TEKNILLINEN TIEDEKUNTA

REACH regulation as a product legislation in the circular economy of ELV, WEEE and C&DW plastics containing brominated flame retardants

Lotta Marjamäki

PROSESSI- JA YMPÄRISTÖTEKNIIKKA

Kandidaatintyö

Syyskuu 2020

TIIVISTELMÄ

REACH lainsäädäntö tuotelainsäädäntönä bromattuja palonestoaineita sisältävien ajoneuvoromu-, SER- ja rakennus- ja purkujätemuovien kiertotaloudessa

Lotta Marjamäki

Oulun yliopisto, Prosessi- ja ympäristötekniikan tutkinto-ohjelma

Kandidaatintyö 2020, 53 s. + 2 liitettä

Työn ohjaaja(t) yliopistolla: Markus Saari

Tämän kandidaatintyön aiheena on tutkia, miten REACH-lainsäädäntö vaikuttaa vaarallisia palonestoaineita sisältäneiden muovien kierrättämiseen, miten sitä kuuluisi käyttää ja keitä se koskee. Sen tavoitteena on helpottaa vaarallisia palonestoaineita sisältävien muovien kierrätystä, ja näin ollen myös parantaa muovien kiertotaloutta. Muovimateriaaleilla on lukuisia hyötyjä ja ne ovat laajasti käytössä, mutta niillä on myös negatiivisia vaikutuksia ilmastoon ja ympäristöön. Kiertotalous on tärkeässä roolissa muovien hiilijalanjäljen pienentämisessä ja muovisaasteen vähentämisessä.

Työ on toteutettu kirjallisuuskatsauksena, joka on jaettu karkeasti kahteen osaan. Ensimmäisessä osassa tarkastellaan kohteina olleita romuajoneuvojen, sähköelektroniikkaromun ja rakennus- ja purkujätteen muovivirtoja ja niiden sisältämiä bromattuja palonestoaineita. Toisessa osassa analysoidaan REACH-lainsäädännön vaikutusta kohdemuovien kierrättämisessä ja hyödyntämisessä.

Tutkimuksen keskeisiä tuloksia ovat, miten kierrätysmuovia tulee tulkita REACH:n näkökulmasta, ja miten lainsäädäntö vaikuttaa niihin. Sen perusteella voidaan määrittää, milloin kierrätetty muovimateriaali on aine tai esine, ja ovatko sen sisältämät bromatut palonestoaineet aineita itsessään vai epäpuhtauksia. Tuloksena lainsäädännön asettamat velvoitteet ja vapautukset on määritelty näille tapauksille. Muoveille ei tyypillisesti ole rekisteröintivelvoitetta, eivätkä ne ole luvanvaraisia. Lainsäädännön vaikutus bromattuihin palonestoaineisiin riippuu siitä, ovatko ne aiemmin rekisteröityjä, ja ovatko ne luvanvaraisia ja rajoitettuja.

Tutkimuksen perusteella NONTOX-projektin toimijat saavat yleiskuvan siitä, miten REACH-lainsäädäntö vaikuttaa bromattuja palonestoaineita sisältävien muovien kierrättämiseen. Tulokset eivät ole suoraan yleistettävissä muiden kierrätysmateriaalien käyttöön, mutta tutkimuksessa analysoidut osat lakitekstistä voivat olla hyödyllisiä lain tulkitsemissa.

Asiasanat: kierrätys, muovi, palonestoaineet, REACH-lainsäädäntö, kiertotalous

ABSTRACT

REACH regulation as product legislation in the circular economy of ELV, WEEE and C&DW plastics containing brominated flame retardants

Lotta Marjamäki

University of Oulu, Degree Programme of Process and Environmental Engineering

Bachelor's thesis 2020, 53 pp. + 2 Appendixes

Supervisor(s) at the university: Markus Saari

The theme of my Bachelor's thesis was to study how REACH regulation affects the circular economy of plastics containing hazardous substances, how it should be used and who have obligations under it. This thesis aims to facilitate the recycling of plastics containing brominated flame retardants, and to improve the circular economy of plastics. Plastics have numerous advantages and they are widely used, but they also negatively impact our climate and environment. The circular economy has an important role in mitigating the plastics carbon foot print and plastic pollution.

The study was carried out as a literature review divided in two sections. The first section studies the target ELV, WEEE and C&DW waste streams' plastics, and the brominated flame retardants they contain. In the second section it is analyzed how the REACH regulation affects the recycled plastics in the NONTOX valuechain's point of view.

Important results of the study are how the plastic recyclate should be interpreted and how the regulation affects it. The study can be used to define, whether the plastic recyclate is a substance or an article, and whether the brominated flame retardants it contains are substances or impurities. The results are the obligations and exemptions from the regulation for these cases. Polymers typically do not have registration obligation, and they are not subject to authorisation. Regulation imposes duties on brominated flame retardants depending on if they have been registered before and if they are subject to authorisation and restrictions.

Actors of the NONTOX project can get an overview of how REACH regulation affects the recycling of the plastics containing brominated flame retardants from the study. The

study was part of the NONTOX policy framework and so on supports the making of policy recommendations that are meant to boost the circular economy. The results cannot be directly generalized for other recycled materials, but the analyzed parts of the legislation in the study may be useful in the interpretation of the regulation.

Keywords: recycling, plastic, flame retardants, REACH regulation, circular economy

ALKUSANAT

Työn tarkoituksena on selventää, miten REACH-lainsäädäntö vaikuttaa bromattuja palonestoaineta sisältävien muovien kiertotalouteen. Työ on osa Euroopan Unionin NONTOX-projektia, jota Teknologian tutkimuskeskus VTT Oy koordinoi. Työ toteutettiin välillä 3.8.2020-15.9.2020, ja se on tehty VTT:n tilauksesta.

Työn ohjaajina toimivat Oulun yliopistosta Markus Saari, ja VTT:ltä Anna Tenhunen. Markus ohjasi kandidaatintyön rakenteeseen ja yliopiston käytäntöihin liittyviä asioita, ja Anna ohjasi työn sisältöä. Kiitokset Markukselle ohjauksesta, ja suurkiitokset Annalle tsemppauksesta ja innostavasta ohjauksesta.

Oulu, 9.9.2020

Lotta Marjamäki
Lotta Marjamäki

TABLE OF CONTENTS

ABBREVIATIONS

ELV	End-of-Life Vehicles
WEEE	Waste Electrical and Electronics Equipment
C&DW	Construction and Demolition Waste
BFR	Brominated Flame Retardants
ABS	acrylonitrile butadiene styrene
EPS	expanded polystyrene
PS	polystyrene
HIPS	high impact polystyrene
PE	polyethylene
PP	polypropylene
EU	European Union
POP	Persistent Organic Pollutants
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
PVC	polyvinyl chloride
PE-HD	polyethylene high density
GHG	Greenhouse Gases
TBBPA	tetrabromobisphenol A
PBDE	polybrominated diphenyl ethers
SDS	Safety Data Sheet
UVCB	Unknown or Variable Composition, Complex reaction products or Biological materials
PBT	persistent, bioaccumulative and toxic
vPvB	very persistent and very bioaccumulative

1 INTRODUCTION

Plastics are in many ways a key material in our lives, and their production is in a constant growth. Plastics are used everywhere: in construction, food packaging, medical devices and even in clothing. Plastic polymers are typically fossil based, and additives, such as stabilizers and flame retardants, are added to give plastic desired properties.

When a plastic product becomes waste, it is typically incinerated or landfilled. The major problem with incineration or landfilling is that both the material and resources used to make it have then gone to waste and can no longer be used. This is problematic, since the Earth has a limited amount of natural resources. It makes more sense to recycle the material rather than let it to go to waste, but still only 30% of plastics produced in EU are recycled. Primary reasons for low recycling rates lay in improper and insufficient waste management and society's perceptions. To answer the growing demand of plastics and to reduce the adverse effects plastics have on the environment, their circular economy has to be improved. This can be done by increasing the recycling rate.

One challenge for recycling of plastics is that there are plastics containing hazardous chemicals that cannot be safely recycled today. Most of these kinds of plastics end up incinerated or landfilled, but even then they are problematic, since the hazardous chemicals can lead to corrosion in the incineration plants or leach into the environment when landfilled. The NONTOX project focuses on these kinds of plastics originating from End-of-Life Vehicles (ELV), Waste Electrical and Electronic Equipment (WEEE) and Construction and Demolition (C&D) waste streams. The project develops and optimizes processes to produce safe and high quality secondary plastic materials from plastics containing hazardous substances. These hazardous substances and their residues in the secondary materials are challenging in the regulatory context, and the purpose of this thesis is to review and analyse how REACH regulation affects their manufacture and

placing on the market. REACH, which stands for Registration, Evaluation and Authorisation of Chemicals, makes the manufacture, placing on the market and the use of chemicals safer. This thesis aims to explain who have duties under REACH, and how it should be used.

Clear instructions on how, when and why REACH affects the recyclate are the expected results. For a clear, easy to understand picture, only brominated flame retardants and polymers are examined. The goal of this thesis is to improve the circular economy of plastics by increasing the recycling rates of ELV, WEEE and C&D plastics.

THE NONTOX PROJECT

NONTOX is a three year EU-project started in 2019, which focuses on the removal of hazardous, undesired substances from targeted plastic waste streams. Its target plastic streams originate from Waste Electrical and Electronics Equipment (WEEE), End of Life Vehicles (ELV) and Construction and Demolition Waste (C&DW) streams, which contain undesired or hazardous additives or compounds, such as flame retardants, stabilizers or fillers. Main secondary plastic outputs include acrylonitrile butadiene styrene (ABS), expanded polystyrene (EPS), polystyrene (PS), high impact polystyrene (HIPS), polyethylene (PE) and polypropylene (PP), which present about half of the EU demand for plastics. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 820895. This thesis was funded by the NONTOX project.

VTT Technical Research Centre of Finland Ltd is the coordinator of the NONTOX project. Project partners are Fraunhofer, UNIVAN - University of Campania Luigi Vanvitelli, Relight, IMDEA Energy Institute, AIMPLAS, Stena Metal Group, GALEA POLYMERS, ECODOM, Norner Research, Aalto University and Coolrec.

2 PLASTICS RECYCLING

Term ‘plastic’ is used to describe a wide range of synthetic or semi-synthetic materials, that are used in a huge and growing range of applications. Plastics are composed of polymers currently mainly produced from fossil sources, e.g. crude oil, and additives. Thousands of different types of plastics exist, but the six most common ones make up for 70% of total global production. (Tenhunen et al. 2020) They have many advantages, including lightness and construction of products in different shapes and sizes not otherwise possible. Plastics are divided into two main categories: thermoplastics and thermosets. Thermoplastics are plastics that can be melted when heated and hardened when cooled. These characteristics are reversible, so the material can be reheated and reshaped into new solidified form repeatedly, enabling mechanical recycling. Thermosets, when heated and formed, create a three dimensional network, which cannot be re-melted and reformed. (Kaartinen et al. 2020) Additives are commonly used to improve processing or product performance of plastics. Those can be plasticizers, flame retardants, antioxidants, acid scavengers, light and heat stabilizers or lubricants. While e.g. flame retardants make products safer to use fire safety wise, they pose significant health and safety implications and create technical challenges during recycling processes, such as equipment corrosion. (Tenhunen et al. 2020)

2.1 The importance of circular plastics economy

The annual plastic demand in Europe is 51.2 million tonnes, and global demand is expected to increase three- to fourfold by 2050. Plastics are a key material in both developing and developed countries. From food packaging to construction materials and medical equipment, it is clear that plastics highly benefit our daily lives. They do, however, have negative effects to the environment and climate. Improper waste management causes plastic to accumulate in the environment and causes environmental, societal and economic harm. Their design for a make-use-dispose economy has significant greenhouse gas emissions (GHG), contributing to climate change. Current GHG emissions from plastics life cycles are 850 million metric tons, almost equal to the

total GHG emissions in Germany in 2019 (855 Mt). It is estimated that by 2050 the cumulative emissions of plastic life cycle will be 10-13% of the global carbon budget calculated based on 1.5 °C target, which is the target limit set for global warming. (Tenhunen et al. 2020)

The problems that come with plastics production, usage and waste management are substantial, but banning plastics is not a viable way to fix the problems, since all the socio-economical benefits would be lost. Transformation from linear plastics economy to a sustainable circular plastics economy can be made possible by eco-design, circular business models and technological solutions. It is an effective way to lengthen the life cycle of plastics, reduce plastic pollution and mitigate the impact on the environment. By a systematic approach that addresses socioeconomic and regulatory aspects it is possible to achieve sustainable circular plastics economy, although there are no one-fits-all solutions. (Tenhunen et al. 2020) Projects like NONTOX are important on the way to the sustainable future. Kaartinen et al. (2020) have calculated the plastics potential for NONTOX from ELV, WEEE and CDW streams combined to be 2.18 million tons per year, which is 4% of the current EU plastic demand. It may sound like a small number, but it is a great improvement from just one project to the current plastics recycling rate in Europe, which is 30% (European Commission 2018).

2.2 The recycling process

Recycling plastics starts from collection, sorting, separation and pretreatment of plastic waste. Separation and sorting are necessary, since different kinds of plastics have different properties, and mixing them can cause the recyclate to lose its value. Plastics can be identified using their physical properties, spectroscopy or visual inspection. (Tenhunen et al. 2020) Pretreatment technologies face multi-material feeds composed of metals, organics and inorganics, and they are separated mostly by physical properties. Pretreatment technologies can be optimized for different purposes, for example extrusion of metals or hazardous chemicals. (Yli-Rantala et al. 2020) Typical methods for recycling itself are mechanical recycling, chemical recycling, solvolysis and depolymerization and thermochemical recycling. (Tenhunen et al. 2020)

Mechanical recycling, which is the currently the main commercially used technology used, focuses on thermal re-processing of waste to recyclate. It implies that while the actual product is destroyed, the molecular integrity of plastic is retained. It is the preferred choice for well-separated and clean plastic streams to produce highest value and best quality recyclates. Its biggest downside is that thermal processing causes material degradation, which is significant after a few extrusion cycles. Chemical recycling, which is not yet used in industrial scale, is applied to plastic waste streams that are not suitable for mechanical recycling because they are e.g. complex multi-material products or contaminated. It typically means to break the polymer chain, which can be done using several different technologies. (Tenhunen et al. 2020)

Plastics in NONTOX project originate from WEEE, ELV and C&DW material streams, which can contain high amounts of chemicals that can be hazardous, especially chemical additives such as brominated flame retardants. Hazardous substances are regulated both in market and in products, and recyclates must meet set limit values, or be incinerated. Generally in the recycling WEEE, ELV and C&DW the main focus has been the extrusion of metals, which has led to the optimization of metals recovery and resulted in less efficient plastics recovery. (Kaartinen et al. 2020)

2.3 End-of-Life Vehicles plastics composition and recycling

The composition of ELV plastics vary depending on age, make and model. On average the share of plastic in new cars is around 14-16% by mass, and it is evaluated that 1.1 million tonnes of ELV plastics is generated in 2020 in EU-28 countries. Most commonly used polymer is PP, with a share of 42% of all polymers, followed by PU (11%), PA/PC (8%), ABS (7%), PVC (7%) and other polymers (12%). In 2011 in EU the proportion of recycled ELV plastics was low, which implies that treatments other than recycling are predominant in the process of ELV plastics. The main driver in the treatment and recycling of ELV waste stream has been the extraction of metals, which could be a reason for low recycling rates. (Kaartinen et al. 2020)

Location of plastics in vehicles is crucial to recycling, since it has to do with how easy it is to dismantle plastic containing parts. Even by machinery exterior parts are easier to dismantle in comparison to interior parts. Exterior parts make up 21.0% of plastics in cars, while interior parts make up 52.5%. 14.5% of plastics are located under the hood, and 12.0% in electrics or lights. Recycling process starts with pre-treatment, which comprises of e.g. removal of batteries and liquefied gas tanks, removal or neutralization of potential explosive components and removal and separate collection and storage of fuel, motor oil, transmission oil etc. After pre-treatment is manual dismantling of parts and components to reused or recycled, and the residual enters the shredder process. Magnetic separators remove ferromagnetic metals, and eddy-current separators remove non-magnetic metals. Plastics are typically density separated by polymer types using tank containing liquid of different densities, but a sensor-based sorting system can also be applied. (Kaartinen et al. 2020)

2.4 Waste Electric and Electronical Equipment plastics composition and recycling

WEEE is one of the fastest growing waste streams in EU. It has a heterogeneous composition with significant variations due to the vast range of different equipment and appliances. This makes it hard to correctly analyze its material composition, but on average WEEE contains 10-51% plastics. Typical plastics composition in WEEE is 30% ABS, 25% HIPS, 10% polycarbonate (PC), 9% PC/ABS, 8% PP and 18% others, but the composition varies a lot, and for example CRT monitors have almost a 50% share of ABS, while LCD screens only have 25%.

Typical recycling process starts from manual sorting and dismantling of WEEE stream. Dismantling is divided into depollution to recover hazardous component, non-valuable materials to be eliminated and recovery of valuable components. Shredding reduces particle size to liberate metals from plastic and wood, and low-intensity magnetic separation is then applied to recover ferrous metals. Eddy-current is used to recover non-ferrous metals and inert (mainly shredded plastic). Optical sorting recovers PCBs or separates brominated plastics from non-brominated ones. Other separation techniques,

including wet ones, can then be applied for optimization. Usually, multiple sorting steps are required to gain a homogeneous single plastic fractions. The main recycling routes after pre-treatment and sorting are either mechanical recycling or chemical recycling. (Kaartinen et al. 2020)

2.5 Construction and demolition waste plastics composition and recycling

Construction and demolition waste comes from construction, renovation and demolition of buildings and infrastructure, demolition representing the highest amount of C&DW. It is a very heterogeneous waste stream, consisting of concrete, bricks, gypsum, wood, glass, metal, plastics, solvents, hazardous substances and excavated soil, making it hard to separate and process. Generally, around one fifth of all plastics are used in construction, typical end-uses being e.g. insulation materials. C&DW contains a wide range of polymer types, and its composition is usually seen as unclear. A rough estimate of 1,7 Mt/a can be made of plastics contained in C&DW in EU. In Finland in 2017 the polymer shares were estimated to be 50-55% PVC, 14-19% PS, 3-8% polyurethane (PU) and 4-9% polyethylene high density (PE-HD). Around 16-20 % of C&DW plastics are recycled by mechanical recycling, while almost half of it is sent to disposal. The recovery rate potential is higher for construction waste than demolition waste, due to it being less mixed and less contaminated. (Kaartinen et al. 2020)

Management of CDW in EU varies significantly, and currently no scheme for treatment of CDW in Europe exists. It is however suggested that by the end of the 2024 the Commission should consider setting a preparing-for-reuse and recycling targets for C&DW and its material-specific fractions. In a case study CDW was sorted at the site to hazardous and non-hazardous components. The nonhazardous waste is typically composed of stony waste, glass, metals and mixed fraction. In pre-sorting, large pieces of waste (e.g. wood) are sorted before installation. In installation finest sand particles are sieved first, and next the ferrous metals are removed with a magnet. Wind-sifting is used to separate the lightest fractions of waste, and the remainder is manually sorted. In final

step, wood, plastics, gypsum and non-ferrous metals are further separated and treated in specified recycling facilities. (Kaartinen et al. 2020)

2.6 Brominated Flame Retardants in plastics

All the target material streams contain additives to some degree. NONTOX focuses on the removal of hazardous substances, with a focus on especially brominated flame retardants. BFRs are prohibited and restricted by POP (EC 2018/1021) and REACH (EC 1907/2006) regulations, but are long present in products produced before restrictions and prohibitions and therefore impact the recycling process. The purpose of adding BFRs to polymers is to inhibit material ignition and slow the rate of combustion, and they have had a significant reduction in fire incidents in the last 40 years. (Kaartinen et al. 2020, Lyche et al. 2015) In vehicles, BFRs were commonly used in plastic components such as dashboards and textiles. In construction products, flame retardants lengthen escape time, reduce heat production, decrease combustion of a material and reduce the production of toxic gases. (Kaartinen et al. 2020)

Halogens are effective flame retardants, as they reduce the propagation of the flame by capturing free radicals. All four halogens (I, Br, Cl, F) are very effective, but bromine has been most commercially used due to their high radical trapping efficiency and lower decomposing temperature. (Alaee et. al 2003) Most organobromine compounds decompose at around 50 °C below host polymers due to weak carbon-bromine bonds. Aromatic bromine compounds are extensively used. (Rahman et al. 2001) One example of BFRs are polybrominated diphenyl ethers (PBDEs), which consist of two halogenated aromatic rings, grouped into penta, octa and deca depending on the number of bromine added to the molecule (Lyche et al. 2015). PBDEs are resistant towards acids, bases, heat, light and to reducing or oxidizing compounds, which makes them persistent in environment. Articles containing BFRS are typically landfilled or incinerated. Incineration of PBDEs produces toxic dioxins, and landfilling can result in them leaching out. (Rahman et al. 2001) Pictured below in figure 1 is the structural formula of decabromodiphenyl ether.

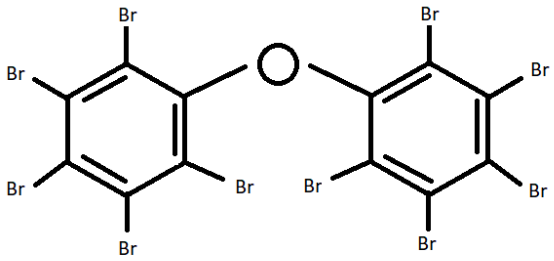

Figure 1. Structural formula of decabromodiphenyl ether.

Brominated flame retardants are divided into three subgroups by their mode of incorporation into the polymers: brominated monomers, reactive and additive. Brominated monomers are used in the production of brominated polymers, which are then blended with non-halogenated polymers or mixed in the feed prior to polymerization, resulting in a polymer containing brominated and non-brominated monomers. Reactive flame retardants are chemically bonded into the plastics, for example tetrabromobisphenol A (TBBPA). Additives are only blended and not chemically bonded with plastic, so they can separate or leach out of products. An example of additives are PBDEs. (Alaee et al. 2003)

BFRs have a chemical structure that makes them persistent and bioaccumulative. They are ubiquitous, and are found in air, water, soil, fish, birds, mammals and humans. Human exposure mainly comes from food of animal origin and inhaled dust. Although they have not been tested on humans, test on rodents have shown potential for disrupted endocrine functions by interfering with thyroid, androgen and estrogen signaling systems, and it has been reported that they can cause morphological changes in liver and kidneys, as well as neurodevelopmental and reproductive effects. Due to the prohibition and restrictions of many BFRs, their concentrations in humans are declining. (Lyche et al. 2015)

BFRs pose a challenge to plastics recycling due to environmental, safety and processing factors, which is why high BFR-content plastic currently just disposed of, and a large part of plastics are incinerated. (Kaartinen et al. 2020) For recycling, it is prerequisite that

BFRs are identified and separated, but currently no methods suitable for online use exists for distinguishing regulated BFRs from other types of BFR. The only practical solution is to identify and separate all bromine-containing materials above certain concentration using sensor based methods that are fast and simple, such as sliding spark spectroscopy. Several methods have been developed for bromine removal such as metallic catalysts, microwave irradiation, mechano-chemical treatment and modular extrusion by thermal decomposition. (Yli-Rantala et al. 2020)

2.7 The NONTOX technology used in plastics recycling

NONTOX further develops Extruclean and CreaSolv® technologies for hazardous substance removal, and also improves knowledge and state of art concerning pretreatment and sorting of hazardous plastic waste. It is comprised of eight work packages, all of which focus on unique parts of the NONTOX value chain, starting on creating a foundation to the concept by gathering reliable information on the subject. It aims to increase the recycling rates of plastics waste containing hazardous substances by developing and optimizing recycling processes to produce safe and high quality secondary plastic materials and by optimizing the overall process economics by integration. As EU Plastic Strategy states, it is crucial to increase recovery rate to put circular economy into effect, as a significant portion of valuable materials are still landfilled or incinerated. (European Commission 2020) The NONTOX process map is presented in figure 2.

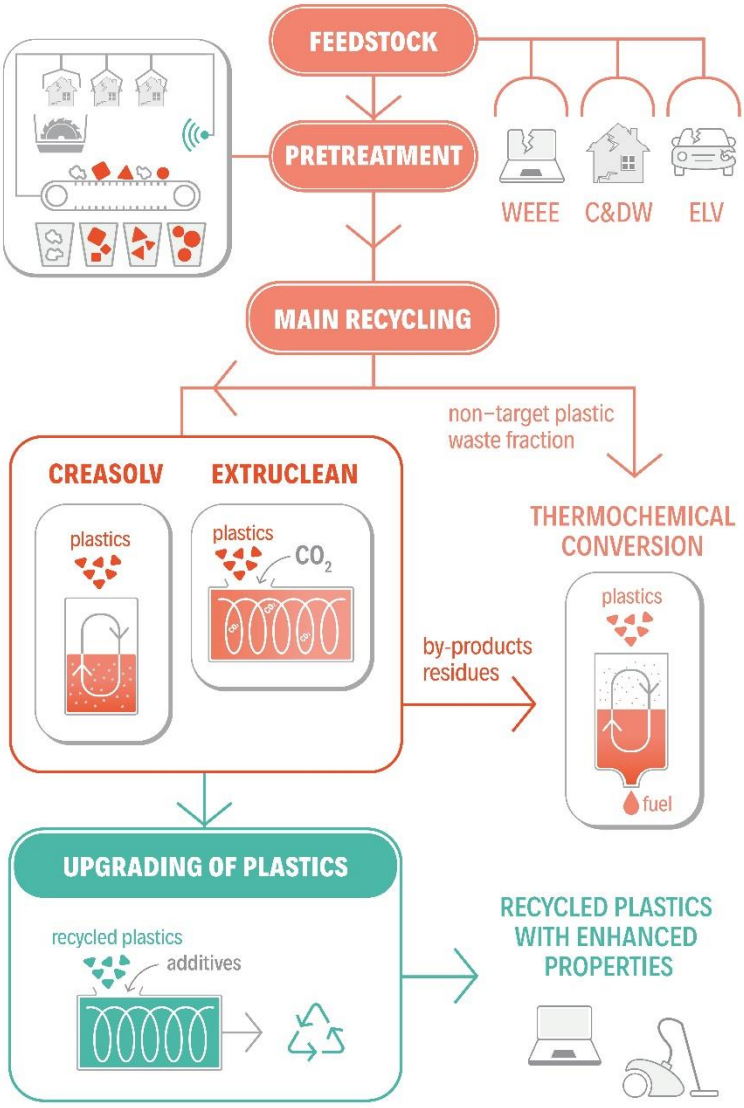

Figure 2. The NONTOX process.

3 REACH REGULATION

REACH, which stands for Registration, Evaluation, Authorization and Restriction of Chemicals, is a regulation of the European Union that entered into force on 1 June 2007. Its purpose is to improve the protection of human health and the environment from possible risks of chemicals, enhance the competitiveness of the EU chemicals industry and to promote alternative methods of risk assessment of substances to reduce animal testing. In principle, it applies to all chemical substances; both industrial and day-to-day ones, making companies impacted by it. European Chemicals Agency (ECHA) is the supervising body. In general, manufacturers that make or use chemicals have at least some responsibilities under REACH, and downstream users that handle chemicals and importers buying outside of the EU/EEA likely have some responsibilities under REACH. (ECHA 2020a) In all EEA countries, overall 101 013 registrations for 23 101 substances have been made by 2020. 34.4% of the registrations were made importers, 30.4% by manufacturers, and 26.3% by an only representative of non-EU company and 8.9% by manufacturers and importers. 66% of all registrations were joint submissions. (ECHA 2020d)

REACH works by establishing procedures for collecting and assessing information on the properties and hazards of substances. Companies (manufacturers and importers) are required to register their substances, and they need to work together with other companies registering the same substance. The registration duty doesn't concern downstream users or companies established outside of EU. Companies buying chemicals from companies established outside EU have the responsibility to fulfill the requirements of REACH, unless the non-EU manufacturer has a representative established in the EU. As the burden of proof is placed on companies, they must identify and manage risks linked to the substances they manufacture and market in the EU, and show how substances can be safely used. Risk management measures must be communicated to the users. ECHA evaluates individual registrations, and EU Member states evaluate selected substances to clarify initial concerns for human health and environment. If risks are unmanageable, authorities will restrict or ban substances. (ECHA 2020a)

The moment REACH is applied depends on the recycling process. Article 2 (2) states: "Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, mixture or article within the meaning of Article 3 of this Regulation." (REACH 2 (2)) For determining when WEEE, ELV and C&DW plastics cease to be waste, End-of-Waste criteria from Waste Framework Directive is to be analyzed. According to its Article 6(1): "--- 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. (Directive 2008/98/EC 6(1))

In the case of NONTOX, REACH only applies after recycling process, when BFRs have been removed and plastics have been recycled. Article 6 (1)(c) is notable in the case of NONTOX, because it requires that the recyclate has to fulfil certain requirements for it to cease being waste, such as limits for specific substances. Term 'bromine compound' is used to reflect the BFR compounds in the recyclate, since the decomposition of BFRs may make it hard to link compounds in the recyclate to the original compounds. As BFRs collected in the recycling process are waste, they are not subject to REACH. To determine if bromine compounds in small concentrations in the recycled plastics are subject to REACH as a substances in a mixture, it has to be analyzed whether or not they can be treated as impurities. There is no need to consider the possibility of BFRs or bromine compounds being additives, since only stabilizers can be additives under REACH. In the *Guidance for identification and naming of substances under REACH and CLP*, impurity is defined as "An unintended constituent present in a substance as manufactured. It may

originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added." (European Chemicals Agency 2017, p. 15) As the bromine compounds originate from the starting materials and their residues in polymers are unintentional, they can be considered impurities in a substance. However, if the substance has an Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), the concept of impurities does not apply. (European Chemicals Agency 2017, p. 37) If that is the case, then the bromine compounds are regarded as substances in a mixture. It is recommended to check *Guidance for identification and naming of substances under REACH and CLP* (European Chemicals Agency 2017) for more information on the chemical composition of substances. It is stated in the ECHA's *Guidance on waste and recovered substances* (2010), that if the recovered material is intentionally selected for the presence of certain constituents, those constituents should also be considered separate substances instead of impurites. For example, if PVC is selected for the presence of flame retardants, it may be necessary to register them. (ECHA 2010 p. 8) This seems to apply in the case where the presence of flame retardants in recyclate is **intended**. If, as is the case in the NONTOX, their presence in the material is not intended, they can be considered impurities.

As REACH applies to recycled plastics, both recovery operators, users of the recyclate and its importers have some duties under it. Recovery operators are typically manufacturers, that are defined in REACH as followed: "any natural or legal person established within the Community who manufactures a substance within the Community". The user of the recycled plastics is typically a downstream user: "any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2 (7)(c) shall be regarded as a downstream user." The use is defined as "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization". For example, a person who makes plastic

toothbrushes from recycled polymer substances is a downstream user, granted that they are not the manufacturer (the recovery operator). (Article 3 (9), (13), (24))

When recycling plastic, additives are commonly used to give the recyclate certain properties. Although these additives are not examined in this work, it should be noted that they most likely are subject to REACH and have to be taken into account. Under REACH, additives are part of the substance, but **only** stabilizers are considered additives. All the other chemicals added to the plastic are substances. For example, if new flame retardant is added to the plastic, it most likely changes the way the regulation applies to it, since the flame retardant is considered a substance in a polymer-flame retardant mixture. The Articles and paragraphs mentioned in this thesis however are applicable to all substances, and can be used to evaluate the duties for certain additives under REACH.

3.1 Registration

REACH places a general obligation to companies to register substances, both in their own, in preparations and in articles. (ECHA 2020a) Prior registration, all substances must either be pre-registered or an inquiry must be submitted according to Article 26. In the first phase of registration, manufacturers and importers need to obtain information on the substances manufactured, and use it to ensure that the risks they present are controlled. All available existing information on the **properties of the substance** has to be collected, including test data, non-test data from alternative methods (such as quantitative structure analysis) and information on manufacture, uses, risk management measures and resulting exposures. For **intrinsic properties of substance**, minimum information requirements differ depend on information of intrinsic properties as well as tonnage, use and exposure. (ECHA 2016, p. 60-61)

When information is gathered, a registration dossier shall be submitted. It consists of two main components: a technical dossier required for all substances subject to the registration obligations, and a chemical safety report required for a substance manufactured/imported in quantities of 10 tonnes or more annually. Joint submission of data by multiple registrants (recovery operators, importers and downstream users) is required when registering the same substance. Considering the nature of the NONTOX project, this type

of “one substance, one registration” model seems beneficial to all actors, as it can minimize costs and reduce testing. All members in joint submission only pay the fee for their own tonnage. In joint submission, the information that needs to be submitted jointly is submitted by one lead registrant on behalf of the other registrants, and other information needs to be submitted by all registrants individually. The lead dossier, submitted by lead registrant, contains the information of the lead registrant and data set required in REACH for the highest tonnage band to be registered for that substance. The member dossier containing individual information is to be submitted by each member of the joint submission. (ECHA 2016 p. 65-69)

Registrants are required to jointly submit the following information: classification and labelling of their substance, (robust) study summaries and proposals for testing (if any) and indication as to which of the submitted information on classification and labelling study summaries and robust study summaries has been reviewed by an assessor chosen by the registrant and having appropriate experience. Individually submitted information must contain registrant’s identity, identity of the substance, information on the manufacture and uses, exposure information for substances in quantities of 1 to 10 tonnes and an indication which of the information on manufacture and use has been reviewed by an assessor. (ECHA 2016, p. 67-68) A registration fee does not exists for a substance in a quantity of between 1 and 10 tonnes where the registration dossier contains full information in Annex VII (Article 74 (2)).

Recovery operator should define whether or not their recyclate is a substance or an article. Their definitions are in Article 3 (1) and (3). In paragraph one, definition for a substance is as follows:
“substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”
For an article, in paragraph 3 reads:
“article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical

composition." According to these two definitions, the recyclate is still a substance, if its chemical composition defines its use rather than its shape, surface or design.

Registration of substances

For recovery operators, there are two things to note when it comes to registration. First one is article 2 paragraph 7(d), which concludes that the following shall be exempt from REACH title II: *Registration of substances*, title V: *Downstream user* and title VI: *Evaluation*: "substances, in their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the community 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" (REACH 2:7d).

The sameness of the substance should be examined carefully. For a BFR substance, the decomposition during recovery process may result in a different bromine compound that was originally registered in the waste material, and the Article 2 (7)(d) will not apply to that specific bromine compound. Information required by Article 31 is a safety data sheet (SDS). Criteria for substances that require a SDS and limits for their concentrations is in paragraph 1 of article 31. In article 32, it is specified what information is required when a SDS is not needed. More information about Articles 31 and 32 will be in chapter 4.5 *Information in the supply chain*.

Second one is Article 6 (3) that "any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), **that have not been already registered by an actor in supply chain**, if both the following conditions are met:

(a) 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);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year." (REACH 6(3))

According to Article 6(3), polymers as substances and in articles are exempt from registration, if they have been registered before. It is also sufficient that the registration was made by another company in another supply chain (ECHA 2012, p. 14). If a monomer has not been registered, it must be registered according the regulation. According to ECHA's Guidance on registration (2016, p. 36): "For most polymer manufacturers the situation will generally be that their monomers and other substances will be registered by the suppliers of these substances". This applies for recovery operators also.

When recyclate is seen as an UVCB, the bromine compounds in the material are substances. When considered as a substance in a mixture, 2 (7d) could exempt them from registration, if the substance has been registered and sufficient information as required in articles 31 and 32 is available. If 2 (7)(d) does not apply, the substance must be registered according to Article 6 (1): "Save where this regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency." If the quantity of a specific bromine compound is less than a 1 tonne per year, it is also then exempt from registration. There seems to be no conditions under which **substances** manufactured or imported less than 1 tonne per year could be required to register. This does not apply for **substances in articles**, which are addressed in the next chapter. Since typically the permitted concentration of a BFR is 0,1% w/w, in tonnes this would mean that quantities less than 1 tonne of a specific BFR is exempt from registration in 1000 tonnes of recycled plastic.

When a substance is produced in quantities of 10 tonnes or more per year, they require a chemical safety assessment to be made for a chemical safety report. It is not needed, if the concentration limits comply with Article 14 paragraph 2. For BFRs that meet the criteria in Annex XIII, the concentration limit is 0,1 % w/w. The registrant has to identify and apply appropriate measures to adequately control identified risks, and recommend them in SDSs. (Article 14 (1), (2), (6)) However, this does not apply when relying on Article 2 (7)(d).

Registration of articles

For bromine compounds as substances in articles, Article 7 in its entirety describes the conditions for when substances in articles must be registered. The last paragraph (7 (6)) reads that registration is not required for substances that have already been registered for "that use". Based on the REACH Articles and an assessment of the NONTOX concept, my opinion is that bromine compounds as substances in recyclate has not been registered for "that use", since their existence in it is not intended, and therefore paragraph 6 does not apply to it. Bromine substances need to be registered, if they fulfill criteria given in the Article 7. In paragraph one, the baseline for registration is given: "Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
(b) The substance is intended to be released under normal or reasonably foreseeable conditions of use. "

In paragraph two, it is specified when any producer or importer of articles must notify the Agency: "if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w)."

For example, decabromodiphenylether has a PBT status matching the Article 57 criteria (ECHA 2020b). However, fore mentioned "shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article" (Article 7 (3)).

It should be known that although the substance might be exempt from registration by the paragraph 1, the Agency may take decisions requiring producers or importers of articles to submit a registration, if following condition are all met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
(b) the Agency has grounds for suspecting that:
    i) the substance is released from the articles, and
    ii) the release of the substance from the articles presents a risk to human health or the environment;
(c) the substance is not subject to paragraph 1. (Article 7 (5))

Conclusions

In conclusion, monomers in polymers most likely do not have to be registered. The BFR residue in the recyclate is referred to as bromine compounds, since it can be hard to get a clear composition of different BFRs in the recyclate due to decomposition. Bromine compounds as substances are to be registered, if they have not been previously registered with sufficient information available, they are present in articles in quantities more than 1 tonne annually and they are intended to be released under normal or reasonably foreseeable conditions, or if the Agency so requires. The bromine compounds in articles typically are to be notified to Agency if they fill the criteria given in Article 7 paragraph 2, when they are exempt from registration by any other Article **except** Article 2 (7)(d). If bromine compounds can be considered impurities, they do not have to be registered, but they might be subject to notification. Recovery operators that benefit from Article 2 (7)(d) are not subject to any Articles under Title II, including notification. For NONTOX concept, bromine compounds most likely can be considered impurities, since they are in small concentrations, unintended and it's difficult to identify them and their concentrations in the recyclate. However, it is possible that the substance would be considered an UVCB if the overall composition of the plastic recyclate is hard to define. In that case, the concept of impurities does not apply, and the bromine compounds would be subject to REACH as substances. However, based on the fact that the bromine compounds are challenging and not the monomer substances in the polymer, it is arguable is that the most feasible way of implementing REACH is to consider them impurities. A flowchart demonstrating the need for registration in different cases is attached in Annex 2.

3.2 Evaluation

ECHA examines all submitted dossiers along with Member States. Evaluation covers two areas: dossier evaluation and substance evaluation. In dossier evaluation, ECHA checks that registration dossiers contain the information on chemicals required by the legislation. In substance evaluation, Member states evaluate substances after they have been identified specific concerns. (ECHA 2020c)

Dossier evaluation

Dossier evaluation consists of compliance check and testing proposal examination. It is divided into four stages: initiation, scientific and legal assessment, decision-making and follow-up. A flowchart demonstrating the whole dossier evaluation process is attached in Annex 1. In the initiation stage dossiers are selected for compliance check either based on the selection criteria or randomly, and all registration dossiers containing testing proposals are assigned for examination of the said testing proposal upon arrival. (ECHA 2019, p.1-2) Registrations of substances which have or may have for example PBT, vPvB, sensitizing or toxic to reproduction properties are prioritized. (REACH Article 40 (1)) In the stage of scientific and legal assessment, case is assigned for evaluation by ECHA Secretariat. If testing on vertebrate animals was proposed in the dossier, third parties are invited to submit scientifically-valid information and studies relating to the substance and endpoint. The invite is published on the Agency website. (ECHA 2019, p. 3) The Agency can draft one of the five decisions given in Article 40 paragraph 3. In the compliance check, the experts decide if information provided meets the requirements of the REACH. Any shortcomings are converted into regulatory requests for information to the registrants concerned. Under testing proposal examination, the need and adequacy of proposed testing is evaluated. If no formal actions towards the registrant are necessary, case is concluded with no action and evaluation is completed. If formal actions (information requests) are needed, draft decision is prepared and notified to the registrants concerned. The registrants then have 30 days to comment the decision. Comments are taken into account and, where appropriate, the request in the draft decision is amended. If no

comment is received within 30 days, the draft decision remains unchanged. (ECHA 2019, p. 3-4) The scientific and legal assessment is demonstrated in a flowchart in Figure 3.

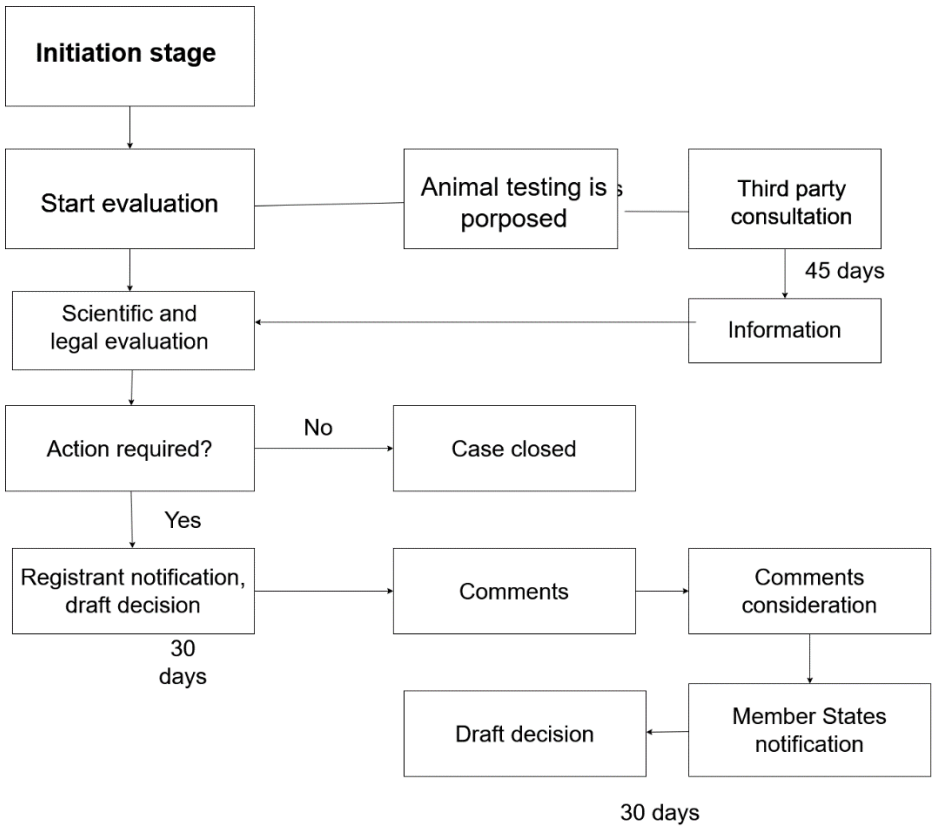

Figure 3. Scientific and legal assessment process demonstrated after initiation stage (Modified from ECHA's 2019 dossier evaluation flowchart).

Third stage, decision-making, is demonstrated in figure 4. It starts with a notification to the Member States of the draft decision. Competent authorities of the Member State consultate the draft decisions. The Member States may propose amendments to the draft decision within 30 days starting from the day of the notification. Registrants concerned of the proposals for amendments are notified. ECHA may amend the draft decision on the basis of a proposal made by a Member State, taking into account comments from registrants. The Member State Committee considers the comments of the registrants and Member State's proposal for amendments. If unanimous agreement is reached, or no Member States have proposed amendments, the decision is adopted and then notified to the registrants concerned and Member State's competent authorities. If unanimous

agreement cannot be reached, the case is referred to the European Commission. (ECHA 2019, p. 4-5)

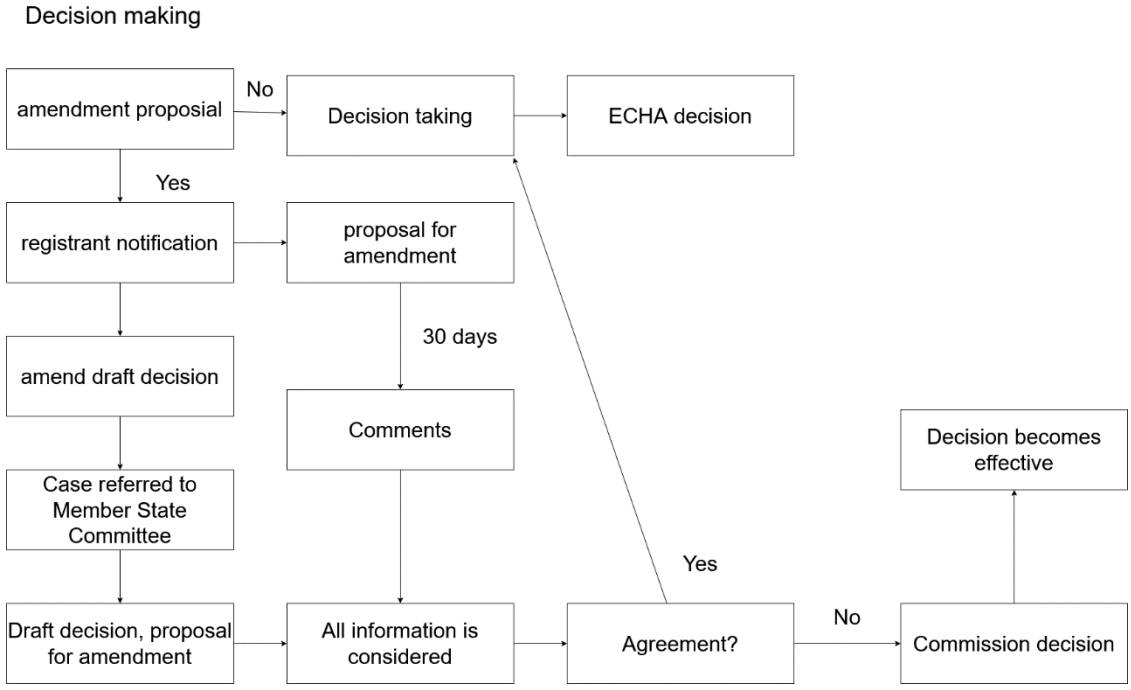

Figure 4. The decision making process demonstrated. (Modified from ECHA's 2019 dossier evaluation flowchart)

In the stage of follow-up of dossier evaluation decisions, ECHA decision becomes effective. The follow-up evaluation process starts when the date set in ECHA decision for updating the dossier with the requested information has passed. ECHA evaluates if information of the joint submission is provided in the form of an updated registration and if the information meets the requirements addressed in the respective ECHA decision. If no relevant information has been submitted, ECHA informs the relevant Member States about the failure to respond the dossier evaluation decision. The Member States respective national enforcement authority is invited to consider enforcement actions towards the registrants concerned. If registrants provide relevant information, but there are remaining or new concerns to be clarified, a new draft decision may be prepared. The new draft decision will be processed as described before. If the information is sufficient, ECHA informs the Member State competent authorities, registrants concerned and the

Commission that the process of dossier evaluation is complete. (ECHA 2019, p. 5-6) The follow-up process is presented below in Figure 5.

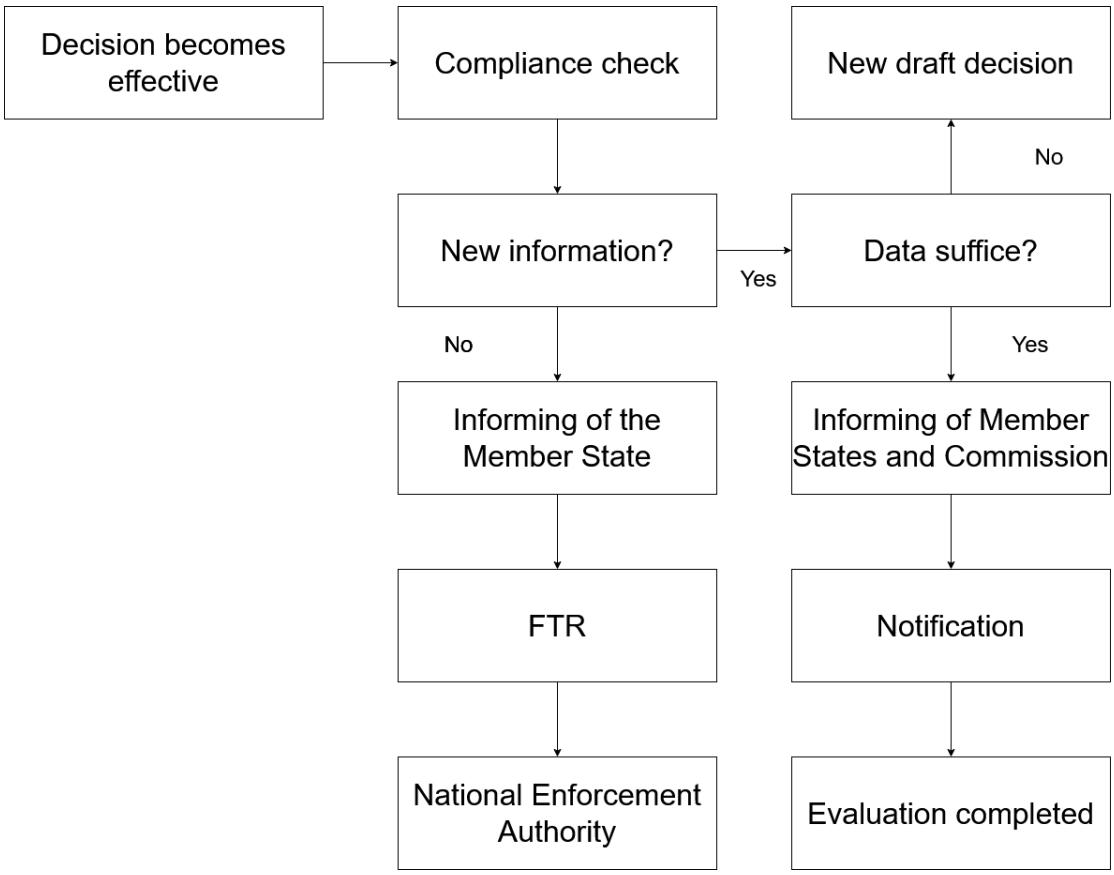

Figure 5. The follow-up stage demonstrated (Modified from ECHA's 2019 dossier evaluation flowchart).

Substance evaluation

ECHA and the Member states have criteria for prioritizing substances to further evaluation. The criteria considers hazard information, exposure information and tonnage, prioritization being risk-based approach. These criteria are used for compiling a draft Community rolling action plan (CoRAP) for three years, which specifies substances to be evaluated every year. Substances are included if they are suspected to constitute a risk to human health or the environment. The Agency adopts the final CoRAP on the basis of an opinion from the Member State Committee and publishes it to Agency's website.

(REACH Article 44) The evaluation of a substance has to be based on all relevant information submitted and on any previous evaluation. (REACH Article 47 (1))

ECHA is responsible for the coordination of the substance evaluation process and ensures of the evaluation of CoRAP. Member States can choose (a) substance(s) from CoRAP to be evaluated and to become the competent authority. (REACH Article 45) If a competent authority considers that further information is required, it shall prepare a draft decision with a deadline within 12 months of the publication of CoRAP, requiring the registrants to submit further information. The competent authority evaluates all information submitted and draft any appropriate decisions within 12 months of submission. Agency is notified accordingly in 12 months of the starts of the evaluation or within 12 months of the information being submitted. (REACH Article 46) Once the substance evaluation is completed, the competent authority informs the ECHA of its conclusions as to whether or how to use the information obtained, and ECHA informs the Commission, the registrant and the competent authorities of the other Member States. (REACH Article 48)

When registrants or downstream users are required to perform a test, an agreement should be reached in 90 days as to who will carry out these tests on behalf of other registrants or downstream users. If decision is not made or informed to ECHA, it will designate one of the registrants or downstream users to perform the test. The cost of the study is shared by all registrants and downstream users, and the copy of the full study report is shared to all concerned. The person performing and submitting the study has a claim against other accordingly. Any person concerned is able to make a claim in order to prohibit another person from manufacturing, importing or placing a substance on the market if that other person fails to pay their share or fails to hand over a copy of the full study report. All claims shall be enforceable in the national courts. (REACH Article 53)

3.3 Authorisation

The aim of authorization is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. It supports the progressive replacement of high concern substances by suitable alternatives

or technologies, when economically and technically viable. (Article 55) Authorization is applicable when bromine compounds are considered substances. When bromine compounds are impurities in (a) monomer substance(s), it is a bit unclear to determine just by the regulation if they are subject to authorization. According to an answer to a question about authorization of impurities in ECHA's website:" The authorization requirement applies to the placing on the market and use of a substance on its own as listed in Annex XIV. Therefore, it usually does not apply if the Annex XIV substance is only an impurity or additive or constituent of another substance, unless this is specified in the Annex XIV entry (e.g. substance W and substances X, Y and Z containing substance W in a concentration ≥ x %) or the other substance is also listed in Annex XIV. If a substance listed in Annex XIV is included as a component in a mixture, the authorization requirement applies for this use (i.e. the formulation of the mixture). Further, the placing on the market and use of such mixtures require authorisation, unless the Annex XIV substance is present in the mixture below the concentration limits set out in REACH Article 56(6)." (ECHA 2018) So, impurities most likely do not require an authorization, unless authorization requirement is specified in the Annex XIV entry.

Some BFRs, such as hexabromocyclododecane, may be included in Annex XIV, or are in the candidate list. Substances included in Annex XIV are subject to Article 56 (1): A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself, unless:

(a) **the use(s) of that substance** on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself **has been authorized** in accordance with Articles 60 to 64; or

(b) **the use(s) of that substance** on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself **has been exempted from the authorization requirement in Annex XIV itself** in accordance with Article 58(2); or

(c) the date referred to in Article 58(1)(c)(i) has not been reached; or

(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorization has not yet been taken; or

(e) in cases where the substance is placed on the market, authorization for that use has been granted to his immediate downstream user.

Substances referred to in Article 56 (1) are subject to Authorization, unless they are present in mixtures:

(a) below a concentration limit of 0,1% w/w (for substances referred to in Article 57(d), (e) and (f))

(b) For all other substances, below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which results in the classification of the mixture as hazardous. (REACH 56(6).

Bromine compounds as substances are subject to fore mentioned paragraphs. Although impurities are usually exempt from authorisation, if Annex XIV contains a restriction for it, it is prohibited to manufacture it or place it on the market, unless it complies with the conditions of restriction (Article 67 (1)). It should be carefully assessed what restrictions different bromine compounds have. Article 60 paragraph 6 states that a substance's use shall not be authorized if this would constitute a relaxation of a restriction set out in Annex XVII.

The Commission is responsible for taking decisions for applications for authorizations and granting authorization. In Article 60 paragraph 2, it is stated that "an authorization shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee of Risk Assessment".

However, if the bromine substance meets any criteria in Article 57, an authorization may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. (Article 60 (4))

A downstream user (the user of recycled material) may use a substance subject to Article 56 paragraph 1, if the use is in accordance with the conditions of an authorization granted to an actor up his supply chain for that use. In practice, a downstream user (e.g. a plastic product manufacturer) does not need authorization if the supplying recovery operator has one for that use. (Article 56 (2)) Downstream users have to notify the Agency within three months of the first supply of the substances, and include the authorization number on the label before placing the substance or a preparation containing it on the market. (Articles 65, 66(1))

Candidate listing procedure

The Candidate list is a listing of all chemicals that are going to be restricted and subject to authorization. Substances that may be included in Annex XIV are categorized in Article 57. When a decision is made to include a substance in Annex XIV, the date(s) from which the prohibition of the substance starts is set. The date(s) by which applications must be received if an applicant wishes to continue to use are set at least 18 months before the prohibition starting date, and continued use is allowed after that until a decision on the authorization is taken. (Article 58 (1) (c)) Before ECHA sends its recommendation to include a substance to the Annex XIV, the intention is published in the ECHA's website. All interested parties are invited to comment within three months of the date of publication, in particular on uses which should be exempt from the authorization requirement. (Article 58 (4)) Substances for which all uses have been prohibited under Title VIII or by other legislation are not included in Annex XIV (Article 58 (7)).

The process of adding a substance to the Annex XIV can start from the Commission or any Member State. The process is demonstrated in figure 6. The Commission can ask the Agency to prepare a dossier for substances which in its opinion meet the criteria in Article 57, and make it available to the Member States. Any Member State can prepare a dossier

that in its opinion meet the criteria set out in Article 57 and forward it to the Agency. The Agency has 30 days to make the dossier available to other Member States. A notice is published to ECHA's website that a dossier has been prepared for a substance, and comments can be submitted within specified deadline. Within 60 days of circulation, the other Member States or the Agency can comment on the substance identification in relation to Article 57. If no comments are received or made, the substance is included to the candidate lists. If comments are made, the dossier is referred to the Member State Committee within 15 days of the end of the 60-day period. If within 30 days of the referral, the Member State Committee reaches an unanimous agreement on the identification, the substance is included in the candidate list. If the Member State Committee fails to reach an unanimous agreement, the Commission prepares a draft proposal on identification within 3 months of receipt of the Member State Committee, and final decision is made accordingly. ECHA publishes and updates the list on its website without delay after a decision has been take. (Article 59)

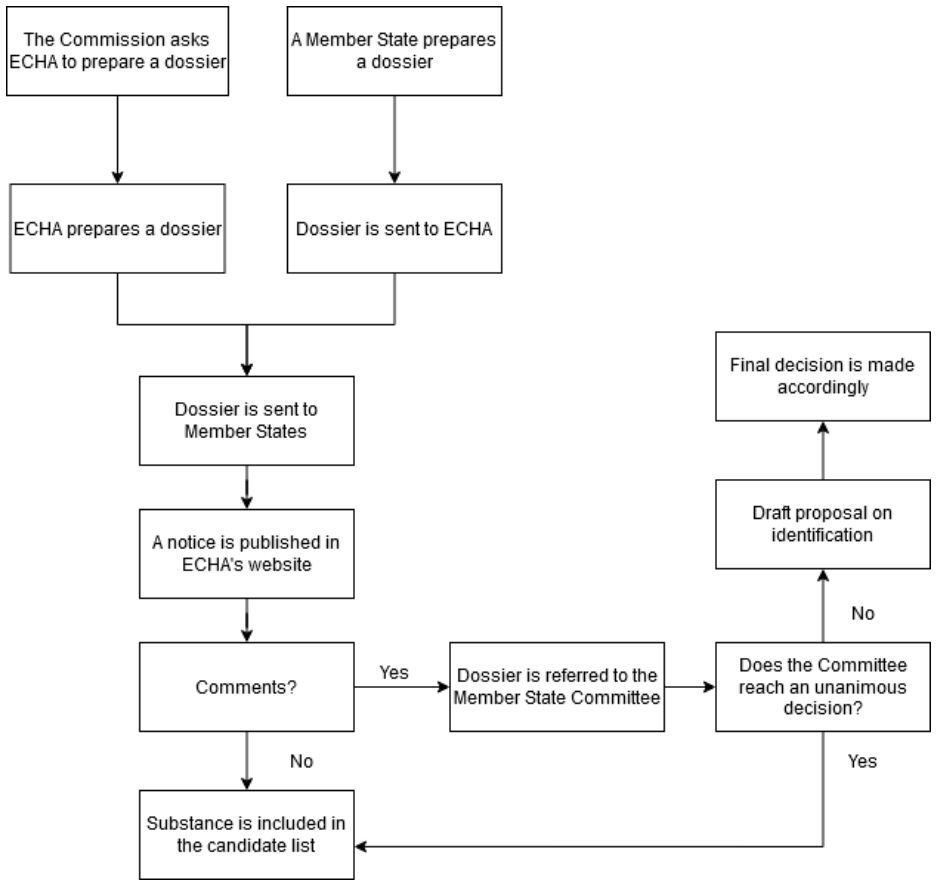

Figure 6. Adding a substance to the candidate list.

The Application process

The Commission is responsible for granting the authorizations for the use of regulated substances, but the applications are made to the Agency. An application for authorization can be made by the manufacturer, importer and/or downstream users, and can be made by one or several persons and for one or several substances. All applications are accompanied by a fee. Information requirements for an application are specified in paragraph 4 and 5 of Article 62. (Article 62) If an application for the use of a substance has been made before, the subsequent applicant may refer to the appropriate parts of the previous one, provided he has permission from the previous applicant. (Article 63 (1)) Application process is demonstrated in figure 7.

After the application is submitted to the Agency, Committees for Risk Assessment and Socio-economic Analysis give their draft opinions within ten months of the date of receipt. The Committees check information in the application and do an information request if necessary. It is made public on the Agency's website which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies can be submitted by third parties. Draft decisions are given by the 10 months deadline. The applicant has one month of receipt to provide a written notice if he or she wishes to comment. If applicant does not wish to comment, the opinions are sent to the Commission, the Member States and the applicant within last 15 days of the one month period or within 15 days of receipt of notice that the applicant does not intend to comment. If the applicant wishes to comment, the written argumentation has to be send to the Agency in two months of the receipt of the draft opinion. The Committees will consider the comments and form their final opinions in two months. Agency will then send the opinions to the Commission, the Member States and the applicant. The Commission prepares a draft authorisation decision wihin three months of receipt, and a final decision granting or refusing authorisation is taken accordingly. (Article 64)

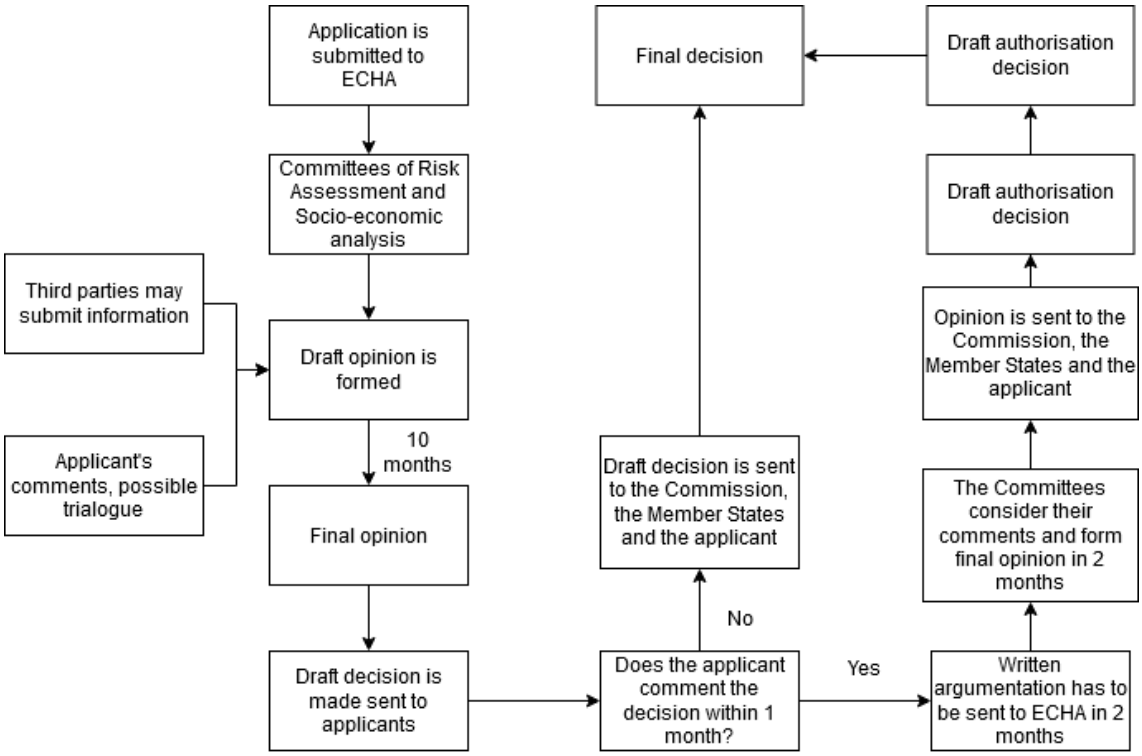

Figure 7. Application process.

3.4 Restrictions

The restriction process starts when there is "an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis". The Annex XVII, which is the list of restricted substance, will then be amended in accordingly. When making a decision, socio-economic impacts of the restriction will be taken into account, as well as the availability of alternatives. (Article 68 (1)) Substances listed in Annex XVII cannot be placed on the market or produced, unless it complies with conditions of restriction (Article 67 (1)). It is important to note however, that restricted substances do not require an authorization if they are not included in Annex XIV. Impurities are subject to restrictions. Conditions of restriction dictate the conditions on when and how substances can be placed on the market. For example, both penta- and octabromodiphenylethers can be placed on market if their concentrations as a substance, a constituent of a mixture or in articles are 0, 1% or less. The restriction process is presented in figure 8.

If the Commission considers that there is a need for a restriction of a substance, it request the Agency to prepare a dossier. The Agency shall within 12 months of the receipt of the request suggest restrictions to initiate restrictions process, if it is necessary to take action on a Community-wide basis. If the Agency considers a need for restrictions, it prepares a dossier. If a Member State considers a need for a restriction of a substance, it proposes that the Agency prepares a dossier. If the substance is not on the Candidate list, the Member State prepares a dossier conforming the requirements of Annex XV within 12 months of notification to the Agency. If an action for a Community-wide basis is necessary, the Member State submits the dossier to the Agency to initiate the restriction process. If a substance is on the Candidate list, no dossier is prepared. (Article 69 (1), (2), (3), (4))

The Committee for Risk Assessment and the Committee for Socio-economic Analysis check whether the dossier submitted conforms to the requirements. The Committees have 30 days (of receipt) to inform Agency of the Member State suggesting restrictions as to whether the dossier conforms. If the dossier does not confirm, the reason is given in 45 days of receipt. The Agency or the Member State brings the dossier into conformity of the reasons within 60 days. Those who have submitted a registration for that substance are informed, and the Agency instigates a restriction procedure for a substance without delay. All dossiers including the restrictions suggested are published on ECHA's website. All interested parties are invited to comment or submit a socio-economic analysis or information which can contribute to one. ((Article 69 (4), (6)) Within 9 months of the date of publication, the Committee for Risk Assessment will formulate an opinion on the appropriateness of restrictions (Article 70). The Committee of Socio-economic Analysis has 12 months to formulate its opinion (Articles 71 (1)).

The opinions of respective Committees are submitted to the Commission (Article 72 (1)). The Commission prepares a draft amendment, if the conditions laid down in Article 68 are fulfilled. The Commission sends the draft amendment to the Member States at least

45 days before voting, and the final decision is made. (Article 73 (1), (2))

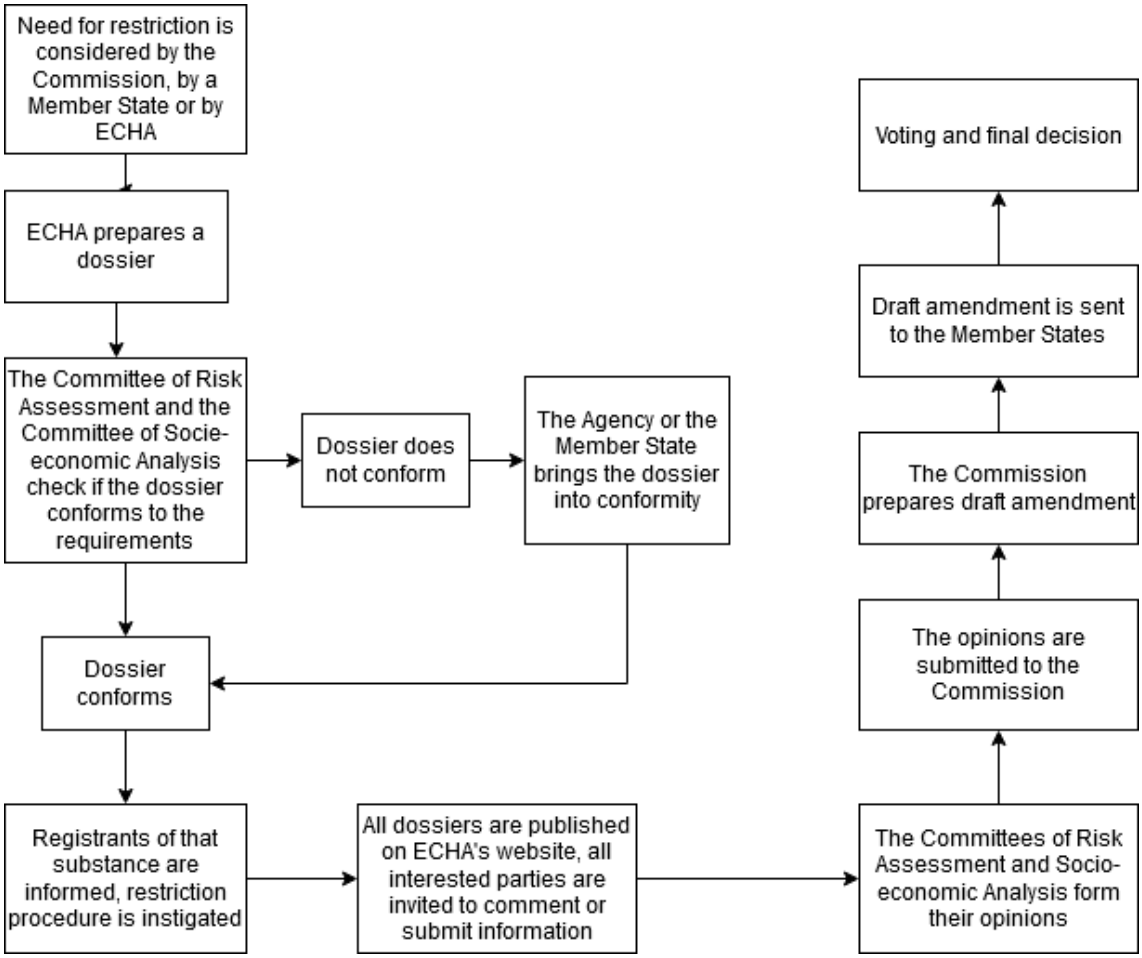

Figure 8. Restriction process.

3.5 Information in the supply chain

REACH requires companies to collect and communicate information for the safe use of substances. Information requirements in Articles 31 and 32 are also required to benefit from the Article 2(7)(d). A recovery operator that can rely on the exemption from Article 2(7)(d) and has the required information available do not need to perform a chemical safety assessment or complete a chemical safety report. He or she should take account existing information and has to provide appropriate risk management measures for safe use. Although recipient of recovered substances will receive either a SDS or safe use information, they do not usually receive a registration number or an exposure scenario for

the subsequent uses within the new life cycle chain from the manufacturer of the recovered substance. (ECHA 2010)

Safety Data Sheets

REACH requires suppliers to provide Safety Data Sheets, when a substance on itself or in a mixture falls under the criteria given in Article 31(1). SDS has to be updated, and provided free of charge. The criteria for substances under 31(1) are:

(a) a substance or mixture meets the criteria for classification as dangerous in accordance with Regulation (EC) No 1272/2008; or
(b) a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or
(c) a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

The supplier has to provide the recipient **at his request** with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:

(a) in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or
(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to preproduction category 1A, 1B and 2, skin sensitizer category 1, respitory sensitizer category 1, or has effects on lactation or is PBT on accordance with criteria set out in Annex XIII or vPvB in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or
(c) a substance for which there are Community workplace exposure limits. (Article 31 (3))

The regulation does not define how a SDS should be acquired; it can be received from an actor in the supply chain or made. The recovery operator has to take care that the data on a received SDS in adequate for the recovered substance, since a difference in the impurity profile might change the substances hazard profile. If data in inadequate, the recovery operator must fix it to prevent liability issues. Impurities over the legal cut-of values

should be addressed in the SDS or safe use information. (ECHA 2010, p.14) When BFRs are considered a substance instead of an impurity, they typically require a SDS. When BFRs are treated as impurities, they are not subject to Article 31(1) and the recovery operator is not obliged to provide a SDS unless the substance (recyclate) they recover requires it. However Article 31(2) could trigger that obligation. (ECHA 2010, p.15) SDS does not need to be supplied where dangerous substances or preparations are offered or sold to the general public, if sufficient information is given to users to take necessary safety measures, unless requested by a downstream user or distributor. (Article 31(4)) Any actor in the supply chain who is required to prepare a chemical safety report has to place the relevant exposure scenarios in an annex to the SDS covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI. Any downstream user has to include relevant exposure scenarios and other useful information from the SDS supplied to him when compiling his own SDS for identified uses. Distributors have to pass on relevant exposure scenarios and other useful information from the safety data sheet when compiling his own SDS. (Article 31 (7))

Duty to communicate information down the supply chain when a safety data sheet is not required

If a substance is not subject to Article 31, information in Article 32 paragraph 1 is required to benefit from Article 2 (7)(d). Article 32 requires a supplier to provide the recipient with the following information:

(a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;
(b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
(c) details of any restriction imposed under Title VIII;
(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.

This information is also to be provided free of charge and kept updated. (Article 32 (2),(3))

Duty to communicate substances in articles and substances on their own or in mixtures

Any supplier of **an article containing a substance** meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % w/w has to provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % w/w shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request. (Article 33 (1), (2))

According to Article 34, any actor in the supply chain of a substance or mixture is required to communicate the following information to the next actor or distributor in the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned;
(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain. (Article 34) The employer has to give access to information of substances or mixtures used or possibly exposed to, to workers and their representatives. Manufacturers, importers, downstream users and distributors are obliged to assemble and keep available information required under REACH for at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. (Article 35, Article 36 (1))

3.6 Downstream users

Any downstream user has the right inform the manufacturer, importer, downstream user or distributor who supplies him the substance of the use with the aim of making this an indentified use. In making a use identified, sufficient information is to be provided to the manufacturer, importer or downstream user to prepare an exposure scenario or a use and exposure category for his use in the manufacturer, importer or downstream user's chemical safety assessment. Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain. (Article 37 (2)) Manufacturer, importer or downstream user has to comply with the obligations in Article 14 before supplying the substance to the downstream user who made the request, if the request was made at least one month before the supply, or within one month after the request, whichever is the later. (Article 37(3)).

Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer has to include this use in section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d). (Article 37 (3))

A downstream user has to prepare a chemical safety report according to Article 37(4), for "any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against." The conditions for when a chemical safety report is not needed are described in the same Article and paragraph. When a chemical safety report is not required, a downstream user has to consider the uses of the substance and identify and apply appropriate risk management measures, and add them to the SDS prepared by him if necessary. (Article 37 (6)) Downstream user has to comply with the requirements of

safety data sheets in Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet. (Article 39 (1))

Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:

(a) the safety data sheet(s) supplied to him;

(b) his own chemical safety assessment;

(c) any information on risk management measures supplied to him in accordance with Article 32. (Article 37 (5))

Downstream users are required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a SDS (Article 39 (1)).

The downstream user has to report to the Agency information specified in Article 38 (2) before commencing or continuing with a particular use of a substance registered by an actor up the supply chain, if the downstream user has to prepare a chemical safety report in accordance with Article 37(4) or he is relying on the exemptions in Article 37(4)(c) or (f). (Article 38 (1)) This information has to be kept up to date (Article 38 (3)). If the classification of a substance is different to that of his supplier, a downstream user has to report this to the Agency, except when it is used by the downstream user in quantities of less than 1 tonne per year for that particular use. The exception does not apply when a downstream user is relying on the exemption in Article 37(4)(c). (Article 38 (4), (5)) The downstream user is required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet (Article 39 (2)).

4 CONCLUSIONS

REACH applies to NONTOX after the recycling process, when plastic waste has ceased to be waste and the recyclate meets the requirements set for it. The recovery operators, downstream users and importers manufacturing, using or importing recycled plastics typically have at least some duties under REACH. When investigating one's duties under REACH, identification of substances is important. First thing to do is to define whether the process results in a substance or an article. The product is still a substance, if its chemical composition defines its use rather than its shape, surface or design. Then it is important to carefully identify the chemical constituents in the substance(s), since the clarity of the composition of monomer substances impacts whether BFR residues can be considered impurities. If the substance has an UVCB, BFRs are considered substances. If the substance has a known, invariable composition, BFRs can be considered impurities and are a part of the monomer substance(s).

When BFRs are considered impurities, the registration applies only to the monomer substance(s) they are part of. Most monomers are registered already, and those are exempt from registration according to Article 6 (3). Monomers and other substances that have not been registered by anyone in any supply chain have to registered. Polymers do not have be registered in articles, since they are not meant to be released from articles.

If BFRs are considered substances, Article 2 (7) (d) may exempt them from registration, even in articles. To benefit from Article 2 (7) (d), the same substance has to have been registered before and adequate information (a SDS or safe use information) has to be available for it. Especially the sameness of the substance should be evaluated carefully, since the decomposition of substances may happen in the recycling process and result in different bromine compounds. If Article 2 (7) (d) is not applicable, the substance has to be registered if it is produced over quantities of 1 tonne or more annually. For BFR substances in articles, they most likely do not have to be registered, if they are not meant to be released from articles and are below a concentration 0,1% w/w. The Agency may decide to require a registration, if it suspects that the substance is released from articles

and it poses a risk to human health or environment. Even if BFR substances didn't have to be registered, they might be subject to notification to the Agency.

Manufacturers and importer have the registration duty. REACH requires that multiple registrants work together to produce a joint submission, if they are all registering the same substance. Joint submission aims to minimize costs and reduce testing, which could benefit actors in the NONTOX project. I would argue that this is a better option than only one actor registering and other ones later benefitting from that registration through e.g. Article 2 (7) (d).

BFRs as substances are subject to authorization, if they are in the authorization list. When BFRs are impurities in a substance, they usually do not require an authorization, unless it is specified in the substance entry in the Annex XIV. Conditions of restriction have to be met in all cases, including impurities.

The supplier has to provide adequate safety information to the recipient of the substance. This may be in the form of a safety data sheet. If the recovery operator is relying on Article 2 (7) (d), the recipient typically will not receive a registration number or an exposure scenario for the subsequent uses within the new life cycle chain from the manufacturer of the recovered substance.

It is important to remember that the regulation typically does not apply the same way to all recovered materials, and it is important to evaluate the substances case-by-case. ECHA's website has a lot of useful tools and documents, which are recommended to use when analyzing one's substances and duties under REACH.

SOURCES

Alaee, M., Arias, P., Sjödin, A., & Bergman, Å. (2003). An overview of commercially used brominated flame retardants, their applications, their use patterns in different countries/regions and possible modes of release. Environment International, 29(6), 683-689. doi:https://doi.org/10.1016/S0160-4120(03)00121-1

European Chemicals Agency. (May 2010) Guidance on waste and recovered substances. Reference: ECHA-10-G-07-EN

European Chemicals Agency (April 2012). Guidance for monomers and polymers. Reference: ECHA-12-G-02-EN Retrieved from: http://echa.europa.eu/

European Chemicals Agency. (November 2016). Guidance on registration. doi: 10.2823/969 Reference: ECHA-16-G-06-EN

European Chemical Agency. (May 2017). Guidance for identification and naming of substances under REACH and CLP. doi: 10.2823/538683 Reference: ECHA-16-B-37.1-EN

Euroean Chemicals Agency. (3.10.2018) Does the authorisation requirement apply to a substance in Annex XIV that is present as an impurity in another substance or mixture? Retrieved from: https://echa.europa.eu/fi/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation [referenced 7.9.2020]

European Chemicals Agency. (1.10.2019) Dossier evaluation. Document code: PRO-0017.10. Retrieved from: https://echa.europa.eu/documents/10162/13607/procedure_dossier_evaluation_en.pdf/362418b9-4ca1-445f-8bf6-c7c176463e27

European Chemicals Agency. (2020a) Understanding REACH. [web document] Retrieved from https://echa.europa.eu/regulations/reach/understanding-reach [referenced 14.8.2020]

European Chemicals Agency. (26.8.2020b) Bis(pentabromophenyl) ether. [web document] Retrieved from https://echa.europa.eu/brief-profile/-/briefprofile/100.013.277 [referenced 2.9.2020]

European Chemicals Agency. (2020c). Evaluation process. [web document] Retrieved from https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure [referenced 27.8.2020]

European Chemicals Agency. (22.7.2020d) REACH registration statistic. Infograph. [web document] Retrieved from: https://echa.europa.eu/fi/registration-statistics-infograph# [referenced 2.9.2020]

European Commission. (2018) Changing the way we use plastics. doi:10.2779/109560

Kaartinen, T., Sessa, T., Vincenti, N., Taveau, M., Campadello, L., Yli-Rantala, E., . . . Tenhunen, A. (2020). Feedstock mapping.

Kaartinen, T., Sessa, T., Vincenti, N., Taveau, M., Campadello, L., Ylirantala, E.,. Tenhunen, A. (2020). Removing hazardous substances to increase recycling rates of WEEE, ELV and CDW plastics.

Lyche, J. L., Rosseland, C., Berge, G., & Polder, A. (2015). Human health risk associated with brominated flame-retardants (BFRs). Environment International, 74, 170-180. doi:https://doi.org/10.1016/j.envint.2014.09.006

Pivnenko, K., Granby, K., Eriksson, E., & Astrup, T. F. (2017). Recycling of plastic waste: Screening for brominated flame retardants (BFRs). Waste Management, 69, 101-109. doi:https://doi.org/10.1016/j.wasman.2017.08.038

Rahman, F., Langford, K., Scrimshaw, M., Lester, J. (2001) Polybrominated diphenyl ether (PBDE) flame retardants. Science of the Total Environment, 275, 1-17. doi: https://doi.org/10.1016/S0048-9697(01)00852-X

Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC Retrievable: http://data.europa.eu/eli/reg/2006/1907/2020-04-28

Tenhunen, A., Pöhler, H. (2020) A Circular Economy of Plastics. A vision for redesigning plastic value chains. VTT. doi: 10.32040/2020. 978-951-38-8824-4

Yli-Rantala, E., Bachér, J., Kaartinen, T., Vincenti, N., & Zhan, M. (2020). Pre-treatment and characterisation of WEEE, ELV and C&DW plastics, regional perspectives on their recycling, and testing of recyclates.

Annex 1. Flowchart modified from ECHA's dossier evaluation flowchart

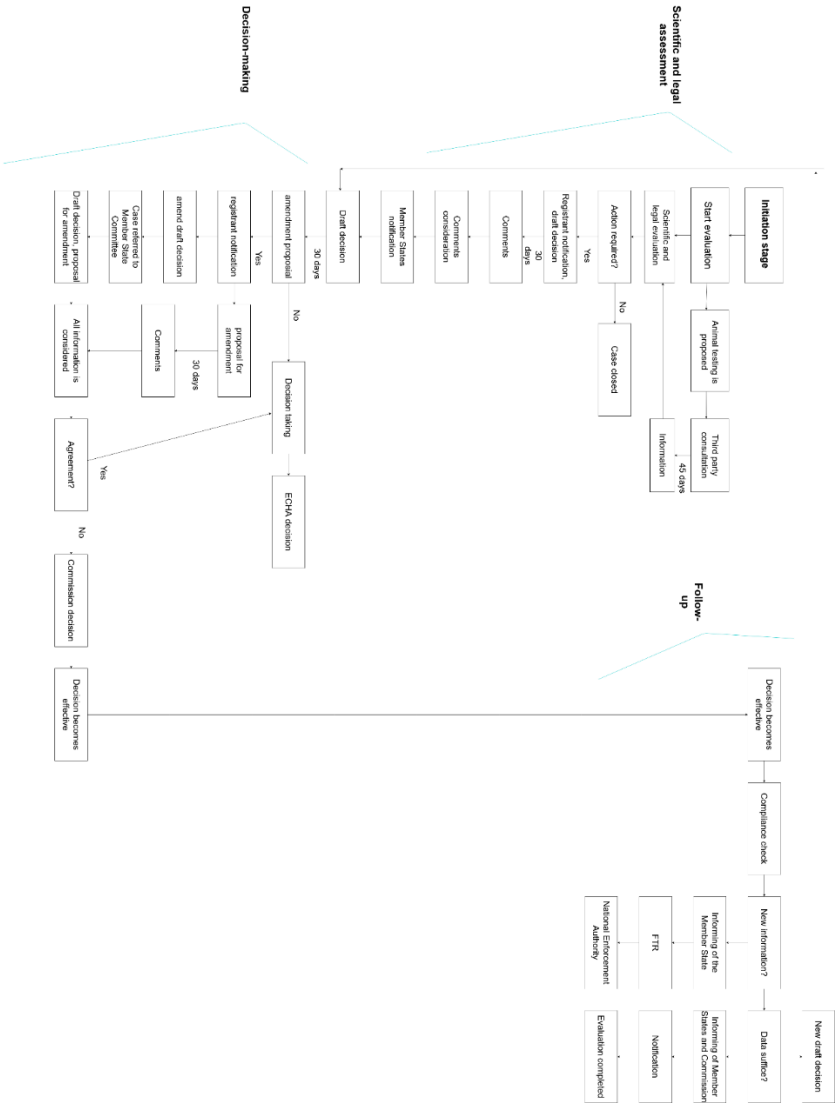

Figure 6. Dossier evaluation process (Modified from ECHA's 2019 flowchart

Annex 2. Flowchart for registration.

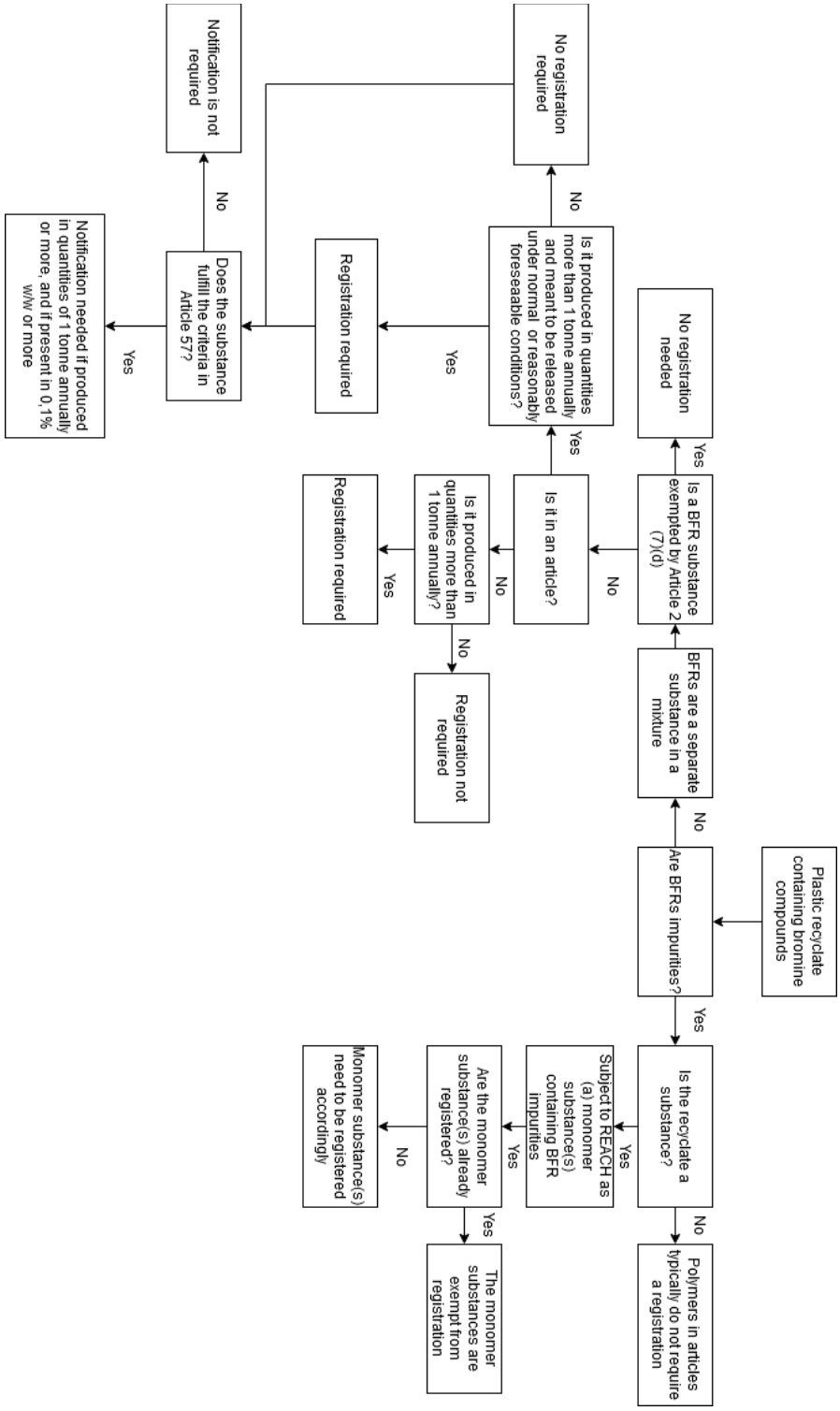

Figure 7. Registration process for polymers and BFRs.