

National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport

Alternative food contact materials on the Dutch market after implementation of the Single Use Plastic Directive and prioritisation of potential migrating chemical substances

Colophon

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Synopsis

Alternative food contact materials on the Dutch market after implementation of the Single Use Plastic Directive and prioritisation of potential migrating chemical substances

As part of efforts to combat the harmful environmental impact of plastic litter, the European Union has been rolling out a series of measures. Among them is a ban – introduced in 2021 – on a range of single-use plastics (SUP). These are plastics that are designed to be used once and then thrown away. Many of these products are used to pack, serve and consume food and beverages. They include drinking straws, stirrers and disposable plates.

Following the ban on using plastic for the manufacture of these products, they are now being made from alternative materials such as paper, wheat straw and bamboo. RIVM investigated for which products these materials are being used and which chemical substances they might contain. It then assessed whether any of these substances might be harmful to health and whether they could migrate into food.

The investigation shows that the materials currently in use *potentially* contain a wide range of substances. To enable targeted research into their potential risks, RIVM has identified which substances and materials would have to be further investigated first.

RIVM conducted this survey on behalf of the Netherlands Food and Consumer Product Safety Authority (NVWA).

Keywords: Single Use Plastics (SUP), Food Contact Materials (FCM)

Publiekssamenvatting

Alternatieve voedselcontactmaterialen op de Nederlandse markt na invoering van het verbod op plastic voor eenmalig gebruik; prioritering van chemische stoffen die eruit kunnen vrijkomen

De Europese Unie wil de schadelijke effecten voor het milieu van plastic zwerfafval tegengaan. Sinds de zomer van 2021 worden daarvoor stap voor stap maatregelen ingevoerd. Zo zijn sinds 2021 verschillende soorten plastic producten verboden die gemaakt zijn om één keer te gebruiken en daarna weg te gooien - de zogeheten Single Use Plastics (SUP). Veel van deze producten worden gebruikt om eten en drinken te verpakken, te serveren of te consumeren. Dat zijn bijvoorbeeld rietjes, roerstaafjes of wegwerpbordjes.

Vanwege het verbod op het gebruik van plastic voor deze producten worden ze nu van andere materialen gemaakt, zoals papier, tarwemeel of bamboe. Het RIVM heeft geïnventariseerd welke materialen worden gebruikt en welke stoffen in die materialen zouden kunnen zitten. Daarna is gekeken welke van deze stoffen mogelijk schadelijk zijn voor de gezondheid en of deze stoffen in voedsel kunnen terechtkomen.

De inventarisatie laat zien dat er in de gebruikte materialen heel veel stoffen zouden kúnnen zitten. Om gerichter onderzoek te kunnen doen naar mogelijke risico's heeft het RIVM aangegeven naar welke stoffen en materialen het eerst onderzoek zou moeten worden gedaan.

Het RIVM heeft dit onderzoek in opdracht van de Nederlandse Voedsel en Waren Autoriteit (NVWA) gedaan.

Kernwoorden: Single Use Plastics (SUP), voedselcontactmaterialen (Food Contact Materials – FCM)

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Summary

This report investigates potential risks related to Food Contact Materials (FCM) that substitute Single Use Plastics (SUP) available on the Dutch market. As of 2021, several SUP-products have been banned as a result of the 'Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment', the so-called SUP Directive (EC, 2019). By implementing various measures over time, the SUP directive aims to ban plastic (containing) products that will be used only once. Consequently, alternative materials are used for these products. This study, commissioned by the Netherlands Food and Consumer Product Safety Authority (NVWA), focuses on the following product categories:

- 1. Cutlery (forks, knifes, spoons, chopsticks)
- 2. Plates and bowls
- 3. Straws
- 4. Beverage stirrers
- 5. Food containers
- 6. Cups for beverage

For these products three research questions were addressed:

- 1. Which alternative materials to SUP FCM are available on the Dutch market?
- 2. Which substances may be present in these materials and which of these substances are of human toxicological concern?
- 3. Which alternative materials should be prioritised for follow-up (laboratory) research?

Approach

To investigate the first question, articles were sampled from supermarkets, household shops and take-away restaurants, between January and April 2022. The focus was on single use and semi-single use products, since these products are expected to change the most upon implementation of the SUP Directive.

Since many articles do not provide information about the type of material they are made of, an indicative overview of product-material combinations was established. Most materials sampled are bio-based. Paper, cardboard and wood were most common. More 'exotic' bio-based materials like bamboo, palm leaves, sugarcane and wheat were found less frequently. It was only specified a few times whether materials were coated and/or with which material. FCM made of plastic were found in products for which the SUP Directive was not yet in force at the time of the survey (e.g., products sold by food vendors), but also in categories for which the use in SUP was already banned.

We have selected materials for further investigation by:

- counting the frequency in which materials were used for each product category separately as well as for all categories together;
- discerning 'novel' materials (those specifically expected to have replaced plastic) from 'known' materials (e.g., glass and metals, including metal alloy and aluminium);

 leaving out bio-plastics, like Polylactic acid (PLA), since these fall under the SUP-Directive as well and will be studied in parallel by the NVWA.

The materials selected for literature review are paper and cardboard, wood, bamboo, sugarcane, palm leaves and wheat. EU and National regulations on these materials used in contact with food are stated.

To address the second research question, a scientific literature search was conducted using the Scopus database to assess which chemicals can be or may be found in (products of) the selected materials (May 2022). Since many studies focus on specific chemicals, and paper and board have the longest history as FCM, the information gathered should not be considered as representative for market shares, but as indicative for the current knowledge base with respect to chemicals in the selected materials. In addition, other, so called 'grey literature' (professional reports, policy documents, business to business information) was reviewed.

Hazards of the (possible) constituents were identified by retrieving hazard information listed on the European Chemicals Agency website (ECHA – last access: February 2023). Some examples of chemical(s) (groups) (thought to be) present in raw material are minerals, terpenes, phenols, flavonoids, quinones, phytosterols and cyanide. Examples of chemical(s) (groups) (thought to be) present in processed materials are: PFAS, alkanes, pesticides, organochlorides, chlorophenols, metals, mycotoxins, formaldehyde, melamine, bisphenol A, cyanide and boric acid.

A further step towards identifying potential risks was to look up information on the concentrations of constituents in or migrating from the alternative materials. For this purpose we have used the Database on Migrating and Extractable Food Contact Chemicals (FCCmigex - Food Packaging Forum, 2022). To determine whether the chemicals retrieved in the previous step can migrate, the number of studies which showed migration was compared to the total number of studies. Only studies describing single-use FCM were included.

Finally, the third research question was addressed by prioritising the chemical substances that were identified in the literature research based on hazard properties and information about migration experiments. The following categories were constructed (an explanation of the abbreviations is provided in 3.5:

Hazard categories:

- Low: Constituents for which no information is available or no hazards are known or which are classified (harmonised or self) as STOT RE 2;
- Medium: Constituents classified (harmonised or self) as CMR category 2 (Carc. 2, Muta. 2 or Repr. 2) or STOT RE 1;
- High: Constituents classified (harmonised or self) as CMR category 1 (Carc. 1A/1B, Muta. 1A/1B *or* Repr. 1A/1B).

Migration categories:

- Low: No migration experiments are available for the constituent or migration of the constituent was detected in less than 50% of the studies;
- Medium: Migration of the constituent was detected in 50% or more of the studies;
- High: Migration of the constituent was detected in 75% or more of the studies, confirmed with at least four experiments including MiF and MiFS experiments.

Constituents were attributed high priority (for further research) if the constituent meets both the high hazard category and the high migration category. Chemicals in the high hazard category that do not meet the high category for migration were labelled as medium priority (regardless of migration level priority). Chemicals in the medium hazard category that are in either the medium or high migration category were labelled as medium priority. Other chemicals were labelled as low priority chemicals.

Results

Six chemicals were given high priority, and all were found to be (possibly) present in FCM made of paper and board, or wood (fibres). One high priority chemical (formaldehyde) was found to be (possibly) present in four alternative materials. Bisphenol A can be present in FCM made of paper and board, and wood. Forty-eight chemicals were given medium priority, of which more than twenty were found to (possibly) be present in paper and board FCM and wood FCM. Seven chemicals with medium priority may be present in two FCM types.

Most prioritised chemicals are (possibly) found in FCM of paper and board and wood. Since only a few chemicals are prioritised in FCM products made of bamboo, palm leaves and sugarcane, and no chemicals are prioritised in wheat FCM, this indicates that further studies could be directed at materials more often used for FCM (first). The lack of information on these materials does also show the need for further research.

Recommendations

When considering product-material relations, our findings suggest that efforts could go towards the detection of chemicals in cutlery and plates/bowls made of wood and paper and board, straws made of paper, food containers made of paper and cups for beverage made of paper and board. Of this type of products, plates/bowls and food containers were most found in our market search, followed by cutlery and drinking cups. Finally, the six chemicals prioritised with high priority could be specifically screened for.

It should be noted that not only the chemical constituents in the materials influence the risk of harmful effects for consumers, but also the way products are used. Many factors influence the level of exposure and therefore affect health risks, e.g., direct contact with the mouth, greater surface area in contact with foods, longer time of contact between food and materials, hot vs cold foods or beverages and fat vs non-fat foods. RIVM letter report 2022-0102

1 Introduction

1.1 Context

In June 2019, the European Union adopted 'Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment', the so-called SUP Directive (EC, 2019). It is recognised that the production and use of Single-Use Plastics (SUP) is growing. The SUP Directive states that these plastics pose 'a severe risk to marine ecosystems, to biodiversity and to human health'. The Directive aims to reduce plastic litter in the environment, especially in the aquatic and marine environment where plastic litter tends to accumulate. The Directive also aims to promote circular alternatives to SUP that are more sustainable, like nontoxic, re-usable products and re-use systems. The Directive contains various elements for this purpose, for example a ban on certain types of SUP products, like cutlery, plates and straws. Furthermore, the Directive introduces Extended Producer Responsibility (EPR) for certain product groups and promotes awareness of products that do contain plastic, e.g., via labelling (EC, 2019).

1.2 Research scope and questions

This research, performed on behalf of the Dutch Food and Consumer Product Safety Authority (NVWA), specifically focusses on the impact of the SUP Directive on food contact materials (FCM) available on the Dutch market. The ban on SUP FCM may result in a growing market for and use of alternative materials used in contact with food. The alternative materials may introduce human health risks when used as FCM. The aim of this report is to investigate what alternative materials are available on the Dutch market as replacement for certain SUP categories and which chemicals of potential interest are present in these materials.

This report addresses the following research questions:

- 1. Which alternative materials to SUP FCM are available on the Dutch market?
- 2. Which substances may be present in these materials and which of these substances are of human toxicological concern?
- 3. Which alternative materials should be prioritised for follow-up (laboratory) research?

1.3 Structure of the report

Chapter 2 provides background information about the implementation of the SUP Directive in the Netherlands and the relevant legislation on FCM. In Chapter 3 we discuss our approach and research scope. Findings for research question 1 are presented in Chapter 4 ('Outcome of the market survey and selection of alternative materials'). For each material selected we discuss findings for research question 2 in Chapter 5 ('Outcome of the literature search: Constituents (possibly) present in alternative materials, including hazard classifications and migration properties'). Research question 3 is addressed in Chapter 6. Chapter 7 discusses outcomes and limitations, as well as findings from stakeholder interviews and other studies. Chapter 8 closes with conclusions with respect to the research questions and provides recommendations for further research. RIVM letter report 2022-0102

2 Relevant Regulations and Directives

2.1 SUP Directive

The Directive is implemented in phases, and Member States are obliged to implement the Directive in their national legislation (EC, 2019). In the Netherlands, the first part of the Directive is implemented via the Decree on SUP products ('Besluit kunststofproducten voor eenmalig gebruik' (NL, 2022b)) that entered into force on 3 July 2021 but was last amended in 2022 (NL, 2022a). This Decree includes adjustments for the 'Decree packaging management 2014' ('Besluit beheer verpakkingen 2014') which was last amended in 2023 (NL, 2023a).

Further implementation is organised via the 'Ministerial Regulation SUP products' ('Ministeriële regeling kunststofproducten voor eenmalig gebruik') that was published on 29 March 2022 (NL, 2022b) and was last amended in 2023 (NL, 2023b).

This report focusses on alternatives that enter the market due to the ban on SUP products that are used as FCM. For these products, the timeline of implementation of measures is as follows:

3 July 2021

Ban on plastic (containing) products:

- Cutlery (forks, knives, spoons, chopsticks) (Art. 2b Besluit kunststofproducten voor eenmalig gebruik);
- Plates (Art. 2c Besluit kunststofproducten voor eenmalig gebruik)
- Straws (except straws for medical use) (Art. 2d Besluit kunststofproducten voor eenmalig gebruik);
- Beverage stirrers (Art. 2e Besluit kunststofproducten voor eenmalig gebruik);
- Food containers made of expanded polystyrene (EPS) which are used to contain food which:
 - is intended for immediate consumption, either on-the-spot or take-away,
 - is typically consumed from the receptacle, and
 - is ready to be consumed without any further preparation, such as cooking, boiling or heating

- Beverage containers made of expanded polystyrene (EPS), including their caps and lids (Art. 15b-b 'Decree Packaging Management 2014' (NL, 2023a));
- Cups for beverage made of EPS, including theirs covers and lids (Art. 15b-c 'Decree Packaging Management 2014' (NL, 2023a)).

Other (non-EPS) plastic drinking cups are not yet banned, however, these need to be marked/labelled to indicate that these products contain plastic (Art. 15e 'Decree Packaging Management 2014' (NL, 2023a)).

Markings on SUP (containing) articles to raise consumer awareness are obliged (Art. 3.3 Ministerial Regulation SUP products (NL, 2023b)).

⁽Art. 15b-a 'Decree Packaging Management 2014' (NL, 2023a));

1 January 2023:

Producers of plastic bags, cups for beverages, food containers, bottles, packets & wrappers, balloons, wet wipes, and cigarettes with filters contribute to the cleaning up of litter in the environment (Art. 3.1, 3.2 Ministerial Regulation) and measures must be taken to raise awareness of consumers of the impact of littering on the environment (Art. 3.3 Ministerial Regulation SUP products (NL, 2023b)).

1 July 2023:

Plastic (containing) drinking cups and food packaging may not be provided free of charge (future Art. 2.2 Ministerial Regulation SUP products (NL, 2022b)).

Producers must offer reusable alternative or give the opportunity to bring your own (future Art. 2.2 Ministerial Regulation SUP products (NL, 2022b)).

1 January 2024:

Offering plastic drinking cups or single-use plastic food packaging for consumption on site is prohibited. An exception is made if SUP is collected on site for high-quality recycling (in increasing percentage, 75% in 2024 and then 5% extra every year) (future Art. 2.1 Ministerial Regulation SUP products (NL, 2022b)).

3 July 2024:

Ensure caps and lids remain attached to beverage containers/bottles during use (future Art. 15c-1 'Decree Packaging Management 2014') (NL, 2022b)).

2025:

Recycled content of polyethylene terephthalate (PET) bottles (up to 3L) should be minimum 25% (future Art. 15c-4 'Decree Packaging Management 2014') (NL, 2022b)).

2030:

Recycled content of PET bottles (up to 3L) should be minimum 30% (future Art. 15c-5 'Decree Packaging Management 2014' (NL, 2022b)).

The Directive covers full plastic products and also products that contain (bio)plastic. For example, paper laminated with plastic (to ensure that the material is water- and fat repellent) is covered by the Directive, also if the laminate (the coating) is produced out of bio-based material and/or if the plastic is biodegradable. The Dutch Regulations emphasise that each addition of polymers is covered by the national implementation of the Directive, to avoid emission to the environment at all. Other measures address targets for plastic waste collection and producer responsibilities.

The Dutch Human Environment and Transport Inspectorate ('Inspectie Leefomgeving en Transport – ILT) enforces the national implementation of the SUP Directive. A visual summary with regard to FCM is provided in the leaflet '<u>Maatregelen om gebruik van plastic wegwerpbekers en - voedselverpakkingen te verminderen</u>'.

2.2 FCM Regulations

Food Contact Materials (FCM) are packaging materials for food and materials that come into contact with food during production or consumption of food. Frequently used materials are plastic, paper and cardboard, glass, ceramic and metals. These materials are sometimes coated to protect either the material or the consumer. Substances can be released from the FCM into the food, this is called migration. For some materials and/or chemical groups, regulations state requirements that FCM need to comply with. In general, only chemicals that are safe can be used. Regulations can be set on European level and national level.

There are two European Regulations with general requirements for FCM (EC, 2022b).

The first is Regulation (EC) No 1935/2004, which sets requirements for FCM on the market (EC, 2021). The aim of the Regulation is that materials are not releasing their constituents into food at levels harmful to human health and that they do not change food composition, taste and odour in an unacceptable way. In this Regulation, seventeen groups of materials are covered: active and intelligent materials and articles, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes and wood. For these groups specific measures may be adopted or amended by the Commission. Measures include e.g., positive lists, special conditions for use, purity standards and specific limits on migration (EC, 2021). The measures relevant for the materials discussed in this report can be found in the chapter on constituents present in the alternative materials. Regulation (EC) No 1935/2004 was last amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain.

The second Regulation, Commission Regulation (EC) No 2023/2006 sets requirements related to good production methods of the production of FCM and the quality assurance system (EC, 2006). This framework does not regulate specific substances.

In addition to the general requirements stated in these two Regulations, several Regulations and Directives for specific materials are in place, namely for plastic (Commission Regulation (EU) No 10/2011), recycled plastic (Commission Regulation (EU) No 2022/1616), active packaging materials that extend the shelf-life, and intelligent packaging materials that monitor the condition of packaged food (Commission Regulation (EC) No 450/2009), ceramics (Commission Directive 84/500/EEC), and regenerated cellulose film (Commission Directive 2007/41/EC). The documents on plastic (EC No 10/2011) and regenerated cellulose film contain positive lists, which includes substances that can be used (if the migration is not higher than the Specific Migration Limits (SMLs) set for these substances).

Also, several legislations on specific substances are in place, namely bisphenol A (Commission Regulation (EU) 2018/213), epoxy derivatives (Commission Regulation 1895/2005/EC) and N-nitrosamines and N-nitrosatable substances from rubber teats and soothers (Commission

Directive 93/11/EEC). Finally, kitchenware made of melamine or polyamide originating or consigned from China or Hong Kong must comply to the import rules of Commission Regulation (EU) No 284/2011 (EC, 2022b). These regulations and directives fall outside of the scope of the report and are not discussed in further detail.

As stated in Regulation (EC) No 1935/2004, EU Member State countries may adopt or maintain own national provisions, Regulations and Directives on FCM in the absence of specific EU measures. National legislations may differ between Member States (EC, 2022b).

The Netherlands implemented the European legislation in the Decree and Regulation on Packaging and Consumer Articles of the Commodities Act (in Dutch: 'Warenwetbesluit' en 'Warenwetregeling verpakkingen en gebruiksartikelen') (NL, 2021a, 2022c). The Regulation on Packaging and Consumer Articles of the Commodities Act also contains requirements for materials that are not (yet) regulated in the EU, and provides additional requirements for EU regulated materials, e.g., for ceramics and plastics. The Regulation ensures the implementation of several articles of the Dutch Commodities Act (in Dutch: 'Warenwet') (NL, 2021b). For instance, in Article 3 it is stated that a material shall be manufactured from the substances listed for that material in the annex of the Regulation. Positive lists of accepted substances with corresponding SMLs are available for several FCM, i.e., paper and cardboard, rubber, metals, textile, wood and cork, coatings, and epoxy polymers. For these materials, a substance can only be used when it is assessed and approved. FCM manufacturers need to submit dossiers to the national Dutch government when using substances that are not on the relevant positive list. Substances can be added to a positive list by the Ministry of Health, Welfare and Sport (VWS) following a positive assessment by the Dutch Commission for safety assessment of FCM (in Dutch: 'Commissie Beoordeling Veiligheid Voedselcontactmaterialen' (CBVV)) (RIVM, 2022; RIVM, 2023; NVWA, 2022; VWS, 2022). Article 4 states that FCM may not be used in manners other than the specified manners of the chapter of the Commodities Act. Article 5 states that migration of constituents should be within the set limits of the constituents (NL, 2022c).

Next to the positive lists, substances may be present that are listed in Article 0.3 of Annex A of the Commodities Act Regulation. A few examples are:

- solvents (except for generated cellulose films);
- the single and double salts of acids, phenols and alcohols on positive lists (within SMLs);
- natural and synthetic polymers of at least 1000 Da, made of listed monomers and used as additives; and
- prepolymers and natural or synthetic macromolecular substances, made of listed monomers (including mixtures thereof) when used as monomers of another precursor.

Moreover, substances that are not on positive lists and do not categorise within the beforementioned groups, can be used when they comply with one of the following rules:

- when there is no migration (determined with a method with a detection limit of 0.01 mg/kg food) and
- the total migration of a group of chemicals which are structurally and toxicologically alike stays below the general threshold of migration (0.01 mg/kg food), and
- only when these substances are not classified as mutagenic, carcinogenic or toxic to reproduction category 1A/1B, nor in nano form).

Lastly, chemicals that are not intentionally added to the FCM can be present, e.g., contaminants of the substances used, intermediate products formed during production and reaction or decomposition products (Article 0.3 of Annex A of Commodities Act Regulation).

In the Netherlands, the Netherlands Food and Consumer Product Safety Authority (in Dutch: 'Nederlandse Voedsel en Warenautoriteit' (NVWA)) is responsible for enforcing and monitoring regulatory compliance. RIVM letter report 2022-0102

Approach

3

The research questions have been addressed by an explorative and stepwise approach, see Figure 1. For each step we will discuss analytic choices below. Additionally, we have compiled background information about the relevant regulations and conducted a limited number of stakeholder interviews.

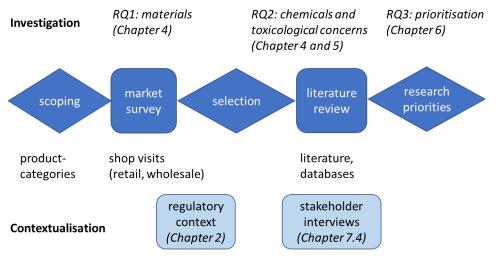


Figure 1 research questions and approach

3.1 Scoping of product categories

The product categories to be included in the market survey were selected as most relevant to the Netherlands Food and Consumer Product Safety Authority:

- 1. Cutlery (forks, knifes, spoons, chopsticks)
- 2. Plates and bowls
- 3. Straws
- 4. Beverage stirrers
- 5. Food containers
- 6. Cups for beverage

In these categories we have focused on single use products, since these products are expected to have become increasingly available upon implementation of the SUP Directive (alternative/new materials are used instead of plastic materials). Still, the market for durable alternatives is likely to grow due to the SUP Directive as well, which may result in new types of materials being used.

There is a grey area between single use and more durable articles. Occasionally, so-called 'semi-single use' articles (e.g., plastic cups that were made out of a bit ticker plastic and said to be washable) where included in the market survey. In principle, all available single use and semi-single use articles that were available in the shops that were visited were included in the survey. However, in case there were many similar products sold (e.g., the same paper plates or cups with different types of prints) only one or two of this article type were included in the survey. Potential risks of reusable products will be investigated in 2023.

3.2 Sale points included in the market survey

The market survey was conducted during Q1 and Q2 of 2022. Three supermarkets, two take-away locations, two utility stores and a whole sale market were visited. Furthermore, colleagues have been asked to assist in sampling packaging from take-away lunches and/or diners. While the sampling from these sites showed saturation in terms of novel products and/or novel materials, an important limitation is that (the packaging of) many articles does not provide information about materials. The selection of materials for further investigation is based on what could be retrieved from material specifications. A preliminary search for information online did not yield additional findings to the shop visits. Social media have not been included in this survey.

3.3 Selection of alternative materials of interest to the Dutch market

For the products included in the market survey, we have observed which materials were used most often 1) for the product groups separately, and 2) for all products combined. In doing so, we have discerned 'raw' materials like wood and processed materials like coated wood. Raw materials that could be seen as an element of the material were combined (wood and wood fibres). Next, we have discerned novel alternative materials from known materials, like plastics, glass and metals (including metal alloy and aluminium). Polylactic acid (PLA) is listed as a novel material but has not been selected for further investigation because it falls under the SUP Directive.

3.4 Literature search to assess potentially relevant constituents in alternative materials of interest to the Dutch market

A literature search in the Scopus database was conducted to assess which chemicals can be or may be found in (products of) alternative materials that come into contact with food. The literature search was performed in May of 2022. Search strategies were developed to capture relevant literature for each of the alternative materials. Search terms were formulated to describe the material and aimed at deriving chemical constituents or the chemical composition. For example, the chemical composition for wood differs from the composition of wood fibres. When the number of articles was too high and results were not specific enough, search terms like 'food packaging', 'food contact material', 'food' and/or 'toxic*' were added to the search string. The obtained references were judged for their relevance based on title/abstract. Articles were excluded when they did not list chemical constituents of the alternative material.

In addition, grey literature was searched using a long list of potentially relevant sources that was developed in the context of Waarzitwatin (https://waarzitwatin.nl/), a Dutch initiative on chemical substances in consumer products, in which RIVM is involved; the search engine Google, and websites of organizations performing food safety assessments. Relevant reports by other national and international institutes or consumer organizations assessing food (contact materials)

were included in the overview. CAS numbers of the various constituents were in most cases obtained using PubChem (NIH, 2022).

3.5 Overview of hazard classifications

Hazards of the (possible) constituents were identified by retrieving hazard information listed on the European Chemicals Agency website (ECHA) (February 2023). The information reported on the ECHA website as "Properties of Concern" are included. Properties are included based on their relevance for FCM, so carcinogenicity, mutagenicity, reproductive toxicity (so called CMR properties), as well as endocrine disruptive (ED) properties. ECHA also notes environmental properties, such as persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB), these are considered not relevant for FCM, so not included in the prioritisation. Systemic toxicity, however, was considered relevant for FCM, and is additionally included (STOT RE from Harmonised C&L).

ECHA uses four levels of certainty with regard to these Properties of Concern: recognised, suspected, broad agreement and minority position.

- "Recognised" means that the concern is indicated in an official resource (from a Harmonised C&L [CLP Regulation Annex VI] or in the Candidate List of substances of very high concern for authorisation [REACH]) (classified as Carc. 1A/1B., Muta. 1A/1B., Repr. 1A/1B).
- "Potential" also comes from official sources only but means that the concern is suspected (Harmonised C&L as Carc. 2, Muta. 2, Repr. 2). Chemicals under assessment for ED also fall under the "potential" certainty.
- "Broad agreement" comes from data submitted by industry to ECHA and indicates that ≥ 50% of the data submitters provide the same concern (so called self-classification).
- PoCs with "minority position" as level of certainty, indicating that data submitted is not aligned since > 5% to < 50% of the data submitters provided the same concern. These are not included in this report

Chemicals listed as Substances of Very High Concern (SVHC), including reasons for listing, are listed as well. Substances can be identified as SVHC when they meet the criteria for classification as CMR category 1A or 1B in accordance with the CLP Regulation, or when they are PBT or vPvB according to REACH Annex XIII, or, on a case-by-case basis, an equivalent level of concern as CMR or PBT/vPvB substances. When identified as SVHC they are added to the Candidate List. From the Candidate List, substances can be included in the Authorisation List (Annex XIV) based on wide dispersive use or high volumes that fall within the scope of the authorisation requirement.

3.6 Overview of the migration from FCM

Information on the concentrations of constituents in the alternative materials present on the Dutch market are almost always lacking. To investigate whether chemicals that were found or might be found in alternative FCM can migrate into food, the Database on Migrating and Extractable Food Contact Chemicals (FCCmigex) database was searched (Food Packaging Forum, 2022). This database contains 3142 food

contact chemicals (FCC) and maps the scientific evidence of FCC that have (not) been found in migrates and extracts from FCM from 1210 studies (Geueke et al., 2022). FCM from plastic, paper and board, metals, glass and ceramics, multi-materials and other materials are included. In the category 'other', FCM of silicone, wood, rubber, cork, textiles were included next to combined FCM and FCM of unclear/unknown material. Since no alternative materials of interest are included in the database, except paper and glass, migration from all materials is listed in the present study as a proxy.

In addition, not only single use, but also repeated use and FCM of which use status is unclear are included in the database. To provide insights into whether the chemicals determined in this study that could be or were found in FCM are able to migrate, the percentage of positive migration studies was calculated. Only studies describing single-use FCM were included. The database solely shows the number of (positive) studies, not the number of samples or the level of migration.

Since alternative materials described in this report, with the exception of paper and board, are not specifically listed in the FCCmigex-database, all FCM materials from which migration was found were listed together. The method by which the migration was tested was listed as well, namely extraction experiments (EX; 55.2% of all data entries), migration into foodstuffs (MiF; 33.0% of all data entries) or migration into food simulants (MiFS; 11.8% of all data entries; i.e., solvents that resemble the properties of food but have a clearly defined chemical composition). Geueke et al. (2022) states that 'evidence for migration implies that the chemical is directly relevant for human exposure, while chemicals detected in extracts typically require further migration testing to confirm exposure potential'.

3.7 Prioritisation of chemicals

The chemical substances that were identified in the literature research were prioritised based on information on hazard and migration. Not all hazard information provided in this report was used to prioritise the chemicals (i.e., ED, and SVHC listing are provided for information only).

For prioritisation based on hazard information, the following categories were chosen:

- Low: Constituent for which no information is available or no hazards are known or which is classified (harmonised or self) as STOT RE 2;
- Medium: Constituents classified (harmonised or self) as CMR category 2 (Carc. 2, Muta. 2 *or* Repr. 2) *or* STOT RE 1;
- High: Constituents classified (harmonised or self) as CMR category 1 (Carc. 1A/1B, Muta. 1A/1B or Repr. 1A/1B).

For prioritisation based on migration information, the following categories were chosen:

• Low: No migration experiments are available for the constituent or migration of the constituent was detected in less than 50% of the studies;

- Medium: Migration of the constituent was detected in 50% or more of the studies;
- High: Migration of the constituent was detected in 75% or more of the studies, confirmed with at least 4 experiments including MiF and MiFS experiments.

The priority level is determined by combining the categories based on hazard and migration information according to the following rules:

| Priority level | Hazard information | Migration information |
|----------------|--------------------|--------------------------|
| High | High | High |
| Medium | High | Medium |
| | High | Low |
| | Medium | High |
| | Medium | Medium |
| Low | Medium | Low |
| | Low | High |
| | Low | Medium |
| | Low | Low |

Table 1 Rules by which chemicals were prioritised

Constituents are listed as high priority if the constituent meets both the high category for hazard and migration. Chemicals with high priority for hazard that do not meet the criteria for high priority migration are labelled as medium priority (regardless of migration level priority). Chemicals with medium priority hazard that have either medium or high priority migration are labelled as medium priority. Other chemicals are labelled as low priority chemicals. It should be noted that absence of hazard information results in a low priority. Further, little or no information on migration results in a low or medium priority (depending also on the hazard category). For groups included, no classification could be stated, so they are not included in the prioritisation. 4

Outcomes of the market survey and selection of alternative materials

The market survey has yielded an overview of materials used in the product categories that have been investigated. In this chapter we will discuss general observations with respect to the products that have been sampled, the overviews presented in Table 2 and 3 and the selection that has been made for the next step (retrieving information about chemical composition and toxicological concerns).

4.1 Market survey observations

The market survey shows that various types of bio-based materials are abundantly available on the Dutch market (Table 2). Especially paper, cardboard and wood were found often. More 'exotic' bio-based materials like bamboo, palm leaves and sugarcane have also been found, but less frequently. We were able to specify the coating of paper and cardboard explicitly when the coating was bio-based (PLA or wax) or implicitly when the paper/cardboard product contained a label stating 'this product contains plastic'. It is expected and observed that, also in case it was not mentioned, paper and cardboard FCM were coated with a layer to make the material water and fat resistant. It is noted that the use of (bio-based) plastic coatings on non-plastic base materials like paper and cardboard is or will be banned by the SUP Directive (actual timing varies by product category).

Although more products made of bio-based materials were found in the market survey, also plastic products appeared to be abundantly available. In most cases plastic was found in products where it has not yet been banned at the time of this market survey (food containers, drinking cups), but also in products for which the use of SUP was already banned, plastic was found. In most of the cases the plastic products then contained claims that the product could be dish washed and these products were made of somewhat thicker plastic then the single-use variant. In a few cases actually banned EPS SUP was still found available on the market (in food containers).

Besides specification of the base material (and sometimes the coating), also other claims and labels were found on the packaging of products. Several products contained the new logo that was introduced by the SUP Directive indicating that the product 'contains plastic' (Figure 2).



Figure 2 SUP logo 'product contains plastic' in Dutch

Almost all products contained the food grade logo and a logo indicating that the producer contributes to the disposal of the product (the German 'Grüne Punkt' logo, mandatory by German law for products on the German market). Many products contained some sort of sustainability claim indicating that the product was made of renewable resources, e.g., is recyclable. Few of the bio-based materials contained a logo or a statement indicating the product is compostable. Paper and cardboard products very often contained a FSC certification. Especially products from the wholesale store contained statements indicating how the products can be used (e.g., up to what temperature). Few times also remarkable statements were found. For example, on a set of paper straws it was mentioned that the straws could give off colour when coming into contact with liquid and the product was indicated to be decoration material (no food grade logo available). (Reusable) bamboo straws contained a claim that bamboo is naturally anti-bacterial meaning there is no need to use fertilisers or pesticides during cultivation.

| Material | Number of articles |
|----------------------------------|-----------------------|
| Bio-based materials | 82 |
| Paper | 28 |
| Cardboard | 17 |
| Wood (fibres) | 11 |
| Cardboard with PLA coating | 7 |
| Bamboo* | 4 |
| Bioplastic (PLA) | 4 |
| Cane (incl. sugarcane) | 3 |
| Palm leaf | 2 |
| Paper, coated | 2 |
| Cardboard with wax-based coating | 1 |
| Cardboard with PE coating | 1 |
| Wheat straw (bran) | 2 |
| Not bio-based material | 62 |
| Plastic, not-specified | 19 |

Table 2 Overview of the market survey results ordered in bio-based and not biobased materials

| Material | Number of articles |
|-------------|-----------------------|
| PP | 18 |
| PS | 8 |
| EPS | 4 |
| Aluminium | 3 |
| rPET | 3 |
| PET | 3 |
| PE-LD | 2 |
| Glass | 1 |
| Metal alloy | 1 |

Abbreviations: PLA: polylactic acid, PE: polyethylene, PP: polypropylene, PS: polystyrene, EPS: expanded polystyrene, rPET: recycled polyethylene terephthalate, PET: polyethylene terephthalate, PE-LD: low density polyethylene, *Sometimes a material is incorrectly referred to as 'bamboo', where actually it is a plastic in which bamboo fibres are used

4.2 Selected materials for further analysis

Materials in Table 3 are indicated as 'old' when they can be assumed as already known quite well (i.e. on the market for more than a decade). Different types of plastic, metals and glass were indicated as 'old'. Materials that are assumed to be less well known as they are relatively new on the market are indicated as 'new' materials. Various bio-based materials, including bio-based plastics were indicated as 'new' materials. Paper and cardboard have also been indicated as 'new' materials since the use of these materials is expected to grow and their composition (coating) may change due to the SUP Directive. All 'new' materials were selected for further investigation (see the chapter on constituents present in alternative materials), except bio-based plastics, since these are also restricted under the SUP Directive.

| Product | Material | Number of | Old/ |
|--------------------------------|--------------------------------------|-----------|------|
| category | | articles | new |
| Cutlery (forks, | Wood | 5 | New |
| knifes, spoons, chopsticks) | Bio-plastic (PLA) | 3 | New |
| chopsticks) | Cardboard | 3 | New |
| | Paper | 3 | New |
| | Bamboo | 2 | New |
| | Plastic, not specified | 3 | Old |
| | PP | 3 | Old |
| Plates and | Cardboard | 6 | New |
| bowls | Cardboard with PLA coating | 4 | New |
| | Wood | 3 | New |
| | Paper | 3 | New |
| | Sugarcane | 3 | New |
| | Cardboard with wax- based coating | 1 | New |

| Table 3 Overview of | the market survey | results p | resented by | product category |
|---------------------|-------------------|-----------|-------------|------------------|
| | | | | |

| Product category | Material | Number of articles | Old/ new |
|---------------------|---|--------------------|-------------|
| | Palm leaf | 1 | New |
| | Wheat bran | 1 | New |
| | Wood fibres | 1 | New |
| | Plastic, not specified | 3 | Old |
| | PP | 2 | Old |
| Beverage | Wood | 1 | New |
| stirrers | Paper | 1 | New |
| | Bamboo | 1 | New |
| | Plastic, not specified | 3 | Old |
| | PS | 1 | Old |
| Straws | Paper | 7 | New |
| | Bamboo | 1 | New |
| | Cane | 1 | New |
| | Wheat straw | 1 | New |
| | Glass | 1 | Old |
| | Metal alloy | 1 | Old |
| | Plastic, not specified | 1 | Old |
| | PP | 1 | Old |
| Food containers | Paper | 11 | New |
| | Sugarcane | 4 | New |
| | Cardboard | 3 | New |
| | rPET | 2 | New |
| | Wood | 1 | New |
| | Palm leaf | 1 | New |
| | Paper, coated | 1 | New |
| | PP | 10 | Old |
| | Plastic, not specified | 4 | Old |
| | EPS | 4 | Old |
| | Aluminium | 3 | Old |
| | PS | 3 | Old |
| | PET | 1 | Old |
| | PE-LD | 1 | Old |
| Cups for | Cardboard | 5 | New |
| beverage | Cardboard with PLA coating | 3 | New |
| | Paper | 3 | New |
| | Bamboo | 1 | New |
| | Bio-plastic (PLA) | 1 | New |
| | Cardboard with PE coating | 1 | New |
| | Paper, with plastic coating (not specified) | 1 | New |

| Product category | Material | Number of articles | Old/ new |
|---------------------|------------------------|-----------------------|-------------|
| | Recycled bio-plastic | 1 | New |
| | Plastic, not specified | 5 | Old |
| | PS | 4 | Old |
| | PET | 2 | Old |
| | PP | 2 | Old |
| | PE-LD | 1 | Old |

PLA: polylactic acid, PE: polyethylene, PP: polypropylene, PS: polystyrene, EPS: expanded polystyrene, rPET: recycled polyethylene terephthalate, PET: polyethylene terephthalate, PE-LD: low density polyethylene

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Outcome of the literature search: Constituents (possibly) present in alternative materials, including hazard classifications and migration properties

The next step in our investigation concerns the chemical composition and toxicological concerns of the materials that have been selected in the previous chapter. For each material we will summarise specific regulatory requirements (in addition to the general requirements of the SUP Directive and FCM Regulations discussed in Chapter 2). A distinction is made between material-dependent constituents (naturally present chemicals) and constituents that could be added to the alternative materials due to the process (from cultivation to transport to the store), either intended (IAS; intentionally added substances) or unintended (NIAS; non-intentionally added substances). In addition, an overview of the hazards and positive migration experiments of the (possibly) present chemicals is provided using the ECHA and FCCmigex databases, respectively. All tables can be found at the end of this chapter.

5.1 Paper and board

5.1.1 Legislation

FCM, including paper and board FCM, should comply with Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food, Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, and relevant national legislation. Paper and board are listed as one of the seventeen FCM groups in Annex I of Framework Regulation (EC) No 1935/2004 (EC, 2021) which may be covered by specific additional measures. No specific measures have been adopted within this Regulation. The European Consumer Organization BEUC recommends specific EU regulations for paper and board FCM chemicals to ensure equal consumer protection within the EU (BEUC, 2019a).

Several Member States have national requirements for paper and board FCM. For instance, the Swiss ordinance (SR 817.023.21) issued by the Swiss Federal Department of Home Affairs (FDHA) lists permitted substances in the manufacturing of printing inks for non-food contact surfaces of paper and board FCM. The German Federal Institute for Risk Assessment (BfR) published recommendations for good manufacturing practice (GMP) which contains a list of authorised substances for use in paper and board (BfR, 2022).

Within the Netherlands, the Commodities Act Regulation contains a list of chemicals that are exclusively allowed for manufacturing and processing of paper and cardboard FCM. This positive list for chemicals in paper and board is included in Annex part A, Chapter II of the Dutch legislation on FCM, the "*Warenwetregeling verpakkingen en gebruiksartikelen*" (NL, 2022c). The Regulation specifies which fibres can be used as raw materials for paper and board FCM. These include fresh cellulose-based firer materials, recycled paper and cardboard, and fibres of plastics, textile, and regenerated cellulose, as long as these fibres comply with the specific requirements on the respective FCM. The total migration of chemicals has to be below the migration limit of 60 mg/kg food as per sections 1.3.1 and 1.3.2 of chapter II of the Annex. Section 1.3.3. sets out specific migration limits for several chemicals and section 1.3.5. specifies that no migration of primary aromatic amines is allowed if the product is manufactured using aromatic isocyanates or diazo dyes.

In the Netherlands, the approval of intentional use in paper and board FCM of PFAS that have one of the following four per- and polyfluoroalkyl substances (PFAS) as starting material, contaminant or degradation product has been withdrawn (NL, 2022b):

- PFOA (Pentadecafluorooctanoic acid)
- PFOS (Heptadecafluorooctane-1-sulphonic acid)
- PFNA (Perfluorononan-1-oic acid)
- PFHxS (Perfluorohexane-1-sulphonic acid and its salts)

At the time of writing, Germany, the Netherlands, Norway, Sweden and Denmark are proposing a ban on all uses of PFAS, so including the use in FCM, except uses that are exempted because they are considered 'essential uses' under REACH (Bock & Laird, 2022).

5.1.2 Material-dependent constituents

Paper and board FCM are derived from cellulose-based natural fibres or synthetic fibres, which are bleached or non-bleached and derived from primary or recycled sources (Simoneau et al., 2016). Paper and board consist typically of 99% cellulose fibres, in addition to starch and mineral fillers (Simoneau et al., 2016; Sahin & Arslan, 2008). Lignin was commonly separated from cellulose, as it was thought to accelerate ageing of paper. New studies showed that lignin did not contribute to the ageing of paper, allowing new applications where lignin can be used in paper pulp to increase the yield (Małachowska et al., 2020, 2021). Minerals can be present as natural constituents or synthetic fillers in paper and board FCM (Hubbe & Gill, 2016). Table 4 gives an overview of these chemical constituents of paper and board FCM, including minerals.

5.1.3 Process constituents

Functional additives are added to allow for properties that make paper and board suitable as FCM. A positive list exists in multiple Member States for these chemicals (BfR, 2022). Furthermore, process chemicals are added to paper in order to improve the efficiency of the paper manufacturing process but are not intended to be present in the final product. Table 5 gives an overview of chemicals that might be introduced into paper and board FCM that were explicitly named as such in relevant studies (Bengtström et al., 2016; Van Bossuyt et al., 2016; Timshina et al., 2021; Geueke et al., 2022; Zimmermann et al., 2022), complete lists of chemicals present in paper and board FCM are more extensive and can be found in the annexes of these studies.

One study gathered 887 chemicals found in paper and board FCM in a database (Geueke et al., 2022). This study indicated that the main sources of food contact chemicals found in paper and board are coatings and printing ink, while chemicals from adhesives, plastic laminates and

waxes were found to a lesser extent (Geueke et al., 2022). Geueke et al. (2022) also indicated that the most frequently detected chemicals in paper and board FCM were mineral oils and phthalates, specifically mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH), dibutyl phthalate (DBP), diethylhexyl phthalate (DEHP) and di-isobutylphthalate (DiBP) (Geueke et al., 2022). Paper and board derived from recycled fibres might contain a higher amount of these chemicals, as non-food grade paper and board, printed materials, adhesives, coatings and additives of the recycling process might be introduced (Geueke et al., 2022).

Zimmermann et al. (2022) systematically analysed the chemicals listed for intentional use in several types of FCM including paper and board. They identified known food contact chemicals of concern (FCCoCs) of which 168 are listed for intentional use in paper and board FCM. Furthermore, 156 carcinogenic, mutagenic or reprotoxic (CMR) chemicals are listed for intentional use in the manufacturing of paper & board, according to the FCC database (Groh et al., 2021). It is noted that Geueke et al. (2022) showed a limited overlap between these chemicals, the ones listed for intentional use and the food contact chemicals extracted from FCM. Only the chemicals for which there is evidence of their presence in paper and board FCM are included in Table 5 (Zimmermann et al., 2022).

The use of synthetic polymers is inherent to the production process of paper and board as FCM, as uncoated paper is unstable in the presence of liquids. These polymers can be applied as a physical coating on the surface of the paper or board or as an additive during or after the pulping process. Zimmermann et al. (2022) showed that several CMR chemicals (e.g., formaldehyde, bisphenol A, and boric acid) and PFAS are listed for intentional use in coatings of paper and cardboard FCM. This can be potentially harmful if these substances migrate into food (Zimmermann et al., 2022). For instance, PFOA and PFHxA migration from paper packaging into food was observed (Zabaleta et al., 2020).

Printing inks are complex chemical mixtures that may include pigments, solvents, photoinitiators and other chemicals with physiochemical properties linked to a high level of migration towards food (Van Bossuyt et al., 2016). Printing inks are commonly applied to the non-food contact side of paper and board FCM, though contamination could occur through diffusion to the food-contact side or through recycling of the FCM (Van Bossuyt et al., 2016). Furthermore, printing inks form the main source of mineral oil contamination in paper and board FCM. Board from recycled fibres shows a higher mineral oil contact than board from non-recycled origin (Biedermann et al., 2013).

NIAS, such as metal ions, may be introduced into paper and board FCM through processing steps, such as pulping and bleaching (Bengtström et al., 2016). Furthermore, primary aromatic amines (PAAs) are potentially carcinogenic chemicals which can be present in paper and board FCM as contamination in printing ink or thermally stressed coatings (BfR, 2013). Recycling of paper and board can result in accumulation of chemicals such as mineral oils, heavy metals and printing ink chemicals (Geueke et al., 2022).

5.1.4 Considerations and toxicological concerns

In the reviewed documents, the following concerns specific to paper and/or board were found:

- ANSES concluded that given the genotoxic and mutagenic nature of some MOAHs present in paper and cardboard FCM, and their possible non-threshold carcinogenic effects, priority should be given to reducing the contamination of food by these chemicals (ANSES, 2017).
- JRC states that paper and board FCM are characterised by a large number of substances of possible concern, of which only 9% are regulated by multiple Member States. Therefore, regulations, and strong sectorial guidance would be beneficial to ensure safety of paper and board FCM (Simoneau et al., 2016).
- The Council of Europe identified known contaminants in paper and board and listed these with specific migration limits in Annex II of the technical guide on paper and board (EDQM, 2021)
- BEUC calls for regulation of printing ink chemicals, such as photoinitiators and primary aromatic amines, in paper and board FCM, as over 5000 substances are used to produce various printing inks, while toxicological data is insufficient for a large amount of these chemicals (BEUC, 2019a).

For the present research, titanium dioxide is classified as category 2 carcinogen based on inhalation exposure (Table 4). As this is not a relevant exposure route for FCM, this chemical is not prioritised.

More than 800 chemicals were detected in paper and food FCM (Geueke et al., 2022). Out of the 50 highlighted substances listed in Table 5 that are introduced in paper and board FCM through processing, 23 substances were classified as toxic to reproduction (1 in category 1A, 19) in category 1B and 3 in category 2), 13 were classified as carcinogenic (1 in category 1A, 8 in category 1B and 4 in category 2, and 6 as mutagenic (2 category in 1B and 4 in category 2). Twenty-seven were identified as SVHC (20 on the Candidate List, 7 on the Authorisation List). Four substances (bisphenol A and three phthalates) listed in this table are classified as toxic to reproduction (category 1B) and assessed to be endocrine disruptors (SVHC), and for these there is also evidence of migration to food products. There is also evidence of migration for the chemicals formaldehyde and epichlorohydrin, both classified as carcinogenic (category 1B), for boric acid, classified as toxic to reproduction (category 1B), for vinyl chloride, classified as carcinogenic (category 1A) and lead, classified as toxic to reproduction (category 1A).

5.2 Wood (fibres)

5.2.1 Legislation

Wood is listed as one of the seventeen FCM listed in the Annex I of Framework Regulation (EC) 1935/2004 (EC, 2021). EFSA states that this is an old authorisation which 'essentially lacks a detailed description of what constitutes as wood'. In addition, no measures have been adopted within this Regulation. There is no EU-wide Regulation or Directive on the use of wood in food contact materials. Some Member States, like France and the Netherlands have requirements for wooden FCM. In the Netherlands, products of solid wood and engineered/composite wood are both allowed as FCM. In the Dutch Regulation it is not specified which wood species are acceptable for use in contact with food. For wood and cork, chapter IX of the annex part A applies, and it contains a positive list of substances that are allowed to be used for wood products, and substances used are subject to restrictions stated therein (NL, 2022c). Wooden FCM may be coated and/or painted on, yet the treatment options are restricted. Additionally, the migration of constituents should be within the set limits of the constituents, as for wood can be found in chapter IX (NL, 2022c).

Chapter IX Warenwetregeling verpakkingen en gebruiksartikelen NL, 2022c states:

- that only wood or mechanically minimised wood can be used as a raw material,
- three preservatives that can only be applied in the country of origin of the raw material and if necessary, like bis(tributyltin)oxide,
- seven (groups of) pesticides that can be used in the process from raw material to end products if the pesticides are admitted based on the Biocides and Plant Protection Products Act (Wgb, 2021), like carbendazim and 2-ethylhexanoic acid,
- a list of adhesives and binders that can be included, including melamine- and formaldehyde condensation products,
- a list of lacquers and impregnating agents that can be included, including all lacquers and impregnating agents listed in appendix I and X,
- a list of softeners that can be included, including all softeners listed in appendix I)
- a list of solvents that can be included, including all softeners that comply with on Article 3 of EG 1935/2004,
- a list of dyes and pigments, including all dyes and pigments listed in appendix XI), and
- a list of 14 (groups of) remaining auxiliary materials, including formaldehyde and triethylene glycol.

For most of the listed chemicals that can be used in wood FCM, the total migration (in mg/dm²) multiplied by a factor describing the goal of the material cannot be more than the migration limit of 60 mg/kg food. For the use of wood as a FCM, a factor of 6 is used since it falls in the category of 'material which wholly or largely encapsulates food' (NL, 2022c). For specific (groups of) chemicals, the specific migration multiplied by the factor of 6 cannot be more than the listed quantity (range of 0.05-40 mg/kg food, e.g., 2.5 mg/kg food for melamine and 15 mg/kg food for formaldehyde and hexamethylenetetramine combined).

5.2.2 Material-dependent constituents

As stated in the assessment of wood in contact with food by EFSA, the composition of wood is complex and dependent on species. Also, composition varies within species depending on age, genetic and geographical factors, as well as growth condition (EFSA CEP Panel, 2019). Most European trees contain 40-44% cellulose, 18-32% lignin,

25-35% hemicellulose, 1-5% extractives and 0.1-1.0% mineral components. The percentage of extractives and amounts of inorganic salts in tropical and subtropic wood types may be up to 20% and 5% respectively (EFSA CEP Panel, 2019).

To evaluate safety of wood in contact with food, migratable substances and their transfer into food are of importance, *i.e.*, extractives and mineral components. Glucoronates or carbonates of calcium (40-70%), potassium (10-30%), magnesium (5-10%), iron (up to 10%) and sodium are mainly present. However, smaller quantities of other metals like manganese and aluminium could also be present depending on the soil composition (EFSA CEP Panel, 2019). Whilst untreated wood will not contain substances listed on the Candidate List, as investigated by the (Ministry of Environment of Denmark (2022), as checked in the database kept up-to-date by ECHA (ECHA, 2023), some extractives are bioactive and protect the wood from fungi, insects and bacteria. As a result, they may be toxic to humans. Table 6 provides an overview of biologically active organic chemicals found in wood (EFSA CEP Panel, 2019). So far, no data is available on the presence of these biologically active constituents in FCM made out of wood (fibres).

EFSA's Compendium of botanicals reports naturally occurring substances of numerous tree species of possible concern for human health when used in food and food supplements (EFSA, 2020a). Based on this Compendium, the Food Standards Agency listed 14 woods that contain potentially toxic substances (FSA, 2002). Table 7 contains the overview of natural occurring substances of possible concern to human health. So far, no data is available on the presence of these naturally occurring substances listed in EFSA's Compendium of botanicals in FCM made out of wood (fibres).

5.2.3 Process constituents

The Danish Environmental Protection Agency (Danish EPA) states that untreated wood will not contain any of the chemicals listed in the Candidate List of ECHA. However, wood can be impregnated, glued and varnished and wood fibres can also be used when combined with binders/resins/glues (Ministry of Environment of Denmark, 2022). All these processes may result in the introduction of listed substances or non-listed toxic substances to FCM made of wood (fibres). An overview of examples of (groups of) chemicals that were found to be introduced in wood FCM through the processing of wood can be found in Table 8. Please note that this list contains chemicals that were detected in wood and/or cork FCM (Zimmermann et al., 2022). Chemicals that could possibly be found in FCM or chemicals that were found in non-FCM made of wood or wine barrels were listed and Table 9.

5.2.4 Considerations and toxicological concerns

In the reviewed documents, the following concerns specific to wood (fibres) were found:

• In the Directive 95/3EC with Ref. No 95920, the additive 'wood flour and fibres, untreated' (FCM No 96) was included in the list of additives for plastic FCM as a filler based on its inertness. In the updated risk assessment of EFSA on FCM No 96, EFSA highlighted concerns regarding the continued authorisation status

of wood flour and fibres in food contact plastics (EFSA CEP Panel, 2019). EFSA recommended that any item containing wood or materials of plant origin should be evaluate on a case-by-case basis.

- The Danish EPA stated that whilst untreated wood will not contain substances listed on the Candidate List, some extractives are bioactive and protect the wood from fungi, insects and bacteria. As a result, they may be toxic to humans (Ministry of Environment of Denmark, 2022).
- EFSA stated that carcinogenicity of wood dust and other health risks due to occupational exposure are not considered relevant when looking at oral exposure from FCM (EFSA CEP Panel, 2019).

In the present research, for one out of 31 naturally occurring biologically active organic chemicals (see Table 6) found in wood that may be present in wooden FCM (kaempferol) is self-classified as mutagenic (category 2). With regard to naturally occurring chemical constituents (see Table 7), one out of 41 chemicals is harmonised classified as Muta 2. Further, prunasin has no harmonised classification, but all 38 notifiers self-classify the substance with Repro 1B. It should be noted that for several substances in these tables no information is available.

Only five of the chemicals that could be introduced to wooden FCM due to processing (see Table 8 and 9), and that were found in non-FCM made of wood (or wine barrels) did not have a harmonised or selfclassification in the ECHA database. Additionally, of the six groups of chemicals that could not be searched since single chemicals were not provided, several are likely classified. Twelve chemicals are listed as SVHC (6 on the Candidate List, 6 on the Authorisation List (Annex XIV)). Seventeen chemicals were listed as carcinogens (4 as category 1A [namely vinyl chloride, isobutane, and two diarsenic oxides], 8 as category 1B, and 6 as category 2). Twelve chemicals are toxic to reproduction (7 category 1B and 2 category 2, and three with a selfclassification as category 1B). Six chemicals were listed as mutagens (4 category 1B and 2 category 2). Sodium dichromate is next to Carc. 1B and Repr. 1B also a classified mutagen (1B). Sodium dichromate is a powerful oxidizing agent which can be used in the production of wood preservatives.

5.3 Bamboo

5.3.1 Legislation

FCM containing bamboo can be made of solid bamboo (whether or not glued together) or of plastics containing bamboo fibres. Bamboo (solid) is not listed as one of the seventeen FCM in Annex I of Framework Regulation (EC) 1935/2004 (EC, 2021), which can be covered by specific measures. The use of bamboo fibres in plastics requires authorisation in accordance with Article 9 – 11 of EC 1935/2004, due to Article 5 of Regulation (EU) No. 10/2011. However, no such authorisation was given for bamboo.

FCM that are made 100% of bamboo or plant material itself are legally on the market, subject to general EU requirements and national legislation (EC, 2022a). No specific regulation on bamboo as a FCM is present on national level. The use of bamboo could be considered as an additive authorised under FCM No 96 "wood flour and fibres, untreated". However, EFSA's Expert Working Group on FCM stated in 2020 that ground bamboo, bamboo flour and many similar substances including corn cannot be considered wood, and would require a specific authorisation (EFSA, 2020b). They concluded that "*plastic FCM containing such unauthorised additives* [bamboo fibres] are not in compliance with the compositional requirements set out in Regulation No 10-2011 when placed on the EU market". However, many plastics including bamboo fibres are still on the market due to misleading advertisement (EFSA, 2020b). Article 3(2) of Framework Regulation (EC) 1935/2004 does require that 'the labelling, advertising and presentation of a material or article shall not mislead consumers'. Plastics containing bamboo fibres will be phased out due to the SUP Directive.

Other constituents of bamboo products have to comply with Annex I (positive list of adhesives) of Regulation (EC) No 1935/2004 and national legislation Article 3 of the Dutch Commodities Act Regulation on Packaging and Consumer Articles (Warenwetregeling). Specifically, the use of melamine resin is regulated by Regulation (EU) No 284/2011.

5.3.2 Material-dependent constituents

A review on the food quality and safety aspect of bamboo states that bamboo shoot is considered an ideal vegetable for health diet as it contains 89% water, 3.9% protein, 17 amino acids, 17 different types of enzymes and 10 mineral elements (Cr, Zn, Mn, Fe, Mg, Ni, Co, Cu etc.) (Satya et al., 2010). Other sources state that bamboo consists for 95% of holocellulose (cellulose + hemicellulose; 56-86%), lignin (10-31%), aqueous extract (2.9-8.5%) and pectin (0.4%) (Nurul Fazita et al., 2016; Yeh & Yang, 2020). Additionally, resins, tannins, waxes and inorganic salts are found in low quantities (Nurul Fazita et al., 2016).

Bamboo shoots can form up to 0.8% cyanide when the shoots are disrupted (Table 10). The content varies between shoots but also between the various parts of the shoots. When bamboo cells are disrupted, cyanogenic glycosides present are broken down by a hydraulic enzyme (β -glycosidase) to a sugar and cyanohydrin. Cyanohydrin rapidly decomposes to hydrogen cyanide and an aldehyde or ketone (Satya et al., 2010). Following harvesting, the cyanide content is reported to decrease (Satya et al., 2010).

Four phytosterols were detected in cups, dishes and jugs made of bamboo fibres, namely 3β -Ergost-5-en-3-ol, stigmasterol, clionasterol and arundion (Osorio et al., 2020). Additionally, in the study the amino acid valine was found (Table 10).

5.3.3 Process constituents

Research shows that products of bamboo fibres contain only 20-35% bamboo fibres and further a high percentage of plastics (CVUA Stuttgart, 2014). Also, these products are often coated to decrease sensitivity to water and reduce the absorption of fat and water (UTwente, 2020). Chemical constituents found in bamboo products can be found in Table 11.

When bamboo fibres are added to plastics in high quantities, the Expert Working Group on FCM states that it may influence migration properties of the plastics (EFSA, 2020b). This is the case for many so called 'bamboo' products. The plastic material used in FCM of bamboo fibres is typically melamine resin (a combination of melamine and formaldehyde). The German Federal Institute for Risk Assessment (BfR) concluded that both melamine and formaldehyde can be transferred from bamboo fibre products to food (BfR, 2019). This is substantiated by an increasing number of notifications under the Rapid Alerts System for Food and Feed (RASFF) where melamine and formaldehyde migrate out of produces at levels above the set specific migration limits (BuRO NVWA, 2021). Ten percent of the notifications were found to be exceeding the specific migration limit of formaldehyde by more than a factor ten (Food Packaging Forum, 2020). CVUA Stuttgart (2014) detected melamine over the specific migration limit in three out of four bamboo samples (plates, bowls, cups). Additionally, research of the Stiftung Warentest (2019) showed that in seven out of twelve bamboo cups, melamine was found above the set EU limit. Formaldehyde was also detected in 50% of the bamboo cups, yet below the limit. Similar results were seen in other investigations as well (Petrova & Bagdassarian 2021). Migration tests mimicking reuse of bamboo cups for drinking coffee showed both high melamine and formaldehyde transference to the liquid even after being used seven times. In 2019, the NVWA performed a similar study in the Netherlands and found that while 88% of the bamboo cups complied with the migration limit of formaldehyde, some bamboo products showed very high migrations values (Bouma et al., 2022). In addition, not only melamine but also melamine derivatives were found over the set EU limits in bamboo products (Osorio et al., 2020). Heating of the bamboo fibre plastic material to high temperatures over 70°C deteriorates the surface which increases the migration of melamine and formaldehyde out of the product. Products should always include a safety warning for microwave use (Stiftung Warentest, 2019).

Other chemicals that were detected in bamboo products are PFAS. PFAS are added to the surface of the product to make it water and fat repellent. Research performed by the University of Antwerp detected PFAS in four out of five bamboo straws at a maximum level of ~3.5 ng/g PFAS (UAntwerpen, 2022). The PFAS that were detected can be found in Table 11.

Two other studies determined the constituents present in respectively cups, dishes and jugs and in a straw (Osorio et al., 2020; Zimmermann et al., 2020). Most of the detected chemicals in bamboo cups, dishes and jugs were alkanes. Alkanes are used as raw material in the production of polymers and might also result from degradation of the material (Osorio et al., 2020). Moreover, melamine and eight melamine derivatives were detected (Table 11). In the bamboo straw, Zimmermann et al. (2020) detected chemicals of which the group, CAS number and use were unknown (Table 11).

While not (yet) detected in FCM made of bamboo, research into bamboo shoots have detected the presence of pesticides (including hexachlorocyclohexane (HCH), 1,1,1-trichlor-2,2-bis(p-

chlorophenyl)ethane (DDT; also found in palm leaves) and pentachloronitrobenzene (PCNB)). Pyrethroid and organophosphorus pesticides were not detected (Ziwu et al., 2011).

5.3.4 Considerations and toxicological concerns

In the reviewed documents, the following concerns specific to bamboo were found:

- EFSA recognised that the use of additives from a natural origin (like bamboo fibres) may contain hazardous substances (EFSA CEP Panel, 2019).
- The Expert Working Group on FCM has stated that additives from a natural origin, such as bamboo, in a plastic matrix may themselves constitute a low health risk (EFSA, 2020b).
- The Food Safety and Standards Authority of India observed that there was no available literature regarding any contamination of food from the use of bamboo materials and concluded that the use of bamboo, if manufactured and maintained under hygienic conditions, is safe (FSSAI, 2019).
- ProductIP (2022) stated that bamboo is a chemically safe FCM when treated with traditional method for removing water, starch and sugars. Modern methods however can introduce chemical substances not suitable for food contact applications (ProductIP, 2022).
- The European Commission stated that when FCM made out of bamboo and plastics are used, the plastic can degrade, and melamine and formaldehyde can migrate to food in risky amounts, which exceed the safe specific migration limits (EC, 2022a).
- BfR stated that an increased risk to health is likely when FCM made of bamboo and plastics are used daily over a long period of time and release high formaldehyde concentrations. Increased risks were described for the daily use of bamboo based FCM in contact with hot liquid foodstuffs (BfR, 2019).
- The NVWA concluded FCM made of bamboo (fibres) and plastics should not be placed on the European market based on an increased risk to health, caused by formaldehyde and melamine (BuRO NVWA, 2021).

None of the material-dependent constituents were harmonised or selfclassified according to the ECHA database. That phytochemicals were not classified does not mean they are not hazardous. For example, cyanide is a known acute poison which can be found in a substantial amount in certain seeds and fruits, like bitter almonds, soy and cassava roots (ATSDR, 2006).

Many process constituents were detected or possibly present in bamboo (see Table 10 and 11). From those, only formaldehyde (Carc. 1B, Muta. 2), PFOA (Repr. 1B, Carc. 2, STOT RE 1) and DDT (Carc. 2, STOT RE 1) have hazard classifications. Bamboo flour has been used as a filler in melamine-formaldehyde resins in so-called 'bamboo' tableware. The use of bamboo in resins is now banned from the market. Exposure to melamine can result in renal injury (as is seen for melamine-tainted milk in China (Hau et al., 2009)), can negatively affect the male reproductive system, and is classified as a probable human carcinogen by the

International Agency for Research on Cancer (IARC) (Petrova & Bagdassarian, 2021). Formaldehyde is carcinogenic to humans, and exposure can lead to irritation of surface areas and can cause corrosive injuries when ingested (ATSDR, 2010) (International Agency for Research on Cancer, 2022). The two alkanes may be fatal if swallowed or if it enters the airways. PFAS have hazardous properties, and EFSA has set a Tolerable Weekly Intake for four PFAS based on the critical effect of reductions in immune response following chronic exposure (EFSA CONTAM Panel, 2020).

5.4 Sugarcane

5.4.1 Legislation

Sugarcane and bagasse, the fibrous residues after the sugary fluids are obtained for sugar production, are not listed as FCM in Annex I of Framework Regulation (EC) 1935/2004 (EU 2021). The use of sugarcane (fibres) requires authorisation in accordance with Article 9 – 11 of EC 135/2004. However, no such authorisation was given.

FCM that are made 100% of plant material are legally on the market, subject to general EU requirements and national legislation (EC, 2022). However, hardly any products on the market are 100% made of sugarcane (bagasse). No Regulation on sugarcane (bagasse) as a FCM is present on national level.

5.4.2 *Material-dependent constituents*

The fibres of bagasse consist of 42-55% cellulose, 20-25% hemicellulose, 18-25% lignin, 3-6% moisture, 0.8-8% ash, 0.8-1% protein and 0.15-0.3% fat (Kim & Day, 2011; Chong et al., 2019; UTwente, 2020; Goodstartpackaging, 2022). Ash is the cumulative measure of inorganic mineral micronutrients. Sugarcane consists of similar levels of lignin, moisture, protein and ash, but more fat (0.8-1.2%). Fat is representative of the hydrophobic components like waxes and oils (Chong et al., 2019). The following minerals were found in sugarcane samples: chromium, copper, iron, manganese and zinc (Chong et al., 2019).

Chong et al. (2019) also identified nine polyphenolic chemicals (very low concentrations) that were present in the petroleum ether fraction of the ethanol extract of sugarcanes exhibiting the highest radical scavenging activity (Table 13). Zheng et al. (2017) and Zhao et al. (2015) also detected phenolic chemicals, yet in bagasse (Table 13). Additionally, Zhao et al. (2015) detected flavonoids in bagasse, yet did not characterise which ones. Duarte-Almeida et al. (2011) detected several flavonoids and phenolic acids (Table 13).

5.4.3 Process constituents

Multiple studies detected process constituents in products made of sugarcane (bagasse). For instance, take away boxes of moulded sugarcane fibres contained PFAS in high quantities (Fidra, 2020). BEUC (2021) also determined the presence fluorinated chemicals, in addition to chloropropanols and pesticide residues in plates and bowls made of sugarcane fibres. In all samples, fluorinated chemicals were detected above the limits used in this study, while eight samples of the 21

contained chloropropanols (two close to and six above the recommended limits) and three samples contained pesticide residues close to the recommended limits (BEUC, 2021) (Table 14).

Only two studies determined the presence of process constituents, of which one is not freely available. The Öko-Test (2018), of which the results are not freely available, stated that organohalogen chemicals were detected. Experts state that these products are often residues from chlorine bleach to brighten the products for market (Öko-Test, 2018). The presence of melamine and formaldehyde in sugarcane products is highlighted by UTwente (2020) (Table 14).

5.4.4 Considerations and toxicological concerns

In the reviewed documents, no concerns specific to sugarcane were found. It should be noted that a specific species of sugarcane (*Saccarum officinarum* L.) is used for the production of sugar. Sugarcane can also be consumed (chewed) after peeling. Juice pressed from sugarcanes can be drank¹. In addition, the Expert Working Group on FCM has stated that additives from a natural origin in a plastic matrix may themselves constitute a low health risk (EFSA, 2020b).

In the present research, of the nineteen material-dependent constituents that were detected or thought to be possibly present in sugarcane, three were self-classified according to the ECHA database. Caffeic acid was self-classified as carcinogenic (category 2) by almost all notifiers. Kaempferol and Quercetin were self-classified as mutagenic (category 2).

Process constituents belonging to the group of chloropropanols and fluorinated chemicals were detected above the recommended limits in sugarcane. Korte et al. (2021) stated that at least two of the substances from the group of chloropropanols are known to be carcinogenic (Korte et al., 2021). Fluorinated chemicals, like PFAS (which have also been detected), have hazardous properties and EFSA has set a Tolerable Weekly Intake for four PFAS based on the critical effect of reductions in immune response (EFSA CONTAM Panel, 2020). Pesticides, which are found close to the legal limits, are brought on the market to negatively affect pests. The divergent group of pesticides is regulated due to their toxic properties (Lushchak et al., 2018), and limits in food and FCM made with other materials are put in place in the Netherlands (see for instance Legislation Wood (fibres)). In the EU, strict rules for pesticides are only in place for food, but not explicitly for food packaging materials (BEUC, 2021). Organohalogen chemicals were also detected, yet not specified. This very wide group consists of organic constituents that are extremely persistent in the environment, bioaccumulative and have long-term health effects (Kodavanti & Loganathan, 2017). These chemicals contain chlorine, bromine or fluorine. Well known (groups of) chemicals are polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), the insecticide DDT, polybrominated diphenyl ethers (PBDEs), and per- and polyfluorinated substances (PFAS) (Kodavanti & Loganathan, 2017). Many of these (groups of) substances have been regulated due to negative health and environmental effects.

Bamboo is often used as filler in melamine-formaldehyde resins in socalled 'bamboo' tableware. Exposure to melamine can result in renal injury (as is seen for melamine-tainted milk in China (Hau et al., 2009), can negatively affect the male reproductive system, and is classified as a probable human carcinogen by IARC (Petrova & Bagdassarian, 2021). Formaldehyde is classified as carcinogenic (category 1B). Exposure can lead to irritation of surface areas and can cause corrosive injuries when ingested (ATSDR, 2010; International Agency for Research on Cancer, 2022).

5.5 Palm leaves

5.5.1 Legislation

Palm leaves are not listed as one of the seventeen FCM in Annex I of Framework Regulation (EC) 1935/2004 (EU 2021). The use of palm leaves requires authorisation in accordance with Article 9 – 11 of EC 135/2004. However, no such authorisation was given.

FCM that are made of 100% plant material are legally on the market, subject to general EU requirements and national legislation (EC, 2022). No Regulation on palm leaves as a FCM is present on national level.

5.5.2 *Material-dependent constituents*

The percentage of fibres in palm leaves depends on the species. For instance, the fibres of Khalasa palm leaves consist out of 47% cellulose, 16% hemicellulose, 35% lignin and 2% ash (Mahdi et al., 2021), while Date palm leaves consist of 39% cellulose, 23% hemicellulose, 15% lignin and 2% ash (Saeed et al., 2017). Elements other than carbon and oxygen were detected in low proportions (2% Na, 0.3% Mg, 0.3% Al, 0.4% Si, 0.7% Ca) (Saeed et al., 2017).

Tannins, flavonoids, catechins, steroids and/or triterpenoids and saponins were detected in leaf extracts of leaves of two palm species (de Oliveira et al., 2016). Constituents of these substance classes are biologically active (EFSA, 2020a). In the leaves of a third species, solely flavonoids, steroids and triterpenes and saponins were detected (de Oliveira et al., 2016). In addition, a mixture of saturated and unsaturated fatty acids, aromatics and terpenes consisting of following ten chemical constituents was detected (de Oliveira et al., 2016) (Table 15).

5.5.3 Process constituents

Only two studies determined the presence of process constituents in palm leaves, of which one is not freely available, the Öko-Test (2018). While the results of the Öko-Test are not available, the summary states that single-use tableware of palm tree leaves contain traces of the banned pesticide DDT. In addition, organohalogen chemicals were detected. Experts state that these products are often residues from chlorine bleach to brighten the products for market (Öko-Test, 2018). BEUC (2021) also determined the presence of pesticides in 16 palm leaf bowls and plates. In six of these products, pesticide residues were detected close to the recommended limits (the used limits can be found in the BEUC, 2021 study). An overview of chemical constituents detected in products of palm leaves can be found in Table 16.

5.5.4 Considerations and toxicological concerns

In the reviewed documents, no concerns specific to palm leaves were found. It should be noted that in some cooking traditions, palm leaves are used for wrapping food (similar to banana leaves) or for steaming². In addition, the Expert Working Group on FCM has stated that additives from a natural origin in a plastic matrix may themselves constitute a low health risk (EFSA, 2020b).

All detected substance classes of material-dependent constituents (Table 15; tannins, flavonoids, catechins, steroids, tripenoids and saponins) in the present research are phytochemicals which can be bioactive. While classifications are not available for groups of chemicals, it is known these phytochemicals can be low (phytosterols, flavonoids, catechins) to moderately toxic (tannins, saponins) (Ling & Jones, 1995; Galati & O'Brien, 2004; Cao et al., 2016; Zaynab et al., 2021; Maugeri et al., 2022). Since the specific constituents that were found were not listed, information on the hazards of these constituents in palm leaves cannot be assessed.

A process contaminant that was detected is the pesticide DDT (dichlorodiphenyltrichloroethane) (Table 16). This organochloride is toxic, as can be seen by the harmonised classification as carcinogen category 2 and STOT RE 1. Other pesticide residues could also be present, however, specific contaminants were not named. Organohalogen chemicals were also detected, yet not specified. This very wide group consists of organic constituents that are extremely persistent in the environment, bioaccumulative and have long-term health effects (Kodavanti & Loganathan, 2017). These chemicals contain chlorine, bromine or fluorine. Well known (groups of) chemicals are polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), the insecticide DDT, polybrominated diphenyl ethers (PBDEs), and per- and polyfluorinated substances (PFAS) (Kodavanti & Loganathan, 2017). Many of these (groups of) substances have been regulated due to negative health and environmental effects.

5.6 Wheat

5.6.1 Legislation

Wheat is not listed as one of the seventeen FCM in Annex I of Framework Regulation (EC) 1935/2004 (EU 2021). The use of wheat requires authorisation in accordance with Article 9 – 11 of EC 135/2004. However, no such authorisation was given.

FCM that are made of 100% plant material are legally on the market, subject to general EU requirements and national legislation (EC, 2022). However, hardly any to no products on the market are 100% made of wheat. No Regulation on wheat as a FCM is present on national level.

5.6.2 *Material-dependent constituents*

Wheat consists of approximately 36% of cellulose, 25% hemicellulose and 25% lignin (Rodríguez-Sanz et al., 2022). No literature describing naturally present constituents was detected. Thathaving said, one report describing possible process constituents in wheat-based FCM mentioned the risk of allergies when allergenic epitopes remain in the produced material and come into contact with the lips of allergenic individuals (BSI, n.d.).

5.6.3 Process constituents

BEUC (2021) determined whether fluorinated chemicals, chloropropanols and pesticides could be detected in two plates made of what straw (origin of plates were France and Spain). Fluorinated chemicals were found above the recommended limits in both products. Both products also contained pesticide residues at concentrations close to the recommended limit used in this study (BEUC, 2021). Chloropropanols were detected above the recommended limits in one of the plates, while in the other plate chloropropanols were not found or found at concentrations clearly below the recommended limits (BEUC, 2021).

Timshina et al. (2021) analysed whether PFAS could be found in 43 commercially available plant-based drinking straws. In the drinking straw made of wheat stalk and produced in China, no PFAS were detected.

A report of the British Standards Institute (BSI) group also mentions that numerous mycotoxins were identified (BSI, n.d.). The mycotoxins most linked to wheat are produced by *Fusarium fungi* and are the ergot alkaloids and ochratoxin A. These mycotoxins can be formed when grain is poorly stored. BSI states that there is potential for these contaminants to remain in FCM once manufactured. The report also mentions the possibility of pesticide residues in FCM of wheat when agrochemicals are mis-used prior to harvest (Table 18).

5.6.4 Considerations and toxicological concerns

In the reviewed documents, concerns specific to this material were not found. It may be valuable to know which types of wheat are included in the production of materials in contact with food. If solely wheats that have been safely used as food are included, toxicological effects of the use of wheats in FCM could be limited.

In the present research, no material-dependent constituents were identified. As a result, the hazards constituents that could be present remain unknown.

Fluorinated chemicals and chloropropanols, which were found above the recommended limits in products, are groups of chemicals for which no specific chemical was listed. Therefore, it is not possible to describe the hazards of these groups. Of chloropropanols it is known, that (at least) two are potentially carcinogenic (Korte et al., 2021). Fluorinated chemicals, like poly- and perfluorinated substances (PFAS), have hazardous properties, and EFSA has set a Tolerable Weekly Intake for four PFAS based on the critical effect of reductions in immune response (EFSA CONTAM Panel, 2020). Pesticides, which are found close to the recommended limits, are brought on the market to negatively affect pests. The divergent group of pesticides is regulated due to their toxic properties (Lushchak et al., 2018), and limits in food and FCM made with other materials are put in place in the Netherlands (see for instance

Legislation Wood (fibres)). In the EU, strict rules for pesticides are only in place for food, but not explicitly for food packaging materials (BEUC, 2021).

Of the constituents that are not detected yet (Table 18), but could be present, the mycotoxin ochratoxin A is self-classified as carcinogenic (category 2). Ergot alkaloids can induce ergotism, which is a pathological syndrome affecting humans and animals that have ingested plant material containing ergot alkaloids (Schardl, 2015).

5.7 Tables and abbreviations

The following pages present all tables related to the materials discussed in this chapter. For explanation of the hazard information and migration data obtained from ECHA and the FCCmigex database, respectively, see Chapter 3. The tables include the following abbreviations:

NA: not applicable since CAS number could not be identified, or group name was provided, not labelled for prioritisation

Hazard information:

- -: no information is available, or the chemical was not included in the ECHA database
- *: Only the chemical classifications of the examples given per constituent group were given. The classification, or lack thereof, does not hold true for the whole group

Carc.: carcinogenic

Muta.: mutagenic

Repr.: toxic to reproduction

- 1A: Harmonised classification largely based on human evidence (certainty level: recognised); category 1A
- 1B: Harmonised classification largely based on animal evidence (certainty level: recognised); category 1B
- 2: Harmonised classification based on evidence from human or animal studies not sufficiently convincing for category 1 classification (certainty level: suspected); category 2
- STOT RE: specific target organ toxicity, repeated exposure (between brackets in some cases the organs of concern are noted)
- 1: Harmonised classification based on significant toxicity in humans *or* evidence from studies in experimental animals in which significant or severe effects were observed at low exposure concentrations
- 2: Harmonised classification based on evidence from studies in experimental animals in which significant effects were observed at moderate exposure concentrations
- ED: endocrine disruptive properties
- ED under assessment: included in ECHA's endocrine disruptor (ED) assessment list
- Self-classified: Self-classification with broad agreement amongst the notifiers: suspected effect based on data submitted by industry to ECHA for which \geq 50% of the data submitters has the same concern (all categories possible)
- SVHC Candidate List: Substance of Very High Concern, listed on the Candidate List (between brackets it is noted for which reason the substance is listed)

SVHC Authorisation List: Substance of Very High Concern, listed on Annex XIV (between brackets it is noted for which reason the substance is listed)

FCCmigex database:

-: was not included in the FCCmigex database or was not tested in single use products

*: Only the chemical classifications of the examples given per constituent group were given. Data on migration, or lack thereof, does not hold true for the whole group

x/y: x number of positives (detects) out of y number of experiments performed

MiF: Migration into Food (type of experiment performed)

EX: Extraction (type of experiment performed)

MiFS: Migration into Food Simulants (type of experiment performed)

P: Plastics (material which was tested)

P&B: Paper & Board (material which was tested)

M: Metals (material which was tested)

MM: Multi-materials (material which was tested)

G&C: Glass & Ceramics (material which was tested)

Other: Other FCM than plastics, paper & board, metals, multi-materials and glass & ceramics (material which was tested)

Paper and/or board

Table 4 Overview of chemical constituents naturally occurring in paper and/or board used as FCM, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|------------------|-------------------------------------|------------|-----------------------|-----------------------|
| Minerals and | Aluminium sulphate ¹ | 10043-01-3 | - | - |
| mineral salts | Aluminium oxide ² | 1344-28-1 | - | - |
| | Barium sulphate ¹ | 7727-43-7 | - | - |
| | Calcium carbonate ² | 471-34-1 | - | - |
| | Calcium sulphate ² | 7778-18-9 | - | - |
| | Kaolinite ² | 1318-74-7 | - | - |
| | Magnesium carbonate ¹ | 546-93-0 | - | - |
| | Magnesium oxide ¹ | 1309-48-4 | - | - |
| | Silicon dioxide ² | 7631-86-9 | - | - |
| | Talc ² | 14807-96-6 | - | - |
| | Titanium dioxide ² | 13463-67-7 | Carc. 2 (inhalation)* | 1/1 (100%), MiFS; MM |
| | Zinc sulphide ¹ | 1314-98-3 | - | - |
| | Zinc oxide ¹ | 1314-13-2 | - | - |
| Polysaccharides | Cellulose ^{1,2} | 9004-34-6 | - | - |
| | Starch ¹ | 9005-25-8 | - | - |
| Organic polymers | Lignin ¹ | 9005-53-2 | - | - |

Sources: ¹: BfR (2022); ²: Hubbe & Gill (2016); * The Carc. 2 classification by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter \leq 10 µm, as a result, this chemical is not labeled as low priority

Table 5 Overview of chemical constituents that might be introduced into paper and/or board used as FCM, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|--------------------------|---|------------|--|--|
| Aldehydes | Formaldehyde ¹ | 50-00-0 | Muta. 2, Carc. 1B | 11/13 (85%) MiF/EX/MiFS; P/P&B/G&C |
| Aromatic amines | 3,3'-Dichlorobiphenyl ⁷ | 2050-67-1 | Self-classified: STOT RE 2 | 1/10 (10%) EX/MiFS; P/P&B/MM |
| | 4,4'-Oxydianiline ³ | 101-80-4 | Muta. 1B, Carc. 1B, Repr. 2 SVHC Candidate List (Carc., Muta.) | 3/23 (13%) MiF/EX/MiFS; P/P&B/MM |
| | 4-Aminotoluene-3- sulfonic acid ⁴ | 88-44-8 | - | - |
| | Bis(4-aminophenyl) methane ³ | 101-77-9 | Carc. 1B, Muta. 2, STOT RE 2 SVHC Authorisation List (Carc.) | 9/30 (30%) MiF/EX/MiFS; P/P%B/M/MM |
| | o-Toluidine ³ | 95-53-4 | Carc. 1B SVHC Candidate List (Carc.) | 4/16 (25%) MiF/EX/MiFS; P/P&B/MM |
| Aromatic hydrocarbons | Styrene ¹ | 100-42-5 | Repr. 2, STOT RE 1 (hearing organs) | 68/83 (82%) MiF/EX/MiFS; P/P&B/MM/G&C/Other |
| Borates | Boric acid ¹ | 10043-35-3 | Repr. 1B SVHC Candidate List (Repr.) | 2/2 (100%) EX; P&B |
| | Disodium tetraborate ¹ | 1330-43-4 | Repr. 1B SVHC Candidate List (Repr.) | - |
| Chlorinated | 1,1-Dichloro-ethylene ¹ | 75-35-4 | Carc. 2 | 3/3 (100%) MiF/EX; P |
| hydrocarbons | Vinyl chloride ¹ | 75-01-4 | Carc. 1A | 2/2 (100%) MiF/EX; P |
| Chloropropanols | 3-Monochloropropane- 1,2-diol ⁷ | 96-24-2 | Self-classified: Repr. 1B, Carc. 2 | 5/7 (71%) MiF/EX/MiFS; P&B/MM |
| | Dichloropropanol ⁷ | 26545-73-3 | - | - |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-------------------|---|-----------|---|--|
| Cyclic anhydrides | 1,2-Cyclohexane dicarboxylic anhydride ³ | 85-42-7 | SVHC Candidate List (Resp. Sens.) | 1/1 (100%) EX; P&B |
| Glycol ethers | Bis(2-methoxyethyl) ether ³ | 111-96-6 | Repr. 1B SVHC Authorisation List (Repr.) | - |
| | Ethylene glycol ¹ | 107-21-1 | - | 11/14 (79%) MiF/EX/MiFS; P/P&B |
| | Ethylene glycol dimethyl ether ¹ | 110-71-4 | Repr. 1B SVHC Candidate List (Repr.) | - |
| | Methoxyacetate ³ | 625-45-6 | Repr. 1B SVHC Candidate List (Repr.) | - |
| | Triethylene glycol dimethyl ether ³ | 112-49-2 | Repr. 1B SVHC Candidate List (Repr.) | - |
| Formamides | Dimethylformamide ³ | 68-12-2 | Repr. 1B SVHC Candidate List (Repr.) | - |
| | Formamide ³ | 75-12-7 | Repr. 1B SVHC Candidate List (Repr.) | - |
| Mineral oils | Mineral oil saturated hydrocarbons (MOSH) ⁵ | NA | NA | NA |
| Mineral ons | Mineral oil aromatic hydrocarbons (MOAH) ⁵ | NA | NA | NA |
| Metals | Cadmium ⁶ | 7440-43-9 | Carc. 1B, Muta. 2, Repr. 2, STOT RE 1 SVHC Candidate List (Carc., STOT RE) | 44/86 (51%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Copper ⁶ | 7440-50-8 | ED under assessment | 39/50 (78%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Lead ⁶ | 7439-92-1 | Repr. 1A Self-classified: STOT RE 2 SVHC Candidate List (Repr.) | 67/87 (77%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Zinc ⁶ | 7440-66-6 | - | 41/56 (73%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|--|---|------------|---|--|
| Phenols | Bisphenol A ¹ | 80-05-7 | Repr. 1B SVHC Candidate List (Repr., ED) | 147/182 (81%) MiF/EX/MiFS; P/P&B/M /MM/G&C/Other |
| Phthalates | Di-isobutylphthalate ⁵ | 84-69-5 | Repr. 1B SVHC Authorisation List (Repr., ED) | 155/171 (91%) MiF/EX/MiFS; P/P&B/M/MM/Other |
| | Dibutyl phthalate ⁵ | 84-74-2 | Repr. 1B SVHC Authorisation List (Repr., ED) | 227/269 (84%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Diethylhexyl phthalate ⁵ | 117-81-7 | Repr. 1B SVHC Authorisation List (Repr., ED) | 251/291 (86%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| PFAS (per- and polyfluoroalkyl | Ammonium perfluoro octanoate (PFOA salt) ¹ | 3825-26-1 | Repr. 1B, Carc, 2, STOT RE 1 SVHC Candidate List (Repr.) | - |
| substances) | Bis(2-hydroxyethyl) ammonium perfluoro octanesulfonate ¹ | 70225-14-8 | Repr. 1B, Carc. 2, STOT RE 1 | - |
| | Perfluorohexanoate acid (PFHxA) ² | 1763-23-1 | Repr. 1B, Carc. 2, STOT RE 1 | 13/44 (30%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Perfluorobutanoic acid (PFBA) ² | 375-22-4 | - | 17/29 (59%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Perfluorooctanoic acid (PFOA) ^{1,2} | 335-67-1 | Repr. 1B, Carc. 2, STOT RE 1 (liver) SVHC Candidate List (Repr., PBT) | 45/67 (67%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Tetraethylammonium perfluoroctanesulfonate ¹ | 56773-42-3 | Self-classified: Repr. 1B, Carc. 2, STOT RE 1 | - |
| Photo initiators/ printing ink chemicals (1/2) | 2-(2H-Benzotriazol-2-yl)- 4,6-di-tert-pentyl phenol ³ | 25973-55-1 | Self-classified: STOT RE 2 SVHC Authorisation List (PBT, vPvB) | 7/8 (88%) MiF/EX/MiFS; P |
| | Bis(2-ethylhexyl) fumarate ⁴ | 141-02-6 | - | 14/16 (88%) MiF/EX/MiFS; B&B/M/MM/Other |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------------------------|--|-----------|--|---|
| | Dimethylsulfate ³ | 77-78-1 | Carc. 1B, Muta. 2 SVHC Candidate List (Carc.) | - |
| | Hydrazine ³ | 302-01-2 | Carc. 1B SVHC Candidate List (Carc.) | - |
| Photo initiators/ printing ink | N-Methylacetamide ³ | 79-16-3 | Repr. 1B SVHC Candidate List (Repr.) | - |
| chemicals (2/2) | N,N-Dimethyl acetamide ³ | 127-19-5 | Repr. 1B SVHC Candidate List (Repr.) | - |
| | Solvent Blue 4 ³ | 6786-83-0 | SVHC Candidate List (Carc.)* | - |
| | Solvent Violet 86 | 561-41-1 | SVHC Authorisation List (Carc.)* | - |
| | Tris(2,3-epoxypropyl) isocyanurate ³ | 2451-62-9 | Muta. 1B, STOT RE 2 SVHC Authorisation List (Muta.) | - |
| Others | Benzophenone ⁴ | 119-61-9 | - | 107/125 (86%) MiF/EX/MiFS; P/P&B/M/MM/Other |
| | Epichlorohydrin ¹ | 106-89-8 | Carc. 1B | 1/1 (100%) EX; M |
| | Ethyl acrylate ¹ | 140-88-5 | - | 0/1 (0%) MiF; MM |

Source: ¹ Zimmermann et al. (2022); ²: Timshina et al. (2021); ³: Van Bossuyt et al. (2016); ⁴: BEUC (2021); ⁵: Geueke et al. (2022); ⁶: Bengtström et al. (2016); ⁷: Food Packaging Forum (2019); * Solvent Blue 4 and Solvent Violet 8 are both in itself not classified under CLP, however, they are classified as Carc. 1B when they contain >0.1% Michler's ketone or base

Wood

Table 6 Overview of naturally occurring biologically active organic constituents found in wood, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|------------------------------------|------------|--------------------------|---------------------------------------|
| Terpenes | a-Pinene | 80-56-8 | - | 5/8 (63%) EX/MiFS; P/M/Other |
| | Δ ³ -Carene | 498-15-7 | - | - |
| | Camphor | 76-22-2 | - | 1/6 (17%) EX/MiFS; P/P&B |
| | Thujone | a:546-80-5 | - | - |
| | β-Thujaplicin | 499-44-5 | - | - |
| | Sesquiterpene lactones | NA | NA | NA |
| | Abietic acid | 514-10-3 | - | 18/18 (100%) MiF/EX/MiFS; P/P&B/MM |
| | Neoabietic acid | 471-77-2 | - | 1/1 (100%) EX; P&B |
| | Saponins | NA | NA | NA |
| Phenols | Coniferalldehyde | 458-36-6 | - | 3/3 (100%) EX/MiFS; P&B |
| | Sinapaldehyde | 4206-58-0 | - | - |
| | Eugenol | 97-53-0 | - | 3/6 (50%) EX/MiFS; P/Other |
| | 3-(Pentadecyl)catechol | 492-89-7 | - | - |
| | 5-(Pentadec-10-enyl) resorcinol | NA | NA | NA |
| Tannins | Catechin derivatives | NA | NA | NA |
| | Leucoanthocyanidin derivatives | NA | NA | NA |
| Flavonoids | Kaempferol | 520-18-3 | Self-classified: Muta. 2 | - |
| | Quercetin | 117-39-5 | - | - |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|-----------------------|------------|--------------------|-----------------------|
| Quinones | 2,5-Dimethoxybenzo | 3117-03-1 | - | - |
| | quinone | | | |
| | 2,6-Dimethoxybenzo | 530-55-2 | - | - |
| | quinone | | | |
| | 3,4-Dimethoxy | 3755-64-4 | - | - |
| | dalbergione | | | |
| | Lapachol | 84-79-7 | - | - |
| | Deoxylapachol | 3568-90-9 | - | - |
| | Juglone | 481-39-0 | - | - |
| | Mansonone A | 7715-94-8 | - | - |
| Lignins | Plicatic acid | 16462-65-0 | - | - |
| Stilbenes | Chlorophorin | 537-41-7 | - | - |
| | Pinosylvin | 22139-77-1 | - | - |
| | 2,3',4',5'-Tetrahydro | NA | NA | NA |
| | stilbene | | | |
| Other | Alkaloids (berberin) | 2086-83-1 | - | - |
| | Furocoumarins | 66-97-7 | - | - |
| | (psoralen) | | | |

Source: EFSA CEP Panel (2019)

Table 7 Overview of naturally occurring chemical constituents of possible concern to human health in various wood types, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance | CAS no. | Wood type | Hazard information | Migration information |
|-----------------------------|---------------------|------------------|---------------------------|--------------------------|
| (or substance class with | | | | |
| example) | | | | |
| Lapachol | 84-79-7 | White Peroba | - | - |
| β-Lapachone | 4707-32-8 | White Peroba | - | - |
| Tectoquinone | 84-54-8 | White Peroba, | - | - |
| | | Lapacho, Pau | | |
| | | d'arco, Ipo roxo | | |
| Deoxylapachol | 3568-90-9 | White Peroba, | - | - |
| | | Lapacho, Pau | | |
| | | d'arco, Ipo roxo | | |
| Plicatic acid | 16462-65-0 | Cypress family | - | - |
| Abietic (sylvic) acid | 514-10-3 | Cypress family | - | 18/18 (100%) MiF/EX/MiFS |
| | | | | ; P/P&B/MM |
| Thymoquinone | 490-91-5 | Cypress family | - | - |
| Tropolones | 533-75-5 | Cypress family | -* | - * |
| (e.g. tropolone) | | | | |
| Thujaplicins (e.g. β- | 499-44-5 + 672-76-4 | Cypress family | -* + | - * + |
| thujaplicin, Y-thujaplicin) | | | -* | - * |
| Benzoquinone | 106-51-4 | Cypress family | - | 1/1 (100%) MiFS; P |
| Prunasin | 99-18-3 | Prunes supp. | Self-classified: Repr. 1B | - |
| Amygdalin | 29883-15-6 | Prunes supp. | - | - |
| Naringenin | 67604-48-2 | Prunes supp. | - | - |
| 3-hydroxyaringenin | NA | Prunes supp. | NA | NA |
| Catechin | 7295-85-4/ | Prunes supp. | - | - |
| | 154-23-4/8001-48-7 | | | |

| Substance (or substance class with | CAS no. | Wood type | Hazard information | Migration information |
|--|-------------------|-----------------------------|--------------------|-----------------------|
| example) 5-hydroxy-1,4-naphtho quinine (Juglone) | 481-39-0 | Jugluladaceae sp. | - | - |
| 2-methyl-1,4-naphtho quinone (menadione) | 58-27-5 | Jugluladaceae sp. | - | - |
| 2,3-dihydro-5-hydroxy-2- methyl-1,4-naphthalene dione (β-hydroplumbagin) | 76372-21-9 | Jugluladaceae sp. | - | - |
| 5-hydroxy-2-methyl-1,4- naphthoquinone (Plumbagin) | 481-42-5 | Jugluladaceae sp. | - | - |
| 5-hydroxy-3-methyl-1,4- naphthoquinone (Isoplumbagin) | 14777-17-4 | Jugluladaceae sp. | - | - |
| 2,3-dimethyl-5-hydroxy- 1,4-naphthoguinone | 80596-51-6 | Jugluladaceae sp. | - | - |
| 2,3-dihydro-5-hydroxy-1,4- naphthalenedione (β- hydrojuglone) | 6312-53-4 | Jugluladaceae sp. | - | - |
| 1,4-naphthoquinone | 130-15-4 | Jugluladaceae sp. | - | - |
| Pyrogallol | 87-66-1 | Quercus sp. | Muta. 2 | 1/1 (100%) EX; P |
| Gallotoxins (e.g. gallic acid) | 149-91-7 | Quercus sp. | - * | 1/1 (100%) EX; Other* |
| Tannic acid | 1401-55-4 | Quercus sp. | - | - |
| Phasin | 1392-87-6 | Black Locust | - | - |
| 4-phenylcoumarins (e.g. | 482-83-7 + 10386- | Dalbergia spp., | - * + | - * + |
| dalbergin, melannein) | 55-7 | Cocobolo | - * | _ * |
| Dalbergiquinols (e.g. latifolin) | 10154-42-4 | Dalbergia spp., Cocobolo | - * | - * |
| Dalbergiquinones (e.g. dalbergenone) | 2543-95-5 | Dalbergia spp., Cocobolo | - * | - * |

| Substance (or substance class with example) | CAS no. | Wood type | Hazard information | Migration information |
|--|---------------------------|-----------------------------|--------------------|-----------------------|
| Dalbergichchromenes (e.g. dalbergichromen) | 32066-31-2 | Dalbergia spp., Cocobolo | - * | - * |
| Barzillins (4-phenyl coumarin) | 15185-05-4 | Dalbergia spp., Cocobolo | - | - |
| Methyoxydalbergiones (R-4 and S-4) | 4646-86-0 + 2543- 95-5 | Dalbergia spp., Cocobolo | - + - | - + - |
| 4'-dimethoxydalbergione | NA | Dalbergia spp., Cocobolo | NA | NA |
| S-4'hydroxy-4-methoxy dalbergione | 3755-63-3 | Dalbergia spp., Cocobolo | - | - |
| Pterocarpans (e.g. ptercarpin isomers, maackiain) | 524-97-0 + 2035-15- 6 | Pteorcarpus sp. | - * + - * | - * + - * |
| Isoflavones (e.g. muningin, santal) | 479-83-4 + 529-60-2 | Pteorcarpus sp. | - * + - * | - * + - * |
| Deoxybenzoins (e.g. angolensin) | 642-39-7 | Pteorcarpus sp. | - * | _ * |
| Alkaloid Taxine | 12607-93-1 | Taxus spp. | - | - |
| Alkaloids (e.g. glaucine, nuciferine) | 475-81-0 + 475-83-2 | Yellow popular | - * + - * | - * + - * |
| Sesquiterpenes (e.g. costunolide, epitulipdienolide) | 553-21-9 + 56064- 68-7 | Yellow popular | - * + - * | - * + - * |

Source: FSA (2002)

Examples of the three families: Cypress family: i.e., Cedars, Pines and Junipers; Prusness supp: i.e., red cherry, Choke cherry, Apricot, Peach and Plum; Jululandaceae sp.: i.e., American Black Walnut, Hickory (Pecan) and Butternut; Quercus sp.: i.e., Red, White and Black Oaks; Dalbergia spp.: i.e., Kingwood, Sisscoo, African Blackwood, Tuilipwoods and Rosewoods; Pteorcarpus sp: i.e., red sandalwood; Taxus spp: i.e., English Yew

Table 8 Overview of chemical constituents that were found to be introduced into wood and cork used as FCM via processing, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|---|---------------------------------------|------------|---|--|
| Alkenes | n-Hexane | 110-54-3 | Repr. 2, STOT RE 2 | 5/5 (100%) EX/MiFS; P/P&B |
| | Isobutane | 75-28-5 | Carc. 1A, Muta. 1B | 1/1 (100%) EX; P |
| Bisphenols | Bisphenol A | 80-05-7 | Repr. 1B | 147/182 (81%) |
| | | | SVHC Candidate List (Repr., | MiF/EX/MiFS; P/P&P/M/MM/C&C/Other |
| Alcohols | Ethanol | 64-17-5 | ED) | P/P&B/M/MM/G&C/Other 5/10 (50%) EX; P/P&B |
| Fatty acids | 2-Ethylhexanoic acid | 149-57-5 | Repr. 2 | 5/7 (71%) MiF/EX; P/M |
| Chlorophenols ² | Pentachlorophenol ^{1,2} | 87-86-5 | Carc. 2 | 8/18 (44%) MiF/EX/MiFS; P/P&B/Other |
| Carbamates | Methyl benzimidazole- carbamate | 10605-21-7 | Muta. 1B, Repr. 1B | 1/1 (100%) EX; P&B |
| Chlorinated hydrocarbon | Vinyl chloride | 75-01-4 | Carc. 1A | 2/2 (100%) MiF/EX; P |
| Cyanides | Acrylonitrile | 107-13-1 | Carc. 1B | 0/1 (0%) MiF; MM |
| Aldehydes | Formaldehyde ¹ | 50-00-0 | Carc. 1B, Muta. 2 | 11/13 (85%) MiF/EX/MiFS; P/P&B/G&C |
| Trialkyl phosphate and organochlorine | Tris(2-chloroethyl) phosphate | 115-96-8 | Repr. 1B, Carc. 2 SVHC Authorisation List (Repr.) | 2/4 (50%) MiF/EX; P/P&B |
| Organochlorides | 1,1-Dichloroethylene | 75-35-4 | Carc. 2 | 3/3 (100%) MiF/EX; P |
| Other | Boric acid | 10043-35-3 | Repr. 1B SVHC Candidate List (Repr.) | 2/2 (100%) EX; P&B |

Source: Zimmermann et al. (2022)

Links to documents stating the possibility that these constituents are introduced into wood (fibres) used as FCM via processing: 1: Eurofins Packaging (2022); 2: EFSA CEP Panel (2019)

Table 9 Overview of chemical constituents that might be introduced into wood (fibres) used as FCM via processing, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|---------------------|--------------------------------------|-------------|--|--|
| | | Inorganic c | constituents | |
| Metals ² | Chromium ¹ | 7440-47-3 | - | 62/88 (70%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Copper ¹ | 7440-50-8 | ED under assessment | 39/50 (78%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| | Arsenic ¹ | 7440-38-2 | - | 28/54 (52%) MiF/EX/MiFS; P/P&B/M/MM/G&C/Other |
| Other | Creosote/Guaiacol ¹ | 8001-58-9 | Carc. 1B Self-classified: Repr. 1B | - |
| | Diarsenic pentaoxide ⁵ | 1303-28-2 | Carc. 1A SVHC Authorisation List (Carc.) | - |
| | Diarsenic trioxide ⁵ | 1327-53-3 | Carc. 1A SVHC Authorisation List (Carc.) | - |
| | Sodium dichromate ⁵ | 10588-01-9 | Carc. 1B, Muta. 1B, Repr. 1B, STOT RE 1 SVHC Authorisation List (Carc., Muta., Repr.) | - |
| | Disodium tetraborate ⁵ | 1330-43-4 | Repr. 1B SVHC Candidate List (Repr.) | - |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|------------------------------|---|------------|--|----------------------------------|
| | | Organic co | onstituents | • |
| Chloroanisoles ³ | 2,4,6-Trichloroanisole (TCA) ³ | 87-40-1 | - | 4/7 (57%) EX; P&B/Other |
| | Tetrachloroanisoles ³ | NA | NA | NA |
| Chlorophenols ³ | 2,4,6-trichlorophenol (TCP) ³ | 88-06-2 | Carc. 2 | 4/7 (57%) EX; P&B/Other |
| | Sodium pentachloro phenate ⁶ | 131-52-2 | Carc. 2 | - |
| | Bromo-2- chlorophenols (BCP) ³ | NA | NA | NA |
| | Dichlorophenols ³ | NA | NA | NA |
| | Tetrachlorophenols ³ | NA | NA | NA |
| Chloropropanols ⁴ | 3-MCPD ⁴ (3-chloro propane-1,2-diol) | 96-24-2 | Self-classified: Repr. 1B, Carc. 2, STOT RE 1 | 5/7 (71%) MiF/EX/MiFS; P&B/MM |
| | 1,3-DCP ⁴ (1,3- dichloro propan-2-ol) | 96-23-1 | Carc. 1B | 4/7 (57%) EX/MiFS; P&B/MM |
| Organotin ² | Bis(tributyltin)oxide ⁶ | 56-35-9 | Self-classified: Repr. 1B, STOT RE 2 SVHC Candidate List (PBT) | - |
| Phenolic benzotriazoles | UV-328 (2-(2H-benzo triazol-2-yl)-4,6- ditertpentylphenol) ⁵ | 25973-55-1 | Self-classified: STOT RE 2 SVHC Authorisation List (PBT, vPvB) | 7/8 (88%) MiF/EX/MiFS; P |
| Polycyclic aromatic | Anthracene ⁵ | 120-12-7 | SVHC Candidate List (PBT) | - |
| hydrocarbon | Anthracene oil ⁵ | 90640-80-5 | Carc. 1B SVHC Authorisation List (Carc., PBT, vPvB) | - |
| Sulfur oxides | Sulfur dioxide ⁶ | 7446-09-5 | ED under assessment | - |
| Petrolium fraction | Ligroine ⁶ | 8032-32-4 | Carc. 1B, Muta. 1B | - |
| Phenols | Catechol ⁶ | 120-80-9 | Carc. 1B, Muta. 2 | 0/1 (0%) MiFS; P |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|---|--------------------------------------|----------|--|------------------------------|
| | Sodium 2-phenyl phenate ⁶ | 132-27-4 | - | - |
| Hydroxy ether | 2-Methoxyethanol ⁶ | 109-86-4 | Repr. 1B SVHC Candidate List (Repr.) | - |
| Polychlorinated dibenzodioxins ³ | NA | NA | NA | NA |
| Polychlorinated dibenzofurans ³ | NA | NA | NA | NA |
| Antimicrobial substances ² | NA | NA | NA | NA |

Sources: ¹: KEMI (2022); ²: Eurofins Packaging (2022); ³: EFSA CEP Panel (2019); ⁴: BEUC (2021); ⁵: Ministry of Environment of Denmark (2022); ⁶: Zimmermann et al. (2022)

Bamboo

Table 10 Overview of naturally occurring chemical constituents detected in bamboo (fibres), including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|----------------------------------|-------------------------|--------------------|--------------------------|
| Cyano | Cyanide ¹ | 57-12-5 | - | - |
| | 3β-Ergost-5-en-3-ol ² | 4651-51-8 / 474-62-4 | - | 3/3 (100%) EX; P&B+Other |
| Phytosterols | Stigmasterol ² | 83-48-7 | - | 4/4 (100%) EX; P&B+Other |
| | Clionasterol ² | 83-47-6 | - | 2/2 (100%) EX; P&B |
| | Arundion ² | 4555-56-0 | - | - |
| Amino acid | Valine ² | 72-18-4 | - | - |

Sources: ¹: Satya et al. (2010); ²: Osorio et al. (2020)

Table 11 Overview of detected process contaminants in products made of bamboo (fibres), including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|--|--|-------------|--|--|
| Aldehyde | Formaldehyde ^{1,2,4,5,7,8} | 50-00-0 | Carc. 1B, Muta. 2 | 11/13 (85%) MiF/EX/MiFS; P/P&B/G&C |
| PFAS (per- and polyfluoroalkyl substances) | Perfluorooctanoic acid (PFOA) ⁹ | 335-67-1 | Repr. 1B, Carc. 2, STOT RE 1 (liver) SVHC Candidate List (Repr., PBT) | 45/67 (67%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Perfluoroundecanoic acid (PFUnDA) ⁹ | 2058-94-8 | SVHC Candidate List (vPvB) | 17/40 (43%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Perfluordodecanoic acid (PFDoDA) ⁹ | 307-55-1 | SVHC Candidate List (vPvB) | 20/41 (49%) MiF/EX/MiFS; P/P&B/MM/Other |
| | Perfluorotridecanoic acid (PFTrDA) ⁹ | 72629-94-8 | SVHC Candidate List (vPvB) | 8/16 (50%) EX/MiFS; P/P&B/MM/Other |
| | Perfluorotetradecenoic acid (PFTeDA) ⁹ | 376-06-7 | SVHC Candidate List (vPvB) | 8/22 (36%) EX/MiFS; P/P&B/MM/Other |
| | 4:2 Fluorotelomer sulfonic acid (4:2 FTS) ⁹ | 757124-72-4 | - | - |
| | Perfluoroheptane sulfonic acid (PFHpS) ⁹ | 375-92-8 | - | 1/4 (25%) EX; P/P&B/Other |
| Tertiary amino | Triethanolamine ⁶ | 102-71-6 | - | 3/3 (100%) EX/MiFS; P/P&B/M |
| Melamine or melamine derivative | Melamine ^{1,2,3,4,5,6} | 108-78-1 | ED under assessment SVHC Candidate List (probable serious effects to human health and to the environment) | 6/15 (40%) MiF/EX/MiFS; P/P&B/M/MM |
| | N-Hydroxymethyl melamine ⁶ | 937-35-9 | - | - |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|--|---|--------------------|-----------------------|
| | N-Hydroxypropyl melamine ⁶ | 91313-29-0 | - | - |
| | N-Hydroxymethyl melamine ⁶ | 937-35-9 | - | - |
| | Methylene melamine ⁶ | 85946-83-4 | - | - |
| | N-(4,6-Diamino-1,3,5-triazin-2-yl) acetamide ⁶ | 16274-60-5 | - | - |
| | 2,4,6-Pyrimidine triamine, 5,5'-azobis ⁶ | 63436-10-2 | - | - |
| | Propanamide, N-(4,6-diamino- 1,3,5-triazin-2-yl)-2-[(4,6-diamino- 1,3,5-triazin-2-yl) amino] ⁶ | 1421766-78- 0 | - | - |
| | Glycine, N-[4-[(1,1-dimethylethyl) amino]-6-(ethylamino)-1,3,5- triazin-2-yl]-N-propyl ⁶ | 2037785-60- 5 | - | - |
| Alkanes (1/2) | Phenacyl formate ⁶ | 55153-12-3 | - | - |
| | 3,3-dimethyoxy-2-butanone ⁶ | 21983-72-2 | - | - |
| | Methyl N-hydroxy benzene carboximidate ⁶ | 67160-14-9 | - | - |
| | Decane ⁶ | 1247-18-5/ 63335-87-5/ 73138-29-1 | - | - |
| | 3,5-dimethyloctane ⁶ | 15869-93-9 | - | 1/1 (100%) EX; MM |
| | 2,3-dimethyldecane ⁶ | 17312-44-6 | - | 2/2 (100%) MiFS; MM |
| | 2,4-dimethylheptane ⁶ | 2213-23-2 | - | 4/4 (100%) EX; P |
| | 2-methylundecane ⁶ | 7045-71-8/ 31807-55-3 | - | 1/1 (100%) EX; P |
| | 2,6,10-trimethyl dodecane ⁶ | 3891-98-3 | - | 1/1 (100%) EX; P |
| | 4,6-dimethyldodecane ⁶ | 61141-72-8 | - | 1/1 (100%) MiFS; P |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|--|-------------|--------------------|--|
| | Hexadecane ⁶ | 544-76-3 | - | 30/30 (100%) EX/MiFS; P/P&B/MM/Other |
| | 3,6-dimethyldecane ⁶ | 17312-53-7 | - | - |
| | 2,4-dimethylundecane ⁶ | 17312-80-0 | - | - |
| | 4,6-dimethylundecane ⁶ | 17312-82-2 | - | - |
| | Tetradecane ⁶ | 629-59-4 | - | 23/23 (100%) MiF/EX/MiFS; P/P&B/M/Other |
| | Eicosane 1 propoxy ⁶ | 281211-96-9 | - | - |
| | 2,4,6-trimethyloctane ⁶ | 62016-37-9 | - | - |
| | 2,6,11-trimethyl dodecane ⁶ | 31295-56-4 | - | 1/1 (100%) EX; P |
| Alkanes (2/2) | Nonadecane ⁶ | 629-92-5 | - | 12/12 (100%) EX/MiFS; P/P&B/MM/Other |
| | Heptacosane ⁶ | 593-49-7 | - | 10/10 (100%) MiF/EX/MiFS; P/P&B/MM |
| | (S)-12-methyltetra decanoic methyl ester ⁶ | 62691-05-8 | - | - |
| Other (1/2) | 1,1'-[1,40-Tetracontane diylbis (oxy)]bis[2-ethynyl-4-(2-methyl-2- propanyl)benzene] ¹⁰ | NA | NA | NA |
| | 3',5'-Dihydroxy-4"-methyl- 1,1':4',1"-terphenyl-2'-yl beta-D- glucopyranoside ¹⁰ | NA | NA | NA |
| | 1,2-Propanediylbis(oxy-2,1- ethanediyl) dihexadecanoate ¹⁰ | NA | NA | NA |
| | (9E)-21-Hydroxy-12-methylene-9- henico senoic acid ¹⁰ | NA | NA | NA |
| | Dioctadecyl tartarate ¹⁰ | NA | NA | NA |
| | pentaerythritol distearate ¹⁰ | NA | NA | NA |
| Other (2/2) | 2-Iodo-N-(7-methyl[1,3]thiazolo [5,4-e][1,3]benzo thiazol-2-yl) benzamide ¹⁰ | NA | NA | NA |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|---|---------|--------------------|-----------------------|
| | 3-(Heptanoyloxy)-2- {[(2- hexyldecanoyl) oxy]methyl}k-2- [(nonanoyloxy)methyl] propyl undecanoate ¹⁰ | NA | NA | NA |
| | N-[(4E,8E)-1-(Hexo pyranosyloxy)-3-hydroxy-9-methyl- 4,8-octadecadien-2-yl]-2- hydroxydocosanamide ¹⁰ | NA | NA | NA |
| | (2E,5E)-2,5-Bis[(2E)-3,7-dimethyl - 2,6-octadien-1-ylidene] cyclo pentanone ¹⁰ | NA | NA | NA |

Sources: ¹: BfR (2019); ²: BuRO NVWA (2021); ³: CVUA Stuttgart (2014); ⁴: Stiftung Warentest (2019); ⁵: Petrova & Bagdassarian (2021); ⁶: Osorio et al. (2020); ⁷: Food Packaging Forum (2020); ⁸: Bouma et al. (2022); ⁹: UAntwerpen (2022); ¹⁰: Zimmermann et al. (2020)

Table 12 Overview of possibly present process constituents in products made of bamboo (fibres), including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|--------------------|---|---------|--------------------|-----------------------|
| Pesticide residues | Hexachlorocyclo hexanes (HCH) | NA | NA | NA |
| | 1,1,1-trichlor-2,2- bis(p-chlorophenyl) ethane (DDT) ¹ | 50-29-3 | Carc. 2, STOT RE 1 | 1/2 (50%) EX; Other |
| | Pentachloronitro benzene (PCNB) | 82-68-8 | - | - |

Source: Ziwu et al. (2011)

Sugarcane

Table 13 Overview of naturally occurring chemical constituents found in sugarcane (bagasse), including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-------------------------|------------------------------------|-------------|--------------------------|--------------------------|
| Phenolic | Ascorbic acid | 50-81-7 | - | - |
| constituents / | (Vitamin C) ¹ | | | |
| Flavonoids ³ | Gallic acid ^{1,2} | 149-91-7 | - | 1/1 (100%) EX; Other |
| | Caffeic acid ^{1,4} | 331-39-5 | Self-classified: Carc. 2 | 1/1 (100%) EX; Other |
| | p-Coumaric acid ^{1,2,3,4} | 501-98-4 | - | - |
| | Ferulic acid ^{1,3,4} | 1135-24-6 | - | 1/1 (100%) EX; Other |
| | Sinapic acid ^{1,3} | 530-59-6 | - | - |
| | Rutin hydrate ¹ | 207671-50-9 | - | - |
| | Quercetin ^{1,2} | 117-39-5 | Self-classified: Muta. 2 | - |
| | (3,3',4',5,7-penta hydroxyflavone) | | | |
| | Kaempferol ¹ | 520-18-3 | Self-classified: Muta. 2 | - |
| | (3,4',5,7-tetrahydroxy flavone) | | | |
| | T4G7G ² | NA | NA | NA |
| | Genistin ² | 529-59-9 | - | - |
| | Genistein ² | 446-72-0 | - | - |
| | Protocatechuic acid ³ | 99-50-3 | - | 3/3 (100%) EX; P&B/Other |
| | p-Hydroxybenzoic acid ³ | 99-96-7 | - | 2/2 (100%) EX; P&B/MM |
| | Vanillic acid ³ | 121-34-6 | - | 1/1 (100%) EX; P&B |
| | Chlorogenic acid ^{3,4} | 327-97-9 | - | - |
| Phenolic | Apigenin | 520-36-5 | - | - |
| constituents / | (chamomile oil) ⁴ | | | |
| Flavonoids ³ | Luteolin ⁴ | 491-70-3 | - | - |
| | Tricin ⁴ | 520-32-1 | - | - |

Sources: ¹: Chong et al. (2019); ²: Zheng et al. (2017); ³: Zhao et al. (2015); ⁴: Duarte-Almeida et al. (2011)

Table 14 Overview of detected process constituents in products made of sugarcane (bagasse), including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|--|---------------------------|--------------|---|---------------------------------------|
| PFAS ¹ / Fluorinated chemicals ² | NA | NA | NA | NA |
| Chloropropanols ² | NA | NA | NA | NA |
| Pesticide residues ² | NA | NA | NA | NA |
| Organohalogen chemicals ³ | NA | NA | NA | NA |
| Other | Melamine ⁴ | 108-78- 1 | ED under assessment SVHC Candidate List (probable serious effects to human health and to the environment) | 6/15 (40%) MiF/EX/MiFS; P/P&B/M/MM |
| | Formaldehyde ⁴ | 50-00-0 | Carc. 1B, Muta. 2 | 11/13 (85%) MiF/EX/MiFS; P/P&B/G&C |

Sources: ¹: Fidra (2020); ²: BEUC (2021); ³: Öko-Test (2018); ⁴: Duarte-Almeida et al. (2011), (UTwente 2020)

Palm leaves

Table 15 Overview of naturally occurring chemical constituents found in palm leaves, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-------------------------------|---------------------------------------|----------|--------------------|--|
| Tannins | NA | NA | NA | NA |
| Flavonoids | NA | NA | NA | NA |
| Catechins | NA | NA | NA | NA |
| Steroids | NA | NA | NA | NA |
| Triterpenes | NA | NA | NA | NA |
| Saponins | NA | NA | NA | NA |
| Saturated fatty acid | Capric acid (decanoic acid) | 334-48-5 | - | 3/3 (100%) EX; P/P&B |
| | Lauric acid (dodecanoic acid) | 143-07-7 | - | 11/11 (100%) EX/MiFS; P&B/M/MM/Other |
| | Myristic acid (tetradecanoic acid) | 544-63-8 | - | 7/7 (100%) EX/MiFS; P/P&B/Other |
| | Palmitic acid (hexadecenoic acid) | 57-10-3 | - | 38/42 (90%) EX/MiFS; P/P&B/M/MM/Other |
| | Stearic acid (octadecanoic acid) | 57-11-4 | - | 30/36 (83%) EX/MiFS; P/P&B/M/Other |
| Unsaturated fatty acid | Linoleic acid | 60-33-3 | - | 5/5 (100%) EX/MiFS; P/P&B/Other |
| | Linolenic acid | 463-40-1 | - | 1/1 (100%) MiFS; P&B |
| Unsaturated acyclic alcohol | Phytol | 150-86-7 | - | 1/1 (100%) EX; Other |
| Aromatic dicarboxylic acid | Phthalic acid | 88-99-3 | - | 6/6 (100%) MiF/EX/MiFS; P/P&B/M/Other |

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------|-------------|----------------------|--------------------|-----------------------|
| Acyclic | Citronellol | 106-22-9/ 26489-01-0 | - | 2/2 (100%) EX; P |
| monoterpenoid | | | | |

Source: de Oliveira et al. (2016)

Table 16 Overview of detected process constituents in products made of palm leaves, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|---|--|---------|--------------------|-----------------------|
| Organohalogen chemicals ¹ | NA | NA | NA | NA |
| Pesticide residues | NA ² | NA | NA | NA |
| | 1,1,1-trichlor-2,2- bis(p- chlorophenyl)ethane (DDT) ¹ | 50-29-3 | Carc. 2, STOT RE 1 | 1/2 (50%) EX; Other |

Sources: 1: : Öko-Test (2018); 2: BEUC (2021)

Wheat

Table 17 Overview of chemical constituents that are detected in wheat-based FCM, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|-----------------------|-----------|---------|--------------------|-----------------------|
| Fluorinated chemicals | NA | NA | NA | NA |
| Pesticide residues | NA | NA | NA | NA |
| Chloropropanols | NA | NA | NA | NA |

Source: BEUC (2021)

Table 18 Overview of chemical constituents that could be present in wheat-based FCM, including CAS number, hazard information (CMR, STOT RE, ED and SVHC listing, retrieved from ECHA database during February 2023), and information from migration experiments (% of studies in which migration was detected, experiment type and material, retrieved from the FCCmigex database during Q3 2022). Chemicals are prioritised as high (dark grey), medium (light grey) and low (w/o colour) in the substance column. The hazard and migration categories in which constituents fall (leading to the overall prioritisation) are also shown as high (dark grey), medium (light grey) and low (w/o colour) (prioritisation rules can be found in the approach section)

| Substance class | Substance | CAS no. | Hazard information | Migration information |
|---------------------------------|-----------------|----------|--------------------------|-----------------------|
| Mycotoxins ¹ | Ergot alkaloids | NA | NA | NA |
| | Ochratoxin A | 303-47-9 | Self-classified: Carc. 2 | - |
| Pesticide residues ¹ | NA | NA | NA | NA |

Source: 1: BSI (n.d.)

Prioritisation of chemicals for further research

To answer the last research question, this chapter prioritises the chemicals that may be of concern to consumers using FCM made of alternative or new materials as replacement of Single Use Plastics. The prioritisation is based on hazard classification listed in the ECHA database and percentage of positive migration experiments listed in the FCCmigex database. Chemicals are listed as high priority if they are harmonised or self-classified under CLP as category CMR category 1A or 1B and are found to migrate in \geq 75% of the experiments (confirmed in \geq 4 experiments including MiF and MiFS experiments; for more details see 3.7.). Chemicals in the high category for hazard that do not meet the criteria for high category for migration are labelled as medium priority (regardless of migration level priority). Chemicals in the medium category for hazard (labelled as CMR category 2 or STOT RE 1) that are in either the medium (migration detected in \geq 50% of the studies) or high category for migration are labelled as medium priority. Other chemicals are labelled as low priority. It should be noted that substances with no information available on hazard (not found in the ECHA database) were prioritised in the low hazard category. Similarly for migration data, when no data was available, the low category was selected. Further, substance groups were not prioritised, as no specific information is gathered.

Table 19 and Table 20 list the high and medium prioritised chemical constituents which were found or could be found in FCM made of alternative materials, respectively. Six chemical constituents were categorised with high priority. These chemicals can be seen as usual suspects. For all chemicals, restrictions in the form of specific migration limits (SML) are present. When no FCM restrictions were set, positive lists for drinking water contact materials and ECHA/EFSA databases were searched. All but one were found to be (possibly) present in either FCM made of paper and/or board or wood (fibres). Formaldehyde was found in FCM of paper and/or board, wood, bamboo and sugarcane. Bisphenol A can be present in FCM made of paper and board, and wood. None of the high priority chemicals were found in FCM from palm leaves. Chemicals (possibly) found in FCM made of wheat are not selected as either high or medium priority.

Forty-eight chemical constituents were categorised with medium priority. Of these 48 medium priority chemicals, 27 and 24 were found to (possibly) be present in paper and board and wood (fibre) FCM, respectively. Additionally, one chemical constituent was categorised with medium priority for palm leaves and sugarcane and two for bamboo FCM, respectively. Of the chemical constituents with medium priority, boric acid, vinyl chloride, 1,1-dychloro-ethylene, disodium tetraborate, PFOA, 3-MCPD and DDT may be present in two FCM types. For about half of the chemical constituents with medium priority, SMLs were set. If not, SMLs were calculated based on toxicological reference values or derived based on maximum tolerable limits.

Table 19 High prioritised chemical constituents that are or could be present in FCM made of alternative materials, grouped per alternative material. The reasoning for prioritisation as high priority and the limit or toxicological reference value is provided

| Substance | CAS no. | (Could be) found in FCM | Priority based on | Limit, or tox. Ref value |
|---------------------------|-----------|--|--|--|
| Formaldehyde | 50-00-0 | Paper and board, Wood, Bamboo, Sugarcane | Carc. 1B; Muta. 2, migration in 85% of studies | SML = 15 mg/kg ² |
| Bisphenol A | 80-05-7 | Paper and board, Wood | Repr. 1B; migration in 81% of studies | SML = 0,05 mg/kg food ^{1,3} ; under re- evaluation by EFSA |
| Di-isobutyl phthalate | 84-69-5 | Paper and board | Repr. 1B; migration in 91% of studies | SML = 1,0 mg/kg food ^{2,4} |
| Dibutyl phthalate | 84-74-2 | Paper and board | Repr. 1B; migration in 91% of studies | SML = 1,0 mg/kg food ^{2,4} |
| Diethylhexyl phthalate | 117-81-7 | Paper and board | Repr. 1B; migration in 86% of studies | SML = 1,5 mg/kg food ² |
| Lead | 7439-92-1 | Paper and board | Repr. 1A; migration in 77% of studies | SML = ND (LOD 0,01 mg/kg) ¹ |

¹: Source: EC (2011); ²: Source: NL (2022c); ³: Additional restriction: Not to be used for the manufacture of polycarbonate infant feeding bottles or PC drinking cups or bottles which are intended for infants and young children; ⁴: SML is for the sum ofdibutylphthalate and di-isobutylphthalate

Abbreviations: The abbreviations used to describe the hazards can be found in the Approach chapter; SML: specific migration limit in mg/kg food; LOD: limit of detection

Table 20 Medium prioritised chemical constituents that are or could be present in FCM made of alternative materials, grouped per alternative material. The reasoning for prioritisation as medium priority and the limit or toxicological reference value is provided

| Substance | CAS no. | | Priority based on | Limit, or tox. Ref value |
|--|------------|----------------------------|---|---|
| Boric acid | 10043-35-3 | Paper and board, Wood | Repr. 1B; migration in 100% of studies (<4) | SML = 6 mg/kg (expressed as boron) ¹ |
| Vinyl chloride | 75-01-4 | Paper and board, Wood | Carc. 1A; migration in 100% of studies (<4) | $SML = ND (LOD 0.01 mg/kg)^1$ |
| 1,1-Dichloro-ethylene | 75-35-4 | Paper and board, Wood | Carc. 2; migration in 100% of studies | $SML = ND (LOD 0.01 mg/kg)^1$ |
| Disodium tetraborate | 1330-43-4 | Paper and board, Wood | Repr. 1B | Boron: SML = 6 mg/kg $(salt of listed boric acid)^1$ |
| 3-Monochloropropane-1,2- diol (3-MCPD) | 96-24-2 | Paper and board, wood | Self-classified: Repr. 1B, Carc. 2 and STOT RE 1; migration in 71% of studies | SML = 0,01 mg/kg ² |
| Perfluorooctanoic acid (PFOA) | 335-67-1 | Paper and board, Bamboo | Repr. 1B; migration in 67% of studies | SML = 0.05 mg/kg food ¹² ; but also EFSA TWI = 4.4 ng/kg bw (sum of 4 PFAS) ^{1,3} |
| 1,1,1-trichlor-2,2-bis(p- chlorophenyl)ethane (DDT) | 50-29-3 | Bamboo, Palm leaves | Carc. 2; migration in 50% of studies | Not on FCM PL's; P-TDI = 0.01 mg/kg bw ^{5,8} |
| Epichlorohydrin | 106-89-8 | Paper and board | Carc. 1B; migration in 100% of studies (<4) | SML = ND (LOD 0.01 mg/kg) or max. 1 mg/kg presence in final product ¹ |
| Styrene | 100-42-5 | Paper and board | Repr. 2; migration in 100% of studies | On FCM PL, without SML ^{1,7} ; under re-evaluation by EFSA |
| Perfluorohexanoate acid (PFHxA) | 307-24-4 | Paper and board | Repr. 1B, Carc. 2; migration in 30% of studies | Not on FCM PL's; RPF = 0.01 as compared to PFOA ⁶ ; EFSA TWI = 4.4 ng/kg bw (sum of 4 PFAS) ^{1,3} |
| Cadmium | 7440-43-9 | Paper and board | Carc. 1, Muta. 2, Repr. 2; migration in 51% of studies | $SML = ND (LOD 0.002 mg/kg)^{1}$ |
| 4,4'-Oxydianiline | 101-80-4 | Paper and board | Carc. 1B, Muta. 1B, Repr. 2; migration in 13% of studies | $SML = 0.002 \text{ mg/kg}^{1,11}$ |

| Substance | CAS no. | (Could be) found in FCM | Priority based on | Limit, or tox. Ref value |
|--|------------|----------------------------|--|--|
| Bis(4-aminophenyl) methane | 101-77-9 | Paper and board | Carc. 1B, Muta. 2; migration in 30% of studies | $SML = 0.002 \text{ mg/kg}^{1,11}$ |
| o-Toluidine | 95-53-4 | Paper and board | Carc. 1B; migration in 25% of studies | $SML = 0.002 \text{ mg/kg}^{1,11}$ |
| Dimethyl sulfate | 77-78-1 | Paper and board | Carc. 1B, Muta. 2 | Not on FCM PL's |
| Hydrazine | 302-01-2 | Paper and board | Carc. 1B | MTC = $0.1 \ \mu g/L^4 \ (\sim SML=ND)^{14}$ |
| N-Methyl acetamide | 79-16-3 | Paper and board | Carc. 1B | Not on FCM PL's |
| N,N-Dimethyl acetamide | 127-19-5 | Paper and board | Carc. 1B | MTC = 2,5 μ g/L ⁴ (~SML=0,05 mg/kg) ¹⁴ |
| Tris(2,3-epoxypropyl) isocyanurate | 2451-62-9 | Paper and board | Muta. 1B | Not on 10/2011, other Isocyanates: ND expressed as isocyanate moiety ¹ |
| Ammonium perfluoro octanoate (PFOA salt) | 3825-26-1 | Paper and board | Repr. 1B, Carc. 2 | PFOA: EFSA TWI = 4.4 ng/kg bw (sum of 4 PFAS) ^{1,3} |
| Bis(2-hydroxyethyl) ammonium perfluorooctane sulfonate (PFOS salt) | 70225-14-8 | Paper and board | Repr. 1B, Carc. 2 | Not on FCM PL's; PFOS: EFSA TWI = 4.4 ng/kg bw (sum of 4 PFAS) ³ |
| Bis(2-methoxy ethyl)ether (diglyme) | 111-96-6 | Paper and board | Repr. 1B | DNEL _{oral} = 0.09 mg/kg bw/day for general population ¹² (\sim SML = 5 mg/kg) and TDI = 0.05 mg/kg bw ¹⁴ (\sim SML = 3 mg/kg) |
| Ethylene glycol dimethyl ether | 110-71-4 | Paper and board | Repr. 1B | Not on 10/2011, other ethylene glycol ethers present in 10/2011: SML(T) = 30 mg/kg (as ethyleneglycol) ¹ |
| Methoxy acetate | 625-45-6 | Paper and board | Repr. 1B | Not on FCM PL's |
| Triethylene glycol dimethyl ether | 112-49-2 | Paper and board | Repr. 1B | Not on 10/2011, other ethylene glycol ethers present in 10/2011: |

| Substance | CAS no. | (Could be) found in FCM | Priority based on | Limit, or tox. Ref value |
|--|------------|----------------------------|---|---|
| | | | | SML(T) = 30 mg/kg (as ethyleneglycol) ¹ |
| Dimethylformamide | 68-12-2 | Paper and board | Repr. 1B | MTC = 2.5 µg/L ⁴ (~SML=0.05 mg/kg) ¹⁴ |
| Formamide | 75-12-7 | Paper and board | Repr. 1B | Not on FCM PL's |
| Tetraethylammonium perfluoroctanesulfonate (PFOS salt) | 56773-42-3 | Paper and board | Self-classified: Repr. 1B, Carc. 2, STOT RE 1 | EFSA TWI = 4.4 ng/kg bw (sum of 4 PFAS) ³ |
| Isobutane | 75-28-5 | Wood | Carc. 1A, Muta. 1B; migration in 100% of studies (<4) | On FCM PL, without SML ^{1,7} |
| Methyl benzimidazole- carbamate | 10605-21-7 | Wood | Muta. 1B, Repr. 1B; migration in 100% of studies (<4) | SML = 1 mg/kg food; |
| Pyrogallol | 87-66-1 | Wood | Muta. 2; migration in 100% of studies | Not on FCM PL's; Genotoxic in vitro and in vivo ⁹ |
| n-Hexane | 110-54-3 | Wood | Repr. 2; migration in 100% of studies | On FCM PL, without SML ^{1,7} |
| 2-Ethylhexanoic acid | 149-57-5 | Wood | Repr. 2; migration in 71% of studies | SML = 30 mg/kg food ² |
| Tris(2-chloroethyl) phosphate | 115-96-8 | Wood | Repr. 1B, Carc. 2; migration in 50% of studies | $SML = ND (LOD 0.01 mg/kg)^1$ |
| 2,4,6-trichlorophenol (TCP) | 88-06-2 | Wood | Carc. 2; migration in 57% of studies | SML "phenols": 0.1 mg/kg food ² |
| 1,3-DCP (1,3- dichloropropan-2-ol) | 96-23-1 | Wood | Carc. 1B; migration in 57% of studies | $SML = ND (LOD 0.01 mg/kg)^2$ |
| Acrylonitrile | 107-13-1 | Wood | Carc. 1B | $SML = ND (LOD 0.01 mg/kg)^1$ |
| Sodium dichromate | 10588-01-9 | Wood | Carc. 1B, Muta. 1B, Repr. 1B | Cr(VI): SML = ND (LOD 0.01 mg/kg) ¹ Cr(III): SML = 3.6^1 |
| Diarsenic pentaoxide | 1303-28-2 | Wood | Carc. 1A | Arsenic: SML = ND (LOD 0.01 $mg/kg)^{1,2}$ |

| Substance | CAS no. | (Could be) found in FCM | Priority based on | Limit, or tox. Ref value |
|---------------------------|------------|----------------------------|---|--|
| Diarsenic trioxide | 1327-53-3 | Wood | Carc. 1A | Arsenic: SML = ND (LOD 0.01 mg/kg) ^{1,2} |
| Creosote | 8001-58-9 | Wood | Carc. 1B | Mixture, coal tar distillate ¹⁵ , not on FCM PL's |
| 2-Methoxy ethanol | 109-86-4 | Wood | Repr. 1B | MTC = 0.15 mg/L^4 (~ SML = 3 mg/kg) ¹⁴ |
| Ligroine (petroleumether) | 8032-32-4 | Wood | Carc. 1B, Muta. 1B | Mixture, acceptance depends on the composition |
| Catechol | 120-80-9 | Wood | Carc. 1B, Muta. 2 | $SML = 6 \text{ mg/kg}^1$ |
| Anthracene oil | 90640-80-5 | Wood | Carc. 1B | Mixture, coal tar distillate ¹⁵ , not on FCM PL's |
| Prunasin | 99-18-3 | Wood | Self-classified: Repr. 1B | Not on FCM PL's |
| Bis(tributyltin)oxide | 56-35-9 | Wood | Self-classified: Repr. 1B | $SML = 0,01 \text{ mg/kg}^2$ |
| Caffeic acid | 331-39-5 | Sugarcane | Self-classified: Carc. 2; migration in 100% of studies (<4) | Not on PCM PL's |

¹: Source: EC (2011); ²: Source: NL (2022c); ³: Source: EFSA (2020c); ⁴: Source: 4MSI CA-OM Part B (2022); ⁵: Source: EFSA Contam Panel (2006); ⁶: Source: Bil et al. (2021); ⁷: The overall migration (sum of all substances) should not exceed 10 mg/dm² which is \approx 60 mg/kg food; ⁸: When no SML is available, the TDI or ADI can be used calculate the SML. The following assumptions are made: a person weighs 60 kg, a person eats 1 kg food that was in contact with FCM; the allocation of the ADI/TDI is 100%, ⁹: Genotoxic substances will be given an SML of ND (LOD 0.01 mg/kg); ¹⁰: a SML of 0.05 mg/kg does not mean that a concentration above this SML is not save since for chemicals that limitedly migrate to food (<0.05 mg/kg food), it is only needed to show that the chemical is not genotoxic. The same is true for a SML of 5 mg/kg (if there is no potential for bioaccumulation) for which only genotoxicity and a 90 days study have to be performed; ¹¹: Source: Reg. 10/2011, Annex II (2): Primary aromatic amines (PAAs) which are listed in entry 43 to Appendix 8 of Annex XVII to Reg.1907/2006 and which are not listed in Annex 1 of 10/2011 shall not be detectable with a method with LOD 0,002mg/kg food; ¹²: Source: RAC and SEAC, 2017; ¹²: In the Netherlands, a drinking water guidance value of 0.44 mg/L is based on this TDI (Van Leerdam, 2018); ¹⁴: An MTC is often obtained from a SML, in which the MTC = SML / 20 (factor 2 since the daily intake of drinking water is twice as high then food, and factor 10 due to the 10% allocation of the TDI or other health based guidance value); ¹⁵: Risk of polyaromatic hydrocarbons. SML = 0,01 mg/kg (NL, 2022) or SML= ND (LOD 0,001 mg/kg) for sum of benzo(a) pyrene, benzo(a) anthracene, benzo(b)fluoranthene and chrysene (EDQM, 2021)

Abbreviations: The abbreviations used to describe the hazards can be found in the Approach chapter; SML(T): (total) specific migration limit in mg/kg food; ND: not detectable; LOD: limit of detection; PL: positive list(s); ADI: acceptable daily intake; TWI: tolerable weekly intake; P-TDI: preliminary tolerable daily intake; RPF: relative potency factor; MTC: maximal tolerable concentration in drinking water; DNELoral: Derived No-Effect Level following oral exposure

7 Discussion

In this chapter we will discuss the prioritisation of chemicals in the previous chapter in relation to the materials that have been selected from the market survey of products, limitations of the research approach, the stakeholder interviews that have been conducted and findings from other reports.

7.1 **Prioritisation: chemicals and/or materials**

Since only a few chemicals are prioritised in FCM products made of bamboo, palm leaves and sugarcane, and no chemicals are prioritised in wheat FCM, this indicates that further studies could be directed at other FCM (first). Most prioritised chemicals are (possibly) found in FCM of paper and board, and wood.

Based on the alternative material used for the manufacturing of FCM in the Netherlands (Table 3), this report indicates (first) efforts could go towards the detection of chemicals in cutlery and plates/bowls made of wood and paper and board, straws made of paper, food containers made of paper and cups for beverage made of paper and board. Of this type of products, plates/bowls and food containers were most sampled on the Dutch market, followed by cutlery and drinking cups (Table 3). The six chemicals prioritised with high priority could be specifically screened for (i.e., formaldehyde, bisphenol A, di-isobutyl phthalate, dibutyl phthalate, diethylhexyl phthalate and lead).

7.2 Limitations of the research approach

7.2.1 Market survey

The market survey was performed in Q1 and Q2 of 2022. Both online and offline shops were visited to obtain information on the type of FCM made of alternative materials available on the Dutch market. The period in which the market survey was performed is before the SUP legislation will be fully enforced. As a result, plastic FCM were banned from shops, but not from food vendors. It is unknown whether the type of alternative FCM that will be used by food vendors in the future is similar to the found materials in the shops. In addition, since some shops still sold banned FCM, the full range of available alternative materials may slightly differ from the one sampled in Q1 and Q2 of 2022. Thus, the FCM considered in this study may not represent the market in following continued implementation of the SUP directive. Moreover, seasonal products, like for Halloween or Christmas, were not sampled outside of Q1 and Q2. It is however thought that, while prints may be seasonal, the materials used are likely the same.

7.2.2 Products on the Dutch market

This survey aimed to identify alternative materials used in single-use FCM. As a result, products that were not considered for single-use were excluded. It should, however, be noted that more reusable products have become available on the Dutch market since single-use products made of plastic are banned from stores. Since this was aimed at by the SUP Directive, this is a positive result.

7.2.3 Prioritisation

It should be noted that for prioritisation of chemicals of concern, as applied in this study, information about hazards (classification) and migration (experiments) has been retrieved from two databases only, respectively the ECHA database and FFCMigex database. The data available from these databases dates back from before the introduction of the SUP Directive and does not cover the full range of substances potentially present in the materials discussed in this report. For the purpose of this study these substances have been attributed low priority. Hence, better prioritisation requires further research. Additionally, the FFCMigex database did not show the actual migration, yet only showed the percentage of experiments which found migration. In further research, if needed, the underlying studies can be investigated in more detail to obtain migration concentrations. In addition, no data on the availability of these chemicals in alternative FCM on the Dutch market was available to support the selection of prioritised chemicals.

EFSA has published two studies on how to identify emerging chemical risks in the food chain (Bitsch et al., 2016; Oltmanns et al., 2019). Both studies follow a similar approach. Information available in the REACH registration dossiers (e.g., information on environmental release, biodegradation in the environment, repeated dose toxicity, reproductive and developmental toxicity, genotoxicity) was used. In addition, quantitative structure-activity relationships (QSARs) were used to obtain information on bioaccumulation in food, while the CLP Regulation was consulted for information on toxicological effects. Chemicals were then prioritised based on either a calculated total score from the individual blocks (e.g., environmental release, toxicity etc.) or on the exceedance of cut-off criteria for each block (Bitsch et al., 2016; Oltmanns et al., 2019). Based on the aim of the study, environmental release, biodegradation, and accumulation in the food chain were noted to be of less interest. With regard to toxicity, in one method chemicals are assigned a toxicity score (i.e., 10 when classified as CMR, STOT RE (all categories) and/or IARC classification, and 1 for no classification). A high toxicity score is considered a requirement in these last methods since 'only substances classified for any of the four endpoints evaluated are likely to induce adverse health effects if present in the food chain' (Oltmanns et al., 2019). Another method is to weigh the severity of the toxicity (e.g., based on toxic dose level, amount of evidence or findings) (Bitsch et al., 2016; Oltmanns et al., 2019). Both methods correspond with the approach this study used to prioritise chemicals.

KEMI collected information on chemicals in consumer articles of paper and paperboard in Sweden. Prioritisation was based on geographical relevance (information on use in Sweden, Europe or global) and paper relevance (certainty about the use of the substance in paper). It should be noted that this included not only paper used as FCM. So, prioritisation was not based on hazardous potential (KEMI, 2019). KEMI also prioritised chemicals without CAS number since these could be potential contaminants. The potential function and properties of the substances without CAS number were evaluated using expert evaluation. KEMI states that the use of substances in paper manufacturing in Sweden and the EU was not expected to differ substantially. Fifty-four percent of the substances of high relevance were associated with inks, pigments, colorants and dyes. Of the six highly prioritised chemicals in our study, the KEMI study detected only one chemical (formaldehyde) paper manufactured in Sweden (and therefore given high priority in the KEMI study) and the five others were found in either Denmark or the Netherlands (and therefore given medium priority in the KEMI study).

To prioritise products, instead of chemicals of potential concern, Selin et al. (2021), Zimmermann et al. (2020) and Osorio et al. (2020) extracted chemicals from FCM using solvents. The complete extracts were then tested for bioactive properties (e.g., oxidative stress, genotoxicity, xenobiotic metabolism, anti-androgenic and anti-estrogenic receptor activity). Using this effect-based approach, products can be identified in which potentially hazardous chemicals are present. In the next step, the chemicals present in the selected products of concern can be identified and quantified. Zimmerman et al. (2020) showed that chemicals extracted from cellulose and starch samples affected most endpoints, especially unspecific toxicity (bioluminescence inhibition in the Microtox assay), while bamboo and Bio-PE samples showed the lowest toxicity. Selin et al. (2021) lists cake/pastry boxes/mats, boxes for infant formula/skimmed milk, pizza boxes, pizza slice trays and bags of cookies as packages of potential concern made of paper and cardboard. Following identification of the chemicals in bamboo-based biopolymer samples, Osorio et al. (2020) added Cramer classes to provide information on toxicological hazards. Since the Cramer class is based on the chemical structure of substances, it could provide insight into the hazards of chemicals for which not experimental data is available. In further research, this could be added to the chemicals in this report lacking hazard data.

7.3 Hazard identification

7.3.1 Chemicals (thought to be) present in FCM

In most of the available research, FCM were screened for the presence of specific chemicals. As a result, other chemicals present are not investigated and the overall results may be biased. Also, since paper and board are used for FCM over the longest period, most research was performed on this material. This could lead to seemingly higher numbers of chemicals in this group compared to others and therefore selection as one of the most hazardous materials. More research into novel FCM materials, especially based on non-targeted chemical screens, could reduce this bias.

7.3.2 Hazards other than chemical hazards

This study focused on the potential health concerns of chemicals present in alternative FCM. As a result, other hazards were not taken into account. However, other hazards (such as physical or microbial) related to the properties of the alternative materials could be present, which could pose health risks in (specific) uses. For instance, the NVWA advised parents and caretakers to pay attention when young children or people with disabilities are using paper straws after 415 notifications were made regarding parts of paper straws ending up in the throat after use (NVWA, 2022). When, for instance, users fall with metal straws in their mouth, or glass straws were to break, this could cause injuries.

In addition, microbiological hazards were not considered in this study. For multiple use, alternative materials that are difficult to clean may pose additional risks to human health.

7.3.3 Other factors shaping potential risks

It should be considered that not only the chemical constituents in the materials influence the risk of harmful effects for consumers but also the way products are used (exposure). Many factors influence the level of exposure, for instance, FCM that are in direct contact with the mouth (e.g., straws and cutlery) may pose a greater health risk than plates. On the other hand, a greater surface area in contact with the food products could also pose greater health risks (e.g., cups with beverages vs. plates). But also the product's typical use, such as the type of food (e.g., hot vs cold food or beverages, fat vs non-fat food, contact time with the food) or typical user (products intended for children with other physiological properties and other behaviour) influence exposure characteristics and therefore affect health risks.

7.4 Observations from stakeholder interviews

Professionals from the packaging sector (an internationally operating wholesale organisation, a packaging materials firm, a centre of expertise) as well as from public research organisations and the Dutch government and inspectorate overseeing the implementation of the SUP Directive were participating in online interviews (7), in which they shared their knowledge and views on materials used as SUP alternatives, substances of concern in such materials, and other thoughts regarding the implementation of the SUP Directive and its effects. The qualitative input from these stakeholder interviews is neither systematic or representative (other professionals that were reached out to were not able or willing to comment) but served to triangulate findings from the market and literature search. The statements made by participants support the conclusions drawn in the next chapter.

Participants mentioned paper and cardboard as the most used alternatives to SUP. Bamboo and wood were mentioned to be used to a lesser extent. Some participants pointed out that coatings are needed to make materials such as paper and cardboard water or fat resistant and suitable as FCM. These coatings are usually made of silicone or natural (e.g., wax or PLA) or synthetic polymers. Sealing is typically achieved through chemicals, like acetate or acrylate, for which companies indicate no suitable alternatives are available as of date. Concerns were raised about paper and board FCM consisting on average for 30% of PE and being often incorrectly labelled as plastic-free. Moreover, paper and cardboard are perceived as being most used as alternative to SUP, since these are the cheapest materials.

With respect to constituents in these materials participants emphasised that many chemicals are added to make SUP alternative materials suitable as FCM. This is especially the case for paper and cardboard.

Normal paper or cardboard already exists for about 15% of added chemicals in order to, for example, bind, whiten or make the product more flexible. Some of these chemicals may be of concern to human health. The substance groups explicitly named by the interviewed parties are listed in Table 21. The table is indicative (i.e., not exhaustive) for substances that the interviewees have concerns about. In general, there is a concern for accumulation of these chemicals, such as mineral oils, due to the recycling process of paper and cardboard into new paper and cardboard products, including FCM. Furthermore, concerns were raised that the chemical composition of the FCM is not always known to the manufacturer. Particularly when materials are imported from outside of the EU, it is known that sometimes the quality of shipments does not comply with regulations or according to certificates of earlier shipments.

| Substance group | Concern | Mentioned to be an issue within |
|--|--|---|
| Biocides | Added to prevent growth of microbes; can potentially migrate into food | Bamboo and wood |
| Free radicals | Present as by-products of polymerisation processes | Coatings |
| Mineral oils | Contamination from printing ink in paper pulp, can accumulate in FCM due to recycling | Paper and cardboard |
| NIAS (non-intentionally added substances) | Contamination from production processes, recycling, or raw materials | Bamboo, wood, paper, and cardboard |
| PFAS (per- and polyfluoroalkyl substances) | Presence is not always known to manufacturer, can be present especially if materials are imported from outside the EU | Paper and cardboard |
| Printing ink chemicals (e. g. isopropyl thioxanthone (ITX)) | Wide range of chemicals of which migration data is unknown | Printing ink |
| Thermosetting polymers (e.g., formaldehyde) | If the two-component production method is suboptimal, single substances can migrate to food | Coatings, bamboo, and wood |
| Xenoestrogens (e.g., bisphenol A) | Small concentrations of a large number of chemicals with possible additive endocrine disruptive effects | Coatings |

Table 21 Substances in alternatives to SUP named as a concern to human health in interviews

7.5 General conclusions from other research

Commissioned by the NVWA, the University of Twente performed a study on the type and composition of bio-based FCM on the Dutch market in 2020 (UTwente, 2020). The study looked into various materials including sugarcane, palm leaves, bamboo, paper and board. Mostly FCM made of PLA and starch were found on the Dutch market. Additionally, the study gathered the following findings regarding the materials of interest in the current study: 1) it is unclear for consumers if and which coatings are used on sugarcane and paper and cardboard FCM, 2) melamine and formaldehyde are often used and found in bamboo FCM, 3) paper and board is coated and glued to obtain characteristics necessary for FCM, 4) inks are often used on paper and board FCM, 5) PFAS are found in paper and board FCM, and 6) literature is scarce on FCM made of bamboo and palm leaves, 7) it is often unknown which materials are used to manufacture FCM, and 8) pesticides may be present in raw materials.

As stated by BEUC (2021), the EU has established strict plant protection product registration processes and maximum residue levels in food. However, EU legislation does not explicitly regulate the presence of plant protection products in FCM. The same report stated that novel legislation for materials other than plastics is crucial to prevent consumer exposure to harmful chemicals migrating from alternative FCM.

In 2021, the NVWA performed a study in which the risk governance in the lifecycle of three innovative bio-based plastic FCM was evaluated (van der A & Sijm, 2021). While this study did not focus on the safety of bio-based food packaging materials, and the current study does not include plastics, similar findings were reported including: various unauthorised substances were found in the tested samples and the found substances were classified into a hazardous category based on their properties. Chemicals that were detected were monomers, plasticisers, additives, fragrance and flavour substances, plant sterols, fatty acids and fatty acids amides, and metals. They also concluded that `current innovation and production practices do not systematically account for potential unexpected risks' (van der A & Sijm, 2021).

Research of Zimmermann et al. (2020) concluded using *in vitro* tests that raw materials of which FCM could be made are less toxic compared to the final products. In addition, they concluded that when comparing conventional plastics to bio-plastics and plant-based alternatives, all products were similarly toxic.

7.6 Future of SUP alternatives

The stakeholder interviews also covered participants' views on effects and efficacy of implementing the SUP Directive with respect to sustainability and circularity. Most participants see a future in circular economy, with a focus on re-useable materials instead of single use products and packaging, possibly strengthened by upcoming Regulations (e.g., packaging Directive). This would require structural changes in infrastructures, such as with distribution, supermarkets and waste management, since the majority of packaging is presently single-use. Producers indicate these materials will most likely be plastics, such as PP, PET or PE. Risks accompanied by re-use of products can include the addition of washing chemicals to clean materials, microbial growth on the materials and altered migration of chemicals or microplastics after erosion from the materials to food due to the re-use of materials.

Furthermore, some participants see a future with coatings from natural polymers that are compostable since the frequently used PLA is biobased but not biodegradable. While new insights are needed to develop natural dispersion coatings that are compostable, this is challenging due to the inclusion of such natural polymers in the SUP Regulation. The only exceptions are natural polymers that are not chemically modified. Natural polymers would introduce different risks, as FCM are not commonly tested for the plant protection products, microbes and aflatoxins that could be introduced using these polymers.

Most participants indicated that the SUP Regulation was implemented too quickly, resulting in solutions that are not desirable from the point of other sustainability goals, such as waste and litter reduction, CO₂ reduction, food waste reduction, and increase in re-use and recycling. This resulted, for instance, in problems for recycling of paper and cardboard, as only a few waste management sites can recycle coatings and extrusions. As a result, chemicals in coatings and extrusions can accumulate in the recycling process. Investment in infrastructure for optimal recycling is therefore needed.

Companies indicate that paper and cardboard are most used as alternative to SUP, as these are the cheapest materials. However, the amount of chemicals that need to be added to this material in order to make it suitable for many applications as FCM makes them less optimal as an alternative for SUP, from a perspective of both environmental and human health.

8 Conclusion and recommendations

8.1 Conclusions

In June 2019, the European Union adopted Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment, the so-called SUP Directive. The ban on SUP FCM may result in a growing market for alternative materials used in contact with food. These alternative materials may introduce human health risks when used as Food Contact Material (FCM). The aim of this study was to investigate what alternatives are available on the Dutch market and if there are indications for chemical related human health risks related to the use of these alternatives by answering the following research questions:

8.1.1 Which alternative materials to SUP FCM are available on the Dutch market?

The market survey into the types of materials used for cutlery, plates and bowls, straws, beverage stirrers, food containers and cups for beverage showed that various types of bio-based materials were abundantly available on the Dutch market. Paper, cardboard and wood were found most often. More 'exotic' bio-based materials like bamboo, palm leaves, sugarcane and wheat were found less frequently. Whether materials were coated and/or with which material was only specified for some products. FCM made of plastic were also abundantly available. In most cases, plastic was found in products in which its use has not yet been banned at the time of this market survey. Nevertheless, plastics were also found in categories in which its use was already banned.

8.1.2 Which substances may be present in these materials and which of these substances are of human toxicological concern?

For each of the selected alternative materials (paper and cardboard, wood, bamboo, sugarcane, palm leaves and wheat) an overview based on literature of chemicals (thought to be) present in the raw material and in the processed materials is provided. Some examples of chemical(s) (groups) (thought to be) present in raw material are: minerals, terpenes, phenols, flavonoids, quinones, phytosterols and cyanide. Examples of chemical(s) (groups) (thought to be) present in processed materials are: PFAS, alkanes, pesticides, organochlorides, chlorophenols, metals, mycotoxins, formaldehyde, melamine, bisphenol A, cyanide and boric acid.

Since solely the (possible) presence of naturally occurring (bioactive) chemicals or (non-)intentionally added substances does not constitute risks to human health, and without the availability of quantitative information on the concentration and migration of the chemicals in/from the materials used for FCM, chemicals that could potentially induce risks to human health were prioritised according the information that could be retrieved with respect to hazard properties and migration data. Six chemicals were given high priority (i.e., formaldehyde, bisphenol A, di-isobutyl phthalate, dibutyl phthalate, diethylhexyl phthalate and lead).

Forty-eight chemicals were given medium priority. An overview of the prioritised chemicals can be found in Table 19 and 20.

8.1.3 Which alternative materials should be prioritised for follow-up (laboratory) research?

All six chemicals given high priority were found to be (possibly) present in FCM made of paper and board or wood (fibres). One high priority chemical (formaldehyde) was found to be (possibly) present in four alternative materials. Bisphenol A can be present in FCM made of paper and board, and wood. Forty-eight chemicals were given medium priority, of which over 20 were found to (possibly) be present in paper and board and wood (fibres) FCM. Only one or two chemical (possibly) present in bamboo, sugarcane and palm leaves FCM were given medium priority, whilst one chemical was given high priority for FCM made of sugarcane and bamboo. The list of chemicals that may be present in FCM made of alternative materials can be found in Tables 19 and 20.

Most prioritised chemicals are (possibly) found in FCM of paper and board and wood. Since only a few chemicals are prioritised (in this report) in FCM products made of bamboo, sugarcane and palm leaves, and no chemicals are prioritised in wheat FCM, this could mean that there is a lack of data on this type of materials. It could be recommended to further investigate which substances would migrate from this type of materials.

Combining the information on the type of alternative material used for the manufacturing of specific types of FCM in the Netherlands and the above selected materials of interest, this report indicates that efforts could go towards the detection of chemicals in cutlery and plates/bowls made of wood and paper and board, straws made of paper, food containers made of paper and cups for beverage made of paper and board. Of this type of products, plates/bowls and food containers were most sampled on the Dutch market, followed by cutlery and drinking cups. The six chemicals prioritised with high priority could be specifically screened for.

8.2 Recommendations

- Further research into substances that are present in alternative materials for which research is limited is recommended since the lack of research does not imply that no hazardous chemicals may be present.
- In-depth investigations into the migration properties of hazardous chemicals could benefit second tier prioritisation.
- The six highly prioritised chemicals (and possibly medium prioritised chemicals) could be specifically screened for in SUP available on the Dutch market since hardly any information on Dutch products is available.
- Efforts could go towards the detection of chemicals in cutlery and plates/bowls made of wood and paper and board, straws made of paper, food containers made of paper and cups for beverage made of paper and board since most prioritised chemicals are (possibly) found in FCM of paper and board and wood.

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