

# Re-evaluation of butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>

## Abstract

The Panel on Food Additives and Flavourings (FAF) provides a scientific opinion re-evaluating the safety of butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives. Butane, isobutane and propane are short-chain ( $C_3$ – $C_4$ ) alkanes, which are in gaseous state at room temperature. Their currently permitted use in food is in vegetable oil pan spray (for professional use only) and water-based emulsion spray as propellants at *quantum satis*. They can also be used in food colour preparations with a maximum residual limit of 1 mg/kg in food. Two interested business operators (IBOs) provided information in response to the call for data published by EFSA reporting typical and maximum use levels. The toxicological hazards of the three gases via inhalation are known, however this route of exposure is not considered relevant for their safety assessment as food additives. Existing EU specifications for the three food additives already contain limits for the toxic impurity 1,3-butadiene (1,3-BD), however due to a lack of information on the manufacturing processes used, uncertainties do remain regarding the potential presence of other impurities not listed in the current EU specifications for food additives. Based on their physicochemical properties, the three gases are considered by the Panel to be of low toxicological concern when used as food additives and their dietary exposure very low. The Panel concluded that the use of butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives at the currently permitted uses and use levels does not raise a safety concern. The Panel made some recommendations for amending existing EU specifications for butane (E 943a), isobutane (E 943b) and propane (E 944).

## KEYWORDS

1,3-butadiene, 106-97-8, 74-98-6, 75-28-5, butane, food additives, isobutane, propane

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## 1 | INTRODUCTION

The present opinion deals with the re-evaluation of butane (E 943a), isobutane (E 943b) and propane (E 944) 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<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> The report "Food additives in Europe 2000"<sup>4</sup> 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

Butane (E 943a), isobutane (E 943b) and propane (E 944) 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,<sup>1</sup> as amended by Commission Regulation (EU) No 2017/874.<sup>5</sup> Specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.<sup>6</sup>

In addition to their currently authorised uses as food additives, butane (E 943a) and propane (E 944) are included in the list of extraction solvents allowed in the production of foodstuffs and food ingredients established in Part I of Annex I to Directive 2009/32/EC.<sup>7</sup>

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>Commission of the European Communities. Report from the Commission on Dietary Food Additive Intake in the European Union. COM (2001) 542 final. Available online <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0542:FIN:EN:PDF>.

<sup>4</sup>Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560. Available online <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0418:FIN:EN:PDF>.

<sup>5</sup>Commission Regulation (EU) 2017/874 of 22 May 2017 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations. OJ L 134, 23.5.2017, p. 18–20.

<sup>6</sup>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. 1–295.

<sup>7</sup>Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L 141, 6.6.2009, p. 3–11.

The use of butane, isobutane and propane in cooking sprays was evaluated by the EU Scientific Committee for Food (SCF) in (1999). The SCF stated that: *'In view of the low residue level of propellant gases the SCF has no toxicological concerns about the use of water-based emulsion sprays and oil-based aerosol sprays for baking and frying purposes, which contain propane, butane or isobutane'*. The 1999 SCF assessment also considered a previous evaluation on the use of these gases as extraction solvents, indicating an acceptable residue level per substance of 1 mg/kg in foods consumed (SCF, 1991).

The 23rd report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) included considerations on propane (INS No 944) and butane (INS No 943) as extraction solvents (JECFA, 1980). As regards propane, JECFA stated that *'Owing to the limited use and limited residues in food of this compound the Committee decided it was not necessary to establish an acceptable daily intake (ADI). No toxicological monograph or specifications were prepared'*. As for butane, JECFA stated that *'the evaluation of the compound was not possible based on the data available. Specifications were not prepared and an ADI was not allocated'*. No toxicological monograph on propane and butane was prepared. EFSA was not able to find information on existing evaluation of isobutane performed by JECFA.

The use of isobutane in food contact materials was assessed by the EFSA Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF Panel) in 2018. In its opinion, the CEF Panel concluded that *'the substance isobutane does not raise a safety concern for the consumer if used as a foaming agent for plastics intended for food contact applications'* (EFSA CEF Panel, 2018).

1,3-Butadiene (1,3-BD) is listed as an impurity (not more than 0.1% v/v) in the EU specifications for butane (E 943a), isobutane (E 943b) and propane (E 944). 1,3-BD, CAS No 106–99–0, is included in Regulation (EC) No 1907/2006<sup>8</sup> (REACH Regulation), under Entry 28 in Appendix 1, listing substances classified as Category 1 A carcinogens and under Entry 29 in Appendix 4, listing substances classified as Category 1 B germ cell mutagens. The same classifications apply also to butane and isobutane when containing  $\geq 0.1\%$  1,3-BD. Occupational exposure limits (OELs) for 1,3-BD have not been established by ECHA, due to classification as a non-threshold carcinogen (ECHA, 2024).

Butane and isobutane containing  $\geq 0.1\%$  w/w butadiene are both included in Annex II to Regulation (EC) No 1223/2009<sup>9</sup> on cosmetic products, indicating the list of substances prohibited in cosmetic products.

Finally, the three gases are labelled as extremely flammable (H220) according to Regulation (EC) No 1272/2008<sup>10</sup> on classification, labelling and packaging of substances and mixtures (CLP Regulation).

Recreational use of propellant gases, including butane, isobutane and propane, is a well-known phenomenon (EUDA, online), however these uses are clearly outside the scope of the present opinion.

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The Panel was not provided with a newly submitted dossier for the re-evaluation of butane (E 943a), isobutane (E 943b) and propane (E 944). EFSA launched a public call for data to collect information from interested parties.<sup>11</sup> 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 the three gases no information falling under points (a)–(d) was made available to EFSA and no business operator nor other party expressed an interest by replying to the calls for data issued by EFSA.

The Panel conducted a literature search for the identification of any relevant literature published on the three 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 publications that were deemed relevant by the Panel for the safety evaluation of the three gases when used as food additives.

The Mintel's Global New Products Database (GNPD) was used to check for the uses of butane (E 943a), isobutane (E 943b) and propane (E 944) 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.<sup>12</sup>

<sup>8</sup>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.

<sup>9</sup>Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

<sup>10</sup>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1–1355.

<sup>11</sup>Call for data for the re-evaluation of food additives in gaseous form. Published 28 June 2023. <https://www.efsa.europa.eu/en/call/call-data-re-evaluation-food-additives-gaseous-form>.

<sup>12</sup><http://www.mintel.com/products/gnpd>.

## 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 Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The Panel assessed the safety of butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives in line with the principles laid down in Regulation (EU) No 257/2010 and the 2012 ANS Panel Guidance for submission for food additive evaluations (EFSA ANS Panel, 2012).

In the context of this re-evaluation, the Panel took also 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).

For converting an inhalation dose (expressed as ppm by the authors) to a dose expressed as mg/kg bw per day, the respiration rate of the test species (i.e. 45 L/kg bw per h in the rat) was used (ECHA, 2012). The duration of daily inhalation exposure as reported in the study and the extent of respiratory absorption were also taken into account. The default assumption was that absorption of the gas via the respiratory tract is 100% of the inhaled dose. The following equation based on that proposed by ECHA (2012) was used, as described in FAF Panel (2022).

## 3 | ASSESSMENT

### 3.1 | Technical data

#### 3.1.1 | Identity of the substances and specifications

Butane is a straight-chain C4 alkane with a molecular weight of 58.12 g/mol and with the CAS number 106-97-8. Isobutane is a C4 branched alkane with a molecular weight of 58.12 g/mol and with the CAS number 75-28-5. Propane is a straight-chain C3 alkane with a molecular weight of 44.09 g/mol and with the CAS number 74-98-6.

The EU specifications describe the three food additives as colourless gases or liquids with a mild, characteristic odour.

The specifications for butane (E 943a), isobutane (E 943b) and propane (E 944) as defined in Commission Regulation (EU) No 231/2012 are listed in Table 1.

**TABLE 1** Specifications for the food additives butane (E 943a), isobutane (E 943b) and propane (E 944) according to Commission Regulation (EU) No 231/2012.

	Butane (E 943a)	Isobutane (E 943b)	Propane (E 944)
<b>Synonyms</b>	<i>n</i> -Butane	2-Methyl propane	–
<b>Definition</b>			
Einecs	–	–	–
Chemical name	Butane	2-methyl propane	Propane
Chemical formula	CH <sub>3</sub> CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>	(CH <sub>3</sub> ) <sub>2</sub> CH CH <sub>3</sub>	CH <sub>3</sub> CH <sub>2</sub> CH <sub>3</sub>
Molecular weight	58.12	58.12	44.09
Assay	Content not less than 96%	Content not less than 94%	Content not less than 95%
<b>Description</b>	Colourless gas or liquid with mild, characteristic odour	Colourless gas or liquid with mild, characteristic odour	Colourless gas or liquid with mild, characteristic odour
<b>Identification</b>			
Vapour pressure	108.935 kPa at 20°C	205.465 kPa at 20°C	732.910 kPa at 20°C
<b>Purity</b>			
Methane	Not more than 0.15% v/v	Not more than 0.15% v/v	Not more than 0.15% v/v
Ethane	Not more than 0.5% v/v	Not more than 0.5% v/v	Not more than 1.5% v/v
Propane	Not more than 1.5% v/v	Not more than 2.0% v/v	–
Isobutane	Not more than 3.0% v/v	–	Not more than 2.0% v/v
<i>n</i> -Butane	–	Not more than 4.0% v/v	Not more than 1.0% v/v
1,3-butadiene	Not more than 0.1% v/v	Not more than 0.1% v/v	Not more than 0.1% v/v
Moisture	Not more than 0.005%	Not more than 0.005%	Not more than 0.005%

The Panel noted that the purity required for butane, isobutane and propane for medicinal use (minimum 99.0% v/v) is higher than the purity indicated in the EU specifications for the same gases when used as food additives (not less than 96% for E 943a; not less than 94% for E 943b; not less than 95% for E 944). There are no named impurities listed in the entries for the three gases in the European Pharmacopoeia (Ph. Eur, 2024a, 2024b, 2024c). The Panel noted that each food additive may contain a small amount of the other gases authorised as food additives.

The specified limit for the impurity 1,3-butadiene is aligned to the limits set in the CLP Legislation and cosmetics legislation (see Section 1.2.1).

The Panel also considered that the CAS numbers 106-97-8, 75-28-5 and 74-98-6 should be included in the existing EU specifications for E 943a, E 943b and E 944, respectively.

The Panel further noted that condensed structural formulas are reported in the EU Specifications for the three gases, instead of the corresponding chemical formulas ( $C_4H_{10}$  for butane and isobutane,  $C_3H_8$  for propane).

### 3.1.2 | Manufacturing process

Existing EU specifications for butane (E 943a), isobutane (E 943b) and propane (E 944) do not contain any information on the manufacturing process(es) applied to the production of these food additives. No IBO or other party provided information in response to the call for data on either of the three gases with respect to this aspect.

According to the scientific literature, saturated hydrocarbons consisting of four carbon atoms (C<sub>4</sub>), such as butane and isobutane, are conventionally derived from natural gas fractionation, as well as produced as side-products of industrial processes in petrochemistry and coal chemistry, where techniques such as fluid catalytic cracking or steam cracking are employed (Agbaje et al., 2021; Schulze & Homann, 2012). C<sub>4</sub> hydrocarbons are often produced as a mixture of other C<sub>4</sub> hydrocarbons. Novel separation techniques under development, for hydrocarbon production, involve the use of membranes and adsorbents in separation of C<sub>4</sub> hydrocarbons (Agbaje et al., 2021). However, hydrocarbons are generally recovered by distillation.

Regarding the manufacturing of isobutane, the literature reports the possibility to obtain isobutane through catalytic isomerisation of butane (*n*-butane) (Urzhuntsev et al., 2014), as well as via catalytic synthesis from synthesis gas or CO<sub>2</sub> hydrogenation (Li et al., 2017).

Propane is obtained mostly from the fractional distillation of crude oil and natural gas (Payne et al., 2023). Zhang et al. (2024) reported catalytic CO<sub>2</sub> hydrogenation as an alternative method to produce propane.

The Panel was unable to confirm whether the manufacturing processes found in the scientific literature and briefly summarised above, are applicable to the manufacturing of the three gases when used as food additives. 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 butane (E 943a), isobutane (E 943b) and propane (E 944) 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 IBO or other party provided information in response to the call for data with respect to methods of analysis in food.

A literature search identified only one method, namely headspace gas chromatography–mass spectrometry (HS-GC–MS). This method was used to determine the release of butane or propane, used as propellants in colouring food aerosol sprays, from food samples (cakes and chocolate) (Varlet et al., 2014).

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

No IBO or other interested party provided information in response to the call for data with respect to the stability of these food additives, and reaction and fate of the food additives in food.

The three gases are simple saturated hydrocarbons that are expected to be chemically inert in the intended food applications. The Panel therefore agrees with the SCF (1999) that: *'No reaction of the hydrocarbon propellant gases with food components at cooking temperatures is to be expected'*, and the Panel considers that this conclusion applies also to the stability of the three gases when used in food colouring sprays.

Consequently, it is the physical fate (evaporation and dissipation) of the three food additives that is the main aspect to be considered. In the previous safety evaluation of these food additives by the SCF, the following considerations were made:

*'The hydrocarbon propellants used are, at all ambient indoor temperatures and at normal atmospheric pressure, in the gaseous state. The least volatile of the group, n-butane, has a boiling point of –0.5°C. The others boil at significantly lower temperatures. Accordingly, also the hydrocarbons that are dissolved in fat or oil at ambient temperatures are present in the vapour state.*

*In the containers (aerosol dispensers) the propellants are present in the liquid state but when the content of the container is discharged, the released hydrocarbon propellant mostly vapourises into the atmosphere leaving only a small amount dissolved in the cooking spray concentrate which is deposited on the surface of the cooking utensil.*

*The residual levels of hydrocarbon propellants in the water-based sprays would be expected to be less than those in the oil-based products because of their low solubility in water. This is confirmed by the analytical data on the levels of residues detected in the cooked food models.*

*Since the solubility of the hydrocarbon propellant gases in the concentrate decreases with temperature the propellants are expelled from the cooking spray during heating. In most cases, temperatures of 200–220°C are reached. The limit of solubility of the propellants in the spray concentrate at these temperatures is reached in the time it normally takes to prepare the fried*

or baked foods, and thus the propellant residues are reduced to a very low level during the time of preparation of the foods. In addition, during frying or baking, the food and cooking spray concentrate are mixed and a portion of any residual hydrocarbon propellant will be transferred to the food. This will dilute the hydrocarbon to a concentration much less than its limit of solubility in the concentrate'. (SCF, 1999).

The Panel also noted that the impurity of toxicological concern, 1,3-butadiene, has a boiling point below zero ( $-4^{\circ}\text{C}$ ) and, therefore, the same considerations would apply to this impurity in the final food products to be consumed.

Varlet et al. (2014) studied the release of propane and butane from food when used as propellants for colouring food aerosol sprays and cooling sprays. Food sprays were applied to confectionary products (butter cakes and chocolate) and the levels of residual gas (propane or butane) were determined via HS-GC-MS analysis. In sprayed foods kept at room temperature, propane could not be detected after 1 h. For butane, it was sufficient to leave the sprayed food at room temperature for 24 h to get a complete release of the gas from the food. Refrigerated storage conditions will slow down gas release.

In recital (7) of Commission Regulation (EU) 2017/874<sup>5</sup> amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations, a reference is made to analytical data provided by an applicant to the European Commission confirming that 1 h after spraying various foods, the residues of butane (E 943a), isobutane (E 943b) and propane (E 944) are below the maximum limit of 1 mg/kg in the final food.

The Panel concurred with the previous evaluation from the SCF (1999) that, given the physicochemical properties of butane (E 943a), isobutane (E 943b) and propane (E 944), their amount in the final food products as consumed would be extremely low, if any.

### 3.2 | Authorised uses and use levels

Currently, butane (E 943a), isobutane (E 943b) and propane (E 944) are authorised food additives in the EU at *quantum satis* (QS) in the food category (FC) 'Vegetable oil pan spray' (FC 02.3), restricted to 'vegetable oil pan spray (for professional use only) and water-based emulsion spray'.

The use of butane (E 943a), isobutane (E 943b) and propane (E 944) in food is also permitted in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008 (for professional use only), with a maximum level in the final food set at 1 mg/kg.

### 3.3 | Exposure data

#### 3.3.1 | Reported use levels of butane (E 943a), isobutane (E 943b) and propane (E 944)

Two IBOs submitted 53 use levels for the three food additives in FC 02.3 'Vegetable oil pan spray' (Documentation provided to EFSA No 1, 2).

The Panel noted that some reported use levels were expressed on a fat weight basis. To ensure comparability among the use levels reported, the Panel converted all use levels to a total weight basis, using the fat percentages indicated by the IBO for each entry expressed on a fat weight basis.

The Panel also noted that some use levels were provided as mg/L in oils and fats of mixed origin. To make the use levels comparable, the Panel converted these use levels to mg/kg considering a representative density of 0.9 g/mL for vegetable oils (Noureddini et al., 1992).

After these two conversions, the average typical use level and maximum use level reported for butane (E 943a) were 126,000 mg/kg and 300,000 mg/kg ( $n=47$ ), respectively. The average typical use level and maximum use level for isobutane (E 943b) were 15,600 mg/kg and 29,700 mg/kg ( $n=2$ ), respectively, and for propane (E 944) 54,600 mg/kg and 150,000 mg/kg ( $n=4$ ), respectively. All use levels are expressed in mg/kg for foods belonging to FC 02.3 'Vegetable oil pan spray' (See Appendix B).

#### 3.3.2 | Summarised data extracted from Mintel's Global New Products Database

Mintel's GNPD was used for checking the labelling of food and beverage products and food supplements for butane (E 943a), isobutane (E 943b) and propane (E 944) within the EU's food market<sup>13</sup> (see Appendix B, Table B.3).

According to Mintel's GNPD, butane (E 943a) was labelled on 10 different products between November 2019 and November 2024, all classified as cooking or baking oil sprays. During the same period, isobutane (E 943b) was reported on the label of five cooking or baking oil sprays, while propane (E 944) was reported on the label of 13 cooking or baking oil sprays and of three products falling under the sub-category of 'Cakes, Pastries & Sweet Goods' of Mintel.

<sup>13</sup>Missing Cyprus, Luxembourg and Malta.

The Panel noted that the current permitted uses of the three food additives is restricted to a large extent to 'professional use' only and therefore they may not be fully covered by the Mintel's GNPD which focuses on retail food products.

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

Galvin and Bond (1999) reported the use of isobutane in aerosol frying pan lubricants at a concentration up to 16.8%. These authors also reported that water-based formulations of aerosol frying pan lubricant may contain higher concentrations of isobutane (30%), and that the isobutane can be used as a propellant in combination with propane.

### 3.4 | Exposure estimate(s)

As explained above (see Section 3.1.4), based on the physicochemical properties and the permitted uses in foods, the Panel assumed that the dietary exposure to butane (E 943a), isobutane (E 943b) and propane (E 944), if any, would be very low. For this reason, a quantitative exposure estimation was considered not relevant for the present opinion.

### 3.5 | Biological and toxicological data

Butane (E 943a), isobutane (E 943b) and propane (E 944) have well-known hazards associated to their inhalation, causing suffocation by displacing oxygen from the air which is inhaled (Bolt, 2023; Galvin & Bond, 1999; National Research Council, 2012). The Panel, however, considers that inhalation exposure of consumers resulting from the currently permitted use in foods of the three gases is extremely low. Therefore, suffocation by displacing oxygen from the air has not been considered relevant for assessing the safety of the three gases as food additives.

The impurity 1,3-butadiene is considered to be a non-threshold carcinogen. In the latest review conducted by ECHA in 2024, it is reported that there is consistent evidence for carcinogenicity of 1,3-butadiene in occupationally exposed humans for lymphohematopoietic system, especially leukaemia. 1,3-butadiene was also clearly carcinogenic in both mice and rats, leading to tumours at multiple sites. The ECHA Committee for Risk Assessment (RAC) considered that these effects were due primarily to a genotoxic mechanism of action mediated by reactive metabolites, with pronounced quantitative differences between species. Concerning non-cancer toxicity, the most sensitive endpoint is ovarian atrophy observed in mice following long-term exposure. RAC also noted that ovarian atrophy, found specifically in mice at low concentrations, could be the main critical effect. However, because of differences in metabolism between species and uncertainty about the mode of action, RAC could not establish an 8-h time-weighted average (TWA)<sup>14</sup> (ECHA, 2024).

Toxicity of the three gases has been investigated in the context of the High Production Volume Challenge Program run by the United States Environmental Protection Agency (US EPA).<sup>15</sup> Under the framework of this programme, the publication from McKee et al. (2014) provides an overview of the toxicological hazards of those petroleum-derived hydrocarbon substances that exist in the gaseous state under conditions of standard temperature and pressure and reports on newly conducted toxicity studies following repeated exposure via inhalation. Alkane gases, including propane, butane and isobutane were tested in combined repeated exposure studies with reproduction/development toxicity screening tests conducted in accordance with OECD TG 422 (OECD, 2016) in rats. The gases tested within this programme had purity > 99%.

The no observed adverse effect concentration (NOAEC) values identified by the authors of this study for the three gases were in the range of 4000–9000 ppm for systemic toxicity and 3000–12,000 ppm for reproductive toxicity. The Panel calculated that the oral dose corresponding to the lowest NOAEC values reported by the authors (3000 ppm for isobutane, 4000 ppm for propane) was approximately 1400 mg/kg bw per day<sup>16</sup>

## 4 | DISCUSSION

The present opinion deals with the re-evaluation of butane (E 943a), isobutane (E 943b) and propane (E 944) when used as food additives.

Butane (E 943a), isobutane (E 943b) and propane (E 944) are authorised as food additives in the EU at *quantum satis* (QS) in FC 02.3, 'Vegetable oil pan spray', restricted to vegetable oil pan spray (for professional use only) and water-based emulsion spray. These food additives are also permitted for use in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008 (for professional use only), with a maximum level of 1 mg/kg in the final food.

<sup>14</sup>The 8-h TWA is established in the context of occupational health and safety to ensure that workers are not exposed to harmful levels of substances over an 8-h work shift.

<sup>15</sup>US EPA. (2000). Data collection and development on high production volume (HPV) chemicals. Federal Register, 65(248), 81686.

<sup>16</sup>Calculation made by the Panel using the methodology described in Section 2.2.

No IBO or other interested party provided information in response to the call for data published by EFSA to support the re-evaluation of the three food additives with respect to their identity and specifications, manufacturing process (including the identification and quantification of potential impurities), methods of analysis, stability and reaction and fate in food.

Butane, isobutane and propane are light alkanes (C3-C4) with boiling points at  $-0.5^{\circ}\text{C}$ ,  $-12^{\circ}\text{C}$  and  $-42^{\circ}\text{C}$ , respectively, meaning that the three food additives are in gaseous state at room temperature and at normal atmospheric pressure.

Minimum purity criteria to comply with existing EU food additive specifications for the three gases range from 94% to 96%.

The impurity 1,3-butadiene is identified as of toxicological concern and has been considered by ECHA to be a non-threshold carcinogen. According to the CLP Regulation, 1,3-butadiene is classified as a Category 1 A carcinogen and as a Category 1 B germ cell mutagen. The same classifications apply also to butane and isobutane when containing  $\geq 0.1\%$  1,3-butadiene. This impurity is already listed in Regulation (EU) No 231/2012 in the current specifications of the three food additives, with a limit of not more than  $0.1\%$  v/v, in line with limits set in the CLP Legislation and cosmetics legislation for the gases butane and isobutane containing this impurity.

The Panel also noted that the boiling point of 1,3-butadiene at normal atmospheric pressure is  $-4^{\circ}\text{C}$ , and therefore this impurity is expected to occur in the gaseous state and dissipates under the permitted conditions of use of the three food additives. The Panel therefore considered that dietary exposure to 1,3-butadiene resulting from the currently permitted uses of the three food additives will be negligible.

Butane (E 943a), isobutane (E 943b) and propane (E 944) are authorised as food additives in the EU at *quantum satis* (QS) in FC 02.3, 'Vegetable oil pan spray', restricted to vegetable oil pan spray (for professional use only) and water-based emulsion spray. These food additives are also permitted for use in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008 (for professional use only), with a maximum level of  $1\text{ mg/kg}$  in the final food.

Two IBOs replied to the call for data issued by EFSA reporting use levels on the three food additives. The submitted data related to the use of the food additives in FC 02.3. 'Vegetable oil pan spray'.

A search of Mintel GNPD for foods labelled with these food additives returned a limited number of entries, almost exclusively in cooking or baking oil sprays, consistent with the currently permitted uses of these food additives.

Based on the physicochemical properties and the permitted uses in foods, the Panel assumed that the dietary exposure to butane (E 943a), isobutane (E 943b) and propane (E 944) would be very low. For this reason, a quantitative exposure estimation was considered not relevant for the present opinion.

The toxicological hazards of the three gases via inhalation are known, however this route of exposure is not considered relevant for their safety assessment as food additives. Based on their physicochemical properties, the three gases are considered by the Panel to be of low toxicological concern when used as food additives, as described 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 the previous considerations expressed by the SCF in 1999 in the opinion supporting their currently permitted uses as propellants. The subsequent extension of use granted by the European Commission in 2017 to allow their use in colour preparations was based on analytical data provided by an applicant confirming that 1 h after spraying various foods, the residues of butane, isobutane and propane were below the maximum limit value of  $1\text{ mg/kg}$  final food.

In the absence of oral toxicity data, the Panel used toxicological information from inhalation studies in animals as supporting evidence, and consequently considered that the use of these gases as food additives does not raise a safety concern. However, due to a lack of information on the manufacturing processes used, uncertainties do remain regarding the potential presence of impurities not listed in the current EU specifications for food additives.

## 5 | CONCLUSIONS

The Panel concluded that the use of butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives at the currently permitted uses and use levels does not raise a safety concern.

## 6 | RECOMMENDATION

The Panel recommended that the European Commission considers amending existing EU specifications for butane (E 943a), isobutane (E 943b) and propane (E 944) introducing the CAS numbers 106-97-8, 75-28-5 and 74-98-6, respectively.

The Panel also recommended changing the term 'molecular formula' to 'condensed structural formula' or replacing the given condensed structural formulae with the corresponding molecular formulae.

## 7 | DOCUMENTATION AS PROVIDED TO EFSA

1. Response to call for data on use levels of butane (E 943a) in FC 2.3 Vegetable oil pan spray. March 2024. Submitted by Mobacc Group.

2. Response to call for data on use levels of butane (E 943a), isobutane (E 943b) and propane (E 944) in FC 2.3 Vegetable oil pan spray. March 2024. Submitted by FEDIMA.

## ABBREVIATIONS

AI	artificial intelligence
ANS	Food Additives and Nutrient Sources Added to Food
CAS	Chemical Abstracts Service
CEF	Food Contact Material, Enzymes, Flavourings and Processing Aids
CLP	classification, labelling and packaging
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EUDA	European Union Drugs Agency
FAF	Food Additives and Flavourings
FC	food category
GC	gas chromatography
GNPD	Global new products database
GRAS	generally recognised as safe
HPV	high production volume
HS-GC-MS	headspace gas chromatography–mass spectrometry
IBO	interested business operator
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NOAEC	no observed adverse effect concentration
OECD	Organisation for Economic and Co-operation and Development
OELs	occupational exposure limits
QS	<i>quantum satis</i>
RAC	Committee for Risk Assessment
SCF	Scientific Committee for Food
TG	test guidelines
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration
1,3-BD	1,3-butadiene

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## REQUESTOR

European Commission

## QUESTION NUMBERS

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## APPENDIX A

### Extensive literature search

#### A.1 | METHODOLOGY AND RESULTS

Literature searches for butane (E 943a), isobutane (E 943b) and propane (E 944) were conducted in October 2024 to identify relevant studies on the relationships between gases and food, manufacturing methods and impurities. The first search for butane, yielded 1062, 858 and 346 studies for the butane and food, manufacturing methods and impurities searches, respectively, the search for isobutane 199, 233 and 86, and the search for propane (E 944), 1978, 2466 and 452. 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 butane (E 943a), isobutane (E 943b) and propane (E 944).

Inclusion criteria	Exclusion criteria
Studies that investigate the manufacturing process and related specifications of butane (E 943a), isobutane (E 943b) and propane (E 944) including: (i) information on manufacturing process, (ii) presence of toxicologically relevant impurities and related specifications.	Studies that do not investigate butane (E 943a), isobutane (E 943b) and propane (E 944) as food additives or their manufacturing processes for use as food additives.
Studies that examine the reaction and fate of butane (E 943a), isobutane (E 943b) and propane (E 944) in food.	Studies that do not provide information on the reaction and fate of butane (E 943a), isobutane (E 943b) and propane (E 944) in food.
Studies that provide information on the estimation of dietary exposure to butane (E 943a), isobutane (E 943b) and propane (E 944), including (i) information on applications as food additives, (ii) information on uses and use levels and (iii) information on residual levels of butane (E 943a), isobutane (E 943b) and propane (E 944) in foods.	Studies that do not provide information on dietary exposure to butane (E 943a), isobutane (E 943b) and propane (E 944).
	Studies that do not report on applications, uses and use levels of butane (E 943a), isobutane (E 943b) and propane (E 944).
	Studies that do not report on residual levels of butane (E 943a), isobutane (E 943b) and propane (E 944) in foods.
	Studies that focus on food additives in gaseous form other than butane (E 943a), isobutane (E 943b) and propane (E 944).
	Studies that do not provide original data or reviews (e.g. editorials, opinion pieces, case reports)

## APPENDIX B

## Exposure data

**TABLE B.1** Summary of reported use levels (mg/kg) of butane (E 943a), isobutane (E 943b) and propane (E 944) as provided by industry, after being converted by the Panel to ensure comparability.<sup>17</sup>

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)	N samples	Min of typical usage levels (mg/L or mg/kg as appropriate)	Mean of typical usage levels (mg/L or mg/kg as appropriate)	Max of typical usage levels (mg/L or mg/kg as appropriate)	Max usage levels (mg/L or mg/kg as appropriate)	Provided by
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 943a	<i>quantum satis</i>	47	82	125,729	299,600	300,000	Mobacc Group, FEDIMA
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 943b	<i>quantum satis</i>	2	15,556	15,556	15,556	29,667	FEDIMA
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 944	<i>quantum satis</i>	4	6850	54,629	130,000	150,000	FEDIMA

<sup>17</sup>The Panel noted that some reported use levels were expressed on a fat weight basis. To ensure comparability among the use levels reported, the Panel converted all the use levels to a total weight basis, using the fat percentages indicated for each entry expressed on a fat weight basis. The Panel also noted that some use levels were provided as mg/L in fats oils of mixed origin. To make the figures comparable, the Panel converted these use levels to mg/kg considering a representative relative density of 0.9 g/mL for vegetable oils (Noureddini et al., 1992).

**TABLE B.2** Summary of reported use levels (mg/kg or mg/L as appropriate) of butane (E 943a), isobutane (E 943b) and propane (E 944) as provided by industry.

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)	N samples	Min of typical usage levels (mg/L or mg/kg as appropriate)	Mean of typical usage levels (mg/L or mg/kg as appropriate)	Max of typical usage levels (mg/L or mg/kg as appropriate)	Max usage levels (mg/L or mg/kg as appropriate)	Provided by
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 943a	<i>quantum satis</i>	47	99	166,826	428,000	428,000	Mobacc Group, FEDIMA
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 943b	<i>quantum satis</i>	2	14,000	14,000	14,000	26,700	FEDIMA
2.3	Vegetable oil pan spray	Only vegetable oil pan spray (for professional use only) and water-based emulsion spray	E 944	<i>quantum satis</i>	4	6850	52,588	130,000	150,000	FEDIMA

**TABLE B.3** Number and percentage of food products labelled with butane (E 943a), isobutane (E 943b) and propane (E 944) out of the total number of food products present in the Mintel's GNPD per food sub-category between 2019 and 2024.

Mintel sub-category <sup>a</sup>	Total number of products	Products labelled with butane (E 943a)		Products labelled with isobutane (E 943b)		Products labelled with propane (E 944)		Indicative corresponding food categories from Reg 1333/2008	Notes
		Number	%	Number	%	Number	%		
Oils	7398	10	0.1	5	<0.1	13	0.2	2.1 and 2.3	In the Mintel GNPD, it is not possible to separate food categories 2.1 from 2.3
Cakes, pastries & sweet goods	10,764	0	0	0	0	3	<0.1	7.2	The use of the food additives is not permitted in this food category. The presence may be due to the carry-over from the use as a propellant in FC 02.3 'Vegetable oil pan spray' (According to Annex II to Reg (EC) 1333/2008) and/or as a additive in colour preparations (according to Part 2 of Annex III to Reg (EC) 1333/2008)
Total sample	18,162	–	–	–	–	16	<0.1		

<sup>a</sup>According to the Mintel GNPD food categorisation. Only the food categories in which at least one of the three substances was present are reported.