CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CRD 3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

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Comments of the European Union

AGENDA ITEM 2 - MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk: Draft and Proposed Draft Lists of Acceptable Previous Cargoes

The European Union (EU) fully supports the mandate given by the Codex Alimentarius Commission (CAC) to identify as a matter of priority, the most critical substances of the List of Acceptable Previous Cargoes for review by JECFA.

The EU is pleased to announce that the European Food Safety Authority (EFSA) has evaluated all the substances on the List of Acceptable Previous Cargoes adopted by the CAC at its 34th session. EFSA evaluated these substances against the Codex Criteria to Assess the Acceptability of Substances for Inclusion in the List of Acceptable Previous Cargoes as adopted by the CAC.

As a result of this evaluation, the EU has concluded that 4 entries / substances do not fulfil the Codex criteria for acceptability. These substances are the following:

- CALCIUM LIGNOSULPHONATE LIQUID (CAS No 8061-52-7)
- CARNAUBA WAX (CAS No 8015-86-9)
- MONTAN WAX (CAS No 8002-53-7)
- SILICON DIOXIDE (CAS No 7631-86-9)

An extract of the opinions for the four substances is attached to this position paper.

Complete information on the outcome of the evaluation performed by EFSA is available on its website:

http://www.efsa.europa.eu/en/efsajournal/pub/1391.htm

http://www.efsa.europa.eu/en/efsajournal/pub/2482.htm

http://www.efsa.europa.eu/en/efsajournal/pub/2703.htm

http://www.efsa.europa.eu/en/efsajournal/pub/2984.htm

In view of the mandate of the CAC to the CCFO to review the List against the criteria as a matter of priority and taking into account the limitation of JECFA resources, the EU would like to propose that JECFA starts an evaluation of the above mentioned substances for consideration at the next session of the CCFO.

In addition to the substances which do not meet the criteria the EU would also like to provide the following comments:

- The EFSA evaluation further made clear that the entry "Molasses" (CAS No 57-50-1) should be restricted to molasses obtained from citrus, sorghum, sugar beet, and sugar cane only, as the term "molasses" can be applicable to any liquid food or feed ingredient obtained from plants that contains in excess of 43 % sugars. Hence, molasses can also be obtained as a by-product of the manufacture of pressed wood.

- As for potable water (CAS No 7732-18-5), the additional condition "only acceptable where the immediate previous cargo is also on the list" would no longer be required taken into account current shipping and cleaning practices.

The EU has found that several substances currently on the list do not appear to be transported as previous cargoes (e.g. candelilla wax (CAS No 8006-44-8), bees wax white (CAS No 8006-40-4) /yellow (CAS No 8012-89-3), etc.). The EU considers that further information on the current shipping practices should be requested in order to avoid that substances which are not used are evaluated by JECFA.

Attachment

SCIENTIFIC OPINION

Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part I of III

EFSA Panel on Contaminants in the Food Chain (CONTAM)
European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Shipping of edible fats and oils into Europe is permitted in bulk tanks, in which substances, included in a positive list, had been previously transported. The European Commission requested EFSA to evaluate the list of substances in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils, taking into account its review of the Scientific Committee on Food (SCF) criteria for acceptable previous cargoes and criteria proposed by the Codex Committee for Fats and Oils. This is the first of three scientific opinions by the Panel on Contaminants in the Food Chain (CONTAM Panel), in which thirteen of these substances have been evaluated. The CONTAM Panel concluded that phosphoric acid, ammonium polyphosphate, benzyl alcohol (pharmaceutical and reagent grades only), epoxidised soyabean oil (with a minimum 7 % - maximum 8 % oxirane oxygen content), ethyl acetate, 2-ethylhexanol, 1,3-butanediol, 1,4-butanediol, propylene glycol, polypropylene glycol (molecular weight greater than 400), methanol and ethanol, would not be of health concern as previous cargoes. In the case of calcium lignosulphonate, there was sufficient information available for the CONTAM Panel to conclude that the risk from short-term exposure to this substance itself, when used as a previous cargo, would not give rise to any toxicological concern. However, the product varies markedly in composition, there is no information on potential impurities, nor is there information on its potential reactivity with fats and oils. The CONTAM Panel therefore concluded that calcium lignosulphonate does not meet the criteria for acceptability as a previous cargo.

3.4. CALCIUM LIGNOSULPHONATE (CAS no 8061-52-7)

Calcium lignosulphonate is an anionic surfactant. After purification, it is a light brown powder and the bulk is soluble in water. Lignosulphonates have very broad ranges of molecular mass (they are polydisperse). A range of from 1,000 to 140,000 Da has been reported for soft wood lignosulphonates, with lower values reported for hard woods.

Lignosulphonates are recovered from the spent sulphite pulping liquids (red or brown liquor) from sulphite pulping. Delignification in sulphite pulping involves acidic cleavage of ether bonds. Sulphonates are formed which are precipitated by addition of excess calcium hydroxide. The largest use for lignosulphonates is as plasticizers in concrete improving workability. Lignosulphonates allow concrete to be made with less water (giving stronger concrete) while maintaining the ability of the concrete to flow. They are applied during the production of cement, where they act as grinding aids in the cement mill and as a raw mix slurry deflocculant (that reduces the viscosity of the slurry). Lignosulphonates are also used for the production of plasterboard to reduce the amount of water required to make the stucco flow and form the layer between two sheets of paper. The reduction in water content allows lower kiln temperatures to dry the plasterboard, saving energy. Calcium lignosulphonates are also used in petroleum drilling (blocking agent, improvement of mud fluidity), asphalt emulsification, tanning leather, dispersant of chemicals and pesticides (improves the suspensibility and wettability of powders), additive of slurry mixture of water and coal, and as additive for feedstuff processing (deflocculant). They were traditionally used to suppress dust on unpaved roads.

A large amount of lignosulphonate is burned in cellulose factories to produce heat.

3.4.1. Previous evaluations

The SCF evaluated calcium lignosulphonate in 1996 and considered this substance as acceptable previous cargo, noting that it was likely to be toxicologically inert and easily removed by tank cleaning, also that it was acceptable as an animal feedstuff15 (SCF, 1997). In the 2003 SCF evaluation of acceptable previous cargoes calcium lignosulphonate was not further evaluated as it was already considered acceptable (SCF, 2003). An ADI of 0-20 mg/kg b.w. per day for calcium lignosulphonate (40-65)16 as a food additive has been established by JECFA (JECFA, 2009) and JECFA has also prepared specifications. Lignosulphonic acid was evaluated as a food contact material with a specific migration limit (SML) of 0.24 mg/kg only to be used as dispersant for plastic dispersion17 (SCF, 1999). Lignosulphonates (E565) are approved as feed additives in the EC and may be used in all animal species and animal categories without maximum levels specified.18 Calcium lignosulphonate (40-65) has been evaluated by EFSA as a food additive (EFSA, 2010). EFSA concluded that the available data on calcium lignosulphonate (40-65) were insufficient to establish an ADI. EFSA have further considered their evaluation in 2011 and have reached the same conclusion (EFSA, 2011).

3.4.2. Current evaluation

3.4.2.1. Expected impurities

Without purification, calcium lignosulphonate is a crude mixture of materials, essentially a waste of low value, used for purposes for which impurities are of little concern. The material might often contain substances that would be undesirable in food. It would be difficult to develop analytical methods enabling identification of all the potentially toxic components.

3.4.2.2. Reactivity and reaction products

Lignosulphonates include a variety of functional groups for which it will be difficult to rule out chemical reaction with lipids.

3.4.2.3. Toxicological profile

Absorption, distribution, metabolism and elimination

As reported by EFSA and JECFA, calcium lignosulphonate (40-65) is poorly absorbed by the oral route, as shown by both *in vitro* and *in vivo* studies (JECFA, 2009; EFSA, 2010). Acute toxicity.The acute toxicity of calcium lignosulphonate is low. An acute oral LD50 of greater than 31.6 g/kg b.w. has been reported in rats (EFSA, 2010). In another study in rats the LD50 was estimated to lie between 10 and 20 g/kg b.w. (EFSA, 2010).

Subacute and subchronic studies

In a 28-day oral toxicity study in rats with calcium lignosulphonate (40-65) at dose levels of 0, 500, 1,500 and 4,000 mg/kg b.w. per day the only adverse effect related to treatment was a higher incidence of chronic inflammation in the rectum of males at the high dose group. In a 90-day oral toxicity study in rats at dose levels of 0, 500, 1,000 and 2,000 mg/kg b.w. per day, there were no treatment-related effects of biological significance other than signs of lymphoid hyperplasia or lymphoid infiltration in different organs, a dose-related histiocytosis in the mesenteric lymph nodes in all treatment groups and renal tubular vacuolation in female at the two highest doses tested (EFSA, 2010). EFSA concluded that this study could not be used for the safety evaluation of calcium lignosulphonate (40-65) due to a possible poor health status of the animals, also considering that longer-term toxicity studies are needed to elucidate whether the histiocytosis in the mesenteric lymph nodes in the rats could progress into a more adverse state with time (EFSA, 2010).

Genotoxicity

The results of one *in vitro* bacterial reverse mutation assay and one mammalian chromosomal aberration assay indicated an absence of genotoxic potential for calcium lignosulphonate (40-65) (EFSA, 2010).

Chronic toxicity and carcinogenicity

No long-term or carcinogenicity studies have been conducted with calcium lignosulphonate (40-65). Developmental and reproductive toxicity. In a developmental toxicity study (21 days) in the rat, no treatment-related effects in dams or foetuses were reported up to the highest dose tested (1,000 mg/kg b.w. per day) (EFSA, 2010).

3.4.2.4. Allergenicity

Contact allergy to calcium lignosulphonate has been described for one single case (Andersson and Göransson, 1980), as previously noted by EFSA (EFSA, 2010). Since there are no further reports the substance can be considered to be of no concern regarding allergenicity.

3.4.3. Conclusion

Although JECFA has established an ADI of 0-20 mg/kg b.w. per day for calcium lignosulphonate with defined specifications, the EFSA ANS Panel concluded that that the available data were insufficient to establish an ADI (EFSA, 2010). The toxicological database has several data gaps (long-term toxicity, carcinogenicity, limited data on reproductive toxicity). The limited data available did not demonstrate any evidence of genotoxicity or significant concern regarding allergenicity. The CONTAM Panel considers that the available information was sufficient to conclude that the risk from short-term exposure to calcium lignosulphonate when used as a previous cargo would not give raise to any toxicological concern.

The CONTAM Panel noted however that the product varies markedly in its grade. There is no information on impurities in crude quality material (the form most in use), nor is there information on the reactivity of calcium lignosulphonate with fats and oils.

The CONTAM Panel therefore concludes that calcium lignosulphonate does not meet the criteria for acceptability as a previous cargo.

SCIENTIFIC OPINION

Scientific Opinion on the evaluation of the substances currently on the list in the annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part II of III EFSA Panel on Contaminants in the Food Chain (CONTAM)

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Shipping of edible fats and oils into Europe is permitted in bulk tanks, in which substances, included in a positive list, had been previously transported. The European Commission requested EFSA to evaluate the list of substances in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils, taking into account its review of the Scientific Committee on Food (SCF) criteria for acceptable previous cargoes and criteria proposed by the Codex Committee for Fats and Oils. This is the second of three scientific opinions by the Panel on Contaminants in the Food Chain (CONTAM Panel), in which thirty-five of these substances or groups of substances have been evaluated. The CONTAM Panel concluded that fatty acids, fatty alcohols, fatty alcohol blends, fatty acid methyl esters, fatty acid esters, and animal, marine and vegetable and hydrogenated oils and fats, all as specified, and acid oils and fatty acid distillates, acetic acid, sulphuric acid, formic acid, acetic anhydride, acetone, *n*-heptane, *n*-hexane, cyclohexane, pentane, iso-propanol, propyl alcohol, methyl isobutyl ketone, methyl ethyl ketone, *n*-propyl acetate, ammonium hydroxide, limonene, methyl tert-butyl ether, urea ammonia nitrate solution, calcium chloride solution, magnesium chloride solution, potable water, potassium hydroxide, sodium hydroxide, silicon dioxide, sorbitol, molasses and beeswax would not be of health concern as previous cargoes. However, because of its insolubility in water and high melting point, silicon dioxide is not suitable for transport in tankers for edible fats and oils. There was insufficient information available on the composition of wine lees for the CONTAM Panel to conclude that it would not be of health concern when used as a previous cargo. The CONTAM Panel made several recommendations regarding the way in which the substances are described in the Annex to Commission Directive 96/3/EC, to correct inaccuracies and to better reflect current transport practices.

3.32. SILICON DIOXIDE (microsilica) (CAS No 7631-86-9)

Silicon dioxide, also called silica, can occur either in crystalline or amorphous form. It is poorly soluble in water (15-68 mg/L in water at 20 °C and pH 5.5-6.6).

Raw silica occurs in nature as quartz or quartz sand, but also in sands from various organisms (diatomaceous earths). Purified silicon dioxide is usually precipitated from water glass (silica gels). Water glass is obtained after heating quartz sand and sodium carbonate to high temperatures, which removes carbon dioxide and yields sodium silicate.

Silicon dioxide is primarily used to form glass, optical fibers (fused silica), silicon wafers for electronics and sun collector panels, but also for ceramics, as an ingredient in Portland cement and tooth paste. Many of these products contain substantial proportions of nano size particles.

3.32.1. Previous evaluations

The SCF evaluated silicon dioxide as a previous cargo in 1996 and considered it acceptable (SCF, 1997a). This conclusion was based on the fact that silicon dioxide was permitted as a food additive (E551, under Directives 95/2/EC59 and 96/77/EC62). It was not necessary to establish an ADI (―ADI not specified‖), as the SCF (1991) considered that following oral exposure to amorphous silicon dioxide, the substance was biologically inert and any material absorbed would be excreted by the kidneys without toxic accumulation. In the 2003 SCF evaluation of acceptable previous cargoes, silicon dioxide was not further evaluated as it was already considered acceptable (SCF, 2003a). JECFA (1970b) evaluated the use of amorphous silica as an anti-caking agent, at its meeting in 1969. It was concluded that use was ―Not limited except for good manufacturing practice‖.

In their draft screening assessment of quartz and cristobalite, Environment Canada concluded ―*However, considering the substances are insoluble, have negligible vapour pressure and that they are particulates, it is unlikely that they would be bioavailable to cause generalised systemic effects or specific effects at the reproductive and developmental level*‖ (Environment Canada, 2011).

Synthetic amorphous silicas are used in a variety of cosmetics and are approved for use in human pharmaceuticals (OECD, 2004).

The US FDA (1979, 2010) has classified silica as GRAS and has approved its use as dietary food additives at levels up to 2 % by weight in food.

3.32.2. Current evaluation

Silicon dioxide is a solid at normal temperature and pressure, with a melting point above 1 400 °C. It is almost insoluble in water (< 70 mg/L). Hence, current shipping practices are such that it is not a suitable cargo for the type of tanker used to transport edible fats and oils by sea (see Documentation provided to EFSA).

3.32.2.1. Expected impurities

Silicon dioxide is not expected to contain impurities of concern.

3.32.2.2. Reactivity and reaction products

No reaction products of concern are known or expected when present in edible fats and oils as carryover.

3.32.2.3. Toxicological profile

Absorption, distribution, metabolism and elimination

Consistent with its physico-chemical properties, there is negligible absorption of silica from the GI tract following oral administration to rats for up to one month (Degussa, 1968; Klosterkoetter, 1969, as cited in OECD, 2004). In 12 human volunteers receiving 2 500 mg synthetic amorphous silica, there was a slight, not statistically significant increase in the urinary excretion of silicon dioxide (Degussa, 1966, as cited in OECD, 2004). OECD (2004) concluded that ―*Intestinal resorption appears to be insignificant in animals and humans*‖. They also noted that ―*the small apparent increases in the urine output (of silica) of human volunteers were remarkably low as compared with the high dose of 2,500 mg SiO2 applied*‖. The CONTAM Panel agrees with the conclusion that there is negligible systemic exposure to silica, following exposure by the oral route.

Acute toxicity

Silica is of low acute toxicity following oral exposure. No deaths were observed following administration of single doses up to >10 000 mg/kg b.w. (cited in OECD, 2004).

Silica is not irritating to the skin of rabbits (OECD, 2004). Prolonged exposure in humans may lead to dryness or degenerative eczema of the skin (Wacker-Chemie, 2000, as cited in OECD, 2004).

Silica has no or only weak and transient irritating effects on the eyes (OECD, 2004). Silica does not require classification for irritation to the eyes.

Subacute, subchronic and chronic toxicity studies

Wistar rats were administered doses of up to 4 000-4 500 mg/kg b.w. per day amorphous silica in their diet for 13 weeks. CD-1 mice were fed up to 8 000 mg/kg b.w. per day amorphous silica in their diet for 6 months. No treatment related findings were observed in either study (OECD, 2004).

Genotoxicity

Tests for chromosome aberration in Chinese hamster ovary cells and human embryonic lung cells (WI-38), mammaliam gene mutation in Chinese hamster ovary cells, bacterial cell mutation with and without metabolic activation in *S. typhimurium* strains, and UDS in cultures rat hepatocytes were all negative.63 Tests for mutations of the HPRT gene in alveolar type-II cells isolated from the lungs of Fischer rats exposed to amorphous silica by inhalation, chromosome aberrations in bone-marrow cells isolated from Sprague-Dawley rats exposed to silica by gavage, dominant lethal effects in Sprague-Dawley rats exposed to silica by gavage, host-mediated mitotic recombination in *Saccharomyces cerevisiae* D-3 in ICR mice exposed to silica by gavage and host-mediated gene mutation in *S. typhimurium* in ICR mice exposed to silica by gavage were also negative.63 Sub-chronic inhalation of crystalline silica has been reported to increase the frequency of mutations of the HPRT gene in alveolar type-II cells isolated from the lungs of Fischer rats (Johnston et al., 2000). The CONTAM Panel concluded that silicon dioxide was not genotoxic.

Carcinogenicity

Groups of B6C3F1 mice were fed food grade micronised silica for 93 weeks to give total cumulative doses of up to 160 g/mouse (corresponding to 7 500 mg silica/kg b.w. per day). Groups of Fischer rats were also fed with this preparation of silica, for 102 weeks to give total cumulative doses of up to 435-580 g/rat (corresponding to 2 500 mg silica/kg b.w. per day). There were no treatment related increases in the incidences of any tumour type, not were there any significant effects on survival or morbidity (Takizawa et al., 1988, as cited in OECD, 2004).

Developmental and reproductive toxicity

In studies in pregnant animals, amorphous silica was administered to rats at doses up to 1 350 mg/kg b.w. for 10 days, to mice at doses up to 1 340 mg/kg b.w. for 10 days, to rabbits at doses up to 1 600 mg/kg b.w. for 13 days, and to hamsters at doses up to 1 600 mg/kg b.w. for 5 days. No effects on development were observed in any of the species tested. In their review of silica, OECD (2004) concluded that ―*based on the weight of evidence, prolonged exposure to synthetic amorphous silica, applied before and during pregnancy at high doses, is not expected to produce harmful*

effects on the reproductive performance or embryonic/foetal development in experimental animals.‖ The CONTAM Panel agrees with this conclusion.

3.32.2.4. Allergenicity

Silica is not known to be an allergen. It may possess some irritant and adjuvant properties, depending on the particle size and specific properties of the preparation (Granum et al., 2001; Hirai et al., 2012; Vallhov et al., 2012). Considering the dilution factor for carryover into a subsequent cargo of edible fats or oils, the CONTAM Panel considers that this would not constitute a problem when silica is used as a previous cargo.

Nanosized silica particles are being investigated for medical applications, but pro-inflammatory activites of some types of nanosized silica particles have been reported as well (Napierska et al., 2010). Considering the dilution factor, the amount of nanosized silica particles resulting from carryover from a previous cargo would not constitute a concern.

3.32.3. Conclusions

Because silicon dioxide is a solid and essentially insoluble in water, current shipping practices mean that it is not possible to transport this substance by sea in a tanker suitable for the transport of edible fats and oils. This is because of difficulties in transfer and cleaning of the tanker.

JECFA has established an ADI ―not limited except for good manufacturing practice‖ and the SCF has established an ADI ―not specified‖ for silicon dioxide, on the basis that there will be negligible absorption from the GI tract. The CONTAM Panel considers this to be appropriate. Consistent with this, silicon dioxide has negligible systemic toxicity. It is not genotoxic and there is no allergenic potential of concern. There are no reaction products or impurities of toxicological concern.

The CONTAM Panel concludes that although silicon dioxide meets the toxicological criteria for acceptability as a previous cargo for edible fats and oils, it is not a suitable cargo on the basis of current shipping practices, due to difficulties in transfer and cleaning of the tanker. The CONTAM Panel therefore recommends that silicon dioxide be deleted from the annex to Commission Directive 96/3/EC.

SCIENTIFIC OPINION

Scientific Opinion on the evaluation of the substances currently on the list in the annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III

EFSA Panel on Contaminants in the Food Chain (CONTAM)

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Shipping of edible fats and oils into Europe is permitted in bulk tanks, in which substances, included in a positive list, had been previously transported. The European Commission requested EFSA to evaluate the list of substances in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils, taking into account its review of the Scientific Committee on Food criteria for acceptable previous cargoes and criteria proposed by the Codex Committee for Fats and Oils. This is the third and last scientific opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) on this topic, in which sixteen of these substances or groups of substances have been evaluated. The CONTAM Panel concluded that sodium silicate (water glass) solution, iso-octanol, iso-nonanol, iso-decanol, 1,3-propanediol, isobutyl acetate, sec-butyl acetate, tert-butyl acetate, n-butyl acetate, propylene tetramer, paraffin wax, candelilla wax, white mineral oils and glycerol would not be of health concern as previous cargoes. The CONTAM Panel concluded that carnauba wax was not acceptable as a previous cargo because of its insolubility in water and high melting point, which raise concerns regarding the efficiency of tank cleaning. There was insufficient information available on the composition of montan wax for the CONTAM Panel to conclude that it would be of no health concern when used as previous cargo and hence it does not meet the criteria for acceptability as previous cargo. The CONTAM Panel made several recommendations regarding the way in which the substances are described in the Annex to Commission Directive 96/3/EC, to correct inaccuracies and to better reflect current transport practices.

3.9. MONTAN WAX (CAS No 8002-53-7)

Montan wax is a hard, brittle, lustrous wax with a melting point around 80 °C extracted with toluene from lignites/brown coal, principally from Central Europe.

Montan wax is formed from resins, waxes and fats of plants. It consists of about 50 % esters of C22-34 fatty acids with C24-C28 alcohols, about 20 % fatty acids and resins of phenols, ketones and asphaltenes.

Montan wax is used for technical purposes, such as sealing concrete, in cleaning agents, lubricants, adhesives, and for electrical insulation in cables.

Montan wax should be distinguished from a variety of products called _montan acid esters‘ or montanic acid esters‘, which are purified (e.g. by bleaching) and modified products. Fatty acids from montan waxes are esterified, e.g., with ethylene glycol or fatty alcohols. Other isolates from montan wax are partially saponified. This entry does not deal with these purified products.

3.9.1. Previous evaluations

The SCF evaluated montan wax (CAS no. 8002-53-7) as a previous cargo in 1996 and considered it provisionally acceptable, noting its solubility (SCF, 1997a). This conclusion was based on the fact the SCF had concluded that montan wax esters (E192) were temporarily acceptable as a food additive, used as a glazing agent for food (SCF, 1992c). In the 2003 SCF evaluation of acceptable previous cargoes, the Committee reconsidered montan wax and concluded that the information available was inadequate. The SCF therefore maintained their opinion as provisionally acceptable (SCF, 2003).

No previous evaluations of natural montan wax have been carried out, by JECFA, SCF, EFSA or other regulatory agencies. Natural montan wax is not authorised as a food additive in the EU,15 although montan acid esters are authorised for the surface treatment of certain fruits, with the E number E 912. Montan wax is approved for use as a food contact additive in plastics under Regulation (EU) 10/2011, with no restrictions other than the generic overall migration limit of 60 mg/kg food. Montan wax is also on the US FDA list of approved indirect additives used in food contact materials (FDA, 2011e).

3.9.2. Current evaluation

3.9.2.1. Expected impurities

As montan wax is a complex mixture with a composition depending on its source, the toxicological evaluation should consider the whole mixture, taking into account variability in composition. Anticipated impurities have not been specifically considered in this opinion.

3.9.2.2. Reactivity and reaction products

The large majority if not all of the components in montan wax are not expected to react in edible fats and oils.

3.9.2.3. Toxicological profile

Absorption, distribution, metabolism and excretion

Montan wax has a high melting point relative to other waxes, is insoluble in water and is hydrophobic in nature. Overall the CONTAM Panel considered that absorption of montan wax from the gastrointestinal tract will be limited. Any alkane constituents of the absorbed wax will be slowly metabolised to the corresponding fatty alcohols and then fatty acids, with some metabolism also occurring in the small intestine, and enter normal biochemical pathways (EFSA, 2012b).

Acute toxicity

Montan wax can be anticipated to be of low acute oral toxicity. An LD50 of > 12 000 mg/kg b.w. has been reported.28 Montan wax has been reported to be only very slightly irritating to skin and eyes, based on the results of *in vitro* tests.28

Subacute, subchronic and chronic toxicity studies

A 90-day toxicity study in Fisher 344 rats has been carried out with montan wax, administered in the diet at levels of 0, 0.56, 1.67 or 5 % (about 260, 835 or 2 500 mg/kg b.w. per day) (Ikeda et al., 2008). Haematological changes occurred in all treated rats, and aspartate aminotransferase (AST) and Re-alanine aminotransferase (ALT) in serum were elevated. Liver, spleen, lung and kidney weights relative to body weight were also increased. Diffuse multiple granulomatous change occurred in the liver in all treated rats, together with severe hepatocyte damage and lymphocytic infiltration. A NOAEL could not therefore be identified in this study.

No chronic toxicity study is available on montan wax.

Genotoxicity

Montan wax was non-mutagenic in a bacterial mutagenicity study using *Salmonella typhimurium* with and without metabolic activation.28

Carcinogenicity

No carcinogenicity study is available on montan wax.

3.9.2.4. Allergenicity

Montan wax was tested in the mouse local lymph node assay (LLNA) according to OECD Guideline 429. Montan wax did not induce skin sensitization in this test (Anonymous, 2009, as cited in ECHA, online). No other information has been found regarding sensitization, adjuvanticity or irritancy of Montan wax. The available data give no indication that montan wax is an allergen or an adjuvant at concentrations expected from its use as a previous cargo.

3.9.3. Conclusion

No ADI or TDI has been established for montan wax by the SCF, JECFA or EFSA. Data recently provided to ECHA indicate that montan wax is not mutagenic in a bacterial mutagenicity test, and the CONTAM Panel considers that it is not likely to be a significant sensitizer, adjuvant or irritant. In a subchronic toxicity study in rats, haematological changes and hepatotoxicity were observed at the lowest dose tested, of approximately 260 mg/kg b.w. per day, and hence no NOAEL could be identified. There are no data on chronic toxicity or carcinogenicity.

Montan wax is an ill-defined material for which it cannot be excluded that it contains components of concern.

The CONTAM Panel therefore concludes that, given the deficiencies in the available data on montan wax, it does not meet the criteria for acceptability as a previous cargo.

3.11. CARNAUBA WAX (Brazil wax) (CAS No 8015-86-9)

Carnauba wax is one of the hardest and highest-melting point natural waxes, with a melting point range between 82 and 86 °C. It is modestly soluble in solvents, virtually insoluble in water, i.e. difficult to remove from a container in solid form. The cleaning of a vessel might be inefficient.

Carnauba wax is mechanically obtained from the leaves of the Brazilian palm trees *Copernicia prunifera* and *Copernicia cerifera*. For purification it is melted and filtered.

Carnauba wax contains about 85 % esters of long chain fatty acids, hydroxy fatty acids and cinnamic acid with long chain alcohols and diols. The remaining material consists of long chain free acids, long chain fatty alcohols and saturated hydrocarbons.

Carnauba wax is used for polishing surfaces (e.g. shoes, furniture, floors, cars), as a release agent for bakery ware and sugar products, in chewing gums, as coatings of fruits, in cosmetics or to protect printed surfaces.

3.11.1. Previous evaluations

The SCF evaluated carnauba wax as a previous cargo in 1996 and considered it acceptable (SCF, 1997a). This conclusion was based on the fact that carnauba wax was temporarily acceptable as a food additive, E903, for use as a glazing agent for food (SCF, 1992d, 1997c). The SCF noted the insolubility of carnauba wax. In the 2003 SCF evaluation of acceptable previous cargoes, carnauba wax was not further evaluated as it was already considered acceptable (SCF, 2003).

The SCF has evaluated carnauba wax as a food additive on several occasions (SCF, 1992d, 1997c, 2001). The SCF did not establish an ADI for carnauba wax, and in its 1992 and 1997 opinions considered its use as a glazing agent as temporarily acceptable. In 2001, based on new toxicological and exposure data the SCF accepted the use of carnauba wax as a glazing agent up to a maximum use level of 200 mg/kg of food and withdrew its temporary status (SCF, 2001).

An ADI of 0-7 mg/kg b.w. for carnauba wax was established by JECFA in 1993 (JECFA, 1993b). In USA carnauba wax is classified as GRAS and is permitted with no other limitation than good manufacturing practice (GMP) in a variety of food products (FDA, 1983a).

Carnauba wax is approved for use as a food contact additive in plastics under Commission Regulation (EU) 10/2011, with no restrictions other than the generic overall migration limit of 60 mg/kg food.

EFSA re-evaluated carnauba wax (E 903) as a food additive in 2012 (EFSA, 2012c). The Panel on Food Additives and Nutrients added to Food (ANS Panel) did not establish an ADI due to the lack of long-term toxicity data. It noted, however, that available toxicity studies consistently reported no adverse effects associated with carnauba wax intake, and that the available data suggests no concern for genotoxicity. In addition, the exposure estimates to carnauba wax indicated sufficient ‗margins of safety', and therefore concluded that its use as a food additive within the currently authorised uses would not be of safety concern.

3.11.2. Current evaluation

3.11.2.1. Expected impurities

Carnauba wax is not expected to contain impurities of concern when transported as a previous cargo.

3.11.2.2. Reactivity and reaction products

Carnauba wax is not expected to produce reaction products with edible fats and oils which are of concern when it is transported as a previous cargo.

3.11.2.3. Toxicological profile

Absorption, distribution, metabolism and excretion

Carnauba wax has a high melting point relative to other waxes, is insoluble in water and is hydrophobic in nature. There are no specific experimental data on the absorption, distribution, metabolism and elimination of carnauba wax (EFSA, 2012c). Overall the CONTAM Panel considered, however, that absorption of carnauba wax from the gastrointestinal tract will be low, if any, and that the wax is unlikely to be susceptible to metabolism by digestive enzymes or the intestinal microbiota. Any degradation products, e.g. long-chain aliphatic esters which are the main components of carnauba wax, will be incorporated into normal cellular metabolic pathways and eliminated thereafter.

Acute toxicity

Carnauba wax is of low acute toxicity, an oral LD50 of greater than 1 100 mg/kg b.w. has been reported (Liebert, 1984). Carnauba wax is not anticipated to have irritant properties.

Subacute, subchronic and chronic toxicity studies

As reported by the SCF (2001) and EFSA (2012c), a 90-day oral study in Wistar rats was carried out with carnauba wax (Rowland et al., 1982) at levels of up to 10 % in the diet, in which no treatment-related effects were reported. A NOAEL of 8 800 mg/kg b.w. per day, the highest dose tested, was identified in this study. A further 90-day feeding study in Fischer F-344 rats was designed to investigate whether components of carnauba wax could be absorbed and accumulate in the liver and other organs of this strain, as seen with high molecular mass mineral oils and other waxes (Edwards, 1998). Groups of 20 male and 20 female rats were fed diets containing carnauba wax corresponding to intakes of 0, 15, 150 and 1 500 mg/kg b.w. per day. No treatment-related effects were identified, there were no dose-related histopathological changes in liver and other tissues, and a NOAEL of 1 500 mg/kg b.w. per day, the highest dose tested, can be identified in this study (Edwards, 1998). A 6-month feeding study has also been carried out in Beagle dogs, using dietary levels of up to 1 % in the diet (equivalent to up to 250 mg/kg b.w. per day) (Parent et al., 1983a). No treatment-related effects were identified. No studies on the chronic toxicity of carnauba wax are available (EFSA, 2012c).

Genotoxicity

As reported by JECFA (1993b) and the SCF (2001), carnauba wax was not mutagenic in *in vitro* tests with *Salmonella typhimurium* and *Saccharomyces cerevisiae*, with and without metabolic activation. As reported by SCF (2001), there was no evidence of clastogenicity of carnauba wax in *in vitro* chromosome aberration tests using human lymphocytes (Edwards, 1996, 1998). The SCF and, more recently, the EFSA ANS Panel (EFSA, 2012c) concluded that carnauba wax was not genotoxic *in vitro*, based on the results of these studies. There are no *in vivo* genotoxicity data available on carnauba wax.

Carcinogenicity

No studies on the carcinogenicity of carnauba wax are available (EFSA, 2012c).

Developmental and reproductive toxicity

No treatment-related effects were reported in a reproductive toxicity study with carnauba wax in which Wistar rats were administered levels of 0, 0.1, 0.3 or 1 % in the diet for 4 weeks prior to mating and through gestation and lactation (Parent et al., 1983b). This study was used by JECFA as the basis for setting the ADI of 7 mg/kg b.w. per day for carnauba wax (rounded up), by applying a 100 uncertainty factor to the NOAEL of approximately 670 mg/kg b.w. per day. As reported by the SCF (2001), no developmental toxicity was evident in a study in which rats were fed 0, 0.1, 0.3 or 1 % carnauba wax in the diet for two weeks before mating and throughout gestation.

3.11.2.4. Allergenicity

One report of a test-proven case of sensitization to carnauba wax has been published (Chowdhury, 2002). In addition, Jacob et al. (2008) report one case of supposed sensitization to carnauba wax, based on reaction to a product containing propolis and carnauba wax and test-proven sensitization to cinnamic acid/cinnamaldehyde, which is a component of both the mentioned substances. However, no testing with carnauba wax was performed. Chowdhury (2002) state that sensitization to carnauba wax is very rare. No other information on sensitizing properties, adjuvanticity or irritancy has been found. The CONTAM Panel considers that taking into account the scarcity of reports of sensitization in the literature as well as the relevant dilution factor, carnauba wax when used as a previous cargo is not likely to be a significant sensitizer, adjuvant or irritant.

3.11.3. Conclusion

JECFA has established an ADI of 0-7 mg/kg b.w. for carnauba wax, while the SCF concluded that its use as a glazing agent up to a maximum use level of 200 mg/kg of food was acceptable. The EFSA ANS Panel noted that available toxicity studies consistently reported no adverse effects associated with carnauba wax intake, and that the available data suggests no concern for genotoxicity. In addition, the exposure estimates to carnauba wax indicated sufficient ‗margins of safety', and therefore concluded that its use as a food additive within the currently authorised uses would not be of safety concern. The CONTAM Panel considered, based on the outcome of these expert evaluations, the likely limited absorption of carnauba wax and the toxicological profile of its main component groups of chemicals, that this wax will not pose any toxicological concern when used as a previous cargo, based on normal assumptions regarding worst case carryover. There is no evidence that it is genotoxic and there is no allergenic potential of concern. It will not give rise to any reaction products with fats and oils of toxicological concern. No impurities of toxicological concern are known or anticipated. The CONTAM Panel noted however, the insolubility of carnauba wax in water, its high melting point (82 to 86 °C) and the fact that heating of ships' tanks is normally to a maximum of 80 °C. The CONTAM Panel therefore has concerns regarding the feasibility of tank cleaning following transport of carnauba wax as a previous cargo, such that carryover may exceed the worst case normally assumed.

The CONTAM Panel concludes that carnauba wax does not meet the criteria for acceptability as a previous cargo because of doubts concerning the efficiency of tank cleaning following transport of carnauba wax as a previous cargo.

According to the information provided to EFSA, carnauba wax does not appear to be transported as a previous cargo.