Final public report

FEASIBILITY OF A MATERIALS' INFORMATION PLATFORM

ECHA SR22BIS

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Content

Figures

Tables

1 INTRODUCTION

ECHA aims to support stakeholders, in particular article importers and producers, in identifying the content of candidate list substances (CLS)[1] in materials, used to produce articles. Therefore, a feasibility study was conducted to identify if it is useful, technically possible and cost-efficient to develop and publicly provide a respective "Materials' Information Platform" (MIP). This report summarizes the core findings of this feasibility study.

Section 2 presents the theoretical concept of the MIP. It integrates the findings from several project activities, in particular on how information gaps for CLS in materials could be bridged using generic data. The MIP should support the identification of CLS in articles via information on the content of CLS in the materials they contain. It should be cost efficient, easily accessible and the MIP's outcome should be understandable to and useful for the core target group of article importers and article producers to focus supply chain communication and, as a last resort, chemical analyses.

Section 3 outlines how the MIP could be put into practice outlining potential implementation steps as well as challenges to overcome. Several pre-conditions to making the MIP operational in accordance with the outlined concept were identified, such as that sufficient information is available to populate the MIP and that the output is sufficiently clear for the core target group to work with it. Some of these aspects might not be existing in reality indicating challenges and open questions for a potential MIP implementation.

Section 4 of this report summarizes the findings and draws conclusions on a potential further work process on the MIP.

2 THE MIP CONCEPT

The "MIP concept" section of this report is divided into a general and a specific part. The general part (Section 2.1 to 2.2) outlines the MIP's aim, the benefits it aims to achieve and the information needs of its potential users identified in the study. It also outlines the information sources which could theoretically be used to populate the MIP. In the second, specific part of the concept (Section 2.3 to 2.5), the content and structure of the MIP is explained as well as how information on substances and materials is intended to be linked. Furthermore, an implementation strategy is outlined.

[1] Also the identification of substances potentially fulfilling the criteria of REACH Article 57 (potential SVHC) might be supported, however at a later stage.

2.1 Terminology

Article

The term "article" is used in this report as defined in REACH Article 3(3):

> *"article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;"*

Product

In this report the term "product" is used to address articles and chemical products, i.e. substances and mixtures.

Material

The term "material" is not defined under REACH. As a working definition the term "material" is used in the MIP concept to address either substances or mixtures which may or may not yet fulfil the definition of an article under REACH and may be of natural or synthetic origin.

Candidate list substance

The term "candidate list substance" (CLS) is used to address substances fulfilling the criteria of Article 57 and which have been identified as SVHC and added to the Candidate List according to Art. 59 and hence, to which the requirements of Article 7(2) and 33 of REACH may apply.

Potential SVHC

The term "potential SVHC" is used for substances potentially fulfilling the criteria of Article 57 but which are not yet listed on the candidate list.

Technical function of a substance

The technical function (TF) of a substance describes:

> *"the role that the substance fulfils when it is used (what it actually does as such in a process or what it actually does in a mixture or article)"*[2]*.*

Information on the technical function of a substance should be provided in safety data sheets but it is not a requirement for the REACH registration. The REACH guidance document includes a list of respective use descriptors.[2]

Material property

Each material fulfils a function in an article and specific material properties, such as rigidity, conductivity (physical properties), acid resistance, water repellence (chemical properties) or shininess and colour (esthetical properties) may be required for that. Materials have certain properties "as such" and others are generated through (chemical) processing of the materials. The material properties may be linked to the use of chemicals, which is one way how generic links between materials (with specific material properties) and substances (with specific technical functions) might be established by the MIP.

[2] ECHA's "Guidance on Information Requirements and Chemical Safety Assessment" Chapter, R.12: Use description, Draft Public Version 3.0 September 2015; p. 73

2.2 Overview of the MIP idea

2.2.1 Aim of the MIP

The main aim of the MIP is to support article producers and importers in fulfilling their responsibility for placing safe products on the market and in particular to fulfil their obligations of REACH Articles 7(2) and 33 regarding candidate list substances (CLS) in articles.

The MIP may also support other actors in their work related to hazardous substances in articles or materials, such as authorities, non-governmental organizations or scientific institutions.

2.2.2 General functioning of the MIP

The MIP should provide information on which substances might be contained in a material. From this, the potential content of these substance in an article consisting of the respective materials could be deduced. The information is generally provided as substance list, to which additional information stored in the MIP can be provided.

Example

Table 1: Possible composition of an outdoor jacket

Article component	Material as identified by importer	Weight [g]
Top layer	100% polyester	200
Inner layer	100% polyester	50
Insert	91% polyester, 9% elasthane	100
Membrane	Polytetraflouroethylene (PTFE)	25
Zippers	Polyamide	15
Hook-and-loop fasteners	Polyamide	5
Buttons	Metallic	20
Cord	Polyester	5
Total weight		420 g

An importer of the outdoor jacket could identify which CLS might be contained in the article by extracting information on the possible content of CLS in the materials in Table 1.

In the MIP, all materials are divided into material groups (plastics, metals etc.) and sub-groups, e.g. polyolefines, synthetic fibres. For each material, information would be included on which technical functions would be contained or needed to achieve a specific material quality. Furthermore, data on specific substances which have been reported to be present in (e.g. identified in analytical measurements) or absent from a material (e.g. based on sector knowledge or physical chemical properties of the material and the CLS) would be included in the MIP. Furthermore, information on the materials' main uses would be specified (e.g. using use descriptors SU and AC or by putting in more specific, non-standardized information). The above described information may be entered at different levels of detail, i.e. relating to a specific material, a material sub-group or main material group.

The MIP is envisaged to cover all CLS at the first stage. The coverage may be extended in the future, e.g. to also cover potential SVHC. For each CLS in the MIP, among others the following information would be included: technical functions (TF), registered uses identified via use descriptors as well as non-standardized information on their use in materials or articles. Further information in the MIP could be related to the likely concentration ranges of a substance in a material as well as the regulatory status (i.e. if it is also restricted in REACH Annex XVII or under authorisation or regulated in specific product legislation, such as the Toys Directive).

A search in the MIP would start with the selection of a material for which information on the CLS content is sought. The material could be selected as main group (plastics) or at higher level of detail (material name or sub-group). The search could be refined by selecting a specific sector or article type a material is used in or by specifying mixtures which are particularly relevant for the material. The user could then generate a list of CLS:

- for which indications exist that they are not contained in a material;
- which might be contained in the material (intended use or impurities).

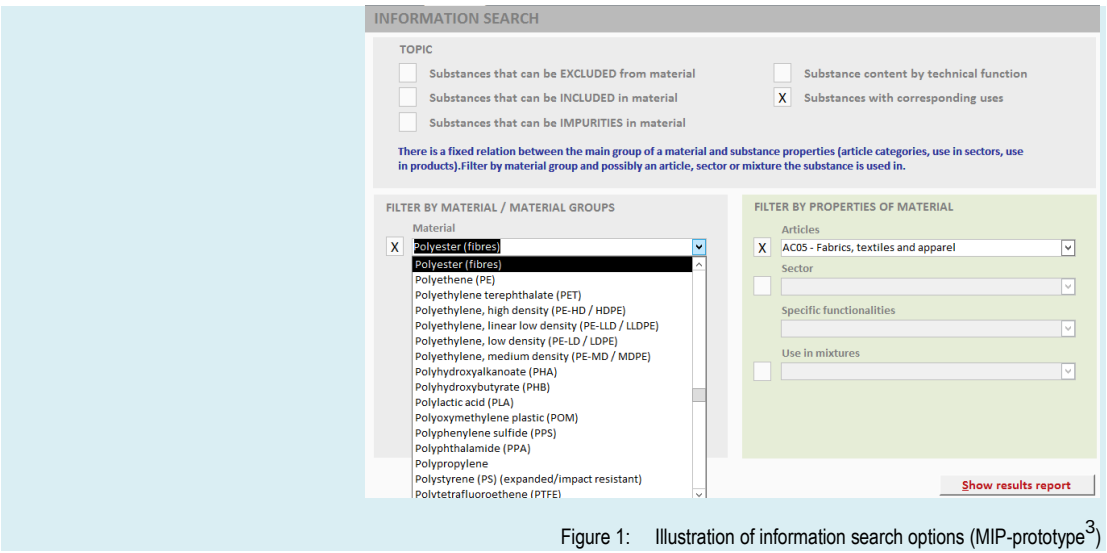

Figure 1: Illustration of information search options (MIP-prototype[3])

Depending on the users' knowledge of the material (e.g. on its material properties or the way it was processed) the search can be further refined.

2.2.3 Expected benefits of the MIP

The MIP is expected to contribute to savings in resources, costs and time from the duty holders.

[3] A prototype of the MIP was developed to support the exemplification in the project. Not all of the information types foreseen in the MIP concept could be programmed in the prototype. Therefore, the illustrative figures from the MIP-prototype may not show all data fields listed. In some cases also the field names do not fully correspond.

These benefits may arise from the use of the MIP, because it:

- provides article importers and producers with a list of CLS which could be included in materials which are used in their articles; the list allows targeting supply chain communication and/or chemical analyses and is considerably shorter than the candidate list;
- provides additional information to support the interpretation of the MIP output regarding the likelihood of CLS presence or absence;
- provides information on the likely concentration ranges of CLS in materials to enable estimating the potentially contained amounts;
- makes available existing information related to the use of substances in materials, among others from ECHA's registration database and other published sources, (better) accessible to the public;

If the number of CLS potentially contained in an article is reduced using the MIP, companies could as a consequence save time and resources in communication with suppliers and customers, increase their level of compliance and also reduce costs for chemical analyses to check the actual content of CLS in their article, as well as consulting costs.

2.2.4 MIP users' information needs

The core information article importers and producers need to comply with Article 7(2) and Article 33 on CLS in articles is:

- presence of CLS in an article to know whether or not a further assessment is necessary,
- amount / concentration of CLS in articles, to know if notification / communication in the supply chain is required.

Furthermore, the following information would be useful:

- information on the "location" of CLS in an article to target chemical analyses, to manage supply chain and to assess substitution possibilities;
- information on the release of CLS from materials to identify potential risks and whether or not to communicate additional information according to REACH Article 33;
- information on potential SVHC in articles in order to pro-actively manage supply chains and / or to better fulfil their producer / importer responsibility.

Table **2** summarizes the information needs of various actors[4].

[4] Information sources of the needs assessment were the survey and stakeholder interviews conducted in this project, experience from former work on substances in articles and assumptions based on comparisons of the actors' tasks and obligations and the information required to fulfil them.

Table 2: Overview of information needs of MIP users

		Information needs regarding substance contents in materials; If information is assumed available to an actor (left column), it is not listed as information need regarding the MIP Colours indicate the importance of the information[5]					
MIP user	**Assumed available information**	**Presence of CLS**	**Concentration of CLS**	**Release potential of CLS**	**Function of CLS / materials**	**Presence and concen-tration potential SVHC**	**Release of potential SVHC**
Article importers	Technical article description, main types of materials, declaration on CLS from supplier	Essential in imported articles; materials in articles	Essential in imported articles; materials in articles	Low priority	Survey: currently not actively searched but wished; interview: may be relevant	Interviews: partly relevant, survey: wish for information	Not needed
Article producer	SDS, information on materials used, Art. 33 information (declaration "free from restricted substances)[6]	Essential in mixtures and articles used as input material	Essential in all input materials to identify notification and communication obligations	Low priority, may be important for larger producers	Survey: not actively searched but wished; interview: may be relevant	Interviews: partly relevant survey: wish for information	Not needed
ECHA	Information from database on registered substances, CLS notifications etc.	Assess need for (further) risk reduction measures	Assess need for (further) risk reduction measures	Assess need for (further) risk reduction measures	Assess availability of alternatives	SVHC prioritisation, assess need for risk reduction measures	SVHC prioritisation, assess need for risk reduction measures
Member States[7]	Information from database on registered substances, CLS notifications etc.	Assess need for (further) risk reduction measures	Assess need for (further) risk reduction measures	Assess need for (further) risk reduction measures	Assess availability of alternatives	SVHC prioritisation, assess need for risk reduction measures	SVHC prioritisation, assess need for risk reduction measures
Enforcement authorities[8]	Information from RIPE as well as experience from enforcement campaigns; RAPEX	Useful but own information may rather be used for enforcement	Useful but own information may rather be used for enforcement	Not relevant for enforcement	Not relevant for enforcement	Relevant if related to restrictions, if one exists	Relevant if related to restrictions, if one exists
Trade associations	Published information and information from member companies on request	Information need depends on members					
NGOs	Published information	Targeting campaigns	Targeting campaigns	Targeting campaigns	Identify substitution options	Consultations (SVHC prio-ritisation, RMM) and targeting campaigns	For consultations (SVHC prioritisation, RMM) and targeting campaigns

[5] Dark green: information important to comply with REACH; light green: information useful for pro-active actions on SVHC in articles, yellow: information nice to have, orange: information not needed

[6] Some companies have restricted substances lists they request suppliers not to use or to use below certain concentrations.

[7] Only 3 Member State representatives participated in the survey and one was interviewed; this is not representative and the information needs should be regarded as "assumed"

[8] No enforcement authority participated in the survey and only one representative was interviewed. Hence, the information needs should be regarded as "assumed".

2.3 List of materials

The backbone of the MIP is the list of materials. It is structured into main materials groups with the most relevant materials listed by name and with established sub-groups, if useful. The following main groups should be covered[9]:

- Ceramics;
- Composite materials;
- Glass;
- Iron and steel;
- Leather;
- Minerals / stone materials;
- Non-ferrous metals;
- Paper;
- Plastics;
- Rubber;
- Textiles;
- Wood and plant material.

2.3.1 Grouping of materials

Several options exist to structure or group materials, for example according to:

- origin / raw materials used to produce a material;
- destination / use area of a material;
- composition of a material;
- functionality of a material;
- production process of a material.

Table 3 shows a possible structure and content of the materials list. The main materials are shaded grey. Examples for the level of detail of material names given in the second column. Some materials are better addressed by sub-groups; these do not include material names. In the third column, the possibilities to create sub-groups are shown with some examples in the last column.

Table 3: Overview of materials list and grouping (exemplary)

Main material	Material names (exemplary)	Possible sub-groups	Sub-group names (exemplary)
Ceramics			
		Use area (rough)	Structural ceramics Refractory ceramics
		Application area detailed	Roof tiles Table ware
		Processing / Modifications	Glazed Porous

[9] Some of these materials may only very seldom contain CLS or not at all. However, during treatment and / or upon inclusion into articles, CLS may be included from the use of mixtures. Therefore, also these materials should be included in the MIP.

Main material	Material names (exemplary)	Possible sub-groups	Sub-group names (exemplary)
Iron and steel			
		Composition rough	Non alloy steels Alloy steels
		Composition and process	Cast iron (high-alloy) Sintered steel
		Application area	Engineering steels Steel for rail use
		Technical qualification	Quality steels (0x & 9x) Tool steels (2x)
Plastic			
	Epoxy (EP)	Composition	Epoxy resins Polyolefines
	Polytetrafluoroethene (PTFE)	Main groups	Thermoplasts Duroplasts
	Polyethylene, low density (PE-LD / LDPE)		
Textile materials			
	Natural Silk	Main groups	Silk Cotton mixed with other fibres
	Cotton	Processing	Optically brightened textiles Water repellent textiles
	Polyester		

The material groups would allow filtering or searching materials at different levels or providing input on the possible CLS – contents at different levels of detail (e.g. to aggregate data and avoid confidentiality issues).

2.4 Data types in the MIP

The backbone of the MIP is formed by the list of materials and the list of (candidate list) substances. For each – materials and substances different information is included in the MIP, as outlined in the following.

2.4.1 Information on materials

The material is defined by its (common) name. Each material would be assigned to a main group and might be assigned to different sub-groups (c.f. Section 2.3). For each material, the following information could be included to further describe it and its potential use in articles[10].

- use in sector and use in articles described with the REACH use descriptor system (SU and AC);
- specific, non-standardised information on articles, in which the material is used in;
- properties a material may have in an article, which is linked to the use of CLS, e.g. flame retarded, anti-static[11];
- indication of the information quality, i.e. actuality, types of information sources, etc.

[10] Not all of these information types were programmed in the MIP – prototype used for exemplification. Therefore, the illustrative figures from the MIP-prototype may not show all data fields listed. In some cases also the field names do not fully correspond.

[11] The type of relevant functionalities are likely to differ for different material groups; some may not have any. Only functionalities linked to the use of candidate list substances need to be included.

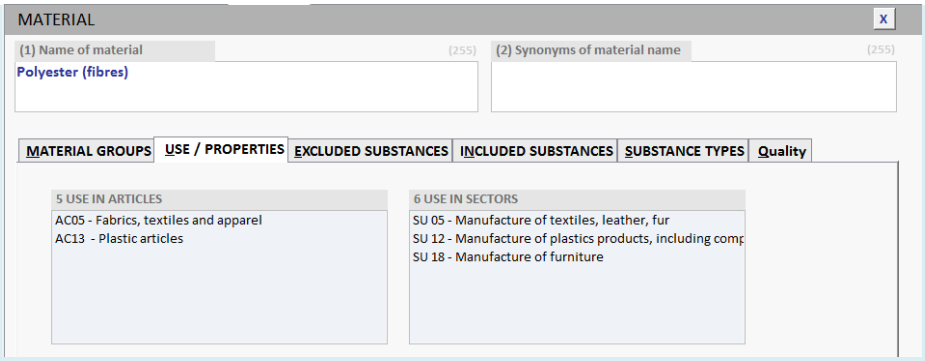

Figure 2: Illustration of information input for materials[12] (MIP-prototype)

2.4.2 Information on substances

For each substance the following information could be included in the MIP:

- scientific name, CAS-number and EC-number and synonyms;
- chemical group the substance belongs to (e.g. metals, phthalates);
- regulatory status, e.g. inclusion on candidate list, restricted under RoHS etc.;
- functionality; this may be described with the REACH use descriptor or the more detailed use categories of the EU TGD;
- use in sectors, articles and mixtures described with the REACH use descriptor system (SU, AC, PC);
- reason for inclusion in the candidate list (if CLS);
- testing methods;
- alternatives to the use of the substance;
- typical applications;
- indicator of data quality; i.e. actuality, types of source used etc.

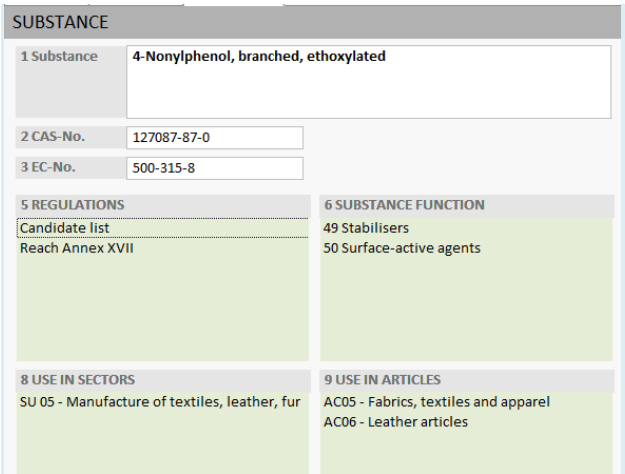

Figure 3: Illustration of information input for substances (MIP-prototype)

[12] The figure shows the input mask in the MIP-prototype. The selected tab allows entering information on the articles and sectors, the material is used in (AC and SU).

2.4.3 Potential additional information types

The information content of the MIP could be extended with further, useful but not essential information. This could be information on analytical methods, available substitutes for a substance in specific materials or information on the release potential of substances from specific materials or release properties of materials as such.

2.4.4 Summary of included information

In Table 4 the data types that could be included in the MIP are listed with an indication of where the data could be obtained from.

Table 4: Information content of the MIP

Type of information	Explanation / comment	Reasoning / use of information	Information availability
Identification of material	Material identity by commonly used name. Allocation to main material group and sub-groups The material list can be extended	Core reference unit Link to articles and link to substances, grouping allows different search strategies	First version of materials list is project output to be verified and expanded e.g. by sectors and university textbooks
Material properties	Different properties are described, which are linked to the content of specific substances and/or substance functions and/or chemical groups	Generic link between materials with certain properties and CLS with respective technical functions or belonging to chemical group	To be generated, it may not be possible to define clear relationships for all material types
Uses of materials	The use of materials is defined with the use descriptors (AC/SU) and as free text.	Refinement of information searches by these parameters and links to substances with the same uses	To be established; information sources e.g. be textbooks, sector information studies
Identification of substances	List of CLS with substance name and CAS-number. The list of substances can be extended	Core information	Candidate list, further substances lists depending on criteria
Chemical group	CLS are allocated to chemical groups, such as Cr and chromium Cr compounds, phthalates etc.	Generic links to materials	Grouping e.g. according to groups proposed by SIN list
Regulatory status	Legislation under which the CLS is regulated	Help for legal compliance, information on likelihood of content	From official sources
Substance use	Information on articles, sectors or mixtures a CLS might be used in as in registration database	Generic link to materials with the same use (profiles)	Available from the registration database
Technical function	Technical functions of CLS in mixtures or materials, such as flame retardant, colorant etc.	Generic link to materials via the technical function and the material properties	Partly available from registration, SIN list and other sources
Substances potentially contained in a material	CLS / chemical groups reported as included in a material; concentration ranges, additional info, if also reported.	Link CLS / chemical group to materials; concentrations e.g. to calculate total content & identify communication requirements	Some (but few) data in published sources.
Substances the presence of which can be excluded from the material	If absence is reported or can be excluded based on PC-properties Disclaimer because exclusion cannot cover all uses of mixtures on the materials	Reported information on CLS content identified	Some data available based on PC-information and from studies
Substance that could be included as impurity	CLS not intentionally added but present in a material as impurity.	May be important in case of substances in processing auxiliaries	Little information available from published sources

The content and structure of the MIP is illustrated in Figure 4.

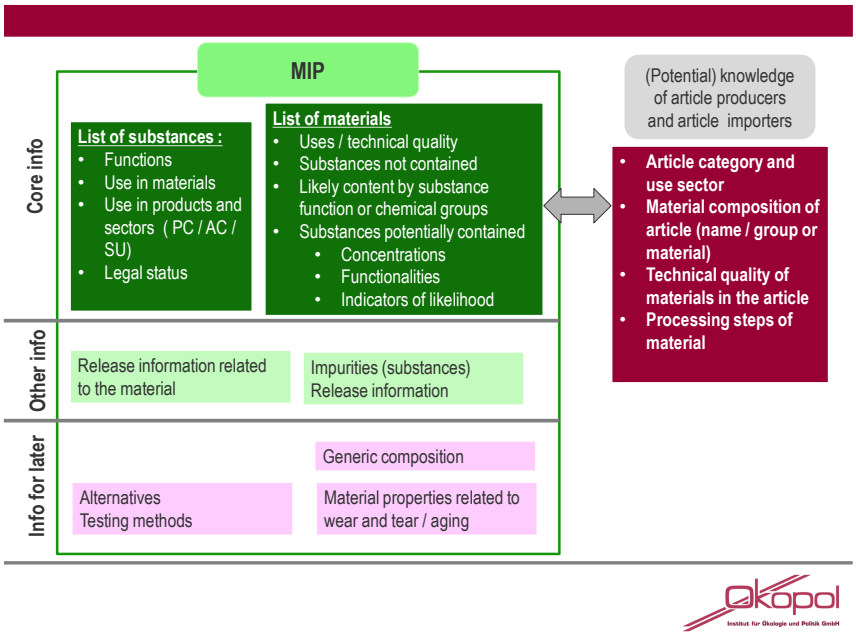

Figure 4: Content and structure of the MIP

2.5 Linking of information

The MIP links materials and substances directly and generically. Direct links are established when specific information on the presence or absence of CLS in a material is reported to the MIP, e.g. from studies, measured data or expert judgement. The MIP would allow entering respective data on:

1) "Exclusion" (by CAS-number or chemical group) if it is known that a specific CLS or a chemical group are not or cannot be contained in a material (e.g. due to physical-chemical properties);
2) "Possible inclusion" (by CAS number or chemical group) if it is known from analyses or stakeholder information that a CLS or a chemical group may be included in a material;
3) Impurities (by CAS-number or chemical group) if it is known that respective contaminations occur.

For the example of an outdoor jacket, information can be found in the MIP, that the use of DecaBDE can be excluded, because no flame retardants are used in polyester used for clothing. In two studies, the content of perfluorinated compounds is reported in outdoor jackets made from polyester; hence for the substances PFOS and PFOA would be listed in a search based on reported information on the content of CLS in polyester. Stakeholders reported that antimony trioxide might be included in polyester as impurity. This information could be included in the MIP, if antimony trioxide was a CLS.

Additional information, such as likely concentration ranges, indicators of likelihood and references to the information source data could also be entered.

Two types of generic links could be established by the MIP:

- For each material the „substance types" likely to be contained are defined. The "substance types" would be linked via their technical functions or by their chemical groups.
  This link could be further narrowed if there is a relationship between a substance type, the technical quality it provides to a material and the technical qualities needed of a material in a specific article.
- Another generic (and less specific) link is established by matching a material with all substances having the same use descriptors (SU, AC and PC).

For the example of the outdoor jacket consisting of polyester, a substance type that is "normally contained" are colorants. In addition, polyester in outdoor jackets should have the specific property of stain and water repellence; this would be associated with a content in surface active substances. Generic searches in the MIP for the outdoor jacket would, among others, extract all CLS with the technical function "anti-static agent" and "surfactant".

A search by commonality of uses of polyester would be conducted using the article category 05 (Fabrics, textiles and apparel) and the sector of use 05 (Manufacture of textiles, leather, fur).

A combination of all searches or search criteria would be possible.

An output a MIP user could obtain from the MIP would be either a compilation of different searches indicating which substances are identified with which search criteria.

In the case studies, several searches were simulated and evaluated. Due to the lack of resources to fully populate the MIP with information on the example materials and quality assure for all information, the results are regarded as indicative and illustrative only.

Table 5: Exemplary MIP output from the case study on polyester (PES) fibres: combined lists[13]

Substance	AC 05	PC 34	PC 32	SU 05	TF	Poss. included	Impu-rity
1,2-benzenedicarboxylic acid, di-C6-8-branched alkylesters, C7-rich (DIHP)	x		x	x	x	x	
Lead chromate	x			x	x	x	
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate)	x	x	x	x	x	x	
Alkanes, C10-13, chloro, SCCP	x		x		x	x	
Diisobutyl phthalate	x		x		x		
Dibutyl phthalate, DBP	x				x		
Tris(2-chloroethyl)phosphate	x		x	x	x	x	

Materials are normally not used in articles as "raw" materials but after certain "processing", which frequently involves the use of substances and mixtures, which may be or included CLS. The MIP as currently envisaged integrates the use of mixtures in material processing for article production via the generic links with the use descriptors as well as the technical functions and material qualities. However, no specific mixture information is included. It was not in the focus of

[13] AC: Article Category; PC: Product Category; SU: Sector of Use category; TF: Technical Function

the project to identify if linking the MIP to specific mixture information would be useful and necessary to provide complete and trustworthy information.

The treatment of materials with mixtures and a potential related inclusion of CLS into or onto a material may be the main source of CLS in some material groups (e.g. textiles, paper). Therefore, it might be further explored, if the MIP could be linked to e.g. the Nordic Product Registers (SPIN2000), which contain information on the substance content in mixtures on the Nordic Markets.

3 FINDINGS FROM THE CASE STUDIES

Case studies were conducted to test the outcome of a potential implementation of the MIP concept. A MIP prototype was developed and populated with the candidate list substances (CLS), information on the uses and technical functions of CLS as well as data for the two example materials polyester fibres and polypropylene. Stakeholders were involved via interviews. Unfortunately, only **little specific information to populate the MIP with data was received from stakeholders**.

No company of the core target group wanting to test the MIP for its articles could be identified. Therefore, searches were performed at the level of materials and for two specific articles (outdoor jacket and hair drier) as theoretical exercise.

With the help of the MIP lists of CLS were generated using different search criteria and using a list of "excluded" substances[14] to deselect CLS which are not relevant for the materials (in articles). The generated lists are considerably shorter than the candidate list. If all substances from all possible searches were combined, the resulting list would be comparatively long (around 100 substances).

Which number of CLS on a list of possibly included substances would be regarded a "sufficiently low" could not be identified in the case studies due to the lack of participation of target group companies. From the consultant's perspective, a list of around 15 – 20 substances is regarded as desirable output.[15]

It was concluded from the case studies that the generic searches of the MIP allow focussing the work on CLS in articles to a lower number of substances than in the candidate list. It could however not be assessed (yet) if the level of information is sufficient for the target group to correctly interpret it and if the

[14] CLS for which information was identified in literature or from stakeholders that they are not used in a material.

[15] This corresponds to a reduction of the current candidate list to approximately 10%. Furthermore, if narrowing down the use of a material to an article category and may be on a material property it is estimated that around 20 substances could theoretically be contained in that material. Finally, it is felt that a list of 15-20 substances is regarded sufficiently short to communicated with suppliers and show that a pre-selection has been made from the candidate list.

resulting lists are complete (if possible no CLS that could be contained are overlooked) and do not include too many substances which are not relevant.

The generic searches based on use descriptors and substance technical functions integrate the use of mixtures for materials processing. The use descriptors are unspecific with regard to the mixture types but specific for the material groups while the substance functions can to some extent be allocated to specific mixtures or processing steps (e.g. colorants) but are not specific for a material. Hence, the use of mixtures is included in the generic searches. However, several uncertainties are related to that starting from the way the use descriptors are designed (broad, to be used in conjunction) and applied (describe potential but not necessarily actual uses) and ending with the question how the use of mixtures for decorative purposes can be appropriately implemented in the MIP. The question if information on the composition of mixtures and a search possibility specifying material processing steps and related mixture use was not assessed in the project.

It also became obvious that **published information on the CLS content in materials is scarce and incomplete**; hence it can be used rather to verify or cross-check generic search results than as self-standing result.

The list of "excluded" substances was identified as very useful to "clean up" generic searches. However, information on the absence of CLS is difficult to obtain if the absence is not based on physical-chemical properties and if the use of mixtures in or on materials is integrated. In any case, the **exclusion of substances from materials should be conducted with care** and it may be advisable not to automatize this step.

The final outcome of the MIP could be a compilation of results from different searches (c.f. Table 5) or a list which further processes this information, e.g. by assigning indicators of likelihood or priorities to CLS. It is however unclear if e.g. the fact that a substance is identified on 5 lists corresponds to a higher likelihood of being present in the material than for a substance which is identified only by one criteria.

Free text and non-standardized information on the uses of substances was observed as useful to make plausibility checks and further narrow down likelihoods of presence of CLS in materials.

All in all, the case studies showed that the **MIP allows focusing on CLS using different searches**. The quality of the resulting list could not be verified and therefore at present no statement on the level of uncertainty or the trustworthiness of results can be made. It is assumed at the present stage that even if the MIP is technically improved and more and better information is put in, **the users might have to invest time to interpret the lists and conclude on their specific article**.

Some of the case studies indicate that obtaining CLS-lists from the MIP saves resources as compared to individual information searches. In addition, **no specific expertise is needed** to obtain the MIP output. Consequently, the benefit of providing accessible information in a resource efficient manner is

regarded as fulfilled. However, the interpretation of these lists and putting them into practice is another step which could not be assessed in the case studies.

In conclusion, the expected benefits of the MIP could only partly be shown as achievable in the case studies; however due to the limited possibilities to populate the MIP, better results could be possible, both regarding the length of lists of potentially included substances in a material and the indicators of likelihood of substance contents.

Table 6: Overview of expected benefits and related conclusions from the case studies

Expected benefit	Conclusion form case study	Comment
Provide a list of CLS that could be contained in a material	Possible	Unclear if focus is sufficient (number of CLS low enough) List is complete but does not contain too many substances which are not included (no false negatives, as few false positives as possible)
Save resources in identifying CLS potentially contained	Yes	Research time / money for consultants
Get information without being an expert	Partly	Lists can be obtained, however checking of information was regarded as necessary. Doubts were voiced that users might not be able to interpret the output
Information on substance concentrations is provided	Only in rare cases	Information is currently not available from published sources; stakeholders were not positive about providing it.

In interpreting the case study results it should also be remembered that textiles and plastics are the most complex materials used in articles, maybe with the exception of composite materials, as regards the CLS content. Hence, more complete and unambiguous results are expected if the MIP is run with less complex material groups, such as metals.

4 MIP IMPLEMENTATION

The following chapters outline possible implementation steps of a MIP and the challenges which might have to be overcome. The thereafter presented steps and questions are not yet decided but reflect the status quo reached in the project and might be subject to further discussion.

4.1 Possible implementation

It is proposed to implement the MIP in a step-wise approach. The initial MIP would cover the materials as described in Section 2.3 and all candidate list substances. The information content would be focused at the initial stage on the generic information (use descriptors, technical functions) and reported information on potential presence and absence of substances in materials. As far as available, information on typical concentration ranges, the regulatory status and indicators of the likelihood of the CLS' presence should be contained.

The MIP structure would have to be programmed and respective data be collected and put into the MIP. This **would require collaboration of actors from different sectors**, among others to compile generic information on materials and their potential properties, the "typical" content of substances identified via the technical function and/or the data on substance which are not likely to be contained in a material (excluded substances).

The information in the MIP would have to be complemented at least each time the **candidate list is being updated** for those substances newly included. Furthermore, information on the **regulatory status would have to be updated**, if legal changes occur. In addition and because it is expected that candidate listing will influence the use of substances in materials and articles, the information on the uses of substances and/or the possible content of CLS in materials should be updated periodically.

It has not been elaborated in the feasibility study **who would own and operate the MIP** and whether or not the access **should be restricted**, e.g. to protect confidential information. In the online survey and the stakeholder interviews conducted in the project, it was observed that the majority of actors would prefer ECHA as owner and operator of the MIP and that access should be limited with regard to the information provision in order to ensure a high data quality. The access for obtaining information should, according to the perceived opinions, not be limited. These aspects might have to be further discussed among the stakeholders.

For the inclusion of specific information in the MIP, a "data import tool" would be developed so all stakeholders can provide their information in a compatible and efficient way.

4.2 Conditions for the MIP implementation

The implementation of the MIP as suggested in this study and which might be a possible and good solution to identify CLS in materials, requires that as a minimum certain basic conditions are fulfilled. These conditions regard different aspects of the MIP. In the following sections these conditions and related assumptions are described and confronted with the findings on the real-life situation as experienced in the research and case study work.

4.2.1 Number of CLS on the MIP output list(s)

The overall goal of the MIP is to provide the users with lists of CLS that could be contained in a material, which support focussing their work on substances in articles. The shorter these lists (without missing substances), the larger the benefit of the MIP.

The minimum length of the MIP output depends on the actual possibilities that a CLS could be contained in relation to the specified determining parameters. The "maximum number" of CLS that could be contained, e.g. in a specific type of plastic material, for which the technical functionalities and uses are defined,

could not be identified. Hence, for plastics and some other materials it is as yet unclear, if the searches of the MIP can result in a low number of CLS.

Due to the production process of metals involving high temperatures, steel is only likely to contain elemental metals. The current candidate list includes only one metal (cadmium). The actual content of CLS in steel is determined by physical-chemical properties (core determining parameter) and the MIP output can be a very short list.

Plastics may have a variety of particular material properties, such as being flame retarded, softened and coloured. Hence, as a minimum three types of additives might be contained. The current version of the candidate list contains 48 substances which have at least one of these technical functions; hence the MIP output could in principle not be shorter than 48 substances, except another parameter is used to reduce the number of CLS on the list. However, this is only possible if from these 48 substances some can actually not be included in the plastic.

Condition to derive the desired result of short CLS-lists:

- the number of combinations between specific materials for which the material properties and general uses are defined and the potentially contained CLS are limited in reality;
- the factors determining the CLS content of a specific material can be identified and data on the possible CLS content is (made) available in relation to these factors;
- the number and complexity of factors determining the potential CLS content of a specific material is low.

For some material groups, such as metals, glass, ceramics or minerals it is comparatively simple to exclude the presence of many CLS based on their physical - chemical properties and general knowledge of the materials and their production processes. This was confirmed in interviews with industry associations.[16] Consequently, as in these material groups only a low number of different CLS could be contained and the determining factors are physical-chemical properties, the above listed conditions are regarded as fulfilled.

For other materials, in particular plastics, composite materials and rubber[17] the number of potentially contained CLS in a material could be much higher and may further increase as the candidate list is extended. In the feasibility study it could not be evaluated if the parameters “material property”, “included substance function” and the standardised uses (AC/PC/SU) are sufficient to unambiguously focus the MIP output to a useful list of potentially contained CLS. It was furthermore questioned (and could not be further assessed), if the MIP users have sufficient information on the materials to actually sufficiently specify their information search to derive the most focussed lists.

Some of the interviewed stakeholders indicated that it is difficult to clearly relate the use of substances in plastics to parameters such as the material property and the use. If these links were established in a conservative way (no false negatives), the number of possible combinations might be high. Furthermore,

[16] In the case studies no verification of whether or not the resulting lists are complete and/or contain CLS which are not normally used in the material could be obtained. Furthermore, little information on the “typical” substance content by technical function was available.

[17] It was specified that only 20 CLS are relevant for rubber at the moment; however the CLS will be extended and more substances contained in rubber may be added.

the feedback from stakeholders pointed to that respective information collection in the sector might be difficult, because of a lack of incentives for the actors to provide this information.

For some main material groups - mainly textiles, paper and leather - the CLS content does not primarily depend on the material but on the way it is treated; i.e. the mixtures used for finishing / modifying determine the CLS-content. This is further discussed in Section 4.2.4.

In order to come to a conclusion on the feasibility of the MIP (for some material groups), it should therefore be clarified:

- if and by which determinants the number of combinations of specific materials and potentially contained CLS can best be reduced and
- if the actors in the respective sectors would be willing to **contribute to the respective development of the MIP**, the identification of generic links and the provision of respective input data to populate the MIP
- if the actors in the respective sectors would be ready to **continuously review and update the MIP**, e.g. if new substances are included in the candidate list and/or significant changes occur to the use of substances (e.g. phase-out).

4.2.2 Adequacy of the MIP for the target group

The MIP should be designed in a way that is adequate to the level of expertise and the availability of resources of the core target group, namely the **small and medium size article importers and article producers who do not yet have a system in place to manage hazardous substances in their supply chains** / articles. In order to be adequate for the target group, the following conditions need to be fulfilled:

- The **MIP can be used without any specific expertise**; however, general knowledge on the material should be available, such as where in an article a material is used and which material properties it may therefore need to have.
- The **MIP results should be understandable** to the target group, i.e. sufficient information should be provided to help the users interpreting the MIP output with regard to the own article and the related requirements.
- The MIP should be easily **accessible**, if possible **free of charge** and provided **in different languages**. This aspect has not been discussed in detail during the feasibility study.

In the case study work, it was intended to involve companies representing the core target group of the MIP in order to identify their specific information needs, their approaches to information collection and their understanding of the MIP output. Misunderstandings could occur, for example, because the MIP output only lists substances which might be contained or because information on "excluded" substances may contradict information on potentially included substances from generic searches.

Unfortunately **it was not possible to involve any of these stakeholders** and hence, no clear answers on these aspects could be obtained.

Some of the interviewed stakeholders provide advice to companies on compliance with REACH Article 33 and 7(2) on a regularly or incidental basis. The majority of these actors stated that **many SME companies might need further explanation** and refinement of the MIP output to fully understand it. Furthermore, the MIP's core target group would frequently need external support to implement follow-up actions in their management. Some answers to the online survey also indicate **doubts that the MIP would be adequate for the target group**, among others because the MIP output would only show the potential CLS content of a material, because it was doubted that it could be simple enough to use and because the number of support tools for the REACH implementation was regarded as too high in general.

In order for the MIP to be useful to the core target group:

- The parameters to specify information searches and the search options should be clearly described from the perspective of the core target group; this requires the **collaboration of the information providers and the information users** in the MIP development (see also Chapter 4.2.1).
- The information included in the MIP should be as specific as possible, including indicators of likelihood and in particular including precise and correct information on the exclusion of CLS in materials. This requires that **respective information is provided from the sector experts and the market actors**.
- The design and guidance to use the MIP should be easily understandable and explained in a concise manner. This requires the MIP developers and the target group to collaborate in the development of the MIP.

4.2.3 Sufficient information is available and provided to populate the MIP

For the MIP to work and provide high quality and up-to-date information the information included in the MIP as well as the generic links between materials, material properties and the substances' technical functions, chemical groups and / or uses of substances need to be of high quality.

For the materials, generic information on the substance functions and chemical groups likely to be contained (in relation to particular technical qualities) are needed as well as their uses (use descriptors AC and SU). To establish direct links on the potential absence and presence of CLS several sources are relevant, including:

- Published studies and surveys on CLS and/or the content of substances in materials
- Databases on CLS / substances in materials or articles
- Information from industry, including associations, material producers, material processors and article producers and importers on:

- the content of CLS, including concentration ranges, if possible (e.g. aggregated at the level of material name and anonymized)
- the absence of CLS in a material / material group
- indicators of likelihood of the CLS content in materials
- information on substance functions

Information on the presence and concentration of CLS in materials are available and accessible as "common knowledge"[18] in published studies and in a few databases, as well as in ECHA's information sources, such as the notifications of CLS in articles. However, **this information is mostly limited** to substances which are regulated already since a longer time and to certain article groups (e.g. toys). Information from textbooks (e.g. the plastic additives handbook) include general information which would need extraction and evaluation before inclusion in the MIP.

In conclusion, it is assumed that a high **quality input to the MIP** can only be ensured (for some of the materials, such as plastics) if information is included from sector associations and industry actors.

Some of the interviewed stakeholders were hesitant regarding the provision of information to the MIP.

- From the interviewed sector association representatives no clear message could be obtained if and which of the needed information is available to them. There was also no clear picture as to whether or not this information would be used exclusively for the member companies (and would hence not be provided to a publicly accessible MIP).
- Scientific institutions were careful about the overall possibility to provide correct information at a general level (no false negatives, few false positives). They had a tendency to refrain from the task of providing the respective information. In addition, they seemed to **lack a particular motivation for respective data provisio**n.
- Interviewed material producers (e.g. formulators of masterbatches and compounds) stated to have **no benefits from providing data to the MIP but only disadvantages**, in particular having to invest resources and potentially loosing competitiveness related to their know-how on the use of substances in materials.
- The article importers and producers which were asked about their willingness to provide data to the MIP had **own systems in place** to manage CLS in their supply chains. Most of the interviewees doubted that they would provide data to the MIP, because of the resource investment, the lack of benefits and the risk of loosing competitive advantages
- Member State authorities and NGOs were not contacted regarding if and which information they could provide.

Only a small number of stakeholders could be interviewed in the project and therefore, the answers may not be representative.

[18] E.g. that phthalates may be contained in plastics

The answers to the online survey on this question were more positive than the feedback obtained in the interviews. Approximately 8% of the survey participants indicated that they are not interested in the MIP and would hence not contribute any data. Around 60% of the survey respondents selected at least one answer which indicated willingness to contribute to the MIP and around 40% of the respondents selected at least one answer indicating that no contributions can be expected from them. 40% of the formulators expressed that they are not interested in the MIP and/or that data provision would be too cumbersome.

The following figure shows the share of respondents within the different stakeholder groups and the conditions under which they would be willing to contribute to the MIP.

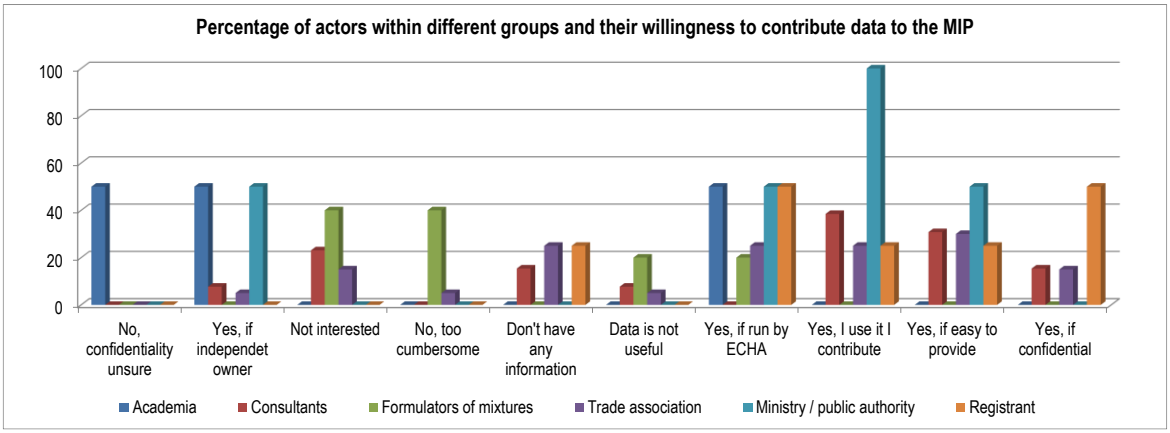

Figure 5: Share of respondents within different stakeholder groups and their willingness to contribute to the MIP

In conclusion it is unclear if and which stakeholders would contribute which type of information to the MIP. Whereas the online survey shows that a number of actors would provide data (under certain conditions), the feedback from stakeholders in interviews was much more careful and less promising regarding their contribution.

Consequently, these aspects should be clarified in dialogue with sector associations, material producers / formulators and article producers / importers and specific commitments should be made.

4.2.4 Coverage of CLS in mixtures used to treat materials

“Raw” materials are usually treated with mixtures which may contain CLS before they become or are included in an article. The treatment with mixtures may be an integrated step in the material production (e.g. additivation of polymers) or may be a step conducted after the “raw” material is produced, (e.g. printing onto textiles). Processing may also regard the application of mixtures to a (finished) material to treat its surface, normally for protective reasons (e.g. anti-corrosion, scratch protection) or for reasons of design (colour, structure, print). Imported articles mainly include “treated” materials, whereas article producers may carry out the treatment themselves (and hence may be able to obtain information from the mixtures’ safety data sheet).

The generic searches in the MIP integrate the use of mixtures on materials, because they apply to sectors, mixtures and finished articles rather than "raw" materials. However, because use descriptors are understood and applied differently by the registrants and because they are not intended to be used "alone" but only in combination, it can neither be ensured that all CLS are covered in a generically derived MIP output nor that there are only those CLS which are relevant in the mixtures used to treat a material. Furthermore, it cannot be clearly communicated "what is covered" and what is not.

The MIP concept does not include specific information on the CLS content of mixtures and options to select (specific)[19] mixtures used in the treatment of materials in articles as a search option for the MIP.

The feedback from stakeholders on the need and usefulness to include information on the CLS content of specific mixtures which may be used to treat materials for use in articles was divided. Some actors stated that this information is essential for the MIP, because it is needed to check REACH compliance and because it is difficult to obtain for the target group. Other actors were of the opinion that too many factors determine which mixtures are used and whether or not and which CLS could be contained to be provided in the MIP. Furthermore the users would not know if and which mixtures are used to in the supply chain of a material and could hence not make respective (specific) searches. This was particularly brought forward by actors from the textile sector.

A potential information source of information on the composition of mixtures are the Nordic Product Registers, which include data on the Nordic markets from an obligatory reporting system (SPIN2000 database). Linking the MIP to SPIN2000 may enable a search for mixture types at a higher level of detail than the applicable REACH use descriptor (PC 34) and could generate a list of CLS reported to the Nordic authorities in the mixtures. Another information source could be published safety data sheets of mixtures; however information would have to be extracted and put into the MIP individually.

In conclusion it could be further explored in a dialogue with the stakeholders:

- if it would be useful to include specific information on CLS in mixtures in the MIP and which level of detail would be adequate; both aspects would require the target group to contribute to the further MIP development (which information on material processing is available and could be used for searches?) as well as experts on the mixtures (at which levels should / could mixtures be differentiated; which factors would determine the use of mixtures?)
- if specific information should be included, where it could be obtained from, e.g.
    - if the Nordic Product Registers could be used
    - if and how data could be collected from existing safety data sheets

[19] As indicated above, it is possible and foreseen that a search can be conducted selecting the relevant PCs. However, these are very broad and may cover a very large number of different specific mixture types.

5 SUMMARY AND PRELIMINARY CONCLUSIONS

The Materials' Information Platform (MIP) should provide stakeholders, in particular article importers and article producers, with information on the potential use of candidate list substances (CLS) in materials. This should ultimately support compliance with Article 33 and 7(2) of REACH and strengthen industry's capacities for placing safe products on the market.

The overall idea of the MIP is to bridge information gaps on substances in articles by providing data on the content of CLS in materials, which could be related to articles based on their material composition.

Different options are envisaged to link information on CLS to materials: generic links would relate material properties to substances' technical functions as well as information on the uses of materials and the uses of substances. Specific links would be derived from published or directly provided information on the presence or absence of CLS in specific materials.

Apart from data on the potential absence and presence of CLS in materials, the MIP could also include information on the CLS' typical concentration ranges in materials, the CLS' regulatory status, additional (specific) information on the use of substances and materials as well as indicators on the likelihood of content of a CLS in a material.

A user would search the MIP by selecting the material he is interested in and specifying e.g. a use sector or a property it should have. The MIP's output would be a list of CLS that could be present in the material including any additional information on the substances as available from the MIP, such as the concentration range or the regulatory status.

The main expected benefits of the MIP consist of reducing the number of substances on the candidate list which could be contained in a material or article to support focussing supply chain communication and potential chemical analyses of their articles. Focusing these actions would lead to savings in resources and costs.

The efforts to implement the MIP consist of the development, programming, hosting and publishing the core database, its population and quality control, updating and maintenance as well as providing support to its users.

For some material groups the MIP implementation appears to be comparatively straight forward and information on CLS and materials seems to be available at sufficient level of detail. Unfortunately this applies mostly to those material groups with low relevance for articles and / or where a CLS content is fairly unlikely based on physical – chemical considerations.

For other, more complex and diversified materials, several open questions were identified which could not be further assessed during the project. The most important questions, which should be answered in order to come to a final conclusion on the feasibility of the MIP are:

- Can generic links between a material and a CLS be established with sufficient confidence and resulting in reliable and useful MIP outputs for those materials, where no physical-chemical reasons exist to exclude the use of substances and where several potential combinations of CLS and materials exist?
- Should information on the composition / content of CLS in mixtures be included in the MIP and if yes, how and which?
- Can the industry actors and other stakeholders, in particular the sector associations and material producers / formulators be motivated to provide relevant, specific and high quality information to the MIP?
- How can the MIP be designed and the output be explained so that the core target group can use the MIP and understand the results of their information requests?

All these aspects are partly interlinked, e.g. the question of understandability of results strongly depends on the level of detail of information put into the MIP.

For the next phase of the MIP feasibility assessment, it should be considered if another consultation with specific industry actors could be useful to get answers to the above questions.