# Complete methodology for selecting substances for inclusion in the SIN List

## CONTEXT AND BACKGROUND

### REACH AND SUBSTANCES OF VERY HIGH CONCERN

In 2007 the European Union's new framework policy on industrial chemicals, REACH[1], entered into force. REACH stands for registration, evaluation, authorisation and restriction of chemicals. REACH aims to ensure that basic information on industrial chemicals used in the EU is provided and that the use of the most hazardous chemicals is limited or prohibited through either restriction or authorisation procedures. The success of REACH will depend on a prompt, effective process for identifying the most hazardous chemicals on the European market and replacing them with safer alternatives.

REACH requires companies to register information about the chemicals they produce or import. The first registration deadline was passed in 2010 for: chemicals classified as CMR category 1A or 1B; substances classified as very toxic to aquatic organisms that may cause long-term adverse effects in the aquatic environment and are manufactured or imported in quantities above 100 tonnes per year; and substances manufactured or imported in quantities above 1,000 tonnes per year.[2] The most hazardous substances in REACH can be designated as Substances of Very High Concern (SVHCs) and are subject to close scrutiny. At the heart of the authorisation process is a Candidate List of chemicals that meet the criteria for Substances of Very High Concern as defined in the legislation, such as those that may cause cancer or persist in our bodies and the environment for long periods of time. Placing of a substance on the Candidate List triggers specific obligations for companies to inform downstream users and consumers about the presence of this substance in products in the supply chain.

However, the mere fulfilment of the SVHC criteria does not mean a substance is automatically placed on the Candidate List. In order for a substance to be listed it needs to be nominated by either an EU member state or the European Chemicals Agency (ECHA) on behalf of the European Commission. These must prepare a dossier describing the scientific findings behind the nomination and then all member states must unanimously decide that it is indeed an SVHC. From the Candidate List, substances are later selected for further scrutiny and eventually restricted or allowed only for specifically authorised purposes.

The EU has started the process of populating the Candidate List with these undesirable substances, but the process has so far been quite slow and unpredictable. The current official list can be found on ECHA's official webpage.[3] SVHCs are divided into six different categories.

1. **Carcinogenic [C]**
2. **Mutagenic [M]**
3. **Toxic to reproduction [R]**
4. **Persistent, bioaccumulative and toxic [PBT]**
5. **Very persistent and very bio-accumulative [vPvB]**
6. **Equivalent level of concern, such as endocrine disruptors [57 (f)]**

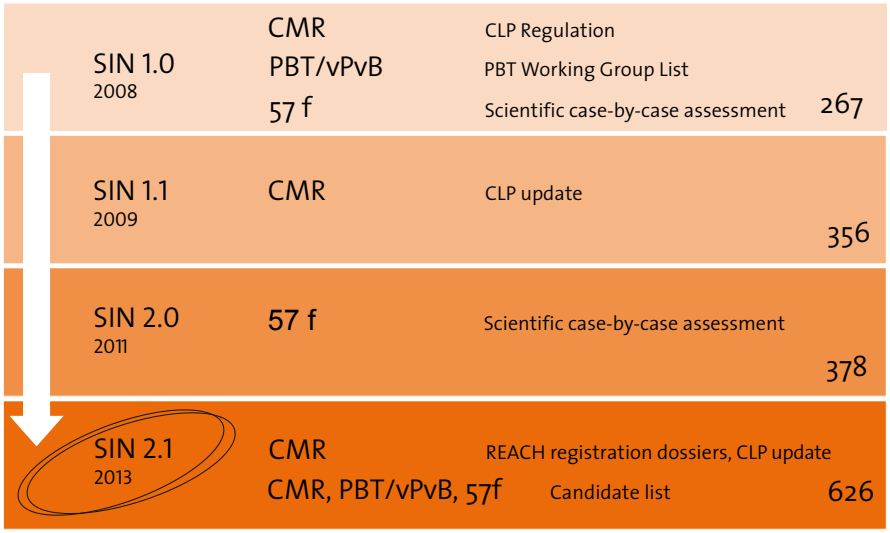
### THE SIN LIST

The SIN (Substitute It Now!) List[4] has been developed to highlight the need for swift implementation of the REACH system for identifying and phasing out high-concern chemicals. It has also proven valuable for companies as well as for financial investors as a preview of which substances are likely to be regulated within the EU in the near future. This paper will explain how the SIN List has emerged and the methodology that has been used for selecting and evaluating substances for the SIN List.

All substances on the SIN List are identified by ChemSec as fulfilling the criteria for SVHCs as defined in the REACH regulation, and fall into at least one of the six categories above. The first SIN List, 1.0, was presented in September 2008, and the SIN List 2.0 released in May 2011 brought into focus endocrine-disrupting chemicals (EDCs) as a group of SVHCs that need to be urgently addressed by the EU. The 1.1 and 2.1 technical updates were introduced following access to new information, revealing more substances of relevance for the SIN List, including newly classified substances (from the EU CLP regulation on Classification, Labelling and Packaging) and using information made official through REACH registration dossiers.

*1. http://echa.europa.eu/regulations/reach*
*2. http://echa.europa.eu/information-on-chemicals/registered-substances*
*3. http://echa.europa.eu/candidate-list-table*
*4. http://www.sinlist.org*

## SIN LIST DEVELOPMENT




*SIN List development: SIN List versions and the years when they were presented, reason for inclusion and total number of SIN List substances and substance groups.*

## GENERAL PRINCIPLES USED FOR THE COMPILATION OF THE SIN LIST

### TARGETING SUBSTANCES SUBJECT TO REACH

All substances on the SIN List – CMRs, PBTs, vPvBs or equivalent level of concern substances – have been screened to identify substances covered by the authorisation provisions in REACH. Substances exempt or otherwise not regulated by REACH, such as pesticides, intermediates and unintentionally produced substances, have accordingly been removed.

### BASED ON PUBLICLY AVAILABLE DATA

All information used for selection and assessment of substances for the SIN List is publicly available, as is described in more detail for the different categories of substances below.

For CMRs the official CLP (Classification, Labelling and Packaging) classification has been used and for PBTs and vPvBs the European PBT working group list has been used. These substances have been agreed on a EU-wide basis to have properties corresponding to the SVHC criteria.

Equivalent level of concern substances (REACH article 57(f)) added to the SIN List 1.0 and 2.0 have undergone a more in-depth scientific evaluation and case-by-case assessment, based on publicly available peer-reviewed scientific studies. The case-by-case evaluation was required since the available guidance documents on how to identify SVHCs[5] are rather general.

### EXCLUSIVE RATHER THAN INCLUSIVE

It should be clearly stated that the screening criteria and methodology applied does not capture all substances that potentially could fulfil the SVHC criteria. In that sense the SIN List is a "conservative" list, exclusive rather than inclusive. Some substances not included, i.e. not passing this conservative evaluation as SVHCs, might nonetheless still have strong indications of a number of concerning properties that should not be neglected, and might thus need further evaluation. ["Absence of evidence is not evidence of absence," Douglas G. Altman.]. Further, the chosen starting points for identifying substances of equivalent level of concern, the 25 black and grey lists for SIN List 1.0 and the European Commission database on EDCs for SIN List 2.0, limited the number of substances to those already suspected when the lists were drawn up. Therefore the SIN List should not be considered as a final list, but rather an important first step towards a more comprehensive list of SVHCs in need of regulation.

*5. Technical guidance documents have been developed by ECHA in cooperation with stakeholders and EU member states in order to provide guidance on how to interpret the legal texts in REACH. However, they are not legally binding documents. http://echa.europa.eu/documents/10162/13638/svhc_en.pdf*

## SELECTION PROCEDURES

### SUBSTANCES OFFICIALLY CLASSIFIED AS CMRS

*CMRs are substances that are carcinogenic, mutagenic, or toxic to reproduction. In other words, they have inherent properties that can cause cancer, alter DNA or damage reproductive systems. These properties correspond to article 57 a-c of REACH.*

To identify CMRs the EU Regulation on Classification, Labelling and Packaging[6] (CLP, EC 1272/2008) was used. The CLP regulation contains a register of all officially classified substances including CMR substances category 1A or 1B. These substances are recognised under REACH as by default meeting the criteria of SVHCs. From the above-mentioned register, pesticides having a standardised name assigned by the International Organisation for Standardization (ISO) have been subsequently removed if not registered with a full REACH registration dossier.

Entries in the above-mentioned register referring to mixtures where one of the substances is a CMR and is present in the mixture in concentrations above 0.1% have been removed. Entries lacking CAS numbers and EC numbers have also been removed since they do not identify a unique substance or a unique substance group. Substances exempted from the authorisation procedure have also been removed, for example complex hydrocarbon distillates occurring foremost in product streams coming from refined or unrefined petroleum (fuels), unless registered with a full registration dossier. These substances are easily identifiable because they have dedicated index number series in the CLP.

The SIN 2.1 update also took advantage of using newly disseminated information from REACH registration dossiers to identify further classified CMRs that had been registered and thus are within the scope of authorisation. This was done for three categories of substances.

One group the SIN List 2.1 update focused on was substances that according to the CLP regulation are defined as complex hydrocarbon distillates occurring mainly in fuel streams (found in table 3.1 of Annex VI of the CLP with all entries from index numbers 648-xxx-xx-x and 649-xxx-xx-x). In earlier versions of the SIN List these substances were excluded, as described above, since it was estimated that the vast majority of them were only used in ways exempted from authorisation. However, information from the REACH registration dossiers showed that most of these substances were in fact not used within the scope of REACH, although a number of them had been fully registered and are therefore within the scope of authorisation. These substances, when classified as CMR category 1A or 1B, were subsequently added to the SIN List.

Another group of substances added to the SIN List 2.1 included substances belonging to a chemical group for which the whole group has a CMR classification according to the CLP regulation. Since the CLP regulation itself gives no indication of which individual substances could be covered by such an entry, the REACH registration dossiers were used to investigate which such substances had been registered. Again, only such substances classified as CMR 1A or 1B have been included on the SIN List. Substances found relevant for inclusion were identified in the following groups: lead compounds, chromium compounds, hydrazine salt compounds and arsenic compounds.

The SIN List 2.1 update also includes minor corrections to earlier versions and updates of the CLP covering in total six substances classified as CMRs in the CLP regulation. Because of an earlier inaccuracy in the classification data published by the European Commission (the ATP01 update), it was noticed that another two substances, classified as CMR 1A, qualified for inclusion in the SIN List and those substances were therefore added. The last update of the CLP regulation entered into force in July 2012 (ATP03), and this update classified two new substances as being CMR 1A or 1B, hence these have now been included on the SIN List 2.1. Two substances identifiers (CAS#) have also been added to already existing entries on the SIN List in order to make the CAS# data more complete.

### SUBSTANCES OFFICIALLY RECOGNISED AS PBT/VPVB

*These substances are Persistent, Bio-accumulative and Toxic (PBT) or very Persistent and very Bio-accumulative (vPvB). These properties correspond to article 57 d-e of REACH. They do not easily break down in nature. Instead they build up in the environment and in, for example, the fatty tissue of mammals, where they have the potential to cause serious and long-term irreversible effects. Due to their longevity, these chemicals have the potential to cause great harm even at low toxicity, since they can build up and multiply over time.*

The PBT Working Group, an official assembly of representatives from EU member states as well as experts from the former European Chemicals Bureau (ECB), has concluded that a number of substances fulfil the EU criteria as PBT or vPvB. These criteria are very similar, although not identical, to those in REACH, but as all substances are agreed upon being PBT/vPvB and the differences between the criteria are small, all 23 substances on the EU PBT working group list were initially included for screening for inclusion on SIN 1.0[7] However REACH does not apply to all of these substances, and substances such as pesticides and non-registered hydrocarbon distillates have accordingly been removed using the same procedure as for CMR substances above.

*6. http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/*
*7. Complete list to be found at http://esis.jrc.ec.europa.eu/index.php?PGM=pbt*

CMR and PBT/vPvB substances have not been further assessed on a case-by-case basis as they are already classified and/or agreed to fulfil the REACH criteria for SVHC in official EU processes.

### SUBSTANCES FULFILLING REACH CRITERIA ON EQUIVALENT LEVEL OF CONCERN

***Finally the last group of Substances of Very High Concern as mentioned above, equivalent level of concern substances, is a category introduced as a safety net in REACH in order to include very hazardous substances of equivalent level of concern as the other categories where there is scientific evidence for probable serious effects (REACH article 57f). Substances with endocrine disrupting effects are mentioned as one example of a group of substances causing such equivalent level of concern.***

While the selection of CMR and PBT/vPvB substances has been more straightforward and based on official and existing agreements in the EU, the selection of chemicals of equivalent level of concern has required more background research and case-by-case evaluations.

There is a wide variety of intrinsic properties among these substances and the ECHA guidance calls for a substance-by-substance identification and assessment, which is how these substances have been included on the SIN List.

In short, identifying equivalent level of concern substances as SVHCs and adding them to the SIN List has been a three-stage process

1. Selection and filtering of substances relevant for REACH
2. Literature research on selected substances
3. Evaluation against REACH criteria for SVHCs

For more details, see specific parts on methods for including 57(f) substances further below.

### SUBSTANCES IDENTIFIED AS SVHCS BY EU MEMBER STATES

***The SIN List identifies substances that are relevant for the REACH Candidate list. However, the 2.1 update of the SIN List also included substances that were already included on the Candidate List. The difference between the lists originated from the strict methodology and principles that apply to the SIN List in contrast with the Candidate List, for which substances are suggested by EU member states and the European Commission, and added on a case-by-case basis.***

The substances added to the SIN List 2.1 update shortly after they were included on the Candidate List include:

- CMR substances, including substances without a CAS number, reaction products and mixtures.
- vPvBs previously not identified as such by the EU PBT Working Group, but for which new data provided in the REACH Annex XV dossiers proved these fulfil vPvB criteria.
- Respiratory sensitisers as equivalent level of concern substances, as information in the REACH Annex XV dossiers supported the identification of these substances as SVHCs.

These substances had not previously been added to the SIN List since they had not passed the strict screening criteria for one or more of the above-mentioned principles or were not on any of the lists used as the starting points for selection of SIN List chemicals. Since these substances have been officially recognised to meet the criteria for Substances of Very High Concern by EU authorities, they were included in the 2.1 update of the SIN List. If the same situation were to occur in the future, this would also be the case for those Candidate List substances.

## METHODS FOR INCLUSION OF 57(F) SUBSTANCES IN SIN 1.0

### FIRST STEP – SCREENING PHASE

First, a rough list was compiled of substances from many different records and lists of recognised hazardous chemicals. Examples of such lists are the OSPAR[8] list of chemicals of possible concern & priority action, the EU Water Framework Directive, the Swedish Chemicals Agency's (KEMI) PRIO list, as well as lists by the US and Canadian Environmental Protection Agencies. Further, substances listed on collaborating companies' grey and black lists were included.

The resulting rough list contained altogether approximately 4,000 substances with different levels of concern. Throughout the compiling procedure, all risk phrases and classifications (official and unofficial) were kept attached to each substance to facilitate the subsequent screening process. To ensure positive identification of each substance, any duplicate entries, references to substance groups and other substances not having a CAS or EC number were removed. Then the Swedish Chemicals Agency

*8. OSPAR is the Convention for the Protection of the Marine Environment of the North-East Atlantic, adopted in 1992*

(KEMI) was asked to search its "Products Register" [9] for the occurrence of these 4,000 substances in chemical products and preparations available to consumers. KEMI responded with a refined list of approximately 250 of the original 4000 substances.[10] Information from the European Chemicals Bureau was then used to obtain information on high production volume chemicals. This refined the list further to roughly 150 substances.

From this point on, substances were manually selected and screened. Substances whose hazardous properties were only of a physical nature (corrosive, explosive, flammable etc.) were removed together with chemicals already officially classified as CMRs (category 1A & 1B) already covered above, pesticides and other substances that are exempted from REACH in total or from the authorisation procedure.

When selecting substances, priority was given to substances whose properties indicated them to be EDC, CMR (category 2), PBT or toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment[11]. This gave a total of 35 substances.

Further high-profile substances often found in human bio-monitoring studies or else frequently mentioned in human health and environmental studies were selected for evaluation. The presence of a man-made chemicals in nature or in human bodies often indicates persistence and possible bioaccumulation. This added another 15 substances.

Endocrine disrupting chemicals (EDCs) assessed to be of high or medium concern in the European Commission report on EDCs (COM (2001/262)[12] added another 10 substances to the list [13] . Making the final number of potential equivalent level of concern substance to be evaluated and assessed 60.

## SECOND AND THIRD STEP – SCIENTIFIC LITERATURE RESEARCH AND ASSESSMENT

In order to make a proper assessment toxicologists were assigned to conduct an exhaustive literature search for each of the 60 substances of potential equivalent level of concern filtered out in the first screening phase. They were also asked to conduct an in-depth assessment on each substance to determine whether these substances would qualify as Substances of Very High Concern under REACH. The toxicologists were instructed to use the official REACH guidance document on how to identify equivalent level of concern SVHCs and prepare an Annex XV dossier as stated in the "Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern"[14] from June 2007. This was then used as a basis for the SVHC assessment.

The background data used was primarily published scientific literature but also data from existing risk assessments and EU studies of these substances, when available. The assessment looked at the combined properties of these substances, meaning that a weighted approach was used, including all known properties and gathered data. The dataset included CMR and endocrine disrupting properties as well as tendencies to persist in nature and/or bio-accumulate and whether the substances had been detected in humans and biota. This combination of different hazards, which individually might not have fulfilled the criteria for SVHC, when assessed together built up a strong case for an equivalent level of concern substance.

>> After the toxicologists' assessments, the background data and conclusions were subject to further scrutiny by external scientists. The final result was the addition to SIN List 1.0 of 30 substances fulfilling REACH criteria for equivalent level of concern SVHCs.

*9. http://kemi.se/start/produktregistret/*

*10. Granted, the chemical uses in the Swedish Product Register might not be representative of all uses in all of Europe. This is nevertheless a good basis for identifying hazardous chemicals to which consumers are exposed. The actual uses, in Europe and globally, presumably go beyond the Swedish Product Register, thus the potential number of chemicals eligible for inclusion may be far greater.*

*11. These properties are based on the information from the original lists and the substances are therefore not necessarily officially classified within the EU according to these risk phrases.*

*12. http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm*

*13. The complete EDC list from this report contains numerous PCBs, DDTs, dioxins/furans, CMRs and pesticides, which were excluded since they were either not subject to REACH or already addressed as classified CMRs. Substances without a CAS number were also removed. One large group of chemicals, tin-organic substances, have both very similar properties and metabolites therefore only the most common tin-organic compounds were selected.*

*14. http://echa.europa.eu/documents/10162/13638/svhc_en.pdf*

## METHODS FOR INCLUSION OF 57(F) SUBSTANCES FOR SIN 2.0

During the development of the SIN List 1.0 endocrine disrupting properties were considered as one property, among many other end-points. Among the chemicals analysed for SIN List 1.0, 25 were designated SIN List chemicals partly due to the evidence of endocrine disrupting properties. However, in the development of SIN List 2.0, only chemicals with endocrine-disrupting properties were considered and included in the assessment.

These substances are only partly covered by official classification within the EU (e.g. as reprotoxic substances) but they pose a threat to human health and the environment due to their negative impacts on the hormone system that can lead to a variety of harmful effects. Many of them are also available in consumer products (articles and preparations) indicating a wide dispersive use, and many of them are produced in high volumes.

### FIRST STEP – SCREENING PHASE

The starting point was the European Commission's database of potential endocrine disruptors[15] developed under the "community strategy for endocrine disruptors". This database consists of 553 substances that have been evaluated with regard to their endocrine disrupting potential. Only substances belonging to the categories 1 or 2, for which there was evidence of EDC properties, were selected – leaving 319 substances.

Based on available information, substances were excluded from the evaluation list based on the same exclusion criteria as used for SIN List 1.0.

This was followed by an evaluation of possible uses for each substance. This evaluation was based on three sources. First, the assessments from the European Commission's database were used to identify uses as reported in the background documentation. Second, the Hazardous Substances Data Bank (HSDB)[16] was used to get further information on potential uses. And finally, for substances for which no uses had been identified, an internet search was carried out to check if there were any other probable uses that had not been addressed by the first two sources.

Substances having no known uses according to the above-mentioned sources were removed along with substances likely to be used only as intermediates or other uses not relevant to REACH such as pharmaceuticals and registered pesticides. To ensure consistency, these process and selection criteria were the same as those used for SIN List 1.0. The application of these filters left a total of 41 substances to be assessed more closely by toxicologists with an expertise in endocrine disrupting chemicals.

### SECOND STEP – LITERATURE RESEARCH

The literature research phase was intended to give a better understanding of the EDC properties associated with the selected substances by verifying the existing data from the European Commission EDC database as well as including the latest research on these substances.

The primary work of this phase was conducted by the members of the scientific staff of The Endocrine Disruption Exchange (TEDX)[17]. The process included a literature search, initial screening, abstract review, selection of studies, data entry and verification, and internal peer review.

**Literature search:** A comprehensive literature search was conducted in PubMed for each chemical. Search terms were selected based on TEDX experience in reading endocrine-related literature. The general approach was to be inclusive, using terms such as endocrine, hormone and receptor, as well as terms for the many organs involved in endocrine activity. For a few chemicals, very little information was found on PubMed, and additional searches were performed in Web of Science and ToxLine.

**Initial screening and abstract review:** The literature search generated a list of publications for each chemical. The initial screening of these lists involved scanning abstracts to remove studies that were not published in peer-reviewed journals, did not represent original primary research, or were clearly irrelevant. For example, studies of pest control, remediation, analytical methods and toxico-kinetics were removed at this level of screening. Review articles and other secondary research were used only to locate further primary research. Most studies of human environmental exposure were removed at this level primarily because they were based on retrospective self-reporting, failed to control for simultaneous exposure to other chemicals, and/or were unable to report any measure of exposure dose.

**Selection of studies:** Following the initial review of abstracts, the remaining studies were downloaded for review. The goal was to select the studies that provided the strongest evidence for endocrine effects. In addition to the oestrogenic, anti-androgenic and thyroid-based effects that tend to be the focus of regulatory attention, evidence of hormonally-based mechanisms of action in other organs, glands and systems and at other levels of effect (e.g. gene expression, signalling mechanisms) was included.

*15. EU COM EDC database: http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm*
*16. HSDB, US National Institutes of Health: http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB*
*17. The Endocrine Disruption Exchange (US): http://www.endocrinedisruption.com/*

Every effort was made to select the most scientifically robust studies. Studies that did not use appropriate control conditions or for which there were inconsistencies in the text or tables were not selected. No studies in which null findings directly contradicted significant findings from another study were found. High dose studies measuring gross endpoints only (e.g. organ weights) in which the mortality rate was excessive were not selected. Exceptions were made for chemicals for which only high dose studies were available and there was evidence of an endocrine effect (not a toxic effect). Additionally, in some cases, effects were found only at the lowest doses studied. Such studies were evaluated carefully and were not rejected for this reason alone, as endocrine-related effects are known to exhibit non-monotonic dose responses.

**Data entry and verification:** Only statistically significant findings were reported, with the rare exception of particularly compelling results for which no statistical analyses were conducted (e.g., gene arrays or changes in morphology). With regard to dose, it was not always practical to present the full range of doses used, as some studies used complex experimental designs and others only reported relative binding affinity.

**Internal peer review:** The final analysis was conducted via a collaborative effort within the researcher team. The researchers reviewed the chemicals one by one, evaluating each study in the database. The test methods employed were discussed as well as the assays used, whether the effects were truly endocrine-related, and how the authors interpreted their results.

According to TEDX, it was not unusual that studies never mentioned endocrine disruption, despite findings that were clearly relevant to the endocrine system. On this point, TEDX relied on the principles of endocrinology that endocrine effects encompass not only direct effects on traditional endocrine glands, their hormones and receptors, but also entire signalling cascades. These cascades affect reproductive function and foetal development, as well as the nervous system, behaviour, immune system, liver, bone and many other organs and glands.

## THIRD STEP – EVALUATION AGAINST REACH CRITERIA FOR SVHCS

The evaluation process to determine whether each substance fulfilled the REACH criteria for Substances of Very High Concern was led by ChemSec with support from an external group of scientists and toxicologists.

The official REACH guidance document on how to identify equivalent level of concern SVHCs and prepare an Annex XV dossier as stated in the "Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern" [18] dating from June 2007 was used as basis for the SVHC assessment. The guidance, however, does not give clear criteria on how to do this beyond that it should be applied on a case-by-case basis. The guidance mentions a few mechanisms and factors to be considered, and acknowledges that substances displaying endocrine-active properties can result in changes in growth, development, reproduction or behaviour in the organism or in future generations.

The guidance document and the definitions developed for the European Commission database, as well as advice from external EDC experts, were used as the basis for our assessment. All eligible substances needed to have robust data, primarily from in vivo tests obtained through studies of documented endocrine disruption in actual and intact animals. Only the studies carefully selected by TEDX, as described above, were considered. This information was then complemented with in vitro data from experiments performed in test tubes and on individual cells, as supporting evidence. To establish a reliable and robust dataset, at least three studies were considered necessary with a minimum of two in-vivo studies, to qualify for in-depth evaluation.

>> Following this approach and the subsequent evaluation, 22 substances were identified as having strong enough evidence to be considered Substances of Very High Concern with regard to their endocrine disrupting properties, and were subsequently added to the SIN List 2.0.


*18. http://echa.europa.eu/documents/10162/13638/svhc_en.pdf*

## REMARKS

Even if the SIN List methodology aims to limit non-REACH relevant substances, we are aware that not all uses of the substances included in the SIN List will *always* fall under REACH or authorisation procedures. Specific uses may still be exempted such as substances used as intermediates, in fuel, or as pesticides.

On the other hand, some of the substances removed in the screening phase may indeed classify as SVHC for specific uses covered by REACH, but we do not currently know which. Substances removed during the screening phase might potentially be considered as SVHC under REACH in the future.

Some of the substance entries on the SIN List are actually substance groups, grouped together in one entry. This grouping corresponds to the official classification documents in Annex VI of the CLP regulation or grouping used by ECHA for the Candidate List.

## ANNEX A
## SIN LIST 2.1 – MAKING UP THE NUMBERS

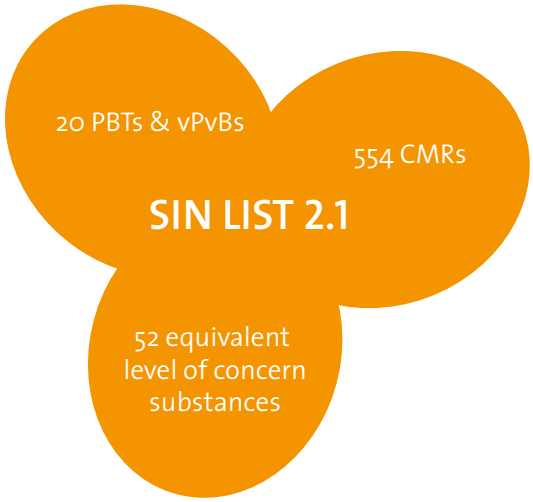
The 2.1 update of the SIN List, applying the grouping approach from the CLP regulation, resulted in one substance previously assessed as a 57f substance, and one substance initially included on the SIN List as a PBT substance, being combined into one CMR group: "lead alkyls". This reduced the total number of entries by one, resulting in a SIN List 2.1 consisting of:

- 220 CMR substances that were included in the first SIN List 1.0. The 1.1 update added 91 CMRs, and the 2.1 update added another 242 CMRs (plus one new group as described above) resulting in 554 CMR substances on the SIN List 2.1.

- 17 PBTs/vPvBs were included in the first SIN List 1.0, and the 2.1 update added another 4 vPvBs, resulting in 20 PBT and vPvB substances on the SIN List 2.1 (after one PBT substance had been moved to a CMR group as described above).

- The first SIN List 1.0 contained 30 equivalent concern substances, however 2 of these were changed with the 1.1 update, as they became recognised as classified CMRs. The 2.0 update added 22 equivalent concern substances, and the 2.1 update another 3 substances, resulting in 52 substances on the SIN List based on the equivalent level of concern criteria (after one substance had been moved to a CMR group as described above).

This resulted in a SIN List 2.1 with a total of 626 substance and substance group entries, hence encompassing 802 unique CAS/EC numbers.




## ANNEX B
## GLOSSARY

| | |
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| Bio-accumulative | A property causing the substance to build up (accumulate) in the body. Such substances build up in fat tissue in the body and cannot be excreted by the body. |
| Candidate List | A list of substances within REACH meeting the criteria for Substances of Very High Concern, and proposed by either the European Commission or the EU member states. These substances are candidates for REACH authorisation. |
| Carcinogenic | A carcinogenic substance causes cancer. |
| CARACAL | Competent Authorities for REACH and Classification and Labelling in the EU member states. |
| CAS number (#) | Chemical Abstracts Services registration number. A unique number assigned to each substance submitted to CAS. Used worldwide to positively identify chemicals. |
| CMR | CMR is the abbreviation for Carcinogenic, Mutagenic and toxic to Reproduction; chemicals with inherent properties which can cause cancer, alter DNA or damage reproductive systems. Part of the REACH Substances of Very High Concern. |

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| EC number (#) | European Commission registration number. The unique number under which a substance is registered in the European Union. |
| ECB | European Chemicals Bureau. ECB's mission has been to provide scientific and technical support to the conception, development, implementation and monitoring of EU policies on chemicals and consumer products. Its duties have now largely been taken over by ECHA. |
| ECHA | The European Chemicals Agency in Helsinki, Finland. The EU authority established to oversee and implement the REACH system. |
| Endocrine disruptor/EDC | Endocrine Disruptor Chemicals. A substance that disrupts or alters the hormonal systems in the body, causing widespread effects throughout the organism. |
| Equivalent level of concern | The safety net of the REACH regulation for substances which do not automatically fall into the categories CMR, PBT or vPvB, but are of equivivalent level of concern in terms of the potential damage they may cause. |
| ESIS | European chemical Substances Information System. An IT system with information on chemicals related to Biocidal Products, PBTs vPvBs, Classification and Labelling, Export and Import of Dangerous Chemicals and HPV/LPV substances. |
| Hazard | Hazard refers to the intrinsic properties of a substance which are always present. See also "Risk" |
| HPV | High Production Volume chemical, manufactured/imported at more than 1000 tonnes/year |
| LPV | Low Production Volume chemical, manufactured/imported at more than 100 tonnes/year |
| MSCA | Member State Competent Authority. The authority in each EU member state which monitors REACH and other chemical issues. |
| Mutagenic | Causes irreparable mutations in the DNA that will be transferred on to the next generation. |
| PBT | Substances that are Persistent, Bioaccumulative and Toxic are substances that do not easily break down, instead they build up in nature and in e.g. the fatty tissue of mammals, with a potential to cause serious and long-term irreversible effects. Part of the REACH Substances of Very High Concern. |
| Persistent | A persistent substance will not break down or degrade in humans, animals or nature. This means that they will remain for a very long time once produced. |
| REACH | REACH is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals, the EU chemical regulation entered into force in 2007. |
| Risk | Risk is the combination of "Hazard", probability and exposure. See also "Hazard". |
| SIN List | The "Substitute It Now" List of Substances of Very High Concern identified by ChemSec in accordance with REACH criteria. A ChemSec project aiming to speed up the REACH implementation process and provide a substitution tool for companies. |
| Substance of Very High Concern | Substances of Very High Concern (SVHCs) are the most hazardous substances according to article 57 of REACH. These are substances that are Carcinogenic, Mutagenic and toxic to Reproduction (CMR), Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) or substances of equivalent level of concern. |
| SVHC | See Substances of Very High Concern. |
| Toxic for Reproduction | A substance which is toxic to reproduction will impair the ability to produce offspring or cause irreversible harm to the offspring itself. |
| Very Bio-accumulative | A very bio-accumulative substance accumulates to an even higher degree in the body than "ordinary" bio-accumulative substances. |
| Very Persistent | A very persistent substance persists to an even higher degree in nature than "ordinary" persistent substances. |
| Working List | ECHA prioritises a number of substances from the Candidate List and works actively to put them through Authorisation. |
| vPvB | vPvBs are substances that are very Persistent and very Bioaccumulative but are not necessarily toxic as defined today. However they persist in the environment and accumulate in the food chain for such a long period of time that they are also considered to be Substances of Very High Concern according to REACH. |

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