

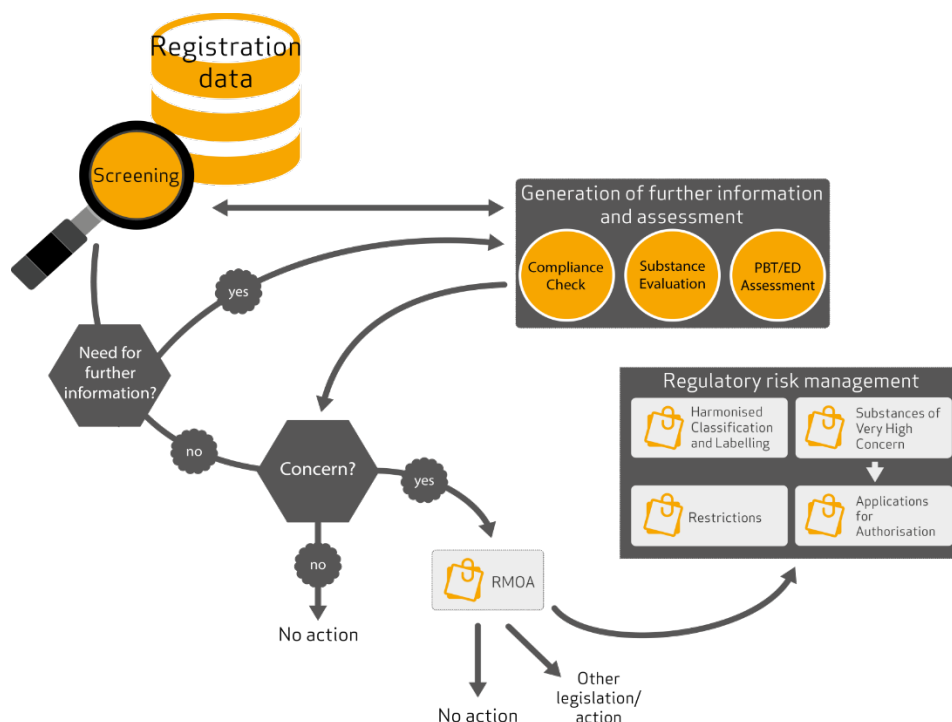
24 October 2017

## Analysis of the SIN LIST

### Introduction

Screening to identify potential substances of (very high) concern is an integral part of the integrated regulatory strategy to focus on the substances that matter most. [The common screening approach](#) has been developed by ECHA together with Member State competent authorities in order to systematically screen the available information on substances in the REACH registration dossiers and other databases to identify substances for the following REACH and CLP processes:

- Compliance check for dossier evaluation;
- Community rolling action plan (CoRAP) under substance evaluation;
- Potential further regulatory risk management measures under the REACH and CLP regulations i.e.:
  - Harmonised classification and labelling
  - Authorisation
  - Restriction



**Figure 1: REACH and CLP machinery serving ECHA's integrated regulatory strategy and the SVHC Roadmap.**

In addition to the internal REACH and CLP databases, ECHA uses external sources of data on both hazard and exposure. These additional sources include lists of substances of concern published by other regulatory bodies and agencies (e.g. the Chemical Management Plan from Canada), NGOs (e.g. SIN list) and trade unions (e.g. ETUC list). The purpose of this inclusion of information in the priority setting work is to make sure that substances, regarded as (potentially) relevant by other organisations are considered.

ECHA together with Member States carefully check and analyse against agreed priority criteria

the substances in these lists to understand whether (further) regulatory action, either evaluation or risk management is needed. This is done by identifying first whether those substances have been or will be under one of the REACH or CLP processes or activities (e.g. Risk Management Option Analysis (RMOA)).

As an example of how ECHA scrutinises lists and actions by other bodies to make sure all relevant substances are addressed, we have examined the substances on the [SIN list](#). The SIN (Substitute It Now) list is maintained by Chemsec and aims at encouraging industry to move away from substances which Chemsec considers as fulfilling the criteria for SVHC.

## Results and discussion

Our analysis of the substances on the SIN List is summarised below. Broadly speaking, the substances on the SIN list can be divided into four categories:

### 1) Substances already regulated or in the process of being regulated

This covers substances that are restricted under REACH<sup>1</sup> ([Annex XVII](#)), subject to Authorisation ([Annex XIV](#)), on the [Candidate List](#) or listed on ECHA's [Registry of Intentions](#) as being considered for inclusion in any of these lists. We have also included substances listed as persistent organic pollutants under the [Stockholm Convention](#) for which regulatory risk management measures are already in place at the global level.

### 2) Substances currently under scrutiny by ECHA or Member States

This covers those substances that are currently under [Substance Evaluation](#) or are listed on the Public Activities Coordination Tool ([PACT](#)) as undergoing [RMOA](#) or informal hazard assessment of [PBT/vPvB](#) (Persistent Bioaccumulative and Toxic/very Persistent and very Bioaccumulative) and or [endocrine disrupting properties](#). We have also included here substances that are under manual screening, for which an [intention or proposal for harmonised classification and labelling](#) is available or those which are addressed under the [PetCo working Group](#), which deals with petroleum and coal stream substances.

### 3) Substances considered of low priority for regulatory action at present (scrutinised by Member States)

Substances are included here if they have been assessed by Member States (or ECHA) under Substance Evaluation, RMOA or manual screening and have been concluded not to warrant further regulatory action at the moment in view of the SVHC Roadmap prioritisation criteria<sup>2</sup>. This group includes also substances that are not (actively) registered under REACH even though not scrutinised by Member States.

### 4) Substances without further action at present (IT screened)

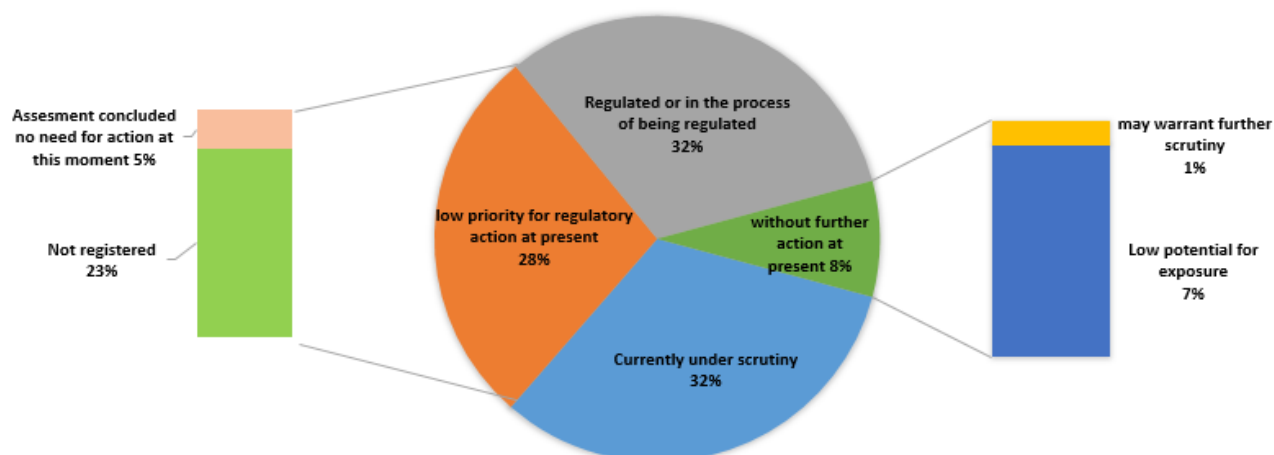
This group covers substances that are registered under REACH and are not covered by any of the three groups above. Majority of these substances are of low priority for further scrutiny based on SVHC Roadmap criteria (i.e. low potential for exposure). The remaining substances may warrant further scrutiny.

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<sup>1</sup> Please note we have not included substances subject to restriction based on entries 28, 29 and 30 of Annex XVII of REACH as these do not cover other uses than in consumer products.

<sup>2</sup> Agreed between Member States, the Commission and ECHA.

Internal



**Figure 2 Regulatory status of the substances in the SIN list**

Figure 2 depicts the outcome of the analysis done by ECHA on the SIN list. From the nearly 900 substances that are included in the SIN list, more than 270<sup>3</sup> are **already regulated in the EU** or in the process of being regulated. An example are the 4 phenolic benzotriazoles (UV-327, UV-328, UV-350 and UV-320), included in the Candidate List and in the process of being recommended for inclusion in the Authorisation list. These substances, mainly used as UV-stabilisers are substances of very high concern (SVHC) for the environment due to their persistence, bioaccumulation and toxicity (PBT) and/or very persistent very bioaccumulative (vPvB) properties. In addition to the hazard properties, there is a concern of release to the environment due to the high tonnage registered (100 - <1,000 t/y) for UV-328 and its widespread use by professional workers and consumers, and its inclusion in articles. Although UV-328 is the only of the four phenolic benzotriazoles registered under REACH, the addition to Annex XIV is recommended for all of them in order to avoid industry to substitute it with these structurally similar substances with similar hazard profile.

The substances in this first group can be considered of low priority for additional work as regulatory measures already oblige industry to either substitute or manage the risks of their substances. In addition all REACH and CLP regulatory processes include reviews and it is therefore always possible to come back with additional measures when there are indications of concerns.

Around 280 of the substances in the SIN list are currently **under scrutiny by ECHA or the Member States**. About 50 of them are under scrutiny in e.g. Substance Evaluation or RMOA. Additionally around 230 of the substances in the SIN List are UVCB petroleum and coal derivatives that are being examined holistically under the [PetCo Working Group](#) set up in the context of the SVHC Roadmap to 2020 implementation.

An example of a substance under scrutiny is 4,4'-methylenediphenol (Bisphenol F), which is currently under RMOA due to its potential endocrine disrupting properties. Although Bisphenol F is not registered under REACH, there is a concern that due to its structural similarity it could potentially be used as a substitute of Bisphenol A, a known endocrine disruptor.

Depending on the outcome of the assessments, the substances in this second group will move either to the group of substances to be further regulated or to the third group if they are concluded not to warrant further regulatory action at present. For most substances in this group generation of hazard information will be most probably required before being able to conclude

<sup>3</sup> This analysis was conducted based on the information extracted from ECHA's database during April-May 2017. Because the number of substances within each process might have changed slightly by the time this article is published, exact numbers are not provided.

on the need for further regulatory risk management. It is important to realise that the generation of new hazard data takes time.

The third group, **substances of low priority for action at present**, includes about 240 of the substances in the SIN list. Around 40 of these substances have been examined by Member States or ECHA through Substance Evaluation or an RMOA and have been concluded not to warrant further regulatory action at present. This could be due to either a low potential for exposure (e.g. the substance is only used as an intermediate and/or in industrial processes) or because they are not considered anymore of an (eco)toxicological concern after the assessment.

An example of a substance concluded as low priority for action at present is Quinoline. This is a substance classified as Carc 1.B, Muta. 2 for which an RMOA concluded that there is no need at this point in time to propose further regulatory risk management given that it is used only in industrial processes at a low to medium tonnage at a limited number of sites and is not included in articles. REACH requires that registrants of Quinoline define company level risk management measures and operational conditions, which ensure that risks are controlled. Risk management measures and operational conditions are then communicated down the supply chain to the industrial users, which in turn have an obligation to implement these measures. Furthermore, REACH acts together and in a complementary manner with other legislations, such as the Occupational Safety and Health at Work (OSH) regulatory framework to ensure that the risks from chemicals are properly controlled at the EU level. National enforcement of the worker protection legislation and REACH requirements should as well help ensuring that the relevant exposures/emissions are well controlled.

The other 200 low priority substances in this group are substances which are not (actively) registered under REACH. Those are either not on the market or in very low amounts and therefore the need for regulatory action is of low priority at present. It is important to note that substances in this third group may become of priority as soon as the uses or registration status will change. ECHA regularly repeats and updates the screening process to ensure that any new information is adequately taken into account for prioritisation. This means that ECHA and Member States will continue to monitor the substances in this category for any changes in either uses or new knowledge on the (eco)toxicological properties. Additionally, substances that are registered only as intermediate or not registered in Europe can still be considered relevant for regulatory action under REACH and CLP if they are identified as potential substitutes to known substances of concern.

The fourth group of **substances without further action at present**, which includes less than 80 of the substances in the SIN list, is of most interest in terms of identifying substances of potential concern. Any REACH registered substance which has not been included in the other groups is included here. The priority for action on these substances was further examined against exposure criteria to humans and release to the environment using automated algorithms. Almost a third of these substances are registered only as intermediates (used in industrial sites for the manufacturing of another substance) and therefore, due to the low exposure potential have never been prioritised as candidates for further scrutiny by Member States in the context of manual screening. Additionally, most of these 80 substances have already a harmonised classification as CMR 1A/1B and are therefore restricted for consumer uses.

Out of the 80 substances, ECHA has identified 7 with high potential for exposure to humans or release to the environment based on the registered uses. ECHA together with Member States will investigate whether those substances warrant further action.

EC	Chemical name
401-500-5	(methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diy))) -1,1'-dipyridinium dichloride dihydrochloride
432-750-3	O-hexyl-N-ethoxy carbonylthiocarbamate
269-929-9	Pyridine, alkyl derivs.
614-455-3	Copper Lead Resorcylate Salicylate Complex
297-907-9	Slags, lead-zinc smelting
308-967-3	Nitric acid, barium salt, reaction products with ammonia, chromic acid (H <sub>2</sub> CrO <sub>4</sub> ) diammonium salt and copper(2+) dinitrate, calcined
201-152-2	1,2-dichloropropane; propylene dichloride

## Conclusions

This analysis of the SIN List illustrates how authorities are using external sources of information in the context of the common screening approach developed to support the integrated regulatory strategy and the identification of substances that matter most in terms of protection of the human health and the environment.

The outcome clearly shows the considerable overlap between the SIN list and the work done by authorities. The vast majority of the substances in the SIN list are already (or in the process of being) regulated or under scrutiny by authorities, suggesting that the SIN list is a valuable tool for industry to predict action by authorities.

In the current analysis, a handful of substances have been identified as potentially warranting further action by authorities. Those substances will be assessed further by ECHA and Member States using the integrated regulatory strategy approach described above.

This highlights that the common screening put in place by Authorities has been able to identify since 2013 those substances having known hazardous properties and to move them for further action<sup>4</sup>. External lists of substances of concern such as the SIN List have been of added value for authorities' work.

Authorities' focus has clearly shifted from already known and in most cases already addressed substances of concern to identification of new substances of concern and generation of data to clarify their concern. A large number of substances are currently under scrutiny and for many it is expected that new hazard data need to be generated to clarify the concern.

To focus resources, authorities have agreed on priority criteria for identifying substances that matter most. Substances of priority for further work by authorities are those combining hazard concern and potential for exposure either to human health or to the environment. Consequently, substances with hazardous properties may be considered as low priority for further work by authorities as reflected in this analysis of the SIN List. However, the review of the prioritisation is embedded in the common screening approach and changes in the use patterns, registration status or hazard of a substance are considered on a regular basis.

In addition, even if a substance is of low priority for further work by authorities in the context of REACH/CLP processes it does not mean there are no risk management measures taking place

<sup>4</sup> The annual reports published by ECHA on the implementation of the SVHC roadmap provide a more in depth analysis on the total number of substances tackled through the different REACH and CLP processes and the outcome of these processes, including screening, data generation and assessment, RMOA and risk management (link: <https://echa.europa.eu/svhc-roadmap-to-2020-implementation> )

on the substance. Other regulations are in place and contribute to the safe use of chemical substances (e.g. occupational legislation for substances with industrial uses).