



A recycler's perspective on the implications of REACH and food contact material (FCM) regulations for the mechanical recycling of FCM plastics



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ABSTRACT

This manuscript provides an overview of the legislative requirements for the use of mechanical recycled plastics in articles placed on the EU market, as seen from the perspective of a plastics recycler. The first part reviews the main principles included in the overarching legislation on Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH) and to what extent these are applicable for mechanical recyclers of plastics. The interactions between REACH and the Waste Framework Directive (WFD) is discussed, as well as the difficulties for recyclers to comply with certain REACH requirements. In a second part, the focus is moved to the use of recycled plastics as Food Contact Material (FCM). The scope of the different applicable EU FCM regulations is inventorised as well as the key legislative principles involved. A final section is dedicated to the discussion on the authorisation of recycling processes under the FCM regulation and the practical challenges involved for the effective introduction of FCMs containing recycled plastics. Altogether it could be concluded that the complexity of the different legal perspectives, a lack of communication and transparency within the plastic value chain together with technical challenges related to recycling processes have been hindering the effective uptake of recycled plastic FCM (with the exception for bottle PET). The development of targeted solutions across the entire value-chain, taking into account different perspectives in terms of legislation and health protection, economic growth and technical innovations, will be crucial in achieving a circular economy for plastics, including recycled plastics for FCM.

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Abbreviations: Regulation (EC) No 178/2002, 'General Food Law Regulation'; Regulation (EC) No 1935/2004, 'FCM framework Regulation'; Commission Regulation (EC) No 2023/2006, 'GMP Regulation'; Commission Regulation (EU) No 10/2011, 'Plastic FCM Regulation'; Commission Regulation (EC) No 282/2008, 'Recycled plastic FCM Regulation'; Regulation (EC) No 1907/2006, 'REACH Regulation'; Regulation (EC) No 1272/2008, 'Classification, Labelling and Packaging Regulation'; Regulation (EU) 2019/1381, 'Transparency and sustainability of the EU risk assessment Regulation'; Directive 2008/98/EC, 'Waste Framework Directive'; CLP, Classification, Labelling and Packaging; DEHP, di/bis(2-ethylhexyl) phthalate; DoC, Declaration of Compliance; ECHA, European Chemicals Authority; EFSA, European Food Safety Authority; EoW, End-of-Waste; eSDS, extended Safety Data Sheet; EU, European Union; FCM, Food Contact Material; GMP, Good Manufacturing Practice; HBCDD, Hexabromocyclododecane; NIAS, Non-Intentionally Added Substances; OML, Overall Migration Limit; PCR, Post-Consumer Recycled (plastics); PET, Polyethylene terephthalate; (HD) PE, (High Density) Polyethylene; PP, Polypropylene; PVC, Polyvinyl chloride; SDS, Safety Data Sheet; SML, Specific Migration Limit; SVHC, Substance of Very High Concern; UK, United Kingdom; WFD, Waste Framework Directive.

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1. Introduction

Plastics nowadays have a key role in our society. With a global EU demand of 51.2 Mt they have become an integral part of our daily lives finding their use in various application areas (PlasticsEurope, 2019). Despite the fact that the use of plastics has many advantages as it combines excellent overall properties with a low cost, over the years it has also generated negative impacts on the environment. It became clear to policymakers that changes needed to be made within the plastics economy from a linear waste producing consumer system to one that preserves the value and benefits of plastics (European Commission, 2019a).

In this respect, the European Commission formulated their vision on a more integrated system in ‘A European strategy for plastics in a circular economy’ (European Commission, 2018a). This communication published in 2018 sets out different goals to implement a more life cycle thinking approach to plastics. Certain aspirations focus mainly on plastic packaging as the packaging industry is the largest outlet for plastics in the EU, with a market share of nearly 40% (PlasticsEurope, 2019). In addition, a lot of packaging materials can be categorized as ‘single use plastics’ which means that they are disposed of very quickly after only a short period of use (European Commission, 2018a). This is one of many reasons why packaging accounts for more than 60% of the total plastic waste yearly generated in the EU. In order to counteract this the European Commission stated that by 2030, all plastic packaging placed on the EU market needs to either be reusable or recyclable in a cost-effective manner. Moreover, they have previously proposed that by 2025 at least 55% of all plastic packaging in the EU should be recycled (European Commission, 2018a).

There is still a lot of work to be done in order to achieve this goal as the recycling rate of plastic packaging currently is only 40% (European Commission, 2018b). However, this is an overestimation since in practice this 40% accounts for the plastic waste which is ‘collected for recycling’. The actual net recycling rate of plastic packaging is in fact lower. A study on the post-consumer plastic packaging recycling network in the Netherlands for instance has indicated an effective recycling yield of only 26% instead of 50% as was reported by the official authorities

(Brouwer et al., 2019). Besides improving recycling rates, the European Commission also stated that it is important for recyclers to work closely together with the chemical industry to help identify wider and high-value applications for their output. This together with the idea of a more circular economy implies the preference of the EU for closed-loop recycling scenarios, in which, for instance, food packaging is recycled to become a food contact material (FCM) once more.

However, for certain packaging applications, there is still a long way to go to achieve this closed-loop recycling goal. Within food packaging for instance, it can be estimated that a mere 5% is nowadays recycled closed-loop within the EU (ING Economics Department, 2019; Lugal et al., 2020). This recycling is mainly done by means of mechanical recycling where washed and sorted plastic waste is re-molten and processed into a new food packaging. However, the recycling process may cause several issues regarding the safe use of the recycled plastics as food packaging due to an increase in possible contamination sources which might migrate into the food, thus imposing a risk to human health. To prevent placing such materials on the market, the EU has several pieces of legislation in place on the use of Food Contact Materials (FCMs) including plastics and recycled plastics. This legislation aims to protect the human health and the environment from the possible adverse effect of the use of those materials by imposing several requirements towards recyclers.

Within the EU, mechanical plastic recyclers (for FCMs) are subject to various regulations, including the framework Regulation (EC) No 1935/2004, Commission Regulation (EC) No 2023/2006 on good manufacturing practice, Commission Regulation (EU) No 10/2011 on plastic FCMs, Commission Regulation (EC) No 282/2008 on recycled plastics as FCM and the overarching Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The – often complicated – interaction between these regulations throughout the life cycle of plastics intended for the use as FCM is illustrated by Fig. 1.

These regulations exist for very good reasons as they guarantee a high level of protection of human health and the environment and do ensure the effective functioning of the internal market by

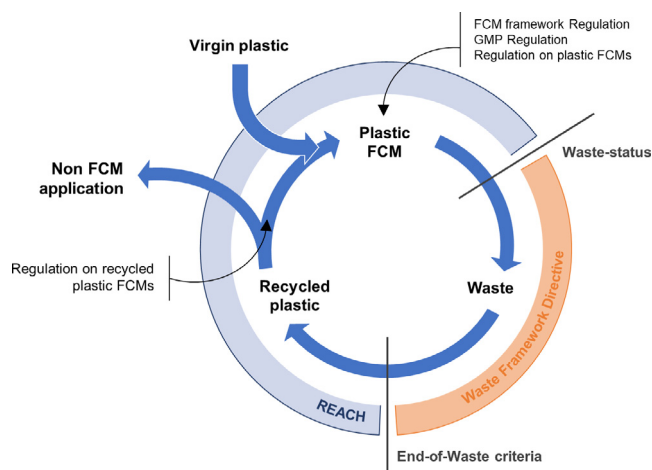


Fig. 1. Graphical representation of the applicability of REACH and EU FCM regulations on (recycled) plastic FCM throughout the entire life cycle.

allowing free movement of FCMs and/or the circulation of substances on that market. Within the EU, health protection is of particular concern when it comes to food safety. Therefore, an overarching and coherent framework for the development of pieces of legislation related to food (including the regulations mentioned above) was established within the General Food Law Regulation or Regulation (EC) No 178/2002 which is applicable to all stages of food production, processing and distribution. Within this regulation it is stipulated that measures relating to food safety must be based on strong science. Therefore it established the structures and mechanism for scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA) together with the principles for risk analysis consisting of (i) risk assessment (independent, objective and transparent based on available science), (ii) risk management and (iii) risk communication. It also invoked the precautionary approach (Article 7 of Regulation (EC) No 178/2002) which refers to specific situations where there are reasonable grounds for concern that an unacceptable level of risk to health exists or when insufficiently complete data are available to enable a comprehensive risk assessment to be made. This precautionary principle allows decision makers or risk managers to take specific measures or other actions, while seeking complete scientific and other data.

Still, the use of recycled plastics as FCM – with the exception for bottle PET – has not yet been successfully established which is clearly reflected by the small closed-loop recycling percentage of food packaging. Typical challenges for recyclates include full traceability, potential misuse during the lifetime and the separation of FCM and non-FCM waste. These are complex technical and logistical questions which require full value-chain solutions that are at the same time able to provide the necessary guarantee on chemical safety and effectively increased recycling rates. With new targets like 30% PCR (Post-Consumer Recycled) plastics uptake in beverage bottles by 2030 (European Parliament, 2019), discussion on how to resolve this stand-off is no longer avoidable.

In the current manuscript, the key legislative principles of the abovementioned regulations are summarized for (recycled) plastics starting with the overarching REACH Regulation and following the legislation on FCM. Their mutual interplay is discussed, as well as the challenges this may lead to for the effective and practical uptake of recycled plastics in FCMs in the EU. It is well-established that the relevant existing pieces of legislation are in place as an important safeguard for the protection of human health. It is not the intent of this manuscript to call those into ques-

tion. Nonetheless, it is often unclear – from the recycler's perspective – as to what exactly needs to be 'done' to realize compliance in practice. The authors have therefore elected to approach this subject from the recycler's perspective.

2. European legislation on chemicals: REACH Regulation

2.1. REACH framework

The use and placing on the market of chemical substances is regulated in Europe by the REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals) Regulation. The purpose of REACH is stipulated in Article 1 of Regulation (EC) No 1907/2006:

1. *The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.*
2. *This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle*

To achieve this purpose, REACH requires substances placed on the market in quantities exceeding one tonne per year per manufacturer or importer to be registered by the manufacturer or importer. This registration dossier needs to contain information on the physical and hazardous properties of the substance and on its conditions of use. The amount and nature of the information to be provided for a substance depends on the volume placed on the market and on its hazardous properties. The registration dossier, which needs to demonstrate safe use of the substance in its entire supply chain, forms the basis for the hazard and risk communication in the supply chain via the extended safety datasheet (eSDS).

Under the scope of REACH, polymers are defined as substances. They themselves are exempt from REACH registration, but the monomers and other reactants used to manufacture the polymer should be registered by the manufacturers or importers of the polymers (European Chemicals Agency, 2012).

The registration dossiers of substances can be scrutinized by ECHA in coordination with Member States competent authorities. This can be either in the context of checking the completeness of the registration dossier (dossier evaluation) or in the context of a concern that a member state might have with a specific substance (substance evaluation), e.g. a concern that a substance may be persistent, bio-accumulative and/or toxic. As a result of these evaluation processes, authorities may request additional data regarding the hazard or use conditions of the substance.

REACH also establishes a certain class of substances as being of very high concern (SVHC). These substances meet the criteria set forth in Art. 57 of REACH. They are considered carcinogenic, mutagenic or reprotoxic substances (category 1) but also substances which can disrupt the endocrine system, substances that are respiratory sensitizing or substances which are persistent, bio-accumulative and toxic or very persistent and very bio-accumulative. In case a substance meets one of these criteria, the risk of continued use of the substance can be managed by the authorities through additional regulatory measures. A first type of such measure is Authorisation. Substances subject to authorisation are listed in Annex XIV of REACH. In practice this means that the substance cannot be used anymore for any use after a certain date, called the Sunset Date, unless an authorisation has been granted for that use (or is under decision if the authorisation application was made timely, i.e. before the latest application date).

Prior to inclusion in Annex XIV, a substance is included in the “Candidate list for inclusion in Annex XIV”. This listing allows companies to prepare the substitution of the substance or prepare for an application for authorisation but also triggers communication obligations in the supply chain.

A second type of regulatory measure is Restriction. Substances which can be subject to restriction (Art. 69.1 of REACH) have to pose an EU-wide risk. Unlike the authorisation process, the substances that can be subject to restriction are not limited to the criteria set forth in Art 57 of REACH, the SVHC criteria. A restriction sets limits to the use of a substance, for instance the substance cannot be used in toys or jewellery. These limits can both affect the use of substances as such, in mixtures or in articles. This means that a restriction can cover the placing on the market of articles containing substances, whereas this cannot be covered by means of the authorisation process. Indeed, because the authorisation regulates the use of the substance and not the placing on the market of it, the manufacturing of an article involving the use of an SVHC requires authorisation, while importing the same article, even containing the SVHC, cannot be regulated by means of an authorisation requirement but can be in scope of a restriction.

However, the uses of the SVHC not affected by the restriction remain allowed within the conditions described in the registration dossier unless they have also been included in Annex XIV of REACH. The restricted uses of substances are listed in Annex XVII of REACH.

The supply chain is notified of the presence of an SVHC included in the candidate list (1) in a mixture if the substance concentration is >0.1 wt% through the safety data sheet (SDS) or (2) in an article through an obligatory communication to the user of the article (Art. 33 of REACH). Authorities are notified of the presence in an article of a substance included in the candidate list through a notification obligation of the article manufacturer (Art. 7(2) of REACH). Through these two regulatory measures, the regulator aims at gradual substitution of these substances with safer alternatives.

Due to the nature of REACH as a European regulation, it is directly enforceable in each member state without translation into national legislation. The enforcement of REACH obligations however remains a responsibility of each member state.

2.2. Applicability of REACH to mechanical recyclers

2.2.1. Interface between waste framework Directive and REACH

The scope of REACH is mainly related to the manufacturing, and use of the substance. In REACH terms, the life cycle of a substance ends when the substance enters the waste stage. At that point, the regulatory context for the substance is defined by the Waste Framework Directive (Directive 2009/98/EC and amended in 2018 by Directive 2018/851/EC). However, after a recycling or a recovery process, a new substance life cycle can start. This split, which is illustrated in Fig. 1, should avoid overlap of regulations and by this avoid any inconsistencies between both regulations.

However, although waste as such is excluded from REACH under Article 2(2), there is still an impact of REACH on the recycling process as REACH is applicable to the entire life cycle of a substance. The life cycle ends with the waste stage and a new life cycle starts when the substance ceases to be waste. The recovery process between the two life cycles focuses on the recovery of substances from the waste and can therefore not be a continuous use of the originally registered substance (European Chemicals Agency, 2010). Nevertheless, for the substances contained in waste and for which in the REACH registration dossier a risk assessment was required, the exposure and risk assessment in the registration dossier shall also consider the exposure and emissions during the recycling process (Annex I of REACH §5.1.1 & §5.2.2) (European Parliament, 2006; Umweltbundesamt (Hrsg.), 2012). This means

that although the recovery process is not a use, measures to reduce exposure and emission need to be described in the registration dossier of the substance.

In case of plastics recycling, this means that the emission and exposure during recycling to monomers, other reactants (e.g. grafting agents) or non-stabilizing additives present in the polymer (e.g. colorants, lubricants), should have been considered in their respective registration dossiers. However, the legislation does not clarify how the recycler should be aware of the conditions for safe use taken into account in the risk assessment. For downstream users of a substance, these conditions of safe use are communicated through the mandatory eSDS, which is nonetheless vital to guarantee lack of adverse effects on human health once materials are converted back into products. For a waste producer it is not mandatory to provide an eSDS or even SDS to the waste handler, nor does the waste handler have access to the chemical safety assessment contained in the registration dossier of the substance. Nevertheless, the recycler has to consider, independently of REACH, legislation regarding industrial safety which require the employer to ascertain the risk of substances used. In that respect, it could be beneficial for the recycler if the legislator could strengthen the legal requirements on the communication regarding the nature of the waste and therefore consider going beyond the current requirements on waste classification.

In general, the recycler brings a substance or mixture of substances on the market which triggers a number of REACH requirements. The aforementioned exclusion of waste under Article 2(2) of the REACH Regulation no longer applies when waste ceases to be waste in accordance with the Waste Framework Directive (Directive 2009/98/EC and amended in 2018 by Directive 2018/851/EC). This is also illustrated in Fig. 1. It is therefore important to consider when and where exactly the processed product ceases to be waste and becomes a substance or a mixture in the scope of REACH.

Article 6(1) of the Waste Framework Directive (WFD as amended in 2018) provides that: “Member States shall take appropriate measures to ensure that waste which has undergone a recycling or other recovery operation is considered to have ceased to be waste if it complies with the following conditions:

- (a) the substance or object is to be used for specific purposes;
- (b) a market or demand exists for such a substance or object;
- (c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and
- (d) the use of the substance or object will not lead to overall adverse environmental or human health impacts”.

For some materials, the Commission has set out additional and specific End-of-Waste (EoW) criteria to further define this scope (e.g. iron, glass, copper). For other materials, a general methodology for the application of EoW-criteria was originally developed (Delgado et al., 2009) and has since been further applied for waste plastics (Villanueva Krzyzaniak and Eder, 2014). However, at this time of writing there are no harmonized EU EoW-criteria applicable for plastics.

Recycling consist of different processing steps and as such it is crucial that the EoW-criteria are defined to that level. The exact process step when waste ceases to be waste and is again subject to the REACH Regulation needs to be identified. This process step where waste ceases to be waste is considered a manufacturing process in the scope of REACH (European Chemicals Agency, 2010). However, since there are no specific harmonised EoW-criteria for plastics, this remains a difficult task where consulting with local authorities can be beneficial to achieve some clarity (Umweltbundesamt (Hrsg.), 2012).

As such recyclers have the same information obligations as the manufacturers or importers of the substances towards the downstream users of the recycled material. In this context the recycler has to classify the recycled material, has to provide an SDS (Art. 31 of REACH) and has to respond to information requests from their customers (e.g. as a result Art. 33 of REACH).

2.2.2. Exemptions from the registration requirement under REACH

According to Art. 2(2) of REACH, waste is not a substance, mixture or article. This definition already limits the applicability of REACH to waste significantly. Additionally, for recycling there is a key exemption regarding REACH registration obligations, relevant for the recyclers of plastics.

The exemption in Article 2(7)(d) of REACH relates to the registration obligation of recycled material. Within certain conditions, a REACH registration is not required for the recycled material if:

- (i) *the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and*
- (ii) *the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery*

To benefit from this exemption, the recycler shall thus identify whether the recycled material is “the same” as a substance (or substances in case the recycled material is a mixture) that has (have) been registered by another actor. For polymers this means that the monomers, the other reactants and additives to manufacture the polymer must have been registered by another actor. For the exemption it is sufficient that a registration was filed for the substance(s) by any registrant. This registrant does not have to be part of the supply chain leading to the waste generation (European Chemicals Agency, 2010).

Regarding substance identity of recovered substances, ECHA's guidance on Waste & Recovered Substances (2010) provides the following clear guideline:

“Recovered substances may contain impurities which may be different from those in a substance not derived from a recovery process. This is in particular the case when recovered materials contain unintended constituents which have no function for the recovered material and the only reason for their presence in the recovered material is that they were part of the input waste for the recovery process. [...] Constituents present in quantities above 20% (w/w) should, however, in general not be considered as impurities but as separate substances in a mixture. In the case that recovered material is intentionally selected for the presence of certain constituent(s), those constituents should also be considered to be separate substances, even if they are present in smaller quantities than 20% (w/w).”

For example, if during the recycling of PVC (polyvinyl chloride) a selection is made to recover a high minimal content of the plasticiser DEHP (di/bis(2-ethylhexyl) phthalate), then DEHP is not an impurity but a separate substance. This means that the recovery operator shall either check whether the Article 2(7)(d) applies for the monomers of PVC and for DEHP, if this is not the case then the recovery operator cannot rely on this exemption and must then register the substances. Since DEHP is a SVHC included in the Authorisation List (Annex XIV of REACH), the authorisation obligation does also apply. This is further explained in Section 2.2.3.

On the one hand, substances which are intentionally added during the recycling process, not originating from the waste, cannot benefit from the Art. 2(7)(d) registration exemption. Impurities present in the recovered material up to a maximum concentration

of 20 wt% which can either originate from the original registered substance or can be present in the waste stream but without function in the recovered material, on the other hand do not require a registration. However, even if impurities do not have to be registered separately, they need to be identified to the extent needed (1) for comparison of substance identity of an already registered substance and (2) for establishing the hazard profile as well as the classification and labelling.

The specific position of waste in the REACH legislation results in a disruption of communication on safe use. The recycler who wants to benefit from the exemption for registration should have legal access to all the relevant safety information of the recovered substance, including the exposure scenarios (Art. 31 of REACH). However, the recycler should provide the downstream user of the recycled substance “sufficient information to allow safe use” (ECHA guidance on waste). Specifically, the recycler should provide the downstream user of the recycled substance an SDS, but the recycler is not obliged to provide exposure scenarios (eSDS) to its downstream user in case the recycler can benefit from the exemption of registration under Article 2(7)(d) of REACH. This means that in certain cases the downstream user receives an exposure scenario for virgin material, but no exposure scenario in case of the same recycled material. Recyclers do normally not receive any SDS or other safety information from the waste handler as they are not legally required to provide such information. As a result, recyclers can often not comply with the criteria set forth under Article 2(7)(d) and are compelled to register their substances themselves. Therefore they often need to rely on external analysis as they are typically not equipped to perform this themselves. Not providing an eSDS since it is not mandatory (when complying with Article 2(7)(d)) or if it is mandatory due to technical reasons may in fact be a competitive disadvantage for the supplier of the recycled material, which means there is an economic incentive to being able to provide this, on top of the obvious concern for human health. While in 2010 ECHA already announced in their guidance that such a situation could be subject to change during a revision of REACH (European Chemicals Agency, 2010), up until now this has not yet been addressed.

In this context, the split between the REACH legislation and the waste legislation is the cause of the complexity. Integrating both pieces of legislation could overcome these burdens and allow a safer and more efficient recovery of substances and as such support a circular economy.

2.2.3. Substances of very high concern (SVHC)

SVHC are of specific concern to recyclers for various reasons. First of all, since REACH defines a recycler as a manufacturer, the recycler is therefore required to classify the substance under the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008. SVHC can affect the hazard classification in a mixture, as of 0.1 wt%. In practice this means that a recycler should have information at this level. In this case, the recycler has a legal obligation to communicate the presence and the concentration of the SVHC via the SDS. In the situation where the recycler would produce an article directly, then the recycler also has a communication and notification obligation for the presence of the SVHC in a concentration >0.1 wt% (REACH Article 33 and 7(2) respectively).

Secondly, the presence of an SVHC is of concern in the context towards a toxic-free environment, which is one of the means towards a circular economy. Indeed, the SVHC present in the recycled material will participate in at least one more life cycle during which exposure could potentially occur, depending on the use. The incoming waste polymers can contain SVHCs such as flame retardants (e.g. HBCDD - hexabromocyclododecane), stabilizers (e.g. Pb), or softeners (e.g. DEHP), and therefore these SVHCs can also

be present as an impurity in the recycled material. Such waste streams will typically be sent to incineration or even landfill.

According to the exposure assessment of DEHP (European Commission, 2008a), 63% of the original DEHP is still present in the waste fraction. If this waste fraction is reused in an application where DEHP still has a function and the exposure to humans can be avoided (e.g. internal liner of garden hoses), not only the plastic base material but also the hazardous additive can be used in a circular fashion without additional risk for humans. Using this softener in a second life cycle also avoids the production of additional new softeners and by this avoiding the consumption of energy, emissions of and exposure to substances during this phase. This type of smart recycling instead of a total avoidance, based on a precautionary principle, of all SVHC in recycled material will help better to meet the circular economy goals in combination with zero carbon and a sustainable economy and could be there for a part of the Green Deal (European Commission, 2019b).

Finally, when an SVHC, included in Annex XIV of REACH, is present in the recycled material, either intentionally and/or in a concentration above 20 wt%, then it is considered a substance in a mixture and not an impurity. REACH Art. 56(6) defines that the use of the SVHC in a mixture (i.e. the recycled material) is subject to authorisation if the concentration of the SVHC is above the specific values in Art. 11.3 of CLP (Regulation (EC) No 1272/2008) or higher than 0.1 wt%. The authorisation obligation comes with a significant cost (estimated to 200.000 € or more per use applied for) and with the obligation to research towards more sustainable alternatives.

As a result of the previous elements, the presence of an SVHC in the recycled material can negatively affect the market value of recycled material, either as a result of the regulatory burden and related costs or as a result of a negative perception in view of a toxic-free environment. The presence of the SVHC then results in a commercial disadvantage compared to virgin material. Although exact impact of this is difficult to estimate, a consultation of various stakeholders (McKinnon et al., 2018) indicate that the viability of the recycling business depends on various factors such as the high price of the recovered plastics versus the virgin plastics. Any additional cost or negative perception will tip the business case. It has been shown that candidate listing of a substance by itself is a significant trigger to initiate substitution activities (Mistry et al., 2017) and in that sense it affects the value of the recycled substance.

It is therefore key for the recycler to know the identity and the concentration of SVHCs in the incoming waste material. In general, the supply chain is notified of the presence of an SVHC included in the candidate list in a mixture if the substance concentration is >0.1 wt% through the SDS. Because the producer of waste does not have to provide an SDS for the waste material, the recycler does not have the information readily available, even if they should so desire for the economic and food safety reasons mentioned earlier. A second communication obligation for SVHC is an obligatory communication to the user of the article (Art. 33 of REACH). This obligation is not extended to the article in the waste stage and hence not applicable for the waste handler. Authorities are also notified of the presence in an article of a substance included in the candidate list through a notification obligation of the article manufacturer (Art. 7(2) of REACH).

However, depending on the source of the waste material, some other strategies can be applied to obtain information on SVHCs (Umweltbundesamt (Hrsg.), 2012).

A first strategy relies on measurement of SVHC in the incoming waste material. To reduce the scope of the substances to measure, literature information can be used on the additive composition of polymers or typical non-intentionally added substances (NIAS) in such waste. But even with a reduced scope of substances to test

for, recyclers are typically neither equipped for extensive testing, nor do they have the possibility to rely on costly external product and/or chemical analyses (estimated cost for analytical testing may range from 5.000 to 30.000 € per substance (Simoneau et al., 2016)). Also it is questionable whether such external 'batch'-testing might even be sufficient to effectively monitor compliance as in a non-controlled post-consumer waste loop, given that the composition of the waste stream may vary over time (de Römph and Van Calster, 2018; EURACTIV, 2012; Federal Public Service Health and Food Chain Safety and Environment Belgium, 2016; Janssen and van Broekhuizen, 2017). For closed-loop recycling processes, communication lines with the waste supplier are short and can be used to obtain information on the presence of SVHCs.

Another strategy may rely on specifications of the materials used (food contact, RoHS (Restriction of Hazardous Substances in Electrical and Electronic Equipment (Directive 2011/65/EU)), ...) to exclude the presence of certain SVHCs. However, because legislation is continuously evolving, legacy substances have to be taken into consideration especially for substances such as construction materials which have a long life cycle (37% of total plastic waste fraction) (European Commission DG ENV, 2011). In practice, the recyclers will have to take a pragmatic approach and use a combination of different strategies to obtain information on the SVHCs in the waste material.

In the future, there will be more information on SVHCs in waste articles. The regulator has included in the recast of the Waste Frame Directive (WFD) of 2018 in Art. 9(1)(i) an obligation to provide information as of Jan 5th, 2021 regarding the presence of candidate list substances in the articles supplied. This obligation, which connects the WFD with REACH, will be implemented through a database developed by the European Chemicals Agency (ECHA), i.e. the SCIP database, which stands for Substances of Concern In articles as such or in complex objects (Products). This database is to be completed by any supplier of the article, with exception of retailers supplying to consumers. The content of the database will be made available to the public, including to the recycler and it should allow the recycler to be more informed about the presence of SVHCs in waste articles. This is also relevant for the recycling of packaging materials because packaging is defined under REACH as an article (ECHA, 2017). It is expected that the effort to complete this database will be significant and will require continuous updating.

Additional to this, the Circular Economy Action Plan suggests the use of digital technologies for tracking and tracing and the use of watermarks to signal the presence of hazardous substances in waste and to support the development of the circular economy (European Commission, 2020).

In case the waste material contains an SVHC, various technologies have been employed to remove the SVHC from the waste material (Wagner and Schlummer, 2020). This can be mechanical selection, extraction by solvent or chemical recycling including chemical purification.

However, in some cases it is impossible to remove the SVHC to a level below 0.1 wt% (or the level in CLP). From the point of view of a non-toxic environment, this is an undesirable situation even in case the recycled substance can be used in conditions without exposure during its life cycle. This position clearly limits the possibility to recycle polymers and thus it limits the success of the European recycling goals (50% for plastic waste by 2025 (European Environment Agency, 2016)). For example, the limit of 0.1% of Pb in recycled PVC may limit the recyclability of PVC (Wagner and Schlummer, 2020).

In conclusion, the recycler has legal obligations under REACH when the recycled material contains a SVHC. Authorisation is required for the use of an SVHC included in Annex XIV of REACH if it is present intentionally and/or in a concentration >20 wt%

(ECHA Q&A 565). The communication obligation on the presence of SVHC in a substance or mixture via the SDS (art 31 of REACH) is triggered typically as of concentrations >0.1 wt%, independently whether the SVHC has a function in the recycled material or not. The recycler placing an article on the market containing an SVHC in a concentration above 0.1 wt% needs to notify the ECHA (Art. 7.2 of REACH) and needs to communicate in the supply chain (Art. 33 of REACH). The article manufacturing itself is also subject to authorisation if a substance on Annex XIV is used.

Thus, it is clear that the presence of an SVHC in waste plastics is not only a technical challenge for the recycler to identify and remove the substance, but it also creates a regulatory burden with potentially high costs. This establishes a commercial disadvantage for a recycled material in comparison to virgin material. Further integration of the REACH and waste legislation, technological developments, and smart recycling could overcome some of the hurdles.

3. Food safety legislation: Overview of EU regulation on food contact materials

3.1. The framework Regulation

Regulation (EC) No 1935/2004 on Food Contact Materials (FCM framework Regulation) sets out the regulatory framework for “materials and articles intended, or of which can reasonably be expected, to come into contact directly or indirectly with food” (Article 1(1) of the FCM Regulation). The main purpose of this FCM Regulation is stipulated in Article 1:

The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

Therefore the framework Regulation sets out general requirements where materials or articles intended to come directly or indirectly into contact with food must be sufficiently inert to preclude substances from being transferred into food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. Also labelling, advertising and presentation of a material or article shall not mislead the consumer (Article 3 of Regulation (EC) No 1935/2004). In addition to that, manufacturers of FCMs should also comply with certain ‘Good Manufacturing Practices’ (GMPs) laid out under Regulation (EC) No 2023/2006 (European Commission, 2006).

There is no strict definition of what a FCM is and therefore it is up to Member State authorities to define them. Consequently, ‘food contact material’ should be interpreted broadly. Annex I to Regulation (EC) No 1935/2004 lists the different types of materials that could be used as FCM, for some of them specific EU measures were adopted in accordance to Article 5 for further regulation (i.e. legislation on plastic materials and recycled plastic materials).

It should be noted that, in the absence of specific EU measures for certain FCMs such as paperboard, Member States may maintain or adopt their own national provisions on FCMs, more strict than the harmonized EU regulation (Article 6 of Regulation (EC) No 1935/2004). National rules in place in Member States may differ from one another and may introduce inconsistencies in the approach to regulating FCMs, hindering the free movement of those materials and articles within the internal market (Simoneau et al., 2016). Clearly, there is an interplay between

FCM regulation and REACH. A previous effort to explain these for virgin plastics has been done by the trade association Plastics Europe (PlasticsEurope, 2013).

Regarding plastics recycling, the scope of the framework Regulation is not limited to the production of the finished article, as it also includes materials under its scope. It applies to the entire life cycle of a food contact material or article starting with the approval and acceptance of the starting material all the way down to the conversion and production up to the point where the article is brought into contact with food. This also includes the packaging, warehousing and transport of those materials along the supply chain (PlasticsEurope et al., 2011). As such, an initial recycler must keep in mind the eventual usage for their recycled waste material. If the intention of the eventual producer is to produce FCMs, the recycler must comply with certain rules on traceability and the declaration of compliance as laid out under the FCM framework.

3.1.1. Traceability

The framework Regulation (EC) No 1935/2004 requires full traceability of FCMs and articles at all stages of manufacture, processing and distribution in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility (Article 17(1) of Regulation (EC) No 1935/2004). Operators shall therefore have systems and/or procedures in place to identify the businesses from which and to which their substances, materials or articles have been supplied. Each product placed on the market should be identifiable by means of labelling or other relevant documentation or information to allow their traceability (European Commission, 2004).

3.1.2. Declaration of compliance

The framework Regulation (EC) No 1935/2004 introduced an additional obligation in the existence of specific measures for certain FCMs. Producers of FCMs should provide a written declaration stating the compliance with all applicable regulations. This Declaration of Compliance (DoC) must be made available throughout all marketing stages, except the retail stage, even for products in their intermediate stages of manufacturing and the substances intended for the manufacturing of those products and materials.

The aim of the DoC is to ensure the compliance of the final FCM or article and to monitor this throughout the supply chain as well as to grant the downstream business operator additional safeguards relating to the specifications and required information of the product. Consequently, recyclers must be aware when selling their recycled polymers for food contact use that they should provide this document to downstream manufacturers (European Commission, 2016, 2008b).

In addition to passing the DoC along the supply chain, business operators must keep all supporting documents showing compliance with the DoC. While the supporting documents are not meant to be passed along the supply chain, they must be made available upon request of the national supervision authority. These documents should at least set out the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning showing compliance with the DoC (European Commission, 2016).

3.2. Good manufacturing practices

Regulation (EC) No 2023/2006 on Good Manufacturing Practices (GMPs) applies to all sectors and all stages of manufacturing, processing and distribution of materials and articles, up to but excluding the production of starting substances (Article 2 of Commission Regulation (EC) No 2023/2006). These principles apply to all FCMs listed in Annex I to the FCM framework Regulation, including plas-

tics regardless of whether they are produced using virgin or recycled content.

Food business operators are required under these principles (i) to establish, implement and ensure adherence to an effective and documented quality assurance system; (ii) to maintain an effective quality control system and (iii) to maintain documentation with respect to the specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article (Articles 5–7 of Commission Regulation (EC) No 2023/2006).

As mentioned above, additional obligations stemming from specific EU measures could be imposed on producers of FCMs. The implementation of additional measures does also apply to the GMP Regulation. The Annex included in the GMP Regulation has been amended in 2008 under Commission Regulation (EC) No 282/2008 on the use of recycled plastic materials and articles imposing additional measures for recycling processes regarding the quality assurance system and supporting documentation. In addition to that, food business operators and food packaging producers are also subject to various industrial guidelines, that, while they do not have a binding power, can be a source of contractual obligation and can prove to be authoritative sources of reference for supervisory authorities (PlasticsEurope et al., 2011).

3.3. EU legislation on specific materials: Plastics

In addition to the general FCM framework Regulation, further material-specific EU measures were adopted by the European Commission on plastic materials and articles intended to come into contact with food in Commission Regulation (EU) No 10/2011. As a general rule, it requires substances to be of a technical quality and purity suitable for the intended use as FCM. The composition of the material is therefore controlled by the establishment of a positive list or Union list of authorised substances limiting the substances which may be intentionally used in the manufacturing of plastic materials and articles (Annex I to Commission Regulation (EU) No 10/2011). This list contains authorised monomers, other starting substances, additives as well as polymer processing aids. The substances on this authorisation list underwent a risk assessment by the European Food Safety Authority (EFSA) prior to authorisation. Depending on the committee's decision on the substances safety, migration limits or other restrictions may be assigned.

3.3.1. Migration limits

The implementation of migration limits is an important part of the plastics Regulation (EU) No 10/2011 which ensures the safety of the final material or article by measuring the quantity of substance that may be transferred from the food contact material into the food. As such, a quantitative migration limit is an expression of the principle of 'sufficient inertness', which applies to all FCMs.

Although this manuscript will not analyse the technical aspects and compliance testing of these migration limits, it is important to note that the regulation provides a generic or Overall Migration Limit (OML) of 60 mg/kg food, or 10 mg/dm² applicable to all substances to control the total amount of substances released from the FCM into the food. Moreover, an additional Specific Migration Limit (SML) may be imposed on some substances on the positive list to further control their migration (European Commission, 2011).

3.3.2. Non-intentionally added substances

As already mentioned, Commission Regulation (EU) No 10/2011 sets out a Union list of authorised substances used for the production of plastic articles intended to come into contact with food. However, plastic FCMs or articles placed on the market may contain certain impurities not included in the Union list (Article 6(4) and recitals 18–20 of Commission Regulation (EU) No 10/2011).

These impurities may originate from the raw materials used in the polymer production or can be formed as reaction and degradation products during the manufacturing of the plastic FCM (Food Packaging Forum and Geueke, 2018; Nerin et al., 2013). The presence of these substances has been acknowledged under the plastics Regulation (EU) No 10/2011 where they are referred to as Non-Intentionally Added Substances (NIAS). NIAS might not be included in the Union list, they are however relevant in risk assessments and should therefore be taken into account. If necessary they should even be included in the specifications of the substance.

3.4. EU legislation on specific materials: Recycled plastic materials

Once plastic FCMs have reached the end of their intended use, they are no longer subject to Commission Regulation (EU) No 10/2011, as they may have been contaminated with other substances due to degradation, packaged goods or misuse during their life cycle (European Commission, 2008b). Therefore, the regulatory framework is further supplemented by Commission Regulation (EC) No 282/2008 on recycled plastic materials intended to come into contact with food. According to this regulation, recycled plastic materials and articles can only be placed on the market if they contain recycled plastics exclusively obtained through an authorised recycling process under Commission Regulation (EC) No 282/2008. This authorisation does not focus on the material or substance as it is the case for the plastics Regulation (EU) No 10/2011, nor does it evaluate a generic recycling process for each polymer type. Within Commission Regulation (EC) No 282/2008 authorisation is based on the safety evaluation on a case-by-case basis of individual recycling processes by EFSA followed by an individual authorisation (European Food Safety Authority (EFSA), 2008).

The process for the authorisation is highly similar to the general authorisation procedure under the FCM framework Regulation to which a technical dossier must be submitted to the European Commission. This dossier should comply with the guidelines set out by EFSA and should describe the recycling process in detail including a flow chart of the key processing steps. The objective of these steps must be indicated (e.g. input control, sorting, cleaning...), and sufficiently detailed information should be supplied to EFSA on the implementation of an appropriate quality assurance system to allow a proper evaluation of any possible risks to human health. EFSA is required to issue a scientific opinion on whether the recycling process complies with the requirement listed under the food contact regulations which is then forwarded to the European Commission to make a decision on the authorisation.

3.4.1. Conditions for the authorisation of recycling processes

Within the dossier submitted for the authorisation of a recycling process, special attention should be paid to certain conditions laid out under Article 4 of Commission Regulation (EC) No 282/2008 regarding the quality control and characterisation of the input material and the final recycled plastics as well as on the establishment of conditions of use. It should contain information on how traceability and input-contamination is addressed. Moreover, the dossier should include a separate section on the determination of the decontamination efficiency of the recycling process. If the input material does not originate from a product loop which is in a closed and controlled chain, a recycler must demonstrate by means of a challenge test or other appropriate scientific evidence that the process is able to reduce the concentration of contaminations so the final material does not pose a risk to human health. The submitted dossier should include all relevant experimental data and the procedure used for challenge testing as well as supporting scientific evidence and literature (European Food Safety Authority (EFSA), 2008). During a challenge test the input material is deliberately contaminated with a known concen-

tration of surrogate substances before being processed through each step of the entire recycling process. After recycling, the residual concentration of the surrogate substances must be at a sufficiently low level to provide the needed scientific evidence to EFSA on the ability of the recycling process to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health (Simoneau et al., 2016).

Article 4 (b) also imposes an additional condition on the input material of the recycling process, where it is stated that the input material must originate from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic FCMs and articles (European Commission, 2008b).

These conditions, while essential for approval, do impose a number of practical challenges for recyclers to place FCMs from recycled plastics on the market. These will be discussed in more detail in Section 4.

3.4.2. Exclusions under Commission Regulation (EC) No 282/2008

Although Commission Regulation (EC) No 282/2008 applies to all FCMs containing recycled plastics, it does exclude several materials from its scope under Article 1, provided that they have been manufactured according to GMP, as laid down in Commission Regulation (EC) No 2023/2006, such as: (i) FCMs from chemically depolymerized plastics; (ii) unused plastic offcuts and scraps in compliance with Commission Regulation (EU) No 10/2011; (iii) plastic materials and articles used behind a plastic functional barrier in compliance with Commission Regulation (EU) No 10/2011 (European Commission, 2008b).

The second exemption mentioned under Article 1 implies that unused industrial offcuts and scraps from the production process or post-industrial plastic waste could be recycled without the need to comply with the strict requirements set out in this regulation, as long as they are recycled in-house or 'used at another site'. Nevertheless, Commission Regulation (EC) No 282/2008 or other pieces of legislation do not clarify what 'use at another site' means. In addition, it does not specify whether this applies to printed materials as well. Commission Regulation (EC) No 2023/2006 has an Annex referring to printing inks applied to the non-food contact side of FCMs. There it is stipulated that printing inks should be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side in concentrations that lead to levels of substance in the food which are not in line with the requirements under Article 3 of the framework Regulation (EC) No 1935/2004. It is also explicitly stated that the printed surface shall not come into direct contact with food. Therefore, it is advisable to adopt a cautious approach to ensure that the aim of the FCM regulations to secure a high level of protection to human health is not undermined.

Recycled plastic materials and articles used behind a functional barrier are - like the offcuts and scraps - not subject to Commission Regulation (EC) No 282/2008. A functional barrier is a layer within FCMs or articles reducing the migration of substances from behind that layer into the food. Behind a functional barrier, non-authorized substances may be used as long as their migration through the barrier layer remains below the maximum level of 0.01 mg/kg in food. Mutagenic, carcinogenic or toxic substances are essentially not covered by the use of a functional barrier (European Commission, 2011).

4. Food contact legislation: Authorisation of recycling processes under the FCM regulation

As has become clear from the previous sections, FCM regulations established certain key concepts which are vital to guarantee a high level of protection to human health. Health concerns have

proved to be valid, given the fact that recycled plastics may be contaminated with other substances due to degradation, packaged goods or misuse during their life cycle and therefore may pose a potential health risk. To do so, the precautionary principle was established, which relates to all regulations pertaining to food, along with traceability requirements and the declaration of compliance. With regard to plastic FCMs, a positive list has been established and migration limits have been imposed to ensure that the substances used are of a technical quality and purity suitable for food contact use and do therefore not endanger human health. The legislative framework also ensures the free movement of FCMs manufactured and marketed within the EU while facilitating global trades of safe FCMs, taking into account international standards and agreements. The conditions for authorisation for recycling processes, as described in the previous section, have a substantial impact on the use of recycled plastics as they give rise to a number of challenges regarding compliance towards traceability, input contaminations and the determination of decontamination efficiency.

4.1. Traceability

One of the most complex technical and regulatory issues for mechanical plastic recyclers producing FCMs is the obligation for producers under the FCM Regulation to ensure traceability of the materials and articles. Recyclers must have systems and/or procedures in place to identify the businesses from which and to which their materials have been supplied by means of labelling or other relevant information/documentation (European Commission, 2004). It is far from clear for recyclers where the obligation of traceability starts due to the ambiguity of the terms 'all stages', 'materials' and 'articles' and the lack of specific EoW-criteria for plastics. While various industrial guidelines on the traceability of material and articles for food contact exist, including for plastic FCMs, no reference is made to recycled plastic FCMs and their difficulties (PlasticsEurope, 2013).

In a post-consumer scenario, the obligation of traceability is highly unlikely to be met, except for very specific collection scenarios like that of bottle PET via deposit schemes. The FCM Regulation does provide producers with a certain amount of flexibility with regard to the technological feasibility of the identification of the businesses from which and to which materials covered by this regulation are supplied. However, in reality EFSA has taken a rather strict approach regarding the traceability in recycled polymer FCMs. Based on their statements in several scientific opinions, it appears that EFSA requires full traceability for recycled plastics used from input to final product. However, this can only be achieved from a recycling process in which the input is obtained from product loops that are in closed and controlled chains preventing products out of the loop to enter the stream. Compliance with this requirement is far from feasible, especially with respect to post-consumer recycling scenarios as limited market communication, a lack of cooperation within the plastic value chain and divided responsibilities between actors are making it very difficult to track and trace materials through the entire chain (McKinnon et al., 2018). The availability and quality of compliance documentation are therefore often hindering proper traceability (Karamfilova and Sacher, 2016).

EFSA has clarified several safety evaluations on the recycling of polyolefins whether the implemented systems ensure complete traceability. In the safety evaluation of the process "CO.N.I.P." used for the closed-loop recycling of PP and PE food contact crates, EFSA concluded that the physical usage of specific trademarks could be a sufficient means to ensure traceability (EFSA CEF Panel, 2013). They came to the same conclusion in the scientific opinion on "INTERSEROH STEP 1" where unique barcodes were used on crates

(EFSA CEF Panel, 2012). Finally, for the safety evaluation of the process “MORSSINKHOF Plastics” used to recycle HDPE and PP crates, the agency held that an internal traceability system by way of identifiers for labelling crates and recoding the type of polymer, the type of supplier and the original use of the input entering the system together with reference and batch numbers for the grinding and washing step during the process, is sufficient to assure full traceability (Silano et al., 2018). However, traceability achieved by for example markers in plastics or digital watermarks in products also have their limitations. The use of tracers for instance might be an issue as chemical substances are added to the polymer, possibly causing accumulation of previous tracers as the eventual recycled material might be composed of different polymers and hence can contain different tracers. Watermarks or other barcodes applied on products are only useful when entire products can be traced. However during post-consumer recycling processes materials are often shredded before being sorted into separate recycling streams. Despite the fact that the examples show that traceability is possible when it comes to a closed and controlled product loop, the shortcomings also demonstrate the clear need for smart tools to be developed that can continuously guarantee traceability within the entire supply chain (European Commission, 2018c).

4.2. Input contamination: NIAS

The presence of NIAS in the raw materials used during production or formed during their manufacturing needs to be taken into account during the FCM risk assessment. With the use of recycled plastics additional NIAS may be present coming from contaminations in the recycled material due to previously packaged food, misuse or the use of additives and their degradation products during recycling.

It is however unclear how the safety and risk analysis for NIAS should be conducted to be compliant with Commission Regulation (EU) No 10/2011. In that regard, the regulation only provides that NIAS should be assessed in accordance with internationally recognised scientific principles. As neither the European Commission nor EFSA has thus far provided guidance on the issue, only industrial guidelines have shed some light on the matter, but cannot reduce regulatory uncertainty.

The risk assessment and identification of NIAS has been the subject of several scientific researches (Muncke et al., 2017; Nerin et al., 2013). The problems regarding the identification of these NIAS and their risk assessment is also intrinsically related to the SVHC described under REACH. It is still unclear for recyclers which steps they need to follow to ensure the appropriate identification of these SVHCs in their input waste stream and how they can effectively manage their recycling process to comply with restrictions and authorisations of these substances under the REACH Regulation. While recent regulatory efforts have been made to ease some concerns in this regard, e.g. ECHA's creation of a database for products most often including SVHCs (ECHA, 2018), uncertainty remains in the daily practice of recyclers of other materials than (bottle) PET.

4.3. Determination of decontamination efficiency

The determination of the decontamination efficiency of a recycling process is another key requirement for the authorisation of a process used under the food contact regulation. According to EFSA's guidelines on the submission of a dossier, specially designed tests or challenge tests need to be performed or other ‘appropriate’ scientific evidence should be delivered on the decontamination efficiency of the process. In that regard, EFSA has developed specific guidelines explaining the principals used to assess compliancy

with these decontamination criteria for PET-recycling in a bottle-to-bottle recycling scenario (EFSA CEF Panel, 2011).

4.3.1. PET guidelines

Since PET is currently the most recycled polymer for food contact use, a lot of recycling knowledge already exists which allowed EFSA to develop specific criteria regarding the safety evaluation for PET recycling in 2011 (EFSA CEF Panel, 2011). The evaluation process is based on demonstrating the decontamination efficiency of the recycling process by means of a challenge test.

According to the EFSA guidelines a PET recycling process is not of a safety concern when it is able to reduce an input contamination of 3 mg/kg PET to a residual modelled concentration corresponding to a migration below 0.1 µg/kg food as the potential dietary exposure can in that case not be higher than 0.0025 µg/kg body weight per day (EFSA CEF Panel, 2011). Those migration values were set based on the most conservative exposure scenario of an infant weighing 5 kg consuming 0.75 l of water every day from a bottle manufactured from 100% recycled PET. From this exposure scenario it can be derived that the highest concentration of a substance that would ensure that the aforementioned dietary exposure is not exceeded is 0.017 µg/kg food ($0.0025 \times 5/0.75 = 0.01667$ or approximately 0.017) (EFSA CEF Panel, 2011; Welle, 2013). However, EFSA rounds the value of 0.017 µg/kg food to 0.1 µg/kg food, overestimating the migration by at least a factor of 5. In addition, this only applies to small molecules, for larger molecules the overestimation is even higher as the current migration model is based on a fixed activation energy (set at 100 kJ/mol) for all potential migrating substances (Welle, 2013).

Aside from the fact that these migration values are an overestimation and do not make any differentiation on the contaminants regarding molecular weight, polarity or volatility, they are also derived from a consumer scenario of a potential intake of an infant drinking from a water bottle from 100% recycled PET making those guidelines only applicable to bottle-to-bottle recycling scenarios. Additionally, the guidelines are based on the ‘worst case’ presumption that all of these contaminations would be highly toxic/carcinogenic, which is not necessarily the case. In fact, the reference concentration level of 3 mg/kg PET was established based on the highest misuse contamination level of toluene found in washed and dried PET flakes from experimental data of an EU survey (EFSA CEF Panel, 2011).

EFSA's very strict recommendation to not intentionally use non-food PET waste as process input and to limit the use of non-food PET to 5% was established based on information from previous applications submitted to EFSA. However, no reference was made to specific figures or a clear scientific reasoning to establish this 5% threshold (EFSA CEF Panel, 2011).

It is evident from a scientific point of view that the contamination surrogates, spiking levels and admissible residual concentrations used in bottle PET-challenge testing are not necessarily relevant for other PET recycling scenarios (e.g. bottle-to-tray, tray-to-tray, etc.) or other plastics including the widely used polyolefins, therefore it still remains unclear what an appropriate challenge test means for those other recycling scenarios as EFSA has not yet issued guidance on this matter (Palkopoulou et al., 2016).

4.3.2. Guidelines for other plastics

In the absence of EFSA's guidance for non-PET recycling scenarios, recyclers should provide the necessary data based on sufficient statistical analysis. Nonetheless, EFSA has held in the safety assessment of the processes “Biffa Polymers” and “CLRrHDPE” that, while migration models are highly polymer specific, the basic principles set out in the PET guidance can be applied to other polymers as well (EFSA CEF Panel, 2015).

The other polymer furthest along in exploring FCM approval is HDPE. Following the same procedure as for PET, EFSA had set a reference contamination level of 0.5 mg/kg for HDPE bottles. According to the experimental data of a UK survey, 0.008% or 2 out of every 2400 bottles were contaminated with misuse contaminants where the highest potential misuse contamination level was set at 6500 mg/kg HDPE resulting in the reference contamination level of 0.5 mg/kg. As for the migration criteria, the same can be used as for PET as it was derived from applying the exposure scenario to the exposure threshold of 0.0025 $\mu\text{m}/\text{kg}$ body weight per day which is independent from the recycled polymer. More important in establishing the migration criteria is keeping in mind the intended use. While the exposure scenario for PET was modelled based on a water bottle scenario, the recycled HDPE is intended to be used as packaging for milk and milk products giving rise to a calculated migration criteria of 0.06 $\mu\text{g}/\text{kg}$ food instead of 0.1 $\mu\text{g}/\text{kg}$ food for the PET water bottle. However due to the limited scope of the statistical evidence provided by recyclers (only encompassing the U.K.), EFSA has stated that these criteria cannot be extrapolated to other HDPE processes in the EU (EFSA CEF Panel, 2015).

Moreover, EFSA held that even after manual sorting, a sorting efficiency of 99% is required to limit the presence of non-food contact grade HDPE in the input-stream which is higher than the applied 95% limit for PET. This limit is less strict for PET since PlasticsEurope clarified the fact that all PET resin grades sold by European manufacturers and placed on the EU market are food contact approved (EFSA CEF Panel, 2011). Moreover, due to the non-polar characteristic and high diffusivity of HDPE, the risk of non-polar contaminants to be absorbed in post-consumer HDPE and their subsequent migration into the food is of several orders of magnitude higher than for PET (EFSA CEF Panel, 2015; Palkopoulou et al., 2016).

The target of 99% previously FCMs was however, as for PET, not set on the basis of scientific data regarding diffusion, sorption or migration but on the achieved sorting efficiency of the recycling process in question. An effective sorting efficiency of 99% previously food contact HDPE is much more challenging than for PET. It is fair to assume that any PET bottle has been a beverage bottle (as its intended use), while the HDPE bottle product category includes containers for milk and juice bottles as well as non-food applications such as detergents or personal care products. Automated sorting systems for separation based on polymer type do not differentiate between FCM and non-FCM HDPE (Ragaert et al., 2017). Additional sorting steps could be employed, sorting on colour foremost among them. This relies on the assumption that the FCM bottles are white or uncoloured. However, depending on markets, this assumption is critically flawed. In the USA market juice bottles are often coloured, leading to false negatives, which in itself is not problematic for the purity of the sorted HDPE but rather for the recovery rate. However, false positives do remain within the sorted HDPE and these come from personal care products (like shampoo bottles) that are also white. The WRAP consortium conducted trials on this as far back as 2005 (Welle, 2005): from a mixed post-consumer plastic waste bag, they set up a sorting line that would first sort positively on PE (by NIR) and then further sort this fraction on colour. Additionally, a sink-float step was included to remove milk bottles that were clumped together with PET bottles. They achieved a final purity of 97.9%. Only by including a handpicking (=manual sorting) step, were they able to achieve the proposed minimum of 99% purity. While these tests are over a decade old, nothing substantial has changed in either sorting technology or HDPE bottle types that would warrant a review of these conclusions. Marker technology for the separation of FCM from non-FCM is an interesting route to explore and has recently received backing from several top-100 companies, as well as the

Ellen Mac Arthur Foundation (Ellen MacArthur Foundation, 2019). To be successful, it would require a coordinated global roll-out, however.

Regarding the prevalence of food grade plastics in the input-stream of recycling processes, EFSA acknowledged the lack of a technologically feasible method or scientific analysis to determine whether a material in the input stream can be labelled as FCM. Therefore, EFSA now uses conservatively extrapolations on the use of food- and non-food-grade plastics in the production of a certain article by a sufficiently large market-share of producers in order to set a reference level regarding a certain collection and sorting process (EFSA CEF Panel, 2015).

Nonetheless the European Commission is taking steps to further clarify these processes on a scientific and regulatory level. While a recast version of Commission Regulation (EC) No 282/2008 is in the works setting out detailed steps for non-PET recycling processes, the new Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain prescribes a more proactive role for EFSA. As from the 27th of March 2021 applicants for authorisation shall be able to request 'pre-submission advice'. EFSA shall then provide advice on the rules applicable to, and the content required for the application or notification, prior to submission, and where appropriate, shall publish general guidance on the design of required studies (Article 32a of Regulation (EC) No 178/2002 as amended under Regulation (EU) 2019/1381). Following the 27th of March 2021 potential applicants shall need to notify EFSA of all studies commissioned or carried out by business operators to support an application when applying for an authorisation to guarantee that companies applying for authorisation submit all information and do not hold back unfavorable studies. Another key element of Regulation (EU) 2019/1381 is ensuring more transparency by improving the access to studies and information submitted by industry on the risk assessment process. EFSA shall make the application for authorisation, relevant supporting documentation and any supplementary information by the applicant public, as well as its scientific opinion. It will also publish detailed guidelines concerning the preparation and the submission of the application.

As things stand, FCM-HDPE recycling remains exploratory at best and the sizeable market for rHDPE bottle remains underserved. Moreover, Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment states that from 2030, plastic beverage bottles should contain 30% recycled content. It remains elusive how this will be reached for HDPE milk and juice bottles.

4.4. Authorised recycling processes

At the time of writing, while EFSA has published over 140 positive safety assessments on recycling processes, the European Commission has not yet authorised any of them (Cassart and PlasticsEurope, 2019). They stated that in order to authorise appropriately, clarification of transitions and obligations are required and should be included in Regulation 282/2008/EC. Nevertheless, the European Commission has expressed its willingness to approve the first batch of authorisations for EFSA-approved PET-recycling processes in a September 2019 presentation (European Commission, 2019c), when the amendments to Commission Regulation (EC) No 282/2008 enter into force. The European Commission has however delayed the authorisation of non-PET processes and requested EFSA to enact proper guidelines relating to these processes before opening the discussion on their authorisation. These delays have negatively affected the entry into force of the authorisation procedure.

While Commission Regulation (EC) No 282/2008, as a whole, has been in force for over 10 years, the majority of specific material

provisions (including the provisions relating to the authorisation requirement of recycling processes) integrated in this regulation are however not yet in force as the entry into force of these specific provisions under Commission Regulation (EC) No 282/2008 is dependent on the submission of draft decisions granting or refusing authorisation of the recycling processes issued by the European Commission via transitional procedure (Articles 13(6) and 16 of Commission Regulation (EC) No 282/2008). Consequently, the authorisation procedure should have entered into force following the submission of these draft decisions, effectively regulating the usage of recycled plastics as FCM. However, the European Commission has not yet submitted any draft decision since the conception of Commission Regulation (EC) No 282/2008 and more so, they are expected to be further delayed (Schupp, 2019). As a consequence the foreseen EU-wide harmonised regulation of recycled plastic FCMs is still a mere diction. Fig. 2 presents a timeline related to the entry into force of Commission Regulation (EC) No 282/2008 comparing the procedure as it was intended to proceed, against the current state.

The aforementioned transitional procedure sets out an initial authorisation phase following the entry into force of Commission Regulation (EC) No 282/2008 on the 20th day following the publication in the Official Journal of the European Union, which was on 17 April 2008 (Article 16 of Commission Regulation (EC) No 282/2008). EFSA received a mandate to issue guidelines for the safety assessment of a recycling process within 6 months following the publication in the Official Journal of the European Union of Commission Regulation (EC) No 282/2008 (Article 5(4) of Commission Regulation (EC) No 282/2008). EFSA completed this mandate on 1 July 2008, on which it published new guidance (European Food Safety Authority (EFSA), 2008). Recyclers had then 18 months to apply for an EFSA safety assessment in the so called ‘initial authorisation phase’ (Article 13(2) of Commission Regulation (EC) No 282/2008). In this initial phase, EFSA did not have to comply with the initial deadline to provide a safety assessment i.e. within

6 months upon submission (Article 13(4) of Commission Regulation (EC) No 282/2008).

Following this initial phase, which finalised on 31 December 2009, the European Commission had to submit draft decisions on authorisation within 6 months of receiving the scientific opinions on the safety of the recycling processes by EFSA (Article 13(6) of Commission Regulation (EC) No 282/2008).

When the European Commission eventually submits a draft decision on any recycling process, the use of some recycled plastics could become unlawful overnight (Articles 13(6) Commission Regulation (EC) No 282/2008).

As the European Commission has stated that the authorisation for non-PET processes would be postponed, this would essentially have the consequence of banning the entire non-PET recycling processes for FCMs already in place (notwithstanding a positive safety assessment by EFSA concerning some of these processes). As a result of this, the European Commission has stated that it will only submit these decisions when it has amended the entry into force of these provisions to avoid certain negative consequences. As such an amendment is set to be adopted that will effectively separate three different streams of approval decisions and the associated entry into force of the relevant provisions. The European Commission is set to separate: (i) PET-recycling processes that have received a positive decision by EFSA, (ii) PET processes that have not yet applied for EFSA-approval or have been modified, and (iii) other plastics. Effectively allowing the commission to adopt authorisation decisions without triggering the entry into force for non-PET recycling processes (Schupp, 2019).

A new transitional approach will as such be enacted through the Regulation amending Commission Regulation (EC) No 282/2008 wherein soon after the entry into force of the amendment the European Commission will authorise all PET recycling processes for which they received an opinion at the day the Regulation enters into force. While under the unamended Commission Regulation (EC) No 282/2008 this would entail the entry into force of the

Entry into Force – as intended

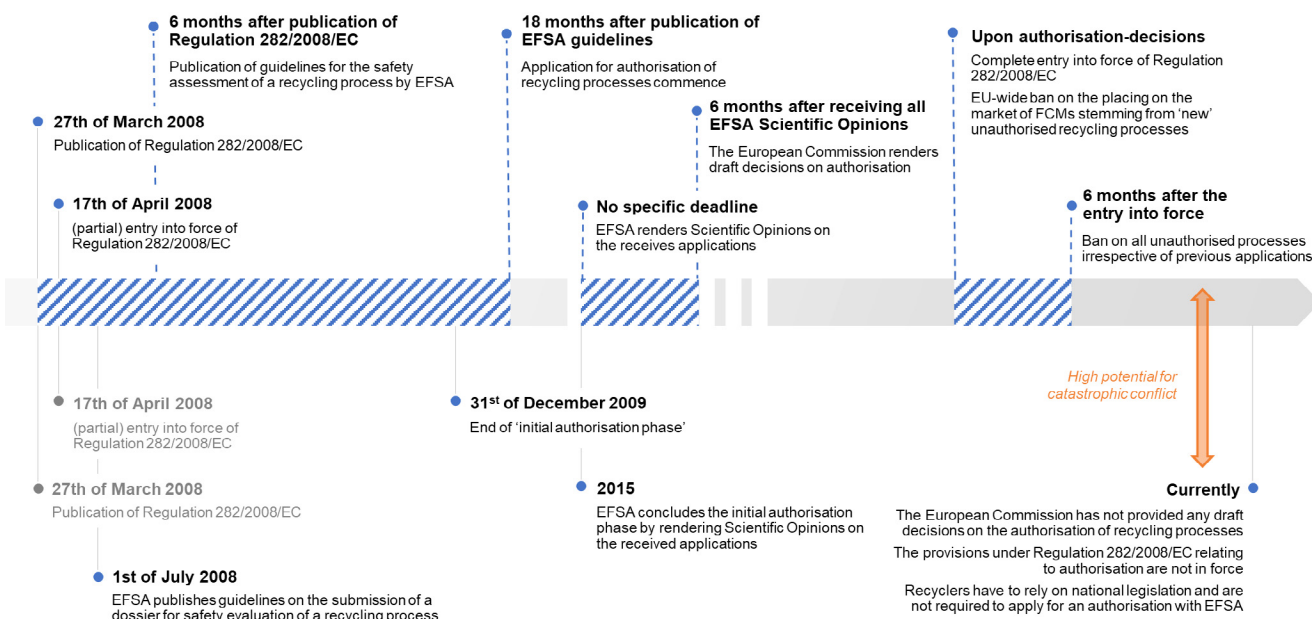


Fig. 2. Entry into force of Regulation 282/2008/EC, as intended (top) and the effective progress (bottom).

authorisation requirement for all plastic FCM recycling processes, through the amended version the entry into force of the provisions of Commission Regulation (EC) No 282/2008 shall be limited to PET-processes. Consequently all recycled PET-FCMs must be manufactured through an authorised process at the latest 6 months after the entry into force. Following this a new transitional period will start wherein those PET recycling process operators sending a valid application to EFSA before the end of the 6 months for PET recycling may remain on the market until there is a decision.

It is only after this that the European Commission will work on authorising non-PET procedures, regardless of their EFSA approval, and as such these processes will not be prohibited on a European level barring the entry into force of their specific amended provisions in the regulation. In the absence of the entry into force of the authorisation procedure for non-PET recycling processes, non-harmonised, national legislation continues to apply to recycled plastic FCMs in conjunction with the general framework legislation (Article 16 of Commission Regulation (EC) No 282/2008). FCMs stemming from non-PET recycling processes have to fall back on the often limited national legislation (Simoneau et al., 2016).

Overall, it can be observed that the recycled FCM market is currently non-existent for polymers other than PET. The industrial drive to use recycled content seems to be there, with FCM rPET market prices remaining consequently higher than that of virgin PET, while colourless non-food grade PET having been up to 300 €/tonne cheaper consistently up to 2019 (Victory, 2020). It is only with the oil price crashing in 2020 that also the non-FCM rPET has become more expensive than virgin PET. Market data on recycled PP and HDPE (Victory, 2020), however, up to date do not even include the differentiation between non-FCM and FCM rHDPE or rPP, making it clear that on a global scale these markets do not exist yet. Moreover, the prices of rHDPE and rPP (again, up to February 2020, which is prior to the oil price crashing) are consistently lower than for their virgin polymers, despite the many global pledges for use of recycled content.

5. Conclusion and outlook

The complex interplay between REACH and the WFD and the absence of EoW-criteria make it unclear whether plastic waste is covered by the WFD or if recyclers should comply with the chemicals legislation. However, when recyclers do become subject to REACH they encounter many challenges in meeting the REACH requirements. The delivery of the appropriate documentation including an SDS becomes very challenging in post-consumer recycling scenarios and in particular with the presence of SVHCs as they do not have this information readily available. Although ECHA recently implemented the SCIP database on the presence of SVHCs in various articles, it still remains unclear from a scientific point of view how they can be identified or removed and what an appropriate risk management approach looks like. This problem resurfaces when recycled materials are intended to be used as FCM with the identification and risk assessment of NIAS.

EFSA's main concern for recycled plastics intended for food contact use relates to those NIAS having an adverse impact on human health or the environment. Therefore only recycled plastics obtained from an authorised recycling process may be placed on the market where the focus during evaluation is on the quality of the input material, traceability and the decontamination efficiency of the process. Recyclers face with several challenges when trying to comply with these requirements, mostly associated with traceability and the lack of communication and transparency within the entire plastic value chain, potential misuse of FCMs or articles during their lifetime and the technical challenge of separating FCM from non-FCM waste. The publication of PET-guidelines by EFSA

has provided some clarity on how to approach the safety assessment with regards to recycling processes. They have held that the basic principles set out in those guidelines, which are based on bottle-to-bottle PET recycling, could also be applied to other plastics or recycling scenarios. However, establishing a similar risk assessment for other types of plastics appears to be not as straightforward for recyclers, who are still, years after the publication of the PET-guidelines, awaiting for the publication of further guidance by EFSA.

Altogether, it can be concluded that plastic recyclers remain largely in a regulatory grey-zone due to the lack of clear legislative measures aimed at the recycling and recovery of all plastics material types. The recycling industry therefore becomes subject to different regulations, each having their own legal perspectives. This together with certain technical and logistical hurdles have been negatively affecting the uptake of recycled plastics in new packaging within the EU.

As potential solutions the authors would propose to investigate the following options: (i) the development of End-of-waste criteria for plastics, thus better integrating REACH and waste legislation; (ii) EU-wide harmonization of FCM approval, which is now still at the national level, pending entry into force of authorisations; (iii) increased cooperation and communication between EFSA and the industry regarding necessary testing procedures and step-by-step transparent guidelines for waste processors and recyclers alike to conclusively achieve FCM-compliance for plastics recycling.

Finally, the concept of several economical instruments to stimulate the uptake of recycled content has been circulating across Europe. Taxation of virgin plastics – which would be an indirect stimulant to the uptake of recycled plastics – was proposed by member states such as Italy (EY, 2020) and the (exiting) United Kingdom. The UK tax would take effect in April 2022 and 'applies to plastic packaging produced in, or imported into the UK that does not contain at least 30% recycled plastic' (UK government, 2020). The Italian tax was proposed in January 2020 to be as much as EUR 450/ton of virgin plastic and was meant to enter into effect July 2020. However, following much protest from their national industry, the tax proposal has first been softened and eventually postponed (Fonte, 2019; Laird, 2020). It remains to be seen if the proposal will disappear altogether with the appearance of the recent new European tax on non-recycled plastic waste.

In July 2020, the European Council has agreed to impose a taxation on non-recycled plastic waste (EU/CO 10/20, 2020). This tax is described as 'a new own resource (that) will be introduced and apply as of 1 January 2021 composed of a share of revenues from a national contribution calculated on the weight of nonrecycled plastic packaging waste with a call rate of EUR 0.80 per kilogram with a mechanism to avoid excessively regressive impact on national contributions'.

This new tax has great potential to effectively create the necessary levers for investment in the plastics recycling industry that would allow for higher-quality recycling, including extended traceability and the overcoming of some of the challenges discussed in this paper. However, to date, the revenue from this tax is not in any way earmarked to be destined for the stimulation of compliant recycling. As such, the risk remains that this tax may not at all benefit plastics recycling. This concern has been voiced through several industrial communications (Baumgarten, 2020; European Plastics Converters, 2020).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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