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Substances of Concern in Ecodesign and Other EU Law

A New Layer of Chemicals Management for Environmental Sustainability

The notion of "substances of concern" is not new in EU chemicals policy, although it has been used in some different contexts (e.g. regulatory risk management, biocides). With the landmark new Ecodesign for Sustainable Products Regulation (ESPR) in force since 18.7.2024 a wide multi-reference and dynamic definition of "substance of concern" has been introduced, based on the European Commission's Chemicals Strategy for Sustainability. The ESPR definition is accompanied by various provisions allowing to foresee performance and information requirements in future ecodesign measures. The same term has also appeared in other existing and emerging EU laws and policy initiatives, namely those under the European Green Deal, where it already triggers reporting actions for certain large companies (corporate sustainability reporting) and the European Commission (for batteries), while other regulations still to be adopted (packaging and packaging waste, vehicles) also make use of it. The aim of this article is to provide a review, compare and assess the main EU legal provisions in force and forthcoming – as far as they govern "substances of concern" – taking the new ESPR provisions as a benchmark. In addition, related EU laws, proposals and other initiatives which do not or only marginally use this terminology as of today, or that can be considered as "false friends" (e.g. "Substances of Very High Concern – SVHC"; "Substances of Concern in Products – SCIP"; "most harmful substances"; REACH restrictions, e.g. "universal" PFAS proposal; "substances of emerging concern"), shall be addressed. Some notable industry approaches to tackle chemicals management including "substances of concern" will also be discussed.

I. Introduction and Outline

The European Green Deal by the European Commission (hereafter also "COM") of 11.12.2019[1] did not yet contain the notion of "substance of concern" (hereafter also "SoC"). However, it set out two key actions as part of its Roadmap which both make reference to SoCs: The (new) Circular Economy Action Plan (CEAP)[2], including a sustainable products initiative; and the Chemicals Strategy for Sustainability (CSS)[3].

1. The CSS as the Starting Point

The term "substance of concern" was roughly defined for the first time in the CSS as follows:

> *"(16) These include, in the context of this strategy and related actions, primarily those related to circular economy, substances having a chronic effect for human health or the environment (Candidate list in REACH and Annex VI to the CLP Regulation) but also those which hamper recycling for safe and high quality secondary raw materials."*[4]

This definition explicitly opens the scope of substances to be addressed by virtue of their hazards (hereafter also "hazard-based SoCs") beyond SVHCs in the Candidate List[5] established under the REACH Regulation[6] to cover also other substances having a *"chronic effect for human health or the environment"* according to Annex VI to the CLP Regulation[7], the list of EU-harmonised classifications. Furthermore, another group next to the hazard-based SoCs are *"also*

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1 *European Commission*, The European Green Deal, COM(2019) 640 final, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2019%3A640%3AFIN (accessed 13.8.2024).

2 *European Commission*, A new Circular Economy Action Plan for a cleaner and more competitive Europe, COM(2020) 98 final, Section 4.2. and Annex with key actions, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A98%3AFIN (accessed 13.8.2024).

3 *European Commission*, Chemicals Strategy for Sustainability towards a toxic-free environment, COM(2020) 667 final, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN (accessed 13.8.2024).

4 *European Commission*, footnote 3.

5 *ECHA*, Candidate List of substances of very high concern for authorisation, available at https://echa.europa.eu/candidate-list-table (accessed 13.8.2024). As of 27.6.2024 the Candidate List had 241 entries. These correspond to over 490 reference substances part of the Candidate List Package for SCIP notifications; see https://echa.europa.eu/candidate-list-package (accessed 13.8.2024).

6 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18.12.2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), latest consolidated version of 6.6.2024, available at http://data.europa.eu/eli/reg/2006/1907/2024-06-06 (accessed 13.8.2024).

7 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16.12.2008 on the classification, labelling and packaging of substances and mixtures (CLP), latest consolidated version of 1.12.2023, available at http://data.europa.eu/eli/reg/2008/1272/2023-12-01 (accessed 13.8.2024).

those which hamper recycling for safe and high quality secondary raw materials", hence SoCs solely by virtue of their negative effect on circularity (hereafter also "circularity-based SoCs").

The stated twofold aim in the CSS with regard to SoCs is that they *"are minimised and substituted as far as possible"*. With regard to the substitution objective, the CSS stressed the importance *"to incentivise industry to prioritise innovation for substituting, as far as possible, substances of concern."* With regard to the minimisation objective – in order to move towards toxic-free material cycles – the European Commission committed to *"introduce legal requirements on the presence of substances of concern in products, including PFAS, through the initiative on sustainable products"* and more specifically to *"ensure availability of information on chemical content and safe use, by introducing information requirements in the context of the Sustainable Product Policy initiative and tracking the presence of substances of concern through the life cycle of materials and products; [...]"*.[8] Hence, information requirements for SoCs are seen in the CSS as the main tool in order to minimise their presence in products, but not necessarily the only one.

2. ESPR and Its New SoC Definition

The new Ecodesign for Sustainable Products Regulation (ESPR)[9,10] establishes a framework for the setting of ecodesign requirements that products have to comply with to be placed on the market or put into service, with the aim of improving the environmental sustainability of products in order to make sustainable products the norm and to reduce the overall carbon footprint and environmental footprint of products over their life cycle, and of ensuring the free movement of sustainable products within the internal market (ESPR Art. 1(1)).

The ecodesign requirements shall serve to improve 16 product aspects, as relevant, which are listed in ESPR Art. 5(1), *"the presence of substances of concern"* (point (g)) being one of them.

In ESPR Art. 2(27) the rough CSS definition of "substance of concern" presented above (Section I.1.) has been further clarified and extended:

- The first sub-group (point (a)) refers to Candidate List SVHCs, also called "REACH-based SoCs" hereafter.
- The second sub-group (point (b)) specifies the required hazard classes or hazard categories for SoCs based on CLP Annex VI, also called "CLP-based SoCs" hereafter.
- The third sub-group (point (c)) refers to substances regulated under Regulation (EU) 2019/1021 on persistent organic pollutants (POP)[11], also called "POP-based SoCs" hereafter. This group was still missing in the COM proposal for ESPR of 30.3.2022[12] and was added during the co-legislative process.
- The fourth and final sub-group (point (d)) rephrases the abovementioned description of a circularity-based SoC more broadly to mean a substance that *"negatively affects the reuse and recycling of materials in the product in which it is present"*.

Table 1 provides an overview of this SoC definition according to the final legal text in ESPR Art. 2(27) with its four independent sub-groups.

It should be noted that the SoC criteria in Art. 2(27) points (a)–(d) are not cumulative. The previous call by a broad group of industries to combine hazard- and circularity-based criteria for the definition of SoCs under ESPR[13] was opposed by a coalition of non-governmental organisations (NGOs)[14] and finally not retained in the legal text.

Especially with regard to CLP-based SoCs, the number of substances that fall within this ESPR definition of SoCs is significant. While a comprehensive list cannot be presented at this stage, it is possible to determine the substances fulfilling this point with regard to CLP Annex VI.[15] According to an analysis made for the European Space Agency (ESA) and its ESA REACH Tool[16], 3,916 substances in CLP

8 See *European Commission*, footnote 3.

9 Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13.6.2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC, available at http://data.europa.eu/eli/reg/2024/1781/oj (accessed 13.8.2024).

10 A Corrigendum to Regulation (EU) 2024/1781 has been published in the Official Journal of the European Union on 7.8.2024, correcting the reference to ESPR in its Articles 77 and 78, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202490493 (accessed 13.8.2024).

11 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20.6.2019 on persistent organic pollutants (recast), current consolidated version of 28.8.2023, available at http://data.europa.eu/eli/reg/2019/1021/2023-08-28 (accessed 13.8.2024).

12 *European Commission*, Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM/2022/142 final, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0142 (accessed 13.8.2024).

13 *Cefic et al.*, Joint letter to the ENVI Committee on substances of concern under the ESPR, 17.5.2023, available at https://www.eurometaux.eu/media/a0kfpm32/2023-05-17_joint-letter-to-the-envi-committee-on-substances-of-concern-under-the-espr.pdf (accessed 13.8.2024).

14 *ECOS et al.*, Joint letter on substances of concern in ESPR, 30.5.2023, available at https://eeb.org/library/joint-letter-on-substances-of-concern-in-espr (accessed 13.8.2024).

15 See also *European Financial Reporting Advisory Group (EFRAG)*, ESRS implementation Q&A platform – Compilation of explanations January–May 2024, Question ID 226 and 301 – Substances of (very high) concern and hazard classes, p. 74 (76), available at https://www.efrag.org/Assets/Download?assetUrl=/sites/webpublishing/SiteAssets/Explanations+January+-+May+2024+%28final+version%29.pdf (accessed 13.8.2024).

16 A software tool to track and analyse the impact of EU REACH and related substance lists on space materials.

Table 1: Substances of Concern (ESPR Art. 2(27))

Hazard-based SoCs	REACH-based SoCs	(a) substance of very high concern included in the REACH Candidate List
	CLP-based SoCs	(b) substance with one following classification in Part 3 of Annex VI to CLP:
		(i) carcinogenicity categories 1 and 2
		(ii) germ cell mutagenicity categories 1 and 2
		(iii) reproductive toxicity categories 1 and 2
		(iv) endocrine disruption for human health categories 1 and 2
		(v) endocrine disruption for the environment categories 1 and 2
		(vi) persistent, mobile and toxic or very persistent, very mobile properties
		(vii) persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties
		(viii) respiratory sensitisation category 1
		(ix) skin sensitisation category 1
		(x) hazardous to the aquatic environment – categories chronic 1 to 4
		(xi) hazardous to the ozone layer
		(xii) specific target organ toxicity – repeated exposure categories 1 and 2
		(xiii) specific target organ toxicity – single exposure categories 1 and 2
	POP-based SoCs	(c) substance regulated under Regulation (EU) 2019/1021 on POPs; or
Circularity-based SoCs		(d) substance that negatively affects the re-use and recycling of materials in the product in which it is present

Annex VI would currently fulfil the definition of ESPR Art. 2(27) lit. (b), comparing to "only" 241 entries in the current REACH Candidate List which correspond to just over 490 SCIP IDs.[17,18] It is evident that this may strongly amplify the possible impact from related regulation governing SoCs on industries and supply chains in EU and beyond.

The number of CLP-based SoCs is expected to grow much further in the future, not least because of the introduction of the new CLP hazard classes for endocrine disruption, persistent, mobile and toxic (PMT) or very persistent, very mobile (vPvM) substances, as well as persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) substances; corresponding to ESPR Art. 2(27), point (b)(iv)-(vii).[19] Further to this, harmonised classification and labelling (CLH) is being used and promoted as the main route to further regulation of substances for which a concern to human health or the environment has been identified; this work is still ongoing for the bulk of substances registered under REACH.[20]

3. Structure and Scope of the Article

This article will first look at the provisions addressing "substances of concern" in the new ESPR (Section II.). The subsequent Section III. will show how the denomination of SoC

17 See *Becker*, Priority actions on EU REACH and issues of concern for the European space sector, 5th ESA REACH workshop, 19.6.2024, p. 11, available at https://atpi.eventsair.com/esa-5th-reach-workshop (accessed 13.8.2024).

18 See above footnote 5 with further references.

19 Commission Delegated Regulation 2023/707 of 19.12.2022 amending CLP Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, available at http://data.europa.eu/eli/reg_del/2023/707/oj (accessed 13.8.2024).

20 See e.g. *ECHA*, Integrated Regulatory Strategy (IRS) workshop, 6.–7.3.2024, materials available at https://echa.europa.eu/-/irs-06/03/2024 (accessed 13.8.2024); more on the IRS can be found below in Section III.1.a.

is used in and pursuant to the REACH Regulation (III.1.), how it relates to the notion of "most harmful substances" (III.2.) and which important substance groups are not (fully) captured by the SoC definition (III.3.). Section IV. will look at the already applicable provisions for SoCs and SVHCs in the new European Sustainability Reporting Standards, also addressing taxonomy disclosures (IV.4.). Section V. will then discuss and compare the different definitions and related provisions governing SoCs in the laws for biocidal products (V.1.), batteries (V.2.) as well as the forthcoming regulations concerning packaging and packaging waste (V.3.) and vehicles (V.4.). The enhanced provisions on substances in the recent revision of Directive 2010/75/EU on industrial emissions will also be mentioned for completeness, even though they are not taking up the SoC concept (V.5.). Following the analysis of laws, Section VI. will shed light on some important practical approaches to tackle SoC management in the chemical (VI.1.) and downstream (VI.2.) industries. Section VII. will summarise the SoC provisions discussed and conclude the article with an outlook on the subject.

It should be noted that a number of contributions relating to this topic have already been made recently in StoffR, namely by the author providing an earlier overview of the original ESPR proposal of 30 March 2022,[21] *Galler* and *Wimmer* looking closely at possible regulatory discrepancies between ESPR and REACH[22] and *Öttinger* analysing substance restrictions in several pieces of EU product legislation and current EU proposals.[23] This article will not repeat but refer to and build on these contributions where appropriate.

Global harmonisation efforts with regard to the identification and management of 'chemicals of concern' are not further discussed in this article. However, they should be kept in mind as part of the bigger picture. Under the United Nations Environment Programme (UNEP), the 2023 Global Framework on Chemicals (GFC) addresses 'harmful substances in products and mixtures' (Target D4) and 'priority chemicals of concern' (Target D6).[24] 'Chemicals of concern' are also part of the on-going deliberations towards an international legally binding instrument on plastic pollution, including in the marine environment, which could be completed by the end of 2024 at the earliest;[25] a dedicated expert group has been formed.[26]

II. SoCs in ESPR Requirements

In line with the CSS (and the CEAP preceding it, see above Section I.), the ESPR addresses SoCs as defined in its Art. 2(27) foremost, but not exclusively, through possible tracking and information requirements. ESPR performance requirements (incl. restrictions) may address the use of SoCs as defined in its Art. 2(27), but may well concern also other substances.[27] The requirements are summarised and discussed in this Section, based on the final ESPR text and the understanding of the European Commission as shared in its online information session of 22.5.2024, which elaborated on this *"twofold approach with different scope and different boundaries"* for SoCs in the ESPR legal text (tracking and restrictions).[28]

1. Information Requirements and Display

According to COM[29] *"by default, all SoCs are tracked"*, however delegated acts will *"define thresholds and exemptions where relevant"*. The stated aim is to enable the information flow in business-to-business relationships and to consumers and to waste treatment operators (recyclers, preparation for reuse, etc.) to improve management of SoCs including via the digital product passport (DPP) and other systems such as labels, tags, etc.

With a view to the ESPR final legal text, some notable observations should be made:

a. Scope of SoCs to Be Tracked

Firstly, the Commission statement that *"by default, all SoCs are tracked"*, is not reflected as such in the final legal text.[30] Recital (31) of ESPR only states that

21 *Becker*, Ecodesign for sustainable products and the EU digital product passport, StoffR 2022, p. 177–188, available at https://stoffr.lexxion.eu/article/STOFFR/2022/3/7 (accessed 13.8.2024).

22 *Galler/Wimmer*, The Chemicals Strategy for Sustainability, StoffR 2023, p. 154–169, available at https://stoffr.lexxion.eu/article/STOFFR/2023/3/3 (accessed 13.8.2024).

23 *Öttinger*, Stoffbeschränkungen in der EU-Batterieverordnung und weiteren aktuellen EU-Vorschlägen, StoffR 2024, p. 19–25, available at https://stoffr.lexxion.eu/article/STOFFR/2024/1/5 (accessed 13.8.2024).

24 *UNEP*, GFC main brochure, p. 20, 21, available at https://www.chemicalsframework.org/sites/default/files/documents/GFC_Main_Brochure__6_March_2024.pdf (accessed 13.8.2024).

25 *UNEP*, Zero draft text of the international legally binding instrument on plastic pollution, including in the marine environment, UNEP/PP/INC.3/4, 4.9.2023, available at https://wedocs.unep.org/bitstream/handle/20.500.11822/43239/ZERODRAFT.pdf (accessed 13.8.2024).

26 See *UNEP*, Ad hoc intersessional open-ended expert groups, Information on expert group 2, available at https://www.unep.org/inc-plastic-pollution/ioeeg (accessed 13.8.2024).

27 See already *Becker*, footnote 21, Section IV.2.

28 *European Commission*, Ecodesign for Sustainable Products Regulation (ESPR), Online information session, 22.5.2024, section on Substances of Concern (SoC), p. 34–40, slides available at https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-products/ecodesign-sustainable-products-regulation_en (accessed 13.8.2024).

29 See *European Commission*, footnote 28, p. 35.

30 Unlike still in Art. 7(5) of the Commission proposal of 30.3.2022 *"[…] shall enable the tracking of all substances of concern […]"*; see above footnote 12.

"[...] requirements concerning the tracking of substances of concern should be included by default where an information requirement is to be set under this Regulation, [...]".

This, in the present understanding, merely corresponds to the nature of SoC requirements set out in ESPR Art. 7(5) as minimum requirements when regulating information requirements for specific products, as set out in ESPR Art. 7(2)(a).

Such a far-reaching default assumption to track all SoCs also appears contrary to the need for the European Commission to carry out an impact assessment and take into consideration the protection of confidential business information (ESPR Art. 5(10), points (b) and (d)) as well as the "negative" criteria in ESPR Art. 5(11) to be met by ecodesign requirements, such as

"(f) there shall be no disproportionate administrative burden on manufacturers or other actors in the value chain, including SMEs, in particular microenterprises".

Nevertheless, it is undisputed that application thresholds, dates and exemptions to SoC reporting will have to be assessed by COM pursuant to ESPR Art. 7(5) and (6) when elaborating product-specific delegated acts. These provisions have been further detailed during the co-legislative procedure as compared to the Commission proposal. The only major limitation to exemptions remains for REACH Candidate List substances (case of ESPR Art. 2(27), point (a)), if they are present in products, their relevant components or spare parts in a concentration above 0.1% weight by weight (ESPR Art. 7(6), point (b)).

As a result, it appears more accurate to view the list of substances in Art. 2(27), points (a)–(d) as a "pool" from which relevant SoCs are selected based on the provisions in ESPR when preparing product-specific ecodesign measures.[31] The respective list of reportable SoCs may depend on the type and diversity of possible downstream applications and product integration phases, e.g. on whether it is a 'component', 'intermediate product' or 'consumer product' (see ESPR Art. 2(2), (3) and (36)). As an example, it will be a crucial element for industry to trace from upstream to downstream a specific SoC that will be relevant in a downstream product group A whereas not in another product group B, depending on its potential to damage circularity.

A notable clarification has been added by the co-legislators with regard to the criteria for a *"substance that negatively affects the re-use and recycling of materials in the product in which it is present"* (case of ESPR Art. 2(27), point (d)) to be considered as a circularity-based SoC. According to ESPR Art. 5(14),

"For each product group concerned by ecodesign requirements, the Commission shall determine, where relevant, which substances fall under the definition in Article 2(27), point (d), taking into account, at least, whether:
(a) based on standard technologies, the substances make the reuse, or recycling process more complicated, costly, environmentally impactful, or energy- or resource-demanding;
(b) the substances impair the technical properties or functionalities, the usefulness or the value of the recycled material coming from the product or products manufactured from that recycled material;
(c) the substances negatively impact aesthetic or olfactory properties of the recycled material."

Against this background, the Commission has emphasised that SoCs in the sense of Art. 2(27) point (d) will be defined in product-specific delegated acts adopted under ESPR. For example, the ban on halogenated flame retardants under Regulation 2019/2021 on ecodesign requirements for electronic displays was given.[32]

A question in this context (see point (a) of ESPR Art. 5(14) above) is how to reflect the dynamic evolution of recycling technologies. This is relevant in particular for products with a long lifetime. A substance may thus be considered as a circularity-based SoC at a given point of time, but no longer in the future. From an industry perspective it was suggested to link the SoC definition to an *"evaluation on an ongoing basis of the state-of the art recycling techniques and waste collection systems"*.[33] However, this wording was not added to the final definition text. It remains to be seen whether this dynamic element will actually lead to issues, as delegated acts may also be updated subsequently. Undesired consequences could occur if a restriction of a circularity-based SoC as part of ESPR performance requirements created a *fait accompli*. If the circularity-based SoC is defined to trigger information requirements only, it is still allowed to use it.

b. Minimum Information Elements for Reportable SoCs

The already detailed list of minimum information elements for reportable SoCs in ESPR Art. 7(5), point (a)–(e) in the Commission's ESPR proposal[34] has been further expanded by the co-legislators in point (a) with respect to the SoC identification (name or numerical code, including the EC or CAS number) and in point (e) by adding to the information rel-

31 So rightfully *Cefic*, Substances of Concern (SoCs) in the context of products circularity, April 2023, available at https://cefic.org/app/uploads/2023/04/Cefic-position-on-Substance-of-Concerns-definition-in-the-context-of-products-circularity.pdf (accessed 13.8.2024).

32 See *European Commission*, footnote 28, p. 40.

33 *Cefic et al.*, footnote 13, p. 3.

34 See already *Becker*, footnote 21, Section 3.a., pointing to the expansion of reportable information as compared to REACH Art. 33 and SCIP; *Galler/Wimmer*, footnote 22, Section 4.b.

Table 2: Minimum information elements for reportable SoCs (ESPR Art. 7(5))

(a) the name or numerical code of the substances of concern present in the product, as follows: (i) name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature, or another international name when IUPAC name is not available; (ii) other names, including usual name, trade name, abbreviation; (iii) European Community (EC) number, as indicated in the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) or the No Longer Polymer (NLP) list or the number assigned by the European Chemicals Agency (ECHA), if available and appropriate; (iv) the Chemical Abstract Service (CAS) name and number, if available	(b) the location of the substances of concern within the product
	(c) the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts
	(d) relevant instructions for the safe use of the product
	(e) information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at end-of-life

evant for disassembly also information relevant for the preparation for reuse, reuse, recycling and the environmentally sound management of the product at end of life (see Table 2).

From an industry point of view, the explicit addition of numerical identifiers (including CAS number if available) in the list of minimum reportable information should be welcome. The information on the SoC location (point (b)) is considered as a critical element in the reporting for complex product manufacturers as it may require a detailed disclosure of the bill of materials (BOM) structure. During the implementation, care should be taken that the reportable information in delegated acts will be limited to information available to the economic operator, in order to not create impossible duties.[35]

2. Performance Requirements (Restrictions)

According to the European Commission[36] performance requirements under ESPR may take the form of restrictions for sustainability reasons, focusing on impact on product aspects in Art. 5(1), such as durability, resource use, presence of substances of concern, possibility of recycling, possibility of remanufacturing or environmental footprint. However, ESPR should not provide for the restriction of substances based primarily on chemical safety, as done under other Union legislation (foremost REACH). Union legislation on chemicals already provides for the restrictions of substances or mixtures related to safety or risk, where needed.[37]

Hence, when it comes to ESPR-based substance restrictions, there is less emphasis on "substances of concern", even though the presence of SoC is among the 16 product aspects that can be addressed as part of ecodesign requirements (ESPR Art. 5(1), point (g)). Furthermore, the use of SoCs is now explicitly mentioned as a particular case in Annex I, point (f), which allows

> *"use of substances, and in particular the use of substances of concern, on their own, as constituents of substances or in mixtures, during the production process of products, or leading to their presence in products, including once those products become waste, and their impacts on human health and the environment; [...]"*

to be regulated (restricted).

In relation to restrictions taking the form of *concentration limits* for substances as referred to in Annex I, point (f) the requirements in Annex II to ESPR should also be noted. For example, any such concentration limit shall be based on a thorough analysis of the sustainability of the substances and their identified alternatives, and they shall also consider aspects of enforceability, such as analytical detection limits.

Furthermore, the co-legislators have added an informative recital (27) to ESPR which provides with regard to ESPR-based restrictions:

> *"The Commission, when setting performance requirements, should be able to introduce requirements to prevent certain substances from being included in a product. The identification of such substances should be part of the Commission's assessment prior to the setting of ecodesign*

35 Inspiration could be taken from the concept of *"known or reasonably ascertainable information"* which is applied under the U.S. Environmental Protection Agency rule under the Toxic Substances Control Act (TSCA) Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping (accessed 13.8.2024).

36 See *European Commission*, footnote 28, p. 35.

37 See ESPR recital (26) and Art. 6(3), to which the following sentence was added in the final text: *"However, the setting of performance requirements shall also, where appropriate, reduce significant risks to human health or the environment."* *Galler/Wimmer*, footnote 22, Section 4.b. conclude rightfully that it is to be expected that the distinction from restrictions for safety reasons will not be easy to be managed in practice.

requirements for a specific product group and the Commission should in that assessment, for instance, take into account whether a substance makes the reuse or recycling of a product more complicated or negatively affects the properties of the recycled material, for example through its colour or smell. Where a substance has already been established as being a substance that hinders circularity for one product group, this can be an indication that it also hinders circularity for other product groups. The identification and possible restriction of a substance should also trigger an information requirement."

This wording reminding of ESPR Art. 5(14) (see above Section II.1.a.) suggests a close link between the determination of circularity-based SoCs in the sense of ESPR Art. 2(27), point (d) and those substances as possible candidates for ESPR-based restrictions. Limiting restrictions under ESPR to circularity-based SoCs could help achieve a clear interface between ESPR and chemical safety-based restrictions.[38]

III. Limitations of SoCs and Related Concepts

It is important to not confuse the SoC definition according to the CSS and ESPR with other uses of the term, e.g. by the European Chemicals Agency (ECHA) (see Section III.1. below) or related terms like "most harmful substances" (see Section III.2. below). Finally, there are some important limitations in the SoC definition according to the CSS and ESPR, like in the case of per- and polyfluoroalkyl substances (PFAS) (see Section III.3. below).

1. Denominations Pursuant to REACH

Under REACH[39] the broader notion of "substances of concern" has no significant legal implications. The only occurrence of the term *"(known) substances of concern"* in the legal text is in the context of criteria for substance evaluation (REACH Art. 44(1)(a)), where it has a hazard-based scope. But the term itself is not further defined. Some other uses of the term "substance of concern" and the related notion of "SVHC" pursuant to REACH are discussed briefly hereafter.

a. ECHA Integrated Regulatory Strategy

More importantly, ECHA refers to "(addressing) substances of concern" in the context of its Integrated Regulatory Strategy (IRS).[40] The IRS has been implemented since 2016 in continuation of the SVHC Roadmap. It brings together the various regulatory processes (mainly under REACH and CLP) in order to efficiently select substances or groups of substances that raise potential concern and may warrant further regulatory risk management. Hence, in the frame of this strategy the term SoC is covering a wider pool of (mainly) substances registered or notified with ECHA than the list-based SoC definition in ESPR. Recent communications by ECHA[41] show no or only little reference to the term "substance of concern" in the context of the IRS. This is welcome as it avoids confusion with other laws and policies where the term is employed.

b. Substances of Very High Concern

The REACH Regulation has coined the more narrow term of "Substances of Very High Concern", introducing the Candidate List as the key tool to identify them for possible subsequent inclusion in the authorisation list. Candidate listing also triggers certain information obligations covering articles containing listed SVHCs above certain thresholds (see REACH Art. 7(2) and 33).

An extension of the SVHC concept in REACH to encompass all SoCs as defined in ESPR is not planned nor is it expected to be manageable. Under the CSS[42] the Commission rather announced a limited modification of the SVHC definition (REACH Art. 57) by adding endocrine disruptors, persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances to the list of SVHCs, as well as addressing "most harmful chemicals" or "most harmful substances" (see below Section III.2.). These would be part of the planned targeted revision of the REACH Regulation, which is currently on hold.

c. SCIP Database

The SVHC REACH Candidate List is also the key reference for the requirements introduced under Art. 9(1), point (i) and Art. 9(2) of the EU Waste Framework Directive (WFD), as revised by Directive (EU) 2018/851.[43] In this regard, prominent use of the term "substances of concern" has been made for the ECHA-coined acronym *"SCIP"*, meaning *"Substances of Concern In articles as such or in complex objects (Products)"*.[44] However, "substances of concern" were not mentioned in Directive (EU) 2018/851, and only the smaller subset of SVHCs included in the REACH Candidate List is covered by the legal reporting scope. An extension to other

38 So already *Galler/Wimmer*, footnote 22, Section 4.b.

39 See footnote 6.

40 See *ECHA*, Addressing substances of concern, available at https://echa.europa.eu/substances-of-potential-concern (accessed 13.8.2024).

41 E.g. *ECHA*, footnote 20.

42 See *European Commission*, footnote 3.

43 Directive (EU) 2018/851 of the European Parliament and of the Council of 30.5.2018 amending Directive 2008/98/EC on waste, available at http://data.europa.eu/eli/dir/2018/851/oj (accessed 13.8.2024).

44 See *ECHA*, SCIP, available at https://echa.europa.eu/scip (accessed 13.8.2024).

SoC subsets as defined in ESPR Art. 2(27) is not expected nor considered meaningful.

2. Most Harmful Substances

The ambition of the CSS is not limited to addressing SoCs. Instead, it sets out a new hierarchy for the EU chemicals policy to respond more rapidly and effectively to the challenges posed by hazardous chemicals:

> *"This includes ensuring that all chemicals are used more safely and sustainably, promoting that chemicals having a chronic effect for human health and the environment – substances of concern – are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products."*[45]

Two different instruments under the CSS to work towards this phase-out of most harmful substances (hereafter also "MHS") are the Commission's 'safe and sustainable by design' ("SSbD") framework (below under a.) and the Essential Use Concept (below under b.).

a. SSbD Framework

As part of the implementation of the CSS, the scope of MHS has already been described in the Commission's Recommendation of 8.12.2022 for a SSbD framework, which is a voluntary approach to guide the innovation process for chemicals and materials.[46] In the SSbD framework MHS are described as including SVHCs identified in the REACH Candidate List (so-called "Group A" substances), while (other) "substances of concern" as described in the CSS and defined in the Commission's ESPR proposal are referred to as "Group B" substances. Both groups have a different assessment level for the initial hazard assessment step according to the SSbD framework, with certain "red flags" that the innovator should consider for MHS.[47]

Despite being described as a voluntary approach, the SSbD framework starts being introduced in EU law. As an example, the new Regulation on Construction Products as adopted by the European Parliament on 10.4.2024[48] foresees that product environmental requirements to be introduced by delegated acts may specify *"the selection of safe, sustainable-by-design, and environmentally benign substances"*.[49] This could be used in the future to exclude some SoC substances, in particular MHS, in line with the SSbD framework, also given that recital (52) calls for the avoidance of "substances of concern" when possible.

b. Essential Use Concept

Building on the SSbD framework, the Commission has recently[50] defined the term of "most harmful substances" (see Info Box 1) to mark out the scope of the Essential Use Concept, whereby a use of a most harmful substance is essential for society (only) if that use is necessary for health or safety or is critical for the functioning of society and there are no acceptable alternatives.

Info Box 1: "Most harmful substances" for essential use

A most harmful substance has one or more of the following hazard properties:
– Carcinogenicity Cat. 1A and 1B
– Germ cell mutagenicity Cat. 1A and 1B
– Reproductive/developmental toxicity Cat. 1A and 1B
– Endocrine disruption Cat. 1 (human health)
– Endocrine disruption Cat. 1 (environment)
– Respiratory sensitisation Cat. 1
– Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity
– Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB)
– Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)
– Hazardous to the ozone layer Cat. 1

It is not clear at this point whether the Commission intends to expand the scope of MHS beyond the well-known concept of SVHC, the Candidate List under REACH and harmonised classifications according to CLP Annex VI. In the present opinion and in line with the SSbD Recommendation, "most harmful substances" should be understood consistently with the SVHC criteria and as a subset of the SoC definition in the CSS and ESPR, linking to the established lists under REACH (Candidate List) and CLP (Annex VI). Opening the scope to include hazard properties not captured by the

45 See *European Commission*, footnote 3, Chapter 1.

46 See *European Commission*, Annex to the Commission Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials, C(2022) 8854 final of 8.12.2022, available at https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/recommendation-safe-and-sustainable-chemicals-published-2022-12-08_en (accessed 13.8.2024).

47 See *Abbate et al.*, Safe and Sustainable by Design chemicals and materials – Methodological Guidance, 2024, Section 4.2.2 and 4.5, available at https://publications.jrc.ec.europa.eu/repository/handle/JRC138035 (accessed 13.8.2024); "most harmful substances" are referred to as "H1" substances here.

48 See *European Parliament*, Position adopted at first reading, T9-0188/2024, available at https://www.europarl.europa.eu/doceo/document/TA-9-2024-0188_EN.html (accessed 13.8.2024).

49 See *European Parliament*, footnote 48, Annex III Product requirements, 3. Inherent product environmental requirements, 3.1., point (d).

50 Communication from the Commission – Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals, C/2024/2894 of 26.4.2024, Section 2.2, available at https://op.europa.eu/en/publication-detail/-/publication/90926c62-0365-11ef-a251-01aa75ed71a1/language-en/format-PDF/source-319809317 (accessed 13.8.2024).

SVHC criteria and to other substances than those with a harmonized classification under CLP Annex VI[51] would cause ever more confusion due to different substance concepts as well as undermine legal certainty and predictability for industry. The latter can be ensured by a clear reference to the aforementioned lists, with CLP Annex VI clarifying hazardous properties of certain substances and the REACH Candidate List as a tool to identify SVHCs for possible further regulatory action.[52]

3. Substances Not Captured as SoCs

The hazard-based sub-groups in the final SoC definition in ESPR Art. 2(27) points (a)–(c) are linked to confined lists of substances in REACH, CLP and POP Regulations. This is welcome in the interest of legal certainty and predictability. The European Parliament did not prevail with its initial position adopted on 12.7.2023 to include all substances meeting SVHC criteria in REACH Art. 57 (regardless of Candidate List inclusion) as well as *"specific restricted substances listed in Annex XVII of [REACH]"*.[53] These proposed extensions would have blurred the boundaries of the SoC definition and caused additional challenges when determining the SoC lists for specific product groups.

But even a wider SoC definition could not have captured all substances addressed by chemical-safety based restrictions. Important examples are the new "microplastics" restriction[54] and the broad restriction proposal for per- and polyfluoroalkyl substances (PFAS).[55] The latter encompasses more than 10,000 chemical substances which have a wide range of uses. The overriding concern used to justify bundling all of them in a single restriction proposal is "persistence", which is as such not a hazard class under CLP as of today. Only some individual PFAS substances or subgroups are included in the REACH Candidate List, have a relevant harmonised classification in CLP Annex VI or are regulated under the POPs Regulation.[56] This means that in an important case such as PFAS the tracking intention of the SoC concept will largely fail to apply, contrary to corresponding considerations of the European Commission at the time of the CSS.[57]

Figure 1 provides a simplified summary illustration of scope and limitations of SoCs as defined in ESPR, while placing them in relation to REACH SVHC-related lists, the concepts of "SVHC" and "most harmful substance".[58] It should be noted that outside the Candidate List "SVHCs" and "most harmful substances" are (hazard-based) SoCs only insofar as they have the corresponding harmonised classification in CLP Annex VI (ESPR Art. 2(27) point (b)); as such, these terms have no role in the ESPR SoC definition. The illustration also shows that restricted substances are only partially covered in the SoC concept, as far as they are on the relevant REACH (Candidate List), CLP (Annex VI) and/or POP Regulations lists.

IV. SoCs in European Sustainability Reporting Standards

"Substances of concern", together with "substances of very high concern", also feature extensively in the first set of European Sustainability Reporting Standards (ESRS) adopted by the European Commission, which started to apply from 1.1.2024.[59] The ESRS specify the sustainability information that an undertaking shall disclose as part of a dedicated statement in accordance with Directive 2013/34/EU (Accounting Directive), as amended by Directive (EU) 2022/2464 (Corporate Sustainability Due Diligence Directive - CSRD).[60]

These reporting requirements will be phased in over time for different types of undertakings. The first entities will

51 As e.g. advocated by *ClientEarth*, Commission Communication on Essential Use, Briefing (Vol 1.1), July 2024, p. 6 under footnote 5, available at https://www.clientearth.org/media/sb5kiel5/clientearth_essential-use_briefing_2024-07-04.pdf (accessed 13.8.2024).

52 Currently the Candidate List includes SVHCs for possible authorisation under REACH, but in practice a number of entries have been addressed subsequently under other regulatory processes, especially REACH restriction, POP and EU workplace legislation. It is expected that this new role of the Candidate List would be formally clarified in an upcoming REACH Regulation revision.

53 *European Parliament*, Amendments adopted on 12.7.2023 on the ESPR proposal, Amendment 59 and 61, available at https://www.europarl.europa.eu/doceo/document/TA-9-2023-0272_EN.html (accessed 13.8.2024).

54 Commission Regulation (EU) 2023/2055 of 25.9.2023 amending Annex XVII to REACH, available at http://data.europa.eu/eli/reg/2023/2055/oj (accessed 13.8.2024).

55 *BAuA et al.*, Annex XV Restriction Report of 22.3.2023, available at https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49 (accessed 13.8.2024).

56 See overview at *ECHA*, How are PFAS regulated in the EU?, available at https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas (accessed 13.8.2024).

57 See *European Commission*, Commission staff working document – Poly- and perfluoroalkyl substances (PFAS), SWD(2020) 249 final, p. 14. Section 7 regarding the use of the sustainable products initiative, available at https://op.europa.eu/en/publication-detail/-/publication/2614f1f2-0f02-11eb-bc07-01aa75ed71a1/language-en (accessed 13.8.2024).

58 As discussed above under Section III.2.b., MHS should *de lege ferenda* be aligned with the definition of SVHC via identification on the Candidate List, according to the present opinion.

59 1st ESRS delegated act: Commission Delegated Regulation (EU) 2023/2772 of 31.7.2023 supplementing Directive 2013/34/EU of the European Parliament and of the Council as regards sustainability reporting standards, available at http://data.europa.eu/eli/reg_del/2023/2772/oj (accessed 13.8.2024).

60 Directive 2013/34/EU, consolidated version of 28.5.2024, available at http://data.europa.eu/eli/dir/2013/34/2024-05-28 (accessed 13.8.2024).

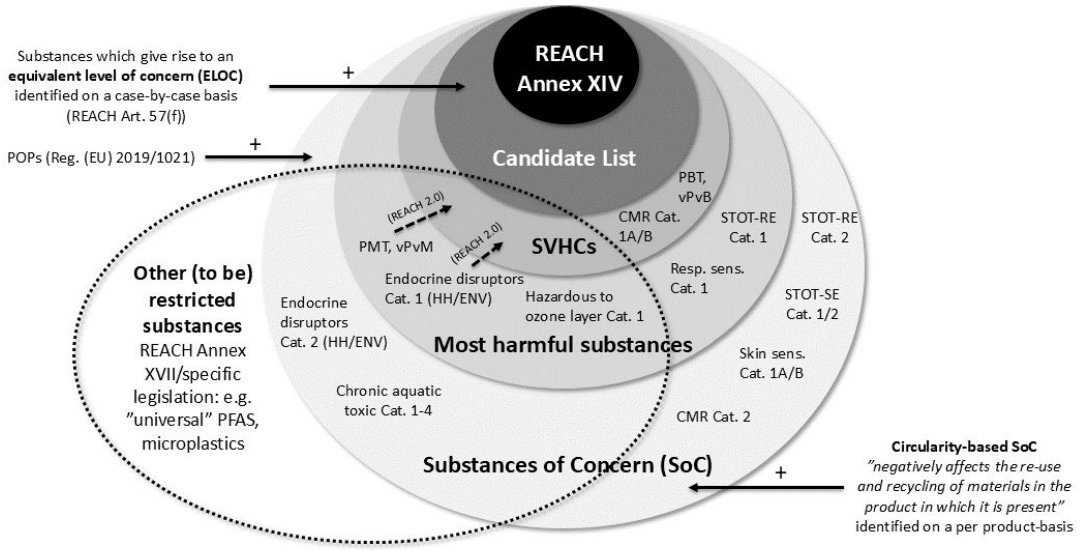

Figure 1: Scope and limitations of SoCs (based on ESPR)

have to apply the new rules for the first time in the 2024 financial year, for reports published in 2025. The second group of companies will follow in 2025, for 2026 reporting.[61]

1. SoC Definition in ESRS

"Substances of Concern" are defined in Annex II: Acronyms and Glossary of Terms of the ESRS. The definition is in line with the Commission proposal for ESPR of 30.3.2022,[62] hence the POP substances regulated under Regulation (EU) 2019/1021 (case of ESPR Art. 2(27), point (c)) are still missing. Therefore, the ESRS definition of SoCs includes all SVHCs in the REACH Candidate List (point i.), substances classified in CLP Annex VI in one of 13 listed hazard classes or hazard categories (point ii.) and each substance which

> *"negatively affects the re-use and recycling of materials in the product in which it is present, as defined in relevant Union product-specific ecodesign requirements" (point iii.).*

"Substances of Very High Concern" (SVHCs) are separately defined in Annex II of the ESRS with reference to the REACH Regulation as substances included in the REACH Candidate List. Thus, they are at the same time a sub-group of SoCs (see point i. above).

With regard to point iii. (circularity-based SoCs), there are currently no Union product-specific ecodesign requirements available; hence, there are no published lists for these substances.[63] For the case of ESPR, based on its Art. 5(14), "*the Commission shall determine, where relevant, which substances fall under the definition in Article 2(27), point (d)"* for each product group concerned by ecodesign requirements. Hence, SoCs negatively affecting the re-use and recycling will be defined in product-specific delegated acts adopted under ESPR only as part of the forthcoming implementation of the Regulation.[64]

However, even in the absence of such a list or defined cases with regard to point iii. the possible need for additional entity-specific disclosures based on ESRS 1 *General requirements* paragraph 11 has been highlighted.[65] Additionally, undertakings subject to ESRS reporting are advised to investigate and monitor relevant developments with regard to such product-specific requirements, in order to anticipate which substances might fall under the SoCs category according to point iii. of the ESRS definition, e.g. by following the

61 See *European Commission*, Frequently asked questions on the implementation of the EU corporate sustainability reporting rules, 7.8.2024, Timeline on p. 13, available at https://finance.ec.europa.eu/publications/frequently-asked-questions-implementation-eu-corporate-sustainability-reporting-rules_en (accessed 13.8.2024).

62 *European Commission*, footnote 12.

63 See *EFRAG*, footnote 15, p. 76.

64 See already above Section II.1.a. with example of flame retardants under Commission Regulation (EU) 2019/2021.

65 See *EFRAG*, footnote 15, p. 76,77.

ESPR preparatory work by the European Product Bureau for specific product groups.[66,67]

2. Disclosure Requirements for SoCs in ESRS E2

SoCs and SVHCs are explicitly listed among the "sustainability matters" ("sub-topic") part of the topical environmental Standard ESRS E2 *Pollution*.[68] When, as a result of the undertaking's impact and financial materiality assessment,[69,70] a given sustainability matter is assessed to be "material", the undertaking shall report material information according to the corresponding disclosure requirements of the relevant topical ESRS.[71]

Disclosure requirements on SoCs aim at providing users with an understanding of actual or potential impacts related to such substances, also taking account of possible restrictions on their use and/or distribution and commercialisation.[72] There are four disclosure requirements in Standard ESRS E2 that address SoCs and SVHCs; they are summarised in Table 3. They are proposed to be broken down into a number of narrative and quantitative datapoints in the EFRAG implementation guidance of 31.5.2024.[73]

As a general observation, it can be seen from these requirements, that information regarding SVHCs should be addressed or presented separately (so explicitly paragraph 35 in Disclosure Requirement E2-5). This is also apparent from Disclosure Requirement E2-1 (paragraph 15(b)), whose purpose is to indicate whether and how the undertaking's policy aligns with the public policy objectives of phasing out SVHCs as outlined in REACH and in line with the ambitions of the CSS.[74] However, it is important to note that this does not imply a general legal obligation to phase out SVHCs on the REACH Candidate List[75] or to minimise SoCs. ESRS set disclosure requirements, not behavioural requirements.[76]

The most detailed provisions under ESRS E2 *Pollution* regarding SoCs and SVHCs are contained in *Disclosure requirement E2-5 – Substances of concern and substances of very high concern*; paragraph 32-35 and Appendix A, AR 28-30. They are summarised in Table 4. The stated objective of this Disclosure Requirement is

> *"to enable an understanding of the impact of the undertaking on health and the environment through substances of concern and through substances of very high concern on their own.[77] It is also to enable an understanding of the undertaking's material risks and opportunities, including exposure to those substances and risks arising from changes in regulations" (paragraph 33).*

These provisions as well as the breakdown in EFRAG IG 3 show that the scope and granularity of information to be reported – if assessed to be material – is very extensive as regards activities, affected objects (the substances on their own, in mixtures or in articles) and the total amounts (especially volume of pollutants) to be reported. As an example, for substances in articles or assemblies thereof (complex objects), there is currently no EU legal requirement for the EU supplier to report substance amounts to the recipient, even in the case of SVHCs. REACH Art. 33 only requires reporting of the name of the SVHC present above 0.1% weight by weight (w/w) in articles supplied (as a minimum) down the supply chain, and even for this minimum obligation high non-compliance rates have been found recently.[78] Also the new ESPR only foresees the reporting on SoC concentrations for products to be regulated in the future (see above Table 2). Hence, information on total substance amounts is typically not available in the case of articles. AR 30 ("Contextual information") may offer some relief for undertakings, if they can use the clause to refer to their reporting on substances in articles under REACH Art. 33 and SCIP (see above Section III.1.c.).

Given these detailed disclosure requirements on SoCs, including SVHCs, the materiality assessment for ESRS E2 *Pollution* as a trigger for the corresponding gains specific importance (see following Section IV.3.).

It should be noted that – beyond ESRS E2 – SoCs or other harmful substances may also trigger disclosure requirements pertaining to other sustainability matters. For example, if an undertaking concludes that health and safety of its own workforce (ESRS S1) is material due to the employees' exposure to harmful chemical substances, it shall provide the required information.[79]

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66 *European Commission*, Product groups, available at https://susproc.jrc.ec.europa.eu/product-bureau/product-groups (accessed 13.8.2024).

67 According to *EFRAG*, footnote 15, p. 76, *"existing standard product specification from CEN/CENELEC, academic literature or other sources could provide valuable guidance to assess the risks of use of certain substances in products that may potentially fall within criterion 3; […]"*.

68 See ESRS, footnote 59, ESRS 1 *General requirements*, Appendix A, AR 16.

69 Regarding the materiality assessment, see ESRS, footnote 59, in general ESRS 1 *General requirements* Chapter 3 *Double materiality as the basis for sustainability disclosures* and Appendix E *Flowchart for determining disclosures under ESRS*; specifically for ESRS E2 *Pollution* see its Appendix A, AR 1-9.

70 See also *EFRAG*, Implementation Guidance 1 (IG 1) – Materiality Assessment, available at https://www.efrag.org/sites/default/files/sites/webpublishing/SiteAssets/IG%201%20Materiality%20Assessment_final.pdf (accessed 30.8.2024).

71 See ESRS, footnote 59, ESRS 1 *General requirements*, Appendix A, AR 16.

72 See ESRS, footnote 59, ESRS E2 *Pollution*, paragraph 6.

73 *EFRAG*, Implementation Guidance 3 (IG 3) – List of ESRS Data Points, tab 'ESRS E2', rows 8, 22, 51-63, 65; available at https://efrag.sharefile.com/share/view/s6e410fb208aa4685bf9c482ee405f48d/foa75419-44c9-4081-85a5-43217a6e8732 (accessed 28.8.2024).

74 See *EFRAG*, footnote 15, p. 67 (68).

75 For Candidate List substances, such a phase-out obligation as a principle could be derived in case of the substance's subsequent inclusion in the REACH authorisation list, in accordance with REACH Art. 55 and

Table 3: Overview of disclosure requirements for SoCs in ESRS E2

Disclosure Requirement in ESRS E2	**Reference to SoCs/SVHCs and summary of disclosure**
Disclosure Requirement E2-1 – Policies related to pollution	Paragraph 15(b): Indicate, with regard to its own operations and its upstream and downstream value chain, whether and how its policies address where material: substituting and minimising the use of SoCs, and phasing out SVHCs, in particular for non-essential societal use and in consumer products
Disclosure Requirement E2-3 – Targets related to pollution	Paragraph 23(d): Indicate whether and how the targets relate to the prevention and control of SoCs and SVHCs
Disclosure Requirement E2-5 – Substances of concern and substances of very high concern	Paragraph 32: Disclose information on the production, use, distribution, commercialisation and import/export of SoCs and SVHCs, on their own, in mixtures or in articles. Further details: Paragraph 33-35 and Appendix A, AR 28-30; Table 4 below
Disclosure Requirement E2-6 – Anticipated financial effects from material pollution-related risks and opportunities	Paragraph 40(a): Include the share of net revenue made with products and services that are or that contain SoCs, and the share of net revenue made with products and services that are or that contain SVHCs. Note: E2-6 is included in ESRS 1 Appendix C List of phased-in Disclosure Requirements

Table 4: Disclosure requirements for SoCs and SVHCs under ESRS E2-5

List of SoCs/SVHCs to be considered	**Information to report***
i. Substances procured	- E.g., embedded in ingredients, semi-finished/final product (AR 28) - Total amounts; volume of pollutants** in mass units, e.g. tonnes or kilogrammes (AR 29) - Split into main hazard classes of substances of concern (par. 34) - Present separately for SVHCs (par. 35) - Contextual information: May refer to information the undertaking is already required to report under other existing legislation (i.e., Directive 2010/75/EU, Regulation (EC) No 166/2006 "E-PRTR"***, etc.) (AR 30)
ii. Substances in the undertaking's own operations (generated or used during the production)	
iii. Substances that leave its facilities as emissions, as products, or as part of products or services	
*See also the detailed breakdown in EFRAG IG 3 – List of ESRS Data Points, tab 'ESRS E2', rows 51-63 (footnote 73). **Pollutant: *"A substance, [...] or other contaminant present in air, water or soil which may be harmful to human health and/or the environment, which may result in damage to material property, or which may impair or interfere with amenities and other legitimate uses of the environment"* (ESRS Annex II, Table 2 Terms defined). ***See also below Section V.5.	

3. Materiality Assessment and Limits

The undertaking can omit all disclosure requirements in a topical standard if it is assessed that the topic in question is not material.[80] However, this judgment may often not be possible to make with certainty.

It should also be noted that the extent of the materiality assessment with regard to SoCs is itself significant, as evidenced by Appendix A to ESRS E2: It requires the undertaking to assess the materiality of pollution not only in its own operations but also *"its upstream and downstream value chain"* (AR 1). The further provisions in the Appendix re-

56. It is also interesting to note in this context that paragraph 15(b) relates the phase-out ambition for SVHCs to the Essential Use Concept; this supports the call for a consistent understanding of SVHCs with "most harmful substances", which the CSS and related initiatives are using to circumscribe the scope of the Essential Use Concept (see above Section III.2.b.).

76 See ESRS, footnote 59, ESRS 1 *General requirements*, Appendix E, preface.

77 The reference to substances of very high concern *"on their own"* could be misunderstood to limit the disclosure scope, thus excluding SVHCs in mixtures and in articles. However, as per the previous paragraph 32 the disclosure concerns both SoCs and SVHCs, *"on their own, in mixtures or in articles"*. Therefore, in the present opinion, this reference is rather to paragraph 35, whereby the information for SVHCs shall be presented separately.

78 See *ECHA*, Forum pilot project substances in articles project report, November 2019, p. 5, 20, available at https://echa.europa.eu/documents/10162/17088/sia_pilot_project_report_en.pdf (accessed 13.8.2024).

79 See *EFRAG*, footnote 70, p. 16, Figure 2 and paragraph 47.

80 See already footnote 69 and 70 above.

garding the use of the four-phase "LEAP approach"[81] to the materiality assessment on environmental subtopics, which is voluntary (*"may consider"*), include additional references to SoCs and SVHCs with regard to the location of relevant sectors or business units (AR 5, point (c)) and the identification of transition risks and opportunities (AR 7, point (a) ii. technology: e.g. substitution of products or services by products or services with a lower impact, transition away from substances of concern).

Given the complexities of multi-layer global supply chains, such wide-scope materiality assessment, as well as the related disclosure, will typically find its limits in what is practically, economically and legally possible. In the latter regard it should also be noted that, even if "material", the undertaking is not required to disclose "classified information" or "sensitive information", as defined in the ESRS.[82]

Furthermore, paragraphs 63 et seqq. of ESRS 1 contain provisions and limitations with regard to the collection of value chain information, the concept of "reasonable effort" and the use of estimates (see paragraph 69 of ESRS 1). The European Commission has clarified recently that such "reasonable effort" should take into consideration the specific facts and circumstances of the undertaking as well as the conditions of the external environment in which it operates, and it has provided a number of criteria to this end (e.g. size and resources, value chain complexity, technical readiness, level of influence).[83]

The development of sector-specific standards[84] could potentially provide further clarity and legal certainty about "material" sustainability matters within certain sectors, e.g. depending on the type of product(s), the undertaking's location in the value chain and customers (consumer or professional).

On the other hand, as clarified early on in the standards, reporting in accordance with the ESRS does not exempt undertakings from other obligations laid down in Union law.[85] Hence, in the present context reporting of Candidate List SVHCs under REACH Art. 33 or SCIP, or reporting of SoCs as part of future ESPR information requirements (see Section II.1.) would not be affected.

4. Taxonomy Disclosures

Pursuant to Art. 8 of Regulation (EU) 2020/852 (Taxonomy Regulation)[86] and the ESRS[87], certain undertakings subject to sustainability reporting shall include in their sustainability statement information on how and to what extent the undertaking's activities are associated with economic activities that qualify as environmentally sustainable under the Taxonomy Regulation, as specified further in Commission Delegated Regulations. The Taxonomy Regulation was adopted on 18.6.2020 and hence before the CSS. Consequently, it does not yet use the notion of "substances of concern". Instead it sets out in its Art. 13(1) that an economic activity shall qualify as contributing substantially to the transition to a circular economy, where that activity

> *"[...]*
> *(d) substantially reduces the content of hazardous substances and substitutes substances of very high concern in materials and products throughout their life cycle, in line with the objectives set out in Union law, including by replacing such substances with safer alternatives and ensuring traceability;*
> *[...]."*

Hence, a broader hazard-based approach is taken in the Taxonomy Regulation, not yet including the concept of circularity-based SoCs from CSS and ESPR. However, the corresponding Environmental Delegated Act of 27.6.2023[88] three years later refers to the CSS ambition *"to substitute or minimise the production and use of substances of concern, as far as possible"* (recital (20)) and *"information on and traceability of substances of concern throughout the lifecycle of the manufactured products"* as part of technical screening criteria to establish that the activity does not significantly harm the transition to a circular economy.[89]

Furthermore, technical screening criteria for the manufacture of plastic packaging goods foresee that substances presenting certain hazardous properties are not added to the feedstock.[90] These 15 hazardous properties roughly[91]

81 LEAP stands for: *L*ocate where the interface with nature takes place (Phase 1); *E*valuate the pollution-related dependencies and impacts (Phase 2); *A*ssess the material risks and opportunities (Phase 3); and *P*repare and report the results of the materiality assessment (Phase 4).

82 See ESRS, footnote 59, ESRS 1 *General requirements*, paragraph 105. and definitions of "classified information" (referring to Council Decision 2013/488/EU) and "sensitive information" (as defined in Regulation (EU) 2021/697) in Annex II of the ESRS.

83 See *European Commission*, footnote 61, FAQ 29, p. 28 et seqq.

84 See ESRS, footnote 59, ESRS 1 *General requirements*, paragraph 10.

85 See ESRS, footnote 59, ESRS 1 *General requirements*, paragraph 1.

86 Regulation (EU) 2020/852 of the European Parliament and of the Council of 18.6.2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088, available at http://data.europa.eu/eli/reg/2020/852/oj (accessed 13.8.2024).

87 See ESRS, footnote 59, ESRS 1 *General requirements*, paragraph 113.

88 Environmental Delegated Act: Commission Delegated Regulation (EU) 2023/2486 of 27.6.2023, available at http://data.europa.eu/eli/reg_del/2023/2486/oj (accessed 13.8.2024).

89 See Environmental Delegated Act, footnote 88, Annex I (Water), Section 1.1., Table 'Technical screening criteria', under Do no significant harm ('DNSH'), point (4) Transition to a circular economy, (d).

90 See Environmental Delegated Act, footnote 88, Annex II (Circular Economy), Section 1.1. Manufacture of plastic packaging goods, para. 3 points (a)-(o).

91 Differences: Endocrine disruption Cat. 2 is not mentioned in point (e), exception for enzymes in point (j) respiratory sensitiser Cat. 1.

correspond to the criteria in ESPR Art. 2(27) points (a) and (b). The *Cefic* call for an alignment with ESPR (now Art. 2(27), point (d)) in that these substances should also impede recyclability and reuse[92] was not taken up. With regard to the CLP classifications listed it should also be noted that there is no link to CLP Annex VI, hence harmonised classification is not required.

The 2023 Environmental Delegated Act retains the broad hazard-based approach as a key part of the assessment.[93] This can also be seen from the *"Generic Criteria for DNSH*[94] *to pollution prevention and control regarding use and presence of chemicals"* which go beyond a number of well-known restrictions (e.g. POP Regulation, REACH Annex XVII) to also cover substances on their own, in mixtures or in articles above 0.1% w/w which fulfil SVHC criteria in REACH Art. 57 in association with the CLP hazard classes or hazard categories mentioned therein, even if not included in the REACH Candidate List.[95/96]

This shows that the criteria for taxonomy-alignment are not fully consistent with ESPR and REACH. Even though the Taxonomy Regulation does not set mandatory requirements on environmental performance, it could thus cause added regulatory pressure for companies to remain attractive for investors.

V. SoCs in Specific EU Product Laws and Revisions

The notion of SoCs in ESPR is not the first time to be defined and addressed specifically in EU product legislation. This section aims to review key provisions in force or forthcoming and compare them with the ESPR provisions as discussed above (Section I. and II.).

1. Biocides: Regulation (EU) No 528/2012

Regulation (EU) No 528/2012,[97] referred to as the Biocidal Products Regulation (BPR), is a first early example which addresses "substances of concern". The BPR has been applicable since 1.9.2013. It aims to improve the functioning of the biocidal products market in the EU, whilst ensuring a high level of protection of both human and animal health and the environment (see BPR Art. 1(1)).[98] All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in them must be previously approved.

As part of the authorisation process, the BPR requires to carry out risk assessments not only on active substances, but also on any "substance of concern" present in the biocidal product as co-formulants.[99] Also, the simplified authorisation procedure under BPR is not applicable, where the biocidal product contains a substance of concern (BPR Art. 25, point (b)).

"Substance of concern" is legally defined in BPR Art. 3(1), point (f) as

> *"any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect. [...]"*

The definition continues to list three cases of substances that would *"normally"* be SoC, including classified co-formulants present in a biocidal product at concentrations leading to the classification of the biocidal product according to Directive 1999/45/EC (as "dangerous") or the CLP Regulation (as "hazardous") and ecotoxicological SoCs because of their POP, PBT and/or vPvB properties.

In addition to these three cases, the ECHA Guidance on BPR: Volume III Parts B+C[100] identifies a list of five *"other grounds for concern"* that can constitute an SoC under BPR, including e.g. substances that have been included in the REACH Candidate List or fulfil the criteria for inclusion in it and are present in the biocidal product at a con-

92 *Cefic*, Views on the draft Delegated Acts on the four remaining environmental objectives of the EU Taxonomy Regulation and amendments to the Climate Delegated Act, Position Paper, May 2023, p. 14–15, available at https://cefic.org/app/uploads/2023/05/Cefic-views-on-the-draft-Delegated-Acts-on-the-four-remaining-environmental-objectives-of-the-EU-Taxonomy-Regulation-and-amendments-to-the-Climate-Delegated-Act.pdf (accessed 13.8.2024).

93 See Environmental Delegated Act, footnote 88, e.g. recital (12) and Annex II (Circular Economy), Section 1.2. Manufacture of electrical and electronic equipment, para. 2.6. Proactive substitution of hazardous substances.

94 Do No Significant Harm.

95 See Environmental Delegated Act, footnote 88, Appendix C in Annex I (regarding water and marine resources), Annex II (regarding the transition to a circular economy) and Annex IV (regarding biodiversity and ecosystems).

96 This applies *"except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions"*, see footnote 95.

97 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22.5.2012 concerning the making available on the market and use of biocidal products, consolidated version of 11.6.2024, available at http://data.europa.eu/eli/reg/2012/528/2024-06-11 (accessed 14.8.2024).

98 See also *ECHA*, Understanding BPR, available at https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr (accessed 14.8.2024).

99 See BPR, footnote 97, Annex VI, points 5., 14., 16.–18., 55.

100 *ECHA*, Guidance on the Biocidal Products Regulation, Volume III Human Health – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017, p. 418–419, available at https://echa.europa.eu/documents/10162/2324906/biocides_guidance_human_health_ra_iii_part_bc_en.pdf (accessed 14.8.2024).

centration ≥ 0.1%, and substances for which there are Community workplace exposure limits which exceed a concentration cut-off value to be determined on a case-by-case basis.

This review shows that – unlike under ESPR – there is no specified catalogue of substances that can fulfil the hazard-based SoC criteria, the definition is more open.[101] SoCs under BPR Art. 3(1), point (f) need to be identified on a case-by-case basis by the applicants for authorisation.[102] Hence, BPR can identify SoCs which are not SoCs under ESPR. Conversely, ESPR can yield SoCs, which are not SoCs under BPR, essentially only for the case of ESPR Art. 2(27), point (d).

As of today, it is difficult to foresee whether and how this discrepancy could lead to issues. The preliminary study on new product priorities for ESPR by the Joint Research Centre (JRC) of the European Commission mentions uses of biocides in the context of various products investigated.[103] Prior SoC identification in the context of individual BPR authorisation processes could possibly help select relevant SoCs under ESPR when preparing ecodesign measures for specific products, e.g. information requirements (see above Section II.1.). Of course, this necessitates proper information channels between the European Commission, ECHA and other BPR competent authorities, which do not have a formal role under ESPR.

2. Batteries: Regulation (EU) 2023/1542

Regulation (EU) 2023/1542,[104] referred to as the Batteries Regulation, entered into force on 17.8.2023. It aims to make batteries more sustainable and safe throughout their lifecycle. To this end a comprehensive set of requirements was introduced (see Art. 1 of the Batteries Regulation).[105]

In relation to substances the Batteries Regulation (Annex I) continues to restrict the use of mercury and cadmium in batteries and introduces a restriction for lead in portable batteries from 18.8.2024. New restrictions can be added to Annex I by the European Commission according to Art. 6(2)

> *"[i]n the event of an unacceptable risk to human health or the environment, arising from the use of a substance in the manufacture of batteries or from the presence of a substance in the batteries when they are placed on the market, or arising during their subsequent life cycle stages, including during repurposing or the treatment of waste batteries, that is not adequately controlled and needs to be addressed on a Union-wide basis [...]".*

ECHA and its Committees for Risk Assessment (RAC) and Socioeconomic Analysis (SEAC) support the Commission in this restriction process (see Art. 86–88). The aim is thus to fully streamline the restriction procedure under the Batteries Regulation with REACH (see also recital (24)).[106] However, in contrast to the REACH restrictions, the scope of the Batteries Regulation includes the waste stage as well, and the Commission will be assisted by a Committee established by the Waste Framework Directive (see Art. 90).[107]

With regard to further restrictions Art. 6(5) of the new Batteries Regulation provides:

> *"By 31 December 2027, the Commission, assisted by [ECHA], shall prepare a report on substances of concern, namely substances having an adverse effect on human health or the environment or hampering recycling for safe and high quality secondary raw materials, present in batteries or used in their manufacture. The Commission shall submit that report to the European Parliament and to the Council detailing its findings and shall consider the appropriate follow-up measures including [restrictions]."*

It can be seen that the description of "substances of concern" in Art. 6(5) for the Commission report ("namely..."), as introduced during the co-legislative process, is much wider than in the CSS (see above Section I.) with regard to *"substances having an adverse effect on human health or the environment"*.

However, recital (22) of the Batteries Regulation refers to the more narrow SoC definition in the CSS (limited to substances having a chronic effect and with links to the REACH Candidate List and CLP Annex VI) for this "mapping" of SoCs. The specific ESPR definition was not finalised at the time when the Batteries Regulation was adopted. Further-

101 *Verband der Chemischen Industry (VCI)*, VCI-Position on Approach to substances of concern in the context of BPR, 11.11.2019, available at https://www.vci.de/langfassungen/langfassungen-pdf/2019-11-11-vci-position-on-soc.pdf (accessed 14.8.2024), therefore cautions that the definition of substances of concern should be restricted to the criteria given in BPR Art. 3(1)(f) and not go beyond the proposal of the ECHA Guidance.

102 See also *ECHA*, footnote 100, p. 421: *"It should be noted that the onus is on applicants to identify SoCs, […]"*.

103 *European Commission*, Ecodesign for Sustainable Products Regulation – preliminary study on new product priorities, Technical Report (draft), 2023, p. 119, 124 (detergents), p. 136, 142 (furniture), p. 159, 160 (paints and varnishes), p. 181 (toys); available at https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2023-01/Preliminary%20ESPR%20WP%20Report_MERGED_CLEAN_.pdf (accessed 14.8.2024).

104 Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12.7.2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC, initial version of 28.7.2023, available at http://data.europa.eu/eli/reg/2023/1542/oj (accessed 14.8.2024).

105 See also *ECHA*, Understanding the Batteries Regulation, available at https://echa.europa.eu/understanding-batteries-regulation (accessed 14.8.2024).

106 See also *Öttinger*, footnote 23, Section II.2, noting that this change to the well-established REACH restriction process might speed up battery-specific substance restrictions in the future.

107 See *Eurometaux*, ECaBaM 1st workshop, Final report, p. 3, available at https://www.reach-metals.eu/uploads/pdf/Batteries/28052024%2520ECABAM%25201st%2520workshop%2520final%2520report.pdf (accessed 14.8.2024).

more, it was stated that the text of the article needs to be seen in context with the development of other laws, such as the ESPR.[108] It was also confirmed that ECHA will look at the SoC definition in ESPR when elaborating its prior report under Art. 6(5) to the European Commission.[109] The further work by ECHA and the Commission under Art. 6(5) will show whether there is full alignment with the more specific ESPR criteria.

ECHA has started work on its SoC report under Art. 6(5) and aims to deliver it to the Commission by the end of 2026.[110] The first workshop, in the context of the Exchange & Capacity-building Group on Battery Materials (ECaBaM) programme set up by Eurometaux, was held in April 2024.[111] A study has been outsourced to a contractor and consists of two phases:

- Phase 1 (by June 2025) comprises the mapping of substances and processes and consideration for further restrictions.
- Phase 2 (by December 2026) aims to produce a list of SoCs and prioritisation delivered to the Commission.[112]

The main issue for the SoC mapping is that only limited information on the estimated 6,500 substances in batteries is available in the REACH registrations, since the information on quantities and technical function is missing.[113]

An open question is, how the regulatory follow-up would look like in a case where the SoC under Art. 6(5) were to be identified for reasons of *"hampering recycling for safe and high quality secondary raw materials"* and not primarily because of chemical safety. Unlike ESPR (performance requirements), the Batteries Regulation does not foresee a separate process for such substances. It is possible that an amendment of the Batteries Regulation could be required if such a case were to be identified.[114]

Hence, the SoC "pool" as described in Art. 6(5) is used as a starting point to assess new restriction candidates. The SoC concept is clearly linked to the restriction process, unlike in ESPR, where the SoC definition is the starting point for defining the list of reportable SoCs in product-specific delegated acts (see above Section II.). Under the Batteries Regulation it is rather the wider group of "hazardous substances" according to CLP which are in scope of information requirements.[115]

3. Packaging and Packaging Waste

Following the European Green Deal, the new CEAP and the CSS, the rules on Packaging and Packaging Waste, as set out in Directive 94/62/EC, are also currently being revised. On 24.4.2024 the European Parliament adopted the provisional agreement reached with the Council on the Commission proposal of November 2022 for a new Packaging and Packaging Waste Regulation (draft PPWR), which is used as a basis for the following analysis.[116]

The PPWR establishes requirements for the entire life cycle of packaging in terms of environmental sustainability and labelling, to allow its placing on the market, among others (see draft PPWR Art. 1(1)). As part of the sustainability requirements draft PPWR Art. 5 proposes to set out detailed requirements for substances in packaging. With regard to "substances of concern" – which are as defined under ESPR Art. 2(27)[117] – paragraph 1 sets out based on recital (19) that

> *"[p]ackaging placed on the market shall be so manufactured that the presence and concentration of substances of concern as constituents of the packaging material or of any of the packaging components is minimised, [...]".*

Furthermore, paragraph 2 of Art. 5 sets out obligations for the Commission to monitor the presence of SoCs in packaging and packaging components and to take, where appropriate, the relevant follow-up measures:

> *"By 31 December 2026, the Commission, assisted by [ECHA], shall prepare a report on the presence of substances of concern in packaging and packaging components, to determine the extent to which they negatively affect the re-use and recycling of materials or impact chemical safety. That report may list the substances of concern present in packaging and packaging components and indicate the extent to which they could present an unacceptable risk to human health and the environment.*
> *The Commission shall submit the report to the European Parliament, to the Council and to the Committee referred to in Article 65 of this Regulation detailing its findings and shall consider appropriate follow-up measures, including:*

108 See *Eurometaux*, footnote 107, p. 4.

109 See *REACHLaw*, 5th ESA REACH workshop 2024 – Summary report, p. 7, available at https://atpi.eventsair.com/esa-5th-reach-workshop (accessed 14.8.2024).

110 See *Doyle*, ECHA update – Authorisation and Restriction, 5th ESA REACH workshop, 19.6.2024, p. 14 et seqq. (17), available at https://atpi.eventsair.com/esa-5th-reach-workshop (accessed 14.8.2024).

111 See *Eurometaux*, footnote 107.

112 See *Doyle*, footnote 110, p. 18.

113 See *Eurometaux*, footnote 107, p. 3.

114 E.g. based on recital (25) of the Batteries Regulation, see footnote 104.

115 See Batteries Regulation, footnote 104: Recital (44); Art. 3(1), point (52); Art. 74(1) point (f); Art. 74(3); Annex VI Part A, point 8; Annex XIII, point 1. (b) regarding publicly accessible information to be included in the battery passport.

116 European Parliament legislative resolution of 24 April 2024 on the proposal for a regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, available at https://www.europarl.europa.eu/doceo/document/TA-9-2024-0318_EN.html (accessed 14.8.2024). The publication of the PPWR in the Official Journal was still pending on the editorial deadline for this article (17.8.2024).

117 Art. 3 of the draft PPWR.

(a) for substances of concern in packaging materials which primarily affect human health or the environment, the use of the procedures referred to in Article 68(1) and (2) of Regulation (EC) No 1907/2006 to adopt new restrictions;

(b) for substances of concern that negatively affect the re-use and recycling of materials in the packaging in which they are present, the establishment of restrictions as a part of design for recycling criteria in accordance with Article 6(4) of this Regulation."

Furthermore, Member States have a role to inform the Commission (and ECHA) by 31.12.2025 (Art. 5(2), last sentence) and request the Commission to consider restrictions in relation to the use of SoCs that potentially negatively affect the re-use and recycling of materials in packaging in which they are present (Art. 5(3)).

Notably also, a restriction for food contact packaging containing PFAS above certain limit values has been added in Art. 5(5) of the draft PPWR.

Hence, these draft PPWR provisions first stipulate a minimisation obligation for packaging manufacturers in relation to the entire pool of SoCs as defined in ESPR Art. 2(27). Regarding SoC restrictions, the approach to prepare a Commission report on the presence of SoCs in packaging and packaging components and (short-)list candidates for restrictions is similar to Art. 6(5) of the Batteries Regulation (see above Section V.2.), while the process and Member State role will differ under PPWR depending on whether the reason for the concern is related primarily to chemical safety (use of the REACH Restriction process) or the SoC's negative effect on the re-use and recycling of materials in the packaging (establishment of restrictions as a part of design for recycling criteria in accordance with Art. 6(4) of the draft PPWR).[118]

Öttinger opposes such a separate restriction possibility of the Commission under PPWR with view to the "One Substance, One Assessment" (OSOA) principle.[119] Yet, the same distinction of restrictions based on chemical safety vs. circularity is now followed under ESPR as well (see above Section II.2.). The OSOA principle rather relates to concurring chemical safety assessments,[120] hence there should be no conflict in case of a circularity-based restriction.

In relation to labelling of packaging, Art. 12(7), second subparagraph of the draft PPWR proposes that

"By 1 January 2030, the identification of substances of concern by means of standardised, open, digital technologies shall also be included and shall include at least the name and concentration of the substance of concern present in each material in a packaging unit. The packaging placed on the market containing substances of concern shall be marked using [standardised, open, digital marking technologies]."

As for the minimisation obligation quoted above, this information requirement appears to cover the entire pool of SoCs as defined in ESPR Art. 2(27). The Commission report to be prepared under Art. 5(2) of the draft PPWR may potentially be helpful to narrow down the list of relevant SoCs.

In conclusion, the draft PPWR foresees extensive requirements to address "substances of concern".

4. Vehicles, Their Parts and Components

On 13.7.2023, the Commission proposed a regulation on circularity requirements for vehicle design and on management of end-of-life vehicles.[121] The Commission proposal contains merely two provisions concerning "substances of concern", for which Art. 3(2)(e) refers to the ESPR definition:

- According to Art. 5 (requirements for substances in vehicles) paragraph (1) *"[t]he presence of substances of concern in vehicles and in their parts and components shall be minimised as far as possible."* Rationale (14) of the proposal refers to the CSS and its SoC minimisation objective (see above Section I.) to this end.
- Additionally, Art. 55(2)(b) of the proposal asks the Commission to evaluate, as part of its future regulation review report *"the measures concerning provision of information on substances of concern present in vehicles and the need of introducing further provisions addressing substances of concern that may affect high-quality recycling of vehicles at their end-of-life"*. According to recital (88) such further provisions could serve to align more closely with the ESPR.

However, it should be noted that there is no proposed provision comparable to Art. 6(5) of the Batteries Regulation or Art. 5(2) of the draft PPWR that would foresee a screening for SoCs in vehicles and evaluation of additional restrictions on top of those referred to in Art. 5(2) of the proposal, including for lead, mercury, cadmium or hexavalent chromium. The proposal clarifies in its recitals (15) and (16), that such additional restrictions are left for REACH, POP and Batteries Regulations.

118 Note: Table 4 (non-exhaustive list of parameters for setting design for recycling criteria under Article 6) in Annex II to the draft PPWR (regarding categories and parameters for assessment of recyclability of packaging) states that: *"The use of inks with substances of concern hinders recycling, as those packaging units cannot be recycled."*

119 *Öttinger*, footnote 23, Section III.1.

120 See *European Commission*, footnote 3, Section 2.3.1.

121 *European Commission*, Proposal for a Regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, COM(2023) 451 final, available at https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2023/0451/COM_COM(2023)0451_EN.pdf (accessed 14.8.2024).

5. Industrial Emissions: Directive (EU) 2024/1785

Directive 2010/75/EU (Industrial Emissions Directive - IED) is the main EU instrument regulating industrial pollutant emissions, covering some 52,000 large agro-industrial installations.[122] Also motivated by the European Green Deal, a revision of the IED has recently been completed through Directive (EU) 2024/1785 which entered into force on 4.8.2024 and is to be transposed by the Member States by 1.7.2026.[123]

The IED revision reinforces the provisions on hazardous and polluting substances significantly. Not being a product-specific law, the (revised) IED does not include the SoC concept known from the CSS and the ESPR. Instead, it pursues an extended hazard- and risk-based approach, with new links to the longer list of pollutants in Annex II to Regulation (EC) No 166/2006[124], the need to consider – for the setting of IED permit conditions – *"all substances, including substances of emerging concern"*, as well as substances fulfilling the SVHC criteria of REACH Art. 57 or substances addressed in restrictions in REACH Annex XVII.[125]

In addition, a new requirement for operators to prepare and implement an Environmental Management System is added to Art. 14a of the revised IED, which should include (par. 2(d)) a *"chemicals inventory of the hazardous substances"* (with special regard given to the aforementioned REACH SVHCs and restricted substances), a risk assessment as well as an analysis of the possibilities for substituting them with safer alternatives or reducing their use or emissions.[126]

To support the chemicals-related work under the revised IED, ECHA now also has a formal role. As part of its tasks, ECHA will provide lists of hazardous substances that are potentially used in the relevant industry sectors and expert advice on chemicals management.[127]

VI. Industry Approaches to Tackle SoC Management

For many actors in the chemical industry and their downstream value chains the increasing magnitude and complexity of regulatory developments and policies addressing substances, as well as the speed of regulatory changes, may seem overwhelming, especially with regard to the EU following the European Green Deal but also globally. At the same time products and sectors are becoming more and more interconnected (dual use, mixed technologies etc.). As a result, the required industry response should be proactive and priority-based, and it strongly benefits from global harmonisation efforts.

Some leading industry approaches may serve as valuable inspiration for others to see how the complex chemicals regulatory issue can be tackled holistically for the purpose of compliance, obsolescence[128] and sustainability management.

1. Portfolio Sustainability Assessment

As an example, the so-called Portfolio Sustainability Assessment (PSA) was launched in 2018 by the World Business Council for Sustainable Development (WBCSD) as a framework for chemicals companies to develop portfolio sustainability management methodologies and processes. On 7.9.2023 a revised 2nd edition of the PSA was published as *"a framework developed by leading chemical companies for all sectors"*.[129]

The analysis of chemical substances in terms of their relevant hazards – as part of a risk-based approach – and anticipated regulatory developments are central elements in the PSA. To this end, substances are proposed to be categorised in priority groups. "Substances of Concern" as defined in ESPR can be either Priority 1 or Priority 2 substances in this PSA framework, depending on their hazard profile and regulatory status. Relevant POPs for example would be included in the list of Priority 1 substances for "Signal Category II", REACH Candidate List substances only if they are progressed to lists of banned or restricted substances (Annex XIV or XVII); otherwise they would be classed as Priority 2 substances.[130]

Consistent with the PSA, some large companies have developed their own sustainability assessment tools and methods, e.g. the Solvay Sustainable Portfolio Management (SPM) Guide[131] or the BASF TripleS Method, which ad-

122 *European Parliament*, EPRS, Revision of the Industrial Emissions Directive, Briefing, March 2024, available at https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733570/EPRS_BRI(2022)733570_EN.pdf (accessed 14.8.2024).

123 Directive (EU) 2024/1785 of 24.4.2024 amending Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC on the landfill of waste, available at http://data.europa.eu/eli/dir/2024/1785/oj (accessed 14.8.2024).

124 Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, consolidated version of 1.1.2020, available at http://data.europa.eu/eli/reg/2006/166/2020-01-01 (accessed 14.8.2024).

125 See Directive (EU) 2024/1785, footnote 123: Recital (56) and Article 1(13), point (a) (ii) and (iii), amending IED Article 14(1).

126 See Directive (EU) 2024/1785, footnote 123: Recital (25) and Article 1(14).

127 See *ECHA*, ECHA gets a role supporting the Industrial Emissions Directive, available at https://echa.europa.eu/-/echa-gets-a-role-supporting-the-industrial-emissions-directive (accessed 14.8.2024).

128 Obsolescence can be defined as the transition from availability to unavailability of a material, mechanical part or process from the manufacturer or supplier.

129 *WBCSD*, Portfolio Sustainability Assessment v2.0, available at https://www.wbcsd.org/resources/portfolio-sustainability-assessment-v2-0 (accessed 14.8.2024).

130 See *WBCSD*, footnote 129, Appendix II. Signal Category I *Chemical hazard and exposure associated with a material* and Signal Category II *Anticipated regulatory developments and global conventions*, p. 29–34.

131 *Solvay*, Sustainability Portfolio Management Guide, available at https://www.solvay.com/en/sustainability/spm (accessed 14.8.2024).

dresses specifically the "Most harmful Substances" and "Substances of Concern".[132]

2. Material Declaration Standards

Another important example are international standardisation efforts by downstream producing sectors for material declarations, which include data exchange formats and declarable substance lists (DSL) for harmonised reporting in supply chains. A growing number of sectorial solutions are already available.[133] Further to this, there is on-going work for an international multi-sector material declaration dual logo standard ISO-IEC 82474-1, which among others would include declarations for compliance, composition and (optionally) process chemicals used against defined DSLs, which would remain sector-specific.[134] Sectors represented for ISO-IEC 82474-1 include e.g. aeronautics and aviation, chemicals, automotive, adhesives, EEE (Electrical, Electronic and Electro-mechanical).

It remains to be seen how the broader scope of SoCs as defined in ESPR, ESRS, etc. and related information elements (see above Section II.1.b. for ESPR and Section IV.2. for ESRS) will be taken up for these material declaration standards, in order to enable the feed into corresponding new reporting tools (DPP, sustainability statements, etc.). Also, the existence of such standards should not hide the fact that implementation across multi-layer global supply chains and especially for very complex products including legal barriers to information disclosure (e.g. confidential business information, export control) remains a big challenge in the foreseeable future and will require significant time for its broad application.

VII. Conclusions and Outlook

This article has shown that the topic of Substances of Concern is multi-faceted in terms of definitions, possible legal implications and related concepts, spanning across an increasing number of EU laws and policies, and to be tackled by industry as part of compliance, obsolescence and sustainability management programmes.

Overall, it can be concluded that the SoC definition in EU law is product- and regulation-specific. ESPR is expected to have a central role, both in the practical application (e.g. criteria for circularity-based SoCs, tracking and restrictions) and by legal reference to the SoC definition in ESPR Art. 2(27).

More specifically, it can be seen that for the SoC definition pursuant to the CSS the initiatives *following* the ESPR regulation outcome refer to the ESPR definition (PPWR, vehicles). But there are some apparent differences in terminology and scope with requirements *preceding* ESPR adoption (Batteries Regulation, ESRS). However, major issues due to this are currently not expected.

The prior shortlisting by the European Commission is required in a number of cases (ESPR, Batteries Regulation, PPWR for possible restrictions). By contrast, duty holders have to consider the entire "pool" of SoCs – as defined in the respective law – for BPR authorisation, ESRS reporting and for the minimisation obligation under the upcoming PPWR and the proposal for vehicles (COM(2023) 451 final).

The SoC status can trigger information requirements (ESPR, ESRS, BPR, PPWR), restrictions (ESPR, Batteries Regulation, PPWR) or additional obligations such as minimisation (in PPWR and the proposal for vehicles).

Despite its wide scope – especially with view to CLP-based SoCs – the tracking intention of the SoC concept largely fails to apply to the CSS priority group of PFAS substances, unless fulfilling a case of ESPR Art. 2(27). In the present opinion, this shortcoming should be addressed by the EU regulators.

A distinction between *chemical safety*-based and *circularity*-based restrictions is emerging. The former refers to the REACH restriction process, while the latter are to be regulated in product law (ESPR, PPWR, open question for the Batteries Regulation). This distinction is welcome because the REACH requirements and evaluating committees are not set up for assessing circularity-based restrictions. The borderline may not be easy to draw in practice, but the implementation needs to be awaited. Silos should be avoided.

Table 5 provides a summary of EU laws and proposals addressing "substances of concern", their definition, scope and regulatory treatment.

This article should not be treated as an exhaustive overview, but rather a comprehensive and structured starting point in a very dynamic and most complex EU and global regulatory environment. The topic of SoCs will surely continue to engage regulators, industry, auditors, users of sustainability statements and NGOs in the foreseeable future and in different discussion fora. The adoption and entry into force of ESRS and ESPR with their wide multi-reference and dynamic definitions of SoCs have given a special impetus in this regard. It will be particularly interesting to keep following the discussions in the Ecodesign Forum to be es-

132 *BASF*, TripleS Manual, notably Section 3.4. *Check for Basic Sustainability Requirements*, available at https://www.basf.com/dam/jcr:f68cf9b4-e794-32f9-968e-3759f7aafc2f/basf/www/global/documents/en/sustainability/we-drive-sustainable-solutions/sustainable-solution-steering/BASF_TripleS_Manual.pdf (accessed 14.8.2024).

133 Examples are in the automotive industry the International Material Data System (IMDS) and the Global Automotive Declarable Substance List (GADSL), and the IPC 1752A and IPC 1754 standards (USA) that are designed to meet the needs of the electronics and aerospace industries. IEC 62474 is an international material declaration standard designed for the electrotechnical industry.

134 See *Kamigaki/Blaszkowski*, Webinar Material Declaration according to ISO-IEC 82474-1, 14./27.9.2023, available at https://tc111.iec.ch/wp-content/uploads/2023/10/ISOIEC82474-1_Webinar_Sep23.pdf (accessed 14.8.2024).

Table 5: Summary table of EU laws and initiatives addressing SoCs

EU law/initiative	**SoC definition**	**Prior shortlisting**	**Legal effects**
Ecodesign for Sustainable Products Regulation (EU) 2024/1781 (ESPR)	hazard- (list) or circularity-based (Art. 2(27))	yes, in product delegated act by COM	- information requirements (in DPP/other) - possible performance requirements (restrictions)
Commission Delegated Regulation (EU) 2023/2772 (ESRS)	hazard- (list) or circularity-based, POPs missing (ESRS Annex II)	none foreseen, but materiality assessment as part of ESRS E2 *Pollution* (and other topical ESRS)	- disclosure requirements for sustainability statement: ESRS E2-1, -3, -5, -6 (entire pool of SoCs as defined)
Biocidal Products Regulation (EU) No 528/2012 (BPR)	risk-based (concentration) (Art. 3(1), point (f))	SoCs to be identified on a case-by-case basis by the applicants for product authorisation	- include identified SoCs in risk assessment for product authorisation - SoCs exclude simplified authorisation procedure (Art. 25, point (b))
Batteries Regulation (EU) 2023/1542	hazard- or circularity-based (Art. 6(5))	yes, in COM Art. 6(5)-report (pre-step for restrictions)	- possible "REACH-like" restrictions - information requirement for "hazardous substances" (e.g., battery passport)
Packaging and Packaging Waste Regulation (PPWR) – draft as per European Parliament resolution of 24.4.2024	link to ESPR Art. 2(27)	yes, in COM Art. 5(2)-report (pre-step for restrictions)	- minimisation, labelling of packaging (entire pool of SoCs as defined) - possible restrictions (based on Art. 5(2)-report)
Circularity requirements for vehicle design and management of end-of-life vehicles (REFIT) – draft as per COM(2023) 451 final	link to ESPR Art. 2(27)	none foreseen in COM proposal	- minimisation (entire pool of SoCs as defined) - COM future evaluation of further SoC provisions (Art. 55(2)(b))

tablished under ESPR in the coming months and among the Competent Authorities for REACH and CLP (CARACAL), where the Commission has proposed a recurring point on the agenda for informal discussions on relevant chemicals provisions in laws other than REACH and CLP and interface issues with regard to the EU's sustainability policies.[135]

135 *European Commission*, Observations and preliminary views on the proposal to create a CARACAL Subgroup on the subject of the interface between REACH(/CLP) and ESPR, 25.6.2024, Doc. CA/25/2024 (Revised version), available at https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/a2c467d6-39e8-4311-b88e-edd3ffc14f8a/details (accessed 14.8.2024).