Adopted: 25 June 2024

DOI: 10.2903/j.efsa.2024.8897

efsa JOURNAL

SCIENTIFIC OPINION

Re-evaluation of shellac (E 904) as a food additive and a new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes

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Abstract

The present opinion deals with the re-evaluation of shellac (E 904) when used as a food additive and with the new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes. The Panel derived an acceptable daily intake (ADI) of 4 mg/kg body weight (bw) per day for wax-free shellac (E 904) produced by physical decolouring, based on a NOAEL of 400 mg/kg bw per day and applying an uncertainty factor of 100. The Panel concluded that the ADI of 4 mg/kg bw per day should be considered temporary for wax-free shellac (E 904) produced by chemical bleaching, while new data are generated on the identity and levels of the organochlorine impurities in E 904. This ADI is not applicable for wax-containing shellac as a food additive. For several age groups, the ADI was exceeded at the 95th percentile in the non-brand-loyal exposure assessment scenario and maximum level exposure assessment scenario. Considering the low exceedance and the fact that both the exposure estimation and the toxicological evaluation of shellac were conservative, the panel concluded that the calculated exceedance of the ADI does not indicate a safety concern. The Panel recommended to the European Commission separating specifications for E 904 depending on the manufacturing process, chemical bleaching and physical decolouring, because they result in different impurities; revising the definition of the food additive to include a description of each manufacturing process; deleting information on wax-containing shellac from the EU specifications; revising the acid value for wax-free shellac produced by chemical bleaching; lowering the maximum limit for lead; to consider introducing limits for other toxic elements potentially present in shellac; including a maximum limit for chloroform and total inorganic chloride in the EU specification for shellac produced by chemical bleaching.

KEYWORDS

chemical bleaching, E 904, extension of use, food additive, physical decolouring, shellac

CONTENTS

SUMMARY

The present opinion deals with the re-evaluation of shellac (E 904) when used as a food additive and with a new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes (FSMP) in tablet and coated tablet form (i.e. FC 13.2 of part E of Annex II to Regulation (EC) No 1333/2008).

In the EU, shellac (E 904) was evaluated as a food additive by the Scientific Committee on Food (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1992 and 1993, respectively. Both committees were not able to allocate an acceptable daily intake (ADI).

Shellac is a low molecular-weight resin mainly composed of a complex mixture of different mono- and polyesters of hydroxyaliphatic acids and sesquiterpenoid acids.

Shellac (E 904) is authorised as a food additive in the EU at a maximum permitted level (MPL) of *quantum satis* (*QS*) in 11 food categories in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012. Six food categories were taken into account in the present exposure estimate (seven food categories for the food supplements consumers' only scenario). In the exposure assessment, it was assumed that 100% of the foods belonging to an authorised food category would contain shellac (E 904), while according to Mintel GNPD, on average only 1.6% of foods per subcategory were labelled with E 904. Taking into account the uncertainties identified, the Panel considered that the exposure estimates for all exposure scenarios resulted in an overestimation of the exposure to shellac (E 904) from its use as a food additive according to Annex II to Regulation (EC) No 1333/2008.

The proposed extension of use of shellac (E 904) in FSMP in tablet and coated tablet form (FC 13.2) would result in an additional exposure of 1.5 mg/kg body weight (bw) per day. Despite the proposed extension of use is foreseen for adults, adolescents could also consume such tablets, and this would result in an additional exposure to shellac of 1.9 mg/kg bw per day for this population group.

Information on two manufacturing processes for refining seedlac, namely the chemical bleaching process using sodium hypochlorite and the physical decolouring process using activated carbon, to produce shellac has been indicated by interested business operators (IBOs). The Panel noted that as a result of the process used, different impurities can be present in shellac.

No analytical data on toxic elements potentially present in shellac were available. A maximum limit for lead of 2 mg/kg is included in the EU specifications for E 904.

As a result of the bleaching process using sodium hypochlorite, the Panel noted that shellac (E 904) contains chloroform, inorganic chloride and organochlorine impurities. Quantitative data on the presence of chloroform and inorganic chloride in shellac were available. Concerning the organochlorine impurities, eight chlorinated compounds were detected; however, the structural identity and their levels in the shellac E 904 were not available. Therefore, the absence of health concerns of these organochlorine impurities cannot be confirmed without information on their identity and amount in the food additive.

The risk assessment of lead and chloroform, based on the available information, was performed to determine whether there could be a possible health concern if these impurities would be present at a certain value in the food additive. The panel recommended to lower the maximum limit for lead and to introduce a maximum limit for chloroform, which based on the data provided could be lower (e.g. 200 mg/kg) than the one proposed by the IBO (400 mg/kg).

The toxicological studies provided were performed with shellac (E 904) produced either by chemical bleaching or by physical decolouring. In addition, all test materials used in the toxicological studies submitted by the three IBOs are wax-free shellac.

Information on absorption, distribution, metabolism, excretion (ADME) was not available to the SCF or JECFA at the time of their evaluations. In a 4-week study in rats, the absorption of what is called 'shellac monomer' (which is an ester derived from jalaric acid and aleuritic acid) was analysed in plasma showing that the absorption of this component was very low.

Shellac (E 904) is considered to be as of low acute toxicity.

No toxicologically relevant effects were seen in the oral subchronic studies in rats with shellac (E 904) produced either by chemical bleached or by physical decolouring at doses amounting to 1600 mg/kg bw per day, the highest dose tested.

The results of the available genotoxicity studies do not raise concern for shellac (E 904) produced either by chemical bleaching or by physical decolouring. However, due to the complex chemical composition of E 904, an in silico assessment of main shellac components was performed. The results obtained do not indicate a genotoxic potential for any of the shellac components evaluated.

In one combined chronic toxicity/carcinogenicity study performed with shellac (E 904) produced by chemical bleaching, the Panel identified a NOAEL at the highest dose tested (452 mg/kg bw per day for males and 569 mg/kg bw per day for females). In another combined chronic toxicity/carcinogenicity study in Wistar rats performed with physical decolouring shellac (E 904), the Panel identified a NOAEL of 500 mg/kg bw per day (based on non-neoplastic lesions observed at the highest dose tested of 1500 mg/kg bw per day).

In an oral dietary reproductive and developmental toxicity screening test with shellac (E 904) produced by chemical bleaching, the low dose (300 mg/kg bw per day) was identified as the NOAEL for maternal toxicity based on decreased body weight gain in the dams, and the high dose (1200 mg/kg bw per day) as the NOAEL for reproductive and developmental toxicity. However, in a dietary two-generation reproductive toxicity study in rats with shellac (E 904) produced by chemical bleaching, the NOAELs for parental, reproductive and developmental toxicity were 800, 1600 and 400 mg/kg bw per day, respectively. In a prenatal developmental toxicity study in rabbits, with shellac produced by chemical bleaching, a NOAEL of 500 mg/kg bw per day for maternal toxicity and a NOAEL of 1000 mg/kg bw per day, the highest dose tested, for developmental toxicity were observed.

No reproductive toxicity study with shellac produced by physical decolouring was available. The Panel noted that the results of the reproductive toxicity studies with shellac produced by chemical bleaching can be extrapolated to shellac produced by physical decolouring. In a prenatal developmental toxicity study in rats and rabbits with shellac produced by physical decolouring the NOAEL for developmental and maternal toxicity was 1000 mg/kg bw per day, the highest dose tested, in both species.

Taking into account the available toxicity database, the Panel identified a NOAEL of 300 mg/kg bw per day based on the decreased body weight gain in the dams observed at 600 mg/kg bw per day from a short-term study. However, in a two-generation reproductive toxicity study of longer duration, a NOAEL of 400 mg/kg bw per day, based on the decreased pup weight (F2), was identified. In addition, no dose-related effects were observed in parental animals up to a dose of 800 mg/kg bw per day. The Panel noted that in chronic studies, no adverse effects were observed at much higher dose levels. Therefore, the Panel considered that the NOAEL of 400 mg/kg bw per day, based on the decreased pup weight (F2) in the two-generation reproductive toxicity study, could be used to derive an ADI for shellac (E 904). Applying an uncertainty factor of 100, an ADI of 4 mg/kg bw per day for wax-free shellac (E 904) produced by physical decolouring was derived by the Panel.

The Panel concluded that the ADI of 4 mg/kg bw per day should be considered temporary for wax-free shellac (E 904) produced by chemical bleaching, while new data are generated on the identity and levels of the organochlorine impurities in E 904 to allow their safety evaluation. In addition, the Panel considered that this ADI is not applicable for wax-containing shellac as a food additive.

The Panel did not identify brand loyalty to a specific food category and therefore, considered the refined non-brand-loyal exposure assessment scenario the most appropriate for the risk assessment. The Panel noted that the mean exposure estimates for the different population groups for this scenario did not exceed the ADI of 4 mg/kg bw per day for shellac (E 904). However, the dietary exposure estimates at the 95th percentile exceeded the ADI of 4 mg/kg bw per day at the maximum of the ranges for toddlers, children and adolescents.

Considering the maximum level exposure assessment scenario as the most conservative scenario, the Panel noted that the mean exposure estimates do not exceed the ADI for any population group. At the 95th percentile, exposure estimates exceeded the ADI of 4 mg/kg bw per day at the maximum of the ranges for toddlers, children, adolescents and adults.

The Panel noted that the major application of shellac is by spraying diluted in ethanol or alkaline solution and after application shellac remains as a coating. Self-esterification or self-polymerisation is expected to occur during storage or after application. Despite some components of shellac will be present as individual substances, it is expected that they will mainly be esterified forming 'oligomers/polymers'. Hence, the main exposure of shellac through food will be to more polymerised material than present in pristine shellac. The Panel noted that shellac in the in vivo toxicological animal studies have been administered as suspended in a solution or via the diet and this can be considered as the worst case of exposure to isolated lower molecular weight components of shellac.

The Panel also considered a request for the extension of use of E 904 in foods for special medical purposes (FSMP) in tablet and coated tablet form (i.e. FC 13.2 of part E of Annex II to Regulation (EC) No 1333/2008) at a proposed maximum use level of 46,000 mg/kg. The proposed extension of use would result in a further exceedance of the ADI at the 95th percentile in the maximum level exposure assessment scenario for adults. In the case adolescents would also consume these tablets, both the mean and the 95th percentile exposure will exceed the ADI for the proposed extension of use in the maximum level exposure assessment scenario, while in the *non-brand loyal exposure assessment scenario*, the ADI would be exceeded at the 95th percentile. The Panel noted that in all scenarios that address the extension of use, the exposure is overestimated because it is also assumed that all FSMP in tablet and coated tablet form contain shellac.

The Panel noted that, for several age groups, the ADI was exceeded at the 95th percentile of exposure. However, taking into account the low exceedance and the fact that both the exposure estimation (and the toxicological evaluation) of shellac were conservative the Panel considered that in this case, the exceedance of the ADI would not indicate a safety concern.

Finally, the Panel recommended that the temporary ADI for shellac (E 904) produced by chemical bleaching should be re-evaluated once the requested data on the identity and levels of the organochlorine impurities in E 904 are generated. Data generated should reflect variability among the different manufacturers of shellac and within shellac produced by the same manufacturer considering alterability of the bleaching process.

Furthermore, the Panel recommended to the European Commission:

- separating specifications for E 904 depending on the manufacturing process, chemical bleaching process and physical decolouring process, because they result in different impurities in shellac;
- revising the definition of the food additive to include a short description of each manufacturing process (chemical bleaching or physical decolouring);
- deleting information on wax-containing shellac from the EU specifications since it is not used as E 904 and no data to confirm its safety were available;
- revising the acid value for wax-free shellac produced by chemical bleaching that can be slightly above the current limit of 89 in line with the specifications in the FCC (2010);
- lowering the maximum limit for lead;
- to consider introducing limits for other toxic elements potentially present in shellac;
- including a maximum limit for chloroform and total inorganic chloride in the EU specification for shellac produced by chemical bleaching.

1 | INTRODUCTION

The present opinion deals with the re-evaluation of shellac (E 904) when used as a food additive and with a new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes.

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

1.1.1 | Background

1.1.1.1 | *Re-evaluation of shellac (E 904) as a food additive under Regulation (EU) No 257/2010*

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. 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 on 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[3] of 2001. 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) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.1.2 | *Application of shellac (E 904) for an extension of use in foods for special medical purposes in tablet and coated tablet form*

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives. Only food additives that are included in the Union list, in particular Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012.[5]

Shellac (E 904) is a glazing agent, which is authorised for use as a food additive in the Union. Since shellac was permitted in the Union before 20 January 2009, it belongs to the group of food additives that are subject to a new risk assessment by EFSA.

The European Commission has received an application from the company HASCO-LEK S.A. for a modification of the conditions of use of shellac. In particular, the applicant requests an extension of use in foods for special medical purposes in tablet and coated tablet form (i.e. the food category 13.2 of part E of Annex II to Regulation (EC) No 1333/2008). The applicant requests the maximum use level of 46,000 mg/kg. According to the applicant the use of this glazing agent would allow the production of enteric-coated tablets to people suffering from intestinal dysfunction or gastrointestinal disorders. Thanks to the use of shellac-containing coating, the tablet is resistant to the gastric environment, i.e. to the effects of gastric acid, and does not disintegrate in the stomach.

If possible, the proposed extension of use should be incorporated in the scientific opinion re-evaluating safety of shellac (E 904) as food additive.

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

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

[3]COM(2001) 542 final.

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

[5]Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.33.2012, p. 1.

1.1.2 | Terms of Reference

1.1.2.1 | *Re-evaluation of shellac (E 904) as a food additive under Regulation (EU) No 257/2010*

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.

1.1.2.2 | *Application of shellac (E 904) for an extension of use in foods for special medical purposes in tablet and coated tablet form*

The European Commission requests the European Food Safety Authority to provide a scientific opinion on the safety of the proposed extension of use of shellac (E 904) in foods for special medical purposes in tablet and coated tablet form (food category 13.2 of part E of Annex II to Regulation (EC) No 1333/2008), with a maximum level of 46,000 mg/kg, in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[6]

1.2 | Information on existing evaluations

Shellac (E 904) is authorised as a food additive in the EU in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012.

Shellac (E 904) was evaluated as a food additive by the Scientific Committee on Food (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1992 and 1993, respectively. Both committees were not able to allocate an acceptable daily intake (ADI) (JECFA, 1992, 1993).

The SCF concluded that the available data were inadequate to establish the safety of the compound but temporarily accepted continuation of use until 1995, to allow further toxicological and technical data on use to be provided (SCF, 1992). No further toxicological data on shellac were submitted.

JECFA commented that shellac was not mutagenic in the Ames test, either without or in the presence of metabolic activation and produced no evidence of treatment-related toxic or pathological effects in two 90-day studies, one including an in utero exposure phase. Therefore, JECFA concluded that the functional uses of shellac (as a coating, glazing, and surface-finishing agent applied externally to food) were of no toxicological concern (JECFA, 1993).

Shellac (E 904) was also reviewed by the Nordic Council of Ministers (TemaNord, 2002), who concluded that the available uses were of no toxicological concern, but they recommended a re-evaluation to remove the temporary status of the approval (TemaNord, 2002).

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) published the evaluation of the feed additive Cylactin® for different animal species in October 2023 (EFSA FEEDAP Panel, 2023). One of the formulations of the additive assessed (Cylactin® LBC ME20 plus) contains wax-free (physically) bleached shellac as a coating agent. The lowest NOEL identified based on the toxicological studies available corresponds to 300 mg/kg bw per day. The FEEDAP Panel concluded that wax-free (physically) bleached shellac used in one of the feed additive formulations does not raise concern for the target species, consumer and environment.

A more recent assessment from the FEEDAP Panel for the renewal of the authorisation of Cylactin® (LBC ME5 PET) for cats and dogs was published in March 2024 (EFSA FEEDAP Panel, 2024). This feed additive contains 13% chemically bleached shellac, and differs from the Cylactin®, mentioned in the paragraph above. The studies provided for the previous evaluation (EFSA FEEDAP Panel, 2013) tested at levels of 70 folds (cats) or 100 folds (dogs) the originally proposed maximum use levels of shellac. The FEEDAP Panel noted that no adverse effects were observed, which support the safety of shellac in the target species.

[6]Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ l 354, 31.12.2008, p. 1.

2 | DATA AND METHODOLOGIES

2.1 | Data

The Panel on Food Additives and Flavourings (FAF) was not provided with a newly submitted dossier. EFSA launched public calls for data[7,8,9,10] to collect information from interested parties.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature.[11] Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based; however, these were not always available to the Panel.

One request for extension of use was also considered in this assessment. The request referred to an extension of use in foods for special medical purposes in tablet and coated tablet form (i.e. the food category 13.2 of part E of Annex II to Regulation (EC) No 1333/2008).

Food consumption data used to estimate the dietary exposure to shellac (E 904) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database[12]).

The Mintel's Global New Products Database (GNPD) was used to verify the uses of shellac (E 904) in food and beverage products and food supplements within the EU's market. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

2.2 | Methodologies

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

The FAF Panel assessed the safety of shellac (E 904) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001) and taking into consideration the Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

When in animal studies, the test substance was administered in the feed or in drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake is calculated by the Panel using the relevant default values. In case of rodents the values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) are applied. In the case of other animal species, the default values by JECFA (2000) are used. In these cases, the dose was expressed as 'equivalent to mg/kg bw per day'. If a concentration in feed or drinking water was reported and the dose in mg/kg bw per day was calculated (by the authors of the study report or the Panel) based on these reported concentrations and on reported consumption data for feed or drinking water, the dose was expressed as 'equal to mg/kg bw per day'.

Dietary exposure to shellac (E 904) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive European Food Consumption Database with reported use levels submitted to EFSA following calls for data. Different scenarios were used to calculate exposure (see Section 3.4.1). Uncertainties on the exposure assessment were identified and discussed.

3 | ASSESSMENT

3.1 | Technical data

3.1.1 | Identity of the food additive and specifications

Shellac (E 904) is purified and bleached lac, which is a resinous secretion from the insect *Laccifer* (*Tachardia*) *lacca* Kerr (Fam. Coccidae) (Commission Regulation (EU) No 231/2012). Bleached shellac and wax-free bleached shellac are described in the EU specifications for E 904 as off-white, amorphous, granular resin and light yellow, amorphous, granular resin, respectively. The content of wax is not more than 5.5% and not more than 0.2% in bleached shellac and wax-free bleached shellac, respectively.

No information on the manufacturing process of bleached shellac is included in the EU specifications for E 904; however according to JECFA (2006), bleached shellac is obtained 'by dissolving the lac in aqueous sodium carbonate, followed by

[7]Call for scientific data on miscellaneous waxes permitted as food additives in the EU. Deadline 23 March 2010.

[8]Call for scientific data on shellac (E 904). Deadline 1 June 2012.

[9]Call for scientific data on shellac (E 904). Deadline 1 December 2012.

[10]Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 6). Deadline 30 November 2017. https://www.efsa.europa.eu/en/data/call/170223.

[11]Up to 14/12/2023.

[12]https://www.efsa.europa.eu/en/food-consumption/comprehensive-database.

bleaching with sodium hypochlorite'. The Panel noted that according to the information provided by IBOs, in addition to bleached shellac produced by bleaching with sodium hypochlorite, shellac is also produced by a physical decolouring process, and the resulting shellac is named by the IBOs as 'physically bleached shellac' or 'flake shellac'.

According to IBOs, shellac is sold as a hard flake and as a powder, and the form of shellac depends on the manufacturing process; flakes are obtained by the physical decolouring process and shellac forms a powder as a result of the bleaching process (Documentation provided to EFSA n. 1 and n. 2).

Three IBOs have submitted data for the re-evaluation of E 904. Two IBOs indicated that only wax-free shellac as E 904 is on the market as food additive. The data provided by the other IBO also correspond to a wax-free shellac.

The specifications for shellac (E 904) as defined in the Commission Regulation (EU) No 231/2012 and by JECFA (2006) are listed in Table 1.

TABLE 1 Specifications for shellac (E 904) according to Commission Regulation (EU) No 231/2012 and JECFA (2006).

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Synonyms	Bleached shellac; white shellac	INS No 904
Definition	Shellac is the purified and bleached lac, the resinous secretion of the insect *Laccifer (Tachardia) lacca* Kerr (Fam. Coccidae)	Shellac is a polyester resin obtained from lac, the resinous secretion of the insect *Laccifer* (*Tachardia*) *lacca* Kerr (Fam. Coccidae). Bleached shellac is obtained by dissolving the lac in aqueous sodium carbonate, followed by bleaching with sodium hypochlorite, precipitation of the bleached lac with dilute sulfuric acid solution, and drying; wax-free bleached shellac is prepared by further treatment whereby the wax is removed by filtration
EINECS	232-549-9	
CAS		9000-59-3
Description	Bleached shellac: off-white, amorphous, granular resin Wax-free bleached shellac: light yellow, amorphous, granular resin	Bleached shellac: off-white to tan, amorphous, granular resin Wax-free bleached shellac: light yellow, amorphous, granular resin
Identification		
Solubility	Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone	Insoluble in water; freely (though very slowly) soluble in ethanol; slightly soluble in acetone and ether
Acid value	Between 60 and 89	Between 60 and 89[a]
Colour reaction		Passes test[a]
Purity		
Loss on drying	Not more than 6.0% (40°C, over silica gel, 15 h)	Not more than 6.0% (40°C, 4 h, then room temperature over silica gel, 15 h
Rosin	Absent	Passes test[a]
Wax	Bleached shellac: not more than 5.5% Wax-free bleached shellac: not more than 0.2%	Bleached shellac: not more than 5.5% Wax-free bleached shellac: not more than 0.2%
Lead	Not more than 2 mg/kg	Lead: not more than 2 mg/kg

[a]A specific test is described in the JECFA specifications (2006).

Shellac is an anionic polymer based on polyesters and consists of a mixture of polyhydroxy polycarboxylic esters, lactones and anhydrides. Main components include aleuritic acid, jalaric acid, shellolic acid and other aliphatic acids (Documentation provided to EFSA n. 3). An IBO indicated that aleuritic acid, butolic acid and shellolic acid may be used as markers for the identification and quantification of E 904 (Documentation provided to EFSA n. 4).

According to an IBO (Documentation provided to EFSA n. 5), shellac contains terpenic acids (such as laccijaric acid and jalaric acid), aleuritic acid and other fatty acids (Figure 1). The components and proportion of the components vary depending on the types of lac insects, that differ depending on the country and the cultivation method. An IBO also stated that the main components of powdered shellac are a shellac monomer, which is an ester derived from jalaric acid and aleuritic acid (Figure 1), its dimer, trimer and tetramer. The powder may also contain (instead of jalaric acid), laccijalaric acid, laksholic acid and trace levels of several aleuritic acid esters (Documentation provided to EFSA n. 6). The percentage of shellac monomer analysed by HPLC in samples of E 904 was around 29% (Documentation provided to EFSA n. 7).

Information provided by another IBO included, in addition to the components mentioned above, lacciaksholic acid (Documentation provided to EFSA n. 8). According to this IBO, shellac is composed of a complex mixture of different mono- and polyesters of hydroxyaliphatic acids, i.e. aleuritic acid and butolic acid, and sesquiterpenoid acids, i.e. jalaric and laccijalaric acids. The reduction of jalaric acid produces laksholic acid and oxidation produces shellolic acid. An illustrative chemical structure for shellac was provided (Figure 2).

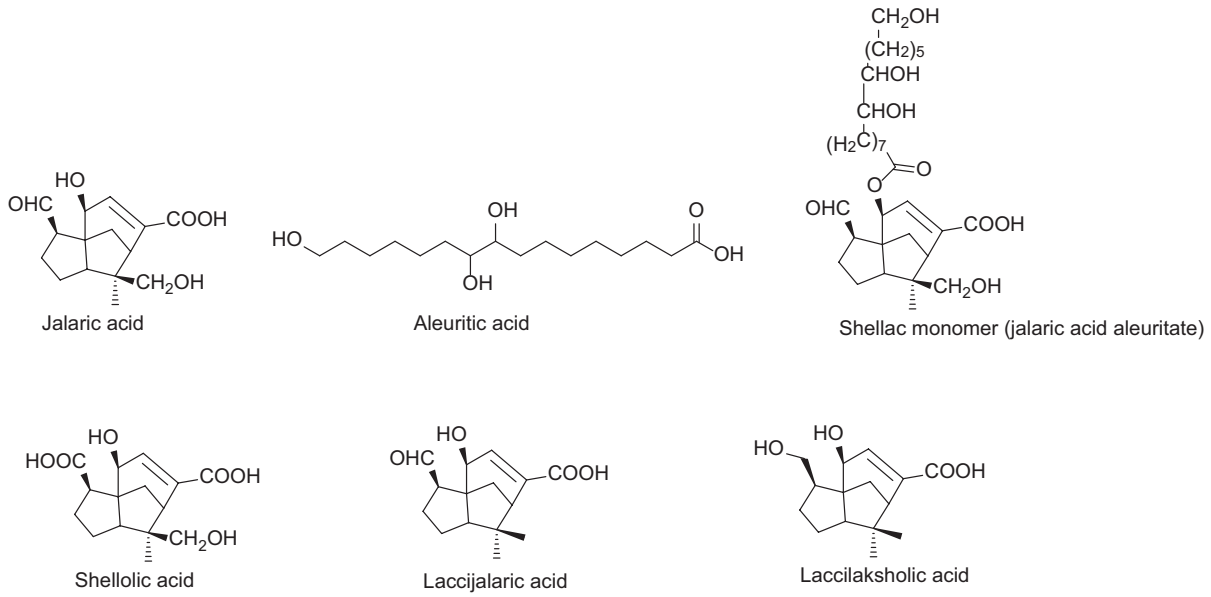

FIGURE 1 Chemical structures of some of the main components of E 904.

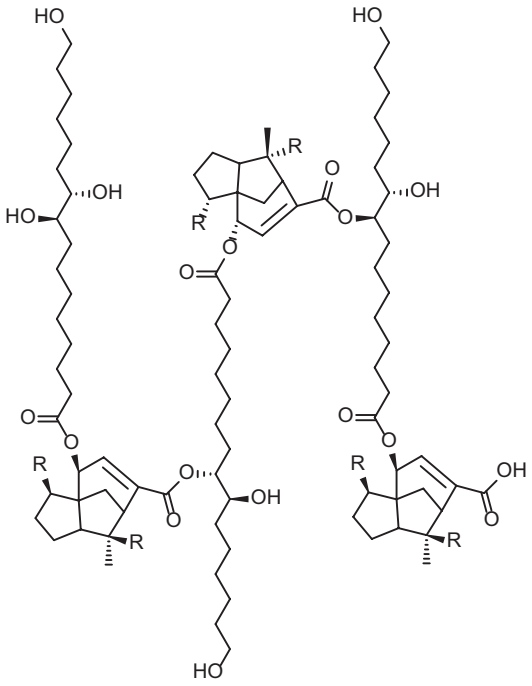

FIGURE 2 Illustrative chemical structure of shellac (Modified from Documentation provided to EFSA N. 8).

The Panel noted that shellac as such is a thermoplastic and after solvent evaporation it is still a thermoplastic. On ageing (with further polymerisation and cross-linking), it converts slowly to a thermoset plastic. Hence, there will be some lower molecular weight components always present, but the main exposure of shellac through food will be to more polymerised material than present in pristine shellac.

Toxic elements

According to the EU specifications for shellac (E 904), only a limit for lead of 2 mg/kg is included. The panel noted that in some certificates of analysis of commercial samples of shellac, lead is analysed and reported as less than 1 mg/kg and arsenic as less than 3 or less than 1 mg/kg.

Acid value[13]

Data on the acid values of 75 samples (2012–2020) of wax-free shellac, prepared by physical decolouring were provided and ranged from 68.3 to 76.8 (Documentation provided to EFSA n. 7).

Another IBO provided the acid values for 562 samples of wax-free shellac produced from 2007 to 2020 by the bleaching process from three different manufacturers. The average value was 80.2, P95 87.9, with three samples slightly above the maximum limit of 89 indicated in the EU specifications [two samples 89.1 and 89.2 and one sample 90] (Documentation provided to EFSA n. 9).

Acid values were also reported for five samples of wax-free shellac produced by the bleaching process ranging from 75.1 to 75.6 (Documentation provided to EFSA n. 8).

The panel noted that according to the Food Chemical Codex (FCC) in which separate specifications are established for wax-free bleached shellac, the acceptance criteria for the acid value are 75–91 (FCC, 2010).

Chloroform

Given the use of sodium hypochlorite in the bleaching step of the manufacturing process, a study determined the content of chloroform by GC-FID (Documentation provided to EFSA n. 10) in the nine samples that ranged from 320 to 900 mg/kg. The same study reported the determination of sodium content by IC, which ranged from 100 to 1690 mg/kg.

The content of chloroform in four of the same bleached shellac samples was also investigated in a new study and ranged from 342 to 963 mg/kg (Documentation provided to EFSA N. 11) showing that the results are consistent with the previous study (Documentation provided to EFSA n. 12).

In a further communication from an IBO, a limit of 400 mg/kg for chloroform, based on the concentration of chloroform in the samples of shellac tested in toxicological studies, has been proposed. The IBO indicated that the high values of chloroform in shellac were due to the high level of hypochlorite and the time used in the bleaching process and that these parameters were subsequently revised. The IBO also indicated that the residual concentrations of chloroform are below 200 mg/kg after optimisation of the production method (Documentation provided to EFSA n. 11).

The content of chloroform in seven samples of bleached shellac was also reported to be 21–204 mg/kg analysed by GC–MS by another IBO, and absent in the two samples of shellac produced by the physical decolouring process (Documentation provided to EFSA n. 13).

Other chlorinated compounds

A study aiming to identify organochlorine compounds and quantify total inorganic chloride in shellac was submitted (Documentation provided to EFSA n. 10 and n. 12). Different samples of shellac and wax-free shellac produced by bleaching or by physical decolouring were analysed. The identification of chlorinated organic compounds was performed by LC–MS/MS. Eight chlorinated compounds were detected. Four were identified as monochlorinated substances (aleuritic acid+Cl, shelloic-aleuritic ester+Cl, jalaric-aleuritic ester+Cl and laccijalaric-aleuritic ester+Cl). Two of the eight chlorinated substance did not have an unequivocal identification (assigned as mono- and dichlorinated jalaric-(16-hydroxyhexadecanoic) ester or laccijalaric-(9,10-dihydroxyhexadecanoic) ester, both have the same molecular formula and mass). The remaining two of the eight chlorinated compounds remained unidentified.

An additional MS study was conducted to confirm the assignment of mono- and dichloro- compounds, using the characteristic ratio of ^{37}Cl to ^{35}Cl. The results confirmed that the chlorinated compounds were present and were only in samples of bleached shellac (Documentation provided to EFSA n. 12). Information on the structural identity and quantification of the individual organochlorine compounds was not available (Documentation provided to EFSA n. 11).

The total inorganic chloride content was determined by titration and varied from 0.115% to 0.125% in bleached shellac, and it was found to be absent in shellac produced by physical decolouring. In the amended study, the content of sodium chloride was also reported and ranged from 0.189% to 0.206% (Documentation provided to EFSA n. 11). The IBO proposed a limit of < 0.14% for total inorganic chloride based on the analytical data. It was also mentioned that a limit of < 0.2% for total chloride is included in the specifications for shellac in China (Documentation provided to EFSA n. 11).

Other potential impurities of shellac produced by the bleaching process

No detailed information on the presence or absence of epoxides, that could be formed during the bleaching process, is available. An IBO considered that the presence of epoxides after the refining of shellac is not expected, but in case some epoxides were formed, the last step in the processing is acidification to precipitate shellac, and epoxides would be expected to be hydrolysed to the corresponding diols (Documentation provided to EFSA n. 11). The Panel agreed with this.

[13] Acid value is expressed as milligram of potassium hydroxide per gram of shellac.

Particle size distribution

Information on the particle size distribution using laser diffraction was submitted (Documentation provided to EFSA n. 8 and 14). The panel noted that the laser diffraction method is not considered a suitable method to investigate the presence of nanosized particles, as it does not provide information on the size of the constituent particles as required by the Guidance on Particle-TR (EFSA Scientific Committee, 2021) and is prone to bias for polydisperse materials (Mech et al., 2020; Rauscher et al., 2019).

Solubility

The solubility of shellac (from the decolouring process) in water was analysed by a method based on OECD TG 105 showing that 0.1 g was not entirely dissolved in 500 mL at 20°C (Documentation provided to EFSA n. 14). According to the IBO, shellac is soluble in ethanol, ammonium carbonate or ammonium bicarbonate which are used to dissolve shellac when used for food coating (Documentation provided to EFSA n. 15).

According to one IBO (Documentation provided to EFSA n. 3), shellac solutions are usually prepared with ammonium hydroxide (25%) at the industrial scale. Other commercial formulations can be prepared using sodium hydroxide, potassium hydroxide, ammonium carbonate or bicarbonate and ethanol.

A study investigating the potential presence of particles in aqueous solutions of shellac (ammonia solution or ammonium bicarbonate solution) was submitted (Documentation provided to EFSA n. 3). The results did not exclude the potential presence of (small) particles.

According to Qi et al. (2013) (Documentation provided to EFSA n. 3), a film from an aqueous shellac ammonia solution was smooth and microscopic images did not indicate the presence of particle structures.

Considering that (i) shellac is dissolved in alkaline aqueous media or ethanol when used as a food additive, and (ii) shellac forms continuous polymeric films/sheets and not particles when in solid form, the Panel considered that the safety of shellac (E 904) can be adequately covered by the conventional risk assessment.

3.1.2 | Manufacturing process

According to an IBO (Documentation provided to EFSA n. 5), lac insects colonise branches in trees that are harvested through cutting branches into 20 cm lengths ('sticklac'). The sticklac comprises branches, lac insects, resin, wax and polysaccharides. Sticklac is crushed and sieved to remove twigs. Insects remain, protein, polysaccharides, water-soluble substances of the pigment elements such as laccaic acid and other impurities such as wood chips are washed away (water-rinsing process). What remains is a resinous substance that is dried, resulting in a material called seedlac.

Refined Shellac is extracted from seedlac through one of two manufacturing processes, a chemical bleaching process using sodium hypochlorite and a physical decolouring process using active coal. The IBOs describe using activated coal. The panel considers that the terms active and activated, and the terms coal, charcoal and carbon are used synonymously the description 'activated carbon' will be used hereon.

IBOs have confirmed that they use both the physical decolourising process and the bleaching process to refine shellac for E 904 (Documentation provided to EFSA n. 1 and n. 2).

In the chemical bleaching method, seedlac is dissolved in alkaline solution (e.g. sodium carbonate) which is sieved to remove insoluble matters such as wax, wood chips and remaining insects. Sodium hypochlorite is added to the filtrate to bleach. In this step, hypochlorite is used to oxidise the pigment erythrolaccin, that is present in seedlac. Sulfuric acid is added to the bleached aqueous solution to precipitate the resin. The resin deposit is then rinsed, separated and dried to yield the bleached shellac. The amount of hypochlorite and the bleaching time determine the amount of remaining inorganic chlorine and chloroform in the final shellac and, therefore, they should be well controlled. The process of washing with water will remove water soluble inorganic chlorine components (e.g. hypochlorite). The use of large quantities of acid media in the rinsing step aids in the conversion of chlorine containing components to chlorine gas which subsequently vents off in the drying process. The drying process also helps to evaporate remaining chloroform (Documentation provided to EFSA n. 5 and n. 11).

In the physical decolouring process, seedlac is dissolved in ethanol. It is sieved with a 1-μm filter to remove insoluble matter such as wax. Activated carbon is used to decolour the filtrate. A second filtration process takes place to remove any colouring matter such as erythrolaccin and coloured-polymer bound to the activated carbon. Finally, the ethanol is evaporated from the clear filtrate to obtain the refined shellac (Documentation provided to EFSA n. 5).

3.1.3 | Methods of analysis in food

The interested parties reported analytical methods for detection of shellac in a test diet and in dose formulations.

A validation study on an analytical method employing high-performance liquid chromatography/mass spectrometry (HPLC–MS/MS) was submitted (Documentation provided to EFSA n. 4). The method was intended to be employed for determination of the analytes aleuritic, butolic and shellolic acids present in bleached shellac (E 904) and taken as markers

for its concentration, stability and homogeneity in test diet and dose formulation. With respect to study plan, standard operating procedures and generated raw data, the study was compliant with the 1998 OECD principles of good laboratory practice (GLP). The validation covered the following aspects: specificity; limit of quantification (LOQ); precision (% relative standard deviation (%RSD)) and accuracy (% recovery) from a test diet and dose formulation.

Another validation study on an analytical method utilising high-performance liquid chromatography with an ultraviolet detector (HPLC/UV, $\lambda = 230$ nm) for the determination of physically decoloured shellac in formulations with 0.5% (w/v) methylcellulose and dimethyl sulfoxide as vehicles was provided (Documentation provided to EFSA n. 5). The method was characterised for linearity, specificity, accuracy and repeatability with a specific focus on detection of shellac monomer (ester derived from jalaric acid and aleuritic acid).

An additional validation study on an analytical method utilising high-performance liquid chromatography with a refractive index detector (HPLC/RI) for the determination of the marker aleuritic acid in dose formulations of shellac (E 904) was provided (Documentation provided to EFSA n. 16). The method was characterised for suitability, precision, accuracy and linearity.

A method for testing for the presence of shellac on apples was developed, based on washing shellac from the peel with ethanol; evaporation of the ethanol solution to dryness followed by re-dissolving the residue in ethanol; thin-layer chromatography (TLC) on silica gel with 96% ethanol mobile phase; detection by spraying the chromatogram with anisaldehyde reagent followed by heating (Gross & Jungkunz, 1989). Shellac gave a dark green spot with a retention factor (Rf) of ~0.5. The presence of shellac could be confirmed by hydrolysis to release aleuritic acid, which was then analysed by TLC on silica gel with a mixture of glacial acetic acid, methanol, chloroform and ethyl acetate (1:8:32:60) with detection as above. Aleuritic acid gave blue–grey–violet spots with an Rf of ~0.6.

To analyse beeswax, candelilla wax, carnauba wax and shellac coatings on apples, a differential scanning calorimetry (DSC) technique was employed (Ritter et al., 2001). From each thermogram, the temperature at the peak maximum and the phase transition enthalpy were obtained as the main criteria. For the genuine surface wax of 10 apple cultivars, the means were 64.4 ± 1.5°C for the maximum temperature and 82 ± 9 J/g for the enthalpy. The four coating agents resulted in divergent peak maxima and in enthalpies above 100 J/g in all cases (for two shellac samples, the values were 76–89°C and 141–208 J/g, respectively). Studies with mixtures of the coating agents and apple wax, and analyses of commercial apple samples marked as waxed confirmed that DSC was suitable as a screening method.

The Panel noted that no official method for analysing shellac on food was identified in the literature or provided following the EFSA call for data. As exemplified above, the analytical methods available seem to be primarily suitable for identification purposes of the individual constituents in shellac.

3.1.4 | Stability of the substance and reaction and fate in food

A study evaluating the release of chlorine (Cl_2) from bleached shellac under warehouse conditions was submitted (Documentation provided to EFSA n. 9). The test was performed in a climatic chamber (glass) simulating cold storage (8 ± 2°C) with 25 kg of shellac placed in the chamber that has a total volume of 101 L. Air samples were analysed at day 0, 7, 14, 30, 45 and 60. The LOQ was 0.07 mg/kg of shellac. Two samples of bleached shellac and shellac produced by the physically decolouring process were analysed. The release of Cl_2 in bleached shellac was measured the first day to be 0.09 mg/kg of shellac, at the LOQ on the 7th day, and from day 14th below the LOQ. The analysis of Cl_2 from shellac produced by physically decolouring process was always below the LOQ. The content of free hypochlorite ion was also analysed and reported as below the LOQ (< 0.2 mg/kg) for all sampling intervals in both types of shellac.

According to an IBO, the shelf-life of bleached shellac can be several years if stored at a temperature below 10°C (Documentation provided to EFSA n. 9).

The stability of shellac in extracts from shellac-coated apples and orange peels was evaluated during storage conditions of 8 ± 2°C and 25 ± 2°C for 90 days (sampling intervals at 0, 30th, 60th and 90th day) (Documentation provided to EFSA n. 9). The concentration of aleuritic acid, as a marker of shellac stability, was measured by LC–MS. The Panel noted that the loss of aleuteric acid is probably due to continuation of the polymerisation process. The concentration of aleuritic acid in coated apples during storage condition at 8 ± 2°C on the 90th day was found to have decreased by 3.1 fold compared to the initial concentration ('0' Day). Whereas, during storage condition at 25 ± 2°C, it was found to have decreased by 4.1 fold. The loss of aleuritic acid was marginally higher in orange peel than in apple peel.

A similar study was performed inside a humidity chamber maintained at 40 ± 2°C for 30 days (Documentation provided by EFSA n. 9). The concentration of aleuritic acid was measured at sampling intervals of 0, 10, 20 and 30 days in the bleached shellac film, 'unbleached' shellac film and in the coated fruit peel extract. The concentration of aleuritic acid in coated apples on the 30th day was found to be decreased by 92.2 folds compared to the initial concentration ('0' Day). In coated oranges, it was decreased by two folds. It was stated that the variation between the fruits may be due to the difference in the surface texture of fruits. The concentration of aleuritic acid was decreased to 5.3 and 18.5 folds in bleached shellac film and 'unbleached' shellac film, respectively, after 30 days under these accelerated conditions.

The panel noted that the loss of aleuteric acid is probably due to continuation of the polymerisation process.

Another IBO stated that colour and form did not change for an analysed shellac, produced by physical decolouring, under storage conditions for 7 days, and the content of monomer was reduced by 10% (Documentation provided to EFSA n. 7).

The stability of shellac produced by chemical bleaching was also investigated under accelerated storage conditions (40°C ± 2°C/75% RH ± 5% RH). Shellac was evaluated for appearance, acid value, the identification of principal components such as aleuritic acid and shellolic acid. The acid value gradually decreased from 73 to 37 after 5 months. The appearance changed from pale yellow powder to an agglomerated brittle crystal form at 5 months. From another experiment, shellac was stable for 3 months at storage conditions (30°C ± 2°C/75% RH ± 5% RH) based on the analysis of acid value (Documentation provided to EFSA n. 8).

According to submitted information (Farag and Leopold, 2009) (Documentation provided to EFSA n. 3 and n. 8), the acid value is a good indicator for the quality of shellac. Since most of the acids in shellac contain more than one hydroxyl group and some more than one carboxyl group, reactions between hydroxyl groups and carboxylic acid groups result in further esterification during storage. This self-esterification or self-polymerisation is accompanied by a loss of solubility, a decrease in the acid value and an increase in the glass transition temperature (resulting in increased hardening with time).

3.2 | Authorised uses and use levels

Maximum levels of shellac (E 904) have been defined in Annex II to Regulation (EC) No 1333/2008[14] on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, shellac (E 904) is an authorised food additive in the EU at *quantum satis* (QS) in 11 food categories (Table 2).

TABLE 2 Maximum permitted levels (MPLs) of shellac (E 904) in food categories according to Annex II to Regulation (EC) No 1333/2008.

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)
04.1.1	Entire fresh fruit and vegetables	Only for the surface treatment of fruit: citrus fruit, melons, apples, pears, peaches, pineapples, pomegranates, mangoes, avocados and papayas and as glazing agent on nuts	E 904	*quantum satis*
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	As glazing agent only	E 904	*quantum satis*
05.2	Other confectionery including breath freshening microsweets	As glazing agent only	E 904	*quantum satis*
05.3	Chewing gum	As glazing agent only	E 904	*quantum satis*
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	As glazing agent only	E 904	*quantum satis*
07.2	Fine bakery wares	Only as glazing agents only for small products of fine bakery wares coated with chocolate	E 904	*quantum satis*
10.2	Processed eggs and egg products	Only on the surface of unpeeled boiled eggs.	E 904	*quantum satis*
14.1.5.1	Coffee, coffee extracts	Only coffee beans, as glazing agent	E 904	*quantum satis*
15.1	Potato-, cereal-, flour- or starch-based snacks	As glazing agents only	E 904	*quantum satis*
15.2	Processed nuts	As glazing agents only	E 904	*quantum satis*
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children		E 904	*quantum satis*

Abbreviation: MPL, maximum permitted level.

Shellac (E 904) is not authorised according to Annex III to Regulation (EC) No 1333/2008.

3.3 | Exposure data

3.3.1 | Reported use levels of shellac (E 904)

Shellac (E 904) is authorised at QS. Information on concentration levels (use levels and/or analytical data) is therefore required to assess the dietary exposure to this food additive.

[14]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.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued three public calls for occurrence data (use levels and/or analytical data) on shellac (E 904). In response to this public call, updated information on the actual use levels of shellac (E 904) in foods was made available to EFSA by industry. No analytical data were provided by the Member States or other interested parties.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with 45 use levels of shellac (E 904) in foods belonging to seven out of the 11 food categories in which it is authorised according to Annex II to Regulation (EC) No 1333/2008 (Table 2). In addition, concentrations of shellac (E 904) were provided for food category (FC) 03 Edible ices with an indication that this additive can be present in ices due to its use in chocolate glaze. The use levels were provided by Association of the European Self-Medication Industry (AESGP) (Documentation provided to EFSA n. 17), Dr Loges Naturheilkunde neu entdecken (Documentation provided to EFSA n. 18), Food Drink Europe (FDE) (Documentation provided to EFSA n. 19), Food Supplement Europe (FSE) (Documentation provided to EFSA n. 20), German Fruit Trade Association (Documentation provided to EFSA n. 21), International Chewing Gum Association (ICGA) (Documentation provided to EFSA n. 22), Intersnack (Documentation provided to EFSA n. 23), L'Alliance 7 (Documentation provided to EFSA n. 24) and Nathura (Documentation provided to EFSA n. 25).

The Panel noted that one of the use levels provided for chewing gum (FC 05.3) referred to a niche product. This use level was included in the exposure assessment, because no other representative use levels for this food category were provided.

Annex A provides use levels of shellac (E 904) in foods as reported by industry.

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

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 4.3 million food and beverage products of which almost 1,350,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 24 out of its 27 member countries and Norway presented in the Mintel GNPD.[15]

In this Scientific Opinion, Mintel's GNPD[16] was used to check the labelling of food and beverage products and food supplements for shellac (E 904) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to Mintel's GNPD, shellac (E 904) was labelled on different products ($n = 3039$) between January 2019 and June 2024, including 'Non-Individually Wrapped Chocolate Pieces', 'Mixed Assortments', 'Standard & Power Mints' and 'Seasonal Chocolate'.

Annex B lists the percentage of the food products labelled with shellac (E 904) out of the total number of food products per food subcategories with at least one food labelled to contain shellac (E 904) according to the Mintel's GNPD food classification. The percentages ranged from less than 0.1% in few food subcategories to 15% in Mintel's GNPD food subcategory 'Non-Individually Wrapped Chocolate Pieces'. The average percentage of foods labelled to contain shellac (E 904) among the food subcategories with at least one food labelled to contain shellac (E 904) was 1.6%.

3.3.3 | Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a)). Consumption surveys added in the Comprehensive database in 2022 were also considered in this assessment.[17]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

[15] Missing Cyprus, Luxembourg and Malta.

[16] https://www.gnpd.com/sinatra/home/.

[17] https://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm.

Food consumption data from infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 43 different dietary surveys carried out in 22 European countries (Table 3).

TABLE 3 Population groups considered for the exposure estimates of shellac (E 904).

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Portugal, Slovenia, Spain
Toddlers[a]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain
Children[b]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
The elderly[b]	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

[a]The term 'toddlers' in the Comprehensive Database (EFSA, 2011a) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.
[b]The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011a).

Consumption records in the Comprehensive Database were codified according to the FoodEx2 classification system (EFSA, 2015). Nomenclature from the FoodEx2 classification system has been linked to the food categorisation system of Annex II of Regulation (EC) No 1333/2008, part D, to perform the exposure assessment of food additives. In practice, the FoodEx2 food codes were matched to the food categories.

Food categories considered for the exposure assessment of shellac (E 904)

The food categories for which use levels of shellac (E 904) were provided were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx2 Level 7) (EFSA, 2011b).

Also, concentrations were provided for the food category (FC) 03 Edible ices, due to the use of shellac (E 904) in chocolate glaze. In Mintel's GNPD, the additive is declared on the label of ice -cream products as a glazing agent on added components (e.g. chocolate pieces, dragées) (see Annex B). Shellac (E 904) is not authorised as such in FC 03 according to Annex II of Regulation (EC) No 1333/2008 (see Table 2). Thus, the concentrations provided by the food industry were attributed to milk-based ice cream (including frozen yoghurt) from FC 03 Edible ices, as it is likely that chocolate glaze is more commonly added to milk-based ice cream rather than to water-based ice cream.

Shellac (E 904) is authorised in foods of the FC 4.1.1 Entire fresh fruit and vegetables, only for the surface treatment of fruit: citrus fruit, melons, apples, pears, peaches, pineapples, pomegranates, mangoes, avocados and papayas and as glazing agent on nuts (see Table 2). Use levels were provided for orange and lemon, only. In addition, these levels referred to a mixture that can be used for the surface treatment of the two fruits, in which the actual level of shellac (E 904) is unknown. Considering that the peel of oranges and lemons is not commonly eaten, and no other data were provided, the use of shellac (E 904) on fruits, vegetables and nuts belonging to FC 4.1.1 was not considered in the exposure assessment.

For FC 07.2 Fine bakery wares, the restriction 'only as glazing agents only for small products of fine bakery wares coated with chocolate' was considered by selecting the biscuits and fine bakery ware products that can be coated with chocolate (e.g. éclair and profiteroles). This should provide more accurate exposure estimates but will nevertheless result in overestimates of the exposure to the food additive as it is unlikely that all these foods will be coated with chocolate.

For the food supplements (FC 17), shellac (E 904) is only allowed in food supplements in a solid form (FC 17.1; Table 2). Therefore, only the solid form of food supplements was considered. This will also result in an overestimation of the exposure as it is unlikely that all these food supplements will contain shellac (E 904).

Furthermore, four food categories in which the use of shellac (E 904) is authorised were not considered in the exposure assessment, because no use levels were provided for these categories (Annex A). These categories included FC 10.2 Processed eggs and egg products, FC 14.1.5.1 Coffee, coffee extracts, FC 15.1 Potato-, cereal-, flour- or starch-based snacks and FC 15.2 Processed nuts.

3.4 | Exposure estimates

3.4.1 | Exposure to shellac (E 904) from its use as a food additive

The panel estimated the chronic dietary exposure to shellac (E 904) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to shellac (E 904) was calculated by multiplying the use levels of shellac (E 904) per food category (Annex C) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). Based on these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from France and Italy, for toddlers from Belgium and Italy and for adolescents from Estonia were not estimated.

Exposure assessment to shellac (E 904) was carried out by the FAF Panel based on two different sets of concentration data: (1) maximum of the reported use levels as provided to EFSA (defined as the *maximum level exposure assessment scenario)*; and (2) all reported use levels (defined as the *refined exposure assessment scenario*). These two scenarios are discussed in detail below.

These exposure scenarios do not consider the exposure to shellac (E 904) via the consumption of food supplements. This exposure is covered in an additional scenario detailed below (*food supplements consumers only scenario*).

Maximum level exposure assessment scenario

The exposure to food additives as part of the re-evaluation of these compounds under Regulation (EU) No 257/2010 (see Section 1.1.2) is typically assessed according to the regulatory maximum level exposure assessment scenario. This scenario is based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008. As shellac (E 904) is authorised according to QS in all food categories (see Table 2), a 'maximum level exposure assessment' scenario was performed instead for this additive. This scenario is based on the maximum reported use levels provided by food industry, excluding exposure via food supplements, as described in the EFSA Conceptual framework (EFSA ANS Panel, 2014). This exposure scenario can consider only the food categories for which these data were available to the Panel.

The Panel considers the exposure estimates derived with this scenario as the most conservative since it is assumed that the population will be exposed to the food additive present in food at the maximum reported use levels over a longer period of time.

Refined exposure assessment scenario

The refined exposure assessment scenario of shellac (E 904) was based on all reported use levels reported by food industry. As for the scenario described above, this exposure scenario can consider only those food categories for which use levels were available to the Panel.

Annex C summarises the use levels of shellac (E 904) used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on two model populations:

- The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to shellac (E 904) present at the maximum reported use level for one food category. This exposure estimate is calculated as follows:
  - Combining food consumption with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.
- The non-brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to shellac (E 904) present at the mean reported use levels in food. This exposure estimate is calculated using the mean of the typical reported use levels for all food categories.

The *maximum level* and *refined exposure assessment* scenarios included six food categories (Annex C).

'Food supplement consumers only' scenario

Shellac (E 904) is authorised in FC 17 Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children (see Table 2). Dietary exposure to shellac from consumption of food supplements could follow

a very different pattern than from consuming food. The number of food supplement consumers may be low depending on populations and surveys, as such an additional scenario was calculated to determine exposure to shellac (E 904) from its use in food supplements. This additional exposure was estimated assuming that consumers of food supplements were exposed to shellac (E 904) present at the maximum reported use level in food supplements daily. For the remaining food categories, the mean of the typical reported use levels was used.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to shellac (E 904) from food supplements is not estimated for these two population groups.

This scenario included seven food categories (Annex C).

Dietary exposure to shellac (E 904)

Table 4 summarises the estimated dietary exposure to shellac (E 904) from its use as a food additive in six population groups (Table 3) according to the *maximum level* and *refined exposure assessment* scenarios. Detailed results per population group and survey are presented in Annex D.

TABLE 4 Summary of dietary exposure to shellac (E 904) from its use as a food additive in the maximum level exposure assessment scenario and in the refined exposure scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day).

	Infants (12 weeks-11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Maximum level exposure assessment scenario						
• Mean	0–0.5	0.1–3.7	0.8–3.3	0.3–2.4	0.1–0.9	< 0.1–0.3
• 95th percentile	< 0.1–1.0	0.6–11.5	2.6–10.2	1.0–7.1	0.4–4.4	0.2–1.6
Refined exposure assessment scenario						
Brand-loyal scenario						
• Mean	0–0.5	0.1–3.6	0.7–2.8	0.3–2.1	0.1–0.8	< 0.1–0.2
• 95th percentile	0–1.0	0–1.0	2.5–9.4	0.9–6.7	0.4–4.4	0.2–1.6
Non-brand-loyal scenario						
• Mean	0–0.3	< 0.1–1.9	0.5–2.0	0.1–1.4	< 0.1–0.4	< 0.1–0.2
• 95th percentile	0–0.4	0.2–7.4	1.1–8.7	0.5–5.6	0.2–2.2	0.1–1.6

In the *maximum level exposure assessment scenario*, mean exposure to shellac (E 904) from its use as a food additive ranged from 0 mg/kg bw per day for infants to 3.7 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 0 to 11.5 mg/kg bw per day in the same two population groups.

In the *refined brand-loyal exposure scenario*, mean and 95th percentile of exposure to shellac (E 904) from its use as a food additive were up to 3.6 mg/kg bw per day and 10.9 mg/kg bw per day, respectively, in infants and toddlers. In the *refined non-brand-loyal scenario*, mean exposure to shellac (E 904) from its use as a food additive was up to 2 mg/kg bw per day in toddlers and children, and the 95th percentile of exposure up to 8.7 mg/kg bw per day in children.

In the *food supplements consumers only scenario*, mean exposure to shellac (E 904) ranged from < 0.1 mg/kg bw per day in adults and the elderly to 3.9 mg/kg bw per day in children. The 95th percentile of exposure ranged from 0.4 mg/kg bw per day in the elderly to 8.6 mg/kg bw per day in children.

Main food categories contributing to exposure to shellac (E 904) using the maximum level exposure assessment scenario and the refined exposure assessment scenarios

In the *maximum level exposure assessment scenario* and both *refined exposure assessment scenarios*, the two main contributing food categories to the total mean exposure to shellac (E 904) were FC 05.1 Cocoa and chocolate products for all age groups and FC 5.2 Other confectionary for all population groups, except for infants. In this population group, FC 03 Edible ices was the other main food category.

Uncertainty analysis

Uncertainties in the exposure assessment of shellac (E 904) have been presented above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

TABLE 5 Qualitative evaluation of influence of uncertainties on the dietary exposure estimate.

Sources of uncertainties	Direction[a]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Methodology used to estimate 95th percentiles of long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Database: uncertainties to which types of food the levels refer	+/–
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data: – use levels considered applicable to all foods within an entire food category, whereas on average 1.6% of the foods, belonging to food categories with at least one food labelled with additive, was labelled with the additive according to Mintel's GNPD	+
Food categories selected for the exposure assessment: inclusion of one out of 11 authorised food categories without considering the restriction/exception food categories	+
Food categories included in the exposure assessment: exclusion of four out of 11 authorised food categories because no use levels were provided	–
Maximum level exposure assessment scenario: – exposure estimates based on the maximum reported use levels (reported use from industries)	+
Refined exposure assessment scenarios: – exposure estimates based on the maximum or mean use levels (reported use from industries)	+/–

[a]+, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

The Panel noted that information from Mintel's GNPD (Annex B) indicated that 25 of 40 food subcategories, categorised according to the Mintel GNPD nomenclature and containing foods labelled with shellac (E 904), were included in the current exposure assessment. These 25 food subcategories represented approximately 89% of the food products labelled with shellac (E 904) in the GNPD. This shows that a large part of the foods labelled with the additive according to the GNPD were included in the assessment. These estimates will not cover future changes of the food additive uses in the market.

Furthermore, GNPD showed that the percentage of foods per subcategory labelled with the additive ranged from less than 1% up to 15% (Annex B). In the exposure assessment it was assumed that 100% of the foods belonging to an authorised food category contained the additive.

Given these two observations, the Panel considered overall that the uncertainties identified resulted in an overestimation of the dietary exposure to shellac (E 904) from its use as a food additive according to Annex II in both the *maximum level* and *refined exposure assessment scenarios*. The panel did not identify brand loyalty to a specific food category for shellac (E 904) and considered the *refined non-brand-loyal scenario* dietary exposure estimates to be the most reflective of the exposure to shellac based on the available data.

3.4.2 | Proposed extension of use of shellac (E 904)

Jointly with the re-evaluation of the already permitted uses of shellac (E 904), the Panel also considered a request for an extension of use for this food additive in foods for special medical purposes (FSMP) in tablet and coated tablet form (i.e. FC 13.2 of part E of Annex II to Regulation (EC) No 1333/2008) at a proposed maximum use level of 46,000 mg/kg (Documentation provided to EFSA N. 26). Since, eating occasions related to this food category are not available in the EFSA Comprehensive Database, the exposure to shellac (E 904) from this use, was estimated by assuming an average daily consumption of two tablets as proposed by the applicant. Furthermore, the applicant indicated that these tablets are meant for adults and the concentration of shellac (E 904) per tablet is 51.5 mg (Documentation provided to EFSA N. 26). Therefore, considering the proposed maximum use level of 46,000 mg/kg, this leads to a tablet weighting of 1.12 gram. The exposure to shellac (E 904) through the consumption of two tablets per day of FC 13.2 would result in an exposure to shellac of 103 mg per day. For an adult weighing 70 kg, this would result in an exposure of 1.5 mg/kg bw per day from FC 13.2 in tablets.

Considering the dietary exposure estimated for an adult in the *maximum level exposure assessment scenario* (0.9 and 4.4 mg/kg bw per day for the mean and 95th percentile, respectively, see Table 4), the mean and 95th percentile exposure to shellac (E 904) including the proposed extension of use in tablets from FC 13.2 would be 2.4 and 5.9 mg/kg bw per day, respectively.

Considering the dietary exposure estimated for an adult in the *refined non-brand-loyal exposure scenario* (0.4 and 2.2 mg/kg bw per day for the mean and 95th percentile, respectively, see Table 4), the mean and 95th percentile of exposure to shellac (E 904) including the proposed extension of use in FC 13.2 would be 1.9 and 3.7 mg/kg bw per day, respectively.

Considering the food supplements consumer only scenario, the 95th percentile exposure to shellac (E 904) for adults is 2.7 mg/kg bw per day. Therefore, for this population, the mean exposure to shellac (E 904), considering the additional consumption from FSMP tablets (FC 13.2) would be 4.2 mg/kg bw per day.

The proposed extension of use is foreseen for adults, however, if adolescents could also consume such tablets, it would add an exposure of 1.9 mg/kg bw per day (assuming a body weight of 53.3 kg based on EFSA Scientific Committee, 2012[18]). Their total exposure to shellac (E 904) considering the dietary exposure estimated in the *maximum level exposure assessment scenario* (2.4 and 7.1 mg/kg bw per day for the mean and 95th percentile, respectively, see Table 4), would thus result in 4.3 and 9 mg/kg bw per day including the proposed extension of use in tablets from FC 13.2. Considering the dietary exposure estimated for adolescents in the *refined non-brand-loyal scenario* (1.4 and 5.6 mg/kg bw per day for the mean and 95th percentile, respectively see Table 4), the mean and 95th percentile of exposure to shellac (E 904) including the proposed extension of use in FC 13.2 would be 3.3 and 7.5 mg/kg bw per day, respectively.

The Panel noted that in all abovementioned scenarios that address the extension of use, the exposure is overestimated because it is assumed that all FSMP tablets and coated tablet form contain shellac.

3.5 | Assessment of the specifications for shellac (E 904)

The potential exposure to impurities from the use of shellac (E 904) can be calculated by assuming that the impurity is present in the food additive up to a limit value, and then by calculation pro-rata to the estimates of dietary exposure to the food additive itself.

A limit for lead (< 2 mg/kg) is included in the EU specifications. When shellac (E 904) is produced by the bleaching process, chloroform, inorganic chloride and organochlorine compounds can be present.

The level of an impurity in shellac (E 904) combined with the estimated dietary exposure to the food additive could result in an exposure to the impurity which can be compared with the reference points presented in Table 7. The risk assessment of the undesirable impurities helps to determine whether there could be a possible health concern if these impurities would be present at a certain value in the food additive. No information on the levels of organochlorine compounds is available (Table 6).

TABLE 6 Reference points for impurities potentially present in shellac (E 904).

Impurity HBGV/RP	Basis/reference
Lead (Pb)/ 0.5 μg/kg bw per day ($BMDL_{01}$)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1 point reduction in IQ (Schwartz, 1994). The EFSA CONTAM Panel mentioned that a 1 point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1 point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the $BMDL_{01}$ (MOE lower than 1) EFSA CONTAM Panel (2010)
Chloroform/15 μg/kg bw per day (TDI)	A TDI of 15 μg/kg bw per day is established based on the non-carcinogenic endpoint hepatotoxicity (WHO, 2004, 2022). Chloroform is classified as Carc Cat 2 (suspected to be carcinogenic) by the European Chemical Agency. Data from a chronic rat study (Jorgenson et al., 1985), in which carcinogenic endpoints have been evaluated were used to perform a Benchmark dose analysis by the panel (Annex F) The resulting BMD confidence interval ranged from 42 to 67 mg/kg bw per day. In the case of chloroform, with a non-genotoxic mode of action (non-genotoxic carcinogen), an MOE of > 1000 would be considered appropriate. Therefore, an exposure of chloroform < 42 μg/kg bw per day would not raise concern. Compared to this exposure the TDI for chloroform for the non-carcinogenic endpoint hepatotoxicity of 15 μg/kg bw per day would be lower and should be used for the risk assessment of chloroform

Regarding the dietary exposure to shellac (E 904), the panel did not identify brand loyalty to a specific food category, and, therefore, considered the *refined non-brand-loyal exposure assessment scenario* the most appropriate (see Section 3.4.1). Considering the estimates presented in Table 4, the rounded highest exposure levels for the mean and 95th percentile among the different population groups were 2 and 9 mg/kg bw per day, respectively, both for children.

A maximum limit for lead of 2 mg/kg is included in the EU specifications for E 904. According to information submitted, lead was reported as below 1 mg/kg (Section 3.1.1). The Panel considered that limits in EU specifications for lead should be based on actual levels in the commercial food additive; however, this information was not available. No analytical data on the presence of other toxic elements were available to the Panel.

An IBO has proposed a maximum limit for chloroform in shellac (E 904) produced by the bleaching process of 400 mg/kg (Section 3.1.1). However, the panel noted that the same IBO reported that using an optimised bleaching process, levels of chloroform can be kept below 200 mg/kg. Data provided by another IBO reported values up to 204 mg/kg. The Panel also noted that shellac (E 904) is authorised only as a coating, glazing and surface-finishing agent applied externally to food. Consequently, not all of the chloroform (Bp 61°C) initially present in the food additive will persist as it can be expected to dissipate from the food.

[18]EFSA Scientific Committee. (2012). Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. *EFSA Journal*, *10*(3), 2579. https://doi.org/10.2903/j.efsa.2012.2579. The default body weight of adolescents 10–17 years old was calculated from this guidance to be 53.3 kg.

The Panel performed the risk assessment that would result if lead and chloroform would be present at different concentrations in shellac (E 904) (Table 7).

TABLE 7 Risk assessment for impurities in shellac (E 904).

i) Scenario considering the presence of lead at the current limit in the EU specifications (Commission Regulation (EU) No 231/2012) for shellac (E 904)		
Exposure to E 904 (mg/kg bw per day)	**MOE for Pb at 2 mg/kg**	
2[c]	125	
ii) Scenario considering the presence of lead and chloroform in shellac based on information provided by an IBO		
Exposure to E 904 (mg/kg bw per day)	**MOE for Pb at 1 mg/kg[a]**	**% of the TDI for chloroform at 400 mg/kg[b]**
2[c]	250	5
9[d]	56	24

[a]Based on the reporting limit by the IBO.

[b]Based on the proposed limit by the IBO.

[c]Highest exposure level among the different population groups (*refined non-brand-loyal exposure assessment scenario* – children – mean.

[d]Highest exposure level among the different population groups (*refined non-brand-loyal exposure assessment scenario* – children – 95th percentile.

If the European Commission decides to revise the specifications, the estimates of impurities exposure as presented in Table 7 could be considered. Taking into account the calculations performed by the Panel (Table 7) and the fact that the food additive is not the only potential dietary source to these impurities, the Panel recommended to lower the maximum limit for lead and to introduce a maximum limit for chloroform, which based on the data provided could be lower (e.g. 200 mg/kg) than the proposed one by the IBO (400 mg/kg, Table 7). The panel noted that the choice of maximum limits for impurities in the EU specifications is in the remit of risk management.

The highest exposure levels to E 904 for the mean and 95th percentile is for children and this age group is not the target of the requested extension of use which are adults. The requested extension of use will result in the exposure to adults of 1.9 and 3.7 mg/kg bw per day which are below the exposure figures for children used for the evaluation of these impurities (Table 7). Consequently, the recommendation indicated above for lead and chloroform is still valid.

Inorganic chloride remains in shellac produced by bleaching process (Section 3.1.1). A limit of < 0.14% for total inorganic chloride has been proposed by an IBO (Documentation provided to EFSA n. 11). The Panel considered this limit as an indirect parameter to limit the amount of hypochlorite used in the chemical bleaching process and so limiting the undesirable formation of chloroform and other organochlorine compounds. The panel considered that the levels of potentially remaining chlorine (Cl_2) will be negligible and, therefore, of no toxicological relevance.

The Panel noted that the EU specifications for shellac E 904 are rather generic and do not describe in detail the manufacturing processes reported by the IBOs, either by chemical bleaching with sodium hypochlorite or by a physical decolouring process based on activated carbon. In addition, the content impurities linked to the hypochlorite bleaching process, i.e. chloroform, organochlorine compounds and inorganic chlorine, is not limited in the EU specifications. Furthermore, the IBOs have stated they use only wax-free shellac. Based on the data provided by IBOs and the considerations made by the Panel, it is recommended that the following changes be considered for shellac E 904:

- To revise the definition of the food additive to include a short description of each manufacturing process (chemical bleaching and physical decolouring);
- To have separate specifications depending on the manufacturing process, because they result in different impurities;
- To revise the acid value for wax-free shellac produced by chemical bleaching that can be slightly above the current limit of 89, to be in line with the specifications in the FCC (2010);
- To delete information on wax-containing shellac since it is not used as E 904 and no data to confirm its safety were available;
- To lower the maximum limit for lead;
- In the case of shellac produced by chemical bleaching, a maximum limit for chloroform and total inorganic chloride should be included.

3.6 | Biological and toxicological data

Following EFSA public calls for data, biological and toxicological data were submitted for the re-evaluation of shellac (E 904). The toxicological studies provided were performed with shellac (E 904) produced either by chemical bleaching or by physical decolouring. In addition, all test materials used in the toxicological studies submitted by the three IBOs are wax-free shellacs. The Panel noted that shellac (E 904) tested in the toxicity and genotoxicity studies submitted by different IBOs has been produced by different manufacturers and even different batches were tested in studies submitted by the same IBO. The studies are accompanied with a certificate of analysis of the test item in which some parameters, as listed in the specifications of E 904 (Table 1), were analysed. In some cases, the content of shellac monomer (reported as around

29%) or specific components (i.e. aleuritic acid, butolic acid and shelloic acid, reported as around 1%, 1.7% and 0.008%, respectively) were also reported.

A few relevant publications were identified from the literature searches and summarised in the opinion.

3.6.1 | Absorption, distribution, metabolism and excretion

Information on absorption, distribution, metabolism, excretion (ADME) was not available to the SCF or JECFA (JECFA, 1993; SCF, 1992). No new relevant information was found in the literature search.

Shellac is used as an excipient in medicinal products to provide an enteric coating for tablets and capsules, preventing disintegration in the stomach, showing that in the acid conditions of the stomach little or no degradation takes place. Depending on treatment and thickness of the layer, treated tablets will disintegrate in the small intestine or in the colon, but no information has been identified describing to what extent shellac is degraded. However, in the short-term rat study quoted by JECFA (JECFA, 1993) (Documentation provided to EFSA N. 27), it is stated that 'no residues of shellac were detected in the test animals' faeces' [the test animals received 2% shellac in the diet].

ADME studies with wax-free shellac produced by physical decolouring

A new study was submitted by one of the IBOs (Documentation provided to EFSA n. 28). A group of five female and five male RccHan: Wistar rats received shellac (E 904) by gavage 1500 mg/kg bw) for 4 weeks. Shellac monomer was analysed to investigate the absorption of shellac. Considering the reported value of 29% of shellac monomer in the test item, the dose was equal to 437.7 mg/kg shellac monomer. Blood was collected from the rats at day 1, on 0.5; 1; 2; 4; 8 and 24 h after dosing and at day 28, on 0.5; 1; 2; 4; 8; 24 and 72 h after dosing. The plasma of the main components in shellac (e.g. shellac monomer, jalaric acid, aleuritic acid, ...) and metabolites (e.g. laccilaksholic acid, laccijalaric acid,...) were analysed using liquid chromatography with tandem mass spectrometry (LC–MS/MS). The Cmax of the shellac monomer ranged from 82.3 to 481 ng/mL (day 28; the Cmax reported at day 1 are within this range). The mean Cmax reported at day 1 were 207 ± 69 ng/mL in males and 239 ± 89 ng/mL in females, whereas the mean Cmax reported at day 28 were 169 ± 51 ng/mL in males and 325 ± 128 ng/mL in females. None of the rats died and no test item-related changes in clinical signs or body weights were observed. Absorption of the shellac monomer was very low. Eleven metabolites were detected. Repeated dosing did not change the major shellac components and metabolite concentrations in plasma, and no sex differences were noted on days 1 and 28.

3.6.2 | Acute toxicity

Both JECFA (1993) and FDA (1981) reported an acute oral toxicity study in rats (Documentation provided to EFSA n. 29). In this study, groups of 10 rats (5 males and 5 females/group, body weight between 200 and 300 g, no information on strain) received by gavage a single dose of 5000 mg/kg bw of one of the following five types of Shellac suspended in water: (1) 'food grade Regular Bleached Bone-dry Shellac', (2) 'food grade Refined Wax-free Bone-dry Bleached Shellac', (3) 'food grade Orange with Wax Shellac', (4) 'food grade Orange Wax free Shellac' and (5) 'food grade Shellac Wax'. No information on the manufacturing process of these types of shellac was mentioned. None of the rats died from the exposure to shellac.

The Panel considered the test material as of low acute toxicity.

3.6.3 | Short-term and subchronic toxicity

Both JECFA (1993) and FDA (1981) reported a tolerance study in rats (Documentation provided to EFSA n. 27). The Panel noted the limited reporting of the characterisation of the test material and of the results, and therefore, the Panel considered this study as not relevant for risk assessment.

Studies with wax-free shellac produced by chemical bleaching

A 90-day study in rats, performed according to the OECD Test Guideline 408 (OECD, 2018a) and reported to be performed in compliance with the principles of GLP, was submitted by one IBO (Documentation provided to EFSA n. 30). Four groups of Wistar rats (10/sex/group) were given 0; 5000; 10,000 or 20,000 mg shellac (E 904)/kg diet (equal to 0; 340; 701 or 1384 mg/kg bw per day for males and 388; 741; 1569 mg/kg bw per day for females) for 90 days. No mortality or morbidity or clinical signs indicative of impaired health status were observed during the study. No treatment-related effects were observed on growth, food consumption, in ophthalmological examination, functional observational battery testing, clinical chemistry or urinalysis parameters, organ weights and gross examination. Haematological examination revealed a statically significant dose-related increase in RBC counts (+ 4%, +4%, +5% at low, mid and high doses, respectively) in males of all treatment groups and a statistically significant decrease in prothrombin time (−9%) in mid-dose females. Microscopic examination revealed minimal periportal microvesicular hepatocellular vacuolation of males and females of all treated

groups (males: 0/10, 9/10, 9/10, 9/10; females: 0/10, 9/10, 10/10, 9/10 in the control and at the low, mid and high doses, respectively). The authors concluded that the tested shellac (E 904) induced an increase in RBC counts as well as periportal microvesicular vacuolation in the liver in all treatment groups when administered via the diet to Wistar rats for 90 days. The Panel considered the minimal increase in RBC in males as not toxicologically relevant, and the minimal microvesicular hepatocellular vacuolation as treatment-related but not adverse. The Panel identified a NOAEL at the highest dose tested (1384 mg/kg bw per day for males and 1569 mg/kg bw per day for females).

Four groups of Wistar rats (10/sex/group) were given 0; 5000; 10,000 or 20,000 mg shellac (E 904) /kg diet (equivalent to 0; 405; 810 or 1620 mg/kg bw per day for males and 0; 455; 810 or 1820 mg/kg bw per day for females) for 90 days (Documentation provided to EFSA n. 31). The study was conducted according to OECD TG 408 (OECD, 2018a) and reported to be performed in compliance with the principles of GLP. Recovery groups (6 rats/sex/group) of the control and high-dose group were included and examined 28 days after the last exposure. No mortality or clinical signs indicative of impaired health status were observed during the study. No treatment-related effects were observed on growth, food consumption, ophthalmological examination, functional observational battery testing, clinical chemistry or urinalysis parameters, organ weights and gross examination. No treatment-related changes were observed in any of the sperm analysis parameters tested. Oestrous cyclicity of all treated and recovery groups was comparable to the respective controls. Histopathological examination did not reveal any treatment-related finding in any of the groups. The Panel identified a NOAEL at the highest dose tested (1620 mg/kg bw per day for males and 1820 mg/kg bw per day for females).

Studies with wax-free shellac produced by physical decolouring

A 90-day study in rats performed according to the OECD Test Guideline 408 (OECD, 2018a) and reported to be performed in compliance with the principles of GLP was submitted by one IBO (Documentation provided to EFSA n. 32). Shellac (E 904) was administered by gavage for 90 days to RccHan:Wist rats (10 rats/sex/dose) at dose levels of 0 (controls treated with the vehicle, 0.5 w/v% methylcellulose solution), 150, 500 or 1500 mg/kg per day. None of the animals died during the study and no test article-related changes were observed in clinical signs, general behaviour and neurobehavioural function, locomotor activity, body weight, food consumption, ophthalmology, urinalysis, haematology, gross or histopathological examination. Clinical chemistry investigations revealed dose-related increases in total cholesterol in all treated males which achieved statistical significance at the high dose (+4%, +14%, +22% at the low, mid and high dose). Data on organ weights revealed statistically significantly higher relative adrenal weight in high dose male (+15%). The Panel noted that the absolute adrenal weight in high dose males was increased but not statistically significant (+15%) and no effect on absolute and relative adrenal weight was seen in females. The Panel noted that the increase in total cholesterol in males and increase in absolute and relative adrenal weight in high-dose males were not observed in the chronic study provided by the same IBO with the same test material (see Section 3.6.5). Therefore, the panel considered these findings of no toxicological relevance. No other toxicologically relevant effects in clinical chemistry and organ weights were observed by the panel. The authors concluded that a NOAEL of 1500 mg/kg bw per day for both males and females of shellac (E 904) was identified. The panel agreed with this conclusion.

Studies with uncharacterised shellac

One subchronic study on shellac has been identified in the literature. Four groups of Wistar rats (20/sex/group) were given 0; 5000; 10,000 or 20,000 mg Shellac (Handmade') /kg diet (equivalent to 0; 405; 810 or 1620 mg/kg bw per day for males and 455; 910; 1820 mg/kg bw per day for females) for 180 days (Srivastava & Thombare, 2017). No mortality or clinical signs indicative of impaired health status were observed during the study. No treatment-related effects were observed on growth, food consumption, organ weights and histopathology. No detailed description which organs were weighed and preserved was given. From the information reported on the relative organ weight, it can be concluded that brain, adrenals, spleen, heart, kidneys, liver and reproductive organs (epididymides, testes, ovaries and uterus) were weighed. Absolute organ weight was not given. The histopathology was described insufficiently (number of animals and incidences not presented). The authors identified a NOAEL at the lowest dose, 405 mg/kg bw per day for males and 455 mg/kg bw for females based on effects in haematology (decrease in platelets in high-dose males, no effect in females) and clinical chemistry (increase in glucose levels similar in mid- and high-dose males; no such effect in females). Because of the several flaws, this study cannot be used for the risk assessment.

Overall, no toxicologically relevant effects were seen in the oral subchronic studies in rats with shellac (E 904) produced either by chemical bleaching or by physical decolouring at doses amounting to 1600 mg/kg bw per day, the highest dose tested.

3.6.4 | Genotoxicity

Studies with wax-free shellac produced by chemical bleaching

Shellac (E 904) was tested in Salmonella Typhimurium strains TA1535, TA1537, TA98 and TA100 in the absence and presence of Aroclor 1254-induced rat liver S9 fraction (S9 mix) at six concentrations ranging from 1 to 10,000 µg/plate using the

plate incorporation procedure and duplicate platings in a single experiment (Documentation provided to EFSA n. 33). At the applied test conditions, shellac (E 904) did not increase the number of revertant colonies in any strain. The study was reported to be performed in compliance with the principles of GLP. In this study, corn oil was used as the vehicle for the test item. The panel noted the limited protocol of the study, and the use of corn oil as vehicle, which is not a recommended for the *Salmonella*/microsome plate incorporation assay (Maron et al., 1981). The Panel considered this study of insufficient reliability and the results of low relevance.

Shellac (E 904) (Documentation provided to EFSA n. 34) was tested in a bacterial reverse mutation test. The material was dissolved in DMSO and tested in the presence and absence of metabolic activation in the Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and the *Escherichia coli* WP2 *uvrA* using the plate incorporation procedure. The study was performed according to the OECD TG 471 (OECD, 2020) and reported to be performed in compliance with the principles of GLP. Based on the results of a preliminary toxicity assay, five doses in the range 312.5–5000 μg/plate were evaluated in replicate experiments using 10% and 20% v/v S9mix. No increase in revertant colonies, and no precipitation or thinning of background bacterial lawn, were observed in either experiment. The Panel evaluated this study as reliable without restrictions and the results obtained of high relevance.

In another study, shellac (E 904) was tested in a bacterial reverse mutation test with the Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and TA102 (Documentation provided to EFSA n. 35). The material was dissolved in DMSO and tested in presence and absence of metabolic activation using the plate incorporation procedure. In the first experiment, 8 concentrations in the range 1.5–5000 μg /plate were tested with and without 5% (v:v) using duplicate plates. In the confirmatory experiment, six concentrations in the range 15,625–5000 μg/plate were tested with and without 10%v (v:v) S9 with triplicate plates. The study was reported to be performed in compliance with the principles of GLP and followed the OECD TG 471 (OECD, 2020). In both experiments, there was no increase in revertant colonies, in any strain and experimental condition. No precipitation or thinning of background bacterial lawn was observed at any dose. The panel evaluated this study as reliable without restrictions and the results obtained of high relevance.

Shellac (E 904) was tested in the in vitro mammalian cell micronucleus test in human peripheral blood lymphocytes (OECD 487, OECD, 2023) in the presence and absence of metabolic activation with 2% v/v S9 mix (Aroclor 1254 induced rat liver S9 fraction) (Documentation provided to EFSA n. 36). The study was performed according to the OECD Test guideline 487 and reported to be performed in compliance with the principles of GLP. Prior to the micronucleus assay, the cytotoxicity of the tested compound in the absence and presence of S9 mix was determined at concentrations ranging from 6.25 to 2000 μg/mL. Shellac was dissolved in ethanol, and stock solutions added to culture medium at 0.1% v/v in order to achieve the desired final concentration. Based on the results of the cytotoxicity testing, the tested concentrations of shellac in the final experiment were 10, 20, 40, 60, 80 and 100 μg/mL in the absence of metabolic activation and 15.625, 31.25, 62.5, 125, 250 and 500 μg/mL in the presence of metabolic activation. The first experiment was performed in the absence of metabolic and presence of metabolic activation and the exposure time was 3.5 h. Cytochalasin (6 μg/mL) was added at the end of the exposure and incubated until harvesting 24 h from the beginning of the treatment. The second experiment was performed in the absence of metabolic activation with 24-h continuous exposure to the test compound in the presence of cytochalasin (6 μg/mL). Two replicates per concentrations were analysed for the presence of micronuclei in 2000 binucleated cells. Under the applied experimental conditions, shellac did not induce statistically significant increases in the number of binucleated cells with micronuclei. The panel evaluated this study as reliable without restrictions and the results obtained of high relevance.

Shellac (E 904) was tested in the in vitro micronucleus test in human peripheral blood lymphocytes (OECD TG 487, OECD, 2023) in the presence and absence of metabolic activation (Documentation provided to EFSA n. 37). The study was performed according to the OECD Test guideline 487 and reported to be performed in compliance with the principles of GLP. A preliminary cytotoxicity assay was performed in the concentration range 8.0–2000 μg/mL of the tested compound in the absence and presence of S9 mix (1% v:v final S9 concentration). DMSO was used as solvent. Based on the results of the cytotoxicity assay, the tested concentrations in the main experiment were 56.25, 112.5 and 225.0 μg/mL in the short-term (4h) and long-term exposure (22 h) in the absence of metabolic activation and in the short-term exposure in the presence of the metabolic activation. The mitotic index at the highest tested concentration was between 40 and 50%. In the absence of metabolic activation in the short-term and long-term exposure, no concentration dependence or significant increase in the percentage of micronuclei in binucleated cells was observed at any tested concentration. In the presence of metabolic activation, a statistically significant increase of the frequency of micronuclei in binucleated cells was observed at the highest tested concentration 225 μg/mL, without concentration dependency (i.e. without any concurrent proportional increase of micronuclei at the lower doses). Based on these results, the authors concluded that, under the tested conditions, shellac (E 904) is genotoxic in cultured human peripheral blood lymphocytes. The panel noted that only one of three conditions required in OECD TG 487 to evaluate a result as clearly positive (namely statistical significance, concentration-response relationship and exceedance of historical control values) was fulfilled and considered the result as equivocal. The panel evaluated this study reliable without restrictions and the equivocal results obtained of limited relevance.

Another in vitro micronucleus assay in human peripheral lymphocytes was performed under similar experimental conditions (see above study summary) with shellac (E 904) (Documentation provided to EFSA n. 38). The study was conducted following the OECD TG 487 (OECD, 2023) and reported to be performed in compliance with the principles of GLP. In a preliminary toxicity experiment, more than 50% cytotoxicity was observed at 250 μg/mL and above, both with short (4 h ± S9mix) and extended (22 h without S9mix) treatment. Based on these findings, the concentrations of 25, 50, 100 and 200 μg/mL were selected for the main study. No statistically significant or concentration-related increase of binucleated

cells with micronuclei was observed under any experimental condition. The panel noted that the equivocal result observed in the first study with shellac (E 904) was not replicated and evaluated the test article as non-clastogenic and non-aneugenic under the experimental conditions applied. The panel evaluated this study as reliable without restrictions and the results obtained of high relevance.

Studies with wax-free shellac produced by physical decolouring

Shellac (E 904) was tested in a bacterial reverse mutation assay (Documentation provided to EFSA n. 39). The test article was dissolved by sonication in DMSO and tested with the Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and TA102 with and without metabolic activation, using the plate incorporation procedure. The study was performed according to the OECD Test guideline 471 (OECD, 2020) and reported to be performed in compliance with the principles of GLP. A preliminary test was performed over the concentration range 1.5–5000 µg/plate using 5% v/v S9mix. A repeat assay was carried out in a narrower concentration range (156–5000 µg/plate) using 10% v/v S9mix. In both experiments, there was no increase in revertant colonies, and no indication of toxicity as shown by the normal background bacterial lawn. The panel evaluated this study as reliable without restrictions and the results obtained of high relevance.

Shellac (E 904) was tested in the bacterial reverse mutation and in vitro micronucleus test (Documentation provided to EFSA n. 40). In the bacterial test, the test material was dissolved in DMSO and tested with the preincubation procedure in the Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* WP2 *uvrA*, with and without metabolic activation. The study was reported to be performed in compliance with the principles of GLP and following the OECD TG 471 (OECD, 2020). Based on the results of a range finding experiment, the following concentration ranges were tested in the main test: 156–5000 µg/plate (TA1535, TA98, TA100 and WP2 *uvrA*) and 39–2500 µg/plate (TA1537). No increase in revertant colonies was observed in any strain, in the presence or absence of metabolic activation. Precipitation was observed from 2500 µg/plate and growth inhibition at 1500 µg/plate and above (TA1537) or 5000 µg/plate (the other strains).

The in vitro micronucleus test was carried out in CHL/IU cells (a fibroblast-like cell line derived from lung of female new-born Chinese hamsters) in the presence and in the absence of metabolic activation with S9 Mix (5% v/v S9 from phenobarbital, 5,6-benzoflavone induced rat liver) (Documentation provided to EFSA n. 41). The study was performed according to the OECD Test guideline 487 (OECD, 2023) and reported to be performed in compliance with the principles of GLP. A concentration range finding experiment was performed at concentrations ranging from 2 to 2000 µg/mL and exposure duration 6 and 24 h. DMSO was used as solvent. Based on the results of the concentration range finding experiment, concentrations in the final experiments were for 6-h and 24-h treatment without metabolic activation, 116, 151, 196, 255, 331, 431 and 560 µg/mL; for the 6-h treatment with metabolic activation, 331, 431, 560, 728, 947, 1230 and 1600 µg/mL. No statistically significant increase of cells with micronuclei was observed in treated cultures, under any treatment condition. The panel evaluated these studies as reliable without restrictions and the results obtained in both the bacterial reversion and in vitro micronucleus test of high relevance.

Studies with uncharacterised shellac

Only one genotoxicity study on shellac has been identified in the literature. In this study, a sample of shellac, claimed by the authors to be used as a food additive, was tested in the *Salmonella*/microsome reverse mutation assay with strains TA92, TA1535, TA100, TA1537, TA94 and TA98, and in a limited chromosomal aberration test in vitro using the Chinese hamster fibroblast cell line CHL without metabolic activation. In both tests, the results were negative (Ishidate et al., 1984). The panel noted the limited protocol applied in this study, not aligned with the recommendations in the OECD TGs 471 (OECD, 2020) and 473 (OECD, 2016b), and the inadequate data reporting.

The mutagenicity of 'shellac wax' was tested with the Salmonella Typhimurium strains TA1535, TA1537 and TA1538 and the yeast *Saccharomyces cerevisiae* strain D4, in the presence and absence of metabolic activation with S9 fractions isolated from liver, lung or testes of mice, rats or monkeys (Documentation provided to EFSA n., 42). At the applied test conditions 'shellac wax' did not induce reverse mutations in *Salmonella* and gene convertants in yeast. The panel noted that the study was performed before the OECD guidelines for genotoxicity were implemented, and that the study protocols were not aligned with the OECD recommendations for the conduct of bacterial reverse mutation assays (OECD TG 471, OECD 2020) and mitotic recombination in yeast (OECD TG 481, OECD, 1986, deleted in 2014).

Beyond the protocol limitations, the Panel also noted that the representativity of the material tested in these studies for the shellac under evaluation is unknown. Consequently, these studies were considered of insufficient reliability and the results obtained of low relevance, and not further considered in the overall evaluation.

A summary of the available genotoxicity studies of shellac (E 904) is presented in Appendix A.

In summary, an adequate set of genotoxicity studies with test material in compliance with the EU specifications for shellac E 904 was available. In these studies, negative results were obtained in bacterial reverse mutation assays with Shellac samples produced either by chemical bleaching or by physical decolouring. In the in vitro micronucleus test, negative results were obtained with physically decoloured shellac; an equivocal positive result was observed in a study with chemical bleached shellac, which was not confirmed in a subsequent test with clearly negative results. Overall, the results of the available studies of shellac (E 904) produced either by chemical bleaching or by physical decolouring do not raise concerns.

The panel noted that due to the complex chemical composition of E 904, the whole mixture approach applied in the studies described above may be of insufficient sensitivity to highlight the genotoxic hazard posed by (minor) individual components of E 904.

This uncertainty was addressed in a in silico assessment of the genotoxicity of the main shellac components using the OECD QSAR Toolbox and VEGA systems. The substances considered were polyesters of hydroxyaliphatic acids: aleuritic and butolic acids, and the sesquiterpenoid acids: jalaric, laksholic, shelloic, laccijalaric and laccilaksholic acids reported as components in shellac, beyond the main component reported as shellac monomer, jalaric acid aleuritate.

A summary of the results of the in silico assessment is presented in Appendix B.

In the OECD QSAR Toolbox, the end-point specific profiler 'Ames test, chromosomal aberrations and micronuclei in vitro by OASIS' did not identify any relevant structural alert in the molecules investigated, while the presence of simple aldehyde group was highlighted by the ISS end-point specific profilers (Ames test and in vivo micronuclei) in jalaric and laccijalaric acids and in the shellac monomer. The latter profiler (in vivo mutagenicity by ISS) also identified the 'H-acceptor-path-3-H-acceptor pathway' as a possible alert, which is however devoid of positive predictive value (Pradeep et al., 2021).

Among general mechanistic profilers, no alert for potential DNA or protein biding was also identified by OASIS, while the potential reactivity to DNA via Schiff base formation was flagged by the OECD profiler.

In VEGA models, a consensus positive prediction for mutagenicity in the Ames test was formulated for Jalaric acid and Laccijalaric acid, while all other substances, including the shellac monomer, were predicted as non-mutagenic. All substances were predicted as inactive in the in vivo micronucleus test, although a positive prediction was made for the in vitro activity.

The Panel noted that in silico predictions of genotoxicity should not be based on the use of a single computational model (EFSA & WHO, 2016). The Panel also noted the limited reliability of some predictions, due to the limitations in the applicability domain and in the accuracy of the predictions in the training set with VEGA models. Therefore, a more in-depth analysis was conducted to assess the reliability of the limited positive predictions for potential in vitro genotoxicity formulated by the OECD Toolbox and/or VEGA models for jalaric acid and laccijalaric acids and the shellac monomer jalaric aleuratitate.

First, a read across was performed with appropriate analogues of the molecules, selected from the ISSSTY (Ames test) database in Toolbox as having the same 'simple aldehyde' and 'Schiff base formation' alerts and similar substructures (checked with Organic Functional Groups profiler). Then, a QSAR analysis based on the discrimination between positive and negative genotoxicity provided by molecular descriptors of hydrophobicity (logP) and bulkiness (molar refractivity) of aldehydes (Benigni et al., 2003) was performed. Both analysis point to the lack of mutagenicity for jalaric acid and laccijalaric acids and the shellac monomer jalaric aleuratitate.

Overall, it is concluded that the (Q)SAR analyses conducted do not raise concerns for the shellac components examined.

3.6.5 | Chronic toxicity and carcinogenicity

Studies with wax-free shellac produced by chemical bleaching

One combined chronic toxicity/carcinogenicity study in rats performed according to the OECD Test Guideline 453 (OECD, 2018c) and reported to be performed in compliance with the principles of GLP has been submitted by one IBO (Documentation provided to EFSA n. 43). In the chronic toxicity study, four groups of 16 Wistar rats/sex/group were given shellac (E 904) at 0; 1000; 5000 or 10,000 mg /kg diet (equal to 0; 51; 255 and 509 mg/kg bw per day for males and 0; 65; 332; and 647 mg/kg bw per day for females) in their diet for 52 weeks. Four groups of 50 rats/sex/group were given 0; 1000; 5000 or 10,000 mg shellac/kg diet (equal to 0; 45; 226 or 452 mg/kg bw per day for males and 0; 56; 300 or 569 mg/kg bw per day for females) for 24 months. No compound-related morbidity, mortality or clinical signs were observed. No treatment-related effects were observed on growth, food consumption, ophthalmological observation, functional observational battery testing, haematology, clinical chemistry, urinalysis, organ weights, gross and histopathological examination.

The authors concluded that the treatment of rats with shellac (E 904) for 52 weeks did not reveal any toxicity or adverse effects up to the highest dose level of 10,000 mg/kg diet (equal to 509 mg/kg bw per day for males and 647 mg/kg bw per day for females). Furthermore, shellac (E 904) did not induce any adverse or carcinogenic effect up to the highest dose level of 10,000 mg/kg diet (452 mg/kg bw per day for males and 569 mg/kg bw per day for females) for 104 weeks. The Panel identified a NOAEL at the highest dose tested (452 mg/kg bw per day for males and 569 mg/kg bw per day for females).

Studies with wax-free shellac produced by physical decolouring

One combined chronic toxicity/carcinogenicity study in rats performed according to the OECD Test Guideline 453 (OECD, 2018c) and reported to be performed in compliance with the principles of GLP has been submitted by another IBO (Documentation provided to EFSA n. 44). In the chronic phase of this study, shellac (E 904) suspended in 0.5 w/v% methylcellulose solution was administered by gavage once daily for 52 weeks at dose levels of 0 (two control groups), 150, 500 and 1500 mg/kg bw per day to 12 male and 12 female RccHan:Wistar rats (6 weeks old at initiation of dosing) per group. Six males and six females were added to the control group and the high-dose group to assess the reversibility of toxicity during a subsequent 4-week recovery period.

Clinical signs, body weight gain, food consumption, ophthalmology, urinalysis, haematology, blood chemistry, gross pathology and organ weights did not reveal any test compound-related changes. At gross observation, males (7/12) and females (1/12) of the highest dose group demonstrated the presence of calculus-like material in the stomach. At microscopic examination, most animals showing this material in the stomach at necropsy demonstrated histopathological changes in the glandular stomach such as degeneration/regeneration of the mucosal surface epithelium, erosions, ulcers and haemorrhages in the mucosa and oedema of the submucosa (males, 7/12; females, 2/12). At the end of the recovery period, these histopathological lesions in the stomach were still present in five of six males and three of six females but not aggravated.

The NOAEL of the chronic toxicity study was identified by the authors to be 500 mg/kg bw per day, since rats exposed to this amount of test compound did not develop the histopathological changes in the stomach as observed in rats of the 1500 mg/kg bw per day group. These histopathological changes were considered by the authors to be the results of mechanical irritation caused by the calculus-like material derived from shellac (E 904).

In the carcinogenicity phase, shellac (E 904) was administrated to 50 male and 50 female RccHan:WIST rats/group for 104 weeks, in the same manner as in the chronic phase. No treatment-related changes were observed in body weight, food consumption or haematology and there were no increases in the incidence of neoplastic lesions in the 1500 mg/kg bw per day group as compared to the control groups.

Similar to the chronic toxicity study, the presence of calculus-like material was found at necropsy in males of the 150 mg/kg bw per day group (2/50) and in males and females of the 500 (2/50 males and 2/50 females) and 1500 mg/kg bw per day groups (43/50 males and 22/50 females). The incidence of this finding in 1500 mg/kg bw per day group (86% males and 44% females) was higher than at the same dose group in the chronic study (58% males and 17% females). In all groups, controls included, microscopic examination of the stomach demonstrated similar histopathological changes as in the chronic study namely degeneration of the mucosal surface epithelium, degeneration/regeneration and erosion/ulcers of the mucosa, and haemorrhages in the mucosa. The severity of these changes in the high-dose group was similar to that observed in the controls and to that in the high-dose group in the chronic study. Since these lesions were also present in the controls, the Panel assumed that they were related to the dosing by gavage. However, their increased incidences in 1500 mg/kg bw per day group indicated that the changes could be caused by the combination of gavage dosing and the presence of calculus-like material derived from shellac.

Non-neoplastic changes in the stomach in the carcinogenicity phase were observed at the 1500 mg/kg bw per day group.

In summary, shellac (E 904) did not have carcinogenic potential when repeatedly administered by gavage, once daily, to rats for 104 weeks. Treatment-related histopathological changes in the stomach were mainly observed in males and females of the 1500 mg/kg bw per day group. The Panel assumed that these lesions may be for a large part ascribed to mechanical irritation (daily dosing by gavage) in combination with the presence of calculus-like material derived from shellac.

The Panel identified a NOAEL of 500 mg/kg bw per day (based on non-neoplastic lesions) from this combined chronic toxicity/carcinogenicity study.

3.6.6 | Reproductive and developmental toxicity

Reproductive toxicity studies

Studies with wax-free shellac produced by chemical bleaching

An oral dietary reproductive and developmental toxicity screening test with shellac (E 904) in Wistar rats ($n = 12$/sex/group), performed according to OECD TG 421 (OECD, 2016a) and reported to be performed in compliance with the principles of GLP was submitted by one IBO (Documentation provided to EFSA n. 45). Shellac was administered via the diet at concentrations of 0, 5000, 10,000 or 20,000 mg/kg diet (equal to 0, 300, 600 or 1200 mg/kg bw per day). No treatment-related mortality or clinical signs were observed. Body weight gain was decreased in the dams of the mid-and high-dose groups (both ~ 16%) from GD 14–20 and GD 0–20 (~ 16%) in the high-dose group. No statistically significant decrease was observed in body weight in the mid- and high-dose groups. No adverse effects were observed in the study on fertility, reproductive and developmental parameters. The authors considered the highest dose group as the NOAEL for maternal, reproductive and developmental toxicity as no effects were observed on pup weights. The Panel considered the low-dose group (300 mg shellac/kg bw per day) as the NOAEL for maternal toxicity based on body weight gain decreased in the dams and the high dose (1200 mg shellac/kg bw per day) as the NOAEL for reproductive and developmental toxicity. The Panel identified a NOAEL of 300 mg shellac/kg bw per day, based on body weight gain decreased in the dams, for maternal toxicity, and a NOAEL of 1200 mg shellac/kg bw per day, the highest dose tested, for reproductive and developmental toxicity.

An oral dietary two-generation reproductive toxicity study in Wistar rats (25/sex/group in both generations), performed according to OECD TG 416 (OECD, 2001) and reported to be performed in compliance with the principles of GLP, was submitted by an IBO (Documentation provided to EFSA n. 46). Shellac (E 904) was administered via the diet at concentrations of 0, 5000, 10,000 or 20,000 mg/kg diet (equal to 0, 400, 800 or 1600 mg/kg bw per day). No treatment-related mortality or clinical signs were observed in the P- and F1-generation. Body weight and body weight gain were decreased in the female F1-animals of the mid-dose group and in the male and female animals of the high-dose group in both generations.

The Panel identified at NOAEL of 800 mg shellac/kg bw per day for parental toxicity. No adverse effects were observed on fertility and reproductive parameters. The Panel identified at NOAEL of 1600 mg shellac/kg bw per day, the highest dose tested, for reproductive toxicity. Decreased pup body weight was observed in the pups of the high-dose group in both generations and in the mid-dose group in the F2-pups. Therefore, the Panel identified at NOAEL of 400 mg shellac/kg bw per day for developmental toxicity. The NOAEL for parental, reproductive and developmental toxicity was 800, 1600 and 400 mg shellac/kg bw per day, respectively.

Studies with wax-free shellac produced by physical decolouring

A two-generation reproductive toxicity study with shellac suspended in 0.5 w/v% methylcellulose solution by gavage was submitted by another IBO (Documentation provided to EFSA, n. 47). The study was performed according to OECD TG 416 (OECD, 2001) and reported to be performed in compliance with the principles of GLP. The test solution was administered once daily during the entire study (two-generations) at dose levels of 0, 500, or 1000 mg/kg bw per day to Crl:CD(SD) rats (24/sex/group in the F0-generation and 23, 23 and 18 rats per sex per group in the F1-generation). The authors noted that the actual dose during the lactation period of the dams of the F1-generation was not adjusted to the most recent body weight, and therefore, during lactation the lowest dose level was 397 to 546 mg/kg bw per day and the high dose level was 831 to 1126 mg/kg bw per day. For the F1-generation 1 pup/sex per litter was selected for the reproduction and 1 pup/sex/litter for the behavioural studies. As the fertility of the F1-generation was low in the animals used for the reproductive performance test (100, 73.9 and 77.8% for the control, 500 and 1000 mg/kg bw group, respectively) also the F1 animals selected for the behavioural tests were mated. Fertility in this group was 90.5, 85.7 and 83.3% for the control, 500 and 1000 mg/kg bw group, respectively. In all groups, F1-dams showed total litter loss. F1-dams of reproductive performance group 3, 4 and 1 lost litters (control, 500 and 1000 mg/kg bw group, respectively). F1-dams of behavioural test group 5, 8 and 6 lost litters (control, 500 and 1000 mg/kg bw group, respectively). The authors related the litter loss to failure of the development of the mammary gland (microscopically observed); this effect was observed in all groups including the control group. Apart from the statistically significant decrease in absolute testis weight in the high-dose group of the F0-generation, no treatment-related effects on mortality, clinical signs, body weight and food intake, fertility, reproductive and developmental parameters were observed in the P-and F1-generations and their pups. The effect on absolute testis weight was not considered relevant by the authors as no histopathological changes were observed. The number of live litters (19, 13 and 12 litters for the control, low- and high-dose groups, respectively) in the reproductive part of the F1-generation was due to these effects below the number of litters necessary to perform a proper evaluation of the study. The F1-males (behavioural part of the study) showed in the open field test a decrease in rearing, grooming and preening (only significant in the low-dose group) and a statistically significant decrease in defaecation in both shellac-treated groups. The behaviour of these shellac treated F1-males was comparable to the behaviour of the F1-females.

The Panel noted that there was an effect on testis weight and lower fertility in the F0-animals of the high-dose group. Litter loss due to failure of development of the mammary gland was observed in the control, low- and high-dose group and was considered by the Panel as possibly related to affected environmental, housing or dietary conditions. Due to the uncertainties around the effects in the F1 generation, the Panel did not use data of this study for the risk assessment.

Developmental toxicity studies

Studies with wax-free shellac produced by chemical bleaching

Rabbits

An oral prenatal developmental toxicity test with shellac (E 904) was performed according to OECD TG 414 (OECD, 2018b) and reported to be performed in compliance with the principles of GLP (Documentation provided to EFSA n. 48). Shellac was suspended in 0.5 w/v% methylcellulose solution and administered by gavage once daily from gestation day (GD) 6–29 at dose levels of 0, 100, 300 and 1000 mg/kg bw per day to New Zealand White rabbits (25 females/group). No treatment-related effect was observed on body weight, body weight gain, uterus weight or food intake of the dams of all groups treated with shellac when compared to the controls. The number of corpora lutea, implantations, live and dead foetuses, resorptions, fetal and placental weight and sex ratio were comparable between the control and treated groups. No differences in fetal external, visceral and skeletal abnormalities were observed. A NOAEL of 1000 mg shellac/kg bw per day, the highest dose tested, for maternal and developmental toxicity was observed in this study.

Studies with wax-free shellac produced by physical decolouring

Rats

An oral prenatal developmental toxicity test was performed according to OECD TG 414 (OECD, 2018b) and reported to be performed in compliance with the principles of GLP (Documentation provided to EFSA). In the prenatal developmental toxicity study, shellac (E 904) suspended in 0.5 w/v% methylcellulose solution was administered by gavage once daily from gestation day (GD) 6–17 at dose levels of 0, 500 and 1000 mg/kg to Crl:CD(SD) rats (20–22 females/group). No

treatment-related effect was observed on body weight, body weight gain or uterus weight or food intake of the dams of all groups treated with decoloured shellac (E 904) when compared to the controls. The number of corpora lutea, implantations, live and dead fetuses, resorptions, fetal and placental weight and sex ratio were comparable between the control and treated groups. No differences in fetal external, visceral and skeletal abnormalities were observed. A NOAEL of 1000 mg shellac/kg bw per day, the highest dose tested, for maternal and developmental toxicity was observed in this study.

Rabbits

An oral prenatal developmental toxicity test was performed with shellac (E 904) according to OECD TG 414 (OECD, 2018b) and reported to be performed in compliance with the principles of GLP (Documentation provided to EFSA, n. 50). In the prenatal developmental toxicity study, the test item suspended in 0.5% w/v methylcellulose solution was administered by gavage once daily from gestation day (GD) 6–27 at dose levels of 0, 250, 500, and 1000 mg/kg bw per day to Kbl:NZW rabbits (20–22 females/group). At the highest dose level, an effect was observed on food intake (GD 22–27). No treatment-related effect was observed on body weight, body weight gain or uterus weight of the dams of all groups treated with shellac (E 904) when compared to the controls. The number of corpora lutea, implantations, live and dead fetuses, resorptions, fetal and placental weight and sex ratio were comparable between the control and treated groups. No differences in fetal external, visceral and skeletal abnormalities were observed. A NOAEL of 500 mg shellac/kg bw per day for maternal toxicity, based on decreased food intake, and a NOAEL of 1000 mg shellac/kg bw per day, the highest dose tested, for developmental toxicity was observed in this study.

3.6.7 | Hypersensitivity

JECFA (1993) quotes a paper by Gelfand (1963), which documents allergies (particularly bronchial asthma and allergic skin reactions) reportedly caused by exposure to chemical compounds in the rubber, lacquer, shellac and beauty industries, through reports of patients exposed to the compounds as customers or workers in these industries. The author suggested that respiratory allergies reported to be associated with inhalation of shellac were not due to shellac but to ethylenediamine and hexamethylenetetramine, which are used as solvent and paint thinner respectively (Gelfand, 1963). JECFA did not elaborate further on the possibility for allergies from shellac in its monograph (JECFA, 1993).

Since then, numerous cases of contact dermatitis due to shellac-containing cosmetics have been reported (Mercader-García et al., 2023).

No food allergic reactions have been reported in the literature, noting its long history of use as a food additive. In addition, due to its chemical nature, the likelihood of shellac to cause food allergic responses is low.

3.7 | Discussion

The present opinion deals with the re-evaluation of shellac (E 904) when used as a food additive and with the assessment of the proposed extension of use in foods for special medical purposes (FSMP) in tablet and coated tablet form (i.e. FC 13.2 of part E of Annex II to Regulation (EC) No 1333/2008).

Based on the data submitted by the IBOs, shellac is a low molecular-weight resin mainly composed of a complex mixture of different mono- and polyesters of hydroxyaliphatic acids, e.g. aleuritic acid and butolic acid, and sesquiterpenoid acids, e.g. shellolic acid, jalaric, laccijalaric acid, laksholic acid, lacciaksholic acid.

Shellac (E 904) is authorised in the EU at a maximum permitted level (MPL) of *quantum satis* (QS) in 11 food categories according to Annex II to Regulation (EC) No 1333/2008. To assess the dietary exposure to shellac (E 904) from its use as a food additive, the exposure was calculated based on (1) maximum levels of data provided to EFSA (defined as the *maximum level exposure assessment scenario)* and (2) the reported use levels (defined as the *refined exposure assessment scenario*) (Section 3.4).

Six food categories were taken into account in the present exposure estimate (seven food categories for the food supplements consumers' only scenario).

The highest exposure estimates in the *maximum level exposure assessment scenario* were 3.7 mg/kg bw per day at the mean and 11.5 mg/kg bw per day at the 95th percentile. The Panel noted that the estimated long-term exposures based on this scenario are very likely conservative, as this scenario assumes that all foods and beverages listed under the annex II to regulation No 1333/2008 contain shellac (E 904) as a food additive at the maximum reported use level.

The highest exposure estimates in the *refined brand-loyal exposure assessment scenario* were 3.6 mg/kg bw per day at the mean and 10.9 mg/kg bw per day at the 95th percentile. For the *non-brand-loyal refined scenario*, highest exposure estimates were 2.0 and 8.7 mg/kg bw per day for the mean and the 95th percentile, respectively.

In the *food supplements consumers only scenario*, mean exposure ranged from < 0.1 mg/kg bw per day in adults and the elderly, to 3.9 mg/kg bw per day in children. At the 95th percentile, exposure to shellac (E 904) ranged from 0.4 mg/kg bw per day for the elderly to 8.6 mg/kg bw per day in children.

Despite no information being available on use levels for some food categories in which E 904 is authorised, approximately 89% of the food products labelled with shellac (E 904) in the Mintel's GNPD belonged to food subcategories that

were considered in the exposure assessment (Annex C). In the exposure assessment, it was assumed that 100% of the foods belonging to an authorised food category would contain shellac (E 904), while according to Mintel GNPD, on average only 1.6% of foods per subcategory were labelled with E 904. Therefore, the Panel considered that the exposure estimates for all exposure scenarios resulted in an overestimation of the exposure to shellac (E 904) from its use as a food additive according to Annex II to Regulation (EC) No 1333/2008 (Section 3.4.1).

The Panel also noted that the refined exposure estimates are based on information provided on the reported level of use of shellac (E 904). If actual practice changes these refined estimates may no longer be representative and should be updated.

The proposed extension of use of shellac (E 904) in foods for special medical purposes (FSMP) in tablet and coated tablet form (FC 13.2) would result in an additional exposure of 1.5 mg/kg bw per day (for adults assuming a body weight of 70 kg). Considering the dietary exposure estimated for an adult in the *refined non-brand-loyal scenario*, the mean and 95th percentile of exposure to shellac (E 904) including the proposed extension of use in FC 13.2 would be, respectively, 1.9 and 3.7 mg/kg bw per day. Considering the *food supplements consumer only scenario*, the 95th percentile exposure to shellac (E 904) for adults is 2.7 mg/kg bw per day, thus, for this population, the mean exposure to shellac (E 904), considering the additional consumption from FSMP tablets (FC 13.2) would be 4.2 mg/kg bw per day.

Despite the proposed extension of use is foreseen for adults, adolescents could also consume such tablets, and this would result in an additional exposure to shellac of 1.9 mg/kg bw per day for this population group (assuming a body weight of 53.3 kg based on EFSA Scientific Committee, 2012). This means that the exposure to E 904 for adolescents considering the *maximum level exposure assessment scenario* would result in 4.3 and 9 mg/kg bw per day including the proposed extension of use in tablets from FC 13.2 for the mean and 95th percentile, respectively. When considering the *refined non-brand-loyal scenario* and including the proposed extension of use in FC 13.2, the mean and 95th percentile of exposure to E 904 would be 3.3 and 7.5 mg/kg bw per day for adolescents, respectively.

Information on two manufacturing processes for refining seedlac, namely the chemical bleaching process using sodium hypochlorite and the physical decolouring process using activated carbon, to produce shellac has been indicated by IBOs. The panel noted that as result of the process used, different impurities can be present in shellac, and the physical description also is different.

Data on the acid values of wax-free shellac produced by physical decolouring and by chemical bleaching were provided. The acid values of only three out of 562 samples produced by bleaching process were slightly above the maximum limit of 89 indicated in the EU specifications. The acceptance criteria for the acid value in the specifications for wax-free bleached shellac in the FCC is 75–91.

A maximum limit for lead of 2 mg/kg is included in the EU specifications for E 904, but according to information submitted, lead was reported as below 1 mg/kg. No analytical data on toxic elements potentially present in shellac were available.

As a result of the bleaching process using sodium hypochlorite, the Panel noted that shellac (E 904) produced by this process contains chloroform, inorganic chloride and organochlorine impurities. Quantitative data on the presence of chloroform and inorganic chloride in shellac were available.

A limit of < 0.14% for total inorganic chloride has been proposed by an IBO. The Panel considered this limit as an indirect parameter to limit the amount of hypochlorite used in the chemical bleaching process and so limiting the undesirable formation of chloroform and other organochlorine compounds.

The risk assessment of lead and chloroform, based on the available information, was performed to determine whether there could be a possible health concern if these impurities would be present at a certain value in the food additive. Taking into account the calculations (Table 7) and the fact that the food additive is not the only potential dietary source to these impurities, the Panel recommended to lower the maximum limit for lead and to introduce a maximum limit for chloroform, which based on the data provided could be lower (e.g. 200 mg/kg) than the one proposed by the IBO (400 mg/kg, Table 7). The Panel noted that the choice of maximum limits for impurities in the EU specifications is in the remit of risk management.

Concerning the other organochlorine impurities, eight chlorinated compounds were detected by LC–MS/MS. Four were assigned to mono-chlorinated aleuritic acid, mono-chlorinated shelloic-aleuritic ester, mono-chlorinated jalaric-aleuritic ester and mono-chlorinated laccijalaric-aleuritic ester. Mono-chlorinated and di-chlorinated jalaric-(16-hydroxyhexadecanoic) ester (and/or laccijalaric-(9,10-dihydroxyhexadecanoic) ester, both have the same molecular formula and mass) was/were also detected along with two more compounds containing chlorine that remained unidentified. The structural identity and the levels of these organochlorine impurities in the shellac E 904 was not available and it is not known if the LC-MS/MS analysis was sufficiently sensitive and comprehensive. The absence of health concerns of these organochlorine impurities cannot be confirmed without information on their identity and amount in the food additive.

The Panel noted that the EU specifications are rather generic and do not describe in detail the manufacturing processes reported by the IBOs. In addition, the contents of chloroform, organochlorine compounds and inorganic chloride are not limited. Additionally, the IBOs have claimed to use only wax-free shellac as a food additive. Based on the data provided by IBOs and the considerations made by the Panel, the following would be recommended:

- To have separate specifications depending on the manufacturing process, chemical bleaching process and physical decolouring process, because they result in different impurities in shellac;
- To revise the definition of the food additive to include a short description of each manufacturing process (chemical bleaching or physical decolouring);

- To revise the acid value for wax-free shellac produced by chemical bleaching process that can be slightly above the current limit of 89, to be in line with the specifications in the FCC (2010);
- To delete information on wax-containing shellac since it is not used as E 904 and no data to confirm its safety were available (see below);
- To lower the maximum limit for lead;
- To consider introducing limits for other toxic elements potentially present in shellac;
- To include a maximum limit for chloroform and total inorganic chloride, in the case of shellac produced by chemical bleaching.

The toxicological studies provided were performed with shellac (E 904) produced either by chemical bleaching or by physical decolouring. In addition, all test materials used in the toxicological studies submitted by the three IBOs are wax-free shellac.

Information on ADME was not available to the SCF or JECFA (JECFA, 1993; SCF, 1992). No new relevant information was found in the literature search. In a new study submitted by one of the IBOs, shellac (E 904) was given by gavage at 1500 mg/kg bw to Wistar rats for 4 weeks. Shellac monomer was analysed in plasma to investigate the absorption of shellac. Considering the reported value of 29% of shellac monomer in the test item, the dose was equal to 437.7 mg/kg shellac monomer. Eleven metabolites were detected. Repeated dosing did not change the major shellac components and metabolite concentrations in plasma, and no sex differences were noted on days 1 and 28. The Panel considered that the absorption of the shellac monomer was very low.

Shellac (E 904) is considered to be as of low acute toxicity.

No toxicologically relevant effects were seen in the oral subchronic studies in rats with shellac (E 904) produced either by chemical bleached or by physical decolouring at doses amounting to 1600 mg/kg bw per day, the highest dose tested.

The results of the available genotoxicity studies do not raise concern for shellac (E 904) produced either by chemical bleaching or by physical decolouring.

However, due to the complex chemical composition of E 904, it might be that the whole mixture approach applied in the genotoxicity studies performed with E 904 could be of insufficient sensitivity to detect the genotoxicity of (minor) individual components of shellac. To this aim, an in silico assessment of main shellac components was performed. The results obtained do not indicate a genotoxic potential for any of the shellac components evaluated.

In one combined chronic toxicity/carcinogenicity study performed with shellac (E 904) produced by chemical bleaching, Wistar rats were given shellac (E 904) at 0, 1000; 5000 or 10,000 mg /kg diet (equal to 0; 45; 226 or 452 mg/kg bw per day for males and 0, 56, 300 or 569 mg/kg bw per day for females) for 24 months. The Panel identified a NOAEL at the highest dose tested (452 mg/kg bw per day for males and 569 mg/kg bw per day for females). In another combined chronic toxicity/carcinogenicity study in Wistar rats performed with physical decolouring shellac (E 904) at dose levels of 0 (two control groups), 150, 500, and 1500 mg/kg bw per day, the Panel identified a NOAEL of 500 mg/kg bw per day (based on non-neoplastic lesions) from this combined chronic toxicity/carcinogenicity study.

In an oral dietary reproductive and developmental toxicity screening test (OECD TG 421, OECD, 2016a) in rats, with shellac (E 904) produced by chemical bleaching the low-dose (300 mg /kg bw per day) was identified as the NOAEL for maternal toxicity based on decreased body weight gain in the dams, and the high-dose (1200 mg /kg bw per day) as the NOAEL for reproductive and developmental toxicity. However, in a dietary two-generation reproductive toxicity study in rats with shellac (E 904) produced by chemical bleaching, the NOAELs for parental, reproductive and developmental toxicity were 800, 1600 and 400 mg/kg bw per day, respectively. In a prenatal developmental toxicity study in rabbits with shellac produced by chemical bleaching a NOAEL of 500 mg /kg bw per day for maternal toxicity and a NOAEL of 1000 mg/kg bw per day, the highest dose tested, for developmental toxicity were observed.

No reproductive toxicity study with shellac produced by physical decolouring was available. In a prenatal developmental toxicity study in rats and rabbits with shellac produced by physical decolouring the NOAEL for developmental and maternal toxicity was 1000 mg/kg bw per day, the highest dose tested, in both species.

The Panel noted that the results of the reproductive toxicity studies with shellac produced by chemical bleaching can be extrapolated to shellac produced by physical decolouring.

The Panel noted no food allergic reactions have been reported in the literature noting its long history of use as a food additive. In addition, due to its chemical nature, the likelihood of shellac to cause food allergic responses is low.

Taking into account the available toxicity database, the Panel identified a NOAEL of 300 mg/kg bw per day based on the decreased body weight gain in the dams observed at 600 mg/kg bw per day from a short-term study (TG OECD 421, OECD, 2016a). However, in a two-generation reproductive toxicity study of longer duration (OECD TG 416, OECD, 2001), a NOAEL of 400 mg/kg bw per day, based on the decreased pup weight (F2), was identified. In addition, no dose-related effects were observed in parental animals up to a dose of 800 mg/kg bw per day. The Panel noted that in chronic studies, no adverse effects were observed at much higher dose levels. Therefore, the Panel considered that the NOAEL of 400 mg/kg bw per day, based on the decreased pup weight (F2) in the two-generation reproductive toxicity study, could be used to derive an ADI for shellac (E 904). Applying an uncertainty factor of 100, an ADI of 4 mg/kg bw per day for shellac (E 904) can be derived.

A safety assessment of wax-containing shellac as a food additive could not be conducted due to the fact that no toxicological data were available and the IBOs reported that this material is not used as a food additive.

The Panel did not identify brand loyalty to a specific food category, and, therefore, considered the refined non-brand-loyal exposure assessment scenario the most appropriate for the risk assessment. The Panel noted that the mean exposure

estimates for the different population groups for this scenario did not exceed the ADI of 4 mg/kg bw per day for shellac (E 904). However, the dietary exposure estimates at the 95th percentile exceeded the ADI of 4 mg/kg bw per day at the maximum of the ranges for toddlers, children and adolescents.

Considering the maximum level exposure assessment scenario, as the most conservative scenario, the Panel noted that the mean exposure estimates do not exceed the ADI for any population group. At the 95th percentile, exposure estimates exceeded the ADI of 4 mg/kg bw per day at the maximum of the ranges for toddlers, children, adolescents and adults.

The Panel noted that the major application of shellac is by spraying diluted in ethanol or alkaline solution and after application shellac remains as a coating. Self-esterification or self-polymerisation is expected to occur during storage or after application. Despite some components of shellac will be present as individual substances, it is expected that they will mainly be esterified forming 'oligomers/polymers'. Hence, the main exposure of shellac through food will be to more polymerised material than present in pristine shellac. The Panel noted that shellac in the in vivo toxicological animal studies have been administered as suspended in a solution or via the diet and this can be considered as the worst case of exposure to isolated lower molecular weight components of shellac.

The Panel also considered a request for an extension of use of E 904 in foods for special medical purposes (FSMP) in tablet and coated tablet form (i.e. FC 13.2 of part E of Annex II to Regulation (EC) No 1333/2008) at a proposed maximum use level of 46,000 mg/kg. The proposed extension of use would result in a further exceedance of the ADI at the 95th percentile in the maximum level exposure assessment scenario for adults. In the case adolescents would also consume these tablets, both the mean and the 95th percentile exposure will exceed the ADI for the proposed extension of use in the maximum level exposure assessment scenario, while in the non-brand loyal exposure assessment scenario, the ADI would be exceeded at the 95th percentile. The Panel noted that in all scenarios that address the extension of use, the exposure is overestimated because it is also assumed that all FSMP in tablet and coated tablet form contain shellac.

The Panel noted that for several age groups the ADI was exceeded at the 95th percentile of exposure. However, taking into account the low exceedance and the fact that both the exposure estimation (see Section 3.4.1) and the toxicological evaluation (see above) of shellac were conservative the Panel considered that in this case the exceedance of the ADI would not indicate a safety concern.

4 | CONCLUSIONS

The Panel derived an ADI of 4 mg/kg bw per day for wax-free shellac (E 904) produced by physical decolouring, based on a NOAEL of 400 mg/kg bw per day and applying an uncertainty factor of 100.

The Panel concluded that the ADI of 4 mg/kg bw per day should be considered temporary for wax-free shellac (E 904) produced by chemical bleaching, while new data are generated on the identity and levels of the organochlorine impurities in E 904 to allow their safety evaluation.

This ADI is not applicable for wax-containing shellac as a food additive.

For several age groups, the ADI was exceeded at the 95th percentile in the *non-brand-loyal exposure assessment scenario* and *maximum level exposure assessment scenario*. An exceedance of the ADI was also observed for the extension of use of E 904 in foods for special medical purposes (FSMP) in tablet and coated tablet form. However, taking into account the low exceedance and the fact that both the exposure estimation and the toxicological evaluation of shellac were conservative, the Panel concluded that in this case the calculated exceedance of the ADI does not indicate a safety concern.

5 | RECOMMENDATIONS

The Panel recommended that the temporary ADI for shellac (E 904) produced by chemical bleaching should be re-evaluated once the requested data on the identity and levels of the organochlorine impurities in E 904 are generated. Data generated should reflect variability among the different manufacturers of shellac and within shellac produced by the same manufacturer considering alterability of the bleaching process.

Furthermore, the Panel recommended to the European Commission:

- separating specifications for E 904 depending on the manufacturing process, chemical bleaching process and physical decolouring process, because they result in different impurities in shellac;
- revising the definition of the food additive to include a short description of each manufacturing process (chemical bleaching or physical decolouring);
- deleting information on wax-containing shellac from the EU specifications since it is not used as E 904 and no data to confirm its safety were available;
- revising the acid value for wax-free shellac produced by chemical bleaching that can be slightly above the current limit of 89 in line with the specifications in the FCC (2010);
- lowering the maximum limit for lead;
- to consider introducing limits for other toxic elements potentially present in shellac;
- including a maximum limit for chloroform and total inorganic chloride in the EU specification for shellac produced by chemical bleaching.

6 | DOCUMENTATION AS PROVIDED TO EFSA

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ABBREVIATIONS

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, excretion
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
BMD	benchmark dose modelling
BMDL	lower confidence limit of the benchmark dose
bw	body weight
CAS	Chemical Abstracts Service
Cl	Chlorine
Cmax	maximum plasma concentration
CONTAM	Panel on Contaminants in the Food Chain
DSC	differential scanning calorimetry
EINECS	European Inventory of Existing Commercial Chemical Substances
FC	food category
FCC	Food Chemical Codex
FDA	Food and Drug administration (USA)
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animail Feed
FSMP	foods for special medical purposes
GLP	Good Laboratory Practices
GNPD	Global New Products Database
GRAS	Generally Recognised as Safe (in the USA)
GS-FID	gas chromatography with flame ionisation detector
GS-MS	gas chromatography–mass spectrometry
HBGV	health-based guidance value
HPLC	high-performance liquid chromatography
HPLC–MS/MS	high performance liquid chromatography-mass spectrometry
HPLC/UV	high performance liquid chromatography with ultraviolet detection
HPLC/RI	high performance liquid chromatography with refractive index detector
IBO	Interested Business Operator
IQS	Institut für Qualitätssicherling GmbH, Germany
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC-MS/MS	liquid chromatography in tandem with mass spectrometry
LOQ	Limit of quantification
MOE	margin of exposure
MPL	maximum permitted level
NOAEL	no observed adverse effect level
OECD TG	Organisation for Economic Co-operation and Development Testing Guidelines
QS	*quantum satis*
RBC	red blood cell
Rf	retention factor
RP	reference point
RSD	relative standard deviation
SCF	Scientific Committee on Food
SD	Sprague–Dawley
TDI	tolerable daily intake
TLC	thin-layer chromatography
WHO	World Health Organisation

ACKNOWLEDGEMENTS
The Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output. The Panel wishes to acknowledge Metka Filipic for her contribution.

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

REQUESTOR
European Commission

AMENDMENT NOTE
An editorial correction was carried out in section 3.4.2 that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the original version of the output has been removed from the EFSA Journal, but is available on request.

QUESTION NUMBERS
EFSA-Q-2011-00705, EFSA-Q-2020-00327

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SUPPORTING INFORMATION

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

How to cite this article: EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes, M., Aquilina, G., Castle, L., Degen, G., Engel, K.-H., Fowler, P., Frutos Fernandez, M. J., Fürst, P., Gürtler, R., Gundert-Remy, U., Husøy, T., Manco, M., Mennes, W., Moldeus, P., Passamonti, S., Shah, R., Waalkens-Berendsen, I., Wright, M., … Frutos Fernandez, M. J. (2024). Re-evaluation of shellac (E 904) as a food additive and a new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes. *EFSA Journal*, *22*(8), e8897. https://doi.org/10.2903/j.efsa.2024.8897

APPENDIX A

Summary of the available genotoxicity studies on shellac (E 904)

Test system	Exposure conditions	Information on the characteristics of the test substance	Result	Reliability/comments	Relevance of the test system/ relevance of the study result	Reference
Wax-free shellac produced by chemical bleaching						
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, TA98 and TA100	Plate incorporation test Dose range 1–10,000 µg/plate ±S9 Vehicle corn oil	Shellac E 904	Negative	3 (insufficient reliability) Study performed before OECD TG 471 implementation Inadequate study protocol (Limited set of tester strains, with no TA102/ WP2, duplicate platings with no repeat experiment, use of corn oil as vehicle)	High/low	Litton Bionetics (1981)
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, TA98 TA100 and WP2 uvrA OECD TG471 GLP compliant	Plate incorporation test Dose range 312.5–5000 µg/plate Replicate experiments ± S9 mix (10% and 20%) Vehicle DMSO	Shellac E 904	Negative	1 reliable without restrictions	High/high	VIMTA study number VLL/0223/G/ T027
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, TA98 TA100 and TA102 OECD TG 471 GLP compliant	Plate incorporation test Dose range 1.5–5000 µg/plate (1st exp. ± S9mix 5%; 156.25–5000 ug/plate (2nd exp. ± S9 mix 10%) Vehicle DMSO	Shellac E 904	Negative	1 reliable without restrictions	High/high	JRF Study number 481-1-06-27618
In vitro micronucleus test in human peripheral blood lymphocytes OECD TG487 GLP compliant	Cytokinesis-block procedure Short treatment (3.5 h ± S9 and 24 h – S9) Doses: 10-100 µg/mL (–S9), 15.625–500 µg/mL (+S9)	Shellac E 904	Negative	1 reliable without restrictions	High/high	JRF Study number 497-1-06-10857
In vitro micronucleus test in human peripheral blood lymphocytes OECD TG487 GLP compliant	Cytokinesis-block procedure Short treatment (4 h ± S9 and 22 h – S9) Doses: 56.25, 112.5, 225 µg/mL	Shellac E 904	Equivocal Statistically significant increase of MNBN at the highest dose (+S9), within the HC range	1 reliable without restrictions	High/limited	VIMTA Study number VLL/0519/G/ T065
In vitro micronucleus test in human peripheral blood lymphocytes OECD TG487 GLP compliant	Cytokinesis-block procedure Short treatment (3.5 h ± S9 and 24 h – S9) Doses: 25, 50, 100 and 200 µg/mL	Shellac E 904	Negative	1 reliable without restrictions	High/high	VIMTA Study number VLL/02223/G/ T028

(Continues)

(Continued)

Test system	Exposure conditions	Information on the characteristics of the test substance	Result	Reliability/comments	Relevance of the test system/ relevance of the study result	Reference
Wax-free shellac produced by physical decolouring						
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, TA98 TA100 and TA102 OECD TG 471 GLP compliant	Plate incorporation assay Dose range: 1.5–5000 µg/plate (1st exp.), 156–5000 µg/plate (2nd exp.)	Shellac E 904	Negative	1 reliable without restrictions	High/high	JRF Study Number 481–1–06-27,591
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, TA98 TA100 and WP2 *uvrA* OECD TG 471 GLP compliant	Pre-incubation test Dose range: 156–5000 µg/plate (TA1535, TA98, TA100 and WP2 uvrA) and 39–2500 µg/plate (TA1537) Vehicle DMSO	Shellac E 904	Negative	1 reliable without restrictions	High/high	Hayashi (2021) Shin Nippon Biomedical Labs, Ltd. Study number SBL 405–017
In vitro micronucleus test in Chinese hamster CHL/IU cells OECD TG487 GLP compliant	6 and 24 h– S9: 116–560 µg/mL; 6 h + S9: 331–1600 µg/mL	Shellac E 904	Negative	1 reliable without restrictions	High/high	Hayashi (2017) Shin Nippon Biomedical Labs, Ltd. Study number SBL 405–003
Uncharacterised shellac						
Bacterial reverse mutation assay (Ames test) with strains TA92, TA1535, TA100, TA1537, TA94 and TA98 Chromosomal aberration assay in CHL cells	Preincubation test; six doses tested, up to 10 mg/plate ± S9; vehicle DMSO 48 h incubation without S9 Three doses tested, up to 0.5 mg/mL; vehicle ethanol	Food additive (shellac) from natural sources Provided by Japan Food Additives Association. No other information available	Negative (no further detail or raw data presented)	3 (insufficient reliability) Limited study protocol and inadequate data presentation	High/low	Ishidate et al. (1984)
Bacterial reverse mutation assay (Ames test) with strains TA1535, TA1537, and TA1538 Mitotic recombination in yeast D4	Spot test (0.03%) and incubation test (0.015, 0.03, 0.06%) ± S9 from mouse, rat, monkey S9 from liver, lung and testes Incubation (4 h at 30°C) with 0.25%, 0.5% and 1.0%	Shellac wax Suspended in DMSO	Negative	3 (insufficient reliability) Study performed before OECD TG implementation Inadequate study protocols and data presentation; Yeast assays not validated for human RA	High/low (Ames test) Low/low (yeast assay)	Litton Bionetics (1975)

APPENDIX B

Summary of QSAR predictions

	OECD QSAR toolbox	VEGA
Aleuritic acid	No alert (H-acceptor-path-3-H-acceptor)	Ames test: non-mutagenic (consensus 0.9), inactive in in vitro chromosomal aberrations, in vitro and in vivo micronucleus
Jalaric acid	DNA binding by OECD: **Schiff base former** In vitro and in vivo mutagenicity by ISS: **simple aldehyde**	Ames test: **mutagenic** (Consensus score: 0.2); Micronucleus: active in vitro, inactive in vivo
Laccijalaric acid	DNA binding by OECD: **Schiff base former** In vitro and in vivo mutagenicity by ISS: **simple aldehyde**	Ames test: **mutagenic** (Consensus score: 0.45); Micronucleus: active in vitro, inactive in vivo
Laccilaksholic acid	No alert	Ames test: non-mutagenic (Consensus score: 0.25); Micronucleus: active in vitro, inactive in vivo
Shelloic acid	No alert	Ames test: non-mutagenic (Consensus score: 0.25); Micronucleus: active in vitro, inactive in vivo
Jalaric aleuratitate/ shellac monomer	DNA binding by OECD: **Schiff base former** In vitro and in vivo mutagenicity by ISS: **simple aldehyde** (H-acceptor-path-3-H-acceptor)	Ames test: non-mutagenic (Consensus score: 0.525); Micronucleus: active in vitro, inactive in vivo
Laksholic acid	No alert	Ames test: non-mutagenic (Consensus score: 0.45); Micronucleus: active in vitro, inactive in vivo
Butolic acid	No alert	Ames test: non-mutagenic (Consensus score: 0.9); Micronucleus: active in vitro, inactive in vivo

ANNEXES

ANNEX A

Summary of reported use levels (mg/kg or mg/L as appropriate) of shellac (E 904) provided by industry

ANNEX B

Number and percentage of food products labelled with shellac (E 904) out of the total number of food products present in the Mintel GNPD per food subcategory between 2019 and 2024

ANNEX C

Concentration levels of shellac (E 904) used in the exposure assessment scenarios (mg/kg or mL/kg as appropriate)

ANNEX D

Summary of total estimated exposure of shellac (E 904) from their use as food additives for the maximum level exposure scenario and the refined exposure assessment

ANNEX E

Main food categories contributing to exposure to shellac (E 904) using the maximum level exposure assessment scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)

ANNEX F

Benchmark dose modelling: report

Annex A_F are available under the Supporting Information section on the online version of the scientific output.