

Workshop on the extension of the generic approach to risk management under the REACH Regulation















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Background paper

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This background paper has two main objectives. On the one hand, it aims to inform the workshop's participants on the analysis carried out so far to identify the uses that will be mainly affected by the planned extension of the generic approach to risk management under the REACH Regulation. In particular, the paper presents the data, methodology and preliminary results of the analysis. On the other hand, the paper aims to gather feedback from stakeholders on any possible gaps of the analysis in terms of affected uses. Such feedback is expected during the workshop discussions in break-out groups, but also in writing to the project team (REACH_WORKSHOP@vva.it) by the 31st of March.

1. Introduction

In 2019, the European Commission adopted the <u>European Green Deal</u> as the core of its policy objectives. As part of a zero pollution ambition, the European Green Deal announced the <u>Chemicals Strategy for Sustainability</u> – Towards a Toxic-Free Environment (CSS), including initiatives to simplify and strengthen the legal framework to better reflect and address risks from the most harmful substances. Based on the REACH Review of 2018¹, the CSS announced a targeted revision of the REACH regulation, including a reform of the REACH authorisation and restriction processes.

One objective of the CSS is to strengthen the EU legal framework to address pressing environmental and health concerns (see section 2.2 of the CSS). One envisaged measure to achieve this objective is the extension of the generic risk management approach (GRA) set out in REACH Article 68(2).

According to REACH Article 68(1), it is a precondition for any new restriction that there is an unacceptable risk originating from the manufacture, use or placing on the market of a substance on the EU market and that this risk needs to be addressed at Community wide level.

Article 68(2) empowers the Commission to propose a restriction based on generic exposure considerations if a substance has certain hazards, i.e. fulfils the criteria of being carcinogenic, mutagenic or reprotoxic (CMR) (cat. 1A or 1B), and if that substance on its own, in mixtures or in articles could be used by consumers. Hence, hazardous properties of the substance and generic exposure considerations are sufficient for the European Commission to propose and substantiate new restrictions for uses by consumers.

In this regard, risk management is enabled based on a generic risk assumption². It should be emphasised that in the past the European Commission used Article 68(2) in REACH to restrict CMR substances (cat. 1A or 1B) mainly on their own or in mixtures for supply to the general public via an extension of entries 28-30 of Annex XVII of REACH. When it comes to these substances in articles used by consumers, generic restrictions have been used to a limited extent (ultimately only in the restriction of certain CMR substances in textiles, entry

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¹ The 2018 REACH Review concluded that REACH is effective, but that there are opportunities for further improvement, simplification, and burden reduction. In its conclusions, the review identified a number of actions to improve the implementation of REACH, including on authorisation and restriction.

² This describes situations where a risk can be assumed as default without the need for further evidence.

72³ and certain PAH compounds in rubber and plastic, entry 50 of Annex XVII). In product specific legislation, there are restrictions for CMR substances with relevance for consumers, e.g., the Toy Safety Directive⁴ or the Cosmetic Products Regulation⁵.

In the CSS, the European Commission identifies the GRA as one of the actions to increase the level of protection of human health and the environment against chemicals with lasting harmful effects more efficiently. This approach would become the rule rather than the exception as regards substances on their own, in mixtures or in articles that are supplied to consumers and professional users. The first aim is to protect against hazard properties already identified as being of concern, i.e., CMRs and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) and substances with an endocrine disrupting effect (ED). Furthermore, an extension of the GRA to further hazard properties, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ should also be examined. In addition to the extension of the GRA to other hazard properties, the CSS also addresses the need to establish the same level of protection that applies to consumers also to professional users, i.e. to certain categories of workers outside industrial settings and self-employed workers (see Table 1).

Table 1: comparison of current scope of the GRA under REACH and future plans for its extension according to CSS

	Current Scope of GRA (art. 68(2))	Envisaged scope of GRA in CSS
Uses covered	Consumer uses Substances Mixtures Articles	Consumer uses Substances Mixtures Articles Professional uses Substances Mixtures Articles
Hazard classes covered	CMR cat. 1A and 1B	CMR cat. 1A and 1B ED (HH and Env) PBT/vPvB STOT (SE and RE ⁶) Resp Sens. Substances affecting the immune or neurological systems

Preliminary definitions used in the study⁷: Use by consumers is any use of a substance on its own, in a mixture or in an article (service life) by a consumer or a private citizen (not

³ The restriction was not imposed on all consumer products but on a clearly defined group of products. In addition, the substances were specifically named and not all substances with a classification as CMR 1A or 1B were included in the restriction.

⁴ Annex III section 4 of Directive 2009/48/EC http://data.europa.eu/eli/dir/2009/48/oj

⁵ Article 15 of Regulation (EC) No 1223/2009 http://data.europa.eu/eli/reg/2009/1223/oj

⁶ It is not explicitly stated in the CSS that both SE and RE will be part of the future system. However, in the context of this study, both categories are examined in order to be able to consider the impacts of both options. This does not, however, represent an anticipation of the later structure of the GRA system.

⁷ It should be noted that the European Commission intends to introduce definitions of 'consumer use' and 'professional use' in the revised REACH Regulation. A discussion on such definitions is planned for a CARACAL meeting on 23 March 2022.

taking place as part of a professional or work-related activity). Use by professional is any use of a substance on its own, in a mixture or in an article by a professional that takes place as part of a work-related activity outside an industrial site.

It is announced in the CSS that the effects of such an extension of the GRA in REACH will be examined within the framework of an impact assessment. A consortium led by the consulting firm VVA was commissioned with this task in autumn 2021.

In this context, this workshop is organised to present the first results and assumptions made in the course of the work and discuss those with stakeholders. This workshop serves in particular to validate the approach taken on the use maps and invites stakeholders to complete and correct the data gathered so far. Those use maps will be presented during the workshop and shall serve as a basis to assess the impacts of potential restrictions based on generic risk assumptions. Therefore, it is important that any comments on the correctness of the use maps are made during or soon after the workshop, before the assessment of impacts starts. The estimated impacts will be the subject of a further workshop, scheduled for the first half of June 2022.

In Section 2 of this document, the general structure of the project is presented. Section 3 presents the current state of the use mapping. It should be noted that these results are not final and are subject to change (including further input during and after the workshop). Finally, Section 4 explains the rationale of the break out groups of the workshop including guiding questions for the discussion during the workshop.

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⁸ This definition follows the logic to distinguish uses at industrial sites and uses by professional workers. See ECHA (2015) "Guidance on Information Requirements and Chemical Safety Assessment - Use description (Chapter R.12) https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197?t=1449153827710

⁹ The terms of reference of the study can be found on: <u>CARACAL - Library (europa.eu)</u>

2. PROJECT CONTEXT

The study contracted by the European Commission (DG GROW)¹⁰ consists of eight tasks, of which the following main tasks are relevant for this workshop:

- Task 2: Mapping uses of the substances that will be subject to the generic approach to risk management;
- Task 3: Assess the uses that would fall under the GRA and quantify the impacts resulting from the extension of the generic approach to risk management.
- Task 4: Assess the impacts of reforming the REACH authorisation and restriction processes.

This background paper will not address task 4, since it is not discussed at this workshop. Nevertheless, it should be noted that an extension of the GRA will interact with the other mechanisms in the reform of the authorisation and restriction framework and cannot be considered independently of this. An overview on the approaches under discussion in this area is given in a CARACAL document dating from January 2022¹¹.

According to the project specifications, task 2 of the project aims at developing use maps to further develop the understanding of how the substances possibly subject to GRA restrictions are used in different products or sectors.

- The starting point for the use maps was the use description and the registered tonnage band in the REACH registration dossiers but the analysis is meant to go beyond the ECHA information and the project team is tasked to review and identify the gaps of data in the ECHA information, as appropriate, fill those gaps and complement the data by own research up to a degree of granularity allowing generation of the necessary estimates for this study.
- For each of the concerned substances, the main uses, types of users and sectors were mapped, in order to allow a high-level identification and visualisation of impacts. Overlaps between substances and uses should be identified and described. The uses shall be further distinguished into uses as substances on their own, in mixtures and/or in articles, as well as between consumers and professional users.
- The granularity of the results shall be such as to allow a good understanding of the main uses of each substance, without going into details or analysing minor uses that will not have a major influence on the overall assessment of impacts of restricting a particular substance.
- The analysis may be focused to substances or groups of substances that are representative for all concerned hazard classes, and for which the highest benefits and the highest costs of restrictions can be expected, taking into account options for a differentiated implementation of the generic risk management approach. The focus of the analysis shall be on substances subject to REACH but shall also cover uses in cosmetics and toys, to serve as an input for separate impact assessments under the respective legislation.

¹⁰ Study title: "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction" GROW/IMA/21/2123/12108 under Framework Contract ENV.F.1/FRA/2019/0001

¹¹ CA/03/2022

In the following sections of this background paper, preliminary results of the use mapping are shown to inform the discussion during the workshop. Firstly, a brief overview of the methodological approach is given. The following work steps are presented in more detail:

- Generation of a Master List of Substances (MLoS) that might fall under the GRA scope (section 2.1)
- 2. Processing of MLoS to eliminate list entries not in the scope of REACH (section 2.2)
- 3. Initial data from registration dossiers (section 3.1)
- 4. Initial use maps (section 3.2)

The impacts on the different sectors that may originate from the extension to the additional hazard classes will be assessed in another step after this workshop and will be the subject of a further workshop planned for the first half of June 2022.

2.1. Generation of a Master List of Substances that might fall under the GRA

An initial master list of substances (MLoS) that might qualify for GRA extension was generated by ECHA independently from the present project work. It was provided to the project team in October 2021.

The list includes substances that may fall into one (or more) of the hazard classes that could be covered by the application of the extended GRA.

The MLoS consists of two baskets (overview shown in **Error! Reference source not found.**). According to an accompanying ECHA document¹², the baskets have the following characteristics:

- Basket 1 Substances with confirmed hazard(s): For hazard classes included in the classification, labelling and packaging (CLP) Regulation, the inclusion of substances in basket 1 is based on either their harmonised classification (inclusion in Annex VI to CLP) or the reported self-classification in the registration dossier¹³. For other hazard classes, these are based on identification as Substances of Very High Concern (SVHCs) (inclusion in the Candidate List), identification under the Biocidal Products Regulation (BPR) or agreed in the ED/PBT Expert Groups. Hazard(s) are based on available information; lists as well as numbers of substances are provided.
- Basket 2 Substances where the hazard(s) are under consideration: These
 are substances with on-going data generation or assessments; lists as well as
 numbers of substances are provided. For this basket, there is an estimate on the
 number of substances for which the hazards are likely to be confirmed (based on
 past experience¹⁴).

¹² ECHA (2021) Issue 1.2 Report (restricted)

¹³ Certain entries on Annex VI to CLP are conditional (e.g. the classification only applies if certain impurities are present). These have been removed from the analysis. In addition, self-classification can be impacted by the presence of impurities. In this analysis, no attempt has been made to identify and remove substances if the self-classification is based on impurities.

¹⁴ Note: There can be overlaps between Basket 1 and 2 for cases where the evidence on one property is already sufficient while for another property, additional data are needed.

A third basket is represented by estimates on how many substances could have the same hazard(s) among the remaining REACH registered substances. Numbers provided were extrapolated to all REACH registered substances using the frequencies of the hazards in Basket 1 and 2. It is important to note that basket 3 is not a list of specific substances and therefore cannot be used for the purpose of this use mapping. However, the estimated numbers composing basket 3 can be used for the purpose of sensitivity analysis in the impact assessment.

The following hazard classes have been covered in the MLoS following this methodology that are considered relevant for the study scope:

- ED (HH and Env)
- PBT/vPvB
- STOT (SE and RE)
- Respiratory sensitisers
- PMT/vPvM

The CSS does not specify that persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances should be subject to extended generic approach to risk management. However, after discussions in the scoping phase, it was decided, in agreement with the European Commission, to include them in the assessment, in order to understand their uses and the potential impacts of possibly regulating this emerging hazard class and its thematic proximity to the subject area under investigation¹⁵. For substances affecting the immune or neurological systems a screening was applied among the STOT substances if these can qualify for these hazard properties.

The initial substance list generated by ECHA did not cover CMR 1A and 1B substances. Since they are relevant to assess the impacts of the extended GRA on professional uses, a list has been generated based on classification in similar way as for basket 1. Substances are covered if there is either a self-classification for CMR 1A/1B in a registration dossier (lead and individual) or there is a harmonised classification in CLP. Contrary to other hazard classes, no estimate has been provided on the number of additional new substances that may be identified CMR 1A/1B (basket 2 equivalent).

¹⁵ Substances identified as persistent, mobile and toxic listed in the Candidate list as having Equivalent Level of Concern (EloC) according to REACH Article 57 (f) were included in the Basket 1. Substances flagged as possible PMT/vPvM in ECHA's and Substances listed in the report by DTU « How many potential vPvM/PMT substances have been registered under REACH? – vPvM/PMT -screening by using the Danish (Q)SAR database » Holmberg. et al (2021) https://backend.orbit.dtu.dk/ws/portalfiles/portal/240040384/111514 909384 DTU Rapport vPvM PMT CB 7kor links.pd

¹⁶ 14 ATP conditional harmonised classifications, as identified by the corresponding notes, have been excluded

2.2. Processing of MLoS to eliminate list entries not in the scope of REACH

Not all substances identified in the initial MLoS are relevant for the use mapping exercise to be carried out for this study. Substances with no other use than as active substances in biocides or plant protection products were eliminated from the initial list. Furthermore, there were substances included in the MLoS Basket 2 that are classified as toxic to reproduction category 2, which are not subject to extended generic approach to risk management, according to the CSS.

In addition, of the 1,500 CMR 1A/1B substances identified by ECHA, only 1,124 are registered, so that it can be assumed that the unregistered are not used or only used in small quantities and are therefore not considered further in the use mapping.

As a result, 4,771 entries remain (3,510 in basket 1 and 1,261 in basket 2). As some substances are listed more than once because they are assigned to several hazard classes or have different classification bases, the exclusion of such duplications reduces the list of individual substances further (not shown here)¹⁷.

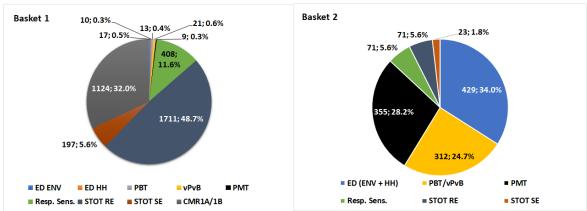


Figure 1: Absolute numbers and relative share of entries per hazard class in Basket 1 (left, total 3,510, and entries per hazard class in Basket 2 of the MLoS right, total 1,261)

The two diagrams show that Basket 1 includes mainly STOT RE/SE and respiratory sensitisers, while Basket 2 includes mainly ED, PBT/vPvB and PMT substances. Basket 1 contains nearly 55% substances of the hazard classes STOT RE/SE and another 11.6 % of Resp. Sens. and 32 % CMR 1A/1B. Basket 1 contains far less substances of the hazard classes PBT/vPvB, PMT and the two ED categories (all below 1 %).

In contrast to basket 1, basket 2 reflects the opposite situation. Only a comparatively small number of substances can be assigned to the STOT SE/RE (1.8 %/5.6 %) and Resp. Sens. (5.6 %) hazard classes. On the other hand, there are considerably more substances from the PBT/vPvB (24.7 %), ED (34 %) and PMT (28.2 %) classes for which further data are required for a final classification of the properties (possibly also non-standard data according to the current REACH Annexes, so that limited data availability can be assumed here, as well).

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¹⁷ In the initial working step in the project, the use mapping, the duplicates were not eliminated, as it was the aim to include all uses relevant per hazard class. Elimination of duplicates will be done later to avoid multiple assignments of impacts.

3. USE MAPPING

In the next step of the analysis, a Use Mapping was prepared. The MLoS was split into sub-lists by the various hazard classes (see Figure 2) to be able to derive different implementation scenarios later (hazard classes included in GRA or excluded, tiered introduction of obligations) that might vary in their impacts.

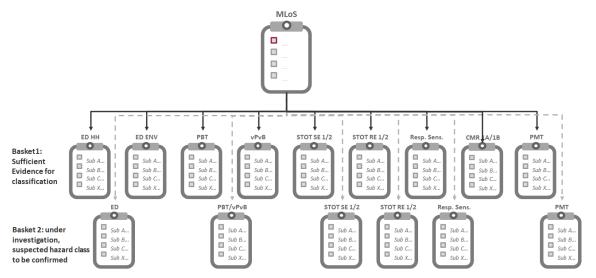


Figure 2: Split of MLoS for initial data request to ECHA by hazard class and Baskets

Based on the hazard classes, an initial use mapping is created for these sub-lists based on use information from registration dossiers (see Figure 3). The main organisational level was the product categories (PC) assigned to the individual substances in the registration dossiers. In addition, the data sets contain information on the functions of the substances, the tonnage bands of the registrations and the extent to which the registrations are active or inactive.

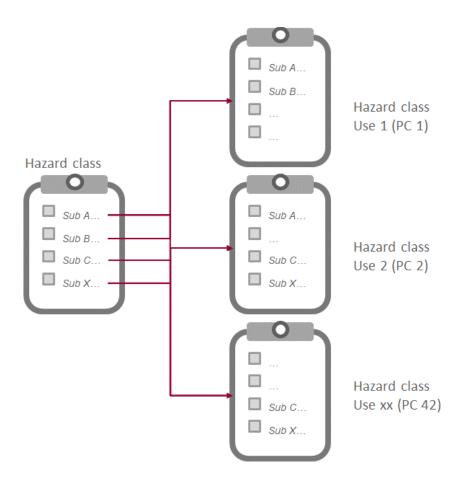


Figure 3: Initial Use Map from ECHA bases on registration data

The datasets were automatically extracted from ECHA's IT systems and reflect the content and quality of registrations dossiers (IUCLID section 3.5).

The dataset shows how many substances or overall registered tonnage (as proxy for potential high impacts) would be affected if a hazard class/category were included in the generic approach to risk management. It is important to consider the reliability of the information on tonnages in the sensitivity analysis. Based on the information, a (initial) use map is generated. Here, the substances can first be subdivided in purely qualitative terms according to whether they are used in numerous applications or only in a few. At this stage there will also be an assessment of the indicated life cycle stages affected (consumers, professionals or industrial), leading to the identification of substances that might only be used in industrial contexts and therefore might be out of scope of the subsequent impact assessment¹⁸.

It should be mentioned that an evaluation of other use descriptors, such as the Article Categories (AC) or the Sector of Uses (SU) in the form of substances counts is not considered helpful, as the data appears to be highly incomplete and is does not support to further identify products beyond the scope of the PC, especially in relation to the service life of articles. Based on further manual analysis of free text fields, information on potentially

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¹⁸ This consolidation step will require further assessment and verification with stakeholders, before final elimination from further assessment.

affected service life is extracted from the registration data. The technical functions are evaluated in particular, as well as other free-text fields that often specify areas of use in more detail (e.g. use names that designate specific products).

The overall picture of which PCs are particularly affected by an extension of the GRA does not change significantly regardless of whether or not STOT RE, the largest hazard class in terms of number in Basket 1, is included. Based on this analysis, the first "hot spots" were identified, i.e. areas that would presumably be strongly affected by a broad implementation of the GRA (see also section 4 with the reasons for breakout groups).

For certain hazard classes, the overlaps with regard to the substances contained are sometimes guite large. For example, almost 100% of the PBT substances in Basket 1 are also vPvB substances. To a somewhat lesser extent, this applies to the distinction between ED HH and ED Env.

During the first analysis of the data received, it became apparent that the data sets also contained substances for which extensive regulations already exist in the EU and for which registration dossiers are available at ECHA, but for which there are no longer any active registrants in the EU. Examples for such a situation are Hexabromocyclododecane EC 247-148-419 or Anthracene oil, anthracene paste, distn. Lights EC 295-278-529 or EC 292-602-**7**²¹.

As far as possible, these types of substances should be eliminated from the assessment by checking the registration status or if existing use limitations are known²², since it can be assumed, that no uses are still performed with them. In the example the two substances are included in Annex XIV and as no authorisations are granted, only intermediate uses (to the extend they take place at industrial sites) or uses for R&D that are outside the scope of GRA are allowed. Thus, no impacts will be generated for these substances if included in the GRA restrictions. There are also other datasets, where it can at least be strongly doubted if these are still valid (e.g. other brominated flame retardants covered under the POP Regulation where professional and consumer uses have been registered). Given the large number of substances included in the assessment, such checks are done within the resource limitations in the project, since a high level of manual data handling is required. It should also be noted that the data from the REACH registration dossiers has not been cross-checked with other sector-specific databases.

The overview of the absolute numbers of substances contained in the various product categories (PCs) already shows some differences regarding the impact on the associated sectors.

The following table (Table 2) summarises the results of this first step of the analysis and shows the uses of certain substance groups in different areas or sectors.

¹⁹ https://echa.europa.eu/brief-profile/-/briefprofile/100.042.848

²⁰ https://echa.europa.eu/brief-profile/-/briefprofile/100.086.578

²¹ https://echa.europa.eu/brief-profile/-/briefprofile/100.084.153

²² E.g. parts basket 1 ED or PBT/vPvB substances are already subjected to candidate listing as described in the ECHA methodology potential restrictions were assessed in ECHA's substance inforcard database to identify use limitations

Table 2: Absolute numbers of substances **Basket 1** included in the initial use maps per PC on basis of REACH registration dossiers²³

Product category	PBT	vPvB	ED HH	ED ENV	Resp. Sens.	STOT SE	STOT RE	PMT	CMR	Sum all hazard classes
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	2	2	1	2	35	18	152	1	93	306
PC 36: Water softeners							23		9	32
PC 37: Water treatment chemicals	1	1		1	29	3	92		66	193
PC 2: Adsorbents	2	2	1		9	2	58		33	107
PC 11: Explosives			1	2	1	4	80		56	144
PC 12: Fertilisers					13	1	79		67	160
PC 27: Plant protection products			1	1	3	9	70		58	142
PC 4: Anti-freeze and de-icing products	2	2				5	64		109	182
PC 35: Washing and cleaning products	6	9	2	3	92	36	273	2	234	657
PC 8: Biocidal products (e.g. disinfectants, pest control)	5	7			8	18	97		58	193
PC 28: Perfumes, fragrances	4	7	1	1	13	17	62		33	138
PC 3: Air care products	3	5			3	15	86		122	234
PC 39: Cosmetics, personal care products	5	8	1		40	16	115		58	243
PC 29: Pharmaceuticals	2	2	1	1	39	28	174	1	96	344
PC 31: Polishes and wax blends	5	7	1		5	21	84		71	194
PC 15: Non-metal-surface treatment products	4	4	1		20	20	128		82	259
PC 24: Lubricants, greases, release products	6	6		3	15	7	164		158	359
PC 25: Metal working fluids	1	1	1		5	3	107		64	182
PC 16: Heat transfer fluids	1	4			3	2	74		69	153
PC 17: Hydraulic fluids	7	1		2	7	2	133		119	271
PC 13: Fuels	5	6		1	17	11	264		311	615

 $^{^{23}}$ Highlighted in bold are the PCs that were assigned the most substances as the sum of all hazard classes

Product category	РВТ	vPvB	ED HH	ED ENV	Resp. Sens.	STOT SE	STOT RE	PMT	CMR	Sum all hazard classes
PC 32: Polymer preparations and compounds	8	12	7	9	100	62	468	4	361	1031
PC 1: Adhesives, sealants	7	10	4	6	52	30	250		204	563
PC 9c: Finger paint	1	2	1		2	2	72		59	139
PC 9b: Fillers, putties, plasters, modelling clay	6	9	3	3	30	13	158		119	341
PC 9a: Coatings and paints, thinners, paint removes	8	11	4	7	77	39	405		316	867
PC 18: Ink and toners	7	8	2	4	29	16	220		193	479
PC 26: Paper and board treatment products	4	4	1	1	32	14	115		42	213
PC 34: Textile dyes, and impregnating products	7	6	1		63	18	130		85	310
PC 23: Leather treatment products	5	5			48	11	88		68	225
PC 14: Metal surface treatment products	1	1		1	29	14	129		59	234
PC 38: Welding and soldering products, flux products					11	8	83		112	214
PC 7: Base metals and alloys	3	3			18	3	76		64	167
PC 33: Semiconductors	2	3			13	2	54		30	104
PC 21: Laboratory chemicals	4	6	3	6	86	53	398	1	351	908
PC 19: Intermediate	8	8	9	9	252	129	997	1	836	2249
PC 40: Extraction agents	1	1			4	4	0		19	29
PC 41: Oil and gas exploration or production products				1	9	1	24		11	46
PC 42: Electrolytes for batteries					3	1	23		8	35
PC 30: Photo-chemicals					5	5	39	2	17	68
PC x1: Food and feed additives					1	1	0		1	3

Table 3 Absolute numbers of substances **Basket 2** included in the initial use maps per PC on basis of REACH registration dossiers²⁴

Product category	vPvB	ED	Resp. Sens.	STOT SE	STOT RE	PMT	Sum all hazard classes
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	37	105	14	13	14	43	226
PC 36: Water softeners	14	26	3		3	16	62
PC 37: Water treatment chemicals	27	54	8	7	4	25	125
PC 2: Adsorbents	25	41	7	5	5	15	98
PC 11: Explosives	16	25	3		4	12	60
PC 12: Fertilisers	20	49	8	6	9	34	126
PC 27: Plant protection products	29	58	5	7	11	39	149
PC 4: Anti-freeze and de-icing products	20	44	6	5	5	15	95
PC 35: Washing and cleaning products	85	168	17	12	17	91	390
PC 8: Biocidal products (e.g. disinfectants, pest control)	51	94	11	9	9	46	220
PC 28: Perfumes, fragrances	53	91	9	4	6	31	194
PC 3: Air care products	46	78	9	8	7	32	180
PC 39: Cosmetics, personal care products	65	118	15	8	8	55	269
PC 29: Pharmaceuticals	27	71	9	5	10	33	155
PC 31: Polishes and wax blends	59	95	9	8	9	46	226
PC 15: Non-metal-surface treatment products	42	79	10	8	11	45	195
PC 24: Lubricants, greases, release products	94	115	18	11	10	43	291
PC 25: Metal working fluids	62	81	7	3	9	27	189
PC 16: Heat transfer fluids	38	53	5	2	4	23	125
PC 17: Hydraulic fluids	59	57	8	3	8	17	152
PC 13: Fuels	47	58	8	6	10	27	156
PC 32: Polymer preparations and compounds	173	281	34	19	38	183	728

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²⁴ Highlighted in bold are the PCs that were assigned the most substances as the sum of all hazard classes

Product category	vPvB	ED	Resp. Sens.	STOT SE	STOT RE	PMT	Sum all hazard classes
PC 1: Adhesives, sealants	98	176	19	14	15	83	405
PC 9c: Finger paint	39	69	9	7	7	38	169
PC 9b: Fillers, putties, plasters, modelling clay	63	140	14	11	14	64	306
PC 9a: Coatings and paints, thinners, paint removes	138	232	24	17	30	133	574
PC 18: Ink and toners	101	147	23	13	24	103	411
PC 26: Paper and board treatment products	60	91	18	7	20	90	286
PC 34: Textile dyes, and impregnating products	60	91	29	9	20	98	307
PC 23: Leather treatment products	58	82	17	8	19	69	253
PC 14: Metal surface treatment products	30	77	10	5	11	41	174
PC 38: Welding and soldering products, flux products	13	33	7	7	7	13	80
PC 7: Base metals and alloys	9	35	8	6	6	14	78
PC 33: Semiconductors	16	31	7	4	2	16	76
PC 21: Laboratory chemicals	108	200	24	20	28	99	479
PC 19: Intermediate	114	252	35	21	32	145	599
PC 40: Extraction agents	10	34	3	2	3	16	68
PC 41: Oil and gas exploration or production products	6	17	0	5	5	5	38
PC 42: Electrolytes for batteries	2			1	1	4	8
PC 30: Photo-chemicals	24	44	7	3	3	35	116
PC x1: Food and feed additives		1	1			1	3

In addition to the assignments of substances to the PCs, the data sets were examined to see whether an assignment of the uses to individual life cycle stages was made. These were industrial, professional and consumer. The number of substances assigned to professional or consumer uses are shown in the individual sections for each break-out group (Sections 4.1.1 to 4.1.7). In a further detailing step, the identifiable products (mixtures and articles) were assigned to the PCs for the respective hazard classes. These overviews are currently still under preparation and will be provided to the members of each breakout group one has been assigned to in the week before the workshop for preparation of the discussion in the groups.

4. Break-out groups

The aim of the workshop and the break-out groups is to critically review the information extracted from the registration data and the use maps prepared based on that date, and validate them with stakeholders. Stakeholders' feedback and input on the following aspects will be particularly important for the discussions:

- Assumptions on the number of hazardous substances in the individual hazard classes: one of the issues to be addressed is whether companies have an overview of hazardous substances that currently already require special monitoring (e.g. substances on the candidate list, restricted substances). Furthermore, it is also of interest for the project team if/which companies additionally monitor all hazardous substances even if they are not yet subject to regulation (e.g. substances of one of the STOT categories or Resp. Sens.) and can therefore estimate the expected impact of an extension of the scope of GRA restrictions. The latter is of particular interest if the substances are used in articles.
- The identified products (mixtures and articles) are to be critically examined and, if
 possible, the area of application of the substances are to be further specified. This
 is particularly important in the area of quite general applications, e.g. for use in
 plastic products that are not specified in more detail, with classification of the more
 concrete functionality and the area of application where these is required.
- Based on the further concretised areas of application, more detailed information on products (especially articles) down the supply chain that depend on the availability of the substances should also be collected.
- If possible, discussions should also take place at the level of technical functionalities.
 This includes, for example, an overview of currently used solutions for a certain product property and the substances used for it and the associated hazardous properties.

The focus of the discussions will therefore be on the basic technical assumptions that form the basis for the actual assessment of impacts, which is planned later in the project. It is not assumed that all questions can be conclusively addressed in the workshop. Therefore, the workshop is also intended as an opportunity to identify stakeholders with whom the discussion can be continued to gather further information for refining the use maps.

It is not the aim of the workshop to collect information on the expected impacts in detail or possible implementation scenarios in general. However, it is understood that missing information on the uses will have a direct impact on the estimated impacts and may therefore be relevant to this workshop and will be documented now to be taken into account later in the project.

Within the framework of the initial Use Map, a focus area was identified on the basis of the information from the registration dossiers, for which a particularly large number of substances could be affected by an extension of the GRA. It should be noted that there are uncertainties with regard to the absolute number of substances possibly affected (e.g. due to false positives or incorrectly assigned product categories), but qualitative distinctions can be made on the basis of the scope (strongly affected - less affected).

Further differences are seen regarding the basic coverage of sectors. Since the PCs initially only relate to mixtures, this is the first reference value to specify the use of the substances. However, regarding the further life cycle after the use of these mixtures, different fates can be assumed.

Some PCs represent mixtures which, after their use, are not included in articles where consequently no service life assessment is needed. Examples of such PC are PC35: Washing and cleaning products or PC 12: Fertilisers. The substances contained are usually disposed of in wastewater or, in the case of applications such as fertilisers, released directly into the environment.

In contrast, other PCs tend to suggest that the use of mixtures will lead more to substances ending up in articles, making service life relevant for consumers and professional users. Examples are PC 34: textile dyes and impregnating agents or PC 32: polymer preparations and components. But here, too, there are differences regarding the specificity of the articles. While the target of PC 34 can be textiles of all kinds (which is still a wide range, but relatively specific), the scope of PC 32 is much broader and unspecific, since plastics are finished in all kinds of forms and with a wide variety of additives, depending on the specific use, which can only be found in the data at this level of detail in exceptional cases. Often, rather generic material designations are used in free text fields for characterisation, e.g. PVC products, PUR foams more rarely more concrete ones e.g. such as a certain technical function in tyres.

In addition, there are also PC where the incorporation of substances into articles can vary depending on the function of the substances in the mixture. In PC1 Adhesives and Sealants, for example, substances are used as solvents in certain products that are released into the environment during use and are later no longer present or only present in traces. Other products contain substances that react during use and are not present as such (e.g. in the case of certain 2-component adhesives that form polymer structures during use).

The break-out groups within the workshop are organised according to main headings. Nevertheless, other PCs than these are to be discussed in the groups. PCs with a similar field of application should also be addressed in the groups and thus give participants the opportunity to feed their point of view into the discussion. For this purpose, further suggestions are made under the break-out group headings where the project team sees common ground (listed in bullets below the heading).

In the context of the individual breakout groups at the workshop, unless critical specific chemicals need to be singled out, less attention will be paid to individual substances. Discussion will be facilitated around product groups such as phthalates, certain polymer groups but also articles in which products might end up etc. or functionalities (e.g. solvents, flame retardants) – such discussions will be part of the discussion in the group for complex articles in particular, see Group 8. Constrains to discuss specific substances originate from confidentiality issues with registration data. The discussion should therefore aim to confirm, refute or refine the data analysis of the initial use maps and clarify if the wide assumptions of the use map reflect the market situation properly. The aim of the groups is to verify a basic level of concern. In other words, for each group the following question should be replied: "is the assessment of concern regarding the hazard class correctly depicted?". The feedback from the participants will serve to identify which main impacts are expected in case of a GRA restriction and to determine the magnitude of these impacts.

Process of group sessions: To enable feedback from participants on the results of the use mapping, the following three steps will be conducted in and before the group sessions of the workshop:

1. Step 1 - Presentation of the uses identified in the different product groups: We will share one week before the workshop a PPT summarising the key results of the use

- mapping in the specific product groups. This is to allow participants also to interact with technical experts in their organisation on the subject.
- 2. Step 2 Presentation of current use maps: After the methodology of the use mapping was presented in the plenary session of the workshop the moderator and rapporteur will take the group members through the specific results for the product group and will respond to any specific questions on those results. Depending on the number of questions this step of settling and explaining the results can last the full morning session or the group can move on quicker to the third stage.
- 3. Step 3 Gaps and further development of use mapping: Following the clarification the members of the group will discuss in which areas the use mapping will need to or can be developed further. The following questions can serve as guidelines for this discussion:
 - Based on the overview of product categories potentially affected per hazard class (see Table 2 and Table 3Table 2) Are you able to identify any significant uses that are missing?
 - The use mapping presented is based on data from registration dossiers. Do you see any limitations of using this data, in addition to those described in section 3.3 of this paper? Especially limitations regarding the split of professional versus consumer uses and limitations regarding mixtures and articles would be an important focus point? If so, can you propose any mitigation measures or point to complementary data sources, e.g. specific to a certain use or product category and in particular to define articles service life better?
 - With regard to the methodology presented in this paper, do you see any major limitations? If so, do you have any suggestions to improve the methodology?
 - Have you analysed your substance portfolio to see if the substances you use could fall under the extended scope of the GRA in the future (e.g. in the frame of the CEFIC activities²⁵)? If so, can you estimate the percentage of your products (production volume, turnover) that would be impacted by extension of GRA? Can you provide an estimate of the breakdown of this percentage in terms of consumer use in mixtures, professional use in mixtures, consumer articles and articles for professionals respectively?

4.1. Break-out groups identified on the basis of the analysis

4.1.1. Group 1 - PC 32: Polymer preparations and compounds

Additional PC to be discussed:

PC 19: Intermediate

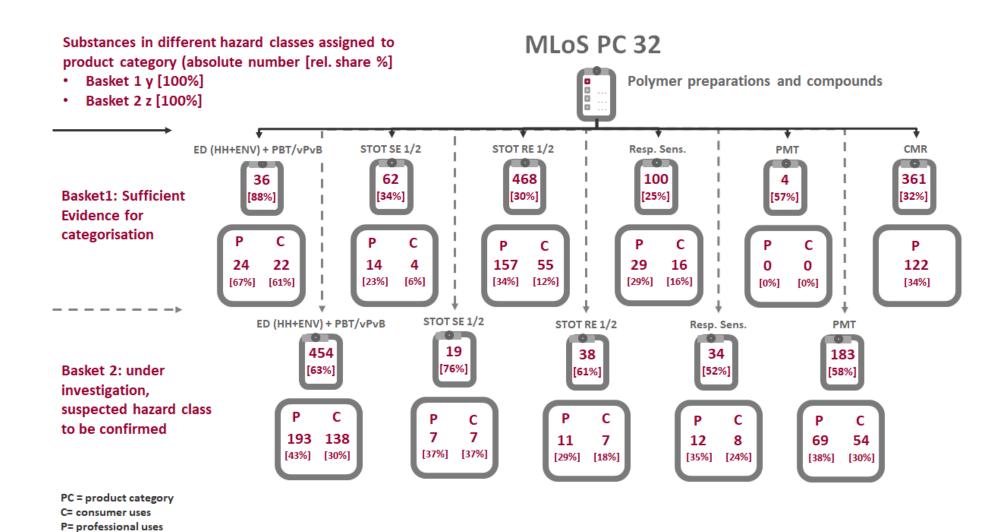
The PC 'polymers' contains the polymers themselves, but can also contain monomers and additives (e.g. stabilisers, flame retardants fillers etc.). Therefore, the PC

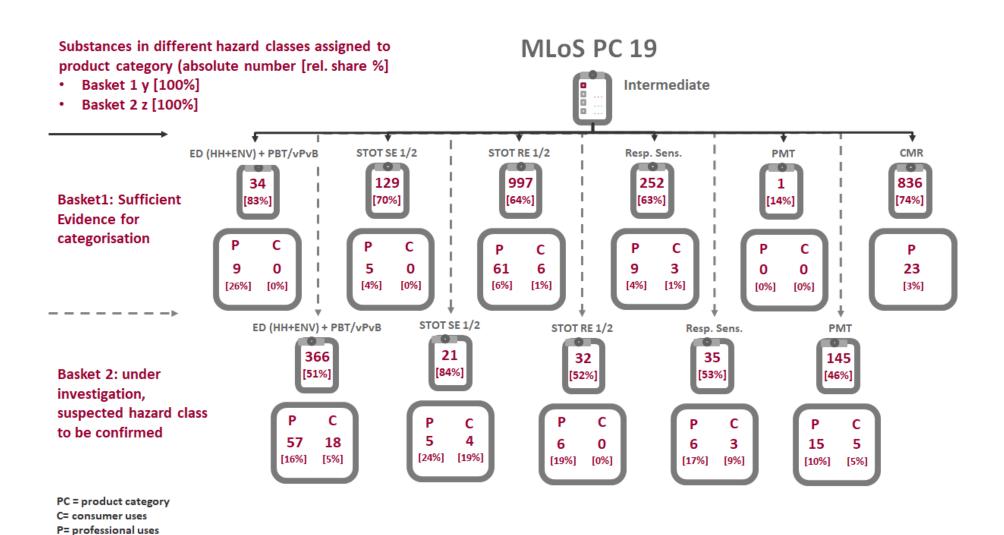
²⁵ Ricardo (2021) "Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability"- Phase 1 Report, Final Report for European Chemicals Industry Council (Cefic) ED 14790 | Issue number 1 | Date 18/11/2021 <a href="https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-the-Impacts-of-the-Imp

'intermediates' has also been assigned to this group, since these also contain reactive polymers and could therefore be discussed in this area. However, for the PC discussion, the focus would be on understanding which functionalities are relevant in the area of additives and building blocks. Furthermore, an essential point for discussion in this group is whether and where significant impacts on downstream user (DU) sectors occur (e.g. although it is known that substances are used that are possibly covered by GRA, they are very difficult to substitute in the DU sectors).

In this PC, the relevance for articles is also discussed in more detail than in the other groups. Article made directly from plastics are of particular interest. Particularly relevant are certain functionalisation and ingredients that are necessary for the design of the plastic component itself (e.g. plastic packaging, furniture, construction products etc.). The same applies to polymer preparations that are incorporated onto/into articles (e.g. as coatings, polymer resins, etc.).

Complex articles (e.g. automotive, aviation etc.) will be discussed in a separate group (group 8).





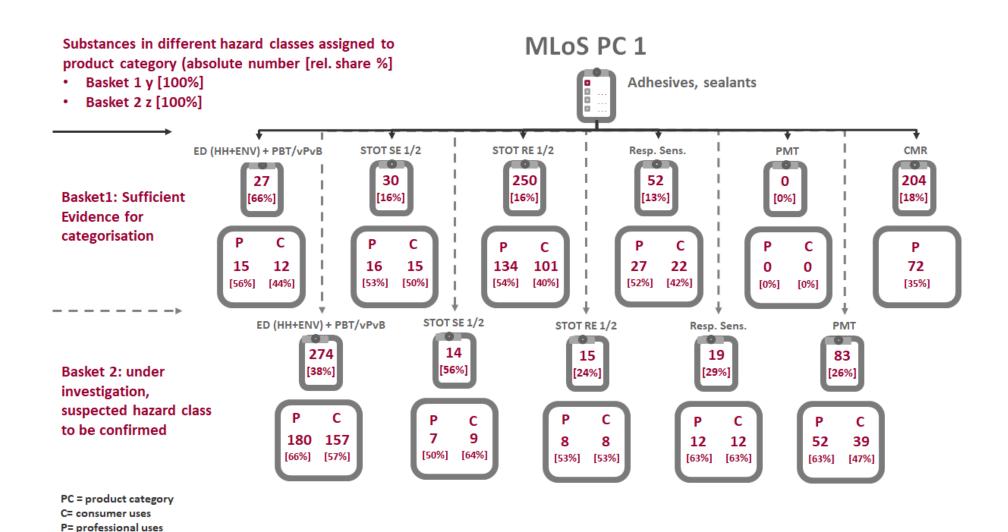
4.1.2. Group 2 - PC 1: Adhesives, sealants

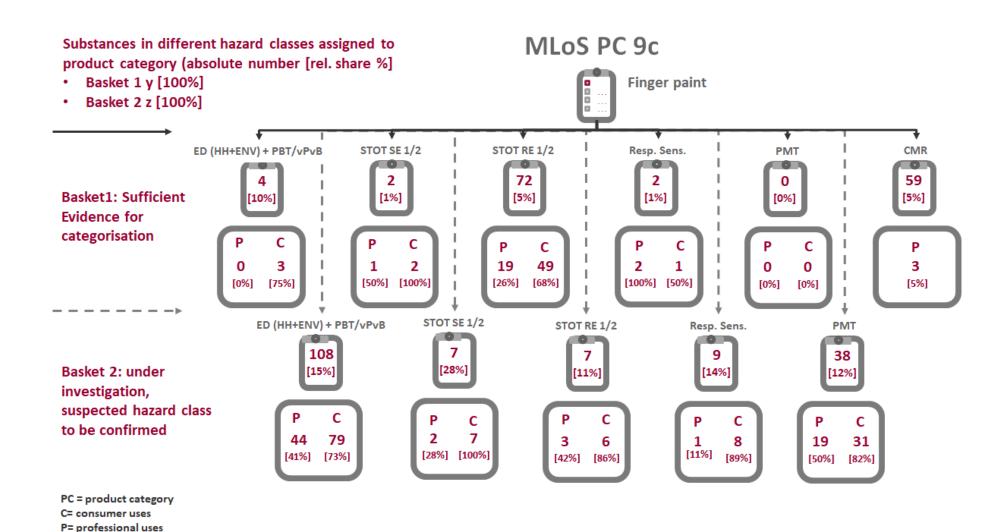
Additional PC to be discussed:

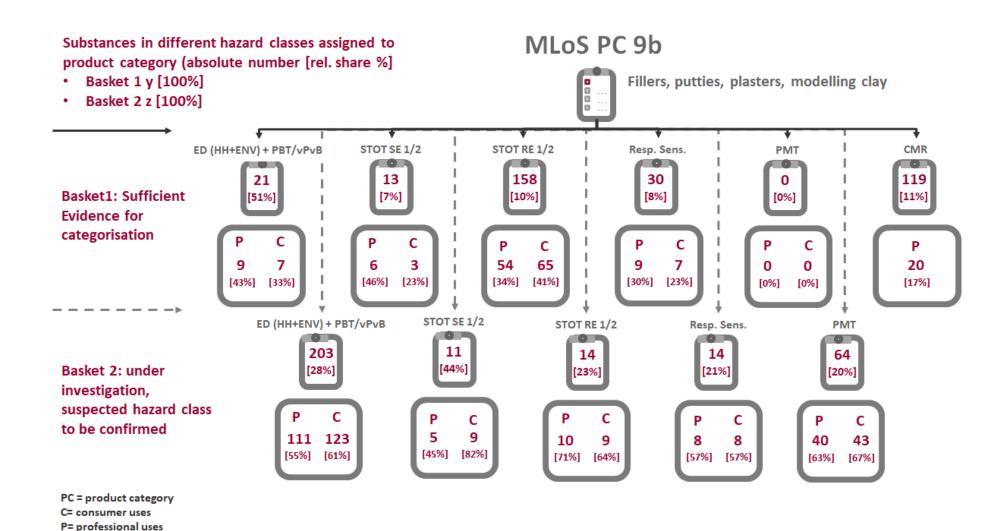
- PC 9c: Finger paint,
- PC 9b: Fillers, putties, plasters, modelling clay,
- PC 9a: Coatings and paints, thinners, paint removes

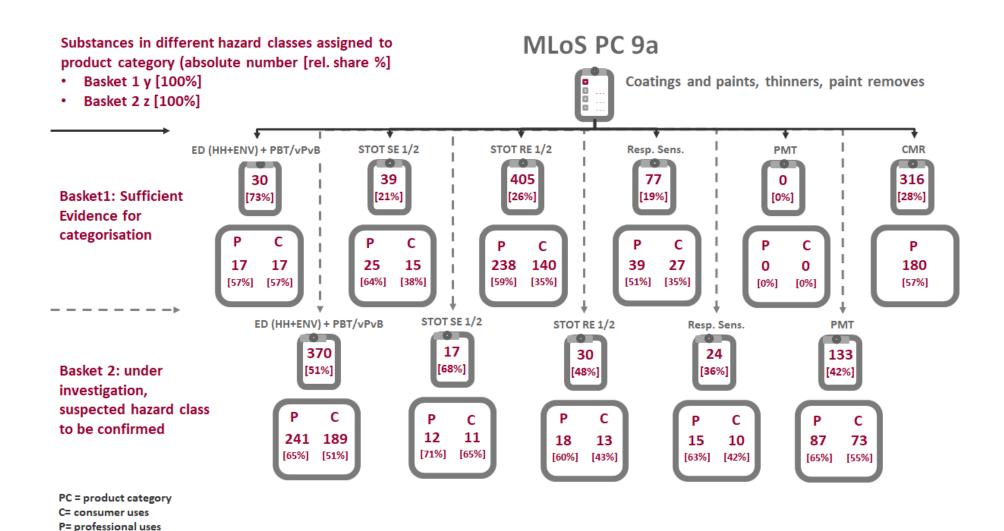
PC 1: Adhesives, sealants is a product category with a very wide range of products that are widely used by consumers and professionals (e.g. in the construction sector). Certain components are also repeatedly assigned to product categories 9a-c (9c with less importance in terms of the number of substances, but nevertheless in view of the fact that it is a particularly sensitive application).

In terms of use, many of the products are only used in direct application (polymeric components react with each other and form new complexes with different toxicity, solvents are released during application).





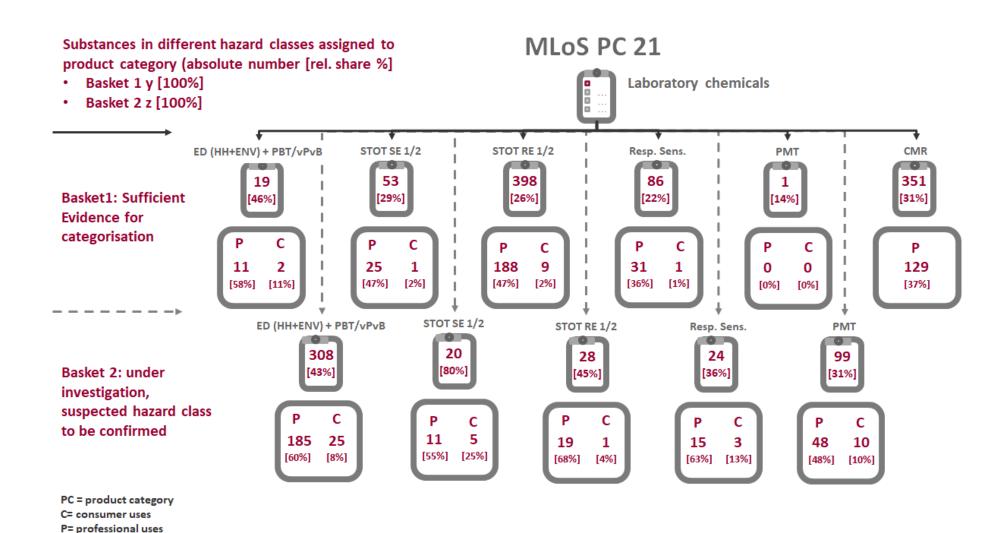




4.1.3. Group 3 - PC 21: Laboratory chemicals

PC 21 was assigned to a large number of substances in the registration dossiers. Nevertheless, the critical (manual) review of the registration data implies that the number of substances concerned could be overestimated.

In the understanding of the project team, the PC should cover substances that are used in products that are used in the laboratory context. Furthermore, products may be included here that are also used by persons who are not specially trained and that contain chemical substances (e.g. Covid rapid tests, test tubes for air pollutants etc.). In the narrower interpretation, however, this does not include substances that are merely manufactured and then subjected to quality control in the laboratory (which could be observed in the data). These substances are understood not to become a Laboratory product then. Another reason for some overestimation is that such substances should then not be referred to as laboratory chemicals. In addition, substances are also made available as standards for laboratory tests to enable their detection in analytical procedures. This would be considered a laboratory product in the narrower sense.

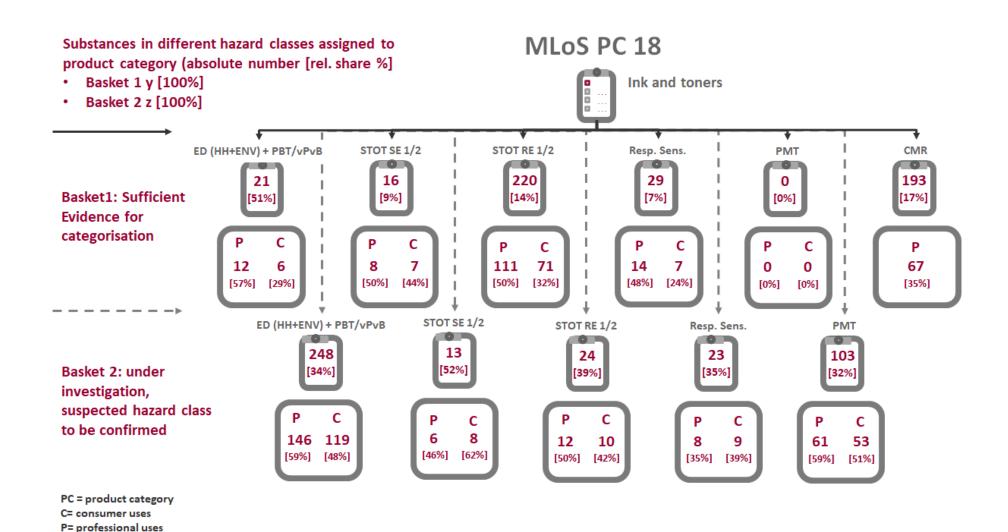


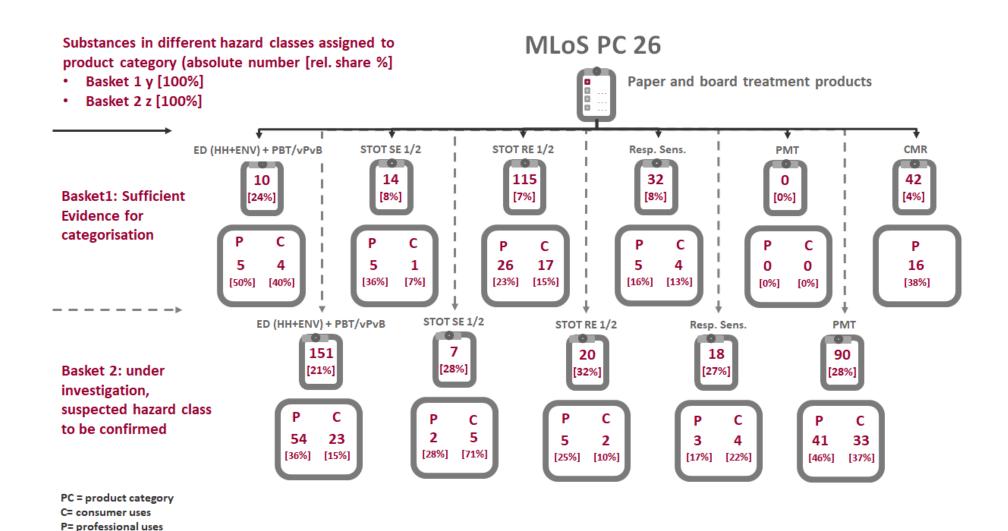
4.1.4. Group 4 - PC 34: Textile dyes, and impregnating products and PC 23: Leather treatment products, PC 18: Ink and toners

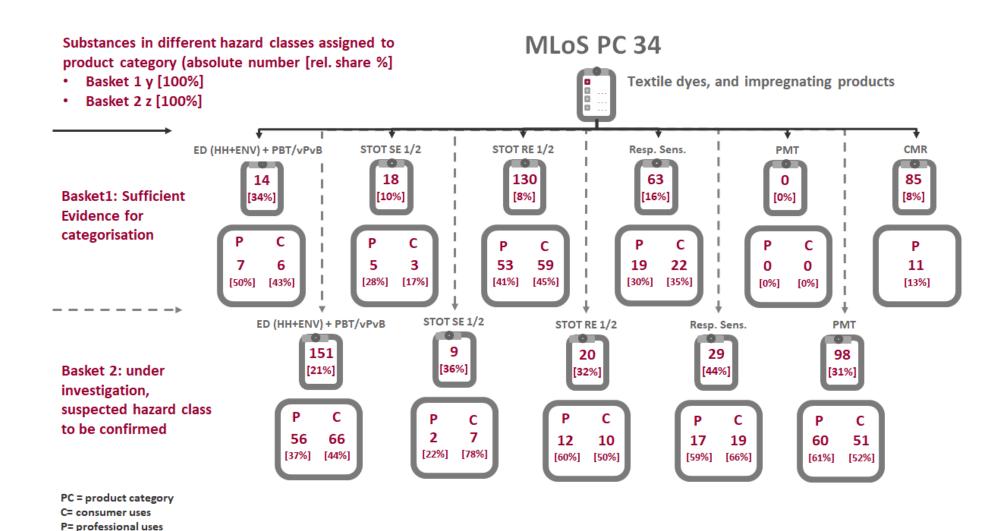
Although the PCs do not have the highest numbers overall in terms of the number of substances, substances are often assigned to these PCs in the same registration dossiers and therefore group.

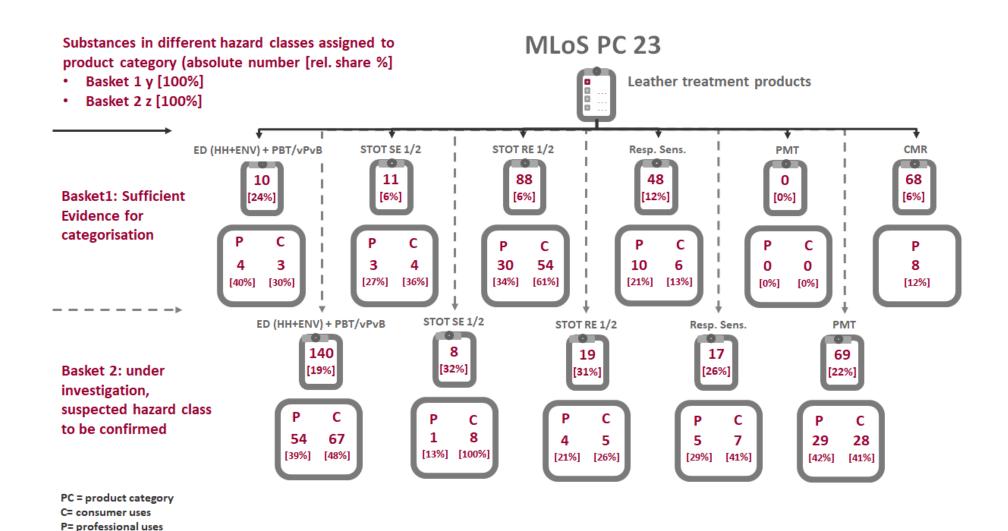
In contrast to PC 1, professional use for substances and mixtures is mainly assumed here (this does not mean no consumer products exist). Substances are also either released or coupled to a product matrix (unlike additives that are introduced into a matrix.

This group will also discuss the relevance for articles produced with these substances. This includes clothing, home textiles and leather products (e.g. furniture, car seats, shoes) as well as paper products (printed matter).







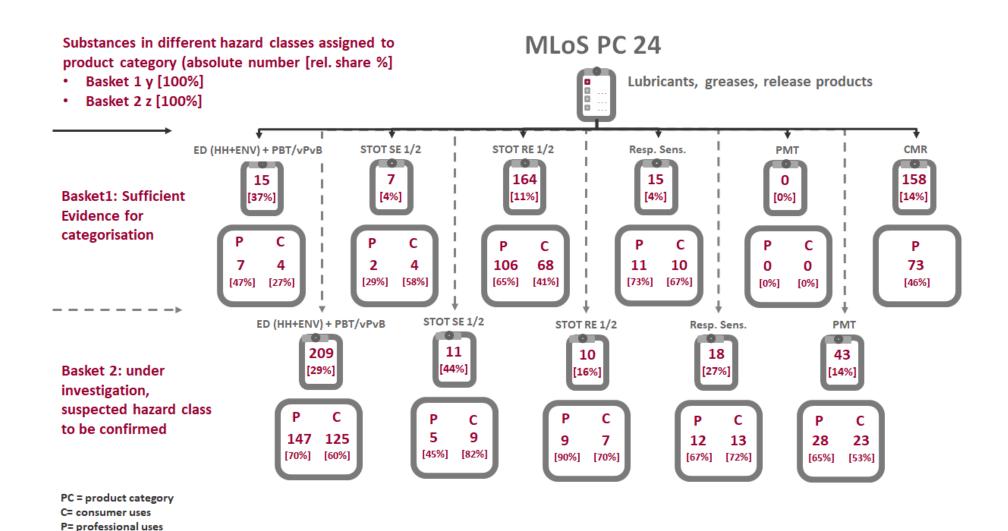


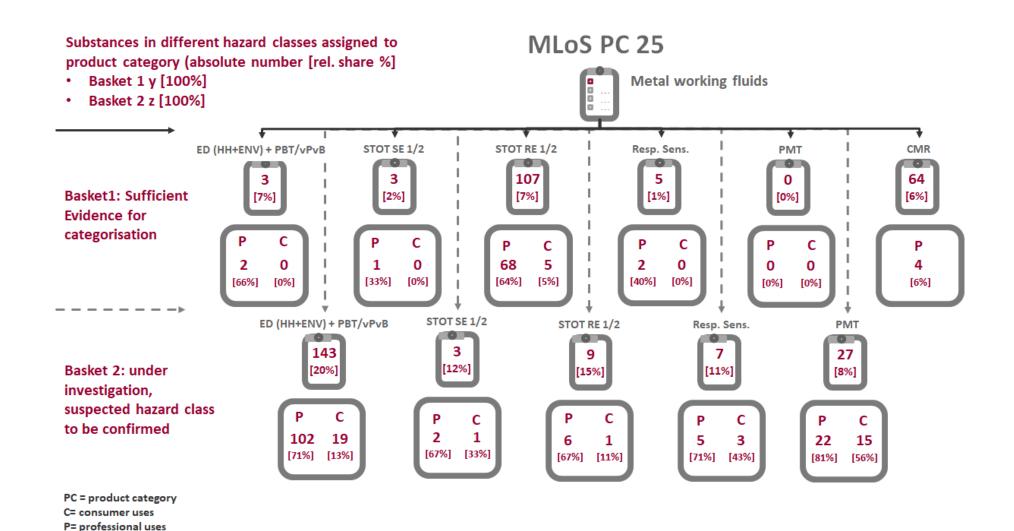
4.1.5. Group 5 - PC 24: Lubricants, greases, release products and PC 25: Metal working fluids

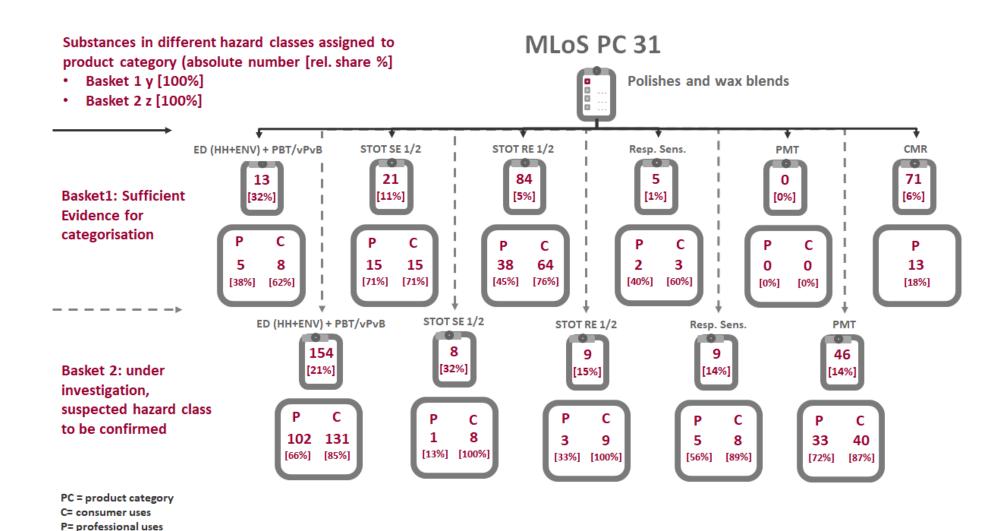
Additional PC to be discussed

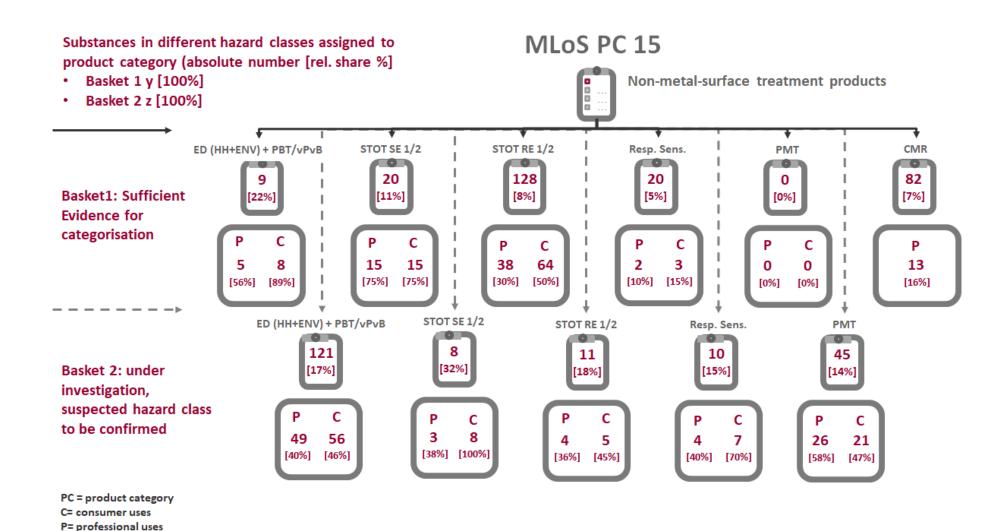
- PC 31: Polishes and wax blends
- PC 15: Non-metal-surface treatment products
- PC 16: Heat transfer fluids
- PC 17: Hydraulic fluids
- PC 13: Fuels
- PC 14: Metal surface treatment products
- PC 38: Welding and soldering products, flux products

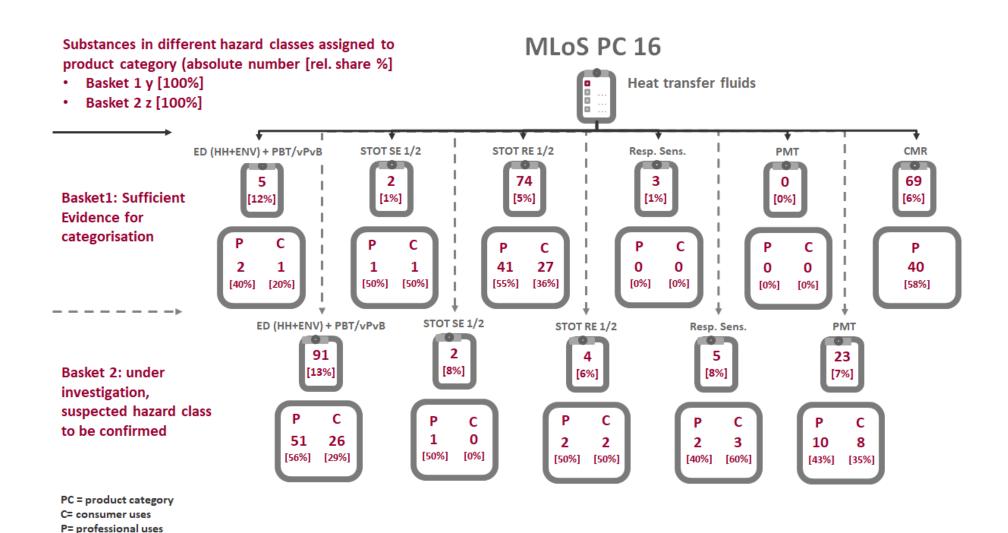
PC 24 contains products that are used in both the consumer and professional sectors. Together with the other assigned PCs, it groups with the other PC when assessing the registration data. In addition, it can be assumed that comparably large quantities are used here to a relevant extent.



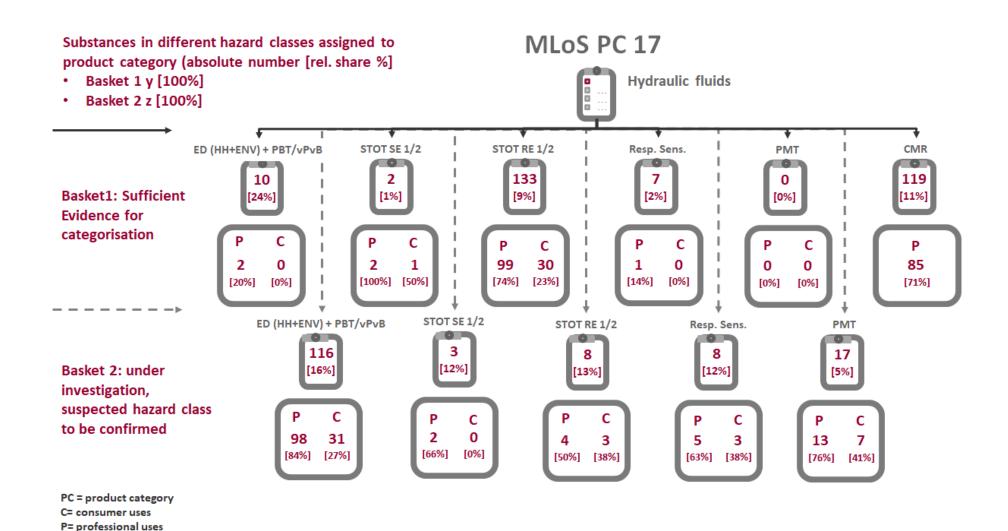


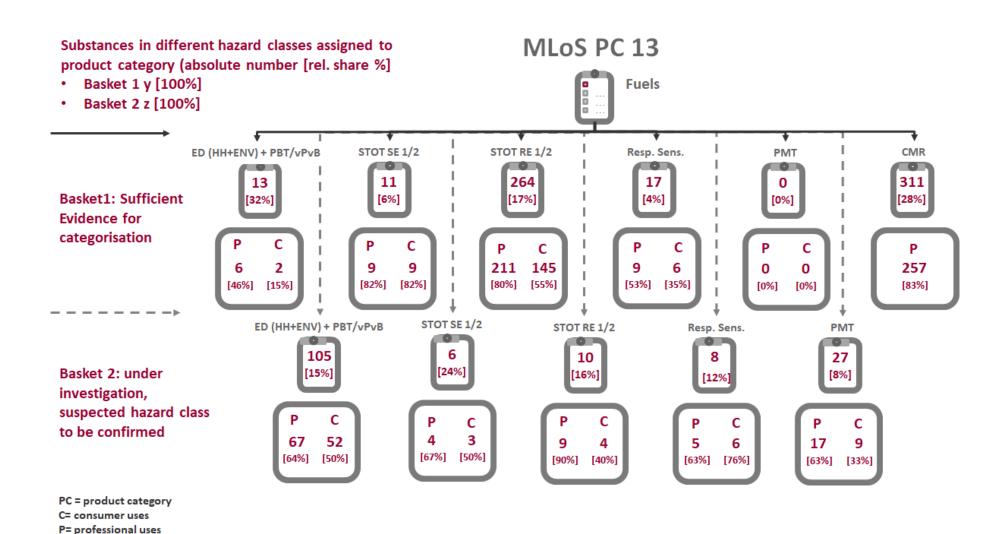


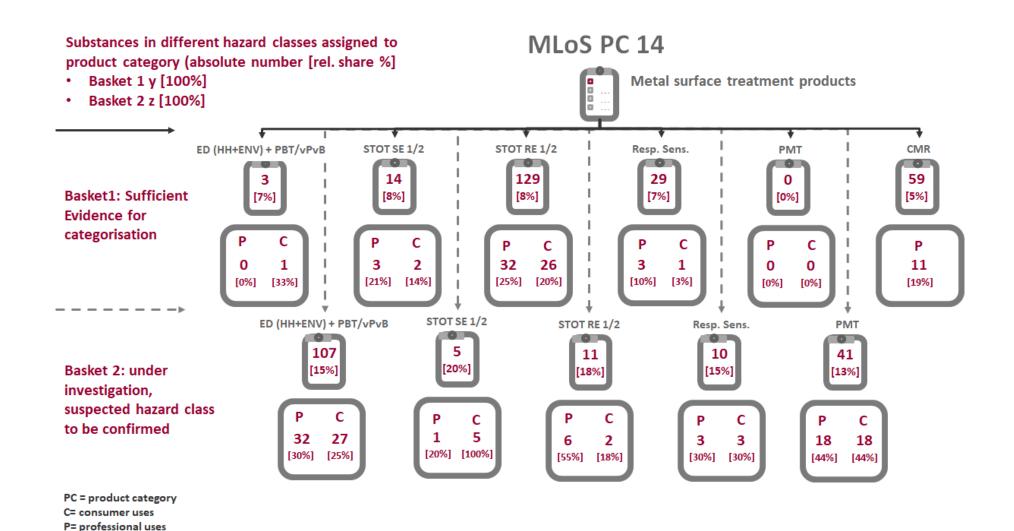


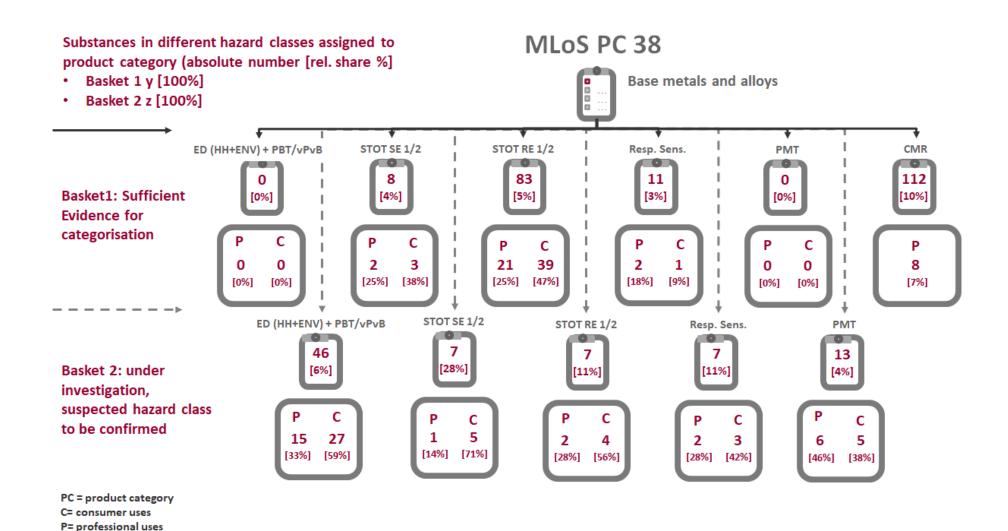


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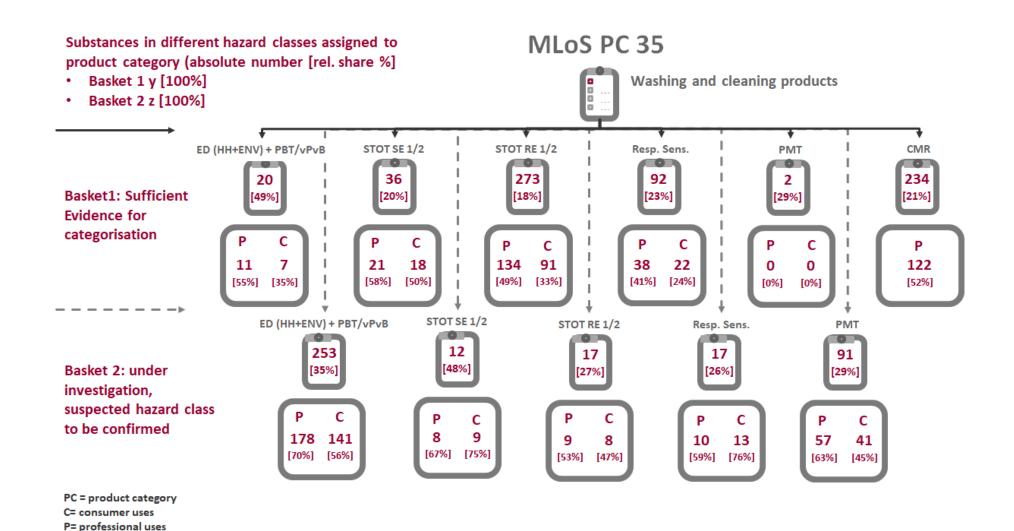


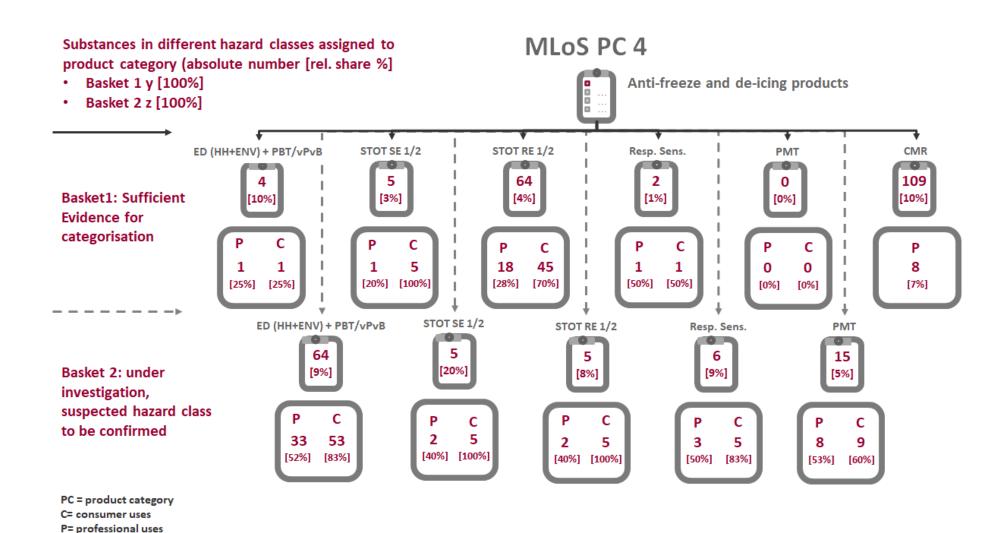
4.1.6. Group 6 - PC 35: Washing and cleaning products

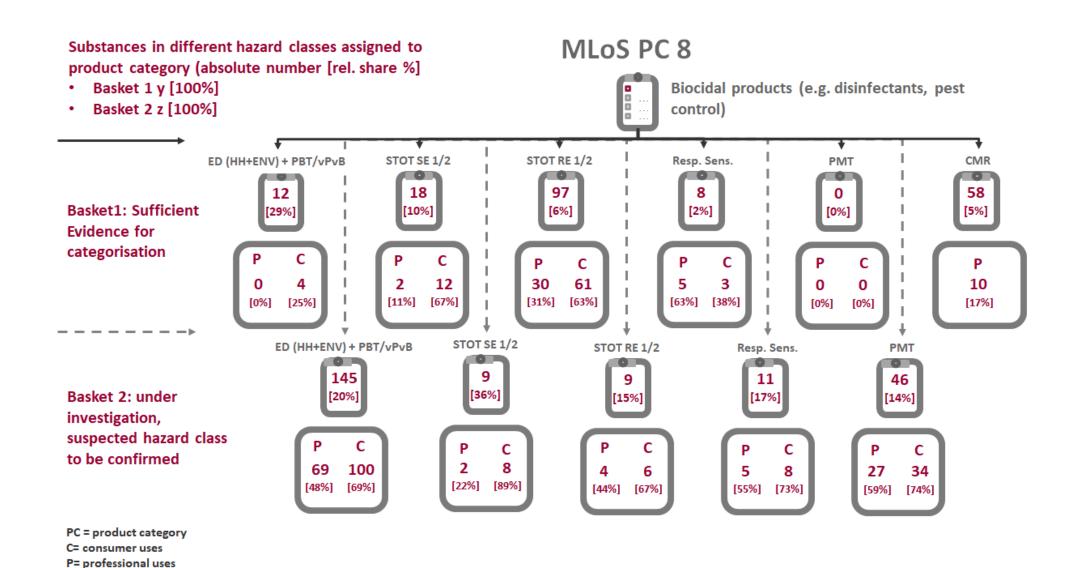
Additional PC to be discussed

- PC 4: Anti-freeze and de-icing products
- PC 8: Biocidal products (e.g. disinfectants, pest control)

PC 35 contains products that are used in both the consumer and professional sectors. Together with the other assigned PCs, it groups with the other PC when assessing the registration data.







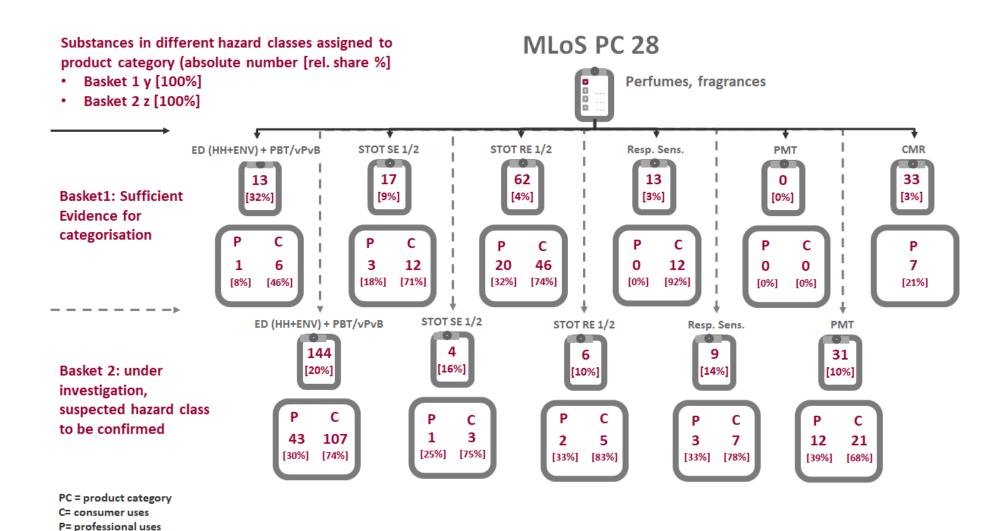
4.1.7. Group 7 - PC 39: Cosmetics, personal care products

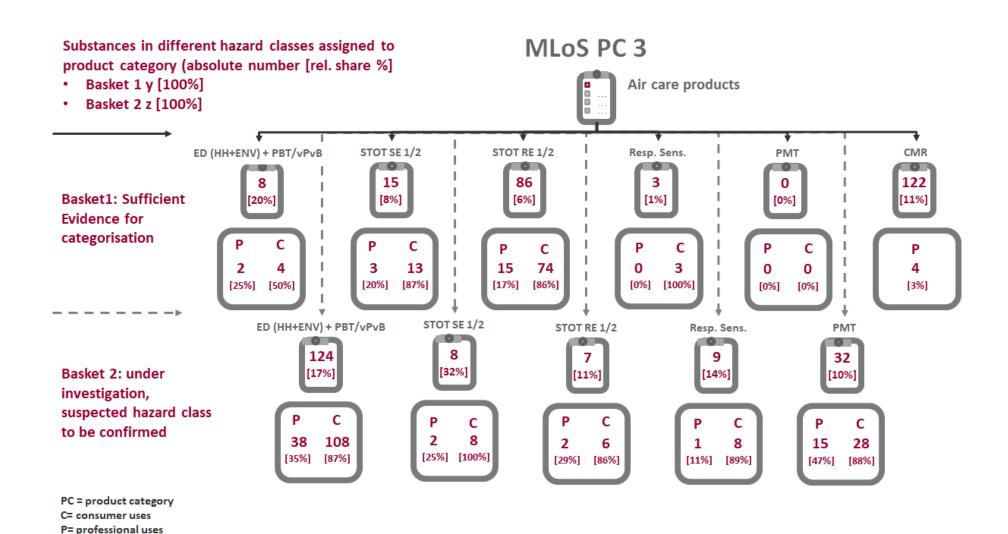
Additional PC to be discussed

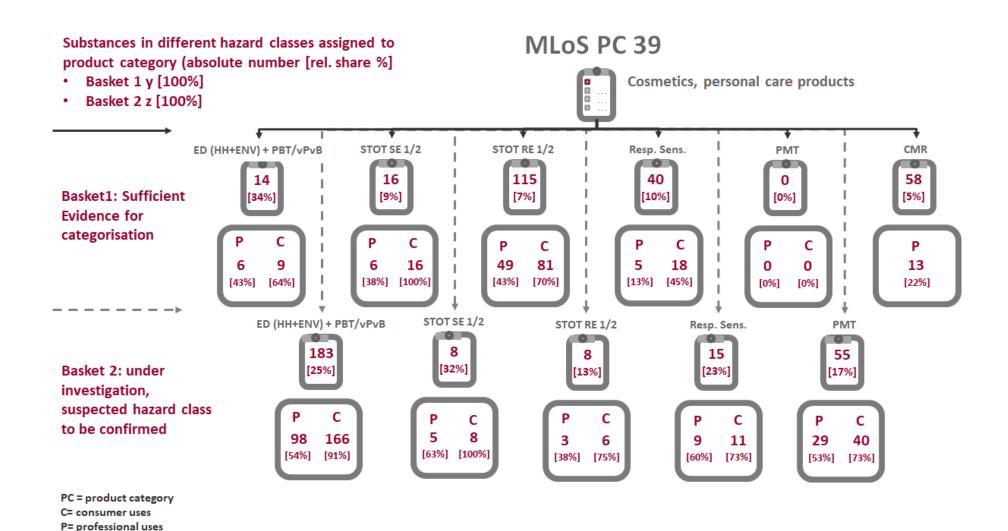
- PC 28: Perfumes, fragrances
- PC 3: Air care products
- PC 29: Pharmaceuticals

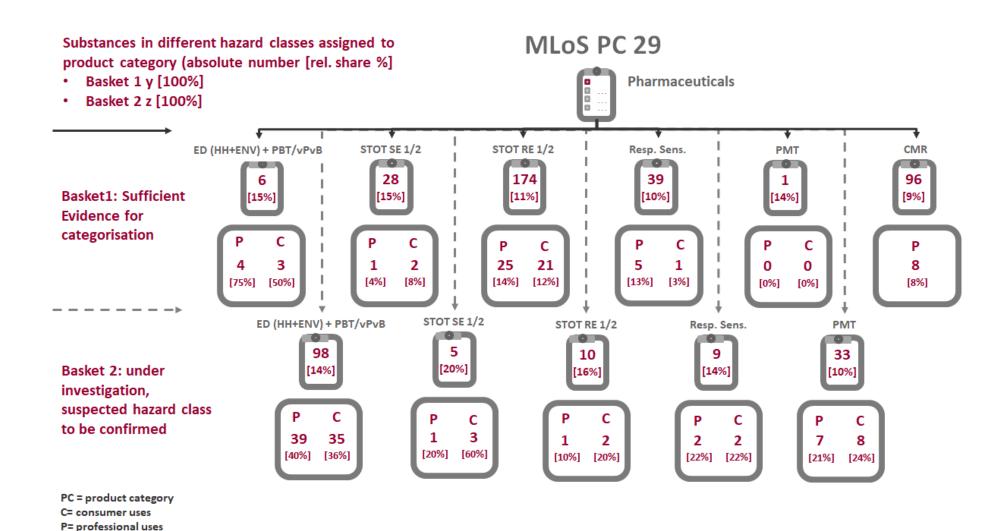
PC 39 and the other PCs contain products that are used in both the consumer and professional sectors.

All products are intended to be used directly in contact with humans. Human health risk would usually not be targeted under REACH but within the product specific regulation, REACH would only apply to environmental risks. Nevertheless, cosmetics is given special focus since this product group is in the scope of the revision of the cosmetics regulation in the near future. Therefore, also human health effects are included in the use map to provide a basis for this activity (this corresponds to the Terms of Reference for the project and is an extra outcome of Task 2). It should be noted that the data presented comes from REACH registration dossiers, as for the other PCs, and has not been cross-checked with other sector-specific databases, e.g. CosIng.









4.1.8. Group 8 – *Complex articles*

A basic problem of the use map based on the registration data is to develop an understanding of which articles the substances end up in when production chains are very complex and branched. Therefore, this group wants to consider the needs of such market actors.

The group will address which functionalities of substances are particularly important for complex products, so that:

- a) the production processes are feasible (focus here on professional activities, i.e. not those that take place in fixed installations and on a large scale, but rather have a manual, craftsman like character);
- b) certain functional or safety-relevant properties of the article are maintained and which are defined in the supply chain (requirement is defined by producer of complex article and communicated to supplier e.g. presence of a certain flame retardant in one part);
- c) The substance is not introduced in the part by the producer of the complex article (such activities are addressed as use of mixtures in other groups and should be addressed there).

This can cover automotive producers, electric and electronic producers, medical devises etc.

It is worth noting that we are aware that this group will need to focus more on the identification of gaps as the current knowledge from the registration dossier is very limited. For the specific challenges and sectors identified in the discussion of the workshop the following consultation exercises will be added.

5. NEXT STEPS

The present workshop is a part of a larger stakeholder engagement strategy for the purpose of this project. In the next months, stakeholders will be able to further contribute to this study by taking a part in:

- The ongoing Public Consultation (closing date 15 of April)
- Participating in a survey (expected to be launched before the end of March)
- Participating in a round of interviews (from the beginning of April),
- Participating in the next project workshop, tentatively scheduled for 7th of June 2022.

The input gathered at the workshop will serve in the assessment of impacts of extension of the generic risk approach, that will be carried out between April and June 2022.