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Review and priority setting for substances that are listed without a specific migration limit in Table 1 of Annex 1 of Regulation 10/2011 on plastic materials and articles intended to come into contact with food

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) was requested by the European Commission to review the substances for which a Specific Migration Limit (SML) is not assigned in Regulation (EU) No 10/2011. These substances had been covered by the Generic SML of 60 mg/kg food, but with Regulation (EU) 2016/1416 it was removed, necessitating their re-examination. EFSA was requested to identify those substances requiring an SML to ensure the authorisation is sufficiently protective to health, grouping them in high, medium and low priority to serve as the basis for future re-evaluations of individual substances. The CEP Panel established a stepwise procedure. This took into account existing hazard assessments for each substance on carcinogenicity/mutagenicity/reprotoxicity (CMR), bioaccumulation and endocrine disruptor (ED) properties along with the use of *in silico* generated predictions on genotoxicity. Molecular weights and boiling points were considered with regard to their effect on potential consumer exposure. This prioritisation procedure was applied to a total of 451 substances, from which 78 substances were eliminated at the outset, as they had previously been evaluated by EFSA as food contact substances. For 89 substances, the Panel concluded that a migration limit should not be needed. These are in the lists 0 and 1 of the Scientific Committee for Food (SCF), defined as substances for which an Acceptable Daily Intake (ADI) does not need to be established, along with substances that are controlled by existing restrictions and/or generic limits. Of the remaining 284 substances, 179 were placed into the low priority group, 102 were placed into the medium priority group and 3 were placed into the high priority group, i.e. salicylic acid (FCM No 121), styrene (FCM No 193) and lauric acid, vinyl ester (FCM No 436).

Keywords: food contact materials, prioritisation, safety assessment

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1. Introduction

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

Following our own review and discussions with the Member States and the industry, it became apparent that Regulation (EU) No 10/2011[1] on plastic food contact materials ('the Regulation') does not assign a Specific Migration Limit (SML) to approximately 460 substances which are listed in Table 1 of Annex 1. Certain substances may nonetheless require the specification of a limit to ensure their authorisation is sufficiently protective to health. EFSA should assess for which substances a limit would need to be determined.

Commission Regulation (EU) 2016/1416[2] of 24 August 2016 which amended the Regulation deleted Article 11(2), thereby removing the so-called Generic Specific Migration Limit (GML). The GML assigned a migration limit of 60 mg/kg food to all substances without an SML. Historically this generic limit complemented overall migration testing only in case of technical problems, but the Regulation made it generally applicable without apparent justification. We deleted the GML because it could cause a significant and often unnecessary testing burden while only for some of these substances an analytical method is available.

For many substances the absence of a limit is correct because their migration may not be of a health concern, or is accounted for otherwise, such as in the overall migration test. However, for certain substances, including volatile substances, this may not be the case. The review of all substances authorised under the Regulation without a specified migration limit is therefore necessary, with the exception of substances for which EFSA published opinions in the context of an application. This review should identify those substances for which EFSA considers that a specific migration limit at or below 60 mg/kg may be required to prevent the transfer of these substances to the food in an amount that could cause adverse health effects.

We therefore ask EFSA to review all substances without an SML and identify those substances for which a specific migration limit would be necessary. Given the large number of the substances concerned, we propose to proceed in two stages.

In the first stage, EFSA should prioritise the need for re-evaluation of these substances in groups of high, medium, and low priority, setting apart substances for which there is no apparent need for a SML. The enclosed synoptic list may facilitate this work for the older substances.

The prioritisation should be done on the basis of criteria EFSA deems appropriate, such as based on theoretical knowledge about the chemistry and toxicology of the substances, the absence of such information, known migration limiting factors, volatility and other appropriate information available to EFSA. A call for data should not be conducted at this stage.

In the second stage, based on the list of the priorities established in the first stage, the Commission will provide EFSA with separate mandates for re-evaluation of the individual substances taking into account the assigned priorities.

Terms of Reference

In accordance with Article 12(3) of Regulation (EC) No 1935/2004[3], the European Commission asks EFSA to review the authorisations of substances listed in Annex I of Regulation (EU) No 10/2011 without a specified Specific Migration Limit (SML). The purpose is to identify those substances requiring a specific migration limit to ensure the authorisation is sufficiently protective to health.

In doing so, EFSA should on the basis of criteria it deems appropriate (e.g. expected toxicity, known migration limiting factors, detection of the substance in overall migration testing, etc.), group these substances in terms of high, medium, and low priority for re-evaluation, as well as those which do not need a SML. The characterisation thus obtained should allow the risk manager to provide EFSA with individual mandates for the subsequent re-evaluation of these substances in order of priority and taking into account other legitimate factors.

[1] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance OJ L 12, 15.1.2011, p. 1–89.
[2] Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance) OJ L 230, 25.8.2016, p. 22–42.
[3] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC OJ L 338, 13.11.2004, p. 4–17.

In carrying out this review, EFSA should not launch a call for data but apply its theoretical knowledge and expertise about the chemistry and toxicology of the substances and about known migration limiting or enhancing factors, (e.g. volatility, polarity, etc.) for the substances and any relevant information available to EFSA.

1.2. Interpretation of the Terms of Reference

Impurities, reaction and transformation products

Substances used to make plastic Food Contact Material (FCM) may contain impurities due to the method of synthesis and production. Food contact substances may also form reaction and transformation products including oligomers when the plastic FCM is made (e.g. polymerisation) and processed (e.g. at high temperature). This review and prioritisation will consider only the food contact substances themselves and not the possible impurities, reaction and transformation products including oligomers, since they are expected to be variable depending on the exact processes used by different business operators. Whereas such information is requested and used in the evaluation of applications for new substances (EFSA, 2008), such information for the substances under consideration here is not available to EFSA and in the absence of a call for data will not become available to EFSA for this prioritisation exercise.

Inorganic substances including minerals and elemental powders

Due to the physical and chemical nature of these types of substances as they are described in the Union list (e.g. metal oxides or halides, aluminium flakes), their migration potential is very limited if not absent. Therefore, establishing SMLs for these substances as listed appears not to be appropriate. Since Regulation (EU) No 10/2011 sets in Table 1 of Annex II general migration limits for metals to be respected – according to Article 10 – as general restrictions related to plastic materials and articles and – according to Article 6(3) – for salts of authorised acids, these substances are under generic control by the migration limits listed in Annex II. As a consequence, substance (as listed) related SMLs are not needed and may not even be possible to be measured due to the dissolution/dissociation effects in the migration test.

Substances possibly in nanoform

Regulation (EU) No 10/2011 makes specific reference to nanosubstances in plastic FCM and established in Article 9(2) that substances in nanoform shall only be used if explicitly authorised. Authorisation of a substance in conventional size/form does not cover the same substance in nanoform. It is stipulated in that Regulation that EFSA will assess substances in nanoform case-by-case before authorisation. This being so, and in the absence of any specific information for the substances under review here, it shall be assumed that the substances are not in nanoform. If any substance under review here would be available and used in nanoform, it is understood that the interested business operator(s) would need to come forward with an application for its evaluation by EFSA and subsequent consideration for authorisation by the Commission.

Database searches based on CAS numbers and other identifiers

Due to the lack of a common unique identifier among the plastic FCM Union list and publicly available lists, such substance searches are inherently incomplete. The CAS identifiers from the Union list were used in database searches. It is also noted that the opinion (especially the tables) uses information from various sources and the way the substance is described has been maintained, although it is not always consistent between the different sources. However, care has been taken to remove any ambiguity, even if some inconsistent numbering and nomenclature persists.

Exposure

The tiered approach for risk evaluation described in EFSA (2008) requires the assessment of exposure prior to hazard, in order to set the toxicity requirements per tier. It was acknowledged that this approach cannot be systematically followed in this prioritisation exercise due to the significant lack of exposure data. The issue is partly addressed by placing some substances which would not migrate (based on their structure and physicochemical properties) into the low priority group. Concerning volatile substances, it is clear that exposure will depend on the volatility, assessed from the boiling point, under the conditions of the particular migration test or food contact application. However, due to a lack of clear-cut criteria on the volatilisation of such substances, quantitative consideration on the

exposure cannot be given. Substances in the gas phase at room temperature may no longer be present in the FCM plastics in amounts significant for potential exposure. Such substances are to be examined on a case-by-case basis and placed in the appropriate priority group where applicable.

2. Data and methodologies

The mandate requests that the prioritisation is based on appropriate criteria, using theoretical knowledge about the chemistry and toxicology of the substances, the absence of such information, known migration-limiting factors, volatility and other appropriate information. Sources of such information included the Synoptic document, the EFSA OpenFoodTox Database, non-confidential information retrieved from ECHA and IARC. Publicly available predictive modelling software, which uses quantitative structure–activity relationship ((Q)SAR) tools, was also applied.

2.1. Data

The initial data set was prepared using the Union list of FCM substances in the latest consolidated version of the Regulation available at the time of receipt of the European Commission mandate. This being Table 1, Annex I of Regulation (EU) No 10/2011, as amended by Regulation (EU) No 2019/37[4] of 10 January 2019. That Union list contained 451 entries (substances) for which an SML or a total specific migration limit (SML(T)) was not assigned.

Following the exclusion of substances for which EFSA has produced a risk evaluation (as a food contact substance) and other substances which could be set apart for other reasons (Section 2.2.1), the remaining substances were checked against the following lists, databases and other types of information:

- Synoptic Document (European Commission, 2005)
- EFSA's OpenFoodTox[5] (Dorne et al., 2017; Ceriani et al., 2018) and the EFSA Register of Questions[6]
- EFSA Emerging Risks list (Oltmanns et al., 2019)
- ECHA substance information[7] under the Registration, Evaluation, Authorisation and Restriction of Chemicals[8] (REACH) Regulation and the Classification, Labelling and Packaging (CLP) Regulation[9]
- ECHA Plastics Additive Initiative[10] (ECHA, 2019)
- IARC classifications[11]
- SINLIST[12]
- Feedback from the EU Member States on FCM risk assessment conducted at national level.

2.2. Methodologies

A stepwise approach was followed in order to define the applicable group of substances, excluding substances not falling under the remit of this European Commission mandate and to apply the prioritisation strategy, which consisted of four sequential steps: setting apart substances for which an SML should not be needed, and then assigning the remaining substances to low, medium and high priority groups (Figure 1).

[4] Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food OJ L 9, 11.1.2019, p. 88–93.
[5] https://www.efsa.europa.eu/en/microstrategy/openfoodtox
[6] http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL
[7] https://echa.europa.eu/information-on-chemicals
[8] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000 21 EC OJ L 396, 30.12.2006, p. 1–849.
[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 OJ L 353, 31.12.2008, p. 1–1355.
[10] https://echa.europa.eu/mapping-exercise-plastic-additives-initiative#table
[11] https://monographs.iarc.fr/agents-classified-by-the-iarc/
[12] https://sinlist.chemsec.org/

2.2.1. Exclusions from the prioritisation exercise

2.2.1.1. EFSA opinions on applications

The European Commission mandate requests the exception of substances for which EFSA has published opinions in the context of an application (i.e. as substances used to make FCM). These were identified following name and CAS number searches from the EFSA Registry of Questions and the EFSA OpenFoodTox Database.

2.2.1.2. Other Union list entries

According to the existing restriction for 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl)ether (also known as bisphenol A diglycidyl ether, BADGE) in Regulation (EU) No 10/2011 referring to Commission Regulation (EC) No 1895/2005[13], the SML(T) of 9 mg/kg food or food simulant applies. Therefore, BADGE can be excluded from the current prioritisation process.

2.2.2. Prioritisation strategy

In order to define the group of substances for which an SML should not be needed and to produce groups of low, medium and high priority substances, a set of criteria was established, which were then applied in a stepwise approach (Figure 1).

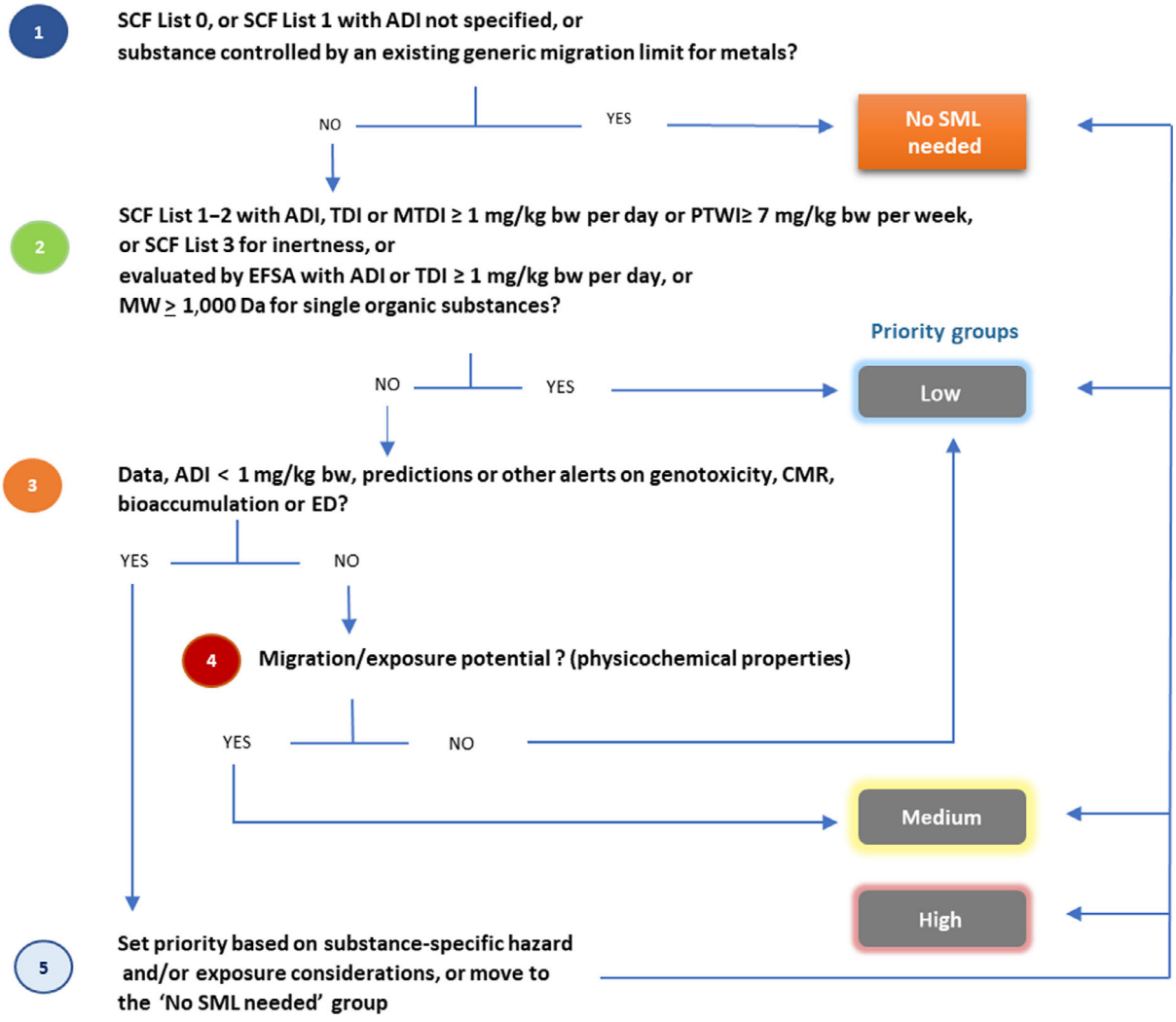

Figure 1: Prioritisation flowchart

[13] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food. OJ L 302, 19.11.2005, p. 28–32.

2.2.2.1. Substances for which an SML should not be needed

SCF classification of FCM substances

The Synoptic document contains a list of all FCM substances which had been risk assessed by the Scientific Committee on Food (SCF) and includes chemical names, identification numbers, SCF classification numbers and risk assessment summary information. Where available, FCM substances without an SML were each assigned to an SCF classification taken from the Synoptic Document. Substances falling under an SCF classification of 0 were placed into the group of substances for which an SML should not be needed. List 0 was defined by the SCF (European Commission, 2005) as follows:

- List 0: Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

Substances with the characterisation 'ADI: not specified' or 'Group ADI: not specified' and classified as SCF List 1 in the Synoptic document were also placed into the group of substances for which an SML should not be needed. The relevant SCF definition (SCF, 1990) is as follows:

- 'ADI not specified' is a term used when, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for these substances.

The Panel did not revisit this classification of substances by the SCF into 'SCF List 0' or 'ADI not specified' but concluded that, with the definitions as described above, they are a reasonable basis for prioritisation and for identifying substances that should not need an SML for safety reasons. As a check, the EFSA OpenFoodTox database was interrogated to determine if any of these substances have been evaluated more recently by EFSA, i.e. since the SCF classification was made.

FCM substances controlled by existing general restrictions and generic limits

For various forms of elemental metals (such as flakes and powders) or metal compounds (such as metal oxides, hydroxides or salts that dissociate in water or dissolve under acidic conditions), the corresponding general metal-related SMLs provided in Table 1 of Annex II of Regulation (EU) No. 10/2011 (Al, Ba, Co, Cu, Fe, Li, Mn, Ni or Zn) can be applied. This waives the need of a substance-as-listed migration control and allows to place these substances into the group of substances for which an SML should not be needed. This approach is supported by the fact that these types of substances also have a very limited migration potential, if any, in their physico-chemical form as listed.

It is noted that the following substances of the positive list (Annex I of Regulation (EU) No 10/2011) may also fall under this category; however, they have already been excluded from priority setting due to existing EFSA evaluations on applications: iron phosphide (FCM No 607) (EFSA, 2004) and copper hydroxide phosphate (FCM No 972) (EFSA CEF Panel, 2010).

2.2.2.2. Low priority group

SCF classification of FCM substances

Substances falling under an SCF classification of 1 or 2 with an ADI/Tolerable Daily Intake (TDI)/ Maximum Tolerable Daily Intake (MTDI) $\geq$ 1 mg/kg body weight (bw) per day or a Provisional Tolerable Weekly Intake (PTWI) $\geq$ 7 mg/kg bw per week were placed in the low priority group. Substances characterised as SCF List 3 due to 'substance inertness' were also placed in the same group. The following criteria were used by SCF to classify FCM substances into lists 1, 2 and 3:

- List 1: Substances, e.g. food additives, for which an ADI, a t-ADI (=temporary ADI), an MTDI, a PMTDI (=Provisional Maximum Tolerable Daily Intake), a (P)TWI (=(Provisional) Tolerable Weekly Intake) or the classification 'acceptable' has been established by SCF or by JECFA.
- List 2: Substances for which a TDI or a t-TDI has been established by SCF.
- List 3: Substances for which an ADI or a TDI could not be established, but where the present use could be accepted. Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set, but the maximum level to be used in any packaging material or a specific limit of migration is stated.

This is because the available toxicological data would give a TDI which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

The CEP Panel noted that for some of the substances falling under the SCF classification of 1 or 2, a health-based guidance value was not available. However, although implicitly with an ADI/TDI/MTDI $\geq$ 1 mg/kg bw per day or (P)TWI > 7 mg/kg bw per week, in line with the set criteria, the CEP Panel considered that those substances were deemed to proceed with the next steps of the prioritisation strategy.

FCM substances evaluated by EFSA with an ADI/TDI $\geq$ 1 mg/kg bw per day

Certain substances used as FCMs are also used in food and feed for other purposes (e.g. food and feed additives, food flavouring substances, pesticide active substances) and, similar to FCM, they have been evaluated by EFSA and/or are authorised under the respective Commission Regulations (e.g. Regulations 1333/2008[14], 1334/2008[15] and their implementing measures). Concerning FCM substances that are also food additives and/or flavouring substances, a non-exhaustive list of such dual-use additives has been reported in the Commission's Guidelines to Regulation (EU) No 10/2011 (European Commission, 2014).

For the identification of those substances without an SML, which have been previously evaluated by EFSA, the OpenFoodTox Database was used as a source and it was searched by CAS number and substance name. The version updated until 20/01/2020 was used.

An ADI or TDI equal to or above 1 mg/kg bw per day which had been established by EFSA or SCF was defined as one of the criteria for prioritisation. This threshold would correspond to an SML of 60 mg/kg of food or higher, assuming a default body weight of 60 kg and a maximum intake of 1 kg of food per person set in the SCF guidelines (SCF, 2001).

The Panel noted that this approach is protective for adults but not necessarily for infants, toddlers or young children due to their higher relative food consumption on a body weight basis compared to that of adults (EFSA CEF Panel, 2016).

FCM substances of high molecular mass

Single organic substances of a molecular mass equal to or higher than 1,000 Da are unlikely to pass biological membranes (Loewenstein, 1981). They are not expected to be absorbed by the gastrointestinal tract and do not present a systemic toxicological hazard, unless they cause local effects to the gastrointestinal tract or hydrolyse to smaller molecules. If this can be excluded, a molecular mass of 1,000 Da can be considered to be a conclusive cut-off value. For poly- and per-fluoro substances, a cut-off value of 1,500 Da could be appropriate, because the molecular volume of C-F is smaller than that of C-H molecules of the same molecular mass (EFSA CEF Panel, 2016). Molecular weight information was retrieved from Scifinder(n), Pubchem, eChemPortal, ChemIDPlus (Toxnet) and specific JECFA monographs. FCM substances meeting the molecular weight cut-off criterion were placed in the low priority group.

2.2.2.3. High priority group

Substances not falling under the low priority group were screened for potential toxicity.

The considered endpoints were genotoxicity, carcinogenicity, mutagenicity, reprotoxicity, bioaccumulation and ED properties. Information was sought from the following sources:

- OpenFoodTox
- ECHA substance information under the REACH and CLP Regulations, providing information on substance evaluations and harmonised classification and labelling (CLH)
- IARC classifications
- Risk evaluations conducted at national level by EU Member States
- Existing priority lists (Potential Emerging Risks list, EFSA; SIN List, ChemSec) and the overview of Plastic Additives (ECHA)

[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. 16–33.

[15] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34–50.

- Genotoxicity alerts triggered by the use of endpoint-specific profilers from (Q)SAR models (VEGA and OECD QSAR Toolbox)

OpenFoodTox

The OpenFoodTox Database (Dorne et al., 2017; Ceriani et al., 2018) was searched for experimental data and assessments on toxicity of substances without an SML, which have been previously evaluated by EFSA. The database provides, among other information, references to the EFSA opinion and the EFSA Panel, the study category (human or animal health, ecotoxicity), the type and details of the study and the guidelines, the type of toxicity (systemic, developmental, reproductive, etc.), its conclusions on mutagenicity/genotoxicity/carcinogenicity and the health-based guidance values derived. Substances with an ADI, group ADI, TDI or group TDI value below 1 mg/kg bw per day were candidates for the high priority group, pending case-by-case considerations.

ECHA information

EFSA received substance information present in the ECHA public database from the ECHA's Prioritisation Unit. Tonnage information and hyperlinks to each Substance Information Page and Factsheet URL were also kindly provided by ECHA. The Authorisation List (Annex XIV to REACH), the Restriction List (Annex XVII to REACH) and the Classification and Labelling (C&L) Inventory (Annex VI to CLP) were searched for FCM substances which have been evaluated for carcinogenic, mutagenic or toxic for reproduction (CMR), persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB) or ED properties by ECHA. Substances that have passed the screening phase of ECHA and Member State Competent Authorities and are currently included under any of the ongoing processes 'Substance Evaluation (SEV)', 'PBT Assessment', 'ED Assessment', 'Harmonised Classification and Labelling (CLH)', 'Regulatory Management Option Analysis (RMOA)' and 'Candidate List of Substances of Very High Concern (SVHC)', were also identified. Before inclusion of these substances into the high priority group, the relevance to FCM of information retrieved from CLH and RMOA evaluations was confirmed.

IARC classifications

The IARC classifications on carcinogenicity (Agents Classified by the IARC Monographs, Volumes 1–124, update of 2019-07-16) were searched for matches with the working list of FCM substances with no SML.

Substances classified by IARC into groups: 1 (carcinogenic to humans), 2A (probably carcinogenic to humans) and 2B (possibly carcinogenic to humans) were assigned to the high priority group. A listing in the IARC group 3 (not classifiable as to its carcinogenicity to humans) was not used for prioritisation.

EU national risk evaluations

EFSA Focal Points, which comprise members from all EU Member States, Iceland and Norway, as well as observers from Switzerland and EU candidate countries, were contacted. They were asked to provide, if available, any additional food safety evaluations conducted at national level regarding the working list of FCM substances with no SML. The information provided was collected and screened based on its relevance to the FCM area and the prioritisation exercise.

Priority lists and overviews

- EFSA's list of potential emerging risks.

  Oltmanns et al. (2019) described a procedure for the identification of potential emerging risks for food safety using substances registered under REACH. The prioritisation was based on the environmental exposure (tonnage and use pattern), biodegradation and bioaccumulation in food/feed (based on modelling) and toxicity (based on classification for CMR and repeated dose toxicity). The list of 212 substances of 'potential emerging risks' identified under this project was searched against the working list of FCM substances without an SML. No matches between the two lists were identified.

- SIN List

  The SIN List, developed by the non-profit organisation ChemSec and based on criteria defined within REACH, is a publicly available list of hazardous substances to human health and the

environment. The version updated up to 29 May 2019 was used to search against the working list of FCM substances without an SML.

- ECHA's Plastic Additives Initiative.

  ECHA in collaboration with industry sector organisations characterised the uses of various plastic additives and estimated their potential for release from articles by modelling (ECHA, 2019). Substance properties determining/driving the release from the polymer matrix and information on the additive function, typical concentrations and the types of polymers and articles was collected. This information was obtained from ECHA. However, the presence of a substance in the Plastic Additives inventory was not used as a tool to assign priorities here, due to differences in the selection criteria (e.g. focus on exposure, tonnage information not specific to FCM applications).

In silico methods: (Q)SAR predictions

As regards (Q)SAR tools, two independent and freely available software programmes were used: VEGA[16] (version 1.1.5) (Benfenati et al., 2019) and the OECD QSAR ToolBox[17] (version 4.3). The VEGA software was selected because it provides information on the applicability domain and makes available the data set on which the models are built (experimental data available) as well as the full report of the predictions performed. The OECD QSAR ToolBox was selected because it contains many databases with updated experimental data. Moreover, the two platforms are generally used and accepted for regulatory purposes (EFSA Scientific Committee, 2017; ECHA, 2016a).

OECD QSAR Toolbox and VEGA were used for predictions of genotoxicity, in particular for the gene mutation endpoint. As regards chromosomal aberration, it was noted that the alerts on this endpoint (e.g. ISS alert for *in vivo* micronucleus test) are not considered reliable and can be dismissed. Therefore, only gene mutation was taken into account (Benigni et al., 2019; Honma et al., 2019).

In silico positive predictions regarding the gene mutation endpoint were compared, when available, with the conclusion on genotoxicity based on experimental data of substances previously evaluated by EFSA Panels. Substances indicated as positive by the (Q)SAR tools based on experimental data and/or positive alerts were candidates for the high priority group. In cases where predictions from (Q)SAR models contradict available experimental data, the experimental evidence prevails.

For those FCM substances which are also authorised as food flavouring substances, the EFSA evaluations in accordance with Article 9(a) of Regulation (EC) No 1334/2008 (on flavourings and certain food ingredients with flavouring properties for use in and on foods) were taken into account. Specifically, if a substance had experimental *in vitro* data and/or (Q)SAR predictions indicating a potential for genotoxicity, but for which, based on experimental data or other considerations, the concern for genotoxicity had been ruled out as part of the EFSA evaluation of flavourings, then the substance was assigned not to the high but to the medium priority group.

2.2.2.4. Medium priority group

Substances not assigned to the 'no SML needed', low or high priority groups were considered on the basis of their physico-chemical properties. When these properties suggested a lack of potential for migration into food (e.g. minerals and substances in the gas phase at room temperature), the substance was placed into the low priority group. If not, it was assigned to the medium priority group.

3. Assessment

3.1. Substances without an SML in the Union List of food contact materials and exclusions

3.1.1. FCM substances without an SML

Four hundred and fifty-one substances without an SML or SML(T) were identified in the Union list of 893 authorised substances of Annex I of Regulation (EU) No 10/2011. The numbers of substances with an SML, SML(T) or an ND characterisation and those without, are shown in Table 1.

[16] www.vegahub.eu
[17] https://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm

Table 1: Numbers of substances with specific migration limits (SML), group restrictions (SML(T)), not to be detected (ND) or without a specific migration limit or restriction

Type of limit or restriction	Number of substances in the Union List
SML	263
SML (T)	139
SML + SML(T)	9
ND	31
No SML or SML(T)	451

The full list of substances without an SML or SML(T) is provided in Appendix A, Table A.1.

3.1.2. Exclusions from the prioritisation exercise

Food contact material substances that have been evaluated by EFSA, following mandates on FCM applications by the Member States or mandates of the Commission were excluded from the prioritisation exercise. In total, 78 substances without an SML have been evaluated by EFSA, of which 77 were evaluated on the basis of an application and one substance (BADGE) on the basis described under paragraph 2.2.1.2 and were excluded. The list of substances and corresponding EFSA opinions is provided in Appendix A, Table A.2.

3.2. Prioritisation

3.2.1. Substances for which an SML should not be needed

Thirty-three of the remaining 373 substances have been classified by the SCF as List 0. They were searched by CAS number and name in the EFSA OpenFoodTox database and, for 19 of these 33 SCF List 0 substances, evaluations by one or more EFSA Panels were identified (Appendix A, Table A.3). In agreement with the earlier SCF classifications, these EFSA evaluations do not raise any safety concern.

During the screening of the SCF List 0 substances, it was noted that the Union list entry β-dextrin, with FCM No 503, Reference number 46080 and CAS number 7585-39-9 has been evaluated in 2016 by EFSA as a food additive (E 459, β-cyclodextrin) with the same CAS number and with the information that β-dextrin is a synonym for β-cyclodextrin. The ADI for E 459 (β-cyclodextrin) and hence for 'β-dextrin' is 5 mg/kg bw per day (EFSA ANS Panel, 2016a). Consequently, this ADI takes priority over the SCF List 0 classification, and therefore, the ADI value for this substance is used according to the prioritisation scheme, leaving 32 substances not considered further, since they are on SCF List 0.

For 38 substances, an SCF List 1 classification and an 'ADI: not specified', or 'Group ADI: not specified' characterisation was assigned by the SCF. For 26 of these 38 entries, information could be retrieved from EFSA opinions via the EFSA OpenFoodTox database (Appendix A, Table A.4). No safety concerns were identified in these EFSA evaluations.

Eighteen substances that are regulated under articles 6(3) and 10 [limits on metals, Annex II of the Commission Regulation (EU) No 10/2011] were also identified.

An SML may not be needed for the above 88 substances and they were not further considered. The 285 remaining substances were subsequently assigned to the low, medium and high priority groups in the next steps.

For one additional substance, FCM No 768 Amines, bis(hydrogenated tallow alkyl) oxidised, which did not fall under any of the above criteria, it was concluded at a later step (Section 3.2.4.4, Figures 1 and 5) that an SML should not be needed, due to existing restrictions of use of this substance under Regulation (EU) No 10/2011. Therefore, the final group of substances for which an SML should not be needed consisted of 89 substances, while 284 substances were finally placed in the low, medium and high priority.

The 89 substances for which an SML should not be needed are listed in Appendix A, Table A.5 and are shown schematically in Figure 2.

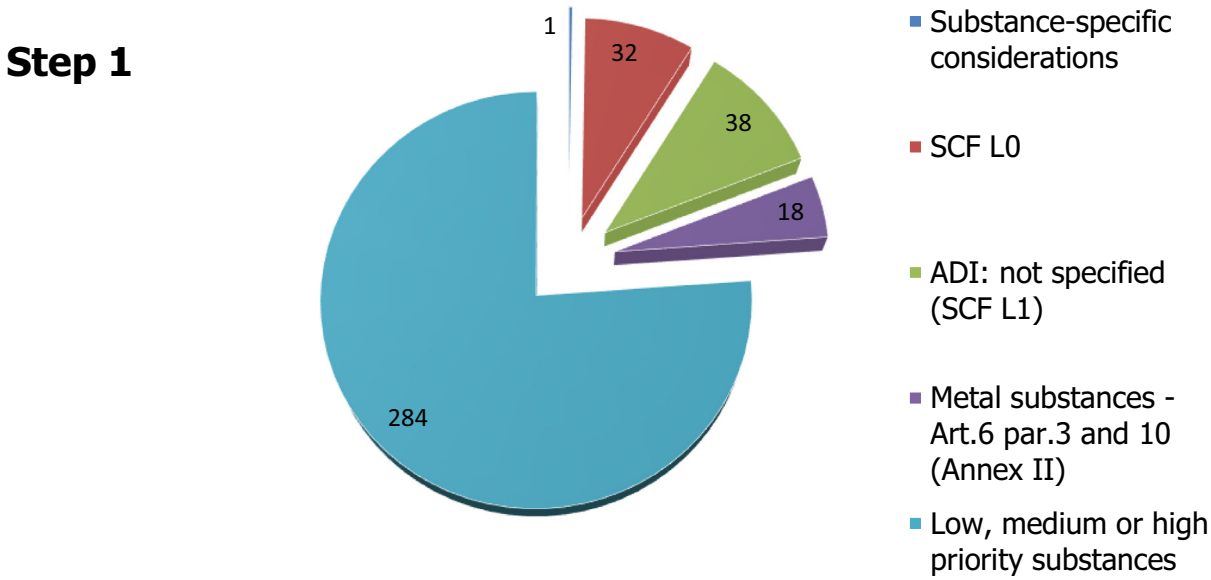

Figure 2: Substances for which no SML should be needed, based on SCF classifications, regulatory provisions on metals, substance-specific considerations and remaining substances for prioritisation

3.2.2. Low priority group

Following the removal of substances for which an SML should not be needed, 160 substances which:

a) Have been classified by the SCF Committee as List 1 or List 2, with ADI/group ADI, TDI/group TDI or MTDI $\geq$ 1 mg/kg bw per day or (P)TWI $\geq$ 7 mg/kg bw per week, or they have been classified as List 3 (for inertness), or/and
b) Have an ADI or TDI $\geq$ 1 mg/kg bw per day established by EFSA, or/and
c) Have a molecular weight higher or equal to 1,000/1,500 Da for single organic substances,

were placed in the low priority group. Twenty-nine of these substances matched more than one of the above criteria.

One hundred and twenty-eight substances fell under criterion (a), with 102 substances being SCF-classified as List 1 or List 2 and 26 classified as SCF List 3 for inertness.

The OpenFoodTox database was searched for substances for which an ADI or TDI equal to, or above 1 mg/kg bw per day has been assigned, by any of the EFSA Panels, according to criterion (b). Twenty-two such substances were identified, mainly from flavouring and food additive EFSA evaluations (AFC, CEF, ANS and FAF Panels).

Thirty-nine substances filled the criterion (c) of high molecular mass. These were either polymeric substances (5), polysaccharides (23) or other substances with a molecular weight higher than 1,000 Da (11). Union list entries for substances with a range of molecular weights, a fraction of which lay below 1,000 Da, were not included in this group.

In addition, 19 substances, which did not fulfil the above criteria, were placed in the low priority group after exclusion from the medium and high priority groups: Ten substances, described under Section 3.2.3, were considered of low potential for migration/exposure (minerals and highly volatile substances) and were moved to the low priority group, as described in the methodology (Section 2.2.2.4). Nine substances which were candidates for the high priority group were also finally placed in the low priority group, following case-by-case considerations (Section 3.2.4.4).

The steps taken to construct the low priority group are shown schematically in Figure 3:

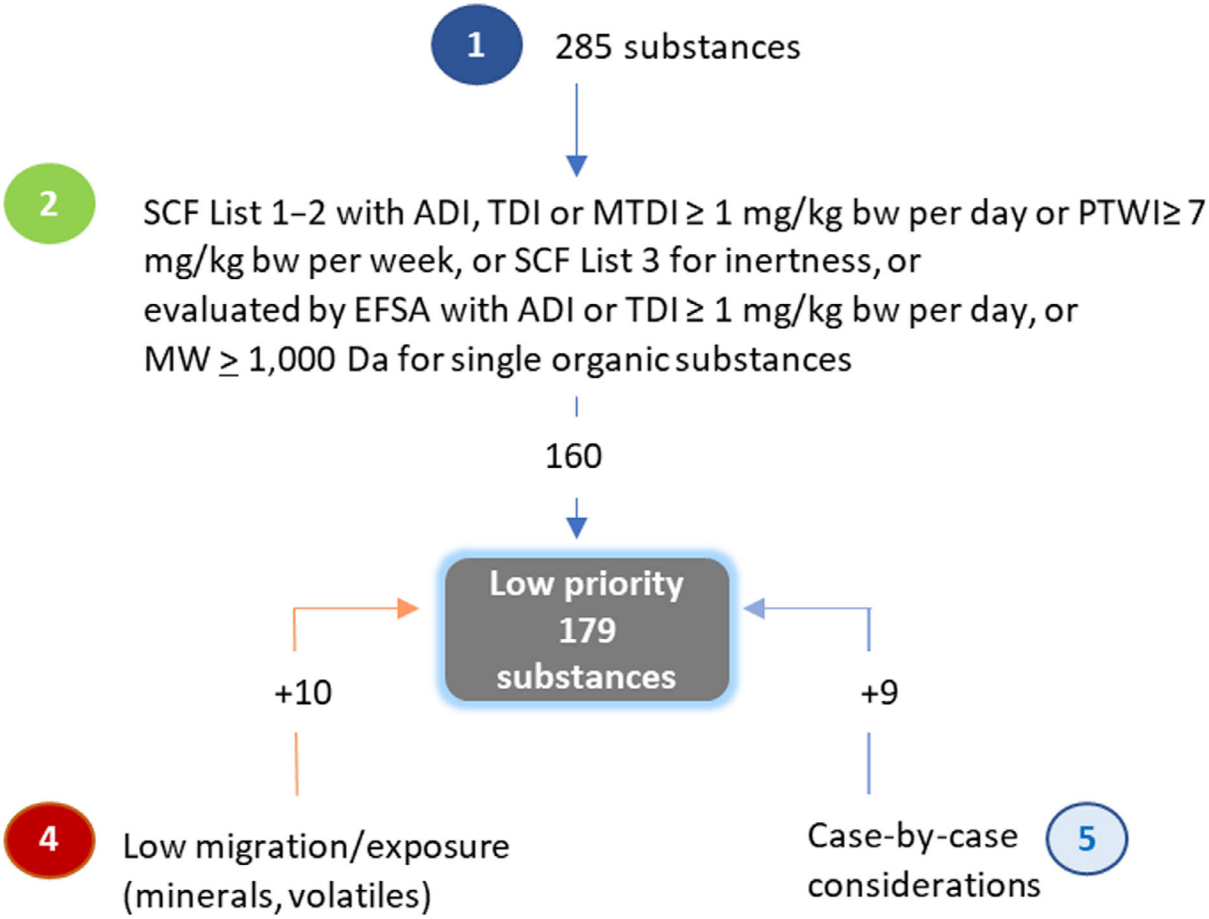

Figure 3: Number of substances placed in the low priority group

The full list of 179 low priority substances is shown in Appendix A, Table A.6. Ten substances that do not fully fall under criterion (a), because of lack of an available or retrievable health-based guidance value were carried forward to the next steps of the prioritisation and are shown in Table A.7.

3.2.3. Medium Priority Group

From the pool of 125 substances remaining after application of the low priority criteria, substances which did not meet the criteria for qualification to high priority were placed in the medium priority group.

Following this rationale, 104 substances were initially placed in the medium priority group. To this group, eight substances were added, because the reasons for initial concern for these substances were considered as not of relevance to the risk assessment of FCMs, as described in Section 3.2.4.4 and in Table A.11.

Ten substances were subsequently excluded from the medium priority group and placed in the low priority group due to very low potential for migration/exposure, as described below (Section 3.2.3.1).

The medium priority group therefore consisted of 102 substances, schematically shown in Figure 3 and listed in Table A.8 of Appendix A.

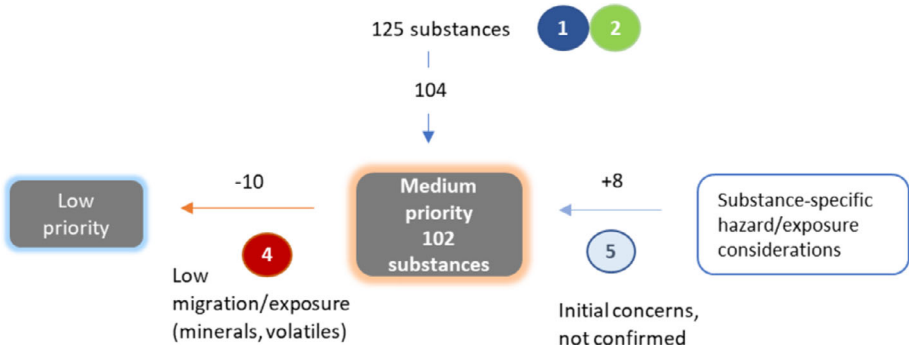

Figure 4: Number of substances placed in the medium priority group

3.2.3.1. Substances with no or very limited potential for migration/exposure

The Union List entries silicates, natural (with the exception of asbestos) (FCM No 84) and vermiculite, reaction product with citric acid, lithium salt (FCM No 757), are minerals and were considered of a low potential for migration. Therefore, these two substances were moved to the low priority group, as mentioned in the previous section.

The following eight volatile substances were also moved from the medium to the low priority group, after considering the likelihood of exposure and relevant hazard information:

FCM No 126: Acetylene and FCM No 125: Ethylene.

Toxicological data on acetylene are limited. According to the reported toxicological studies from ECHA registrations,[18] acetylene was negative in three *in vitro* mutagenicity tests and gave no indications for genotoxicity.

According to the available toxicological studies on ethylene, a low toxicity can be assumed[19] (OECD, 2002). However, inhaled ethylene can be metabolically converted to ethylene oxide. Ethylene oxide is a potent alkylating agent and classified as a carcinogen (IARC, 1994). DNA and haemoglobin-adducts have also been detected after exposure to ethylene in animals, although *in vitro* and *in vivo* genotoxicity studies gave no indications for genotoxicity (OECD, 2002). Furthermore, a long-term inhalation study generated no convincing evidence of carcinogenicity in rats. This absence of toxicity may be due to saturation of ethylene metabolism (Segerbäck, 1983). Indeed, the metabolic conversion of ethylene to ethylene oxide seems to be a rate-limiting step whereby the produced amount of ethylene oxide via inhalation is insignificant (Bolt and Filser, 1987, Csanády et al., 2000, as reported from ECHA registrations[20]). No information regarding absorption, distribution, metabolism and excretion (ADME) and carcinogenicity are available for the oral route.

The two substances are gases with very low boiling points of −100°C for ethylene and −84°C for acetylene. Due to the very high volatility of these monomers, it can be expected that they will be effectively volatilised after the polymerisation process and during manufacture of the food contact polymers. On this basis, exposure to ethylene and acetylene due to migration from food contact materials can be excluded. Consequently, these two substances are moved to the low priority group.

FCM No 131: 1,1-Difluoroethane

According to the OECD Existing Chemicals Database (OECD, 2006), 1,1-difluoroethane was tested negative in an *in vitro* bacterial reverse mutation test (Ames test) but showed a weak clastogenic response in an *in vitro* human lymphocyte chromosome aberration test in the absence of metabolic activation. The clastogenic potential was further tested in an *in vivo* micronucleus assay which gave negative results. No treatment-related tumours were observed in male and female rats in a 2-year inhalation study. In addition, the 2-year inhalation study revealed no clear evidence of toxicity from repeated exposure to 1,1-difluoroethane at concentrations of up to 67,500 mg/m^3.

1,1-Difluoroethane is a gas with a boiling point of −25°C and may be used as a polymer production aid for manufacture of fluorinated polymers. Due to the high volatility of this substance and high temperatures applied in the manufacture of such polymers, it is expected that the substance will be volatilised during manufacture of the food contact polymers and not be any longer present in

[18] https://echa.europa.eu/it/registration-dossier/-/registered-dossier/15518/7/7/2
[19] https://echa.europa.eu/bg/registration-dossier/-/registered-dossier/16094/7/2/1

significant amounts in the final food contact material or article. It is concluded that exposure from food consumption, if any, will be very low and, consequently, this substance is moved to the low priority group.

FCM No 222: 1-Butene, FCM No 224: 2-Butene and FCM No 276: iso-Butene

1-Butene, 2-butene and iso-butene (also known as isobutylene) were assessed within a category approach by the OECD (OECD, 2004). Based on the results presented in the assessment, the substances seem to have a low subchronic toxicity and gave no indications for developmental or reproductive toxicity. In a combined repeated toxicity study with reproduction/development toxicity screening by inhalation exposure, the No Observed Adverse Effect Concentration (NOAEC) was higher than 18,400 mg/m^3 for 1-butene and higher or equal to 11,500 mg/m^3 for 2-butene. Isobutylene was not toxic to rats or mice exposed to concentrations up to 4,600 mg/m^3 for 105 weeks. For all three substances, no mutagenic responses were observed either *in vitro* or *in vivo*.

These three substances are monomers and are gaseous at room temperature, with boiling points of −7°C for 1-butene, ranging from +0.9°C to +3.7°C for 2-butene (*cis/trans* mixture) and −7°C for iso-butene. Due to their high volatility, it can be expected that these substances will be volatilised during manufacture of the food contact polymers and may be present there only in very low residual amounts. Therefore, exposure to these butenes due to migration from food contact materials, if any, will be very low and, consequently, the three substances were moved to the low priority group.

FCM No 143: iso-Pentane and FCM No 244: Pentane

According to publicly available data, studies regarding the general toxicity of iso-pentane are scarce and are restricted to a 4-week oral toxicity screening study (as cited by ECHA[20]). For *n*-pentane, toxicity studies on the oral route are restricted to a reproductive study in rats (McKee et al., 1998) and a 4-week oral nephrotoxicity screening study in rats (API, 1985). Nevertheless, taking into account general ADME and systemic toxicity of n- and iso-alkanes, it is considered that both substances are of low toxicity. According to the available information by ECHA[18], in the 4-week oral toxicity screening study in rats with iso-pentane, mortality was reported to be 10% and 90% in the low- and the high-dose groups (500 and 2,000 mg/kg bw per day), respectively. In the 4-week oral nephrotoxicity screening study on n-pentane, a higher mortality (40%) and narcotic effects (20%) relative to controls were reported in the high-dose group (2,000 mg/kg bw per day). In this study, reported data on histopathology are scarce. Kidneys were the only organs examined microscopically, which were not remarkably changed by the substance. Gross examination of tissue and organs only revealed stomach lesions that could be observed in some animals at the highest dose tested. In a 90-day repeated dose inhalation study in rats with n-pentane, no systemic toxicity was observed up to a dose of at least ≥ 20,000 mg/m^3, equivalent to 1,766 mg/kg bw per day (US-EPA, 2009; ECB, 2003).

These two pentane isomers are substances with boiling points of +28°C for iso-pentane and +36°C for n-pentane, and hence characterised by high intrinsic volatility. These substances when used as polymer production aids are expected to be volatilised during the thermal conditions in the manufacture of food contact polymers and may be present there only in low residual amounts. Therefore, it is concluded that exposure to these pentanes due to migration from food contact materials will be low and, consequently, these two substances are moved to the low priority group.

In total, 10 substances with a low potential for migration or high volatility were moved to the low priority group.

3.2.4. High Priority Group

Substances complying with any of the criteria described in the methodology section (par. 2.2.2.3) were candidates for the high priority group.

3.2.4.1. Information on genotoxicity, carcinogenicity, mutagenicity, reprotoxicity, bioaccumulation and ED properties

- The EFSA OpenFoodTox database was searched for FCM substances not in the low priority group with safety intake levels (ADI, group ADI, TDI and group TDI) below 1 mg/kg bw per day. Two substances were identified: acetone (FCM No 119) and chlorine (FCM No 522).

[20] https://echa.europa.eu/it/registration-dossier/-/registered-dossier/15838/7/6/2/?documentUUID=9566ec40-7702-4480-9931-3169983f21ea

- Three substances were present in the IARC list of classifications: ethanol (FCM No 113), classified as Group 1, styrene (FCM No 193), classified as Group 2A and titanium dioxide (FCM No 610), classified as Group 2B.
- No substances were present in the ECHA Candidate list of SVHCs. The list includes substances which meet the criteria for classification as CMR category 1A or 1B in accordance with the CLP Regulation, substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII, or substances of an equivalent level of concern as CMR or PBT/vPvB substances.
- The FCM substances were also checked against the formal regulatory provisions of CLP and REACH, i.e. the C&L Inventory (Annex VI to CLP) for CLH, the Authorisation List of identified SVHCs (Annex XIV to REACH) and the Restriction List (Annex XVII to REACH). One substance with a restriction under REACH (methanol, FCM No 117) and six substances with a CLH were identified (methanol, FCM No 117; salicylic acid. FCM No 121; styrene, FCM No 193; butane, FCM No 221; carbon monoxide, FCM No 362; and titanium dioxide, FCM No 610). No substances were identified in the Authorisation list of REACH.
- FCM substances not in the low priority group were also checked against the RMOA tool of ECHA, used to identify appropriate regulatory actions or the most appropriate measures to address concerns. Two substances (methanol, FCM No 117 and styrene, FCM No 193) were found under this category. For methanol, it was concluded (in the RMOA) that there is no need to initiate further regulatory risk management action.
- The EU Member States were also requested to provide information on risk assessments of FCM substances conducted at national level. The feedback received, which was mainly based on EFSA hazard assessments, was used as additional information for specific substances, however, it was not used to guide the prioritisation to low, medium and high priority groups. A number of SCF evaluation dossiers were also retrieved through this communication channel.

3.2.4.2. Genotoxicity – *in silico* predictions

One hundred and twenty-five substances passed the criteria as candidates for the medium or high priority groups and reached the (Q)SAR prediction step. For 96 substances, the CAS numbers and chemical names were available. The SMILES codes, needed to run the (Q)SAR models, were retrieved by manually checking on PubChem,[21] ChemIDPlus[22] or ChemSpider,[23] using the CAS numbers as input. The SMILES codes were not found for 13 substances, nine substances were classified as inorganic and one as salt or mixture. Since (Q)SAR models are not able to read inorganic compounds or salts/mixtures, these substances were deleted from the data set. The final data set comprised 73 substances.

VEGA was run using the consensus model for genotoxicity. This model provides a qualitative prediction of mutagenicity (Ames test) based on the outcome of the single VEGA mutagenicity models (CAESAR, SarPy, ISS and KNN). Within the VEGA consensus model for genotoxicity, some elements are statistical-based models and other are built with rules/structural alerts defined by human experts.

The OECD QSAR Toolbox was used applying the following profilers: '*In vitro* mutagenicity (Ames test) alerts by ISS' and 'DNA alerts for AMES by OASIS'. Only the models predicting genotoxicity based on the Ames test were selected as models proving most reliable predictions (Benigni et al., 2019; Honma et al., 2019). Indeed, (Q)SAR models providing predictions based on Ames test experimental data give satisfactory results that are comparable with the experimental variability of the test. The reliability of the (Q)SAR models for endpoints other than the Ames test are far less good, giving results close to the random predictions. This can be due to the higher availability and better quality of experimental data for the Ames test used to build the models, compared to the data available for other genotoxicity endpoints.

Results for positive (Mutagen) predictions are reported in Table 2. Negative predictions (Non-mutagen) are reported in Appendix A, in Tables A.9 and A.10.

In the VEGA platform, the level of reliability for the predictions for non-mutagenic (or mutagenic) substances is measured by a score which goes from 0 to 1. If this score is close to zero, the level of uncertainty in the prediction is high. If the score is greater than 0.5, then the level of reliability is acceptable. When the score is 1, it means that experimental data for the specific substance are available in the training/test set of the models.

[21] Available online: https://pubchem.ncbi.nlm.nih.gov/
[22] Available online: https://chem.nlm.nih.gov/chemidplus/
[23] Available online: http://www.chemspider.com/

Out of 73 substances, only one, propylene (FCM No 275), was predicted by VEGA software as 'Mutagen' (Table 2), this substance was predicted with a high score since an experimental value is available. This result was not confirmed by the other two predictions obtained with the OECD QSAR Toolbox that did not find any structural alert. However, considering the availability of experimental data for this substance, propylene should be considered as a mutagen.

Two substances, propionaldehyde (FCM No 296) and butyraldehyde (FCM No 298), were predicted as positive by the module *In vitro* mutagenicity (Ames test) alerts by ISS within the OECD QSAR ToolBox (Appendix A, Table A.9). The structural alert found is 'simple aldehyde' which has a very low predictivity (33%) (Benigni et al., 2008). These predictions were not confirmed by the other models used. Moreover, for these two substances, the VEGA software has experimental values in support of negative genotoxicity (Appendix A, Table A.9). Considering the availability of experimental data, propionaldehyde and butyraldehyde should be considered as non-mutagenic. In addition, the EFSA CEF Panel (EFSA CEF Panel, 2017) ruled out a safety concern regarding genotoxicity and the two substances are authorised food flavourings.

For the substance lauric acid, vinyl ester (FCM No 436), a structural alert (alpha, beta-unsaturated aliphatic alkoxy group) was found for the module *In vitro* mutagenicity (Ames test) alerts by ISS within the OECD QSAR ToolBox (Table 2). The predictivity of the structural alert found (50%) is not very high and the prediction is not confirmed by the other models. However, experimental values are not available. Following a conservative approach, this substance should be considered as mutagenic.

The two substances amines, bis(hydrogenated tallow alkyl) oxidised (FCM No 768) and ascorbyl stearate (FCM No 591) were predicted as positive based on the module 'DNA alerts for AMES by OASIS' present in the OECD QSAR ToolBox (Table 2). The predictions were not confirmed by the other models. However, the negative predictions obtained with VEGA for these substances have a low predictivity score (Table 2) that may indicate low reliability of the result. Based on this, to be conservative, these substances should be considered as mutagenic before further analyses.

Table 2: Results for positive predictions from VEGA or OECD QSAR ToolBox

			OECD QSAR ToolBox		VEGA			
FCM no	**CAS no**	**Chemical name**	***In vitro* mutagenicity (Ames test) alerts by ISS**	**DNA alerts for AMES by OASIS**	**Consensus Model**	**Mutagenic score**	**Non-mutagenic score**	**Experimental data available**
275	115-07-1	Propylene	No alert found	No alert found	Mutagenic	1	0	YES
436	2146-71-6	Lauric acid, vinyl ester	Alpha,beta-unsaturated aliphatic alkoxy group	No alert found	Non-mutagenic	0	0.825	NO
591	10605-09-1	Ascorbyl stearate	No alert found	AN2 >> Schiff base formation >> Dicarbonyl compounds	Non-mutagenic	0	0.45	NO
768	143925-92-2	Amines, bis (hydrogenated tallow alkyl) oxidised	No alert found	'SN2 >> Acylation >> N-Hydroxylamines; SN1 >> Nucleophilic attack after nitrenium ion formation >> N-Hydroxylamines; Radical >> Radical mechanism via ROS formation (indirect) >> N-Hydroxylamines; AN2 >> Carbamoylation after isocyanate formation >> N-Hydroxylamines'	Non-mutagenic	0	0.4	NO

A total of 72 substances were predicted as negative by VEGA, 68 of which had a consensus score ≥ 0.5 (Appendix A, Table A.9). Out of 68 substances, 36 had experimental data confirming the non-mutagenicity activity. For the other substances, the negative predictions were supported by the results obtained with the other two profilers available in the OECD QSAR ToolBox, except for one substance (lauric acid, vinyl ester, FCM No 436) for which a structural alert was found with the other two models available in the OECD QSAR ToolBox (α,β-unsaturated aliphatic alkoxy group) with the module of *in vitro* mutagenicity (Ames test) alerts by ISS. This substance was already considered above. Four substances were predicted as negative (non-mutagenic) by VEGA with a score < 0.5 (Appendix A, Table A.10). Experimental data for these substances were not available. The negative predictions in VEGA were supported by the results obtained with the other two profilers available in the OECD QSAR ToolBox, except for two substances (FCM No 591 and FCM No 768) for which structural alerts were found; these substances have already been discussed above (Table 2).

3.2.4.3. Alerts from existing priority lists and screening

- Two FCM substances were found in the SIN List: styrene (FCM No 193) and carbon monoxide (FCM No 362).
- The ECHA database of chemicals registered under REACH and CLP was searched for ongoing risk evaluations, i.e. for substance registrations that have passed the initial screening and compliance check phases and are in the substance evaluation phase. Two substances are currently under assessment by ECHA: Styrene (FCM No 193) under RMOA for concerns on endocrine disruption, mutagenicity and reprotoxicity, and Rosin, hydrogenated, ester with glycerol (FCM No 718): under evaluation as PBT.
- No FCM substances of interest were found in the EFSA priority list of potential emerging risks.

3.2.4.4. Case-by-case considerations of candidate substances for the high priority group

Eight substances originally identified as being evaluated by ECHA were excluded from the high priority group due to lack of relevance to FCM risk assessment. These substances remain in the medium priority group and are listed in Appendix A, Table A.11.

The 10 substances: ethanol (FCM No 113), methanol (FCM No 117), acetone (FCM No 119), butane (FCM No 221), propylene (FCM No 275), carbon monoxide (FCM No 362), chlorine (FCM No 552), ascorbyl stearate (FCM No 591), titanium dioxide (FCM No 610) and amines, bis(hydrogenated tallow alkyl) oxidised (FCM No 768), were also excluded, for the reasons described below. The initial alerts for these substances are listed in Appendix A, Table A.12.

FCM No 113: Ethanol

Ethanol was classified by IARC with carcinogenic hazard to humans in Group 1 based on the evidence of cancers observed in heavy drinkers of alcoholic beverages (IARC, 2012). Potential exposure due to migration of ethanol from plastics when used as a substance for the manufacture of polymers is expected to be several orders of magnitude lower than that from alcoholic beverages. Ethanol is authorised as an extraction solvent to be used in compliance with good manufacturing practice for all uses, during the processing of raw materials, of foodstuffs, of food components or of food ingredients.[24] It is concluded that the toxicological and epidemiological basis for the IARC classification is not relevant (in terms of dose) for the potential migration of ethanol from FCMs, and hence, ethanol is placed into the low priority group.

FCM No 117: Methanol

EFSA evaluated the available toxicological information on methanol in the frame of its safety evaluation of the food additive aspartame (E 951) since metabolism of aspartame releases a corresponding 10% by weight of methanol (EFSA ANS Panel, 2013). The ANS Panel concluded that there would be no risk from methanol derived from aspartame, at the ADI for aspartame of 40 mg/kg bw per day.

The ANS Panel also considered the metabolite of methanol, formaldehyde, in its risk assessment. It concluded that based on measurements of basal levels of formaldehyde in blood and on the modelling of its biological turnover and steady-state concentration in cells, formaldehyde formed from

[24] Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (Recast) OJ L 141, 6.6.2009, p. 3–11.

aspartame-derived methanol would not be of safety concern at the ADI for aspartame of 40 mg/kg bw per day (EFSA, 2014).

These conclusions of the ANS Panel on methanol and on formaldehyde derived from methanol can be used to support that an exposure to methanol of 4 mg/kg bw per day (i.e. 10% of the ADI value for aspartame) is of no safety concern. Since this value is above 1 mg/kg bw per day and according to the prioritisation scheme (Figure 1 and Section 2.2.2.2), methanol was assigned to the low priority group.

FCM No 119: Acetone

Acetone is authorised as an extraction solvent to be used in compliance with good manufacturing practice for all uses during the processing of raw materials, of foodstuffs, of food components or of food ingredients.[25] The EFSA CONTAM Panel established for acetone a health-based guidance value of 0.9 mg/kg bw per day (EFSA CONTAM Panel, 2012), similar to the reference dose for oral exposure previously established by U.S. EPA (US-EPA, 2003). This value was derived from a No Observed Adverse Effect Level (NOAEL) of 900 mg/kg bw per day, identified in a 90-day oral study in rats. In the absence of data from chronic exposure, the CONTAM Panel and the US EPA used an additional safety factor of 10, beyond the standard safety factor of 100, to allow for possible chronic exposure. However, according to the Scientific Committee Guideline on default values to be used in the absence of measured data (EFSA Scientific Committee, 2012), an additional factor of 2, instead of 10, should be used to extrapolate from subchronic to chronic exposure. This would result in an ADI higher than 1 mg/kg bw per day, with consequent allocation of acetone to the low priority group. Consequently, acetone is moved to the low priority group.

FCM No 221: Butane

Butane is classified as carcinogenic and mutagenic according to Regulation (EU) No 1272/2008 when containing more than 0.1% 1,3-butadiene as an impurity. Butane itself is not classified as mutagenic and carcinogenic. 1,3-Butadiene is regulated under Regulation (EU) No 10/2011. Additionally, it is noted that the SCF did not have a toxicological concern about the use of water-based emulsion sprays and oil-based aerosol sprays for baking and frying purposes, which contain propane, butane or isobutane (SCF, 1999). The food additive butane (E 943a) is authorised *quantum satis* in vegetable oil pan spray and water-based emulsion spray, according to Regulation (EC) No 1333/2008. Butane is authorised as an extraction solvent to be used in compliance with good manufacturing practice for all uses during the processing of raw materials, of foodstuffs, of food components or of food ingredients[25]. Butane is a gas with a boiling point of −1°C, thus, any exposure from FCM is expected to be low. Consequently, for these reasons, butane is moved to the low priority group.

FCM No 275: Propylene

IARC (1994) did not classify propylene as a carcinogen to humans but indicated that: 'Alkylation products of the metabolite, propylene oxide, were found in haemoglobin and in DNA from mice exposed to propylene by inhalation'. The mutagenicity potential is considered to be associated with the formation of propylene oxide (possibly carcinogenic to humans (IARC, 1994)). Propylene was tested positive in one bacteria strain with metabolic activation (Ames test). *In vivo* tests of propylene were reported as negative (OECD, 2003).

Propylene is a gas with a boiling point of −48°C. Due to the high volatility of this substance and the relatively high intrinsic diffusion properties of polypropylene polymers it can be expected that the substance will be effectively volatilised during manufacture of the food contact polymers. It is concluded that significant amounts of propylene in food contact materials are unlikely and, hence, exposure from food consumption is considered to be low, if any. Consequently, propylene is moved to the low priority group.

FCM No 362: Carbon monoxide

Carbon monoxide is classified as toxic for reproduction according to Annex VI of Regulation (EC) No 1272/2008. However, based on the boiling point of carbon monoxide (−191°C), it is concluded that its presence and subsequent migration in/from food contact materials are highly unlikely and hence exposure from food consumption can be excluded. Consequently, carbon monoxide is moved to the low priority group.

FCM No 552: Chlorine

The AFC Panel in 2006 endorsed the ADI from WHO set at 0.15 mg/kg bw per day for chlorine. Migration to food could lead to what have become known as chlorinated byproducts. However, it is considered that migration of chlorine into food would be negligible, if any, due to its high reactivity, high volatility (boiling point of −34°C) and self-limiting odor. Chlorine may also be used for the chlorination of polyolefins and the low molecular weight fraction of such polymers may contain chlorinated species of potential toxicological concern. Reaction and transformation products including oligomers are outside the scope of this prioritisation exercise (see section 1.2). Based on these considerations, the CEP Panel moved chlorine to the low priority group.

FCM No 591: Ascorbyl stearate

Ascorbyl stearate (FCM No 591) is very similar in structure to ascorbyl palmitate (FCM No 321) but whereas the palmitate had a positive SCF Opinion placing it into SCF List 1, the stearate seems to have been assigned to SCF list 1 in the Synoptic document by an assumed read-across from the palmitate but with no traceable SCF Opinion. Ascorbyl stearate and ascorbyl palmitate are authorised for use as food additives (E 304(i) and E 304(ii)) in the EU and the EFSA ANS Panel re-evaluated these additives in 2015 (EFSA ANS Panel, 2015). The CAS numbers for the food additives are the same as those for the food contact substances and refer specifically to the enantiomers L-ascorbyl palmitate and L-ascorbyl stearate (CAS Nos. 137-66-6 and 10605-09-1, respectively). Although the available toxicological data were too limited to establish an ADI, the ANS Panel concluded that there is no safety concern for the use of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii)) as food additives at the reported uses and use levels, which could give exposure (individually or in combination) of up to 10.8 mg/kg bw per day. Based on this information, both ascorbyl stearate and ascorbyl palmitate are placed into the low priority group.

FCM No 610: Titanium dioxide

Titanium dioxide is used by the food industry in the EU in different applications. In the food contact material sector TiO2 is authorised, but not in a nanoform (Regulation (EU) No 10/2011). Titanium dioxide is also authorised for use as a food additive (E 171) in many food categories, but its specifications do not characterise its particle size distribution (Regulation (EU) No 231/2012[25], current consolidated version of 23/10/2019). EFSA has been requested to review new and emerging evidence on several occasions (EFSA ANS Panel, 2016b; EFSA ANS Panel, 2018; EFSA, 2019; EFSA FAF Panel, 2019). In 2016, the EFSA ANS Panel completed the re-evaluation of titanium dioxide E 171 (EFSA ANS Panel, 2016b). Due to limitations of the toxicity database, the ANS Panel did not establish an ADI but used a Margin of Safety (MoS) approach based on an NOAEL of 2,250 mg/kg bw per day from a long-term chronic study in mice and rats. The calculated MoS was 400 at the mean and 150 at the 95th percentile. The ANS Panel concluded that at the estimated levels of exposure the food additive E 171, which, according to the data reported by the food industry, contains a small component of unavoidable but unintended nanoparticles, was not of safety concern. The ANS Panel recommended the characterisation of the particle size distribution of the food additive E 171. In order to address the uncertainties in the characterisation of the material and in the limitations of the database, the European Commission launched a public call for data on the particle size distribution, and for the performance of a new extended one-generation reproductive toxicity study (EOGRTS) in rodents. In 2019, the FAF Panel proposed in its published opinion an amendment of the EU specifications for the food additive titanium dioxide (E 171) (EFSA FAF Panel, 2019). A new scientific opinion on the safety of titanium dioxide (E 171) considering all the new relevant data including those falling under the scope of the 2018 Scientific Committee Guidance (EFSA Scientific Committee, 2018) on nanotechnologies is expected by the end of 2020.[26]

The EFSA CEP Panel recently evaluated the food contact substance 'titanium dioxide surface treated with fluoride-modified alumina' which is a defined mixture of particles of which a fraction of particles have a diameter in the range of 1–100 nm (EFSA CEP Panel, 2019). This is intended to be used as filler and colourant up to 25% w/w in potentially all polymer types. The data evaluated demonstrated that the plastic additive particles stay embedded even in swollen polar polymers such as polyamide, and do not migrate, neither by diffusion nor as a result of abrasion. From these data along with

[25] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.
[26] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262

theoretical considerations it can be concluded that for the substance titanium dioxide, modified or not, used as a plastic additive, no migration can be anticipated.

Therefore, based on the above considerations, in the specific context of food contact materials, titanium dioxide is placed into the low priority group.

FCM No 768: Amines, bis(hydrogenated tallow alkyl) oxidised

The substance 'Amines, bis(hydrogenated tallow alkyl) oxidised' has been evaluated by the SCF (SCF, 2003) for its use as a processing stabiliser in polyolefins at up to 0.1% (w/w) and in PET up to 0.25% (w/w). It includes: (i) the main substance, bis(hydrogenated tallow, C16–C18, alkyl) hydroxylamine (63–80%) along with lower amounts of; (ii) bis(hydrogenated tallow, C16–C18, alkyl) amine (12–20%); (iii) bis(hydrogenated tallow, C16–C18, alkyl) nitrones (2–10%); (iv) hydrogenated tallow, C16–C18, alkyl) oximes (2–10%); (v) fatty acids (C16–C18) (0–5%); and (vi) (C16–C18) secondary amides (0–7%).

According to the SCF opinion, Amines, bis(hydrogenated tallow alkyl)oxidised, as well as the three migrating substances (ii, iii and iv above) did not show genotoxic properties in the available *in vitro* studies (gene mutations assays in bacteria and cultured mammalian cells and *in vitro* chromosomal aberration studies). Therefore, the *in silico* alerts obtained for this substance, which triggered its consideration for the high priority group, are over-ruled by the experimental data available.

According to the SCF 2003 evaluation, the main component, bis(hydrogenated tallow, C16–C18, alkyl) hydroxylamine, was not found to migrate and the other components and/or reaction products do not follow a uniform pattern of migration from different types of polyolefins under different time/temperature conditions. For these reasons, an SML was not set by the SCF, which suggested instead, restrictions of use in polyolefins and PET. These were incorporated into regulatory provisions, currently described in Regulation (EU) No 10/2011 as 'Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down. Only to be used in: (a) polyolefins at 0.1% (w/w) and in (b) PET at 0.25% (w/w)'. Considering that the substance is already regulated by restriction of use in polymers and with the exclusion of fatty food contact, the substance Amines, bis(hydrogenated tallow alkyl) oxidised is placed into the group 'no SML should be needed'.

3.2.4.5. The high priority group of substances

Following the considerations described in the previous section and schematically shown in the flowchart of Figure 5, three substances comprise the final high priority group, listed in Table 3. The evidence from risk evaluations and predictions is summarised in Appendix A, Table A.13.

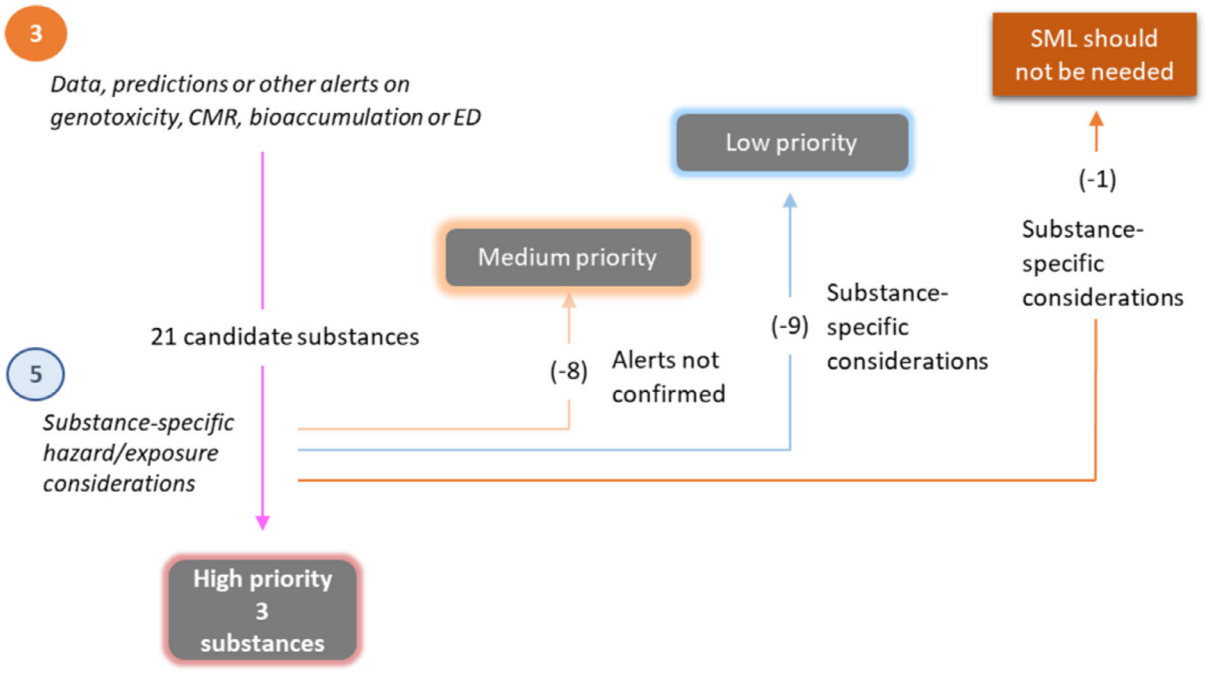

Figure 5: Number of substances placed in the high priority group

Table 3: Substances of the high priority group

FCM substance no.	CAS No.	Substance name
121	69-72-7	Salicylic acid
193	100-42-5	Styrene
436	2146-71-6	Lauric acid, vinyl ester

FCM No 121: Salicylic acid

Classification of salicylic acid is based on teratogenic properties shown in animals (ECHA, 2016b). Based on the lowest NOAEL of 75 mg/kg bw per day from a developmental toxicity study in rats (Tanaka et al., 1973a,b), the most sensitive species, a tolerable daily intake below 1 mg/kg bw per day could be derived by applying a default uncertainty factor of 100 for inter- and intra-species differences. Therefore, this substance was placed in the high priority group.

FCM No 193: Styrene

As a consequence of a Commission request to assess the IARC reclassification of its carcinogenicity, styrene is currently under risk evaluation by the EFSA CEP Panel.[27] According to the European Commission mandate, EFSA should assess whether the evidence examined by IARC would have an impact on the safety of styrene in FCMs and if needed, should determine under what conditions the substance could be safely used in FCM. Therefore, styrene was placed in the high priority group and its re-evaluation by EFSA is taking place in the context of another mandate.

FCM no. 436: Lauric acid, vinyl ester

According to the Synoptic Document (European Commission, 2005), complete hydrolysis occurs in simulated intestinal fluid into lauric acid (FCM No 330, no SML) and acetaldehyde (FCM No 128, SML (T) of 6 mg/kg food). Gene mutations and chromosomal aberrations observed in *in vitro* studies are most likely due to the formation of acetaldehyde. According to Table 2 of Annex I of Regulation (EU) No 10/2011, the group restriction no. (1) with an SML(T) of 6 mg/kg food (expressed as acetaldehyde), covers also propionic acid, vinylester (FCM No 211), which like lauric acid, vinyl ester, is a chemical precursor of acetaldehyde *in vivo*. Therefore, lauric acid, vinyl ester, was placed in the high priority group and it is proposed to include it on a temporary basis into the group restriction no. (1) with an SML(T) of 6 mg/kg food, expressed as acetaldehyde, pending a full evaluation.

4. Discussion

As requested by the Terms of Reference of the mandate received from the European Commission, the CEP Panel has undertaken this review and prioritisation exercise for substances that are listed without a specific migration limit in Table 1 of Annex 1 of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Certain substances may require an SML (or some other form of limitation) to ensure that their authorisation is sufficiently protective to health.

The Panel considers that prioritisation is a ranking process and it is not a (final) evaluation of any of the substances involved. For this reason, this Opinion has identified substances for which an SML should not be needed along with substances for which an SML may be needed, placed into low, medium and high priority groups. The high, medium and low priority groups should not be interpreted as meaning that an SML is necessary. Rather, the absence of an SML merits further consideration which should be guided by the prioritisation provided.

This review and prioritisation were conducted using existing information that could be retrieved for each substance. As mandated by the Terms of Reference, there was not a call for data from interested parties (other than Member States) nor from business operators that may use the substances. The number of substances actually used nowadays by the industry is not known. Similarly, the technical function and therefore the extent and conditions of use of many substances are not obvious.

Regarding the absence of a call for data, the Panel takes note of the provisions in the Regulation (EC) No 1935/2004, the so-called 'Framework Regulation' on plastic materials and articles. That Regulation provides for the listing of substances. Those substances listed and thus 'authorised' can be used by everyone, subject to the restrictions set out in the authorisation. Importantly, at Article 10

[27] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686

('Opinion of the Authority') it is a requirement that *'The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment*.' This being the case, even in the absence of any call for data for this prioritisation exercise, business operators have the responsibility to inform the Commission of any relevant information that may have developed since the authorisation was made.

The main criteria used for prioritisation were hazard-based. This took into account existing hazard assessments that could be retrieved for each substance on CMR, bioaccumulation and ED properties and from the qualified structure–activity relationship ((Q)SAR) profiles regarding alerts for genotoxicity. Use of (Q)SAR profilers other than predictions on mutagenicity (based on the Ames test) proved not to be reliable (e.g. alerts for *in vivo* micronucleus test, for the chromosomal aberration endpoint).

A modelling approach to understand relative levels of exposure was not carried out. It was precluded by the high number and the nature of the uncertainties, mostly stemming from the absence of information on the types of use, use levels and migration levels, of the substances in/from plastic materials in contact with food. The exposure considerations were limited to the default assumption of a person of body weight of 60 kg consuming a maximum of 1 kg of food per day and that food containing the substance having migrated from a plastic used in contact with the food (SCF, 2001). This default exposure scenario is conservative, especially for substances that are used in only niche applications. On the other hand, exposure from other dietary sources, including from non-plastic FCM, is not known. Also, as already noted, this scenario is generally protective for adults but not necessarily for infants, toddlers or young children due to their higher relative food consumption on a body weight basis compared to that of adults (EFSA CEF Panel, 2016).

The potential for consumer exposure considered the physico-chemical properties of the substances, notably the molecular weight and boiling point. According to a general understanding of the diffusion process by which chemical migration occurs, the molecular weight (more exactly, the size) of a substance is a major determinant in the extent of migration. The boiling point of a substance indicates its volatility and thus informs on the likelihood or not of the persistence of a substance in a manufactured FCM – which in turn will influence the possible migration levels. These properties of molecular weight (–> size) and boiling point (–> volatility) are used and discussed in a narrative manner in the cases where no clear cut-off values can be derived and used as such.

5. Conclusions

A total of 451 substances for which an SML or SML(T) was not assigned were put through the prioritisation procedure. These substances were taken from Table 1, Annex I of Regulation (EU) No 10/2011, as amended by Regulation (EU) 2019/37 of 10 January 2019. The full list of substances without an SML or SML(T) is provided in Appendix A, Table A.1.

Seventy-eight substances have been evaluated previously by EFSA as food contact substances, and therefore, they were eliminated at the outset, according to the mandate received. The list of substances and the corresponding EFSA opinions is provided in Appendix A, Table A.2.

For 89 substances, it was concluded by the Panel that an SML should not be needed. The 89 substances for which an SML should not be needed are listed in Appendix A, Table A.5. The main criteria that defined this group were:

- an SCF classification as List 0 or List 1, and/or
- an 'ADI not specified' by the SCF, and/or
- substances that are controlled by existing restrictions and/or generic limits (e.g. salts where the anion is controlled by the general metal-related SMLs on the corresponding cation) and
- no conflict with subsequent EFSA evaluations in domains other than food contact plastics.

One hundred and seventy-nine substances were placed in the low priority group. The list of 179 low priority substances is shown in Appendix A, Table A.6. The main criteria that defined this group were substances:

- for which other EFSA Panels have assigned or endorsed an ADI of ≥ 1 mg/kg bw per day (22 substances, mainly food additives and flavouring substances), and/or
- having an ADI set by the SCF of ≥ 1 mg/kg bw per day (102 substances), and/or
- with a molecular weight above 1,000 Da (39 substances), and/or
- classified by the SCF as List 3 'inert' (26 substances), and/or
- with high volatility (8 substances)

One hundred and two substances were placed in the medium priority group. The list of 102 medium priority substances is shown in Appendix A, Table A.8. This group comprises substances for which the information available was not adequate to place them into the 'low', 'high' or 'no SML needed' groups.

Three substances were placed into the high priority group. These three substances that are judged to merit the highest priority for reassessment are salicylic acid (FCM No 121), styrene (FCM No 193) and lauric acid, vinyl ester (FCM No 436). The evidence from risk evaluations and predictions for these high priority substances is summarised in Appendix A, Table A.13. The high prioritisation was due to:

- hazard alert(s) from one or more of evaluations by IARC, ECHA or EFSA and/or from (Q)SAR predictions, and
- where the hazard alert was not over-ruled by considerations of low migration/exposure, and/or absence of relevance of the alert to FCM.

6. Recommendations

For lauric acid, vinyl ester, the Panel recommends to include this substance on a temporary basis into the group restriction no. (1) with an SML(T) of 6 mg/kg food, expressed as acetaldehyde, pending a full evaluation.

References

API (American Petroleum Institute), 1985. Four-week oral nephrotoxicity screening study in male F344 rats. TSCATS Section FYI. Fiche #OTS0000280-2 Unpublished report. Cited in US-EPA, 2009. Available online: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0128tr.pdf

Benfenati E, Roncaglioni A, Lombardo A and Manganaro A, 2019. Integrating QSAR, Read-Across and Screening Tools: the VEGAHUB Platform as an Example. In: Huixiao H (ed.). Advances in Computational Toxicology: methodologies and Applications in Regulatory Science. Springer Nature, pp. 365–382. https://doi.org/10.1007/978-3-030-16443-0_18

Benigni R, Bossa C, Jeliazkovab N, Netzevac T and Worthc A, 2008. The Benigni/Bossa rulebase for mutagenicity and carcinogenicity – a module of Toxtree. EUR 23241 EN – 2008. Available online: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/benigni-bossa-rulebase-mutagenicity-and-carcinogenicity-module-toxtree

Benigni R, Battistelli CL, Bossa C, Giuliani A, Fioravanzo E, Bassan A, Gatnik MF, Rathman J, Yang C and Tcheremenskaia O, 2019. Evaluation of the applicability of existing (Q)SAR models for predicting the genotoxicity of pesticides and similarity analysis related with genotoxicity of pesticides for facilitating of grouping and read across. EFSA supporting publication 2019:EN-1598, 221 pp. https://doi.org/10.2903/sp.efsa.2019.en-1598

Bolt HM and Filser JG, 1987. Kinetics and disposition in toxicology. Archives of Toxicology, 60, 73–76. https://doi.org/10.1007/BF00296951

Ceriani L, Ciacci A, Baldin R, Kovarich S, Pavan M, Fioravanzo E and Bassan A, 2018. Final report on the update and maintenance of OpenFoodTox: EFSA's Chemical Hazards Database. EFSA supporting publication 2018:EN-1438, 59 pp. https://doi.org/10.2903/sp.efsa.2018.en-1438

Csanády GA, Denka B, Pütz C, Kreuzer PE, Kessler W, Bau C, Gargas ML and Filser JC, 2000. A Physiological Toxicokinetic Model for Exogenous and Endogenous Ethylene and Ethylene Oxide in Rat, Mouse, and Human: formation of 2-Hydroxyethyl Adducts with Hemoglobin and DNA. Toxicology and Applied Pharmacology, 165, 1–26. https://doi.org/10.1006/taap.2000.8918

Dorne JL, Richardson J, Kass G, Georgiadis N, Monguidi M, Pasinato L, Cappe S, Verhagen H and Robinson T, 2017. Editorial: openFoodTox: EFSA's open source toxicological database on chemical hazards in food and feed. EFSA Journal, 15, e15011, 3pp. https://doi.org/10.2903/j.efsa.2017.e15011

ECB (European Chemicals Bureau), 2003. European Union Risk Assessment Report. Pentane (CAS No: 109-66-0. EINECS No: 203-692-4). Joint Research Center - Institute for Health and Consumer Protection (JRC-IHCP). Available online: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC26088/EUR%2020845%20EN.pdf

ECHA (European Chemical Agency), 2016a. Preparation of an inventory of substances suspected to meet REACH Annex III criteria. Technical documentation. Available online: https://echa.europa.eu/documents/10162/22332820/annex_iii_preparation_inventory_en.pdf/e42ea5b1-28f0-4390-8d34-6d09e2875ebd

ECHA (European Chemical Agency), 2016b. Committee for Risk Assessment (RAC), Opinion proposing harmonised classification and labelling at EU level of Salicylic acid, EC Number: 200-712-3, CAS Number: 69-72-7, CLH-O-0000001412-86-110/F, Adopted 10 March 2016. Available online: https://echa.europa.eu/documents/10162/13794bcd-8882-b609-46b4-a4bc1263e6e3

ECHA (European Chemicals Agency), 2019. Plastic additives initiative. Supplementary Information on Scope and Methods. Available online: https://echa.europa.eu/documents/10162/13630/plastic_additives_supplementary_en.pdf

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 6th list of substances for food contact materials. EFSA Journal 2004;161, 13 pp. https://doi.org/10.2903/j.efsa.2004.161

EFSA (European Food Safety Authority), 2008. Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials. Available online: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2008.21r

EFSA (European Food Safety Authority), 2014. Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources. EFSA Journal 2014;12(2):3550, 11 pp. https://doi.org/10.2903/j.efsa.2014.3550

EFSA (European Food Safety), 2019. EFSA statement on the review of the risks related to the exposure to the food additive titanium dioxide (E 171) performed by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). EFSA Journal 2019;17(6):5714, 11 pp. https://doi.org/10.2903/j.efsa.2019.5714

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2013. Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive. EFSA Journal 2013;11(12):3496, 263 pp. https://doi.org/10.2903/j.efsa.2013.3496

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii)) as food additives. EFSA Journal 2015;13(11):4289, 57 pp. https://doi.org/10.2903/j.efsa.2015.4289

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016a. Scientific opinion on the re-evaluation of β-cyclodextrin (E 459) as a food additive. EFSA Journal 2016; 14(12):4628, 44 pp. https://doi.org/10.2903/j.efsa.2016.4628

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016b. Scientific Opinion on the re-evaluation of titanium dioxide (E 171) as a food additive. EFSA Journal 2016;14(9):4545, 83 pp. https://doi.org/10.2903/j.efsa.2016.4545

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2018. Scientific Opinion on the evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171). EFSA Journal 2018;16(7):5366, 27 pp. https://doi.org/10.2903/j.efsa.2018.5366

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2010. Scientific Opinion on the safety evaluation of the substance, copper hydroxide phosphate, CAS No. 12158-74-6, for use in food contact materials. EFSA Journal 2010;8(10):1838, 11pp. https://doi.org/10.2903/j.efsa.2010.1838.

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016; 14(1):4357, 28 pp. https://doi.org/10.2903/j.efsa.2016.4357

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2017. Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'. EFSA Journal 2017;15(9):4973, 33p. https://doi.org/10.2903/j.efsa.2017.4973

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), 2019. Scientific Opinion on the safety assessment of the substance, titanium dioxide surface treated with fluoride-modified alumina, for use in food contact materials. EFSA Journal 2019;17(6):5737, 11 pp. https://doi.org/10.2903/j.efsa.2019.5737

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012. 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 Journal 2012;10(5):2703, 151pp. https://doi.org/10.2903/j.efsa.2012.2703

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2019. Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution. EFSA Journal 2019;17(7):5760, 23 pp. https://doi.org/10.2903/j.efsa.2019.5760

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 2012;10(3):2579, 32 pp. https://doi.org/10.2903/j.efsa.2012.2579

EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Benfenati E, Chaudhry QM, Craig P, Frampton G, Greiner M, Hart A, Hogstrand C, Lambre C, Luttik R, Makowski D, Siani A, Wahlstroem H, Aguilera J, Dorne J-L, Fernandez Dumont A, Hempen M, Valtueña Mart ınez S, Martino L, Smeraldi C, Terron A, Georgiadis N and Younes M, 2017. Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. https://doi.org/10.2903/j.efsa.2017.4971

EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Chaudhry Q, Cubadda F, Gott D, Oomen A, Weigel S, Karamitrou M, Schoonjans R and Mortensen A, 2018. Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: part 1, human and animal health. EFSA Journal 2018;16(7):5327, 95 pp. https://doi.org/10.2903/j.efsa.2018.5327

European Commission, 2005. 'Synoptic Document'. Provisional list of monomers and additives notified to European Commission as substances which may be used in the manufacture of plastics and coatings intended to come into contact with foodstuffs (updated to June 2005). SANCO D3/AS D(2005).

European Commission, 2014. Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf

Honma M, Kitazawa A, Cayley A, Williams RV, Barber C, Hanser T, Saiakhov R, Chakravarti S, Myatt GJ, Cross KP, Benfenati E, Raitano G, Mekenyan O, Petkov P, Bossa C, Benigni R, Battistelli CL, Giuliani A, Tcheremenskaia O, DeMeo C, Norinder U, Koga H, Jose C, Jeliazkova N, Kochev N, Paskaleva V, Yang C, Daga PR, Clark RD and Rathman J, 2019. Improvement of quantitative structure-activity relationship (QSAR) tools for predicting Ames mutagenicity: outcomes of the Ames/QSAR International Challenge Project. Mutagenesis, 34, 3–16. https://doi.org/10.1093/mutage/gey031

IARC (International Agency for Research on Cancer), 1994. Some industrial chemicals. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 60, 1–560. Available online: http://publications.iarc.fr/78

IARC (International Agency for Research on Cancer), 2012. Personal Habits and Indoor Combustions. Consumption on alcoholic beverages. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 100E, 373-499. Available online: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100E-11.pdf

Loewenstein WR, 1981. Junctional intercellular communication: the cell-to-cell membrane channel. Physiological Reviews, 61, 829–913, 84 pp. https://doi.org/10.1152/physrev.1981.61.4.829

McKee R, Frank E, Heath J, Owen D, Przygoda R, Trimmer G and Whitman F, 1998. Toxicology of n-pentane (CAS No. 109-66-0). Journal of Applied Toxicology, 18, 431–442. https://doi.org/10.1002/(sici)1099-1263(199811/12)18:6<431::aid-jat524>3.0.co;2-l

OECD (Organisation for Economic Co-operation and Development), 2002. SIDS Final Assessment Report. Ethylene. Available online: https://hpvchemicals.oecd.org/UI/handler.axd?id=e5d777a4-516f-4fdb-a76d-4ffec89e3aa3 (accessed 16/04/2020).

OECD (Organisation for Economic Co-operation and Development), 2003. SIDS Final Assessment Report. Propylene. Available online: https://hpvchemicals.oecd.org/UI/handler.axd?id=05bca44c-4720-4926-843d-653-9599b3de4 (accessed 16/04/2020).

OECD (Organisation for Economic Co-operation and Development), 2004. SIDS Final Assessment Report. Butenes. Available online: https://hpvchemicals.oecd.org/UI/handler.axd?id=11f46903-9226-4233-a9db-36a4c2a81e28 (accessed 16/04/2020).

OECD (Organisation for Economic Co-operation and Development), 2006. SIDS Final Assessment Report. 1,1-Difluoroethane. Available online: https://hpvchemicals.oecd.org/UI/handler.axd?id=6415a8cf-4a7b-4c8e-b943-f61ed5304b0d (accessed 16/04/2020).

Oltmanns J, Bohlen M-L, Escher S, Schwarz M and Licht O, 2019. Final report: applying a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH – REACH 2. External Scientific Report. OC/EFSA/SCER/2016/01-CT1.EFSA supporting publication 2019:EN-1597. 263 pp. https://doi.org/10.2903/sp.efsa.2019.en-1597

SCF (Scientific Committee for Food), 1990. First series of food additives of various technological functions (Opinion expressed on 18 May 1990). Reports of the Scientific Committee for Food (Twenty fifth series). Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_reports_25.pdf

SCF (Scientific Committee fo Food), 1999. Opinion on propane, butane and iso-butane as propellant gases for vegetable oil-based aerosol cooking sprays and water-based emulsion cooking sprays. SCF/CS/ADD/MsAd/178 Final. 24 March 1999. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out26_en.pdf

SCF (Scientific Committee for Food), 2001. Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. SCF/CS/PLEN/GEN/100 Final. 19 December 2001. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf

SCF (Scientific Committee for Food), 2003. Opinion of the Scientific Committee on Food on the 22nd additional list of monomers and additives for food contact materials (Opinion expressed on 4 April 2003). SCF/CS/PM/GEN/M94 Final. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out180_en.pdf

Segerbäck D, 1983. Alkylation of DNA and haemoglobin in the mouse following exposure to ethene and ethene oxide. Chemico-Biological Interactions, 45, 139–151. https://doi.org/10.1016/0009-2797(83)90064-9

Tanaka S, Kawashima K, Nakaura S, Nagao S, Kuwamura T, Takanaka A and Omori Y, 1973a. Studies on teratogenic effects of salicylic acid and aspirin in rats as related to fetal distribution. Department of Pharmacology, National Institute of Hygienic Sciences, Tokyo, Japan, 13, 73–84.

Tanaka S, Kawashima K, Nakaura S, Nagao S, Kuwamura T, Takanaka A and Omori Y, 1973b. Studies on the teratogenicity of food additives (3): teratogenic effect of dietary salicylic acid in rats. Journal of the Food Hygienic Society of Japan, 14, 549–557. Available online: https://www.jstage.jst.go.jp/article/shokueishi1960/14/6/14_6_549/_pdf

US-EPA (United States - Environmental Protection Agency), 2003. Toxicological review of acetone. (CAS No. 67-64-1). In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-03/004. Available online: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0128tr.pdf

US-EPA (United States - Environmental Protection Agency), 2009. Provisional Peer-Reviewed Toxicity Values for n-Pentane. (CASRN 109–66-0). EPA/690/R-09/044F. Available online: https://cfpub.epa.gov/ncea/pprtv/documents/Pentanen.pdf

Abbreviations

AFC Panel	EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ADI	Acceptable Daily Intake
ADME	Absorption, Distribution, Metabolism, and Excretion Absorption, Distribution, Metabolism, Excretion
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources Added to Food
CAS	Chemical Abstracts Service
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
C&L	Classification and Labelling
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenicity, Mutagenicity, Reproductive toxicity
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
eMSCA	evaluating Member State Competent Authority
FAF Panel	EFSA Panel on Food Additives and Flavourings
FCM	Food contact materials
GML	Generic Specific Migration Limit
IARC	International Agency for Research on Cancer
JECFA	Joint Expert Committee on Food Additives
MTDI	Maximum Tolerable Daily Intake
MW	Molecular Weight
ND	Not Detectable
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PET	Polyethylene terephthalate
PMTDI	Provisional Maximum Tolerable Daily Intake
(P)TWI	Provisional Tolerable Weekly Intake
(Q)SAR	Quantitative Structure-Activity Relationships
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOA	Regulatory Management Option Analysis
SC	Scientific Committee
SCF	Scientific Committee for Food
SML	Specific Migration Limit
SML(T)	Total Specific Migration Limit
SVHC	Substances of Very High Concern
TDI	Tolerable Daily Intake
t-TDI	temporary Tolerable Daily Intake
ToR	Terms of Reference
vPvB	very Persistent, very Bioaccumulative
WG	Working Group

Appendix A – Tables of substances

Table A.1: Substances without an SML or SML(T)

FCM substance no.	Ref. no.	CAS no.	Substance name
1	12310	266309-43-7	Albumin
2	12340		Albumin, coagulated by formaldehyde
3	12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)
7	30370		Acetylacetic acid, salts
9	30610		Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)
10	30612		Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters
11	30960		Acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol
12	31328		Acids, fatty, from animal or vegetable food fats and oils
13	33120		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C24)
17	34281		Alkyl(C8-C22)sulphuric acids, linear, primary with an even number of carbon atoms
18	34475		Aluminium calcium hydroxide phosphite, hydrate
21	42500		Carbonic acid, salts
22	43200		Castor oil, mono- and diglycerides
24	45280		Cotton fibers
34	54270		Ethylhydroxymethylcellulose
35	54280		Ethylhydroxypropylcellulose
36	54450		Fats and oils, from animal or vegetable food sources
37	54480		Fats and oils, hydrogenated, from animal or vegetable food sources
38	55520		Glass fibers
39	55600		Glass microballs
40	56360		Glycerol, esters with acetic acid
41	56486		Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C14-C18) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C16-C18)
42	56487		Glycerol, esters with butyric acid
43	56490		Glycerol, esters with erucic acid
44	56495		Glycerol, esters with 12-hydroxystearic acid
45	56500		Glycerol, esters with lauric acid
46	56510		Glycerol, esters with linoleic acid
47	56520		Glycerol, esters with myristic acid
48	56535		Glycerol, esters with nonanoic acid
49	56540		Glycerol, esters with oleic acid
50	56550		Glycerol, esters with palmitic acid
51	56570		Glycerol, esters with propionic acid
52	56580		Glycerol, esters with ricinoleic acid
53	56585		Glycerol, esters with stearic acid

FCM substance no.	Ref. no.	CAS no.	Substance name
54	57040		Glycerol monooleate, ester with ascorbic acid
55	57120		Glycerol monooleate, ester with citric acid
56	57200		Glycerol monopalmitate, ester with ascorbic acid
57	57280		Glycerol monopalmitate, ester with citric acid
58	57600		Glycerol monostearate, ester with ascorbic acid
59	57680		Glycerol monostearate, ester with citric acid
60	58300		Glycine, salts
62	64500		Lysine, salts
63	65440		Manganese pyrophosphite
64	66695		Methylhydroxymethylcellulose
65	67155		Mixture of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene, 4,4′-bis(2-benzoxazolyl) stilbene and 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene
67	67840		Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol
75	77702		Polyethyleneglycol esters of aliph. monocarb. acids (c6-c22) and their ammonium and sodium sulphates
79	80640		Polyoxyalkyl (c2-c4) dimethylpolysiloxane
80	81760		Powders, flakes and fibers of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron
81	83320		Propylhydroxyethylcellulose
82	83325		Propylhydroxymethylcellulose
83	83330		Propylhydroxypropylcellulose
84	85601		Silicates, natural (with the exception of asbestos)
85	85610		Silicates, natural, silanated (with the exception of asbestos)
86	86000		Silicic acid, silylated
87	86285		Silicon dioxide, silanated
90	92195		Taurine, salts
94	95859		Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity
95	95883		White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks
96	95920		Wood flour and fibers, untreated
97	720810		Petroleum hydrocarbon resins (hydrogenated)
99	19460 - 62960	50-21-5	Lactic acid
100	24490 - 88320	50-70-4	Sorbitol
101	36000	50-81-7	Ascorbic acid
102	17530	50-99-7	Glucose
103	18100 - 55920	56-81-5	Glycerol
105	22780 - 70400	57-10-3	Palmitic acid
106	24550 - 89040	57-11-4	Stearic acid
107	25960	57-13-6	Urea
108	24880	57-50-1	Sucrose
109	23740 - 81840	57-55-6	1,2-Propanediol
110	93520	59-02-9 10191-41-0	α-Tocopherol
111	53600	60-00-4	Ethylenediaminetetraacetic acid
112	64015	60-33-3	Linoleic acid

FCM substance no.	Ref. no.	CAS no.	Substance name
113	16780 - 52800	64-17-5	Ethanol
114	55040	64-18-6	Formic acid
115	10090 - 30000	64-19-7	Acetic acid
116	13090 - 37600	65-85-0	Benzoic acid
117	21550	67-56-1	Methanol
118	23830 - 81882	67-63-0	2-Propanol
119	30295	67-64-1	Acetone
120	49540	67-68-5	Dimethyl sulphoxide
121	24270 - 84640	69-72-7	Salicylic acid
122	23800	71-23-8	1-Propanol
123	13840	71-36-3	1-Butanol
124	22870	71-41-0	1-Pentanol
125	16950	74-85-1	Ethylene
126	10210	74-86-2	Acetylene
131	48460	75-37-6	1,1-Difluoroethane
136	41680	76-22-2	Camphor
139	14680 - 44160	77-92-9	Citric acid
143	62450	78-78-4	Isopentane
146	23890 - 82000	79-09-4	Propionic acid
155	23470	80-56-8	α-Pinene
158	23380 - 76320	85-44-9	Phthalic anhydride
161	92160	87-69-4	L-(+)-Tartaric acid
162	65520	87-78-5	Mannitol
165	23200 -74480	88-99-3	o-Phthalic acid
171	38080	93-58-3	Benzoic acid, methyl ester
172	37840	93-89-0	Benzoic acid, ethyl ester
173	60240	94-13-3	4-Hydroxybenzoic acid, propyl ester
174	14740	95-48-7	o-Cresol
182	19270	97-65-4	Itaconic acid
189	60200	99-76-3	4-Hydroxybenzoic acid, methyl ester
190	18880	99-96-7	p-Hydroxybenzoic acid
193	24610	100-42-5	Styrene
194	13150	100-51-6	Benzyl alcohol
195	37360	100-52-7	Benzaldehyde
204	25180 - 92640	102-60-3	N,N,N′,N′-tetrakis(2-hydroxypropyl)ethylenediamine
205	25385	102-70-5	Triallylamine
210	13390 - 14880	105-08-8	1,4-Bis(hydroxymethyl)cyclohexane
213	82400	105-62-4	1,2-Propyleneglycol dioleate
214	61840	106-14-9	12-Hydroxystearic acid
215	14170	106-31-0	Butyric anhydride
216	14770	106-44-5	p-Cresol
221	40570	106-97-8	Butane
222	13870	106-98-9	1-Butene
224	13900	107-01-7	2-Butene
228	13690	107-88-0	1,3-Butanediol
229	14140	107-92-6	Butyric acid
232	10150 - 30280	108-24-7	Acetic anhydride
233	24850	108-30-5	Succinic anhydride

FCM substance no.	Ref. no.	CAS no.	Substance name
235	14710	108-39-4	m-Cresol
238	18070	108-55-4	Glutaric anhydride
240	45760	108-91-8	Cyclohexylamine
244	71720	109-66-0	Pentane
247	24820 - 90960	110-15-6	Succinic acid
249	17290 - 55120	110-17-8	Fumaric acid
250	53520	110-30-5	N,N′-Ethylenebisstearamide
251	53360	110-31-6	N,N′-Ethylenebisoleamide
252	87200	110-44-1	Sorbic acid
253	15250	110-60-1	1,4-Diaminobutane
256	18010 - 55680	110-94-1	Glutaric acid
257	13550 - 16660 - 51760	110-98-5	Dipropyleneglycol
258	70480	111-06-8	Palmitic acid, butyl ester
259	58720	111-14-8	Heptanoic acid
260	24280	111-20-6	Sebacic acid
265	22600	111-87-5	1-octanol
266	25510 - 94320	112-27-6	Triethyleneglycol
267	15100	112-30-1	1-decanol
269	25090 - 92350	112-60-7	Tetraethyleneglycol
270	22763 - 69040	112-80-1	Oleic acid
271	52720	112-84-5	Erucamide
272	37040	112-85-6	Behenic acid
273	52730	112-86-7	Erucic acid
275	23980	115-07-1	Propylene
276	19000	115-11-7	Isobutene
279	22840 - 71600	115-77-5	Pentaerythritol
287	60160	120-47-8	4-Hydroxybenzoic acid, ethyl ester
288	24970	120-61-6	Terephthalic acid, dimethyl ester
296	23860	123-38-6	Propionaldehyde
297	23950	123-62-6	Propionic anhydride
298	14110	123-72-8	Butyraldehyde
299	63840	123-76-2	Levulinic acid
300	30045	123-86-4	Acetic acid, butyl ester
301	89120	123-95-5	Stearic acid, butyl ester
302	12820	123-99-9	Azelaic acid
303	12130 - 31730	124-04-9	Adipic acid
304	14320 - 41960	124-07-2	Caprylic acid
306	88960	124-26-5	Stearamide
307	42160	124-38-9	Carbon dioxide
308	91200	126-13-6	Sucrose acetate isobutyrate
309	91360	126-14-7	Sucrose octaacetate
311	16480 - 51200	126-58-9	Dipentaerythritol
314	23500	127-91-3	β-Pinene
320	37680	136-60-7	Benzoic acid, butyl ester
321	36080	137-66-6	Ascorbyl palmitate
322	63040	138-22-7	Lactic acid, butyl ester
327	30140	141-78-6	Acetic acid, ethyl ester
328	65040	141-82-2	Malonic acid

FCM substance no.	Ref. no.	CAS no.	Substance name
329	59360	142-62-1	Hexanoic acid
330	19470 - 63280	143-07-7	Lauric acid
331	22480	143-08-8	1-Nonanol
332	69760	143-28-2	Oleyl alcohol
335	68960	301-02-0	Oleamide
336	15095 - 45940	334-48-5	n-Decanoic acid
338	71020	373-49-9	Palmitoleic acid
339	86160	409-21-2	Silicon carbide
345	35840	506-30-9	Arachidic acid
346	10030	514-10-3	Abietic acid
348	22350 - 67891	544-63-8	Myristic acid
350	63920	557-59-5	Lignoceric acid
360	57920	620-67-7	Glycerol triheptanoate
362	14350	630-08-0	Carbon monoxide
367	16697	693-23-2	n-Dodecanedioic acid
393	37280	1302-78-9	Bentonite
394	41280	1305-62-0	Calcium hydroxide
395	41520	1305-78-8	Calcium oxide
396	64640	1309-42-8	Magnesium hydroxide
397	64720	1309-48-4	Magnesium oxide
399	81600	1310-58-3	Potassium hydroxide
400	86720	1310-73-2	Sodium hydroxide
401	24475	1313-82-2	Sodium sulphide
402	96240	1314-13-2	Zinc oxide
403	96320	1314-98-3	Zinc sulphide
404	67200	1317-33-5	Molybdenum disulphide
406	83300	1323-39-3	1,2-Propyleneglycol monostearate
408	82960	1330-80-9	1,2-Propyleneglycol monooleate
409	62240	1332-37-2	Iron oxide
410	62720	1332-58-7	Kaolin
411	42080	1333-86-4	Carbon black
413	35600	1336-21-6	Ammonium hydroxide
414	87600	1338-39-2	Sorbitan monolaurate
415	87840	1338-41-6	Sorbitan monostearate
416	87680	1338-43-8	Sorbitan monooleate
417	85680	1343-98-2	Silicic acid
418	34720	1344-28-1	Aluminium oxide
419	92150	1401-55-4	Tannic acids
421	13000	1477-55-0	1,3-Benzenedimethanamine
426	13510 - 13610	1675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether
428	95200	1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene
432	12280	2035-75-8	Adipic anhydride
436	19480	2146-71-6	Lauric acid, vinyl ester
441	38160	2315-68-6	benzoic acid, propyl ester
445	83440	2466-09-3	Pyrophosphoric acid
450	24430	2561-88-8	Sebacic anhydride

FCM substance no.	Ref. no.	CAS no.	Substance name
458	36960	3061-75-4	Behenamide
459	46870	3135-18-0	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester
465	68040	3333-62-8	7-[2h-naphtho-(1,2-d)triazol-2-yl]-3-phenylcoumarin
468	71960	3825-26-1	Perfluorooctanoic acid, ammonium salt
478	60180	4191-73-5	4-Hydroxybenzoic acid, isopropyl ester
479	12970	4196-95-6	Azelaic anhydride
480	46790	4221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester
486	54005	5136-44-7	Ethylene-n-palmitamide-n′-stearamide
488	53440	5518-18-3	n,n′-Ethylenebispalmitamide
489	41040	5743-36-2	Calcium butyrate
491	82720	6182-11-2	1,2-Propyleneglycol distearate
494	62140	6303-21-5	Hypophosphorous acid
496	71680	6683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]
499	19965 - 65020	6915-15-7	Malic acid
501	34480		Aluminium fibers, flakes and powders
503	46080	7585-39-9	β-Dextrin
504	86240	7631-86-9	Silicon dioxide
507	59990	7647-01-0	Hydrochloric acid
508	86560	7647-15-6	Sodium bromide
509	23170 - 72640	7664-38-2	Phosphoric acid
510	12789 - 35320	7664-41-7	Ammonia
511	91920	7664-93-9	Sulphuric acid
514	91840	7704-34-9	Sulphur
515	26360 - 95855	7732-18-5	Water
517	81520	7758-02-3	Potassium bromide
518	35845	7771-44-0	Arachidonic acid
520	65120	7773-01-5	Manganese chloride
521	58320	7782-42-5	Graphite
522	14530	7782-50-5	Chlorine
523	45195	7787-70-4	Copper bromide
524	24520	8001-22-7	Soybean oil
525	62640	8001-39-6	Japan wax
526	43440	8001-75-0	Ceresin
527	14411 - 42880	8001-79-4	Castor oil
528	63760	8002-43-5	Lecithin
529	67850	8002-53-7	Montan wax
530	41760	8006-44-8	Candelilla wax
531	36880	8012-89-3	Beeswax
533	42720	8015-86-9	Carnauba wax
534	80720	8017-16-1	Polyphosphoric acids
535	24100 - 24130 - 24190 - 83840	8050-09-7	Rosin
536	84320	8050-15-5	Rosin, hydrogenated, ester with methanol
537	84080	8050-26-8	Rosin, ester with pentaerythritol
538	84000	8050-31-5	Rosin, ester with glycerol
539	24160	8052-10-6	Rosin tall oil

FCM substance no.	Ref. no.	CAS no.	Substance name
541	58480	9000-01-5	Gum arabic
542	42640	9000-11-7	Carboxymethylcellulose
543	45920	9000-16-2	Dammar
544	58400	9000-30-0	Guar gum
545	93680	9000-65-1	Tragacanth gum
546	71440	9000-69-5	Pectin
547	55440	9000-70-8	Gelatin
548	42800	9000-71-9	Casein
549	80000	9002-88-4	Polyethylene wax
550	81060	9003-07-0	Polypropylene wax
551	79920	9003-11-6 106392-12-5	Poly(ethylene propylene) glycol
552	81500	9003-39-8	Polyvinylpyrrolidone
553	14500 - 43280	9004-34-6	Cellulose
554	43300	9004-36-8	Cellulose acetate butyrate
555	53280	9004-57-3	Ethylcellulose
556	54260	9004-58-4	Ethylhydroxyethylcellulose
557	66640	9004-59-5	Methylethylcellulose
558	60560	9004-62-0	Hydroxyethylcellulose
559	61680	9004-64-2	Hydroxypropylcellulose
560	66700	9004-65-3	Methylhydroxypropylcellulose
561	66240	9004-67-5	Methylcellulose
562	22450	9004-70-0	Nitrocellulose
564	24540 - 88800	9005-25-8	Starch, edible
565	61120	9005-27-0	Hydroxyethyl starch
566	33350	9005-32-7	Alginic acid
567	82080	9005-37-2	1,2-Propyleneglycol alginate
568	79040	9005-64-5	Polyethyleneglycol sorbitan monolaurate
569	79120	9005-65-6	Polyethyleneglycol sorbitan monooleate
570	79200	9005-66-7	Polyethyleneglycol sorbitan monopalmitate
571	79280	9005-67-8	Polyethyleneglycol sorbitan monostearate
572	79360	9005-70-3	Polyethyleneglycol sorbitan trioleate
573	79440	9005-71-4	Polyethyleneglycol sorbitan tristearate
574	24250 - 84560	9006-04-6	Rubber, natural
575	76721	63148-62-9	Polydimethylsiloxane (mw > 6,800 da)
576	60880	9032-42-2	Hydroxyethylmethylcellulose
577	62280	9044-17-1	Isobutylene-butene copolymer
579	61800	9049-76-7	Hydroxypropyl starch
580	46070	10016-20-3	α-Dextrin
581	36800	10022-31-8	Barium nitrate
585	41120	10043-52-4	Calcium chloride
586	65280	10043-84-2	Manganese hypophosphite
589	52645	10436-08-5	Cis-11-eicosenamide
591	36160	10605-09-1	Ascorbyl stearate
592	34690	11097-59-9	Aluminium magnesium carbonate hydroxide
593	44960	11104-61-3	Cobalt oxide
594	65360	11129-60-5	Manganese oxide
595	19510	11132-73-3	Lignocellulose

FCM substance no.	Ref. no.	CAS no.	Substance name
596	95935	11138-66-2	Xanthan gum
597	67120	12001-26-2	Mica
598	41600	12004-14-7	Calcium sulphoaluminate
600	60030	12072-90-1	Hydromagnesite
601	35440	12124-97-9	Ammonium bromide
602	70240	12198-93-5	Ozokerite
603	83460	12269-78-2	Pyrophyllite
604	60080	12304-65-3	Hydrotalcite
606	65200	12626-88-9	Manganese hydroxide
607	62245	12751-22-3	Iron phosphide
609	83455	13445-56-2	Pyrophosphorous acid
610	93440	13463-67-7	Titanium dioxide
611	35120	13560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether
613	95905	13983-17-0	Wollastonite
614	45560	14464-46-1	Cristobalite
615	92080	14807-96-6	Talc
616	83470	14808-60-7	Quartz
623	52640	16389-88-1	Dolomite
625	36720	17194-00-2	Barium hydroxide
626	57800	18641-57-1	Glycerol tribehenate
627	59760	19569-21-2	Huntite
628	96190	20427-58-1	Zinc hydroxide
629	34560	21645-51-2	Aluminium hydroxide
630	82240	22788-19-8	1,2-Propyleneglycol dilaurate
634	25910	24800-44-0	Tripropyleneglycol
638	23590 - 76960	25322-68-3	Polyethyleneglycol
639	23651 - 80800	25322-69-4	Polypropyleneglycol
642	64990	25736-61-2	Maleic anhydride-styrene, copolymer, sodium salt
643	87760	26266-57-9	Sorbitan monopalmitate
644	88080	26266-58-0	Sorbitan trioleate
647	56720	26402-23-3	Glycerol monohexanoate
648	56880	26402-26-6	Glycerol monooctanoate
649	47210	26427-07-6	Dibutylthiostannoic acid polymer
651	88240	26658-19-5	Sorbitan tristearate
654	88600	26836-47-5	Sorbitol monostearate
659	82800	27194-74-7	1,2-Propyleneglycol monolaurate
663	64150	28290-79-1	Linolenic acid
664	95000	28931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer
665	83120	29013-28-3	1,2-Propyleneglycol monopalmitate
666	87280	29116-98-1	Sorbitan dioleate
667	55190	29204-02-2	Gadoleic acid
668	80240	29894-35-7	Polyglycerol ricinoleate
669	56610	30233-64-8	Glycerol monobehenate
671	74240	31570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester
674	46480	32647-67-9	Dibenzylidene sorbitol
677	82560	33587-20-1	1,2-Propyleneglycol dipalmitate

FCM substance no.	Ref. no.	CAS no.	Substance name
681	18310	36653-82-4	1-Hexadecanol
682	53270	37205-99-5	Ethylcarboxymethylcellulose
683	66200	37206-01-2	Methylcarboxymethylcellulose
684	68125	37244-96-5	Nepheline syenite
686	61390	37353-59-6	Hydroxymethylcellulose
693	88160	54140-20-4	Sorbitan tripalmitate
696	92205	57569-40-1	Terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)
699	90720	58446-52-9	Stearoylbenzoylmethane
702	87920	61752-68-9	Sorbitan tetrastearate
703	17170	61788-47-4	Fatty acids, coco
704	77600	61788-85-0	Polyethyleneglycol ester of hydrogenated castor oil
706	17230	61790-12-3	Fatty acids, tall oil
707	46375	61790-53-2	Diatomaceous earth
709	87520	62568-11-0	Sorbitan monobehenate
712	42960	64147-40-6	Castor oil, dehydrated
713	43480	64365-11-3	Charcoal, activated
714	84400	64365-17-9	Rosin, hydrogenated, ester with pentaerythritol
717	84210	65997-06-0	Rosin, hydrogenated
718	84240	65997-13-9	Rosin, hydrogenated, ester with glycerol
719	65920	66822-60-4	n-Methacryloyloxyethyl-n,n-dimethyl-n-carboxymethylammonium chloride, sodium salt - octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-n-vinyl-2-pyrrolidone, copolymers
721	46800	67845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester
722	17200	68308-53-2	Fatty acids, soya
723	88880	68412-29-3	Starch, hydrolysed
724	24903	68425-17-2	Syrups, hydrolysed starch, hydrogenated
727	43360	68442-85-3	Cellulose, regenerated
730	66930	68554-70-1	Methylsilsesquioxane
734	46380	68855-54-9	Diatomaceous earth, soda ash flux-calcined
737	77370	70142-34-6	Polyethyleneglycol-30 dipolyhydroxystearate
739	70000	70331-94-1	2,2′-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]
741	24070 - 83610	73138-82-6	Resin acids and rosin acids
743	38950	79072-96-1	Bis(4-ethylbenzylidene)sorbitol
751	81515	87189-25-1	Poly(zinc glycerolate)
752	39890	87826-41-3	Bis(methylbenzylidene)sorbitol
753	62800	92704-41-1	Kaolin, calcined
754	56020	99880-64-5	Glycerol dibehenate
757	95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt
766	38879	135861-56-2	Bis(3,4-dimethylbenzylidene)sorbitol
768	34850	143925-92-2	Amines, bis(hydrogenated tallow alkyl) oxidised
776	76723	167883-16-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4′-diisocyanate
777	31542	174254-23-0	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, c16-c18 alkyl esters

FCM substance no.	Ref. no.	CAS no.	Substance name
782	76725	661476-41-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane
789	60027		Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (mw: 440–12 000)
794	18117	79-14-1	Glycolic acid
800	94425	867-13-0	Triethyl phosphonoacetate
801	30607		Acids, c2-c24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt
803	33535	152261-33-1	α-Alkenes(c20-c24) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine
804	80510	1010121-89-7	Poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly (x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid
805	93450		Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris (methylenephosphonic acid), penta sodium salt]
807	93485		Titanium nitride, nanoparticles
812	80350	124578-12-7	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer
820	76420		Pimelic acid, salts
821	90810		Stearoyl-2-lactylic acid, salts
854	71943	329238-24-6	Perfluoro acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups
855	40560		(Butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate
856	40563	25101-28-4	(Butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate
857	66765	37953-21-2	(Methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer
859			(Butadiene, ethyl acrylate, methyl methacrylate, styrene) Copolymer crosslinked with divinylbenzene, in nanoform
860	71980	51798-33-5	Perfluoro[2-(poly(n-propoxy))propanoic acid]
861	71990	13252-13-6	Perfluoro[2-(n-propoxy)propanoic acid]
865	40619	25322-99-0	(Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer
866	40620		(Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate
867	40815	40471-03-2	(Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer
868	53245	9010-88-2	(Ethyl acrylate, methyl methacrylate) copolymer
869	66763	27136-15-8	(Butyl acrylate, methyl methacrylate, styrene) copolymer
871		287916-86-3	Dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene
873	93460		Titanium dioxide reacted with octyltriethoxysilane

FCM substance no.	Ref. no.	CAS no.	Substance name
878	31335		Acids, fatty (c8-c22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (c3-c22)
879	31336		Acids, fatty (c8-c22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (c1-c22)
880	31348		Acids, fatty (c8-c22), esters with pentaerythritol'
885	45676	263244-54-8	Cyclic oligomers of (butylene terephthalate)
896	71958	958445-44-8	3h-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt
902		128-44-9	1,2-Benzisothiazol-3(2h)-one 1,1-dioxide, sodium salt
903		37486-69-4	2h-Perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]
926	71955	908020-52-0	Perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt
969		24937-78-8	Ethylene-vinyl acetate copolymer wax
971	25885	2459-10-1	Trimethyl trimellitate
972	45197	12158-74-6	Copper hydroxide phosphate
973	22931	19430-93-4	(Perfluorobutyl)ethylene
979	79987		(Polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer
998			(Butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform
1007		976-56-7	Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl] methyl]phosphonate
1016			(Methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform
1017		25618-55-7	Polyglycerol
1030			Montmorillonite clay modified by dimethyldialkyl(c16-c18) ammonium chloride
1043			(Butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform
1045		1190931-27-1	Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl) oxy]}, ammonium salt
1046			Zinc oxide, nanoparticles, coated with [3-(methacryloxy) propyl] trimethoxysilane (fcm no 788)
1050			Zinc oxide, nanoparticles, uncoated
1053			Fatty acids, c16–18 saturated, esters with dipentaerythritol
1055		7695-91-2 58-95-7	α-Tocopherol acetate
1060			Ground sunflower seed hulls
1061		80512-44-3	2,4,4′-trifluorobenzophenone
1062			Mixture composed of 97% tetraethyl orthosilicate (teos) with cas no 78-10-4 and 3% hexamethyldisilazane (hmds) with cas no 999-97-3
1063		1547-26-8	2,3,3,4,4,5,5-heptafluoro-1-pentene
1067		616-38-6	Dimethyl carbonate
1068		2530-83-8	[3-(2,3-epoxypropoxy)propyl]trimethoxy silane
1069		75-28-5	Isobutane

Table A.2: EFSA opinions on applications of FCM substances without an SML and EFSA opinion on BADGE

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
87	86285		Silicon dioxide, silanated	EFSA CEF	Statement on the safety assessment of the substance silicon dioxide, silanated, FCM Substance No 87 for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3712
97	720810		Petroleum hydrocarbon resins (hydrogenated)	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to a 13th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2006.418
258	70480	111-06-8	Palmitic acid, butyl ester	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 14th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2007.452
270	22763 - 69040	112-80-1	Oleic acid	EFSA AFC	Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to a 1st list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2003.3
301	89120	123-95-5	Stearic acid, butyl ester	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 14th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2007.452
411	42080	1333-86-4	Carbon black	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 9th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2005.248a
426	13510 - 13610	1675-54-3	2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether	EFSA CEF	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to 2,2-bis(4-hydroxyphenyl)propane bis (2,3-epoxypropyl)ether (Bisphenol A diglycidyl ether, BADGE). REF. No 13510 and 39700	https://doi.org/10.2903/j.efsa.2004.86
468	71960	3825-26-1	Perfluorooctanoic acid, ammonium salt	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 9th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2005.248a

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
499	19965 - 65020	6915-15-7	Malic acid	EFSA CEF	22nd list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.961
549	80000	9002-88-4	Polyethylene wax	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 3rd list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.37
550	81060	9003-07-0	Polypropylene wax	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 3rd list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.37
551	79920	9003-11-6106392-12-5	Poly(ethylene propylene) glycol	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to an 11th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2006.316
552	81500	9003-39-8	Polyvinylpyrrolidone	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 12th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2006.395
577	62280	9044-17-1	Isobutylene-butene copolymer	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 15th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2007.516
586	65280	10043-84-2	Manganese hypophosphite	EFSA CEF	Scientific Report of EFSA on the risk assessment of salts of authorised acids, phenols or alcohols for use in food contact materials	https://doi.org/10.2903/j.efsa.2009.1364
607	62245	12751-22-3	Iron phosphide	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 6th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.161
642	64990	25736-61-2	Maleic anhydride-styrene, copolymer, sodium salt	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 6th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.161

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
671	74240	31570-04-4	Phosphorous acid, tris (2,4-di-tert-butylphenyl) ester	EFSA CEF	Safety assessment of the substance phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters for use in food contact materials	https://doi.org/10.2903/j.efsa.2017.4841
713	43480	64365-11-3	Charcoal, activated	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 5th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.109
724	24903	68425-17-2	Syrups, hydrolysed starch, hydrogenated	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 5th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.109
730	66930	68554-70-1	Methylsilsesquioxane	EFSA AFC	Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to a 4th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.65a
737	77370	70142-34-6	Polyethyleneglycol-30 dipolyhydroxystearate	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 5th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2004.109
776	76723	167883-16-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4′-diisocyanate	EFSA AFC	Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 16th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2007.555
777	31542	174254-23-0	Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters	EFSA AFC	Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to a 1st list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2003.3
782	76725	661476-41-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	EFSA AFC	Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 16th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2007.555

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
789	60027		Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440–12 000)	EFSA CEF	Scientific Opinion on the safety evaluation of the substance hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000) for use in food contact materials	https://doi.org/10.2903/j.efsa.2010.1521
794	18117	79-14-1	Glycolic acid	EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 18th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2008.628
800	94425	867-13-0	Triethyl phosphonoacetate	EFSA AFC	19th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2008.699
801	30607		Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt	EFSA CEF	20th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2008.816
803	33535	152261-33-1	α-Alkenes(C20-C24) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	EFSA CEF	20th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2008.816
804	80510	1010121-89-7	Poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	EFSA CEF	20th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2008.816

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
805	93450		Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris (methylenephosphonic acid), penta sodium salt]	EFSA CEF	20th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2008.816
807	93485		Titanium nitride, nanoparticles	EFSA CEF	20th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2008.816
812	80350	124578-12-7	Poly(12-hydroxystearic acid)-polyethyleneimine copolymer	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, poly(12-hydroxystearic acid)-polyethyleneimine copolymer, CAS No. 124578-12-7, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2125
854	71943	329238-24-6	Perfluoro acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups	EFSA CEF	Scientific Opinion on the safety evaluation of the substance perfluoro acetic acid, alpha-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups, CAS No. 329238-24-6 for use in food contact materials - EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2010.1519
855	40560		(Butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate, for use in food contact materials	https://doi.org/10.2903/j.efsa.2011.2122
856	40563	25101-28-4	(Butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate for use in food contact materials	https://doi.org/10.2903/j.efsa.2011.2123

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
857	66765	37953-21-2	(Methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer, CAS No. 37953-21-2, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2124
859			(Butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	EFSA CEF	Scientific Opinion on the safety assessment of the substances (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer either not crosslinked or crosslinked with divinylbenzene or 1,3-butanediol dimethacrylate, in nanoform, for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3635
860	71980	51798-33-5	Perfluoro[2-(poly(n-propoxy))propanoic acid]	EFSA CEF	24th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.1157
861	71990	13252-13-6	Perfluoro[2-(n-propoxy) propanoic acid]	EFSA CEF	24th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.1157
865	40619	25322-99-0	(Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (butyl acrylate, butyl methacrylate, methyl methacrylate) copolymer, CAS No. 25322-99-0, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2463
866	40620		(Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate	EFSA CEF	25th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2009.1196
867	40815	40471-03-2	(Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer	EFSA CEF	25th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.1196
868	53245	9010-88-2	(Ethyl acrylate, methyl methacrylate) copolymer	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (ethyl acrylate, methyl methacrylate) copolymer, CAS No. 9010-88-2, for use in food contact materials - EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2464

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
869	66763	27136-15-8	(Butyl acrylate, methyl methacrylate, styrene) copolymer	EFSA CEF	25th list of substances for food contact materials – Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.1196
871		287916-86-3	Dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene	EFSA CEF	Scientific Opinion on the safety assessment of the substance, dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, alpha-hydro-omega-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene, CAS No 287916-86-3, for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3909
873	93460		Titanium dioxide reacted with octyltriethoxysilane	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, titanium dioxide reacted with octyltriethoxysilane, CAS no. not assigned, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2003
878	31335		Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)	EFSA CEF	24th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2009.1157
879	31336		Acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)	EFSA CEF	24th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2009.1157
880	31348		Acids, fatty (C8-C22), esters with pentaerythritol'	EFSA CEF	24th list of substances for food contact materials	https://doi.org/10.2903/j.efsa.2009.1157
885	45676	263244-54-8	Cyclic oligomers of (butylene terephthalate)	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, cyclic oligomers of (butylene terephthalate), CAS No. 263244-54-8, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2009.1399

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
896	71958	958445-44-8	3H-Perfluoro-3-[(3-methoxy-propoxy) propanoic acid], ammonium salt	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt, CAS No. 958445-44-8, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2182
902		128-44-9	1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt, CAS No. 128-44-9, for use in food contact materials - EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2012.2640
903		37486-69-4	2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] CAS No 37486-69-4 for use in food contact materials.	https://doi.org/10.2903/j.efsa.2012.2978
926	71955	908020-52-0	Perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, Perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt, CAS No. 908020-52-0, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2183
969		24937-78-8	Ethylene-vinyl acetate copolymer wax	EFSA CEF	Scientific Opinion on the safety assessment of the substance ethylene-vinyl acetate copolymer wax, CAS No 24937-78-8 for use in food contact materials.	https://doi.org/10.2903/j.efsa.2014.3555
971	25885	2459-10-1	Trimethyl trimellitate	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, trimethyl trimellitate, CAS No. 2459-10-1, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.1997
972	45197	12158-74-6	copper hydroxide phosphate	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, copper hydroxide phosphate, CAS No. 12158-74-6, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2010.1838
973	22931	19430-93-4	(Perfluorobutyl)ethylene	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (perfluorobutyl)ethylene, CAS No. 19430-93-4, for use in food contact materials – EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	https://doi.org/10.2903/j.efsa.2011.2000

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
979	79987		(Polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer	EFSA CEF	Scientific Opinion on the safety evaluation of the substance, (polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer, for use in food contact materials	https://doi.org/10.2903/j.efsa.2011.2462
998			(Butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform	EFSA CEF	Scientific Opinion on the safety assessment of the substances (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer either not crosslinked or crosslinked with divinylbenzene or 1,3-butanediol dimethacrylate, in nanoform, for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3635
1007		976-56-7	Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate	EFSA CEF	Safety assessment of the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4536
1016			(Methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	EFSA CEF	Scientific Opinion on the safety assessment of the substance (methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform for use in food contact materials	https://doi.org/10.2903/j.efsa.2015.4008
1017		25618-55-7	Polyglycerol	EFSA CEF	Scientific Opinion on the safety assessment of the substance, polyglycerol, CAS No 25618-55-7, for use in food contact materials.	https://doi.org/10.2903/j.efsa.2013.3389
1030			Montmorillonite clay modified by dimethyldialkyl(C16-C18) ammonium chloride		Safety assessment of the substance montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride for use in food contact materials	https://doi.org/10.2903/j.efsa.2015.4285
1043			(Bbutadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform	EFSA CEF	Scientific Opinion on the safety assessment of the substances (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer either not crosslinked or crosslinked with divinylbenzene or 1,3-butanediol dimethacrylate, in nanoform, for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3635

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
1045		1190931-27-1	Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt	EFSA CEF	Scientific Opinion on the safety assessment of the substance, Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, CAS No 1190931-27-1, for use in food contact materials	https://doi.org/10.2903/j.efsa.2014.3718
1046			Zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788)	EFSA CEF	Scientific Opinion on the safety evaluation of the substance zinc oxide, nanoparticles, uncoated and coated with [3-(methacryloxy)propyl] trimethoxysilane, for use in food contact materials	https://doi.org/10.2903/j.efsa.2015.4063
1050			Zinc oxide, nanoparticles, uncoated	EFSA CEF	Scientific Opinion on the safety evaluation of the substance zinc oxide, nanoparticles, uncoated and coated with [3-(methacryloxy)propyl] trimethoxysilane, for use in food contact materials	https://doi.org/10.2903/j.efsa.2015.4063
1053			Fatty acids, C16–18 saturated, esters with dipentaerythritol	EFSA CEF	Scientific Opinion on the safety assessment of the substance fatty acids, C16–18 saturated, hexaesters with dipentaerythritol for use in food contact materials	https://doi.org/10.2903/j.efsa.2015.4021
1055		7695-91-258-95-7	α-tocopherol acetate	EFSA CEF	Safety assessment of the substance α-tocopherol acetate for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4412
1060			Ground sunflower seed hulls	EFSA CEF	Safety assessment of the substance ground sunflower seed hulls, for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4534
1061		80512-44-3	2,4,4′-Trifluorobenzophenone	EFSA CEF	Safety assessment of the substance 2,4,4′-trifluorobenzophenone, for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4532
1062			Mixture composed of 97% tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3% hexamethyldisilazane (HMDS) with CAS No 999-97-3	EFSA CEF	Scientific Opinion on the safety assessment of the substances tetraethyl orthosilicate, CAS No. 78-10-4, and hexamethyldisilazane, CAS No. 999 97 3, for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4337
1063		1547-26-8	2,3,3,4,4,5,5-Heptafluoro-1-pentene	EFSA CEF	Safety assessment of the substance 2,3,3,4,4,5,5-heptafluoro-1-pentene, for use in food contact materials	https://doi.org/10.2903/j.efsa.2016.4582

FCM substance no.	Ref. no.	CAS no.	Substance name	EFSA panel	EFSA opinion title	EFSA opinion link
1067		616-38-6	Dimethyl carbonate	EFSA CEF	Safety assessment of the substance dimethyl carbonate for use in food contact materials	https://doi.org/10.2903/j.efsa.2017.4901
1068		2530-83-8	[3-(2,3-Epoxypropoxy) propyl]trimethoxy silane	EFSA CEF	Safety assessment of the substance [3-(2,3-epoxypropoxy) propyl]trimethoxy silane, for use in food contact materials	https://doi.org/10.2903/j.efsa.2017.5014
1069		75-28-5	Isobutane	EFSA CEF	Safety assessment of the substance isobutane, for use in food contact materials	https://doi.org/10.2903/j.efsa.2018.5116

Table A.3: Substances from the SCF List 0 group, for which EFSA opinions have subsequently been produced

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
580	α-Dextrin	EFSA NDA	Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of alpha-cyclodextrin	2007	Negative	Negative	Negative	
553	Cellulose	EFSA ANS	Safety of the proposed amendment of the specifications for microcrystalline cellulose (E 460(i)) as a food additive	2017	No data	No data	No data	The Panel concluded that the amendment to the specifications as regards the solubility of microcrystalline cellulose (E 46(i)) proposed by the applicant would not give rise to a safety concern. However, the Panel recommended that the concentration of sodium hydroxide solution to be used in the solubility test should be indicated in the EU specifications
		EFSA ANS	Re-evaluation of celluloses E 460 (i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 as food additives	2018	Negative	Negative	Negative	
		EFSA CEF	Scientific Opinion on the safety evaluation of the active substances iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite for use in food contact materials	2013	No data	No data	No data	The CEF Panel concluded that the substances: iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite, do not raise a safety concern when used in oxygen absorbers in sachets, patches or cards, placed in the headspace of the packaging or when used in direct contact with food, excluding liquid food or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat. Activated carbon should in addition comply with the same purity requirements as for Vegetable

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
								Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 1% (w/w)
		EFSA CEF	Scientific Opinion on the safety assessment of the active substances, sodium erythorbate, sodium carbonate, sodium bicarbonate, iron sulphate, activated carbon, cellulose, calcium hydroxide, calcium chloride and water, for use as active system in food contact materials	2014	Negative	Negative	No data	
531	Beeswax	EFSA AFC	Beeswax (E 901) as a glazing agent and as carrier for flavours	2007	Negative	Negative	Negative	
		EFSA CONTAM	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	2012	Negative	Negative	Negative	Although specific information on beeswax is very limited, there is sufficient information from its human uses, its poor absorption and on its main component groups of chemicals for the CONTAM Panel to conclude that it will not pose any toxicological concern when used as a previous cargo. 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 therefore concludes that beeswax meets the criteria for acceptability as a previous cargo for edible fats and oils
515	Water	EFSA CONTAM	Scientific Opinion on the abiotic risks for public and animal health of glycerine as co-product from the biodiesel production from Category 1 animal by-products (ABP) and vegetable oils	2010	No data	No data	No data	

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	
		EFSA NDA	Scientific Opinion on the safety of 'Lentinus edodes extract' (Lentinex) as a Novel Food ingredient	2010	No data	No data	No data	
		EFSA CEF	Scientific Opinion on the safety evaluation of the active substances iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite for use in food contact materials	2013	No data	No data	No data	The CEF Panel concluded that the substances: iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite, do not raise a safety concern when used in oxygen absorbers in sachets, patches or cards, placed in the headspace of the packaging or when used in direct contact with food, excluding liquid food or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat. Activated carbon should in addition comply with the same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 1% (w/w)
		EFSA CEF	Scientific Opinion on the safety assessment of the active substances, sodium erythorbate, sodium carbonate, sodium bicarbonate, iron sulfate, activated carbon, cellulose,	2014	Negative	Negative	Negative	

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
			calcium hydroxide, calcium chloride and water, for use as active system in food contact materials.					
		EFSA CEF	Scientific Opinion on the safety evaluation of the active substances, activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride for use as active component in food contact materials	2012	No data	No data	No data	
		EFSA CONTAM	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	2012	Negative	Negative	Negative	
503	β-Dextrin	EFSA ANS	Re-evaluation of Beta-cyclodextrin (E 459) as a food additive	2016	Negative	Negative	Negative	The Scientific Committee on Food (SCF) allocated an acceptable daily intake (ADI) of -5 mg/kg body weight (bw) per day to beta-cyclodextrin (E 459) in 1996. The Panel concluded that, based on the available toxicological database, there is no reason to revise the curresnt ADI of 5 mg/kg bw per day for beta-cyclodextrin. Based on the available reported use and use levels, the Panel also concluded that the ADI was exceeded in the refined brand-loyal scenario (considered the most relevant scenario) in all population groups except for infants at the mean and in all population groups at the 95th percentile
112	Linoleic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel, therefore, concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
			for edible fats and oils – Part II of III					and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
108	Sucrose	EFSA CONTAM	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	2012	Ambiguous	Ambiguous	No data	Given its long history of use as a food, and the available information on its components, there are no toxicological concerns regarding the use of molasses obtained from sugar cane, sugar beet, citrus or sorghum, as a previous cargo for edible fats and oils. The amount of sulfite present in some molasses would not be of concern following dilution in edible fats and oils as subsequent cargo. No other impurities or reaction products of concern are known or anticipated. The CONTAM Panel, therefore, concludes that molasses, which has been produced from the conventional sugar processing industry using sugar cane, sugar beet, citrus or sorghum, meets the criteria for acceptability as a previous cargo for edible fats and oils
107	Urea	EFSA FEEDAP	Scientific Opinion on the safety and efficacy of Urea for ruminants	2012	No data	No data	No data	
		EFSA	Conclusion on the peer review of the pesticide risk assessment of the active substance urea	2012	No data	No data	No data	With regard to consumer exposure, it is not necessary to derive an ADI or an ARfD in view of the representative uses (Urea can be used as a fungicide to be applied on fresh-cut stumps of conifers in forests. It can also be used as an insect attractant for the control and the suppression of the olive fruit fly and the Mediterranean fruit fly in olive trees as a spot bait spray treatment in combination with an insecticide)

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
		EFSA CONTAM	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	2012	Negative	Negative	Not applicable	The CONTAM Panel has previously evaluated calcium ammonium nitrate solution and calcium nitrate (CN-9) solution and concluded that they meet the criteria for acceptability as previous cargoes. Based on the evaluations for urea, ammonium hydroxide and nitrate, the Panel considers that there are no toxicological concerns regarding urea ammonium nitrate when it is used as a previous cargo. There are no reactions of concern with edible fats and oils, nor are any anticipated impurities likely to be present at levels of toxicological relevance. Therefore, the CONTAM Panel concludes that urea ammonia nitrate solution meets the criteria for acceptability as a previous cargo for edible fats and oils
102	Glucose	EFSA NDA	Scientific Opinion on the safety of 'Lentinus edodes extract' (Lentinex) as a Novel Food ingredient	2010	No data	No data	No data	
345	Arachidic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
338	Palmitoleic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
			for edible fats and oils - Part II of III					and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
336	n-Decanoic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	
330	Lauric acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	
329	Hexanoic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
			for edible fats and oils – Part II of III					and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	
304	Caprylic acid	EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
		EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	
		EFSA AFC	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to Treatment of poultry carcasses with chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids	2006	No data	No data	No data	

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
299	Levulinic acid	EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
272	Behenic acid	EFSA NDA	Scientific Opinion related to a notification from DuPont Nutrition Biosciences Aps on behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers pursuant to Article 21 (2) of Regulation (EU) No 1169/2011 – for permanent exemption from labelling	2016	No data	No data	No data	
		EFSA CONTAM	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	2012	Not applicable	Not applicable	Not applicable	The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation
256	Glutaric acid	EFSA CEF	Scientific Opinion on Flavouring Group Evaluation 10, Revision 3 (FGE.10Rev3): Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30	2012	Negative	Negative	Not determined	METABOLISM: It can be anticipated that, at the estimated levels of intake as flavouring substance, the candidate substance is metabolised to innocuous products, many of which are endogenous in humans. GENOTOXICITY: For the candidate substance, the genotoxic potential cannot be assessed adequately, however, from the limited data available there were no indications that genotoxicity for these substances should give rise to safety concern. The Panel therefore decided that the substance could be taken through the Procedure. OUTCOME ON THE NAMED COMPOUND: No safety concern based on intake calculated by the MSDI approach of

FCM no.	Substance name	Panel	Opinion title	Year	Conclusions on:			Remarks
					Mutagenicity	Genotoxicity	Carcinogenicity	
								the named compound. OUTCOME ON THE MATERIAL OF COMMERCE: No safety concern at estimated level of intake of the material of commerce meeting the specification (based on intake calculated by the MSDI approach)
229	Butyric acid	EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	

Table A.4: Substances with a List 1 classification and an 'ADI: not specified' characterisation by SCF, for which EFSA has produced an opinion

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
103	Glycerol	Group ADI: not specified for glycerol, glycerol diacetate, glycerol triacetate and glycerol monoacetate (SCF, 11th Series, 1981)	EFSA CONTAM	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	2012	Negative	Negative	Negative	Both JECFA and the SCF have established an ADI not specified for glycerol, which the CONTAM Panel considers appropriate.
			EFSA ANS	Re-evaluation of glycerol (E 422) as a food additive	2017	Negative	Negative	Negative	
			EFSA CEF	Scientific Opinion on the safety evaluation of the active substances iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite for use in food contact materials	2013	No data	No data	No data	The CEF Panel concluded that the substances: iron, sodium chloride, water, silica gel, activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite, hydroxypropyl cellulose, potassium carbonate, sodium thiosulfate, propylene glycol, glycerin, polyethyleneglycol sorbitan monooleate, sodium propionate and clinoptilolite, do not raise a safety concern when used in oxygen absorbers in sachets, patches or cards, placed in the headspace of the packaging or when used in direct contact with food, excluding liquid food or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat.

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
									Activated carbon should in addition comply with the same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 10% (w/w).
105	Palmitic acid	ADI: not specified (SCF, 25th Series, 1990)	EFSA NDA	Scientific Opinion on the safety of 'coriander seed oil' as a Novel Food ingredient.	2013	Negative	Negative	No data	
			EFSA CONTAM	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	2012				The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation.
106	Stearic acid	ADI: not specified (SCF, 25th Series, 1990)	EFSA NDA	Scientific Opinion on the safety of 'coriander seed oil' as a Novel Food ingredient	2013	Negative	Negative	No data	
			EFSA CONTAM	Scientific Opinion on the evaluation of the substances currently on the list in the annex to	2012				The fatty acids listed are of no toxicological concern when used as previous cargoes. The CONTAM Panel therefore

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
				Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part II of III					concludes that the fatty acids specified meet the criteria for acceptability as previous cargoes for edible fats and oils, provided the dioxin and PCB levels in the fatty acids are such that the final concentration in the fats and oils as subsequent cargoes complies with the European legislation.
			EFSA ANS	Scientific Opinion on the re-evaluation of sodium stearoyl-2-lactylate (E 481) and calcium stea royl-2-lactylate (E 482) as food additives.	2013				
115	Acetic acid	Group ADI: not specified (SCF, 25th Series, 1990).	EFSA CONTAM	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	2012	Negative	Negative	Negative	On the basis of its low toxicity and its natural occurrence in food and in the body, the CONTAM Panel does not consider it necessary to establish an ADI for acetic acid. It causes adverse effects only when it is present at sufficient concentration to change the H+ concentration. Studies in experimental animals and humans have shown that the maximum potential levels of acetic acid arising in fats or oils following its transport as a previous cargo would be of no concern. The CONTAM

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
									Panel therefore concludes that acetic acid meets the criteria for acceptability as a previous cargo for edible fats and oils.
			EFSA	Conclusion on the peer review of the pesticide risk assessment of the active substance acetic acid	2013	Negative	Negative	Negative	The establishment of an ADI and ARfD for the oral intake of acetic acid is not considered necessary based on the widespread presence of acetic acid in human food and the fact that the substance is a normal metabolite in humans and animals.
			EFSA CEP	Evaluation of the safety and efficacy of the organic acids lactic and acetic acids to reduce microbiological surface contamination on pork carcasses and pork cuts	2018	No data	No data	No data	
			EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined	Not determined	
			EFSA CEF	Scientific opinion of Flavouring Group Evaluation 503 (FGE.503): grill flavour 'Grillin' CB-200SF'	2017	Not determined	Not determined	Not determined	

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
			EFSA FEEDAP	Scientific Opinion on the safety and efficacy of acetic acid, sodium diacetate and calcium acetate as preservatives for feed for all animal species	2012	Not determined	Not determined	No data	JECFA allocated an ADI of 0 to 15 mg/kg body weight for sodium diacetate. However, the basis for this ADI is not known.
139	Citric acid	Group ADI: not specified for citric acid and its salts (SCF, 25th Series, 1990).	EFSA ANS	Safety of trimagnesium dicitrate anhydrous (TMDC) to be used as a food additive in food supplements in solid and chewable forms	2016	No data	No data	No data	
			EFSA CEF	Safety assessment of the active substances citric acid and sodium hydrogen carbonate for use in active food contact materials	2016				
146	Propionic acid	Group ADI: not specified (SCF, 1st Series, 1974).	EFSA CEF	Scientific opinion of Flavouring Group Evaluation 502 (FGE.502): grill flavour 'Grillin' 5078'	2017	Not determined	Not determined		
			EFSA ANS	Scientific Opinion on the re-evaluation of propionic acid (E 280), sodium propionate (E 281), calcium propionate (E 282) and potassium propionate (E 283) as food additives	2014				
247	Succinic acid	ADI: not specified (SCF, 25th Series, 1990).	EFSA FEEDAP	Scientific Opinion on the safety and efficacy of primary aliphatic saturated or unsaturated	2012	No data	No data	No data	

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
				alcohols/aldehydes/acids/acetals/esters with a second primary, secondary or tertiary oxygenated functional group including aliphatic lactones (chemical group 9) when used as flavourings for all animal species					
327	Acetic acid, ethyl ester	ADI: not specified. (SCF, 11th Series, 1981).	EFSA CONTAM	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	2011	Negative	Negative	No data	JECFA established an ADI of 0–25 mg/kg bw for ethyl acetate, which the CONTAM Panel endorses.
348	Myristic acid	ADI: Not specified (SCF, 25th Series, 1989).	EFSA CONTAM	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	2012	Not applicable	Not applicable		
394	Calcium hydroxide	ADI: not specified (SCF, 25th Series, 1991)	EFSA CEF	Scientific Opinion on the safety assessment of the active substances iron, iron oxides, sodium chloride and calcium hydroxide for use in food contact materials.	2013	No data	No data	No data	

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
			EFSA CEF	Scientific Opinion on the safety assessment of the active substances, sodium erythorbate, sodium carbonate, sodium bicarbonate, iron sulphate, activated carbon, cellulose, calcium hydroxide, calcium chloride and water, for use as active system in food contact materials.	2014	Negative	Negative	No data	
399	Potassium hydroxide	ADI: not specified (SCF, 25th Series, 1991)	EFSA CONTAM	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	2012	Negative	Negative	Negative	
400	Sodium hydroxide	ADI: not specified (SCF, 25th Series, 1991)	EFSA CONTAM	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	2012	Negative	Negative	Negative	
410	Kaolin	ADI: not specified (SCF, 25th Series, 1990).	EFSA CONTAM	Scientific Opinion on the evaluation of substances as acceptable previous cargoes for edible fats and oils	2009	No data	No data	No data	Kaolin has been evaluated by JECFA (ADI not specified) and is a permitted anti-caking food additive (up to 2.5%).

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
413	Ammonium hydroxide	ADI: not specified (SCF, 25th Series, 1991)	EFSA CONTAM	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	2012	Negative	Negative		
504	Silicon dioxide	ADI: not specified (SCF, 25th Series, 1991)	EFSA NDA	Scientific Opinion on the safety of 'Cetyl Myristoleate Complex' as a food ingredient	2010	No data	No data	No data	
			EFSA NDA	Statement on the safety of 'Cetyl Myristoleate Complex' as an ingredient in food supplements.	2010	No data	No data	No data	
			EFSA NDA	Statement on the safety of 'Cetyl Myristoleate Complex' as an ingredient in food supplements	2014	No data	No data	No data	
			EFSA NDA	Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Silicon Calcium silicate and silicon dioxide/silicic acid gel added for nutritional purposes to food supplements	2004	Negative	Negative	Negative	

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
			EFSA ANS	Calcium silicate and silicon dioxide/silicic acid gel added for nutritional purposes to food supplements	2009	Negative	Negative	No data	
			EFSA CONTAM	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	2012	Negative	Negative	Negative	
			EFSA ANS	Re-evaluation of silicon dioxide (E 551) as a food additive	2018	Negative	Negative	Negative	
510	Ammonia	ADI: not specified (SCF, 25th Series, 1991).	EFSA CEF	Scientific Opinion on Flavouring Group Evaluation 46, Revision 1 (FGE.46Rev1): Ammonia and three ammonium salts from chemical group 30	2011	Not determined	Not determined	Not determined	METABOLISM: The candidate substance is expected to be metabolised to innocuous substances at the anticipated levels of intake as flavouring substance. GENOTOXICITY: Although the genotoxicity data for the flavouring substances in this group are limited, the available data on genotoxicity do not preclude an evaluation of the candidate substances through the Procedure. OUTCOME ON THE NAMED COMPOUND: No safety concern based on intake calculated by the MSDI approach of the named compound. OUTCOME ON

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
									THE MATERIAL OF COMMERCE: Tentatively regarded as presenting no safety concern (based on intake calculated by the MSDI approach) pending further information on the purity of the material of commerce and/or information on stereoisomerism
			EFSA AFC	Opinion Flavouring Group Evaluation 46 (FGE.46): Ammonia and two ammonium salts from chemical group 30 Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC)	2009	Not determined	Not determined	Not determined	METABOLISM: The substance is accordingly expected to be metabolised to innocuous substances at the anticipated levels of intake as flavouring substance. OUTCOME ON THE NAMED COMPOUND: No safety concern based on intake calculated by the MSDI approach of the named compound. OUTCOME ON THE MATERIAL OF COMMERCE: Tentatively regarded as presenting no safety concern (based on intake calculated by the MSDI approach) pending further information on the purity of the material of commerce and/or information on stereoisomerism
511	Sulphuric acid	ADI: not specified (SCF, 25th Series, 1991)	EFSA CONTAM	Scientific Opinion on the evaluation of the substa nces currently on the list in the annex to Commission Directive 96/ 3/EC as	2012	Negative	Negative	No data	No ADI has been established for sulphuric acid. Sulphuric acid is toxic only when it is present at a sufficient concentration to change the H+ concentration. It will be

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
				acceptable previous ca rgoes for edible fats and oils - Part II of III					diluted and buffered by the contents of the GI tract so that the levels that would occur following oral ingestion of fats or oils transported subsequent to sulphuric acid do not give rise to any toxicological concern. Studies in experimental animals and humans have shown that the maximum potential levels of sulphuric acid arising in fats or oils following its transport as a previous cargo would be of no concern. No impurities of toxicological concern are known or anticipated. The CONTAM Panel therefore concludes that sulphuric acid meets the criteria for acceptability as a previous cargo for edible fats and oils
528	Lecithin	ADI: not specified (JECFA 17 M., 1973).	EFSA ANS	Re-evaluation of lecithins (E 322) as a food additive	2017	Negative	Negative	Negative	No adverse effects were reported in chronic and carcinogenicity study in rats at the highest dose tested of 3,750 mg lecithins/kg bw per day
541	Gum arabic	ADI: not specified (JECFA, 35 M., 1989).	EFSA ANS	Re-evaluation of acacia gum (E 414) as a food additive	2017	Negative	Negative	Negative	
544	Guar gum	ADI: not specified (SCF, 7th Series, 1978).	EFSA ANS	Re-evaluation of guar gum (E 412) as a food additive	2017	Negative	Negative	Negative	The Panel concluded that there is no need for a numerical ADI for guar gum (E 412), and that there is no

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
									safety concern for the general population at the refined exposure assessment for the reported uses of guar gum (E 412) as a food additive
545	Tragacanth gum	ADI: not specified (SCF, 21th Series, 1989).	EFSA ANS	Re-evaluation of tragacanth (E 413) as a food additive	2017	Negative	Negative	Negative	Tragacanth had no observed effects on clinical chemistry, haematological indices, urinalysis parameters, glucose and insulin levels, serum cholesterol, triglycerides and phospholipids, breath hydrogen and methane concentrations
546	Pectin	ADI: not specified (SCF, 7th Series, 1978).	EFSA ANS	Re-evaluation of pectin (E 440i) and amidated pectin (E 440ii) as food additives	2017	Negative	Negative	Negative	
566	Alginic acid	ADI: not specified (JECFA, 39M., 1992).	EFSA ANS	Re-evaluation of alginic acid and its sodium, potassium, ammonium and calcium salts (E 400-E 404) as food additives	2017	Negative	Negative	Negative	
			EFSA ANS	Re-evaluation of propane-1,2-diol alginate (E 405) as a food additive	2018	Negative	Negative	Negative	
585	Calcium chloride	ADI: not specified (SCF, 25th Series, 1991)	EFSA CONTAM	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	2012	Negative	Negative	No data	

FCM no.	Substance name	Synoptic SCF Opinion	Panel	Opinion title	Year	Conclusion on:			Remarks
						Mutagenicity	Genotoxicity	Carcinogenicity	
596	Xanthan gum	ADI: not specified (JECFA, 30M., 1986).	EFSA NDA	Safety of alginate-konjac-xanthan polysaccharide complex (PGX) as a novel food pursuant to Regulation (EC) No 258/97	2017	Negative	Negative	No data	
			EFSA ANS	Re-evaluation of xanthan gum (E 415) as a food additive	2017	Negative	Negative	Negative	
615	Talc	ADI: not specified (SCF, 25th Series, 1991)	EFSA ANS	Re-evaluation of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) as food additives	2018	Negative	Negative	No data	

Table A.5: Substances for which an SML should not be needed

FCM substance no.	Ref. no.	CAS no.	Substance name	Metal or metal compound[(a)]	SCF list[(a)]	ADI: not specified[(a)]
1	12310	266309-43-7	Albumin		**0**	
7	30370		Acetylacetic acid, salts		**0**	
18	34475		Aluminium calcium hydroxide phosphite, hydrate	**Yes**	2–3	
21	42500		Carbonic acid, salts		**1**	**ADI: not specified**
55	57120		Glycerol monooleate, ester with citric acid		**1**	**ADI: not specified**
57	57280		Glycerol monopalmitate, ester with citric acid		**1**	**ADI: not specified**
59	57680		Glycerol monostearate, ester with citric acid		**1**	**ADI: not specified**
62	64500		Lysine, salts		**0**	
63	65440		Manganese pyrophosphite	**Yes**	2-3	
80	81760		Powders, flakes and fibers of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	**Yes**	2	
90	92195		Taurine, salts		**0**	
99	19460 - 62960	50-21-5	Lactic acid		**1**	**ADI: not specified**
102	17530	50-99-7	Glucose		**0**	
103	18100 - 55920	56-81-5	Glycerol		**1**	**ADI: not specified**
105	22780 - 70400	57-10-3	Palmitic acid		**1**	**ADI: not specified**
106	24550 - 89040	57-11-4	Stearic acid		**1**	**ADI: not specified**
107	25960	57-13-6	Urea		0	
108	24880	57-50-1	Sucrose		0	
112	64015	60-33-3	Linoleic acid		**0**	
115	10090 - 30000	64-19-7	Acetic acid		**1**	**ADI: not specified**
139	14680 - 44160	77-92-9	Citric acid		**1**	**ADI: not specified**
146	23890 - 82000	79-09-4	Propionic acid		**1**	**ADI: not specified**
182	19270	97-65-4	Itaconic acid		**0**	
229	14140	107-92-6	Butyric acid		**0**	
247	24820 - 90960	110-15-6	Succinic acid		**1**	**ADI: not specified**
256	18010 - 55680	110-94-1	Glutaric acid		**0**	
272	37040	112-85-6	Behenic acid		**0**	
297	23950	123-62-6	Propionic anhydride		**1**	**ADI: not specified**
299	63840	123-76-2	Levulinic acid		**0**	

FCM substance no.	Ref. no.	CAS no.	Substance name	Metal or metal compound[(a)]	SCF list[(a)]	ADI: not specified[(a)]
304	14320 - 41960	124-07-2	Caprylic acid		**0**	
307	42160	124-38-9	Carbon dioxide		**1**	**ADI: not specified**
327	30140	141-78-6	Acetic acid, ethyl ester		**1**	**ADI: not specified**
329	59360	142-62-1	Hexanoic acid		**0**	
330	19470 - 63280	143-07-7	Lauric acid		**0**	
336	15095 - 45940	334-48-5	n-Decanoic acid		**0**	
338	71020	373-49-9	Palmitoleic acid		**0**	
345	35840	506-30-9	Arachidic acid		**0**	
348	22350 - 67891	544-63-8	Myristic acid		**1**	**ADI: not specified**
350	63920	557-59-5	Lignoceric acid		**0**	
394	41280	1305-62-0	Calcium hydroxide		**1**	**ADI: not specified**
395	41520	1305-78-8	Calcium oxide		**1**	**ADI: not specified**
396	64640	1309-42-8	Magnesium hydroxide		**1**	**ADI: not specified**
397	64720	1309-48-4	Magnesium oxide		**1**	**ADI: not specified**
399	81600	1310-58-3	Potassium hydroxide		**1**	**ADI: not specified**
400	86720	1310-73-2	Sodium hydroxide		**1**	**ADI: not specified**
402	96240	1314-13-2	Zinc oxide	**Yes**	2	
403	96320	1314-98-3	Zinc sulphide	**Yes**	2	
409	62240	1332-37-2	Iron oxide	**Yes**	2	**ADI: not specified**
410	62720	1332-58-7	Kaolin		**1**	**ADI: not specified**
413	35600	1336-21-6	Ammonium hydroxide		**1**	**ADI: not specified**
418	34720	1344-28-1	Aluminium oxide	**Yes**	2	
489	41040	5743-36-2	Calcium butyrate		0	
501	34480		Aluminium fibers, fibers and powders	**Yes**	2	
504	86240	7631-86-9	Silicon dioxide		**1**	**ADI: not specified**
507	59990	7647-01-0	Hydrochloric acid		**1**	**ADI: not specified**
510	12789 - 35320	7664-41-7	Ammonia		**1**	**ADI: not specified**
511	91920	7664-93-9	Sulphuric acid		**1**	**ADI: not specified**
515	26360 - 95855	7732-18-5	Water		**0**	
518	35845	7771-44-0	Arachidonic acid		**0**	
520	65120	7773-01-5	Manganese chloride	**Yes**	2	

FCM substance no.	Ref. no.	CAS no.	Substance name	Metal or metal compound[(a)]	SCF list[(a)]	ADI: not specified[(a)]
523	45195	7787-70-4	Copper bromide	**Yes**	2	
528	63760	8002-43-5	Lecithin		**1**	**ADI: not specified**
531	36880	8012-89-3	Beeswax		**0**	
541	58480	9000-01-5	Gum arabic		**1**	**ADI: not specified**
544	58400	9000-30-0	Guar gum		**1**	**ADI: not specified**
545	93680	9000-65-1	Tragacanth gum		**1**	**ADI: not specified**
546	71440	9000-69-5	Pectin		**1**	**ADI: not specified**
547	55440	9000-70-8	Gelatin		**0**	
548	42800	9000-71-9	Casein		**0**	
553	14500 - 43280	9004-34-6	Cellulose		**0**	
564	24540 - 88800	9005-25-8	Starch, edible		**0**	
566	33350	9005-32-7	Alginic acid		**1**	**ADI: not specified**
579	61800	9049-76-7	Hydroxypropyl starch		**1**	**ADI: not specified**
580	46070	10016-20-3	α-Dextrin		**0**	
581	36800	10022-31-8	Barium nitrate	**Yes**	2–3	
585	41120	10043-52-4	Calcium chloride		**1**	**ADI: not specified**
586	65280	10043-84-2	Manganese hypophosphite	**Yes**	2–3	
592	34690	11097-59-9	Aluminium magnesium carbonate hydroxide	**Yes**	3	
594	65360	11129-60-5	Manganese oxide	**Yes**	2	
596	95935	11138-66-2	Xanthan gum		**1**	**ADI: not specified**
606	65200	12626-88-9	Manganese hydroxide	**Yes**	2	
615	92080	14807-96-6	Talc		**1**	**ADI: not specified**
625	36720	17194-00-2	Barium hydroxide	**Yes**	3	
628	96190	20427-58-1	Zinc hydroxide	**Yes**	2	
629	34560	21645-51-2	Aluminium hydroxide	**Yes**	2	
663	64150	28290-79-1	Linolenic acid		**0**	
667	55190	29204-02-2	Gadoleic acid		**0**	
723	88880	68412-29-3	Starch, hydrolysed		**0**	
768	34850	143925-92-2	Amines, bis(hydrogenated tallow alkyl) oxidised		3	

(a): Data complying with the relevant criteria for inclusion in the group of substances for which an SML should not be needed (Section 2.2.2.1) are shown in bold.

Table A.6: Low Priority Group of substances

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[(a)]	Molecular mass, chemical category[(a)]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[(a)]	EFSA Panel	Link to the opinion
2	12340		Albumin, coagulated by formaldehyde	3	**MW ≥ 1,000**			
11	30960		Acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol	**1**	Range, low fraction MW < 1,000			
24	45280		Cotton fibers	**3 -inert**	**Polysaccharide**			
34	54270		Ethylhydroxymethylcellulose	2	**Polysaccharide**			
35	54280		Ethylhydroxypropylcellulose	2	**Polysaccharide**			
38	55520		Glass fibers	**3 -inert**	Inorganic			
39	55600		Glass microballs	**3 -inert**	Inorganic			
64	66695		Methylhydroxymethylcellulose	**2**	**Polysaccharide**			
75	77702		Polyethyleneglycol esters of aliph. monocarb. acids (C6-C22) and their ammonium and sodium sulphates	**2**	Range, low fraction MW < 1,000			
79	80640		Polyoxyalkyl (C2-C4) dimethylpolysiloxane	3	**Polymeric**			
81	83320		Propylhydroxyethylcellulose	2	**Polysaccharide**			
82	83325		Propylhydroxymethylcellulose	2	**Polysaccharide**			
83	83330		Propylhydroxypropylcellulose	2	**Polysaccharide**			
84	85601		Silicates, natural (with the exception of asbestos)	3	**Mineral**			
85	85610		Silicates, natural, silanated (with the exception of asbestos)	**3 -inert**	Mineral			
86	86000		Silicic acid, silylated	**3 -inert**				
94	95859		Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	**2**	Wax			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
95	95883		White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	**2**	Wax			
96	95920		Wood flour and fibers, untreated	**3 -inert**				
109	23740 - 81840	57-55-6	1,2-Propanediol	**1**	76.09	**25**	CONTAM CEF ANS ANS	https://doi.org/10.2903/j.efsa.2011.2482 https://doi.org/10.2903/j.efsa.2010.1453 https://doi.org/10.2903/j.efsa.2018.5235 https://doi.org/10.2903/j.efsa.2018.5371
111	53600	60-00-4	Ethylenediaminetetraacetic acid	**2**	292.24			
113	16780 - 52800	64-17-5	Ethanol	1	46.07			
114	55040	64-18-6	Formic acid	**1**	46.03	0–3	CONTAM	https://doi.org/10.2903/j.efsa.2012.2703
116	13090 - 37600	65-85-0	Benzoic acid	1	122.12	**5**	ANS	https://doi.org/10.2903/j.efsa.2016.4433
117	21550	67-56-1	Methanol	3	32.04			
118	23830 - 81882	67-63-0	2-Propanol	1	60.10	**2.4**	AFC CONTAM	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2005.202 https://doi.org/10.2903/j.efsa.2012.2703
119	30295	67-64-1	Acetone	3	58.08	0.9	CONTAM	https://doi.org/10.2903/j.efsa.2012.2703
125	16950	74-85-1	Ethylene	3	28.05			
126	10210	74-86-2	Acetylene	3	26.04			
131	48460	75-37-6	1,1-Difluoroethane	3	66.05			
143	62450	78-78-4	Isopentane	3	72.15			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
158	23380 - 76320	85-44-9	Phthalic anhydride	**2**	148.12			
161	92160	87-69-4	L-(+)-Tartaric acid	**1**	150.09	**30**	AFC	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2003.19
165	23200 - 74480	88-99-3	o-Phthalic acid	**2**	166.13			
171	38080	93-58-3	Benzoic acid, methyl ester	**2**	136.15			
172	37840	93-89-0	Benzoic acid, ethyl ester	**2**	150.17			
173	60240	94-13-3	4-Hydroxybenzoic acid, propyl ester	**1**	180.20			
189	60200	99-76-3	4-Hydroxybenzoic acid, methyl ester	**1**	152.15	**10**	AFC	https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2004.83
190	18880	99-96-7	p-Hydroxybenzoic acid	**2**	138.12			
194	13150	100-51-6	Benzyl alcohol	**1**	108.14	**4** **5**	FAF CONTAM	https://doi.org/10.2903/j.efsa.2019.5876 https://doi.org/10.2903/j.efsa.2011.2482
195	37360	100-52-7	Benzaldehyde	**1**	106.12			
204	25180 - 92640	102-60-3	N,N,N′,N′-Tetrakis(2-hydroxypropyl)ethylenediamine	**2**	292.41			
213	82400	105-62-4	1,2-Propyleneglycol dioleate	**1**	604.99			
221	40570	106-97-8	Butane	3	58.12			
222	13870	106-98-9	1-Butene	3	56.11			
224	13900	107-01-7	2-Butene	3	56.11			
228	13690	107-88-0	1,3-Butanediol	**1**	90.12	**4**	CONTAM CEF	https://doi.org/10.2903/j.efsa.2011.2482 https://doi.org/10.2903/j.efsa.2011.2164
240	45760	108-91-8	Cyclohexylamine	**2**	99.17			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[(a)]	Molecular mass, chemical category[(a)]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[(a)]	EFSA Panel	Link to the opinion
244	71720	109-66-0	Pentane	3	72.15			
249	17290 - 55120	110-17-8	Fumaric acid	**1**	116.07			
252	87200	110-44-1	Sorbic acid	**1**	112.13	**3**	CEF CEF ANS	https://doi.org/10.2903/j.efsa.2009.1205 https://doi.org/10.2903/j.efsa.2011.1924 https://doi.org/10.2903/j.efsa.2015.4144
257	13550 - 16660 - 51760	110-98-5	Dipropyleneglycol	**2**	134.17			
260	24280	111-20-6	Sebacic acid	**2**	202.25			
266	25510 - 94320	112-27-6	Triethyleneglycol	**2**	150.17			
269	25090 - 92350	112-60-7	Tetraethyleneglycol	**1**	194.23			
273	52730	112-86-7	Erucic acid	3	338.57	**7**	CONTAM	https://doi.org/10.2903/j.efsa.2016.4593
275	23980	115-07-1	Propylene	3	42.08			
276	19000	115-11-7	Isobutene	3	56.11			
279	22840 - 71600	115-77-5	Pentaerythritol	**2**	136.15			
287	60160	120-47-8	4-Hydroxybenzoic acid, ethyl ester	**1**	166.17	**10**	AFC CEF AFC	https://doi.org/10.2903/j.efsa.2006.296 https://doi.org/10.2903/j.efsa.2012.2994 https://doi.org/10.2903/j.efsa.2004.83
288	24970	120-61-6	Terephthalic acid, dimethyl ester	**2**	194.18			
300	30045	123-86-4	Acetic acid, butyl ester	**1**	116.16	**6**	CONTAM	https://doi.org/10.2903/j.efsa.2012.2984

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
302	12820	123-99-9	Azelaic acid	**2**	188.22			
303	12130 - 31730	124-04-9	Adipic acid	**1**	146.14			
308	91200	126-13-6	Sucrose acetate isobutyrate	**1**	846.91	**20**	ANS	https://doi.org/10.2903/j.efsa.2016.4489
311	16480 - 51200	126-58-9	Dipentaerythritol	**2**	254.28			
320	37680	136-60-7	Benzoic acid, butyl ester	**2**	178.23			
339	86160	409-21-2	Silicon carbide	**3 -inert**	40.10			
346	10030	514-10-3	Abietic acid	**2**	302.45			
362	14350	630-08-0	Carbon monoxide	3	28.01			
393	37280	1302-78-9	Bentonite	**3 -inert**	180.06			
404	67200	1317-33-5	Molybdenum disulphide	**3 -inert**	160.07			
406	83300	1323-39-3	1,2-Propyleneglycol monostearate	**1**	342.56			
408	82960	1330-80-9	1,2-Propyleneglycol monooleate	**1**	340.54			
414	87600	1338-39-2	Sorbitan monolaurate	**1**	346.46			
415	87840	1338-41-6	Sorbitan monostearate	**1**	430.62			
416	87680	1338-43-8	Sorbitan monooleate	**1**	428.61			
419	92150	1401-55-4	Tannic acids	3	**1,701.20**			
432	12280	2035-75-8	Adipic anhydride	**2**	128.13			
441	38160	2315-68-6	Benzoic acid, propyl ester	**2**	164.20			
445	83440	2466-09-3	Pyrophosphoric acid	**1**	177.98			
450	24430	2561-88-8	Sebacic anhydride	**2**	184.23			
459	46870	3135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	**2**	805.29			
465	68040	3333-62-8	7-[2H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	**2**	389.41			
478	60180	4191-73-5	4-Hydroxybenzoic acid, isopropyl ester	**2**	180.20			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[(a)]	Molecular mass, chemical category[(a)]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[(a)]	EFSA Panel	Link to the opinion
479	12970	4196-95-6	Azelaic anhydride	**2**	170.21			
480	46790	4221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	**2**	438.64			
491	82720	6182-11-2	1,2-Propyleneglycol distearate	**1**	609.02			
496	71680	6683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	**2**	**1,177.63**			
503	46080	7585-39-9	β-Dextrin	0	**1,134.98**	**5**	ANS	https://doi.org/10.2903/j.efsa.2016.4628
508	86560	7647-15-6	Sodium bromide	**1**	102.89			
509	23170 - 72640	7664-38-2	Phosphoric acid	**1**	98.00	**70**	CONTAM	https://doi.org/10.2903/j.efsa.2011.2482
514	91840	7704-34-9	Sulphur	**3 -inert**	32.07			
517	81520	7758-02-3	Potassium bromide	**1**	119.00			
521	58320	7782-42-5	Graphite	**3 -inert**	12.01			
522	7782-50-5	7782-50-5	Chlorine	3	70.91	0.15	AFC	https://doi.org/10.2903/j.efsa.2006.297
529	67850	8002-53-7	Montan wax	**3 -inert**	Wax			
534	80720	8017-16-1	Polyphosphoric acids	**1**	MW < 1,000			
535	24100 - 24130 - 24190 – 83840	8050-09-7	Rosin	**2**				
536	84320	8050-15-5	Rosin, hydrogenated, ester with methanol	**2**				
537	84080	8050-26-8	Rosin, ester with pentaerythritol	**2**				
538	84000	8050-31-5	Rosin, ester with glycerol	**1**				
542	42640	9000-11-7	Carboxymethylcellulose	**2**	**Polysaccharide**			
554	43300	9004-36-8	Cellulose acetate butyrate	**3 -inert**	**Polysaccharide**			
555	53280	9004-57-3	Ethylcellulose	2	**Polysaccharide**			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
556	54260	9004-58-4	Ethylhydroxyethylcellulose	2	**Polysaccharide**			
557	66640	9004-59-5	Methylethylcellulose	2	**Polysaccharide**			
558	60560	9004-62-0	Hydroxyethylcellulose	2	**Polysaccharide**			
559	61680	9004-64-2	Hydroxypropylcellulose	2	**Polysaccharide**			
560	66700	9004-65-3	Methylhydroxypropylcellulose	2	**Polysaccharide**			
561	66240	9004-67-5	Methylcellulose	2	**Polysaccharide**			
562	22450	9004-70-0	Nitrocellulose	3	**MW ≥ 1,000**			
565	61120	9005-27-0	Hydroxyethyl starch	2	**Polysaccharide**			
567	82080	9005-37-2	1,2-Propyleneglycol alginate	**1**	**MW ≥ 1,000**	**55**	ANS	https://doi.org/10.2903/j.efsa.2018.5371
568	79040	9005-64-5	Polyethyleneglycol sorbitan monolaurate	**1**	520.66	**25**	ANS	https://doi.org/10.2903/j.efsa.2015.4152
569	79120	9005-65-6	Polyethyleneglycol sorbitan monooleate	**2**	604.82			
570	79200	9005-66-7	Polyethyleneglycol sorbitan monopalmitate	**1**	522.671	**25**	ANS	https://doi.org/10.2903/j.efsa.2015.4152
571	79280	9005-67-8	Polyethyleneglycol sorbitan monostearate	**1**	606.83	**25**	ANS	https://doi.org/10.2903/j.efsa.2015.4152
572	79360	9005-70-3	Polyethyleneglycol sorbitan trioleate	**2**	**1,132.71**			
573	79440	9005-71-4	Polyethyleneglycol sorbitan tristearate	**1**	**1,138.76**	**25**	ANS	https://doi.org/10.2903/j.efsa.2015.4152
574	24250 - 84560	9006-04-6	Rubber, natural	3	**Polymeric**			
575	76721	63148-62-9	Polydimethylsiloxane (Mw > 6,800 Da)	**2**	**MW ≥ 1,000**			
576	60880	9032-42-2	Hydroxyethylmethylcellulose	2	**Polysaccharide**			
591	36160	10605-09-1	Ascorbyl stearate	1	442.59			
595	19510	11132-73-3	Lignocellulose	3	**Polysaccharide**			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
597	67120	12001-26-2	Mica	**3 -inert**	**Polysaccharide**			
598	41600	12004-14-7	Calcium sulphoaluminate	**2**	678.61			
600	60030	12072-90-1	Hydromagnesite	**3 -inert**	467.64			
601	35440	12124-97-9	Ammonium bromide	**1**	97.94			
603	83460	12269-78-2	Pyrophyllite	**3 -inert**	181.16			
604	60080	12304-65-3	Hydrotalcite	**3 -inert**	603.97			
610	93440	13463-67-7	Titanium dioxide	1	79.87			
611	35120	13560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	**2**	288.36			
613	95905	13983-17-0	Wollastonite	**3 -inert**	116.16			
614	45560	14464-46-1	Cristobalite	**3 -inert**	60.08			
616	83470	14808-60-7	Quartz	**3 -inert**	60.08			
623	52640	16389-88-1	Dolomite	**3 -inert**	184.40			
626	57800	18641-57-1	Glycerol tribehenate	3	**1,059.80**			
627	59760	19569-21-2	Huntite	**3 -inert**	Mineral			
630	82240	22788-19-8	1,2-Propyleneglycol dilaurate	**1**	440.70			
634	25910	24800-44-0	Tripropyleneglycol	**2**	192.25			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[a]	Molecular mass, chemical category[a]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[a]	EFSA Panel	Link to the opinion
638	23590 - 76960	25322-68-3	Polyethyleneglycol	**2**	Range, low fraction MW < 1,000			
639	23651 - 80800	25322-69-4	Polypropyleneglycol	3	Range, low fraction MW < 1,000	**1.5**	CONTAM	https://doi.org/10.2903/j.efsa.2011.2482
643	87760	26266-57-9	Sorbitan monopalmitate	**1**	402.57	**10**	ANS	https://doi.org/10.2903/j.efsa.2017.4788
644	88080	26266-58-0	Sorbitan trioleate	2	957.51			
649	47210	26427-07-6	Dibutylthiostannoic acid polymer	**2**	Polymeric – UL restriction n = 1.5–2, i.e. MW < 1 kDa			
651	88240	26658-19-5	Sorbitan tristearate	**1**	963.55	**10**	ANS	https://doi.org/10.2903/j.efsa.2017.4788
659	82800	27194-74-7	1,2-Propyleneglycol monolaurate	**1**	258.40			
664	95000	28931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	3	**Polymeric**			
665	83120	29013-28-3	1,2-Propyleneglycol monopalmitate	**1**	314.51			
666	87280	29116-98-1	Sorbitan dioleate	**2**	693.06			
668	80240	29894-35-7	Polyglycerol ricinoleate	**1**	520.70			
674	46480	32647-67-9	Dibenzylidene sorbitol	**2**	358.39			
677	82560	33587-20-1	1,2-Propyleneglycol dipalmitate	**1**	552.91			
682	53270	37205-99-5	Ethylcarboxymethylcellulose	2	**Polysaccharide**			
683	66200	37206-01-2	Methylcarboxymethylcellulose	2	**Polysaccharide**			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[(a)]	Molecular mass, chemical category[(a)]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[(a)]	EFSA Panel	Link to the opinion
684	68125	37244-96-5	Nepheline syenite	**3 -inert**	Mineral			
686	61390	37353-59-6	Hydroxymethylcellulose	2	**Polysaccharide**			
693	88160	54140-20-4	Sorbitan tripalmitate	**2**	879.39			
696	92205	57569-40-1	Terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)	**2**	811.10			
699	90720	58446-52-9	Stearoylbenzoylmethane	**2**	386.61			
702	87920	61752-68-9	Sorbitan tetrastearate	**2**	**1,230.02**			
707	46375	61790-53-2	Diatomaceous earth	**3 -inert**	Mineral			
709	87520	62568-11-0	Sorbitan monobehenate	**2**	486.73			
714	84400	64365-17-9	Rosin, hydrogenated, ester with pentaerythritol	**2**	420.59			
717	84210	65997-06-0	Rosin, hydrogenated	**2**				
719	65920	66822-60-4	N-Methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	**2**	**Polymeric**			
721	46800	67845-93-6	3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	**2**	474.76			
727	43360	68442-85-3	Cellulose, regenerated	2	**Polysaccharide**			

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF List[(a)]	Molecular mass, chemical category[(a)]	ADI or TDI (mg/kg bw per day)		
						Value established or endorsed[(a)]	EFSA Panel	Link to the opinion
734	46380	68855-54-9	Diatomaceous earth, soda ash flux-calcined	**3 -inert**	Mineral			
739	70000	70331-94-1	2,2′-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	**2**	696.91			
741	24070 - 83610	73138-82-6	Resin acids and rosin acids	**2**				
743	38950	79072-96-1	Bis(4-ethylbenzylidene)sorbitol	**2**	414.49			
751	81515	87189-25-1	Poly(zinc glycerolate)	2-3	**Polymeric**			
752	39890	87826-41-3	Bis(methylbenzylidene)sorbitol	**2**	386.44			
753	62800	92704-41-1	Kaolin, calcined	**3 -inert**	Mineral			
757	95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	2	**Mineral**			
766	38879	135861-56-2	Bis(3,4-dimethylbenzylidene) sorbitol	**2**	414.49			
821	90810		Stearoyl-2-lactylic acid, salts	**1**	range, MW < 1,000			

(a): Information in bold indicates the reason for categorising the substance in the low priority group.

Table A.7: Substances falling under an SCF classification in list 1 or 2 for which the health-based guidance value was not available

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF list	Synoptic SCF Opinion
60	58300		Glycine, salts	1	ADI: acceptable (SCF, 25th Series, 1991)
162	65520	87-78-5	Mannitol	1	ADI: acceptable (SCF, 16th Series, 1985)
113	16780 - 52800	64-17-5	Ethanol	1	Acceptable (SCF, 11th Series, 1981)
110	93520	59-02-9 10191-41-0	α-Tocopherol	1	Acceptable (SCF, 22th Series, 1989)
101	36000	50-81-7	Ascorbic acid	1	Acceptable (SCF, 22th Series, 1989)
100	24490 - 88320	50-70-4	Sorbitol	1	Acceptable (SCF, 16th Series, 1985).
428	95200	1709-70-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	2	t-TDI: 1 mg/kg bw pending check of the reports 2-year oral studies in rats and dogs and oral carcinogenicity studies in mice and rats. (Shell reports n. TLGR 0023.68. March 1969, TLGR. 0024.68, Sept. 1968, TLGR. 0019.69, March 1969)
321	36080	137-66-6	Ascorbyl palmitate	1	Acceptable (SCF, 22th Series, 1989)
610	93440	13463-67-7	Titanium dioxide	1	Acceptable (SCF, 1st Series, 1975)
591	36160	10605-09-1	Ascorbyl stearate	1	Acceptable. Covered by the assessment for ascorbyl palmitate

Table A.8: Medium priority group of substances

FCM substance no.	Ref. no.	CAS no.	Substance name
3	12375		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)
9	30610		Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)
10	30612		Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters
12	31328		Acids, fatty, from animal or vegetable food fats and oils
13	33120		Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C24)
17	34281		Alkyl(C8-C22) sulphuric acids, linear, primary with an even number of carbon atoms
22	43200		Castor oil, mono- and diglycerides
36	54450		Fats and oils, from animal or vegetable food sources
37	54480		Fats and oils, hydrogenated, from animal or vegetable food sources
40	56360		Glycerol, esters with acetic acid
41	56486		Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C14-C18) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C16-C18)
42	56487		Glycerol, esters with butyric acid
43	56490		Glycerol, esters with erucic acid
44	56495		Glycerol, esters with 12-hydroxystearic acid
45	56500		Glycerol, esters with lauric acid
46	56510		Glycerol, esters with linoleic acid
47	56520		Glycerol, esters with myristic acid
48	56535		Glycerol, esters with nonanoic acid
49	56540		Glycerol, esters with oleic acid
50	56550		Glycerol, esters with palmitic acid
51	56570		Glycerol, esters with propionic acid
52	56580		Glycerol, esters with ricinoleic acid
53	56585		Glycerol, esters with stearic acid
54	57040		Glycerol monooleate, ester with ascorbic acid
56	57200		Glycerol monopalmitate, ester with ascorbic acid
58	57600		Glycerol monostearate, ester with ascorbic acid
60	58300		Glycine, salts
65	67155		Mixture of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene, 4,4′-bis(2-benzoxazolyl) stilbene and 4,4′-bis (5-methyl-2-benzoxazolyl)stilbene
67	67840		Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol

FCM substance no.	Ref. no.	CAS no.	Substance name
100	24490 - 88320	50-70-4	Sorbitol
101	36000	50-81-7	Ascorbic acid
110	93520	59-02-9 10191-41-0	α-Tocopherol
120	49540	67-68-5	Dimethyl sulphoxide
122	23800	71-23-8	1-Propanol
123	13840	71-36-3	1-Butanol
124	22870	71-41-0	1-Pentanol
136	41680	76-22-2	Camphor
155	23470	80-56-8	α-Pinene
162	65520	87-78-5	Mannitol
174	14740	95-48-7	o-Cresol
205	25385	102-70-5	Triallylamine
210	13390 - 14880	105-08-8	1,4-Bis(hydroxymethyl)cyclohexane
214	61840	106-14-9	12-Hydroxystearic acid
215	14170	106-31-0	Butyric anhydride
216	14770	106-44-5	p-Cresol
232	10150 - 30280	108-24-7	Acetic anhydride
233	24850	108-30-5	Succinic anhydride
235	14710	108-39-4	m-Cresol
238	18070	108-55-4	Glutaric anhydride
250	53520	110-30-5	N,N′-Ethylenebisstearamide
251	53360	110-31-6	N,N′-Ethylenebisoleamide
253	15250	110-60-1	1,4-Diaminobutane
259	58720	111-14-8	Heptanoic acid
265	22600	111-87-5	1-Octanol
267	15100	112-30-1	1-Decanol
271	52720	112-84-5	Erucamide
296	23860	123-38-6	Propionaldehyde
298	14110	123-72-8	Butyraldehyde
306	88960	124-26-5	Stearamide
309	91360	126-14-7	Sucrose octaacetate

FCM substance no.	Ref. no.	CAS no.	Substance name
314	23500	127-91-3	β-Pinene
321	36080	137-66-6	Ascorbyl palmitate
322	63040	138-22-7	Lactic acid, butyl ester
328	65040	141-82-2	Malonic acid
331	22480	143-08-8	1-Nonanol
332	69760	143-28-2	Oleyl alcohol
335	68960	301-02-0	Oleamide
360	57920	620-67-7	Glycerol triheptanoate
367	16697	693-23-2	n-Dodecanedioic acid
401	24475	1313-82-2	Sodium sulphide
417	85680	1343-98-2	Silicic acid
421	13000	1477-55-0	1,3-Benzenedimethanamine
428	95200	1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene
458	36960	3061-75-4	Behenamide
486	54005	5136-44-7	Ethylene-N-palmitamide-N′-stearamide
488	53440	5518-18-3	N,N′-Ethylenebispalmitamide
494	62140	6303-21-5	Hypophosphorous acid
524	24520	8001-22-7	Soybean oil
525	62640	8001-39-6	Japan wax
526	43440	8001-75-0	Ceresin
527	14411 - 42880	8001-79-4	Castor oil
530	41760	8006-44-8	Candelilla wax
533	42720	8015-86-9	Carnauba wax
539	24160	8052-10-6	Rosin tall oil
543	45920	9000-16-2	Dammar
589	52645	10436-08-5	Cis-11-eicosenamide
593	44960	11104-61-3	Cobalt oxide
602	70240	12198-93-5	Ozokerite
609	83455	13445-56-2	Pyrophosphorous acid
647	56720	26402-23-3	Glycerol monohexanoate
648	56880	26402-26-6	Glycerol monooctanoate
654	88600	26836-47-5	Sorbitol monostearate

FCM substance no.	Ref. no.	CAS no.	Substance name
669	56610	30233-64-8	Glycerol monobehenate
681	18310	36653-82-4	1-Hexadecanol
703	17170	61788-47-4	Fatty acids, coco
704	77600	61788-85-0	Polyethyleneglycol ester of hydrogenated castor oil
706	17230	61790-12-3	Fatty acids, tall oil
712	42960	64147-40-6	Castor oil, dehydrated
718	84240	65997-13-9	Rosin, hydrogenated, ester with glycerol
722	17200	68308-53-2	Fatty acids, soya
754	56020	99880-64-5	Glycerol dibehenate
820	76420		Pimelic acid, salts

Table A.9: Results for negative predictions considering a score for VEGA ≥ 0.5

CAS number	Chemical name	OECD QSAR ToolBox		VEGA			
		In vitro mutagenicity (Ames test) alerts by ISS	DNA alerts for AMES by OASIS	Consensus model	Mutagenic score	Non-mutagenic score	Experimental data available
99880-64-5	Glycerol dibehenate	No alert found	No alert found	NON-mutagenic	0	0.75	No
61788-47-4	Fatty acids, coco	No alert found	No alert found	NON-mutagenic	0	0.825	No
67-56-1	Methanol	No alert found	No alert found	NON-mutagenic	0	1	YES
67-64-1	Acetone	No alert found	No alert found	NON-mutagenic	0	1	YES
67-68-5	Dimethyl sulphoxide	No alert found	No alert found	NON-mutagenic	0	1	YES
69-72-7	Salicylic acid	No alert found	No alert found	NON-mutagenic	0	1	YES
71-23-8	1-Propanol	No alert found	No alert found	NON-mutagenic	0	1	YES
71-36-3	1-Butanol	No alert found	No alert found	NON-mutagenic	0	1	YES
71-41-0	1-Pentanol	No alert found	No alert found	NON-mutagenic	0	1	YES
74-85-1	Ethylene	No alert found	No alert found	NON-mutagenic	0	1	YES
26402-26-6	Glycerol monooctanoate	No alert found	No alert found	NON-mutagenic	0	0.75	No
78-78-4	Isopentane	No alert found	No alert found	NON-mutagenic	0	1	YES
80-56-8	α-Pinene	No alert found	No alert found	NON-mutagenic	0	1	YES
95-48-7	o-Cresol	No alert found	No alert found	NON-mutagenic	0	1	YES
10436-08-5	Cis-11-Eicosenamide	No alert found	No alert found	NON-mutagenic	0	0.75	No
100-42-5	Styrene	No alert found	No alert found	NON-mutagenic	0	1	YES
102-70-5	Triallylamine	No alert found	No alert found	NON-mutagenic	0	1	YES
106-14-9	12-Hydroxystearic acid	No alert found	No alert found	NON-mutagenic	0	0.9	No
106-31-0	Butyric anhydride	No alert found	No alert found	NON-mutagenic	0	0.9	No
106-44-5	p-Cresol	No alert found	No alert found	NON-mutagenic	0	1	YES
106-97-8	Butane	No alert found	No alert found	NON-mutagenic	0	1	YES
106-98-9	1-Butene	No alert found	No alert found	NON-mutagenic	0	0.75	No
107-01-7	2-Butene	No alert found	No alert found	NON-mutagenic	0	1	YES
108-39-4	m-Cresol	No alert found	No alert found	NON-mutagenic	0	1	YES
108-55-4	Glutaric anhydride	No alert found	No alert found	NON-mutagenic	0	0.75	No
109-66-0	Pentane	No alert found	No alert found	NON-mutagenic	0	1	YES

CAS number	Chemical name	OECD QSAR ToolBox		VEGA			
		In vitro mutagenicity (Ames test) alerts by ISS	DNA alerts for AMES by OASIS	Consensus model	Mutagenic score	Non-mutagenic score	Experimental data available
110-30-5	N,N′-ethylenebisstearamide	No alert found	No alert found	NON-mutagenic	0	1	YES
111-14-8	Heptanoic acid	No alert found	No alert found	NON-mutagenic	0	1	YES
111-87-5	1-octanol	No alert found	No alert found	NON-mutagenic	0	1	YES
112-30-1	1-decanol	No alert found	No alert found	NON-mutagenic	0	1	YES
112-84-5	Erucamide	No alert found	No alert found	NON-mutagenic	0	0.75	No
115-11-7	Isobutene	No alert found	No alert found	NON-mutagenic	0	1	YES
8001-75-0	Ceresin	No alert found	No alert found	NON-mutagenic	0	0.75	No
123-38-6	Propionaldehyde	Simple aldehyde	No alert found	NON-mutagenic	0	1	YES
123-72-8	Butyraldehyde	Simple aldehyde	No alert found	NON-mutagenic	0	1	YES
124-26-5	Stearamide	No alert found	No alert found	NON-mutagenic	0	1	YES
127-91-3	β-pinene	No alert found	No alert found	NON-mutagenic	0	1	YES
141-82-2	Malonic acid	No alert found	No alert found	NON-mutagenic	0	0.825	No
143-28-2	Oleyl alcohol	No alert found	No alert found	NON-mutagenic	0	0.825	No
301-02-0	Oleamide	No alert found	No alert found	NON-mutagenic	0	0.75	No
3061-75-4	Behenamide	No alert found	No alert found	NON-mutagenic	0	0.825	No
2146-71-6	Lauric acid, vinyl ester	alpha,beta-unsaturated aliphatic alkoxy group	No alert found	NON-mutagenic	0	0.825	No
1477-55-0	1,3-Benzenedimethanamine	No alert found	No alert found	NON-mutagenic	0	1	YES
620-67-7	Glycerol triheptanoate	No alert found	No alert found	NON-mutagenic	0	0.75	No
693-23-2	n-Dodecanedioic acid	No alert found	No alert found	NON-mutagenic	0	0.9	No
36653-82-4	1-Hexadecanol	No alert found	No alert found	NON-mutagenic	0	0.675	No
30233-64-8	Glycerol monobehenate	No alert found	No alert found	NON-mutagenic	0	0.675	No
76-22-2	Camphor	No alert found	No alert found	NON-mutagenic	0	0.575	No
110-31-6	N,N′-Ethylenebisoleamide	No alert found	No alert found	NON-mutagenic	0	0.5	No
8006-44-8	Candelilla wax	No alert found	No alert found	NON-mutagenic	0	0.5	No

CAS number	Chemical name	OECD QSAR ToolBox		VEGA			
		In vitro mutagenicity (Ames test) alerts by ISS	DNA alerts for AMES by OASIS	Consensus model	Mutagenic score	Non-mutagenic score	Experimental data available
8001-79-4	Castor oil	No alert found	No alert found	NON-mutagenic	0	0.5	No
126-14-7	Sucrose octaacetate	No alert found	No alert found	NON-mutagenic	0	0.5	No
5518-18-3	N,N′-ethylenebispalmitamide	No alert found	No alert found	NON-mutagenic	0	0.675	No
5136-44-7	Ethylene-N-palmitamide-N′-stearamide	No alert found	No alert found	NON-mutagenic	0	0.6	No
143-08-8	1-Nonanol	No alert found	No alert found	NON-mutagenic	0	0.675	No
105-08-8	1,4-Bis(hydroxymethyl) cyclohexane	No alert found	No alert found	NON-mutagenic	0.05	0.525	No
108-24-7	Acetic oxide	No alert found	No alert found	NON-mutagenic	0	1	Yes
108-30-5	Succinic anhydride	No alert found	No alert found	NON-mutagenic	0	1	Yes
110-60-1	Putrescine (1,4-diaminobutane)	No alert found	No alert found	NON-mutagenic (Consensus score: 0.825)	0	0.85	No
137-66-6	Ascorbyl palmitate	No alert found	AN2 >> Schiff base formation >> Dicarbonyl compounds	NON-mutagenic	0	1	Yes
138-22-7	Butyl lactate	No alert found	No alert found	NON-mutagenic	0	0.9	No
1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene	No alert found	No alert found	NON-mutagenic	0	0.5	No
26836-47-5	D-glucitol monostearate	No alert found	No alert found	NON-mutagenic (Consensus score: 0.525)	0	0.525	No
50-70-4	Sorbitol	No alert found	No alert found	NON-mutagenic (Consensus score: 1)	0	1	Yes
50-81-7	VITAMIN C (ascorbic acid)	No alert found	AN2 >> Schiff base formation >> Dicarbonyl compounds	NON-mutagenic (Consensus score: 1)	0	1	Yes

CAS number	Chemical name	OECD QSAR ToolBox		VEGA			
		In vitro mutagenicity (Ames test) alerts by ISS	DNA alerts for AMES by OASIS	Consensus model	Mutagenic score	Non-mutagenic score	Experimental data available
59-02-9	Alpha-tocopherol	No alert found	No alert found	NON-mutagenic (Consensus score: 1)	0	1	Yes
64-17-5	Ethanol	No alert found	No alert found	NON-mutagenic (Consensus score: 1)	0	1	Yes
87-78-5	Mannitol	No alert found	No alert found	NON-mutagenic (Consensus score: 1)	0	1	Yes

Table A.10: Results for negative predictions considering a consensus score for VEGA < 0.5

CAS number	Chemical name	OECD QSAR ToolBox		VEGA			
		In vitro mutagenicity (Ames test) alerts by ISS	DNA alerts for AMES by OASIS	Consensus model	Mutagenic score	NON-mutagenic score	Experimental data available
143925-92-2	Amines, bis (hydrogenated tallow alkyl) oxidised	No alert found	SN2 >> Acylation >> N-Hydroxylamines; SN1 >> Nucleophilic attack after nitrenium ion formation >> N-Hydroxylamines; Radical >> Radical mechanism via ROS formation (indirect) >> N-Hydroxylamines; AN2 >> Carbamoylation after isocyanate formation >> N-Hydroxylamines	NON-mutagenic	0	0.4	No
74-86-2	Acetylene	No alert found	No alert found	NON-mutagenic	0.067	0.133	No
75-37-6	1,1-Difluoroethane	No alert found	No alert found	NON-mutagenic	0.05	0.35	No
10605-09-1	Ascorbyl stearate	No alert found	AN2 >> Schiff base formation >> Dicarbonyl compounds	NON-mutagenic	0	0.45	No

Table A.11: Substances not included in the high priority group due to rejection criteria

FCM no.	CAS	Name	ECHA stage	Substance information card	ECHA concerns, not of relevance to FCM risk evaluation
235	108-39-4	m-Cresol	CLH	https://echa.europa.eu/substance-information/-/substanceinfo/100.003.253	Harmonised classification and labelling: Acute Tox. 3 (H301): is toxic if swallowed Acute Tox. 3 (H311): is toxic in contact with skin Skin Corr. 1B (H314): causes severe skin burns and eye damage
267	112-30-1	1-Decanol	Substance evaluation	https://echa.europa.eu/substance-information/-/substanceinfo/100.003.597	Based on information available, the evaluating Member State Competent Authority (eMSCA) of Italy supports the human health self-classification as Eye Irrit. 2 H319 and the notified classification as Skin Irrit. 2 H315, STOT SE 3 H335 (Respiratory tract) and STOT SE 2 H371 (Central Nervous System) as further explained in the SEV (Substance Evaluation Conclusion and Evaluation Report). Therefore, a harmonised classification of the substance is envisaged as a follow-up at EU level for these human health endpoints
123	71-36-3	1-Butanol	Substance evaluation	https://echa.europa.eu/substance-information/-/substanceinfo/100.000.683	Conclusion by the eMSCA of Hungary on RMOA concerns for reproductive toxicity and developmental neurotoxicity: no need for regulatory follow-up action at EU level (CoRAP document and Substance Evaluation Conclusion and Evaluation Report). Harmonised classification and labelling: Acute Tox. 4 (H302): harmful if swallowed Skin Irrit. 2 (H315): causes skin irritation Eye Dam. 1 (H318): causes serious eye damage STOT SE 3 (H335): may cause respiratory irritation STOT SE 3 (H336): may cause drowsiness or dizziness
124	71-41-0	1-Pentanol	Substance evaluation	https://echa.europa.eu/substance-information/-/substanceinfo/100.000.684	According to the evaluation of the eMSCA of Lithuania, the classification as eye damage category 1 with H318 (Causes serious eye damage) is supported. The harmonised classification and labelling to be updated to include eye damage/irritation (Substance Evaluation Conclusion and Evaluation Report). Harmonised classification and labelling: Flam. Liq. 3 (H226): is a flammable liquid and vapour Skin Irrit. 2 (H315): causes skin irritation Acute Tox. 4 (H332): harmful if inhaled STOT SE 3 (H335): may cause respiratory irritation
174	95-48-7	o-Cresol	CLH	https://echa.europa.eu/substance-information/-/substanceinfo/100.002.204	Harmonised classification and labelling: Acute Tox. 3 (H301): is toxic if swallowed Acute Tox. 3 (H311): is toxic in contact with skin Skin Corr. 1B (H314): causes severe skin burns and eye damage

FCM no.	CAS	Name	ECHA stage	Substance information card	ECHA concerns, not of relevance to FCM risk evaluation
233	108-30-5	Succinic anhydride	Substance evaluation, CLH	https://echa.europa.eu/substance-information/-/substanceinfo/100.003.246	Initial grounds of concern: CMR, Sensitiser, High (aggregated) tonnage, High RCR. According to the eMSCA of Austria, data available demonstrate that succinic anhydride requires further harmonised classification for its sensitising properties (Skin Sens. 1; H317: may cause an allergic skin reaction; Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled). Furthermore, data demonstrate that succinic anhydride has corrosive properties and needs to be classified as Skin Corr. 1B (H314: Causes severe skin burns and eye damage) and Eye Dam. 1 (H318: Causes serious eye damage) (Substance Evaluation Conclusion and Evaluation Report) Harmonised classification and labelling: Skin Corr. 1 (H314): causes severe skin burns and eye damage. Acute Tox. 4 (H302): harmful if swallowed. Eye Dam. 1 (H318): causes serious eye damage. Skin Sens. 1 (H317): may cause an allergic skin reaction. Resp. Sens. 1 (H334): may cause allergy or asthma symptoms or breathing difficulties if inhaled
253	110-60-1	1,4-Diaminobutane	CLH	https://echa.europa.eu/substance-information/-/substanceinfo/100.003.440	No Harmonised Classification and Labelling CLH proposal withdrawn
718	65997-13-9	Rosin, hydrogenated, ester with glycerol	Substance evaluation, PBT	https://echa.europa.eu/substance-information/-/substanceinfo/100.060.020	No Harmonised Classification and Labelling Initial grounds of concern: Suspected PBT/vPvB, exposure to the environment (CoRAP document and Substance Evaluation Decision) PBT under development (no document available)

Table A.12: Substances assigned to the low priority or 'no SML needed' groups, following expert judgement

FCM substance no.	CAS no.	Substance name	SCF list	Synoptic SCF Opinion	Boiling point (°C)	ADI or TDI (mg/kg bw)[(a)]	EFSA Panel	QSAR Mutagenicity (Ames test)[(a)]	Evaluation Stage under REACH or CLP[(a)]	IARC[(a)]	SIN list[(a)]
113	64-17-5	Ethanol	1	Acceptable (SCF, 11th Series, 1981)	78.2				Dossier evaluation	**1**	
117	67-56-1	Methanol	3	The toxicity profile well known also from intoxication of man. The potential migration into food will not be of toxicological significance (SCF, 6th Series, 1978)	64.7				**Substance evaluation, CLH, RMOA, Restriction**		
119	67-64-1	Acetone	3	Residue in food less than 5 mg/kg. (SCF, 11th Series, 1981)	56.0	**0.9**	CONTAM		Screening, Dossier evaluation		
221	106-97-8	Butane	3	Volatile compound	−0.5				**CLH**		
275	115-07-1	Propylene	3	Residues of this gas in plastics are very small. The gas has a low toxic potential. Migration into food will be toxicologically negligible.(Patty's Industrial Hygiene and Toxicology, 3rd edition, 1981)	−47.6			**Positive**	Dossier evaluation	3	
362	630-08-0	Carbon monoxide	3	Low migration	−191.5				Dossier evaluation, **CLH**		'Classified CMR according to Annex VI of Regulation 1272/2008'
522	7782-50-5	Chlorine	3	Residues of this gas in plastics will be very small. Migration into food would	−34.0	**0.15**	AFC				

FCM substance no.	CAS no.	Substance name	SCF list	Synoptic SCF Opinion	Boiling point (°C)	ADI or TDI (mg/kg bw)[a]	EFSA Panel	QSAR Mutagenicity (Ames test)[a]	Evaluation Stage under REACH or CLP[a]	IARC[a]	SIN list[a]
				be self-limiting because of odour							
591	10605-09-1	Ascorbyl stearate	1	Acceptable Covered by the assessment for ascorbyl palmitate	536.0			**Positive**			
610	13463-67-7	Titanium dioxide	1	Acceptable (SCF, 1st Series, 1975)	2,900.0 (approximate value)				**Substance evaluation, CLH**	**2B**	
768	143925-92-2	Amines, bis (hydrogenated tallow alkyl) oxidised	3	SCF_List: 3 Restriction: Only to be used: ·in polyolefins at 0.1% (w/w) and not for fatty food with a simulant D Reduction Factor less than 3 ·in PET at 0.25% (w/w) and only for food for which simulant D is not required. Remark for Commission: To make sure that also for the migration of Bis (hydrogenated tallow, C16-18, alkyl) nitrones and (Hydrogenated tallow, C16-18, alkyl) oximes into fatty foods a sufficient safety margin to the NOEL in the subchronic oral rat study exists the following restriction is proposed: Qm 0,1% in polyolefins, not for fatty foods with a Reduction Factor < 3. See				**Positive**			

FCM substance no.	CAS no.	Substance name	SCF list	Synoptic SCF Opinion	Boiling point (°C)	ADI or TDI (mg/kg bw)[(a)]	EFSA Panel	QSAR Mutagenicity (Ames test)[(a)]	Evaluation Stage under REACH or CLP[(a)]	IARC[(a)]	SIN list[(a)]
				SCF evaluation in the website: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out180_en.pdf							

(a): Information in bold indicates the reason for categorising the substance as a possible candidate for the high priority group.

Table A.13: High Priority Group of substances

FCM substance no.	Ref. no.	CAS no.	Substance name	SCF list	Genotoxicity prediction (Ames test)[(a)]	ECHA evaluation stage under REACH or CLP[(a)]	IARC classification group[(a)]	SIN list (reasons for inclusion)[(a)]
121	24270 - 84640	69-72-7	Salicylic acid	3		**CLH**, Screening under REACH		
193	24610	100-42-5	Styrene	4B		**CLH, RMOA: under development**	**2A**	'Styrene is an endocrine disruptor (ED) (cat 1). Reprotoxic as well as carcinogenic and mutagenic effects have been reported. It is highly toxic to aquatic species.'
436	19480	2146-71-6	Lauric acid, vinyl ester	3	**Positive** (OECD Toolbox alerts by ISS)	Dossier evaluation under REACH		

(a): Information in bold indicates the reason for categorising the substance in the high priority group.