ZEROF

Report on regulatory, certification and essential requirements mapping

Deliverable D6.2

Version N°1

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Table of contents

1 Introduction 8
2 Background 9
2.1 The EU Green Deal 9
2.1.1 EU policy framework 10
2.2 The EU Chemicals strategy for Sustainability 11
2.3 Ecodesign 11
2.4 Zero Pollution Action Plan 11
2.5 Circular Economy Action Plan 11
3 Description of the case studies 13
3.1 ORMOCER® 13
3.2 CeFAE 13
4 Overarching regulations 15
4.1 General Product Safety Directive 15
4.2 REACH Regulation 16
4.2.1 Substances of Very High Concern 16
4.3 CLP Regulation 18
4.4 Polymers under REACH and CLP 19
4.5 POP Regulation 20
5 Sector specific regulations 22
5.1 Food Contact Materials 22
5.1.1 Directive on Food Contact Materials 22
5.1.2 EU Plastics Regulation 22
5.1.3 EU Good Manufacturing Practice Regulation 23
5.1.4 National Regulations of Special Importance 23
5.1.4.1 German BfR recommendations 23
5.1.4.2 The Netherlands 24
5.1.4.3 Italy 24
5.1.5 Inventory of Food Contact Substances Listed in 21CFR (FDA) 24
5.1.6 EU legislation of Packaging and Packaging Waste 24
5.1.7 Single-use Plastics Directive 25
5.1.8 Information Requirements for an EFSA Safety Dossier 26
5.2 Textiles 27
5.2.1 EU Strategy for Sustainable and Circular Textiles 27
5.2.2 ECHA requirements on textiles 28

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5.2.3 Recommendation for safe and sustainable chemicals 28
5.2.4 Fibre name and textile labelling Regulation 29
5.2.5 Extended Producer Responsibility for textiles 29
6 Overview of available standards 30
6.1 Standards testing product functionality 30
6.2 Voluntary Standards 31
6.2.1 Oeko-tex 31
6.2.2 Bluesign 31
6.2.3 Nordic Swan Ecolabel 32
6.2.4 Blue Angel 32
6.2.5 GOTS 32
6.2.6 ZDHC 32
6.2.7 EU Ecolabel 33
6.2.8 NF Environment 33
6.2.9 GUT 33
6.2.10 Textile Exchange 33
6.2.11 Compostable and Biodegradable standard 34
7 Future update of the Regulatory Landscape in Europe 35
7.1 Upcoming regulations for plastics 35
7.2 ECHA's restriction dossier 35
7.3 The Extended Product Responsibility (EPR) Principle 36
7.4 EU Strategy of Plastics in Circular Economy 36
7.5 Food and Food Contact Materials 36
7.6 Textiles 37
8 Conclusion 39

List of figures

Figure 1 Goals of the European Green Deal Policies 9
Figure 2 European Commission proposal for the Integration of SSbD in the innovation cycle. 10
Figure 3 ORMOCER® combines structure and properties of inorganic and organic components. 13
Figure 4 Summary of key actions put forward by the European Commission to achieve Sustainable and Circular Textiles by 2030. 38

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Summary

This deliverable, D6.2 *Report on regulatory, certification and essential requirements mapping*, is created as part of Task 6.2 *Regulation & certification mapping and roadmap* which places the ZeroF coating applications in the existing regulatory, standards and certification landscape. This task aims to identify the current legislative, standards and certification requirements for the intended applications of the new coatings, to identify gaps, and develop a roadmap to integrate key sustainability criteria in standards and certification criteria (D6.7). Moreover, the task aims to guide the development of the Safe and Sustainable by Design framework, which should be geared toward relevant regulatory needs.

The present deliverable covers a scoping exercise regarding regulation, certification and requirements on the ZeroF developed materials, anticipating future needs from the on-going Action Plans under the European Commission regarding plastics, food and textiles. The deliverable begins by providing background of the regulatory scheme the project operates in. Then, the case studies ORMOCER® and CeFAE are introduced. This is followed by descriptions of overarching as well as sector specific regulations. The following chapter presents an overview of available standards in this context, while the next chapter provides some insights into the future regulatory landscape in Europe. Finally, conclusions are presented.

Keywords

Regulation, Standards, Green Deal, European Commission, Food Contact Materials, coatings, textiles, Safe and Sustainable by Design.

Abbreviations and acronyms

Acronym	Description
WP	Work Package
GD	Green Deal
SSbD	Safe and Sustainable by Design
CSS	Chemicals Strategy for Sustainability
EC	European Commission

1 Introduction

The development of EU policies supporting sustainability is one main goal of the European Commission, supported by different Action Plans under the European Green Deal (GD). One such example is the Chemicals Strategy for Sustainability (CSS) towards a toxic-free environment which underlines that sustainability is the ultimate goal with safety falling under different sustainability classes. The CSS supports the replacement of chemicals which may be harmful to human and environment fostering substitutions and gearing innovation towards circularity.

To support those activities, the European Commission published the first version of their Safe and Sustainable by Design framework for chemicals, which is currently undergoing a two-year review period by stakeholders. As part of CSS, the EC published a Strategic Research and Innovation Plan for safe and sustainable Chemicals and Materials. It predicts future needs for toxicity and eco-toxicity testing, release/exposure assessment, risk management measures and other assessment tools, which may be highly relevant for the elimination of pollutants, such as microplastics.

This deliverable has been created as part of Work Package 6 *Safe- and sustainable-by-design integration, assessment and certification,* and, in particular, Task 6.2 *Regulation & certification mapping and roadmap*. The deliverable is a result of a mapping exercise of the certification, standards and regulatory needs regarding the coatings proposed in ZeroF. The mapping has led to the identification of potential gaps in current requirements in the context of the project which are presented in this deliverable. Moreover, the deliverable provides an overview of the regulatory framework as well as essential requirements and available standards relevant to the project.

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2 Background

Several EU strategies are paving the way toward the transition to achieve a more sustainable European economy, with several tight deadlines and goals by 2030 such as the creation of 160000 additional green jobs in the construction sector and 35 million buildings renovated, 55% reduction of emission gases from cars, and zero emission from new cars by 2035, and Europe to be first climate neutral continent by 2050. The overarching approach to achieve the abovementioned goals is set up in the European Green Deal (GD) and several other Action Plans presented in the below sections.

2.1 The EU Green Deal

The European GD[1] presents a roadmap for making the EU's economy sustainable by turning climate and environmental challenges into opportunities across all policy areas and making the transition just and inclusive for all (Figure 1). It expresses the Commission's commitment to tackling climate change and reduce pollution, so protecting human life and its environment. The European Commission recognizes that major investments are required to ensure these goals. Enabling and emerging technologies, and in particular new materials with promising sustainability potential, such as those developed in ZeroF, are regarded pivotal to find solutions for the challenges ahead.

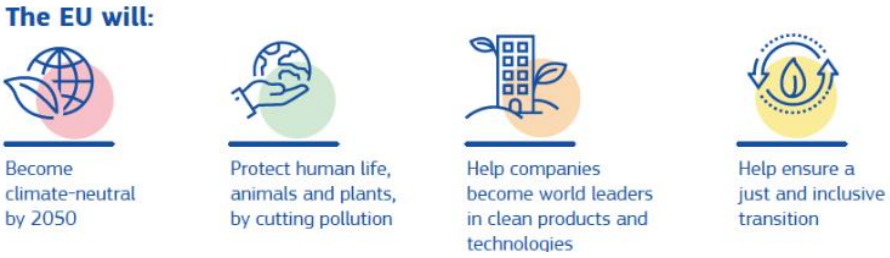

Figure 1 Goals of the European Green Deal Policies

These ambitious GD goals are implemented through a whole suite of strategies and action plans, which are slowly shaping into new regulations[2]. These include actions regarding environmental remediation, pollution prevention, increased control over the production and application of chemicals (in particular substances of very high concern). The challenge provided by the high cost and more ethical safety testing, infinite possibilities of new materials and a call for more ethical and Mode of Action driven safety assessments, paved the way a few years back to the development of Safe by Design strategies (SbD) which, which, to meet the goals of the GD, has turned into SSbD (Fig 2). The focus of such strategies is to shift from risk management to risk prevention, introducing sustainability at early material development. Several EU initiatives including ZeroF, are currently developing integrated strategies to facilitate the integration of sustainability, safety and functionality issues at early innovation process development to meet GD goals.

[1] Fetting, C. (2020). "The European Green Deal", ESDN Report, December 2020, ESDN Office, Vienna
[2] https://echa.europa.eu/registry-of-restriction-intentions

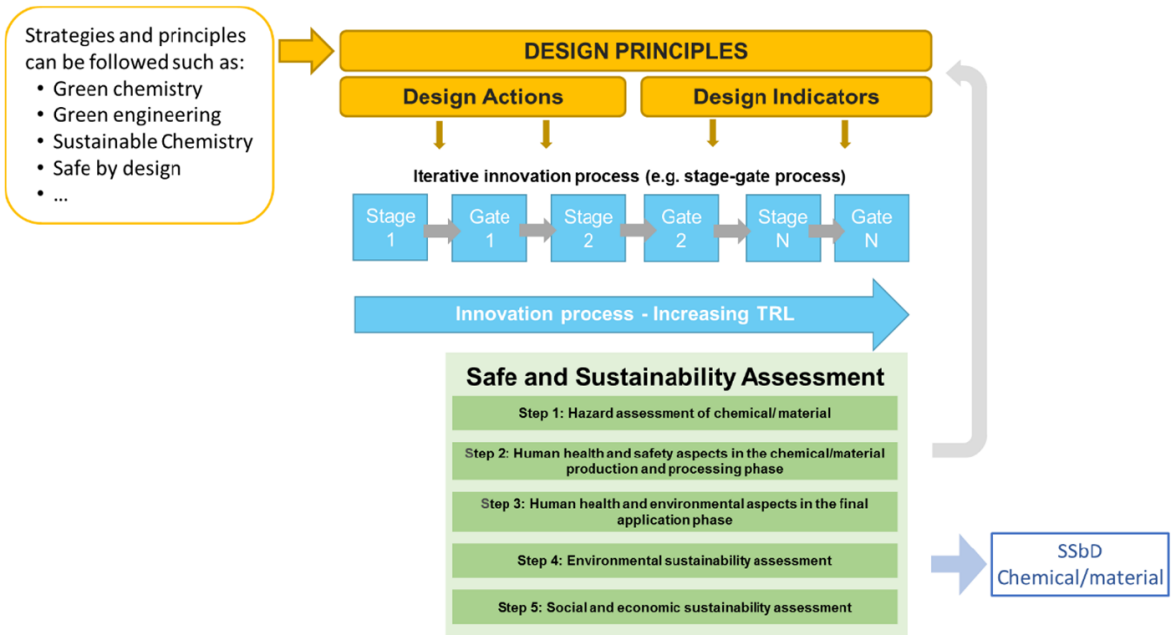

Figure 2 European Commission proposal for the Integration of SSbD in the innovation cycle[3].

2.1.1 EU policy framework

The EU policy framework on biobased, biodegradable and compostable plastics guides the development of legislation. Biobased, biodegradable and compostable plastics are widely perceived, in Europe and internationally, as more environmentally friendly than conventional plastics, which are fossil based and non-biodegradable. At the same time, there is increasing scientific evidence and awareness that a number of conditions have to be met to ensure that the production and use of these plastics result in overall positive environmental outcomes and do not exacerbate problems of plastic pollution, climate change and biodiversity loss. While making plastics from biomass or ensuring that plastic products can biodegrade in some receiving environments can bring a number of benefits compared to conventional plastics, these solutions have their own sustainability challenges and trade-offs that should be well understood and duly taken into account. They should also not detract from the need to align the lifecycle of plastics with the circular economy and to ensure, as a priority, that resource use is reduced in the first place, that materials of all feedstocks, including biobased feedstocks, are kept in the loop for as long as possible, and that secondary raw materials are preferred to primary raw materials. Though EU policies and legislation address some aspects and applications of biobased, biodegradable and compostable plastics, it would be better to take a more systemic approach to underpin decisions by both the public and private sector. This approach should be based on the European Green Deal[1], the circular economy action plan[4] and the EU plastics strategy[5] . Furthermore, the zero pollution action plan[6] aims to reduce plastic litter at sea by 50%, and microplastics released into the environment by 30% by 2030. The focus of the EU soil strategy[7] is to prevent soil contamination at source.

[3] JRC Technical Report 2022 Safe and Sustainable by Design chemicals and materials
[4] COM(2020) 98 final
[5] COM(2018) 28
[6] COM(2021) 400
[7] COM(2021) 699 final

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2.2 The EU Chemicals strategy for Sustainability

This strategy directly links to the Safe and sustainable materials. It is a part of the EU's zero pollution ambition – a key commitment of the European Green Deal – and aims to better protect citizens and the environment from harmful chemicals, and promote the use of safer and more sustainable chemicals. The strategy strives for a toxic-free environment, where chemicals are produced and used in a way that maximises their contribution to society including achieving the green and digital transition, while avoiding harm to the planet and to current and future generations. It envisages the EU industry as a globally competitive player in the production and use of safe and sustainable chemicals. and includes actions to simplify and strengthen the legal framework on chemicals, build a comprehensive knowledge base to support evidence-based policy making, and set the example of sound management of chemicals globally.

2.3 Ecodesign

The proposal for a Regulation on Ecodesign links to sustainable products addressing product design. This Strategy determines up to 80% of a product's lifecycle environmental impact. It sets new requirements to make products more durable, reliable, reusable, upgradable, reparable, easier to maintain, refurbish and recycle, and energy and resource efficient. In addition, product-specific information requirements will ensure consumers know the environmental impacts of their purchases. To achieve this the European Commission has introduced the term Digital Product Passport, as a policy initiative which will require various layers of product data at all life cycle stages to deliver transparency, traceability and trust to the European Consumers[8]. This will make it easier to repair or recycle products and facilitate tracking substances of concern along the supply chain. The new proposal extends the existing Ecodesign framework in two ways: first, to cover the broadest possible range of products; and second, to broaden the scope of the requirements with which products are to comply.

2.4 Zero Pollution Action Plan

The Zero Pollution Action Plan includes pollution prevention. It provides a compass to mainstream pollution prevention in all relevant EU policies, to step up implementation of the relevant EU legislation and to identify possible gaps. The zero pollution vision for 2050 is for air, water and soil pollution to be reduced to levels no longer considered harmful to health and natural ecosystems, that respect the boundaries with which our planet can cope, thereby creating a toxic-free environment. The action plan aims to strengthen the EU green, digital and economic leadership, whilst creating a healthier, socially fairer Europe and planet. It provides a compass to mainstream pollution prevention in all relevant EU policies, to step up implementation of the relevant EU legislation and to identify possible gaps.

2.5 Circular Economy Action Plan

The Circular Economy Action Plan also covers the full life cycle of products. It has been adopted with a view to boosting global competitiveness, fostering sustainable economic growth and generating new jobs. It consists of two EU Action Plans for the Circular Economy (CEAPI,2015 and CEAPII,2020), with measures covering the full life cycle of products: from production and consumption to waste management and the market for secondary raw

[8] The EU Digital Product Passport shapes the future of value chains: What it is and how to prepare now by WBCSD 2022

materials. Building on the work done on circular economy since 2015, the CEAP II focuses on resource intensive sectors where the potential for circularity is high. Aiming to keep resources in economic cycles as long as possible, the plan addresses key product value chains: electronics and ICT, batteries and vehicles, packaging, plastics, textiles and food.

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3 Description of the case studies

The ZeroF proposal will deliver a SSbD framework adapted to hybrid coatings developed to substitute PFAS-containing alternatives in two selected key value chains: textile (upholstery segment) and packaging (fibre-based food packaging segment). Two case studies were selected to developed and test tools and criteria for testing the ZeroF SSbD Framework. The two selected case studies are presented in the sections below.

3.1 ORMOCER®

ORMOCER®s are hybrid polymeric materials comprised of interconnecting inorganic oxidic (Si, Al, Ti, Zr, etc.) and organic (polymethylmethacrylates, polyethylene oxides, etc.) components (Fig 3). They are generally prepared from functionalized organoalkoxysilanes by first hydrolysis and condensation reactions. The first step of the synthetic process is the hydrolysis of a silicon alkoxide followed by condensation polymerization forming silicone (Si-O-Si) network. The final step of the process of the ORMOCER® synthesis is the organic crosslinking of the organic groups by polymerization, after thermal, chemical initiation, or UV radiation. This curing procedure results in forming a cross-linked three dimensional network. ORMOCER®s can be used as a functional coating on various surfaces, such as on packaging and on textiles, to impart hydrophobicity and oleophobicity. PFASes are currently used to add these functionalities to textiles. As ORMOCER is a hybrid polymer graft onto a polymer (plastic or textile), the material can be classified as a "polymer" and "plastic" according to regulatory definitions.

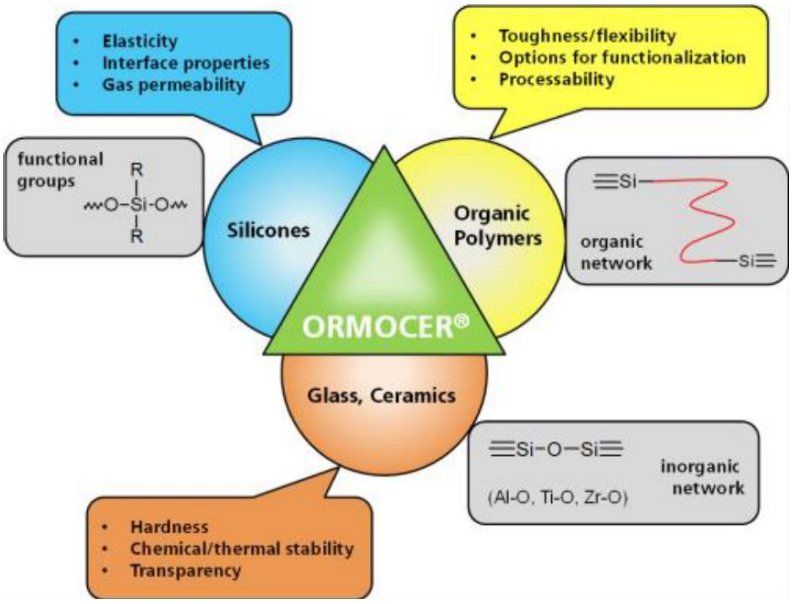

Figure 3 ORMOCER® combines structure and properties of inorganic and organic components.

3.2 CeFAE

Cellulose fatty acid esters (CeFAEs) are the group of chemical derivatives of cellulose, where cellulose is used as a backbone for attaching fatty acid groups. Cellulose has three free hydroxyls, so that the material can be made in degrees of substitution (DS) between 0 and 3. The base cellulose and the added fatty acids can be varied. Despite being a derivative of two natural materials, the creation of the new ester bond makes the material a "plastic" in regulatory definitions. Besides this, factually, the material is not biodegradable, at least at

DS>1. Substituted celluloses no longer fit to the active sites of cellulose-degrading enzymes in microbes. However, the limit of DS where there is no longer any biodegradability is not known.

At high DS (2-3), the material behaves as a thermoplastic polymer and can be molded into shapes using regular polymer extrusion equipment. Regulation of plastic packaging is therefore the applicable law or standard to it. However, the goal is to apply the same material to coatings, where there is a different set of regulations and standards.

CeFAEs have a hydrophobic surface with water and water vapor barrier properties. They also have some grease barrier properties (in a KIT test) by themselves, but are not as good as Ormocers. In ZeroF, plans are to make Ormocer derivatives of CeFAEs. These would be regulated similarly to Ormocer. Regardless of biodegradability, the inherent advantage of over PFASes is that they are fluorine-free.

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4 Overarching regulations

The following regulations are required to place safe products in the EU market based on the intended use of ZeroF developed materials.

4.1 General Product Safety Directive

The General Product Safety Directive (GPSD) stands as a major piece of EU legislation providing the framework for the safety of a product which is not covered by specific legislation. The scope of the GPSD is to assure that only safe products are placed on the EU market. This is assured by providing general concepts, establishing the responsibilities of the value chain actors, and by indicating harmonized standards (safety rules), which are methods officially accepted by the EU to evaluate the safety of certain products. Specific safety rules apply e.g. to toys, electrical and electronic goods, cosmetics, and chemicals [56]. According to the GPSD, the producer has the responsibility to place a safe product on the market. According to the legislation, safe means:

"*any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular*:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly."

This list enumerates all elements of the product that need to be considered for the product to be safe. Even if GPSD does not indicate how to evaluate safety, it provides a non-exhaustive list of methods to be used.

"(a) voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;

(b) the standards drawn up in the Member State in which the product is marketed;

(c) Commission recommendations setting guidelines on product safety assessment;

(d) product safety codes of good practice in force in the sector concerned;

(e) the state of the art and technology;

(f) reasonable consumer expectations concerning safety.

Regarding consumers, appropriate information on the product or packaging, the risks that the product might pose, the identification of the product/batch, and the responsible person for communication should be included. Concerning distributors, it is important to inform

them about risks in product batches, the procedures in place to monitor safety of the product once it is on the market, and the results of this monitoring.

4.2 REACH Regulation

The REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) Regulation and the CLP (Classification, Labelling, and Packaging) Regulation are two key pieces of legislation that regulate the safety of chemicals and products placed on the European Union (EU) market.

The REACH Regulation (Regulation (EC) 1907/2006) covers the registration, evaluation, and authorization of substances produced or imported into the EU in quantities of 1 ton or more per year. All chemicals manufactured or imported above 1 t/y have to be registered according to REACH, and depending on the amount produced, a Chemical Safety Report and an Exposure Scenario (demonstration that a certain use is safe for health and environment) has to be produced by the company placing the substance onto the market. If the substance is not registered, it cannot be commercialized.

In fact, manufacturers and importers must register their substances (for quantities of 1 ton or more per year) with the European Chemicals Agency (ECHA) and provide information on their properties, uses, and safe handling measures. Moreover, companies placing substances on the market in quantities above 10 tons per year must provide a Chemical Safety Report, which assesses the risks associated with the substance and includes recommendations for safe use. Along with the CSR, companies must provide an exposure scenario that demonstrates the safe use of the substance for health and the environment. Regarding exposure scenarios definition, besides manufacturers and importers, also downstream users (i.e., who is using a substance, either on its own or in a preparation, in the course of their industrial or professional activities) have requirements in REACH. The downstream user has the requirement to assure that her/his use of the substance is safe for the workers and for the environment. In this case, consumer safety is covered by the GPSD. Therefore, the downstream user needs to be proactive and ask the substance supplier for a use scenario that covers the specific use, and implement the safety indications provided in the specific use. If it is not the case, the downstream user has to communicate to the European Chemicals Agency (ECHA) the specific use scenario, which is normally done by the industry sector association, which collects all information from the associates to submit an integrated use map table.

4.2.1 Substances of Very High Concern

REACH can restrict or ban the use of certain hazardous substances if they pose significant risks to human health or the environment. In order to use these substances, a separate Authorization under REACH is required for substances of very high concern (SVHC) that are listed on the Candidate List. Authorization requires the manufacturer to demonstrate the necessity of using that particular substance and the absence of safer alternatives. This introduces significant regulatory burden, and there is a separate fee for Authorization in addition to the fee for Registration.

Substances of Very High Concern (SVHCs) are substances fulfilling one or more of the criteria defined in Article 57 of the REACH Regulation. These are substances that have severe impacts on human health due to some of their characteristic properties; they can be Carcinogenic, Mutagenic or toxic to Reproduction (CMRs), Persistent, Bio accumulative & Toxic (PBTs) or Very persistent very bioaccumulative (vPvBs). All identified SVHCs are

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included in the so-called REACH Candidate List, which is managed by the European Chemicals Agency (ECHA). This Candidate List is updated twice a year with newly identified SVHCs. For example, it includes certain phthalates, brominated flame retardants and perfluorinated compounds.

In June 2019, January 2020 and January 2023, three groups of PFAS were identified as SVHCs. The SVHC identification was based on their persistence, mobility and toxicity, which were considered to pose a threat to human health and wildlife when exposed through the environment (including through drinking water). These PFAS were identified as of equivalent concern to carcinogens, mutagens and reprotoxicants (CMRs) and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) chemicals10. Inclusion in the candidate list entails immediate obligations for suppliers of the substance, such as providing a safety data sheet and providing information on the safe use.

In addition, there are also certain obligations that concerns articles containing an SVHC in quantities above one tonne per producer/importer per year and if the substance is present in these articles. In fact, SVHCs are sometimes used in the production of articles, to give the article certain desired characteristics. Examples of such material characteristics or properties include cleavage, density, ductility, electrical conductivity, hardness, magnetism, melting point, etc. If a substance listed on the Candidate List is contained in articles, this may trigger certain obligations for companies producing, importing or supplying these articles. Among the obligations for articles containing Candidate List substances:

- Registration for substances with quantities of one tonne or more per year placed on the market per manufacturer or importer (Article 7(1)). A registration needs to be submitted to ECHA by EU manufacturers or importers of a substance or of articles under certain circumstances, or Only representatives established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU to fulfil the registration obligations of importers (Article 8 REACH).
- Notification of substances in articles (Article 7(2)): in fact, Producers and importers of an article must, under certain conditions, submit a notification to ECHA.
- Communication in the supply chain (Article 33.1): Suppliers of an article must, under certain conditions, communicate information down the supply chain and responding to consumer enquiries within 45 days (Article 33(2)).

It should be noted that ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation list as a priority. Once a substance has been added to the Authorisation list, it must not be used without an authorisation granted by the European Commission after the so-called sunset date. Manufacturers, importers or downstream users in the EU can apply for an authorisation for the placing on the market or the use of an SVHC which is listed in Annex XIV.

Please also note that certain substances are included in the so-called Restriction List. The restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels.

In February 2023, a restriction proposal regarding per- and polyfluoroalkyl substances (PFASs) was published and is currently open for consultation since March 2023 and will last until September 2023. The proposal concerns any substance that contains at least one fully

fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it), which could be roughly estimated to encompass 10000 possible PFAS substances. The proposal provides two restriction options: either a full ban or a ban with use-specific derogations. The derogations for the second option will be based on analyses of alternatives and the socio-economic considerations. The restriction could become effective as of the year 2026 or 2027.

Besides the European Union, OECD has published a Comprehensive Global Database of PFASs in its portal on Per and Poly Fluorinated Chemicals.

4.3 CLP Regulation

The CLP (Classification, Labelling, and Packaging) Regulation (Regulation (EC) 1272/2008) is the other key piece of legislation in the European Union (EU) that governs the classification, labelling, and packaging of substances and mixtures. It ensures that manufacturers and suppliers provide accurate information about the hazards of chemicals and products to protect human health and the environment. CLP is strongly linked to the REACH Regulation in particular with regard to safety data sheets.

CLP requirements apply to chemical substances, mixtures and explosives (section 2.1, Annex I CLP). However, the CLP Regulation shall not apply to Radioactive substances and mixtures (Council Directive 96/29/Euratom); Substances and mixtures which are subject to customs supervision; non-isolated intermediates; Substances and mixtures for scientific research and development; Waste (Directive 2006/12/EC).

CLP shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

- Medicinal products (Directive 2001/83/EC);
- Veterinary medicinal products (Directive 2001/82/EC);
- Cosmetic products (Directive 76/768/EEC);
- Medical devices (Directives 90/385/EEC, 93/42/EEC and 98/79/EC);
- Food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used as a food additive in foodstuffs (Directive 89/107/EEC), as a flavouring in foodstuffs (Directive 88/388/EEC and Decision 1999/217/EC), as an additive in feeding stuffs (Regulation (EC) No 1831/2003), in animal nutrition (Directive 82/471/EEC).

Note that there are no exemptions under the CLP Regulation in contrast to the REACH Regulation (tonnage dependent registration obligation > 1t/y, Annex V, polymers). Thus, any hazardous chemical is in the scope of CLP and has to be notified in the C&L inventory.

When it comes to the classification procedure under CLP, all substances which are placed on the EU market must be classified by manufacturers, importers or downstream users of chemical substances or mixtures according to Article 4.1 CLP. This obligation applies regardless of the tonnage manufactured, imported or placed on the market. However, there are two types of classification:

- The harmonised classification that concerns substances for which a classification has been decided upon at the European level. When a harmonised classification and labelling exist, companies must apply this classification. Harmonised classifications can be found in the tables of Annex VI of CLP. A harmonised classification only

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applies to substances and not to mixtures. The harmonized classification and labelling for hazardous substances are listed in the C&L (Classification and Labelling) Inventory of ECHA, providing a standardized system for hazard communication.

- The self-classification which is required when substances do not have a harmonised classification or where a harmonised classification only covers certain hazard classes. The self-classification must be done by Manufacturers of substances; Importers of substances or mixtures; Producers or importers of explosive articles or articles for which REACH provides a registration or notification duty; Downstream users, including formulators.

The European Commission has published a Delegated Regulation (EU) 2023/707 amending CLP Regulation, which sets out new hazard classes and criteria for the classification, labelling and packaging of substances and mixtures. The new rules are in force as of 20 April 2023 with the application of certain transition periods.

The new hazard classes are:

- ED HH in Category 1 and Category 2 (Endocrine disruption for human health)
- ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment)
- PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)
- PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

Another important procedure under the CLP Regulation is the labelling of substances and mixtures. Suppliers or importers of a substance or mixture are required to label the product if this product is classified as hazardous. In addition, if a mixture contains at least one substance that is classified as hazardous, the product must be labelled as well. Manufacturers and suppliers are obligated to label substances and mixtures with standardized hazard pictograms, signal words, hazard statements, and precautionary statements.

Additionally, the CLP Regulation sets requirements for packaging of hazardous substances and mixtures to ensure their safe handling and transport. Packaging must be designed to prevent leaks, spills, and other risks during storage and transportation.

Another requirement in relation to notification of Hazardous mixtures and according to article 45 CLP, companies have to provide information on their hazardous mixtures (mixtures classified for any health or physical hazard) to appointed bodies where they plan to place their mixtures on the market according to Annex VIII to the CLP. In the same line of requirements, and according to Annex II REACH (as amended by Regulation (EU) 2020/878), companies have to provide an emergency telephone number in section 1.4 of their Safety Data Sheets (SDS).

The products intended to be developed in ZeroF will be non-hazardous polymers and polymer grafts. However, any novel functionalizing agents and reactive additives need to be reported under CLP, as they are monomers possessing significant chemical hazards.

4.4 Polymers under REACH and CLP

Functionalized surfaces such as Ormocer-coated products and coatings such as CeFAE coatings are polymers. Currently, and according to article 2(9) REACH, polymers are exempt from the registration obligation (Title II) and the evaluation (Title VI) under REACH, however,

registration is required for monomers and other substances comprising the polymer, if (Article 6(3) REACH):

- *The polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);* and
- *The total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year (the total quantity in this context is the total quantity of monomer or other substance ending up chemically bound to the polymer).*

Additionally, polymers may be subject to authorisation under REACH. The monomers and polymers may also be subject to restrictions.

The importer or manufacturer of a polymer has to classify, label and package the polymer in accordance with CLP requirements. Note that the classification of the polymer should take into account the classification of all its constituents, such as the unreacted monomers.

It is worth noting that polymers are not exempted from the CLP Regulation. A polymer is a substance and as such has to be notified when placed on the market in cases where it fulfils the criteria for classification as hazardous (Article 39(b) CLP).

Polymers could be required to be registered at some point in the future. According to Article 138(2) REACH, the European Commission (EC) may come up with a legislative proposal to amend REACH requesting registration of a range of selected polymers. The final decision on the polymer registration must try to minimise the costs for industry including those for innovation and competition, while maximising the benefits to human health and the environment. The recent studies mentioned above contribute to the conclusion that polymers might face additional regulatory requirements in the future.

4.5 POP Regulation

The POP Regulation (Regulation (EU) 2019/1021) concerns persistent organic pollutants (POPs). In the international framework, persistent organic pollutants are regulated through the Stockholm convention and the Aarhus protocol. These two international legislations have the same objectives: the reduction, control and elimination of emissions of POPs substances into the environment. Within the European Union, these initiatives have been translated into EU Regulation (EU) 2019/1021 (or "POPs Regulation"). Regulation (EU) No 2019/1021 on persistent organic pollutants is a regulation replaces the previous EU regulation on POPs (Regulation (EC) No 850/2004) and aligns the EU's legal framework with the provisions of the Stockholm Convention on Persistent Organic Pollutants.

The general objective of the POP Regulation according to its Article 1 is, with regard to the precautionary principle, "to protect human health and the environment from POPs by prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, or the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of those substances."

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The regulation prohibits or restricts the production, placing on the market and use of the listed POPs, with some exemptions for essential uses such as in medical devices and equipment for the detection and analysis of POPs. According to the article 3 of this regulation "The manufacturing, placing on the market and use of substances listed in Annex I, whether on their own, in mixtures or in articles, shall be prohibited, subject to Article 4." In addition, "The manufacturing, placing on the market and use of substances listed in Annex II, whether on their own, in mixtures or in articles, shall be restricted, subject to Article 4." The article 4 prides information on the exemptions from control measures.

The regulation also requires industry to take measures to manage waste containing POPs. According to article 7 "Producers and holders of waste shall undertake all reasonable efforts to avoid, where feasible, contamination of this waste with substances listed in Annex IV." "[…] waste consisting of, containing or contaminated by any substance listed in Annex IV to this Regulation shall be disposed of or recovered, without undue delay and in accordance with Part 1 of Annex V to this Regulation, in such a way as to ensure that the POP content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of POPs." Additionally, "Disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use on their own of the substances listed in Annex IV shall be prohibited."

However, article 7 also provided exemptions carried on with concentration limits. In fact, according to article 7. 4 "waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Union legislation, provided that the content of the listed substances in the waste is below the concentration limits specified in Annex IV". Finally, "a Member State or the competent authority designated by that Member State may, in exceptional cases, allow wastes listed in Part 2 of Annex V containing or contaminated by a substance listed in Annex IV up to concentration limits specified in Part 2 of Annex V to be otherwise dealt with in accordance with a method listed in Part 2 of Annex V" provided that certain conditions are fulfilled.

The annex IV and V of the POP regulation were amended in 2022 through Regulation (EU) 2022/2400 by introducing more substances to the Annexes or changing certain concentration limits of already listed substances.

5 Sector specific regulations

5.1 Food Contact Materials

5.1.1 Directive on Food Contact Materials

The framework directive overseeing food contact materials is Regulation (EC) No 1935/2004, which is based on the principle that materials and objects intended to come into direct or indirect contact with food must be sufficiently inert to avoid potential leakage of the material into food from posing a risk to human health. The regulation also forbids any unacceptable change in the composition of food and any adverse effect on its smell, taste, colour, or appearance caused by a food contact material. This framework regulation also applies to "active" and "intelligent" materials. In each case, materials are individually assessed by the European Food Standard Agency (EFSA) in terms of health risk before the European Commission authorizes them to be used in food contact materials.

- Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption

Here under article (22) it states "*The risk assessment by the applicant or national authority should cover health risks arising from the potential migration under worst foreseeable conditions of use and from the toxicity. Based on the risk assessment, the European positive lists should, if necessary, set out specifications for the starting substance, composition or constituent and restrictions of use, quantitative restrictions or migration limits for the starting substance, composition or constituent, possible impurities and reaction products or constituents in order to ensure the safety of the final material to be used in a product in contact with water intended for human consumption*."

Article 11, it must be ensured that there is no: 1) adversely affect the colour, odour or taste of the water, 2) enhance microbial growth 3) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose of the material

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
- Article (8): […] "*Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.*"

For research in ZeroF, the consequences are that care needs to be taken to demonstrate that the reactions run to completion and leave no residues of the functionalizing agents. These residues could compromise tests of performance and safety. This could in practice be a method like exhaustive Soxhlet extraction with aqueous ethanol followed by quantitative GC-MS. However, the expected TRL level at the end of the project is not necessarily advanced enough to require this. For development of regulations in ZeroF, these overarching rules remain in force and will have to be taken into account.

5.1.2 EU Plastics Regulation

The EU's Plastics Regulation (Commission Regulation (EU) No. 10/2011) on plastic materials and articles intended to come into contact with food) sets out specific requirements for the

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manufacture and marketing within the European Union of plastic materials and articles (i) intended to come into contact with food, or (ii) already in contact with food, or (iii) which can reasonably be expected to come into contact with food. The Regulation lays down detailed compositional requirements. The Annex lays down the European Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids.

5.1.3 EU Good Manufacturing Practice Regulation

The EU GMP Regulation (Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP)) sets out requirements for the manufacture of materials and articles. Manufacturing must comply with good manufacturing practice (GMP) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities that could: (a) endanger human health, (b) bring about an unacceptable change in the composition of the food, or (c) bring about a deterioration in the organoleptic properties of the food.

5.1.4 National Regulations of Special Importance

The Framework Regulation allows for the adoption of specific measures for different types of food contact materials. Annex I contain a list of seventeen groups of materials or articles that may be regulated by specific measures. When specific (harmonised) measures have not been adopted at European level, member states may adopt national provisions that apply to products placed on their market. “Paper and board” are a category of food contact materials that is included in the list in Annex I although to date no harmonised measures have been adopted for this category. Certain countries have adopted national provisions for paper and board intended to come into contact with food. According to the experience of the project partners, compliance to certain national regulations are commonly demanded by customers. These include regulations from Germany, Netherlands and Italy.

Compliance with the German BfR Recommendations is generally required by the industry in the EU. It should be noted that the BfR Recommendations are not legally binding measures in Germany. However, they are considered to represent the current state of the scientific and technical knowledge for the conditions under which food contact materials can be considered as meeting the requirements of Article 3.1 of the European Framework Regulation on materials and articles in contact with food.

The role of other national legislations (Italy and Netherlands) in the food contact materials is in that if the final paper and board product is manufactured in Italy or the Netherlands, the produced material or article is in the scope of those national legislations. Both Italian and Netherlands legislations include a list of substances that can be used in the production of paper and board products. Therefore, in addition to the BfR Recommendations, a separate authorization process to the two local legislations may be relevant, depending on the country of production of the food contact material or article.

5.1.4.1 German BfR recommendations

The BfR Recommendations on Food Contact Materials are to ensure that materials do not release substances into foods which could cause a health risk for consumers. The goal of the BfR Recommendations is to define the conditions under which no migration of substances with a health risk occurs from the contact materials to the foods BfR recommendation XIV lists the monomers or other starting substances listed in the Commission Regulation (EU) No. 10/2011 that may be used, with specific limits. BfR recommendation XXXVI applies to single and multi-layered commodities (materials and

articles) made of paper and paperboard, as well as fiber casting, which are intended to come into contact with food, including paper and paperboard which are intended to be used at temperatures up to 90 °C. BfR recommendation XXXVI/1 Applies to overall raw materials (Section I), overall production aids (Section II) and special raw materials and production aids (Section III) used in the manufacture of food contact paper (that comes into contact with aqueous food), paperboard and board. BfR recommendation XXXVI/2 applies to paper and paperboard that comes into contact with food during baking. The paper and paperboard must be able to withstand a temperature of at least 220 °C for the intended period of heating without decomposing.

5.1.4.2 The Netherlands

Food packaging materials are regulated in the Netherlands pursuant to a Decree of 1 October 1979 on Packaging and Articles of Daily Use ("Verpakkingen-en Gebruiksartikelen-besluit (Warenwet)"). This decree is implemented by the Ministerial Regulation of 25 January 1980 (the "Regeling verpakkingen en gebruiksartikelen (Warenwet)," as amended). These regulations are essentially a compilation of "positive lists" for different types of substances, including plastics, that are permitted in the Netherlands for use in manufacturing food packaging materials. The Warenwet Regulations are structured in 10 chapters that regulate plastics, paper and board, rubber, metals, glass, ceramics, textiles, regenerated cellulose, wood and cork, and coatings, respectively.

5.1.4.3 Italy

Food contact materials in Italy are regulated under the Decree of 21 March 1973 on Hygienic Requirements for Packaging, Containers, and Utensils Intended to Be used in direct contact with food and substances for personal use ("the 1973 Decree"), as amended. This decree establishes rules for the authorization and control of objects intended to come into contact with food substances. Article 3, Title I of the 1973 Decree stipulates that food contact materials must be prepared exclusively from components specifically listed in an attachment to the law for different categories of materials (such as plastic, rubber, regenerated cellulose, paper, and cardboard, glass, and stainless steel) and must otherwise comply with any conditions or limitations prescribed therein.

5.1.5 Inventory of Food Contact Substances Listed in 21CFR (FDA)

This represents a database which contains an inventory of substances authorized in Title 21 of the U.S. Code of Federal Regulations (21 CFR) for uses in contact with foods. The database contains information on the substance identity and listed FDA regulations for the specific intended uses and use conditions authorized. The listing includes Food Contact Substances (FCSs) including indirect food additives listed under 21 CFR Parts 175-178, 179.45, and 180.22 as well as secondary direct additives listed in 21 CFR 173, prior-sanctioned food ingredients listed in 21 CFR 181, and substances affirmed as generally recognized as safe listed in 21 CFR 186. The inventory also contains information on substances listed in 21 CFR 189 that are prohibited from use as food contact substances. In addition to ingredients authorized and listed in 21 CFR, FDA maintains separate inventories for premarket authorizations for food contact substances issued under the Food Contact Substance Notification (FCN) and Threshold of Regulation Exemptions (TOR) programs.

5.1.6 EU legislation of Packaging and Packaging Waste

The Packaging and Packaging Waste Directive (PPWD – Directive 94/62/EC) lays down measures to prevent the production of packaging waste, and to promote reuse of

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packaging and recycling and other forms of recovering packaging waste. It also sets out the requirements that all packaging placed on the EU market must meet. These provisions are designed to reduce the disposal of packaging waste and to promote a more circular economy and were updated in 2022 as part of the European GD and the Circular Economy Action Plan.

This legislation has three main objectives:

1. To prevent the generation of packaging waste: reduce it in quantity, restrict unnecessary packaging and promote reusable and refillable packaging solutions.
2. To boost high quality ('closed loop') recycling: make all packaging on the EU market recyclable in an economically viable way by 2030.
3. To reduce the need for primary natural resources and create a well-functioning market for secondary raw materials, increasing the use of recycled plastics in packaging through mandatory targets.

The target is to:

1. To reduce packaging waste by 15% by 2040 per Member State per capita, compared to 2018. This would lead to an overall waste reduction in the EU of some 37% compared to a scenario without changing the legislation. It will happen through both reuse and recycling.
2. To foster reuse or refill of packaging, which has declined steeply in the last 20 years, companies will have to offer a certain percentage of their products to consumers in reusable or refillable packaging, for example takeaway drinks and meals or e-commerce deliveries. There will also be some standardisation of packaging formats and clear labelling of reusable packaging.
3. To address clearly unnecessary packaging, certain forms of packaging will be banned, for example single-use packaging for food and beverages when consumed inside restaurants and cafes, single-use packaging for fruits and vegetables, miniature shampoo bottles and other miniature packaging in hotels.
4. Many measures aim to make packaging fully recyclable by 2030. This includes setting design criteria for packaging; creating mandatory deposit return systems for plastic bottles and aluminium cans; and making it clear which very limited types of packaging must be compostable so that consumers can throw these to biowaste.
5. There will also be mandatory rates of recycled content that producers have to include in new plastic packaging. This will help turn recycled plastic into a valuable raw material – as already shown by the example of PET bottles in the context of the Single-Use Plastics Directive.

In ZeroF, the main technical case is for a fiber-based package coated with a CeFAE-based dispersion coating. These will likely be disposable, because there is an inescapable tradeoff between biodegradability and durability for reuse purposes. If such packaging is recycled, it will be recycled together with cardboard, where sieving is used to separate the coating material. As such, the novel materials from ZeroF will be regulated in the same way as existing dispersion coating formulations.

5.1.7 Single-use Plastics Directive

The Single-use Plastics Directive (Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment), or SUPD, is a directive aimed at reducing microplastics emissions through

regulation of single-use packaging. SUPD is based on the five actions denominated in the European Union Circular Economy Action Plan (CEAP): restrict intentionally added microplastics, limit unintentional microplastics release (caused by degradation of macroplastics), require labeling of plastic products, issue recycling mandates to capture discarded plastic products, and finally, to implement actions to measure the level of microplastics contamination and develop the science of microplastics. The SUPD lists specific products individually and specifically: cotton bud sticks, straws, beverage stirrers, balloon sticks, disposable cutlery, disposable plates and disposable food containers and cups made of expanded polystyrene (EPS). For ZeroF, the most relevant case is disposable cups for food and beverages. The approach chosen is simple: SUPD allows the use of monomers and natural polymers, but not synthetic polymers. Importantly, this is regardless of their biodegradability. This has an effect on directing research in ZeroF, because synthetic polymers, polymer grafts and functionalized natural polymers are not allowed in wares subject to SUPD. However, such SUPD bans do not cover reusable packaging. Instead, the approach is promoting the use of recyclable, returnable packages. To remain usefully reusable, coatings should have more durability than those used in single-use wares.

5.1.8 Information Requirements for an EFSA Safety Dossier

When preparing a technical dossier for a new chemical to be used as FCM, applicants are directed to follow the scientific requirements described in the 'Note for Guidance for Food Contact Materials' (EFSA, 2017) and submit the requested information in the appropriate section. This approach will need to be followed in ZeroF and the main sections are highlighted below:

0 Summary of the Dossier

1 Identity of the Substance

2 Physical and chemical properties of the substance

3 Intended application of the substance

4 Authorisation of the substance

5 Data on migration of substance

6 Data on residual content of substance in the FCM

7 Microbiological properties of the substance

8 Toxicological data

- Genotoxicity
- *In vitro* mammalian cell micronucleus test
- *In vivo* Comet assay
- Transgenic rodent gene mutation assay
- Repeated dose 90-day oral toxicity study
- Combined chronic toxicity/carcinogenicity
- Reproduction/teratogenicity
- Metabolism
- Absorption, distribution, biotransformation and excretion

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- Accumulation in man
- Effects on the immune system
- Neurotoxicity

Given the expected TRL level, it is not expected that a full dataset could be collected in ZeroF. However, care needs to be taken to ensure the absence of any precursors known to have any of the toxic effects mentioned above.

5.2 Textiles

Several frameworks and regulations are being detailed lately related to textile sustainability, which also affects the chemicals used on them and its hazardous properties. Specifically, the European Commission has tracked the presence of chemicals of concern in the EU market's textile products, of which "around 60 are considered as carcinogenic, mutagenic or toxic to reproduction". EU looks to impose a ban on several chemicals of a similar structure (ECHA), with the announcement to ban 200 PFAS substances in phases, with the proposal launched on February 2023. Some of the legal texts related to PFAS are explained below and under REACH in previous sections.

5.2.1 EU Strategy for Sustainable and Circular Textiles

The strategy aims to create a coherent framework and a vision for the transition of the textiles sector whereby:

"By 2030 textile products placed on the EU market are long-lived and recyclable, to a great extent made of recycled fibres, **free of hazardous substances** and produced in respect of social rights and the environment. Consumers benefit longer from high-quality affordable textiles, fast fashion is out of fashion, and economically profitable re-use and repair services are widely available. In a competitive, resilient and innovative textiles sector, producers take responsibility for their products along the value chain, including when they become waste. The circular textiles ecosystem is thriving, driven by sufficient capacities for innovative fibre-to-fibre recycling, while the incineration and landfilling of textiles is reduced to the minimum."

The EU Strategy for Sustainable and Circular Textiles outlines several steps that will be taken to enable this shift, starting with the obvious need for mandatory "eco-design" requirements. The Commission will develop under the Ecodesign for Sustainable Products Regulation "product-specific eco-design requirements to increase textiles' performance in terms of durability, reusability, reparability, fibre-to-fibre recyclability and mandatory recycled fibre content, **to minimise and track the presence of substances of concern** and to reduce the adverse impacts on climate and the environment." The Commission says it will use the existing voluntary EU Ecolabel for Textile Products developed by the Commission and the EU Green Public Procurement (EU GPP) criteria for textiles products and services which both have "detailed criteria for good quality and durable products, restrictions of hazardous chemicals, as well as requirements on environmentally sustainable sourcing of textile fibres[9]."

[9]https://www.linkedin.com/pulse/why-defining-criteria-chemical-bans-challenge-eu-roxane-uzureau-zhu/?trk=public_post

5.2.2 ECHA requirements on textiles

In the absence of migration experiments, ECHA (2019) proposed a default migration fraction in its restriction dossier on sensitisers. A specific experiment on textile to simulate migration onto sweat and in saliva for kids is needed.

A new EU-wide restriction, which applies from November 2020, limits the use of 33 substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR). These substances may be used in production processes or to give specific properties to the product, such as to make cloth shrink-proof or crease-resistant. The restriction applies to both EU-made and imported clothing, textiles such as bed linen and upholstery, and footwear.

Each of the restricted substances has different properties and they are used in different processes in the textile and footwear industries, so maximum concentration limits have been specified for individual substances or groups of substances.

The restriction covers substances from the following groups[10]:

- cadmium, chromium, arsenic and lead compounds
- benzene and polyaromatic hydrocarbons (PAHs); -
- chlorinated aromatic hydrocarbons;
- formaldehyde;
- phthalates;
- polar aprotic solvents;
- azo-dyes and acrylamines
- quinoline

This represents the traditional (pre-REACH), and previously mostly used approach to legislation, where a set of banned substances is individually named, instead of providing overarching principles and obligations on all products. In the SSbD approach, we aim to avoid equally or more harmful substitutes ("regrettable substition") by assessing the inherent safety of the alternatives proposed.

5.2.3 Recommendation for safe and sustainable chemicals

On December 2022 the Commission adopted a recommendation and annex to promote research and innovation for safer and more sustainable chemicals and materials[11]. The proposed European framework is an important step to increase the protection of human health and the environment against hazardous substances and improve the circularity of chemicals and materials.

The 'safe and sustainable by design' framework encourages innovation to replace hazardous substances in products and processes, for example in food-contact materials, like plastic wrap or food containers, textiles or information and communications technologies products, such as laptops or tablets. It aims to develop new chemicals and

[10] https://chemicalsinourlife.echa.europa.eu/substances-we-dont-want-in-our-clothes

[11]https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/recommendation-safe-and-sustainable-chemicals-published-2022-12-08_en

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materials, optimise or redesign production processes and the use of substances currently on the market to improve their safety and sustainability.

5.2.4 Fibre name and textile labelling Regulation

Regulation (EU) No 1007/2011 [64] represents a of reference to understand what kind of safety information is required when placing a new fibre on the market (which will be in contact with the skin). This regulation specifies that manufacturers can ask the Commission to include a new name in the list of fibres. This request has to be issued together with a technical dossier showing the safety of the fibre. Annex II of the regulation specifies the information required, among which the following can be mentioned: i) chemical composition; ii) safety information on allergic reactions or other adverse effects of the new textile fibre on human health, including results of tests conducted to that effect in compliance with relevant European Union legislation.

New updates to be implemented in 2023 include:

- Clear information and performance requirements on textile product aspects (including unintentional release of microplastics from synthetic textiles).
- Address the destruction of unsold or returned textiles
- Information and traceability tool (DPP)
- Digital and physical labels for textile products with accessible, accurate and comparable information for consumers
- Information to consumers on durability, reliability and green claims
- Mandatory Extended Producer Responsibility for textiles with eco-modulation of fees
- Horizontal reporting and due diligence obligation regarding impact on human rights (including social rights) and the environment.
- Prohibit the placing on the EU market of products made by forced labour, including forced child labour

5.2.5 Extended Producer Responsibility for textiles

The EU Strategy for Sustainable and Circular Textiles EU Strategy for Sustainable and Circular Textiles harmonizes EU rules on extended producer responsibility (EPR) for textiles[12,13], and economic incentives to make products more sustainable ("eco-modulation of fees"), as part of the revision of the Waste Framework Directive in 2023. Harmonised EPR regulations across the EU offer significant economic and environmental benefits. They make reuse and recycling of textile waste more economically viable, diverting textiles from landfill and incineration.

[12] https://ec.europa.eu/commission/presscorner/detail/en/QANDA_22_2015
[13] https://ellenmacarthurfoundation.org/extended-producer-responsibility-for-textiles"

6 Overview of available standards

This section covers a state-of-the art overview of methods developed by OECD / CEN / ISO", relevant to ZeroF as well as harmonised test guidelines and guidance documents from the OECD. The OECD develops methods for regulatory testing, which are globally recognised for this purpose under the Mutual Acceptance of Data agreement (MAD).

6.1 Standards testing product functionality

- BS 5651:1978 Cleansing and wetting procedures.
- BS 5722:1984 Specification for flammability performance of fabrics and fabric assemblies used in sleepwear and dressing gowns.
- EN 16785-1: Bio-based products Bio-based content - Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis
- EN 16785-2: Bio-based product Bio-based content - Part 2: Determination of the bio-based content using the material balance method
- EN 16640: Bio-based products Determination of the bio-based carbon content of products using the radiocarbon method
- CEN/TR 16721: Bio-based products Overview of methods to determine the bio-based content
- EN 17351:2020: Bio-based products Determination of the oxygen content using an elemental analyser
- EN 16575: Bio-based products – Vocabulary
- EN 16848: Bio-based products - Template for B2B reporting and communication of characteristics - Data sheet
- EN 16935: Bio-based products - Business-to-Consumer communication and claims
- EN 16766: Bio-based products - Bio-based solvents - Requirements test methods

- ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 16532-1:2008 Paper and board — Determination of grease resistance — Part 1: Permeability test
- ISO 16532-2:2007 Paper and board — Determination of grease resistance — Part 2: Surface repellency test
- ISO 16532-3:2010 Paper and board — Determination of grease resistance — Part 3: Turpentine test for voids in glassine and greaseproof papers
- ISO 22000 Food Safety Management including packaging
- ISO 4920:2012 Textile fabrics - Determination of resistance to surface wetting (spray test).
- ISO 14419:2010 Textiles - Oil repellency - Hydrocarbon resistance test
- ISO 5636-6:2015 Paper and board — Determination of air permeance (medium range) — Part 6: Oken method
- ASTM D2482-97(2002) Standard Test Method for Surface Strength of Paper (Wax Pick Method)
- EN13432-2000. Requirements for packaging recoverable through composting and biodegradation
- ISO 16532 Paper and board — Determination of grease resistance:
    - Part 1: Grease permeability method

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- Part 2: Surface repellency test
- Part 3: Turpentine test for voids in glassine and greaseproof papers

6.2 Voluntary Standards

Besides mandatory legal standards, certification of products according to private voluntary safety and sustainability standards is common in the industry. This is especially the case with textiles, where the legislation itself does not cover aspects of safety, sustainability and social responsibility demanded by consumers. This gap is filled by private companies offering certification services. To certify a product according to a private standard, a manufacturer pays various registration, subscription and inspection fees.

6.2.1 Oeko-tex

This is a voluntary standard, which is accepted by the whole textile value chain, and is recognized as a certification of safety. The certification is based on the chemical analysis of the textile in all its parts, and comparison to a list of substances which must not be present over a certain concentration. The usefulness of this list is that it is possible to check the composition of the materials and verify the absence of these substances, similar to the Substances of Very High Concern (SVHC) list in REACH and the substances in the RoHS Directive. It represents an additional evaluation.

In regard to PFAS, OEKO-TEX® has issued a general ban on the use of perfluorinated and polyfluorinated alkyl substances (PFAS/PFC) in textiles, leather and footwear for the STANDARD 100, LEATHER STANDARD and ECO PASSPORT certifications.

6.2.2 Bluesign

Bluesign is an independent system which aims to minimize the environmental impact throughout the production process or the entire textile supply chain. It does not test finished products; it is applied at the starting point of the production ensuring that substances and raw materials are verified. The bluesign system is based on five principles:

- Resource productivity
- Consumer safety
- Water emission
- Air emission
- Occupational health & safety

Like Oeko-Tex, bluesign maintains a subscription-based service and a database of chemical classifications.

With the prospect of new PFAS being restricted in the short- or mid-term, Bluesign has planned that from July 2023 all PFAS based chemicals will be phased out from the bluesign® FINDER and as of July 2024 all bluesign® APPROVED fabrics that are treated with PFAS formulations will be removed from the bluesign® GUIDE.

Cradle2Cradle

Cradle to Cradle is a multi-attribute standard which assess the safety, circularity and responsibility of materials and products across five categories of sustainability performance:

- Material health

- Product Circularity
- Clean Air & Climate Protection
- Water & Soil Stewardship
- Social Fairness

6.2.3 Nordic Swan Ecolabel

The Nordic Swan Ecolabel is the official and most recognised environmental label in the Nordics. The ecolabel is based on voluntary certification. It is noted for its stringency and is granted to products and services that are the best in their product group in terms of environmental friendliness. The Nordic Swan Ecolabel assesses all the relevant environmental parameters and the entire life cycle of the products. In particular, it excludes or limits PFOA and PFOS.

6.2.4 Blue Angel

The Blue Angel ecolabel was initiated by the German government and is awarded to a company that offers or produces and disposes its products or services in a particularly environmentally friendly way. The label promotes the concerns of both environmental protection and consumer protection. Therefore, it is awarded to products and services which are particularly beneficial for the environment in an all-round consideration, and which also fulfil high standards of occupational health and safety and fitness for use.

6.2.5 GOTS

The Global Organic Textile Standard (GOTS) is the worldwide leading textile processing standard for organic fibres, including both ecological and social criteria, backed up by independent certification (third party). The aim is to define world-wide requirements that ensure organic status of textiles throughout the entire textile supply chain. In principle, any product that can be considered as a textile fibre product is covered under the scope of this standard, but it does not cover containing electronic textiles or non-fibre materials such as leather. There are two label-grades in which the standard is subdivided:

- Label-grade 1 - “Organic”: >95% certified organic fibres, <5% non-organic natural or synthetic fibres
- Label-grade 2 - “Made with X% organic”: >70% certified organic fibres, <30% non-organic fibres, but maximum of 10% synthetic fibres (25% for socks, leggings and sportswear, effectively for allowing for the use of elastane, which has no natural equivalent) as long as the raw materials used are not from certified organic origin, a sustainable forestry management program or recycled.

6.2.6 ZDHC

The ZDHC foundation’s “Roadmap to Zero” programme is aimed to paving the way for sustainable chemical management within the fashion industry. The ZDHC Manufacturing Restricted Substances List (ZDHC MRSL) is a list of chemical substances banned from intentional use in suppliers that process textile materials and trim parts in textile, apparel, leather, and footwear. The ZDHC MRSL is a living document, and is updated as needed to expand the materials and processes covered and to add substances that should be phased out of the value chain.

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6.2.7 EU Ecolabel

The EU Ecolabel is the official European Union voluntary label for environmental excellence. It was established in 1992 and has been since recognised across Europe and worldwide, the EU Ecolabel certifies products with a guaranteed, independently-verified low environmental impact. To be awarded the EU Ecolabel, goods and services should meet high environmental standards throughout their entire life cycle, from raw material extraction through production and distribution to disposal. The label also encourages companies to develop innovative products that are durable, easy to repair and recyclable. The Regulation (EC) No 66/2010 lays down rules for the establishment and application of the voluntary EU Ecolabel scheme. In relation to PFAS, EU Ecolabel criteria state that fluorinated water, stain and oil repellent treatments shall not be used. These shall include perfluorinated and polyfluorinated treatments.

6.2.8 NF Environment

NF Environment is a French voluntary certification mark. This label is issued for products having a reduced impact on the environment while at the same time guaranteeing the same fitness for purpose as the other products on the market. It applies to furniture products for domestic and professional use and it addresses issues related to:

- Quality and durability of the product.
- Health and safety of the user
- Environment

6.2.9 GUT

The GUT voluntary standard, also known as Gemeinschaft Umweltfreundlicher Teppichboden e.V (Association of environmentally Friendly Carpets), aims to improving continuously all environmental and consumer protection aspects throughout the life cycle of a textile floor covering. It also promotes environmentally friendly solutions for the installation of carpets and provides objective information on all aspects of carpets. Regarding the scope of the certification, it only covers textile floor coverings, and the requirements stablished are the following:

- Some chemical substances are banned or limited.
- Emission limit values for some substances.
- Odour limits.

A long list of per- and polyfluorinated alkylated substances that are known or suspected to have a negative impact on humans or the environment are not allowed within the GUT-system.

6.2.10 Textile Exchange

Textile Exchange is a global non-profit organization whose work commitment is to identify and share best practices regarding farming materials, processing, traceability and product end-of-life, in order to reduce the negative impacts of the textile industry. They have developed several standards to support specific claims; some examples are the following:

- Content Claim Standard (CCS): A generic chain of custody standard used for the chain of custody requirements for a number of standards, including OCS, RCS and GRS, which provides companies a tool to verify that one or more input materials are in final product.

- Organic Content Standard (OCS): Provides a third-party verification of organic material content in a product and options for corresponding consumer-facing claims. It does not address the use of chemicals or any social or environmental aspect of production beyond the integrity of the organic material. Neither the certification of the raw material itself.
- Recycled claim Standard (RCS): Tracks recycled raw materials through the supply chain.
- Global Recycled Standard (GRS): A holistic certification for products with recycled content that applies to products that contain at least 20% recycled material. The desired effect is to provide brands with a tool for more accurate labelling, to encourage innovation in the use of reclaimed materials, to establish more transparency in the supply chain and to provide better information to consumers. It does not address quality or legal compliance.

6.2.11 Compostable and Biodegradable standard

Packaging is one of the aspects that has to be considered when assessing the safety of the general product. In general, it is intended as an assurance that there is no release of harmful substances from the packaging of the product. The application of eco-design principles represents an aspect that could also be considered while designing the packaging, always taking into account that the technical functionality of the product is not compromised. Development of the packaging should be compliant with the EN 13432:2000 standard (translating the indications of Directive 94/62/EC).

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7 Future update of the Regulatory Landscape in Europe

7.1 Upcoming regulations for plastics

Microplastics are defined as small particles of plastics typically no more than 5 mm across. This definition has not been standardised but it is also aligned with that proposed by the National Oceanic and Atmospheric Administration (NOAA). In 2022 the European Commission released a draft proposal regarding the restriction of synthetic polymer microparticles[14]. The restriction comprises synthetic polymer microparticles below 5 mm, and fibre-like particles below 15 mm, intentionally added to products. Natural, degradable and soluble polymers are excluded from the definition of synthetic polymer microparticles. The draft Commission proposal does not include a lower limit on microplastic size, however it includes text stating that where the concentration of microparticles cannot be determined only particles of 0.1 µm or above shall be considered – for microfibres this is 0.3 µm in length. This restriction is expected to be adopted by the European Commission in Q3 of 2023 and includes de following measures[15]:

- A restriction on the placing on the market of microplastics (and nanoplastics) on their won, or in mixtures, where their use inevitably results in releases to the environment, irrespective of the conditions of use. A transitional period is proposed for some of these products, e.g., In the example of artificial turf six years have been proposed, four years for rinse off and 6 years for rinse on cosmetic products, 5 to 8 years for the encapsulation of fragrances in detergents and cosmetic products, 5 years for detergents and maintenance products (waxes, polishes and "air care" products), five years for fertilising products which are not regulated by the new fertilisers regulation (No 2019/1009) and other agricultural and horticultural uses including seed treatment and eight years for Plant Protection Products and Biocides.
- A labelling requirement to minimise releases to the environment for uses of microplastics (and nanoplastics) where they are not inevitable released to the environment, but where residual releases could occur if they are not used or disposed off appropriately. These products are not proposed to be banned but need to be reported to ECHA for further monitoring, enabling also information exchange along the supply chain.
- A reporting requirement to improve the quality of information available to assess the potential for risks for remaining uses of microplastics (and nanoplastics) in the future.

7.2 ECHA's restriction dossier

The registry of restriction intentions until outcome lists the intentions and Annex XV restriction proposals received by ECHA.[16]

A restriction proposal may be prepared by a Member State or by ECHA at the request of the Commission or on its own initiative for substances in the Authorisation List. It is a legal requirement for a Member State to notify ECHA of its intention to prepare a restriction dossier. The advance notice enables interested parties to plan and prepare for commenting

[14] https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/1/consult
[15] ECHA, 2019 European Commission draft proposal regarding the restriction of synthetic polymer microparticles, Comitology register

later on. At present stakeholders can follow the progress of a proposal through the restriction process, from the notification of the intention to the adoption of the final opinions by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC), and the adoption of the restriction by the European Commission. Stakeholders are encouraged to submit any relevant information to the dossier submitters during the preparation of the restriction proposal and during the consultations.

7.3 The Extended Product Responsibility (EPR) Principle

This principle[16] aims to transfer the elimination costs of used products from the taxpayer to the consumer by integrating them in the sales prices of the new products. Member States can introduce the EPR concept into its own legal framework and decide how to encourage manufacturers to link with the prevention, re-use, recycling and recovery of used plastic products. One example posed by the Commission is the implementation of National Collecting Schemes in several countries to encourage recycle of agri-plastics.

7.4 EU Strategy of Plastics in Circular Economy

The main aim of this strategy[16] is to protect the environment from plastic pollution. The main points address by the strategy are:

- Make recycling profitable for businesses (by 2030 all plastics on the EU market should be recyclable).
- Curb plastic waste; reduction of single use plastic, plastic fishing gear, restriction of intentional use of microplastics under REACH.
- Stop littering at sea.
- Drive investment and innovation to minimise plastic waste at the source.
- Spur change across the globe.

7.5 Food and Food Contact Materials

In 2019 the SAM report was published following a series of publications from EFSA and others on the presence of micro and nanoplastics in food. The report concludes that there is evidence of irreversible long term ecological risks for some coastal waters and sediments, if emissions to the environment continue at the current rate or increase, ecological risks could be wide spread within a century, toxicity and easy of microplastics crossing biological barriers is expect to increase with decrease size, at present there is no evidence of a wide-spread risk to humans, better understanding is needed on the effects of increase concentrations, compositions, sizes and shapes on ecosystems and humans.

The conclusions from the European Commission regarding food indicate that regulatory measures for micro and nanoplastics in food can only be implemented when there is evidence that they pose a risk to human health, hence a human health risk assessment is needed. To achieve this more data on food and drinking water is needed. Regarding exposure assessment only rough estimates are available, currently, these show an intake up to the weight of a credit card in microplastics each week, however, more accurate estimates are needed. Data on microbiological risks, chemical risks due to absorption and risks pose by particles themselves are lacking to perform risk assessment. Until these data are still missing, EFSA cannot start regulating microplastics in food and food contact materials. On this front, EFSA aligns with the European Commission on regulatory priorities, which have

[16] https://ec.europa.eu/environment/pdf/circular-economy/plastics-strategy.pdf

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been set us; 1) harmonised definitions for micro and nanoplastics, 2) develop validated analytical and sampling methods, 3) harmonise method requirements. Only once these have been achieved toxicological and toxicokinetic studies can be implemented, sources of plastics in food identified together with good practices to mitigate the introduction of microplastics in food.

Within the food and feed domain, by January 2024 the European Commission will supplement the **EU Drinking Water Directive** by adopting a methodology to measure microplastics, so they can be included in the watch list of substances of concern to the public or the scientific community on health grounds. On this front, and no later than 2029, the European Commission will produce a report to the European Parliament and the Council on the potential threat of microplastics to sources of water intended for human consumption.

The current lack of data does not allow to include microplastics under the regulatory framework contaminants in food (EEC No. 315/93[17] and (EC) 1881/2006[18]).

7.6 Textiles

The Commission 2030 vision for textiles aims to create a textile sector which is more competitive and more resistant to global fluctuations and to achieve these goals it is working toward a textile ecosystem transition pathway and a final policy report with concrete actions due in 2023. The strategy seeks to develop by 2030 textile products which are durable, repairable and recyclable, and, as far as possible, made from recycle fibres, free of hazardous substances and produced respecting social and environmental sustainability goals. This strategy aims to end fast fashion and make profitability from reuse and repair services. Producers should take responsibility of their products along the value chain, maximising recycling against incineration or land filling. The Commission is working on design requirements to make textiles last longer, easier to repair and recycle. The introduction of a Digital Product Passport is also envisaged to ensure consumers have access to green product claims. This strategy aims to stop overproduction and destruction of unsold textiles and harmonises EU Extender Producer Responsibility rules for textiles. Unintentional release of microplastics from synthetic textiles will also be considered. The Commission is looking into the adoption of an EU toolbox against counterfeiting during 2023. Revisions to the Ecodesign for sustainable products and textiles, WFD and DPP are currently in place. The key actions from the Textile Strategy are shown in Figure 4.

[17] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

[18] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance)

Figure 4 Summary of key actions put forward by the European Commission to achieve Sustainable and Circular Textiles by 2030.

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8 Conclusion

In Europe, several directives and strategies are in place to cover for the use of plastics both as food contact materials and textiles. These have been collected and reviewed in this deliverable spanning from chemicals (REACH) to products and to cover the whole value chain. This deliverable also reviews relevant standards as required to fulfil product claims.

As far as EU future trends are concerned, the EU Green Deal, together with several Action Plans in place have also been reviewed, as several strategies currently on-going will have a future impact on the way materials are sourced, used and recycled/disposed. Several strategies such as the Plastics in Circular Economy or the 2030 Vision for Textiles, anticipate the implementation in a few years' time (up to 7) of regulations which foster transparency regarding sourcing of materials, eco claims, biodegradation, reuse and sustainability, including social concerns due to forced labour. The European Commission has also identified priorities to limit the release of microplastics to the environment. As a first recommendation, the European Commission is seeking to broaden policy cover to prevent and reduce the use of microplastics through existing legal frameworks such as the Water Directive, Air quality legislation or the use of sewage sludge as fertilisers. Furthermore, these policies should be supplemented with measures which are substance- and context-specific, e.g., the introduction of standards for washing machines and tighter licencing conditions for pellet producers under the Industrial Emissions Directive. Actions in the Green Deal include for example the Single-use Plastics Directive (SUPD), which regulates a named list of products. SUPD allows only natural polymers and monomers, and the functionalized polymers and polymer grafts are currently not allowed under SUPD.

Regarding safety of chemicals, in 2023 the European Commission added new hazard classes from REACH to the classification, labelling and packaging (CLP) of substances and mixtures, which includes endocrine disrupting chemicals (EDCs) and also introduces hazard classes for the following properties: persistent, bioaccumulative, and toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, and toxic (PMT); and very persistent, very mobile (vPvM). In ZeroF, it is essential to study if the coating materials developed, or their probable breakdown products, do not create a new environmental persistence problem. If reduction of environmental persistence is a desired impact, there needs to be a method to evaluate it in a transparent way.

Several knowledge gaps still remain and need to be addressed if the goals of the European GD are to be implemented following the agreed timeline (Europe to become the first climate neutral continent by 2050), for example, protocols to detect microplastics concentrations are underdeveloped but essential to understand their behaviour leading to pollution, so further safety measures can be put in place. The European Commission is also looking for economically viable solutions to Circularity in Textiles (VAT reductions, education programs for consumers), or plastic pollution which should follow a circular economy logic. On these lines, ZeroF proposes alternatives to the emerging PFAS concern while minimising trade-offs in performance and costs to assure consumers acceptability while environmental sustainability will be assessed by means of LCA, and the indicators proposed by the World Business Council for Sustainable Development to assess circularity will be used as a baseline in this project.

In the next steps of the project, ZeroF applies Safe-and-Sustainable by Design (SSbD) principles to develop new alternatives for PFASes. The intrinsic hazards of the chemicals

used, and their breakdown products will be evaluated and reflected against the current regulation. To verify the performance, we will compare the environmental and safety performance of the alternatives with the requirements in regulations. There is a target for carbon neutrality in the EU GD. However, sustainability metrics such as energy efficiency and carbon footprint are lacking current regulation. We can quantify the carbon footprint, zero pollution and circularity and evaluate how they fit into the current regulation.

This deliverable represents a scooping exercise to feed D6.7 Report strategic certification/standardisation roadmap to achieve cost-effective certification compliance.

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