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SCIENTIFIC OPINION

Re-evaluation of oxygen (E 948) and hydrogen (E 949) 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 oxygen (E 948) and hydrogen (E 949) as food additives. Their currently permitted use in food in the European Union (EU) is in all food categories, including in foods for infants and young children at quantum satis (QS). They can also be used in food additive preparations, food enzymes and nutrients also at QS. No interested business operators (IBOs) provided information in response to the call for data published by EFSA to support their re-evaluation. The original evaluation by the EU in 1990 indicated their use as packaging gases, and in the case of oxygen (E 948), also as propellant. The Panel considered the two gases to be of low toxicological concern when used as food additives and their dietary exposure very low. The Panel concluded that the use of oxygen (E 948) and hydrogen (E 949) as food additives does not raise a safety concern. The Panel made some recommendations for amending existing EU specifications for both oxygen (E 948) and hydrogen (E 949).

KEYWORDS

1333-74-0, 7782-44-7, E 948, E 949, food additives, hydrogen, oxygen

CONTENTS

1 | INTRODUCTION

The present opinion deals with the re-evaluation of oxygen (E 948) and hydrogen (E 949) 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

Oxygen (E 948) and hydrogen (E 949) 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.[1] Specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.[5]

The use of oxygen (E 948) 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: '*Man is permanently exposed to these atmospheric gases. Additionally, carbon dioxide is a natural metabolite. Compared to this exposure, the intake from their use as packaging gases and propellants is insignificant. The establishment of ADI's for these compounds is unnecessary. The Committee considers these compounds acceptable as packaging gases and propellants provided they comply with a food grade specification*' (SCF, 1991).

[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, pp. 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, pp. 19–27.

[3]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.

[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. Available online https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0418:FIN:EN:PDF.

[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.

Also hydrogen (E 949) was evaluated by the EU SCF in 1990 for use as a packaging gas. As outlined in the SFC opinion: *'Apart from drawing attention to its explosive properties, the Committee considers the establishment of an ADI unnecessary. Its use as a packaging gas is toxicologically acceptable provided a food grade specification is available'*. (SCF, 1991).

Specifications for oxygen (INS No 948) were established at the 53rd JECFA meeting in 1999 (JECFA, 1999) but no toxicological monograph was prepared. JECFA specifications indicate that the functional use of oxygen is as a packaging gas.

There are no entries for hydrogen in the JECFA evaluations database.[6]

In addition to the authorised uses as food additive, in the EU, oxygen is also listed in Commission Delegated Regulation (EU) No 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013[7] on authorised oenological practices for the oenological process of aeration or oxygenation and among the permitted gases and packaging gases.

In the EU, hydrogen is permitted as an antioxidant and oxygen is permitted as a skin conditioning agent in cosmetic products (European Commission database-CosIng[8]).

Both oxygen and hydrogen are included in Annex V to Regulation (EC) No 1907/2006[9] (REACH Regulation) among the substances that are exempted from registration with ECHA because registration is deemed inappropriate and unnecessary for these substances.

The EU Pharmacopoeia contains two monographs for oxygen intended for medicinal use corresponding to 'oxygen (0417)' and 'oxygen (93%) (2455)'. A third monograph for 'oxygen (98%) (3098)' has been published and submitted for adoption to the European Pharmacopoeia Commission (Ph. Eur., 2025a, 2025b, 2025c). The different monographs reflect the evolution in the manufacturing methods of the gas (see Section 3.1.2).

Lastly, hydrogen is labelled as extremely flammable (H220) and oxygen as oxidiser may cause or intensify fire (H270) according to Regulation (EC) No 1272/2008[10] on classification, labelling and packaging of substances and mixtures (CLP Regulation).

2 | DATA AND METHODOLOGIES

2.1 | Data

The Panel was not provided with a newly submitted dossier for the re-evaluation of oxygen (E 948) and hydrogen (E 949). EFSA launched a public call for data to collect information from interested parties.[11] 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 two 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.

For the present opinion, the Panel deemed it unfeasible to conduct an extensive search of the published literature to identify relevant evidence, as foreseen under point (e) of Article 4 of Regulation (EU) No 257/2010. The insufficient information provided in response to the call for data did not allow for a refinement of the search strategy which yielded an excessively high volume of records (> 100,000). Consequently, this task was limited to the review of selected references that were deemed relevant by the Panel for the safety evaluation of the two gases when used as food additives.

The Mintel's Global New Products Database (GNPD) was used to check for the uses of oxygen (E 948) and hydrogen (E 949) in food and beverage products and food supplements within the EU market. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.[12]

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.

[6]Available online: https://apps.who.int/food-additives-contaminants-jecfa-database/.

[7]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, pp. 1–52.

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

[9]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, pp. 1–849.

[10]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, pp. 1–1355.

[11]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.

[12]http://www.mintel.com/products/gnpd.

The Panel assessed the safety of oxygen (E 948) and hydrogen (E 949) 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).

3 | ASSESSMENT

3.1 | Technical data

3.1.1 | Identity of the substances and specifications

Oxygen (O_2) is a diatomic molecule with a molecular weight of 32 g/mol and with the CAS number 7727-44-7. The EU specifications describe oxygen as a colourless, odourless and non-flammable gas.

Hydrogen (H_2) is a diatomic molecule with a molecular weight of 2 g/mol and with the CAS number 215-605-7. The EU specifications describe hydrogen as a colourless, odourless and highly flammable gas.

The specifications for oxygen (E 948) and hydrogen (E 949) as defined in Commission Regulation (EU) No 231/2012 and the specifications for oxygen (INS No 948) by JECFA (1999) are listed in Table 1.

TABLE 1 Specifications for the food additives oxygen (E 948) and hydrogen (E 949) according to Commission Regulation (EU) No 231/2012 and for oxygen (E 948) according to JECFA (1999).

	Oxygen (E 948)		**Hydrogen (E 949)**
	Commission Regulation (EU) No 231/2012	**JECFA (1999)**	**Commission Regulation (EU) No 231/2012**
Synonyms		INS No. 948	
Definition			
Einecs	231-956-9		215-605-7
CAS Number		7727-44-7	
Chemical name	Oxygen	Oxygen	Hydrogen
Chemical formula	O_2	O_2	H_2
Molecular weight	32	32.0	2
Assay	Not less than 99%	Not less than 99% by volume	Content not less than 99%
Description	Colourless, odourless and non-flammable gas	Colourless and odourless gas	Colourless, odourless and highly flammable gas
Identification			
Flame test		A glowing splinter, in contact with the gas, bursts into flame	
Purity			
Water content	Not more than 0.05%		Not more than 0.005% v/v
Methane and other hydrocarbons	Not more than 100 µL/L (calculated as methane)		
Carbon dioxide		Not more than 300 µL/L	
Carbon monoxide		Not more than 10 µL/L	
Oxygen			Not more than 0.001% v/v
Nitrogen			Not more than 0.07% v/v
Odour		No appreciable odour is discernible	

The Panel noted that oxygen used for medicinal use can have different grades of purity, ranging from a minimum of 93% to 99.5% (v/v), depending on the manufacturing process applied. In the case of oxygen with purity at least 99.5%, the remainder mainly consists of argon and nitrogen. The specified impurities for oxygen for medicinal use depend on the manufacturing process. Water, carbon dioxide and carbon monoxide are common to all three monographs. Nitrogen monoxide and nitrogen dioxide, sulfur dioxide and oil are listed as possible impurities in the monographs for the two oxygen products of lower purity, produced using adsorption of ambient air on different zeolites/molecular sieves to reduce the levels of nitrogen and argon (see also Section 3.1.2 Manufacturing process).

The Panel noted that JECFA specifications refer to CAS number 7727-44-7 to identify oxygen (INS No 948), however the one corresponding to oxygen is CAS Number 7782-44-7, as reported also in the EU Pharmacopeia. The Panel considered that the CAS Number 7782-44-7 should be included in the existing EU specifications for E 948.

The Panel also considered that the CAS number 1333-74-0 should be included in the existing EU specifications for E 949.

3.1.2 | Manufacturing process

Existing EU specifications for oxygen (E 948) and hydrogen (E 949) 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 two gases with respect to this aspect.

According to the scientific literature, cryogenic distillation is reported as the most common way to produce high-purity oxygen (> 99%) at a large scale (Belaissaoui et al., 2014; Das et al., 2023). The method relies on the principle of separating the different components of the liquified air at low temperatures, based on their boiling points. The process begins with air pre-treatment, where contaminants such as water, carbon dioxide and hydrocarbons are removed downstream of air compression. The air is then cooled to cryogenic temperatures to liquify, followed by fractional distillation to separate oxygen from nitrogen and argon (Smith & Klosek, 2001).

A summary of the evolution of the manufacturing methods used for the production of oxygen for medicinal use can be found in the Knowledge Database[13] of the European Directorate for the Quality of Medicines & HealthCare (EDQM). According to the information reported, cryogenic distillation of ambient air was the method used to produce oxygen with a purity of 99.5% V/V for use in healthcare facilities (Ph. Eur., 2025a). A second monograph for oxygen (93%) was later added to the EU Pharmacopeia to cover oxygen produced on healthcare facility sites using a single-stage adsorption plant. These plants use zeolites/molecular sieves to separate the oxygen from ambient air, producing oxygen with a nominal content between 90.0% and 96.0%, with the remainder being argon and nitrogen (Ph. Eur., 2025b). The latest monograph added to the EU Pharmacopoeia was introduced to cover the technical advances made in the design of adsorption plants used to produce oxygen with a nominal content varying between 96 and 100% (Ph. Eur., 2025c), in particular the introduction of a two-stage adsorption plant, applying differential pressures to the adsorption vessels and argon in the ambient air used as the source of oxygen. This method, known as Pressure-Swing Adsorption (PSA), is described in the published literature as being applicable both to small-scale (such as the one sought for the delivery of oxygen to patients requiring it for long term therapy) and to large-scale production (Ackley, 2019). In practice, however, the efficiency is more relevant for small and medium-scale production rather than industrial scale for which the cryogenic method is still the preferred one allowing for the production of large volumes of oxygen (Si et al., 2025).

Various methods are described in the scientific literature for the production of hydrogen (Afanasev et al., 2024). Among these, steam reforming of natural gas is the most employed in commercial applications today and is typically paired with PSA to produce high-purity hydrogen (Oh & Lee, 2024; Song et al., 2015). In this process, natural gas undergoes extraction, treatment (including compression and purification), and conversion into hydrogen and carbon dioxide. This occurs in two stages: initially, methane and superheated water vapour react in a tubular reactor with a nickel catalyst to produce synthesis gas, primarily consisting of hydrogen and carbon monoxide. In the second stage, carbon monoxide is further converted into hydrogen and carbon dioxide through the 'water–gas shift reaction'. The process operates at high temperatures, with the first stage occurring at 800–1000°C and the second stage at 200–550°C, each utilising different catalysts (Afanasev et al., 2024). In the final step, PSA is used to separate carbon dioxide and other impurities from the gas stream. This process involves alternating pressure changes to adsorb impurities onto solid adsorbents, leaving behind hydrogen with high purity. The purity of the hydrogen typically ranges from 99.9% to over 99.999%, depending on the specific PSA configuration and operating conditions (Sircar & Golden, 2000).

On a small scale (e.g. domestic) hydrogen can be produced using a water electrolysis unit: this method is commonly used for the preparation of water enriched with hydrogen (Hatae & Miwa, 2021). Alternatively, the production of water enriched with hydrogen can be achieved by the dissolution of magnesium in water (Johnsen et al., 2023).

Both methods, steam reforming of natural gas for hydrogen and cryogenic distillation for oxygen, are considered as highly energy-intensive and may, in the future, be replaced by new sustainable techniques, which are under development, such as ion transport membranes for oxygen (Das et al., 2023) and in situ generation within petroleum reservoirs for hydrogen (Afanasev et al., 2024).

The Panel was unable to confirm whether the manufacturing processes found in the scientific literature and summarised above, are applicable to the manufacturing of the two 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 oxygen (E 948) and hydrogen (E 949) adequately cover all the impurities (already listed or unlisted) that may pose any hazard to health.

[13] https://www.edqm.eu/en/knowledge-database.

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 variety of analytical methods are described in the literature for the determination of oxygen in foods and beverages, however it should be borne in mind that all the measurements of oxygen in foods are affected by the possible interference with atmospheric oxygen during sampling and by the oxygen consumption in chemical reactions.

A review of some of the analytical methods available for the measurement of oxygen levels in food lists gravimetry; chemical titration (Winkler Test or other colorimetric measures); manometry; gas chromatography; electrochemical methods (such as the Clark Electrode) and luminescence sensors (Pénicaud et al., 2012). Solid-state oxygen sensors are widely available commercially and are the most commonly used approach to measure the oxygen content of the headspace of food packages in tests of food stability, shelf-life and the effect of modified atmosphere packaging (MAP).

The determination of hydrogen in foods is reported as a marker for the detection of irradiation of foods, resulting from the radiolysis of water and other food components. In non-irradiated food, the presence of hydrogen can be expected only as a result of metabolism by certain anaerobic species. The method described is based on an electronic sensor incorporated into a headspace analyser (Hitchcock, 2000).

Two methods for determining hydrogen in hydrogen-rich water were identified in the literature. The first involves the use of a diaphragm polarographic electrode-type dissolved hydrogen meter (Hatae & Miwa, 2021). The second method utilises a redox titration with H2Blue reagent, a methylene blue-platinum colloid (Reszke et al., 2022).

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.

Owing to its reactivity, oxygen is detrimental to the stability of many foods, particularly those with a high content of unsaturated lipids, however the Panel noted that the possible interaction of oxygen with foods when the gas is used as a food additive leads to the generation of the same type of degradation products as under atmospheric air.

Concerning the reactivity of hydrogen, the Panel noted that it is used in the processing of edible fats and oils, particularly in the catalytic hydrogenation of unsaturated fatty acids. This process typically involves the use of nickel-based catalysts under elevated temperatures (180–200°C) and pressures (1–3 atm). The process enables the production of stable fat products but it can also lead to the formation of trans-fatty acids. A high intake of trans-fatty acids is a risk factor for the development of coronary heart disease and other adverse effects on blood lipids and their dietary intake should be as low as possible (EFSA, 2018).

The Panel considered that the conditions applied to the industrial hydrogenation of unsaturated fatty acids are not relevant to the possible interaction of hydrogen with foods when the gas is used as a food additive.

3.2 | Authorised uses and use levels

Currently, oxygen (E 948) and hydrogen (E 949) 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 2, 3 and 5 of Regulation (EC) No 1333/2008, E 948 and E 949 are permitted also at QS to be used in food additive preparations, food enzymes and nutrients.

3.3 | Exposure data

No IBO or other interested party has reported use levels or analytical data of oxygen (E 948) and hydrogen (E 949) in foods in response to the call for data with respect to this aspect of the re-evaluation.

3.3.1 | Information on uses retrieved from the Mintel database

According to Mintel's GNPD between January 2020 and April 2025, oxygen (E 948) was labelled in 41 different food products mainly in the Mintel's subcategories 'Flavoured water' and 'Fresh cheese & cream cheese'. In the same period, hydrogen (E 949) was labelled in five different products in Mintel's subcategories 'Fresh Cheese & Cream Cheese', 'Meat Pastes & Pates', 'Vitamins & Dietary Supplements' and 'Water'.

In Appendix A, Tables A.1 and A.2 list the percentage of the food and beverage products labelled with E 948 and E 949, respectively, out of the total number of food and beverage products per food subcategory according to Mintel's GNPD food classification.

The Panel noted that oxygen (E 948) and hydrogen (E 949) were labelled in only a limited number of products. Across the Mintel subcategories with at least one food item labelled with E 948, on average 0.1% of all foods was labelled to contain E 948. This average occurrence was less than 0.1% in the case of E 949.

The Panel acknowledged that in case oxygen (E 948) and hydrogen (E 949) are used as packaging gases, they must not be designated in the list of ingredients by the name of their category followed by their specific name or E number (since 'packaging gases' is not mentioned among the categories of Part C of Annex VII of Regulation 1169/2011), but their use must be indicated to consumers through the indication 'packaged in a protective atmosphere'. Therefore, the use of oxygen (E 948) and hydrogen (E 949) as packaging gases may not be captured by Mintel's database.

3.3.2 | Information on uses retrieved from the published literature

Oxygen is commonly used in modified atmosphere packaging (MAP) to preserve and enhance the visual appeal of fresh food products, particularly meat (Kim et al., 2010). High oxygen modified atmosphere packaging (HOMAP) is also applied in the storage of fresh fruits and vegetables (Kader & Ben-Yehoshua, 2000; Zheng et al., 2008; Zheng & Wang, 2007).

The use of hydrogen in food preservation and processing is reported for a range of products and processes, for reducing oxidative degradation (Alwazeer, 2020; Alwazeer et al., 2003; Cachon & Alwazeer, 2019).

Beyond packaging and processing, and as highlighted by the information retrieved in the Mintel database, water and other beverages enriched with oxygen and hydrogen are commercially available. The Panel noted that in the case of beverages enriched with either oxygen or hydrogen, the purpose of the addition of the gases is unlikely to be relevant to their use as food additives, i.e. as packaging gas and/or propellant.

3.4 | Exposure estimates

Based on the physicochemical properties of the two gases and the permitted uses in foods, the Panel assumed that the dietary exposure to oxygen (E 948) and hydrogen (E 949) when used as food additives, if any, would be low.

When used as packaging gases, the concentration of oxygen and hydrogen in the packaged foodstuffs will be low due to the fact that the gases have only a low solubility. The solubility of oxygen and hydrogen in water is 31 mL/L (ca. 40 mg/L) at 20°C and 1.62 mg/L at 21°C (ICSC database, online[14]), respectively. Since the concentration of both gases in foodstuffs of any character (dry, aqueous, fatty, mixed) will also be low, the dietary exposure via said foods would be low too.

For this reason, a quantitative exposure estimation was considered not relevant for the present opinion.

3.5 | Biological and toxicological data

3.5.1 | Oxygen

3.5.1.1 | *Physiological background*

Oxygen is essential for living organisms, in particular in mammalian organisms including humans. Inhaled air contains roughly 21% of oxygen. Oxygen diffuses through the alveoli in the lung into the blood where it is bound to haemoglobin of the red blood cells (around 98.5% of total blood oxygen) and directly dissolved in the plasma (only around 1.5% of total blood oxygen content). The haemoglobin oxygen saturation indicates the percentage of oxygenated haemoglobin. The partial pressure of oxygen (PO_2) is a measure for the oxygen dissolved in the plasma. Blood entering the lungs typically has a partial pressure (PO) of 40 mm Hg, while blood leaving the lungs has normally a PO of approximately 100 mm Hg. Oxygenated blood reaches tissues by the blood stream, where oxygen is delivered to cells. In the cell, oxygen is the terminal electron acceptor moiety of the mitochondrial electron transport chain in generating energy in the form of adenosine triphosphate through oxidative phosphorylation. Hypoxemia and hypoxia may result in failure to deliver oxygen to the mitochondria (Aung et al., 2019).

Oxygen is reactive and can be converted to so-called reactive oxygen species (ROS). ROS include the superoxide anion (O_2^-), hydrogen peroxide (H_2O_2), the hydroxyl radical ($^{\bullet}OH$), singlet oxygen ($^1O_2$), the hypochlorous anion (OCl^-) and ozone (O_3). ROS can cause structural damage to lipid membranes, proteins and nucleic acids, and can lead to a wide spectrum of cellular damage, including genotoxicity and cellular necrosis. The production of ROS takes place even at physiological levels of oxygen and is balanced out by scavenging systems (Dröge, 2002).

Normobaric administration of oxygen at high concentrations will increase the production of ROS and hyperbaric conditions further increase the production, which at a certain level cannot be counterbalanced anymore by the scavenging systems such as superoxide dismutase (SOD), catalase, the glutathione redox cycle, as well as vitamins C and E, beta-carotene and uric acid (Davies, 2000).

[14] https://chemicalsafety.ilo.org/dyn/icsc/showcard.listcards3?p_lang=en.

3.5.1.2 | *Therapeutic use*

Oxygen is medically used in patients being at risk for or suffering from hypoxia. Whereas a high inspired fraction of oxygen (FiO_2) can be tolerated for a short term without damaging the lung alveoli, alveolar membrane damage may start with a FiO_2 above 60% when applied for prolonged periods (Kallet & Matthay, 2013).

Newborn infants, especially premature infants, have a particular risk to experience oxygen toxicity. Traditionally, resuscitation was performed with 100% oxygen. However, epidemiological data have shown an association between higher oxygen saturation targets and retinopathy in premature and newborn infants. Therefore, systematic reviews and meta-analyses have led to a reduction in the use of high FiO_2 for both neonatal resuscitation and respiratory dysfunction (Manley et al., 2017) and also in adult patients.

3.5.1.3 | *Comparison of the oxygen exposure in medical conditions and exposure by use of oxygen as a food additive*

As pointed out above, even a high percentage of oxygen in the inspired air (up to 100%) can be tolerated for short term exposure (some hours) without toxicity. The scenario when using oxygen as a food additive could in principle increase the content of oxygen present in the air to a small extent, however surely not to 100% (FiO_2 1.0). When considering a room, filled with normal air with 21% of oxygen, the supply with 100% O_2 must be roughly 1.5-fold the volume of the room to get the room filled with 50% O_2 which is still tolerated, even for prolonged periods without toxicity.

Thus, the volume of oxygen used as food additive does not raise a health concern.

3.5.2 | Hydrogen

Hydrogen is one of the least abundant gases in the atmosphere, present in only trace amounts in the air since this lightest of all of the elements can escape earth's gravity. The human large intestine typically produces approximately 70–140 mL of hydrogen daily through the action of coliform bacteria such as *Escherichia coli*. This production can increase with the intake of dietary fibres and sugars (Sun et al., 2015).

Hydrogen gas is nontoxic and despite growing interest in its possible therapeutic applications as an antioxidant and cellular protective compound (Russell et al., 2021), its use remains largely anecdotal and currently its efficacy is not sufficiently substantiated to include it in clinical guidelines. The Panel considered that no conclusions on the safety of hydrogen as a food additive can be drawn from clinical studies on hydrogen-rich water described in published systematic reviews (Dhillon et al., 2024; Johnsen et al., 2023).

Possible health effects include suffocation by diluting the concentration of oxygen in the air below levels necessary to support life. The Panel considers that inhalation exposure of consumers resulting from the currently permitted uses of hydrogen in food is extremely low. Therefore, suffocation by displacing oxygen from the air has not been considered relevant for assessing the safety of the gas as a food additive.

In summary, the potential hazard of suffocation is not of concern under realistic exposure conditions. Therefore, the Panel considers that hydrogen as a food additive does not raise concerns.

4 | DISCUSSION

The present opinion deals with the re-evaluation of oxygen (E 948) and hydrogen (E 949) when used as food additives.

Oxygen (O_2) and hydrogen (H_2) are two gases, the former abundantly present in the air and essential for life, the latter present in only trace amounts in the air but formed endogenously in the body through the action of coliform bacteria.

The two food additives, oxygen (E 948) and hydrogen (E 949) 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 2, 3 and 5 of Regulation (EC) No 1333/2008, E 948 and E 949 are permitted to be used in food additive preparations, food enzymes 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.). No data on uses and use levels of oxygen (E 948) and hydrogen (E 949) have been provided to EFSA in response to the call for data.

Information retrieved from the published literature indicate that both gases have applications in modified atmosphere packaging, consistent with the technological function reported in the original evaluation by the SCF.

Hydrogen gas (H_2) is used in the processing of edible fats and oils, particularly in the hydrogenation of unsaturated fatty acids using catalysts and elevated temperature and pressure. The process can lead to the formation of undesirable trans-fatty acids. The Panel noted that the conditions applied to the industrial hydrogenation of unsaturated fatty acids are unlikely to be relevant when the gas is used as a food additive.

A search of Mintel's GNPD for foods labelled with oxygen (E 948) and hydrogen (E 949) returned a limited number of entries, including the Mintel subcategories 'Flavoured water' and 'Fresh cheese & cream cheese'. The Panel noted that in the case of beverages enriched with either oxygen or hydrogen, the purpose of the addition of the gases is unlikely to be relevant to their use as food additives, i.e. as packaging gas and/or propellant.

Based on the physicochemical properties and the permitted uses in foods, the Panel assumed that dietary exposure to oxygen (E 948) and hydrogen (E 949) when used as food additives would be low, if any, and a quantitative exposure estimation was considered not relevant for the present opinion.

Both 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). No information was available on the potential presence of impurities of toxicological concern resulting from the manufacturing process(es) of the food additives E 948 and E 949. The Panel however noted that a minimum purity of 99% 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 the manufacturing processes, uncertainties do remain about potential presence of impurities.

5 | CONCLUSIONS

The Panel concluded that the use of oxygen (E 948) and hydrogen (E 949) as food additives does not raise a safety concern.

6 | RECOMMENDATION

The Panel recommended that the European Commission considers amending existing EU specifications for oxygen (E 948) and hydrogen (E 949) introducing the CAS numbers 7782-44-7 and 1333-74-0, respectively.

ABBREVIATIONS

ADI	acceptable daily intake
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines
FAF Panel	EFSA Panel on Food Additives and Flavourings
FiO_2	fraction of oxygen
H_2	hydrogen
H_2O_2	peroxide
$HOCl^-$	hypochlorous anion
HOMAP	high oxygen modified atmosphere packaging
HPLC	high-performance liquid chromatography
IBO(s)	interested business operator(s)
ICSC	International Chemical Safety Cards
JECFA	Joint FAO/WHO Experts Committee on Food Additives
MAP	modified atmosphere packaging
Mintel's GNPD	Mintel's Global New Products Database
MS	mass spectrometry
O^-	singlet oxygen
O_2^-	superoxide anion
O_3	ozone
OH^-	hydroxyl radical
PO_2	partial pressure of oxygen
PSA	pressure-swing adsorption
QS	*Quantum satis*
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
ROS	reactive oxygen species
SCF	Scientific Committee on Food
SOD	superoxide dismutase

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REQUESTOR

European Commission

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REFERENCES

Ackley, M. (2019). Medical oxygen concentrators: A review of progress in air separation technology. *Adsorption*, *25*(8), 1437–1474.

Afanasev, P., Askarova, A., Alekhina, T., Popov, E., Markovic, S., Mukhametdinova, A., Cheremisin, A., & Mukhina, E. (2024). An overview of hydrogen production methods: Focus on hydrocarbon feedstock. *International Journal of Hydrogen Energy*, *78*, 805–828. https://doi.org/10.1016/j.ijhydene.2024.06.369

Alwazeer, D. (2020). Importance of consideration of oxidoreduction potential as a critical quality parameter in food industries. *Food Research International*, *132*, 109108. https://doi.org/10.1016/j.foodres.2020.109108

Alwazeer, D., Delbeau, C., Divies, C., & Cachon, R. (2003). Use of redox potential modification by gas improves microbial quality, color retention, and ascorbic acid stability of pasteurized orange juice. *International Journal of Food Microbiology*, *89*(1), 21–29. https://doi.org/10.1016/s0168-1605(03)00125-9

Aung, H. H., Sivakumar, A., Gholami, S. K., Venkateswaran, S. P., Gorain, B., & Shadab, M. D. (2019). Chapter 1. An overview of the anatomy and physiology of the lung. In H. H. Aung, A. Sivakumar, & S. K. Gholami (Eds.), *Nanotechnology-based drug delivery systems for lung cancer* (pp. 1–20). Academic Press.

Belaissaoui, B., Le Moullec, Y., Hagi, H., & Favre, E. (2014). Energy efficiency of oxygen enriched air production technologies: Cryogeny vs membranes. *Separation and Purification Technology*, *125*, 142–150. https://doi.org/10.1016/j.seppur.2014.01.043

Cachon, R., & Alwazeer, D. (2019). Quality performance assessment of gas injection during juice processing and conventional preservation technologies. In *Value-added ingredients and enrichments of beverages* (pp. 465–485). Academic Press. https://doi.org/10.1016/b978-0-12-816687-1.00014-x

Das, A., Peu, S. D., Hossain, M. S., & Das, B. K. (2023). Integration of ion transport membrane with conventional powerplant to enhance the plant capacity with improved power production. *Heliyon*, *9*(6), e16387. https://doi.org/10.1016/j.heliyon.2023.e16387

Davies, K. J. (2000). Oxidative stress, antioxidant defences, and damage removal, repair, and replacement systems. *IUBMB Life*, *50*(4–5), 279–289.

Dhillon, G., Buddhavarapu, V., Grewal, H., Sharma, P., Verma, R. K., Munjal, R., Devadoss, R., & Kashyap, R. (2024). Hydrogen water: Extra healthy or a hoax? – A systematic review. *International Journal of Molecular Sciences*, *25*, 973. https://doi.org/10.3390/ijms25020973

Dröge, W. (2002). Free radical in the physiological control of cell function. *Physiological Reviews*, *82*(2002), 47–95. https://doi.org/10.1152/physrev.00018.2001

EFSA (European Food Safety Authority). (2018). Scientific and technical assistance on trans fatty acids. *EFSA Supporting Publication*, *15*(6), EN-1433. https://doi.org/10.2903/sp.efsa.2018.EN-1433

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food). (2012). Guidance for submission for food additive evaluations. *EFSA Journal*, *10*(7), 2760. https://doi.org/10.2903/j.efsa.2012.2760

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food). (2014). Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under commission regulation (EU) No 257/2010. *EFSA Journal*, *12*(6), 3697. https://doi.org/10.2903/j.efsa.2014.3697

EFSA Scientific Committee. (2009). Guidance of the scientific committee on transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: General principles. *EFSA Journal*, *7*(11), 1051. https://doi.org/10.2903/j.efsa.2009.1051

Hatae, T., & Miwa, N. (2021). Electrolytic hydrogen-generating bottle supplies drinking water with free/combined chlorine and ozone repressed within safety standard under hydrogen-rich conditions. *Medical Gas Research*, *11*(2), 61–65. https://doi.org/10.4103/2045-9912.311496

Hitchcock, C. H. S. (2000). Determination of hydrogen as a marker in irradiated frozen food. *Journal of the Science of Food and Agriculture*, *80*(1), 131–136. https://doi.org/10.1002/(SICI)1097-0010(20000101)80:1<131::AID-JSFA500>3.0.CO;2-4

JECFA (Joint FAO/WHO Expert Committee on Food Additives). (1999). *Compendium of food additive specifications (Addendum 7)*. Joint FAO/WHO Expert Committee on Food Additives 53rd Session Rome, 1–10 June 1999. https://openknowledge.fao.org/handle/20.500.14283/x3860e

Johnsen, H. M., Hiorth, M., & Klaveness, J. (2023). Molecular hydrogen therapy – A review on clinical studies and outcomes. *Molecules*, *28*(23), 7785. https://doi.org/10.3390/molecules28237785

Kader, A. A., & Ben-Yehoshua, S. (2000). Effects of superatmospheric oxygen levels on postharvest physiology and quality of fresh fruits and vegetables. *Postharvest Biology and Technology*, *20*(1), 1–13. https://doi.org/10.1016/S0925-5214(00)00122-8

Kallet, R. H., & Matthay, M. A. (2013). Hyperoxic acute lung injury. *Respiratory Care*, *58*(1), 123–141. 2.

Kim, Y. H., Huff-Lonergan, E., Sebranek, J. G., & Lonergan, S. M. (2010). High-oxygen modified atmosphere packaging system induces lipid and myoglobin oxidation and protein polymerization. *Meat Science*, *85*(4), 759–767. https://doi.org/10.1016/j.meatsci.2010.04.001

Manley, B. J., Owen, L. S., Hooper, S. B., Jacobs, S. E., Cheong, J. L. Y., Doyle, L. W., & Davis, P. G. (2017). Towards evidence-based resuscitation of the newborn infant. *Lancet*, *389*(10079), 1639–1648.

Oh, T., & Lee, S. (2024). Optimization of steam-methane reforming process using PSA off gas. *International Journal of Hydrogen Energy*, *95*, 902–915. https://doi.org/10.1016/j.ijhydene.2024.11.149

Pénicaud, C., Peyron, S., Gontard, N., & Guillard, V. (2012). Oxygen quantification methods and application to the determination of oxygen diffusion and solubility coefficients in food. *Food Reviews International*, *28*(2), 113–145. https://doi.org/10.1080/87559129.2011.595021

Ph. Eur. (European Pharmacopoeia). (2025a). *European Pharmacopoeia* (11th ed.) Oxygen, text number: 0417.

Ph. Eur. (European Pharmacopoeia). (2025b). *European Pharmacopoeia* (11th ed.). Oxygen (93 per cent), text number: 2455.

Ph. Eur. (European Pharmacopoeia). (2025c). *European Pharmacopoeia* (11th ed.). Oxygen (98 per cent), text number: 3098.

Reszke, E., Binkiewicz, G., & Schroeder, G. (2022). Process technology for production of hydrogen-rich water and water characterizing by highly negative oxidation reduction potential. *Asian Journal of Applied Chemistry Research*, *12*, 41–55. https://doi.org/10.9734/ajacr/2022/v12i1214

Russell, G., Nenov, A., Kisher, H., & Hancock, J. T. (2021). Molecular hydrogen as medicine: An assessment of administration methods. *Hydrogen*, *2*(4), 444–460. https://doi.org/10.3390/hydrogen2040025

SCF (Scientific Committee for Food). (1991). *Reports of the Scientific Committee for Food (twenty-fifth series)*. Food sciences and techniques. https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_reports_25.pdf

Si, H., Hong, Q., Chen, X. H., & Jiang, L. (2025). Pressure swing adsorption for oxygen production: Adsorbents, reactors, processes and perspective. *Chemical Engineering Journal*, *509*, 161273. https://doi.org/10.1016/j.cej.2025.161273

Sircar, S., & Golden, T. C. (2000). Purification of hydrogen by pressure swing adsorption. *Separation Science and Technology*, *35*(5), 667–687. https://doi.org/10.1081/ss-100100183

Smith, A. R., & Klosek, J. (2001). A review of air separation technologies and their integration with energy conversion processes. *Fuel Processing Technology*, *70*(2), 115–134. https://doi.org/10.1016/S0378-3820(01)00131-X

Song, C., Liu, Q., Ji, N., Kansha, Y., & Tsutsumi, A. (2015). Optimization of steam methane reforming coupled with pressure swing adsorption hydrogen production process by heat integration. *Applied Energy*, *154*, 392–401. https://doi.org/10.1016/j.apenergy.2015.05.038

Sun, Q., Han, W., & Nakao, A. (2015). Biological Safety of Hydrogen. In X. Sun, S. Ohta, & A. Nakao (Eds.), *Hydrogen molecular biology and medicine* (pp. 35–48). Springer. https://doi.org/10.1007/978-94-017-9691-0_3

Zheng, Y., & Wang, C. (2007). Effect of high oxygen atmospheres on quality of fruits and vegetables. *Stewart Postharvest Review*, *3*, 1–8. https://doi.org/10.2212/spr.2007.2.1

Zheng, Y., Yang, Z., & Chen, X. (2008). Effect of high oxygen atmospheres on fruit decay and quality in Chinese bayberries, strawberries and blueberries. *Food Control*, *19*(5), 470–474. https://doi.org/10.1016/j.foodcont.2007.05.011

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APPENDIX A

Exposure data

TABLE A.1 Number and percentage of food products labelled with oxygen (E 948) of the total number of food products present in Mintel's GNPD per subcategory where at least one food product is labelled with E 948. Information refers to the period between January 2020 and April 2025.

Mintel subcategories[a]	Tot # of food samples per subcategory	Products labelled with E 948	
		n	% out of total samples
Chilled desserts	3474	6	0.2
Flavoured water	1041	9	0.9
Fresh cheese & cream cheese	2096	8	0.4
Hors d'oeuvres/canapes	3153	4	0.1
Meat products	19,818	5	0.0
Seasonal chocolate	9047	2	0.0
Soft cheese desserts	730	2	0.3
Spoonable yogurt	4920	4	0.1
Wet soup	2544	1	0.0
Total	**46,823**	**41**	**0.1**

[a]According to the Mintel GNPD food categorisation. Only the food categories where at least one food product is labelled with oxygen (E 948) are reported.

TABLE A.2 Number and percentage of food products labelled with hydrogen (E 949) of the total number of food products present in Mintel's GNPD per subcategory where at least one food product is labelled with E 949. Information refers to the period between January 2020 and April 2025.

Mintel subcategories[a]	Tot # of food samples per subcategory	Products labelled with E 949	
		n	% out of total samples
Fresh cheese & cream cheese	2096	2	0.1
Meat pastes & pates	2202	1	< 0.1
Vitamins & dietary supplements	14,131	1	< 0.1
Water	1365	1	0.1
Total	**19,794**	**5**	**< 0.1**

[a]According to the Mintel GNPD food categorisation. Only the food categories where at least one food product is labelled with hydrogen (E 949) are reported.