless and non-flammable gas.

The specifications for argon (E 938) as defined in Commission Regulation (EU) No 231/2012 and by JECFA (1999a) are listed in Table 1.

**TABLE 1** Specifications for the food additive argon (E 938) according to Commission Regulation (EU) No 231/2012 and JECFA (1999a).

| | Commission Regulation (EU) No 231/2012 | JECFA (1999a) |
|---|---|---|
| **Synonyms** | | INS No. 938 |
| **Definition** | | |
| **Einecs** | 231-147-0 | |
| **CAS Number** | | 7440-37-1 |
| **Chemical name** | Argon | |
| **Chemical formula** | Ar | |
| **Atomic weight** | 40 | 40.0 |
| **Assay** | Not less than 99% | Not less than 99.0% by volume |
| **Description** | Colourless, odourless, non-flammable gas | Colourless and odourless gas |
| **Identification** | | |
| **Flame test** | | The flame of a burning splinter of wood is extinguished when inserted into an upright test tube filled with argon |
| **Purity** | | |
| Water content | Not more than 0.05% | Passes test[a] |
| Methane and other hydrocarbons | Not more than 100 µL/L (calculated as methane) | |
| Oxygen, nitrogen, hydrogen | | Not more than 1% in combination[a] |
| **Odour** | | No appreciable odour is discernible |

[a]A specific test is described in the JECFA specifications (1999a).

The Panel noted that the purity required for argon used for medicinal use (minimum 99.995 per cent v/v) is higher than the one indicated in the EU specifications for argon when used as food additive (not less than 99%). The specified impurities for argon for medicinal use are oxygen and water. Nitrogen and methane are listed as other detectable impurities (EU Phar 11.0).

The Panel also considered that the CAS number 7440-37-1 should be included in the existing EU specifications for E 938.

#### 3.1.1.2 | *Helium (E 939)*

Helium (He) is a noble gas with an atomic weight of 4 g/mol. The EU specifications describe helium as a colourless, odourless and non-flammable gas.

The specifications for helium (E 939) as defined in Commission Regulation (EU) No 231/2012 and by JECFA (1999b) are listed in Table 2.

**TABLE 2** Specifications for the food additive helium (E 939) according to Commission Regulation (EU) No 231/2012 and JECFA (1999b).

| | Commission Regulation (EU) No 231/2012 | JECFA (1999b) |
|---|---|---|
| **Synonyms** | | INS No. 939 |
| **Definition** | | |
| **Einecs** | 231-168-5 | |
| **CAS Number** | | 7440-59-7 |
| **Chemical name** | Helium | |
| **Chemical formula** | He | He |
| **Atomic weight** | 4 | 4.0 |
| **Assay** | Not less than 99% | Not less than 99.0% by volume |
| **Description** | Colourless, odourless, non-flammable gas | Colourless and odourless gas |
| **Identification** | | |
| **Flame test** | | The flame of a burning splinter of wood is extinguished when inserted into an upright test tube filled with helium |
| **GC test** | | See Method of Assay[a] |
| **Purity** | | |
| Water content | Not more than 0.05% | |
| Methane and other hydrocarbons | Not more than 100 µL/L (calculated as methane) | |
| Air | | Not more than 1%, by volume[a] |
| Carbon monoxide | | Not more than 10 µL/L, by volume |
| **Odour** | | No appreciable odour is discernible |

[a]A specific test is described in the JECFA specifications (1999b).

The Panel noted that the purity required for helium used for medicinal use (minimum 99.5 per cent v/v) is higher than that indicated in the EU specifications for helium used as a food additive (not less than 99%). The specified impurities for helium for medicinal use are oxygen, methane and water (EU Phar 11.0).

The Panel also considered that the CAS number 7440-59-7 should be included in the existing EU specifications for E 938.

In the absence of analytical data on argon and helium used as food additives the Panel is unable to assess whether the existing specifications are adequately representative for the actual materials used as food additives in the EU.

### 3.1.2 | Manufacturing process

Existing EU specifications for argon (E 938) and helium (E 939) do not contain any information on the manufacturing process(es) used for the production of these food additives. No interested business operator (IBO) or other interested party has provided information in response to the call for data either on argon (E 938) or helium (E 939) with respect to this aspect.

According to information available in the public domain, argon is the third most abundant gas in air and is obtained from the fractional distillation of liquefied air into oxygen, nitrogen and argon, at cryogenic temperatures (Ceylan et al., 2017).

Argon can also be recovered from the exhaust streams of certain ammonia plants (Healy, 1992). The Panel noted that this manufacturing process could explain why methane is one of the listed impurities in the existing food additive specifications.

Helium is reported to be extracted from natural gas through fractional distillation, with the intention of being separated from hydrocarbons and nitrogenous compounds. The initial stage of the industrial process involves natural gas extraction and processing, where helium is treated as a valuable by-product and separated through cryogenic processes from other components, e.g. carbon dioxide, hydrogen, nitrogen and hydrocarbons. At this point, the so-called 'crude helium' is obtained, with a purity of 60%–80%. To achieve a higher purity, different gases, such as hydrogen, oxygen and water are separated from the crude helium to produce 'Grade-A' helium, i.e. helium with a purity of 99.99% (Serra Leal et al., 2023).

The Panel noted that, according to the monographs in the EU Pharmacopoeia, for the two gases for medicinal use, argon is obtained by fractional distillation of ambient air while helium is obtained by separation from natural gas.

The Panel was unable to confirm whether the manufacturing processes described above, and found in the scientific literature, are applicable also to the manufacturing of the two gases when used as food additives. Equally, in the absence of

information on the production methods used to manufacture the food additives, the Panel was unable to assess whether the existing EU specifications for argon (E 938) and helium (E 939) adequately cover all the impurities (already listed or unlisted) that may pose any hazard to health.

#### 3.1.3 | Methods of analysis in food

No business operators or other interested party has provided information in response to the call for data either on argon (E 938) or helium (E 939) with respect to this aspect.

Since no information was provided on how the food additives are applied to food to exert their intended technological function (e.g. at which stage of the manufacturing, processing, packaging and/or distribution of foods, how the food additive is included in the food, under which conditions of temperature and pressure, etc.), the Panel after performing a search of the literature to address this point, could not identify relevant information on methods of analysis.

#### 3.1.4 | Stability of the food additives and reaction and fate in food

No IBO or other interested party has provided information in response to the call for data on either argon (E 938) or helium (E 939) with respect to this aspect.

The physicochemical properties of the two noble gases are universally acknowledged and served as the basis for the original evaluations by other bodies. The Panel was also of the view that argon (E 938) and helium (E 939) can be considered chemically inert under most conditions and unable to form stable compounds at temperatures normally used in food preparation/processing/storage/packaging.

### 3.2 | Authorised uses and use levels

Currently, argon (E 938) and helium (E 939) are authorised food additives in the EU at *quantum satis* (QS) in all food categories as set by Annex II to Regulation (EC) No 1333/2008, including foods for infants and young children. Additionally, according to Annex III, Parts 3 and 4 of Regulation (EC) No 1333/2008, E 938 and E 939 are permitted also at QS to be used in enzyme preparations and nutrients.

### 3.3 | Exposure data

No IBO or other interested party has provided information in response to the call for data for helium (E 939) with respect to this aspect of the re-evaluation.

#### 3.3.1 | Reported use levels or data on analytical levels of argon (E 938)

Use level data of argon (E 938) as a packaging gas in food category (FC) 14.2.4 'Fruit wine and made wine' were provided by one IBO (Documentation provided to EFSA No.1). Within this FC, the reported use levels in 'fruit wine-cocktail, aromatised' were 1000 mg/L and 1500 mg/L for the typical and the maximum use level, respectively.

#### 3.3.2 | Summarised data extracted from the Mintel's global new products database

The Mintel's GNPD was used for checking the labelling of food and beverage products and food supplements for argon (E 938) and helium (E 939) within the EU's food market.[10] This search indicated that neither gas is listed in the labels of any food product.

#### 3.3.3 | Information on uses retrieved from the published literature

Based on selected information retrieved from the published literature, argon is used in food packaging to increase the shelf life, preserve the flavour and reduce the oxidation of perishable foods (Spencer & Humphreys, 2001). When introduced into the packaging, argon creates a modified atmosphere that reduces the amount of available oxygen and moisture, hence hindering a series of chemical reactions, such as hydrolysis and peroxidation. Within drinks, argon is added to wine barrels

[10]Missing Cyprus, Luxembourg and Malta.

to remove the excess of air, as it settles above the liquid protecting the wine from souring and oxidation. In dairy products, argon could be used to inactivate the bacteria in raw milk so as to increase the shelf life of milk and dairy products (Kasih, Mangindaan, Ningrum, Sebastian, & Widyaningrum, 2021).

Similarly, helium is used by the food industry, introduced into the packaging, to aid the long-term storage of foods. The scientific literature provides numerous examples of helium being used in post-harvest treatment of food, e.g. to control bacterial growth in packaged raw fish (Üçok et al., 2024) and minimally processed vegetables (Silveira et al., 2014), to inactivate pathogens in processed meats (Kim et al., 2011) and to reduce the content of biogenic amines in red wines (Niedźwiedź et al., 2022).

### 3.4 | Exposure estimate(s)

Owing to the lack of information on the applications of argon (E 938) and helium (E 939) in foods, the dietary exposure to these food additives was not estimated.

Nevertheless, it can be assumed that dietary exposure, if any, will be low. When used as a packaging gas to create an inert atmosphere, the concentration of argon and helium in the packaged foodstuffs will be low due to the fact that the gases have only a low solubility. The solubility of argon and helium in water at STP (standard temperature and pressure, 25°C and 1 atm of the packaging gas.) is approximately 56 mg/L and 1.6 mg/L respectively (IUPAC, 1979, 1980). The solubility of argon and helium in 1-octanol (considered by the Panel to be a suitable simulant for food oils and fats, in the absence of readily available solubility data for oils and fats) is ca. 330 mg/L and 3.0 mg/L respectively (IUPAC, 1979, 1980). Since the concentration of both gases in foodstuffs of any character (dry, aqueous, fatty, mixed) will always be low, the dietary exposure via said foods would be low too.

### 3.5 | Biological and toxicological data

Argon and helium are two noble gases, highly stable single atoms. Their chemical inertness is well known and therefore, intrinsic toxic properties have not to be considered.

The Panel noted that inhalation exposure may lead to suffocation by displacing oxygen from the air which is inhaled. It is expected that the inhalation exposure for the consumers resulting from use in foods of argon and helium is extremely low, and therefore this effect has not been considered relevant for assessing the safety of the two gases as food additives.

## 4 | DISCUSSION

The present opinion deals with the re-evaluation of argon (E 938) and helium (E 939) when used as food additives.

Argon (Ar) and helium (He) are two noble gases, highly stable single atoms. Their chemical inertness is well known.

The two food additives, argon (E 938) and helium (E 939), are authorised in the EU at *quantum satis* (QS) in all food categories as set by Annex II to Regulation (EC) No 1333/2008, including foods for infants and young children. Additionally, according to Annex III, Parts 3 and 4 of Regulation (EC) No 1333/2008, E 938 and E 939 are permitted to be used in enzyme preparations and nutrients, again at QS.

No business operator or other interested party provided information in response to the call for data published by EFSA to support the re-evaluation of these two food additives with respect to their identity and specifications, manufacturing process (including the identification and quantification of potential impurities) and how they are applied to food to exert their technological function (e.g. at which stage of the manufacturing, processing, packaging and/or distribution of foods, how the food additive is included in the food, under which conditions of temperature and pressure, etc.). One business operator replied to the call for data issued by EFSA reporting use levels on argon (E 938) as a packaging gas in one food category (Documentation provided to EFSA No. 1).

A search of the Mintel database for foods that report the use of these food additives on their labels returned no entry, suggesting that the use of these food additives does not serve any other technological function other than packaging gases.

Based on their physicochemical properties, both gases are considered by the Panel to be of low toxicological concern when used as food additives, as described in in the 2014 ANS Panel 'Conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EC) No 257/2010' (EFSA ANS Panel, 2014). This is in line with considerations by other scientific bodies (SCF, JECFA) and the same rationale has been followed in the context of the REACH Regulation to exempt the two gases from registration with ECHA. No information was available on the potential presence of impurities of toxicological concern resulting from the manufacturing process(es) applied to the production of the food additives E 938 and E 939. The Panel however noted that a minimum purity of 99.0% is required to comply with existing EU specifications and that the listed impurities do not raise a concern.

Despite the absence of a full dataset covering detailed information on exposure and toxicity, the Panel considered that the use of these food additives does not raise a safety concern. However, due to a lack of data on use and use levels and on the manufacturing processes, uncertainties do remain. For helium (E 939), these include the question if this gas is used at

all as food additive in EU. For both gases, the potential presence of impurities, currently unlisted in the EU Specifications, represents a minor uncertainty.

## 5 | CONCLUSIONS

The Panel concluded that the use of argon (E 938) and helium (E 939) as food additives does not raise a safety concern.

## 6 | RECOMMENDATION

The Panel recommended that the European Commission considers amending existing EU specifications for argon (E 938) and helium (E 939) introducing the CAS numbers 7440-37-1 and 7440-59-7, respectively.

## 7 | DOCUMENTATION AS PROVIDED TO EFSA (IF APPROPRIATE)

Response to Call for data for the re-evaluation of food additives in gaseous form. April 2024. Submitted by Fruchtwein- und Fruchtschaumwein-Industrie e.V.

### ABBREVIATIONS

| | |
|---|---|
| ANS | Food additives and nutrient sources added to food |
| CAS | Chemical Abstracts Service |
| ECHA | European Chemicals Agency |
| EINECS | European INventory of Existing Commercial chemical Substances |
| FAF | Food Additives and Flavourings |
| FC | Food Category |
| GNPD | Global New Products Database |
| GRAS | generally recognised as safe |
| IBO | interested business operator |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| MHLW | Minister of Health, Labour and Welfare |
| QS | *quantum satis* |
| SCF | Scientific Committee for Food |
| STP | standard temperature and pressure |
| US FDA | United States Food and Drug Administration |

### REQUESTOR

European Commission

### QUESTION NUMBERS

EFSA-Q-2011-00712, EFSA-Q-2011-00713

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# APPENDIX A

## Protocol for a comprehensive literature search supporting the re-evaluation of argon (E 938) and helium (E 939) as food additives

### A.1 | EXTENSIVE LITERATURE SEARCH

#### A.1.1. | Methodology

Two separate literature searches were conducted in May 2024 to identify relevant studies on the relationships between gases and food, manufacturing methods and impurities. The first search, focused on argon (E 938) and yielded 2109, 2267 and 1431 studies for the argon and food, manufacturing methods and impurities searches, respectively. The second search, focused on helium (E 939) and yielded 1525, 2525 and 1670 studies for the corresponding searches. Both searches were performed in Scopus, Web of Science and Scifinder-n, limited to English-language studies and were conducted by an information specialist at EFSA.

Following duplicate removal using Endnote (ver. 20), studies retrieved from the literature searches were uploaded to DistillerSR (ver. 2.35) for artificial intelligence (AI) assisted title and abstract screening using inclusion and exclusion criteria outlined in Table A.1. Following screening, publications deemed relevant by the Panel for the safety evaluation of these two gases were included in the present opinion.

**TABLE A.1** Inclusion/exclusion criteria applied to the literature search for argon (E 938) and helium (E 939).

| Inclusion criteria | Exclusion criteria |
|---|---|
| Studies that investigate the manufacturing process and related specifications of argon (E 938) or helium (E 939) including: (i) information on manufacturing process, (ii) presence of toxicologically relevant impurities and related specifications | Studies that do not investigate argon (E 938) or helium (E 939) as food additives or their manufacturing processes for use as food additives |
| Studies that examine the reaction and fate of argon (E 938) or helium (E 939) in food | Studies that do not provide information on the reaction and fate of argon (E 938) or helium (E 939) in food |
| Studies that provide information on the estimation of dietary exposure to argon (E 938) or helium (E 939), including (i) information on applications as food additives, (ii) information on uses and use levels and (iii) information on residual levels of argon (E 938) or helium (E 939) in foods | Studies that do not provide information on dietary exposure to argon (E 938) or helium (E 939) |
| | Studies that do not report on applications, uses and use levels of argon (E 938) or helium (E 939) |
| | Studies that do not report on residual levels of argon (E 938) or helium (E 939) in foods |
| | Studies that focus on food additives in gaseous form other than argon (E 938) or helium (E 939) |
| | Studies that do not provide original data or reviews (e.g. editorials, opinion pieces, case reports) |

### A.2 | Results

The final numbers of references that were screened, after removal of duplicates (based on title, year, author, journal, volume, issue and page numbers) were 5807 for argon (E 938) and 5820 for helium (E 939). Following AI assisted screening using DistillerSR, publications deemed relevant by the Panel for the safety evaluation of these two gases were included in the present opinion.