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Choosing the best for preventing the worst: A structured analysis of the selection of risk management options in REACH restriction dossiers

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ABSTRACT

Under the European chemicals legislation REACH (Registration, Evaluation, Authorisation and restriction of CHemicals), the use of chemicals posing an unacceptable risk for humans and the environment can be restricted. This requires that regulatory authorities of EU member states, or the European Chemicals Agency on request of the Commission, submit a restriction proposal in which they suggest one or multiple risk management options (RMOs). The options are recommended to be evaluated in a socio-economic analysis (SEA) using defined criteria. This paper explores the drivers of the selection of the preferred RMO in 32 restriction dossiers. Applying principal component analysis reveals that the selection of the preferred RMO, and the evaluation of possible trade-offs between alternative RMOs, is determined by criteria characterizing a measure's effectiveness and practicality, in particular its risk reduction capacity (*R*) and proportionality. A logistic regression using quantitative estimates provided in SEA suggests that the probability for an RMO to be selected is the higher the higher its *R* and the lower the costs of the restriction. Based on our analysis we conclude that the selection process of RMOs in REACH restriction dossiers could be strengthened by defining a limited but unambiguous set of criteria, conducting a score-based evaluation as a default, and by defining transparent decision rules.

1. Introduction

The overall objective of the European chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of CHemicals) (REACH, EC, 2006) is "[…] to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry" (ECHA, 2019e). Under REACH, two main regulatory instruments are used for achieving this aim, authorisation and restriction. While authorisation predominantly focuses on "Substances of Very High Concern" (SVHC (ECHA, 2019a)), restriction may "[…] apply to any substance on its own, in a mixture or in an article, including those that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers"(ECHA, 2019c). Thus, substances that are restricted can be, but do not have to be, SVHC. Additionally, all registrants are required to demonstrate safe use for hazardous chemicals registered at annual production or import volumes of more than 10 tons.

A REACH restriction process can be initiated by regulatory authorities of EU member states, by the European CHemicals Agency (ECHA) either on its own initiative or on request of the European Commission (EC), or – in specific cases - by the European Commission (ECHA, 2020). Applicants have to prepare a restriction dossier following Annex XV of REACH explaining the need for restricting the production, manufacture or use of a substance at a Community-wide level, and proposing a restriction measure that is considered appropriate to reduce or eliminate the risks arising from the use of the substance on its own or in articles for human health and the environment (ECHA, 2007). Based on available (scientific) information about a substance's physico-chemical properties, hazards, exposure, risks, and uses, the dossier submitter (DS) proposes a restriction measure which has to be justified by evaluating its effectiveness, practicality and monitorability and their sub-criteria in comparison to the business-as-usual situation (called 'baseline scenario') (ECHA, 2007).

If in addition to the proposed restriction other risk management options (RMO) are available (e.g. voluntary risk management measures

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adopted by industry, other existing Community legislation, or applying for authorisation), the DS has to evaluate all measures with respect to the abovementioned criteria. To underpin the evaluation process and to facilitate the selection of the preferred option, the REACH guidance for preparing an Annex XV restriction proposal recommends conducting a socio-economic analysis (SEA), offering (quantitative) information about positive and negative impacts of the proposed restriction and, where appropriate, other RMOs (ECHA, 2007). Based on the evaluation the DS identifies the preferred restriction. This can be the initially proposed restriction, one of the alternative RMOs, or a combination of RMOs (ECHA, 2007). The restriction dossier is then reviewed by the ECHA Risk Assessment Committee (RAC) and the Socio-economic Assessment Committee (SEAC) and, if necessary, revised based on comments provided by RAC and SEAC. The final decision on the adoption of the restriction is taken by the European Commission involving EU Member States and the European Parliament (ECHA, 2020c).

Restricting dangerous chemicals is a key regulatory instrument in REACH, with important and potentially long-term implications for both producers and consumers, and the environment. Restriction measures which fail to achieve their expected goals can cause high costs to society. Obviously, the evaluation process of available restriction options, and the selection of the preferred restriction, depends on the scoping of the restriction defined by the DS, the type of information gathered by the DS, and how this information is used. Collecting this information, e.g. for conducting SEA, is time- and resource consuming. Hence, the DS must decide how much effort is worthwhile investing in a restriction dossier. Moreover, there may be trade-offs between different RMOs. For instance, a DS can evaluate RMO 1 to be highly effective. An alternative RMO 2, on the contrary, may be straightforward to implement, but is of relatively low effectiveness compared to RMO 1. Such trade-offs require a mechanism to weigh different RMOs against each other in order to enable the DS to select the preferred RMO in a coherent way. So far, however, little is known related to how preferred restriction options are identified and selected.

The overall aim of this paper is, therefore, to examine the drivers of the selection of the preferred restriction in REACH restriction dossiers. Specifically, the aim is to understand (i) if general patterns regarding the selection of the preferred restriction option can be identified, and (ii) how DSs have balanced trade-offs between RMOs and their evaluation criteria, if there are any, to arrive at an overall conclusion about the (relative) performance of a restriction option. Implications from the analysis will be summarized as recommendations.

The paper is, to the best of our knowledge, the first offering a structured analysis of the process used to choose the preferred restriction in REACH restriction dossiers. It analyses the relative influence of the evaluation criteria 'effectiveness', 'practicality' and 'monitorability' of ranking different restriction options using a Principal Component Analysis (PCA). In addition, by applying descriptive statistics and a logistic regression analysis, it is investigated whether key outcomes of the SEA, i.e. estimates of expected costs of a restriction measure and the expected risk reduction capacity, impact the selection of the preferred option. Finally, we discuss how DSs solve trade-offs between alternative RMOs by evaluating rankings of RMOs provided in restriction dossiers.

2. Materials and methods

2.1. Criteria for evaluating restriction options as suggested in REACH guidance documents

Following the provisions of REACH Annex XV and the information provided in the REACH guidance document on preparing an Annex XV restriction dossier (ECHA, 2007), the initial restriction and other RMOs have to be evaluated regarding their effectiveness, practicality and monitorability. These main criteria are further specified with different sub-criteria explained in Box 1 below.

Box 1
Base and sub-criteria for evaluating restriction options proposed in an Annex XV dossier (ECHA, 2007).

Effectiveness: Is the restriction measure targeted to the effects causing the risks?

a) *Risk reduction capacity*:
- Assessment/evaluation of a restriction option's ability to reduce exposure to a level that is considered acceptable and that allows for an adequate control of the remaining risks.
- Assessment/evaluation of the expected costs of the restriction as well as expected risks of possible alternative substances or technologies.
- Documentation of the proposed timeline for reducing exposure to an acceptable level.

b) *Proportionality*:
- Evaluation whether the proposed restriction is targeting the intended reduction of risks, cost-effective and well-balanced regarding the relationship of achieved effects to the required effort for implementation, enforcement and the time required by industry to comply with the restriction.
- Evaluation whether the restriction is compatible with existing legal frameworks.

Practicality: Can the restriction measure be operationalised?

a) *Implementability:* Actors affected by the proposed restriction should be able to practically implement the proposed restriction.
b) *Regulatory enforceability* at reasonable effort.
c) *Manageability*: The burden of implementation for the actors involved is proportional to the avoided risks.

Monitorability: Can the (intermediate) results of the restriction be monitored over time?

a) *Availability of indicators*
b) *Availability of monitoring mechanisms*
c) *Ease of monitoring* in terms of effort

Source: ECHA (2007).

2.2. Substances included in the evaluation

So far, restrictions for 70 chemicals (ECHA, 2019d) have been adopted under REACH. Of these, 38 substances (ECHA, 2019b) had already been restricted under the "Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations" (Council Directive, 1976). These chemicals were transferred to Annex XVII of REACH (the list of restricted substances) without preparing a detailed restriction dossier (EC, 2006) . The analysis addresses the 32 substances for which Annex XV restriction dossiers were prepared, and for which a final decision has already been adopted by the European Commission (ECHA, 2019b) or to which the ECHA Risk Assessment Committee (RAC) and the Socio-economic Assessment Committee (SEAC) have added their opinions. Of these, 14 are SVHC according to the DS. Relevant documents related to these restrictions (Annex XV restriction proposal, RAC and SEAC opinions, final background document) can be retrieved from the ECHA website (ECHA, 2019b).

2.3. Data analysis

2.3.1. Data sources and tools used for analysis

The analysis is based on the information provided in the final background documents, i.e. the restriction proposal prepared by the DS and amended by the opinions of RAC, and SEAC. Table 1 provides key data of the substances addressed in this paper (substance name, CAS number(s), main uses, proposed and preferred RMOs). For evaluating the proposed initial restriction and possible alternative RMOs along the criteria explained in Box 1 the DSs use different tools and/or approaches illustrated in Fig. 1. In all 32 dossiers the restriction option(s) are evaluated qualitatively. In addition to this, 15 dossiers offer a criteria matrix, where DSs assign an evaluation score for the base and the sub-criteria (Box 1) for each restriction option. The scores can take the form of "+"/"-" or "low"/"medium"/"high". The relative relevance of the base and the sub-criteria is analyzed using a PCA (see section 2.3.3 and Supplementary Information (SI), Table S1 for further details). In addition to the scoring of the evaluation criteria, an SEA can assess different types of positive and negative impacts (e.g. human health impact, environmental impacts, economic impacts) (ECHA, 2007). Ten of 32 dossiers conduct a quantitative SEA. In 21 dossiers the impacts from restriction options are evaluated by means of a qualitative (explorative) analysis only (note that the dossier "Cadmium in artist paints" does not contain an SEA, which is reflected in the shorter beam in the third level of Fig. 1).

2.3.2. Frequency plot analysis

For the dossiers not containing a criteria matrix (17 of 32) the criteria that the DS considered most relevant for selecting the RMO are examined by means of a frequency- or barplot (Fig. 2).

2.3.3. Principal component analysis

The aim of the PCA is to examine (cor)relations between the sub-criteria (i.e. variables or eigenvectors in PCA terminology) and the sub-criteria and RMOs (i.e. observations in PCA terminology), respectively. More specifically, the PCA reduces the multidimensional dataset comprising of variables and observations but keeps trends and patterns in the dataset (Lever et al., 2017). This is achieved by transforming the m-dimensional dataset into a two-dimensional plot that covers the variance of the m-dimensional data as far as possible (see SI, section S1 for further details).

For conducting a PCA the qualitative scores provided in the criteria matrix of a restriction dossier are transformed into numerical score values ranging from 1 to 4 (see Table S1, substances in Table 1 that entered the PCA are written in *italics*). This allows aggregating score values across the evaluation criteria "risk reduction capacity" (*R*), "proportionality" (*P*), "implementability" (*I*), "enforceability" (*E*), "manageability" (*Ma*), and "monitorability" (*Mo*). In the PCA these criteria are referred to as variables (*x*). Note that in most restriction dossiers the sub-criteria subsumed under *Mo* (Box 1) are not explicitly listed in the criteria matrices and therefore omitted in the analysis. As a consequence, the list of variables reduces from eight to six.

The two main principal components (PCs) identified with the PCA, and their relation to the variables and the RMOs suggested in a dossier are shown in biplots (Fig. 3). Principal component 1 (Fig. 3, lower x-axis) discriminates according to the sum of the values of each RMO (Table S1) and PC2 (Fig. 3, left y-axis) according the values of each RMO with respect to each of the six/four criteria (Fig. 3A/B). Note that the numbers of the lower x- and the left y-axis denote the scores of the PCA, not the score values of the RMOs as shown in Table S1. The upper x-axis and the right y-axis belong to the Eigenvectors and their values are listed in Table S3. Observations outside the circles indicate outliers.

2.3.4. Logistic regression

A key purpose of an SEA is to facilitate the comparison of the proposed initial restriction and other RMOs by offering a systematic and detailed analysis of expected positive and negative impacts of either option. Thus, an SEA offers supportive information about a restriction option's effectiveness, practicality and monitorability (ECHA, 2008). For a detailed analysis of the methodological approaches applied in SEA, and a comparison of quantitative SEA outcomes see Gabbert and Hilber (2020).

To explore the influence of the SEA on the selection of a specific RMO we run a logistic regression. Seven out of 10 restriction dossiers (Fig. 1) offer a quantitative assessment of the risk reduction capacity and the expected costs of more than one restriction option and could therefore be included in the analysis. While the costs of a restriction, comprising compliance and implementation costs, are usually expressed in monetary terms, different metrics can be used for quantifying risk reduction capacity, e.g. the amount of emissions reduced per year, the number of health incidences avoided, or the change of the percentage of the population at risk. To make estimates of the risk reduction capacity comparable across dossiers they are transformed into percentage values (i.e. percentage of risk reduction relative to the baseline scenario).

In the logistic regression the selection of an RMO (yes/no) is the dependent variable, taking the values 1 or 0, respectively. Quantitative cost estimates and the risk reduction capacity (%) serve as independent variables. Where ranges of cost estimates, of the risk reduction capacity, or of other variables are provided in the dossiers (logistic regression) mean values are used (Table S5). Please note that we do not evaluate the uncertainty of the data presented in the dossiers.

The logistic regression is based on the following model (see SI, section S2 for further details):

$$log\left(\frac{p(Y_i=1)}{1-p(Y_i=1)}\right) = a + b_1x_1 + b_2x_2 + \varepsilon, \quad (1)$$

with the notation presented in Table 2 below:

Table 1
General information about substances included in the evaluation. The submission date refers to the date on the final background document. The preferred (selected) risk management option (RMO) is written in **bold**. "***Proposed***" is mentioned in **bold** and *italic* if this RMO differs from the selected option. Risk management options not evaluated by the DS were not included in the table. Substances feeding into the principal component analysis (n = 15) are in *italic*. RMOs that entered the logistic regression ($n = 23$) are underlined.

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
1	Dimethylfumarate (DMFu) 14/06/2011	624-49-7	Furniture, clothing, shoes etc. to prevent moulds that may deteriorate the product during transport and storage. DMFu is added either in little sachets that are put to the product or sprayed directly onto it	**RMO1: DMFu shall not be used in articles in concentration >0.1 mg/kg. Articles containing DMFu >0.1 mg/kg shall not be placed on the market.** RMO2: Regulate manufacturing of DMFu. RMO3: Restrict import. RMO4: Restrict use of DMFu in mixtures (mixtures containing DMFu for non-biocidal purpose, e.g. as a desiccant, are not covered by the Biocidal Products Directive).	Risks related to DMFu containing products are managed by the EU Decision 2009/251/EC, prolonged by Commission Decision 2010/153/EU. The restriction will turn permanent the business as usual situation (EU Decision, 2009/251/EC). (The French Competent Authority, 2011).
2	Mercury (Hg) 15/09/2011	7439-97-6	Thermometers (incl. hygrometers), sphygmomanometers (i.e. blood pressure meters), barometers, manometers (incl. tensiometers), metering devices for the determination of softening point, pycnometers, strain gauges used with plethysmographs	**RMO1: Restrictions with derogations are suggested for Hg measuring devices (see cell to the left) in professional and industrial uses.**	
3	*Phenylmercury compounds (Phenyl-Hg)* 15/09/2011	Phenylhg acetate 62-38-4 phenylhg propionate 103-27-5 phenylhg 2-ethylhexanoate 13302-00-6 Phenylhg octanoate 13864-38-5 Phenylhg neodecanoate 26545-49-3	Polyurethane coatings, adhesives, sealants and elastomers	**PHEHg1: All five phenyl-Hg compounds would be covered by restriction (manufacture, placing on the market, use as substances or in mixtures; and placing on the market of articles containing the substances) and adopted until 2012. Hg concentration in a mixture or in any sample from one article shall not exceed 0.01% weight by weight (w/w) Hg. Phase out within 5 y.** PHEHg2: Restriction adopted within 2 y. PHEHg3: Phase-out over a shorter period (3 y; alternative option introduced by the risk assessment committee (RAC)).	The dossier submitter's choice (RMO1) was taken for further analysis. RMO3 was not considered in the criteria matrix of the dossier. Instead, an authorization under REACH (PHEHgauth in Table S1) was included in the evaluation and thus in the PCA.
4	*Lead (Pb) in jewellery* 25/09/2011	7439-92-1	Jewellery, jewellery coatings	Pbjewel1: Restriction on the use and placing on the market of fashion jewellery based on the Pb migration rate. **Pbjewel2: Restriction on the use and placing on the market of jewellery (fashion and precious) based on the Pb migration rate** Pbjewel3: Restriction on the use and placing on the market of fashion jewellery based on the Pb migration rate and the Pb content. Pbjewel4: Ban on Pb and its compounds in fashion jewellery which is used and placed on the market. Pbjewel5: Ban on Pb and its compounds in some fashion jewellery which are used and	No Pb concentration limit RMO7: (the two steps approach initially suggested by RAC and SEAC): Two-steps option for Restriction on the use and placing on the market of jewellery (fashion and precious) based on the Pb content and (under conditions) on Pb migration rate.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				placed on the market. Pbjewel6**:** Restriction on the use and placing on the market of fashion jewellery based on the Pb content.	
5	*Chromium VI compounds(CrVI)* 19/03/2012	n.a.[c]	Tanning processes	**CrVI1: Restriction of the Cr (VI) of articles of leather which may come into direct and prolonged (see remark) contact with the human skin.** CrVI2: Restriction of Cr (VI) of all articles of leather. CrVI3: Restriction of total Cr (CrIII and CrVI) content of leather.	RAC proposed: Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain Cr (VI) in concentrations ≥3 mg/kg (0,0003%) Cr (VI) of the total dry weight of the leather.
6	*Phthalates (Phth)* 05/12/2012	Diisobutyl phthalate (DIBP) 84-69-5 Dibutyl phthalate (DBP) 84-74-2 Benzyl butyl phthalate (BBP) 85-68-7 Bis(2-ehtylhexyl)phthalate (DEHP) 117-81-7	Softener of PVC and other plastics, in dispersions, paints and varnishes, carpets, tablecloths, curtains, bags, brief-/suitcases, electric & electronic equipment (EEE), water beds, air mattresses, wallpaper, tapestry, footwear, bathing equipment, balls, etc.	**Phth1: Ban for placing on the market of all articles intended for indoor use or articles that may come in contact with the skin or mucous membranes if the articles contain one or more of the four phthalates DEHP, DBP, BBP and DIBP in concentrations >0.1% of any plasticised parts.** Phth **Phth1a:** Restriction on the placing on the market of all articles which contain one or more of the four phthalates DEHP, DBB, BBP or DIBP in a concentration ≥0.1% (w/w) of any plasticised material. Exemptions will apply for articles solely used outdoors (including storage) Phth2: Wider scope - restriction on all articles. Phth3: Narrower scope – restriction on identified groups of articles. Phth4: Migration based restriction. Phth5 Consumer articles and construction material	Toys containing DEHP, DBP and BBP are covered (banned) by entry 51 (ECHA, 2019b). That's why this restriction specifically considers DIBP in toys. RMO1a and 5 not evaluated by the DS.
7	*Nonylphenol varieties incl. ethoxylated nonylphenol (NP/NPE)* 09/09/2014	n.a	Textile and leather auxiliaries, additives in concrete, plastics, food packaging, photographic chemicals, lab chemicals	**NP1: Limit value of 100 mg NP/NPE per kg textile with a transitional period of 5 y.** NP2: Limit value 20–50 mg NP/NPE per kg textile with a transitional period of 5 y.	
8	Cadmium (Cd) in paints 25/11/2014	7440-43-9	(Antifouling) paints, TARIC codes [3208] [3209]	**RMO1: Restriction on placing on the market with a concentration limit value of 0.01%.** RMO2: Restriction on placing on the market with a concentration limit of 0.01%, with a derogation for copper-based anti-fouling paint with a concentration limit of 0.0175%.	Entry 24 (Danish Competent Authority for REACH, 2012) only prohibits the use of Cd in paints. The restriction dossier extents the prohibition to the placing on the market. The adding of a numerical concentration limit makes the monitoring and enforcement clearer and more efficient.
9	*Pb and its compounds in consumer articles (Pb cons)* 07/04/2014	7439-92-1	Metal alloys, pigments/dyes, as pure metal and as stabiliser in plastic	**Pb_cons1: Restriction of Pb content in articles that can be mouthed.** Pb_cons2: Restriction of Pb migration in articles that can be mouthed. Pb_cons3: Restriction of Pb content in (all accessible parts of) clothes, accessories and shoes.	Pb concentration (expressed as metal) in the article ≥0.05% by weight.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				Pb_cons4: Restriction of Pb migration in all articles.	
10	Cd in artists' paints 09/03/2015	7440-43-9	Oil, acrylic, water colours, gouache, pure pigments, TARIC codes [3212] [3213]	RMO1: Complete ban of Cd based artists' paints (with a transitional period of 1 y). **RMO2: Ban on Cd based artists' paints, with an exemption for restoration and maintenance of historical pieces of art.**	The dossier extents restriction to artist's paints as these are not covered by the above and entry 24.
11	*Chrysotile (CHRY)* 09/03/2015	12001-29-5 132207-32-0	Cells for electrolysis, production of chlorine	CHRYa1: CHRY free substitute is viable to Dow and tested during phase out from 2015-25; Continuing the current derogation with time-limited exemptions of national legislations (10 y). Exemptions can be renewed. CHRYa2: CHRY free substitute is viable to Dow and tested during phase out from 2015-25; **Derogation with a fixed end date (2025) specified in the entry. Exemptions can principally be extended via a regular Annex XV restriction procedure** CHRYa3: CHRY free substitute is viable to Dow and tested during phase out from 2015-25; Limitation of the amount of CHRY used. CHRYb1: CHRY free substitute is NOT viable to Dow and tested during phase out from 2015-25; Continuing the current derogation with time-limited exemptions of national legislations (10 y). Exemptions can be renewed. CHRYb2: CHRY free substitute is NOT viable to Dow and tested during phase out from 2015-25; Derogation with a fixed end date (2025) specified in the entry. Exemptions can principally be extended via a regular Annex XV restriction procedure **CHRYb3:** CHRY free substitute is NOT viable to Dow and tested during phase out from 2015-25; Limitation of the amount of CHRY used.	Due to the focus on the two electrolysis installations currently relying on this exemption (of entry 6 that covers six types of asbestos fibres already (ECHA, 2019b)) – Aarhus Karlshamn Sweden AB (AAK) and Dow in Stade, Germany – ECHA has consulted with these two companies in 2013. Given the phase out of CHRY in AAK, the assessment therefore focuses on impacts related to Dow.
12	p-*dichlorobenzene (DCB)* 11/04/2015	106-46-7	Lab chemical, carrier for textile dyes, crop protection and paper industry, pharmaceuticals, agrochemicals, leather and fabrics, cosmetics, toilet blocks, air fresheners, moth repellents, toilet limescale removers, corrosion inhibitors, odour control agents, embalming powder, chemicals of grinding wheels, monomer for the production of polyphenylenesulphide	DCB1: Restriction of the substance for consumer use (96 t/y amount placed on market). DCB2: Restriction of the substance for professional use (713 t/y amount placed on market). **DCB3: Restriction of the substance for both consumer and professional use (809 t/y amount placed on market).**	
13	*Ammonium salts (NH_4)* 19/06/2015	ammonium sulphate 7783-20-2 ammonium dihydrogenorthophosphate 7722-76-1 diammonium	Cellulose insulation materials	**$NH_4$1: Restriction on ammonia emission.** **$NH_4$2**: Composition-based restriction. RMO3: Authorisation. **$NH_4$4**: Construction Products	$NH_4$3 not included in PCA.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
		hydrogenorthophosphate 7783-28-0		Regulation (EU/305/2011). **$NH_4$5**: Providing information to retailers and consumers through labelling. **$NH_4$6**: Voluntary agreement from the industry.	
14	Decabromodiphenyl ether (DecaBDE) 09/10/2015	1163-19-5	Additive flame retardant in furniture, textiles, in transport, construction and mining sector	**RMO0: Overall restriction on manufacturing, use, and placing on the market of decaBDE and mixtures containing decaBDE (incl. also second-hand market, recycling, aviation sector and RoHS (restriction of hazardous substances) Directive). Exemption: electrical and electronic equipment falling under the RoHS Directive.** RMO1: Restriction on plastics used indoors. RMO2: Restriction on plastics used outdoors. RMO3: Restriction on textiles used indoors. RMO4: Restriction on textiles used outdoors. RMO5: Restriction on production. RMO6: Restriction on placing on the market. RMO7: Impose conditions on waste mgmt.	The proposed RMO0 is a combination of option 1, 2, 3 and 4 (or options 5 + 6).
15	*N-methylpyrrolidone (NMP)* 25/11/2015	872-50-4	Solvent and cleaning agent in petrochemical, agricultural, pharmaceutical, electronics and textile industries	NMP1: Total ban of NMP (all risk characterization ratios (RCR) for workers are 0). NMP2: Restriction on the use of NMP in coatings **NMP3: Exposure limit value (at the level of the harmonised detected no effect level (DNEL)) of 5 mg/m^3.** RMO3aa: Harmonised DNEL of 10 mg/m^3. RMO3b: Exposure limit value of 20 mg/m^3. NMP4: Authorisation.	In line with RAC's conclusions on the DNEL, an additional limit value of 10 mg/m^3 (NMP3) has been added to the analysis as an adjustment to RMO3a.
16	Perfluorooctanoic acid (PFOA) 04/12/2015	335-67-1	Pans and other cooking utiles, photographic applications, semiconductor industry, textiles and leather, firefighting foams, in paper, paints, inks	**RMO1a: Phase out of PFOA and PFOA-related substances within 18 months.** ***RMO1b (proposed): Phase out of PFOA and PFOA-related substances* >18 months *including possible exemptions*.**	PFOA including its salts and any other substance having linear or branched perfluoroheptyl derivatives.
17	*Bisphenol-A (BPA)* 04/12/2015	80-05-7	Dye developer in point-of-sales tickets, receipts, self-adhesive labels, lottery tickets, fax paper	**BPA1: Limitation of BPA in thermal paper to <0.02%. The transitional period proposed for the entry into force is 3 y.** BPA2: Limitation of the migration of BPA in thermal paper (idea: coat thermal paper to avoid absorption by contact)	Since 2017 BPA is considered to be an SVHC (ECHA, 2020a), but it was not at the time of the Commission's decision on restriction.
18	Methanol (MeOH) 11/03/2016	67-56-1	Paints, varnishes, windshield washer fluids, antifreezes, adhesives, de-icers and cleaning agents	**RMO1: MeOH shall not be placed on the market for supply to the general public as a constituent of windshield washing fluids (incl. windshield defrosters) in concentration ≥3.0% by**	

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				weight and as an additive to denaturated alcohol (methylated spirit, denaturated alcohol, brennspiritus) in concentrations ≥3.0% by weight.	
19	Octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane (D4/D5) 06/09/2016	D4: 556-67-2 D5: 541-02-6	Shampoos, shower-gels, make-up removing products	**RMO1a: Restriction on placing on the market and use of wash-off personal care products (PCPs) containing >0.1% w/w D4 or D5 (phase-out 2 y).** RMO1b: Restriction on placing on the market and use of wash-off PCPs containing >0.1% w/w D4 or D5 (phase-out 5 y). RMO2: Registration under REACH (update to the existing registration dossier). RMO3: REACH Authorisation RMO4: Regulation (EC) No 850/2004 on persistent organic pollutants. RMO5: Water Framework Directive (WFD, 2000/60/EC) provides a framework for the protection of inland surface waters, transitional waters, coastal water and groundwater. RMO6: Volunteer measures: Industry has set up a volunteer product stewardship arrangement.	
20	(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (TDFA) 15/06/2017	n.a.	Water proof articles (textiles, leather, tiles, ceramic), provides water and oil repellence to surfaces such as stone, glass and enamels	**RMO1: Ban of mixtures containing TDFAs and organic solvent in spray products (aerosol dispensers, pump and trigger sprays and mixtures marketed for spray application) for consumer use in a concentration of TDFAs ≥2 ppb by weight.** RMO2: Risk-based ban of mixtures containing TDFAs and organic solvent in spray products for consumer use in a concentration of TDFAs ≥800 ppb. To address that the TDFAs may be present as impurities. RMO3: Ban of mixtures containing TDFAs and organic solvent in aerosol dispensers for consumer use in a concentration of TDFAs ≥2 ppb by weight.	
21	Phthalates 15/09/2017	DIBP 84-69-5 DBP 84-74-2 BBP 85-68-7 DEHP 117-81-7	Articles including mainly flooring material, coated fabrics and paper, recreational gear & equipment, mattresses, footwear, office supplies and equipment, other articles moulded from or coated with plastic	**RMO1: Restriction on articles containing the four phthalates for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes.** RMO2: Restriction of placing on the market & EU article production.	Restriction builds upon the earlier proposal (see above), but provides additional information and assessments on hazard, and new information on exposure and the benefits of a restriction, additional data on costs and trends in substitution. Furthermore, the restriction accounts for previous discussions on a better targeting of the proposal and the adjustment of the baseline.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
22	Diisocyanates 15/03/2018	n.a.	Polyurethanes (PU), PU foams assembly foams (e.g. insulation panels), foundry cores (casting), coating materials (paints, lacquers, varnishes), adhesives and glues, elastomers, sealants, pre-polymers in chemical synthesis, engineering plastics, PU fibres	**RMO1: Implementation of restrictive conditions of the use described in the proposed Appendix on "Trainings and Measures" (mostly affected are workers at high risk) and in the Appendix on "Exemptions" (mostly affected are workers at low risk).** RMO2: Only implementation of restrictive conditions of use according to proposed appendix on "Trainings and Measures". (All workers need to be trained, without an option for exemption.) RMO3: Complete ban of the use of diisocyanates and diisocyanates based products.	May be identified as SVHC under REACH, Art. 57(f).... However, the SVHC/ authorisation route was not chosen as a restriction is more appropriate due to the extreme complexity of the supply chain where diisocyanates are used and the unlikely substitution of it.
23	Pb-polymers or copolymers of vinyl chloride (Pb-PVC) 15/03/2018	n.a.	Stabilisers in window profiles, fittings, pipes and tubes, rolling shutters and gutters, wires and cables, roofing and flooring tiles, etc.	**RMO1: Restriction on Pb and its compounds in all PVC articles with a concentration limit of 0.1%, with derogations for:** **- Specific PVC articles (building and construction applications) containing recycled PVC with a concentration of 1.0% for a period of 15 y,** **- PVC-silica separators in Pb acid batteries for a period of 10 y,** **- Articles covered under existing EU legislation,** **- Second-hand articles.** RMO2: A restriction on Pb and its compounds in all PVC articles with a concentration limit of 0.1% for all articles. (This option will not provide any specific derogations from the proposed restriction.) RMO3: A restriction on Pb and its compounds in all PVC articles with a concentration limit between 0.1 and 0.5% which will apply for all PVC articles (based on both virgin and PVC material) with the following derogations: - PVC-silica separators in Pb acid batteries for a period of 10 y, - Articles covered under existing EU legislation - Second-hand articles.	
24	Pb in gunshot 15/03/2018	7439-92-1	Small pellets, called gunshot or a solid projectile called a slug that contain Pb	**RMO0: Pb shall not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. Pb gunshot shall not be in the possession of persons in wetlands.** RMO1: Restriction on the placing on the market and use of Pb gunshot. RMO2: Restriction on the use of Pb gunshot for all hunting. RMO3: Restriction on the use of Pb gunshot for all hunting of birds or hunting of	

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				waterfowl (e.g. ducks, geese and swans). RMO4: Restriction on the use of Pb shot in or over Ramsar sites and/or SPAs within the Natura 2000 network. RMO5: Phased approach to implementing a restriction on the use of Pb gunshot in wetlands. RMO6: No additional restriction on the use of Pb gunshot.	
25	N, N-*Dimethylformamide (DMF)* 05/10/2018	68-12-2	For the production of • fine chemicals • pharmaceuticals • polymers • textiles, leather, and fur For the manufacture of • non-metallic mineral products • perfumes and fragrances In the petrolchemistry and as laboratory agent	DMF1: Total ban of the substance **DMF2: Restriction of the uses of DMF on its own or in mixtures in a concentration ≥0.3%. An 8 h TWA (time-weighted average) exposure must remain <3.2 mg/m^3 and the dermal exposure shall be < 0.79 mg/(kg*day).** DMF3: Authorisation	
26	Cobalt salts (Co-salts) 19/12/2018	Cobalt sulphate 10124-43-3 Cobalt dichloride 7646-79-9 Cobalt dinitrate 10141-05-6 Cobalt carbonate 513-79-1 Cobalt di(acetate) 71-48-7	Manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc.	**RMO1: Exposure limit (to an excess lifetime cancer risk level)** a: 10 µg Co/m^3 (ELR (excess life cancer risk level) 0.01) b: 1 µg Co/m^3 (ELR 0.001) c: 0.1 µg Co/m^3 (ELR 0.0001) **d: 0.01 µg Co/m^3 (ELR 0.00001)** RMO2: Technical requirement a: mechanical ventilation b: local exhaust ventilation (LEV) c: closed systems or partially enclosed systems with LEV d: closed systems with integrated LEV	
27	*Octamethylcyclotetrasiloxane (D4)* *Decamethylcyclopentasiloxane (D5)* *Dodecamethylcyclohexasiloxane (D6),* *D4/D5/D6 (all are cyclic volatile methyl siloxanes reported as cVMS)* 20/03/2019	D4 556-67-2 D5 541-02-6 D6 540-97-6	cVMS used in cosmetic leave-on and wash-off products (the latter mainly related to D6), dry cleaning (only for professional use), detergent, household care, and vehicle maintenance products (professional and consumer use), pharmaceuticals (professional and consumer use), medical devices, head-lice treatment (consumer use) and cleaning of art and antiques (professional use)	**cVMS1: Restriction on placing cVMS on the market (concentration limit of 0.1% w/w) in consumer and professional products including justified derogations, and transitional periods of different durations to avoid disproportionate socio-economic impacts.** **cVMS**2: Restriction on the placing on the market of all products intended for consumer and professional use containing cVMS, with no derogations, nor concentration limit. **cVMS**3: As RMO1 but with a concentration limit of 0.01% w/w. **cVMS**4: Restriction on placing cVMS on the market in selected product forms (e.g. only mixtures). **cVMS**5: Restriction on the placing cVMS on the market in selected sectors or categories of products (e.g. cosmetics, or even specific categories of cosmetics). **cVMS**6: Restriction on the	Since the restriction for D4 and D5 (see above) in wash-off cosmetic products, which entered into force on 30/1/2018 and applies from 31/01/2020, the identified uses for the substances have been revised.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				placing cVMS on the market unless specific product labelling conditions were met.	
28	Formaldehyde and formaldehyde releasers 20/03/2019	50-00-0	Formaldehyde is mostly used as a chemical intermediate to manufacture formaldehyde based-resins and other chemicals and has limited applications as biocide. Formaldehyde releasers are primarily used in wood-based products such as furniture, wall coverings, foams and textiles from which formaldehyde can be released during use.	RMO1: Full ban of formaldehyde releasing articles and mixtures. RMO2: Concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures. RMO3: Emission limit for wood-based panels consistent with formaldehyde emission class E1. **RMO4: Emission limit of ≥0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1for all articles releasing formaldehyde.**	Formaldehyde release from the consumer use of mixtures for non-biocidal use is adequately controlled and the use of formaldehyde in mixtures for consumer use in concentration ≥0.1% is prohibited according to Commission Regulation (EU) 2018/675
29	Perfluorohexane sulfonic acid, its salts and PFHxS-related substances (PFHxS) 13/06/2019	n.a.	PFHxS is used in firefighting foams, water- and stain-protective coatings, in textiles, carpets, leather, paper, intermediate feedstocks, electronics and semiconductors, etc.	**RMO1: PFHxS shall not be manufactured or placed on the market as substances on their own, in the production of or placed on the market in another substance, as a constituent, a mixture, an article or any parts thereof, in a concentration equal to or above 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances.** RMO2: A restriction on the production of PFHxS during manufacture of perfluorooctane sulfonic acid (PFOS) or perfluorobutane sulfonic acid (PFBS) RMO3: A requirement to remove all fire-fighting foams from stocks which exceed the 25 ppb limit for mixtures	
30	*Skin sensitising substances (SSS)* 14/07/2019	n.a.	• Functional (or effect) chemicals: Remain in the finished textile article to give it certain properties, e.g. dyestuffs and crease resisting agents. • Auxiliary (or process) chemicals: Not intended to remain in the finished textile article but may remain as an impurity. These substances are necessary for the textile production process to work, e. g. solvents and softeners. • Degradation products: No function in the finished article or in the production process but present as residues or degradation products, e.g. formaldehyde released from certain resins and arylamines from certain azo dyes.	**SSS1: All substances classified as Skin Sens. 1/1A/1B in Annex VI to Regulation (EC) No 1272/2008, as well as a list of disperse dyes without harmonised classification but with skin sensitising properties, are covered. Concentration limits based on a combination of data-driven and preventive-driven approaches are set.** SSS2: All substances classified as Skin Sens. Category 1/1A/1B in Annex VI to Regulation (EC) No 1272/2008, but without a list of additional disperse dye substances of concern. SSS3: Narrow list of substances, including disperse dyes only (with harmonised classification as Skin Sens. according to the "Classification, Labelling and Packaging" (CLP) regulation as well as the ones listed in	Entry 47 of the REACH Annex XVII related to chromium VI (see above) in leather also belongs to SSS RMO1b (not further assessed): Comparable to RMO1a, however it includes additional conditions of labelling requirements.

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Table 1 (*continued*)

No	Substance[a] (abbreviation), Submission date	CAS Nr.	Main uses	Risk management option(s) (RMO)[b]	Comment/remark
				the list of substances of concern).	
31	Calcium cyanamide ($CaCN_2$) 19/07/2019	156-62-7	Fertiliser	RMO1: Ban of powder form (inhalation concern). RMO2: Detailed regulation of acceptable agricultural production methods: Max. kg/ha limit; mandatory adoption of buffer zones; limits for broadcasting on bare land; mandatory incorporation of fertiliser; other. RMO3: Utilisation of existing Common Agricultural Policy (CAP) measures e.g. mandatory adoption of cross-compliance measures where $CaCN_2$ is used. **RMO4: total ban of $CaCN_2$ use.**	
32	*Intentionally added microplastics (microplastics)* 22/08/2019	n.a.	• Agriculture and horticulture (in fertilisers and plant protection products) • Cosmetic products (both rinse-off and leave-on products) • Detergents and maintenance products (e.g. as fragrance encapsulation in laundry • Detergents and fabric softeners as well as in products for cleaning and polishing) • Paints, coatings and inks (in professional and consumer uses) • Chemicals used in the oil and gas sector • Construction material • Medicinal products • Medical devices • Food supplements and medical food	**Micro1: Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 shall not be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration ≥0.01% w/w** **Micro2**: Restriction of placing on the market and use of all mixtures or articles intended for consumer and professional use containing intentionally added microplastics (≥0.01% w/w) (without derogations (except for industrial uses or to avoid double regulation) or transitional periods) **Micro3**: Labelling of all mixtures or articles for consumer and professional use containing intentionally added microplastics (≥0.01% w/w) with the phrase 'contains microplastics > 0.01%' **Micro4**: Restriction on the placing on the market and use of specifically identified mixtures for consumer and professional use containing intentionally added microbeads (≥0.01% w/w) (with derogations) **Micro5**: Restriction on the placing on the market and use of all mixtures or articles for consumer and professional use containing intentionally added microplastics as an abrasive (microbeads, ≥ 0.01% w/w) (without derogations) **Micro6**: Restriction on the use of microplastics in consumer and professional products (≥0.01% w/w) with a size range of 1 μm ≤ x ≤ 1 mm **Micro7**: Restriction on thermoform and thermoset organic polymer 'plastics' only (>0.01% w/w)	

[a]Source (ECHA, 2020b).
[b]Risk management options that were included in the PCA are listed with a substance acronym and numbered consecutively. All other risk management options were abbreviated as RMO and listed consecutively following the order of RMOs in the restriction dossier.
[c]n.a.: not available.

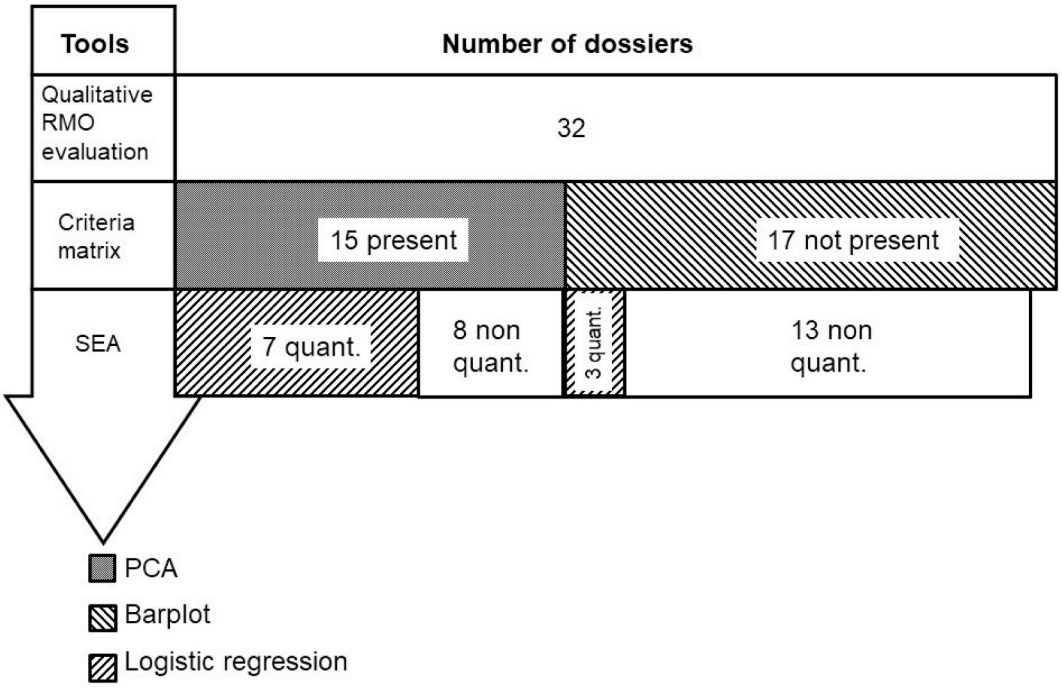

Fig. 1. Tools for analysing the selection process of the preferred risk management option (RMO). Fifteen out of 32 dossiers compiled a criteria matrix, ten dossiers quantified one or more RMOs in a socio-economic analysis (SEA). Cadmium in paints did not contain an SEA, indicated by the shorter bar.

Table 2
Explanation of the variables in eq. (1).

Variable	Interpretation
p	Probability
Y	Risk management option (RMO); min. probability 0, max. probability 1
i	Substance
a	Intercept
x_1	Compliance costs incl. substitution costs
x_2	Risk reduction capacity
b_1, b_2	Slopes of x_1 and x_2
ε	Residues

3. Results

3.1. Results of the barplot analysis

The barplot in Fig. 2 shows how frequently a certain evaluation criterion in the restriction dossiers was mentioned. This frequency can be regarded a first indication of the relative relevance of a particular criterion. The criteria proportionality and risk reduction capacity, which both characterise the effectiveness of a restriction option, were most frequently mentioned.

3.2. Results of the PCA

The outcomes of the PCA are depicted in the biplots (Fig. 3A and B). Generally, the long arrows, being the eigenvectors, indicate a high influence of the variables/sub-criteria on the selection of the preferred restriction option. Eigenvectors that are close to each other are assumed to correlate positively, eigenvectors pointing in opposite directions correlate negatively, and those positioned orthogonally to each other are assumed to have no correlation. In panel A of Fig. 3, observations (i.e. a particular RMO, characterised by the substance abbreviation in combination with a number corresponding to Tables 1 and S1) that are close to each other are scored similarly by the DS, whereas observations which lie apart are evaluated differently. Specifically, manageability and proportionality show a high correlation ($r = 0.61$), implying that a restriction option with a high manageability often also scored high in proportionality and vice versa (Table S2). In contrast, we find that a high risk reduction capacity is not correlated with enforceability ($r = 0.04$) or implementability ($r = -0.19$). After this first evaluation the dimensions are reduced (panel B in Fig. 3). In particular, values for manageability are removed from the dataset due to the high correlation with proportionality. Furthermore, values for monitorability were removed due to their low representativeness, which is indicated by a short arrow. The latter also holds for manageability (Fig. 3A). Since variables with a low representativeness contribute little to the overall variance of the data (section S1), they are not relevant for differentiating the RMOs of a substance.

In the second PCA, considering only risk reduction capacity, proportionality, enforceability, and implementability, PC1 covers 43% of the overall variance and PC2 38% (Fig. 3B and Table S3). Hence, the dimension reduction increased the variance of PC1 by 4% (43%–39%) and of PC2 by 12% (38%–26%, Fig. 3A/B). The cut-off of PC1 for the

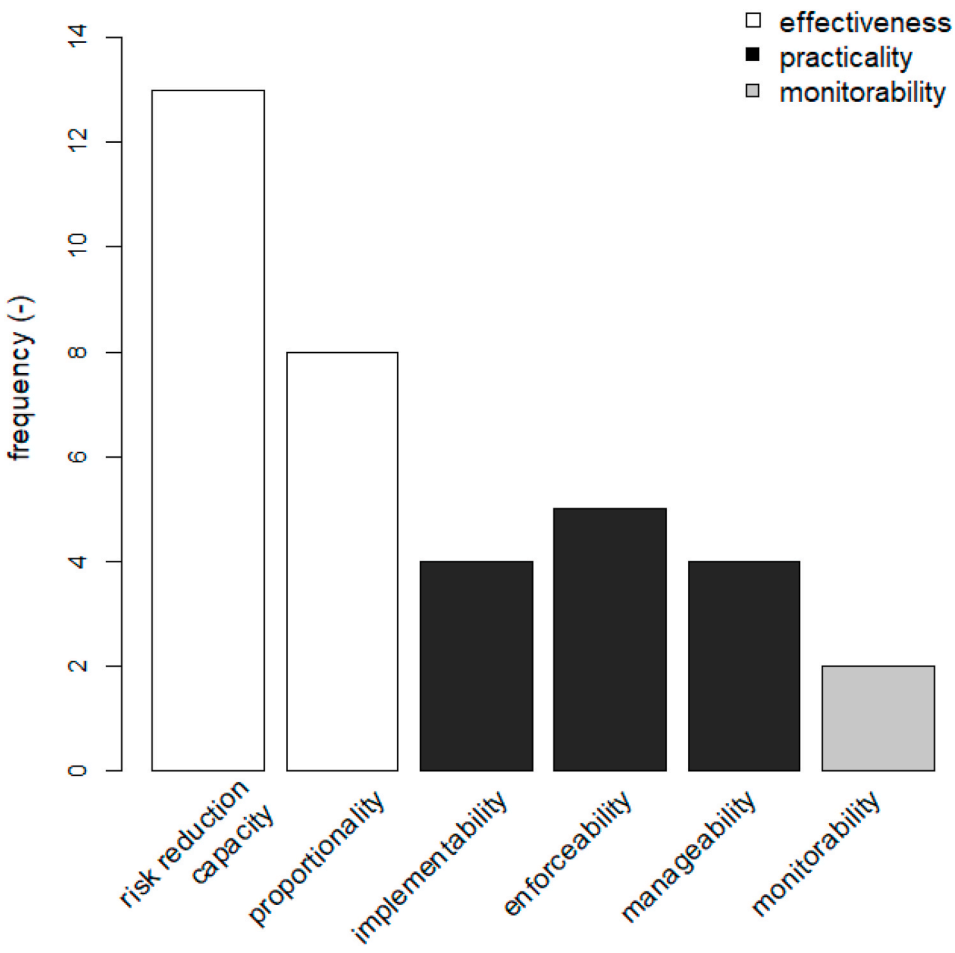

Fig. 2. Frequency of naming different criteria for evaluating restriction options in 17 REACH restriction dossiers, addressing the substances perfluorooctanoic acid, decabromodiphenyl ether, (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives, octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane, cadmium in paints, cadmium in artists' paints, phthalates 2017, dimethylfumarate, mercury, methanol, diisocyanates, lead-polymers or copolymers of vinyl chloride, lead in gunshot, cobalt salts, formaldehyde, perfluorohexane sulfonic acid, and microplastics (Table 1). Main evaluation categories are indicated with grayscales.

aggregate score value assigned to risk reduction capacity, proportionality, enforceability, and implementability is 10 because RMOs with an overall aggregated score ≤10 (Table S1) are placed on the left side of the biplot (Fig. 3B, vertical 0-line) and those having an aggregate score value of ≥10 on the right side. Principal component 2 shows the values of the observations in relation to the four sub-criteria (risk reduction capacity, proportionality, enforceability and implementability, horizontal line). For instance, restriction options 1 and 4 of the dossier on NH_4 ($NH_4$1, $NH_4$4) are positioned between the two pairs risk reduction capacity/proportionality (*R/P*) and enforceability/implementability (*I/E*) because they were assigned the maximum score values in all four criteria (16 for risk reduction capacity, proportionality, implementability and enforceability, and 24 and 23 for all six sub-criteria, respectively, see Table S1). In contrast, option 2 of NH_4 ($NH_4$2) has low values in enforceability and implementability (2, 2, Table S1) and is thus located farthest away from enforceability and implementability and relatively closer to risk reduction capacity/proportionality (4, 3). In the space between the arrows for risk reduction capacity/proportionality (*R/P*) and enforceability/implementability (*I/E*) are those RMOs with aggregate score values for all sub-criteria ≥14 and thus those RMOs that were selected by the DS (Table S1, column 6).

3.3. Results of the logistic regression

Seven dossiers (Fig. 1) apply an SEA to the proposed and to at least one alternative restriction option and could therefore be included in the logistic regression. From these dossiers 23 entries providing quantitative information on a restriction option's risk reduction capacity and compliance costs are fed into the logistic regression (Table 1, RMOs of substances included in the model are underlined, values are listed in Table S5). The results illustrate that the probability of an RMO to be selected (estimated slopes indicated in Table S4) is the higher the lower expected costs (compliance and substitution costs) and the higher risk reduction capacity. These results are, however, not significant. The model's probability estimates of eq. (1) and the entries are plotted in Fig. 4, which is designed as a zoomed plot due to risk reduction capacity levels starting at 50% and of costs ≤200 million €/y (a full scale plot is provided in Fig. S1). The probabilities are depicted as gray contour lines.

4. Discussion

The barplot analysis, referring to 17 out of 32 dossiers (Fig. 2), points to a high relevance of the criterion 'risk reduction capacity', followed by 'proportionality'. Since the barplot analysis is based on textual analysis it can only provide a first indication of an evaluation criterion's relevance for selecting an RMO. Results revealed from the PCA (including 15 dossiers) show that the arrows of risk reduction capacity, proportionality, enforceability, and implementability are equally long and, thus, risk reduction capacity/proportionality are of equal relevance as enforceability/implementability (Fig. 3A/B). Moreover, they have a high variance, despite the higher aggregate values (sum) of enforceability/implementability in Table S1. Hence, the four criteria contribute equally to the variance of the data. Furthermore, both figures show more observations for risk reduction capacity/proportionality (bottom half Fig. 3A and upper half, Fig. 3B) than for enforceability/implementability.

It is obvious from Figs. 2 and 3A that monitorability (Box 1) is of minor importance for the selection of an RMO. A possible explanation is that DSs implicitly include aspects related to monitorability such as, for instance, a concentration limit or a ban, in their evaluation of

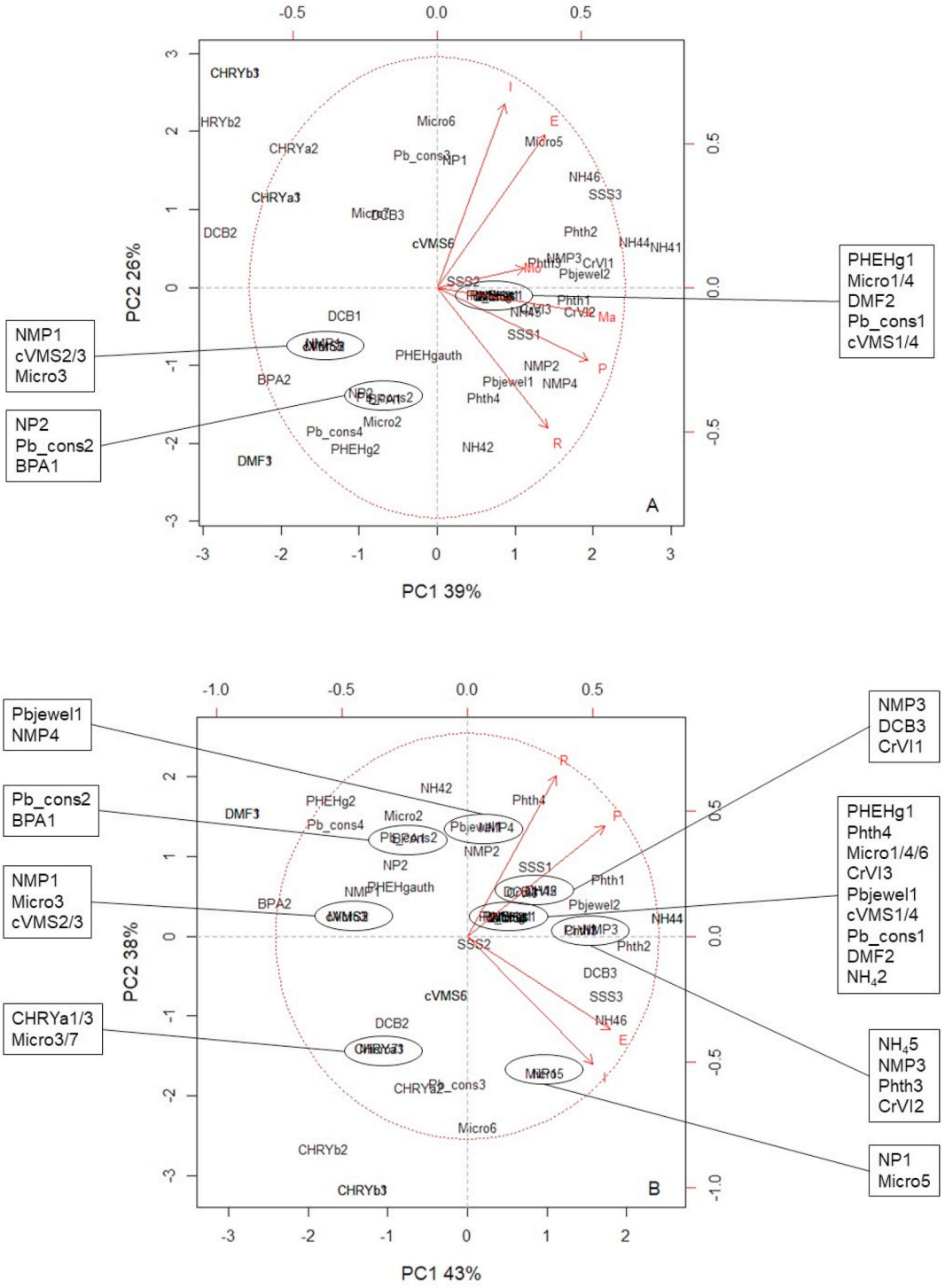

Fig. 3. Biplots depicting the first two principal components (PC) derived by a PC analysis (PCA) based on values assigned to RMOs (Table S1). Principal component 1 (PC1, scores on the lower x-axis) discriminates according the total values and PC2 (scores on the left y-axis) according the criteria values (Table S1). Substances outside the red circle are outliers. The eigenvectors (red arrows) denote the variables that indicate the evaluation criteria manageability (*Ma*), implementability (*I*), enforceability (*E*), risk reduction capacity (*R*), proportionality (*P*), and monitorability (*Mo*). The upper x- and the right y-axis refer to the Eigenvectors (Table S3 shows the values of the eigenvectors of panel B) and the lower x- and left y-axis show the scores of PC1 and PC2, respectively. The abbreviations of the observations correspond to the substance-specific RMOs for dichlorobenzene [DCB], chrysotile [CHRY], nonylphenol [NP] and NP varieties, bisphenol-A [BPA], phenylmercury [PHEHg], N-methylpyrrolidone [NMP], ammonium salts [NH4], chromium VI [CrVI] compounds, phthalates ([Phth], dossier from 2012), lead (Pb) in jewellery [Pbjewel], Pb in consumer articles [Pb], *N, N*-dimethylformamide [DMF], octamethylcyclotetrasiloxane (D4) decamethylcyclopentasiloxane (D5) dodecamethylcyclohexasiloxane (D6) [cVMS or D4/D5/D6], skin sensitising substances [SSS], and microplastics [micropl] (Table 1 and Table S1). Where observations overlap, we have added boxes with the RMO abbreviations to the left and the right of the biplots. Panel A shows the PCA before, panel B after the dimension reduction.

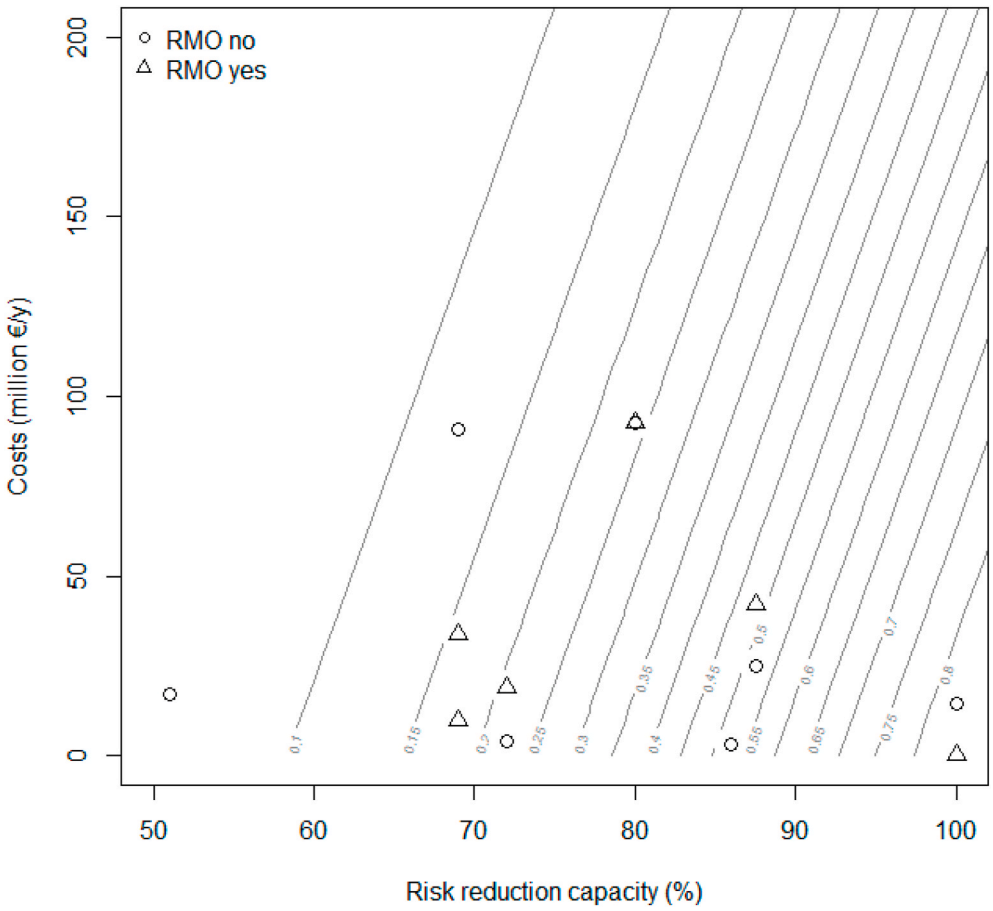

Fig. 4. Logistic regression model of seven substances (dichlorobenzene, octamethylcyclotetra- and decamethylcyclopentasiloxane, phenylmercury, *N*-methylpyrrolidone, chromium VI, lead in consumer articles, cobalt salts) depicted in a zoomed-in contour plot (full scale contour plot provided in Fig. S1). The gray lines indicate the probability that a risk management option (RMO) will be proposed in dependence of the costs (million €/year) and of the risk reduction capacity (%). Circles indicate that an RMO was rejected. Triangles indicate that an RMO was selected. Values that entered the model are provided in Table S5.

practicality (thus enforceability, implementability, manageability). Furthermore, the ECHA (2007) guidance for an Annex XV restriction dossiers defines monitorability rather vaguely as being "[…] understood widely […]" and prescribes the monitoring as "[…] measuring the relevant emission and/or exposure levels". The SEA Guidance on Socio-Economic Analysis for Restrictions, ECHA (2008), states that "[…] it must be possible to monitor the results of the implementation […]". This could, basically, be achieved by defining concentration limits or by proclaiming a ban, which are often key outcomes of a restriction procedure (Table S5).

The analysis of the qualitative scores assigned to RMOs shows that, generally, the restriction option receiving the highest total score value (last column, Table S1) is selected. Trade-offs between criteria exist for RMOs evaluated in the dossiers on Phth (RMO1-2), NMP (RMO2-4), SSS (RMO1/3), microplastics (RMO1/4/5), and cVMS (D4/5/6, RMO1/4). Here, alternative RMOs had identical or even higher aggregate scores than the preferred restriction option (Table S1, bold numbers). Looking into, for example, the restriction dossier on Phth, the DS preferred RMO 1 with a higher effectiveness score over RMO 2 having a higher practicality score (Table S1). This reflects that the DS attaches higher priority to economic criteria. The dossiers on SSS, microplastics, and cVMS are the most recent dossiers on our list (Table 1). In these, the criteria matrix contained a mixture of base and sub-criteria. In the dossiers on SSS and microplastics, effectiveness was split into risk reduction capacity and proportionality, but practicality and monitorability were evaluated as a cluster. The dossier on cVMS, to the contrary, evaluated the three base criteria effectiveness, practicality and monitorability without further distinguishing them into sub-criteria (see Box 1 in section 2.1). The submitter of the restriction dossier on SSS concluded that RMO 3 (i.e. a restriction applying to a narrower list of substances) performs best according to the aggregate score, which dominates scores assigned to RMOs 1 and 2 in several criteria. However, RMO 1 (i.e. a regulation of a broader list of substances) was selected. The reason is that this RMO has a higher risk reduction capacity compared to the other RMOs. A similar pattern can be observed in the balancing of trade-offs between restriction options in the dossier on microplastics and cVMS. This indicates that, overall, DSs tend to assign a higher relevance to the classic economic criteria, i.e. those informing the effectiveness, a composite of risk reduction capacity and proportionality, of a restriction. Furthermore, in the balancing of different criteria between RMOs the DSs seems to judge procedural criteria such as implementability, manageability and monitorability to be of lower relevance than effectiveness and its subcriteria. This holds even if an RMO received higher score values in these criteria compared to other RMOs (see, e.g. NMP).

In the majority of restriction dossiers the EC adopted the selected RMOs, but also followed in several cases the opinions of the RAC and the SEAC to add modifications, for example by specifying concentration or risk limits of the substance in articles (e.g. Pb in jewellery, Pb in consumer articles, NMP, DCB), defining a different compliance or transition period (e.g. NH_4, PFOA, CrIV, DCB) and by defining derogations (e.g. Hg, PFOA, DecaBDE, see Table S6 and Gabbert and Hilber (2020) for further details). Analyzing the process of opinion formation in the RAC/SEAC committees, and the determinants steering the decision-process of the European Commission is, however, an aspect that is beyond the focus of this paper and therefore left to further research.

The results obtained from the logistic regression provide further insights into the relative importance of risk reduction capacity and proportionality. Proportionality is the criterion reflecting the economic justifiability of an RMO. It usually received high score values if compliance costs of an RMO were comparably lower than that of alternative RMOs while having a similar risk reduction capacity, which

renders an RMO proportionate. Similar findings were discussed in Brouwer et al. (2014). This is also confirmed by the results revealed from the logistic regression illustrating that the probability for selecting an RMO is the higher the lower the costs and the higher risk reduction capacity (Table S4, slope of costs (−0.004 million €/y) and risk reduction capacity (0.047%)). The influence of risk reduction capacity on the probability for an RMO to be selected is close to the significance level of 0.05 (Table S4). Likewise, Fig. 4 shows that an RMO with a risk reduction capacity <65% and costs >100 million €/y will very likely not be selected as preferred option (probability <0.15).

A possible explanation for not seeing significant model results might be the small number of entries. First, the relatively small number of quantitative entries for risk reduction capacity and costs may result from the fact that (except for the dossier on PFOA) the initially proposed restriction option was often *a priori* also the preferred option (Table 1). This indicates that in the uppermost number of restriction procedures the evaluation of RMOs was used to underpin a pre-selected option. As a consequence, a DS compiled quantitative estimates for costs and risk reduction capacity for the proposed option only but not for alternative RMOs. Second, about half of the substances were classified as SVHC, e.g. due to PBT/vPvB properties (Gabbert and Hilber, 2020). For SVHC the overall aim is to minimize the emissions and exposure to humans and the environment (REACH Annex I, section 3.2). However, DSs did usually not consider conducting a quantitative risk or even impact assessment because following REACH Annex XIII this is considered not possible with sufficient reliability (ECHA, 2014; ECHA, 2016; ECHA, 2017). Another reason for the deficiency of quantitative impact information is the lack of data and methodological approaches for assessing risks and impacts of SVHC substances (Gabbert and Hilber, 2020). As a consequence, DSs addressing SVHC often refer to previous dossiers to justify the lack of quantitative estimates, or to reason on the appropriateness of quantitative risk and cost estimates from earlier dossiers (see, for instance, the dossiers on microplastics, TDFA, Pb-PVC, NMP).

Besides limited quantitative estimates for costs, risks or impacts the information on all criteria used for evaluating RMOs is subject to different types of uncertainty, for example parameter and data uncertainty, but also uncertainty with regard to model selection and model boundaries. The uncertainty underlying to impact assessment is often addressed by means of scenario and sensitivity analysis. Notwithstanding, given the complexity of the underlying regulatory problem on the one hand, and the limited time available for composing a restriction dossier on the other (1 year), the evaluation of the proposed restriction option and alternative RMOs can hardly comply with an exhaustive scientific analysis but has to be based on simplifying assumptions.

5. Conclusions and recommendations

The selection of an RMO in REACH restriction dossiers is mainly driven by a DSs' evaluation of effectiveness, and in particular by the sub-criteria risk reduction capacity and proportionality, which reflect if and how an RMO is able to adequately reduce the risks associated with a chemical's use. In several dossiers trade-offs between the evaluations of RMOs can be observed. Again, effectiveness proves to be the decisive criterion for an RMO to be selected.

Obviously, the analysis cannot claim to provide an exhaustive picture of the relative importance of evaluation criteria adopted in REACH restriction dossiers. Rather, the results reflect current practise of evaluating and selecting restriction options as suggested in the REACH guidance (ECHA, 2007), and thus provide an indication of the patterns underlying to this process given the uncertainties in the assessments of the dossiers. Despite their tentativeness, our findings warrant some general recommendations for improving the structure, information content, coherence and, thus, the overall credibility of the restriction options' evaluation process:

1. Since a quantitative assessment of all impacts may not be possible in the short term and for a large number of substances (Gabbert et al., 2018), a score-based evaluation of restriction dossiers should become mandatory to ensure a more transparent and uniform evaluation process both within and across REACH restriction dossiers. Thus, evaluating different RMOs by means of semi-quantitative scores in, for instance, a criteria matrix, should be the default practice.
2. Given the results of this analysis, the base criteria effectiveness and practicality, characterised by the sub-criteria risk reduction capacity, proportionality, enforceability, and implementability, may be sufficient for motivating the selection of the preferred RMO. Furthermore, base criteria should consist of an equal number of sub-criteria in order to avoid bias by design. If particular criteria (e.g. effectiveness) are of relatively higher importance to the DSs, this should be made explicit, for example by assigning a higher weight.
3. Qualitative or semi-quantitative scores should be defined such that the proposed and possible alternative restriction options become clearly distinguishable. This can be achieved by, for instance, defining a maximum and minimum score value for each criterion. To ensure coherence of evaluations across restriction dossiers, the range of scores should be exogenous (e.g. be defined in the guidance documents) and not be determined by the DS.
4. If two or more RMOs reveal equivalent overall scores a decision-rule has to be defined in order to guide the selection of the preferred restriction option in a coherent and meaningful way. This will reduce arbitrariness of the evaluation.

Declaration of competing interest

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

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Appendix A. Supplementary data

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References

Brouwer, R., Cauchi, J., Verhoeven, J., 2014. Regulatory decision-making under uncertainty: are costs proportionate to benefits when restricting dangerous chemicals on European markets? Regul. Toxicol. Pharmacol. 68, 438–446.

Council Directive, 1976. COUNCIL DIRECTIVE of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Official Journal of the European Communities 76/769/EEC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31976L0769. accessed January 2020.

Danish Competent Authority for Reach, 2012. Background document to the opinions on the Annex XV dossier proposing restrictions on chromium VI in leather articles. https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e180d737d9 accessed June 2019, 172.

ECHA, 2020. Restriction Process. ECHA, Helsinki, Finland accessed June, 2020. https://echa.europa.eu/restriction-process.

ECHA, 2007. Guidance for the preparation of an Annex XV dossier for restrictions, guidance for the implementation of REACH. https://echa.europa.eu/documents/10162/23036412/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6 accessed January 2020.

ECHA, 2008. Guidance on socio-economic analysis – restrictions. Guidance for the implementation of REACH. refers to REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. https://echa.europa.eu/guidance-documents/guidance-on-reach. accessed January 2020.

ECHA, 2014. Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8 accessed December 2018. 132.

EC, 2006. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official journal of the European Union 1–512.

ECHA, 2016. Evaluation of Restriction Reports and Applications for Authorisation for PBT and vPvB Substances in SEAC, vol. 7. ECHA, Helsinki. SEAC/31/2016/05_Rev.1.

ECHA, 2017. Guidance on Information Requirements and Chemical Safety Assessment Part C: PBT/vPvB Assessment. ECHA, Annankatu 18, P.O. Box 400. FI-00121 Helsinki, Finland. Version 3.0, 22.

ECHA, 2019a. Authorisation. ECHA, Annankatu 18, P.O. Box 400. FI-00121 Helsinki, Finland. https://echa.europa.eu/substances-of-very-high-concern-identification-explained. accessed January 2020.

ECHA, 2019b. Registry of restriction intentions until outcome. https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions accessed January 2020.

ECHA, 2019c. Restriction. ECHA, Annankatu 18, P.O. Box 400. FI-00121 Helsinki, Finland. https://www.echa.europa.eu/web/guest/regulations/reach/restriction. accessed January 2020.

ECHA, 2019d. Substances Restricted under REACH. ECHA, Helsinki, Finland. https://echa.europa.eu/substances-restricted-under-reach. accessed June 2019.

ECHA, 2019e. Understanding REACH. ECHA. Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland. https://echa.europa.eu/regulations/reach/understanding-reach. accessed January 2020.

ECHA, 2020. Candidate List of Substances of Very High Concern for Authorisation. ECHA, Helsinki, Finland. https://echa.europa.eu/candidate-list-table. accessed January 2020.

ECHA, 2020. Registry of Restriction Intentions until Outcome. ECHA, Helsinki, Finland. https://echa.europa.eu/registry-of-restriction-intentions. (Accessed January 2020). accessed.

Gabbert, S., Hahn, S., Klein, M., Nendza, M., Oosterhuis, F., 2018. Approach for Evaluation of PBTs Subject to Authorisation and Restriction Procedures in Context of Socio-Economic Analysis, vol. 198. European Commission, Brussels.

Gabbert, S., Hilber, I., 2020. Socio-economic analysis in REACH restriction dossiers for chemicals management: a critical review. Ambio 49, 1394–1411.

Lever, J., Krzywinski, M., Altman, N., 2017. Principal component analysis. Nat. Methods 14, 641.

The French Competent Authority, 2011. Background Document to the Opinions on the Annex XV Dossier Proposing Restrictions on Dimethylfumarate (DMFu), vol. 130. https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e180d73a15. accessed June 2019.