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Analytisches Laboratorium
für Umweltuntersuchungen und Auftragsforschung
Bestimmung und Bewertung von Umweltdaten

Final Report Version 2

FKZ 360 12 019

Regulation under REACH: Identification of potential candidate chemicals based on literature, environmental monitoring, (non)European regulations and listings of substances of concern.

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15. Zusätzliche Angaben

16. Kurzfassung

REACH erfordert die Identifizierung und Überwachung besonders besorgniserregender Stoffe (SVHC). In dem vorliegenden Gutachten wurden verschiedene Informationsquellen auf ihre Eignung hinsichtlich der Beurteilung des Gefährdungspotentials von möglichen Kandidatensubstanzen ausgewertet, basierend auf z.B. Expositionswahrscheinlichkeit, Informationen bezgl. Einstufung und Kennzeichnung, Stoffzusammenstellungen aus anderen Rechtsbereichen als REACH, Stofflisten anderer Behörden und Informationsquellen, die ein mögliches Gefährdungspotential ausschließen.
Für die Identifizierung möglicher SVHC erfolgte zuerst eine vergleichende Analyse der quantitativen und qualitativen Kriterien, die zu einer Aufnahme der Substanzen in die entsprechenden Stofflisten geführt hatten. Es wurde eine Rangfolge der Substanzen erstellt, basierend auf der Schwere der Effekte, numerischen kriterienbezogenen Schwellenwerten und dem Bezug zu REACH Art. 57 (wie Persistenz, Bioakkumulation, Klimaveränderung, Exposition und Risiko).

Durch kombinatorische Analyse und hierarchische Identifizierung von Kandidatensubstanzen, basierend auf der Priorisierung innerhalb der Kriterienkategorien, konnte eine anfängliche Menge von ca. 3700 Kandidatensubstanzen auf ca. 900 umweltrelevante Chemikalien reduziert werden. Eine weitere Konzentrierung auf 234 Substanzen erfolgte durch Kombination zweier Konzepte:

- Anzahl der multiplen Besorgniskriterien (z.B. PBT, EDC, LRT und/oder Klimaverändeurng);
- Charakteristische Kombinationen von Gefährdungsmerkmalen (z.B. arktische Kontaminanten aufgrund von LRT plus BCF).

Die Liste der Stoffe, die auf Basis der beiden Bewertungskonzepte erhalten wurde, stimmte in 93 Fällen überein und identifizierte damit prioritäre Kandidaten für Stoffe mit möglicherweise besorgniserregenden Eigenschaften. Die Validierung dieser möglichen SVHCs erfordert in einem weiteren Schritt eine detaillierte Überprüfung der intrinsischen Stoffeigenschaften durch Sachverständige.

17. Schlagwörter
REACH, SVHC, Priorisierung

18. Preis 60 854 €	19.	20.

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16. Abstract

Registration of chemicals according to REACH requires the identification of substances of very high concern (SVHC). As part of this study, diverse information sources have been evaluated for their usefulness to provide information on the hazard potential of chemicals (e.g. listings of chemicals covered by regulations other than REACH, listings compiled by other competent authorities as well as information sources indicating absence of hazards, hazard ranking, probability of exposure, classification and labelling). Based on the information obtained potential SVHC candidates were identified.

The identification of SVHC candidates started with a comparative analysis of quantitative and qualitative criteria of concern. The substances were ranked according to the severity of observed effects, thresholds for observed criteria and relevance to REACH Art. 57 (e.g. persistence, bioaccumulation, toxicity, climate change, exposure and risk).

Combinatorial analyses and hierarchical identification of candidate chemicals were carried out within the different criteria categories. An initial pool of ~3700 candidate chemicals was processed to obtain an intermediate list of ~900 environmentally relevant chemicals. A further reduction to 234 compounds was achieved by the combination of two principal concepts:

- Selection according to number of multiple concerns (e.g. PBT, EDC, LRT and/or climate change)
- Selection based on characteristic combinations of hazards (e.g. arctic contaminants due to LRT plus BCF).

The lists of substances obtained with the two concepts coincided with 93 substances which are thus representing primary candidates of major concern. The validation of the identified chemicals requires a further more detailed assessment of the intrinsic properties based on expert judgement.

17. Keywords

REACH, SVHC, priority setting

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Report Cover Sheet 06/2000

Contents

Tables

Figures

Abbreviations

BCF **B**io**C**oncentration **F**actor

C & L **C**lassification and **L**abelling

CMR **C**arcinogens, **M**utagens and **R**eproductive toxicants

ECHA **E**uropean **CH**emicals **A**gency

EDC **E**ndocrine **D**isrupting **C**hemicals

EQS **E**nvironmental **Q**uality **S**tandards

FDA US **F**ood and **D**rug **A**dministration

GDCh **G**esellschaft **D**eutscher **Ch**emiker (German Chemical Society)

HPV **H**igh **P**roduction **V**olume

HPVC **H**igh **P**roduction **V**olume **C**hemicals

LRT **L**ong-**R**ange **T**ransport potential

PBT **P**ersistent, **B**ioaccumulative and **T**oxic chemicals

PCBs **P**oly**C**hlorinated **B**iphenyls

PEC **P**redicted **E**nvironmental **C**oncentration

PNEC **P**redicted **N**o-**E**ffect **C**oncentration

POP **P**ersistent **O**rganic **P**ollutants

PRTR **P**ollutant **R**elease and **T**ransfer **R**egister

REACH **R**egistration, **E**valuation, **A**uthorization and restriction of **CH**emicals

RoI **R**egistry **o**f **I**ntentions

SVCH **S**ubstances of **V**ery **H**igh **C**oncern

UBA **U**mwelt**B**undes**A**mt (German Environmental Agency)

vPvB **v**ery **P**ersistent and **v**ery **B**ioaccumulative

WFD **W**ater **F**ramework **D**irective

WGK **W**asser**G**efährdungs**K**lasse (German Water Hazard Class)

1 Introduction and outline

The European regulation concerning registration, evaluation, authorization and restriction of chemicals (**REACH**) requires demonstration of safe manufacture and use of chemicals throughout the supply chain [1]. Substances of very high concern, such as persistent, bioaccumulative and toxic (**PBT**) chemicals and very persistent, very bioaccumulative (**vPvB**) chemicals, carcinogens, mutagens and reproductive toxicants (**CMR**), as well as substances for which there is scientific evidence of an equivalent level of concern and which are identified on a case-by-case basis (e.g. **endocrine disruptors**), may be subject to authorisation.

Articles 57, 58 and 59 of the REACH regulation define the criteria for identification and the procedure for including substances in **Annex XIV** (List of **substances subject to authorisation**). The aim of the authorisation provisions is **risk reduction** by properly controlling the risks from substances of very high concern (**SVHC**) and by replacing these substances progressively by suitable alternative substances or technologies.

In February 2009, ECHA published a first version of the candidate list of substances of very high concern for eventual inclusion in Annex XIV. The candidate list will be regularly updated when more substances are identified as SVHC, by proposals from Member States Competent Authorities or the ECHA, on request by the Commission. On 1 June 2009, ECHA has recommended seven substances for the inclusion in Annex XIV of REACH:

- Musk xylene (vPvB);
- 4,4`-Diaminodiphenylmethane - MDA (carcinogenic);
- Short Chain Chlorinated Paraffins - SCCPs (PBT and vPvB);
- Hexabromocyclododecane - HBCDD (PBT);
- Bis(2-ethylhexyl)phthalate - DEHP (Toxic to Reproduction);
- Benzylbutylphthalate - BBP (Toxic to Reproduction);
- Dibutylphthalate - DBP (Toxic to Reproduction).

In support of the efforts by UBA to identify chemicals of concern and eventually prioritise further SVHC-candidates, this study reviews literature, environmental monitoring, (non)European regulations and listings of substances of concern to provide a collection of potential candidate chemicals that may by assessed by UBA and might be subject to regulation under REACH. The study addresses three major targets:

Target 1: Collection and organisation of information sources in a data-base tool:

A large variety of more than 130 information sources has been evaluated with regard to their usefulness to serve as indicator or derogator of chemicals of concern. The information sources cover multiple aspects:

- Inventories in support of hazard ranking, e.g. persistence, bioaccumulation potential; toxic or other adverse effects of substances;
- Registries indicating probability of exposure;
- Inventories based on risk-related criteria, i.e. including considerations of exposure and effects;
- Inventories based on political criteria, e.g. 'environmental relevance' or 'concern' assigned by expert judgement;
- Information sources indicating absence of hazardous properties and concerns;
- Information on chemicals covered by regulations other than REACH;
- Information on chemicals covered by other Competent Authorities;
- Information on chemicals covered by other Member States (e.g. RoI (Registry of intentions));
- Information from Classification and Labelling.

Deliberately, the different information sources represent positive and negative evidence of concern. The underlying rationale is that some records serve to identify potential concern (i.e. selection of candidates) whereas others advocate minor hazards (i.e. derogation of candidates). Other information sources do not directly address hazards but are useful for prioritisation. Section 2 details the evaluation of information sources and their selection for integration in the data-base tool (for technical specifications see ANNEX 1).

Target 2: Identification of potential REACH-related candidate chemicals of concern:

The quantitative and qualitative criteria of concern that motivated the inclusion of substances into any of the inventories were comparatively analysed (Section 3). The criteria categories concern:

- **P** Persistence-related criteria;
- **B** Bioaccumulation-related criteria;
- **T** Toxicity-related criteria;
- **C** Climate change-related criteria;

- **E** Exposure-related criteria;
- **R** Risk-related criteria;
- **X** Political criteria;
- **§** Regulations other than REACH.

Within each category, the inventories were ranked with regard to severeness of effects, numerical criteria thresholds and relevance to REACH Art. 57. Assigned scores prioritise the information sources and are the key to a transparent and reproducible extraction of potential candidate chemicals (Section 4).

The devised strategy is very flexible to focus different targets of concern alone or in combination, e.g., persistence, long-range transport potential and/or endocrine disruption. Based on the ranking and grouping of information sources, the data-base tool has been used for combinatorial analyses and hierarchical identification of chemicals of concern. Core and key instrument for effective operation are the priorities within the criteria categories (Section 4, in particular Table **17**). The criteria and their ranking are also provided in the data-base tool (Section 3.4). The **initial pool of candidate chemicals (~3700 compounds)** was focussed to obtain an intermediate list of **environmental chemicals (~900 compounds)**. Further concentration was achieved with the combination of two principal concepts to identify chemicals with high probability of concern (~230 compounds):

- **Identification of multiple hazards:** The number of 'concerns', i.e. the number of criteria categories (e.g. PBT, EDC, LRT and/or climate change) that are addressed by the records of the candidate chemicals (i.e. How many of these criteria are met by the candidate substance concerned and with which priority?);

- **Identification of defined concerns:** The occurrence of characteristic combinations of hazards indicates specific groups of pollutants. For example, **arctic contaminants** are frequently associated with long-range transport potential combined with major bioaccumulation.

These two schemes deliver similar results and both contribute to a targeted **joint list of 234 candidate chemicals based on defined concerns and multiple hazards** (Section 4). Perhaps surprisingly, 93 chemicals are equally identified by both schemes, which render themselves primary candidates of major concern. The extracted list provides a sound basis **for detailed identification and prioritisation of potential SVHC by UBA.**

Target 3: Practical recommendations for prioritisation of REACH-related candidate chemicals by UBA:

This study has produced several recommendations and suggestions (Section 5) that have been discussed with UBA. It has been recognised that UBA requires a modular approach to be able to focus the candidate chemicals of major concern and to adapt limited resources to technical and political demands. If the principal limitations of the selected evidence-based approach (Section 4.2) are considered, the candidate chemicals may be successfully focussed by prioritisation as well as deferment. The complementary options comprise:

- Derogation of chemicals that are covered by REACH and other regulations (e.g. known SVHC, Convention POPs, Annex I pesticides), by other Competent Authorities (e.g. CMR), or by other Member States (e.g. RoI (Registry of intentions));
- Prioritisation of chemicals by environmental relevance related to, e.g., actual exposures and wide dispersive use;
- Prioritisation of chemicals by number of 'concerns', assuming that these chemicals have highest probability of adverse effects;
- Prioritisation of chemicals with regard to specific 'concerns', e.g. endocrine disruptors or arctic contaminants, to reflect the specific relevance of the chemicals in question;
- Prioritisation of chemicals by intrinsic properties (e.g. ecotoxicity, persistence, bioaccumulation, biodegradation) within categories of concern;
- De-prioritisation of chemicals absent of Classification and Labelling or with physico-chemical property profiles subject to waiving;
- Aspects of climate change may be suspended because the responsible chemicals are well known, limited in number and a global political effort, rather than scientific expertise, is required to effectively reduce their impact.

As a consequence of the principal limitations of the selected approach, the focussed list of candidate chemicals is NOT a list of SVHC candidates as yet, but a **sound basis for detailed identification and prioritisation of potential SVHC** by UBA and requires further processing **based on expert judgement** (cf. follow-up study on verification of candidate chemicals by intrinsic properties and prioritisation by relevance with regard to environmental criteria of REACH). There, the objective will be to explicitly name priority chemicals for thorough assessment of substances by UBA to be nominated as potential SVHC (Annex XIV of REACH), likely candidates for restrictions (Annex XVII of REACH), or for further needs for data and information.

2 Information sources and records of chemicals of concern

The evaluated information sources comprise lists of (priority) chemicals published by competent authorities and NGOs of diverse (non)European countries for a variety of purposes, e.g. protection of environment and human health, monitoring of water pollution, regulations beyond REACH, scientific literature and results from (ongoing) research projects. Depending on the respective objectives, the records of (priority) chemicals differ greatly in their size and composition, and with respect to the criteria that were used to include substances. Major efforts were invested to cover the most relevant information sources and to evaluate their usefulness with regard to identifying

- potential SVHC,
- innovative (combinations of) criteria of concern.

2.1 Search strategy for information sources and records of chemicals of concern

Starting with the information sources and records of chemicals of concern already available to the project team from previous studies, an extensive collection of inventories, lists and records was retrieved, also using personal contacts (expert interviews) and peer input through professional societies, e.g. GDCh.

The collection of information sources was strategically compiled to include positive and negative evidence of concern. The underlying rationale is that some records serve to identify potential concern (i.e. selection of candidates) whereas others advocate minor hazards (i.e. derogation of candidates):

- Inventories in support of hazard ranking that feature information on, e.g. persistence, bioaccumulation potential, toxic or other adverse effects of substances. These information sources were grouped depending on the hazard criteria used, e.g. PBT, LRT or climate change and ranked within the groups by thresholds of concern, if possible;
- Registries indicating probability of exposure, e.g. records of monitoring and environmental surveys of chemicals of concern, PRTR (pollutant release and transfer registers) from different countries worldwide or inventories of HPV substances;
- Inventories based on risk-related criteria, i.e. including considerations of exposure and effects, e.g. PEC/PNEC approaches. However, because exposure varies on the spatial and temporal scale, risk is site-specific (local or regional) and may not be generalised;
- Inventories based on political criteria, e.g. ‘environmental relevance’ or ‘concern’ assigned by expert judgement. Political criteria frequently lack sufficient

documentation and transparency, but may nevertheless contribute valuable indications on hazardous priority substances of concern;

- Information sources indicating absence of hazardous properties and concerns, mostly with regard to particular concerns, e.g. not PBT or no aquatic toxicity (according to German WGK classification);
- Information on chemicals covered by regulations other than REACH (e.g. the recognised POPs of the Stockholm Convention as listed in Regulation 850/2004) or by directives (e.g. Biocides Directive 98/8/EC, Water Framework Directive 2000/60/EC);
- Information on chemicals covered by other Member States (e.g. RoI (Registry of intentions));
- Information on chemicals covered by other Competent Authorities, e.g. CMR substances may be dealt with human health assessments;
- Information from Classification and Labelling.

The types of collected information sources and records of chemicals of concern comprise (Table 1):

- Priority list: Compounds on such lists have been prioritised for inclusion;
- Monitoring list: Compounds on such lists have been analytically measured in the environment;
- Environmentally relevant list: Compounds on such lists have been recognised to be potentially hazardous and they occur in the environment;
- General-purpose substance list: Compounds on such lists have been compiled based on specific properties (factual data-bases);
- Criteria;
- Other information sources.

2.2 Evaluation and selection of relevant information sources and records of chemicals of concern

The collected information sources and records of chemicals of concern were evaluated with regard to their usefulness to serve as an indicator or derogator of chemicals of concern. Positive evaluation prompted the selection of an information source for integration in the project's data-base tool (for technical specifications see ANNEX 1). The detailed outcome of the evaluation and associated comments on information sources and records of chemicals of concern are reported in ANNEX 2 in Table A 2-1 (information sources included in the data-

base tool for extracting potential SVHC candidates) and Table A 2-2 (information sources NOT included in the data-base tool for extracting potential SVHC candidates).

Information sources and records of chemicals of concern were selected for inclusion in the data-base tool for extracting potential SVHC candidates if they feature relevance to REACH Art. 57:

- concerns with regard to PBT or vPvB properties,
- concerns with regard to CMR properties,
- equivalent level of concern (e.g. endocrine disruption, long range transport potential, climate change),
- concerns with regard to wide dispersive use,
- concerns with regard to high volumes.

Further requirements relate to:

- plausibility of criteria used to establish priorities,
- relevant documentation.

If compliance with the above sets of requirements was insufficient, information sources and records of chemicals of concern were not included. Further criteria for exclusion relate to lack of relevant focus, such as:

- general purpose data-bases,
- general information systems,
- previous versions of selected information sources,
- methodology information, e.g., analytical methods,
- concerns with regard to human health only.

Selected reference criteria for prioritisation of chemicals, e.g. for PBT properties, were included in the data-base tool to provide easy access for comparative analyses. Furthermore, some on-going research projects have been listed that have not delivered results as yet, but may become interesting for future updates of the data-base tool.

The types of the ~130 collected information sources and records of chemicals of concern are summarised in Table 1. Information sources were included preferentially if they focus

REACH Art. 57, i.e. lists of priority chemicals and monitoring records have been considered more important to the objectives of this project as compared to lists of vaguely environmentally relevant chemicals. The least significance was attributed to general-purpose substance lists.

Table 1: Type of information sources and records of chemicals of concern considered for inclusion in the data-base tool for extracting potential SVHC candidates.

Type	Included	NOT included
Priority list	38	2
Monitoring list	10	3
Environmentally relevant list	7	3
General-purpose substance list	15	36
Criteria	5*	0
Other information sources	5	11

* no compound lists associated

Table 2 details the media-specificity of information sources, a very useful feature to prioritise inventories of chemicals with regard to subject of protection. When used alone or in combination, they allow to focus specific compartments. Most of the available records relate to aquatic environments, including water and sediment phases and (partly) aquatic organisms. Notion of biota may indicate either effects on organisms or biomonitoring targets. Terrestrial ecosystems are less frequently addressed, mostly in relation to possible exposure to air and soil via PRTR. However, for most inventories, no target medium has been specified.

Table 2: Media-specificity of information sources and records of chemicals of concern that have been included in the data-base tool.

(Note: Because several information sources and records of chemicals of concern relate to multiple media, the total number in this table exceeds the number of information sources and records of chemicals of concern that have been included in the data-base tool.)

Medium	Number of information sources
Water	42
Air	16
Soil	18
Sediment	17
Biota	37
Not specified	62

2.3 Organisation of the collected information in a data-base tool

The collected information sources and records of chemicals of concern are documented in the project's data-base tool (for technical specifications see ANNEX 1) and described by:

- Type of information source (priority list, monitoring list, environmentally relevant list, general-purpose substance list, criteria, other information source (Table 1));
- Title (brief description of content);
- Author(s) or responsible institution;
- Number of substances;
- Medium (water, air, soil, sediment, biota, not specified (Table 2));
- Criteria of concern (PBT, monitoring, others, e.g. LRT, CMR, EDC (Section 3);
- Evaluation of the usefulness of the information source for identifying chemicals of concern (ANNEX 2);
- (Sub)lists that were extracted to focus relevant criteria of concern;
- Explanatory comments to assist in further evaluation of the relevance and the applicability of the information source;
- Citation, reference.

If the evaluation of the usefulness of an information source for identifying chemicals of concern was positive, tables that list the respective substances have been extracted. In total, 75 information sources and 5 sets of reference criteria have been selected for inclusion in the data-base tool. If appropriate, the records were divided into sublists to focus relevant criteria of concern.

Another six inventories were compiled as an internal means to de-select chemicals not primarily covered by REACH like pesticides (1001 INT PSM Alanwood, 1002 INT Pflanzenschutzmittelwirkstoffe UBA, 1006 INT PSM Collected), biocides (1004 INT Biozidwirkstoffe), pharmaceuticals (1003 INT Humanarzneimittelwirkstoffe), or veterinary products (1005 INT Tierarzneimittelwirkstoffe).

Figure 1 provides an overview of the numbers of compounds covered by the collected information sources and records of chemicals of concern that have been included in the data-base tool. Most inventories have less than 100 entries, many comprise 100 to 500 substances and some even feature > 1000 compounds. The latter group are particularly registries of substances in products that had to be included to address the aspect of wide dispersive use. Another example of very large records are comprehensive environmental inventories like the German water hazard classification with WGK 1 indicating minor hazard

to water for > 4000 substances. The WGK 0 and 1 listings are examples of inventories related to ‘absence of major hazard’ and a useful tool to de-prioritise chemicals with regard to aquatic toxicity. As well, these inventories tend to be very large and may artificially expand the data-base. To avoid numerous entries without substantial information content, chemicals were excluded if they exclusively appear in records of ‘negative’ effects.

Because of limited overlap between the collected information sources and records of chemicals of concern, the initial version of the data-base of chemicals in the tool consisted of ~34.000 entries. The exclusion of chemicals only appearing on negative records (see above) as well as grouping of similar substances (see below) reduced the final version of the data-base to ~18.000 entries.

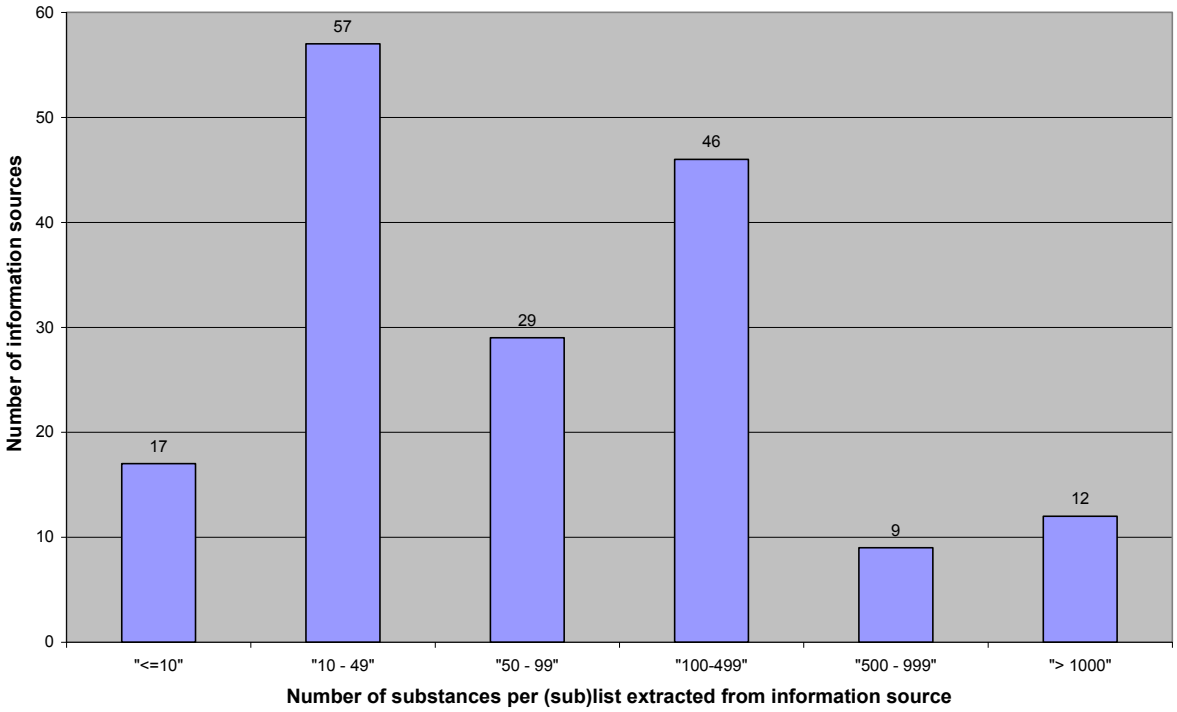


Figure 1: Overview of numbers of substances covered by information sources and (sub)lists of chemicals of concern that have been included in the data-base tool.

The chemicals from each selected information source were identified by CAS registry number and (multiple) names. Major efforts were invested to obtain proper identities of the chemical entries, e.g. by seeking missing CAS numbers, correcting wrong CAS numbers, misspelled names and flawed CAS/name matches, identifying a unique CAS number for compounds with more than one CAS number (e.g. in the case of cis/trans-isomers, mixtures

of isomers). Inconsistencies with regard to multiple entries with same name but different CAS numbers have been eliminated as far as possible.

In order to improve handling of the data-base of chemicals in the tool, the possibility to form groups of substances has been implemented, e.g. nonylphenols, chlorosilanes, organotin compounds, halogenated naphthalenes etc. Group names covering multiple CAS numbers of similar compounds have been introduced. The major advantage of the grouping approach concerns the concentration on joint hazards of the grouped substances.

If available from the original information source, further details about the relevant concerns and intrinsic hazards have been maintained in the data-base. Examples are in record 13 'List of substances hazardous to waters' a field detailing the water hazard class (WGK) or in record 28 'SIN List 1.0' a field discriminating PBT/vPvB chemicals, CMR compounds and substances of equivalent level of concern. Either quantitative or qualitative differentiation has been used to set up sublists of the inventories as to allow the user to better focus particular concerns whilst having the opportunity to exempt less hazardous chemicals. The sublist approach means in case of record 13 'List of substances hazardous to waters' that 4 sublists are available, one for WGK 3, WGK 2, WGK 1 and no WGK, respectively that may either identify hazards to aquatic environments, particularly sublist WGK 3, or advocate for absence of such effects, i.e. sublist no WGK. In case of record 28 'SIN List 1.0', three sublists have been established detailing whether a chemical has been included in this inventory for having either PBT/vPvB or CMR properties, or give rise to an equivalent level of concern, i.e. endocrine disruptors. The splitting of information sources is documented in detail in the data-base tool (see Menu: 'Kriterien'). The use of sublists to efficiently extract candidate chemicals of major concern is demonstrated in Section 4. An overview of the tables extracted from the selected information sources and records of chemicals of concern with their associated sublists is provided in ANNEX 3.

3 Principal criteria indicating hazards

The selected information sources from literature, environmental monitoring, (non)European regulations and listings of priority chemicals feature a wide variety of reasons that triggered the inclusion of substances into any inventory. While many criteria are quantitative in nature and based on scientific reasoning, a substantial number of priority measures remain vague and resist immediate insight. Insufficient documentation confounds the reliability of some information sources. For some others, e.g. monitoring campaigns, no logic is provided about the composition of the lists of analytes. Lack of transparency is frequently associated with so-called political criteria, e.g. 'concern' assigned by expert judgement. Despite their limitations, it is recognised that these inventories nevertheless may contain valuable indications on priority substances of concern and therefore some of them were included in the data-base tool for supplementary evidence in consecutive prioritisation exercises.

3.1 Qualitative comparison of criteria

The criteria used for the identification of substances of concern were extracted from the information sources and grouped into principal categories of environmental relevance:

Fate-related criteria: **PB**T (Persistent, Bioaccumulative), POP (Persistent Organic Pollutants), LRT (Long-Range Transport), biomagnification;

Effect-related criteria: PB**T** (Toxic), aquatic toxicity (e.g. WGK), EDC (Endocrine Disrupting Chemicals), CMR (Carcinogens, Mutagens, Reproductive toxicants), neurotoxicity, sensitisation, C & L (Classification and Labelling);

Climate-change related criteria: ozone depletion, global warming;

Exposure-related criteria: monitoring, HPVC (High Production Volume Chemicals), product registries;

Risk-related criteria: PEC/PNEC (Predicted Environmental Concentration, Predicted No-Effect Concentration), SPEAR Index (SPEcies At Risk), river health, EQS (Environmental Quality Standards according WFD (Water Framework Directive));

Political criteria: 'concern', expert judgement.

Regulation other than REACH: e.g. POPs of the Stockholm Convention as listed in Regulation 850/2004, Biocides Directive 98/8/EC, Water Framework Directive 2000/60/EC.

Systematic prefixes to group information sources: The eight-character code indicates whether or not a criteria category was used to set up the respective inventory:

P Persistence-related criteria;
B Bioaccumulation-related criteria;
T Toxicity-related criteria;
C Climate change-related criteria;
E Exposure-related criteria;
R Risk-related criteria;
X Political criteria;
§ Regulations other than REACH.

The criteria categories were used to group information sources. The categories assist in handling the (sub)lists of chemicals of concern relating to REACH Article 57 a - c (CMR), d - e (PBT or vPvB), f (equivalent level of concern, e.g., EDC, hazards to water bodies, climate change) and Article 58 3b - 3c (wide dispersive use, high volumes). The grouping of information sources is facilitated by systematic prefixes to their names. The eight-character code (P (persistence), B (bioaccumulation), T (toxicity), C (climate change), E (exposure), R (risk), X (political criteria), § (regulation), _ (not considered)) indicates whether or not a criteria category was used to set up the respective inventory. Assignments of the code only denote that an information source relates to this criteria category, but it does not necessarily mean that all substances on the original list fulfil these criteria. For example, a list with the prefix "PBT_____" may contain PBT chemicals as well as chemicals identified as not having PBT properties. If this is the case, respective (sub)lists are differentiated, e.g., "PBT_____PBT ESIS fulfilling PBT" and "PBT_____PBT ESIS notfulfilling PBT".

Table 3 provides a compilation of the analysed inventories sorted by the type of criteria (P, B, T, C, E, R, X, §) used for identifying chemicals of respective concern. The column "Criteria" provides an overview of the wide variety of criteria for prioritisation. It is easily evident that many priority lists were assembled based on a combination of multiple properties, among which PBT schemes are most prominent (Table 4). The most frequent parameter is toxicity, representing a wide variety of effects from acute hazards, e.g. aquatic EC_{50}, NOEC, to chronic and specific effects, e.g. CMR, EDC, and exposure-related monitoring lists and production inventories.

The detailed criteria used for identifying chemicals of concern for the information sources and records of chemicals of concern included in the data-base tool are provided in ANNEX 4. Persistence, bioaccumulation and toxicity criteria are detailed if quantitative thresholds were provided in the documentation; else the fields are frequently blank. Further reasons for priority setting are listed under other criteria.

Table 3: **Overview of collected information sources and associated principal criteria.**

Principal criteria: P (persistence), B (bioaccumulation), T (toxicity), C (climate change), E (exposure), R (risk), X (political criteria), § (regulation); The systematic prefix consists of an eight-character code (P, B, T, C, E, R, X, §, _ (not considered)) that indicates whether or not a criteria category was used to set up the respective list.

Type of list/information source: P: Priority list, E: Environmentally relevant list, M: Monitoring list, S: general-purpose Substance list, C: Criteria.
M = medium (wat: water, soil, air, sed: sediment, bio: biota, ns: not media specific).

Prefix	Content	No	Criteria	P	B	T	C	E	R	X	§	Type	M
PBTC____	PRIO- Hazardous Substances prioritised for risk reduction measures, Sweden	14	PBT CMR EDC Ozone depletion	X	X	X	X					P	wat sed bio
PBTC ____	List of Undesirable Substances (LOUS), Denmark	16	PBT	X	X	X	X					P	ns
PBT_ER__	Trade Union Priority List for REACH Authorisation	129	PBT CMR EDC Neurotoxicity Sensitizer Occupational hazards HPV Wide dispersive use	X	X	X		X	X			--	wat bio
PBT_E_X_	Selection of substances, deserving policy attention, not subject of other risk assessment programmes, Netherlands	44	Monitoring Bioaccumulation Biodegradation	X	X	X		X		X		M	wat sed bio
PBT_E__§	ECHA Candidate List of Substances of Very High Concern for Authorisation	81	PBT CMR Wide dispersive use HPV	X	X	X		X			X	P	wat soil sed bio
PBT_E___	OSPAR List of Chemicals for Priority Action (Update 2007)	7	PBT	X	X	X		X				P	wat bio
PBT_E___	SIN List 1.0	28	CMR PBT HPV EDC	X	X	X		X				P	wat soil bio
PBT_E___	Toxic Release Inventory - Database	36	PBT Release	X	X	X		X				E	ns
PBT__R__	Canada Domestic Substance List	92	Concern	X	X	X			X X			S	wat soil air sed bio
PBT__R__	Priority Substances, Norway	95	PBT	X	X	X			X			P	ns
PBT___X_	NICNAS Chemical Assessment Reports	25	Concern	X	X	X				X		S	ns
PBT___X_	EC/304/2003 CONCERNING THE EXPORT AND IMPORT OF DANGEROUS CHEMICALS	116	Hazard	X	X	X				X		S	ns
PBT____§	ESIS: European chemical Substances Information System / PBT Liste	4	PBT	X	X	X					X	P	wat sed bio
PBT____§	Stockholm Convention on Persistent Organic Pollutants (POPs)	10	PBT POP LRT	X	X	X					X	P	wat soil air sed bio
PBT____§	PBT Profiler	20	PBT	X	X	X					X	P	ns
PBT____§	Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants	100	PBT POP LRT	X	X	X					X	P	wat soil air sed bio
PBT____§	Persistent Bioaccumulating Toxins, State of Washington	111	PBT	X	X	X					X	P	wat soil sed bio

Prefix	Content	No	Criteria	P	B	T	C	E	R	X	§	Type	M
PBT_____	TGD: Technical Guidance Document	6	PBT									C	wat sed bio
PBT_____	List of Potential Substances of Concern to be Considered by HELCOM	9	PBT POP EDC	X	X	X						P	wat bio
PBT_____	Priority Substances Assessment Programm (Environment Canada)	24	PBT	X	X	X						P	wat soil air sed bio
PBT_____	Existing Substances Programme at Environment Canada	31	PBT	X	X	X						M	wat soil air sed bio
PBT_____	Green Screen - Flame Retardants for TV Enclosures	119	PBT Phys.-chem. Properties	X	X	X						P	wat soil sed bio
PBT_____	Screening criteria for P, vP, B, vB and T	127	PBT									C	ns
PBT_____	Persistence, Bioaccumulation Potential, and Inherent Toxicity to Non-human Organisms	128	PBT									C	wat soil air sed bio
PB_C__X_	Restricted substances and materials for the Olympic Games in London 2012	121	EDC PBT Neurotoxicity Ozone depletion Global warming Sensitizer CMR	X	X		X			X		P	ns
PB__E___	Persistent Organic Pollutants and Potential Arctic Contaminants	43	Biomagnification LRT HPV	X	X			X				M	ns
PB______	Potential Arctic Contaminants	42	Biomagnification									C	bio
PB______	Bioaccumulative and persistent substances with long-range atmospheric transport potential	122	PBT LRT	X	X							P	air bio
P___E___	Survey of polar organic persistent pollutants in European river waters	113	Monitoring	X				X				M	wat
P___E___	Sucralose screening in European surface waters	114	Monitoring	X				X				M	wat
P_______	Overall persistence criteria	101	PBT LRT									C	air
_BT_____	Liste of substances hazardous to waters	13	WGK		X	X						E	wat
_B______	Food Web-Specific Biomagnification of Persistent Organic Pollutants	46	Biomagnification		X							M	bio
__T_E__§	Endocrine Disrupting Screening Program (EDSP)	21	Monitoring			X		X			X	E	ns
__T_E___	Hormonal active substances in Austrian waters (Results of 3-year research)	118	EDC Monitoring			X		X				M	wat
__T__R_§	Water Framework Directive	132				X			X		X	--	ns
__T__R__	Observation List, Norway	96	C&L			X			X			P	ns
__T___X_	Register of Critical Materials	87	???			X				X		P	ns
__T____§	Priority list of substances for further evaluation of their endocrine disrupting effects (2004-2006)	3	EDC			X					X	P	ns
__T____§	Annex XVII REACH Regulation; Appendix 1-10	133				X					X	--	ns
__T_____	Annex VI to CLP (2009): Database for substances labelled regarding hazard to health and environment in the EU	5	C&L (R50/53 = H400; H410))			X						S	ns
__T_____	EDKB Endocrine Disruptor Knowledge Base	23	EDC			X						S	ns
__T_____	Reproductive Toxicants with Potential ED-Activity	27	Reproductive toxicity EDC			X						P	bio
__T_____	EU-Project - CASCADE-Risk Assessment Information on Bisphenol A, Vinclozoline and Dioxins	56	EDC			X						M	bio

Prefix	Content	No	Criteria	P	B	T	C	E	R	X	§	Type	M
__T_____	EU-Project - ENDOMET	60	EDC			X						S	bio
__T_____	Chemicals known to the State California to cause cancer or reproductive toxicity	80	CMR			X						P	bio
__T_____	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans	86	CMR			X						P	bio
__T_____	Substances with (anti)estrogenic/(anti)androgenic activity in-vitro	99	EDC			X						S	bio
__T_____	Substances with acute and chronic effects, Chile	112	Human health			X						S	bio
____ER__	Priority Substances in European Waters	1	PBT Monitoring					X	X			P	wat
____ER__	Monitoringdata of the river Elbe	37	Monitoring SPEAR Index					X	X			M	wat
____ER__	Japan: AIST Risk Assesment for substances of concern	40	Monitoring Risk					X	X			E	ns
____ER__	CERCLA Priority List of Hazardous Substances 2007 (USA)	89	PBT Exposure and toxicity					X	X			P	ns
____E_X_	Chemical Substances Portal: Environmental Database	41	Monitoring Legislation					X		X		S	wat
____E__§	Pollutant Release and Transfer Register (PRTR) for EU	29	Emission					X			X	E	wat soil air
____E___	OECD: HPV-Programm (List of High Production Volume Chemicals)	12	HPV					X				S	ns
____E___	CHAMP Programm USA: High Production Volume Chemicals	32	HPV Monitoring					X				S	ns
____E___	Rhine Substance list 2007	38	Monitoring					X				P	wat
____E___	Global Automotive Declarable Substance List (GADSL)	67	Product registries					X				S	ns
____E___	High Production Volume (HPV) Challenge	85	HPV					X				S	ns
____E___	Japan METI High Priority Chemicals	91	HPV					X				P	ns
____E___	European Pollutant Emission Register (EPER)	93	Emission					X				S	wat air
____E___	The Pollutant Emission Register in the Netherlands	94	Emission					X				E	wat soil air
____E___	Pollutant Release and Transfer Register (PRTR) for Australia	120	Emissions					X				P	wat soil air
____E___	Pollutant Release and Transfer Register (PRTR) for the Czech Republic	123	Emissions					X				P	wat soil air
____E___	Pollutant Release and Transfer Register (PRTR) for France	124	Emissions					X				P	wat soil air
____E___	Pollutant Release and Transfer Register (PRTR) for Japan	125	Emissions					X				P	wat soil air
____E___	Pollutant Release and Transfer Register (PRTR) for United Kingdom	126	Emissions					X				P	wat soil air
_____RX_	Priority list of existing substances in the EU	2	Risk						X	X		P	ns
_____RX_	Rotterdam Convention	82	Harm						X	X		P	ns
_____RX_	Basel Convention	83	Hazardous wastes						X	X		P	ns
_____R_§	Annex XVII REACH Regulation	130							X		X	--	ns
_____R_§	EDEXIM Regulation 689/2008	131							X		X	--	ns
_____R__	International Programme on Chemical Safety (IPCS)	11	Risk						X			S	ns
_____R__	Priority substances (Austria)	65	WFD						X			P	wat
_____R__	Priority substances within the context of the WFD, The Netherlands	104	PEC/PNEC						X			P	wat sed bio
_____R__	National and International Approaches to the Classification of River Health	106	River health						X			P	wat sed

Prefix	Content	No	Criteria	P	B	T	C	E	R	X	§	Type	M
_____X§	The NORMAN Network	110	Emerging pollutants							X	X	M	ns
_____X_	BUA-Reports	115	Environmental relevance							X		E	ns
_____§	Annex I of Dir 67/548/EEC	134									X	--	ns

Table 4: Frequencies and combinations of criteria used for identifying chemicals of concern.

Persistence	Bioaccum.	Toxicity	Climate	Exposure	Risk	Political	Regulated	Number of lists
P	B	T	C					2
P	B	T		E	R			1
P	B	T		E		X		1
P	B	T		E			§	1
P	B	T		E				3
P	B	T			R			2
P	B	T				X		2
P	B	T					§	5
P	B	T						4
P	B		C			X		1
P	B			E				1
P	B							1
P				E				2
	B	T						1
	B							1
		T			R		§	1
		T			R			1
		T		E			§	1
		T		E				1
		T				X		1
		T					§	2
		T						9
				E	R			4
				E		X		1
				E			§	1
				E				13
					R	X		3
					R		§	2
					R			4
						X	§	1
						X		1
							§	1

3.2 Quantitative comparison and ranking of criteria

The criteria used for the identification of chemicals of concern were comparatively analysed within the principal criteria categories. They are a key to the transparent and reproducible extraction and listing of potential candidate chemicals of concern based on ranked information sources (see sections 3.3 and 4). The underlying rationale is that priority substances on lists with very high thresholds will definitively fulfil the respective REACH criterion and shall have highest weight in the identification of substances of concern (priority score = 1). Inventories based on lower thresholds may have less weight, as they may partly list chemicals of lesser concern according to the REACH regulation (priority score 2). Two rankings are not further detailed in this section, because they are self-explaining, and brought forward in section 3.3: Inventories representing minor, but not negligible hazards were assigned the priority score of 3 (low priority). The priority code ‘u’ was reserved for the cases of firm evidence for absence of the respective hazard (unlikely effect/priority).

The quantitative criteria in persistence, bioaccumulation and toxicity were ranked relative to the respective REACH criteria. For this purpose, the information sources were sorted by threshold metrics with reference to the criteria of REACH (yellow). Formal ranking in terms of priority scores was realised by assigning the priority score of 1 to information sources at least as strict as REACH and the priority score of 2 to information sources less strict than REACH.

Ranking of criteria:

To illustrate the approach, the B-criteria are used as an example: Inventories that feature BCF cut-off values equal to or higher than REACH (≥ 2000) were assigned priority 1, records that base on a BCF cut-off lower than REACH (500 up to < 2000) were assigned priority 2, and information sources that feature a BCF cut-off much lower than REACH (< 500) were assigned priority 3. The underlying rationale is that priority substances on lists with very high BCF thresholds will definitively fulfil the REACH criteria for bioaccumulation and shall have highest weight in the identification of bioaccumulating chemicals. Inventories based on lower thresholds (BCF < 2000) may have less weight, as they may partly list non-B chemicals according to the REACH regulation. Information sources that definitively rule out substantial BCF, e.g. by stating ‘no bioaccumulation potential’ or ‘non-B’, were assigned to priority category u. The latter lists have major potential for de-prioritising substances with regard to the given criterion.

The criteria in long-range transport, climate change, status of regulation and exposure have been ranked in a categorical manner by presence or absence of the features. The procedure is based on consistent assumptions, but may be affected by expert judgement. Priority scores were differentiated whether either exact data are present (priority score of 1) versus evidence without robust documentation (priority score of 2). An illustrative example is climate change (Table 12). The case of exposure required combination of multiple indicators, e.g., environmental monitoring, release, emission, high production volume and/or wide dispersive use. Only if information from monitoring campaigns was available, the priority score of 1 was assigned, the more indirect indicators of exposure prompted a priority score of 2.

The qualitative risk-related and political criteria have been ranked by expert judgement giving more weight to quantitative assessments (priority score of 1). Lesser weight (priority score of 2) was attributed to qualitative assumptions of hazard and risk.

For more details about the priority scores, please see the explanations and tables per criterion/endpoint in the following paragraphs of this section 3.2, as well as Table 17 where also the sublists of information sources are explicitly differentiated. If appropriate and possible, the priority scores assigned to information sources, are listed in the tables per criterion/endpoint of this section 3.2, but will be discussed in more detail and effectively be used in sections 3.3 and 4.

Persistence-related criteria: Though persistence is frequently related to concern, numerical criteria are used only in some inventories. Quantitative P-criteria (Table 5) are available with 17 records, 12 of which (4, 7, 10, 14, 16, 20, 28, 81, 100, 111, 119, 129) feature half-life thresholds that are similar to those of the REACH regulation, indicating similar level of concern. The three records by Environment Canada (24, 31, 92) base on even larger values, which implies that their priority substances will definitively fulfil the REACH criteria for persistence and shall have highest weight in the identification of persistent chemicals.

Quantitative vP-criteria (Table 6) are almost identical among the seven records (4, 14, 16, 20, 28, 81, 119) such that no differential ranking of these information sources for the identification of persistent chemicals is necessary.

Another four inventories (5, 9, 95, 121) consider persistence based on qualitative criteria (Table 7). Numeric criteria are not reported, but expert judgement is evident.

Table 5: Comparison of quantitative P-criteria (half-life thresholds in water, sediment, soil, air).

No	Institution/Authors	Water	Sediment	Soil	Air	PS
7 129	OSPAR ETUC	> 50 d	---	---	---	1
119	Greenscreen	> 40 d	> 60 d	> 60 d	---	1
111	Washington State	> 60 d	> 60 d	> 60 d	---	1
20	US EPA	> 60 d	> 60 d	> 60 d	> 2 d	1
4 6* 28	ESIS TGD* SIN List 1.0	> 40 d (freshwater) > 60 d (marine)	> 120 d (freshwater) > 180 d (marine)	---	---	1
81 14 16	***REACH*** KEMI Sweden Danish EPA	***> 40 d (freshwater)*** ***> 60 d (marine)***	***> 120 d (freshwater)*** ***> 180 d (marine)***	***> 120 d***	***---***	1
10 100	Stockholm Convention EU POP	> 2 months	> 6 months	> 6 months	---	1
122 43	Muir & Howard 2006; Brown & Wania 2008	---	---	---	> 2 d	1
101*	Overall Persistence*	> 90 d	> 90 d	> 90 d	> 2 d	1
24 31 92 128*	Environment Canada Environment Canada Environment Canada Environment Canada*	> 182 d	> 365 d	> 182 d	> 2 d	1

* reference/screening criteria, no list in data-base tool
PS: priority score for ranking of information sources and/or their (sub)lists

Table 6: Comparison of quantitative vP-criteria (half-life thresholds in water, sediment, soil, air).

No	Institution/Authors	Water	Sediment	Soil	Air	PS
4 6* 28	ESIS TGD* SIN List 1.0	> 60 d	> 180 d	---	---	1
81 14 16 119	***REACH*** KEMI Sweden Danish EPA Greenscreen	***> 60 d***	***> 180 d***	***> 180 d***	***---***	***1***
20	US EPA	> 180 d	> 180 d	> 180 d	> 2 d	1

* reference criteria, no list in data-base tool
PS: priority score for ranking of information sources and/or their (sub)lists

Table 7: Compilation of information sources and records of chemicals of concern making use of qualitative persistence-related criteria.

No	Institution/Authors	Criteria	PS
9	HELCOM	Long-term occurrence in the marine environment	1
95	Norway, priority substances	Low biodegradability	2
121	Olympic Games in London 2012	Persistence	2

PS: priority score for ranking of information sources and/or their (sub)lists

Bioaccumulation-related criteria: The bioaccumulation potential of substances is generally considered a major concern, because it provides a link between exposure and the probability of effects. The bioaccumulation potential is frequently evaluated in terms of bioconcentration factor (BCF). In absence of such data the 1-octanol/water partition coefficient (log K_{OW}) may be used as a screening or surrogate parameter. While many information sources qualitatively state that bioaccumulation should be low, only some inventories feature numerical criteria.

Table 8: Comparison of quantitative B-criteria (BCF (BioConcentration Factor), BAF (BioAccumulation Factor), log K_{OW} (1-octanol/water partition coefficient)).

No	Institution/Authors	BCF / BAF	log K_{OW}	PS
10 100 24 31 92 128*	Stockholm Convention EU POP Environment Canada Environment Canada Environment Canada Environment Canada*	> 5000	> 5	1
81 4 6* 14 16 28	***REACH*** ESIS TGD* KEMI Sweden Danish EPA SIN List 1.0	***> 2000***	***> 3, > 4.5***	***1***
111	Washington State	> 1000	> 5	2
119	Greenscreen	> 1000	> 4.5	2
20	US EPA	> 1000	---	2
7 129	OSPAR ETUC	> 500	> 4	2
	CLP-Regulation on classification, labelling and packaging (GHS) formerly in 67/548/EC	≥ 500 ≥ 100	≥ 4 ≥ 3	2
43	Brown & Wania 2008	---	> 3.5	2

* reference/screening criteria, no list in data-base tool
PS: priority score for ranking of information sources and/or their (sub)lists

Quantitative B-criteria (Table 8) are available from 16 records, five of which (4, 14, 16, 28, 81) feature the threshold (BCF 2000) of the REACH regulation, indicating the same level of concern. The three records by Environment Canada (24, 31, 92) and the Stockholm Convention (10, 100) base on a larger value (BCF 5000), which implies that their priority substances will definitively fulfil the REACH criteria for bioaccumulation and shall have highest weight in the identification of bioaccumulating chemicals. The five inventories (7, 20, 111, 119, 129) based on lower thresholds (BCF 500-1000) may have less weight in the

identification of bioaccumulating chemicals, as they may partly list non-B chemicals according to the REACH regulation.

Quantitative vB-criteria (Table 9) in BCF/BAF are identical among the six records (4, 14, 16, 20, 81, 119) such that no ranking of these information sources for the identification of bioaccumulating chemicals is necessary.

Table 9: Comparison of quantitative vB-criteria (BCF (BioConcentration Factor), BAF (BioAccumulation Factor), log K_{OW} (1-octanol/water partition coefficient)).

No	Institution/Authors	BCF / BAF	log K_{OW}	PS
81 4 6* 14 16 20	***REACH*** ESIS TGD* KEMI Sweden Danish EPA US EPA	***> 5000***	***---***	***1***
119*	Greenscreen	> 5000	> 5	--

* reference criteria, no list in data-base tool
PS: priority score for ranking of information sources and/or their (sub)lists

Another six inventories (9, 11, 44, 95, 121, 122) consider bioaccumulation based on qualitative criteria (Table 10). Numeric criteria are not reported, but expert judgement is evident.

Table 10: Compilation of information sources and records of chemicals of concern making use of qualitative bioaccumulation-related criteria.

No	Institution/Authors	Criteria	PS
9	HELCOM	Enrichment in biota	1
122	Muir & Howard 2006	High predicted bioconcentration	1
44 95 121	RIVM, NL Norway, priority substances Olympic Games in London 2012	Bioaccumulation potential	2

PS: priority score for ranking of information sources and/or their (sub)lists

Toxicity-related criteria: The toxicity parameters used to identify hazardous chemicals in many inventories represent a wide variety of effects on humans and the environment. They cover acute hazards, e.g. aquatic EC_{50}, NOEC, chronic and specific effects, e.g. CMR, EDC, neurotoxicity, corrosive and irritating properties, sensitisation, immunotoxicity and incidence

of occupational diseases, partly based on Classification & Labelling and including non-quantitative criteria using expert judgement (Table 11).

Quantitative criteria in aquatic ecotoxicity are associated with 15 records (4, 5, 7, 14, 16, 20, 24, 28, 31 81, 92, 111, 119, 121, 129). Because the REACH criterion (chronic NOEC 0.01 mg/L) is by a factor of 10 lower than with most other inventories, many substances on these lists may not be priority chemicals under REACH.

Among the categorical toxicity criteria, potential endocrine activities are covered by 16 records (3, 4, 9, 14, 16, 23, 27, 28, 56, 60, 81, 99, 118, 119, 121, 129).

All other effects criteria are more oriented towards human health hazards, hence of lesser relevance to priority setting by UBA. The CMR scheme is prominent with 16 inventories (4, 5, 7, 9, 14, 16, 28, 80, 81, 85, 86, 111, 112, 119, 121, 129). Several records feature multiple toxicity-related criteria (4, 5, 14, 16, 28, 81, 111, 119, 129), reflecting that a comprehensive coverage of diverse toxic hazards is necessary to identify chemicals of concern. Only two lists feature numerical criteria in mammalian toxicity, as the focus of this collection is on environmental hazards. The ‘less environmental’ toxicity criteria are nevertheless included for two major reasons:

- Most inventories combine criteria for environment and human health.
- Specific toxicities may be used as additional evidence for priority chemicals if environmental hazards are at the same level.

The information sources displayed in Table 11 have been ranked with regard to multiple criteria, namely ATox (aquatic toxicity), CMR, EDC, MTox (multiple toxicity related criteria (neurotoxicity, sensitisation, immunotoxicity, mammalian or avian toxicity). The priority scores for the information sources and their sublists are listed for each of the multiple toxicity criteria in Table 17.

Table 11: Comparison of information sources and records of chemicals of concern making use of toxicity-related (non)quantitative criteria.

No	Institution/Authors	Aquatic ecotoxicity	Carcinogenicity	Mutagenicity	Reproduct. toxicity	Endocrine activity	Neurotoxicity	Corrosion, irritation	Sensitisation	Immunotoxicity	Occupat. diseases	Human, mammalian or avian toxicity
24 31 92 128*	Environment Canada Environment Canada Environment Canada Environment Canada*	acute LC_{50} < 1.0 mg/L chronic NOEC < 0.1 mg/L										
20	US EPA PBT Profiler	fish chronic value < 0.1 mg/L										
7	OSPAR	acute LC_{50} < 1.0 mg/L chronic NOEC < 0.1 mg/L	X	X	X							chronic toxicity
129	ETUC	acute LC_{50} < 1.0 mg/L chronic NOEC < 0.1 mg/L	X	X	X	X	X		X		X	chronic toxicity
119	Greenscreen	acute LC_{50} < 1.0 mg/L chronic NOEC < 0.1 mg/L	X	X	X	X	X	X	X	X		Systemic toxicity/organ effects
111	Washington State	acute NOEC < 1.0 mg/L chronic NOEC < 0.1 mg/L	X		X		X					< 0.003 mg/kg/day
127*	ECHA*	acute LC_{50} < 0.1 - 0.01 mg/L										Avian NOEC < 30 mg/kg food
81 16 121	***REACH*** Danish EPA Olympic Games 2012	***chronic NOEC < 0.01 mg/L***	***X***	***X***	***X***	***X***						***H372, H373***
4 6* 28	ESIS TGD* SIN List 1.0	chronic NOEC < 0.01 mg/L	X	X	X	X						
5	EU	H400 (very toxic to aquatic life), H410 (very toxic to aquatic life with long lasting effects), H411 (toxic to aquat. life with long lasting effects)	X	X	X							H370 (causes damage to organs)
14	KEMI Sweden	H400, H410, H411	X	X	X	X						H362, H372, H 373
9	HELCOM	acute, (sub)chronic toxicity	X	X	X	X						
85	US EPA HPV	ecotoxicity	X	X	X							toxicity
11	IPCS	ecotoxic properties										toxic properties
37	Monitoring Elbe	SPEAR Index										
95 96	Norway, priority subst. Norway, observation	(serious) long-term impact										
112	Chile		X	X	X							rat acute: oral LD_{50} < 50 mg/kg inhal. LD_{50} < 2 mg/L derm. LD_{50} < 200 mg/L
86	IARC		X									
80	California State		X		X							
27	FhG-ITEM				X	X						
3 23 56 60 99 118	EU-EDC EDKB CASCADE ENDOMET UBA-EDC Austria-EDC					X						

* reference/screening criteria, no list in data-base tool

Climate change-related criteria: Ozone depletion and global warming are currently considered explicitly by only three information sources (Table 12). The frequent neglect of climate change may be attributed in part to the novelty of recognizing this phenomenon and in part to the fact that the responsible chemicals are well known. These ubiquitous (mostly very small) molecules are very volatile and very persistent. The number of relevant substances is limited and a global political effort, rather than scientific expertise, is required to effectively reduce their impact on climate change.

Table 12: Compilation of information sources and records of chemicals of concern making use of climate change-related criteria.

No	Institution/Authors	Criteria	PS
14	KEMI Sweden	Ozone depletion	1
16	Danish EPA	Ozone depletion	1
121	Olympic Games in London 2012	Ozone depletion, global warming	2*

PS: priority score for ranking of information sources and/or their (sub)lists
* The priority score of 2 was assigned to this list because the authors did not inform about the specific concerns with the chemicals on their list (see explanation in database, ANNEX 2).

Exposure-related criteria: Likelihood of exposure is an additional criterion to categorise hazardous chemicals. The information sources and records of chemicals of concern featuring exposure-related criteria (Table 13) can be subdivided into three groups:

- Quantitative assessment of exposure by environmental monitoring;
- Semi-quantitative estimates of exposure based on release and emission;
- Qualitative assumption of possible exposure due to high production volume and/or wide dispersive use.

It shall be considered, though that for most monitoring campaigns, no logic is provided about the composition of the lists of analytes. If compounds are not covered, it only means that they had not been recognised to be of interest at that time. Still, the 11 inventories (1, 21, 28, 37, 38, 40, 41, 44, 113, 114, 118) based on monitoring data may have more weight (priority score of 1) than the 12 records (29, 36, 67, 89, 93, 94, 120, 123, 124, 125, 126, 129) using semi-quantitative estimates of exposure. The least weight may be attributed to the six lists (12, 32, 43, 81, 85, 91) based on qualitative assumption of likely exposure due to high production volume and/or wide dispersive use, as they may partly overestimate concern.

It has to be noted, however, that several information sources with low rank in exposure-related criteria may have very high priority with regard to other criteria due to using exposure only as a supplementary parameter to focus other aspects of concern. Because of the associated uncertainties, prioritisation based on exposure inventories is recommended only as a second step to support relevance of inherent hazards.

Table 13: Comparison of information sources and records of chemicals of concern making use of exposure-related criteria.

No	Institution/Authors	Monitoring	Release	Emission	Occupat. exposure	Consumer products	HPV	Wide dispersive use	PS
1	EU WFD	X							1
21	US EPA EDSP	X							1
28	SIN List 1.0	X				X	X		1
37	Elbe monitoring	X							1
38	Stoffliste Rhein	X							1
40	Japan AIST	X							1
41	RSDE	X							1
44	NL RIVM	X							1
113	EU ECB	X							1
114	EU ECB	X							1
118	Austria ARCEM	X							1
36	US EPA TRI		X						2
89	USA CERCLA		X						2
29	EU PRTR			X					2
93	EU EPER			X					2
94	NL PER			X					2
120	Australia PRTR			X					2
123	Czech PRTR			X					2
124	France PRTR			X					2
125	Japan PRTR			X					2
126	UK PRTR			X					2
67	GADSL					X			2
129	ETUC				X		X	X	2
81	***REACH***						***X***	***X***	***HPV***
12	OECD						X		HPV
32	US EPA CHAMP						X		HPV
43	Brown & Wania 2008						X		HPV
85	US EPA HPV						X		HPV
91	Japan METI						X		HPV

PS: priority score for ranking of information sources and/or their (sub)lists

Risk-related criteria: The probability that exposure concentrations may exceed toxicity thresholds is a measure of risk and frequently formalised by the PEC/PNEC approach (PEC: Predicted Environmental Concentration, PNEC Predicted No-Effect Concentration). Because exposure varies on the spatial and temporal scale, risk is site-specific (local or regional) and may not be generalised.

The information sources and records of chemicals of concern based on risk-related criteria (Table 14) can be subdivided into two groups:

- Quantitative assessment of risk based on actual exposure and effect concentrations;
- Qualitative assumption of risk due to likely exposure based on high production volume and/or wide dispersive use.

The 11 inventories (1, 2, 37, 40, 65, 82, 89, 95, 104, 131, 132) based on quantitative assessment of risk may have more weight (priority score of 1) than those (11, 83, 92, 96, 106, 129) based on qualitative assumption of risk due to likely exposure (priority score of 2), as those may partly overestimate concern.

Table 14: Compilation of information sources and records of chemicals of concern making use of risk-related criteria.

No	Institution/Authors	Criteria	PS
Quantitative assessment of risk			1
1	EU WFD	PBT and monitoring: combined relative criteria (COMMPS procedure)	1
2	EU priority	EURAM (EU Risk rAnking Method) and expert judgement	1
37	Elbe monitoring	Monitoring data of the river Elbe and SPEAR Index	1
40 131 132	Japan AIST EDEXIM Prioritäre Stoffe	Risk from exposure/effect for substances of concern	1
65 104	Austria WFD NL WFD	Water quality criteria (PEC/PNEC ratio)	1
82 89 95	Rotterdam Convention Cercla Priority List Norwegen Priority List	Potential harm to human health and the environment	1
Qualitative assumption of risk			2
11 92 96	IPCS EC: Not low concern Norwegen Observation List	Probability of exposure, HPV	2
83	Basel Convention	Generation, management, transboundary movements and disposal of hazardous wastes	2
106	UBA 21/99	River health	2
129	ETUC	HPV, wide dispersive use, occupational exposure	2

PS: priority score for ranking of information sources and/or their (sub)lists

Political criteria: Insufficient documentation and lack of transparency is frequently associated with the so-called political criteria, e.g. 'concern' assigned by expert judgement. These priority measures remain vague and resist immediate insight into what triggered the inclusion of substances into the inventories (Table 15). Despite their limitations, it is recognised that these inventories nevertheless may contain valuable indications on substances of concern and therefore some of them were included in the data-base tool for providing supplementary evidence in consecutive prioritisation exercises.

The ranking of political information sources required further expert judgement giving more weight to severity and probability of anticipated hazards (priority score of 1) and lesser weight (priority score of 2) to unproven concerns.

Table 15: Compilation of information sources and records of chemicals of concern making use of political criteria.

No	Institution/Authors	Criteria	PS
44 83 116 121	RIVM frequently addressed Basel Convention EDEXIM EC/304/2003 Olympic Games in London 2012	Hazard	1
82	Rotterdam Convention	Harm	1
110	The NORMAN Network	Emerging pollutants	1
115	BUA-Reports	Environmental relevance	1
2	EU Priority	Expert judgement	2
41	SIAR	Legislation, concern	2
25 92	NICNAS Environment Canada	Concern	2
87	DEQ Michigan	Critical Materials	2

PS: priority score for ranking of information sources and/or their (sub)lists

Regulations other than REACH: Information about chemicals covered by regulations other than REACH provides valuable indications for consecutive prioritisation of substances by UBA (Table 16). These inventories may be used as a tool to focus REACH-related candidate chemicals by means of de-selecting chemicals subject to other regulations, e.g. POPs, directives, e.g. biocides, pesticides, or conventions, e.g. OSPAR, HELCOM.

Substances manufactured or imported solely for the use (a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC (veterinary medicinal products) and Directive 2001/83/EC (medicinal products for human

use) or (b) in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 are exempted from registration and authorisation requirements under REACH (Article 2(5)).

According to Article 15, active substances and co-formulants manufactured or imported for use in plant protection products only (par. 1), or active substances manufactured or imported for use in biocidal products only (par. 2), are regarded as being registered. Regarding the authorisation of substances of very high concern, there are some exceptions: The following uses of substances as specified in Art. 56(4) and Art. 56(5) are generally exempted from the authorisation requirement only: a) uses in plant protection products, b) uses in biocidal products, c) use as motor fuels, d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems; and e) uses in cosmetic products and in f) food contact materials.

The compilation below focuses on environmentally relevant regulations and directives but others are also included. Several regulations and directives deal with human health only and they were therefore not further considered in this project.

In the following Table 16, the column header 'No' identifies entries of information sources in the data-base tool that may be used to exclude substances subject to these regulations.

Table 16: Compilation of regulations of chemical substances other than REACH.

No	Title	Subject
Regulations		
100	Regulation 850/2004	POP Regulation (Stockholm Convention). The new Regulation (EC) No 850/2004 complements the earlier Community legislation on POPs and aligns it with the provisions of the international agreements on POPs. To certain extent the Regulation goes further than the international agreements emphasising the aim to eliminate the production and use of the internationally recognised POPs.
131	Regulation 689/2008	Regulation concerning export and import of dangerous substances (EDEXIM)
134	Regulation 1272/2008	Table 3.2 in Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) is essentially identical with Annex I of previous Directive 67/548/EEC.
1003[2]	Regulation 726/2004/EC	Use in medicinal products for human use
1005[2]	Regulation 726/2004/EC	Use in medicinal products for veterinary use
-[1]	Regulation 178/2002/EC	Food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use [1]
-	upcoming regulation: COM(2009)267	On 12 June 2009, the European Commission adopted a proposal for a Regulation concerning the placing on the market and use of biocidal products (COM(2009)267). The proposed Regulation will repeal and replace the current Directive 98/8/EC concerning the placing of biocidal products on the market.

No	Title	Subject
Directives		
-	Directive 85/467/EEC	Council Directive 85/467/EEC of 1 October 1985 amending for the sixth time (PCBs/PCTs) Directive 76/769/EEC 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
1004[2]	Directive 98/8/EC	Concerning the placing of biocidal products on the market, upcoming regulation COM(2009)267
1002[2]	Directive 91/414/EC	Directive 91/414/EC. On 13 January 2009 the European Parliament adopted the proposal with a view to the adoption of Regulation (EC) No .../2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (EP-PE_TC2-COD(2006)0136). Plant protection products: here the list of active substances provided by German UBA is used.
1005[2]	Directive 2001/82/EC	Directive relating to medicinal products for veterinary use.
1003[2]	Directive 2001/83/EC	Directive relating to medicinal products for human use (Consolidated version: 30/12/2008).
1 132	Directive 2000/60/EC	The EU Water Framework Directive - integrated river basin management for Europe (Annex X priority substances; Annex IX Emission limit values and environmental quality standards)
-	Directive 2006/11/EC	On pollution caused by certain dangerous substances discharged into the aquatic environment of the Community. Annex I, List I contains eight families and groups of substances, selected mainly on the basis of their toxicity, persistence and bioaccumulation, with the exception of those which are biologically harmless or which are rapidly converted into substances which are biologically harmless. Annex I, List II refers to substances which have a deleterious effect on the aquatic environment, which can, however, be confined to a given area and which depends on the characteristics and location of the water into which such substances are discharged. Several families and groups of substances are referred to in the second indent.
-	Directive 1999/13/EC	Limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (substances not specified).
-	Directive 2004/42/EC	Limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC. Product categories falling within the scope of the Directive can be marketed in the EU only if they comply with the specifications in Annex II (substances not specified).
-	Directive 2002/95/EC	Article 4(1) of Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment provides 'that from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, PBB or PBDE.' The annex to the Directive lists a number of applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4(1).

No	Title	Subject
-	Directive 86/278/EEC	Protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture
-[1]	Several directives:	Food contact material: Legislation on individual substances[1]; For an overview regarding legislation on food contact materials see Figure 2
Conventions		
83	Basel Convention	Sets out procedures for the transboundary movement (import and export) of hazardous wastes. Movements which do not meet these requirements are deemed illegal traffic and a criminal act.
7	HELCOM Convention	Helsinki Commission - Baltic Marine Environment Protection Commission. Convention on the Protection of the Marine Environment of the Baltic Sea Area, 1992 (entered into force on 17 January 2000).
9	OSPAR Convention	The OSPAR Convention is the current legal instrument guiding international cooperation on the protection of the marine environment of the North-East Atlantic. Work under the Convention is managed by the OSPAR Commission, made up of representatives of the Governments of 15 Contracting Parties and the European Commission, representing the European Community.
82	Rotterdam Convention	Prior Informed Consent (PIC) Procedure for Hazardous Chemicals and Pesticides. The Convention does not ban trade but gives each party the option to ban or restrict imports based on its assessment of the risks involved and its national circumstances.
10	Stockholm Convention	Included in Regulation 850/2004.

[1] not considered further in this project due to the focus of the regulations on human health.
[2] only active substances provided by UBA.

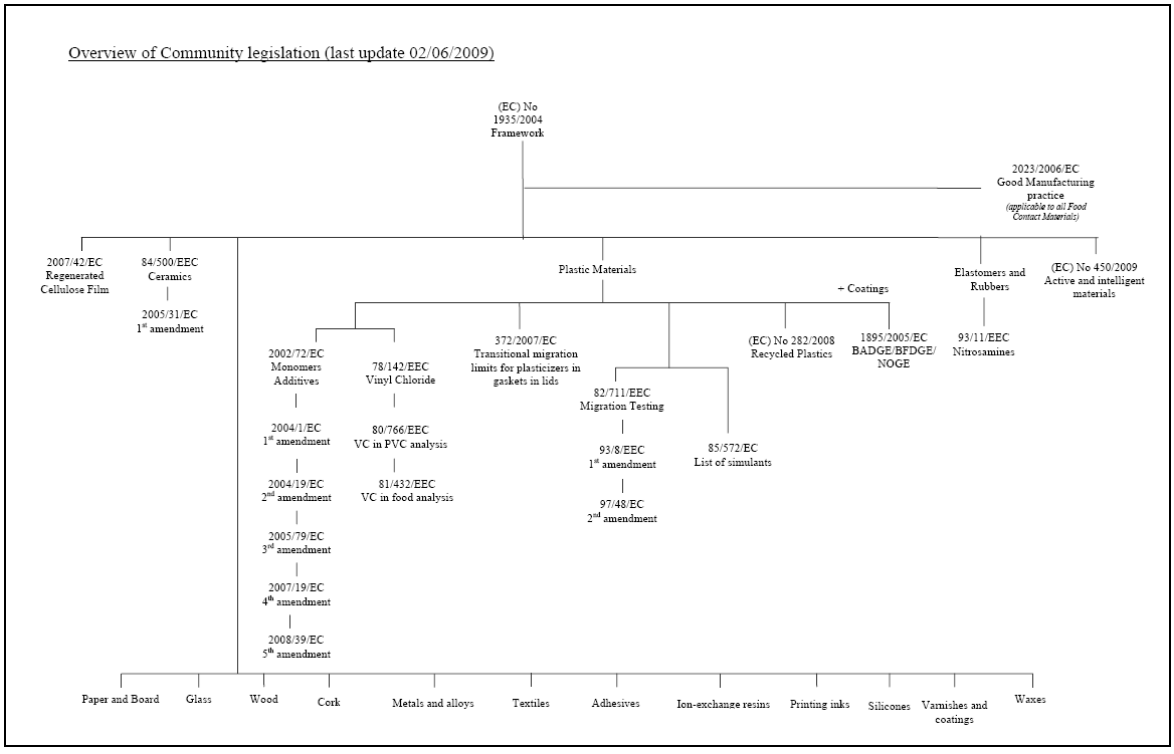


Figure 2: Overview regarding legislation on food contact materials

3.3 Ranking of information sources and lists of chemicals of concern

The information sources and lists of chemicals of concern were ranked in 4 grades within each criteria category (P (persistence), B (bioaccumulation), T (toxicity, subdivided into: ATox (aquatic toxicity), CMR, EDC, MTox (multiple toxicity related criteria (neurotoxicity, sensitisation, immunotoxicity, mammalian or avian toxicity)), LRT (long-range transport), climate change, risk-related criteria, political criteria, exposure, regulation):

1 very high priority
2 high priority
3 low priority
u unlikely effect/priority

Within the criteria categories, the respective quantitative thresholds were decisive for assigning priority scores. See Section 3.2 for the details on the individual criteria and the cut-off values used in different inventories.

The matrix provided in Table **17** impressively demonstrates that many information sources and records of chemicals of concern relate to multiple criteria and are useful for multiple purposes. Most inventories and information sources are ranked for at least one criterion, many of them for several criteria. A few inventories could not be ranked in a sensible manner, e.g., when they feature ‘uncertain evidence’, ‘likely inactive’ in one species or no effect in selected bioassays. The available information indicates low priority with regard to the hazard of concern (priority score < 3), but it does not allow to exclude the respective effects (priority code ‘u’). A typical example is the sublist ‘in vitro negative’ of inventory 99, which, if standing alone, is insufficient to conclude on the absence of endocrine effects. It may, however, provide supporting evidence in combination with other information.

Information from classification and labelling may be used to prioritise other records and inventories in several ways: The combination of risk phrases R50/R53 (H410) and Label N (GHS09) indicates particular hazards to aquatic environments, whereas R50 alone (H400) or R51/R53 (H411) is associated with lesser hazard and absence of "not readily biodegradable and potential to bioaccumulate" (R53) advocates likely harmlessness to the environment. Similar evidence is provided by the sublists to record 13 ‘List of substances hazardous to waters’ that may either identify hazards to aquatic environments, particularly sublist WGK 3, or support absence of such effects, i.e. sublist no WGK.

Another aspect of grouping information sources and records of chemicals relates to the possibility of excluding substances from further processing because they are covered by

regulations other than REACH (e.g. the POPs of the Stockholm Convention as listed in Regulation 850/2004) or by directives (e.g. Biocides Directive 98/8/EC, Plant Protection Directive 91/414/EC or use in cosmetic products and in food contact materials) (Table 16). Similar considerations apply to chemicals that are covered by other Member States as listed in the RoI (Registry of intentions) or by other Competent Authorities, e.g. CMR substances may be dealt with human health assessments.

Table 17: Prioritised information sources and records of chemicals within criteria categories.

Criteria categories: P (persistence), B (bioaccumulation), ATox (aquatic toxicity), CMR, EDC, MTox (multiple toxicity related criteria (neurotoxicity, sensitisation, immunotoxicity, mammalian or avian toxicity), LRT, CC (climate change), RISK, POL (political criteria), EXP (exposure), HPV, REG (regulation), SVHC.

Criteria ranking: 1: very high priority, 2: high priority, 3: low priority, u: unlikely effect/priority.
X: Presence of HPV or SVHC status; §: subject to regulation other than REACH

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
129	PBT_ER____Trade Union Priority List PBT	1	2	1						2			X		
81	PBT_E__§__ECHA	1	1	1								2		§	X
28	PBT_E_____SIN LIST PBT vPvB	1	1	1									X		
36	PBT_E_____EPA TRI PBT	1	1	1								2			
7	PBT_E_____OSPAR no production no use	1	2	2								u			
95	PBT__R____Norwegen List of Priority Substances	2	2	2			2			1					
92	PBT__R____UVCB Organic metal salts Low Concern	u	u	u						u					
92	PBT__R____UVCB inorganics Low Concern	u	u	u						u					
92	PBT__R____UVCB Biologicals Low Concern	u	u	u						u					
92	PBT__R____Polymers Low Concern	u	u	u						u					
25	PBT___X___NICNAS bioaccumulative	2	2	2							2				
25	PBT___X___NICNAS low concern	u	u	u							u				
4	PBT____§__PBT ESIS fulfilling PBT & vPvB	1	1	1										§	
4	PBT____§__PBT ESIS fulfilling PBT	1	1	1										§	
4	PBT____§__PBT ESIS fulfilling POP	1	1	2										§	
100	PBT____§__EU POP	1	1	2				1						§	X
10	PBT____§__ConventionPOPs	1	1	2				1						§	X
20	PBT____§__PBT Liste	1	2	1										§	
111	PBT____§__Washington State PBT	2	2	1										§	
14	PBT_____Prio KEMI PBT vPvB	1	1	1											
92	PBT_____organics P or B and toxic	1	1	1				2							

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
31	PBT_____Environ Canada high priority pollutants	1	1	1											
16	PBT_____Danish EPA List PBT	1	1	1											
24	PBT_____Canada PSL	1	1	1											
9	PBT_____HELCOM HazardousSubstances	1	1	2											
116	PBT_____EDEXIM AnnexV	1	1	2											
119	PBT_____Greenscreen Flame retartands	1	2	1	2	2									
7	PBT_____OSPAR	1	2	2											
92	PBT_____organics P or B not Toxic	1	1	u				2							
4	PBT_____PBT ESIS under evaluation or deferred	2	2	2											
31	PBT_____Environ Canada other	2	2	2											
92	PBT_____organics not P not B not Toxic	u	u	u											
121	PB_C__X___LOCOG Restricted substances and materials	2	2						2		1				
44	PB__E_____RIVM Substances exposure	2	2									1			
43	PB__E_____Arctic Contaminant Brown Wanja 2008	1	2					1					X		
122	PB_____Muir and Howard 2006 B-P-LGT substances from DSL Canada	1	1					1							
122	PB_____Muir and Howard 2006 B-P-substances from DSL Canada	2	1												
4	PB_____PBT ESIS notfulfilling PBT & vPvB	u	u												
114	P___E_____Sucralose	1										1			
113	P___E_____PPPs polar persistent	1										1			
13	_BT_____UBA wassergefährdende Stoffe WGK1		u	3											
13	_BT_____UBA wassergefährdende Stoffe nicht WG		u	u											
44	_B__E_X___RIVM Substances frequently addressed		2								1	2			
46	_B_____Biomagnification Kelly 2007		1												
129	__T_ER____Trade Union Priority List EDC					1				2			X		
129	__T_ER____Trade Union Priority List CMR				1					2			X		
21	__T_E__§__EDSP US EPA Pesticide					2						1		§	
28	__T_E_____SIN LIST equivalent level of concern			2		1	2						X		

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
28	__T_E_____SIN LIST CMR				1								X		
21	__T_E_____EDSP US EPA NOT Pesticide					2						1	X		
118	__T_E_____ARCEM Estrogens Austria					1						1			
96	__T__R____NPRI			3			3			2					
133	__T____§__REACH VO Anhang 17 Toxic to reproduction cat 1				1									§	
133	__T____§__REACH VO Anhang 17 Carcinogenes category 1				1									§	
133	__T____§__REACH VO Anhang 17 Azocolourants				1		1							§	
133	__T____§__REACH VO Anhang 17 Toxic to reproduction cat 2				2									§	
133	__T____§__REACH VO Anhang 17 Mutagens category 2				2									§	
133	__T____§__REACH VO Anhang 17 Carcinogenes category 2				2									§	
3	__T____§__EDS 2003 evidently active PSM und Arzneimittelwirkstoffe					1								§	
3	__T____§__EDS 2003 potentially active PSM					2								§	
3	__T____§__EDS 2003 uncertain evidence PSM					3								§	
13	__T_____UBA wassergefährdende Stoffe WGK3			1											
14	__T_____Prio KEMI Particularly hazardous metals			1											
14	__T_____Prio KEMI Environmentally hazardous long term			1											
5	__T_____ECB C&L aquatox T			1			1								
5	__T_____ECB C&L aquatox CMR			1	1										
5	__T_____ECB C&L aquatox			1											
13	__T_____UBA wassergefährdende Stoffe WGK2			2											
5	__T_____ECB C&L H411			2	2										
16	__T_____Danish EPA List dangerous substances			2			2								
5	__T_____ECB H400 ECB C&L H400			3											
86	__T_____IARC Group4 Probably not carcinogenic to humans				X										
87	__T_____Michigan kritische Stoffe mit Meldeschwellen_CMR				1										
86	__T_____IARC Group2A Probably carcinogenic to humans				1										
86	__T_____IARC Group1 Carcinogenic to humans				1										

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
14	__T_____Prio KEMI CMR				2										
27	__T_____ITEM potential endocrin in vivo				2	1									
86	__T_____IARC Group2B Possibly carcinogenic to humans				2										
80	__T_____California Cancer Reprotox Human				2										
86	__T_____IARC Group3 Not classifiable as to carcinogenicity to human				3										
44	__T_____RIVM Substances estrogenic					1									
14	__T_____Prio KEMI EDC					1									
99	__T_____Endokrinliste IME in vitro positive					1									
3	__T_____EDS 2003 evidently active without PSM					1									
23	__T_____EDKB Positive Endocrine Disruptor Knowledge Base FDA					1									
16	__T_____Danish EPA List endocrine					1									
60	__T_____ENDOMET					2									
3	__T_____EDS 2003 potentially active without PSM					2									
56	__T_____CASCADE					2									
3	__T_____EDS 2003 uncertain evidence without PSM					3									
23	__T_____EDKB Negative Endocrine Disruptor Knowledge Base FDA					u									
99	__T_____Endokrinliste IME in vitro negative					X									
14	__T_____Prio KEMI Very high acute toxicity human						1								
14	__T_____Prio KEMI High chronic toxicity human						1								
14	__T_____Prio KEMI Allergenic						2								
16	__T_____Danish EPA List partial restrictions						2								
112	__T_____Chile Chronic Toxic human						2								
112	__T_____Chile Acute Toxic human						3								
14	___C_____Prio KEMI Ozone depleting substances								1						
16	___C_____Danish EPA List phased out ozone								1						
1	____ER____WRRL									1		1			
40	____ER____Japan AIST Risk Assesment for substances of concern									1		1			

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
89	____ER____Cercla 2007 Priority List of Hazardous Substances									1		2			
37	____ER____Elbe Monitoringdata									1		1			
29	____E__§__PRTR Pesticides											2		§	
38	____E_____Stoffliste Rhein OSPAR											1			
38	____E_____Stoffliste Rhein nicht OSPAR											1			
41	____E_____INERIS RSDE											1			
32	____E_____EPA IUR Top 100 HPV 2006 exposure relevant											1	X		
12	____E_____OECD HPV												X		
85	____E_____EPA HPV Hazard Data Availability Table											2	X		
91	____E_____Japan METI Priority List											3	X		
29	____E_____PRTR without Pesticides											2			
126	____E_____PRTR UK											2			
125	____E_____PRTR JP											2			
124	____E_____PRTR FR											2			
123	____E_____PRTR CZ											2			
94	____E_____PER NL											2			
120	____E_____NPI											2			
67	____E_____GADSL Legally regulated											2			
67	____E_____GADSL for Assessment											2			
93	____E_____EPER											2			
82	_____RX___Rotterdam									1	1				
2	_____RX___PrioEU Altstoff PL3									1	2				
2	_____RX___PrioEU Altstoff PL2									1	2				
2	_____RX___PrioEU Altstoff PL1									1	2				
83	_____RX___BaselConvention									2	1				
2	_____RX___PrioEU Altstoff PL4									2	2				
130	_____R_§__REACH Beschraenkungen Annex 17									1				§	

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
132	_____R_§__Liste prioritaerer Stoffe im Bereich der Wasserpolitik			1						1				§	
131	_____R_§__EDEXIM Chemikalien PIC Verfahren Rotterdam									1				§	
131	_____R_§__EDEXIM Chemikalien PIC Notifikation									1				§	
131	_____R_§__EDEXIM Ausfuhrnotifikation Chemikalien									1				§	
104	_____R____NL WFD									1					
11	_____R____IPCS EHS									1					
11	_____R____IPCS CICADS									1					
65	_____R____AT Liste Beilage4									1					
65	_____R____AT Liste Beilage3									1					
92	_____R____UVCB Organic metal salts Not Low Concern									2					
92	_____R____UVCB inorganics Not Low Concern									2					
92	_____R____UVCB Biologicals Not Low Concern									2					
106	_____R____River health									2					
92	_____R____Polymers Not Low Concern									2					
11	_____R____IPCS HSG									2					
65	_____R____AT Liste Beilage5									2					
92	_____R____UVCB Polymers Under Review									3					
92	_____R____UVCB Organometallics Under Review									3					
92	_____R____UVCB Organics Under Review									3					
92	_____R____UVCB Organic metal salts Under Review									3					
92	_____R____UVCB Organic Metal Salts									3					
92	_____R____UVCB inorganics Under Review									3					
92	_____R____UVCB Biologicals Under Review									3					
92	_____R____salts									3					
92	_____R____Polymers Under Review									3					
110	______X___NORMAN Network other										1				
116	______X___EDEXIM AnnexIPart3										1				

ListID	Table	P	B	A Tox	CMR	EDC	M Tox	LRT	CC	RISK	POL	EXP	HPV	REG	SVHC
116	_____X___EDEXIM AnnexIPart2										1				
116	_____X___EDEXIM AnnexIPart1										1				
115	_____X___BUA Stoffberichte										1				
87	_____X___Michigan kritische Stoffe mit Meldeschwellen_Andere										2				
41	_____X___INERIS SIAR										2				
25	_____X___NICNAS human health										2				
110	_____§__NORMAN Network Pesticides Pharmaceuticals													§	
134	_____§__C&L Annex_1													§	

3.4 Data-base tools for combinatorial analysis of information sources

The data-base tool has been designed to allow flexible combination of information sources and records of chemicals of concern in user-defined lists. The underlying rationale is that presence of substances in certain inventories is an indication of respective hazards and the higher the priority of an inventory, the stronger is the evidence.

To assist the combinatorial analysis of information sources, the data-base tool explicitly features the priority ranking of the information sources and records of chemicals within criteria categories (P (persistence), B (bioaccumulation), ATox (aquatic toxicity), CMR, EDC, MTox (multiple toxicity related criteria (neurotoxicity, sensitisation, immunotoxicity, mammalian or avian toxicity), LRT, Clim (climate change), R (risk), Pol (political criteria), Ex (exposure), HPV, §, SVHC) in terms of: 1: very high priority, 2: high priority, 3: low priority, u: unlikely effect/priority (Figure 3).

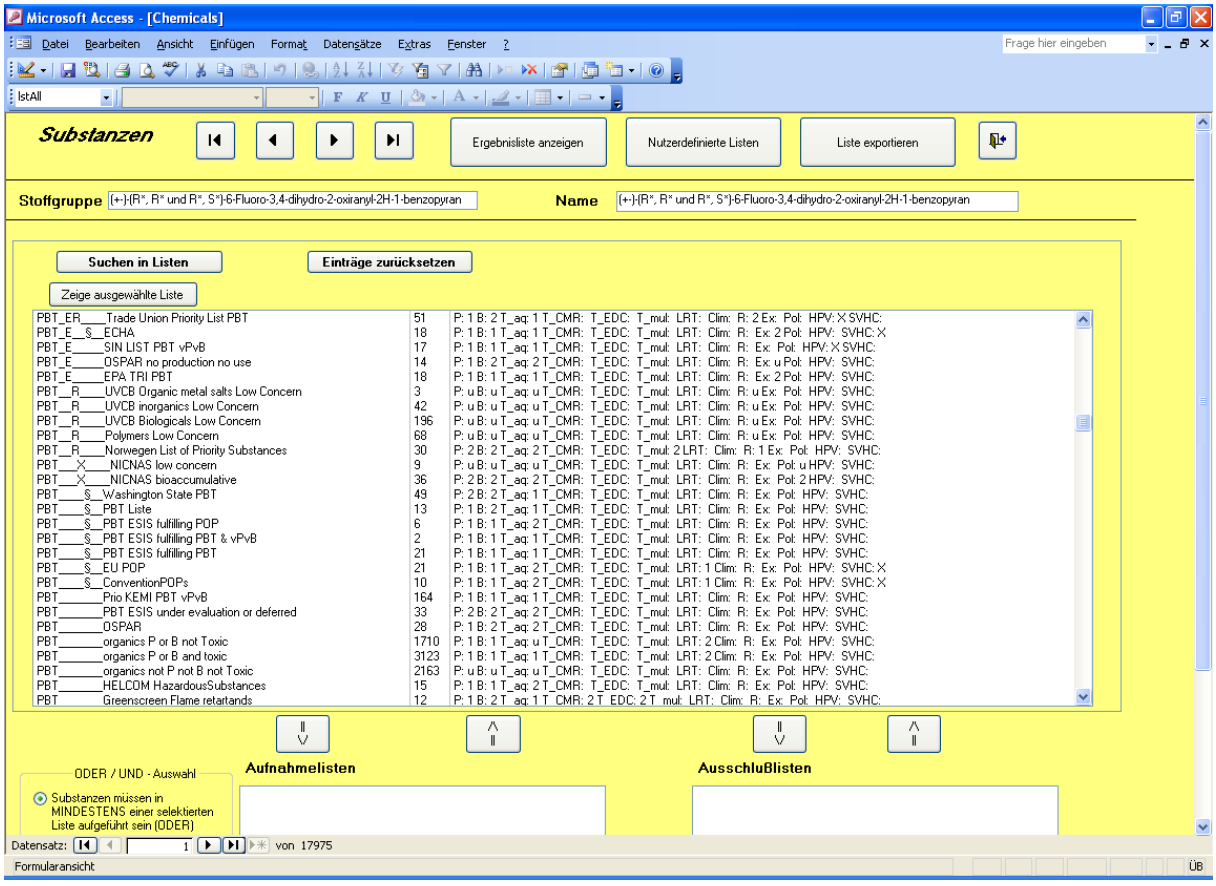


Figure 3: Screenshot of window featuring priority ranking of information sources and (sub)lists of chemicals of concern.

Combination of selected information sources and records of chemicals is possible with the arguments ‘OR’ (the substances are listed in at least one of the selected records), ‘AND’ (the substances are listed in all of the selected records), or ‘NOT’ (the substances are not listed in the selected records). The options of combinations are illustrated with the example of endocrine disruptors (Figure 4).

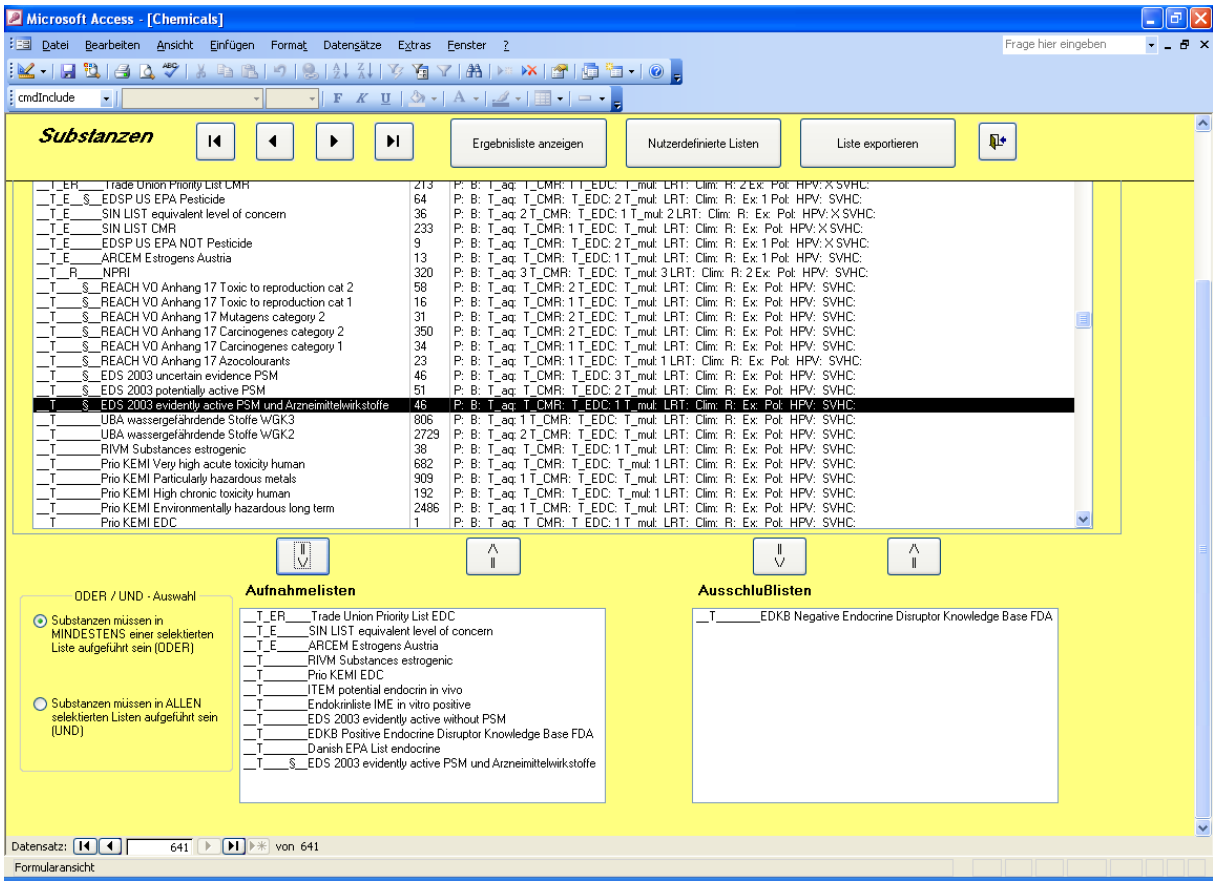


Figure 4: Screenshot of window featuring possible combinations of information sources and (sub)lists of chemicals of concern to produce new user-defined lists.

The 11 records with priority ‘1’ in the category ‘EDC’ may be combined with the ‘OR’ argument to create a new sublist with 745 chemicals of suspected endocrine activity (U_cand_EDC_1). The lack of consistency between the different inventories is indicated by two observations: (1) The combination of the same 11 inventories with the ‘AND’ argument produces no hits, i.e. not a single chemical is recognised EDC by all 11 information sources. Multiple nominations by several (but not all) of the 11 information sources do occur, of course. (2) One list is available to indicate absence of endocrine activity for 402 substances, i.e. priority ‘u’ in the category ‘EDC’ (U_cand_EDC_u). Interestingly, subtracting this list from

the 11 inventories with priority ‘1’ in the category ‘EDC’ yields a reduction by 104 entries to 641 substances, i.e. 104 chemicals (or >10%) suspected to have endocrine activity by any of 11 institutions are evaluated to be negative EDC by FDA. In other words, there is a discrepancy of at least 10 % as to whether or not a substance may have endocrine activity. The respective uncertainties must be propagated throughout the process of identification of candidate chemicals of concern and cannot be resolved without detailed assessment of intrinsic properties of the chemicals in question.

4 Identification of potential candidate chemicals of concern

The comparative analyses of (non)quantitative criteria used for prioritisation of chemicals of concern (Section 3) is the key to transparent and reproducible identification and extraction of potential candidate chemicals of concern.

4.1 Strategy for selecting candidate chemicals

The iterative process of prioritising chemicals of environmental concern has to base on two major aspects:

- Inherent hazards of the chemical in question;
- Probability of exposure of vulnerable species to this chemical.

The flow-chart of hierarchical application of ranked criteria for identification of chemicals of concern outlines the principal approach (Figure 5). For most inventories, the 1st stage of selection shall identify the inherent environmental hazards of chemicals in terms of:

- Persistence (P and vP chemicals);
- Bioaccumulation potential (B and vB chemicals);
- Toxic effects on biota (Aquatic ecotoxicity: chronic NOEC < 0.1 mg/L, EDC);
- Adverse effects on abiotic structures (ozone depletion, global warming).

For this purpose, well-defined (robust) indicators, e.g. numerical cut-off trigger (Section 3), information from Classification and Labelling and supplementary qualitative criteria are available.

The 2nd stage of selection shall reflect the probability of exposure to the candidate chemicals. It has to be noted that exposure-related criteria are a supplementary parameter to focus the relevance of inherent hazards. For this purpose, three groups of exposure-related criteria can be used (with decreasing weight):

- Quantitative assessment of exposure by environmental monitoring;
- Semi-quantitative estimates of exposure based on release and emission;
- Qualitative assumption of possible exposure due to high production volume and/or wide dispersive use.

If monitoring data are available, they may provide strong evidence for exposures above or below hazard thresholds. If monitoring data are absent, release and emission registers are the second choice (semi-quantitative estimates of exposure). The least weight may be attributed to the qualitative assumption of exposure due to high production volume and/or wide dispersive use.

The **pool of candidate chemicals** is accomplished with inventories based on risk-related criteria that have already included considerations of exposure and effects as well as with lists based on political criteria which, despite their lack of transparency, may provide valuable indications on substances of concern by including expert judgement (complementary evidence).

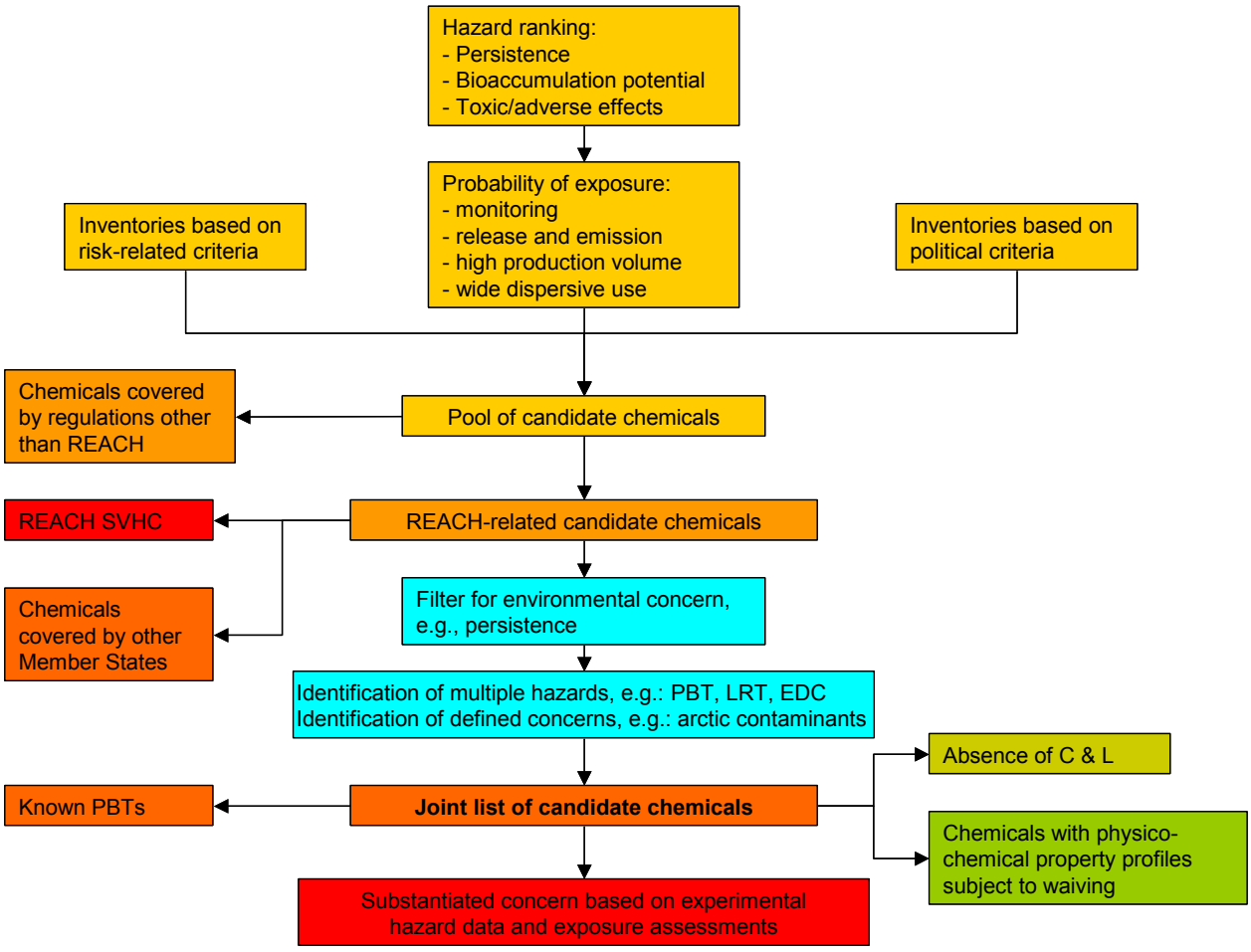


Figure 5: Flow-chart of hierarchical application of ranked criteria for identification of chemicals of concern.

The pool of candidate chemicals may be reduced by those chemicals covered by other regulations to focus **REACH-related candidate chemicals**. This relates to, for example, the POPs of the Stockholm Convention as listed in regulation 850/2004. The situation is less clear with regard to pesticides and biocides, because these are currently subject to directives, i.e. lower level jurisdiction that is overruled by regulations like REACH (e.g. for biocides or pesticides used outside the respective directives). Conventions like OSPAR or HELCOM provide valuable information in the prioritisation process, but cannot substantiate exclusion of substances because they are legally not binding.

Within REACH, already identified SVHC candidates (ECHA candidate list) as well as chemicals covered by other Member States (RoI) can be excluded from further prioritisation. There is also some relation to Annex XVII, where, in order to protect human health and the environment, a substance is listed if it is restricted or prohibited in manufacture, placing on the market or use on its own, in a preparation or in an article. Annex XVII includes the restrictions developed under Directive 76/769/EEC. It needs to be considered though that Annex XVII is a potential pool for candidate chemicals but not all restricted substances are necessarily SVHC.

The pool of REACH-related candidate chemicals may be **filtered for environmental concern**, e.g. persistence, and focussed by identification of multiple hazards, e.g. PBT, LRT, EDC, and defined concerns, e.g. arctic contaminants. This step delivers a **joint list of candidate chemicals**, reflecting the kind and weight of the criteria used. To concentrate on most hazardous compounds, further steps devoted to de-selecting substances from these lists may be applied. Very promising arguments relate to the absence of C & L and to chemicals with physico-chemical property profiles subject to waiving.

The final step requires to substantiate the suspected level of concern for selected substances with experimental hazard data and exposure assessments (cf. follow-up study on verification of candidate chemicals by intrinsic properties and prioritisation by relevance with regard to environmental criteria of REACH).

4.2 Identification of candidate chemicals based of defined concerns and multiple hazards

Based on the prioritisation of information sources and records of chemicals of concern (Section 3.3), the data-base tool has been used to identify candidate chemicals for thorough assessment of substances by UBA to be nominated as potential SVHC (Annex XIV of REACH), likely candidates for restrictions (Annex XVII of REACH), or for further needs for data and information. The hierarchical selection of chemicals of concern in a transparent and reproducible manner follows the conceptual approach outlined in Section 4.1.

The presented strategy is very flexible to focus different targets alone or in combination, e.g. persistence, long-range transport potential and/or endocrine disruption. Core and key instrument for effective operation are the priorities within criteria categories laid out in Table **17**, and also provided in the data-base tool.

The starting point is to recruit a **pool of candidate chemicals** based on, e.g., hazard and exposure categories, risk or political criteria.

1. Hazardous chemicals were identified from all (sub)lists with priority 1 with regard to criteria in persistence, LRT, climate change, PBT, EDC, CMR or MTox (~7400 substances with one or more inherent hazards) that reduced to ~2000 compounds with 'wide dispersive use' (Exposure priority 1 and 2 or HPV).
   [The following user-defined lists have been extracted (Table **17**):
   1. The list 'hazard' consists of all substances on any record with priority 1 in persistence, LRT, climate change, PBT (requires priority 1 in P, B, 'AND' T), EDC, CMR or Priority 1 or 2 in MTox (~7400 compounds).
   2. The list 'exposure' consists of all substances on any record with priority 1 or 2 in exposure or an X for HPV, subtracting any list with rank 'u' in the exposure criterion (~6300 compounds).
   3. The resultant list 'candidate_hazard' is obtained by combining the two lists above with the 'AND' argument (~2000 compounds).]

2. The risk-based selection (risk priority 1 and 2 minus 'no_risk') delivered ~2600 chemicals.
   [The following user-defined lists have been extracted (Table **17**):
   The list 'candidate_risk' consists of all substances on any record with priority 1 or 2 in risk, subtracting any record with rank 'u' in the risk criterion.]

3. Political criteria (political priority 1 and 2) collected another ~900 substances.
   [The following user-defined lists have been extracted (Table **17**):
   The list 'candidate_polit' consists of all substances on any record with priority 1 or 2 in political criteria, subtracting any record with respective rank 'u'.]

The joint **pool of candidate chemicals** based on hazard, risk and expert judgement contains **~4200 substances** that were reduced by ~500 compounds by de-selecting two groups of chemicals:

- Chemicals not covered by REACH, e.g. pesticides, biocides, pharmaceuticals, veterinary products (see Table 16);
- Recognised SVHC, e.g. ECHA candidates, Convention POPs.

[The following user-defined lists have been extracted (Table **17**):
1. The lists 'candidate_hazard', 'candidate_risk' and 'candidate_polit' are combined with the 'OR' argument.
2. The lists 'excl_psm', 'excl_biocide' and 'excl_pharma' consist of all (sub)lists on pesticides, biocides and human and veterinary pharmaceuticals, respectively (identified from the names of the (sub)lists). The list 'excl_SVHC' consists of the records 10 (ConventionPOPs), 81 (ECHA SVHC candidates), 100 (EU POP) and 116 (EDEXIM AnnexV).
3. The lists 'excl_psm', 'excl_biocide', 'excl_pharma' and 'excl_SVHC' are subtracted from the joint lists 'candidate_hazard', 'candidate_risk' and 'candidate_polit' to obtain the list 'candidate_REACH' (**~3700 compounds**).]

To focus the **REACH-related candidate chemicals** for environmental concerns, the **persistence criterion** was selected as the **primary filter**. From the list 'candidate_REACH', **877 substances** have been extracted that are likely persistent (priority 1).
[The following user-defined lists have been extracted (Table **17**):
1. The list 'P_1' consists of all substances on any record with priority 1 in persistence.
2. The lists 'candidate_REACH', and 'P_1' are combined with the 'AND' argument to obtain the list 'candidate_REACH_P1' (877 compounds).]

The subset of **REACH-related candidate chemicals of environmental relevance** (877 compounds) comprises 782 chemicals with **long-range transport potential**, 507 **PBT** candidates, 127 potential **endocrine disruptors**, and 33 substances that possibly affect **climate change** (evidence based on priorities 1 or 2 in the respective properties).

Among the 877 REACH-related candidate chemicals of environmental relevance are 107 known PBTs collected from governmental and NGO sources (e.g. OSPAR, HELCOM, EU

ESIS, Danish EPA, KEMI, US EPA, Environment Canada, SIN, ETUC (list 'excl_known_PBT'). These chemicals have been already identified as substances of major PBT concerns, thus require in-depth evaluation, but may not need further hazard identification. For reasons of comprehensiveness, however, the known, but not regulated, PBTs were not yet excluded and carried through the next steps of the analyses.

The next steps in the hazard identification process may be oriented either towards multiple hazards or towards defined concerns:

Identification of multiple hazards: The occurrence of multiple hazards provides an indicator of candidate chemicals of concern via the number of associated hazard categories. To avoid undue focus due to multiple nominations of chemicals by parallel inventories, not the number of 'hits' within each category, but the priority scores (Section 3.3) have been used as weight factors. Counting the presence of criteria categories with priority 1 or 2 in PBT, EDC, LRT, climate change, CMR or MTox, revealed 21 chemicals associated with five or more dangerous properties. All of them are CMR candidates (except one: nonylphenolethoxylate) and feature high aquatic toxicity and endocrine disruption potential. Four hazards (in different combinations) were identified with 76 candidate chemicals, only five of which are not related to CMR properties. Any three hazards were identified with **190 candidate chemicals**, with particular environmental concerns occurring in terms of PBT (n = 124), EDC (n = 121), LRT (n = 8) and climate change (n = 6).

Identification of defined concerns: The occurrence of characteristic combinations of hazards indicates specific groups of pollutants. For example, **arctic contaminants** are frequently associated with long-range transport potential combined with major bioaccumulation. There are 33 compounds on the list 'candidate_REACH_P1' that are ranked priority 1 with regard to both the bioaccumulation and the LRT criteria. Evidence for **endocrine activity** has been identified for 88 chemicals on the list 'candidate_REACH_P1' in terms of priority 1 with regard to both the aquatic toxicity and the EDC criteria. Another 18 persistent substances of wide dispersive use on the list 'candidate_REACH_P1' are ranked priority 1 with regard to **climate change**. Merging the three lists of candidate chemicals of defined concerns delivers **135 candidate chemicals**, four of them are likely arctic contaminants with potential endocrine activity (hexachlorocyclopentadiene, ammonium salt of PFOA, 4-tert-butylbenzoic acid, tridecafluoro-1-octanol).

Finally, the two candidate lists based on multiple hazards (n = 190) or defined concerns (n = 135) have been merged into a **joint list of 234 candidate chemicals based on defined**

concerns and multiple hazards. With this list, the hierarchical identification procedure has delivered candidate chemicals in a transparent and reproducible manner:

1. The identification of candidate chemicals from either multiple hazards or defined concerns is based on very different concepts, but delivers matching results: 91 candidate chemicals are equally identified by both schemes, i.e., based on multiple hazards as well as defined concerns. These 91 candidates render themselves primary candidates of major concern.

2. Candidate chemicals with particular environmental concerns have been identified in terms of PBT (n = 141), aquatic toxicity (n = 167), EDC (n = 125), LRT (n = 34) and climate change (n = 20). Among the 141 suspected PBTs are only 49 of the known PBTs (see above), indicating particular strength of the hierarchical procedure to detect new candidates.

3. Many candidate chemicals (n = 149) are, in addition to environmental concerns, associated with CMR properties. This finding implies that the CMR criterion is not suitable to exclude environmental concern and early de-selection of CMRs would falsely eliminate many environmentally relevant chemicals.

Among the selected substances are many chemicals of well-known concerns, e.g. brominated diphenylether, anthracene oils, diverse phthalates or organometallic compounds, but inclusion of some other chemicals is rather a surprise. A striking example is acetone, not usually a SVHC-candidate. Acetone has entered the joint candidate list because four hazards (LRT, EDC, CMR and mammalian toxicity) have been triggered, but acetone is not listed due to defined concerns. Several facts support the nomination of acetone:

- Acetone is frequently listed for high production volume and wide dispersive use;
- Acetone is called reproductive toxicant and/or endocrine disruptor by two major information sources;
- Acetone is listed as P or B (but not toxic) by a competent authority [This listing caused a P1 priority score for persistence, but which is contradicted by ready biodegradability of acetone.];
- Acetone is listed on a priority list of hazardous substances.

To this end, the listing of acetone on the joint candidate list is formally correct, but draws attention to characteristics and principal limitations of the selected evidence-based approach:

- This approach relies solely on secondary evidence by using existing inventories without consideration of intrinsic properties of the substances;
- Evidence-based approaches require very large sample size to compensate for major variability;
- Multiple nominations of chemicals by parallel inventories may produce undue focus;
- The combination of inclusion/exclusion rules is non-linear in nature due to multiple criteria associated with each chemical. As a consequence, the order of the prioritisation steps is critical for reasonable results;
- Expert judgement is absolutely necessary to consolidate the results of this evidence-based approach.

As a consequence of these principal limitations, the focussed list of candidate chemicals is NOT a list of SVHC candidates as yet, but a **sound basis for detailed identification and prioritisation of potential SVHC** by UBA and requires further processing **based on expert judgement** (cf. follow-up study on verification of candidate chemicals by intrinsic properties and prioritisation by relevance with regard to environmental criteria of REACH).

5 Recommendations and suggestions

Practical recommendations and suggestions for prioritisation of REACH-related candidate chemicals for eventual regulation have been discussed with UBA. It has been recognised that UBA requires a modular approach to be able to focus the chemicals of actual concern and to adapt limited resources to technical and political demands. The initial idea of a computerised decision support system has been abandoned because it is hardly flexible enough to adapt to changing needs of UBA, except at major costs.

The favourable alternative combines the computerised data-base tool with schemes reflecting and documenting the logic of prioritisation in a transparent and reproducible manner (for details see Section 4, particularly Figure 5). Quality assurance standards can be preserved while flexibly adapting to changing needs of UBA, e.g. if the relevant criteria vary depending on the objective of prioritisation.

The **principal prioritisation procedure** shall cover four major aspects:

- Preliminary prioritisation of chemicals is based on membership in substance lists included in the data-base tool. Combined search in multiple lists allows increased evidence of concern in case of manifold nominations;
- Advanced prioritisation of chemicals shall be based on quantitative criteria. Weight factors (priority ranking 1, 2, 3, u) have been implemented to explicate hierarchical impact of numerically different quantitative criteria (e.g. BCF 500, 1000, 2000, 5000) on the priority setting. Further refinement may be obtained from developing available descriptive and qualitative criteria towards quantitative metrics for priority ranking;
- Focussed prioritisation depends on preferential requirements of UBA with regard to environmental objectives, e.g. biomagnifying substances or ozone-depleting chemicals. Simultaneous use of all criteria for 'highest overall concern' is not recommended due to lack of overlap between priority lists with different purposes;
- 'De-Prioritisation' is considered a useful instrument for eliminating less hazardous chemicals, e.g. low toxicity, not P and not B, unlikely exposure.

Intensive combinatorial analyses have revealed major potential, but also **limitations of the selected approach**: The information sources and records of chemicals of concern collated in the data-base tool reflect hazards to the environment, but also analytical and technical possibilities and preferences at that time as well as the *'popularity'* of substances *('pollutant of the month'*). Particularly for the latter, priority ranking is frequently exaggerated. Rational identification of such substances with the data-base tool is principally impossible and critical filtering of prioritised substances is required based on **expert judgement**.

Characteristics and principal limitations of the selected evidence-based approach:

- This approach relies solely on secondary evidence by using existing inventories without consideration of intrinsic properties of the substances;
- Evidence-based approaches require very large sample size to compensate for major variability;
- Multiple nominations of chemicals by parallel inventories may produce undue focus;
- The combination of inclusion/exclusion rules is non-linear in nature due to multiple criteria associated with each chemical. As a consequence, the order of the prioritisation steps is critical for reasonable results;
- Expert judgement is absolutely necessary to consolidate the results of this evidence-based approach.

If the limitations of the selected evidence-based approach are considered, the principal prioritisation procedure may be successfully realised according to the **practical recommendations** below. To this end, the candidate chemicals may be focussed by prioritisation as well as deferment. The complementary options comprise:

- Derogation of chemicals that are covered by REACH and other regulations (e.g. known SVHC, Convention POPs, Annex I pesticides), by other Competent Authorities (e.g. CMR substances may be dealt with human health assessments), or by other Member States (e.g. RoI (Registry of intentions));
- Prioritisation of chemicals by environmental relevance related to, e.g., actual exposures and wide dispersive use or production volume as indicator of possible exposure: e.g. pre-registered substances with ECHA in the high tonnage bands (>100 t/a and >1000 t/a);
- Prioritisation of chemicals by number of ‘concerns’, assuming that these chemicals have highest probability of adverse effects;
- Prioritisation of chemicals with regard to specific ‘concerns’, e.g. endocrine disruptors or arctic contaminants, to reflect the specific relevance of the chemicals in question;
- Prioritisation of chemicals by intrinsic properties (e.g. ecotoxicity, persistence, bioaccumulation, biodegradation) within categories of concern:
  (i) Extraction of hazardous substances from data bases, e.g., chemicals with aquatic toxicity NOEC < 0.01 mg/L and/or BCF > 2000,
  (II) Application of QSAR models: Estimation of data by existing QSARs and their assessment relative to respective screening criteria: log K_{OW}, ready biodegradability,

atmospheric degradation (for long-range transport potential), classification of (non)specifically acting toxicants, identification of potential ER/AR ligands;

- De-prioritisation of chemicals absent of Classification and Labelling or with physico-chemical property profiles subject to waiving;
- Aspects of climate change may be suspended because the responsible chemicals are well known, limited in number and a global political effort, rather than scientific expertise, is required to effectively reduce their impact.

As a consequence of the principal limitations of the selected approach, the focussed list of candidate chemicals is NOT a list of SVHC candidates as yet, but a **sound basis for detailed identification and prioritisation of potential SVHC** by UBA and requires further processing **based on expert judgement** (cf. follow-up study on verification of candidate chemicals by intrinsic properties and prioritisation by relevance with regard to environmental criteria of REACH). There, the objective will be to explicitly name priority chemicals for thorough assessment of substances by UBA to be nominated as potential SVHC (Annex XIV of REACH), likely candidates for restrictions (Annex XVII of REACH), or for further needs for data and information.

6 Literature

[1] European Commission (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. European Commission, Brussels, Belgium.

[2] European Commission (2007). Reference preliminary technical guidance document Chapter PBT and vPvB assessment - Draft. European Commission, Brussels, Belgium.

[3] Scheringer, M. (2002). Persistence and spatial range of environmental chemicals. Wiley VCH, Weinheim.

[4] Beyer, A., Matthies, M. (2001). Criteria for atmospheric long-range transport potential and persistence of pesticides and industrial chemicals. Bericht, Umweltbundesamt, Berlin.

[5] Klasmeyer et al (2006). Application of multimedia models for screening assessment of long-range transport potential and overall persistence. Environ. Sci. Technol., 40, 53-60.

[6] OECD (2004). Guidance document on the use of multimedia fate models for estimating overall environmental persistence and long-range transport. Organisation for Economic Cooperation and Development (OECD), OECD Series on Testing and Assessment No. 45, Paris.

[7] European Communities (2003). Technical guidance document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Commission, Joint Research Centre, Ispra, Italy.

[8] Scheringer, M., MacLeod, M., Matthies, M., Klasmeier, J. (2006). Persistence criteria in the REACH legislation: critical evaluation and recommendations. Final Report, Umweltbundesamt, 21.12.2006, Berlin.

[9] U.S.EPA (2005). EPI Suite v 3.12. http://www.epa.gov/opptintr/exposure/docs/episuite.htm. U.S.Environmental Protection Agency, Washington, DC.

[10] OECD (1996). Guidelines for testing of chemicals. 305. Bioconcentration: Flow-through fish test. OECD, Paris.

[11] Arnot, J. A., Gobas, F. A. P. C. (2003). A generic QSAR for assessing the bio-accumulation potential of organic chemicals in aquatic food webs. QSAR Combi. Sci., 22, 337-345.

[12] Sijm, D. T. H. M., Rikken, M. G. J., Rorije, E., Traas, T. P., McLachlan, M. S., Peijnenburg, W. J. G. M. (2007). Transport, Accumulation and Transformation Processes. In: van Leeuwen, CJ, Vermeire, TG (Eds.) Risk assessment of chemicals: an introduction, 2nd edition, Springer, Dordrecht.

[13] Comber, M., Robertson, S., Sijm, D. T. H. M. (2006). Discussion paper for the TC NES subgroup on PBTs. ACHS/06/11A, http://www.defra.gov.uk/environment/chemicals/achs/060606/agenda.htm.

[14] ILSI HESI / JRC /SETAC-EU (2006). Workshop on Bioaccumulation Assessments, Dutch Congress Centre, The Hague, The Netherlands, May 5-6.

[15] Nendza, M., Müller, M. (2007). Literature study: Effects of molecular size and lipid solubility on bioaccumulation potential. Umweltbundesamt, Dessau.

[16] van Leeuwen, C. J., Patlewicz, G. Y., Worth, A. P. (2007). Intelligent testing strategies. In: van Leeuwen, CJ, Vermeire, TG (Eds.) Risk assessment of chemicals: an introduction, 2nd edition, Springer, Dordrecht.

[17] Klimisch, H. J., Andreae, E., Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and ecotoxicological data. Regul. Toxicol. Pharmacol., 25, 1-5.

[18] Zweers, P. G. P. C., Vermeire, T. G. (2007). Data: Needs, availability, sources and evaluation. 357-374. In: van Leeuwen, CJ, Vermeire, TG (Eds.) Risk assessment of chemicals: an introduction, 2nd edition, Springer, Dordrecht.

[19] OECD (2008). QSAR Application Toolbox. Paris.

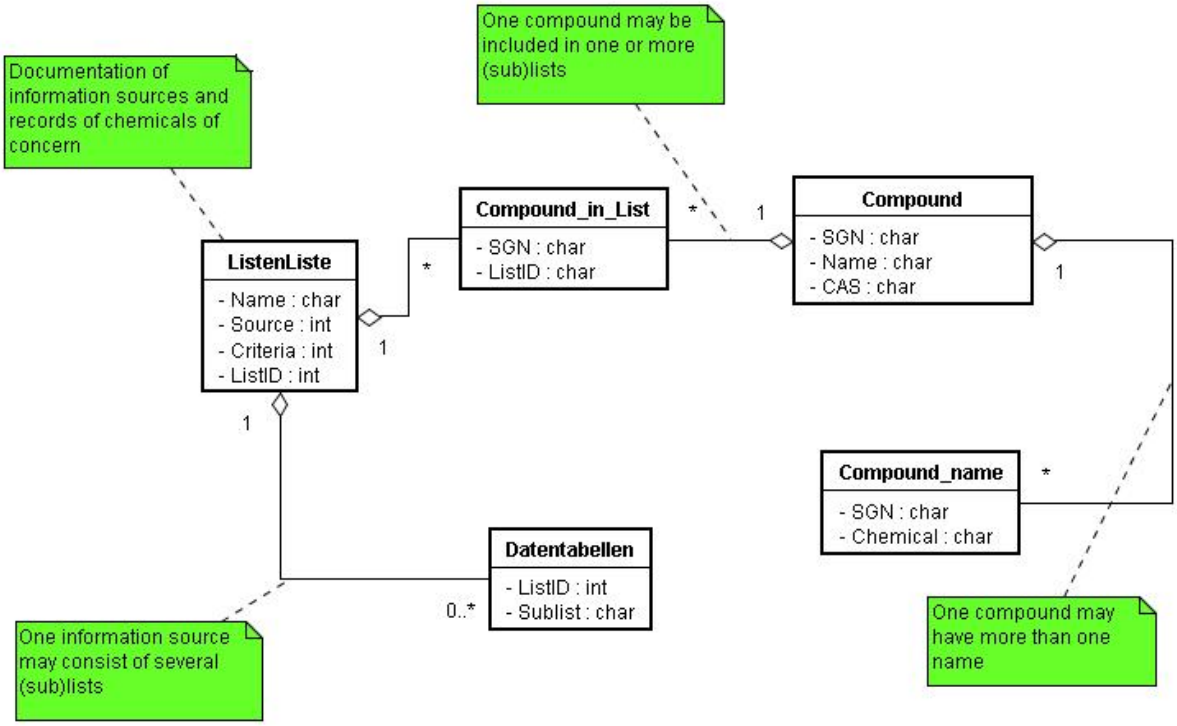
7 Annex 1. Data-base tool (technical details).

The data-base tool has been developed using Microsoft Access 2003, but may be used with Microsoft Access 2007 as well. Each (sub)list is stored in its own Microsoft Access table, the format of the tables varies according to the content of the respective (sub)list. Common to each table are the following fields for identifying compounds: “CAS” for the CAS registry number, “Chemical” for the chemical name, “SGN”: substance group number for identifying compounds in the same group of compounds (cf. Section 2.3).

The information sources and records of chemicals of concern included in the data-base tool are connected and made amenable to the analyses described in Section 2.3 and Section 3.4 by the following tables:

Name of Table	**Description**
ListenListe	This table includes the description of the information sources and records of chemicals of concern as described in Section 2.3.
Compounds	In this table, the SGN number is unique. The table is used to identify each compound.
Compound_name	In this table, the combination of SGN number and chemical name is unique. The table is used to store the different names of each compound.
Compound_in_list	In this table the combination of SGN number and (sub)listname is unique. The table is used to identify, in which (sub)list a compound with a given SGN number can be found.
Datentabellen	This table is used as a complement to “ListenListe” to store information on the individual (sub)lists.
Userlisten	This table is used to store the names and unique ID for user-defined lists.

The following figure illustrates the interrelation between the tables:



8 ANNEX 2. Evaluation of information sources and records of chemicals of concern.

Tab. Annex 2-1: Evaluation of information sources that were included in the data-base tool.

The systematic prefix consists of an eight-character code (P (persistence), B (bioaccumulation), T (toxicity), C (climate change), E (exposure), R (risk), X (political criteria), § (regulation), _ (not considered)) that indicates whether or not a criteria category was used to set up the respective list (for details see Section 3.1).

Prefix	Content	No	Evaluation	Comment
PBTC____	PRIO- Hazardous Substances prioritised for risk reduction measures, Sweden	14	Compilationh of phase-out substances and priority risk-reduction substances from 10 categories: - CMR, - PBT/vPvB, - endocrine disruptor, - ozone-depleting properties, - hazardous metals (Cd, Hg, Pb), - very high acute toxicity (health), - high chronic toxicity (health), - allergenic properties, - long-term effects, - environmental hazards.	PRIO is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals. PRIO replaces the Swedish Chemicals Agency's Observation (OBS) list.
PBTC____	List of Undesirable Substances (LOUS), Denmark	16	The List of Undesirable Substances was extracted from the List of Effects (approx. 6,400 substances), List of Dangerous Substances (2002), the EU list of substances with documented endocrine-disrupting effects that have been prioritised for further testing, high-tonnage substances suspected in the EU of having PBT and vPvB characteristics, and the Danish EPA's Advisory List for Self-classification of Dangerous Substances.	If they are used for commercial purposes in Denmark, dangerous chemical substances and products must be reported to the Danish Product Register. Manufacturers and importers are obliged to update this information when changes occur. The data from the Danish Product Register formed the basis for the selection of substances for the list. The List of Effects and the Danish Product Register, the substances that are today used in Denmark as well as the amount used, formed the basis for the List of Undesirable Substances.
PBT_ER_ _	Trade Union Priority List for REACH Authorisation	129	The chemicals considered as SVHC in the Trade Union Priority List are CMRs category 1, 2 or 3 listed in Annex I of Directive 67/548/EEC, carcinogens classified 1, 2A or 2B by IARC, PBT substances listed in the framework of the OSPAR Convention, known and suspected endocrine disruptors listed in the Community Strategy for Endocrine Disruptors, neurotoxic substances listed by Vela et al (2003) and sensitisers listed in the Annex I of Directive 67/548/EEC. Due to the lack of reliable data on occupational exposure to these SVHC, the high production volume has been used as a proxy for wide occupational and environmental exposure. All chemicals included in the Trade Union Priority List are High Production Volume Chemicals (HPVC) and as a consequence also meet the criteria to be eventually prioritised in the Authorisation List. 3 categories are discriminated: - CMR, - EDC, - PBT.	The purpose of the European Trade Union Confederation (ETUC) Priority List is to feed into the debate on the choice of substances of very high concern for inclusion in the Candidate List and potentially in the Authorisation List. The ETUC is convinced that including the union-listed chemicals in the Candidate List for REACH authorisation would cut the incidence of chemical-related occupational diseases and the attendant costs for the community, workers and industry itself.
PBT_E_X_	Selection of substances, deserving policy attention, not subject of other risk assessment programmes, Netherlands	44	In the current report an inventory is made of chemicals that may require extra policy attention. The focus is on chemicals that are of relevance for the Netherlands, and that have not planned to be the subject of (inter)national risk assessment programmes. Chemicals that are encountered and identified during analytical-chemical surveys are listed. As a second category groups of potentially hazardous chemicals that are frequently mentioned in recent literature are discussed. Finally, information from the Dutch registration on emission of substances is used to identify substances of possible concern.	592 chemicals or groups of chemicals considered as non-relevant for the purpose of the RIVM report to identify substances deserving policy attention, not subject of other risk assessment programmes. Examples are wastes of certain uses, general environmental parameters such as pH or heat, complex mixtures such as cement or milk powder, or compounds for which the expected problems do not occur via toxicological mechanisms. 262 chemicals that are relevant in terms of ecotoxicological risks; the risks are generally known. 137 compounds that are not expected to bring about high ecotoxicological risk to ecosystems, for reasons of high biodegradability or low bioavailability. 87 compounds that are expected to bring about ecotoxicological risks for ecosystems, which do not seem to be well-realized based on the information found in open literature. 621

Prefix	Content	No	Evaluation	Comment
				compounds on which the authors do not have an opinion.
PBT_E__§	ECHA Candidate List of Substances of Very High Concern for Authorisation	81	Reference list of SVHC (Supporting documentation available for each candidate).	Candidate List of Substances of Very High Concern for Authorisation: Substances that are included in the Candidate List have been identified as Substances of Very High Concern (SVHC). These substances may have very serious and often irreversible effects on humans and the environment. Substances on the Candidate List may subsequently become subject to authorisation by decision of the European Commission. Substances are added to the Candidate List by ECHA. The inclusion of a substance in the List may have legal obligations on companies. These obligations are linked to the listed substances: - on their own, - in preparations, - present in articles.
PBT_E___	OSPAR List of Chemicals for Priority Action (Update 2007)	7	List of 28 (groups of) chemicals for priority action by OSPAR due to rankings in terms of persistency, liability to bioaccumulate and toxicity (PBT). Another 14 (groups of) chemicals were identified as PBT but which are intermediates in closed systems or there is no current production or use interest.	The List of Chemicals for Priority Action in its current form was adopted in 2002. There are currently 42 substances or groups of substances on the List of Chemicals for Priority Action. OSPAR action is focused on the substances on Part A of the List. For each of these substances or groups of substances a Background Document has been prepared. Since 2002 the list has been revised to reflect removal of substances from this list, as well as the List of Substances of Possible Concern. The Background Documents assess the situation for the substance and conclude on what actions OSPAR should take to move towards the cessation target. OSPAR has adopted monitoring strategies for the hazardous substances for which background documents have been prepared. These describe information to be collected in order to monitor progress towards the cessation target.
PBT_E___	SIN List 1.0	28	Article 57 in REACH has a set of criteria (57 a-f), corresponding to different categories of SVHCs. In order to identify substances subject to the Authorisation procedure which cover at least one of the criteria in article 57, substances on SIN List 1.0 were identified by the following six criteria: a) Carcinogenic category 1 or 2 (C) b) Mutagenic category 1 or 2 (M) c) Toxic for reproduction category 1 or 2 (R) d) Persistent, bioaccumulative and toxic (PBT) e) Very persistent and very bioaccumulative (vPvB) f) Equivalent level of concern, such as endocrine disruptors	The SIN List (*Substitute It Now!) is an NGO driven project to catalyze the transition to toxic free products and processes project. The aim is to fast-track the most urgent Substances of Very High Concern for substitution, by informing Authorities and providing advance guidance to companies, consumers and regulators on high concern chemicals. The first SIN List (version1.0) was released at the ChemSec Substitution Conference on 17 September 2008 in Brussels, Belgium. The SIN List version 1.0 contains 267 high concern substances, all fulfilling the criteria for SVHS in accordance with REACH. Lists used for compilation of first rough list of SIN 1.0: OSPAR List of chemicals of possible concern: http://www.ospar.org/eng/html/welcome.html Helsinki Convention (HELCOM) on the Protection of the Marine Environment of the Baltic Sea Area: http://www.helcom.fi/stc/files/Convention/Conv0704.pdf Stockholm Convention on POPs: http://www.pops.int/documents/pops/default.htm EU Water Framework Directive 76/464/EEC, List I of the Annex: http://ec.europa.eu/environment/water/waterframework/priority_substances.htm EU Water Framework Directive, Priority substance list (Decision 2455/2001/EC): http://ec.europa.eu/environment/water/water-framework/index_en.html EU Directive 67/548/EEC, Classification, Packaging & Labelling new entries for 30th Adaptation to Technical Progress (ATP): http://ecb.jrc.it/DOCUMENTS/Classification-Labelling/PROPOSAL_FOR_THE_30TH_ATP/Annex_1G_-_New_Entries_EN.pdf U.S. Environmental Protection Agency list: http://iaspub.epa.gov/srs/SEARCH$.STARTUP ; Intersection of AFS, CAMEO, CERCLIS, ECOTOX, GCES, TSCATS, HSDB and NTP Ch. R. Canadian Environmental Protection Agency PBTs in the Domestic Substances List: http://www.ec.gc.ca/CEPARegistry/subs_list/dsl/dslsearch.cfm KEMI Classification Database (Klassificeringsdatabasen): http://apps.kemi.se/klassificeringslistan/default.cfm Swedish H-Class Database: http://apps.kemi.se/hclass/ Danish Advisory list for self-classification of dangerous

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				substances: http://glwww.mst.dk/chemi/01050000.htm Nokia Substance List version 10.0: http://www.nokia.com/A41041092 PUMA, Restricted Substances List: http://about.puma.com/downloads/61858056.pdf Dell, Restricted materials guidance document: www.dell.com/environment Sony Ericsson list of banned substances (in products): www.sonyericsson.com/environment Sony Ericsson list of banned substances (in production): www.sonyericsson.com/environment Sony Ericsson list of restricted substances (in products): www.sonyericsson.com/environment Sony Ericsson list of restricted substances (in production): www.sonyericsson.com/environment Boots, Priority Substances List, Materials Restricted for Use: Received directly from Boots Boots Chemical Report 2005: http://www.boots-csr.com/main.asp?pid=636 Marks & Spencer, Chemicals on Finished Products App. 6, App. 9, App. 10, November 2006: Received directly from Marks & Spencer H&M Chemical Restrictions 2005 (restricted substances in products): Received directly from H & M H&M Cosmetic Restrictions 2007: Received directly from H & M Skanska In Sweden Restricted substances list: Received directly from Skanska.
PBT_E___	Toxic Release Inventory - Database	36	The current TRI toxic chemical list contains 581 individually listed chemicals and 30 chemical categories (including 3 delimited categories containing 58 chemicals). If the members of the three delimited categories are counted as separate chemicals then the total number of chemicals and chemical categories is 666 (i.e., 581 + 27 + 58).	There are 16 PBT chemicals and 4 PBT chemical compound categories which are subject to reporting under the EPCRA section 313: http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm (see connected list). For other information see: The U.S. Environmental Protection Agency (EPA) maintains this information in a national database called the Toxics Release Inventory, which is available to the public via the Internet (www.epa.gov/tri).
PBT__R__	Canada Domestic Substance List	92	Each substance is assigned e.g. "of concern, no concern, under assessment". Defined organics are listed by 3 criteria: - P or P and T, - P or B and not T, - not P, not B, not T. The multiple lists from Environment Canada for other substances are discriminated into 3 categories: - not low concern, - under review, - low concern.	There are six tables for different substance groups: Progress on Organic Substances (11128) , this group is subdivided in 3 groups, see criteria Progress on Inorganic Substances (1022 substances), Progress on Organic Metal Salts (443), Progress on Polymers (4008 substances), Progress on UVCBs (Unknown or Variable composition Complex reaction products or Biological materials) (4171). Progress on UVCB Organometallics (260),
PBT__R__	Priority Substances, Norway	95	The priority list was first published in a white paper in 1997: Report to the Storting No. 58 (1996-97) Environmental Policy for a Sustainable Development. Norway's national targets are to eliminate or substantially reduce emissions of the substances on the list by 2000, 2005 or 2010. The priority list includes about 30 substances and groups of substances.	Sub-list of list no 96.
PBT___X_	NICNAS Chemical Assessment Reports	25	NICNAS assessment reports on new and existing chemicals: No priority list, but 45 detailed assessment reports for 'substances of concern'.	New Chemical Full Public Reports (n > 1000): Each chemical being introduced into Australia by import or manufacture is assessed by NICNAS for its effects on workers, the general public and the environment. Priority Existing Chemicals Assessment Reports (n = 30): These are reports on chemicals already in use in Australia that were declared Priority Existing Chemicals due to health and/or environmental concerns, which anyone is entitled to raise with NICNAS. Other Assessments (n= 15): These are reports on chemicals already in use in Australia conducted to fulfil a specific need for data on the chemical due to health and/or environmental concerns.
PBT___X_	EC/304/2003 CONCERNING THE EXPORT AND IMPORT OF DANGEROUS CHEMICALS	116	List of hazardous chemicals and pesticides which are important in international trade. 4 categories: - Annex I Part 1 (n=134), - Annex I Part 2 (n=44), - Annex I Part 3 (n=38), - Annex V (n=10).	Regulation (EC) No 304/2003 of the European Parliament and the Council of 28 January 2003 concerning the export and import of dangerous chemicals is the latest in a series of measures over the years that seek to address this issue. It implements within the Community the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for certain hazardous chemicals and pesticides in international trade, with a view to protecting human health and the environment from potential harm and contributing to

Prefix	Content	No	Evaluation	Comment
				the environmentally sound use of such chemicals. The Regulation has several objectives: (i) to implement the Rotterdam Convention (in some cases going beyond its provisions); (ii) to impose the same packaging and labelling requirements for exports of all dangerous chemicals as apply within the EU.
PBT____§	ESIS: European chemical Substances Information System / PBT Liste	4	Substances subject to evaluation of their PBT properties (not all substances on the list are PBT): 8 categories: - PBT - PBT and POP - PBT and vPvB - PBT and vPvB and POP - POP - not PBT, vPvB - under evaluation - deferred	24 substances fulfilling PBT criteria, 2 substances fulfilling PBT and POP criteria, 4 substances fullfilling POP criteria, 10 substances deferred.
PBT____§	Stockholm Convention on Persistent Organic Pollutants (POPs)	10	Chemicals to be eliminated (Annex A) or restricted (Annex B) in production, use, export and import due to persistence and long-range transport.	The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically and accumulate in the fatty tissue of humans and wildlife. Exposure to Persistent Organic Pollutants (POPs) can lead serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and even diminished intelligence. Given their long range transport, no one government acting alone can protect is citizens or its environment from POPs. In response, the Stockholm Convention, which was adopted in 2001 and entered into force 2004, requires Parties to take measures to eliminate or reduce the release of POPs into the environment. The Convention is administered by the United Nations Environment Programme and based in Geneva, Switzerland.
PBT____§	PBT Profiler	20	Priority PBT Profiles: This is a listing of the priority PBTs currently being addressed under the PBT initiative. Under most chemicals there are chemical profile fact sheets and action plans. Action plans for all the chemicals will be added as they are developed.	The PBT Profiler is an online risk-screening tool that predicts a chemical's potential to persist in the environment, bio-concentrate in animals, and be toxic, properties which cause concern for human health and the environment. The initial page for each chemical has some basic background information about the chemical. Aldrin/dieldrin, Chlordane, DDT, Mirex, and Toxaphene's action plans all fall under the pesticide action plan. For mercury, the link provides access to the chemical profile found on the Agency's mercury website.
PBT____§	Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants	100	POPs addressed by the Stockholm Convention, the UNECE Protocol on POPs and those additional ones proposed by the Parties so far.	This Commission Staff Working Paper (dated 9.3.2007) presents the final version of the European Community Implementation Plan on Persistent Organic Pollutants (POPs) which, according to Regulation (EC) No 850/2004 on persistent organic pollutants, is to be developed within two years from entry into force of the Regulation.
PBT____§	Persistent Bioaccumulating Toxins, State of Washington	111	74 chemicals or chemical groups are included on the PBT list: (1) Chemicals and chemical groups that the Department of Ecology has determined to meet the criteria specified in WAC 173-333-320. (2) PBT list: Dept. Ecology has determined that the listed chemicals or chemical groups meet the criteria specified in WAC 173-333-320. Two metals (cadmium and lead) are also identified to pose threats to human health and the environment in Washington.	Reduction and phase-out PBT uses, releases and exposures in Washington. Exemptions: Pesticides with a currently (2006) valid registration.
PBT_____	List of Potential Substances of Concern to be Considered by HELCOM	9	HELCOM RECOMMENDATION 19/5 (adopted 26 March 1998): 42 of 280 substances have been selected for immediate priority action due to persistency, liability to bioaccumulate and toxicity, including endocrine disruptor potential.	List of substances which are candidates for selection, assessment and prioritisation according to section 3.1 of the Strategy to Implement HELCOM Objective with Regard to Hazardous Substances 1: List of substances identified as of concern by HELCOM (HELCOM 12/18, Annex 6, and HELCOM 14/18, Paragraph 6.40, Helsinki Convention 1992, Annex I, Part 2, Banned substances, and Part 3, Pesticides) 2: List of Substances for international Action within the UNECE LRTAP POP- and Heavy Metal-protocols (under negotiation) 3: List of Substances for international Action, including a global

Prefix	Content	No	Evaluation	Comment
				legally binding instrument (UNEP POP-Programme) 4: List of substances identified as of concern by OSPAR in the period 1991-1996, which are part of the OSPAR Work-Programme 5: List of priority substances agreed by the Third North Sea Conference (Annex 1A, The Hague Declaration) 6: Reference List of Substances agreed by the Third and Fourth North Sea Conference (e.g. Annex 1 D to The Hague Declaration), for further selection of priority substances 7: Pesticides referred to in paragraph 27 of the Esbjerg Declaration (Annex 2, Appendix 1 of the Esbjerg Declaration), for priority review within the framework of EU Council Directive 91/414 8: OSPAR List of Potential Endocrine Disruptors - Part A, which have been reported in the scientific literature to induce changes to the endocrine system of varying severity in the course of in vivo tests 9: OSPAR List of Potential Endocrine Disruptors - Part B, which have been reported in the scientific literature to induce changes to the endocrine system of varying severity in the course of in vitro tests.
PBT_____	Priority Substances Assessment Programm (Environment Canada)	24	Priority Substances Lists (PSL) that identifies substances to be assessed on a priority basis to determine whether they pose a significant risk to the health of Canadians or to the environment according to The Canadian Environmental Protection Act (CEPA). A substance is "toxic" acc. to Sect 64 CEPA, if it enters or may enter the environment in amounts or under conditions that may pose a risk to human health, the environment or its biological diversity, or to the environment that supports life. Thus "toxic" in the context of CEPA is a function of both the inherent properties of a substance and of the amounts, concentrations, or nature of entry of the substance in the Canadian environment.	There are two lists: PSL1: First Priority Substance List including 44 substances or groups of substances and was completed by February 1994 PSL2: Second Priority Substance List contains 25 substances or substance groups, added to the PSL following recommendations of a multi-stakeholder Expert Advisory Panel (Canada Gazette Part 1, on December 16, 1995). Assessment reports for each of these PSL substances were completed and published. In some cases. Conclusions could not be reached. Follow-up reports have been undertaken.
PBT_____	Existing Substances Programme at Environment Canada	31	List of substances of highest priority to Canada for dossier compilation and assessment.	The approximately 200 substances of highest priority have been divided up into a number of smaller groups ("batches") of substances, which are being addressed sequentially. These batches comprising all of the substances will be launched within a three-year timeframe.
PBT_____	Green Screen - Flame Retardants for TV Enclosures	119	The Green Screen for Safer Chemicals defines a path to chemicals that are safer for humans and the environment. It is a rigorous, hazard-based screening method that is designed to inform decision making by businesses, governments, and individuals concerned with the risks posed by chemicals and to advance the development of green chemistry. The Green Screen defines four benchmarks on the path to safer chemicals, with each benchmark defining a progressively safer chemical: • Benchmark 1: Avoid - Chemical of high concern • Benchmark 2: Use but search for safer substitutes • Benchmark 3: Use but still opportunity for improvement • Benchmark 4: Prefer - Safer chemical The use of flame retardants in TV enclosures -the external plastic housing of a TV- as a test case for applying the Green Screen approach. The Green Screen approach evaluates a chemical along with its known and predicted breakdown products based upon its hazards.	To test the Green Screen, three flame retardants that currently meet performance criteria for use in the external plastic housing of televisions (TVs) were evaluated. With the European Union restricting decabromodiphenyl ether (decaBDE) in electronics and with similar legislative initiatives under consideration at the state level in the United States, a recurring question emerges: are alternative flame retardants safer than decaBDE from the perspective of human and environmental health and safety? In the report, three TV flame retardants using the Green Screen approach were evaluated: decaBDE and two phosphorous-based alternatives, resorcinol bis(diphenylphosphate) (RDP), and bisphenol A diphosphate (BAPP or BPADP). Of the three flame retardants, RDP was the only flame retardant to pass all criteria under Benchmark 1 of the Green Screen. Both decaBDE and BPADP scored lower on the Green Screen because of their degradation products. Thus RDP, at Benchmark 2, is the most preferred of the three flame retardants. In the Green Screen approach the hazards of a chemical are defined by: its potential to cause acute or chronic adverse effects in humans or wildlife, its fate in the environment, and certain physical/chemical properties of concern to human health. Acute mammalian toxicity (lethality) and irritation of the skin or eye are examples of acute adverse effects that can result from inhalation, ingestion, or dermal contact with a chemical. Chronic effects occur after repeated exposures and include cancer and adverse effects to the reproductive, neurological, endocrine, or immune systems. The

Prefix	Content	No	Evaluation	Comment
				fate of a chemical in the environment (environmental fate) is strongly determined by its rate of degradation (defined as persistence) and its tendency to accumulate in tissues and organs (bioaccumulation). The physical/chemical properties of concern in the Green Screen are flammability and explodability.
PB_C__X_	Restricted substances and materials for the Olympic Games in London 2012	121	Substances and materials NOT to be used in products and services for the Olympic Games in London 2012 due to potential damage to human health and the environment.	The vision regarding Healthy Materials): LOCOG encourages the use of substances and materials that represent a low risk to human health and the environment. Where practicable, suppliers and licensees will seek to use non-polluting and non-toxic materials and substances in the products and services they supply. All materials and substances must comply with relevant legislation. Sustainable sourcing is the procurement of products and services with environmental, social and ethical issues in mind. The Olympic Games represent an opportunity to deliver a truly world class event and a lasting legacy for London and the UK. What are the core principles of the Code? To achieve our sustainability objectives for the Games, LOCOG is encouraging our suppliers and licensees to adopt, or further develop, practices that are environmentally sound, socially responsible and ethical, based upon the following four principles: 1. Responsible sourcing: ensuring that products and services are sourced and produced under a set of internationally acceptable environmental, social and ethical guidelines and standards. 2. Use of secondary material: maximising the use of materials with recycled content, minimising packaging and designing products that can either be reused or recycled. 3. Minimising embodied impact: maximising resource and energy efficiency in the manufacturing and supply process in order to minimise environmental impacts. 4. Healthy materials: ensuring non-polluting/non-toxic materials and substances are used.
PB__E___	Persistent Organic Pollutants and Potential Arctic Contaminants	43	120 HPV chemicals predicted to become arctic contaminats or which match the structural profile of known arctic contaminants (AC-BAP = arctic contamination and bioaccumulating potential).	Publication. The method for identification of potential AC-BAP is under development. According to the authors "The selectivity of the screening method could be varied by changing the criteria thresholds. For example, the net could be cast wider by defining the thresholds for the partitioning properties based on 1 % of maximum AC-BAP70 or could be made for selective BA raising the threshold for atmospheric oxidation half-life".
PB_____	Bioaccumulative and persistent substances with long-range atmospheric transport potential	122	Publication on chemicals with high predicted bioconcentration, low rate of biodegradation and long-range atmospheric transport potential based on predicted atmospheric half-lives > 2 days and log-air-water partition coefficients >=5 and <=1. 2 categories are discriminated: - P and B with LRT-potential, - P and B without LRT-potential.	The authors used data from Environment Canada for categorization and listedt, for discussion purposes, 30 chemicals with high predicted bioconcentration and low rate of biodegradation and 28 with long-range atmospheric transport potential based on predicted atmospheric half-lives > 2 days and log-air-water partition coefficients >=5 and <=1. These chemicals are a diverse group including halogenated organics, cyclic siloxanes, and substituted aromatics. Some of these chemicals and their transformation products may be candidates for future environmental monitoring. However, to improve these predictions data on emissions from end use are needed to refine environmental fate predictions, and analytical methods may need to be developed.
P___E___	Survey of polar organic persistent pollutants in European river waters	113	The target compounds were selected because previous research identified them as prevalent in the environment. Another selection criterion was their relative easy extraction behavior by SPE (at neutral pH) and the straightforward LC-MS2 analysis for those compounds.	This study provides the first EU-wide reconnaissance of the occurrence of polar organic persistent pollutants in European river waters. More than 100 individual water samples from over 100 European rivers from 27 European Countries were analysed for 35 selected compounds, comprising pharmaceuticals, pesticides, PFOS, PFOA, benzotriazoles, hormones, and endocrine disruptors.
P___E___	Sucralose screening in European surface waters	114	The analysis of 120 river surface water samples from 27 European countries showed that sucralose, which is in use in Europe since beginning 2005, can be found in the aquatic environment, at concentrations up to 1 mg/L. Sucralose was predominately found in samples from the UK, Belgium, the	Analysis of sucralose, a persistent chlorinated calorie-free sugar substitute, in European surface waters.

Prefix	Content	No	Evaluation	Comment
			Netherlands, France, Switzerland, Spain, Italy, Norway, and Sweden, suggesting an increased use of the substance in Western Europe.	
_BT_____	Liste of substances hazardous to waters	13	A list of substances, which are hazardous to water. In a positive list substances are listed, which are harmless to water. 4 categories are discriminated: - WGK 1 - WGK 2 - WGK 3 - not WG	Classification of substances as hazardous to water according to: 1) Listing of the substance in Annex 1 or 2 of the Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes (VwVwS), 2) Documented Water Hazard Class (WGK) according to Annex 3 of the VwVwS, 3) Decision of the “Commission for the Evaluation of Substances Hazardous to Waters” (KBwS) to be adopted into Annex 1 or 2 in the next amendment of the VwVwS.
_B_____	Food Web-Specific Biomagnification of Persistent Organic Pollutants	46	It is shown that poorly metabolizable, moderately hydrophobic substances with a KOW between 100 and 100,000, which do not biomagnify (that is, increase in chemical concentration in organisms with increasing trophic level) in aquatic food webs, can biomagnify to a high degree in food webs containing air-breathing animals (including humans) because of their high octanol-air partition coefficient (KOA) and corresponding low rate of respiratory elimination to air. These low KOW high KOA chemicals, representing a third of organic chemicals in commercial use, constitute an unidentified class of potentially bioaccumulative substances that require regulatory assessment to prevent possible ecosystem and human-health consequences.	Publication, model for identifying substances with the potential for biomagnification in food webs containing air-breathing animals (including humans). Criteria were selected based on measured and compiled concentrations of organic contaminants of varying hydrophobicity and KOW in a piscivorous food web (water-respiring organisms only), a terrestrial food web (air-breathing organisms only), and a combined marine mammalian food web (including water-respiring and air-breathing organisms) from northern Canada (Materials and methods, physical-chemical properties of substances are available as supporting material on Science Online). Data for 20 selected substances are presented.
__T_E__§	Endocrine Disrupting Screening Program (EDSP)	21	This page presents a draft list of the 73 substances, pesticide active ingredients (June 2007) and HPV/pesticide inert chemicals selected for Tier 1 screening. This draft list was published in a Federal Register Notice in June 2007. Because this list of chemicals was selected on the basis of exposure potential only, it should not be construed or characterized as a list of known or likely endocrine disruptors.	Applying the Chemical Selection Approach: As described in the September 2005 Federal Register Notice, EPA analyzed data for four exposure pathways for pesticide active ingredients and data for four exposure pathways for High Production Volume (HPV) chemicals used as pesticide inerts. The four exposure pathways identified for pesticide active ingredients include: food, drinking water, residential use, and occupational exposure. The four exposure pathways identified for HPV/pesticide inert chemicals include: human biological monitoring, ecological biomonitoring, drinking water, and indoor air. The Agency evaluated the data sources for each pathway to produce four candidate lists of chemicals of pesticide active ingredients and four candidate lists of HPV/pesticide inert chemicals for potential screening. Because there were a large number of chemicals on one or more of these candidate lists, it was necessary to establish priorities for selecting chemicals for initial screening. Integration of Pathway Priorities for Pesticide Active Ingredients EPA identified an initial list of 64 pesticide active ingredients to undergo Tier 1 screening in the EDSP. In choosing which pesticide active ingredients to include on the initial screening list, EPA gave priority to those that: 1. Appeared in four exposure pathways, and 2. Appeared in three exposure pathways where the food and occupational exposure pathways were represented. Integration of Pathway Priorities for High Production Volume/Pesticide Inerts EPA identified an initial list of 9 HPV/pesticide inert chemicals to undergo Tier 1 screening in the EDSP. In choosing which HPV/pesticide inert chemicals to include on the initial screening list, EPA gave priority to those that: 1. Appeared in four exposure pathways, and 2. Appeared in three exposure pathways where the human biological monitoring exposure pathway was represented.
__T_E___	Hormonal active substances in Austrian waters (Results of 3-year research)	118	The following groups of substances have been identified: - natural estrogens and synthetic estrogens in pharmaceuticals due to high hormonal activity; - industrial chemicals Bisphenol A and Nonylphenol e.g. in plastics, adhesives, resins; - pesticides due to high emissions.	The "Austrian Research Co-operation on Endocrine Modulators (ARCEM)" comprised scientists from the university of Vienna, the veterinary university, Vienna, the technical university of Vienna and the university for soil culture, the Umweltbundesamt GmbH and the Austrian Ministry for agriculture and forestry, environment- and watersupply

Prefix	Content	No	Evaluation	Comment
				companies. Their objective was the assessment and management of actual risks of hormonally active substances in Austrian waters; in detail by: - Analyses of the most relevant emissions of hormonally active substances in Austria as a basis for reductions. Comprehensive monitoring of concentrations of hormonally active substances in Austrian surface- and groundwaters –Description of concentration levels of hormonally active substances in selected Austrian rivers with fish as indicator organisms. Evaluation of the risks to native fishfauna and human health (consumption of fish, drinking water). Investigation of the technical potentials of different procedures for clean-up of drinking water and in waste water treatment.
__T__R_§	Water Framework Directive	132	The substances were considered relevant for listing in: 132_Liste_prioritaerer_Stoffe_im_Bereich_der_Wasserpolitik	On 23 October 2000, the "Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy" or, in short, the EU Water Framework Directive (or even shorter the WFD) was finally adopted.
__T__R__	Observation List, Norway	96	The observation list gives examples of chemicals that according to the information currently available, represents problems in Norway. If their use is not reduced in the long term, further measures may be taken, depending on the risk involved in each case. Subset of the "dangerous substances" list selected due to some dangerous properties.	Selection from list no 97, basis for list no 95.
__T___X_	Register of Critical Materials	87	Register of Critical Materials based on EPA Toxic Release Inventory (TRI) program CHEMICAL 1. carcinogens, 2. pesticides (not included), 3. others, e.g. compounds containing the elements Pb, Hg, Ni, Ag, As, Be, Cd, Cr, Cu, Zn, Se.	Criteria for critical materials not given/ not transparent.
__T____§	Priority list of substances for further evaluation of their endocrine disrupting effects (2004-2006)	3	Priority list of substances for further evaluation of their endocrine disrupting effects: Starting in the year 2000, 575 chemical substances were screened and evaluated as to their endocrine disrupting (ED) effects and a preliminary priority list was established at the end of 2006. Out of the 575 substances, 320 substances showed evidence or potential evidence for ED effects, while in total, 109 substances were not retained in the priority list, either due to insufficient data on ED effects or insufficient scientific evidence. 147 substances have been excluded from the evaluation during the process as they were identified as double entries, mixtures or of doubtful relevance. An assessment of the legal status of the substances with evidence or potential evidence of endocrine disrupting effects showed that the majority of them are already subject to a ban or restriction or are addressed under existing Community legislation, although for reasons not necessarily related to endocrine disruption. 4 categories have been discriminated: - evidently active - potentially active - uncertain evidence - non active	Commission Staff Working Document on the implementation of the 'Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife'. This document, published in November 2007 is the third progress report on the implementation of the Strategy and covers the period 2004-2006. The "Community Strategy for Endocrine Disrupters" contains activities in the short, medium and long term. The short and medium term actions focus on gathering scientific data on "candidate substances" with a view to prioritising testing, guide research and monitoring efforts and to identify specific cases of consumer use and ecosystem exposure. The long-term actions focus on review and possible adaptation of policy and Community legislation. The DG Environment has financed five studies on endocrine disrupters: - Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting, - Study on the scientific evaluation of 12 substances in the context of endocrine disrupter priority list of actions", - Study on gathering information on 435 substances with insufficient data, - Information Exchange and International Coordination on Endocrine Disrupters, - Study on enhancing the endocrine disruptor priority list with a focus on low production volume chemical.
__T____§	Annex XVII REACH Regulation; Appendix 1-10	133	According to the structure of the Appendices (Anlagen) of Annex XVII, the following sublists were taken: 133_REACH_VO_Anhang_17_Azocolourants (Appendix 8-10) 133_REACH_VO_Anhang_17_Carcinogenes_category_1 (Appendix 1) 133_REACH_VO_Anhang_17_Carcinogenes_category_2 (Appendix 2) 133_REACH_VO_Anhang_17_Mutagens_category_2 (Appendix 4); No substances in Appendix 3: Mutagens_category 1 133_REACH_VO_Anhang_17_Toxic_to_reproduction_cat_1 (Appendix 5)	REACH, Article 67, General provisions: 1. A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted. Restrictions process, Article 68, Introducing new and amending

Prefix	Content	No	Evaluation	Comment
			133_REACH_VO_Anhang_17_Toxic_to_reproduction_cat_2 (Appendix 6) Appendix 7: Asbestos compounds were not included	current restrictions 1. When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives. The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate. 2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.
__T_____	Annex VI to CLP (2009): Database for substances labelled regarding hazard to health and environment in the EU	5	List no 5 contains substances or mixtures/preparations with intrinsic hazard to the environment (formerly R50/53, R51/53). Substances with lower toxicity to aquatic organisms (formerly R52) are not included in this list. New Label/Symbol: GSH09Classification: Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410), Aquatic Chronic 2 (H411). The data were subdivided in "sublists" based on the classifications for toxic or very toxic aquatic toxicity: - 005_ECB_H400_ECB_C&L_H400 => very toxic to aquatic organisms, - 005_ECB_H400_H410_ECB_C&L_aquatox => very toxic to aquatic organisms AND/OR long-term effects - 005_ECB_H400_H410_H340_H350_H360_ECB__C&L_aquatox_CMR => very toxic to aquatic organisms, long-term effects AND CMR - 005_ECB_H400_H410_H370_ECB_C&L_aquatox_T => very toxic to aquatic organisms, long-term effects AND "spec. target organ toxicity" - 005_ECB_H411_ECB_C&L_H411 => toxic to aquatic organisms AND long-term effects	Around 1400 substances labelled GSH09 (formerly N) regarding hazard to the environment were extracted. The new Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) entered into force on the 20 January 2009. CLP implements the Globally harmonised System (GHS). CLP will stepwise replace Directive 67/548/EEC (substances) and Directive 1999/45/EC (preparations). The C&L of substances of special concern is included in the EU harmonised list in Annex VI to 1272/2008 CLP, which is legally binding. Annex VI of the CLP Regulation only incorporates up to the 29th ATP (as of July 29, 2009, http://ec.europa.eu/enterprise/reach/ghs/legislation/index_en.htm) ! The 30th and 31st ATPs amended Annex I to Directive 67/548/EEC by introducing new and updated harmonised classifications. These harmonised classifications is currently (Sept. 2009) not incorporated into Annex VI to the Classification, Labelling and Packaging Regulation (CLP Regulation 1272/2008, OJ L353/1, 31.12.2008). The 1st Adaptation to Technical Progress (ATP) to (transfer of the 30th and 31st ATP to) amend Regulation (EC) No 1272/2008 was approved by the REACH Committee on 25 March 2009 and has been sent to the Parliament for scrutiny by end of March. The 1st ATP will most probably be published summer 2009. 30th ATP makes following changes to Annex 1: the addition of 380 new entries, in many cases due to their carcinogenic, mutagenic or reproductive toxicity effects; and the revision of the classification and labelling of 516 substances and deletion of 3 substances currently in Annex I. 31th ATP: The changes are contained in three annexes to the draft directive: Annex 1 A: Revised C&L for existing entries => 83 entries (6 on nickels covering 12 out of 100 substances) Annex 1 B: C&L for new entries => 385 entries (45 entries on Nickels covering 97 out of 500 substances) Annex 1 C: Deleted entries => 4 entries
__T_____	EDKB Endocrine Disruptor Knowledge Base	23	The Endocrine Disruptor Knowledge Base (EDKB) website consists of a biological activity database, relevant literature citations, computational models, and ultimately, models for risk assessment. It is designed to help research and regulatory scientists, and other interested parties set priorities for testing of endocrine disrupting compounds, make use of the existing body of knowledge, and reduce dependency upon slow and expensive animal experiments.	The website provides access to a relational database comprising in vitro and in vivo experimental data (3257). A major element of the EDKB program has been the development of computer-based predictive models to predict affinity for binding of compounds to the estrogen and androgen nuclear receptor proteins. These models have been developed using commercial, state-of-the-art chemometric, SAR and QSAR software packages that are commonly used in drug discovery and development. Hence, the models cannot be automated for use through this website. In the future, US FDA may develop models that can be used online within the website.

Prefix	Content	No	Evaluation	Comment
__T_____	Reproductive Toxicants with Potential ED-Activity	27	This list contains toxicants with effects on reproductive organs that have been extracted from RepDose (1) and FeDTex (2) based on multiple filter criteria for potential endocrine effects. CAVE: There is a potential probability of false positives, i.e. not all of these chemicals are necessarily EDCs.	Both databases were developed at the Fraunhofer Institut of Toxicology and Experimental Medicine, Hannover. (1) REPDOSE: A database on repeated dose toxicity studies of commercial chemicals--A multifunctional tool. Bitsch A, Jacobi S, Melber C, Wahnschaffe U, Simetska N, Mangelsdorf I. Regul Toxicol Pharmacol. 2006 Dec;46(3):202-10. Epub 2006 Aug 28. (2) RepDose and FeDTex: Two databases focusing on systemic toxicity. First examples from analyses of repeated dose toxicity and reprotoxicity studies. Bitsch A, Escher S, Lewin G, Melber C, Simetska N, Mangelsdorf I. Toxicology Letters 2008. 180 (Suppl. 1): S45
__T_____	EU-Project - CASCADE-Risk Assessment Information on Bisphenol A, Vinclozoline and Dioxins	56	The CASCADE Network published health risk assessments for three model compounds: Bisphenol A, Vinclozoline and Dioxins: http://www.cascadenet.org/projectweb/portalproject/CASCADE%20Model%20Compounds.htm These are living documents which will be frequently revised. The compounds were chosen because they occur in our closest environment and cause adverse health effects. In a joint effort CASCADE researchers have compiled information on the compounds toxicities, mechanisms of actions, human exposure levels, data gaps, research needs and many more.	CASCADE Network of Excellence, an EU-funded network of scientists studying endocrine disrupting chemicals, EU contract no. FOOD-CT-2004-506319. Duration: 5 years from February 2004 to January 2009. The CASCADE Network of Excellence seeks durable coordination and integration of European research on the human health effects of chemical residues in food. CASCADE brings 24 research groups from nine EU member states together and the network is financed by the European Commission. The research within CASCADE focuses on human health effects of chemical residues in food and drinking water. These residues can interfere, even at low levels, with the function of hormone systems in the body. The chemicals mimic human hormones by interaction with cellular structures called nuclear receptors. This family of receptors includes receptors for hormones like estrogen, testosterone and thyroid hormone. A disrupted nuclear receptor function may be linked to increased risk of widespread conditions, like cardiovascular disease, obesity, diabetes, reduced fertility, breast cancer, prostate cancer, colon cancer and neurodegenerative disease. CASCADE conducts research into how the body’s hormone system is affected by a range of substances called endocrine disrupting chemicals (three model compounds Bisphenol A, Dioxins and Vinclozolin).
__T_____	EU-Project - ENDOMET	60	The overall objectives of ENDOMET were to determine whether plasticisers, which are widespread environmental contaminants, could affect not only the human reproductive system but also human neuronal and thyroid development and function and which mechanisms might be involved.	ENDOMET - Dysregulation of endogenous steroid metabolism potentially alters neuronal and reproductive system development: effects of environmental plasticisers. In vitro tests were to be developed to identify compounds with endocrine disrupting potential.The key objectives were therefore: 1. To determine the effects of plasticisers on the enzymes involved in steroid metabolism, using human cell lines. 2. To determine the effects of plasticisers on steroid receptors, signalling pathways and uptake mechanisms. 3. To determine how plasticisers may act as reproductive toxicants. 4. Correlation of the above objectives, using a proteomic/genomic approach, to give effective in vitro tests for endocrine disrupting potential. 5. Assessment of risk perception in EU populations. 6. Dissemination of results. Duration: 01/01/03 - 30/06/06; Summary report not complete (part of pages missing). No detailed results given.
__T_____	Chemicals known to the State California to cause cancer or reproductive toxicity	80	Chemicals known to the State of California to cause cancer or reproductive toxicity (September 2008).	The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list. For easy reference, chemicals which are shown underlined are newly added. Chemicals or endpoints shown in strikeout were placed on the Proposition 65 list on the date noted, and have subsequently been removed. For those chemicals for which a no significant risk level (NSRL) for carcinogens or maximum allowable dose level (MADL) for reproductive

Prefix	Content	No	Evaluation	Comment
				toxicants has been adopted, it is denoted in the column, "NSRL or MADL (µg/day)."
__T_____	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans	86	List of substances evaluated with respect to their carcinogenic risks to humans. 1: carcinogenic to humans, 2a: probably carcinogenic to humans, 2b: possibly carcinogenic to humans, 3: not classifiable as carcinogenic to humans, 4: probably not carcinogenic to humans.	Monographs and risk assessment reports on carcinogenic risk.
__T_____	Substances with (anti)estrogenic/(anti)androgenic activity in-vitro	99	Literature data on in-vitro activity, receptor ER and/or AR mediated.	
__T_____	Substances with acute and chronic effects, Chile	112	List of substances classified into 2 categories: - acute toxicity to humans (n=106), - chronic toxicity to humans (n=235).	Criteria for classification of toxicity are only for human health, no classification for environmental organisms included. No priority chemicals were identified out of the chronic and acute substances.
____ER__	Priority Substances in European Waters	1	The EU list of priority substances in the field of European water policy and identified as priority hazardous substance. Priority List of the Water Framework Directive (2000/60/EC) was developed on Directive 76/464/EEC (Water pollution by discharges of certain dangerous substances).	Establishment of a list of priority substances to become Annex X of the Water Framework Directive (2000/60/EC) : The preparation of the priority list, included a procedure called COMMPS which was developed to identify the substances of highest concern at Community level. The list identifies 33 substances or groups of substances, which have been shown to be of major concern for European Waters. Within this list, 11 substances have been identified as priority hazardous substances which are of particular concern for the inland, transitional, coastal and territorial waters. These substances will be subject to cessation or phasing out of discharges, emissions and losses within an appropriate timetable that shall not exceed 20 years. A further 14 substances were identified as being subject to review for identification as possible "priority hazardous substances". The Commission proposal (COM(2006)397 final) setting environmental quality standards for surface waters of 41 dangerous chemical substances includes the 33 priority substances and 8 other pollutants, including selected existing chemicals, plant protection products, biocides, metals and other groups like Polyaromatic Hydrocarbons (PAH) that are mainly incineration by-products and Polybrominated Biphenylethers (PBDE) that are used as flame retardants.
____ER__	Monitoring data of the river Elbe	37	Substance list with measured concentrations. Abstract of the publication: We analyzed the detection frequencies for 331 organic compounds measured between 1994 and 2004 in the four largest rivers of North Germany and assessed the potential risk for the aquatic fauna using experimental and predicted acute toxicity data for the green algae Selenastrum capricornutum, the crustacean Daphnia magna and the fish Pimephales promelas. The detection frequency for most compounds decreased significantly from 1994 to 2004. Polycyclic aromatic hydrocarbons (PAHs) were most frequently detected, pesticides were the most important chemical group concerning toxicity for the test organisms. The predicted toxicity for Daphnia magna was significantly higher than for the other organisms and reached levels that suggest acute toxic effects on the invertebrate fauna. The Species At Risk (SPEAR) index used on biological monitoring data for the sites indicated impacts of organic toxicants. Most of the compounds responsible for potential acute effects on aquatic organisms are currently not considered as priority pollutants in the European Union, while only 2 of the 29 measured priority pollutants occurred in levels that may be relevant in terms of toxicity for the selected test organisms. We conclude that pesticides and other organic toxicants should play an important role in river basin management.	Data submitted for publication. Abstract and water concentrations are provided. Other data from German Länder possibly available. Project leader: Dr. Peter von der Ohe (UFZ, Leipzig, Germany). Telephone 0341 235 1581. Explanation of the abbreviations for chemicals can be inserted after publication.

Prefix	Content	No	Evaluation	Comment
____ER__	Japan: AIST Risk Assessment for substances of concern	40	Though this is not a priority list, the substances are included in the data-base tool due to valuable information on substances of concern.	For 7 chemicals and 2 chemical groups (short-chain chlorinated paraffins, coplanar-PCB) out of Japanese priority chemicals, detailed risk assessment reports were prepared. Measured concentrations are not presented in all reports.
____ER__	CERCLA Priority List of Hazardous Substances 2007 (USA)	89	Priority List of Hazardous Substances.	CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act, USA. By US Congressional mandate, the Agency for Toxic Substances and Disease Registry (ATSDR) produces "toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed from a priority list of 275 substances. ATSDR also prepares toxicological profiles for the Department of Defense (DOD) and the Department of Energy (DOE) on substances related to federal sites. So far, 302 toxicological profiles have been published or are under development as finals or drafts for public comment; 289 profiles were published as finals; 130 profiles have been updated. Currently, 7 profiles are being revised based on public comments received; 2 profiles are under development or review. These profiles cover more than 250 substances.
____E_X_	Chemical Substances Portal: Environmental Database	41	INERIS Environmental database (n = 967) is a general database on environmental properties of chemicals (data sheets with links to, e.g., EU RAR (if available). Two Sub-lists were extracted: RSDE: List of substances from the French action for the monitoring and reduction of hazardous chemical releases in water (n = 119), SIAR: List of chemicals for which a SIDS Initial Assessment Report has been published (n = 257).	
____E__§	Pollutant Release and Transfer Register (PRTR) for EU	29	Inventory of emissions to air, water and soil.	Based on E-PRTR 166/2006 EU, industrial enterprises of the 27 EU Member States report pollutant emissions to air, water and land, as well as off-site transfers of wastes and of pollutants in waste water, which is discharged into external treatment plants. Emissions from specific installations are reported (industrial activities).
____E___	OECD: HPV-Programme (List of High Production Volume Chemicals)	12	This document lists those chemicals which are produced at levels greater than 1,000 tonnes per year in at least one member country/region. It has been compiled based upon submissions from 24 member countries including the European Union's HPV list according to EC Regulation 793/93. It is used by member countries to choose chemicals on which to make a hazard assessment for human health and the environment in the context of the OECD HPV Chemicals Programme.	In the Council Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/Final] it was decided that Member countries shall cooperatively investigate high production volume (HPV) chemicals in order to identify those which are potentially hazardous to the environment and/or to the health of the general public or workers [and] For purposes of this Decision-Recommendation HPV chemicals are those chemicals included In the OECD Representative List of High Production Volume (HPV) Chemicals, as established and updated regularly. This is the updated (2004) list of chemicals referred to in the Council Act. The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology recommended that this list be derestricted. It has been made public under the responsibility of the Secretary-General of the OECD.
____E___	CHAMP Programme USA: High Production Volume Chemicals	32	EPA 2006 Inventory Update Reporting (IUR): The list contains the Top 100 chemical substances in commerce in 2006.	EPA's new Chemical Assessment and Management Program (ChAMP) Under ChAMP, EPA is fulfilling U.S. commitments made under the Security and Prosperity Partnership of North America (SPP). The SPP of North America Leaders' Summit, held in Montebello, Canada, in August 2007, called for cooperation on chemicals and outlined commitments on behalf of the United States, Canada, and Mexico to work together to ensure the safe manufacture and use of industrial chemicals. Each country is sharing scientific information and approaches to chemical testing and risk management. To fulfill its part of the SPP commitment, the United States will, by 2012, complete screening-level hazard and risk characterizations and initiate action, as appropriate, on more than

Prefix	Content	No	Evaluation	Comment
				6,750 (based on preliminary statistics from 2006 Inventory Update Reporting data, see connected lists)) chemicals produced above 25,000 pounds per year. The U.S. commitment to complete assessments and initiate needed action on these chemicals will apply the results of EPA's work on High-Production Volume (HPV) chemicals - those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year - and extend its efforts to moderate production volume (MPV) chemicals - those produced or imported in quantities above 25,000 and less than 1 million pounds per year. As an initial effort under ChAMP, EPA began, in 2007, posting screening-level hazard characterizations and expanded this effort in 2008 by posting risk-based prioritizations (RBPs). The RBPs summarize basic hazard and exposure information on HPV chemicals, identify potential risks, note scientific issues and uncertainties, and indicate the initial priority being assigned by the Agency for potential future appropriate action.
___E___	Rhine Substance list 2007	38	Comprehensive substance list for the river Rhine, composed of the previous Rhine list and other chemical priority lists.	The New Rhine substance lists is compiled from the following: 1) Action programme Rhine 1987-2000 / Programme Rhine 2020; 1, 2 or 3: highest result of actual vs. target comparison 2001-2003 (for DDD/DDE 2000, 2002 and 2003, for Drine 1998-2000), 2) Rhine-relevant substances (Annex VIII WFD, 1-9), 3) Substances of the EU-Directive 76/464/EEC (24, March 2006 amended to 2006/11/EU), where substances from daughter directives (Annex IX WFD) are printed in bold, 4) Priority (hazardous) substances; priority hazardous substances (printed in bold) (Annex X WFD), 5) OSPAR list of chemicals for priority action, type A, (x marked substances have to be examined in more detail taking OSPAR monitoring strategies into account), 6) Drinking water relevant substances (proposed by International Association of Waterworks in the Rhine Catchment Area (IAWR)).
___E___	Global Automotive Declarable Substance List (GADSL)	67	The Global Automotive Declarable Substance List (GADSL) provides reason codes that have been developed to explain why a substance has been included in the GADSL. 3 categories are discriminated: - FA: for assessment - LR: legally regulated - FI: for information (not included)	Each declarable substance will be listed with one of the following reason codes to facilitate dialog within the supply chain: LR = Legally Regulated A substance legally regulated because its use in a vehicle part or material poses a significant risk to health and or the environment. FA = For Assessment A substance projected to be regulated by government agencies, upon decision by the GASG Steering Committee. FI = For Information A substance tracked for information purposes only, upon decision by the GASG Steering Committee. After discussion at the GASG Steering Committee and on an exceptional basis, an automobile manufacturer may include an individual substance or family of substances on the list under this (FI) reason code. LR, FA and FI substances should not be construed to mean that the substance is prohibited from being used in a vehicle part, or is to be de-selected from use.
___E___	High Production Volume (HPV) Challenge	85	Compilation of substances based on production volumes. No list of prioritised substances. The Master Summary Table for the US High Production Volume (HPV) Chemical Hazard Data Availability Study contains information on whether or not data on six hazard endpoints are publicly available for 2863 US HPV organic chemicals (68 inorganic HPV chemicals were deleted from the original database of 2931 HPV chemicals reported under the 1990 Inventory Update Rule). The six hazard endpoints (acute toxicity, chronic toxicity, teratogenicity or developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate) comprise the "Screening Information Data Set" (SIDS) test battery established by the Organization for Economic Cooperation and Development (OECD, 1998a).	The High Production Volume Information System (HPVIS) is a database that provides access to health and environmental effects information obtained through the High Production Volume (HPV) Challenge. This program "challenges" companies to make this data publicly available on chemicals produced or imported into the United States in quantities of 1 million pounds or more per year. In the HPV Challenge Program, companies have sponsored more than 2,200 HPV chemicals, with approximately 1,400 chemicals sponsored directly through the HPV Challenge Program and over 860 chemicals sponsored indirectly through international efforts. Under the program, when companies, such as chemical manufacturers and trade associations, voluntarily sponsor a set of HPV chemicals, they provide existing data or perform tests on the chemicals, and submit their test data to this database. To ensure consistency, sponsors follow the

Prefix	Content	No	Evaluation	Comment
			Variable names for each column are shown in the first row of the database. The remaining rows contain the information on hazard data availability for the chemicals. The first column contains CAS.NO. An "X" is shown in the third column (ACUTE), if EPA was able to locate any information on acute toxicity testing. Columns 4 (CHRONIC), 5 (TERARE), 6 (MUTAGEN), 7 (ECOTOX), and 8 (FATE) are also marked with an "X" if hazard data were located for chronic toxicity, teratogenicity or developmental/reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate, respectively. The total number of six hazard test data endpoints located for each chemical is shown in Column 10 (TOTAL). Some 277 of the 2863 US HPV chemicals are part of the ongoing OECD SIDS international program. Some of the SIDS testing is complete, but many of those studies have not yet been entered into publicly accessible databases, although all of the information will be available in the future as those databases are updated. A "C" or "U" is marked in Column 9 (SIDS) if the chemical is part of the OECD SIDS testing program. A "C" indicates that testing has been completed, and a "U" denotes that testing is ongoing. Copies of completed SIDS dossiers are available through the United Nations Environmental Programme (UNEP, 1996). The Master Summary Table will be updated to include the SIDS information once the hazard data become available. Additional columns in the table indicate whether the chemical is a high release TRI chemical (TRI HIGH), whether the chemical is on the 1995 TRI database (TRI), whether an OSHA PEL (OSHA PEL) is in place for the chemical, and whether the chemical is a consumer product chemical (CPC) listed in EPA's Source Ranking Database.	Screening Information Data Set (SIDS), developed by the Organization for Economic Cooperation and Development (OECD). SIDS provides internationally agreed upon tests for screening chemicals for human and environmental hazards. HPVIS consists of basic hazard (toxicity) and environmental fate information on HPV chemicals that can be used by environmental managers, public decision-makers, and others in their own health and environmental protection activities.
____E___	Japan METI High Priority Chemicals	91	Priority substances due to high production or imported volumes, equivalent to potential of exposure.	
____E___	European Pollutant Emission Register (EPER)	93	Inventory of emissions to air, water.	EPER is the first European-wide register of industrial emissions into air and water. It gives you access to information on the annual emissions of approx. 9,200 industrial facilities in the 15 Member States of the EU as well as Norway and Hungary mostly for the year 2001 and approx. 12,000 facilities in the 25 Member States of the EU and Norway for the year 2004. It lets you group information easily, by pollutant, activity (sector), air and water (direct or via a sewerage system) or by country. It is also possible to see detailed data on individual facilities.
____E___	The Pollutant Emission Register in the Netherlands	94	Inventory of emissions to air, water, soil.	The Emission Register contains the yearly releases of more than 350 pollutants to air, soil and water The Emission Register project covers the whole process of collecting, processing and reporting of the emission data in the Netherlands. The emission from individual point sources (companies or facilities) and the diffuse emissions, calculated from national statistics by the so called task forces) are stored into one central database. Components are selected according to the international reporting obligations: the Kyoto Protocol, the Water Framework Directive, the 'European Pollution Release and Transfer Register' (E-PRTR) and various UN and EU obligations. Additionally monitored are components for following national environmental policies.
____E___	Pollutant Release and Transfer Register (PRTR) for Australia	120	Inventory of emissions to air, water, soil.	The National Pollutant Inventory (NPI) provides the community, industry and government with free information about substance emissions in Australia. The NPI shows emission estimates for 87 toxic substances and the source and location of these

Prefix	Content	No	Evaluation	Comment
				emissions.
____E___	Pollutant Release and Transfer Register (PRTR) for the Czech Republic	123	Inventory of emissions to air, water, soil.	The list of chemical substances is a suggestion. There is the possibility for every one to make suggestions via internet.
____E___	Pollutant Release and Transfer Register (PRTR) for France	124	Inventory of emissions to air, water, soil.	Register for industrial pollutant emissions into the air, water (direct, indirect) and soil. Since 2004 the PRTR for France is linked with the European PRTR.
____E___	Pollutant Release and Transfer Register (PRTR) for Japan	125	Inventory of emissions to air, water, soil.	A list that reports pollutants to air, public water bodies, the land (on-site) and landfill disposal.
____E___	Pollutant Release and Transfer Register (PRTR) for United Kingdom	126	Inventory of emissions to air, water, soil.	The Pollution Inventory (PI) is an annual record of pollution in England and Wales from selected activities. The main objectives of the pollution inventory are to tell the public about pollution from industrial and other sources in their local area and nationally, help environmental regulators to protect the environment, help the Government to meet national and international commitments and reporting obligations.
_____RX_	Priority list of existing substances in the EU	2	Four priority lists (PL) have been adopted under the regulation up to now : PL1: 1st Priority List (42 substances) PL2: 2nd Priority List (36 substances) PL3: 3rd Priority List (32 substances) PL4: 4th Priority List (31 substances) based on risk (EURAM: EU Risk Ranking Method) and expert judgement.	The practical implementation of the procedure laid down in the Regulation 793/93 is the following stepwise process: STEP 1 First EURAM (EU Risk Ranking Method) Rankings: Preparation of the automated rankings based on the IUCLID data and generated automatically using the EURAM data selection routine and applying the EURAM method to the resulting database. STEP 2 Technical Meeting Commenting on the EURAM Rankings: Member States, Industry and other NGOs Commenting on the EURAM Database and adding flags on the ranking on concerns not reflected in the ranking of the substance. STEP 3 Preparing the Working Lists: Using Expert Judgement to select substances from the EURAM rankings to place them on the Working List. Working list of national priorities is developed. STEP 4 Preparing the Priority Lists: Using Expert Judgement substances are selected from the working list for the priority lists. National priorities are also included. The size of the priority lists will be determined, to a large degree, by the number of priority substances which have been completed. The process is developed for a smooth a practical implementation. For this reason the discussion focuses on the EURAM Rankings. The inclusion of national priorities is only done for those substances which are not selected for the working list based on the EURAM Ranking. In nominating such substances, the reason for concern should be summarised. National priority lists are incorporated into the working list through the EURAM Database or Ranking commenting step. If the EURAM data base has selected non representative data for the substance, then representative data can be submitted during the commenting step. This could result in an altered score which could place the substance on the initial working list. If this is not possible, then the reason for the substance being a national priority can be placed on the ranking and taken into account when preparing the working lists.
_____RX_	Rotterdam Convention	82	Substances with potential harm to human health and the environment.	The Convention entered into force on 24 February 2004. The objectives of the Convention are: * to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm; * to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Convention creates legally binding obligations for the implementation of the Prior

Prefix	Content	No	Evaluation	Comment
				Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006. Major Provisions: The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention, Severely hazardous pesticide formulations that present a hazard under conditions of use in developing countries or countries with economies in transition may also be nominated for inclusion in Annex III. There are 39 chemicals listed in Annex III of the Convention and subject to the PIC procedure, including 24 pesticides, 4 severely hazardous pesticide formulations and 11 industrial chemicals. Many more chemicals are expected to be added in the future. The Conference of the Parties decides on the inclusion of new chemicals. Once a chemical is included in Annex III, a "decision guidance document" (DGD) containing information concerning the chemical and the regulatory decisions to ban or severely restrict the chemical for health or environmental reasons, is circulated to all Parties.
_____RX_	Basel Convention	83	Groups of chemicals in hazardous wastes with potential adverse effects on human health and the environment.	The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal is the most comprehensive global environmental treaty on hazardous and other wastes. It has 170 member countries (Parties) and aims to protect human health and the environment against the adverse effects resulting from the generation, management, transboundary movements and disposal of hazardous and other wastes. In Annex 1 there are given wastes having as constituents 27 different chemicals/chemical groups.
_____R_§	Annex XVII REACH Regulation	130	Annex XVII contains substances restricted regarding ‘Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles’. Substances listed in this Annex are found to be dangerous or toxic and they are therefore restricted or banned. Because these substances are carefully checked by experts regarding their harmful effects, they can be excluded from further evaluation concerning potential SVHC under REACH in the frame of this project.	The European Commission has amended REACH Annex XVII in order to transfer restrictions that were introduced in Annex I of the EU marketing and use Directive shortly before the REACH Regulation was adopted. The Directive has now been repealed and replaced by REACH. REACH Annex XVII includes the most recently adopted restrictions under Directive 76/769/EEC on PFOS , arsenic, mercury in measuring devices, 2(2-methoxyethoxy)ethanol (DEGME), 2-(2-butoxyethoxy)ethanol (DEGBE), methylenediphenyl diisocyanate (MDI), cyclohexane and ammonium nitrate.
_____R_§	EDEXIM Regulation 689/2008	131	The EDEXIM source shows three lists with substances related to: Annex I Part 1: List of chemicals subject to export notification procedure Annex I Part 2: List of chemicals qualifying for PIC notification Annex I Part 3: List of chemicals subject to the PIC procedure under the Rotterdam Convention Annex V: Chemicals and articles subject to export ban	REGULATION (EC) No 689/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUCIL of 17 June 2008 concerning export and import of dangerous substances
_____R__	International Programme on Chemical Safety (IPCS)	11	Information on substances and risk assessment available in: - Concise International Chemical Assessment Document (CICADS) for 72 substances or groups of substances. Assessment of the risks a chemical may cause to human health or environment. - Environmental Health Criteria (EHC) Monographs, 236 substances or groups of substances, provide international, critical reviews on the effects of chemicals or combinations of chemicals and physical and biological agents on human health and the environment. - OECD Screening Information DataSet (SIDS) High Production Volume Chemicals (see comments to list 12 (OECD HPV) - International Chemical Safety Cards provide essential health and safety information on chemicals to promote their safe use (1500, not included in the database) - Health and	The International Programme on Chemical Safety (IPCS), established in 1980, is a joint programme of three Cooperating Organizations - WHO, ILO and UNEP, implementing activities related to chemical safety. Peer reviewed information on chemicals commonly used throughout the world, which may also occur as contaminants in the environment and food. The chemical may be a priority chemical for IPCS risk assessment, if * there is a probability of exposure; * the chemical has toxic or ecotoxic properties, or may accumulate in the body or in the environment; * there is significant international trade or the substance is of transboundary concern; * high production volume with dispersive use; the substance is of concern to a range of countries for possible risk management: developed, developing and those with economies in transition; Chemicals assessment:The objective of chemicals assessment is to provide a consensus scientific

Prefix	Content	No	Evaluation	Comment
			Safety Guides (109): provide concise information in non-technical language, for decision-makers on risks from exposure to chemicals, together with practical advice on medical and administrative issues. Includes hazard evaluation for human and environment.	description of the risks of chemical exposures.
_____R__	Priority substances (Austria)	65	Extended priority substances lists for Austria according WFD: - Beilage 3: Substances of List 1 under 76/464/EEC; - Beilage 4: Priority substances according to WFD (Art. 16(2)); - Beilage 5: Relevant priority substances in Austrian surface waters.	The Water Framework Directive 2000/60/EC requires that Member States define good water status in surface water by environmental quality standards for hazardous substances. Based on recommendations by Prof. W: Bursch (Vienna), the working group on Chemical Monitoring and Targets set up by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) developed the strategy with three Austria-specific annexes (Beilagen): Beilage 5: Environmental quality standards of other relevant substances in Austria. Selection criteria for substances on annex 5 are based on the procedure according to Annex V, 1.2.6 of the Water Framework Directive or the detailed provisions of the EU Guide-line on the Risk Assessment of Chemical Substances (EK, 2002), or, if no valid data were available, based on an evaluation of European quality standards.
_____R__	Priority substances within the context of the WFD, The Netherlands	104	Priority substances within the context of the WFD (PEC/PNEC approach).	
_____R__	National and International Approaches to the Classification of River Health	106	Integrated list of priority substances in river water and sediments from 23 countries: 16 metals and 46 organics in river water, 8 metals and 18 organics in river sediment.	Study from 1999 = prior to WFD.
_____X§	The NORMAN Network	110	A list of emerging substances most frequently discussed is presented: — Algal toxins — Antifoaming agents — Antioxidants — Antifouling compounds — Bio-terrorism/ sabotage agents — Complexing agents — Detergents — Disinfection by-products (drinking water) — Plasticizers — Flame retardants — Fragrances — Gasoline additives — Industrial chemicals — Nanoparticles — Perfluoroalkylated substances and their transformation products — Personal care products — Pesticides — Biocides — Pharmaceuticals — Trace metals and their compounds — Anticorrosives — Wood preservatives — Other	The NORMAN project is funded under the 6th Framework Programme Priority 6.3 "Global Change and Ecosystems" (Contract N° 018486 - Start date 1st September 2005). Network of reference laboratories for monitoring emerging environmental pollutions. Introduction: Our focus is on emerging environmental substances. Emerging substances are not necessarily new chemicals. They are substances that have often long been present in the environment but whose presence and significance are only now being elucidated. Data for emerging substances are often scarce and measurement methods are often at the research and development stage or have not yet been harmonised at the European level. This makes it difficult to interpret and compare the results and represents a major difficulty for regulatory bodies in their decision-making. Our objective is to establish a European network of reference laboratories, research centres and related organisations (including standardisation bodies) in order to: * improve the exchange of information on emerging environmental contaminants * encourage the validation and harmonisation of common measurement methods and monitoring tools so that the demands of risk assessors and risk managers can be better met. As a source of information on emerging environmental substances NORMAN will help to keep you informed about the state of the monitoring, risk assessment and management of emerging substances and specific problems relating to them. On this website you will find access to: * NORMAN databases on emerging substances * Workshops organised by NORMAN or other relevant events in the field of monitoring, risk assessment and management of emerging substances * NORMAN newsletter * QA/QC activities organised within NORMAN The NORMAN network relies on a number of Contact Points identified in each EU country to help the network gather information in the different countries about on-going initiatives on emerging substances.
_____X_	BUA-Reports	115	Comprehensive reports on substances that were selected based on	In 1982, the German Advisory Committee on Existing Chemicals of Environmental

Prefix	Content	No	Evaluation	Comment
			consensus ranking and expert judgement.	Relevance (BUA) was established to developed a procedure for priority setting, to select the most hazardous substances with regard to environmental relevance and compile comprehensive assessment reports for (groups of) substances with high hazard and exposure potential.
_____§	Annex I of Dir 67/548/EEC	134	In data source No. 5 the Annex VI to CLP (2009) " Database for substances labelled regarding hazard to health and environment in the EU" is shown (equivalent to Table 3.1 of CLP). However, in No. 5 only substances. List No 5 contains substances or mixtures/preparations with intrinsic hazard to the environment (formerly R50/53, R51/53). Substances with lower toxicity to aquatic organisms (formerly R52) are not included in this list. New Label/Symbol: GSH09 (N); Classification: Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410), Aquatic Chronic 2 (H411). The data of No. 5 were subdivided in "sublists" based on the classifications for toxic or very toxic aquatic toxicity. See No. 5. Substances only listed in Annex I 67/548 (No. 124) were excluded from further evaluation regarding potential candidates for SVHC under REACh.	Annex I of Directive 67/548/EEC is deleted by the entering into force of Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) on 20 January 2009. Annex I is replaced by Table 3.2 in Annex VI to CLP. As Table 3.2 is a transfer from Annex I these entries can be found in the ClassLab database, but note that Table 3.2 and Annex I are not totally identical due to some corrigendum issues. C&L of substances of special concern are included in the EU harmonised list in Annex VI to CLP. In Table 3.1 the entries are classified and labelled in accordance with the criteria in CLP. In Table 3.2 the entries are classified and labelled in accordance with the criteria in Directive 67/548/EEC. Table 3.2 replaces Annex I to Directive 67/548/EEC from 20 January 2009. The C&L in Annex VI is legally binding. Annex VI to CLP, as previously Annex I to Directive 67/548/EEC, will be updated by Adaptations to Technical Progress (ATP). The 1st ATP is planned to include both ATP30 and ATP31 to Directive 67/548/EEC. (taken from Joint Research Centre Ispra homepage September 9, 2009).

Tab. Annex 2-2: Evaluation of information sources that were NOT included in the data-base tool.

The systematic prefix consists of an eight-character code (P (persistence), B (bioaccumulation), T (toxicity), C (climate change), E (exposure), R (risk), X (political criteria), § (regulation), _ (not considered)) that indicates whether or not a criteria category was used to set up the respective list. (for details see Section 3.1).

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PBT____	TGD: Technical Guidance Document	6	It is not a substance list, but provides EU reference criteria for PBT assessment.	Technical Guidance on Risk Assessment.
PBT____	Screening criteria for P, vP, B, vB and T	127	This is not a substance list. The ECHA document provides screening criteria for P, vP, B, vB and T assessment.	
PBT____	Persistence, Bioaccumulation Potential, and Inherent Toxicity to Non-human Organisms	128	No substance list. The Guidance Manual provides criteria for persistence and bioaccumulation as well as criteria for acute and chronic toxicity to aquatic species (algae, invertebrates, fish)	
P_____	Overall persistence criteria	101	No substance list. The project report provides persistence criteria in the REACH Legislation for overall persistence including long-range transport	Research project
_B_____	Potential Arctic Contaminants	42	No substance list. Background and criteria for the model to identify AC-BAP chemicals are presented (see list no. 43). The publication deals with the same criteria as Brown and Wania 2008.	The AC-BAP (Arctic-contamination and bioaccumulation potential) is defined as the quotient of the human body burden of the chemical and the quantity of chemical cumulatively emitted to the global environment. The highest AC-BAP values (up to 3.7×10-11 person-1) were obtained for hypothetical multimedia chemicals with intermediate volatility and hydrophobicity. Perfectly persistent chemicals with 3.5 < log KOW < 8.5 and log KOA > 6 had AC-BAP values of at least 10% of the maximum value, indicating that a broad range of chemicals are potential Arctic contaminants if they are persistent. Moreover, the simulation results suggest that a chemical's potential to bioaccumulate has a stronger impact on the overall potential to become an Arctic contaminant in humans than its potential for long-range transport. This modelling exercise demonstrates how linking nonsteady state models of chemical bioaccumulation and of global chemical fate can provide a valuable tool for assessing a chemical's potential to be a contaminant in remote regions.
_B_____	EURAS bioconcentration factor (BCF) Gold Standard Database	105	No further evaluation, since it is general-purpose BCF database without prioritisation.	May be later used to extract (non)bioaccumulating substances based on measured BCF values, possibly censored by cut-offs (BCF 500, 1000, 2000, 5000).
__T_E__	Environmental Residue-Effects Database (ERED)	22	The ERED contains residue-effects information on many environmental contaminants of potential concern. Although the database is the result of an extensive literature search of known residue-effects data, the search was not exhaustive. Currently the system contains data from 2180 studies published between 1964 and 2007. From these studies, 13,981 distinct observations have been included on-line. The ERED includes data on 404 analytes, 446 species, 15 effect classes, and 74 endpoints. Most papers involving mixtures of contaminants were excluded from the database because effects could not be linked to a specific contaminant.	The U.S. Army Corps of Engineers/U.S. Environmental Protection Agency Environmental Residue-Effects Database (ERED) is a compilation of data, taken from the literature, where biological effects (e.g., reduced survival, growth, etc.) and tissue contaminant concentrations were simultaneously measured in the same organism. Currently, the database is limited to those instances where biological effects observed in an organism are linked to a specific contaminant within its tissues.
__T____	Annex I of Directive 67/548/EEC	15	More recent list on C&L can be obtained from ESIS (http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=cla), now Regulation (EC) 1272/2008 (see list no 5).	The new Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) entered into force on the 20 January 2009. Annex I of Directive 67/548/EEC contains a list of harmonised classifications and labellings for substances or groups of substances, which are legally binding within the EU.
__T____	EnviChem, Finish Environmental	17	Database - No further evaluation, since it is a general information system on	The main content of the database consists of information on the toxicity of substances in

Prefix	Content	No	Evaluation	Comment
	Institute		environmentally relevant substance data.	relation to different species, especially aquatic organisms, together with information on the persistence and accumulation of these substances in the environment. The information is mainly compiled from scientific literature, handbooks and databases in the field of ecotoxicology which have been available to environmental protection authorities. The scientific value of the compiled information has not been assessed.
__T____	KemI-Riskline database, Sweden	18	No further evaluation, since the KemI-Riskline database will no longer be updated. Last update: July 1, 2007.	The Swedish KemI-Riskline contains substance information on both environment and health. It is a bibliographic database with exclusively peer reviewed information on these two subject areas.
__T____	EU-Project - DEVNERTOX	57	Three compounds have been studied alone and in combination, MeHg and two PCBs with different chemical properties; the non-dioxin-like di-ortho-substituted PCB 153 and the coplanar dioxin-like PCB 126.	DEVNERTOX (Toxic threats to the developing nervous system: in vivo and in vitro studies on the effects of mixture of neurotoxic substances potentially contaminating food). Main aims and expected outcome: Develop experimental models to improve predictive toxicity testing and mechanism-based risk assessment for neurotoxic food contaminants.
__T____	EU-Project - EASYRING	58	EASYRING aimed to improve the information relating to the environmental levels of some known EDCs and their biological effects on reproduction as measured with traditional and newly developed innovative tools to aquatic species and for mammalian risk assessment. The water and sediment of the River Lambro were analysed for their estrogenic and androgenic potential using a toxicity identification evaluation (TIE) approach that combined samples' fractioning with a battery of in vitro tests; no substance list.	EASYRING - Environmental Agents Susceptibility assessment utilizing existing and novel biomarker as rapid non-invasive testing methods. EU-Project number: QLK4-2002-02286 One of the main targets of EAYRING was the improvement of analytical methods (chemical and biological). Start Date: 2003-01-01- End Date: 2005-12-31
__T____	EU-Project - EDERA	59	No substance list, research project with focus on methodology, no substance list.	EDERA - Development and implementation of new 'in vivo' and 'in vitro' systems for the characterization of endocrine disruptors. QLK4-CT-2002-02221, 1 Jan 2003 - 30 Jun 2006. The aims of the EDERA project were: - to set up protocols based on bioluminescence techniques enabling to measure the activity of estrogenic compounds in living animals and to establish their efficiency; - to validate the ERE-Luc model system for the study of compounds with estrogenic activity present in diet and environment by measuring the effects of selected estrogenic compounds on ER transcriptional activity in vitro and in vivo; - to improve the original ERE-Luc reporter mouse generating a model with which to discriminate between compounds acting on each of the two receptor subtypes (ERα or ERβ); - to set up methodologies for the preparation of 3-D cell cultures from animal tissues; - to generate vectors for the preparation of novel reporter mice.
__T____	Toxicology and Carcinogenesis Study Reports	88	It is not a priority substance list, clear evaluation criteria are not provided.	Detailed reports on toxicology and carcinogenesis studies (1976-2008)
__T____	Dangerous Substances, Norway	97	Basis for lists no. 96 and 95, not included.	Information about health and environmental hazards for approximately 3500 substances: These substances are included in the Norwegian List of Dangerous Substances. The list is the Norwegian implementation of the Annex 1 to Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. The list is updated through the 29 ATP (Adaption to Technical Progress).
__T____	ECB Endocrin List	98	Basis for categorisation of substances concerning their endocrine potential is unknown, the origin of the list is not known.	ED categories associated with 106 chemicals
__T____	India - Hazardous chemical rules	102	No further evaluation, since it concerns human health and worker safety only.	Hazardous chemical rules (2000): Acutely toxic (oral, dermal, inhalation) chemicals which, owing to their physical and chemical properties, are capable of producing major accident hazards.

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__T____	DSSTox	107	No further evaluation, since it features multiple databases without prioritisation.	Distributed Structure-Searchable Toxicity (DSSTox) Database Network is a project of EPA's National Center for Computational Toxicology, helping to build a public data foundation for improved structure-activity and predictive toxicology capabilities. The DSSTox website provides a public forum for publishing downloadable, structure-searchable, standardized chemical structure files associated with toxicity data: ARYEXP: European Bioinformatics Institute (EBI) ArrayExpress Repository for Gene Expression Experiments. Carcinogenic Potency Database: Tumor target site incidence, TD50 potencies, summary activity calls for rat, mouse, hamster, dog, and/or non-human primate; data reviewed and compiled from literature and NTP studies. EPA Water Disinfection By-Products with Carcinogenicity Estimates Database: Carcinogenicity estimates (high, moderate, low concern). EPA Fathead Minnow Acute Toxicity Database: Acute toxicities of 617 chemicals. FDA Center for Drug Evaluation & Research - Maximum (Recommended) Daily Dose Database. National Center for Biotechnology Information (NCBI) Gene Expression Omnibus (GEO). EPA High Production Volume Challenge Program. EPA High Production Volume Information System (HPV-IS). EPA Integrated Risk Information System (IRIS). FDA National Center for Toxicological Research (NCTR) - Estrogen Receptor Binding Database. National Toxicology Program (NTP) On-line Chemical Bioassay Database. National Toxicology Program (NTP) High-Throughput Screening Project. Research Chemical Inventory for EPA's ToxCast TM Program. ISSCAN: Istituto Superiore di Sanita, “CHEMICAL CARCINOGENS: STRUCTURES AND EXPERIMENTAL DATA”.
____E__	SPIN: Database of Nordic Countries on the use of Substances in Products	19	SPIN is a database on the use of Substances in Products in the Nordic Countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland.	
____E__	Contaminate Candidate List CCL3 Drinking water	33	No further evaluation, since it concerns human health only.	Procedure: * Identifying a broad universe of potential drinking water contaminants (called the CCL 3 Universe) of approximately 7,500 potential chemical and microbial contaminants. * Applying screening criteria to the universe identified 560 of those contaminants that should be further evaluated (the preliminary CCL or PCCL) based on a contaminant’s potential to occur in public water systems and the potential for public health concern. * Selection of 104 contaminants from the PCCL to include on the CCL based on more detailed evaluation of occurrence and health effects and expert judgment applied in a transparent reproducible manner. * Information from the public, expert input, and expert review was incorporated in the CCL process.
____E__	Unregulated Contaminants Monitoring Rule UCMR-2	34	No further evaluation, since it concerns analytical processes only.	EPA is requiring select public water systems (PWSs) to monitor for 25 chemicals using five different analytical methods). All PWSs serving more than 10,000 people, and a representative sample of 800 PWSs serving 10,000 or fewer people, are required to conduct Assessment Monitoring (List 1) for 10 chemicals during a 12-month period during January 2008-December 2010. All PWSs serving more than 100,000 people, 320 selected PWSs serving 10,001 to 100,000 people, and 480 selected PWSs serving 10,000 or fewer people are required to conduct the Screening Survey (List 2) for 15 contaminants during a 12-month period during January 2008-December 2010.
____E__	EU-Network - SEDNET	61	SedNet is the European network aimed at incorporating sediment issues and knowledge into European strategies to support the achievement of a good environmental status and to develop new tools for sediment management.	The SedNet (EVK1-CT-2001-20002) focus is on all sediment quality and quantity issues on a river basin scale, ranging from freshwater to estuarine and marine sediments. Objectives: Sediments mainly got local attention of water managers confronted with manmade sediment-traps, especially when associated contamination poses an environmental or human risk. More and more managers, port authorities and

Prefix	Content	No	Evaluation	Comment
				researchers express the need to exchange, at least at river basin level, these local experiences and to develop sediment management guidelines based on a multidisciplinary, coordinated and harmonised approach. Thus opposing to the scattered responsibilities for sediment management and to the scattered development of knowledge. Due to the trans-boundary nature, no single water manager or country has the responsibility for solving sediment management problems at river basin level. SEDNET will provide an international platform to facilitate information and knowledge exchange and to produce a joint document, containing recommendations and guidelines for integrated, sustainable management of sediment, from local to river basin level.
____E__	Infosystem for dangerous working materials	66	No further evaluation, since it concerns worker safety only.	Information system (in Dutch), not freely accessible (password protected).
____E__	BASTA, Sweden	74	No further evaluation, since it is a database of not-hazardous products (only in Swedish (password required)).	PHASING OUT VERY DANGEROUS SUBSTANCES FROM THE CONSTRUCTION INDUSTRY A product may qualify for registration in the database of the BASTA system if it meets some fundamental requirements in relation to environmental and health properties. These ´properties criteria´ are applicable to all types of construction products and apply to their properties on delivery to a construction site. They are stricter than the Swedish legislation and have been geared towards reducing the use of substances with particularly hazardous properties. The properties criteria indicate a number of principal headings for undesirable properties. The criteria relate to both impact on the environment and on human health. The properties criteria are based on the properties identified in the forthcoming REACH regulation, plus the phase-out substances identified by the Swedish Parliament, lead, cadmium and mercury. The criteria mean that products must not contain chemical substances (above stated concentrations) with the following properties: * carcinogenic substances * mutagenic substances category (cause heritable genetic damage) * substances toxic to reproduction category (impair fertility) * persistent or very persistent substances (low degradability) * bioaccumulative or very bioaccumulative substances (accumulate in tissue) The content of sensitising substances, solvents and acutely toxic substances is also limited in chemical products.
____E__	SSG Product Database	75	No further evaluation, since it is a general information system.	The SSG Product Database is a searchable database of disposable products and spare parts used in industry (with LogIn).
____E__	WINGIS	76	No further evaluation, since it is a general information system.	Hazardous materials information system, MSDS for construction industry.
_____R_	EU-Project - SOCOPSE (Source Control of Priority Substances in Europe)	64	No further evaluation, since it is focussed on the priority substances of WFD (see list no 1).	The overall objective of this project is to support the implementation process for the Water Framework Directive (WFD) by providing guidelines and decision support tools for the management of priority pollutants (PP). To fulfil this overall objective the project includes the following activities: - To conduct a material flow analysis for selected priority pollutants. - To evaluate available and emerging measures and management options for PPs. - To develop a decision support tool for identification and selection of relevant measures on European, national and regional level. - To evaluate different potential measures by applying the decision support tools in case studies. - To facilitate the development of collective action plans (i.e. river basin management plans) involving all stakeholders (industries, authorities, citizens, NGOs). - To disseminate results to stake-holders and to strongly interact with industrial organisations, research networks, authorities and NGOs. Cooperation with the industrial sector, the different authorities and other stakeholders (public, NGOs) ensures the accuracy and relevance of basic data collection, as well as the applicability, acceptance and relevance of the results from this project.

Prefix	Content	No	Evaluation	Comment
_____X	Workplace hazardous materials information system (engl. WHMIS, franz. SIMDUT) Canada	117	The Service makes available to its clientele access to its databank on chemical or biological products. WHMIS divides hazardous materials into six main classes based on their specific hazards. If a product corresponds to one or more of these classes, it becomes a « controlled » product. A: Compressed gases, B: Flammable and combustible materials, C: Oxidizing materials, D1 Materials causing immediate and serious toxic effects, D2 Materials causing other toxic effects; D3 Biohazardous infectious materials; E Corrosive materials; F Dangerously reactive materials.	
_____	Estimation Program Interface (EPI) Suite	26	No further evaluation, since the Physprop component of EPISuite is a general information system on phys.-chem. property data.	The EPI (Estimation Programs Interface) EPI Suite is a Windows® based suite of physical/chemical property and environmental fate estimation models developed by the EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC). EPI Suite uses a single input to run the following estimation models: KOWWIN, AOPWIN, HENRYWIN, MPBPWIN, BIOWIN, BioHCWIN, PCKOCWIN, WSKOWWIN, WATERNT, BCFWIN, HYDROWIN, KOAWIN and AEROWIN, and the fate models STPWIN, WVOLWIN, and LEV3EPI. EPI Suite was previously called EPIWIN. EPI Suite is a screening level tool and should not be used if representative measured values are available.
_____	Recently Developed Methods from the Office of Research and Development	35	No further evaluation, since it concerns methodology only.	List of analytical methods.
_____	Toxnet - Toxicology Data Network	47	No further evaluation, since it is a general information system.	TOXNET includes several databases on toxicology, hazardous chemicals, environmental health, and toxic releases., e.g. HSDB (peer reviewed data), Toxline for publications.
_____	DIMDI Database	48	No further evaluation, since it is a general information system.	The online database service is a subordinated administration of the German Federal Ministry of Health, and provides databases with the focus on medicine, pharmacology and toxicology (around 70 databases, including MEDLINE and BIOSIS). Partly with costs.
_____	STN International Database	49	No further evaluation, since it is a general information system.	STN is an online database service that provides global access to published research, journal literature, patents, structures, sequences, properties, and other data (like comprehensive, peer-reviewed toxicology data in Hazardous Substances Data Bank (HSDB, 5000 chemicals).
_____	NLM-PubMed Database	50	No further evaluation, since it is a general information system.	PubMed is a service of the U.S. National Library of Medicine that includes over 18 million citations from MEDLINE and other life science journals for biomedical articles back to 1948. PubMed includes links to full text articles and other related resources.
_____	Scirus	51	No further evaluation, since it is a general information system.	Scirus is a comprehensive science-specific search engine on the Internet. - Pinpoint scientific, scholarly, technical and medical data on the Web. - Find the latest reports, peer-reviewed articles, patents, pre prints and journals that other search engines miss. - Offer unique functionalities designed for scientists and researchers. Owned and operated by Elsevier B.V., Radarweg 29, 1043 NX Amsterdam, The Netherlands,
_____	ETOX	52	No further evaluation, since it is a information system on environmental contaminants.	ETOX: Information System Ecotoxicology and Environmental Quality Targets The ETOX database allows access to evaluated effects information from aquatic and terrestrial ecotoxicology. Details of the respective evaluation methods are provided. Furthermore, ETOX contains information on various national and international environmental quality guidelines, targets, standards, criteria, and limit values. Currently, the ETOX database contains approximately 30,000 entries on effects to aquatic organisms, approximately 5,000 entries on effects to terrestrial organisms, as well as approximately 3,500 entries

Prefix	Content	No	Evaluation	Comment
				on various national and international environmental quality guidelines, targets, standards, criteria, and limit values for the protection of water and soil. ETOX contains as well the ecotoxicological effect data of GSBL.
_____	GSBL - Gemeinsamer Stoffdatenpool des Bundes und der Länder	53	No further evaluation, since it is a general information system.	GSBL (Gemeinsamer Stoffdatenpool des Bundes und der Länder) provides extensive information about chemical substances, their physico-chemical and hazardous properties (toxicological and ecotoxicological), environmental, consumer and worker protection as well as 1st-aid measures and substance-related legislation. The ecotoxicological effect data of GSBL are contained in ETOX (no 52).
_____	Ecotox Database (incl. AQUIRE)	54	No further evaluation, since it is a general database.	Data for aquatic and terrestrial effects of substances.
_____	PAN Pesticides database	55	No further evaluation, since it is a general information system on pesticides.	
_____	EU-Project - OSIRIS	62	No further evaluation, since it is not a substance list.	The goal of the project OSIRIS is to develop integrated testing strategies (ITS) fit for REACH that enable to significantly increase the use of non-testing information for regulatory decision making, and thus to minimise the need for animal testing. To this end, operational procedures are developed, tested and disseminated that guide a transparent and scientifically sound evaluation of chemical substances in a risk-driven, context-specific and substance-tailored manner.
_____	EU-Project - MODELKEY	63	No further evaluation, since the project will produce no lists before 2010.	KEYTOX, a subproject of MODELKEY concerns development and application of new tools for "key toxicant identification" in fresh water and marine ecosystems. KEYTOX work components are structured into four work packages. KEYTOX 1 (Innovative tool development) is a multidisciplinary thematic programme of work aimed at filling the gaps in techniques available for identifying toxicants, KEYTOX 2 is a package aimed at toolbox design, inter-laboratory comparison and validation of available techniques so that they can be used on a multinational level, KEYTOX 3 applies the developed and validated techniques to identify the key toxicants present in the three study sites in relation to SITE and KEYTOX 4 is focused on developing an Internet access database that will facilitate the identification of key toxicants through providing easily accessible data for their identification.
_____	GESTIS-database on hazardous substances	68	No further evaluation, since it is a general information system.	The GESTIS-substance database contains information for the safe handling of hazardous substances and other chemical substances at work, e.g. health effects, necessary protective measures and such in case of danger (incl. First Aid). Furthermore the user is offered information upon important physical and chemical properties for these substances as well as special statutory regulations and regulations of the Berufsgenossenschaften. The available information relates to about 8,000 substances. Data are updated after publication of new official regulations or after the issue of new scientific results.
_____	Gefahrstoffdatenbank der Länder	69	No further evaluation, since it is a general information system.	Hazardous substances database with focus on worker safety.
_____	IGS Public	70	No further evaluation, since it is a general information system. The database is not fully accessible for public use.	IGS, the INFORMATION SYSTEM FOR HAZARDOUS SUBSTANCES is provided by the State Office for Nature, Environment and Consumer Protection of NRW together with several partners. The heart of IGS is a factual database containing information on approximately 25,000 substances and products; for each substance up to 400 individual pieces of information are stored. The IGS application programs "IGS substance list", "IGS-Check", "IGS-Fire", "IGS Public" and "VTU - library of Technical Environmental Norms", are specific databases with chemical information for effective work and prepared specifically for the technical necessities.The data are updated regularly;

Prefix	Content	No	Evaluation	Comment
				approximately every 6 months an update appears.
_____	International Chemical Safety Cards-Database (ICSC)	71	No further evaluation, since it is a general information system.	The BGIA-ICSC-database is the German version of the International Chemical Safety Cards (ICSC) providing essential health and safety information on chemicals to promote their safe use (see list no 11).
_____	INCHEM	72	No further evaluation, since it is a general information system.	Chemical Safety Information from Intergovernmental Organizations IPCS INCHEM is an invaluable tool for those concerned with chemical safety and the sound management of chemicals. Produced through cooperation between the International Programme on Chemical Safety (IPCS) and the Canadian Centre for Occupational Health and Safety (CCOHS); IPCS INCHEM directly responds to one of the Intergovernmental Forum on Chemical Safety (IFCS) priority actions to consolidate current, internationally peer-reviewed chemical safety-related publications and database records from international bodies, for public access. IPCS INCHEM offers quick and easy electronic access to thousands of searchable full-text documents on chemical risks and the sound management of chemicals, helping countries fulfill their commitments under UNCED's Agenda 21, Chapter 19. IPCS INCHEM contains the following: * Concise International Chemical Assessment Document (CICADS) * Environmental Health Criteria (EHC) monographs * Harmonization Project Publications * Health and Safety Guides (HSGs) * International Agency for Research on Cancer (IARC) - Summaries and Evaluations * International Chemical Safety Cards (ICSCs) * IPCS/CEC Evaluation of Antidotes Series * Joint Expert Committee on Food Additives (JECFA) - Monographs and evaluations * Joint Meeting on Pesticide Residues (JMPR) - Monographs and evaluations * KemI-Riskline * Pesticide Data Sheets (PDSs) * Poisons Information Monographs (PIMs) * Screening Information Data Set (SIDS) for High Production Volume Chemicals
_____	HazMap	73	No further evaluation, since it is a general information system.	Database linked to TOXNET (no 47) and ChemIDplus (no 79).
_____	Isi	77	No further evaluation, since it is a general information system.	Collection of MSDS, guest access to ~ 28000 freely available MSDS, else resticted access.
_____	euSDB	78	No further evaluation, since it is a general information system.	Database of ~ 205 000 MSDS from different manufacturers and suppliers.
_____	ChemIDplus Advanced	79	No further evaluation, since it is a general information system.	Database of over 380,000 chemicals, synonyms, structures, regulatory list information, and links to other databases. ChemIDplus is a database provided under SIS (specialised information service) of the U.S. National Library of Medicine. Also avalaible under PubMed.
_____	The Substances List Database	84	No further evaluation, since it is a general information system.	Search engine for Chemicals and Polymers: New Substances Notification (NSN) to Environment Canada prior to importing or manufacturing.
_____	Industrial hygiene, occupational health and safety industries	90	No further evaluation, since it is a general information system.	For ACGIH members only!
_____	Russia	103	Information requested in October 2008: Unfortunately, no response.	
_____	Chile	108	Substance list see list no 112.	Information requested in January 2009 via contact persons of IME.
_____	China	109	Information requested in January 2009: Unfortunately, no response.	

9 ANNEX 3. Overview of the tables and (sub)lists extracted from selected information sources and records of chemicals of concern.

The no. of entries provides total numbers of chemicals on the (sub)lists, NOT all of them were included in the data analyses.

ListID	(Sub)list	no. of entries
1	**____ER____WRRL**	**52**
2	_____RX___PrioEU Altstoff PL1	42
2	_____RX___PrioEU Altstoff PL2	36
2	_____RX___PrioEU Altstoff PL3	32
2	_____RX___PrioEU Altstoff PL4	31
	PrioEU Altstoff PL (total)	**141**
3	__T____§__EDS 2003 evidently active PSM und Arzneimittelwirkstoffe	70
3	__T_____EDS 2003 evidently active without PSM	122
3	__T____§__EDS 2003 potentially active PSM	54
3	__T_____EDS 2003 potentially active without PSM	70
3	__T____§__EDS 2003 uncertain evidence PSM	46
3	__T_____EDS 2003 uncertain evidence without PSM	60
	EDS 2003 (total)	**422**
4	PBT____§__PBT ESIS fulfilling PBT	21
4	PBT____§__PBT ESIS fulfilling PBT & vPvB	2
4	PBT____§__PBT ESIS fulfilling POP	6
4	PB_____PBT ESIS notfulfilling PBT & vPvB	66
4	PBT_____PBT ESIS under evaluation or deferred	34
	PBT ESIS (total)	**129**
5	__T_____ECB H400 ECB C&L H400	113
5	__T_____ECB C&L aquatox	796
5	__T_____ECB C&L aquatox CMR	9
5	__T_____ECB C&L aquatox T	1
5	__T_____ECB C&L H411	468
	ECB (total)	**1387**
7	PBT_____OSPAR	28
7	PBT_E_____OSPAR no production no use	20
	OSPAR (total)	**48**
9	**PBT_____HELCOM HazardousSubstances**	**18**
10	**PBT____§__ConventionPOPs**	**10**
11	_____R____IPCS CICADS	73
11	_____R____IPCS EHS	173
11	_____R____IPCS HSG	109
	IPCS (total)	**355**

12	**____E_____OECD HPV**	**4805**
13	_BT_____UBA wassergefährdende Stoffe nicht WG	784
13	_BT_____UBA wassergefährdende Stoffe WGK1	4199
13	__T_____UBA wassergefährdende Stoffe WGK2	3100
13	__T_____UBA wassergefährdende Stoffe WGK3	1058
	UBA wassergefährdende Stoffe (total)	**9141**
14	__T_____Prio KEMI Allergenic	917
14	__T_____Prio KEMI CMR	1669
14	__T_____Prio KEMI EDC	1
14	__T_____Prio KEMI Environmentally hazardous long term	2556
14	__T_____Prio KEMI High chronic toxicity human	195
14	___C_____Prio KEMI Ozone depleting substances	125
14	__T_____Prio KEMI Particularly hazardous metals	918
14	PBT_____Prio KEMI PBT vPvB	194
14	__T_____Prio KEMI Very high acute toxicity human	696
	Prio KEMI (total)	**7271**
16	__T_____Danish EPA List dangerous substances	96
16	__T_____Danish EPA List endocrine	30
16	__T_____Danish EPA List partial restrictions	28
16	PBT_____Danish EPA List PBT	31
16	___C_____Danish EPA List phased out ozone	8
	Danish EPA List (total)	**193**
20	**PBT____§__PBT Liste**	**15**
21	__T_E_____EDSP US EPA NOT Pesticide	9
21	__T_E__§__EDSP US EPA Pesticide	64
	EDSP US EPA (total)	**73**
23	__T_____EDKB Negative Endocrine Disruptor Knowledge Base FDA	1210
23	__T_____EDKB Positive Endocrine Disruptor Knowledge Base FDA	378
	EDKB Positive Endocrine Disruptor Knowledge Base FDA (total)	**1588**
24	**PBT_____Canada PSL**	**61**
25	PBT___X____NICNAS bioaccumulative	47
25	_____X____NICNAS human health	63
25	PBT___X____NICNAS low concern	14
	_NICNAS (total)	**124**
27	**__T_____ITEM potential endocrin in vivo**	**227**
28	__T_E_____SIN LIST CMR	238
28	__T_E_____SIN LIST equivalent level of concern	47
28	PBT_E_____SIN LIST PBT vPvB	17
	SIN LIST (total)	**302**
29	____E__§__PRTR Pesticides	29
29	____E_____PRTR without Pesticides	62
	PRTR (total)	**91**

31	PBT_____Environ Canada high priority pollutants	10
31	PBT_____Environ Canada other	111
	Environ Canada (total)	**121**
32	**____E_____EPA IUR Top 100 HPV 2006 exposure relevant**	**100**
36	**PBT_E_____EPA TRI PBT**	**18**
37	**____ER____Elbe Monitoringdata**	**331**
38	____E_____Stoffliste Rhein nicht OSPAR	160
38	____E_____Stoffliste Rhein OSPAR	28
	Stoffliste Rhein (total)	**188**
40	**____ER____Japan AIST Risk Assesment for substances of concern**	**27**
41	____E_____INERIS RSDE	119
41	_____X___INERIS SIAR	257
	INERIS (total)	**376**
43	**PB__E_____Arctic Contaminant Brown Wanja 2008**	**120**
44	__T_____RIVM Substances estrogenic	44
44	PB__E_____RIVM Substances exposure	12
44	_B__E_X____RIVM Substances frequently addressed	80
	RIVM Substances (total)	**136**
46	**_B_____Biomagnification Kelly 2007**	**20**
56	**__T_____CASCADE**	**3**
60	**__T_____ENDOMET**	**16**
65	_____R____AT Liste Beilage3	14
65	_____R____AT Liste Beilage4	35
65	_____R____AT Liste Beilage5	42
	AT Liste (total)	**91**
67	____E_____GADSL for Assessment	304
67	____E_____GADSL Legally regulated	1148
	GADSL (total)	**1452**
80	**__T_____California Cancer Reprotox Human**	**700**
81	**PBT_E__§__ECHA**	**19**
82	**_____RX___Rotterdam**	**44**
83	**_____RX___BaselConvention**	**9**
85	**____E_____EPA HPV Hazard Data Availability Table**	**2863**

86	__T_____IARC Group1 Carcinogenic to humans	57
86	__T_____IARC Group2A Probably carcinogenic to humans	53
86	__T_____IARC Group2B Possibly carcinogenic to humans	228
86	__T_____IARC Group3 Not classifiable as to carcinogenicity to human	481
86	__T_____IARC Group4 Probably not carcinogenic to humans	1
	IARC Group (total)	**820**
87	_____X___Michigan kritische Stoffe mit Meldeschwellen_Andere	27
87	__T_____Michigan kritische Stoffe mit Meldeschwellen_CMR	34
	Michigan kritische Stoffe mit Meldeschwellen (total)	**61**
89	**____ER____Cercla 2007 Priority List of Hazardous Substances**	**275**
91	**____E_____Japan METI Priority List**	**665**
92	PBT_____organics not P not B not Toxic	6173
92	PBT_____organics P or B and toxic	3229
92	PBT_____organics P or B not Toxic	1724
92	PBT__R____Polymers Low Concern	1546
92	_____R____Polymers Not Low Concern	1155
92	_____R____Polymers Under Review	1307
92	_____R____salts	434
92	PBT__R____UVCB Biologicals Low Concern	775
92	_____R____UVCB Biologicals Not Low Concern	340
92	_____R____UVCB Biologicals Under Review	733
92	PBT__R____UVCB inorganics Low Concern	91
92	_____R____UVCB inorganics Not Low Concern	47
92	_____R____UVCB inorganics Under Review	190
92	_____R____UVCB Organic Metal Salts	285
92	PBT__R____UVCB Organic metal salts Low Concern	3
92	_____R____UVCB Organic metal salts Not Low Concern	76
92	_____R____UVCB Organic metal salts Under Review	206
92	_____R____UVCB Organics Under Review	1426
92	_____R____UVCB Organometallics Under Review	260
92	_____R____UVCB Polymers Under Review	276
	Substance List (total)	**20276**
93	**____E_____EPER**	**51**
94	**____E_____PER NL**	**301**
95	**PBT__R____Norwegen List of Priority Substances**	**31**
96	**__T__R____NPRI**	**349**
99	__T_____Endokrinliste IME in vitro negative	413
99	__T_____Endokrinliste IME in vitro positive	272
	Endokrinliste IME in vitro (total)	**685**
100	**PBT____§__EU POP**	**25**
104	**_____R____NL WFD**	**23**

106	**_____R____River health**	**78**
110	_____X___NORMAN Network other	184
110	_____§__NORMAN Network Pesticides Pharmaceuticals	202
	NORMAN Network (total)	**386**
111	**PBT____§__Washington State PBT**	**75**
112	__T_____Chile Acute Toxic human	105
112	__T_____Chile Chronic Toxic human	238
	Chile (total)	**343**
113	**P___E_____PPPs polar persistent**	**35**
114	**P___E_____Sucralose**	**1**
115	**_____X___BUA Stoffberichte**	**274**
116	_____X___EDEXIM AnnexIPart1	137
116	_____X___EDEXIM AnnexIPart2	44
116	_____X___EDEXIM AnnexIPart3	41
116	PBT_____EDEXIM AnnexV	10
	EDEXIM (total)	**232**
118	**__T_E_____ARCEM Estrogens Austria**	**14**
119	**PBT_____Greenscreen Flame retartands**	**14**
120	**____E_____NPI**	**87**
121	**PB_C__X___LOCOG Restricted substances and materials**	**50**
122	PB_____Muir and Howard 2006 B-P-LGT substances from DSL Canada	30
122	PB_____Muir and Howard 2006 B-P-substances from DSL Canada	30
	Muir and Howard 2006 (total)	**60**
123	**____E_____PRTR CZ**	**130**
124	**____E_____PRTR FR**	**96**
125	**____E_____PRTR JP**	**329**
126	**____E_____PRTR UK**	**235**
129	__T_ER____Trade Union Priority List CMR	298
129	__T_ER____Trade Union Priority List EDC	62
129	PBT_ER____Trade Union Priority List PBT	54
	Trade Union Priority List (total)	**414**
130	**_____R_§__REACH Beschraenkungen Annex 17**	**88**
131	_____R_§__EDEXIM Ausfuhrnotifikation Chemikalien	96

131	_____R_§__EDEXIM Chemikalien PIC Notifikation	35
131	_____R_§__EDEXIM Chemikalien PIC Verfahren Rotterdam	46
	EDEXIM (total)	**177**
132	**_____R_§__Liste prioritaerer Stoffe im Bereich der Wasserpolitik**	**44**
133	__T____§__REACH VO Anhang 17 Azocolourants	23
133	__T____§__REACH VO Anhang 17 Carcinogenes category 1	191
133	__T____§__REACH VO Anhang 17 Carcinogenes category 2	779
133	__T____§__REACH VO Anhang 17 Mutagens category 2	175
133	__T____§__REACH VO Anhang 17 Toxic to reproduction cat 1	16
133	__T____§__REACH VO Anhang 17 Toxic to reproduction cat 2	59
	REACH VO Anhang 17 (total)	**1243**
134	**_____§__C&L Annex_1**	**3815**

10 ANNEX 4 Documentation of detailed criteria used for identifying chemicals of concern.

Tab. Annex 4-1: Documentation of detailed criteria used for identifying chemicals of concern.
The selected information sources from literature, environmental monitoring, (non)european regulations and records of priority chemicals feature a wide variety of reasons that triggered the inclusion of substances into any inventory. The criteria used for the identification of the respective substances of concern can be grouped into principal categories of environmental relevance:
Fate-related: **PB**T (Persistent, Bioaccumulative), POP (Persistent Organic Pollutants), LRT (Long-Range Transport), biomagnification;
Effect-related: PB**T** (Toxic), EDC (Endocrine Disrupting Chemicals), CMR (Carcinogens, Mutagens, Reproductive toxicants), neurotoxicity, sensitisation. C&L (Classification and Labelling);
Climate-change related: ozone depletion, global warming;
Exposure-related: monitoring, HPVC (High Production Volume Chemicals), product registries;
Risk-related: PEC/PNEC (Predicted Environmental Concentration, Predicted No-Effect Concentration), SPEAR Index (SPEcies At Risk), river health, EQS (Environmental Quality Standards according WFD (Water Framework Directive));
Political criteria: 'concern', expert judgement.
Regulation other than REACH: e.g. POPs of the Stockholm Convention as listed in Regulation 850/2004, Biocides Directive 98/8/EC, Water Framework Directive 2000/60/EC
The systematic prefix consists of an eight-character code (P (persistence), B (bioaccumulation), T (toxicity), C (climate change), E (exposure), R (risk), X (political criteria), § (regulation), _ (not considered)) that indicates whether or not a criteria category was used to set up the respective list (for details see Section 3.1).

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
PBTC____	PRIO- Hazardous Substances prioritised for risk reduction measures, Sweden	14	PBT CMR EDC Ozone depletion	Half-life > 60 d in seawater or > 40 d in freshwater or > 180 d in marine sediment or > 120 d freshwater sediment or >120 d in soil (vPvB: Half-life > 60 d in seawater or freshwater or > 180 d in marine or freshwater sediment >180 d in soil)	BCF > 2000 (vPvB: BCF > 5000)	Environmentally hazardous and long term effects: The criteria for these substances are the same as the classification criteria for substances that are classified N;R50-53 or R53 according to the Swedish Chemicals Agency Code of Statutes KIFS 2005:7. In the PRIO database at present only includes those substances classified N;R50-53 or R53 in Annex I of the Council directive 67/548/EEC. This list is equivalent ECB Classification and Labelling (005). From List 005 very toxic substances are extracted (formerly R50/53). See List 005_ECB_H400_H410 High	The criteria for the respective property that are used in assessing whether a substance is a phase-out or priority risk-reduction substance follow below. Phase-out substances: * CMR (Carcinogenic, Mutagenic or toxic to Reproduction), Category 1 and 2 (= R45 May cause cancer R49 May cause cancer by inhalation; R46 May cause heritable genetic damage; R60 May impair fertility R61 May cause harm to the unborn child; Endocrine disrupter; Particularly hazardous metals (Cd, Hg, Pb)); * PBT/vPvB (Persistent, bioaccumulating and toxic/very persistent and very bioaccumulating) = ; * Particularly hazardous metals

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
						chronic toxicity (Human health): Substances that following repeated or prolonged exposure by inhalation, swallowing or uptake through the skin of small quantities can cause transient or permanent damage or lead to death. R48/23, R48/24, R48/25. Endocrine disruptor: there are no generally accepted criteria as yet for endocrine-disruptive substances. An assessment is made on a case-by-case basis. Guidance is provided for instance in the Chemicals Inquiry report (SOU 2000:53) Non-Hazardous Products, Annex 5. Work is in progress internationally, for instance within the OECD (EDTA. Endocrine Disrupters Testing and Assessment Task Force) to develop standardised test methods so that substances with endocrine-disruptive properties may be identified. Very high acute toxicity (human health): Substances that following single, short exposure by inhalation, swallowing or uptake through the skin of very small quantities can cause temporary or permanent harm. R26, R27, R28, R39/26, R39/27, R39/28. CMR: The criteria are the same as the classification criteria in accordance with KIFS 2005:7 for the stated properties. Carcinogenic (C): Substances that by inhalation, swallowing or skin contact may cause cancer or increase its incidence. Substances in Category 1 are carcinogenic in humans. Substances in Category 2 are to be regarded as though they are so. R45, R49 Mutagenic (M): Substances that by inhalation,	(mercury, cadmium, lead and their compounds); * Endocrine disruptive; * Ozone-depleting. Priority risk-reduction substances: * Very high acute toxicity (health); * Allergenic; * Mutagenic Category 3; * High chronic toxicity (health); * Environmentally hazardous, long-term effects; * Potential PBT/vPvB.

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
						swallowing or uptake through the skin can cause heritable genetic defects or increase their incidence. Substances in Category 1 are mutagenic in humans. Substances in Category 2 are to be regarded as though they are so. R46. Toxic to Reproduction (R): Substances that by inhalation, swallowing or uptake through the skin can cause, or increase the incidence of, non-heritable damage to the offspring or impaired male or female fertility. Substances in Category 1 impair fertility in humans and/or cause toxic effects to the embryo/foetus or offspring in humans. Substances in Category 2 are to be regarded as though they do so. R60, R61 CMR classified substances according to risk phrases (now H) are also included in List 005, if also very high aquatic toxic. Please refer to 005_ECB_H400_H410_CMR Particularly hazardous metals (Hg, Cd, Pb and their compounds): Mercury, cadmium, lead and compounds containing these metals are all phase-out substances. There are no special criteria as the presence of the metals is sufficient, and the PRIO tool recommends the user as far as possible to replace these substances with less hazardous substances or make use of alternative methods.	
PBTC____	List of Undesirable Substances (LOUS), Denmark	16	PBT	A substance fulfils the persistence criterion (P-) when: * the half-life in marine water is higher than 60 days, or * the half-life in fresh- or estuary water is higher than 40 days, or * the half-life in a marine sediment is higher than 180 days, or * the half-life in	A substance fulfils the bioaccumulation criterion (B-) when: * the bioconcentration factor (BCF) is higher than 2000 The assessment of bioaccumulation must be based on measured data on bioconcentration in aquatic	A substance fulfils the toxicity criterion (T-) when: * the long term no-observed effect concentration (NOEC) - for marine or fresh water organisms is less than 0.01 mg/L, or * the substance is classified as carcinogenic (category 1 or 2), mutagenic	The List of Dangerous Substances contains a list of the substances that in the EU, have been evaluated and classified as to their physiochemical properties, the danger they pose to human health and their environmental effects. For each substance on the list, which includes

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
				a fresh- or estuary water sediment is higher than 120 days, or * the half-life in soil is higher than 120 days. The assessment of the persistency in the environment must be based on available half-life data collected under adequate conditions, which must be described by the registrant. A substance fulfils the "very persistent" criterion (vP-) when: * the half-life in marine, fresh- or estuary water is higher than 60 days, or * the half-life in marine, fresh- or estuary water sediment is higher than 180 days, or * the half-life in soil is higher than 180 days.	species. Data from fresh water as well as marine water species can be used. A substance fulfils the "very bioaccumulative" criterion (vB-) when: * the bioconcentration factor is greater than 5000	(category 1 or 2) or toxic to reproduction (category 1, 2 or 3), or * there is any other evidence on chronic toxicity as identified by the classifications: T, R48 or Xn, R48 under Directive 67/548/EEC.	approx. 7000 substances/substance groups, the danger classification is stated, including risk phrases that briefly identify the inherent dangerous properties of the substances. On the basis of the List of Dangerous Substances, the Danish EPA has chosen to concentrate on the substances that could cause very serious and long-term damage. In other words, substances which may cause chronic damage to human health or which may impact future generations. Precisely these substances are among those that the EU has indicated as particularly problematic in the new regulatory framework for chemicals and which will be subject to an authorisation system. More specifically, this means that substances classified for the so-called CMR effects in categories 1 and 2 (carcinogens, mutagens, reproduction toxins) are subject to authorisation for specific application before they can be used. Therefore, the substances are candidates for the LOUS. Moreover, the Danish EPA has decided that substances under suspicion for having the same effects (CMR-category-3 substances); substances posing a risk of serious damage to human health by prolonged exposure; and substances that are extremely toxic to aquatic organisms and that may, at the same time, cause undesirable long-term effects in the aquatic environment are so problematic that they are also candidates for the LOUS.
PBT_ER__	Trade Union Priority List for REACH Authorisation	129	PBT CMR EDC Neurotoxicity Sensitizer	= OSPAR (no 7): Half-life (T1/2) of 50 days	= OSPAR (no 7): log Kow >=4 or BCF>=500	For ecotox = OSPAR (no 7): Taq: acute L(E)C50=	occupational exposure wide dispersive use HPVC

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
			Occupational hazards HPV Wide dispersive use				
PBT_E_X_	Selection of substances, deserving policy attention, not subject of other risk assesment programmes, Netherlands	44	Monitoring Bioaccumulation Biodegradation		Compounds that are measured in biota are bioaccumulative, are not readily biotransformated and steric hindrance does not obstruct the uptake. Substances that are detected in so-called biomimetric extracts are probably bioaccumulative. Compounds that are measured in effluents possibly will also be encountered in surface waters. So, the weight of the argument declines from substances in biota to substances detected in effluents. The other compounds are selected based on recent interest by scientists. None of the compounds is subject of assessment. Both lists of chemicals can be concerned as compounds that may deserve more policy attention.		
PBT_E__§	ECHA Candidate List of Substances of Very High Concern for Authorisation	81	PBT CMR Wide dispersive use HPV	P-Criteria (REACH article 57, Annex XIII): Half-life in marine water > 60 days, or Half-life in fresh- or estuarine water > 40 days, or Half-life in marine sediment > 180 days, or Half-life in fresh- or estuarine water sediment > 120 days, or Half-life in soil is > 120 days. vP-Criteria Half-life in marine, fresh- or estuarine water > 60 days, or Half-life in marine, fresh- or estuarine water sediment > 180 days, or Half-life in soil > 180.	B-Criteria (REACH article 57, Annex XIII): Bioconcentration factor (BCF) > 2 000 vB-Criterion: Bioconcentration factor (BCF) > 5 000	T-Criteria (REACH article 57, Annex XIII): Long-term no-observed effect concentration (Noec) for marine or freshwater organisms < 0,01 mg/l, or Classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or Evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC Endocrine disrupting properties Equivalent level of concern	According to Article 58(3) priority for inclusion in Annex XIV shall normally be given to substances with a) PBT or vPvB properties; or b) wide dispersive use; or c) high volumes.
PBT_E___	OSPAR List of Chemicals for Priority Action (Update 2007)	7	PBT	Half-life (T1/2) of 50 days	log Kow >=4 or BCF>=500	Taq: acute L(E)C50=	
PBT_E___	SIN List 1.0	28	CMR PBT HPV	- P: EU PBT working group	- B: EU PBT working group	- CMR (Annex 1 of dircetive 67/548/EEC) - T: EU PBT working group - EDC (BKH-list)	= presence in consumer preparations = HPV = high Profile ((human) bio-monitoring)

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
			EDC				
PBT_E___	Toxic Release Inventory - Database	36	PBT Release				Release, PBT
PBT__R__	Canada Domestic Substance List	92	Concern	Air : Half-life >= 2 days Water: Half-life >= 182 days Sediment: Half-life >= 1 year Soil: Half-life >= 182 days Substances that have the potential to be transported to remote areas of the globe are considered persistent, and the relevant evidence for long-range transport (LRT) will be taken into consideration in determining the persistence of substances.Persistent substances are included in the lists "092_organics_P_or_ B_toxic" or in the list "092_organics_P_or_B-not_toxic" Not persistent substances are listed in "092_organics_not_P_not_B_not_T"	BAF >= 5,000 or BCF >= 5,000 or Log Kow >= 5 Bioaccumulative substances are included in the lists "092_organics_P_or_ B_toxic" or in the list "092_organics_P_or_B-not_toxic" Not bioaccumulative substances are listed in "092_organics_not_P_not_B_not_ T"	Inherent toxicity refers to the hazard a substance presents to an organism. It is demonstrated by the concentration of a substance that produces a toxic effect in an organism, tested under laboratory conditions or in other studies. Acute: LC50(EC50) <= 1 mg/L Chronic: NOEC <= 0.1 mg/LToxic substances are included in the lists "092_organics_P_or_ B_toxic" (including uncertain toxicity) Non toxic substances are listed in "092_organics_not_P_not_B_not_ T"	For inorganics and organics there is the column "Categorized in" with (y=1, n=0, IS=Insufficient Data). The catogorisation based on outcome of the Toxicity , Persistence & Biooaccumulative columns. If substance is T and P or B it is categorized "in", otherwise it is categorized "out". "Level of concern" for polymers and UVCB: (Unknown or Variable composition Complex reaction products or Biological materials) "low concern", "not low concern" and "under review"
PBT__R__	Priority Substances, Norway	95	PBT	low biodegradability	bioaccumulation	serious long-term impact on health, or are highly toxic for the environment.	A set of criteria has been developed On the basis of a more recent white paper (Report No. 25 (2002-2003) on the Government's environmental policy and the state of the environment in Norway), a set of criteria was drawn up defining the types of substances that are to be given priority in addition to the substances named in the list. These include substances that exhibit low biodegradability that bioaccumulate and that have a serious long-term impact on health, or are highly toxic for the environment. Emissions of such substances are also to be substantially reduced by 2010.
PBT___X_	NICNAS Chemical Assessment Reports	25	Concern				health and/or environmental concerns
PBT___X_	EC/304/2003 CONCERNING THE EXPORT AND IMPORT OF DANGEROUS CHEMICALS	116	Hazard				List of hazardous chemicals and pesticides which are important in international trade, dangerous to

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
							human health and/or the environment. Annex I Part 1: List of chemicals subject to export notification procedure Annex I Part 2: List of chemicals qualifiying for PIC notification Annex I Part 3: List of chemicals subject to the PIC procedure under the Rotterdam Convention Annex V: Chemicals and articles subject to export ban = Persistent organic pollutants as listed in Annexes A and B of the Stockholm Convention and Cosmetic soaps containing mercury (CN# 3401 11 00 , 3401 19 00 , 3401 20 10 , 3401 20 90 , 3401 30 00)
PBT____§	ESIS: European chemical Substances Information System / PBT Liste	4	PBT	The criteria for identification of PBT/vPvB substances are set in the Technical Guidance Document. The numeric criteria are: P: half-life > 60 d in marine water or half-life > 40 d in freshwater or half-life > 180 d in marine sediment or half-life > 120 d in freshwater sediment vP:half-life > 60 d in marine- or freshwater or half-life > 180 in marine or freshwater sediment	The criteria for identification of PBT/vPvB substances are set in the Technical Guidance Document. The numeric criteria are: B: BCF > 2,000 vB: BCF > 5,000	The criteria for identification of PBT/vPvB substances are set in the Technical Guidance Document. The numeric criteria are: T: chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects	Many types of data can be taken into account when identifying substances of concern. There is also room for flexibility in the interpretation of the data and the criteria can be applied in a combined way. For instance in cases where one criterion is marginally not fulfilled but the others are exceeded considerably. For example, a substance, which clearly fulfils the B and the T -criteria but just fails fulfilling the P -criterion, may be considered to fulfil the combined set of criteria. In addition, measured data can be used in certain cases e.g., as evidence of persistence. High potential for long-range transport has also been taken into account when considering whether a substance meets the combined set of criteria. Technical Guidance Document also defines screening criteria for identifying potential PBT/vPvB substances as for most chemicals sufficient test data for a complete PBT/vPvB assessment are not available.
PBT____§	Stockholm Convention on Persistent Organic Pollutants (POPs)	10	PBT POP LRT	Half-life(water)>2month or half-Life(soil or sediment)>6month LTR: qualitative consideration, no numeric criterion	BCF>5000 or logKow>5	evidence/potential to damage human health or the environment	

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PBT____§	PBT Profiler	20	PBT	Half-life in water, soil, and sediment > 2 months (> 60 days) = P; > 6 months (> 180 days) = vP Half-life in Air > 2 days	Bioconcentration factor (BCF) > 1000 (B); > 5000 (vB)	Fish Chronic Value (mg/l) > 10 mg/l (Low Concern); 0.1 - 10 mg/l (Moderate Concern); < 0.1 mg/l (High Concern)	
PBT____§	Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants	100	PBT POP LRT	Half-life(water)>2month or half-Life(soil or sediment)>6month LTR: qualitative consideration, no numeric criterion	BCF>5000 or logKow>5	evidence/potential to damage human health or the environment	PBT and LRT
PBT____§	Persistent Bioaccumulating Toxins, State of Washington	111	PBT	The chemical or chemical group can persist in the environment based on credible scientific information that: (i) The half-life of the chemical in water is greater than or equal to 60 days; or (ii) The half-life of the chemical in soil is greater than or equal to 60 days; or (iii) The half-life of the chemical in sediments is greater than or equal to 60 days;	The chemical or chemical group has a high potential to bioaccumulate based on credible scientific information that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1000 or, in the absence of such data that the log-octanol water partition coefficient (log Kow) is greater than 5.	The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on credible scientific information that: (i) The chemical (or chemical group) is a carcinogen, a developmental or reproductive toxicant or a neurotoxicant; (ii) The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day; or (iii) The chemical (or chemical group) has a chronic no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L.	Additional criteria applicable to metals. The chemical or chemical group is a metal and ecology determines that it is likely to be present in forms that are bioavailable. Degradation products. Dept. Ecology will consider both the parent chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (PBT) of this section. If a parent chemical does not meet the PBT criteria in this section but degrades into chemicals that do meet the criteria in subsection (PBT) of this section, the parent chemical may be considered for inclusion on the PBT list and in the development of a CAP (Chemical Actino Plan). Alternately, Dept. Ecology may decide not to include the parent chemical on the PBT list, but consider it during the development of a CAP for derivative chemicals.
PBT_____	List of Potential Substances of Concern to be Considered by HELCOM	9	PBT POP EDC	A substance is defined to be persistent if its conversion or the conversion of its degradation products is slow enough to permit long-term occurrence and widespread distribution in the marine environment.	Bioaccumulation is defined as the enrichment of a substance in an organism and includes bioconcentration from environmental concentrations and additional uptake via the food chain; bioaccumulation includes all routes, i.e. via the air, water, soil and food.	Toxicity is defined as the capacity of a substance to cause toxic effects to organisms or their progeny such as: - reduction in survival, growth and reproduction; - carcinogenicity, mutagenicity or teratogenicity; - adverse effects as result of endocrine disruption. Depending on the exposure time and life cycle of the target organism, toxicity can be classified as: - acute toxicity: lethal and/or sublethal toxicity	The criteria used in these selection and prioritisation mechanisms may include that the substances or groups of substances: a) are a general threat to the aquatic environment due to their hazardous properties; b) show indications of risks for the marine environment or may endanger human health via consumption of food directly or indirectly from the marine environment; c) have been found in one or more compartments of the

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
						resulting from intermittent or continuous exposure to a substance or mixture of substances for a period substantially shorter than the life cycle of the organism in question (e.g. 96 h LC50 for a fish with a life cycle measured in months or years); - subchronic toxicity: sublethal (and possibly also lethal) toxicity resulting from intermittent or continuous exposure to a substance or mixture of substances for a period which is a substantial proportion of the life cycle of the organism in question (e.g. 21 day reproductive NOEC for a crustacean with a life cycle measured in weeks or months); - chronic toxicity: sublethal toxicity resulting from intermittent or continuous exposure to a substance or mixture of substances for a period not less than the life cycle of the organism in question (e.g. lifecycle reproductive NOEC for a fish which includes measurements of the F1 generation).	Convention Area; d) reach, or are likely to reach, the marine environment, for instance from a diversity of sources through various pathways.
PBT_____	Priority Substances Assessment Programm (Environment Canada)	24	PBT	A substance is persistent when it has at least one of the following characteristics: (a) in air: (i) its half-life is equal to or greater than 2 days, or (ii) it is subject to atmospheric transport from its source to a remote area; (b) in water, its half-life is equal to or greater than 182 days; (c) in sediments, its half-life is equal to or greater than 365 days; or (d) in soil, its half-life is equal to or greater than 182 days.	A substance is bioaccumulative (a) when its bioaccumulation factor is equal to or greater than 5 000; (b) if its bioaccumulation factor cannot be determined in accordance with a method referred to in section 5, when its bioconcentration factor is equal to or greater than 5 000; and (c) if neither its bioaccumulation factor nor its bioconcentration factor can be determined in accordance with a method referred to in section 5, when the logarithm of its octanol-water partition coefficient is equal to or greater than 5.	The categorization for inherent toxicity is based on numerical criteria. This cut-off is used in various European Union (EU) and U.S. Environmental Protection Agency (EPA) initiatives. When reliable results on chronic studies are available, the chronic toxicity values will be applied. Criteria for acute and chronic toxicity to aquatic species (algae, invertebrates, fish) Exposure duration Criteria Acute LC50 (EC50) =1 mg/L Chronic NOEC*	
PBT_____	Existing Substances Programme at Environment Canada	31	PBT	Half-life: Air: >= 2 days; Water: >= 182 days; Sediment: >= 1	BAF >= 5,000 or BCF >= 5,000 or Log KOW >= 5	Acute: LC50(EC50) <= 1 mg/L Chronic: NOEC <= 0.1 mg/L	Criteria are described at http://www.ec.gc.ca/substances/ese/

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				year; Soil >= 182 days			eng/dsl/cat_criteria_process.cfm
PBT_____	Green Screen - Flame Retardants for TV Enclosures	119	PBT Phys.-chem. Properties	(half-life in days) Very high (v): Soil or sediment >180 days; or Water >60 days High (H): Soil or sediment >60 to 180 days; Water >40 to 60 days; or Potential for long-range environmental transport Moderate (M): Soil or sediment 30 to 60 days; or Water 7 to 40 days, Low: Soil or sediment	Very High (V): BCF/BAF >5000; or absent such data, log Kow >5 High (H): BCF/BAF >1000 to 5000; Absent such data, log Kow >4.5-5; or • Weight of evidence demonstrates bioaccumulation in humans or wildlife Moderate (M): BCF/BAF 500 to 1000; Absent such data, log Kow 4-4.5; or Suggestive evidence of bioaccumulation in humans or wildlife Low (Low): BCF/BAF < 4	Ecotoxicity: Acute Aquatic Toxicity High (H): LC50/EC50/IC50 100 mg/L Chronic Aquatic Toxicity: High (H): NOEC 10 mg/L Human Health (3 levels for all criteria: H= 0 high; M = moderate; L = low) Carcinogenicity Mutagenicity/ Genotoxicity Reproductive toxicity Developmental toxicity Endocrine Disruption Neurotoxicity* Acute Toxicity (oral, dermal, or inhalation) Corrosion/Irritation of the Skin or Eye Sensitization of the Skin or Respiratory System Immune System Effects Systemic Toxicity/Organ Effects Via single or repeated exposure)	Physical/Chemical Properties: Explosive, Flammable
PBT____	TGD: Technical Guidance Document	6	PBT	Half-life > 60 d (marine water) or > 40 d (freshwater) or > 180 d (marine sediment) or > 120 d (freshwater sediment) (P) Half-life > 60 d (marine water or freshwater) or > 180 d (marine or freshwater sediment) (vP)	BCF > 2000 (B); > 5000 (vB)	Chronic NOEC < 0.01 mg/l or CMR or EDC	
PBT____	Screening criteria for P, vP, B, vB and T	127	PBT	Ready biodegradability test: readily biodegradable -> Not P and not vP Enhanced ready biodegradability test: readily biodegradable -> Not P and not vP Specified tests on inherent biodegradability: Zahn-Wellens (OECD 302) ≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum -> Not P MITI II test (OECD 302C) ≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum -> Not P QSAR: Biowin 2 (non-linear model prediction) or 6 (MITI non-linear model prediction) and Biowin 3 (ultimate	Convincing evidence that a substance can biomagnify in the food chain (e.g. field data) e.g. BMF > 1 -> B or vB, definitive assignment possible Octanol-water partitioning coefficient (experimentally determined or estimated by valid QSAR) Log Kow ≤ 4.5 -> Not B and not vB	Short-term aquatic toxicity (algae, daphnia, fish): EC50 or LC50 < 0.01 mg/L -> T, criterion considered to be definitely fulfilled Short-term aquatic toxicity (algae, daphnia, fish): EC50 or LC50 < 0.1 mg/L -> T Avian toxicity (subchronic or chronic toxicity or toxic for reproduction): NOEC < 30 mg/kg food -> T	

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				biodegradation time): Does not biodegrade fast (probability < 0.5) and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2) -> P			
PBT____	Persistence, Bioaccumulation Potential, and Inherent Toxicity to Non-human Organisms	128	PBT	Air =2 days Water =6 months Sediment =1 year Soil =6 months	BAF > 5000 or BCF > 5000 or log Kow > 5	Acute LC50 (EC50) =1 mg/L Chronic NOEC	
PB_C__X_	Restricted substances and materials for the Olympic Games in London 2012	121	EDC PBT Neurotoxicity Ozone depletion Global warming Sensitizer CMR				Restricted substances and materials Upon request, suppliers and licensees will need to confirm to LOCOG the extent to which they are Registration, Evaluation, Authorisation and restriction of CHemicals (REACH) compliant. Except where permitted under the section below, suppliers and licensees will seek to avoid supplying products, services or packaging as set out in the linked list of restricted substances. Heavy metals and brominated fire retardants Suppliers and licensees will, as far as is possible, minimise the concentrations of heavy metals and brominated fire retardants in products and packaging being supplied. See linked list of restricted substances for more information. The level of certain heavy metals and brominated fire retardants in electrical and electronic equipment is controlled by the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2006 (as amended). The level of certain heavy metals in packaging is controlled by the Packaging (Essential Requirements) Regulations 2003 (as amended). The total content of each of the following heavy metals in packaging or in any packaging components must not exceed 100 ppm: Cadmium; Hexavalent Chromium; Lead; Mercury. Suppliers and licensees will

Prefix	Content	No	Criteria	P-Criteria	B-Criteria	T-Criteria	Other Criteria
							keep details on the substances and materials associated with products and services supplied. Where required, they will also make available material safety data sheets and risk assessments.
PB__E___	Persistent Organic Pollutants and Potential Arctic Contaminants	43	Biomagnification LRT HPV	Persistent: Potential for long-range transport: Indicates if the chemical has an OH t1/2 (hydroxyl radical atmospheric half-life) greater than 2 days Profile: Indicates if the chemical matches the structural profile of known arctic contaminants. Pesticide: Indicates if the chemical appears on one of the three pesticides lists: Canadian Domestic Substances List, U.S. EPA list of registered pesticides, Word Health Organisation's list of current use pesticides.	AC-BAP (arctic contamination and bioaccumulating potential): Indicates if the chemical falls within the area of elevated Arctic Contamination and Bioaccumulation Potential logKOW ≥ 3.5 logKOA ≥ 6 logKAW ≤ 0.5 or ≥ -7; ≤ -1.78xlogKOA+14.56		HPV: All substance have a high production volume based on one of five different lists: The Canadian Domestic Substances List (≥ 1000 t metric), U.S EPA's HPBV Challenge Progam (≥ 454 t (1 mollion pounds), European Chemical Bureau's ESIS - European chemical Substances Information System HPV List (≥ 1000 t), OECD list of HPV chemicals (≥ 1000 t), U.S. Toxic Substances Control Act (TSCA) (≥ 454 t (1 mollion pounds).
PB_____	Bioaccumulative and persistent substances with long-range atmospheric transport potential	122	PBT LRT	low rate of biodegradation long-range atmospheric transport potential based on predicted atmospheric half-lives > 2 days and log-air-water partition coefficients >=5 and <=1.	high predicted bioconcentration		
P___E___	Survey of polar organic persistent pollutants in European river waters	113	Monitoring				prevalence in the environment
P___E___	Sucralose screening in European surface waters	114	Monitoring				prevalence in the environment
P_____	Overall persistence criteria	101	PBT LRT	Half-life (overall environment) > 90d Half-life (air(AOP)) > 2 d Screening: not ready biodegradable (test!)			
_BT_____	Liste of substances hazardous to waters	13	WGK				WGK1, WGK2, WGK3, no WGK
_B_____	Food Web-Specific Biomagnification of Persistent Organic Pollutants	46	Biomagnification		Biomagnification in air breathing organisms: log KOW (octanol/water) > 2 causing slow elimination in urine or nitrogenous wastes, and log KOA (octanol/air) ≥ 6 causes slow respiratory elimination In the marine		

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					mammalian food web (includes water-respiring invertebrates and fish and air-breathing birds and mammals), poorly metabolizing chemicals with a KOW ≥ 105 and KOA ≥ 106 biomagnify. Less hydrophobic chemicals with KOW < 105 and KOA ≥ 106 also biomagnify strongly. Chemicals with KOW < 102 do not biomagnify in this food web regardless of their high KOA because airbreathing animals eliminate them through urinary excretion. In terrestrial food webs: Chemicals with a KOW between 102 and 1010 and a KOA ≥106 can biomagnify up to 400-fold if not metabolized Chemicals with a KOW between ~103 and 109 achieve a similar degree of biomagnification, given the same KOA.		
_B_____	Potential Arctic Contaminants	42	Biomagnification		Biomagnification		
_B_____	EURAS bioconcentration factor (BCF) Gold Standard Database	105	BCF		BCF > ?		
__T_E__§	Endocrine Disrupting Screening Program (EDSP)	21	Monitoring				Occurrence: Data for four exposure pathways for pesticide active ingredients and for High Production Volume (HPV) chemicals Selection of pesticides for the draft list: Appeared in four exposure pathways, and appeared in three exposure pathways where the food and occupational exposure pathways were represented. Selection of HPV for the draft list: Appeared in four exposure pathways, and appeared in three exposure pathways where the human biological monitoring exposure pathway was represented.
__T_E___	Hormonal active substances in Austrian waters (Results of 3-year research)	118	EDC Monitoring			PEC/PNEC assessment Effect: Vitellogenin induction and reproductive effects in fish from laboratory studies. It is concluded that, for most Autrian rivers,	Monitoring and bioindication in fish from three rivers: Exposure of estrogenic substances in two rivers (Leitha, Wienfluß) are below bioindicator thresholds, but above

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						negative effects on fish by 17α-ethinylestradiol and nonylphenol cannot be excluded and their emissions should be reduced.	bioindicator thresholds in river Schwechat. Based on these results, effects on fish are likely, though changes in sex ratio were not observed.
__T_E__	Environmental Residue-Effects Database (ERED)	22	Monitoring				Residue-effects information: biological effects (e.g., reduced survival, growth, etc.) and tissue contaminant concentrations were simultaneously measured in the same organism.
__T__R_§	Water Framework Directive	132	Risk			PEC/PNEC	Risk to aquatic life Regulation
__T__R__	Observation List, Norway	96	C&L				particularly dangerous among classified substances of list no. 97 (No. 97 = not included)
__T___X_	Register of Critical Materials	87	???				Criteria for critical materials not given/ not transparent
__T____§	Priority list of substances for further evaluation of their endocrine disrupting effects (2004-2006)	3	EDC			Evidence or potential evidence of ED effects. Category_HH = Human health Category_WL= Wildlife Category_Comb = Overall classification of HH and WL, highest Category 27 substances with evidence or potential evidence of ED effects which are neither restricted nor currently being addressed under existing Community legislation Category 1: E (evidently active) Category 2: P (potentialy active) Category 3A and 3B: U (uncertain evidence) Category 3C: N (non active)	Monitoring levels of suspect chemicals in food and the environment. Identification of vulnerable groups of people (such as children) who need to be given special consideration.
__T____§	Annex XVII REACH Regulation; Appendix 1-10	133				Hazard	Regulation
__T_____	Annex VI to CLP (2009): Database for substances labelled regarding hazard to health and environment in the EU	5	C&L (R50/53 = H400; H410))	not readily biodegradable in the aquatic environment: formerly R53: Aquatic Chronic Category 1 according to CLP	BCF >= 500 and/or log Kow >=4 (according to CLP)	Classification and labelling (C&L) involves an evaluation of the intrinsic hazard of a substance or mixture/preparation and a communication of that hazard via the label. For health and environment. Here: GSH09 substances extracted. An aquatic long-term NOEC of > 1 mg/L is used as an exclusion criterium for	

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						Aquatic Chronic Categories 2-4.	
__T_____	EDKB Endocrine Disruptor Knowledge Base	23	EDC			EDC - potential for endocrine disruption Endocrine disruptors are chemicals that interfere with the endocrine systems, leading to adverse effects. Some chemicals do this by binding to receptors, such as the estrogen and androgen receptors. Currently, most in vitro and in vivo data are derived from assays that measure estrogenic activity, and fewer data are for assays that measure androgen activity. In the database results of tests on - AR-, ER-Receptorbinding studies (230/616), as LOGRBA (relative binding activity), - ER-Reportergenasseays (544), as LOGRP (relative receptor potency) - E-Screen (141) and proliferation-tests (19), as LOGRPP (relative proliferative potency) - as well as 1707 in-vivo uterotrophic assay, as LOGRP (relative receptor potency) are presented (in percent of positive standard like 17b-Estradiol for ER binding).	
__T_____	Reproductive Toxicants with Potential ED-Activity	27	Reproductive toxicity EDC			Reproductive Toxicity with Potential ED-Activity	
__T_____	EU-Project - CASCADE-Risk Assessment Information on Bisphenol A, Vinclozoline and Dioxins	56	EDC			risk for humans from exposure to endocrine active compounds in food and drinking water	
__T_____	EU-Project - ENDOMET	60	EDC			Endocrine effects, see table with data and following summaries from summary report (http://ec.europa.eu/research/quality-of-life/ka4/pdf/report_endomet_en.pdf): Effects of plasticisers on the reproductive system Porcine ovarian granulosa cells were used as a test system to show effects	

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						of plasticisers on steroid hormone production. Treatment with bisphenol-A and other phenols induced stimulation of basal progesterone production while the alkylphenols were generally inhibitory; FSHstimulated progesterone production was inhibited. Basal oestradiol synthesis was inhibited by 2-phenylphenol and most of the plasticisers inhibited the FSH-stimulated oestradiol production. Using porcine oocytes as a test system gave a complex picture but most of the plasticisers affected the number of completely mature oocytes formed, robably by affecting steroid synthesis. In vivo studies with rats confirmed that bisphenol-A and bis-ethylhexylphthalate had ED activity.	
__T_____	Chemicals known to the State California to cause cancer or reproductive toxicity	80	CMR			cancer and reproductive toxicity	
__T_____	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans	86	CMR			Group 1: The agent is carcinogenic to humans. Group 2A: The agent is probably carcinogenic to humans. Group 2B: The agent is possibly carcinogenic to humans. Group 3: The agent is not classifiable as to its carcinogenicity to humans. Group 4: The agent is probably not carcinogenic to humans.	
__T_____	Substances with (anti)estrogenic/(anti)androgenic activity in-vitro	99	EDC			(anti)estrogenic/(anti)androgenic activity in-vitro (receptor binding and receptor activiation)	
__T_____	Substances with acute and chronic effects, Chile	112	Human health			Acute toxic: LD50 rat oral less or equal to 50 mg/kg bw LD50 inhalative less or equal to 2 mg/litre LD50 dermal less or equal to 200 mg/litre Chronic toxic: accumulative, mutagenic, carcinogenic, teratogenic.	

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						Concentration of the residue if cancerogenic is > CTAL/1000, CTAL is value for acute toxicity Concentration of the residue if accumulative is > CTAL/100, CTA is he acute toxicity of the chronic toxic substance	
__T____	Annex I of Directive 67/548/EEC	15	C&L				C&L
__T____	EnviChem, Finish Environmental Institute	17	ecotox			ecotoxicology	
__T____	KemI-Riskline database, Sweden	18	Environmental and health effects				health and environmental properties
__T____	EU-Project - DEVNERTOX	57	Neurotoxicity			toxic threats to the developing nervous system	
__T____	EU-Project - EASYRING	58	EDC			EASYRING will improve information regarding the environmental levels of pollutants, their biological effects as measured with innovative tools to aquatic species and for mammalian risk assessment. It aims to develop and validate novel non-invasive methods for the detection of known and new biomarkers of endocrine disrupters. (Ends) directly in the mucus of aquatic species. Short/long term and low dose exposures to endocrine disrupting chemicals will be investigated both in aquatic species and mammals. In parallel, integrated testing in vitro protocols will permit a wider understanding and evaluation of effects and new instrumental analytical techniques will be developed and validated for easier and more complete detection of chemicals in water and biota. Quantitative structure-activity relationships (Tsars) for the prediction of chemicals able to elicit endocrine disruption and quantitative activity-activity relationships (Quarts) to extrapolate the response of	(E2), estriol (E3), nonylphenols mix (NPs), bisphenol A (BPA), and t-octylphenol (t OP). ®In-vitro tests consistently identified a small number of fractions as being mainly responsible for estrogenicity. Chemical analyses undertaken on these fractions identifying a small number of known estrogenic chemicals i.e. estrone (E1), estradiol-17

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						different experimental models will be compared with test data developed in this project. The final aim will be to extend mathematical models to human toxicity.	
__T____	EU-Project - EDERA	59	EDC			No substance list, research project with focus on methodology: ER transcriptional activity in vitro and in vivo	
__T____	Toxicology and Carcinogenesis Study Reports	88	Mammalian toxicity Carcinogen			human toxicology and carcinogenesis	
__T____	Dangerous Substances, Norway	97	C&L				see: Annex I of Directive 67/548/EEC
__T____	ECB Endocrin List	98	EDC			Category 1: E (evidently active) - 43 substances Category 2: P (potentialy active) - 43 substances Category 3A and 3B: U (uncertain evidence) - 17 substances Category 3C: N (non active) - 3 substances	
__T____	India - Hazardous chemical rules	102	Accident hazards				accident hazards
__T____	DSSTox	107	---				
____ER__	Priority Substances in European Waters	1	PBT Monitoring				PBT and monitoring (included a procedure called COMMPS), combined relative criteria.
____ER__	Monitoringdata of the river Elbe	37	Monitoring SPEAR Index			Aquatic toxicity: Potential risk for the aquatic fauna using experimental and predicted acute toxicity data for the green algae Selenastrum capricornutum, the crustacean Daphnia magna and the fish Pimephales promelas. The Species At Risk (SPEAR) index used on biological monitoring data for the sites indicated impacts of organic toxicants.	
____ER__	Japan: AIST Risk Assesment for substances of concern	40	Monitoring Risk				risk from exposure/effect
____ER__	CERCLA Priority List of Hazardous Substances 2007 (USA)	89	PBT Exposure and toxicity				several criteria: exposure and toxicity

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____E_X_	Chemical Substances Portal: Environmental Database	41	Monitoring Legislation				RSDE-list: substances from the French action for the monitoring and reduction of hazardous chemical releases in water SIAR-list: chemicals for which a SIAR has been published (SIDS Initial Assessment Report)
____E__§	Pollutant Release and Transfer Register (PRTR) for EU	29	Emission				emission
____E___	OECD: HPV-Programm (List of High Production Volume Chemicals)	12	HPV				THE 2004 OECD LIST OF HIGH PRODUCTION VOLUME CHEMICALS The list in this document contains those chemicals which are produced at levels greater than 1,000 tonnes per year in at least one member country/region. In the attached 2004 OECD List of High Production Volume Chemicals, the various columns indicate: CAS No. Chemicals Abstract Registry Number; SIDS: Those chemicals which are currently or have been investigated in the OECD HPV Chemicals Programme; (details can be found on the OECD HPV database http://cs3-hq.oecd.org/scripts/hpv/) Chemical: The name of the chemical, abbreviated as necessary to 80 characters; EXICHEM: The availability of data in the OECD Existing Chemicals pointer database (details can be found on http://webdomino1.oecd.org/ehs/exichem.nsf) EHC: The availability and reference number of IPCS Environmental Health Criteria documents; CICAD The availability and reference number of IPCS Concise International Chemical Assessment Documents; HSG The availability and reference number of IPCS Health and Safety Guide; ICSC The availability and reference number of International Chemical Safety Cards produced by IPCS;

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____E___	CHAMP Programm USA: High Production Volume Chemicals	32	HPV Monitoring				High Production Volume Chemicals
____E___	Rhine Substance list 2007	38	Monitoring				relevance for river Rhine
____E___	Global Automotive Declarable Substance List (GADSL)	67	Product registries				Use of substances in automotive products, legislation.
____E___	High Production Volume (HPV) Challenge	85	HPV			acute toxicity, chronic toxicity, teratogenicity or developmental and reproductive toxicity, mutagenicity, ecotoxicity	High Production Volume Chemicals, environmental fate
____E___	Japan METI High Priority Chemicals	91	HPV				High Production Volume Chemicals
____E___	European Pollutant Emission Register (EPER)	93	Emission				Industrial emissions into air and water
____E___	The Pollutant Emission Register in the Netherlands	94	Emission				yearly releases of more than 350 pollutants to air, soil and water
____E___	Pollutant Release and Transfer Register (PRTR) for Australia	120	Emissions				substance emissions in Australia
____E___	Pollutant Release and Transfer Register (PRTR) for the Czech Republic	123	Emissions				
____E___	Pollutant Release and Transfer Register (PRTR) for France	124	Emissions				
____E___	Pollutant Release and Transfer Register (PRTR) for Japan	125	Emissions				Chemical substances that are subject to the PRTR are called Class I Designated Chemical Substances. Class I Designated Chemical Substances are designated in the PRTR order and determined based on advice given by the Pharmaceutical Affairs and Food Sanitation Council (MHLW), the Chemical Substances Council (METI), and the Central Environment Council (MOE). Hazardous substances are selected based on their degree of hazard and the possibility of exposure. Class I Designated Chemical Substances are those that come under any of the following conditions of hazard and are recognized as being persistent in the environment over a substantial area: *Chemical substances that may be hazardous to human health

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							and/or may adversely affect the ecosystem, *Chemical substances that may easily form hazardous chemical substances through a naturally-occurring chemical transformation, *Chemical substances that deplete the ozone layer. Japan designates the specific substances such as carcinogens, and regulates them with more stringent rules than non-specific PRTR substances among the PRTR substances. Within the 354 substances, 12 carcinogen substances are designated as Specific Class I Designated Chemical Substance. For these 12 substances, the threshold for reporting business operators based on annual amount handled is set to 0.5t (1t for others). http://www.env.go.jp/en/chemi/prtr/about/substances.html
____E___	Pollutant Release and Transfer Register (PRTR) for United Kingdom	126	Emissions				There are Fact sheets for each substance in the UK PRTR, in which the question is answered: " Why was this substance selected for the Pollution Inventory?" Criteria are e.g, "Included in : Environment Agency categorisation as a hazardous Volatile Organic Compound (VOC)" or "For water releases included in : UK Surface Waters (Dangerous Substances) (Classification) Regulations reporting requirements; European Union Water Framework Directive (WFD) Priority list substances"
____E__	SPIN: Database of Nordic Countries on the use of Substances in Products	19	Product registries				Use of substances in products in the Nordic Countries
____E__	Contaminate Candidate List CCL3 Drinking water	33	Potential drinking water contaminants				contaminant’s potential to occur in public water systems and the potential for public health concern
____E__	Unregulated Contaminants Monitoring Rule UCMR-2	34	Public water contaminants				Monitoring in public water systems

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____E__	EU-Network - SEDNET	61	Monitoring				Vol. 4: Elsevier 2008, 265 pp, EUR 82.95, ISBN 978-0-444-51961-0 unclear whether monitoring data are published in the booklet (booklet was not available)
____E__	Infosystem for dangerous working materials	66	Worker exposure				worker exposure
____E__	BASTA, Sweden	74	Product registries				Use of substances in Swedish construction industries
____E__	SSG Product Database	75	Product registries				Use of substances in products
____E__	WINGIS	76	Product registries				Use of substances in German construction industries
_____RX_	Priority list of existing substances in the EU	2	Risk				Four priority lists (PL1 to PL4) have been adopted up to now. The PL1 is not necessarily the list with the substances of the highest concern. The practical implementation of the procedure laid down in the Regulation 793/93: STEP 1 First EURAM (EU Risk rAnking Method) Rankings: Preparation of the automated rankings based on the IUCLID data and generated automatically using the EURAM data selection routine and applying the EURAM method to the resulting database. STEP 2 Technical Meeting Commenting on the EURAM Rankings: Member States, Industry and other NGOs Commenting on the EURAM Database and adding flags on the ranking on concerns not reflected in the ranking of the substance. STEP 3 Preparing the Working Lists: Using Expert Judgement to select substances from the EURAM rankings to place them on the Working List. Working list of national priorities is developed. STEP 4 Preparing the Priority Lists: Using Expert Judgement substances are selected from the working list for the priority lists. National priorities are also included. The size of the priority lists will be determined, to a large degree, by the number of

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							priority substances which have been completed.
_____RX_	Rotterdam Convention	82	Harm				potential harm to human health and the environment
_____RX_	Basel Convention	83	Hazardous wastes				protection of human health and the environment against the adverse effects resulting from the generation, management, transboundary movements and disposal of hazardous and other wastes
_____R_§	Annex XVII REACH Regulation	130	Risk				Regulation
_____R_§	EDEXIM Regulation 689/2008	131	Risk				Regulation
_____R__	International Programme on Chemical Safety (IPCS)	11	Risk		the chemical may accumulate in the body or in the environment;	the chemical has toxic or ecotoxic properties	Consensus scientific description of the risks of chemical exposures The chemical may be a priority chemical for IPCS risk assessment, if * there is a probability of exposure; * there is significant international trade or the the substance is of transboundary concern; * high production volume with dispersive use; the substance is of concern to a range of countries for possible risk management: developed, developing and those with economies in transition;
_____R__	Priority substances (Austria)	65	WFD				water quality criteria (PEC < PNEC)
_____R__	Priority substances within the context of the WFD, The Netherlands	104	PEC/PNEC				water quality criteria (PEC < PNEC)
_____R__	National and International Approaches to the Classification of River Health	106	River health			no numerical criteria	river health
_____R_	EU-Project - SOCOPSE (Source Control of Priority Substances in Europe)	64	WFD				water quality
______X§	The NORMAN Network	110	Emerging pollutants				new emerging substances., most frequently discussed
______X_	BUA-Reports	115	Environmental relevance				"envionmental relevance"
______X	Workplace hazardous materials information system (engl. WHMIS, franz. SIMDUT) Canada	117	Hazard			Hazardous materials:divided into into six main classes based on their specific hazards. If a product corresponds to one or more of	Hazardous materials:divided into into six main classes based on their specific hazards. If a product corresponds to one or more of these

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						these classes, it becomes a « controlled » product. D1 Materials causing immediate and serious toxic effects, D2 Materials causing other toxic effects; D3 Biohazardous infectious materials	classes, it becomes a « controlled » product. A: Compressed gases, B: Flammable and combustible materials, C: Oxidizing materialsE Corrosive materials; F Dangerously reactive materials.
_____§	Annex I of Dir 67/548/EEC	134					Regulation