# Appendix 1. Analysis of all relevant currently known substances of very high concern (SVHCs)

### 1 Introduction

In early 2013, the Member States, the European Commission and ECHA agreed an objective to have all relevant currently known substances of very high concern (SVHCs) on the Candidate List by 2020. When setting up the SVHC Roadmap<sup>13</sup>, authorities considered that for an efficient use of resources, there was a need to define which substances currently on the EU market should be addressed as a priority. To this end, criteria for selecting the substances that are relevant for further regulatory action were set out in the roadmap.

**Relevant** substances under the SVHC Roadmap have been defined as being substances that are registered for uses within the scope of authorisation. This means that priority is given to the substances on the EU market with consumer, professional and non-intermediate industrial uses.

**Currently known** substances are substances for which we have clarified the hazard properties and concluded that they are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs), or endocrine disruptors (EDs).

In accordance with the roadmap and its implementation plan, authorities have also further elaborated whether and when respiratory and skin sensitisers could be regarded as SVHCs. As a separate work stream, an approach to address petroleum and coal stream substances has been developed and its implementation started.

By 2020, all currently known CMRs, PBT/vPvBs and EDs should have been either:

- included in the Candidate List or identified for other regulatory risk management measures (e.g. restriction); or
- considered as not requiring further regulatory risk management action at present.

In addition, the system that we have implemented for identifying substances of potential concern and moving the confirmed ones to regulatory risk management has enabled the identification of new substances of concern which may still be under scrutiny by 2020, as data needs to be generated and assessed first. This system also supports informed substitution. It does this by identifying non-registered substances, or substances registered as intermediated only, that are structurally similar to those regarded as relevant substances.

To get an overview of how far we are in achieving the SVHC Roadmap objective, an analysis of the work done by authorities on substances with (potential) CMR, PBT/vPvB and ED properties has been carried out. The analysis takes into account all substances known to be CMRs and any known or potential EDs or PBT/vPvB substances from before the implementation of the SVHC Roadmap and tracks whether these substances:

- (i) have been scrutinised by authorities and appropriate regulatory action has been taken;
- (ii) are currently under scrutiny; or
- (iii) are of low priority for the time being (e.g. not registered, no relevant uses).

<sup>&</sup>lt;sup>13</sup> The SVHC Roadmap and the SVHC Roadmap implementation plan are available at: https://echa.europa.eu/svhc-roadmap-to-2020-implementation.

# 2 Identification of substances of concern – overview of the work done by authorities

## 2.1 Work done before the setting up of the common screening

Authorities have been working together since REACH entered into force to identify SVHCs. Already in 2009 an informal expert group involving six Member States worked on identifying potential SVHCs on the basis of substances already identified as CMRs or PBT/vPvBs. The aim of the project was to identify the SVHCs that should be prioritised for inclusion in the Candidate List.

The sources of known CMRs and PBTs at that time were, respectively, Annex I to the Dangerous Substances Directive (67/548/ED) and the results from the Technical Committee of New and Existing Chemicals (TC NES) working group on PBT identification set up to support the implementation of the pre-REACH chemicals legislation<sup>14</sup>. Member States used indicators such as exposure, uses and volume to prioritise these substances. However, this work was carried out at a time when there were no registration dossiers available and consequently the information on uses and volumes was limited. The work resulted in a list of 99 substances, of which several, including many CMRs, were included in the Candidate List in the early years. Substances on this list which were not included before the end of 2012 have been regularly scrutinised as part of the common screening.

We can therefore conclude that the pool of harmonised **CMR and known PBT/vPvB substances** has been extensively and regularly scrutinised by Member States and ECHA.

Authorities have also actively worked in identifying **potential new CMRs**, **PBTs/vPvBs** and substances with **potential endocrine-disrupting effects** (EDs) in the context of substance evaluation. Since 2011, candidates for substance evaluation are listed in the Community rolling action plan (CoRAP). Selection criteria for the CoRAP include potential CMRs, PBT/vPvBs, EDs as well as **sensitisers**<sup>15</sup>.

In addition, before the setting up of the PBT Expert Group under REACH in 2012, several Member States and ECHA continued the work that started under the PBT working group of the Technical Committee of New and Existing Chemicals. Substances not finalised under the previous regime were followed up and new PBT/vPvB substances were identified. Prioritisation exercises to identify potential PBT/vPvB substances had been done by ECHA under the CoRAP and by the Netherlands, Germany and the United Kingdom. The list put together based on all this work included around 200 substances and was used as a starting point for the current PBT Expert Group under REACH.

Besides the CoRAP screening, since 2012 ECHA has together with Member States screened on a regular basis the potential **ED substances** listed on the Commission list<sup>16</sup> and on the SIN List<sup>17</sup>.

https://echa.europa.eu/documents/10162/13628/background doc criteria ed 32 2011 en.pdf/67441c3c-75be-4ecd-992e-b90ab2041805.

<sup>&</sup>lt;sup>14</sup> Existing chemicals regulation and new chemical regulation (NONs)

<sup>&</sup>lt;sup>15</sup> Available at:

<sup>&</sup>lt;sup>16</sup> Available at: <a href="http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances\_en.htm">http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances\_en.htm</a>

<sup>&</sup>lt;sup>17</sup> Substitute It Now (SIN) list maintained by ChemSec and aiming at encouraging industry to move away from substances which ChemSec considers as fulfilling the SVHC criteria.

## 2.2 Common screening since 2013

From 2013 onwards, ECHA and Member States have been running the common screening approach to identify substances of potential concern. Harmonised CMR substances and known/potential ED or PBT substances which have relevant uses within the scope of authorisation as well as substances that are structurally similar to those already identified as SVHCs have been included in this common screening approach. We have even examined substances which contain these substances as constituents or impurities above the concentration limits for classification and PBT/vPvB identification. In addition to the work on the known substances, the common screening approach has also worked on identifying new substances of concern through, for example, reviewing self-classifications and reported data in REACH registrations.

# 3 Analysis of the different groups of SVHCs within the scope of the SVHC Roadmap

#### 3.1 Introduction

The SVHC Roadmap identified groups of SVHC substances to be addressed by the implementation of the roadmap. These groups were CMRs, PBTs and vPvBs and equivalent level of concern substances such as EDs and sensitisers. In addition, the roadmap identified the need to develop an approach on how to address petroleum and coal stream substances.

A detailed analysis has been done for CMR, PBT/vPvB and ED substances as described below.

Both respiratory and skin sensitisers were addressed under the SVHC Roadmap, as they can potentially be considered of equivalent level of concern to CMRs. An analysis of the work done on sensitisers and the suggested way forward for managing the potential risks posed by them has already been documented and introduced to authorities and stakeholders at CARACAL<sup>18</sup>. More details can be found in Annex 2 to this appendix.

Member States, the Commission and ECHA are working towards addressing the concern posed by skin sensitisers. Two restriction proposals are under way or being considered for skin sensitisers. One aims to restrict the use of skin sensitisers in textiles and the other focuses on skin sensitisers in tattoo inks.

# 3.2 Analysis of known CMRs and potential and known PBTs/vPvBs and EDs – the starting pool of substances

In the context of the SVHC Roadmap, a **known CMR substance** is a substance that is classified in Annex VI to the CLP Regulation for carcinogenicity, mutagenicity or reproductive toxicity in categories 1A or 1B. Annex VI to CLP contains the legally binding harmonised classification and labelling for over 4 500 substances, which must be followed throughout the EU. There are about 1 100 entries, covering around 1 200 substances, classified as CMRs in categories 1A or 1B in Annex VI to CLP, with about 10 new CMR 1A/1B entries added each year. A handful of these entries are so-called group entries, which cover an open number of substances defined by a certain property (e.g. lead compounds). For clarity, in the analysis reported below we have only included substances identified by EC/CAS numbers on Annex VI to CLP. However, considerable work has been done by ECHA and Member States to identify substances falling under these group entries and many have already been scrutinised. With the inclusion of the tenth adaptation

<sup>&</sup>lt;sup>18</sup> CARACAL meetings of competent authorities for REACH and CLP.

to technical and scientific progress (ATP) to the CLP Regulation, a total of **1 146** substances have been included in this analysis.

We have considered that **potential and known PBT/vPvB substances** are substances which had been assessed by the Technical Committee of New and Existing Chemicals subgroup on identification of PBT and vPvB substances under the previous EU chemicals legislation. Substances under both the existing and the new chemical regulation (so-called NONs) have been considered in the analysis. In addition, we have included in the analysis substances from the SIN List, which ChemSec considers as fulfilling the criteria for PBTs/vPvBs. In total, **250** substances<sup>19</sup> considered to be potential or known PBT/vPvB substances have been analysed.

**Potential and known ED substances** are substances that have been identified as potential EDs by the Commission (Categories 1 and 2 only). This Commission list contains 293 substances (with available EC or CAS number). 84 substances identified by ChemSec as potential EDs and included in the SIN list were also added. In total, 377 substances with known or potential ED properties have been analysed.

## 3.3 Methodology

The lists were analysed with the use of IT tools that retrieve information from ECHA's databases based on the CAS and/or EC numbers provided. Based on the information extracted, substances were assigned to one of five categories, as described in the table below.

<sup>&</sup>lt;sup>19</sup> 224 substances (126 existing chemicals, 98 new chemicals) going through the TC NES subgroup on PBT identification and 26 substances from the SIN List.

Categories and their descriptions					
Categories		Description			
	es under regulatory yond Annex VI to CLP	A substance was included in this category if it is: - included in Annex XIV to REACH or in the Candidate List, or is formally proposed for SVHC identification; or - included in Annex XVII to REACH (excluding entries 28 to 30, which cover restriction of only consumer uses for substances having a harmonised classification as CMR Cat. 1A/1B), or is formally proposed for restriction; or - listed under the POP Regulation (EC) 850/2004 (Annexes I, III, IV, V) and the Stockholm Convention, UNEP (Annexes A, B, C).			
2. Substance scrutiny	es currently under	A substance was considered under scrutiny if not listed under category 1 and if it is: - currently under RMOA; or - currently under substance evaluation or included in the (draft) CoRAP; or - currently under PBT or ED assessment by the expert groups; or - manually screened, with follow-up actions identified; or - being addressed by the Petroleum and Coal stream Substances (PetCo) Working Group.			
	es not considered of riority after being	A substance was included in this category if it was not listed under categories 1 or 2 and if:  - it has been manually screened by ECHA or a Member State and concluded on with no need for further regulatory action at the moment; or  - an RMOA or substance evaluation concluded that there is no need for further regulatory action at the moment; or  - the PBT or ED Expert Groups concluded, based on currently available data, that the substance is not a PBT/vPvB or ED; or  - it was not considered a PBT/vPvB based on the assessment done under previous EU chemical legislations (TC NES).			
current pr potential registered intermedi	es not considered of riority based on low for exposure (not d, registered only as ates, or with uses only)	<ul> <li>A substance was included in this category if not listed under categories 1, 2 or 3 and if:</li> <li>it is not registered under REACH, or is registered only as an intermediate; or</li> <li>the only uses reported in the registration are industrial uses (no professional, consumer uses or article service life for this substance).</li> </ul>			
5. Substance further sc	es that may require rutiny	A substance was listed here if it was not included in any of the other groups.			

### 3.4 Results

A full overview of the number of substances in each category for all properties is available in Table 1. A further analysis for each category is provided in the sections below.

# 3.4.1 Overview of the number of substances under each category having PBT/vPvB, CMRs and/or ED properties

Note that some substances fulfil more than one endpoint and therefore appear in more than one category. As a consequence, the entries in the CMR, PBT and ED columns add up to a number greater than the total number of substances included in the analysis.

Table 1: Overview of the number of substances falling under each category by property.						
	Total	CMR	ED	РВТ		
Number of substances	1699	1146	377	250		
1. Regulated substances	262	158	99	46		
Annex XIV (included or recommended)	65	52	11	14		
Candidate List	154	118	32	36		
SVHC dossier submitted/intention	13	6	5	4		
Restriction	70	55	21	4		
POPs (EC regulation + Stockholm Convention)	63	5	55	12		
2. Substances currently under scrutiny	427	352	40	49		
RMOA under development/on hold	40	20	18	7		
RMOA concluded – need for regulatory action	20	14	3	9		
Substance evaluation ongoing	40	3	21	20		
Substance evaluation concluded  – need for further regulatory action	2	2	0	0		
PBT EG work ongoing/unspecified/postponed	36	4	10	24		
ED EG work ongoing	25	0	18	10		
PBT EG concluded substance to be PBT	0	0	0	0		
ED EG concluded substance to	1	0	1	0		

Table 1: Overview of the number of substances falling under each category by property.						
	Total	CMR	ED	РВТ		
be ED						
Manually screened (outcome other than no action)	36	11	10	18		
PetCo	320	319	0	6		
3. Not of current priority after assessment	127	37	16	80		
Manually screened (outcome – no action)	11	9	2	2		
Manually screened (prior to integrated screening)	18	7	5	7		
RMOA concluded – no need for further regulatory action	22	21	0	1		
PBT EG concluded substance not to be PBT	9	1	2	7		
Substance does not fulfil PBT/vBvP criteria under the previous EU chemicals legislation	77	1	3	77		
ED EG concluded substance not to be ED	2	0	2	0		
Substance evaluation concluded  – no need for further regulatory action	6	0	6	0		
4. Not of current priority based on low potential for exposure (not registered, registered only as intermediates, or with industrial uses only)	870	599	222	62		
Not registered (or inactive)	762	541	209	22		
Registered as intermediate	33	20	9	6		
Registered with industrial uses only (no professional, consumers uses or article service life)	75	38	4	34		
5. May require further scrutiny	13	0	0	13		
Registered with widespread uses	13	0	0	13		

## 3.4.2 Analysis of known CMRs

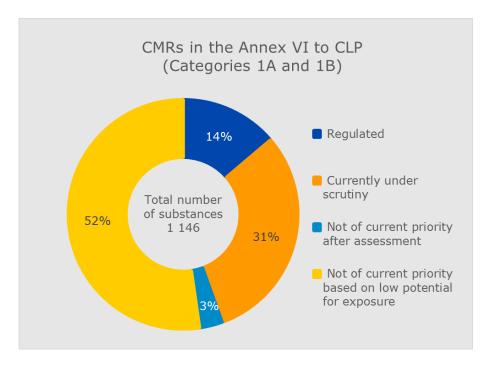


Figure 1: Outcome of the analysis of known CMRs.

Figure 1 shows that over half of the known CMRs in Annex VI to the CLP Regulation are not of current priority. The majority of these substances are actually not registered under REACH.

About one third of the substances (31 %) are currently under scrutiny. Most of those are petroleum and coal stream substances currently being addressed by the PetCo Working Group<sup>20</sup>. There are 330 petroleum and coal stream substances in Annex VI to the CLP Regulation, 275 of which have a conditional classification (notes J, K, L, M, N, P). This means that classification as a CMR applies to those substances only in defined conditions, for example, when a particular constituent is present above a certain concentration.

In this analysis, none of the known CMR substances were found to require further scrutiny. This confirms that all known and relevant CMR substances have been addressed or are currently under scrutiny.

### 3.4.3 Analysis of potential and known PBTs/vPvBs

Figure 2 shows the outcome of the analysis of potential and known PBTs/vPvBs. It shows that a quarter of the currently known PBT/vPvB substances are not of current priority as they are either not registered or only registered for intermediate uses. This is a much lower fraction than for CMRs and EDs (see Figures 1 and 3).

Another third of the substances has been assessed and concluded on as not being a current priority. Most of these assessments were already concluded by the TC NES working group on PBT identification before REACH came into force. Other substances were concluded not to be PBTs by the PBT Expert Group or in the context of manual screening and RMOA.

 $<sup>{}^{20} \ \</sup>text{More information on the work done under this group is available at: } \underline{\text{https://echa.europa.eu/petco-working-group}}.$ 

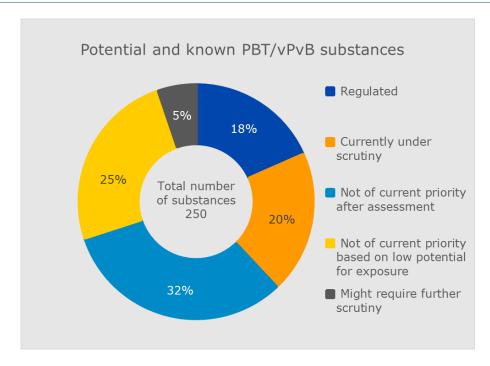


Figure 2: Outcome of the analysis of potential and known PBTs/vPvBs.

There is still a substantial number of substances under scrutiny (20 %). It takes time before a conclusion on their PBT properties can be made as in most cases there is first a need to generate further hazard data.

In this analysis, 13 substances were found that may require further scrutiny (see Annex 2). These are all old NONs which need to be further looked at by authorities in the context of screening. There may be different reasons why these substances have not been picked by the common screening, such as recent updating of the NONs dossiers submitted, or that the screening scenarios did not identify a concern from the information available in the registration dossier. Member States were in charge of these dossiers in the past and have followed them since REACH entered into force. ECHA together with Member States will discuss how to ensure that these substances will be sufficiently addressed.

### 3.4.4 Analysis of potential and known EDs

Figure 3 provides the outcome of the analysis of potential and known EDs. Almost 60 % of the potential ED substances analysed are not of current priority, with most of them not being registered under REACH. Most of these substances are currently being used only as pesticides and/or biocides (Figure 3).

Most of the substances left in the analysis are already regulated or under scrutiny, and very few have been considered not to be of current priority after assessment.

In this analysis, none of the known ED substances were found to require further scrutiny.

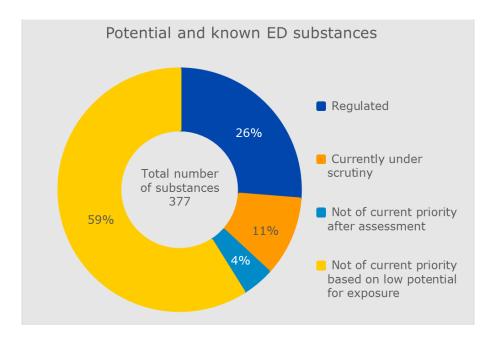


Figure 3: Outcome of the analysis of potential and known EDs.

### 4 Conclusions

It is clear that the extensive work done by Member States and ECHA both prior to the start of the SVHC Roadmap and in recent years has led to a situation in which virtually all **currently known and relevant** SVHCs have been or are being scrutinised. Among the 1 700 substances, there are only 13 potential PBT/vPvB substances (old NONs) that may require further work to confirm whether or not they are PBTs/vPvBs. ECHA will initiate further discussion with the Member States on what further work is needed to clarify this situation and, where relevant, will initiate regulatory actions.

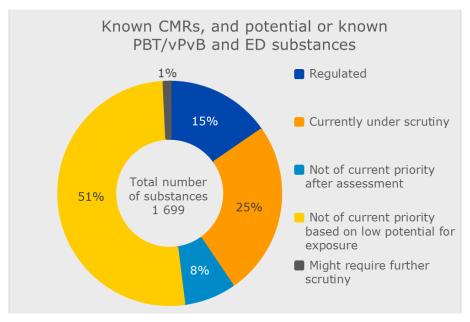


Figure 4: Outcome of the analysis of all substances and their properties.

Figure 4 shows the outcome of the analysis of all substances and their properties, showing that around half of the substances analysed are not a current priority and are therefore not considered relevant under the SVHC Roadmap. Most of these are substances not registered under REACH. Should the status of these substances change, the common screening set up by ECHA together with Member States and the Commission will identify these and move them under regulatory action.

As further explained in the 2017 progress report on the SVHC Roadmap, the focus of our work is now primarily on 'new' substances for which concerns have not yet been clarified and on ensuring that the substances under scrutiny move forward in the regulatory process swiftly.

Annex 1: Analysis of the work done so far in screening and moving substances with sensitising properties to further regulatory action as described in the SVHC Roadmap implementation plan (CARACAL CA/41/2016)

Note that this document is a copy of the CARACAL paper developed in 2016 (without any updates).

### 1. Background

Sensitisers were addressed under the SVHC Roadmap as they can potentially be considered of equivalent level of concern (ELoC) to CMRs. Both respiratory sensitisers and skin sensitisers are covered by the Roadmap and its implementation plan and have been included under the common screening approach<sup>21</sup> for substances of concern from the start. Currently, almost all substances with a harmonised classification for respiratory sensitisation have been examined, as have a large part of harmonised skin sensitisers. As of now, few skin sensitisers have been subject to further evaluation (such as RMOA) after common screening and no further regulatory risk management has been put in place for skin sensitisers as a result of screening. Some respiratory sensitisers have been found to be of equivalent level of concern to CMRs and placed on the Candidate List while no skin sensitiser has yet been identified as such. However, other regulatory measures, such as restriction, have been proposed or initiated for some skin sensitisers based on work carried out under previous legislation or national activities.

### 2. Progress made

Overall analysis

Substantial effort has been made in identifying and prioritising sensitisers under common screening for potential regulatory actions. Harmonised sensitisers that have been registered under REACH or notified to the C&L Inventory have been identified, including those falling under group entries on Annex VI to CLP. To date, around 800 skin sensitisers and around 80 respiratory sensitisers have been registered. These registered sensitisers have been further prioritised based on their reported uses and the potential for exposure to humans. Substances where most of the tonnage goes to wide dispersive uses (widespread uses combined with potential for exposure to human (or release to the environment)) have the highest priority. The next priority goes to substances with at least some widespread uses. For the purpose of this paper and in order to give a wider picture of the potential priority of both skin and respiratory sensitisers, all registered substances with widespread uses have been considered in the analysis.

Figures 1 and 2 show the breakdown of the registered skin and respiratory sensitisers respectively, into those with widespread uses and those without widespread uses. They also give the breakdown of the work already carried out on those substances with widespread uses. Please note that the numbers are approximate and based on an IT analysis with limited manual verification. They are not absolutely accurate but give a very good approximation. Please also note that although these substances are sensitisers, the properties for which further regulatory action has been proposed can be different. For instance, several substances with a harmonised classification for skin sensitisation are on the Candidate List, but none of them were identified as SVHCs based on their skin sensitisation properties.

<sup>&</sup>lt;sup>21</sup> http://echa.europa.eu/documents/10162/19126370/common\_screening\_approach\_en.pdf

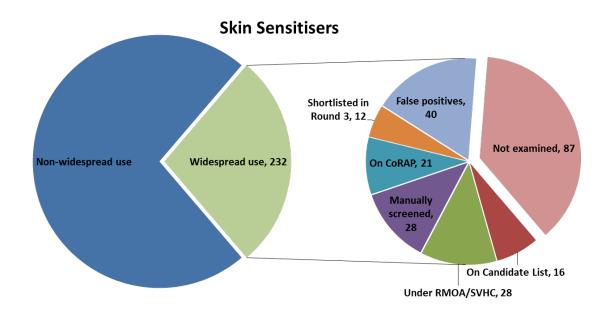


Fig. 1: Registered skin sensitisers and their breakdown into those with widespread uses and those without. Those with widespread uses are then further broken down depending on whether they have been under manual scrutiny. The (hazard-based) false positive rate is an estimate based on a quick manual examination. Although these substances are skin sensitisers, the properties for which further regulatory action has been proposed can be different. False positives are mainly due to poor substance ID in registration dossiers (e.g. wrong IUPAC name). All numbers are approximate and subject to some change.

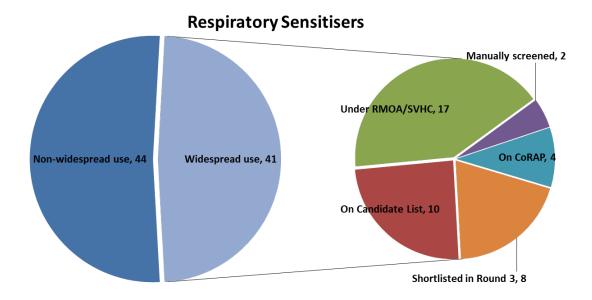


Fig. 2: Registered respiratory sensitisers and their breakdown into those with widespread uses and those without. Those with widespread uses are then further broken down depending on whether they have been under manual scrutiny. Although these substances are respiratory sensitisers, the properties for which further regulatory action has been proposed can be different. All numbers are approximate and subject to some change.

As can be seen from figures 1 and 2, all registered respiratory sensitisers with widespread uses

have been examined or are currently under examination. For skin sensitisers, about a third of substances with widespread uses have not been manually examined.

### Manual screening of skin sensitisers

Substances with a harmonised classification for skin sensitisation have been included on the shortlist of substances of potential concern under common screening for the last three rounds (2014-2016). Figure 3 shows the outcome of the manual screening for substances shortlisted solely for skin sensitisation in round 1 and 2 of screening. Manual screening for round 3, where 6 substances were shortlisted for skin sensitisation only, is currently ongoing. As can be seen from Fig. 3, 26 substances out of the 41 shortlisted were selected for manual screening. Of those, only five were proposed for risk management option analysis (RMOA). It should be pointed out that not all of those five were proposed for RMOA for skin sensitisation properties but rather for other properties discovered during manual screening. The five substances are listed in Table 1. None of them have been proposed for SVHC identification based on skin sensitisation. Those substances proposed for other action such as Substance Evaluation or Compliance check were not done so based on their skin sensitisation properties as these substances all have a harmonised classification for skin sensitisation and no further clarification or assessment is required.

As said above, none of the substances shortlisted for skin sensitisation have resulted in a proposal for SVHC identification. However, it should be noted that hexamethylene diacrylate (HDDA), which was proposed for SVHC identification by Sweden based on skin sensitisation, would have been shortlisted in round 2 if action had not already started on the substance. The MSC did not unanimously agree that HDDA was a SVHC and the dossier was forwarded to the Commission.

Please note that the analysis in Fig. 3 includes those substances which were shortlisted for skin sensitisation only and did not have other hazardous properties such as CMRs or PBTs. In total, 52 substances with harmonised classification as skin sensitiser have been shortlisted and 37 were selected for manual screening. For some of these, regulatory risk management measures have been initiated but not based on skin sensitisation concerns.

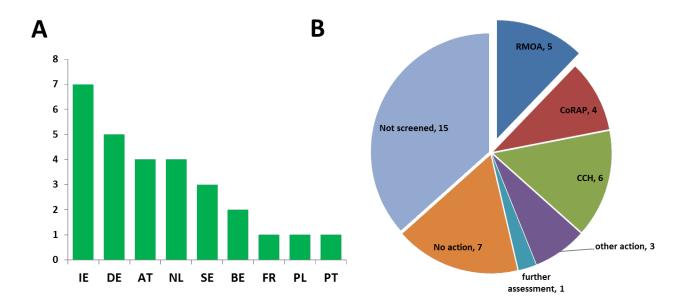


Fig. 3: Outcome of manual screening of substances shortlisted solely for skin sensitisation in rounds 1 and 2 of common screening. Out of 41 substances shortlisted, 36 were selected for manual screening and only

five were proposed for Risk Management Option Analysis. Not all of those five were proposed for RMOA due to skin sensitisation. CoRAP and CCH proposals are based on other properties than skin sensitisation.

Risk Management Option Analysis of sensitisers

To date, around 30 RMOAs have been or are being conducted for substances with sensitisation properties. Some of them cover a group of substances (such as diisocyanates) or a particular sector (such as skin sensitisers in textiles) while others cover only one substance (e.g. HDDA). A review of all these RMOAs and their conclusions is beyond the scope of this paper. Such review could be beneficial to conduct in order to increase common understanding on the most appropriate risk management measures for sensitisers.

#### Conclusions and next steps

All registered respiratory sensitisers that are relevant from an exposure point of view have been identified and examined. Registered and harmonised skin sensitisers have been extensively scrutinised under the SVHC Roadmap. Very few of the substances proposed for manual screening have been subject to further regulatory action and no skin sensitiser has been identified as an SVHC yet.

From the experience gained so far it is unlikely that the systematic screening of the remaining skin sensitisers would identify further candidates for regulatory action. Therefore, it is proposed that further systematic screening for skin sensitisers by ECHA in the common screening programme is discontinued for the time being. The resources can be reallocated to other tasks. ECHA can provide a list of those skin sensitisers not yet examined, including their registration and use status, to those Member States still wishing to continue the work on them. The systematic screening for skin sensitisers could be repeated after 2018 registration data is available.

It is further proposed that the interested Member States could review the RMOAs already conducted on sensitising substances in order to increase common understanding on how to best regulate those substances. This could also help to re-focus the work on sensitisers.

Screening of respiratory sensitisers will continue to take into account potential changes in registration status or in uses.

Annex 2: Substances for which further scrutiny may be required.

EC Number	Substance name	Registration
250-709-6	Tris(2,4-ditert-butylphenyl)phosphite	10 000-100 000 tonnes per
401-280-0	1-(N,N-bis(2-ethylhexyl)aminomethyl)-1,2,4- triazole	10+ tonnes per year
402-130-7	4,4'-methylen-Bis-(3-Chlor-2,6-Diethylanilin)	100+ tonnes per year
406-200-8	3',5'-dichloro-4'-ethyl-2'-hydroxypalmitanilide	100+ tonnes per year
412-210-3	2-[[2-(acetyloxy)-3-(1,1-dimethylethyl)-5-methylphenyl]methyl]-6-(1,1-dimethylethyl)-4-methylphenol	Confidential
416-250-2	3,6-bis(4-tert-butylphenyl)-1H,2H,4H,5H- pyrrolo[3,4-c]pyrrole-1,4-dione	100+ tonnes per year
418-550-9	Hexadecyl 4-chloro-3-[2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-4,4-dimethyl-3-oxopentamido]benzoate	1+ tonnes per year
420-470-4	A mixture of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide]	Confidential
427-090-8	A mixture of: ethyl (2R,3R)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate; ethyl (2S,3S)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate	10+ tonnes per year
434-210-2	Polyurea grease thickener	Confidential
438-390-3	Alkane 6	1 000 - 10 000 tonnes per year
448-060-0	2-[2-(3-butoxypropyl)-1,1-dioxo-1,2,4-benzothiadiazin-3-yl]-5'-tert-butyl-2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-2'-[(2-ethylhexyl)thio]acetanilide	10-100 tonnes per year
459-290-6	3,4-dichloro-N-(5-chloro-4-{2-[4-[(2-hexyldecyloxy)phenylsulfonyl]butyramido-2-hydroxyphenyl) benzamide	1+ tonnes per year