Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2023)1/ANN2

Unclassified **English - Or. English**

27 February 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

ANNEX 1. Background Report - Government policies and regulations impacting the sustainable design of flexible food-grade packaging

Series on Risk Management
No. 76

This is an Annex that was prepared as a background report to the workshop held in Paris, 20-21 September 2022.

This document is available in PDF format only. The workshop report is available under the cote ENV/CBC/MONO(2023)1.

JT03513164

OECD Environment, Health and Safety Publications
Series on Risk Management
No. 76

ANNEX 2. Background Report - Government policies and regulations impacting the sustainable design of flexible food-grade packaging

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Paris 2023

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**OECD Environment Directorate,
Environment, Health and Safety Division
2, rue André-Pascal
75775 Paris cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

Note from the secretariat

This is an Annex to the report on the OECD Workshop on Flexible Food-Grade Packaging – Economic, Regulatory or Technical Barriers to Sustainable Design from a Chemicals Perspective – How Can Policy Makers Help?

Two background papers were developed to support the workshop discussions and are available as Annexes to the workshop report. Annex 1: Background Report - Barriers to sustainable design from a chemicals perspective for flexible food-grade plastic packaging – was developed by Partners for Innovation. Annex 2: Background Report - Government policies and regulations impacting the sustainable design of flexible food-grade packaging – was developed by Stena Circular Consulting.

The workshop report is available under the cote ENV/CBC/MONO(2023)1. The workshop report was endorsed for publication by the Working Party on Risk Management and is published under the responsibility of the Chemicals and Biotechnology Committee.

ANNEX 2. Background Report - Government policies and regulations impacting the sustainable design of flexible food-grade packaging

Background paper for the workshop

Developed for the OECD by Mats Linder | Stena Circular Consulting | April 2022

Mats Linder
Stena Circular Consulting
Tel: +46707352244

Executive Summary

This report aims to document policy approaches or initiatives that have been put into place (or are about to be put into place) to enable or incentivise *design of more sustainable plastic packaging from a chemicals perspective*. The work builds on several OECD reports published over the past few years, and adds insights derived from desk research and 18 expert interviews.

The report focuses *on flexible plastic packaging materials used for food packaging*. As such, these packaging materials are classified as Food Contact Materials (FCM), for which there are often specific regulations or policies. The primary geographical scope is the list of 38 OECD members (of which 22 countries are also members of the EU). The OECD definition of *sustainable plastics*, "plastics used in products that provide societal benefits while enhancing human and environmental health and safety across the entire product life cycle", is used as the reference point for what policy initiatives enabling or incentivising sustainable design should be driving towards.

It is well-established throughout numerous reports and research articles that on the one hand, flexible plastic packaging plays a crucial role in the present food system, by protecting and transporting food through the supply chain. On the other hand, the same flexible plastic packaging poses significant sustainability challenges, not least through its high waste volumes, complex reprocessing and the multitude of added and non-intentional chemical substances within the materials.

One of the biggest of these challenges is the ability to recycle flexible plastic food packaging into useful new materials, not the least new FCMs. This is partly a technical challenge at the product end-of-life, where collection, sorting and reprocessing technologies can improve; partly an economic challenge, where the cost of collection and reprocessing tend to exceed the price of virgin film (which can be kept low due to the small amount of material used); partly a *design challenge* since the way flexible plastic packaging is designed sets the limitations for how (and into what) it can be recycled. Chemicals play a large role in setting those limitations, particularly due to the challenges of information transparency and traceability as plastics move through the supply chain, and finally to the end-of-life stage.

The solution space for flexible plastic food packaging is as complex as the above-mentioned challenges, and it should be noted that recycling is one of several options to design for. This report briefly mentions reusable and refillable packaging, alternative materials (e.g., compostables), and chemical recycling.

Enveloping all of this are policies. Policies define the playing field and set the boundaries for how we may design and use plastic packaging and treat it at end-of-life. From a chemicals point of view, it should come as no surprise that a large body of policies within the OECD are regulations focusing on chemical safety, since FCMs can transfer chemicals into the food we eat. In general, where different sets of policy motives exist for chemicals in flexible plastics packaging, (chemical safety vs. recyclability or use of recycled content) chemical safety tends to get priority. One way in which this priority manifests itself is how the stringency of the EU Food Contact Directive (EU No 10/2011) makes it very difficult to use recycled materials in FCM plastics.

While a large share of identified policies regarding the design of flexible plastic food packaging from a chemicals perspective are regulations, the report also highlights and discusses a (non-exhaustive) list of other policy initiatives to illustrate how policymakers address the various challenges with sustainable design. These initiatives include, among others, *The EU chemicals strategy for sustainability, the EU circular economy action plan, the use of positive lists of substances, regulation for minimum recycled content, bio-based and compostable plastics initiatives, Incentives to grow reusable packaging, and innovation challenges (such as the 'Plastics Challenge' in Canada)*. Collectively, they illustrate that there is a broad range of policy initiatives to learn and take inspiration from. Given the complexity of the sustainable design challenge, it is reasonable to presume that an effective policy response must include several different initiatives, in a way that complement and balance each other.

Having gone through the body of policies available within the scope of this report, it is clear that there are several challenges where policies are either insufficiently clear or stringent today, or where different policy objectives might lead to contradictory design incentives.

- The most prominent theme is the challenge to of ensure robust *chemical safety* of flexible plastic FCMs, while also incentivising and facilitating *resource efficiency and circular economy*.
- Non-intentionally added substances (NIAS) is another difficult area to address. NIAS are abundant in plastic packaging, but the amount and (thus) hazard level is difficult to assess, it has proven difficult to create effective policy around these issues.
- Chemical safety of FCMs is generally evaluated with very low threshold concentrations, and without adjusting for the difference in processing and safety validation when using post-consumer recycled content. This has led some to argue that the current policy approach in many markets (particularly the EU) is hampering innovation of new recycling techniques and the use of more circulated materials.
- So far, chemical risk regulation has only relied on single-substance assessments, even though there is growing scientific evidence that a significant portion of the risk comes from mixture toxicity (the so-called 'cocktail effect), which is much more complex and difficult to measure comprehensively. In this context, the relatively widespread use of 'positive materials lists' leads to challenges with non-negligible risks flying under the radar.
- In general, most information about the chemical contents of plastic packaging is lost throughout its lifecycle, even though there are policies mandating such information to be passed on along the value chain. There is scope to share more information between stakeholders but maintaining confidentiality of proprietary information remains a challenge. A modern, simplified, and digitalized system could improve such information exchange.

The report concludes by listing three potential actions for improved chemical policies for flexible plastic food-grade packaging:

- Facilitate cross-regional alignment.
- Address practical and regulatory challenges with recycled plastics in food packaging.
- Create a robust framework for chemical traceability to align with more sustainable packaging.

It refrains from going deeper into discussing particular action to be taken by the OECD or its members, as this is the topic of the workshop this document is part of preparing.

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List of Abbreviations

AS	Australian Standard
BEIS	The Department for Business, Energy and Industrial Strategy
BOPP	Biaxially-oriented polypropylene
CAGR	Compound annual growth rate
CEFLEX	Circular Economy for Flexible Packaging initiative
CEPA	Canadian Environmental Protection Act
CFR	Council on Foreign Relations
CSS	Chemicals Strategy for Sustainability
Defra	The Department for Environment, Food and Rural Affairs
DoC	Declaration of Compliance
EC	European Commission
ECCC	Environment and Climate Change Canada
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
EVOH	Ethylene vinyl alcohol
FAP	Food Additive Petition
FCA	Food contact articles
FCC	Food contact chemicals
FCM	Food contact materials
FCN	Food Contact Notification Program
FDA	U.S. Food and Drug Administration
FP7	EU's 7th Framework Programme for Research and Technological Development
FPF	Food Packaging Forum
FSANZ	Food Standards Australia New Zealand
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practices
HD-PE	High-density polyethylene
HC	Health Canada
IASS	Institute for Advanced Sustainability Studies
JHAVDC	Japan Hygienic Association of Vinylidene Chloride
JHOSPA	Japan Hygienic Olefin and Styrene Plastics Association
JHPA	Japan Hygienic PVC Association
JPA	Japan Paper Association
JRC	Joint Research Centre
LCA	Life cycle assessment
MERCOSUR	The Southern Common Market

MHLW	Ministry of Health, Labour, and Welfare in Japan
NIAS	Non-intentionally added substances
NOM	Norma Oficial Mexicanas
OECD	Organisation for Economic Co-operation and Development
PA	Polyamide
PE	Polyethylene
PET	Polyethylene Terephthalate
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
PP	Polypropylene
PS	Polystyrene
PVC	Polyvinyl Chloride
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SML	Specific Migration Limits
SSbD	Safe and Sustainable by Design
ToR	Threshold of Regulation
UK	The United Kingdom
UKRI	UK Research and Innovation
US	The United States
WEEE	Waste Electrical and Electronic Equipment Directive

1. Introduction

Because of the widely recognised advantages, the use of flexible plastic food packaging is steadily increasing on a global scale, with sales of USD 233 billion in 2020 and projected growth to USD 300 billion by 2026, implying a compound annual growth rate (CAGR) of 4.37% between 2021 and 2026 [1]. In order to obtain its desired properties, flexible plastic packaging needs a significant number of additives, i.e., chemicals blended with the polymer resin. These intentionally used chemicals, together with non-intentionally added substances (NIAS) that are present in manufactured plastics, can migrate and pose a risk to human health and the environment. Some of the intentionally used chemicals in plastics have been tested to a limited extent for their hazardous features, but most of the NIAS have not been tested in this regard [2], [3]. While not all the substances are equally dangerous, some harm the immunological, respiratory, endocrine, reproductive, and cardiovascular systems. Furthermore, chemical pollution is one of the major factors endangering the world, increasing planetary crises such as climate change, biodiversity loss, and ecosystem degradation. Therefore, new materials must be fundamentally safe and sustainable, from production to end-of-life. [4]. Moreover, as there are generally multiple substances used in plastics, and since they can migrate together with the NIAS, the mixture toxicity of the entire migrating chemical mix (the so-called 'cocktail effect' [5]) remains unassessed, as there is currently no regulatory requirement for addressing it. At the same time, economies worldwide strive for more sustainable use of plastics, through increased reuse of materials as well as renewable and recycled content, emphasising the need to keep harmful chemicals out of the loop more than ever before [6].

Over the last three years, 83% of the legal measures linked to sustainable packaging worldwide have focused on plastics, with a total of 147 have been found, with the European Union and Asia having the most legislation [7]. Aiming to move to a resource-efficient circular economy across markets such as in the EU, policymakers are considering new regulations to incentivise more sustainable design of plastic packaging to improve human and environmental safety, for example through increased reuse of materials, renewable or recycled content. As such policies gain traction, the bar for what chemicals are allowed in the system rises. For instance, there is a growing awareness of the chemical hazards present in everyday materials such as flexible food-grade packaging. And when economies start increasing plastics recycling, legacy chemicals (banned hazardous substances which are still present in the material loop) account for an additional concern since they may remain in the system for long time periods after their final use.

In the field of food packaging, different policy objectives for sustainability run the risk of working against each other. One illustration is an approach demanding a minimum quota of recycled content in products (such minimum requirements are, for example, considered by the United Kingdom (UK) and France as well as California in the United States). However, legislation addressing safety of food-contact materials requires high levels of proven chemical integrity (such as the EU 10/2011 regulation), effectively creates a high barrier to the use of recycled content in food packaging [8]. While the worldwide packaging regulation is going through continuous revisions and changes, more than 80% of Europeans have been estimated to worry about the impact of chemicals in everyday products on their health and the environment [8].

This report is a part of the preparatory work of background material for the workshop *Flexible food grade packaging – Economic, regulatory or technical barriers to sustainable design from a chemicals perspective – How can policymakers help?*, organized by OECD. It builds on previous work done by the OECD to understand and disseminate how design, technology, and policy can be used to increase the sustainability of plastics and draws on the findings made in previous OECD reports, notably [9], [10], and [11].

1.1 Objectives of the report

This report aims to document policy approaches or initiatives that have been put into place (or are about to be put into place) by governments or other institutions, to enable or incentivise *sustainable packaging design from a chemicals perspective*. To this end, the following activities have been conducted:

- Desk research to identify policy approaches put in place to incentivise sustainable design across the life cycle of plastic packaging, including source materials, production, use, reuse, and end-of-life.
- Interviews with delegates from the OECD's expert group to identify relevant approaches and understand challenges, policy gaps, barriers, and potential solutions.
- Tabulation summaries of the identified approaches and developing a discussion about the findings.
- Compilation of the relevant research material into a structured report to support workshop discussions.

1.2 Scope of the report

1.2.1 Product and application scope

The report focuses *on flexible plastic packaging materials used for food packaging*. Materials used to package food are among those commonly referred to as Food Contact Materials (FCM) (Figure 1). With 'plastic materials', we refer to materials where the entire or a significant part of the bulk is one of the conventional thermoplastic polymers () novel polymeric materials generally identified as plastics (e.g., PLA, the PHA-group), or multi-layer flexible films. With 'substances' or 'starting substances' we refer to the individual chemicals comprising these plastic materials.

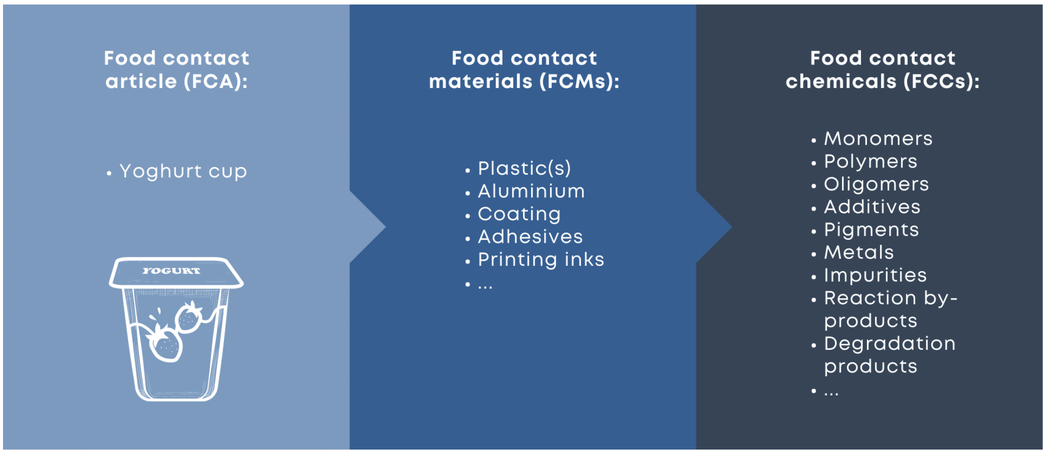

Figure 1. "Explanation of key terms. Food contact articles (FCAs) are combinations of different FCMs, which consist of food contact chemicals (FCCs) (e.g., a yoghurt cup made of polystyrene with printing inks and a coated aluminium cover glued on with adhesives). Food contact materials consist of mixtures of many FCCs. Food contact chemicals are defined as substances used and/or present in the manufacture of FCMs and/or present in FCMs and/or FCAs. Some FCCs are starting substances that no longer exist in the FCM/FCA. Some FCCs are generated during the manufacture of an FCM/FCA. Not all FCCs require an authorization, and they are not necessarily subject to risk assessment by an authority." (adapted from [12]).

1.2.2 Geographical scope

The geographical scope of the project primarily focuses on the OECD member countries. However, the research has not been exhaustive in the sense that the policies of each member country have been systematically and comprehensively researched.

1.3 Sustainable plastics

As defined by the OECD, *sustainable plastics* are "plastics used in products that provide societal benefits while enhancing human and environmental health and safety across the entire product life cycle" [13]. Sustainable plastics should limit the creation of waste, toxins, and pollution from their inception to their next use or end-of-life. They should thus have a reduced (negative) impact on the climate, help promote a more circular economy, and help meet the objectives of the United Nations' Sustainable Development Goals.

2. Methodology

2.1 Research approach

The complexity of policy mapping is explicitly described in the report *Non-harmonized food contact materials in the EU: regulatory and market situation* by the Joint Research Centre (JRC) of the European Commission. Unclear relationships between national rules, national documents of questionable legal nature, cross-referencing between legal documents, regulations in various languages, and various databases listing thousands of chemical substances were some of the major challenges reported, all of which were encountered during the present research project. While the scope of this work is narrower and focuses on policies incentivising more sustainable flexible food packaging design, it is worth mentioning that it took two years to compose the aforementioned paper [14].

The information for the present report was acquired by interviews with experts from various OECD countries, coupled with extensive desk research of relevant policies by the research team to map relevant policy initiatives. A complete list of the interviewees can be found in Appendix A.

22 of the 38 OECD member countries are EU members, where EU regulation on chemicals in plastic FCMs is central. Therefore, the policy research focused on two major country groups, one consisting of the EU countries, and one consisting of a non-exhaustive selection of remaining countries. It should be noted that the scope of this work has not allowed for an exhaustive deep-dive into national legislation on chemicals in plastics for each country Instead, the team attempted to cover the major policy themes with an outlook of obtaining insights into the gaps that exist between present policies and sustainability ambitions going forward.

2.2 Methodological framework

2.2.1 Policy categorisation

For the purpose of clarity, policies were categorized (to the best effort) as an adaptation to the types of measures presented in the OECD Paper *Policy Approaches to Incentivise Sustainable Plastic Design* [15]. Each identified policy initiative was categorized based on whether it is a regulation governing the use of plastics in FCM packaging, a policy governing the use of recycled plastics in FCM packaging or a voluntary standard or guideline (Table 2).

Table 1 shows a representation of types of policies versus different aspects of sustainable design they might incentivise. Based on what the research team has and hasn't found in the interviews and documentation, the relative prominence of these aspects is presented as a 'heatmap'.

One can infer from the heatmap that health and safety is the most prominent design incentive identified, while for example recycled content and design simplifications are only somewhat covered by voluntary standards and guidelines today.

Table 1. Aspects of policies for sustainable plastics design. Ranking order: Dark blue: Broadly addressed – White: Not addressed

TYPES OF INCENTIVES FOR SUSTAINABLE DESIGN	REGULATION	POLICY/INCENTIVES TO USE MORE SUSTAINABLE MATERIALS & DESIGN	VOLUNTARY STANDARDS OR GUIDELINES
Renewable content			
Recycled content			
Novel materials			
Benign manufacturing			
Health & Safety for users			
Design simplifications			
Material/Chemical transparency			
Environmental protection			

2.2.2 Summary of research and data gathering

The main frames of regulatory policy are relatively straightforward to come by. It should be noted that regulations concerning the specifics of chemical use in flexible plastic food packaging are always embedded in broader legislative pieces, such as the European Commission (EC) regulation EU 10/2011 on plastic materials and articles intended to come in contact with food. As such, it is challenging to determine exactly what part of such policy explicitly concerns the use of chemicals and what is more of an implicit effect of the policy, or if there are elements of the policies influencing (explicitly or implicitly) the sustainable design of flexible food packaging from a chemicals point of view. As is reflected in this report, the main body of legislation in OECD countries concerning plastics deals with health and safety on the one hand, and environmental protection on the other. 'Sustainability' does not seem to be an explicit goal for policies regarding chemicals in plastics, historically. Therefore, much of the identified incentives for sustainable plastics design are rather implicit in the two policy areas mentioned above *when looking specifically at the chemicals perspective.*

Even though the EU regulation governing the use of chemicals in plastic FCMs is harmonized, meaning that all member states must comply with it, they can follow additional national regulations when they are able to present arguments to support their request. However, given the time constraints of this work and the fact that most EU member countries follow the central EU directives, the team has not gone into depth to explore modifications to these policies imposed by additional national regulations.

Policy documentation has been complemented by additional references, both OECD-produced reports and independent, third-party reports and academic publications.

18 experts were interviewed for this report, as per the interview list provided in Appendix A. Their area of work ranges from policy officers at authorities such as environmental protection agencies to researchers at institutes or non-governmental organisations. The core of the expert group was provided by the OECD while a small number of additional people were added, either by recommendation from other interviewees or identified by the research team.

Overall, the interviews coupled with the researched documentation provided a good overview of current and ongoing policy initiatives for sustainable flexible food packaging design from a chemicals perspective. However, it cannot be claimed to be fully exhaustive. Due to the limited scope and timeline of this project, not all possible documentation or interviews have been pursued in full.

3. Results

3.1 Technical landscape – Flexible food packaging

Flexible plastic packaging is an important part of the modern world which helps ensure that products reach consumers safe and fresh, preserving nutrients, taste, and quality. Being lightweight and thin, flexible packaging reduces transportation emissions, prolongs the shelf-life of the packaged products, has a relatively low price, and uses far less material than alternative packaging [16]. For these reasons, flexible plastic packaging has been the fastest-growing packaging category in recent years in terms of market size. According to Circular Economy for Flexible Packaging (CEFLEX), 50% of food packaging is flexible food packaging and its global demand grew by 56% between 2010 and 2014 [17].

At the same time, the heavy increase in single-use plastic consumption, its expected continual growth, and insufficient waste management systems contribute to the problem of plastic pollution [18]. Only 9% of plastics are recycled globally, and roughly 90% of recycled plastics are transported from affluent countries to developing countries, where waste management facilities are often inadequate. And while single-use plastic might have a lower environmental impact during production, transportation or reduced input resources, other aspects such as the end-of-life or the effect on marine and terrestrial species have to be taken into account. Continued production of single-use plastics will not stimulate more sustainable resource use, while retaining 'business as usual' will intensify global plastic waste mismanagement [19].

In addition, flexible packaging can be very complex in terms of composition and chemical content, as well as coming in a vast variety of mono- and multi-material variants, making it a challenge for regulators, consumers, and the recycling system. Due to environmental concerns, policymakers, as well as industry initiatives now, try to overcome these challenges and deliver a circular economy for flexible food packaging.

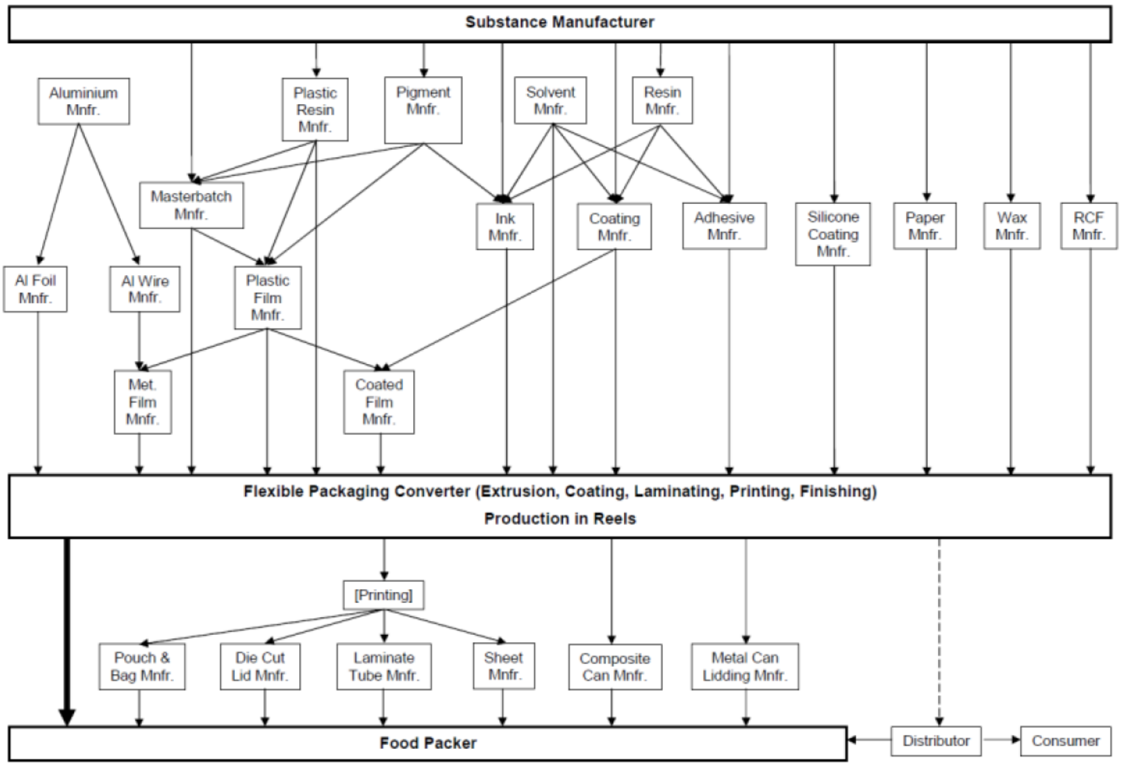

Figure 2. The supply chain for the flexible plastics sector as represented by Flexible Packaging Europe [14].

A recent summary of the current state of play for plastics by the OECD points to several concerning trends which, with flexible plastics packaging being a such a significant part of the market, are especially relevant for this category [9]:

- Despite a host of commitments and 5+ years of spotlights on the challenges of single-use plastics, the plastics value chain remains largely linear.
- Plastic production and waste generation continue to grow, and the COVID-19 pandemic has increased plastic waste generation to new high levels.
- Significantly increasing the demand for secondary plastics is seen as a critical driver for reducing plastics leakage, yet secondary plastics production contributed to only 6% of total plastics production in 2019. Boosting demand through various policy measures, including supply 'push' and demand 'pull' are seen as key levers.
- The chemical content of plastics remains a significant challenge when trying to use more secondary plastics in packaging. This is especially true for food packaging. Irrespective of what might be legally allowed (e.g., under the European FCM regulation (EC) No 1935/2004 or recycled plastics regulation (EC) 282/2008), the technical difficulty of knowing the chemical composition of secondary plastics, and whether it is safe in contact with edible goods, is a large deterrent.

3.1.1 Most common flexible plastic food packaging by type and use

By material type, the global flexible plastic packaging market is segmented into polyethene (PE), polypropylene (PP), polyvinyl chloride (PVC), polystyrene (PS), polyethene terephthalate (PET), polyamide (PA), and ethylene vinyl alcohol (EVOH). Among these, the BOPP (Biaxially-Oriented Polypropylene) material sees the highest demand. These materials are used for packaging e.g., potato chips, packing snacks, reusable woven bags for shopping, in labels, and wrapping films [20].

Some common applications for flexible packaging polymers are [21]:

- High-density polyethene (HD-PE) is used in applications such as containers, milk bottles, food bags, cereal box liners, and wrapping films.
- PP is used in films such as confectionery wrappers.
- PVC is used in, films (cling film) and sealing gaskets;
- While PS mostly finds use in rigid plastic food packaging it is also used in its flexible form, due to its breathability, for packaging fresh food products.
- PA is used in demanding applications because of its good barrier properties and high-temperature resistance and is used for boil-in-the-bag applications.
- PET is used in high-barrier films and containers used for oven applications.
- EVOH is known for having superior barrier properties which makes it particularly suited as a barrier layer when packaging food, drugs, cosmetics, and other perishable products.

3.1.2 Chemicals in flexible plastic food packaging

There are currently more than 4,000 known chemicals that are possibly used in the manufacturing of plastic packaging or present in the final packaging articles [22]. In order to improve the characteristics and functionality of the polymers, an array of chemical additives is used in plastics. Apart from the known chemicals, NIAS are found in plastics as reaction by-products, breakdown products, or contaminants [20] (Figure 3).

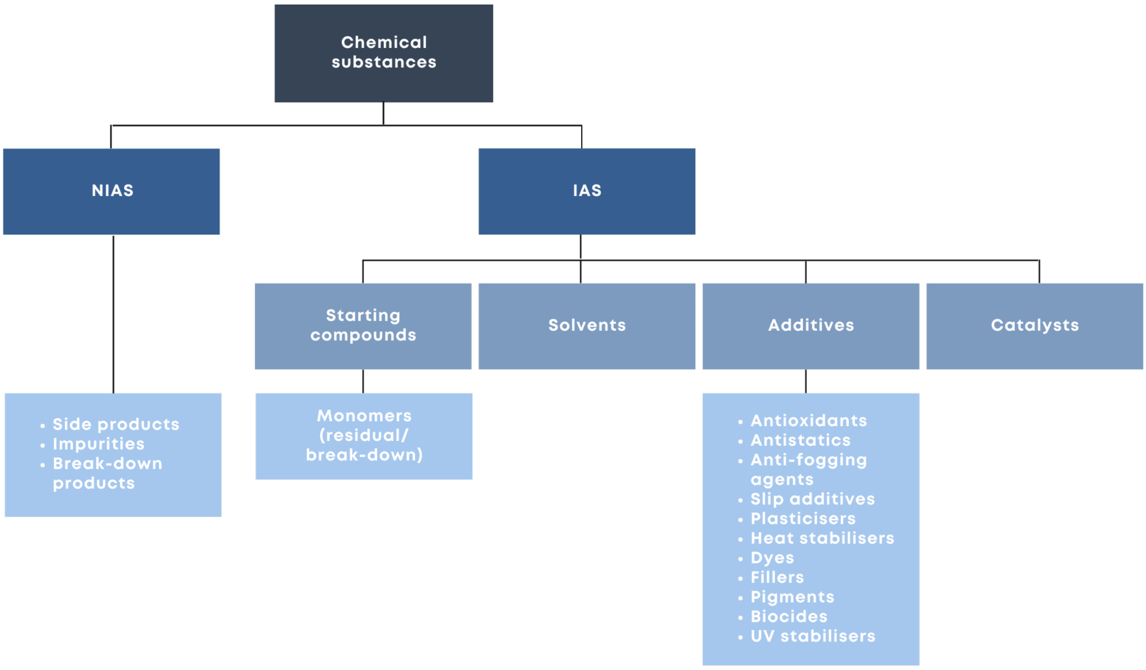

Figure 3. Classification of possible chemical substance migrants from food packaging (adapted from [23]).

Potentially hazardous substances that can leak from plastic food packaging in foodstuffs are [24]:

- **Monomers**: plastic polymers are built from smaller monomers, several of which are hazardous. Leakage might occur due to either incomplete polymerization during material formation or material degradation over time [25]. Bisphenol A, S and F, melamine, acrylamide, styrene, and vinyl chloride are some examples of hazardous monomers. However, not all of them are forbidden if they are bound in the final product and/or stay below the migration limit.
- **NIAS:** may be present as impurities in the starting materials in plastics manufacture, as reaction intermediates formed during the polymerization processes, or as decomposition or reaction products formed during polymerization to make the plastics or during thermal processing of the plastics to make the packaging. The two categories of NIAS are the known NIAS, although unintentionally added, and unknown NIAS with unknown structure and identity [18].
- **Plasticisers**: also known as softeners, are added to the polymers to increase flexibility, mainly for PVC. Phthalates, several of which are known to be hazardous, are a type of widely used softeners. The amount of plasticisers added to a plastic material can be high, up to 30–40% by weight. As the phthalates are not bound in the polymer, they leak out over time and large amounts can remain present after recycling. Specifically for PVC, there is an increasing concern about its use in food packaging, and many companies such as Danone and Nestlé are trying to avoid it or phase it out. However, PVC (including softeners) is still an authorized material for food contact packaging in the EU [26].
- **Stabilisers**: help preserve the material from degradation due to light, for example. Toxic heavy metals such as lead and cadmium are known to have been used in the past, as well as UV filters such as benzophenones, which are hazardous.
- **Surfactants**: are used to change surface properties. Common surfactants include the problematic family of PFAS chemicals and alkylphenols.

3.1.3 Flexible plastic food packaging: a recycling challenge

Recycling challenges for flexible food packaging are covered in a parallel report in the present work. Therefore, the issues will only be briefly mentioned here, mainly to create a comprehensive backdrop for understanding different policy initiatives.

The numerous types of flexible plastic packaging in use, make it a formidable challenge to the recycling industry. The increasingly common multi-layered laminates are technically difficult to separate and even when one manages to create homogenous material flows, the low weight of flexible films undermines the economics of the secondary materials produced. This has led to most markets not recycle flexible food packaging, but rather incinerate or landfill them [27].

If flexible plastic packaging were to be recycled which is part of the desired outcomes in the OECD definition of ‘sustainable plastics’, additives and NIAS pose a challenge by limiting the possible applications of the recycled material. The chemical content of a new product with recycled content depends not only on what is added during the production process but also on what is already present in any recycled material.

By using mechanical recycling, most chemical content already present in the input material will stay in the recycled material as well. This means that the chemicals already present in the system mix and spread over the recycling cycles – potentially leading to an accumulation of chemicals. The only profound ways to tackle this issue are to:

1. phase out chemicals of concern from the production of new plastics as soon as possible and consider recyclability, including chemical content, right from the design stage [8];
2. develop authorized methods to decontaminate plastics from chemicals as part of a recycling stage [28], [9].

As has been extensively reported and commented [9], [27], [28], (thermo)chemical recycling is seen as a new possible pathway for especially flexible films, which would allow, i) the breakdown of complex and mixed plastic grades to feedstocks that can be processed into new materials, and ii) the ability to produce (formally) recycled plastics of virgin-grade quality. This proposition relies on a rapid multi-billion-dollar investment in new thermochemical recycling capacity on the one hand, and on the ability to make recognizable claims about recycled content (through, e.g., a standardized mass-balance protocol) on the other, even if reprocessing of chemically recycled feedstock generally does not allow full traceability of substances through the petrochemical processes yielding new plastics. The latter is currently a contentious issue where policymakers can have a say in determining the outcome. In addition, two unanswered questions linger:

- The ability of chemical recycling to be truly complementary to mechanical recycling by taking low/mixed grades as inputs. Several of the many start-up operators are communicating that they need high purity and low contamination of inputs, which would essentially make them compete for the same material as mechanical recyclers.
- The energy use and subsequent GHG emissions are high since the thermochemical process burns light fractions from the output to fuel the process. The few LCAs published thus far seems to indicate an end-to-end material yield of ~50% and life-cycle emissions lower than incineration but significantly higher than for mechanical recycling.

Considering the current and potential future endpoints, sustainable design from a chemicals perspective is clearly a factor since it determines if (or how much) of hazardous chemicals are generated upon incineration, landfill, or (chemical) recycling. If one adds the technical possibility of using (some) mechanically recycled content in flexible plastic films, the transparency challenge is perhaps the most important to consider.

3.1.4 The future of sustainable flexible plastic food packaging

In summary, the (non-exclusive) options on the table for flexible food packaging to be designed as sustainable as possible are:

- **Sourcing & manufacturing**
  - Choose primary renewable (or chemically recycled) feedstocks to decouple the use of virgin-grade material use from fossil feedstocks.

  - Select chemicals and manufacturing processes to eliminate or minimize occupational exposures and releases to the environment.
- **Use phase**
  - Improve safety and environmental compatibility of adhesives, inks/pigments, and other additives, and consider the trade-offs between convenient use and non-hazardous resource-efficient sourcing/end of life in a choice of packaging design.
- **End of life & recycling**
  - Keep the lightweight single-use paradigm and opt for feedstocks made of renewable, sustainably sourced carbon or made with (chemical) recycling. Chemical safety mainly concerns emissions incineration, landfill leakage or chemical recycling, or any chemical migration into food that happens during the use phase. Consider allowance for substitution to certified compostable plastics in markets where appropriate collection and processing infrastructure are in place and aligned with standards.
  - Build robust protocols for using and validating safe recyclable content in single-use, flexible food packaging, while incentivising markets on both the demand side and by pushing packaging design towards easier-to-recycle materials (such as mono-materials with minimum amounts of colourants and inks, coatings compatible with the recycling process, etc.).
  - Substitute those business models relying on single-use plastic packaging with novel business models that use deposit-return schemes, for products packaged in low migrating, inert, and permanent packaging materials (suitable for refilling, reusing, and closed-loop permanent recycling).

A more detailed account of all design considerations along the different life cycle stages can be found in a recent OECD case study [29].

In addition to policies targeting incentivising sustainable use of chemicals and information transparency, policies targeting any of the above areas are also of significant importance for the chemical used in flexible food packaging [28, 9].

3.2 Mapping of policy approaches and initiatives

Following the framework presented in a recent OECD report *Policy Approaches to Incentivise Sustainable Plastic Design*, a first observation when mapping policies for chemicals in plastic packaging is that they predominantly target the sourcing and/or end-of-life of the material. This should come as no surprise since chemical regulation is most directly applicable to the point in the value chain when a chemical is added to a material or product (sourcing), or when governing what may or may not be done with an end-of-life material containing chemicals [11].

An overview of the key policy initiatives identified in this work is given in Table 2, which is complemented by the aggregated heatmap in Table 1. One notable aspect is that the overwhelming majority of identified policy initiatives are of the 'regulation' type (again using the categorization from), and the general consensus from interviews seems to be that regulation is the most effective form of policy for use of chemicals in sustainable plastics design. As for the implementation of the policies, financial penalties (e.g., taxes, fines, and fees) represent the main and preferred strategy for sustainability change in the packaging industry, compared to subsidies [7].

However, more and more markets have introduced or consider introducing policies to boost demand for recycled plastics. This affects the approach to chemicals since recycled plastics will (in general) also bring chemicals in the form of additives, as well as NIAS [8], [30]. For this reason, policies considering the use of recycled plastics have also been included in Table 2. Finally, to the extent they have been found, Table 2 also documents voluntary standards or guidelines, which are regarded as policy initiatives here if they come from a governmental institution.

A more detailed review of relevant policies for the sustainable design of flexible food packaging can be found in Appendix B.

Table 2. Overview of relevant policy initiatives concerning chemicals in flexible plastic food packaging.

POLICY INITIATIVES COVERING CHEMICALS IN FLEXIBLE PLASTICS FOOD PACKAGING	REGULATION	POLICY / INCENTIVES TO USE MORE SUSTAINABLE MATERIALS & DESIGN	VOLUNTARY STANDARDS OR GUIDELINES
EUROPEAN UNION	– (EC) No 1935/2004 on materials and articles intended to come into contact with food – (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food – (EC) No 10/2011 on plastic materials and articles intended to come into contact with food – (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) – (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food – (EC) No 1895/2005 on the restriction of the use of certain epoxy derivatives in materials and articles intended to come into contact with food – Commission Directive 93/11/EEC concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers – (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods	– Market-based incentives such as Extended producer responsibility, Pay-As-You-Throw schemes, Deposit Refund Systems for beverage bottles, and Environmental Taxes on plastic) – including: • for Sustainability • which, among others, aims to clarify the role of biobased, biodegradable and compostable plastics • Farm to Fork Strategy that will revise the FCM regulation – (EU) No 2019/904 'Single-Use Plastics Directive' on the reduction of the impact of certain plastic products on the environment	– National PVC bans – Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain – CEFLEX's 'Designing for a Circular Economy' guidelines
UNITED KINGDOM	– The Materials and Articles in Contact with Food Regulations 2012 including retained EU legislation: • England • Scotland • Wales • Northern Ireland	– Plastics Packaging Tax came into force in April, 2022	– WRAP's Considerations for Compostable Plastic Packaging – UKRI's Policy brief on Compostable Plastics – Strategy for Substitution to Compostable Flexibles by Ellen MacArthur Foundation

POLICY INITIATIVES COVERING CHEMICALS IN FLEXIBLE PLASTICS FOOD PACKAGING	REGULATION	POLICY / INCENTIVES TO USE MORE SUSTAINABLE MATERIALS & DESIGN	VOLUNTARY STANDARDS OR GUIDELINES
UNITED STATES	– Code of Federal Regulation, Title 21, Food and Drugs – State PVC bans – State PFAS bans (Federal ban under discussion) – State bans on compostable plastics		– Guidance document: Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations, published by US FDA – Guidance documents: Ingredients, Additives, GRAS & Packaging Guidance Documents & Regulatory Information, published by US FDA
CANADA	– Division 23 of the Canadian Food and Drug Regulations, Section B.23.001 – Prohibition of Certain Toxic Substances Regulations, 2012 – Proposed regulation for minimum recycled content for certain plastic manufactured items		– Voluntarily submission of FCMs to the Food Directorate (FD) – As a result of the above, No objection letter was issued by FD to assure the recipients' customers for chemical safety – Positive List of issued No Objection Letters for polymers on the Health Canada website – Guidance Document Information requirements for food packaging submissions – Guidance Document Guidelines for Determining the Acceptability and Use of Recycled Plastics in Food Packaging Applications
AUSTRALIA & NEW ZEALAND	– FSANZ Food Standard Code: Standard 1.1.1 (10, 12) and Standard 1.4.1		– Australian Standard AS 2070-1999 on Plastics materials for food contact use – National Compostable Packaging Strategy proposed by APCO
JAPAN	Food Sanitation Law Positive List introduced (June 2020)		– Voluntary Industry Food Contact Standards by the following associations: • Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) • Japan Hygienic PVC Association (JHPA) • Japan Hygienic Association of Vinylidene Chloride (JHAVDC)
SOUTH KOREA	– Food Sanitation Act, Chapter 3 – PVC ban		
CHILE	– Sanitary Regulation for Food Products, Decree No. 977 – Ban on specific single-use plastics (2021)		– Good manufacturing practice standards for finished materials – Official Food Packaging Standards by the National Institute of Standardization – The Ministry of Environment is planning Environmental Education programs for citizens to raise awareness about single-use products' impact and promote reusable/returnable products

Overall, the majority of OECD member countries have adopted chemical management regulations that govern use in FCMs specifically. The regulations range from simply demanding that "the packaging material is not likely to cause food contamination" such as the Australia Food Standards Code, to stricter regulatory acts which only allow the use of specific substances via Positive Lists and even specify permitted levels of chemical substances used in packaging, such as the EU 10/2011 FCM regulation. So far, according to the EC, the EU has one of the most comprehensive and protective regulatory frameworks for chemicals which is supported by the most advanced knowledge base globally [31]. From a sustainable design incentive perspective, chemical management regulation contributes by putting a hard limit on which materials and additives may or may not be used in packaging.

To provide an overview of where policies exist that stand out from the 'baseline' consisting of regulations on chemicals in FCMs, Table 3 shows representative examples of measures that incentivise sustainable packaging design one way or the other. It is not intended to be an exhaustive collection; the aim is rather to illustrate the variety of policy initiatives employed to incentivise sustainable packaging design from a chemicals perspective and to show areas for which there are no such initiatives. An elaboration on each of the policy initiatives included in Table 3 follows below.

Table 3. Selected policy initiatives that incentivize sustainable plastic packaging design from a chemicals perspective. (Active = has been adopted; Ongoing = is in a process of implementation; Planning stage = has been suggested by the government's organisation and/or is planned to be adopted in the future; N/A = aggregate of several initiatives or not applicable to talk in terms of planning vs. ongoing vs. active)

	Policy characteristics		*Relevance in the value chain*			
POLICY INITIATIVES COVERING CHEMICALS IN FLEXIBLE PLASTICS FOOD PACKAGING	**STATUS**	**TYPE OF DESIGN INCENTIVE**	**MATERIAL SOURCING**	**MANUFACTURING**	**USE**	**END-OF-USE**
1. EU CHEMICALS STRATEGY FOR SUSTAINABILITY	Ongoing	Health & safety for users, Benign manufacturing, Design simplifications, Environmental protection	x	x	x	x
2. EU CIRCULAR ECONOMY ACTION PLAN	Ongoing	Environmental protection, Recycled content, Design simplifications			x	x
3. REVISION OF THE EU FCM LEGISLATION	Planning stage	Health & safety for users, Environmental protection, design simplifications	x	x		
4. POSITIVE LISTS	N/A	Health & safety for users	x			
5. PVC PHASE-OUTS	N/A	Health & safety for users, Environmental protection	x			x
6. REGULATION FOR MIN. RECYCLED CONTENT FOR CERTAIN PLASTICS	Planning stage	Environmental protection, Recycled content	x	x		
7. BIO-BASED, BIODEGRADABLE & COMPOSTABLE PLASTICS INITIATIVES	Active (in several cities in the USA), planning stage in other locations	Environmental protection	x			x

POLICY INITIATIVES COVERING CHEMICALS IN FLEXIBLE PLASTICS FOOD PACKAGING	*Policy characteristics*		*Relevance in the value chain*			
	STATUS	TYPE OF DESIGN INCENTIVE	MATERIAL SOURCING	MANUFACTURING	USE	END-OF-USE
8. REUSABLE PACKAGING	N/A	Health & safety for users, Environmental protection	x	x	x	
9. EU-FUNDED PROJECTS	N/A	Renewable content, Recycled content, Novel materials, Health & safety for users, Design simplifications	x	x		x
10. SAFE AND CIRCULAR MATERIALS COLLABORATIVE	Ongoing	Renewable content, Recycled content, Novel materials, Health & Safety for users, Design simplifications, Material/Chemical transparency	x			x
11. PLASTICS CHALLENGE, CANADA	Ongoing	Novel materials, Design simplifications	x	x		x
12. ACT ON PROMOTION OF RESOURCE CIRCULATION FOR PLASTICS, JAPAN	Planning stage	Design simplifications, Health & Safety for users, Environmental protection, Benign manufacturing	x	x	x	x
13. NATIONAL EU MEMBER COUNTRIES' POLICIES FOR COATINGS, ADHESIVES, PRINTING INKS, IONS EXCHANGE RESINS, RUBBER, SILICONE, COLOURANTS, SOLVENTS, AND AIDS TO POLYMERIZATION	Active	Health & Safety for users, Environmental protection	x			

1. EU Chemicals Strategy for Sustainability (CSS)

Being a part of the European Green Deal, the Chemicals Strategy for Sustainability (CSS) sets out the principles on which REACH and CLP Regulations and the related Cosmetic Products Regulation will be revised. Some of the objectives of the strategy are to ban the most harmful chemicals in consumer products (no exposure = no risk), account for the cocktail effect when assessing risks from chemicals, phase out the PFAS group of chemicals (unless their use is essential), boost the investment and innovative capacity for production and use of chemicals that are *Safe and Sustainable by Design* (SSbD), and establish a 'one substance one assessment' process for the risk and hazard assessment of chemicals [32]. The 'generic approach to risk management' is a move forward from the current FCM rules, i.e. establishing limits for how much of a substance is allowed to migrate into food. Generic risk assessment (or hazard-based approach), targets chemicals for regulatory action based on intrinsic hazard properties – regardless of where and how they will be used [33].

As defined by the EC, "Safe and sustainable-by-design can be defined as a pre-market approach to chemicals that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimizing the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a lifecycle perspective." [31]. The development of an SSbD approach has the potential to reward the production and use of safe and sustainable chemicals, instead of (as a hindsight measure) regulating the hazardous ones. In 2021, the EC conducted research and consequently published the study *Mapping study for the development of Sustainable-by-Design criteria* which focused on existing EU and non-EU policies that affect the life cycle of chemicals, materials, and products. The analysis showed that there is a significant number of relevant activities both in the EU (e.g., EC's Sustainable Product Initiative and Sustainable Finance criteria) and outside the EU (e.g., the Green Seal and Safer Choice in the US which certify food packaging amongst other products) [34].

What this means for sustainable packaging design: The objectives of the CSS will affect the sourcing of starting substances used in the production of food packaging, as well as influence more parts of a product's life cycle. For example, banning the most harmful chemicals and addressing the cocktail effect eliminates a degree of uncertainty when producing new FCMs from recycled material and potentially contributes to higher recycling and recyclable material use rates. Similarly, the SSbD approach will take into account the whole life cycle of chemicals and products to assess their sustainability subsequently affecting product design, including plastic food packaging.

2. EU Circular Economy Action Plan

The sustainability objectives of EU's Circular Economy Action Plan, one of the main EU Green Deal's components, aim to promote circular economy practices and sustainable consumption. The plan is focusing on resource-demanding sectors with a high circularity potential, including packaging, plastics, and others. Regarding packaging, the goal is to eliminate (over)packing and packaging waste through target setting, encourage re-use and recyclability of packaging, and simplify packaging materials [35]. The Action Plan also specifically targets hazardous substances in the circular economy in order to improve circularity in a toxic-free environment and shift to the use of chemicals that are 'safe-by-design'. In terms of recycled materials, the action plan intends to establish methodologies for reducing problematic chemicals in recycled materials and goods manufactured from them, as well as standardize systems for tracking and managing information about and the presence of these substances in waste [36].

The concrete measures will depend on the implementation of many initiatives which will in turn create the need for a more sustainable design of food packaging. Such initiatives may be the faster authorization of recycling processes for FCMs by European Food Safety Authority (EFSA), an improved waste management infrastructure, and investments in innovation and design of food packaging for recyclability and circularity [37].

What this means for sustainable packaging design: With a higher number of authorized recycling facilities for FCMs and improved waste management infrastructure, the availability of recycled food-grade plastics in the market might increase as well. Higher availability may result in lower prices for the recycled material, and which will then be able to compete with the low prices of virgin materials. The investments in innovative design solutions may boost the research and development of FCM plastics with low content in chemicals as well as technology development in chemical recycling. Furthermore, since traceability is one of the main bottlenecks of recycling FCMs, a developed standardised chemical tracking system and information management might increase the recycled volumes as the content of substances in FCMs would become more transparent.

3. Revision of the EU FCM legislation

Another part of the EU Green Deal, the Farm to Fork Strategy, commits to revising the FCM legislation (Commission adoption planned for Q2, 2023) in order to improve food safety and public health (mainly by reducing the use of hazardous chemicals), enable the use of environmentally friendly, reusable and recyclable materials to support the use of innovative and sustainable packaging solutions and reduce food waste. The ongoing evaluation, initiated in 2018, covers both the general FCM framework (EC) 1935/2004 and other relevant FCM legislation, including (EC) 10/2011 on plastic FCMs. The revision intends to tackle the existing lack of safety focus on the final products; improve the insufficient and non-transparent information exchange in the supply chain; and develop rules that support and encourage sustainable alternatives to packaging, incentivise innovation, and address the recyclability of all materials and new technologies, such as chemical recycling [38].

What this means for sustainable packaging design: It is likely that this would bring similar benefits as the EU Circular Economy Action Plan mentioned above. A focus on the final products (i.e., not just the safety of the initial substances used to make plastic FCMs, but also the safety of the final product, which may comprise of a mix of polymers and additives, and therefore may have different properties than the initial chemical mix) should lead to safer materials and easier-to-recycle FCMs since the final composition of the material will be known. More transparency in the supply chain will enable everyone to identify what chemicals enter the FCM market and thus what chemicals may be found in the end-of-life FCMs (and would correspondingly allow more consistent recycling).

4. Positive Lists

Positive Lists are regulated registers including substances, such as monomers and additives, that have been cleared based on a toxicological evaluation, regardless of exposure, and prohibit the use of any substances not listed. The use of Positive Lists in FCM regulation has become widespread, with the EU, China, Japan, the Southern Common Market (MERCOSUR), and Gulf Cooperation Council (GCC) being some jurisdictions that have adopted a Positive List system for plastics [39]. However, in EC's Inception Impact Assessment report for the upcoming revision of EU rules on FCMs, it is reported that the Positive List of starting substances for plastic FCMs has led to extremely complex technical rules, practical problems in implementation and management, and excessive burdens for public authorities and industry. It is also mentioned that the assessments are limited to the starting substances and do not assess the safety of the final product, including impurities and substances formed during the manufacturing process [38].

What this means for sustainable packaging design: One of the Positive List's implications is the limited scientific knowledge of current compounds and their interactions with other substances, which demands ongoing re-evaluation [40]. After the plastic FCMs reached their intended use time, the Positive Lists no longer apply to them, because they might be contaminated with other chemicals as a result of degradation, packed products, or mistreatment during their life cycle. Instead, different regulations apply [41], [42]. Therefore, the main reasons why Positive Lists are not used for recycled materials are related to a number of issues in terms of traceability, input contaminations, and determining decontamination efficiency, thus posing a safety risk [41].

5. PVC Phase-outs

PVC is one of the most versatile polymers since it can accommodate a broad range of additives at relatively high levels. As a result, it should come as no surprise that all of these additives contribute to the sustainability concerns of the PVC life cycle. In particular, stabilisers and plasticisers are the two types of additives that contain heavy metals [43]. The EC report *The use of PVC (Poly Vinyl Chloride) in the context of a non-toxic environment* concluded that most PVC additives are not covalently bound to the polymer and can migrate out of the polymer matrix. Moreover, additives tend to have a higher migration rate in flexible than in rigid PVC. However, extensive data on migration potential and bioavailability of PVC additives is limited and a more critical assessment may be necessary [44]. The paper *The polyvinyl chloride debate: Why PVC remains a problematic material* by Health Care Without Harm, 2021, with the input and support of 18 leading health and environmental organisations, calls on European policymakers to develop a strategy for PVC phase-out in Europe [26]. Similarly, many actors such as governments, corporations, and civil society groups have called for PVC phase-out, including Ellen MacArthur Foundation and over 400 organisations that have signed its New Plastics Economy Global Commitment. Some examples of PVC phase-outs include the Czech Republic which banned PVC packaging at the national level in 1997 (although it had to abandon this regulation upon joining the EU); over 60 cities in Spain that declared themselves PVC-free; South Korea banned all PVC food and beverage packaging in 2019; California, US, which has introduced legislation to ban PVC packaging and 19 other states which have laws restricting heavy metals in the packaging (found in PVC) [26]. The EC report indicates that there are economically viable and technically feasible alternatives in most PVC applications [44].

What this means for sustainable packaging design: Energy recovery of PVC remains controversial due to the release of hazardous substances, including hydrogen chloride and carbon monoxide [45]. Even though the combustion facilities have filters and other decontamination steps in place, the substances stay in the combustion ashes which are landfilled and may leach into the environment. End-of-life PVC packaging that is littered is also a source of environmental risk through chemical migration. By this reasoning, phasing out PVC from food packaging use inherently incentivises more sustainable packaging to be used.

6. Regulation for minimum recycled content for certain plastics, Canada

The Government of Canada will require plastic packaging in Canada to contain at least 50% recycled content by 2030 as part of Canada's plan to achieve zero plastic waste by 2030. The government ran an open consultation for comments on the proposed measures between February 11th and March 14th, 2022, while the regulation is due to be published by the end of 2022 [46]. While beverage containers are considered by the proposed regulation, primary food packaging is excluded from the regulations at this time. However, Environment and Climate Change Canada will potentially include plastic food packaging in future regulations [47].

What this means for sustainable packaging design: Such regulatory actions will increase the market demand for recycled food-grade plastics which may in turn incentivise additional actions for more sustainable plastic packaging design in order to cover the need for post-consumer recyclate. This will be accompanied by investments into collection, sorting, and recycling facilities mainly on the local and national level, as the demand for recyclates will increase the necessity to keep the resources in the same area. Finally, the use of recycled resin instead of virgin resin will have a substantial influence on energy and pollution reduction.

7. Bio-based, biodegradable, and compostable plastics initiatives

Bio-based, biodegradable, and compostable plastics are increasingly promoted as a potential solution to some of the sustainability issues caused by fossil-based plastics. Although such materials bring new opportunities, presentation as a sustainable solution to the plastic waste problem has led to widespread confusion about their disposal, what the differentiation between the terms bio-based, biodegradable, and compostable is (considering that their end-of-life treatment varies significantly), and whether such materials pose a risk to the environment [48]. Most of the products from these materials are not properly disposed at their end-of-life and are mixed with standard plastics due to a lack of infrastructure and consumer misunderstanding of what biodegradability means, resulting in a reduced quality of the recycled plastics produced [49].

Therefore, many organisations and initiatives across the globe call for clearer governmental actions to impose international standards, improve the infrastructure of waste management and increase consumer awareness to eliminate risks streaming from bio-based plastics and increase their utilisation. Some of the examples are the UKRI's policy brief on compostable plastics [50] or The Department for Environment, Food and Rural Affairs' (Defra) and The Department for Business, Energy and Industrial Strategy's (BEIS) proposal for Standards for bio-based, biodegradable, and compostable plastics in the UK [51]; or the National Compostable Packaging Strategy proposed by Australian Packaging Covenant Organisation in Australia [52]. Other examples include the EU which currently assesses how to address such materials in a framework under the EU Green Deal [53]. In the US, different (sometimes conflicting) policies are imposed in various cities. For instance, while Berkley, California, approved an ordinance on mandating compostable foodware for to-go orders and reusable dine-in foodware [54], other cities such as Los Angeles or Portland banned single-use plastic, including single-use biodegradable and/or compostable plastics due to non-existing facilities ensuring biodegradation of compostable plastics [55]. On August 6th, 2021, Chile passed Law 21368 banning single-use plastic items in the food sector. The ban applies to restaurants that provide single-use products for food (including containers for prepared food) that is consumed within the establishment; single-use products provided for use outside the establishment must be made of materials other than plastic. Moreover, Law 9786 established that restaurants can use plastics which completely or partially consist of materials made from renewable resources. The law also dictates that at least 15% by 2025 and 25% by 2030 of all plastic collected and recycled within Chile must be incorporated into disposable plastic bottles [56]. OECD published a report in 2013 (extended in 2021), mapping actions towards the development of bioplastics through e.g., further research and development, public procurement, quotas, subsidies and taxes reductions, standards, labels and consumer awareness [57], [58].

What this means for sustainable packaging design: While the manufacturing of bio-based compounds is not, by definition, sustainable, the primary raw material source has the potential to be sustainable if harvesting and production processes are established with appropriate care [59]. On the other hand, the customers' behaviour and waste management of products from such materials seems to be lacking behind the initiatives and therefore face a backfire.

8. Reusable packaging

There are several market-based incentives that encourage reusable packaging, such as Extended producer responsibility, Pay-As-You-Throw schemes, Deposit Refund Systems and Environmental Taxes on plastic, however, strict legislations on reuse are not in place. Reusable forms of packaging offer a significant opportunity to preserve the material's and product's functioning while also reducing material use and environmental impact. It is not a new concept; reusable packaging has long been utilised in a variety of applications and is still used today. However, in recent decades, we have seen a shift away from reusable packaging toward single-use packaging [60]. Transport distances influenced by (reverse) logistics, return rates, and the impact of sorting, cleaning, and maintenance, as well as influences on product damage, are key elements that affect both the economics and environmental implications of reusable packaging [61].

What this means for sustainable packaging design: Is it safer to reuse some plastic food containers than others? What is a 'safe' level of exposure to the chemicals included in them? There are many questions surrounding reusable packaging; however, answers alter as new research is published, and recommended exposure limits for various chemicals present in plastic food packaging and containers are continually changing [62]. In general, reuse does not appear to have a major impact on chemical, physical, or surface qualities caused by repeated washing. Similarly, it does not significantly influence the material's features (including chemical migration) [60]. However, plastics are complicated materials that contain a variety of chemicals that can leach from the container into the food they transport or come in a contact. The type of plastic, contact time, temperature, food type, and size of the contact area between the plastic container and the food all have a role in chemical migration into food. That implies that the reusability of a plastic container depends on how it was designed and how was it used. FPF suggests four main situations under which the chemical migration is the highest – extended time period, high temperatures, contact with fatty and/or acidic food, and when packaged in small serving sizes [62]. Another issue is that flavour may be transferred to a new filling in the case of intensely flavoured items [60]. In a case study of reusable soft drink PET bottles in Brazil, Lemos Junior et al. (2019) found that improper use of the bottles by users was the major contributor to introducing substances affecting the flavour. A good management system for returned bottles, on the other hand, helped to lower the rejection rate to 1% [63]. Finally, IASS's policy brief suggests, along with other ideas, standardising the reusable packaging by using industry-wide materials and designing the packaging in a way that is suitable for a broad range of products [64].

9. EU-funded projects

Several EU-funded projects under the 7th Framework Programme (FP7) and its successor Horizon 2020 (H2020) focused on the development of sustainable flexible plastic food packaging. Some examples are the project (FP7) which aimed to develop functional barriers to be positioned between packaging layers made of recycled plastics, the BIOSMART project (H2020) which aimed to develop fully bio-based multilayer flexible plastic packages and the project (FP7) which aimed to develop biopolymer packaging which also exhibited low toxicity when tested. H2020 is succeeded by Horizon Europe (2021-2027).

What this means for sustainable packaging design: such projects can potentially contribute to valuable knowledge on developing more sustainable novel packaging materials and articles, increase the use of recycled plastic content – while minimizing the use of virgin polymers –, extend the shelf life of food products and hold the use of chemicals to a minimum.

10. Safe and Circular Materials Collaborative

Inspired by the *Impacts of Food Contact Chemicals on Human Health Consensus Statement*, signed by 33 scientists and more than 200 environmental groups warning about the outdated and inadequate global regulations of chemicals in food packaging, the critical gaps in risk assessments and the need for a chemical-safe circular economy, this partnership between Sustainable Packaging Coalition and ChemFORWARD aims to address these challenges and explore safer alternatives. The focus of the Collaborative will include compostable packaging for its ability to contribute high-quality feedstock material to the biological cycle and recyclable packaging for its ability to contribute to high-quality post-consumer feedstock for recycled content. Some of the desired outcomes are to focus industry efforts on the most hazardous chemicals, demonstrate the availability of verified safer alternatives, develop a central registry for the verified alternatives, and create a common agenda to accelerate necessary systems change. The project is expected to be completed in April 2022 [65].

What this means for sustainable packaging design: such initiatives can help forward-thinking packaging manufacturers to go beyond regulations and lead the non-toxic and circular packaging market. Apart from creating new sustainable packaging design solutions, the Collaborative may increase public awareness and thus the demand for sustainable packaging. Verified evidence on alternative materials may even inspire the regulative authorities to revise laws governing FCMs.

11. Plastics challenge, Canada

Environment and Climate Change Canada launched a funding competition (Closing date: May 29th, 2020) focusing on the development of innovative alternative reusable or recyclable products that can replace one or more ‘challenging’ plastic packaging products that contribute to plastic waste and pollution. The winning concept received a grant of $150,000 to develop a graphene-reinforced recycled paper with high-performance properties as a sustainable alternative to plastic packaging, like plastic grocery bags and can be used to produce strong and reusable paper products [66], [67]. It should be noted that this particular challenge was not solely on food packaging, and did not mention chemicals. However, the concept could be applied to a more narrowly defined design challenge.

What this means for sustainable packaging design: such initiatives incentivise innovative thinking and may lead to new sustainable plastic packaging design solutions that can function as an alternative to conventional single-use non-recyclable plastic packaging.

12. Act on Promotion of Resource Circulation for Plastics, Japan

On March 9th, 2021, the Cabinet of Japan approved the Bill for the Act on Promotion of Resource Circulation for Plastics which shall come into effect within a period of one year from the promulgation date. The Bill aims to increase the resource circulation for plastics, targeting all stakeholders involved in the entire lifecycle of plastic-containing products, from design to waste disposal. Namely, the Bill is considering new guidelines for the environment-friendly design of plastic-containing products; the rational use of specified plastic-containing products; sorting and recycling by municipalities; collection and recycling by manufacturers, sellers, and other businesses; and waste reduction and recycling by waste generating businesses [68], .

What this means for sustainable packaging design: given that the Act is considering the whole life cycle of plastics, it may accelerate the development of sustainable plastic packaging since the manufacturers will need to comply with the design guidelines and the rest of the value chain stakeholders will eventually demand such solutions.

13. National EU member countries' policies for coatings, adhesives, printing inks, ions exchange resins, rubber, silicon, colourants, solvents, and aids to polymerisation

The above-mentioned materials are used in the manufacturing process of plastic food contact packaging but have no specific measures (e.g., migration limits) at the EU level. Therefore, several EU member countries have set material-specific measures and/or standards for these FCMs, such as Positive Lists. However, according to the *mutual recognition* principle, in the case of intra-EU trade of goods, a product complying with regulation in one EU member country – and not subject to Union harmonization –, should be allowed to be marketed in any other member country, even if the product does not fully comply with the rules of the destination country. Despite that, a member country can still pose bans or restrictions on a product or substance [70], [14].

When printing inks, coatings, and adhesives applied on plastic substrates contain substances which are listed in the Plastics Regulation, and these substances have been assigned specific migration limits, the contribution to the migration of those substances from the inks, coatings, and adhesives must be factored in when assessing compliance in the Plastics Regulation.

What this means for sustainable packaging design: national policies for non-harmonized FCMs may enhance efforts for sustainable packaging design at the national level, such as innovative design solutions and experimenting with alternative non-toxic materials. This knowledge could be later used at the EU level, in case the rules for these FCMs will be harmonized.

4. Discussion

This section discusses the ramifications of the existing and emerging policy incentives for sustainable packaging design from a chemicals perspective, presented in Section 3.2. In particular, the challenge of providing robust chemical safety policies for FCMs while also incentivising design for more reuse, recycling and recycled content use is discussed as this is the area where a large share of challenges is identified.

Although some of the following conclusions are drawn based on the EU legislation, they may be generalised, to a varying degree, to all OECD member countries.

4.1 Key policy challenges from a chemicals perspective for sustainable design of flexible food packaging

4.1.1 Safety vs. circularity?

There is a clear dichotomy between, on the one hand, regulations designed to keep food contact materials safe and chemicals from migrating into food, and on the other, the ambition to reduce depletion of natural resources, material consumption and energy loss, as detailed in the circular economy strategy [71]. The most favourable option for packaging circularity is reduction and reuse, but to date, most policy actions have focused only on increasing the recycled content of plastic packaging. This focus on plastics recycling is problematic as it leads to higher levels of hazardous chemicals that migrate into foodstuffs [72]. Despite this concern, a new EU draft regulation on recycled plastic FCM will likely enter into force in 2022 which will further incentivise the use of recycled content for food packaging. The only such recycling system in use at scale today is the separate PET bottle collection and recycling, often driven by a Deposit-refund scheme. Reusable packaging (which we in this context think of as potential substitutes for single-use flexible packaging) would not face the same 'legacy problem' as designing with recycled content if one assumes that the original packaging uses virgin materials. However, since reusable packaging could instead accumulate contaminants over its multiple use cycles, policy needs to show how to monitor and ensure safe levels of such contaminants are kept in order to build confidence that reuse can be a large-scale option.

Incentivising more compostable packaging comes with different but related trade-offs: Not only is the LCA footprint of a functional unit of compostable packaging often quite high in comparison to conventional flexible plastics, but it is also hard for compostable materials to match state-of-the-art flexible plastic packaging (e.g., multi-material films) on parameters such as gas & moisture barriers, weight, and chemical migration. Consequently, design choices that are more compatible with environmentally sustainable material sourcing and end-of-life might lead to drawbacks on chemical safety.

As seen from Section 3.2, there are policy initiatives to address these challenges, but the question remains whether they will be enough to move the needle in a significant way towards designing food packaging with more reuse models, in compostable materials or with recycled content. The policy challenge should be seen in connection to reducing the overall plastic packaging use that leads to (household) waste in the first place, along with identifying uses of single-use plastic packaging that are currently critical for ensuring the food supply and developing a roadmap for their replacement. For instance, the Swedish Action plan on plastics with an aligning Swedish EPA's roadmap focuses on i) Production and product design of plastics and plastic products, ii) Consumption and use of plastics and plastic products, iii) Non-toxic and circular plastic and plastic products, iv) Driving force for business and other actors that promote innovation and circular business models for plastics and plastic products.

Next, an infrastructure allowing for reusable and refillable packaging made of inert/low-migrating and permanent materials is needed. And lastly, the policies have to tackle the significant logistical and technical challenge of collecting, sorting and recycling plastic single-use FCM in an efficient way that generates materials that can be downcycled into other uses.

From a chemical point of view, designing sustainably while also incorporating previously used materials becomes a problem of how to assess the potential presence of hazardous substances cost-efficiently. Sampling studies have for example found brominated flame retardants in plastic FCMs on the European market, as a result of illegal recycling of Waste Electrical and Electronic Equipment Directive (WEEE) plastic into food contact articles. [28] Therefore, updating safety requirements for chemicals migrating from plastic packaging into food based on current scientific understanding and supporting the optimization of essential plastics is a must [73]. In other words, the barriers to recycling flexible plastics in FCMs into new FCM (or just a high-quality resin), which are both compliant with the safety regulations and economically feasible, are major.

4.1.2 'The known unknown'

Even though it is legally required, the identification of NIAS in finished FCMs is challenging – if not impossible in many cases – leaving these substances unknown. Specifically for the EU, information on substances present in FCMs after the first manufacturing step of polymerization, including NIAS, is submitted to EFSA for safety review. The fact that this information is not made publicly available is intensifying the uncertainty that has been built around NIAS. In addition, NIAS present in used plastics pose a subsequent issue for recycled plastics. Enforcement of the legal requirements to assess NIAS has proven to be challenging with little response and insufficient information provided to authorities from plastic resin manufacturers. At the same time, the EC has not issued any guidance for assessing NIAS in plastic FCMs [28].

4.1.3 The impact of stringency in risk assessment of post-consumer plastic FCMs on sustainable design

The approach taken to risk assessment of post-consumer recycled plastics can have a significant impact on the extent to which recycling and the use of recycled content can be explicitly designed for when seeking to make flexible packaging as sustainable as possible. The EFSA evaluation of post-consumer plastics in direct food contact is mainly based on three parameters (concentrations in post-consumers input materials, cleaning efficiency of the recycling process, exposure to customers) and other side assumptions. EFSA uses worst-case assumptions for its evaluation (e.g., assuming 100% recycled content in applications when assessing them), which in itself is a common practice when evaluating the safety of FCMs. However, in the case of post-consumer recyclates, several individual steps with individual safety factors are evaluated, the multiplication of which leads to what some denote as overly conservative thresholds in the food safety evaluation. An example of this practice is EFSA's refusal to authorize the recycling of milk bottles into new food packaging in the UK, despite 14 years of practice and strong historical performance [74].

Not all parameters need to represent the worst-case scenario; rather, they can bring an action that will enable boosting the number of applications that could use post-consumer plastic FCMs and ease the transition to a more circular economy while safety for consumers requires further evaluation [3]. Indeed, as has been shown by Gerassimidou and colleagues, mechanically recycled PET has higher levels of migrating hazardous chemicals, including known carcinogens (formaldehyde) and endocrine disrupters (bisphenol A), therefore the study's authors stress the importance of carefully evaluating the safety of recycled plastics [72]. Another issue of concern regarding the safety of (recycled) plastic packaging are micro- and nano-plastics which can be generated during the intended use of plastic packaging [75], [76], [77], [78]. A different approach to EFSA is taken in, e.g., the US and Canada, which according to some interviewed experts would make it easier to establish and scale novel recycling technologies to de-contaminate and produce recycled plastics of FCM quality, thus increasing the possibility to include recycled content as a parameter when designing flexible food packaging.

4.1.4 Addressing the 'cocktail effect' and the use of positive materials lists

As of today, the EU REACH is evaluating chemicals in their initial form; before they are used in the production. However, when combined, the potential synergistic effects of those chemicals may change their characteristics regarding food migration. While being a well-known concern for years, it has only recently been addressed during the EU's evaluation of FCM legislation, the results of which will be released in 2022 [79].

Positive Lists are regulated registers including substances, such as monomers and additives, that have been cleared based on a toxicological evaluation, regardless of exposure, and prohibit the use of any substances not listed. The use of Positive Lists in FCM regulation is becoming widespread with the EU, China, Japan, MERCOSUR and GCC being some jurisdictions that have adopted a Positive List system for plastics [39].

While the use of positive materials list facilitates sustainable design from a chemicals perspective by providing a single source of information on what can and cannot be used, the scientific community sees a number of challenges with the way such lists are compiled and used. As an example, the research of Groh et al. (2021) [6] can be used to comprehensively describe the international state of play and the large diversity of food contact chemicals (FCC). The researchers compiled a database of internationally used FCCs, listing 12285 substances based on 67 FCC lists from publicly available sources such as regulatory lists and industry inventories. Of more than 12000 substances identified, 325 used in FCM production were classified as hazardous by the authors. 85 of these substances are enlisted in the EU Positive List for plastic FCMs (as updated on 2019-02-12), while others are enlisted in Swiss, Dutch, German and Japanese national lists. 17 out of the 85 substances were listed on the REACH Candidate list of SVHCs for Authorization, while 5 were listed on the REACH Authorization list.

The authors highlight that the regulation continues to rely on single-substance assessment and management approaches which do not incorporate the most current scientific understanding while missing out on the importance of mixture toxicity (i.e., the 'cocktail effect'), low-dose effects, and non-standard testing approaches. They also call for more transparency on the side of producers and more coordinated efforts on the side of regulators to ensure systematic assessment and enforcement of FCM safety [6]. In other words, Positive Lists can be a helpful tool for sustainable design, but there are currently significant gaps in the information used to compile such lists to make them robust tools for safe and sustainable design.

4.1.5 Improved chemical traceability through the supply chain

A key issue for the ability to design sustainable packaging is to know what is in the materials used. If it cannot be established what is in a given plastic formula, the confidence needed to innovate (e.g., by designing new formats, using more recycled content, designing for a specific end-point, etc.) will be limited.

At the EU level, although a written Declaration of Compliance (DoC) is mandatory for plastic FCMs, the exchange of information across the supply chain is not sufficient and transparent enough. But based on views gathered in the interviews, it appears that the DoC makes available, in principle, a larger amount of chemical information for a given plastic compound than is generally assumed.

The challenge is to pass on such information in a way that does not violate any confidentiality, while also being possible to aggregate with many other materials so that, for example, a recycler or waste manager can obtain an approximate idea of what is in the material they are handling. A modern, simplified, and digitalized system could improve the information exchange and compliance work [80]. A DoC is not mandatory in international legislation, but a harmonized global declaration system could make up for various inter-legislative gaps.

4.2 Potential actions for improved chemical policies for flexible plastic food-grade packaging

Based on the observations made from the policy mapping work, taking both documentation and expert interviews into account, three chemical policy themes stand out as important to explore to improve policies for more sustainable design in flexible plastic food packaging. One of the themes outlined below concerns the harmonisation of chemical policies across regions, while two focus on the challenge of providing stringent chemical policy at the same time as creating enabling conditions for more sustainable food packaging.

Facilitate cross-regional alignment. Given the gravitas and stringency of core EU regulations on chemicals in flexible plastic food packaging, it appears reasonable to find a systematic way of broadening alignment between such regulations and regions outside of the EU. As countries like Canada and Australia have to pay attention to the EU chemicals legislation on an international chemicals market in any case, creating an approach to facilitate that process could be helpful. This is not to say that all chemicals legislation should be the same, but it might help the industry to make consistent progress towards more sustainable design and having more harmonised materials if there is a level of cross-regional alignment.

Address practical and regulatory challenges with recycled plastics in food packaging. As this report has shown, food packaging applications are effectively blocked for recycled content due to a combination of technical constraints and regulations designed to safeguard health. Since food packaging constitutes approximately 40% of all plastic packaging [81], a significant share of which is flexible plastics, it means that a large portion of the total ‘pool’ of available plastics currently has to be based on virgin feedstock, which is inherently less sustainable according to the OECD definition

(Section 3.1). Addressing the challenges hindering i) recycling plastics into high-quality and safe secondary raw materials, and ii) feasible authorization pathways for such solutions, could be a suitable priority for more stringent chemical policies.

Create a robust framework for chemical traceability to align with more sustainable packaging. Since prolonged material use over one or multiple life cycles (e.g., longer use of packaging through reuse, or multiple recycling cycles) is a cornerstone to more sustainable packaging, it would be helpful to address how information transparency and chemical traceability could be managed in this context. How can policy incentivise the industry to provide data and the transparency needed for more sustainable packaging (whilst staying reasonably competitive)?

There is a common concern that documentation and traceability of information regarding chemical content in plastic packaging and, specifically, the presence of chemical hazards, is generally missing [6], [8], [28]. This lack of transparency would make it virtually impossible to, at the point of recycling, assess the level of chemical safety or hazard of recycled content, which in turn impedes the options for sustainable design and innovation.

Most methodologies proposed to address the chemical contamination problem focus on different ways of decontamination at end-of-life (solvent purification, chemical breakdown, hot-washing, supercritical CO_2) [28], [82], and could benefit from better chemical traceability. Conversely, understanding what types of additives and contaminants such methods are able to remove to produce FCM-compatible outputs would help to design more sustainable packaging materials from the start.

Moreover, since there are protocols in place in the EU for tracing chemical additives along the value chain, it could in principle be possible to have an independently managed library of material passports, both at the application and material level, which would make it easier to determine which recycled materials (mechanically recycled or decontaminated) would be feasible to use in sustainable design of flexible food packaging. However, a major sticking point with such a database is the protection of intellectual property: who should have access to such data and how do you protect trade secrets? There are technical solutions to such problems, and it would be an intriguing prospect to test the idea from a policy point of view.

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Appendix A – List of interviews

Affiliation
Environmental and Climate Change Canada
Veterinary and Food Administration, Denmark
Department of the Environment, Australia
Royal Society of Chemistry, UK
DG Environment, EU
Food Standards Agency, UK
Department of Environment & Health, Italy
Environmental Protection Agency, Sweden
Nextek, UK
Environment and Climate Change Canada
Health Products and Food Branch – Health Canada
Tohoku University

Appendix B – Country policy deep-dives

European Union

The Framework Regulation

The EU has introduced two main pieces of framework regulation governing the FCM value chain, i.e.:

- *The Framework Regulation* *(EC) No 1935/2004*: provides a harmonized legal framework which determines the general principles of safety and inertness of all FCMs. This framework is currently under revision to, among other reasons, promote the use of innovative and sustainable packaging solutions using environmentally friendly, reusable and recyclable materials (planned adoption in Q2, 2023) [38].
- *Good Manufacturing Practices (GMP) Regulation* *(EC) No 2023/2006*: controls the manufacturing process so that the specifications for FCMs remain in conformity with the legislation. The regulation applies to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

Certain FCMs, including plastics and recycled plastics, are regulated by specific EU measures. More specifically, plastic is controlled by the most comprehensive regulation compared to other materials.

Legislation on plastic FCMs

EU's most comprehensive legislation on a specific category of food contact materials to date is the Plastics Regulation (EU) No 10/2011 which sets out rules on the safety and composition of plastic FCMs. It also establishes a regularly amended Positive List which covers the monomers and other starting substances to manufacture polymers that are permitted for use in the manufacture of plastic FCMs (885 substances listed to date). It also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles. The regulation sets out *Specific Migration Limits* (SML), established by EFSA on the basis of toxicity data of each specific substance, which specify the maximum amount of substances allowed to migrate to food.

The plastics regulation is *harmonised* for monomers and additives, meaning that it doesn't allow the EU member countries to impose additional or different requirements on plastic FCMs, except under narrow circumstances. It also contains certain exemptions, including for the use of substances that are not on the list for a plastic layer that is not in direct contact with food and is separated by a functional barrier in a multi-material, multi-layer material or article, and the presence of NIAS. However, the plastics regulation exempts several substances from regulatory scrutiny and does not require any authorization, even though they may become an integral part of the plastic. These substances are coatings, adhesives, printing inks, ions exchange resins, rubber, silicone, colourants, solvents, and aids to polymerization [83]. Some of these substances are controlled by national regulations across the EU member countries. For example, Croatia, Greece, Italy, the Netherlands, Spain and Slovakia use Positive Lists for coatings [14], [70].

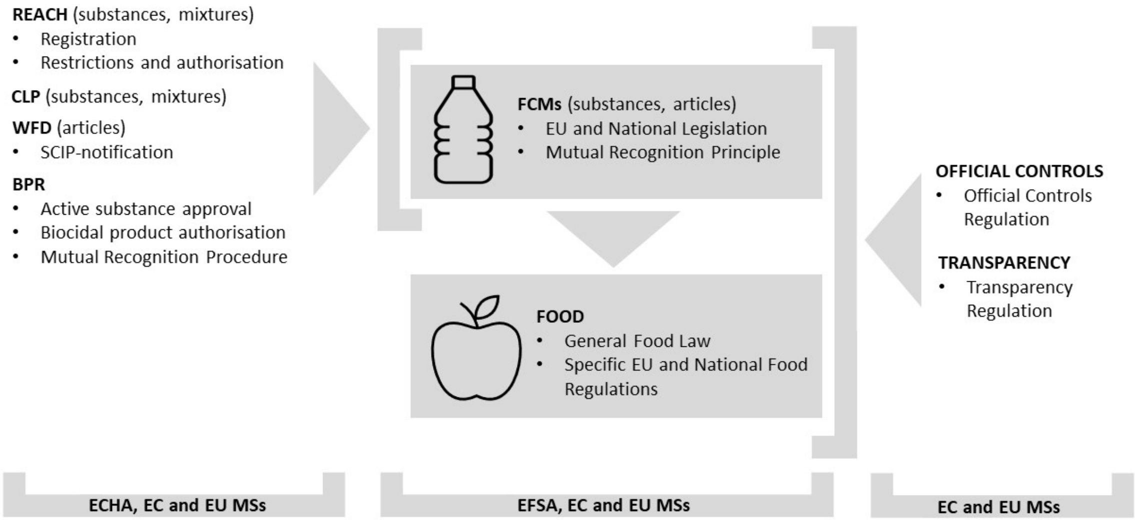

Figure 4. Regulations and regulatory bodies influencing chemicals in FCMs. EFSA is currently the main regulatory body of chemicals in FCMs. CLP = Classification, Labelling and Packaging of substances and mixtures; WFD = Waste Framework Directive; BPR = Biocidal Products Regulation, MSs = Member States. Figure sourced from [84].

Declaration of Compliance (DoC)

According to Article 16 of (EC) No 1935/2004, at all marketing stages other than at the retail stage, a written declaration shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles, stating that they comply with the rules applicable to them.

Recycled plastic FCMs

EU Commission Regulation (EC) 282/2008 is a harmonized regulation which controls the recycling processes of recycled plastic materials and articles intended to come into contact with foods. For a producer to be granted permission to produce FCMs from recycled plastic, it should be demonstrated that the recycling process can efficiently reduce potential contamination to a level that does not pose a risk to human health. Moreover, the plastic input must originate from food-grade plastic materials and articles (i.e., it must be 'FCM to FCM'), and it must be proved that the material has not been contaminated. Up to now, only facilities producing secondary PET FCMs have been assessed by EFSA in the EU. The demand for high-quality food-safe recycled PET has been boosted by the Single-use Plastics Directive (EU) 2019/904 which provides specific enforcement dates for certain levels of recycled PET in beverage bottles (25% and 30% in 2025 and 2030 respectively). Recycled PET is also a popular material for other food-grade applications. However, since non-bottle PET packaging is rarely recycled, and because recycling of these secondary materials is not approved for FCMs, such applications currently end up not being recycled again.

The European Commission announced a draft act on December 6, 2021, that will update the EU legislative framework to simplify the processes around the development, certification, and use of recycled plastic FCMs and intends to amend the current (EC) 282/2008. The feedback period for public consultation ended on 18 January 2022 and the Commission is planning to proceed to adoption in the first second half of 2022 The regulation demands, amongst others, that the recycled materials and articles are manufactured using a suitable recycling technology or a 'novel technology', meeting specific requirements on monitoring and reporting, in which case the recycled materials could be approved for FCM use. The amendment is designed to enable more recycled FCM plastics without the currently rigid demand on traceability, as long as the recycling and decontamination method is in accordance with stated requirements, such as [85]:

- labelling and documenting of individual batches of recycled plastics with their origin, instructions to the converters and final users regarding its use;
- decontamination that ensures compliance with manufacturing restrictions and specifications on a high level of safety for human health;
- the input for recycled FCM plastics can only originate from municipal waste, food retail or other food businesses if it was only intended and used for contact with food.

Legislation on Specific Substances

- Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials.
- Commission Regulation 1895/2005/EC is restricting the use of certain epoxy derivatives in FCMs
- Commission Directive 93/11/EEC - release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers.
- Apart from all the aforementioned EU regulations, the important chemicals regulations REACH (Regulation (EC) No 1907/2006 of the European Parliament and the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures) have to be followed by FCM manufacturers.

United Kingdom

The Food Standards Agency is the independent government department working to protect public health and consumers' wider interests in relation to food and is regulating FCMs.

Until the expiry of the transition period of Brexit, when the EU produced a new regulation for FCMs, it automatically became a part of the UK food contact legislation. Currently, in the post-transition period, this does no longer happen with a risk that the legislation in the UK will deviate from the EU rules which are constantly evolving. Specifically for plastics, the food contact substances on the Positive List of the EU's Plastics Regulation (EU) 10/2011 authorized by the EC before January 1, 2021, do not need to be reauthorized by UK authorities in order to be placed on the market in Great Britain (England, Wales and Scotland). For substances not on the Positive List before this date, an application for authorization has to be submitted. For authorization applications in Northern Ireland after the transition period, the EU authorization rules have to be followed since Northern Ireland will continue to follow EU rules while Great Britain will follow the retained EU regulations. The UK authorities foresee that the processing of the applications for authorization, including risk assessment and the final risk management decision, will take up to 15 months [86].

A Positive List for recycled plastic processes has not yet been established in the UK legislation and, until in place, these products may be placed on the market in Great Britain if they meet the requirements of the General Food Law Regulations and any general criteria in the FCM's legislation [87], [86].

Plastic Packaging Tax

A new tax will be applied to plastic packaging manufactured in, or imported into the UK, that does not contain at least 30% recycled plastic. This measure will affect UK manufacturers of plastic packaging, importers of plastic packaging, business customers of manufacturers and importers of plastic packaging, and consumers who buy plastic packaging or goods in plastic packaging in the UK. Manufacturers or importers of less than 10 tonnes of plastic packaging per year will be exempted. The objective of the policy is to incentivise the use of recycled plastic in plastic packaging and subsequently increase the demand for this material, and the collection and recycling levels. The tax took effect on 1 April 2022 [88].

United States

Legislation on FCMs

The US Food and Drug Administration (FDA) is the regulatory authority in the USA, which under the Title 21 of the Code of Federal Regulation (CFR), regulates food and drugs, cosmetics and medical products, including FCMs. According to FDA, a food additive is "any substance the intended use of which results in or may reasonably be expected to result in its becoming a component of food". Food additives are divided into three categories: direct, secondary direct and indirect. Thus, FCMs should comply with requirements at the latest.

Food packaging needs to be FDA compliant to be put on the US market. The three ways to achieve compliance are through the following [89]:

- **Title 21 of the CFR (parts 170-199)**: the FDA regulations cover almost all classes of food packaging, including plastics. Part 177 covers different types of polymers and lists definitions of material types, permitted additives, specifications, test methods, and end-use restrictions.
- **Food Contact Notification (FCN) Program**: was introduced by FDA's Modernization Act in 2000. The FCN program regards new FCMs that need to be registered before being put on the market. The FCN should contain a migration study, an estimate of dietary exposure, toxicology data and an environmental impact assessment. For higher exposure levels, a Food Additive Petition (FAP) or Threshold of Regulation (ToR) submission may be needed. After the submission of the FCN, the FDA has a 120-day time limit to raise any objections. In the case of no-objection, the packaging

materials are automatically legal. It is, in most cases, the food contact substance producers which would apply for FCN approval for a new food contact substance or when they plan to use an already approved substance in a new application. Users of food contact materials, like packaging managers, do not usually apply for FCN approval since they mostly rely on pre-approved substances. Worth mentioning is that the FCN approval is proprietary, meaning that the materials must be produced only by the approved entity. In any other case, a new FCN may be required.
- **Exemptions from FDA Regulations**: which regard a number of packaging materials falling in the following categories: A) *Prior Sanction*: any substance that received a letter of approval before 1958, such as PVC. However, it might be sometimes required certainty of safety before placing a product on the market; B) *Substances Generally Recognized As Safe (GRAS)*: a list of safe substances; C) *No Migration Exemption*: if a substance is not reasonably expected to migrate to food, then it is not considered as a food additive according to the FDA regulation and thus, not a subject of it. The threshold level is less than 50 ppb, except for high exposure applications such as milk and carbonated soft drinks where the threshold level is at 10 ppb. The no migration exemption does not apply to substances of special concern like heavy metals and carcinogens, or if the substance can cause toxic reactions at levels lower than 40 ppb in the diet of humans and animals.
- **PFAS in Food Containers:** In November 2021, the Keep Food Containers Safe from PFAS Act was introduced in the Senate and House and aims to ban the use of intentionally added PFAS as a food contact substance. The bill gives the FDA until 2022 to enforce this ban. However, some states such as California and Washington have already taken the lead and have passed legislation to ban or phase out PFAS in food packaging [46].

Legislation on recycled FCMs

FDA does not mandate special regulatory review or preclearance of recycled FCMs. This is because FDA, in contrast to the EU, regulates FCMs based on their composition, not on the specific process by which they are manufactured or the source of the recycled content. Recycled FCMs should meet the same regulatory specifications as virgin material and comply with GMP requirements. FDA provides guidance on the use of recycled plastic in its July 2021 *document Use of Recycled Plastics in Food Packaging (Chemistry Considerations): Guidance for Industry*.

Recyclers can get authorization by demonstrating the safety of their material by contamination and, in some cases, migration testing. Namely, if the contamination tests show that the residual contaminant levels are within those noted in the guidance, the resin is considered safe. If the maximum residual levels are exceeded, several follow-up tests are conducted, such as migration studies that simulate the actual use conditions to determine whether the contaminants are likely to transfer to food, blending the recycled material with virgin polymers to dilute out the level of contaminants, limiting to specific end uses with no concern of migration, and using the recycled materials with a functional barrier that prevents migration to the food.

Canada

Food packaging regulations

The safety of all FCMs in Canada is controlled under *Food and Drugs Act and Regulations, Section B.23.001, Division 23* which prohibits the sale of food in packaging that may transmit any substance to the contents that may be harmful to the consumer. The responsibility to ensure the safety of packaging material and compliance with B.23.001 lies solely on the food seller (manufacturer, distributor). However, there is a requirement that specific information is provided to Health Canada (HC) on materials used to pack infant formula (*Division 25*), foods for special dietary use (*Division 24*) and novel foods (*Division 28*), for which packaging is a part of the evaluation process [90].

Voluntary premarket assessments and Letters of No Objection

Although there are no Positive Lists for permitted packaging ingredients in the Canadian regulation, FCMs may be submitted voluntarily to the *Food Directorate* (FD) for a premarket assessment of their chemical safety in relation to *Section B.23.001*. FCMs that receive a favourable opinion obtain a Letter of No Objection which can be used by the recipients to assure their customers of the chemical safety of their products. Such letters, however, do not constitute approvals in a legal sense, still holding the food sellers accountable for compliance with *Section B.23.001* [90].

Guidance documents and guidelines

Food packaging material suppliers may consult the guidance document entitled *Information Requirements For Food Packaging Submissions* for details concerning this process, published by HC [90].

Recycled plastic FCMs

Recycled plastic FCMs are subject to the same regulations as virgin plastics in terms of their chemical safety. Food packaging suppliers with products containing recycled plastics may consult the document entitled *Guidelines for Determining the Acceptability and Use of Recycled Plastics in Food Packaging Applications*, published by HC [90].

The Canadian government has just terminated the feedback period (14 March 2022) on the proposed development of regulations under the *Canadian Environmental Protection Act, 1999* (CEPA) that would set the minimum recycled contents requirements for certain plastic manufactured items, including FCMs. The *Environment and Climate Change Canada* (ECCC), which is the department of the government responsible for coordinating environmental policies and programs, proposed to exclude direct contact food packaging from the regulations at this time, except beverage containers. ECCC intends to develop instruments and approaches that will increase recycled content in FCMs which could include future regulation [47].

Australia

Food Standards Australia New Zealand (FSANZ) is an agency in the Australian Government Health portfolio which develops standards for food and FCMs for Australia and New Zealand. The agency established the Australia New Zealand Food Standards Code ('the Code') which is enforced by state and territory departments, agencies, and local councils in Australia; the Ministry for Primary Industries in New Zealand and the Australian Department of Agriculture and Water Resources for food imported into Australia [91].

The Code mandates that food packaging must be safe and sets out requirements for food packaging materials in Standard 1.1.1- (10, 11) but does not specify permitted levels of additives or chemicals used in packaging. Standard 1.4.1 – Contaminants and Natural Toxicants, sets out the maximum levels of metal and non-metal contaminants as well as natural toxicants that may be present in food because of contact with FCMs. Standard 1.1.1-12 clarifies that the Code's packaging provisions also apply to food that is imported in the packaging in which it is intended to be sold.

The 2016 guidance document *Safe Food Australia* refers to the *Australian Standard AS 2070-1999 Plastic Materials for Food Contact Use* which is rather voluntary than mandatory and provides measures on the production of plastics, including processing aids, additives/colourants, printing inks, coatings, and manufacture of multilayer products for food contact use. AS 2070-1999 refers to both US FDA 21 CFR regulations and EU FCM directives noting that they are useful for companies looking for guidance on suitable packaging formulation. The packaging manufacturer or supplier using chemicals with no legal limit specified must still ensure that the packaging material will not endanger the safety and suitability of the food in contact with it [92].

The guidance document also states that recycled materials may be used for food packaging if they are suitable for food contact use and will not contaminate the food. It points out that the food business should consider potential risks posed to food safety and suitability from recycled or reused materials as some packaging comprised of recycled material may include added protection (e.g., an inner bag or coating) to prevent any chemicals from leaching into food. The Australian Packaging Covenant website with useful guidance on recycled materials used for food contact is also mentioned [92].

Japan

In Japan, the Ministry of Health, Labour, and Welfare (MHLW) has established specifications under the Food Sanitation Law for various food contact materials and their raw materials. The Food Sanitation Law prohibits the sale of utensils and food containers and packaging that contain any toxic or harmful substances.

A part of the Food Sanitation Law was amended and a Positive List system was introduced that allowed only safety-evaluated substances to be used in food utensils/containers and packaging, which came into effect on June 1, 2020, with a 5-year transitional period. The list is currently being restructured and a tentative list is available on the webpage of the MHLW. For all polymers and additives not included in the list, the migration limit is 0,01 mg/kg of food. Producers must prove compliance through migration studies with food simulants or computer modelling [93].

Voluntary Industry Food Contact Standards

In Japan, trade associations also play a key role in food contact legislation compliance. The Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), the Japan Hygienic PVC Association (JHPA), and the Japan Hygienic Association of Vinylidene Chloride (JHAVDC), and the Japan Paper Association (JPA) have all established voluntary industry for their food contact materials. Those standards are so well respected that customers often require a supplier to have its product certified by the appropriate trade association before a purchase can be made [94].

South Korea

In South Korea, FCMs and FCAs are regulated under the Food Sanitation Act. In Chapter 3, the Act prohibits the presence or use of toxic and harmful chemicals in food contact utensils, containers and packaging which could endanger human health. The Act sets the Ministry of Food and Drug Safety in charge to establish standards and specifications for these products. In September 2021, the Ministry issued a notice with the latest food contact requirements under *Standards and Specifications for Utensils, Containers and Packaging* and, amongst others, regulates the use of recycled synthetic resins, including improved standards for recycled PET [95]. Moreover, Korea banned all PVC food and beverage packaging, including laminates, labels, and coatings in an attempt to minimize dioxin and furan releases during incineration and phase out products that are difficult to recycle [26].

Chile

Food and food packaging is regulated by the Ministry of Health under Decree No. 977, the Sanitary Regulation for Food Products, which provides that FCMs must not release substances that are toxic or otherwise contaminate the food. Article 126 of the Decree requires that plastic FCMs may not contain substances that may be hazardous to health. FCMs are also subject to official standards provided by the National Institute of Standardization [96].

On August 6, 2021, Chile passed Law 21368 banning single-use plastic items in the food sector. The ban applies to restaurants that provide single-use products for food – including containers for prepared food – that is consumed within the establishment; single-use products provided for use outside the establishment must be made of materials other than plastic. Moreover, Law 9786 established that restaurants can use plastics that totally or partially consist of materials made from renewable resources. The law also dictates that at least 15% by 2025 and 25% by 2030 of all plastic collected and recycled within Chile must be incorporated into disposable plastic bottles. The Ministry of Environment will also implement Environmental Education programs for citizens to raise awareness about the impact of single-use plastic products and promote reusable and returnable product use [56].