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Inventory of reusable food contact materials on the Dutch market as alternatives to single-use plastics and an evaluation of possible safety issues

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Synopsis

Inventory of reusable food contact materials on the Dutch market as alternatives to single-use plastics and an evaluation of possible safety issues

The European Union aims to reduce the presence of plastic waste in the environment. Therefore, since 2021, various types of plastic products that are only used once - so-called single-use plastics (SUP) - have been banned. Instead of these products, there are now many reusable products on the market. These include straws, coffee cups, drinking bottles and festival cups made of reusable plastics, stainless steel or silicone.

The RIVM has inventoried which materials are used in reusable products available on the Dutch market as alternatives to SUP. Following this, substances which can be released from these materials were listed and the associated potential toxicological issues were investigated. In addition, potential microbiological safety issues of reusing for example a coffee cup were investigated. Furthermore, it was examined whether reusable products can cause physical damage to the body.

This reports shows that plastics, stainless steel and silicone are the most commonly used materials in reusable products. The literature search revealed that various substances can be released from these materials. The RIVM recommends more targeted research into the possible release of 20 substances into food. These 20 substances have been prioritised based on their toxicological potential and their potential to be released into food. The RIVM has indicated which materials and substances should be examined first in future research.

If you regularly clean a reusable product, the chance of becoming ill from bacteria, for example, is small. If people share a drinking bottle with others, this chance may increase. Good hygiene is then important. In addition, walking or running with a reusable product like metal straws can cause injury, especially in young children.

The RIVM conducted this research on behalf of the Dutch Food and Consumer Product Safety Authority (NVWA).

Keywords: single-use plastics (SUP), food contact materials (FCM), reuse

Publiekssamenvatting

Herbruikbare voedselcontactmaterialen als alternatief voor wegwerpplastic in Nederland. Een inventarisatie van mogelijke veiligheidsproblemen.

De Europese Unie wil de schadelijke effecten van plastic zwerfafval voor het milieu stap voor stap tegengaan. Zo zijn sinds 2021 verschillende soorten plastic producten verboden die één keer worden gebruikt en daarna weggegooid - de zogeheten Single Use Plastics (SUP). In plaats van deze producten zijn er nu veel herbruikbare producten op de Nederlandse markt, zoals rietjes, drinkflessen en koffiebekers van siliconen, roestvrijstaal (RVS) of herbruikbaar plastic.

Het RIVM heeft geïnventariseerd welke herbruikbare voedselcontactmaterialen in Nederland op de markt zijn en van welke materialen ze zijn gemaakt. Daarna is op een rij gezet welke stoffen uit deze materialen zouden kunnen vrijkomen. Ook is gekeken hoe hygiënisch het is om bijvoorbeeld een koffiebeker verschillende keren te gebruiken. Verder is gekeken of het type materiaal het lichaam kan beschadigen.

Uit het onderzoek blijkt dat plastic, RVS en siliconen de meest gebruikte materialen zijn. Literatuuronderzoek lat zien dat uit deze materialen onder bepaalde omstandigheden verschillende stoffen kunnen vrijkomen. Het RIVM adviseert om gerichter onderzoek te doen naar mogelijke schadelijke effecten van 20 stoffen, zoals melamine en dibutylftalaat. Deze stoffen zijn geselecteerd op basis van hun schadelijke eigenschappen en de kans dat ze ook echt uit het materiaal vrijkomen. Het RIVM heeft daarbij aangegeven welke materialen en stoffen het eerst moeten worden onderzocht.

Als je een herbruikbaar product regelmatig schoonmaakt, is de kans klein om bijvoorbeeld ziek te worden van bacteriën. Als mensen een drinkfles delen met anderen, is dat wel mogelijk. Goede hygiëne is dan belangrijk. Lopen of rennen met een herbruikbaar product als metalen rietjes kan, vooral bij jonge kinderen, letsel veroorzaken.

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), hergebruik

Contents

Summary

This report performed a survey on reusable food contact materials (FCMs) substituting single-use plastics (SUP) available on the Dutch market. Chemicals that can migrate from these materials were listed and the associated potential toxicological issues were investigated. Furthermore, potential microbiological and physical safety issues associated with the use of reusable products made from these materials were investigated.

Since 2021, several SUPs have been banned following the implementation of the 'Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment', commonly referred to as the SUP Directive. Through a series of measures implemented over time, the SUP Directive aims to eliminate plastic products designed for single use.

In a previous report, the type of alternative single-use FCMs on the Dutch market following the implementation of the SUP Directive were investigated. As a follow-up, this report aims to identify reusable FCMs on the Dutch market that are used as alternatives to SUP.

This research focuses on four selected product categories, namely:
- Straws
- Tea/coffee cups
- Drinking bottles
- Party/festival cups

For these products three research questions were addressed:
1. What reusable FCMs are available on the Dutch market as alternatives to SUP?
2. What potential toxicological, microbiological and physical safety issues could be associated with the use of these reusable FCMs?
3. Which reusable FCMs would be relevant candidates for further investigation or future actions?

Approach

To answer the first research question, a market search was conducted during Q1 and Q2 of 2023. An inventory of reusable products was created by visiting shops, supermarkets and web shops. The specifications of the products were recorded, especially the materials with which products were made. Reusable products made from the most commonly used materials were selected for further investigation of potential toxicological, microbiological and physical safety issues.

A scientific literature search was conducted using Embase to address the second research question. In particular, the literature search conducted for the toxicological part was aimed at gathering hazard and migration information on the chemicals in the selected reusable FCMs, in order to find and prioritise relevant candidates for further investigation.

Information on the migration of chemicals from FCMs was gathered from the Database on Migrating and Extractable Food Contact Chemicals (FCCmigex), and to a lesser extent from other scientific publications. Chemicals detected in migrates of food/food simulants with >2 database entries in the FCCmigex database were considered for further evaluation. These chemicals were then prioritised based on the available migration and hazard information.

The scientific references from the database entries were checked for specific migration information and the highest relevant measured migration concentration was selected per chemical, based on expert judgement and without further quality check of the data. Chemicals were considered prioritised when the migration concentrations were above regulatory or derived migration limit values (e.g. specific migration limits (SML)).

Hazard information for the chemicals with >2 database entries was obtained using the harmonised classification according to the CLP Regulation ((EC) No 1272/2008) and information on endocrine disruption (ED) properties as stated in the ECHA database. Prioritised chemicals were determined to be those with hazard classifications and properties of concern relevant for FCMs, thus, carcinogenicity, mutagenicity, reproductive toxicity (CMR), specific target organ toxicity after repeated exposure (STOT RE), and ED properties.

Overall, prioritised chemicals were those with >2 database entries, migration levels above SMLs and relevant harmonised hazard classifications or properties of concern for FCMs.

Results

The three most commonly used materials over all product categories were plastics, stainless steel, and silicone. Plastics were divided into several polymers for further investigation. Recycled plastic and bioplastic were not included in this report. To note, in some cases the materials used in reusable products could not be identified due to lack of labelling information.

Toxicological safety issues

Potential toxicological safety issues may arise when the selected reusable FCMs contain chemicals with hazards and properties of concern relevant for human health, and when these chemicals can migrate into food in amounts surpassing the set SMLs. The literature search and the prioritisation carried out revealed that the reusable FCMs investigated may potentially present such issues, as in total 20 different chemicals have been identified in plastics, stainless steel and silicone FCMs that fulfil these criteria. For plastics, these concern two chemicals each for polypropylene (silver and dibutyl phthalate), melamine (melamine and formaldehyde) and polycarbonate (bisphenol A and dibutyl phthalate), one chemical for polyethylene (silver), whereas for polyamide 10 non-intentionally added substances (NIAS) were prioritised. Furthermore, four chemicals were prioritised for stainless steel (nickel, cadmium, lead and cobalt), noting though that the migration data for stainless steel FCMs arose from studies outside the EU (China). Two chemicals were

prioritised for silicone (cyclic siloxanes and aniline). No chemicals were prioritised for the following plastics: tritan, polyethylene terephthalate, polystyrene and polyvinylchloride.

Overall, it can be concluded that the reusable FCMs investigated potentially pose toxicological safety issues, as there are in total 20 different harmful chemicals that can migrate from them into food in amounts exceeding the set SMLs. Polyamide was the FCM with the highest number of harmful migrating chemicals exceeding SMLs. Three of the 20 prioritised chemicals (silver, dibutyl phthalate and aniline) were prioritised for more than one material.

Microbiological safety issues
Reusing products made of plastics, silicone or stainless steel introduces a potential bacterial contamination risk. However, it was concluded that although reusable FCMs are a hygiene issue, they form a low microbiological safety issue for human health.

Physical safety issues
A few incidents have occurred where young children sustained injuries from falling while using stainless steel straws. This may indicate that the increased use of reusable straws may lead to an increase in fall-related injuries.

Recommendations

Toxicological
Screening tests could be recommended to determine whether the prioritised chemicals actually migrate from the respective FCMs available on the Dutch market (especially polyamide) and to what degree this migration occurs (in relation to the SMLs). With additional migration data for these materials, more insight is gained into the level of exposure of harmful chemicals migrating from them, and whether or not these levels could potentially present a health risk. Furthermore, enforcement actions could then be directed at those chemicals with migration above their regulatory SMLs.

Further research on migrating chemicals from reusable tritan and polyethylene terephthalate could be recommended since there is a lack of (relevant) research on these materials which does not necessarily imply that no hazardous chemicals migrate.

For some hazardous chemicals, no SML or other migration limit value could be identified. This was especially the case for NIAS for which an SML should be considered on a case-by-case basis. More research into deriving appropriate SMLs for chemicals which have no migration limit value could be a valuable step in better understanding and controlling their potential risk.

Microbiological
No recommendations are provided since the potential for microbiological safety issues is deemed low.

Physical
A warning symbol could be recommended on the packaging of hard plastic, metal or glass straws, as walking or running while using these straws may cause injury upon falling.

Samenvatting

Dit rapport beschrijft een onderzoek naar herbruikbare voedselcontactmaterialen (FCMs) die op de Nederlandse markt beschikbaar zijn ter vervanging van de zogenaamde single-use plastics (SUP, kunststofproducten voor eenmalig gebruik). De chemische stoffen die uit deze materialen kunnen vrijkomen en hun bijbehorende mogelijke toxicologische veiligheidsproblemen zijn geanalyseerd. Verder zijn mogelijke microbiologische en fysieke veiligheidsproblemen die kunnen ontstaan bij het gebruik van herbruikbare producten onderzocht.

Sinds 2021 zijn sommige SUP FCMs verboden na het ingaan van de 'Richtlijn (EU) 2019/904 inzake de vermindering van de impact van bepaalde kunststofproducten op het milieu', algemeen bekend als de SUP-richtlijn. De SUP-richtlijn streeft ernaar kunststofproducten voor eenmalig gebruik te verbieden door een reeks van ingevoerde maatregelen.

In een eerder rapport werden alternatieve FCMs op de Nederlandse markt bedoeld voor eenmalig gebruik onderzocht. Als vervolg hierop, heeft dit rapport het doel herbruikbare FCMs die als alternatieven voor SUP worden gebruikt op de Nederlandse mark te identificeren.

Dit onderzoek richt zich op vier productcategorieën, namelijk:
- Rietjes
- Thee/koffiekopjes
- Drinkflessen
- Feest/festivalbekers

Voor deze producten werden drie onderzoeksvragen gesteld:
1. Welke herbruikbare FCMs zijn beschikbaar op de Nederlandse markt als alternatieven voor SUP?
2. Welke mogelijke toxicologische, microbiologische en fysische veiligheidsproblemen kunnen verbonden zijn aan het gebruik van deze herbruikbare FCMs?
3. Welke herbruikbare FCM’s zouden relevant kunnen zijn voor verder onderzoek of verdere acties?

Methode

In Q1 en Q2 van 2023 werd een marktonderzoek uitgevoerd om de eerste onderzoeksvraag te beantwoorden. Herbruikbare FCM-producten werden geïdentificeerd in winkels, supermarkten en webshops, om inzicht te krijgen in de herbruikbare producten die beschikbaar zijn op de Nederlandse markt. Van deze producten werden de specificaties vastgelegd, vooral de materialen waarvan deze producten zijn gemaakt. Na het marktonderzoek werden materialen van de herbruikbare FCMs geselecteerd voor verder onderzoek naar hun toxicologische, microbiologische en fysische veiligheid.

Om de tweede onderzoeksvraag te beantwoorden werd een wetenschappelijk literatuuronderzoek uitgevoerd met behulp van

Embase. Informatie over de migratie van chemische stoffen uit FCMs werd verzameld uit de Database over Migrerende en Extracteerbare Chemische Stoffen voor Voedselcontact (FCCmigex), en in mindere mate uit andere wetenschappelijke publicaties. Chemische stoffen die werden gedetecteerd in migraten van voedsel en voedselsimulanten met twee of meer vermeldingen in de database werden opgenomen in het rapport. Deze chemische stoffen werden geprioriteerd op basis van zowel migratie data als gevaarseigenschappen.

Wetenschappelijke referenties achter de vermeldingen in de database werden doorzocht op specifieke migratiegegevens en het hoogste relevante gemeten migratieniveau werd geselecteerd per chemische stof, zonder verdere kwaliteitscheck van de data. Chemische stoffen werden als prioriteit beschouwd wanneer de migratieniveaus boven wettelijke of geadviseerde specifieke migratielimieten (SML) lagen.

Informatie over de gevaren van de geselecteerde chemische stoffen werd verkregen met behulp van de geharmoniseerde classificatie volgens de CLP Verordening ((EG) nr. 1272/2008) en informatie over hormoonverstorende (ED) eigenschappen zoals vermeld in de ECHA-database. Chemische stoffen kregen een prioriteit wanneer ze gevarenclassificaties en eigenschappen van zorg hebben die relevant zijn voor FCMs, zoals carcinogeniteit, mutageniteit, reproductietoxiciteit (CMR), specifieke toxiciteit voor een doelorgaan na herhaalde blootstelling (STOT RE) en ED-eigenschappen.

Chemische stoffen met zowel migratieniveaus boven de SMLs en gevaareigenschappen relevant voor FCMs werden geprioriteerd.

Resultaten

Kunststoffen, roestvrij staal en silicone waren de drie meest gebruikte materialen over alle productcategorieën heen. Kunststoffen werden verdeeld in verschillende polymeren voor verder onderzoek. Gerecycleerde kunststof en bio-kunststof werden niet opgenomen in dit rapport. In sommige gevallen ontbrak de etiketteringsinformatie, waardoor het niet mogelijk was om de gebruikte materialen in deze herbruikbare producten te identificeren.

Toxicologisch veiligheidsproblemen
Mogelijke toxicologische veiligheidsproblemen kunnen ontstaan wanneer een product chemische stoffen bevat met gevaarseigenschappen die relevant zijn voor de menselijke gezondheid, en wanneer deze chemische stoffen de vastgestelde SMLs overschrijden. Uit de uitgevoerde prioritering bleek dat voor de geselecteerde herbruikbare FCMs mogelijk dergelijke problemen kunnen ontstaan aangezien in totaal 20 verschillende chemische stoffen zijn geïdentificeerd die aan deze criteria voldoen.

Voor kunststoffen werden twee chemische stoffen geprioriteerd voor polypropyleen (zilver en dibutylftalaat), melamine (melamine en formaldehyde) en polycarbonaat (bisfenol A en dibutylftalaat), één chemische stof voor polyethyleen (zilver) en 10 niet-intentioneel toegevoegde chemische stoffen (NIAS) voor polyamide. Verder werden

vier chemische stoffen (cadmium, lood, kobalt en nikkel) geprioriteerd voor roestvrijstaal. De migratiegegevens voor roestvrijstalen FCMs waren wel afkomstig uit studies uitgevoerd buiten de EU (China). Daarnaast werden twee chemische stoffen (cyclische siloxanen en aniline) geprioriteerd voor siliconen. Er werden geen chemische stoffen geprioriteerd voor tritan, polyethyleentereftalaat, polystyreen en polyvinylchloride

Over het algemeen kan worden geconcludeerd dat voor de onderzochte herbruikbare FCMs mogelijke toxicologische veiligheidsproblemen kunnen ontstaan, aangezien 20 verschillende mogelijk gevaarlijke chemische stoffen geprioriteerd zijn die naar voedsel kunnen migreren in niveaus boven SMLs. De meeste geprioriteerde stoffen werden gevonden in polyamide. Drie van de 20 geprioriteerde chemische stoffen (zilver, dibutylftalaat en aniline) werden geprioriteerd voor meer dan één materiaal.

Microbiologisch veiligheidsproblemen
Het hergebruiken van producten gemaakt van plastic, siliconen of roestvrijstaal vormt een potentieel risico voor bacteriële besmetting. Desalniettemin wordt geconcludeerd dat hoewel herbruikbare FCMs een hygiëneprobleem vormen, ze een laag microbiologisch risico vormen voor de humane gezondheid.

Fysiek veiligheidsproblemen
Er zijn incidenten voorgekomen waarbij jonge kinderen letsel opliepen door te vallen tijdens het gebruik van roestvrijstalen rietjes. Dit geeft aan dat het toenemende gebruik van deze herbruikbare rietjes zou kunnen leiden tot een toename van letsel door vallen.

Aanbevelingen

Toxicologisch
Screeningtests kunnen worden aanbevolen om te bepalen of de geprioriteerde chemische stoffen migreren boven de wettelijke of geadviseerde SMLs uit FCMs beschikbaar op de Nederlandse markt (voornamelijk polyamide). Met aanvullende migratiedata wordt meer inzicht verkregen in het niveau van blootstelling aan schadelijke chemische stoffen die uit deze materialen kunnen vrijkomen, en of deze niveaus mogelijk een gezondheidsrisico kunnen vormen. Bovendien kunnen handhavingsmaatregelen dan worden gericht op die chemische stoffen met een migratie niveau boven hun wettelijke SMLs.

Verder onderzoek naar migrerende chemische stoffen uit herbruikbare FCMs gemaakt van tritan en polyethyleentereftalaat kan worden aanbevolen, aangezien het ontbreken van (relevante) onderzoeken niet noodzakelijkerwijs betekent dat er geen mogelijk gevaarlijke chemische stoffen migreren uit deze FCMs.

Voor enkele mogelijk gevaarlijke chemische stoffen was geen SML of andere grensreferentiewaarde beschikbaar. Dit was vooral het geval voor NIAS. Meer onderzoek naar het afleiden van geschikte SMLs voor chemische stoffen die geen vastgestelde grenswaarde hebben, zou een

waardevolle stap kunnen zijn in het beter begrijpen van de mogelijke risico's.

Microbiologisch
Er worden hier geen aanbevelingen gedaan, omdat de microbiologische risico's laag worden geacht.

Fysiek
Het plaatsen van een waarschuwingssymbool op de verpakking van harde plastic, metalen of glazen rietjes kan worden overwogen, aangezien lopen of rennen tijdens het gebruik van deze rietjes letsel kan veroorzaken bij vallen.

1 Introduction

1.1 Context

In the European Union (EU), around 25.8 million tonnes of plastic waste are generated every year. Of that, less than 30% is collected for recycling while landfilling and incineration rates of plastic waste remain high (European Commission 2018a). Food packaging represents a significant application for the plastics industry, around 60% of all plastic packaging is used for food and beverages (Groh, Backhaus et al. 2019). Apart from the wrapping and storage function of plastics in packaging, they also protect food against spoilage and contamination. Additionally, plastics can help to enhance the availability and convenience of the food we consume. In the food industry, single-use plastics (SUP) are majorly used. However, the use of SUP leads to a large amount of plastic waste. Recently, several steps have been taken in the EU to address plastic waste associated with food contact materials (FCM).

Food contact materials (FCM) are materials that come into contact with food during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles include food packaging and containers, machinery to process food, and kitchenware and tableware.

In 2018, the EU adopted a European strategy for plastics as part of the EU's circular economy action plan to tackle plastic waste (European Commission 2018a). The aim of the EU's plastic strategy is to transform the way plastic products are designed, produced, used and recycled. One of the main objectives of this strategy is to ensure that all plastic packaging can be reusable or easily recyclable in a cost-effective way by 2030.

As part of the EU's strategy for plastics, the EU adopted the 'Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment', more commonly known as the SUP Directive (European Commission 2019a). The SUP Directive states that plastic poses 'a severe risk to marine ecosystems, to biodiversity and to human health.' The objective of the Directive is to minimise the presence of plastic waste in the environment, particularly in aquatic and marine ecosystems, where plastic waste accumulates. This Directive largely promotes the adoption of circular alternatives to SUP that are more eco-friendly, such as repeat-use products and reuse systems. Moreover, it also promotes the use of alternative materials for products that were previously made with plastics.

Additionally, the EU has adopted an 'Implementing Decision (EU) 2022/162' which lays down rules for the application of the SUP Directive as regards the calculation, verification and reporting on the reduction in the consumption of certain SUP products and the measures taken by Member States to achieve such reduction (European Commission 2019a). Like the SUP Directive, this Implementing Decision places emphasis on reusable alternatives to SUP. According to this

Implementing Decision, the actions taken by Member States to reduce SUP in their jurisdiction will be monitored and published by the European Commission.

To tackle packaging waste and to boost reuse, the EU has published the proposed revision of the legislation on Packaging and Packaging Waste (European Commission 2022a). One of the main objectives in the revised legislation is to prevent the generation of packaging waste by restricting unnecessary packaging and promoting reusable and refillable packaging solutions. The target is to reduce packaging waste by 37% in the EU by 2040.

Given the increasing push towards reusable products as opposed to single-use products, it is important to determine the types of reusable products available on the market and to investigate their safety.

1.2 Research scope and questions

Zwartsen et al. (2022) previously published a report investigating alternative single-use FCMs to plastics on the Dutch market following the implementation of the SUP Directive. This research was performed on behalf of the Netherlands Food and Consumer Product Safety Authority (in Dutch: 'Nederlandse Voedsel- en Warenautoriteit' (NVWA)). Several single-use FCMs were identified as substitutes for SUP including paper, cardboard, wood and bamboo. The potential health risks associated with their use was also investigated and six chemicals of concern were reported.

As a follow-up to this previous research and as requested by the NVWA, this report aims to identify reusable products (and the materials with which they are made) on the Dutch market which can be used as alternatives to SUP. Notably, reusable products are those that are designed to be repeatedly used for the same purpose that they were originally created for (e.g., refilling at home or on the go).

This research focuses on the following product categories: straws; tea/coffee cups; drinking bottles; and party/festival cups. Furthermore, an assessment of the potential safety issues associated with the reusable FCMs will be presented. This assessment will focus on a) potential toxicological safety issues due to chemical migration into food; b) potential microbiological safety issues when microbiological contamination remains on materials; and c) potential physical safety issues associated with the use of materials.

The following research questions are addressed in this report with respect to the selected four product categories:

1. What reusable FCMs are available on the Dutch market as alternatives to SUP?
2. What potential toxicological, microbiological and physical safety issues could be associated with the use of these reusable FCMs?
3. Which reusable FCMs would be relevant candidates for further investigation or future actions?

2 Food contact materials and their legislation

FCMs are materials that are intended to come into contact with food during the production, processing, storage, packaging, transportation, or serving stages. These materials are intended to be used in contact with food to preserve the food's quality, maintain its safety and facilitate its handling. FCMs can be made from a variety of materials, including plastics, metals, glass, silicone, paper and cardboard. These materials are sometimes coated to protect either the material or the consumer.

Chemicals can be released from FCMs into food, which is known as migration. The degree of chemical migration into food can depend on several factors such as temperature, storage time, the nature of the packaging material and the characteristics of the food. Common examples of migrating chemicals from food packaging include monomers, additives, plasticisers, antioxidants or stabilisers, colorants, lubricants and processing aids.

Regulatory agencies and scientific authorities worldwide establish guidelines and regulations for FCMs to ensure that they are safe and do not negatively impact food quality or consumer health. Scientific evaluations and risk assessments help inform these regulations. Regulations can be set on European level and national level.

In the EU, FCMs are governed by two general Regulations. Firstly, Regulation (EC) No 1935/2004 sets general requirements for FCMs on the market (European Commission 2004). The principles set out in this regulation require that materials do not release 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. To note, Regulation (EC) No 1935/2004 was amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (European Commission 2019b). Secondly, Regulation (EC) No 2023/2006 sets requirements related to good production methods of the production of FCM and the quality assurance system (European Commission 2006).

Regulation (EC) No 1935/2004 identifies seventeen groups of materials for which specific measures may be adopted or amended by the European Commission: 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. Measures may include positive lists, special conditions for use, purity standards and specific migration limits (SML).

> "Specific migration limit (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants."
>
> - Regulation (EU) No 10/2011

Until now, such specific legislation exists for plastic materials (Regulation (EU) No 10/2011) (European Commission 2011a), active and intelligent materials (Regulation (EC) No 450/2009) (European Commission 2009), recycled plastic materials (Regulation (EU) 2022/1616) (European Commission 2022b), ceramics (Directive 84/500/EEC) (European Council 1984) and regenerated cellulose films (Directive 2007/42/EC) (European Commission 2007).

Besides material specific regulations, three substance-specific regulations exist: bisphenol A (BPA) in infant bottles, coatings and varnishes (Regulation (EU) 2018/213) (European Commission 2018b), on certain epoxy derivatives (Regulation 1895/2005/EC) (European Commission 2005) and on nitrosamines in elastomers and rubbers (Directive 93/11/EEC) (European Commission 1993).

As stated in Regulation (EC) No 1935/2004, EU Member States may adopt or maintain their own national provisions, regulations and directives on FCMs in the absence of specific EU measures. The Netherlands implemented the Commodities Act Decree and Regulation on Packaging and Consumer Articles (in Dutch: 'Warenwetbesluit' en 'Warenwetregeling verpakkingen en gebruiksartikelen') (NL 2021a, NL 2022). The Regulation ensures the implementation of several articles of the Dutch Commodities Act (in Dutch: 'Warenwet') (NL 2021b). This national regulation contains requirements for materials that are not (yet) specifically regulated in the EU, and it provides additional requirements for some materials that already are. Importantly, it contains a positive list of accepted chemicals for use in FCMs with corresponding SMLs (where available). Substances can be added to this positive list by the Ministry of Health, Welfare and Sport (VWS) following a positive assessment by the Dutch Committee for safety assessment of food contact materials (in Dutch: 'Commissie Beoordeling Veiligheid Voedselcontactmaterialen' (CBVV)) (NVWA 2023, VWS 2023, RIVM 2023a, RIVM 2023b). Additionally, the NVWA is responsible for enforcing and monitoring regulatory compliance.

3 Methods

3.1 Overview of methods

As the first step in this research, a market search was performed to create an inventory of reusable FCMs available to Dutch consumers. Based on this information gathered, the most commonly used materials were identified and further evaluated for potential toxicological, microbiological and physical safety issues. Following this, materials and chemicals therein that would be relevant candidates for future research or actions were selected.

3.2 Scoping of product categories

The product categories were selected based on current wide use and expected wide use in the future following the adoption of the SUP Directive in 2019. The product categories to be included in the market search were as follows:

- Straws;
- Tea/coffee cups;
- Drinking bottles; and
- Party/festival cups.

An extensive inventory of reusable products falling under the selected product categories was created. The following information was recorded for each product entry:

- Type of product (e.g., reusable straws, 4-pack, including cleaning brush);
- Brand name;
- Date of entry;
- Material with which the product was made (e.g., stainless steel and silicone);
- Claims (e.g., BPA free);
- General comments (e.g., transparent with gold stripes); and
- Link to website, where applicable.

All reusable products that were available in the shops and/or websites visited were included in the inventory. However, in cases where there were many comparable products sold (e.g., identical stainless steel drinking straws sold as a 4-, 6- or 8-pack), not all were included in the inventory.

3.3 Exploring the market

The market search was conducted during Q1 and Q2 of 2023 and it consisted of shop/supermarket visits and browsing web shops which were accessible to Dutch consumers. Social media was not used in this market search.

3.4 Selection of food contact materials for further investigation

Following the market search, the materials most commonly used in the reusable products were selected for further investigation. Materials were selected by considering the following:

1. Materials that were most often used in specific product categories; and
2. Materials that were most frequently occurring across all product categories.

Once the materials were chosen, an investigation of the potential toxicological, microbiological and physical safety issues associated with these materials was conducted by means of a literature review.

3.5 Toxicological evaluation

3.5.1 Literature review

A literature review was conducted on the selected materials most often found in the reusable products. The aim of this search was to identify existing literature on the safety of the materials. Specifically, information regarding the migration of chemicals from materials into food/food simulants during repeat-use scenarios was of interest. Hazard information of materials and migrating chemicals was also gathered. Both grey and scientifically published literature were included.

3.5.2 Grey literature

The websites of the following (inter)national organisations and institutes were visited aiming to identify relevant information on the topic:

- Danish Agricultural Agency (DAA)
- Danish Veterinary and Food Administration (DVFA)
- European Chemicals Agency (ECHA)
- European Food Safety Authority (EFSA)
- German Federal Institute for Risk Assessment (BfR)
- Food Packaging Forum
- French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
- German Environment Agency (UBA)
- RIVM
- Trade Organisation Silicones Europe (CES)
- Technical University of Denmark (DTU)
- U.S. Environmental Protection Agency (EPA)
- U.S. Food and Drug Administration (FDA)
- World Health Organization (WHO)

Several international organisations and institutes were also contacted (via e-mail or contact form) to determine if they had been or were currently working on similar projects. Contact was made with the following groups:

- ANSES
- BfR
- Danish Environmental Protection Agency (DEPA)
- European Consumer Organisation (BEUC)
- Swedish Chemicals Agency (KEMI)

3.5.3 Scientific literature

The search was conducted using Embase on the 27th of July 2023. The specific search terms used to retrieve relevant literature are displayed in Table 1. Hits from the last 20 years were retrieved. Only articles with an

abstract and written in English were included. Furthermore, a manual search was conducted on google and google scholar.

Following the scientific literature search, the final 136 hits were uploaded onto Rayyan for title and abstract screening. Rayyan is a free online tool designed to help researchers working on systematic reviews (Rayyan 2023). After this screening process, the remaining articles were subject to full text screening.

Table 1 Search terms used to retrieve relevant toxicological literature for the selected materials in Embase.

Search No.	Terms	Hits
#1	('food contact material' OR 'food packaging'):ti,ab	3,744
#2	'plastic'/exp OR 'polypropylene'/exp OR 'tritan' OR 'polyethylene terephthalate'/exp OR 'melamine'/exp OR 'polycarbonate'/exp OR 'polyester'/exp OR 'polystyrene'/exp OR 'recycled plastic' OR 'bioplastic'/exp OR 'polyamide'/exp OR 'polyethylene'/exp OR 'polyvinylchloride'/exp OR 'stainless steel'/exp OR 'steel'/exp OR 'metal'/exp or 'silicone'/exp OR 'rubber'/exp	2,029,113
#3	'use*' OR 'reuse*' OR 're-use' OR 'reusable' OR 're-usable' OR 'alternative*' OR 'repeat*' OR 'sustain*'	13,064,809
#4	'hazard'/exp OR 'toxicity'/exp OR 'risk'/exp OR 'safety'/exp OR 'migration'/exp	4,467,825
#5	#1 AND #2 AND #3 AND #4	163
#6	#1 AND #2 AND #3 AND #4 AND [english]/lim AND [abstracts]/lim AND [2003-2023]/py	136

3.5.4 Prioritisation of chemicals

A potential toxicological safety issue arises when the selected reusable FCMs contain chemicals with hazards and properties of concern relevant for human health and when these chemicals can migrate into food in amounts surpassing the set SMLs. Therefore, the literature search conducted was aimed at gathering hazard and migration information on the chemicals in the selected reusable FCMs, in order to find and prioritise relevant candidates. An overview of the prioritisation criteria is displayed in Figure 1.

Information on the migration of chemicals from FCMs was mainly gathered from the Database on Migrating and Extractable Food Contact Chemicals (FCCmigex) (Food Packaging Forum 2023), and to a lesser extent from other scientific publications.

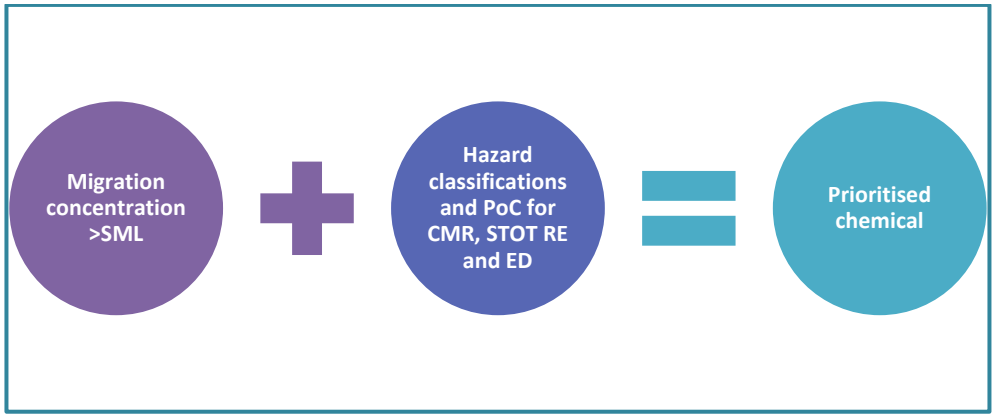

Figure 1 Overview of the prioritisation criteria for chemicals based on migration and hazard information. Abbreviations: CMR, carcinogenicity, mutagenicity and reproductive toxicity; ED, endocrine disruption; PoC, properties of concern; SML, specific migration limit; STOT RE, specific target organ toxicity - repeated exposure.

The FCCmigex database is updated periodically by the Food Packaging Forum. It was first published in May 2022 and has been updated in April 2023. At the time of our research, a total of 3919 entries in the FCCmigex database related to reusable FCMs. The database contained 893 food contact chemicals related to reusable FCMs and mapped the scientific evidence from 298 studies. The following types of reusable FCMs were included in the database at the time of our research:

- Plastics;
- Paper and board;
- Metals;
- Multi-materials;
- Glass and ceramic; and
- Other FCMs (i.e., silicone, wood, rubber).

For this research, chemicals which were detected in migrates of food/food simulants (including water) were of interest (see Figure 2). This research did not consider chemicals detected in extraction experiments since this data does not depict migration in standard settings. In the database, the number of database entries per chemical depicts the number of times that a chemical has been detected in migrates of an FCM. Information regarding the level of migration and the testing strategy are not provided directly, however, the tool allows you to find the original scientific references for all database entries.

Chemicals with >2 database entries per FCM were pre-selected for further investigation. Following this, the respective scientific references were checked for specific migration data. Based on expert judgement, the highest relevant migration data for reusable FCMs were extracted from the scientific references. Due to time limitations, the data were taken as such from the scientific references, i.e. without a quality check of the references and the migration protocols used therein. It is thus unknown whether the migration protocols used are compliant with relevant regulations.

Overall, prioritised chemicals were determined to be those with migration levels above their respective SMLs.

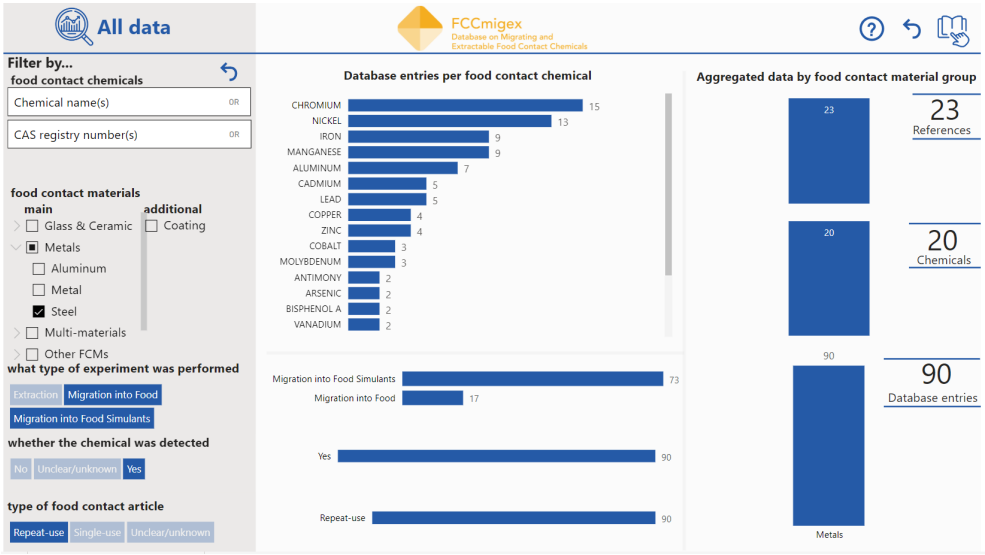

Figure 2 Image of the FCCmigex database user interface. As an example, steel is the selected material, and the red lines indicate our selections for data retrieval in the database.

Specifically, SMLs are regulatory limits set on the amount of a chemical that is allowed to migrate from an FCM or article into food/food simulants. SMLs are established to ensure the safety of FCMs by preventing excessive transfer of potentially harmful substances into food. This process involves a thorough evaluation of scientific data on the substance's toxicity, migration levels, and potential risks to human health. Several SMLs have been set for chemicals in Regulation (EU) No 10/2011 and are legally binding in the EU (European Commission 2011a). For some chemicals, no SML or other migration limit values (MLV) have been established, especially in relation to Non-Intentionally Added Substances (NIAS). In such instances, an SML should be considered on a case-by-case basis (e.g. by using the Threshold of Toxicological Concern approach whereby a default MLV of 0.09 mg/kg food for non-genotoxic chemicals can be applied). In other cases, MLVs can be self-derived using previously established maximum tolerable concentrations (MTC_{tap}) in drinking water or based on other migration limits found in the literature. However, such limits are not legally binding.

Maximum tolerable concentration at the tap (MTC_{tap}) means the maximum permitted concentration of a substance transferred from a specific material into water intended for human consumption.

Since the FCCmigex database may not include all existing publications, migration data was also retrieved from scientific publications found during the literature search that were not included in the FCCmigex database. This was especially relevant for FCMs that were not included in the database at the time of this research (e.g., the plastic polymer tritan).

Hazard information of the most frequently migrating chemicals (>2 database entries) was then gathered. This information was mainly retrieved from the ECHA database. Specifically, information reported under the following sections of the ECHA database were included:

- Hazard classification & labelling
- Properties of concern
- Important to know

Harmonised hazard classifications according to Regulation (EC) No 1272/2008 (European Commission 2008) were taken into consideration. In addition to this, self-hazard classifications were considered but only when reported under the properties of concern section.

Chemicals with hazard classifications and properties of concern relevant for FCMs (i.e., those resulting from repeated oral exposure), thus, carcinogenicity, mutagenicity and reproductive toxicity (namely CMR properties), as well as endocrine disruption (ED) properties were prioritised. Systemic toxicity following repeated exposure was also considered relevant for FCMs and was included (STOT RE = Specific Target Organ Toxicity Repeated Exposure). Dermal exposure related classifications were not included (i.e. skin sensitisation and skin corrosion/irritation). Overall, the following hazard classifications and properties of concern were considered relevant for chemical prioritisation:

Harmonised hazard classification & labelling

- Carcinogenicity 1A, 1B and 2
- Mutagenicity 1A, 1B and 2
- Reproductive toxicity 1A, 1B and 2
- STOT RE 1 and 2

Properties of concern

- Officially recognised in the EU as carcinogenic/mutagenic/toxic to reproduction/ED
- Suspected to be carcinogenic/mutagenic/toxic to reproduction/ED
- Data submitters (registrants) indicate they consider this substance as carcinogenic/mutagenic/toxic to reproduction/ED in their self-classifications

Overall, prioritised chemicals were those that had >2 database entries in the FCCmigex database, migration concentrations above their respective SMLs and relevant harmonised hazard classifications or properties of concern for FCMs.

3.6 Microbiological evaluation

A scientific literature search was conducted to identify the potential microbiological hazards which may arise from using the selected FCMs. This search was performed in Embase on the 10th of October 2023. The specific search terms used to retrieve relevant literature are displayed in Table 2. A total of 47 hits were retrieved and were subject to title and abstract screening, followed by full text screening using Rayyan. Furthermore, a manual search was conducted on google and google scholar. The information obtained from the studies gathered in the

literature search was used to identify potential microbiological hazards associated with the selected FCM.

Table 2 Search terms used to retrieve relevant microbiological literature for the selected materials in Embase.

Search No.	Terms	Hits
#1	'plastic' OR 'polypropylene' OR 'tritan' OR 'polyethylene terephthalate' OR 'melamine' OR 'polycarbonate' OR 'polyester' OR 'polystyrene' OR 'recycled plastic' OR 'bioplastic' OR 'polyamide' OR 'polyethylene' OR 'polyvinylchloride' OR 'stainless steel' OR 'steel' OR 'metal' or 'silicone' OR 'rubber'	2,725,693
#2	'hazard' OR 'pathogen' OR 'microb*' OR 'risk' OR 'safety' OR 'contamination' OR 'adhesion'	9,087,086
#3	'drinking straw' OR 'metal straw' OR 'silicone straw' OR 'steel straw' OR 'coffee cup' OR 'water bottle'	656
#4	#1 AND #2 AND #3	47

3.7 Physical evaluation

A scientific literature search was conducted to identify the potential physical hazards arising from the use of the selected FCMs. The search was performed in Embase on the 10th of October 2023. The specific search terms used to retrieve relevant literature are displayed in Table 3. A total of 40 hits were retrieved and were subject to title and abstract screening, followed by full text screening using Rayyan. Furthermore, a manual search was conducted on google and google scholar. The information obtained from the studies gathered in the literature search was used to identify potential physical hazards associated with the selected FCM.

Table 3 Search terms used to retrieve relevant physical hazard literature for the selected materials in Embase.

Search No.	Terms	Hits
#1	'plastic' OR 'polypropylene' OR 'tritan' OR 'polyethylene terephthalate' OR 'melamine' OR 'polycarbonate' OR 'polyester' OR 'polystyrene' OR 'recycled plastic' OR 'bioplastic' OR 'polyamide' OR 'polyethylene' OR 'polyvinylchloride' OR 'stainless steel' OR 'steel' OR 'metal' or 'silicone' OR 'rubber'	2,725,693
#2	'drinking straw' OR 'metal straw' OR 'silicone straw' OR 'steel straw' OR 'coffee cup' OR 'water bottle'	656
#3	'injury' OR 'hazard' OR 'risk' OR 'accident'	7,168,366
#4	#1 AND #2 AND #3	40

4 Results

4.1 Market survey and inventory

To answer the first research question, an extensive market search was conducted and an inventory of reusable FCMs which were available as alternatives to SUP in the Netherlands was created, with a focus on the four selected product categories. The search was performed in shops/supermarkets and online in web shops.

An overview of the inventory is displayed in Table 4. Some of the identified products consisted of more than one material (e.g., tea/coffee cup with a glass cup and plastic lid). In such cases, all materials which come in contact with food are reported, resulting in a higher count for the materials than for the products. In some cases, the materials used in reusable products could not be identified due to lack of labelling information.

In the straws category, stainless steel was the most common material used, followed by silicone, plastic, bamboo and glass. Additionally, the material of one product found was unknown. In the tea/coffee cups category, plastic was the most common material used, followed by silicone, stainless steel, bamboo, glass, ceramic, cardboard and wood. Also in this category, the material of one product found was unknown. In the drinking bottles category, plastic was the most common material used, followed by stainless steel, glass, silicone, bamboo and sugarcane. In the party/festival cups category, plastic was the most common material used, followed by stainless steel.

Table 4 Inventory of reusable materials in specific product categories.

Product category	**Material**	**Count**
Straws (*n*=39)	Stainless steel	17
	Silicone	8
	Plastics *of which unspecified* *of which polypropylene* *of which polyethylene terephthalate*	7 *4* *2* *1*
	Bamboo	5
	Glass *of which unspecified* *of which borosilicate*	5 *3* *2*
	Unknown	1
Tea/coffee cups (*n*=25)	Plastics *of which unspecified* *of which polypropylene* *of which bioplastic* *of which melamine*	15 *10* *2* *2* *1*
	Silicone	6
	Stainless steel	6
	Bamboo	4
	Glass	3

Product category	Material	Count
	Ceramic	2
	Cardboard	1
	Wood	1
	Unknown	1
Drinking bottles (*n*=34)	Plastics *of which unspecified* *of which polypropylene* *of which tritan* *of which polyethylene terephthalate* *of which recycled plastic* *of which polystyrene* *of which polycarbonate*	24 *9* *5* *3* *3* *2* *1* *1*
	Stainless steel	9
	Glass *of which unspecified* *of which borosilicate*	6 *3* *3*
	Silicone	6
	Bamboo	2
	Sugarcane	1
Party/festival cups (*n*=9)	Plastics *of which unspecified* *of which polypropylene* *of which polycarbonate* *of which melamine*	9 *6* *1* *1* *1*
	Stainless steel	1

Across all product categories, plastics were the most common material used as shown in Table 5. The second and third most used materials were stainless steel and silicone, respectively. Therefore, plastics, stainless steel and silicone were selected for further investigation of their chemical composition and toxicological relevance. Additionally, the potential microbiological and physical safety issues associated with these three materials were also evaluated.

Table 5 Inventory of reusable FCMs across all product categories.

Material	Count
Plastics *of which unspecified* *of which polypropylene* *of which tritan* *of which polyethylene terephthalate* *of which melamine* *of which polycarbonate* *of which recycled plastic* *of which bioplastic* *of which polystyrene*	55 29 10 3 4 2 2 2 2 1
Stainless steel	33
Silicone	20
Glass *of which unspecified*	14 9

Material	Count
of which borosilicate	5
Bamboo	11
Ceramic	2
Unknown	2
Cardboard	1
Sugar cane	1
Wood	1
Total no. materials	**140**

4.2 Toxicological evaluation

4.2.1 Plastics

4.2.1.1 Legislation

The EU's Plastics Regulation (EU) No 10/2011 (European Commission 2011a) applies to plastics materials and articles intended to come into contact with food. This regulation covers plastics as monolayers, multilayers, or multi-materials and adhesive bound or unbound. Printed plastic articles and those covered by coatings also fall within the scope of this regulation.

A positive list, also known as the 'Union List', is included in the Plastics Regulation. It consists of permissible monomers and other starting chemicals, additives and some polymer production aids. Exemptions from listing based on the functional barrier concept can be permitted under certain circumstances (except for vinyl chloride monomers). A functional barrier is defined as a 'barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation'. Non-listed substances are those that have not been listed, however, they are still subject to an assessment.

National laws and the mutual recognition principle apply to the use of colorants and solvents in food contact plastics. Regarding polymer production aids, those listed in the Union List must comply with the restrictions and specifications set therein. However, substances other than those included in the Union List may also be used as polymer production aids in the manufacture of plastics, subject to national laws and the mutual recognition principle. In the Netherlands, polymer production aids are regulated under the Commodities Act Regulation on Packaging and Consumer Articles (NL 2022).

Aids to polymerisation and NIAS that may be present in food contact plastics are not subject to positive list requirements both at the EU or national level. Aids to polymerisation are intentionally added chemicals used to initiate control and cease the polymerisation reaction, such as catalysts, chain transfer, chain extending and chain terminating reagents. However, they are not intended to be in the final polymer and thus, are subject to risk assessment in accordance with internationally recognised scientific principles on risk assessment (European Commission 2000, European Commission 2003, Plastics Europe 2014). NIAS encompass not only impurities that may be present in raw materials used, but also reaction and degradation products that can be formed during manufacture and use of plastics. The Plastics Regulation

requires that any potential risk arising from the presence of NIAS must also be assessed, although no specific guidance is provided to industry on how such risk assessment should be conducted.

The Plastics Regulation covers the migration of chemicals from food contact plastics, and it outlines the methods that are required to measure and interpret migration. Migration testing specific to repeat-use articles is also outlined. It states that 'if the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.' Additionally, specific migration testing specifications can also be set on a national level. National legislation of the Netherlands on FCMs has established a classification for repeat-use rubber materials based on the R-value indicating whether migration testing is required or not. The R-value considers in more detail specificities of repeated use applications (Brandsch and Schuster 2020). Such has not yet been developed for plastics, but the approach has been investigated in a study by Brandsch & Schuster (2020). They concluded that for reusable plastic FCMs the approach implemented for rubber can be extended to plastics as well.

The Plastics Regulation provides an Overall Migration Limit (OML) of 10 mg/dm^2 for all plastic chemicals that come in contact with food. The OML is set at 60 mg/kg for food contact plastics intended to be used in products for infants and young children.

"Overall migration limit' (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants."

- Regulation (EU) No 10/2011

SMLs for certain chemicals are also specified in the Plastics Regulation. Such SMLs are established by EFSA based on the available toxicity data of the substance. In cases where worst-case migration calculations or mathematic modelling cannot demonstrate compliance with the applicable SMLs, migration testing is required. Several chemicals on the Union List have not been assigned an SML. EFSA reported that 'for many substances, the absence of a limit is correct because their migration may not be of a health concern' (EFSA 2020b). The process of establishing an SML involves a comprehensive review of available data on a chemical's safety, and that can be updated as new scientific information becomes available. Where no SML is available, different approaches to ensure the safety of the substance and its use in food packaging can be taken (e.g., the application of the Threshold of Toxicological Concern concept (EFSA 2019)). Additionally, SMLs for chemicals may be set on a national level as stated in Regulation (EC) No 1935/2004. In the Netherlands, SMLs for chemicals are outlined in the Commodities Act Decree and Regulation on Packaging and Consumer Articles (NL 2022).

4.2.1.2 Polymer selection

Across all product categories, plastic was the most common material used in reusable products (Table 5). The following plastic polymers were identified in reusable products:

- Polypropylene
- Tritan
- Polyethylene terephthalate
- Melamine
- Polycarbonate
- Polystyrene
- Recycled plastic
- Bioplastic

Recycled plastic and bioplastic were not considered for further investigation as part of this report due to time restraints. They could be investigated further in future projects.

The market search uncovered that the specific type of plastic used in reusable products was not reported in approximately half of the cases (29/55). To ensure that no plastic polymers were overlooked in this project, the FCCmigex database was checked for plastic polymer entries specific for repeat-use. Three additional plastic polymers that were not identified in our market research had several database entries for reusable products in the database, namely, polyamide, polyethylene and polyvinylchloride. They were also considered for further investigation.

4.2.1.3 Migrating chemicals and their toxicological properties

Below, per type of plastic FCM, the prioritised chemicals were identified by 1) checking the FCCmigex database for chemicals with >2 database entries; 2) checking if reported migration of these chemicals was higher than their SML; and 3) checking if the hazards or properties of concern for these chemicals were relevant for FCMs.

4.2.1.3.1 Polypropylene

Polypropylene is a plastic polymer that is formed by the polymerisation of propylene monomers. It is widely used in the production of reusable food packaging due to its versatility, low cost and inherent properties.

In the FCCmigex database, 111 chemicals were detected in migrates from reusable food contact polypropylene. A total of 172 database entries related to polypropylene at the time of this research. The most frequently (>2 database entries) detected chemicals in migrates were silver, 2,4-di-tert-butylphenol, 2,6-di-tert-butylbenzoquinone, dibutyl phthalate, bisphenol A, Irgafos 168, Irganox 1010, methyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate and 2-butoxyethyl acetate (Table 6).

Based on the available migration and hazard information, two chemicals were prioritised, namely silver and dibutyl phthalate (coloured grey in the table).

Dibutyl phthalate is one of four phthalates (including bis(2-ethylhexyl) phthalate, diisobutyl phthalate and benzyl butyl phthalate) which have been restricted under REACH since 2020. Notably, the four substances

are restricted to a concentration ≤0.1% by weight individually or in any combination in any plasticised material in articles used by consumers or in indoor areas (but with some exemptions). This restriction does not apply to FCMs other than articles for feeding of children. Currently, all four substances can be found in the Union List for food contact plastics. However, further restrictions on these chemicals are anticipated.

Table 6 Chemicals reported to migrate most frequently from reusable polypropylene products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Silver	7440-22-4	Active substance	Repr. 2[10] STOT RE 2[10]	Some data submitters indicate Toxic to Reproduction	Included in the CoRAP	1.09[11] (Ding, Yang et al. 2018) 0.042 (Ozaki, Kishi et al. 2016) 0.57[11] (von Goetz, Fabricius et al. 2013)	SML(T)=0.05[1]
2,4-di-tert-butylphenol	96-76-4	NIAS	-	-	Included in the CoRAP	0.065 (Coulier, Orbons and Rijk 2007) 0.055 (Oliveira, Monsalve et al. 2020) 0.118 (Onghena, Negreira et al. 2016a) 0.419 (Simoneau, Van den Eede and Valzacchi 2012)	MLV=5[2]
2,6-di-tert-butylbenzo-quinone	719-22-2	NIAS	-	-	-	0.053 (Oliveira, Monsalve et al. 2020)[12]	MLV=0.05[2]
Dibutyl phthalate	84-74-2	Plasticiser	Repr. 1B	Toxic to reproduction ED	SVHC and included in the candidate list	0.005 (Onghena, Negreira et al. 2016a)	SML=0.12[3,4,5] SML=0.3[6]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
					SVHC requiring authorisation before it is used Some uses of this substance are restricted	0.60 (Fang, Wang and Lynch 2017) 0.235 (da Silva Oliveira, de Souza et al. 2017) 0.002 (Li, Xu et al. 2016)	
Bisphenol A	80-05-7	NIAS	Repr. 1B	Toxic to reproduction ED	Included in the CoRAP SVHC and included in the candidate list Some uses of this substance are restricted	0.00005 (Mansilha, Silva et al. 2013) 0.00004 (Kovačič, Gys et al. 2020)	SML=0.05[3,7]
Irgafos 168 (tris(2,4-di-tert-butylphenyl) phosphite)	31570-04-4	Antioxidant	-	-	-	8.17 (Coulier, Orbons and Rijk 2007)[12]	OML=60[8]
Irganox 1010 (pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate))	6683-19-8	Antioxidant	-	-	-	4.40 (Coulier, Orbons and Rijk 2007)[12]	OML=60[8]
Methyl-3-(3,5-di-tert-butyl-4-	6386-38-5	NIAS	-	-	-	0.281 (Coulier, Orbons and Rijk 2007)[8]	MLV=1[2]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
hydroxyphenyl) propionate							
2-butoxyethyl acetate	112-07-2	NIAS	-	-	-	0.946 (Onghena, Negreira et al. 2016a) 0.778 (Simoneau, Van den Eede and Valzacchi 2012)	MLV=0.09[9]

[1]Group restriction of 0.05 mg silver/kg food proposed by the AFC Panel in 2004 (EFSA 2004).
[2]MLVs were self-derived by the authors of this report from previously established MTC_{tap} values (MTC_{tap}*20=SML) (4MSI 2021).
[3]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[4]SML(T) means the maximum permitted sum of particular substances released in food/food simulants expressed as total of moiety of the substances indicated. An SML(T) of 0.6 mg/kg food applies for the sum of dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl) phthalate, expressed as bis(2-ethylhexyl) phthalate equivalents using the following equation: dibutyl phthalate*5 + diisobutyl phthalate*4 + benzyl butyl phthalate*0.1 + bis(2-ethylhexyl) phthalate*1. An SML of 0.12 mg/kg food for dibutyl phthalate applies when none of the other phthalates are present.
[5]Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0.05% in the final product.
[6]Warenwetregeling verpakkingen en gebruiksartikelen (NL 2022).
[7]Not to be used for the manufacture of polycarbonate infant feeding bottles. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children.
[8]No specific SML is available, but the OML should not exceed 10 mg/dm^2 which is ≈ 60 mg/kg (European Commission 2011a).
[9]No specific SML is available and since this substance is a NIAS with no indications of genotoxicity (no harmonised classification), a default MLV of 0.09 mg/kg food is considered to apply based on the principles of the Threshold of Toxicological Concern and considering the lowest exposure tier (EFSA 2019).
[10]RAC proposes to classify silver as Repr. 2 and STOT RE 2 (nervous system) (ECHA 2022).
[11]The migration was measured as 'mg/dm^2' or 'ng/cm^2'. These values are converted to 'mg/kg food' by assuming a surface to volume ratio of 6 dm^2/kg food.
[12]Chemical did have >2 database entries, however, not all migration concentrations could be reported (e.g. concentrations were below the limit of detection).
Abbreviations: AFC, Food Additives, Flavourings, Processing Aids and Materials in Contact with Food; CoRAP, Community Rolling Action Plan; ED, endocrine disruption; MLV, migration limit value; MTC_{tap}, Maximum Tolerable Concentration at the tap; NIAS, non-intentionally added substance; OML, overall migration limit; SML, specific migration limit; SML(T), total SML; SVHC, substance of very high concern; -, not applicable.

4.2.1.3.2 Tritan

Tritan is a novel co-polyester produced from a combination of different monomers including but not limited to dimethyl terephthalate, 1,4-cyclohexanedimethanol and 2,2,4,4-tetramethyl-1,3-cyclobutanediol. It is considered a potential substitute of polycarbonate in reusable products as it is free from BPA and other bisphenols. Tritan is mainly used in the production of sports bottles and food storage containers. It is known for its durability, clarity and resistance to impact.

No entries for tritan could be found in the FCCmigex database. However, studies investigating the migration of chemicals from tritan have been performed and were found in our literature search. Migration data retrieved from the respective studies is displayed in Table 7. Chemicals detected in migrates were benzyl butyl phthalate, dimethyl isophthalate, Irgafos 168, 2,2,4-trimethyl-1,3-pentanediol diisobutyrate, 4-propylbenzaldehyde and dicyclopentyl(dimethoxy)silane.

For tritan, none of the chemicals met the prioritisation criteria. It is however noteworthy that little migration information is currently available on this relatively novel material. That would in principle make tritan still a relevant candidate for future research.

Table 7 Chemicals reported to migrate most frequently from reusable tritan products into food/food simulants and their toxicological properties.

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Benzyl butyl phthalate	85-68-7	Plasticiser	Repr. 1B	Toxic to reproduction ED	SVHC and included in the candidate list SVHC requiring authorisation before it is used Some uses of this substance are restricted	0.00005 (Guart, Wagner et al. 2013)	SML(T)=6.0[1,2,3]
Dimethyl isophthalate	1459-93-4	Plasticiser	-	-	-	0.00009 (Guart, Wagner et al. 2013)	SML=0.05[1]
Irgafos 168 (tris(2,4-di-tert-butylphenyl) phosphite)	31570-04-4	Antioxidant	-	-	-	0.14 (He, Qin et al. 2021)	OML=60[4]
2,2,4-trimethyl-1,3-pentanediol diisobutyrate	6846-50-0	Plasticiser	-	-	-	0.013 (Onghena, Van Hoeck et al. 2016b)	SML=5.0[1,5]
4-Propylbenz-aldehyde	28785-06-0	NIAS	-	-	-	0.008 (Onghena, Van Hoeck et al. 2016b)	MLV=0.09[6]
Dicyclopentyl(dimethoxy)silane	126990-35-0	NIAS	-	-	-	0.001 (Onghena, Van Hoeck et al. 2016b)	MLV=0.09[6]

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]SML(T) means the maximum permitted sum of particular substances released in food/food simulants expressed as total of moiety of the substances indicated. An SML(T) of 0.6 mg/kg food applies for the sum of dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl) phthalate, expressed as bis(2-ethylhexyl) phthalate equivalents using the following equation: dibutyl phthalate*5 + diisobutyl phthalate*4 + benzyl

butyl phthalate*0.1 + bis(2-ethylhexyl) phthalate*1. An SML of 6 mg/kg food for benzyl butyl phthalate applies when none of the other phthalates are present.
[3]Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formula and follow-on formula; (c) technical support agent in concentrations up to 0.1% (w/w) in the final product.
[4]No specific SML is available, but the OML should not exceed 10 mg/dm^2 which is ≈ 60 mg/kg (European Commission 2011a).
[5]Only to be used in single-use gloves.
[6]No specific SML is available and since this substance is a NIAS with no indications of genotoxicity (no harmonised classification), a default MLV of 0.09 mg/kg food is considered to apply based on the principles of the Threshold of Toxicological Concern and considering the lowest exposure tier (EFSA 2019).
Abbreviations: ED, endocrine disruption; MLV, migration limit value; NIAS, non-intentionally added substance; OML, overall migration limit; SML, specific migration limit; SML(T), total SML; SVHC, substance of very high concern; -, not applicable.

4.2.1.3.3 Polyethylene terephthalate

Polyethylene terephthalate, commonly known as PET, is a type of plastic polymer made from a combination of two main monomers, namely ethylene glycol and terephthalic acid. While polyethylene terephthalate is most often used for single-use food packaging, especially beverage bottles, it is also used in the production of reusable food packaging. The combination of durability, transparency, lightweight design and recyclability makes polyethylene terephthalate a practical and popular choice for creating reusable food packaging.

In the FCCmigex database, 17 chemicals were detected in migrates from reusable food contact polyethylene terephthalate. A total of 27 database entries related to polyethylene terephthalate. The most frequently (>2 database entries) detected chemicals in migrates were di(2-ethylexyl) phthalate and acetaldehyde (Table 8).

No chemicals were prioritised based on the available migration and hazard information.

Often, polyethylene terephthalate beverage bottles intended for single-use, are re-filled and reused. While polyethylene terephthalate is generally considered safe for single-use beverage bottles, multiple reuse can lead to accelerated leaching of chemicals from the plastic into the contents of the bottle. This leaching can be influenced when bottles are exposed to heat and/or UV light (e.g., inside a hot car during sunny days) or when they become scratched or worn.

Some of the migration studies investigated the effects of temperature and/or UV light on migration levels. For di(2-ethylhexyl) phthalate, one study that did not directly measure the effects of temperature on migration levels of plasticisers but gathered and compared such migration data from other studies, reported that the highest di(2-ethylhexyl) phthalate levels were observed following exposure at 45°C compared to exposure at 25°C or 35°C (Mukhopadhyay, Jalal et al. 2022). Another study investigated the impact of sun exposure on the migration of plasticisers into the contents of bottles following 1) shade; 2) sun ambient; and 3) sun 60°C (Schmid, Kohler et al. 2008). Only minor differences in plasticiser concentrations were observed following the different exposure scenarios. The most decisive factor was the country of origin of bottles.

For acetaldehyde, migration data was extracted from a study which investigated the effects of temperature and UV light on the migration into food (Baumjohann and Harms 2015). The migration of acetaldehyde into the contents of PET bottles was increased significantly following exposure to 1) UV light; 2) high temperature (40°C); and 3) UV light exposure in combination with high temperature (40°C) compared to storage at 20°C without UV light exposure. The exposure scenario of UV light exposure in combination with high temperature (40°C) resulted in the highest migration values.

Table 8 Chemicals reported to migrate most frequently from reusable polyethylene terephthalate products into food/food simulants and their toxicological properties.

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Di(2-ethylhexyl) phthalate	117-81-7	Plasticiser	Repr. 1B	Toxic to Reproduction ED	SVHC and included in the candidate list SVHC requiring authorisation before it is used Some uses of this substance are restricted	0.000008 (Lee, Gurudatt et al. 2022) 0.0027 (Mukhopadhyay, Jalal et al. 2022) 0.0004 (Schmid, Kohler et al. 2008)	SML(T)=0.6[1,2,3] SML=1.5[4]
Acetaldehyde	75-07-0	NIAS	Muta. 2 Carc. 1B	Carcinogenic Suspected to be Mutagenic	-	0.0196 (Baumjohann and Harms 2015)[6]	SML(T)=6.0[1,5]

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]SML(T) means the maximum permitted sum of particular substances released in food/food simulants expressed as total of moiety of the substances indicated. An SML(T) of 0.6 mg/kg food applies for the sum of dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl) phthalate, expressed as bis(2-ethylhexyl) phthalate equivalents using the following equation: dibutyl phthalate*5 + diisobutyl phthalate*4 + benzyl butyl phthalate*0.1 + bis(2-ethylhexyl) phthalate*1. An SML of 0.6 mg/kg for bis(2-ethylhexyl) phthalate applies when none of the other phthalates are present.
[3]Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0.1% in the final product.
[4]Warenwetregeling verpakkingen en gebruiksartikelen (NL 2022).
[5]Group migration limit for acetaldehyde and propionic acid, vinyl ester, expressed as acetaldehyde.
[6]Chemical did have >2 database entries, however, not all migration concentrations could be reported (e.g. concentrations were below the limit of detection).
Abbreviations: ED, endocrine disruption; NIAS, non-intentionally added substance; SML, specific migration limit; SML(T), total SML; SVHC, substance of very high concern; -, not applicable.

4.2.1.3.4 Melamine (resin)

Melamine is a plastic polymer manufactured using urea and hydrogen cyanide as raw materials. Melamine resin is another type of polymer produced by the polymerisation of melamine and formaldehyde, and it is commonly used as a coating material. Both are used in the production of reusable food packaging due to their durability, heat resistance and cost-effectiveness.

In the FCCmigex database, 45 chemicals were detected in migrates from reusable food contact melamine (resin). A total of 87 database entries related to melamine (resin). The most frequently (>2 database entries) detected chemicals in migrates were melamine and formaldehyde (Table 9).

Based on the available migration and hazard information, both formaldehyde and melamine were prioritised (chemicals coloured grey in the table).

This finding is not surprising since melamine and formaldehyde are starting materials for the production of melamine plastics. In a previous risk assessment, EFSA reported that the SML for melamine from FCMs should be reconsidered in the light of the refined tolerable daily intake (EFSA 2010), and in 2011, the European Commission lowered the SML of melamine by a factor of 12 to 2.5 mg/kg food (European Commission 2011b).

In recent years, tableware made of melamine resin mixed with bio-based powders or fibres, such as bamboo, entered the market. Due to this, a large amount of research has been conducted in this field, and bio-based fillers were found to decrease the materials' stability, promote the migration of melamine and formaldehyde and lead to the exceedance of SMLs (BfR 2019a, Bouma, Kalsbeek-van Wijk and Sijm 2022). Consequently, the European Commission states that the use of bamboo and other plant-based fillers in plastic FCMs is not authorised according to Regulation (EU) No 10/2011. Based on the findings of our research, melamine and formaldehyde migration concentrations from melamine (resin) plastics (not mixed with bio-based fibres) may still be an issue.

Table 9 Chemicals reported to migrate most frequently from reusable melamine (resin) products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Melamine	108-78-1	Monomer	STOT RE 2 Carc. 2	Suspected to be carcinogenic	SVHC and included in the candidate list	3.14 (Kim, Lee et al. 2021) 1.09 (Arce, Sanllorente and Ortiz 2019) 6.44 (Mannoni, Padula et al. 2017) 3.27 (García Ibarra, Rodríguez Bernaldo de Quirós and Sendón 2016) 3.0 (Mattarozzi, Milioli et al. 2012) 1.48 (Chik, Haron et al. 2011) 4.60 (Bradley, Castle et al. 2010)	SML=2.5[2]
Formaldehyde	50-00-0	Starting material	Muta. 2 Carc. 1B	Carcinogenic Suspected to be mutagenic	Included in the CoRAP	1.59 (Kim, Lee et al. 2021) 3.86 (Arce, Sanllorente and Ortiz 2019) 93.6 (Mannoni, Padula et al. 2017)	SML(T)=15.0[1,2,3]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						155.0 (García Ibarra, Rodríguez Bernaldo de Quirós and Sendón 2016) 4.61 (Poovarodom, Junsrisuriyawong et al. 2014)	

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]Warenwetregeling verpakkingen en gebruiksartikelen (NL 2022).
[3]Group migration limit for formaldehyde and hexamethylenetetramine, expressed as formaldehyde.
Abbreviations: CoRAP, Community Rolling Action Plan; ED, endocrine disruption; SML, specific migration limit; SML(T), total specific migration limit; STOT RE, specific target organ toxicity - repeated exposure; SVHC, substance of very high concern.

4.2.1.3.5 Polycarbonate

Polycarbonate is a plastic polymer that is manufactured using mainly BPA and phosgene as raw materials. Due to its high impact resistance, optical clarity and inherent properties it is used in the production of reusable products.

In the FCCmigex database, 73 chemicals were detected in migrates from reusable food contact polycarbonate. A total of 122 database entries related to polycarbonate. The most frequently (>2 database entries) detected chemicals in migrates were BPA and dibutyl phthalate (Table 10). Notably, due to incomplete hydrolysis or polymerisation of polycarbonate, residual BPA can migrate into food (Hoekstra and Simoneau 2013).

Based on the available migration and hazard information, both BPA and dibutyl phthalate were prioritised (coloured grey in the table).

As expected, BPA was prioritised since it is a starting material in the synthesis of polycarbonate plastics. In April 2023, EFSA published a re-evaluation of the safety of BPA, significantly reducing the tolerable daily intake value (20,000 times lower than the previous value) (EFSA 2023). Based on EFSA's findings, follow-up regulatory measures are expected from the European Commission and national authorities including the setting of a new SML for BPA or introducing other specific restrictions to protect consumers. Additionally, further restrictions on the use of dibutyl phthalate in FCMs will likely come into play as discussed in Section 4.2.1.3.1.

Table 10 Chemicals reported to migrate most frequently from reusable polycarbonate products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	**CAS no.**	**Use**	**Harmonised hazard classification**	**ECHA: Properties of concern**	**ECHA: Important to know**	**Migration (mg/kg food)**	**Migration limit value (mg/kg food)**
Bisphenol A	80-05-7	Monomer	Repr. 1B	Toxic to reproduction ED	Included in the CoRAP SVHC and included in the candidate list Some uses of this substance are restricted	0.39 (Agarwal, Gandhi et al. 2022) 0.0001 (Amiridou and Voutsa 2011) 0.0056 (Arce, Ortiz and Sanllorente 2021) 0.055 (Bashir and Audu 2021) 58.0 (Biles, McNeal et al. 1997) 0.0084 (Brede, Fjeldal et al. 2003) 0.521 (Cao and Corriveau 2008) 0.0007 (Ehlert, Beumer and Groot 2008) 0.0044 (Guart, Bono-Blay et al. 2011)	SML=0.05[1,2]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						12.25 (Han, Song et al. 2021) 0.00187 (Kovačič, Gys et al. 2020) 0.00239 (Kubwabo, Kosarac et al. 2009) 0.00192 (Le, Carlson et al. 2008) 0.00032 (Li, Ying et al. 2010) 0.0084 (Lim, Kwack et al. 2009) 67.0 (Maia, Cruz et al. 2009) 520.3 (Maia, Cruz et al. 2010) 0.0152 (Mansilha, Silva et al. 2013) 0.0036 (Lázaro Martínez, Leal Denis et al. 2009)	

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						0.0047 (McNeal, Biles et al. 2000) 149.0 (Mercea 2009) 0.0082 (Oca, Sarabia et al. 2014) 0.0543 (Park, Park et al. 2018) 0.0133 (Reguera, Sanllorente et al. 2018) 0.0017 (Rowell, Kuiper and Preud'Homme 2016) 0.012 (Santillana, Ruiz et al. 2011) 0.00042 (Simoneau, Valzacchi et al. 2011) 0.711 (Spagnuolo, Marini et al. 2017)	
Dibutyl phthalate	84-74-2	Plasticiser	Repr. 1B	Toxic to reproduction ED	SVHC and included in the candidate list	1.34 (Yusà, López et al. 2021)	SML(T)=0.12[1,3,4] SML=0.3[5]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
					SVHC requiring authorisation before it is used Some uses of this substance are restricted	0.0006 (Wang, Huang et al. 2021) 0.00016 (Fasano, Bono-Blay et al. 2012)	

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]Not to be used for the manufacture of polycarbonate infant feeding bottles. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children.
[3]SML(T) means the maximum permitted sum of particular substances released in food/food simulants expressed as total of moiety of the substances indicated. An SML(T) of 0.6 mg/kg food applies for the sum of dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl) phthalate, expressed as bis(2-ethylhexyl) phthalate equivalents using the following equation: dibutyl phthalate*5 + diisobutyl phthalate*4 + benzyl butyl phthalate*0.1 + bis(2-ethylhexyl) phthalate*1. An SML of 0.12 mg/kg for dibutyl phthalate applies when none of the other phthalates are present.
[4]Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0.05% in the final product.
[5]Warenwetregeling verpakkingen en gebruiksartikelen (NL 2022).
Abbreviations: ED, endocrine disruption; SML, specific migration limit; SML(T), total SML; SVHC, substance of very high concern.

4.2.1.3.6 Polystyrene

Polystyrene is a plastic polymer made from styrene monomers. Polystyrene is most used as single-use food packaging due to its insulating and cushioning properties. It can also be used in reusable food packaging. However, due to human health and environmental concerns, there is a transition away from polystyrene in all types of food packaging.

In the FCCmigex database, 7 chemicals were detected in migrates from reusable food contact polystyrene. A total of 8 database entries related to polystyrene. None of the reported chemicals were detected more often than two times. Studies investigating the migration of styrene from polystyrene food packaging were identified in the literature search and the results are displayed in Table 11.

The monomer styrene did not meet the prioritisation criteria based on the available migration and hazard information.

In 2020, EFSA re-evaluated the safety of styrene for use in plastic FCMs following its classification by the International Agency for Research on Cancer (IARC) as 'probably carcinogenic to humans' (group 1B) (EFSA 2020a). This classification was based on data from high-dose occupational exposure studies (inhalation route of exposure) and animal studies (also mainly by inhalation). EFSA considered that the IARC conclusions cannot be directly applied to the evaluation of risks for consumers from the oral exposure to styrene, but also concluded that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. Overall, EFSA concluded that a systematic review of genotoxicity and mechanistic data, comparative toxicokinetics and analysis of species differences is required for assessing the safety of styrene for its use in FCMs. Depending on the outcome of this systematic review, it is possible that further restrictions will come into place for styrene use in food packaging.

Table 11 Chemicals reported to migrate most frequently from reusable polystyrene products into food/food simulants and their toxicological properties.

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Styrene	100-42-5	Monomer	STOT RE 1 Repr. 2	Suspected to be Toxic to Reproduction	-	0.163 (Genualdi, Nyman and Begley 2014) 2.4 (Gelbke, Banton et al. 2019)	OML=60[1]

[1]No specific SML is available, but the OML should not exceed 10 mg/dm2 which is ≈ 60 mg/kg (European Commission 2011a).
Abbreviations: OML, overall migration limit; STOT RE, specific target organ toxicity – repeated exposure; -, not applicable.

4.2.1.3.7 Polyamide

Polyamide, commonly known as nylon, is a plastic polymer typically produced using amine monomers and carboxylic acid. It is a versatile polymer that can be used in various forms for reusable food packaging. Polyamide is known for its strength, durability and barrier properties, which make it suitable for protecting and preserving food items.

In the FCCmigex database, 93 chemicals were detected in migrates from reusable food contact polyamide. A total of 218 database entries related to polyamide. The most frequently (>2 database entries) detected chemicals in migrates were 4,4'-methylenedianiline, aniline, polyamide 66, polyamide 6 (not including caprolactam), caprolactam, 2,4 toluene diamine, 3,3'-dimethylbenzidine, 2,6-toluenediamine, azacyclotridecan-2-one, benzidine, O-anisidine, O-toluidine, 4-chloroaniline, 4-chloro-O-toluidine and M-phenylenediamine (Table 12).

Based on the available migration and hazard information, 10 of the 15 chemicals, all NIAS, were prioritised (those coloured grey in the table).

It is to be noted that two of these chemicals, the oligomers PA 6 and PA 66, did not actually meet the prioritisation criteria. There is, however, little to no experimental toxicological data on PA oligomers available, which makes their hazard assessment difficult. In combination with their relatively high migration, that would in principle make these oligomers still relevant candidates for future research.

Table 12 Chemicals reported to migrate most frequently from reusable polyamide products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
4,4'-methylene-dianiline	101-77-9	NIAS	Carc. 1B Muta. 2 STOT RE 2	Carcinogenic Suspected to be Mutagenic	SVHC and included in the candidate list SVHC requiring authorisation before it is used	18.52 (Arrizabalaga-Larrañaga, de Juan-de Juan et al. 2022) 19.72 (Sanchis, Coscollà et al. 2015) 4.17 (McCall, Keegan and Foley 2012)	DA=0.002[1,2]
Aniline	62-53-3	NIAS	Carc. 2 STOT RE 1 Muta. 2	Suspected to be Carcinogenic Suspected to be Mutagenic	-	0.122 (Arrizabalaga-Larrañaga, de Juan-de Juan et al. 2022) 0.667 (Perez, Padula et al. 2019) 0.283 (Sanchis, Coscollà et al. 2015) 0.081 (McCall, Keegan and Foley 2012)	DA=0.01[1,2]
PA 66[6]	-	NIAS	-	-	-	12.0 (Canellas, Vera et al. 2021) 36.4 (Kappenstein, Ebner et al. 2018)	Group MLV=5[3]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
PA 6 (not including caprolactam)[6]	-	NIAS	-	-	-	1.2 (Canellas, Vera et al. 2021) 8.46 (Kappenstein, Ebner et al. 2018) 10.78 (Hu, Du et al. 2021)	Group MLV=5[3]
Caprolactam	105-60-2	NIAS	-	-	-	3.2 (Canellas, Vera et al. 2021) 1.75 (Hu, Du et al. 2021)	SML(T)=15[1,4]
2,4-toluene diamine	95-80-7	NIAS	Carc. 1B Muta. 2 STOT RE 2 Repr. 2	Carcinogenic Suspected to be Mutagenic Suspected to be Toxic to Reproduction	SVHC and included in the candidate list	0.012 (Sanchis, Coscollà et al. 2015) 0.437 (McCall, Keegan and Foley 2012)	DA=0.002[1,2]
3,3'-dimethyl-benzidine	119-90-4	NIAS	Carc. 1B	Carcinogenic	Some uses of this substance are restricted	0.045 (Perez, Padula et al. 2019) 0.049 (Sanchis, Coscollà et al. 2015) 0.0046 (McCall, Keegan and Foley 2012)	DA=0.002[1,2]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
2,6-toluenediamine	823-40-5	NIAS	Muta. 2	Suspected to be Mutagenic	-	0.0047 (Sanchis, Coscollà et al. 2015) 0.063 (McCall, Keegan and Foley 2012)	DA=0.01[1,2]
Azacyclotridecan-2-one	25038-74-8	NIAS	-	-	-	0.924 (Onghena, Van Hoeck et al. 2016b)[7]	MLV=0.09[5]
Benzidine	92-87-5	NIAS	Carc. 1A	Carcinogenic	Some uses of this substance are restricted	0.0018 (Arrizabalaga-Larrañaga, de Juan-de Juan et al. 2022)[7]	DA=0.002[1,2]
O-anisidine	90-04-0	NIAS	Carc. 1B Muta. 2	Carcinogenic Suspected to be Mutagenic	SVHC and included in the candidate list	0.082 (Arrizabalaga-Larrañaga, de Juan-de Juan et al. 2022) 0.0023 (Perez, Padula et al. 2019)	DA=0.002[1,2]
O-toluidine	95-53-4	NIAS	Carc. 1B	Carcinogenic	SVHC and included in the candidate list	0.012 (Arrizabalaga-Larrañaga, de Juan-de Juan et al. 2022) 0.0013 (Perez, Padula et al. 2019) 0.0009 (McCall, Keegan and Foley 2012)	DA=0.002[1,2]
4-chloroaniline	106-47-8	NIAS	Carc. 1B	Carcinogenic	-	0.00026 (Szabo, Jakab et al. 2021)[7]	DA=0.002[1,2]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
4-chloro-O-toluidine	3165-93-3	NIAS	Muta. 2 Carc. 1B	Carcinogenic Suspected to be Mutagenic	-	0.00024 (Szabo, Jakab et al. 2021)[7]	DA=0.01[1,2]
M-phenylene-diamine	108-45-2	NIAS	Muta. 2	Suspected to be Mutagenic	Included in the CoRAP	0.002 (Sanchis, Coscollà et al. 2015)[7]	ND[1]

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]Primary aromatic amines 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 0.002 mg/kg. Those not listed in in entry 43 to Appendix 8 of Annex XVII to Reg.1907/2006 shall have a detection limit of 0.01 mg/kg.
[3]Opinion paper on polyamide whereby a group MLV of 5 mg/kg food was derived for PA 6 and PA 66 (BfR 2019b).
[4]Group migration limit for caprolactam and caprolactam sodium salt, expressed as caprolactam.
[5]No specific SML is available and since this substance is a NIAS with no indications of genotoxicity (no harmonised classification), a default MLV of 0.09 mg/kg food is considered to apply based on the principles of the Threshold of Toxicological Concern and considering the lowest exposure tier (EFSA 2019).
[6]This is a group of chemicals and therefore no CAS no. applies. Hazard classification information could not be specifically gathered which does not mean that no hazard classifications apply.
[7]Chemical did have >2 database entries, however, not all migration concentrations could be reported (e.g. concentrations were below the limit of detection).
Abbreviations: CoRAP, Community Rolling Action Plan; DA; detectable amount; ED, endocrine disruption; MLV, migration limit value; ND, not detectable; NIAS, non-intentionally added substance; OML, overall migration limit; PA: polyamide; SML, specific migration limit; SML(T), total SML; STOT RE, specific target organ toxicity - repeated exposure;; SVHC, substance of very high concern; -: not applicable.

4.2.1.3.8 Polyethylene

Polyethylene is a plastic polymer produced by the polymerisation of ethylene monomer with a high variety of crystalline structures, depending on its chain branching and density. Polyethylene is commonly found in two main variations which are high-density polyethylene and low-density polyethylene. It is commonly used in the manufacture of reusable food packaging.

In the FCCmigex database, 57 chemicals were detected in migrates from reusable food contact polyethylene. A total of 85 database entries related to polyethylene. The most frequently (>2 database entries) detected chemical in migrates was silver (Table 13).

Silver was prioritised based on the available migration and hazard information.

Table 13 Chemical reported to migrate most frequently from reusable polyethylene products into food/food simulants and its toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg)	Migration limit value (mg/kg)
Silver	7440-22-4	Active substance	Repr. 2[2] STOT RE 2[2]	Some data submitters indicate they consider this substance as Toxic to Reproduction	Included in the CoRAP	0.6 (Addo Ntim, Norris et al. 2018) 0.0289 (Metak, Nabhani and Connolly 2015)	SML(T)=0.05[1]

[1]Group restriction of 0.05 mg silver/kg food proposed by the AFC Panel in 2004 (EFSA 2004).
[2]RAC proposes to classify silver as Repr. 2 and STOT RE 2 (nervous system) (ECHA 2022).
Abbreviations: CoRAP, Community Rolling Action Plan; -: not applicable.

4.2.1.3.9 Polyvinylchloride

Polyvinylchloride is a plastic polymer primarily made from two main raw materials, namely ethylene and chlorine. It is known for its versatility and is used in a wide range of applications, including food packaging. Polyvinylchloride is mostly used in single-use food packaging and to a lesser extent in reusable food packaging. The production and disposal of polyvinylchloride have raised human health and environmental concerns due to the release of chlorine-based compounds, therefore, alternative FCMs are more favourable for reusable products.

In the FCCmigex database, 11 chemicals were associated with reusable food contact polyvinylchloride. A total of 13 database entries related to polyvinylchloride, however, no chemicals had >2 database entries.

4.2.2 Stainless steel

Stainless steel is an iron-based alloy that contains a minimum of 10.5% chromium by mass. It is known for its exceptional corrosion resistance, high strength and durability. The composition of stainless steel typically includes iron, carbon and various alloying elements, with chromium being the key component that impacts its corrosion-resistant properties. The specific composition of stainless steel can vary depending on the desired properties and applications. Besides chromium, other common alloying elements found in stainless steel include nickel, molybdenum, manganese, copper, phosphorus, silicon, sulphur, selenium, tungsten, titanium and nitrogen (Schmidt, Erickson et al. 2012). These elements play a crucial role in enhancing specific characteristics, such as increased resistance to corrosion, improved strength and heat resistance. The chromium content forms a thin, protective oxide layer on the surface of the steel, known as the passive layer. This oxide layer prevents the underlying steel from reacting with the surrounding environment, making stainless steel resistant to rust and corrosion even in challenging conditions. Nevertheless, low levels of metals can be released from stainless steel in contact with fluids (Hedberg and Odnevall Wallinder 2015).

4.2.2.1 Legislation

Stainless steel FCMs are regulated by Regulation (EC) No 1935/2004 (European Commission 2004). There is no further EU legislation specific for stainless steel FCMs, however, Regulation (EU) 2023/915 on contaminants in foods (European Commission 2023) sets maximum levels for several metals from all sources, including release from FCMs.

There are also several standards for stainless steel FCMs, such as the European standards for stainless steel developed by the European Committee for Standardization (CEN) through the Technical Committee CEN/TC 459 "Stainless steels". These standards ensure the quality, safety and performance of stainless steel materials, products and components used in various industries. The most referenced standards for stainless steel in the EU are part of the EN (European Norm) series. Some important European standards related to stainless steel grades are included in EN 10088, including chemical composition of stainless steels.

The Council of Europe (CoE) resolution CM/Res (2013)9 on metals and alloys used in FCMs and articles sets specific release limits (SRLs) for metals based on toxicological information (European Council 2013). To note, SRLs are similar to SMLs but are specific to metals. It additionally recommends that Member State governments adopt legislative and other measures aimed to reduce the health risks arising from consumer exposure to certain metal ions released into food from the contact with metals and alloys.

> "Specific release limit (SRL) describes the maximum permitted amount of a given metal ion or metalloid ion (in mg) when released from a material or article of a defined surface area into food (in kg) or food simulants."
>
> - CM/Res(2013)9

The Nordic guidance for authorities, industry and trade also gives an overview of toxicology and guidance values for release of metals from FCMs based on the CoE resolution as well as analytical feasibility (Norden 2015).

National rules for stainless steel as FCMs apply in 10 Member States (Simoneau, Raffael et al. 2016). In the Netherlands, the Commodities Act Decree and Regulation on Packaging and Consumer Articles establishes SMLs for metal release from FCMs (NL 2022).

4.2.2.2 Migrating chemicals and their toxicological properties

In the FCCmigex database, 20 chemicals were associated with reusable food contact steel. A total of 90 database entries related to steel. The most frequently (>2 database entries) detected chemicals in migrates were chromium, nickel, iron, manganese, aluminium, cadmium, lead, copper, zinc, cobalt and molybdenum (Table 14).

Based on the available migration and hazard information, four metals were prioritised, namely, nickel, cobalt, cadmium and lead (coloured grey in the Table). These heavy metals were prioritised based on high migration concentrations (exceeding SRLs) retrieved from two studies which investigated chemical migration from stainless steel reusable products available on the Chinese market (Wu, Keegan and Behan 2021, Yang, Zhu et al. 2022). This indicates that heavy metal contamination may be of concern for imported stainless steel FCMs rather than for stainless steel FCMs manufactured within the EU.

Chromium migrating from FCMs could be a potential safety issue if it concerns chromium (VI), which the majority of data submitters classify as carcinogenic. It is unknown whether chromium (VI) is present in FCMs, though even if this form of chromium migrates from FCMs, it would be quickly reduced to chromium (III) in food. Therefore, it is assumed that all chromium measured in food is chromium (III) and chromium is not considered prioritised in the scope of this report (Wijnhoven, Brand et al. 2019).

Table 14 Chemicals reported to migrate most frequently from reusable stainless steel products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	**CAS no.**	**Use**	**Harmonised hazard classification**	**ECHA: Properties of concern**	**ECHA: Important to know**	**Migration (mg/kg food)**	**Migration limit value (mg/kg food)**
Chromium	7440-47-3	Alloying element	**-**	-	**-**	34.96 (Yang, Zhu et al. 2022) 9.5 (Casaroli, Boniardi et al. 2022) 0.0595 (Qiu, Yang et al. 2021)[3] 0.168 (Koo, Pack et al. 2020) 0.21 (Mazinanian, Herting et al. 2016) 0.105 (Dalipi, Borgese et al. 2016) 0.721 (Herting, Odnevall Wallinder and Leygraf 2008)	SRL=0.25[1]
Nickel	7440-02-0	Alloying element	Carc. 2 STOT RE 1	Suspected to be Carcinogenic	Some uses of this substance are restricted	0.714 (Yang, Zhu et al. 2022) 0.103 (Casaroli, Boniardi et al. 2022)	SRL=0.14[1]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						0.203 (Wu, Keegan and Behan 2021) 0.022 (Qiu, Yang et al. 2021)[3] 0.009 (Koo, Pack et al. 2020) 0.062 (Mazinanian, Herting et al. 2016) 0.066 (Dalipi, Borgese et al. 2016)	
Iron	7439-89-6	Alloying element	-	-	-	360.8 (Yang, Zhu et al. 2022) 139.4 (Wu, Keegan and Behan 2021) 5.97 (Qiu, Yang et al. 2021)[3] 7.0 (Mazinanian, Herting et al. 2016) 12.5 (Herting, Odnevall Wallinder and Leygraf 2008)	SRL=40[1]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Manganese	7439-96-5	Alloying element	-	-	-	3.23 (Yang, Zhu et al. 2022) 0.470 (Casaroli, Boniardi et al. 2022) 6.436 (Zhang, Xing et al. 2022) 0.156 (Qiu, Yang et al. 2021)[3] 0.35 (Mazinanian, Herting et al. 2016) 0.894 (Dalipi, Borgese et al. 2016)	SRL=1.8[1] SML=0.6[2]
Aluminium	7429-90-5	Alloying element	-	-	-	6.84 (Wu, Keegan and Behan 2021) 0.181 (Qiu, Yang et al. 2021)[3]	SRL=5[1]
Cadmium	7440-43-9	NIAS	Muta. 2 Carc. 1B STOT RE 1 Repr. 2	Carcinogenic Suspected to be Mutagenic Suspected to be Toxic to Reproduction	SVHC and included in the candidate list Some uses of this substance are restricted	0.009 (Yang, Zhu et al. 2022) 0.00016 (Qiu, Yang et al. 2021)[3] 0.00002 (Koo, Pack et al. 2020)	SRL=0.005[1]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
Lead	7439-92-1	NIAS	Repr. 1A	Toxic to Reproduction Some data submitters indicate they consider this substance as Carcinogenic	SVHC and included in the candidate list Some uses of this substance are restricted	0.0303 (Yang, Zhu et al. 2022) 0.0071 (Qiu, Yang et al. 2021)[3] 0.00184 (Koo, Pack et al. 2020)	SRL=0.01[1]
Copper	7440-50-8	Alloying element	-	-	-	0.533 (Yang, Zhu et al. 2022) 0.0023 (Qiu, Yang et al. 2021)[3]	SRL=4[1]
Zinc	7440-66-6	Alloying element	-	-	-	2.78 (Yang, Zhu et al. 2022) 0.0032 (Qiu, Yang et al. 2021)*	SRL=5[1]
Cobalt	7440-48-4	Alloying element	Muta. 2 Carc. 1B Repr. 1B	Carcinogenic Suspected to be Mutagenic Toxic to Reproduction	-	0.0023 (Qiu, Yang et al. 2021)[3] 0.066 (Yang, Zhu et al. 2022)	SRL=0.02[1]
Molybdenum	7439-98-7	Alloying element	-	-	-	0.003 (Qiu, Yang et al. 2021)[3]	SRL=0.12[1]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						0.021 (Mazinanian, Herting et al. 2016) 0.0306 (Yang, Zhu et al. 2022)	

[1]Metals and alloys used in food contact materials and articles: A practical guide for manufacturers and regulators (European Council 2013).
[2]Warenwetregeling verpakkingen en gebruiksartikelen (NL 2022).
[3]Stainless steel grade 30Cr13 was excluded as this is not used for prolonged contact with food.
Abbreviations: CoRAP, Community Rolling Action Plan; NIAS, non-intentionally added substance; SML, specific migration limit; SRL, specific release limit; STOT RE, specific target organ toxicity - repeated exposure; SVHC, substance of very high concern; -: not applicable.

4.2.3 Silicone

Silicone is a synthetic polymer made up of repeating units of dimethyl siloxane, with silicone and oxygen atoms forming the backbone. Methyl groups attached to the silicone atoms create a unique chemical structure that contributes to silicone's heat resistance and flexibility.

4.2.3.1 Legislation

Silicone FCMs are regulated under Regulation (EC) No 1935/2004 (European Commission 2004). There is no further regulation on EU level specific for silicone FCMs.

CoE Resolution AP (2004)5 for silicones in FCMs contains a positive list and a negative list for chemicals and SML values (European Council 2004). It recommends that Member States adopt legislative and other measures aimed to reduce the health risks arising from consumer exposure to chemicals released into food from contact with silicones.

In the Dutch Commodities Act Decree and Regulation on Packaging and Consumer Articles, silicones are regulated together with natural and synthetic rubber, and it establishes SMLs for chemical release from silicone FCMs. Rubber materials are divided into categories based on a calculated R-value, which indicates whether migration testing is required or not. The R-value considers in more detail specificities of repeat-use applications (Brandsch and Schuster 2020).
The total migration of components of rubber products into foodstuffs under reasonably foreseeable conditions of use should not exceed 20 mg/kg for category I rubber products for which extra attention is warranted, such as baby bottles. Products with an R-value exceeding 0.001 are classified as category II rubber products. For these products migration tests are required and a migration limit of 100 mg/kg determined in water or 60 mg/kg determined in ethanol or olive oil applies. Products with an R-value below 0.001 are classified as category III rubber products for which migration is assumed to be negligible.

4.2.3.2 Migrating chemicals and their toxicological properties

In the FCCmigex database, 167 chemicals were associated with reusable food contact silicone. A total of 308 database entries related to silicone. The most frequently (>2 database entries) detected chemicals in migrates were cyclic siloxanes (D3-D18), 2,6-di-tert-butylbenzoquinone, 2-ethylhexyl salicylate, benzophenone, 2,2,4-trimethyl-1,3-pentanediol diisobutyrate, aniline, dibutyl phthalate, diisobutyl phthalate, isopropyl palmitate, palmitic acid and silver (Table 15).

Based on the available migration and hazard information, two chemicals, both NIAS, were prioritised for silicones, namely cyclic siloxanes (D3-D18) and aniline (coloured grey in the table).

For benzophenone, one study identified in our research reported concentrations slightly exceeding the SML of 0.6 mg/kg from reusable silicone bottles (Simoneau, Van den Eede and Valzacchi 2012). Interestingly, these bottles contained a piece of cardboard when purchased. Only trace amounts of benzophenone were found when the silicone bottles were dissolved, therefore, the authors suggested that the benzophenone might have migrated from the cardboard rather than from the silicone. Therefore, benzophenone is not considered to be a prioritised chemical.

Table 15 Chemicals reported to migrate most frequently from reusable silicone products into food/food simulants and their toxicological properties. Prioritised chemicals are those with relevant hazard classifications/properties of concern and migration levels exceeding migration limit values (coloured grey).

Chemical name	**CAS no.**	**Use**	**Harmonised hazard classification**	**ECHA: Properties of concern**	**ECHA: Important to know**	**Migration (mg/kg food)**	**Migration limit value (mg/kg food)**
Cyclic siloxanes (D3-D18)	-	NIAS	Repr. 2 (D4)	Suspected to be Toxic to Reproduction (D4)	Some uses of the substance are restricted (D4 and D5) SVHC and included in the candidate list (D4, D5 and D6)	895.0 (Asensio, Uranga and Nerín 2022) 484.4 (Feng, Zhang et al. 2019) 20.03 (Fromme, Witte et al. 2019) 2500.0 (Liu, Wrona et al. 2021) 7.5 (Liu, Yu et al. 2020) 0.155 (Zhang, Wong et al. 2012) 570.0 (Cederberg and Jensen 2017)	SML=1.5[1] (organopolysiloxanes)
2,6-di-tert-butylbenzoquinone	719-22-2	NIAS	-	-	-	0.3 (Asensio, Uranga and Nerín 2022) 0.008 (Onghena, Negreira et al. 2016a, Onghena, Van Hoeck et al. 2016b)	MLV=0.05[2]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
						0.382 (Simoneau, Van den Eede and Valzacchi 2012)	
2-ethylhexyl salicylate	118-60-5	NIAS	-	-	Included in the CoRAP	Not quantified (Asensio, Uranga and Nerín 2022)[7]	MLV=0.09[3]
Benzophenone	119-61-9	NIAS	Carc. 1B	Carcinogenic	Included in the CoRAP	0.009 (Onghena, Negreira et al. 2016a) 0.014 (Onghena, Van Hoeck et al. 2016b) 0.637 (Simoneau, Van den Eede and Valzacchi 2012)	SML=0.6[1]
2,2,4-trimethyl-1,3-pentanediol diisobutyrate	6846-50-0	Plasticiser	-	-	-	0.118 (Onghena, Van Hoeck et al. 2016b) 0.574 (Simoneau, Van den Eede and Valzacchi 2012)	SML= 5.0[1]
Aniline	62-53-3	NIAS	Carc. 2 STOT RE 1 Muta. 2	Suspected to be Carcinogenic Suspected to be Mutagenic	-	0.00154 (Szabo, Jakab et al. 2021) >0.01 (Paseiro-Cerrato, Noonan and Begley 2014) 0.0027 (Perez, Padula et al. 2019)	DA=0.002[1]
Dibutyl phthalate	84-74-2	Plasticiser	Repr. 1B	Toxic to reproduction ED	SVHC and included in the candidate list	0.011 (Onghena, Negreira et al. 2016a) 0.011 (Onghena, Van Hoeck et al. 2016b)	SML=0.12[1,4,5] SML=0.3[6]

Chemical name	CAS no.	Use	Harmonised hazard classification	ECHA: Properties of concern	ECHA: Important to know	Migration (mg/kg food)	Migration limit value (mg/kg food)
					SVHC requiring authorisation before it is used Some uses of this substance are restricted		
Diisobutyl phthalate	84-69-5	Plasticiser	Repr. 1B	Toxic to Reproduction ED	SVHC and included in the candidate list SVHC requiring authorisation before it is used Some uses of this substance are restricted	0.015 (Onghena, Negreira et al. 2016a) 0.024 (Onghena, Van Hoeck et al. 2016b)	SML(T)=0.15[1,4,5]
Isopropyl palmitate	142-91-6	Additive	-	-	-	10.6 (Asensio, Uranga and Nerín 2022)[7]	OML=60[1]
Palmitic acid	57-10-3	Additive	-	-	-	4.3 (Asensio, Uranga and Nerín 2022) 9.54 (Simoneau, Van den Eede and Valzacchi 2012)	OML=60[1]
Silver	7440-22-4	Active substance	Repr. 2[8] STOT RE 2[8]	Some data submitters indicate Toxic to Reproduction	Included in the CoRAP	0.0018 (Choi, Chae et al. 2018) 0.002 (Ding, Yang et al. 2018)	SML(T)=0.05[6]

[1]Commission Regulation (EU) No 10/2011 (European Commission 2011a).
[2]MLVs were self-derived by the authors of this report from previously established MTC_{tap} values (MTC_{tap}*20=SML) (4MSI 2021).

[3]No specific SML is available and since this substance is a NIAS with no indications of genotoxicity (no harmonised classification), a default MLV of 0.09 mg/kg food is considered to apply based on the principles of the Threshold of Toxicological Concern and considering the lowest exposure tier (EFSA 2019).
[3]No specific SML is available, but the OML should not exceed 10 mg/dm^2 which is ≈ 60 mg/kg (European Commission 2011a).
[4]SML(T) means the maximum permitted sum of particular substances released in food/food simulants expressed as total of moiety of the substances indicated. An SML(T) of 0.6 mg/kg food applies for the sum of dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate and bis(2-ethylhexyl) phthalate, expressed as bis(2-ethylhexyl) phthalate equivalents using the following equation: dibutyl phthalate*5 + diisobutyl phthalate*4 + benzyl butyl phthalate*0.1 + bis(2-ethylhexyl) phthalate*1. An SML of 0.15 mg/kg for diisobutyl phthalate applies when none of the other phthalates are present.
[5]Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0.05% in the final product.
[6]Group restriction of 0.05 mg silver/kg food proposed by the AFC Panel in 2004 (EFSA 2004).
[7]Chemical did have >2 database entries, however, not all migration concentrations could be reported (e.g. concentrations were below the limit of detection).
[8]RAC proposes to classify silver as Repr. 2 and STOT RE 2 (nervous system) (ECHA 2022).
Abbreviations: CoRAP, Community Rolling Action Plan; DA, detectable amount; ED, endocrine disruption; MLV, migration limit value; NIAS, non-intentionally added substance; OML, overall migration limit; SML, specific migration limit; SML(T), total SML; STOT RE, specific target organ toxicity - repeated exposure; SVHC, substance of very high concern; -: not applicable.

4.2.4 Overview of prioritised chemicals

To answer part of the second research question, this chapter provides an overview of the prioritised chemicals that may be of concern to consumers using reusable FCMs made from plastics, stainless steel and silicone. The prioritisation process was based on migration and hazard information of chemicals migrating from the selected FCMs. Overall, prioritised chemicals were those with >2 database entries, migration concentrations above SMLs and relevant harmonised hazard classifications or properties of concern for FCMs.

A total of 20 different chemicals were prioritised over the three material types. For the plastic polymers, one chemical was prioritised for polyethylene (silver), two chemicals were prioritised for polypropylene (silver and dibutyl phthalate), melamine (resin) (melamine and formaldehyde) and polycarbonate (bisphenol A and dibutyl phthalate). Polyamide was the FCM with the highest number of harmful migrating chemicals exceeding SMLs. A total of 10 chemicals were prioritised, all NIAS (4,4'-methylenedianiline, aniline, PA 66, PA 6 (not including caprolactam), 2,4-toluene diamine, 3,3'-dimethylbenzidine, 2,6-toluenediamine, O-anisidine, O-toluidine and M-phenylenediamine).

Interestingly, many of the chemicals which were prioritised in this report for plastics have also been prioritised in the work conducted by Geueke et al. (2023) on reusable plastics.

No chemicals were prioritised for the following plastics: titan, polyethylene terephthalate, polystyrene and polyvinylchloride. To note, the total amount of database entries was lower for these materials compared to the other FCMs. For tritan, this is apparent since it is a relatively new plastic polymer used to make FCMs, and thus, limited research has been conducted so far. For polyethylene terephthalate, polystyrene and polyvinylchloride, there were few database entries likely because they are more commonly used for single-use FCM applications. For the latter two there is a transition away from their use in FCMs due to associated human health and environmental concerns.

For stainless steel, four heavy metals were prioritised (nickel, cadmium, lead and cobalt). Furthermore, two chemicals were prioritised for silicone FCMs (cyclic siloxanes (D3-D18) and aniline).

Table 16 List of prioritised chemicals in each material category based on the criteria set out in Section 3.5.4.

FCM	Database entries	Chemicals in FCCmigex	>2 database entries	Prioritised chemicals	Hazard data	Range of migration (mg/kg food)	Use
Plastics							
Polypropylene	172	111	9	Silver (CAS no. 7440-22-4)	Some data submitters indicate Toxic to Reproduction, Repr. 2, STOT RE 2	0.042-1.09 (SML(T)=0.05)	Active substance
				Dibutyl phthalate (CAS no. 84-74-2)	Toxic to reproduction (Repr. 1B), ED	0.002-0.60 (SML=0.12)	Plasticiser
Tritan	-	-	-	-[1]	-	-	-
Polyethylene terephthalate	27	17	2	-	-	-	-
Melamine	87	45	2	Melamine (CAS no. 108-78-1)	Suspected to be carcinogenic (Carc. 2), STOT RE 2	1.09-6.44 (SML=2.5)	Monomer
				Formaldehyde (CAS no. 50-00-0)	Carcinogenic (Carc. 1B), Suspected to be mutagenic (Muta. 2)	1.59-155.0 (SML(T)=15)	Starting material
Polycarbonate	122	73	2	Bisphenol A (CAS no. 80-05-7)	Toxic to reproduction (Repr. 1B), ED	0.0001-520.3 (SML=0.05)	Monomer
				Dibutyl phthalate (CAS no. 84-74-2)	Toxic to reproduction (Repr. 1B), ED	0.00016-1.34 (SML=0.12)	Plasticiser
Polystyrene	8	7	0	-	-	-	-
Polyamide	218	93	15	4,4'-methylenedianiline (CAS no. 101-77-9)	Carcinogenic (Carc. 1B), Suspected to be Mutagenic (Muta. 2), STOT RE 2	4.17-19.72 (DA=0.002)	NIAS
				Aniline (CAS no. 62-53-3)	Suspected to be Carcinogenic (Carc. 2),	0.081-0.667 (DA=0.01)	NIAS

FCM	Database entries	Chemicals in FCCmigex	>2 database entries	Prioritised chemicals	Hazard data	Range of migration (mg/kg food)	Use
					Suspected to be Mutagenic (Muta. 2), STOT RE 1		
				2,4-toluene diamine (CAS no. 95-80-7)	Carcinogenic (Carc. 1B), Suspected to be Mutagenic (Muta. 2), Suspected to be Toxic to Reproduction (Repr. 2), STOT RE 2	0.012-0.437 (DA=0.002)	NIAS
				3,3'-dimethylbenzidine (CAS no. 119-90-4)	Carcinogenic (Carc. 1B)	0.0046-0.049 (DA=0.002)	NIAS
				2,6-toluenediamine (CAS no. 823-40-5)	Suspected to be Mutagenic (Muta. 2)	0.0047-0.063 (DA=0.01)	NIAS
				O-anisidine (CAS no. 90-04-0)	Carcinogenic (Carc. 1B), Suspected to be Mutagenic (Muta. 2)	0.0023-0.082 (DA=0.002)	NIAS
				O-toluidine (CAS no. 95-53-4)	Carcinogenic (Carc. 1B)	0.0009-0.012 (DA=0.002)	NIAS
				M-phenylenediamine (CAS no. 108-45-2)	Suspected to be Mutagenic (Muta. 2)	0.002 (ND)	NIAS
				PA 66	-	12.0-36.4 (Group MLV=5)	NIAS
				PA 6 (not including caprolactam)	-	1.2-10.78 (Group MLV=5)	NIAS
Polyethylene	85	57	1	Silver (CAS no. 7440-22-4)	Some data submitters indicate Toxic to Reproduction, Repr. 2, STOT RE 2	0.0289-0.6 (SML(T)=0.05)	Active substance
Polyvinylchloride	13	11	0	-	-	-	-

FCM	Database entries	Chemicals in FCCmigex	>2 database entries	Prioritised chemicals	Hazard data	Range of migration (mg/kg food)	Use
Stainless steel	90	20	11	Nickel (CAS no. 7440-02-0)	Suspected to be Carcinogenic (Carc. 2), STOT RE 1	0.009-0.714 (SRL=0.14)	Alloying element
				Cadmium (CAS no. 7440-43-9)	Carcinogenic (Carc. 1B), Suspected to be Mutagenic (Muta. 2), Suspected to be Toxic to Reproduction (Repr. 2), STOT RE 1	0.00002-0.009 (SRL=0.005)	NIAS
				Lead (CAS no. 7439-92-1)	Toxic to Reproduction (Repr. 1A), Some data submitters indicate they consider this substance as Carcinogenic	0.00184-0.0303 (SRL=0.01)	NIAS
				Cobalt (CAS no. 7440-48-4)	Carcinogenic (Carc. 1B), Suspected to be Mutagenic (Muta. 2), Toxic to Reproduction (Repr. 1B)	0.0023-0.066 (SRL=0.02)	Alloying element
Silicone	308	167	11	Cyclic siloxanes	Suspected to be Toxic to Reproduction (Repr. 2)	0.155-2500.0 (SML=1.5)	NIAS
				Aniline (CAS no. 62-53-3)	Suspected to be Carcinogenic (Carc. 2), Suspected to be Mutagenic (Muta. 2)	0.00154-0.0027 (DA=0.002)	NIAS

[1]No entries for tritan could be found in the FCCmigex database. Studies investigating the migration of chemicals from tritan were identified and several migrating chemicals were found but none of which met the prioritisation criteria.
Abbreviations: DA, detectable amount; ED, endocrine disruption; MLV; migration limit value; NIAS, non-intentionally added substance; ND, not detectable, SML, specific migration limit; SML(T), total SML; SRL, specific release limit; STOT RE, specific target organ toxicity - repeated exposure; -: not applicable.

4.2.5 Additional considerations

In addition to the chemicals migrating from the FCMs, increasing the re-use of FCMs can result in increased exposure to dishwashing liquids since the products are washed and reused as opposed to thrown away directly. Notably, exposure to dishwashing-related chemicals is already apparent due to reusing and dishwashing tableware and cutlery in the home and at restaurants.

The composition of dishwasher liquids often includes surfactants, disinfectants, preservatives, solvents, and fragrances. Many of such chemicals have associated adverse effects on health (Ramirez-Martinez, Wesolek et al. 2014, Sanidad, Xiao and Zhang 2019, Ogulur, Pat et al. 2023). One study detected a total of 1145 dishwasher related chemicals in tap water from reusable glass and plastic bottles (Tisler and Christensen 2022). However, flushing with cold water almost completely removed these chemicals from glass bottles in this study. Overall, enough water should be used to rinse reusable FCMs after dishwashing to ensure minimal detergent residues remain on the surface (Zhao, Dong et al. 2017).

4.3 Microbiological evaluation

Straws, cups, beakers and bottles made of plastics, silicone or stainless steel can become a favourable environment for bacteria when they are reused without proper cleaning and sanitisation. The uneven surface in combination with moisture and residual organic material like sugars and proteins from e.g. beverages, smoothies and shakes might promote the growth of microorganisms, leading to contamination (Liu, Wang and Hu 2023).

Stainless steel food contact surfaces seem to be less adherent for bacteria than silicone or plastics, but plastic surfaces are easier to clean (Sinde and Carballo 2000). Although no significant difference could be found between daily or monthly cleaning of stainless steel water bottles used for water (Tabaco 2018), biofilms can be formed over time on rough, but not polished, stainless steel surfaces when nutrients are available from left-over sugary drinks (Lomander, Schreuders et al. 2004). This can present possible health concerns since harmful bacteria can reside in biofilms.

When products are reused but not shared with other people, this contamination will most probably not result in a health safety issue as the source of contaminating microorganisms is the user themself. Sharing reusable products with other people might give a potential microbiological safety issue, but only when one of the users carries a pathogenic microorganism (Hubbard, Newire et al. 2020). Reusing products made of plastic, stainless steel or silicone is rather a hygiene issue than a matter of public health. The potential safety issues associated with reuse will be similar to reusing tableware and cutlery which has already been done at home, in restaurants or at festivals for a long period of time.

Reusing straws, cups, beakers and bottles can lead to physical wear and tear, such as scratches and cracks. Plastics are more prone to wear and

tear than stainless steel and silicone. Imperfections can harbour bacteria and make it harder to clean the bottles effectively (Verran, Rowe et al. 2000). However, assuming that 1) a person's saliva contains no or low numbers of pathogenic microorganisms of which outgrowth is limited, and; 2) that present bacteria in reusable products most likely originate from the user themself, the reuse of products, with or without scratches or cracks, does not form a significant (additional) microbiological safety issue compared to the use of SUP.

4.4 Physical evaluation

Replacing single-use straws with stainless steel or hard plastic straws can cause an increase in fall-related injuries. Falling while using a stainless steel straw to drink may result in injuries such as cuts, bruises, and fractures, especially to the face and mouth. There are a few rare cases in which young children sustained injuries from falling with stainless steel straws, such as perforation of the neck or oropharynx (Duggan, Theron et al. 2016, Tsivitis, Kozlowski et al. 2023) and soft tissue trauma (Reina 2020). Especially when used with lids or in bottles with a narrow head that prevent movement of the straws, falling while using straws can cause injury.

Biting or clenching down on (single-use) drinking straws is common behaviour for young children. Accidental biting down on reuse stainless steel or hard plastic straws can potentially be harmful for teeth and damage dental work, like crowns or fillings. Although no case studies could be found, product recalls following reports of children being hurt from mouth lacerations caused by stainless steel straws have been reported (U.S. Consumer Product Safety Commission 2016). There are also a few cases of metal water bottles causing tongue entrapment in children (Whited, Rocke and Lee 2011). Furthermore, small metal, silicone or plastic components or detachable parts, such as silicone attachments on some stainless steel drinking straws, may pose a choking hazard for young children.

Over time, reusable straws and coffee cups made of metal, silicone, or plastics can become more prone to breakage or fractures due to repeated use and accidental drops (Verran, Rowe et al. 2000, Winkler, Santo et al. 2019). These physical defects can lead to sharp edges or small pieces of material breaking off, potentially posing a risk of injury, such as cuts or choking hazards. Stainless steel straws can conduct heat if they come into contact with very hot liquids, potentially causing burns on lips or fingers while using these straws.

However, it is noted that single-use paper straws may pose larger physical hazards as an alternative to SUP, as small pieces of paper coming loose during prolonged use may pose a suffocation risk for young children or susceptible adults (NVWA 2022).

5 Conclusions and recommendations

5.1 Conclusions

The EU faces a significant challenge with the generation and management of plastic waste. Food packaging constitutes a substantial portion of plastic usage, emphasising the need for sustainable alternatives. In response to this challenge, the EU has implemented a comprehensive strategy for plastics, aiming to revolutionise the lifecycle of plastic products. It advocates for reusable alternatives to SUP, better plastic recycling processes, and encourages the adoption of environmentally friendly materials.

The aim of this study was to investigate which reusable alternatives are available as FCMs on the Dutch market, what could potentially be human health safety issues associated with the use of these alternatives, and what materials or chemicals can be identified that would be of interest for further investigation or future action. Thereto, the following three research questions were addressed:

1. *What reusable FCMs are available on the Dutch market as alternatives to SUP?*

An extensive market search was undertaken to compile an inventory of reusable FCMs available in the Netherlands, with a specific focus on four product categories. The inventory accounted for cases where products comprised of multiple materials. As a result, some products consisted of various materials that came into contact with food. The materials found per product category are listed below:

- Straws category: stainless steel was found to be the most common material, followed by silicone, plastic, bamboo and glass.
- Tea/coffee cups category: plastic was most often used, succeeded by silicone, stainless steel, bamboo, glass, ceramic, cardboard and wood.
- Drinking bottles: plastic was the most common material used, followed by stainless steel, glass, silicone, bamboo and sugarcane.
- Party/festival cups category: plastic was most often used, followed by stainless steel.

Overall, plastics were the most prevalent material across all four categories. The market search uncovered that the specific type of plastic used in reusable products was not specified in approximately half of the cases. In the other half, the types specified included polypropylene, melamine, polyethylene terephthalate, tritan, polystyrene and polycarbonate. Three other plastic types were additionally identified in the FCCmigex database, namely polyamide, polyethylene and polyvinylchloride. Stainless steel and silicone were the second and third most identified materials, respectively. Consequently, plastics, stainless steel and silicone were singled out for a more comprehensive examination of their chemical migration and toxicological properties. All

other materials were not further assessed (including glass, bamboo, ceramic, cardboard, wood and sugarcane).

In addition to a toxicological evaluation, a microbiological and physical evaluation of potential issues associated with the use of these three materials (plastics, stainless steel and silicone) were conducted. The evaluation of plastics concerned the nine polymer types mentioned above.

2. *What potential toxicological, microbiological and physical safety issues could be associated with the use of these reusable FCMs?*

Toxicological safety issues
A review of the scientific literature on hazard and migration information on the three selected materials was undertaken to investigate 1) whether these materials contain chemicals with hazards and properties of concern relevant for human health; and 2) whether these chemicals can migrate into food in amounts surpassing the set SMLs. This with the aim to identify the materials and chemicals which could potentially present a toxicological safety issue, and which would therefore be priority candidates for further research. Based on the available migration and hazard information, we prioritised chemicals with >2 database entries in the FCCmigex database, migration concentrations above SMLs and relevant harmonised hazard classifications or properties of concern for FCMs.

A total of 20 different chemicals were prioritised across the material types. For plastics, in total 17 priority chemicals were identified for five out of the nine polymer types investigated. These concerned one chemical for polyethylene plastic (silver), two chemicals each for polypropylene (silver and dibutyl phthalate), melamine (resin) (melamine and formaldehyde) and polycarbonate (bisphenol A and dibutyl phthalate), and 10 chemicals, all NIAS, for polyamide (4,4'-methylenedianiline, aniline, PA 66, PA 6 (not including caprolactam), 2,4-toluene diamine, 3,3'-dimethylbenzidine, 2,6-toluenediamine, O-anisidine, O-toluidine and M-phenylenediamine).

No chemicals were prioritised for the remaining four polymer types: titan, polyethylene terephthalate, polystyrene and polyvinylchloride.

For stainless steel, four heavy metals were prioritised (nickel, cadmium, lead and cobalt). Furthermore, two chemicals were prioritised for silicone FCMs (cyclic siloxanes (D3-D18) and aniline).

Overall, it can be concluded that the reusable FCMs investigated potentially pose toxicological safety issues, as there are in total 20 different harmful chemicals that can migrate from them into food in amounts exceeding the set SMLs. Polyamide was the FCM with the highest number of harmful migrating chemicals exceeding SMLs. Three of the 20 prioritised chemicals (silver, dibutyl phthalate and aniline) were prioritised for more than one material.

Microbiological safety issues
Reusing products made of plastics, silicone, or stainless steel introduces a potential bacterial contamination risk. The combination of irregular surfaces, moisture and residual organic materials from beverages can foster microorganism growth. However, it is concluded that reusable FCMs are rather a hygiene issue than a matter of public health. The additional microbiological issues of reusable FCMs replacing SUP are considered to be low.

Physical safety issues
The use of reusable FCMs could potentially lead to an increase in fall-related injuries, particularly if a person falls while using a straw. Notably, incidents involving young children sustaining injuries from stainless steel straws have been documented. Additionally, there are concerns regarding potential dental harm, especially among young children who may inadvertently bite down on these more rigid straws. Ultimately, the choice of reusable materials should be made with consideration of potential safety implications, especially for vulnerable populations, and appropriate usage guidelines should be followed.

3. *Which reusable FCMs would be relevant candidates for further investigation or future actions?*

Within the limits and possibilities of our research, we have identified the following materials as relevant candidates for further investigation as they potentially pose toxicological safety issues: stainless steel, silicone and the plastics polypropylene, polycarbonate, melamine (resin), polyethylene, and polyamide. Especially polyamide seems a good candidate, as it had a considerably higher number of prioritised chemicals compared to other FCMs (see Table 12, Section 4.2.1.3.7). Interestingly, polyamide was identified from the FCCmigex database, it was not a plastic polymer identified in products found in the market search. The latter does not necessary mean that none of the products found in our market search were made from polyamide, as more than half of the products were made from unspecified plastic.

In addition to the materials mentioned above, we consider two other materials relevant candidates for further investigation. The first one is tritan, even though it did not meet the prioritisation criteria. Tritan is, however, a relatively new material and consequently limited research into e.g. migration has been conducted so far. For instance, tritan was not included in the FCCmigex database at the time of this research. Hence, it is not clear at the moment whether tritan could potentially pose a toxicological safety issue.

The second one is polyethylene terephthalate. This material also did not meet the prioritisation criteria. It is noted though that compared to other FCMs, the number of database entries was lower for polyethylene terephthalate. This could be due to the fact that it is mostly used for single-use FCMs. Nevertheless, as it is also used in reusable FCMs, further investigations into this material could be relevant.
Reusable products made from polystyrene and polyvinylchloride are not considered relevant candidates for further investigation since a

transition away from their use in FCMs is ongoing due to environmental and health concerns associated with these materials.

5.2 Recommendations

5.2.1 Toxicological

Screening tests could be recommended to determine whether the prioritised chemicals (see Table 16, Section 4.2.4) actually migrate from the respective FCMs (especially polyamide) available on the Dutch market, and to what degree this migration occurs. With additional migration data for these materials, more insight is gained into the level of exposure of harmful chemicals migrating from them, and whether or not these levels could potentially present a health risk. Furthermore, enforcement actions could then be directed at those chemicals with migration above their regulatory SMLs.

Further research on migrating chemicals from reusable tritan and polyethylene terephthalate could be recommended since there is a lack of (relevant) research on this topic which does not necessarily imply that no hazardous chemicals migrate.

For some chemicals, no SML or other MLV could be identified. This was especially the case for NIAS whereby an SML should be considered on a case-by-case basis. In some cases, a default MLV of 0.09 mg/kg food for non-genotoxic chemicals can be applied based on the Threshold of Toxicological Concern approach which is not substance specific and may lead to an over- or underestimation of risk. In other cases, MLVs were self-derived by the authors of this report from previously established MTC_{tap} values in drinking water or based on other migration limit values found in the literature. Such limits are not legally binding. More research into deriving appropriate SMLs for chemicals which have no limit value could be a valuable step in better understanding their potential risk.

5.2.2 Microbiological

No recommendations are provided here since microbiological safety issues are deemed low.

5.2.3 Physical

A warning symbol could be recommended on the packaging of hard plastic, metal or glass straws, as walking or running while using these straws may cause injury upon falling (Figure 3).

Figure 3 Example of a warning symbol which could be used to inform the public on the risks of walking or running while using hard plastic, metal or glass straws (Reina 2020).

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7 List of abbreviations

ANSES	French Agency for Food, Environmental and Occupational Health & Safety
BEUC	European Consumer Organisation
BfR	German Federal Institute for Risk Assessment
BPA	Bisphenol A
CBVV	Dutch Commission for Safety Assessment of FCM
CES	Silicones Europe
CMR	Carcinogenic, Mutagenic and Reproductive toxic
CoE	Council of Europe
CoRAP	Community Rolling Action Plan
DA	Detectable Amount
DAA	Danish Agricultural Agency
DEPA	Danish Environmental Protection Agency
DTU	Technical University of Denmark
DVFA	Danish Veterinary and Food Administration
EC	European Commission
ECHA	European Chemicals Agency
ED	Endocrine Disruption
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
EU	European Union
FCCmigex	Database on Migrating and Extractable Food Contact Chemicals
FCM	Food Contact Material
FDA	U.S. Food and Drug Administration
IARC	International Agency for Research on Cancer
KEMI	Swedish Chemicals Agency
MLV	Migration Limit Value
MTC_{tap}	Maximum Tolerable Concentration at the tap
NA	Not Detectable
NIAS	Non-Intentionally Added Substances
NVWA	Netherlands Food and Consumer Product Safety Authority
OML	Overall Migration Limit
RIVM	National Institute for Public Health and the Environment
SML	Specific Migration Limit
SML(T)	Total Specific Migration Limit
SRL	Specific Release Limit
STOT RE	Specific Target Organ Toxicity – Repeated Exposure
SUP	Single-Use Plastics
SVHC	Substance of Very High Concern
UBA	German Environment Agency (Umwelt Bundesamt)
VWS	Ministry of Health, Welfare and Sport
WHO	World Health Organisation

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