

APPENDIX D
TO THE INVESTIGATION REPORT
ON
PVC AND PVC ADDITIVES

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym/ abbreviation	Meaning
BAT	Best available technique
BREF	BAT reference documents
BOEL	Binding occupational exposure limit
CEAP	Circular Economy Action Plan
CMR	Carcinogenic, mutagenic, or toxic for reproduction
CPR	Construction Products Regulation
CWW	Common waste water
DWD	Drinking Water Directive
ED	Endocrine disruptor
EEE	Electrical and electronic equipment
ELV	End-of-life Vehicles Directive
EPD	Environmental Products Declaration
EPR	Extended Producer Responsibility
EQS	Environmental Quality Standard
ESPR	Eco-design for Sustainable Products Regulation
FCM	Food contact materials
GPP	Green Public Procurement
GPSR	General Product Safety Regulation
HPD	Healthy Products Declaration
IED	Industrial Emissions Directive
INC	International Negotiating Committee
ISO	International Organization for Standardization
MDR	Medical Devices Regulation
MSFD	Marine Strategy Framework Directive

Acronym/ abbreviation	Meaning
OEL	Occupational exposure limit
POP	Persistent organic pollutant
PVC	Polyvinyl chloride
RAC	Risk assessment committee
REACH	Registration, evaluation, authorisation and restriction of chemicals
RoHS	Restriction of (the use of certain) Hazardous Substances
SCIP	Substances of concern in articles as such or in complex objects
SEAC	Socio-economic analysis committee
VIAQ	Vehicle interior air quality
VOC	Volatile organic compounds
WEEE	Waste from electrical and electronic equipment
WFD	Waste framework Directive

APPENDIX

D. Regulatory overview

Appendix D investigates the regulatory framework surrounding PVC additives and PVC itself.¹ Regulations impacting the different life-stages of PVC and its uses are numerous. The appendix first gives an overview of the regulatory framework for plastics and outlines briefly the specifics of PVC itself throughout its lifecycle and then details the chemical and product-related regulations impacting the use of PVC additives in applications identified in Appendix A.1.2. The last part focuses on the waste stage and the framework for recycling of PVC. The specifics of PVC as a plastic material in the production stage will be noted but are discussed in more detail in the main report.

D.1. Regulatory framework for plastics

PVC is a plastic material and as such targeted together with other plastics in several policies and regulations. In this section an overview of the regulatory framework for plastic materials is provided with the aim to give a wider picture of broad policy objectives for plastics and therefore also PVC.

Plastics are tackled by various initiatives at different levels. Recently, the development of a plastics treaty at UN level was announced and work is progressing in different fora. UN Environment is mandated to negotiate the treaty and the International Negotiating Committee (INC) is tasked to prepare a legally binding treaty by 2024. The treaty's main objective is to tackle plastic pollution, but chemicals are considered as an area requiring consideration and discussions how they could be addressed under the treaty are ongoing.

The importance and challenges related to plastic materials are recognised on the EU level. Plastics are addressed in different policies and Figure 1 gives an overview of the EU policy framework. Recent efforts to tackle concerns related to plastics were mainly approached from the objective to achieve a circular economy. The **Circular Economy Action Plan** which was published in 2015 identified plastics as a key priority and was followed up by the **EU Plastics Strategy** in 2018. The Plastics Strategy intends to transform the way plastic products are designed, produced, used and recycled. It aims at increasing the recyclability of plastics and increasing the demand for recycled plastics and sets out the goal that all plastic packaging is recyclable by 2030. It also foresees regulatory measures, which by now are already developed and partially in force: the Single-use Plastics Directive and a REACH restriction of intentionally added microplastics.

The **Green Deal**, which was published in 2019, sets out a roadmap to achieve climate neutrality by 2050 and aims at decoupling economic growth from resource use. It specifically mentions the need to follow-up on the Plastic Strategy and identifies regulatory measures to tackle plastics. The Green Deal is the basis for other more specific policy initiatives which further formulate measures to address concerns related to plastics such as the New Circular Economy Action Plan in 2020, the Zero Pollution Action Plan or the Chemicals Strategy for Sustainability.

¹ This appendix is based on information available up to July 2023.

The **New Circular Economy Action Plan (CEAP)** aims at making sustainable products the norm in the EU and contains plans for a number of specific legislative measures. Sectors in focus are those with a high resource use and a high potential for circularity such as: electronics and ICT, batteries and vehicles, packaging, plastics, textiles, construction and buildings, food, water and nutrients. Measures proposed in the CEAP include the revision of the following legal acts: the Packaging and Packaging Waste Directive, the Construction Products Regulation and the Industrial emissions Directive, updates on the rules on persistent organic pollutants in waste and new rules on waste shipment.

The core of the **Sustainable Product Initiative** is the recast of the Ecodesign Directive and the implementation of the new Eco-design for Sustainable Products Regulation (ESPR). The scope, which has so far been limited to energy related products will be broadened. The new legislative initiative aims at making products placed on the EU market more sustainable, i.e. more durable, reusable, repairable, recyclable, and energy-efficient. The initiative also tackles the presence of harmful chemicals, lays out principles to require recycled content for some products and establishes a Digital Product Passport. Green public procurement is seen as one of the key actions for circular and sustainable products.

Microplastic pollution is targeted by the **Zero Pollution Action Plan** which also provides the basis for the EU microplastics initiative. The initiative is expected to be adopted in 2023 and aims to reduce the release of microplastics to the environment by 30 % by 2030.

In addition, plastic related issues are also addressed in other policies. The **Textile Strategy** considered specifically the need to tackle microplastics, the **Farm to Fork Strategy** aims at reducing packaging.

While the **Chemicals Strategy for Sustainability** does not focus on plastics, it emphasises the need to achieve non-toxic material cycles and mentions in this context that tackling the presence of legacy substances in waste streams is particularly important for plastics. The Safe and Sustainable by Design initiative recognise the need for plastics free from hazardous chemicals and product performance requirements allowing for sustainable production and recycling.

Measures to reduce plastic waste are also taken in other policy areas. A so-called plastic tax was introduced to encourage Member States to take measures to reduce plastic waste.² The measure is an own resource to the 2021-2027 EU budget and was initially proposed in 2018 but introduced as part of the post-Covid recovery plan. It requires Member States to contribute to the EU budget by a levy calculated based on the weight of non-recycled plastic packaging waste.

² https://ec.europa.eu/info/strategy/eu-budget/long-term-eu-budget/2021-2027/revenue/own-resources/plastics-own-resource_en (3.11.2022).

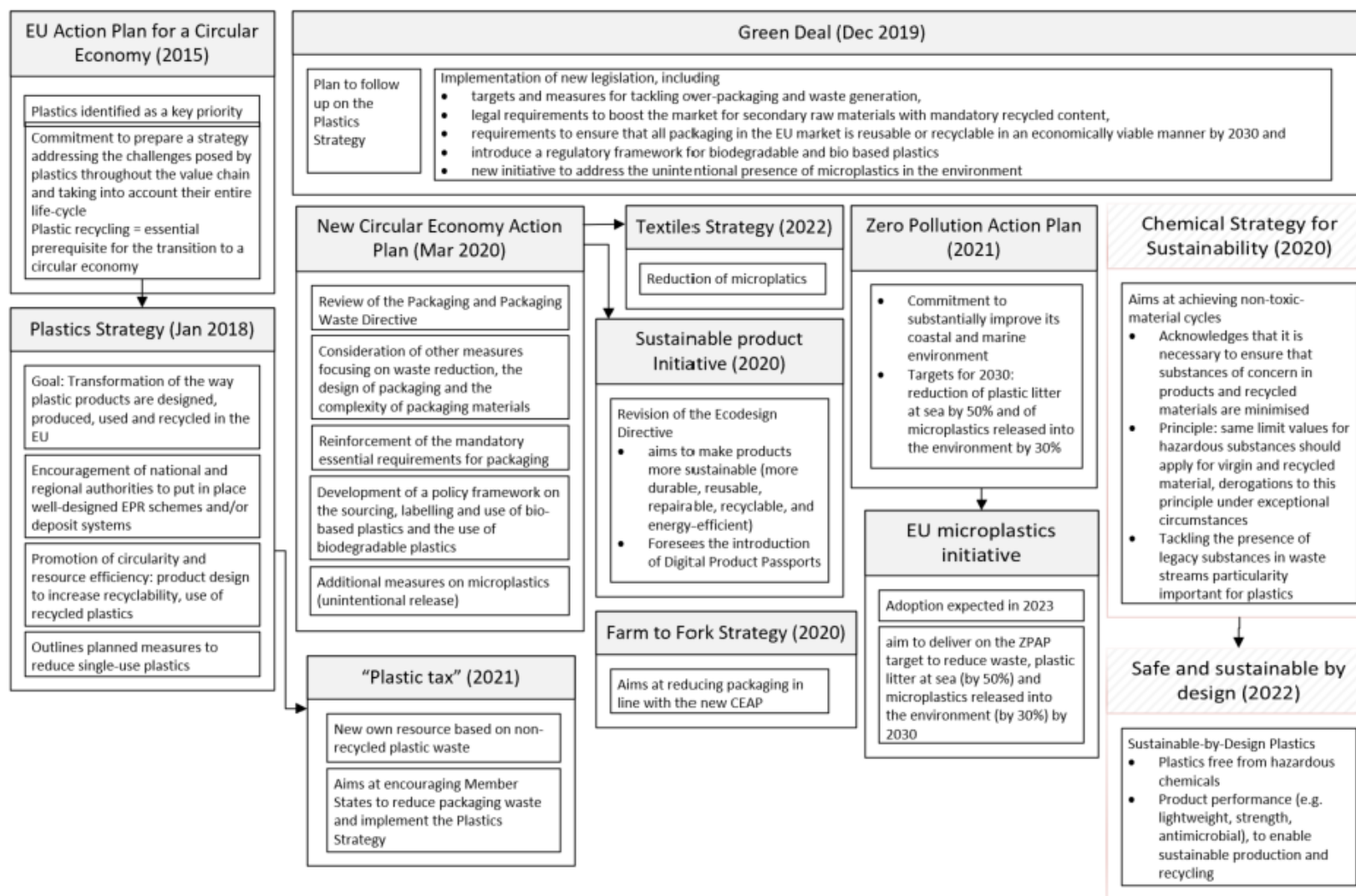


Figure 1. EU policies addressing plastics

Specific regulations impacting plastics are mostly waste related regulations. The Waste Framework Directive sets out the general principles and overall recycling targets, while specific requirements impacting plastics (including PVC) are Packaging and Packaging Waste Directive or the Landfill Directive. These legal acts are discussed in more detail in section D.3. The already mentioned Single-Use Plastics Directive (Directive (EU) 2019/904) is described here as is it impacting plastic materials in general, but does not have a strong link to the identified PVC uses. It introduces extended producer responsibility (EPR) schemes for certain types of packaging and obliges producers of wet wipes, balloons and tobacco products to cover certain waste related costs, including those relating to cleaning up litter. The directive includes collection targets, specifically a separate collection for plastic bottles of 77 % by 2025 and 90 % by 2029. It also requires incorporating 25 % of recycled plastic in PET bottles as from 2025 and 30 % in all plastic bottles as from 2030. The regulation includes the ban of oxo-degradable plastics. In 2015, Directive (EU) 2015/720 (Plastic Bags Directive) addressed specifically lightweight plastic carrier bags and came as an amendment of the Packaging and Packaging Waste Directive which is discussed in more detail in the next section.

Microplastics are considered in various policies and regulations. Different legislative acts address both primary (purposefully manufactured) and secondary microplastics. A number of uses of intentionally added microplastics are in the scope of a new REACH restriction on microplastics. The Fertilising Products Regulations sets biodegradability criteria to ensure that the use of polymers does not lead to accumulations in the environment and sets limits for plastics in compost and digestate. Addressing Microplastics is also discussed in the context of the revision of the water directives (Water Framework Directive, Groundwater Directive and Environmental Quality Standards Directive). It was considered to add an environmental quality standard (EQS) for surface waters for microplastics, however, they were not yet selected as a candidate priority substance; setting an EQS was considered as an option at a later stage (EC, 2022a). The Marine Strategy Framework Directive (MSFD) is another regulation tackling microplastics and requires EU Member States to ensure that "properties and quantities of marine litter do not cause harm to the coastal and marine environment". Measures to prevent microplastics pollution are also taken or discussed on national level. For example, Sweden is working on specific guidelines regarding microplastics in stormwater and guidelines to minimize emissions of microplastics from industrial production of primary microplastics (FanPLESStic-sea, 2019). France took legal measures to minimise losses of industrial plastic granules during production, handling and transport.³ Measures mainly targeting the minimisation of plastic pollution also specifically mention microplastic and by reducing the amount of plastic waste also impact the formation of secondary microplastics.

Concerns related to plastics are the growing plastics production, the fossil fuel-based origin of the feedstock and fact that the recycling potential remains largely unexploited (EC, 2018). Plastic waste and pollution are a major concern. In this context specific aspects, such as microplastics, single-use plastics, marine litter, non-degradability, export and pollution outside the EU are highlighted (EC, 2018).

³ Décret n° 2021-461 du 16 avril 2021 relatif à la prévention des pertes de granulés de plastiques industriels dans l'environnement.

A transition to a circular economy is considered to be a promising solution to combat plastic pollution (Crippa et al., 2019). Measures foreseen in current legislation are waste prevention, recycling targets, extended producer responsibility, deposit return schemes, criteria to define when a material ceases to be waste (end of waste criteria), waste collection, measures to ensure recovery and disposal without causing harm, information sharing systems, product marking and consumption reduction. The Plastic Strategy specifically mentions measures to improve the economics and quality of plastic recycling (improved product design, increased recycled content, separate collection of plastic waste), reduction of plastic waste (e.g. tackling single-use plastics, reduction of microplastic pollution) and measures to driving investment and innovation towards circular solutions.

The concerns identified for plastic materials in general as well as the measures identified and in place are also relevant for PVC. Specific characteristics of PVC in comparison to other plastic materials are the wide use of additives, specifics at the production stage (worker safety) and waste stage (incineration, recycling and landfilling). These risk-related aspects are covered in Appendix A and B and section D.3 of this appendix. During the use phase dioxin and HCl emissions may occur in case of accidental fires which are not in the scope of this report. However, if these properties impact the ability to use PVC in certain applications (fire safety requirements), they are taken into account in this appendix.

The regulatory environment for plastics and the attempts to make material streams circular are interrelated with the regulation of PVC additives. Recycling is considered important to the pursuit of circular economy and should be prioritised over energy recovery and disposal according to the waste hierarchy. However, it is acknowledged that deviating from the general principles may be warranted for certain waste streams. This is considered to be the case when problematic substances are kept in material cycles (EC, 2020).

The regulatory framework of additives in PVC will be addressed in the next section.

D.2. Regulatory framework impacting PVC uses and PVC additives

Additives used in PVC are impacted by regulations (chemicals regulations, fire performance standards) voluntary measures (industry phase-outs) or customer requirements (ecolabels, Green Building, procurement policies). The below table contains product specific regulations and specifically provisions impacting the additives potentially used in these product categories. More information on the regulation, their scope and the impact on PVC and PVC additives is compiled later in this section and in the section on waste and recycling.

Table 1. Regulatory requirements per PVC use

PVC sector	PVC use	Regulatory framework (potentially) impacting the use of PVC additives (including voluntary schemes)
Building and construction	Construction products (general)	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - POP Regulation - Construction Products Regulation (CPR) and related EN standards - VOC requirements <p><u>Voluntary schemes:</u></p> <ul style="list-style-type: none"> - Ecolabels: e.g. Nordic Swan,

PVC sector	PVC use	Regulatory framework (potentially) impacting the use of PVC additives (including voluntary schemes)
		<ul style="list-style-type: none"> - Green building requirements (Red List, ...) <p><u>Recycling targets</u></p> <ul style="list-style-type: none"> - Revised Construction Product Regulation (proposed)
	Pipes and pipe fittings	<p><u>Legal obligations for drinking water pipes (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII (specifics: entry 63(18)(e): derogation not applicable for pipes and pipe fittings for drinking water) - REACH Annex XIV (e.g. DOTE) - DWD <p><u>Legal obligations for most other types of pipes (in addition to the above)</u></p> <ul style="list-style-type: none"> - CPR (e.g. EN 15874, EN 15876, EN 15877, EN 22391 – do not allow for the use of recycled material due to the required pressure resistance) - REACH Annex XVII (specifics: entry 63(18)(e): derogation for PVC multi-layer pipes containing recovered rigid PVC in the middle layer; entry 63(18)(f): derogation for pipe fittings PVC) - REACH Annex XIV (e.g. DOTE) - CPR (e.g. EN 1401 - Plastics piping systems for soil and waste discharge)
	Cables intended for construction work	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - CPR (e.g. EN 50575 Cable Compliance Standards), - RoHS
	Cable ducts	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - CPR
	Flooring	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - CPR (e.g. EN 14041: Resilient, textile and laminate floor coverings - Essential characteristics; EN 13501 Fire classification for Building Products) - VOC <p><u>Voluntary schemes</u></p> <ul style="list-style-type: none"> - Ecolabels: e.g. Nordic Swan
	Roofing	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - CPR (e.g. EN 13501 Fire classification for Building Products) <p><u>Voluntary schemes</u></p> <ul style="list-style-type: none"> - EU Ecolabel
	Wallpaper	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - CPR (e.g. EN 13501 Fire classification for Building Products) - VOC <p><u>Voluntary schemes</u></p> <ul style="list-style-type: none"> - Ecolabels: e.g. Nordic Swan
	Window frames	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII (specifics: entry 23 – higher threshold for cadmium in recycled building materials; new entry 63 – derogation for use of rigid PVC in window profiles under certain conditions) - CPR (e.g. EN 13501 Fire classification for Building Products) - REACH Annex XIV (e.g. DOTE)

PVC sector	PVC use	Regulatory framework (potentially) impacting the use of PVC additives (including voluntary schemes)
		<ul style="list-style-type: none"> - VOC? <p><u>Voluntary schemes</u></p> <ul style="list-style-type: none"> - Ecolabels: e.g. Nordic Swan
	Road furniture	<p><u>Legal obligations (in addition to the above)</u></p> <ul style="list-style-type: none"> - REACH Annex XVII (specifics: not in scope of the phthalates restriction (entry 51)) - CPR (EN 12899 – road vertical signs, EN 1317 – road restraint systems, EN 12767 – vehicle security barriers, EN 1794 – Road traffic noise reducing devices), note that PVC road furniture may not be allowed to be used in tunnels - Potentially requirements in national soil protections regulations
Medical applications	Blood bags	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - REACH Annex XIV (specifics: DEHP, sunset date 27.05.2025 - authorisation requirement for DEHP for medical devices as a consequence of the classification as ED for environment - REACH Annex XVII - MDR <p>Guidelines on phthalates in medical devices (Link)</p>
	Oxygen masks	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - MDR
	Other rigid PVC applications, e.g. connectors	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - MDR
	Other soft PVC application including tubing, gloves, other than blood bags	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - REACH Annex XIV (specifics: DEHP, sunset date 27.05.2025) - MDR
	Medical packaging (blister packs)	<p><u>Legal obligations for blister packs:</u></p> <ul style="list-style-type: none"> - REACH Annex XVII - REACH Annex XIV (DEHP, sunset date 14.12.2024) - MDR <p><u>Standards</u></p> <ul style="list-style-type: none"> - EU pharmacopodia - Plastic primary packaging materials - Scientific guideline (Link)
Plastic products	Toys (general)	<p><u>Legal obligations</u></p> <ul style="list-style-type: none"> - Toy Safety Directive - REACH Annex XVII <p><u>Standards</u></p> <ul style="list-style-type: none"> - EN 71 series: Migration limits set in EN 71-3 <p><u>Voluntary schemes and agreements</u></p> <ul style="list-style-type: none"> - Ecolabels: e.g. German Blue Angel (https://www.blauer-engel.de/en/productworld/toys/toys), Nordic Swan (https://www.nordic-swan-ecolabel.org/criteria/toys-095/) - Voluntary agreements to improve toys safety: <ul style="list-style-type: none"> o Voluntary agreement between the European Commission and the Toy Industries of Europe (Link)

PVC sector	PVC use	Regulatory framework (potentially) impacting the use of PVC additives (including voluntary schemes)
		<ul style="list-style-type: none"> ○ Voluntary agreement between the European Commission and Eurocommerce, the European Retail Round Table, Toy Traders of Europe and the European Promotional Products Association (Link)
	Toys containing electronic parts	In addition to the above-mentioned legal obligations: <ul style="list-style-type: none"> - RoHS
	Packaging	<u>Legal obligations</u> <ul style="list-style-type: none"> - REACH Annex XVII - For rigid packaging: REACH Annex XIV (e.g. DOTE) - Packaging and packaging waste Directive: substance restrictions <u>Recycling targets</u> <ul style="list-style-type: none"> - Packaging and packaging waste Directive
	Food contact materials	<u>Legal obligations</u> <ul style="list-style-type: none"> - REACH Annex XIV (specifics: DEHP, sunset date 14.12.2024) - FCM <ul style="list-style-type: none"> ○ Union list for plastics
Textiles, leather and fur	Artificial leather	<u>Legal obligations</u> <ul style="list-style-type: none"> - REACH Annex XVII - Flammability requirements depending on the use may impact the use of PVC – furniture and upholstery, toys and automotive
Vehicles	Automotive	<u>Legal obligations for substance requirements</u> <ul style="list-style-type: none"> - REACH Annex XVII - REACH Annex XIV - POP Regulation (specifics: DecaBDE, SCCP and related POP waste limits, PFOA) - ELV: substance restrictions - In exceptional cases: RoHS (removable items with do not form an integral part of the vehicle) <u>Standards</u> <ul style="list-style-type: none"> - Vehicle Interior Air Quality (VIAQ) <u>Recycling targets</u> <ul style="list-style-type: none"> - ELV: recycling targets
	Cables	<u>Legal obligations</u> <ul style="list-style-type: none"> - REACH Annex XVII - POP Regulation - ELV: substance restrictions <u>Standards</u> <ul style="list-style-type: none"> - ISO automotive electric cable standards (ISO 6722): includes requirement for fire performance

Table 2 below gives an overview of regulations relevant to the different product categories above with a focus on the provisions relevant for PVC or additives used in PVC. The first part comprises of horizontal legislation and voluntary schemes generally applicable to all PVC uses. In the second part voluntary schemes, customer requirements and industry commitments are listed. Regulatory requirements for products falling under the PVC uses mentioned above are detailed in the third section of the table.

Table 2. Overview of regulations covering identified uses/product sectors

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
Horizontal legislation	
REACH (Regulation (EC) No 1907/2006) Restrictions (Annex XVII REACH)	<p>The REACH regulation includes restrictions of substances and substances whose use is subject to authorisation. Those requirements impact the use of PVC.</p> <p>REACH Restrictions (Annex XVII)</p> <p>Current restrictions cover additives used in PVC, however, some entries have a limited scope and/or contain derogations for recycled material.</p> <p>Relevant entries including a short description are listed below:</p> <ul style="list-style-type: none"> - Entry 20 (Organostannic compounds): Organotin substances cannot be placed on the market as a biocide in free association paints, to prevent the fouling by micro-organisms, plants or animals of crafts, appliances or equipment used in water or for the treatment of industrial waters. In addition, dibutyltin compounds cannot be used in concentrations higher than 0.1% (w/w) in mixtures and articles for supply to the general public and dioctyltin compounds (e.g. DOTE, DOT-MaEt) cannot be used in concentrations higher than 0.1% (w/w) in the following articles for supply to, or used by, the general public: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies and RTV-2 moulding kits. - Entry 23 (Cadmium and its compounds): The restriction entry explicitly restricts the use of cadmium in mixtures and articles produced from polymers or copolymers of vinyl chloride (PVC). Mixtures and articles produced from PVC shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. The entry contains derogations for second hand articles (placed on the market before 2011) for the use of cadmium in recycled PVC. The recycling derogation was added via Commission Regulation (EU) No 494/2011. - Entry 28/Entry 29/Entry 30: CMR substances (Carc 1A or 1B, Muta 1A or 1B, Repr. 1A or 1B, e.g. MOTE) are not allowed to be placed on the market or used for supply to the general public as substances, as constituents of other substances or in mixtures when the concentration is equal to or greater than the specified limits or the generic concentration limit. Entry 30 restricts the supply to the general public of substances classified as Repr. 1A or 1B (e.g. MOTE) at or above the specific. Derogations are foreseen. - Entry 51 (Ortho-phthalates): DEHP, DBP, BBP and DIBP are restricted in toys and childcare articles. The threshold for the plasticised material is $\geq 0.1\%$ (w/w) individually or in any combination of the phthalates. The restriction was amended to restrict also restrict the use of the substances $>0.1\%$ (w/w) (individually or in combination) in plasticised materials in articles used by consumers or indoors (e.g. cables, coated fabrics, sports equipment). Relevant derogations exist for articles exclusively for industrial or agricultural uses and also for outdoor uses provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin. Products covered by other legislation such as electrical and electronic equipment, medical device or food contact materials or immediate packaging or medical devices are not in scope of the restriction entry. - Entry 52 (DINP, DIDP, DnOP): those ortho-phthalates are restricted in concentrations greater than 0.1% (w/w) in the plasticised material in toys and childcare articles which can be placed in the mouth by children. - Entry 63 (Lead and its compounds): The use of lead in jewellery and articles supplied to the general public if those articles or accessible parts thereof maybe placed in the mouth by children. Recently, the restriction on Lead in PVC (Commission Regulation (EU) 2023/923) has been adopted and will be effective from 29 November 2024. PVC articles shall not be placed on the market, if the concentration of lead is equal to or greater than 0,1 % by weight of the PVC material. A derogation for recycled soft PVC was initially proposed but is not

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
	<p>foreseen anymore. A derogation for certain PVC articles containing recovered rigid PVC is foreseen under the conditions that recovered rigid PVC in derogated articles is entirely enclosed within a layer of newly produced PVC, recovered PVC or other suitable material that contains less than 0,1 % of lead by weight, unless the derogated article is inaccessible during normal use. Products placed on the market before November 2024 are exempted as well as products already covered by specified other legislative acts such as the RoHS Directive, the Toys Safety Directive, or the Packaging Directive.</p> <ul style="list-style-type: none"> - Entry 76 (N,N-dimethylformamide): Dimethylformamide is used as a heat stabiliser and restricted in a concentration above 0.3 %, no restriction for imported articles. <p>(Potential) future restrictions</p> <p>The restriction on intentionally added microplastics is expected to enter into force soon. Future possible restrictions with a potential impact on the use of PVC are the restriction proposal of chloroalkanes (C14 to C17) of certain bisphenols (also referred to as BPA+) and a possible future restriction of CMRs in childcare articles.</p> <p>Authorisation (Annex XIV)</p> <p>Certain additives used or previously used in PVC are included in Annex XIV to REACH. The use of those substances generally requires an authorisation. However, product groups in the scope of this investigation report – food contact materials (see Article 56(5)(b) REACH) and medical devices (Articles 60(2) and 62(6) REACH) - are exempted from authorisation if the substance is only identified for human health hazards. Manufacture, and correspondingly also recycling, which is currently considered as manufacture, is also excluded from authorisation process.</p> <p>Phthalates were added to the authorisation list and require recycling operators to apply for authorisation for the use of DEHP in recycled PVC (containing the respective phthalates in a concentration above or equal to 0.1% by weight). Vinyloop Ferrara, Stena Recycling and Plastic Planet, applied for such uses and where granted an authorisation by the European Commission. Plastic Planet reapplied (ECHA, 2023a); a decision on this case has not been issued. Discussion in SEAC arose with respect to the review period. While SEAC proposed a 7-year review period, a joint minority position was submitted by 4 members arguing that a 12-year review period would be justified (ECHA, 2023a). It is noted that these authorisation cases encompassed compounding and conversion steps taking place partially at recycling plants, whereas the initial recycling step was not assessed as it is exempted under the authorisation process.</p> <p>Originally BBP, DBP, DIBP and DEHP were included based on their toxicity for reproduction, but the European Commission has amended the entries in the Authorisation List to include the endocrine disruption properties. This means that some uses of the four orthophthalates which until now have been exempted may require authorisation. Authorisation is needed for uses of DEHP in medical devices and food contact materials within the scope of Regulation (EC) No 1935/2004 after 27 May 2025 (sunset date). However, the Commission may postpone the latest application date for some of the uses until 2029. Authorisation is also required for the use of DEHP, BBP and DBP in the immediate packaging of medicinal products covered by Regulation (EC) No 726/2004⁴</p>

⁴ The need for authorisation follows the re-assessment by COM of the exemption set out in Annex XIV of REACH following the judgment of the Court of Justice of 13 July 2017 in Case C-651/15 P, VECCO and Others v. Commission

Category and regulations	<p>Overview/Scope</p> <p>Current requirements related to the presence of additives and recycling</p>
	<p>Other relevant substance included in Annex XIV are certain arsenic compounds, chromium (VI) compounds and HBCDD, a flame retardant. DOTE (EC 239-622-4) and the reaction mass of DOTE and MOTE (not registered) have been added Annex XIV. ECHA expects to receive applications for authorisation for the use of DOTE as an additive in PVC.</p> <p>Recycling materials need to meet the authorisation requirements and applications for authorisations were submitted and granted in the past for DEHP, and challenged in court (EGC (T-108/17, <i>ClientEarth v Commission</i>) and CJEU, 06.10.2021 - C-458/19 P, <i>ClientEarth v Commission</i>). This does not however cover the actual recycling step of turning waste into new raw material, but subsequent steps only (compounding, conversion).</p>
<p>POP Regulation (Regulation (EU) 2019/1021)</p>	<p>The POPs Regulation implements the provisions of the Stockholm Convention. It places prohibitions, phase-outs and restrictions on the production, placing on the market and use of POPs and provisions regarding the management of waste containing POPs.</p> <p>The POPs Regulations covers several substances previously contained in PVC such as polychlorinated biphenyls (PCBs) and HBCD not considered to be relevant anymore, but also substances which may still be present in recycled materials, mainly namely PBDE (including DecaBDE) and short chain chlorinated paraffins (SCCP) which were used as flame retardants, the latter also as plasticizers. Hexabromocyclododecane (HBCD) is restricted and although previously used as a plasticizers, past or current uses in PVC are not known.</p> <p>In the future, chlorinated paraffins with longer chains are expected to be added. The UK proposed to list 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels $\geq 45\%$ ' as a POP under the Stockholm Convention in 2019. In the meanwhile, these substances are also proposed to be restricted under the REACH Regulation. Once listed in the Stockholm Convention, the entry would be moved to the POP Regulation.</p> <p><u>POP waste</u></p> <p>The POP Regulation sets out two limit values for Annex I substances contained in waste to ensure the environmentally sound management of these wastes. The low POP concentration limit (Annex IV) defines the concentration limit above which POPs content in waste shall be subject to destruction or irreversible transformation. Waste containing a POP above this limit cannot be recycled and disposal options are limited to certain treatments (treatment in accordance with Article 7 (2) and (3)). However, exceptions for certain wastes can be granted by Member States. Derogations cannot be granted for wastes containing POPs above the maximum POP concentration limit (Annex V).</p> <p>Annexes IV and V were recently revised to include concentration limits for newly added substances and adapt existing limits to scientific and technical progress. The proposed adaptations also concern the flame retardants PBDEs (including DecaBDE) and SCCPs.</p> <p>The POP Regulation set a concentration limit (Annex IV) of 1000 mg/kg for waste containing brominated flame retardants (decabromodiphenyl ether (DecaBDE) and the polybrominated diphenyl ethers (PBDE) tetra-, penta-, hexa- and heptabromodiphenyl ether in 2019. Recycling of plastics containing the substances above the threshold is not permitted. The Annexes VI and V were adjusted recently (Regulation (EU) 2022/2400) and as of 10 June 2023, this threshold is lowered to 500 mg/kg and should be lowered to 350 mg/kg from 30 December 2025 and 200 mg/kg from 30 December 2027. While lowering the concentration limit for SCCPs from 1500 mg/kg to 420 mg/kg was initially proposed, the limit was kept at 1500 mg/kg and the Commission is required to review the concentration limit and, where appropriate, propose a lower limit latest 30 December 2027.</p>
<p>Voluntary measures, customer requirements, others</p>	
<p>EU Ecolabel and</p>	<p>Voluntary labelling schemes and standards often include criteria for the use of materials</p>

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
product ecolabels/Green building standards	<p>and chemical content in materials. While these schemes do not directly bind manufacturers, they can be requested by customers (often cooperations and institutional customers) and they sometimes are requirements in public procurement. Green Public procurement (GPP) for example promotes the use of ecolabels. In Germany, for example, the sustainability strategy requires federal authorities to source products with meet the standards of the German Blue Angel ecolabel (see below) or other ecolabels wherever possible.</p> <p>The EU Ecolabel (established under Regulation (EC) No 66/2010) can generally not be awarded to goods containing substances or mixtures meeting CMR criteria. Identified SVHCs cannot be present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (w/w). The EU Ecolabel incentivises the use recycled plastics. For the product groups investigated in this report, requirements are not established, however, the packaging requirements for the covered product groups are of interest (e.g. 25% post-consumer plastic requirement in packaging of lubricants⁵) as well as material specifications (e.g. PVC use is not allowed in the closure of dishwasher detergents in combination with a PVC closure in combination with a PET, PP or HDPE bottle⁶).</p> <p>Other regional or national schemes have requirements impacting the use of PVC. Some examples are mentioned in the following:</p> <p>The Nordic Swan ecolabel includes requirements for the use of PVC. PVC use in products is generally restricted if alternatives fulfilling the same function are available. It also sets requirements for recycled content (e.g. requirement of a specific recycling content for window frames). The ecolabel covers certain building materials including flooring, wall covering and roofing. The ecolabel cannot be awarded in flooring containing PVC (see the criteria for floor coverings, version 6.11), however possibilities of the use of PVC could be considered in the future. The Nordic Swan Ecolabel criteria for furniture and fitments 031 (version 5.6) do not allow to use of PVC, except for the use in electrical wiring/cables and electronic components.</p> <p>The Blue Angel ecolabel is the ecolabel of the German Federal Government. It includes criteria for textiles, construction products (among others for wallpapers and flooring), and household appliances. The focus for flooring are low emitting materials, but if for example also does not allow for the presence of Candidate list substances or phthalates in the final product. Recycled PVC (other than production scrap) can generally not be used for flooring awarded with the Blue Angel unless the material is approved by the German Environmental Agency and added to the exemption list.</p> <p>Green building schemes are voluntary rating systems and include requirements for the materials used. The use of PVC or additives used in PVC is addressed in most schemes. PVC is, for example, on the Red List of the International Living Futures Institute (ILFI) and included in the Cradle to Cradle (C2C) banned list.</p> <p>Product certificates or labels are often linked to Green Building Standards and contain substance related requirements, such as concentration limits but also often requirements for indoor air quality. Examples of product certificates are Environmental Product</p>

⁵ Commission Decision (EU) 2018/1702 of 8 November 2018 establishing the EU Ecolabel criteria for lubricants (notified under document C(2018) 7125)

⁶ Commission Decision (EU) 2017/1216 of 23 June 2017 establishing the EU Ecolabel criteria for dishwasher detergents (notified under document C(2017) 4240)

Category and regulations	<p>Overview/Scope</p> <p>Current requirements related to the presence of additives and recycling</p>
	<p>Declarations (EPDs) and Healthy Product Declarations (HPD).</p> <p>The revision of the Construction Product Regulation may impact ecolabels for buildings as the Commission proposal foresees that environmental requirements would be set via standards and would not allow the use of ecolabels. However, this proposal does not seem to be supported by the European Parliament and the Member States.</p>
<p>Industry commitments and labels</p>	<p>The EU PVC industry (PVC manufacturers, PVC additive producers and PVC converters as represented by ECVM, ECPI, ESPA, EuPC) Manufacturers phased out the use of cadmium in all stabilised systems placed on the European market in 2001 (ECVM, 2000). The phase-out in the EU 27 was completed in 2007.</p> <p>Since 2016, the EU PVC industry has voluntarily phased out the use of lead-based stabilisers under the Voluntary agreement (also known as VinylPlus scheme) and replaced them with mainly Ca-based systems. However, based on the information gathered in the context of the lead in PVC restriction proposal (published in 2016) SMEs in a few EU Member States were still using lead stabilisers in limited quantities in specific products (e.g. in vitro diagnostic medical equipment or in PVC silica separators in batteries) or more general applications (e.g. cables). In particular for cables, there is no indication of these uses anymore.</p> <p>The use of Bisphenol A (BPA) was completely phased out by 70% EU based PVC manufacturers before 2010 (ECHA, 2023b). According to information received in CFE1, BPA is currently not supported for the use in PVC. In the registration dossiers the use of BPA is currently supported for polycarbonate and epoxy resins.</p> <p>The EU plastics industry under the umbrella of PlasticsEurope is taking action to combat plastic pollution (Operation Clean Sweep®) (Plastics Europe, 2018). In addition, different operators and associations are engaging in initiatives to increase recycling rates (and quality) of PVC.</p> <p>The VinylPlus® Product Label was introduced to certify sustainable PVC products. The label is recognised by one of the major Green Building schemes, BREEAM (Building Research Establishment Environmental Assessment Method).</p>
<p>Green public procurement</p> <p>Directive 2014/24/EU – Articles 67(3)</p> <p>EU Public procurement directives</p>	<p>Green or sustainable procurement aims at procuring goods or services with a reduced environmental impact throughout their cycle. In the past, PVC-free purchasing policies were introduced by some cities and healthcare institutions.</p> <p>EU Green Public procurement (GPP) is a voluntary concept. The Commission has developed criteria for products and services. However, no EU Green Public Procurement criteria defined for the identified product groups. Directive 2014/24/EU on public procurement sets out EU tendering rules and allows to promote environmental management systems (Article 62) and labelling schemes (Article 43). It allows a direct reference to an ecolabel if conditions mainly to ensure that a label is not used in a discriminatory manner are met. The opportunities to pursue green public procurement are further outlined in the EU Commission’s publication Buying green! – A handbook on green public procurement (3rd Edition).</p>
<p>Product related regulations (including extended producer responsibility)</p>	
<p>General Product Safety Regulation (Regulation (EU) 2023/988) and Market Surveillance</p>	<p>The Product Safety and Market Surveillance regime consists of legislative and non-legislative measures and aims at improving consumer product safety and strengthening market surveillance of products in the EU.</p> <p>The GPSD/GPSR is a framework legislation and sets out general safety requirement for non-food consumer products (i.e. products intended for use by consumer) and complements sector-specific legislation. It was overhauled and the revised regulations</p>

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
<p>(Regulation (EU) 2019/1020)</p> <p><i>Under revision</i></p>	<p>aimed at streamlining and simplifying the operation of general product safety provisions with other Union legislation. The General Product Safety Regulation was published on the Official Journal of the EU on 23 May 2023 and will enter into effect on 12 June 2023. Economic operators are obliged to only place safe products on the market or only make safe products available. Specific sector-specific regulations such as the Toy Safety Directive are applicable alongside the GPSD. Consumer products that comply with the relevant specific sectoral regulations that aim at ensuring the health and safety of persons are presumed to be safe. The directive does not include a reference to REACH, however, aspects for assessing the safety of products (Article 6 both in the GPSD and GPSR) include the composition of the product and labelling and other information regarding the product.</p> <p>The General Product Safety legislation sets general principles for product recalls and emergency procedures. Such an emergency measure was taken by the Commission (with agreement of the Member States) in 1999 to ban some oral baby toys made from polyvinyl chloride (PVC) softened with phthalates.⁷</p> <p>The GPSD is accompanied by the Market Surveillance Regulation and established the RAPEX system.</p>
<p>Toy Safety Directive (Directive 2009/48/EC)</p> <p><i>Under revision</i></p>	<p>The Toy Safety Directive covers products designed or intended, whether or not exclusively, for use in play by children under 14 years of age and prohibits the use of substances classified as CMR category 1A, 1B or 2 under the CLP Regulation in toys, in components of toys or in micro-structurally distinct parts of toys (point 3 of Annex II), but allows for certain derogations (points 4 to 7 of Annex II) and included the possibility to request derogations. Additional specific restrictions exist, such as a</p> <ul style="list-style-type: none"> • ban on nitrosamines and nitrosable substances in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances (point 8 of Annex II). • ban on a number of allergenic fragrances (points 11 and 12 of Annex II) and migration limits for heavy metals (point 13 of Annex II). <p>The Toy Safety Directive is currently under revision and among the changes discussed is a total ban of CMR substances with no derogations, extending the generic assessment approach to endocrine disrupting chemicals and the removal of distinctions on chemical safety between toys for children under 36 months and those over 36 months.</p>
<p>Construction Product Regulation (CPR)</p> <p>Regulation (EU) No 305/2011</p> <p><i>Under revision</i></p>	<p>The Construction Product Regulation defines criteria for assessing the performance of construction products and the conditions of use for CE marking. The knowledge of product quality is a requirement, and this includes the presence of hazardous substances.</p> <p>Basic requirements are laid down in Annex I and are the based for the preparations of standardisation mandates and European Technical Assessment.</p> <p>Based on the basic requirement, more specific harmonised norms or technical specifications can be developed. For products covered by harmonised norms based on the CPR or which follow a European Technical Assessment, producers need to draw up a declaration of performance.</p>

⁷ https://ec.europa.eu/commission/presscorner/detail/en/IP_99_829

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
Standards	<p>The Construction Products Regulation does not contain any specific provisions regarding the chemical composition of construction products or emissions. However, harmonised standards can set threshold levels for releases of hazardous substances. This is for example the case for formaldehyde in wood-based panels.</p> <p>Standards relevant for fire safety are relevant for PVC uses in the construction sector. The relevant standard for fire classification of construction products is EN 13501 and EN 50575. The CPR does not set requirements for specific performance levels. Those are sets on member state or regional level. Also, other factors may require the adherence to certain performance level, such as requirements sets out by insurance companies or contractual obligations.</p> <p>The CPR is currently under revision and the revised CPR will likely incentivise the use of recyclable materials and materials gained from recycling. The proposed revised CPR includes minimum recycled content obligations and requires manufacturers to deliver environmental information about the life-cycle of their products. The revised CPR is expected to include (the basis for) stricter requirement on chemical composition and VOC releases. The use of ecolabels for construction products may be hampered (see already above).</p> <p>In addition to EU legislation, some Member States (e.g. DE and NL) have specific substance specific regulations for building products. In Germany the relevant provisions are in the Prohibition of Chemicals Ordinance (Chemikalien-Verbotsverordnung).</p>
Ecodesign Directive (Directive 2009/125/EC) <i>Under revision</i>	<p>The Ecodesign Directive currently covers the manufacturing, packaging, transport, and distribution; installation and maintenance, use, and end-of-life of energy-related products. The products need to undergo a conformity assessment and products covered by implementing measures need to be labelled with the CE marking. The use of hazardous substances as well as the generation of hazardous waste are taken into account in the assessment.</p> <p>The Ecodesign Directive restricts from 1 March 2021 onwards the use of any halogenated flame retardant in the enclosure and stand of electronic displays. Although this was challenged in court (<i>BSEF v Commission</i>, Case T-113/20), the court dismissed the action and stated that a ban of all brominated flame retardants is possible under the Ecodesign Directive to increase the recyclability. The directive would allow to add other specific substance restrictions to increase the recyclability.</p> <p>The Ecodesign Directive is currently under revision. As a core instrument of the Circular Economy Action Plan and its Sustainable Product Initiative the scope is proposed to be widened and new requirements are proposed including a new Digital Product Passport, which will include information about the chemical composition. The proposed so-called Eco-design Regulation for Sustainable Products (ESPR) included a definition of substances of concern and aims at restricting their use in products limiting the recyclability or posing a risk to human health.</p> <p>The proposal also includes a provision on green public procurement which allows the Commission to adopt implementing acts specifying minimum requirements for public contracts. Under the directive delegated acts for specific product groups such as textiles are planned.</p>
RoHS (Directive 2011/65/EC) <i>Under revision</i>	<p>The RoHS Directive restricts the placing of the market in various types of electronic and electrical equipment (EEE) including medical devices containing listed hazardous substances in heavy metals as well as four phthalates (DBP, BBP, DEHP and DIBP) and some flame retardants (PBB and PBDE) in a concentration of 0.1w% in the homogenous material except for cadmium, which has a limit of 0.01w%.</p> <p>Exempted applications are listed in Annexes III and IV. EEE used in vehicles (cars) is mostly exempted and falls under ELV.</p> <p>The RoHS Directive is under revision and a new regulation is planned; however, the</p>

Category and regulations	<p>Overview/Scope</p> <p>Current requirements related to the presence of additives and recycling</p>
	<p>proposal is delayed. In the context of the recast the introduction of requirements regarding the recycled content is discussed.</p>
<p>WEEE Directive (Directive 2012/19/EU on waste electrical and electronic equipment (WEEE))</p>	<p>The WEEE Directive sets criteria for the collection, recycling and recovery of EEE and selective treatment of certain materials and components and is linked to the RoHS Directive. It requires that EEE users are provided with information regarding hazards substances and available means of disposal, and that treatment facilities receive detailed instructions to facilitate the safe treatment of each type of EEE.</p> <p>The WEEE directive requires the Member States to ensure that all separately collected WEEE undergoes proper treatment.</p> <p>The technical requirements for the treatment are listed in Annex VIII to the WEEE Directive and are generic. The European Commission requested European Standardization Organisations (ESOs) to develop European standards (ENs) for the collection, logistics and treatment, including recovery, recycling and preparing for re-use, of WEEE.</p> <p>The WEEE Directive sets minimum rates for separate collection of WEEE and recovery targets. As of 2019 the minimum rates for separate collection are 65% of EEE put on the market or 85% of WEEE generated on the territory of the respective Member State. The Member States can choose which rate they report. The recovery and recycling/preparing for reuse targets differ depending on the product category.</p>
<p>ELV (Directive 2000/53/EC)</p> <p><i>Under revision</i></p>	<p>The End-of-Life Vehicles (ELV) Directive aims to prevent and limit waste from ELVs and requires vehicle manufacturers and importers to limit the use of hazardous substances in new vehicles, to design and produce vehicles in a way which facilitates re-use and recycling, and to increase the use of recycled materials.</p> <p>Materials and components of vehicles placed on the market must not contain certain heavy metals – mercury, hexavalent chromium, cadmium and lead, in a concentration exceeding 0.1% by weight in homogeneous material (0.01 by weight for cadmium). Exemptions exist for certain applications set out in Annex II of the Directive, which lists the materials and components subject to the exemption and the scope and expiry date of the exemption in each case. The Commission reviews the exemptions on a regular basis.</p> <p>The ELV Directive regulates the treatment of articles (vehicles) after they become waste. It requires the Member States to take measures to ensure the recycling targets set out by the directive are met. The recycling targets were in place from 2006 (reuse and recovery: min 85 %, reuse and recycling min 80%, both by average weight per vehicle and year; lower limits for cars produced before 1980) and became more stringent in 2015, from whereon the minimum reuse and recovery is 95% and the re-use and recycling target 85% by an average weight per vehicle and year.</p>
<p>Drinking Water Directive (Directive (EU) 2020/2184)</p>	<p>The Drinking Water Directive (DWD) aims at protecting human health from adverse effects of any contamination of drinking water.</p> <p>The recast of the Drinking Water Directive will contain an EU positive list of chemicals that can be safely used in materials that come into contact with drinking water. The first positive list is expected to cover around 1 500 chemicals and will be adopted by the European Commission by 2024.</p>
<p>Medical devices (Regulation (EU) 2017/745)</p>	<p>The Medical Device Regulation (MDR) regulates the placing on the market of medical devices and their accessories in the EU and sets essential requirements applicable to medical devices (Annex I), including requirements related to chemical, physical and biological properties. The MDR sets a concentration limit of 0.1% (w/w) for CMR substances (category 1A or 1B) as well as for substances which have endocrine-disrupting properties (ED) in medical devices or parts thereof or materials that are invasive and come into direct contact with the human body, (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body</p>

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
	<p>(Section 10.4 of Annex I).</p> <p>The use of these substances in medical devices above this concentration limit is only allowed when a proper justification by companies based on a benefit-risk assessment can be provided. A specific guidance document has been published for phthalates: Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates, which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties.</p>
<p>Food contact materials</p> <p><i>Under revision</i></p>	<p>Food Contact Materials are covered by several regulations. Food contact materials legislation covers in principle all materials and products intended to come into contact (directly or indirectly) with food, or already in contact with food and were intended to come or can reasonably be expected to come in contact with food.</p> <p>The Framework Regulation (EC) No 1935/2004 sets general requirements for all food contact materials and is currently under revision. Article 5 mandates the Commission to adopt or amend specific measures for groups of materials and articles listed in Annex I. Specific measure may include list requirements for the substance used such as positive lists for substances used in the manufacturing or migration limits.</p> <p>Positive lists (Union lists) have been adopted so far for: plastics, recycled plastics, ceramics, regenerated cellulose film, and active and intelligent materials and articles. Substances included on the list can be used under the conditions mentioned in the list. The use of substances not included in such a list is subject to authorisation by EFSA. A specific authorisation was for example required for Bisphenol A (see Commission Regulation (EU) 2018/213 regarding the use of bisphenol A in varnishes and coatings as regards the use in plastic food contact materials.</p> <p>The Plastics FCM Regulation (Commission Regulation (EU) No 10/2011) sets out rules on the composition of plastic food contact materials (FCMs), and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. DAP, DBP, BBP, DEHP, DINP and DIDP are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU Regulation 10/2011).</p> <p>Commission Regulation (EU) 2022/1616 sets specific requirements for the placing on the market for use of recycled plastic materials intended to come into contact with foods. One requirement for the use of recycled plastic as a food contact material is that the recycling process was approved by EFSA. Article 13 requires the monitoring and reporting of contamination levels.</p> <p>The Commission proposed to update the plastics FCM Regulation to change existing authorisations, specific migrations limits (SML) and add 5 substances. The proposed addition of substances also impacts substances with specific uses in PVC. For instance, tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate is proposed to be permitted for the use as a plasticiser in the manufacture of soft PVC (SML of 1% (w/w)) and cannot be used in FCM coming in contact with foods intended for infants. Triethanolamine-perchlorate, sodium salt will be authorised for the use in rigid PVC in contact with certain foods. The draft regulation proposes a new total specific migration limit (SML(T)) for certain uses of the phthalates group containing DBP, BBP, DEHP and DINP. The existing individual SMLs are kept.</p> <p>Member States may adopt additional lists for materials and articles not covered by an existing Union lists.</p> <p>Regulation EC 2023/2006 describes good Manufacturing Practices for materials and articles intended to come in contact with food.</p>
<p>Soil (national)</p>	<p>Protection of soils is largely within the competence of the Member States. Only a few EU</p>

Category and regulations	Overview/Scope Current requirements related to the presence of additives and recycling
regulations)	<p>legal measures address soil pollution, e.g. the IED framework or the Environmental Liability Directive (Directive 2004/34/EC)). However, recently a legislative initiative for healthy soils (Soil health – protecting, sustainably managing and restoring EU soils) was launched on EU level.</p> <p>National legislation can limit the use of certain product uses that could negatively impact the functioning of the soil. For example, the German Soil Protection Ordinance (Bodenschutzverordnung) sets threshold limits for the pathway soil groundwater for some substances inorganic substances including lead and cadmium and organic substances including PAKs, BTEX, LCKW, PCBs, Naphthalin. Some products made from recycled PVC used outdoors (e.g. paddock mats) are tested against these thresholds.</p>
<p>Packaging and packaging waste Directive (Directive 94/62/EC)</p> <p><i>Under revision</i></p>	<p>The objective of Directive 94/62/EC (the Packaging and Packaging Waste Directive) is to harmonise national measures in order to prevent or reduce the impact of packaging and packaging waste on the environment.</p> <p>The Packaging Directive includes concentration limits for lead, cadmium, mercury and hexavalent chromium in packaging (Article 11).</p> <p>The directive sets recycling targets and requires the Member States to introduce systems for the return and/or collection of used packaging.</p> <p>The directive was amended in 2015 by Directive (EU) 2015/720 (Plastic Bags Directive) and requires Member States to take action to address the unsustainable consumption and use of lightweight plastic carrier bags.</p> <p>The amendment of the Packaging and Packaging Waste Directive in 2018 by Directive (EC) 2018/852 led to the strengthening of the recycling targets:</p> <ul style="list-style-type: none"> - Municipal waste: 50% by 2020, 55% by 2025, 60% by 2030 and 65% by 2035; - Packaging: 65% by 2025 and 70% by 2030; - Plastics: 50% by 2025 and 55% by 2030; - Specific packaging materials, inter alia Plastic (55%) <p>In addition, a binding landfill target to reduce landfill to maximum of 10% of municipal waste by 2035 was introduced.</p>
<p>VOC standards</p> <p>National requirements</p>	<p>Indoor air quality is addressed on the EU level, in Member State legislation, in standards and voluntary schemes. In 2021, the European Parliament called on the Commission to regulate indoor air quality independently or as part of sustainable building legislation to ensure the safety of workers and the general public from hazardous substances in consumer products in its resolution on the implementation of the Ambient Air Quality Directives.⁸</p> <p>Some Member States set requirements for VOC for building products. Examples of such legal acts or standards are listed in the following: French VOC regulation (Decree No. 2011-321), Belgian VOC Regulation, German AgBB scheme. The German Committee for Health-related Evaluation of Building Products (AgBB) Committee develops testing and assessment criteria for building products suitable for indoor use.</p> <p>VOC standards are also relevant for vehicles. While no general legal requirements in place, car manufacturers generally require their suppliers to meet their own standards on Vehicle Interior Air Quality (VIAQ).</p>

⁸ European Parliament resolution of 25 March 2021 on the implementation of the Ambient Air Quality Directives: Directive 2004/107/EC and Directive 2008/50/EC (2020/2091(INI))

In addition to the regulations, standards and voluntary schemes mentioned above there are also other requirements which may impact the use of PVC in products such as indoor air pollution requirements or worker safety requirements (e.g. OELs)⁹.

Fire safety standards (adding to the ones mentioned for building products above) may impact the PVC as they may require the use of flame retardants. This aspect has been investigated in the Flame Retardants strategy (ECHA, 2023c).

D.3. Waste related regulations - PVC and recycling

Recycling is considered a corner stone of a circular economy. This section aims at outlining the regulatory framework around waste management with a specific focus on recycling activities and limitations relevant to PVC. The investigation is focusing on legal requirements; however, it needs to be noted that for waste management illegal practices are expected and have been highlighted in previous reports (EC, 2022b).

Below relevant waste related regulations are listed. Extended producer responsibility related product legislation was already included in the table in the previous chapter.

Table 3. Waste related legislation

<p>Waste Framework Directive (Directive 2008/98/EC) and European list of waste (2000/532/EC)</p>	<p>The Waste Framework Directive provides a legislative framework for waste management including a definition of waste, conditions under which waste ceases to be waste (end-of-waste criteria), waste prevention measures, the collection, transport, recovery and disposal of waste, minimum requirements for extended producer responsibility and necessary measures to ensure waste is recovered or disposed of without endangering human health or causing harm to the environment.</p> <p>Of specific interest for this report are the waste definition, the classification as hazardous waste, end-of waste criteria.</p> <p>Waste definition</p> <p>Waste is defined as “any substance or object which the holder discards or intends or is required to discard” (Article 3(1) WFD) and therefore consists of an objective and an subjective element. The requirement to discard is e.g. foreseen by the POP Regulation.</p> <p>Production waste is relevant in PVC production and reused. Production waste is a by-product and no falling under the waste definition.</p> <p>Hazardous waste</p> <p>Hazardous waste’ means waste which displays one or more of the hazardous properties listed in Annex III (so called “H-criteria”). Waste needs to be classified in accordance with Article 3(2) WFD and the List of waste (LoW, Commission Decision 2000/532/EC, sometimes also referred to as the European Waste Catalogue). In addition to the legal basis, the Commission drew up a notice to provide clarification and guidance on the classification of waste: Commission notice on technical guidance on the classification of waste (2018/C 124/01).</p> <p>The European List of Waste provides industry and MSCA with harmonised reference nomenclature and classification for waste streams/types. It contains around 800 entries and is regularly amended. Any waste generated in the EU needs to be assigned one of the six-digit codes in the LoW by the one who generates the waste. The List of Waste differentiates ‘Absolute hazardous’ entries and ‘Absolute non-hazardous’ entries. Wastes assigned to either</p>
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⁹ See also Appendix A.

of the categories cannot generally be assigned to the other category and are considered to belong to the category without further assessment. Entries for hazardous waste are marked with an asterisk (*). The third category of entries are mirror entries which require the waste operator to characterise the waste stream and take an expert decision on whether it is hazardous or non-hazardous waste. In case of mirror entries there are two identical entries. Where necessary, limit values for the concentration of hazardous substances need to be taken into account.

Member states can deviate from the classifications in the LoW. If Member States deviate from the assignment as hazardous, they need to notify the Commission and provide all relevant information. The Commission should review the LoW based on the notification received by the MS.

The LoW does not contain any entries explicitly mentioning PVC, however there are several entries which also cover PVC containing waste. Some examples are listed below:

Chapter/sub-chapter	Entry	Code	Entry type
Wastes from agriculture, horticulture, aquaculture, forestry, hunting and fishing	waste plastics (except packaging)	02 01 04	Absolute Non-hazardous
packaging (including separately collected municipal packaging waste)	plastic packaging	15 01 02	Absolute Non-hazardous
end-of-life vehicles from different means of transport (including off-road machinery) and wastes from dismantling of end-of-life vehicles and vehicle maintenance (except 13, 14, 16 06 and 16 08)	plastic	16 01 19	Absolute Non-hazardous
construction and demolition wastes (including excavated soil from contaminated sites)	Plastic	17 02 03 / 17 02 04*	Mirror entry: plastic / glass, plastic and wood containing or contaminated with hazardous substances
wastes from shredding of metal-containing wastes	fluff-light fraction	19 10 03* / 19 10 04	Mirror entry: fluff-light fraction and dust containing hazardous substances / fluff-light fraction and dust other than those mentioned in 19 10 03
wastes from the mechanical treatment of waste (for example sorting, crushing, compacting, pelletising) not otherwise specified (Remark: "shredder")	other wastes	19 12 11* / 19 12 12	Mirror entry: other wastes (including mixtures of materials) from mechanical treatment of waste containing hazardous substances / other wastes (including mixtures of materials) from mechanical treatment of wastes other than those mentioned in 19 12 11

Entries relevant for PVC are mostly mirror entries and oblige the waste holder to assess whether the concrete waste is hazardous or non-hazardous. In practice, most actors seem to classify PVC mixtures as non-hazardous and generally, PVC containing waste also does not seem to be treated as hazardous in the Member States. The argument provided by the actors is that additives are bound in the polymer matrix and do not migrate and hence are not bioavailable (EC, 2022b). However, this argument would need to be supported by robust data showing lack of bioavailability (see Article 12(b) of the CLP Regulation). As pointed out in a study prepared for the Commission (EC, 2022b) a more critical assessment of the classification of PVC mixtures as hazardous or non-hazardous may be necessary.

The Waste Framework Directive foresees **stricter conditions for the management of hazardous waste**. For example, Article 18 provides for a general mixing ban for hazardous waste, which allows for derogations. Member States are required to keep record of information related to hazardous waste (Article 35 WFD). Requirements to exempt hazardous waste facilities from permitting are more restrictive (Article 25 WFD). In addition, Article 19 foresees specific labelling and packaging obligations in the course of handling of hazardous waste.

The designation as hazardous waste has also consequences in other legislations. Certain hazardous wastes cannot be landfilled, landfills for hazardous waste need to fulfil specific requirements, notification procedure for the transboundary shipment of waste and limitation of transboundary shipments. The WEEE and ELV Directives require the removal of hazardous materials and components.

End-of-waste criteria

End-of-waste criteria can be defined but need to meet the criteria set out in Articles 6 of the WFD. For PVC, no end-of-waste criteria have been defined on the EU level and for PVC recyclates containing legacy additives meeting the conditions of Article 6(c) and (d) might be a challenge ((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.)

A JRC report investigated end-of-waste criteria for plastic waste (Villanueva and Eder, 2014). The authors state that *“plastic recyclate can be given EoW status only if the original plastic waste has not been designated as hazardous waste on the basis of the CLP and the POP regulation or, if this is the case, the processing method is recognised under the Basel Convention and the recyclate is permitted on the market under the REACH Regulation.”*

Note that in a recent JRC report (Orveillon et al., 2022) PVC was not considered a priority for future end-of-waste criteria definition. Figure 2 below shows the rating leading to this conclusion. A low rating was given for the low potential to recover critical raw materials and the possible presence of hazardous substances.

Waste/by-product stream category	Specific material stream	Level of support (w=3)	Collection and recycling (w=2)	Uses (w=2)	EU market value (w=3)	Intra-EU shipments (w=1)	Extra-EU shipments (w=1)	Purity (w=1)	Critical raw materials (w=1)	Evidence of demand (w=3)	Existing standards (w=2)	Existing criteria (w=2)	Expected impacts (w=3)	WEIGHTED SUM (WS)
	Polystyrene (and expanded polystyrene)	2	2	3	3	2	2	3	1	2	3	3	2	57
	Polyurethane	2	1	1	1	3	2	3	1	2	1	3	2	42
	Polyvinyl chloride	2	3	2	2	2	2	3	1	2	3	3	1	51

Polyvinyl chloride	Possible risk of contamination with heat stabilisers, plasticisers, per- and poly-fluoroalkyl substances and other hazardous substances (e.g. chlorine, mercury, fluorinated substances, cadmium, lead, phthalates, bromine).	1
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Figure 2. Rating of PVC waste as a possible candidate for the development of end-of-waste criteria based on JRC end-of-waste scoping report

Defining end-of waste criteria for PVC waste would lead to harmonisation and for example simplify shipments of PVC granules. Specific requirements for the output material in terms of additive content or usage could be defined. While this could include limit values for specific additives, it would not impact the use of additives in imported materials/articles. **Recycling targets**

The WFD includes recycling targets for construction and household waste (Article 11). The directive required the Member States to take measures to achieve the following re-use and recycling targets:

- For waste materials from households: preparing for re-use and recycling min. 50 % by weight by 2020
- For non-hazardous construction and demolition waste: preparing for re-use and

	<p>recycling minimum 70% by weight by 2020</p> <ul style="list-style-type: none"> • Got municipal waste: preparing for re-use and recycling: min of 55%, 60% and 65% by weight by 2025, 2030 and 2035 respectively. <p>SCIP Database</p> <p>The SCIP database is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the WFD. It aims to increase the knowledge of hazardous chemicals in articles and products throughout their whole lifecycle - including at the waste stage.</p> <p>All articles (as defined under REACH) placed on the market after 5 January 2021 containing a Candidate List substance in a concentration above 0.1% w/w are covered by the obligation of the supplier to submit a SCIP notification. Substances and mixtures are not in the scope unless they are an integral part of an article.</p>
<p>Recovered substance (REACH)</p>	<p>According to Article 2(2) of REACH, waste as defined by the WFD (Article 3 (1)) is not considered as a substance or mixture under REACH and is therefore exempted from the REACH Regulation. However, waste may cease to be waste when it has undergone a recovery (including recycling) operation, if it complies with specific criteria/ legal conditions (established at EU or national level). However, substances obtained from waste or used in the place of raw materials at the end of the waste, need to meet REACH and CLP requirements.</p> <p>Polymers meeting the criteria of the REACH polymer definition (Article 3(5)) are exempted from the registration requirement. However, monomers and other substances that serve as starting materials, in quantities of more than 1 tonne/year in the EU must be registered.</p> <p>Article 2(7)(d)) REACH exempts recovered substances if they meet the following conditions: The same substance as the substance resulting from the recover process has already been registered and information in accordance with Articles 31 and 32 has to available to the recovery operator.</p> <p>A recent FORUM pilot project investigated the enforcement of criteria described in REACH Article 2(7)(d) regarding exemptions for recovered substances from REACH registration obligations.¹⁰</p>
<p>Landfilling</p>	<p>Landfilling is the least preferable EU waste management option according to the EU waste hierarchy. Regulations on landfilling are set on the EU level and on Member State level. The requirements and landfilling practices diver greatly between different Member States.</p> <p>The Landfill Directive (Council Directive 1999/31/EC) aims at preventing or reducing the negative effects from the landfilling of waste on human health and the environment. It contains standard procedures for the acceptance of waste in a landfill and a system of operating permits for landfill sites. Specific requirements are set depending on the type of waste (municipal waste, hazardous waste according to the WFD, non-hazardous waste and inert waste) and the landfill class (liquid waste, flammable waste and explosive or oxidising waste) and certain wastes are banned from landfills (e.g. liquid waste, flammable waste and explosive or oxidising waste). Decision 2003/33/EC, the so-called WAC decision establishes criteria for the acceptance of waste at landfills. Waste acceptance criteria are established for inert waste, non-hazardous waste, hazardous waste acceptable at landfills for non-hazardous waste, waste acceptable at landfills for hazardous waste, underground storage.</p> <p>According to the recent Commission report on PVC it seems that in most Member States PVC directed for landfilling goes to landfills for non-hazardous waste (EC, 2022b).</p> <p>The Landfill Directive was revised in 2018 and foresees that Member States need to restrict landfilling of all waste that is suitable for recycling or other material or energy recovery from</p>

¹⁰ https://echa.europa.eu/documents/10162/17088/pilot_recovered_substances_en.pdf/bf588a50-705c-1b0f-b3f4-77eb5a59c5b8?t=1667885572609

	<p>2030. The share of municipal waste landfilled cannot exceed 10% of the total amount of municipal waste generated by 2035.</p> <p>Some EU member states ban or restrict landfilling of plastic waste, notably Germany, Austria, the Netherlands, Sweden, Denmark, Luxembourg, Belgium and Finland as well as the non-EU members Norway and Switzerland (EC, 2022b).</p>
<p>Shipment of waste</p> <p>Basel Convention¹¹</p> <p>OECD Decision¹²</p> <p>Waste Shipments Regulation (Regulation (EC) No 1013/2006)</p> <p><i>Under revision</i></p>	<p>On the international level, shipments of waste are governed by the Basel convention and the EU Waste Shipment Regulation. In addition, the OECD adopted a decision on the control of transboundary movements of waste for recovery operations.</p> <p>The EU Waste Shipment Regulation implements the provisions of the Basel Convention and the OECD Decision, but also includes stricter measures as it prohibits exporting waste for disposal outside EFTA countries and exporting some non-hazardous wastes from the EU to non-OECD countries. The Waste Shipment Regulation was amended by Delegated Regulation (EU) 2020/2174 on plastic waste shipments to implement the decision taken under the Basel convention to include a new entries and requirements for hazardous and non-hazardous plastic waste (decision BC-14/12). The new provisions came into effect on 1 January 2021 and provide for a ban of the export of plastic waste to non-OECD countries except for clean plastic waste sent for recycling. A guideline that represents the common understanding of all Member States on how the Waste Shipment Regulation should be interpreted was issued.¹³ The guidance includes clarifications on the classification of PVC and PVC containing waste. PVC is listed in entry EU3011 in its fourth indent, but not in entry B3011 (both ("Green" listed waste)) and therefore allows shipments destined for recycling within the EU (intra-EU shipments). If PVC waste exhibits a hazardous characteristic, it falls under entry AC300. The guideline states that the <i>"presence of certain additives in plastic waste, such as brominated flame retardants that are persistent organic pollutants or lead or cadmium in PVC, may lead to a classification of the plastic waste in question as hazardous waste and covered by entries A3210 or AC300."</i></p> <p>The revision of the Waste Shipment Regulation is currently under discussion and aims at addressing the shortcomings identified. The proposed revised Waste Shipment Regulation aims at ensuring that the EU does not export its waste challenges to third countries, simplifying the transport of waste for recycling and reuse in the EU, and addressing illegal waste shipments. The European Parliament voted on the proposal in January 2023 and proposed more stringent measures to limit shipments of plastic waste with the aim to promote reuse and recycling and reduce pollution. It proposes that exports of plastic waste to non-OECD countries should be banned and shipments to OECD countries should be phased out within four years after the entry into force.¹⁴ The parliament also envisages that the limitations to export plastics should be accompanied by measures to increase the recycling content in products, specifically plastic products. It proposes a requirement for the Commission to publish a report on the establishment of mandatory recycled content targets in Member States and come up with legislative proposals, where appropriate.</p> <p>Third countries have become increasingly reluctant to import plastic waste. China banned the import of certain types of plastic waste in 2019.</p>
<p>Industrial Emissions Directive (Directive</p>	<p>The Industrial Emissions Directive (Directive 2010/75/EU, IED) is relevant for the PVC production and waste management related activities. It lays down the rules on integrated prevention and control of pollution from industrial activities. It replaces the earlier Integrated Pollution Prevention and Control (IPPC) Directive and aims to prevent, or where this is not possible, to reduce emissions to air, water and land and to prevent the generation</p>

¹¹ Basel Convention of 22 March 1989 on the control of transboundary movements of hazardous wastes and their disposal.

¹² Council Decision C(92)39/FINAL on the control of transboundary movements of wastes destined for recovery operations. This Decision was amended and the current version is Decision of the Council on the Control of Transboundary Movements of Wastes Destined for Recovery Operations (OECD/LEGAL/0266).

¹³ [Correspondent's Guidelines No 12 \(Classification of plastic waste\)](#)

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52023AP0003>

<p>2010/75/EU)</p> <p><i>Under revision</i></p>	<p>of waste.</p> <p>The IED requires operators of industrial installations in scope (Annex I, capacity thresholds)) of the directive to obtain a permit from the national authorities. Generally large-scale installations are in scope of the IED. Permits contains conditions for the operations covering the whole environmental performance of the plant, such as emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents and restoration of the site upon closure. The permits contain emission limit values based on Best Available Techniques (BAT), as described in BREF documents (Best available techniques Reference documents) and published by the Commission for different sectors. The POL BREF (Production of Polymers) and the Large Volume Organic Chemicals (LVOC) BREF are relevant for the production process of PVC, In the future, the Waste Gas from Chemicals (WGC) BREF (under approval) will cover air emission aspects in the PVC production. In addition, BREFs applicable horizontally need to be taken into account, such as the Common Waste Water (CWW) BREF.</p> <p>The IED sets for certain activities, i.e. large combustion plants, waste incineration and co-incineration plants, EU wide emission limit values for selected pollutants.</p> <p>The IED is relevant for waste management activities. The IED Directive covers waste incineration and sets emission limit values. These emission limits contain dioxin limits and are impacting the waste incineration of PVC containing waste. Installations involved in activities related to waste treatment may be in the scope of the IED. The BREF for Waste Treatment provides guidance on best available techniques for different waste management processes and techniques.¹⁵</p>
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In addition to the EU legislative framework outlined in the table, national legislation is of specific importance in waste legislation.

D.3.1. Current measures in place to meet waste management targets

The waste targets outlined in policy papers and the Waste Framework Regulation are pursued by different regulatory measures. The table below outlines the measures in place for the different targets.

Table 4. Current tools and measures to achieve waste targets

	Tools to achieve waste targets	Regulatory measures implemented (selection)
Waste Framework Directive	Waste prevention measures	Single-Use Plastics Directive (Directive (EU) 2019/904) Packaging and Packaging Waste Directive WEEE Directive Landfill Directive: indirectly by limiting the landfill capacity
	Recycling targets	Waste Framework Directive: overall recycling targets

¹⁵ https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/JRC113018_WT_Bref.pdf

		<p>Packaging and Packaging Waste Directive</p> <p>WEEE Directive</p> <p>ELV Directive</p> <p>Single-Use Plastics Directive (Directive (EU) 2019/904)</p>
	Extended producer responsibility	<p>RoHS</p> <p>ELV Directive</p> <p>Packaging and Packaging waste Directive</p> <p>WEEE Directive</p> <p>Single-Use Plastics Directive (Directive (EU) 2019/904)</p>
	Deposit return schemes	<p>WFD encourage the use of deposit return schemes</p> <p>No mandatory requirements on EU level</p>
	End of waste criteria	<p>End-of-waste criteria (EU and national): Proposal for EU EoW criteria for plastics not further pursued so far</p> <p>JRC Scoping report: 5 candidate streams related to waste (mixed plastics only one of relevant for PVC)</p> <p>Building materials (including pipes) considered</p>
	Waste collection	<p>WEEE Directive</p> <p>Packaging and Packaging waste Directive</p> <p>ELV Directive</p>
	Measures to ensure recovery and disposal without causing harm	<p>Landfill Directive</p> <p>WEEE Directive</p> <p>ELV Directive</p> <p>IED Directive</p>
	Information sharing systems	<p>WFD Article 9 (SCIP)</p> <p>Labels and marking – see below</p>
	Marking	<p>REACH Annex XVII: Restriction of the use of intentionally added microplastics</p> <p>REACH Annex XVII entry 63(19): PVC articles containing recovered rigid PVC should be marked if they contain lead in a concentration equal or greater 0,1 % by weight of the PVC material</p> <p>Packaging and Packaging waste Directive: use of recycling symbols (e.g. Mobius loop), identification of the material, e.g. the identification code (RIC)</p> <p>Single-Use Plastics Directive: labelling requirements for specific plastic products</p>

Appendix D to Investigation Report on PVC and PVC additives

	Consumption reduction	Single-Use Plastics Directive
	Improved product design	Ecodesign Directive

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