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proactive alliance

towards a global material reporting standard

Discussion Paper with Technical Recommendations

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Explanatory note

The findings in this discussion paper are based on the results of the processes within the Proactive Alliance; in particular on the outcomes of the four working groups.[1]

An earlier draft version of this document was shared for internal review with the participants in the Proactive Alliance processes between June and September 2020. A consolidated draft was subject to public consultation in November and December 2020 by means of the website of the Proactive Alliance and a webinar thankfully hosted by Chemical Watch at the 8th of December.

The 16th Technical Coordination Meeting of the Proactive Alliance in December 2020 considered the collected feedback received from organisations such as ACC, ICCA, JAMP, JCIA and JEMA (summarized in appendix 5.8).

The Proactive Alliance now publishes the discussion paper with its "technical recommendations" with the intention to initiate global uptake.

In 2018, the Proactive Alliance asked the research group sofia to lead the PA processes in an open, transparent and inclusive manner.

[1] See https://www.proactive-alliance.info/how-we-work.

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		Explanatory note (where appropriate)
CAS	Chemicals Abstracts Service	
CBI	Confidential Business Information	
CiP	Chemicals in Products	
CJEU	Court of Justice of the EU	
CN	Combined Nomenclature	
DSL	Declarable Substance List	Covers substances that have to be communicated in the supply chain, such as substances mentioned in the EU REACH Candidate List for Authorisation (SVHC)
ECHA	European Chemicals Agency	
HPD	Health Product Declaration	
IEC	International Electrotechnical Committee	Standard Development Organisation for Electrical & Electronic sectors like ISO
IMDS	International Material Data System	
IPC	Association Connecting Electronics Industries	USA trade association, also Standard Development Organisation under ANSI procedure
IUPAC	International Union of Pure and Applied Chemistry	
FMD	Full Material Declaration	
GADSL	Global Automotive Declarable Substance List	
JAMP	Joint Article Management Promotion	Japanese consortium
MRSL	Manufacturing Restricted Substance List	Textile sector
OECD	Organisation for Economic Co-operation and Development	
PA	Proactive Alliance	
POP	Persistent Organic Pollutants	
ROHS	Restriction of Hazardous Substances	
RSL	Restricted Substance List	Like the EU RoHS RSL
SCIP	Substances of Concern in Products	European database put in place by the European Chemical Agency (ECHA) to support the Waste Framework Directive (WFD), Article 9(1.i, 2)
SiA	Substances in Articles	Articles in accordance with the EU REACH Regulation (excluding substances and mixtures in particular)
SIN	Substitute It Now	
SRL	Substances Reporting List	Generic term adopted by the Proactive Alliance for the DSL and RSL wherever the list includes regulatory requirements or industry standards
SVHC	Substances of Very High Concern	Substances in the EU REACH Candidate List
TARIC	Integrated Tariff of the European Union	TARIC code
USP	Unique Selling Point	
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological Materials	

1 Executive summary

Industries are facing new challenges from **"Substances in Articles" (SiA)** communication arising from customer demands, information requirements under the REACH Regulation and other legislation in the EU and around the globe, as well as resulting from the aim of being compliant with the legal requirements, both now and in the future.

In the Proactive Alliance, representatives from industry and trade are working together in anticipation that **inter-sector cooperation** based on a common agreement will reduce the burdens placed on supply chain actors in terms of SiA communication. The group acknowledges that the more that data demands are based on a common understanding, the stronger is the voice of the different sectors in obtaining a sufficient level of information from their suppliers. The Proactive Alliance brings together representatives who view themselves as global players from various sectors including chemicals, electrical and electronics, furniture, home textiles, textiles and sporting goods, and medical devices and insulation (see participants list in Appendix 5.7). In addition, a number of representatives from sectors such as automotive, aerospace & defence, and metalworking and metal articles have contributed as observers to the efforts of the Proactive Alliance.

The Proactive Alliance participants have the joint aim of reaching a cross-sectoral harmonisation on how to report on Substances in Articles along the supply chain at a global level. This document formulates a set of recommendations for achieving this goal. This will eventually result in the following benefits for the stakeholders along the supply chains (see the following table).

Table 1: Benefits for the stakeholders along the supply chains

1. Meeting **existing legal requirements** for supply chain communication and consumer information, e.g. under
   - general product safety, quality management and liability provisions as well as, in particular,
   - the EU REACH Regulation and its Articles 33 (1)/(2) / 7 (2), and
   - data transfer to the SCIP database under Article 9 (1)(i);
2. Meeting **contractual obligations** towards the customer;
3. **Being prepared** to be compliant with future legal requirements and contractual obligations including; e.g.,
   - EU REACH Regulation Article 59 (10) as well as new restrictions under sectoral legislation
   - legal requirements resulting from EU Green Deal implementation, such as developments enabling a Circular Economy. In this respect, a trustful information flow on material content of articles is key. It has to include the entire upstream supply chain in order to enable efficient material recycling.
4. **Enhanced manageability** in terms of the aforementioned tasks and challenges;
5. **Reducing the burden** on supply chain stakeholders through cross-sector cooperation based on a common understanding, and finally
6. **Saving costs** through effective communication systems.

As stated in its mission statement, the main outcome of the Proactive Alliance is this discussion paper with recommendations for the development of a global cross-sector standard for the communication of Substances in Articles ("Article" as defined by the EU REACH Regulation). The intention is not to create a new standard but to **build on existing standards** and, where required, to enhance existing ones where these, e.g. show gaps, with the aim of producing a harmonised global cross-sector approach.

The Proactive Alliance calls on the relevant industry stakeholders to consider the recommendations detailed in this discussion paper. It proposes criteria and technical information as a benchmark for such standards, in particular in terms of **data generation and collection** (i.e. data quality, reliability, comprehensiveness and exchange formats as well as basic rules governing data protection and security) and in terms of the development and maintenance of **Substance Reporting Lists**. The recommendations apply to communication within the professional supply chain; they do not address the disclosure of data to third parties. However, trustworthy communication between the supply chain stakeholders is the precondition for ensuring product quality and product safety as well as reporting obligations under different legal frameworks or due to contractual requirements.

This document aims to contribute to the following **medium- and long-term objectives**:

- Creating more efficient technical and governance frameworks for supporting the regulations on SiA;
- Making data collection a more automated process with lower costs and better data quality;
- Creating value for companies that perform well in this matter.

The vision for achieving these objectives consists of developing more **system to system data exchanges** based on standardised data structures and data formats, in order to promote IT-supported processes for requesting and collecting data along the supply chain.

In addition, the Proactive Alliance has developed **two strategies** for implementing the recommendations, i.e. contributing to standardisation bodies and processes at different levels.

How does the Proactive Alliance work?

The Proactive Alliance participants have established four distinct working groups,[2] the results of which are presented in this discussion paper.

The Proactive Alliance sets out recommendations for different topics:

1. The harmonisation of criteria for Substance Reporting Lists (SRL) (Chapter 2)
2. The harmonisation of Material Reporting Standards (Chapter3)
3. Cooperation at a global level (Chapter 4)

(1) Harmonisation of criteria for Substance Reporting Lists (SRL)

The Proactive Alliance recommends that sectors develop their own **Substances Reporting List (SRL)** to facilitate the **"Substances in Articles" reporting** in their supply chain. A SRL of this kind would merge all the relevant requirements for their sectors and products into a single substance list for reporting. The SRL would include various substances subject to disclosure and communication requirements (such as the EU REACH Candidate List) or restrictions (such as the European Union RoHS Directive, REACH Annex XVII or POP Regulation).

When developing a SRL, the Proactive Alliance recommends the following five criteria to be considered in order to allow a harmonised data exchange. These criteria are mainly built on criteria used in existing standards for substance and material reporting from the automotive, aerospace, electrical & electronic and textile sectors. Chapter 2 describes these criteria in more detail and relates to differing recommendations from the consultation phase (as documented in the annex).

[2] See https://www.proactive-alliance.info/how-we-work.

Table 2: Recommendations on substances to be reported at a glance

1 Definition of the reporting requirement	1a: Hazard-based requirements	+
	1b: Other requirements	0
2 Definition of the trigger for substance selection	2a: Legal Approach	+
	2b: Proactive Legal Approach	+
	2c: Risk Approach	+
	2d: Hazard Approach	0
	2e: Reputation Approach (if 1b selected)	0
3 Definition of the threshold	3a: Threshold by law	+
	3b: Threshold by own/external data	0
4 Definition of the geographic scope of the jurisdiction	4a: Global scope (best in class)	+
	4b: Regional scope	-
5 Definition of the scope of the SRL application	5a: Product (=article) scope	+
	5b: Production scope	0
	5c: Accessories	-
	5d: Pre- & Postproduction	-

For further explanations see Table 5, on page 6.

Companies can of course always report only in line with the regulatory requirements. The definition of the scope of "Substances in Articles" reporting is a Business to Business (B2B) agreement between manufacturers and their suppliers.

2. Harmonisation of Material Reporting Standards

The Proactive Alliance recommends improving the interoperability of material reporting standards between existing standards and industries and ensuring the compatibility with FMD reporting.

Table 3: Recommendations on harmonisation of Material Reporting Standards

Improvement of existing standards	Improve existing standards in terms of interoperability between standards and industries
Development perspective	Ensure any standard is compatible with Full Material Declaration (FMD) reporting and supports the Regulatory Compliance Declaration (RCD) promoting the cross participation of experts from different industries while respecting justified claims to keep business information confidential (CBI).

Further arguments in support of these recommendations can be found in Chapter 3.

3. Cooperation at a global level

The Proactive Alliance recommends the development of a shared roadmap with intermediate targets to reach a joint vision. A joint vision could cover the following aspects (see Chapter 4):

Table 4: Recommendations for aspects to integrate in a joint vision

Governance and creation of standards	The reporting obligations must ensure that the regulatory requirements are met. In cases where the technical solutions fall short of the statutory reporting requirements, business stakeholders are confronted with additional communication burdens.
Simple processes	Put in place simple processes in operations for supporting the "Substances in Articles" obligations with low costs for Small and Medium-sized Businesses/Enterprises (SMB/SME)
System-to-system data exchanges	Promote system-to-system data exchanges for requesting and collecting the product material declarations in the supply chain, including consideration of cross-sector exchanges. Systems would allow an increase in data checks and improve final data quality.
Include authorities	Include authorities like the ECHA (Europe) in order to ensure that authorities at least recognise and in future use the same data exchange formats as the industry for publishing their reference data and collecting their product data.

Procedural remark

The draft version of this document was shared for internal review between June 2020 and September 2020 with the participants in the Proactive Alliance processes. A consolidated draft was subject to public consultation in November and December 2020 by means of the website of the Proactive Alliance and a webinar thankfully hosted by Chemical Watch at the 8th of December.

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The Proactive Alliance now publishes the discussion paper with its "technical recommendations" with the intention to initiate global uptake.

2 Harmonisation of criteria for Substance Reporting Lists (SRL)

Substance Reporting Lists may have different purposes which can range from the banning of substances in individual companies or sectors to facilitation of a reporting scheme of substances in articles (SiA) or even in the complete value chain, including the production processes. The scope of the SRL is intended to facilitate reporting of the industrial substance usage (i.e. in articles and/or in the production process) and thus exceeds the purpose of a restricted substance list which only lists prohibited/restricted substances.

In order to facilitate the protection of confidential business information (CBI), insofar as confidentiality is justified, and at the same time to collect all the necessary substance information throughout the supply chain, the SRL shall contain only the necessary substance entries – subject to the criteria set out below.

The purpose of a sectoral SRL is efficient chemical compliance management while protecting justified confidential business information. It provides several main benefits:

- Communication of business requirements/specifications along the supply chain
- Stipulation of proactive substance substitutions if required by regulations
- Avoidance of substitution
- Collection of information to perform risk/impact assessments of substances in products

The Proactive Alliance aims to harmonise the criteria on which SRLs are built while acknowledging that it may not be possible to achieve a single list for all industries. The following sections therefore provide recommendations for industry sectors to compile an SRL. The more sectors and companies within an industry sector are able to harmonise their specific SRLs, the less effort is required in their common supply chain when reporting and declaring against the SRL. This will ideally result in one SRL per industry sector.

All the recommendations in this guidance are based on the experience of the PA experts.

IMPORTANT: These recommendations do not require the development of a unique global substances reporting list (SRL): each sectoral SRL will remain the responsibility of its sector. As maintaining a sectoral SRL of this type represents a huge cost, sectors could collaborate in sharing some activities such as screening updates to regulations, and establish a master list that each sector could filter for their specific usage.

2.1 Definition of Substance Reporting List (SRL) criteria

When developing an SRL, the PA recommends consideration of the following five criteria to allow harmonised data exchange. These criteria are mainly built on criteria used in existing standards for substance and material reporting from the automotive, aerospace, electrical & electronic, and textile sectors.

Keeping in mind the overall goal of harmonising substance reporting and to increase efficiency, an SRL should not be developed by an individual company but by a whole industry sector.

Criterion 1: Definition of the reporting requirement
Criterion 2: Definition of the trigger for substance selection
Criterion 3: Definition of the threshold
Criterion 4: Definition of the geographic jurisdiction
Criterion 5: Definition of the scope of the SRL application

Each criterion is further specified by several options. For details, see the description in Appendix 5.1

2.2 Assessment of Substance Lists

In order to validate the relevance of the criteria and to check how far existing sectoral standards have already been harmonised, PA participants examined the extent to which these criteria are already used in sector-specific substance reporting lists.

There are already some significant signs of harmonisation but there are also obvious differences. The analysis did not examine a specific standard in a sector but instead examined the application of the criteria in existing SRLs for the automotive, textile, electronics & electrical, and aerospace and medical industries.

The assessment showed that harmonisation exists for all the criteria that the Proactive Alliance designates as "generally recommended" (Chapter 2.3). This means that each sector has substance reporting lists that are based on criteria evaluated by the PA as "generally recommended".

Divergences exist for criteria which the PA has assessed as "could be considered" or as "generally not recommended". As an example, for criterion 2 (definition of the trigger for substance selection), the PA assessed option 2d (the hazard approach) as "could be considered". While the automotive, textile and electronic & electrical sector standards do not require reporting of this criteria, it is part of substance reporting lists in the medical sector and aerospace industry. Moreover, the PA does not generally recommend applying the accessories approach (criteria 5c) as the scope of the SRL application, although this approach exists in substance reporting lists belonging to the textile, electronics & electrical and aerospace industries.

2.3 Recommendations for future sectoral Substance Reporting Lists (SRL)

The PA recommends referring to each identified criterion during the development of an SRL. However, including each individual option belonging to a criterion is not considered to give added value. The PA therefore assessed the options of each criterion against the SRL's main purpose – supporting a reporting on substances in articles. The group is now able to specify a selection of criteria, recommended as a basis for SRL development. The assessment and recommendations are based on experience, consider the pros and cons of the different options in terms of compliance and SRL maintenance and flexibility, and reflect on the industry perspective. A detailed description of the criteria is given in Appendix 5.1.

These recommendations serve as guidance for decision-making. Deviations from these recommendations might become necessary, depending on the individual case.

Recommendations follow a three-tier scheme:

Table 5: Three-tier scheme to assess the options for the substances to be reported

+	This option is generally **recommended**
0	This option could be **considered**, depending on the sector's specific situation as well as on the desired usage / purpose of the SRL. In such a case, it is highly recommended to assess the related plus and minus implications of this option carefully prior to final implementation.
-	This option is generally **NOT recommended**

Table 6 shows the criteria and recommendations. Appendix 5.1 gives further explanations about the recommendations.

Table 6: Summary of recommendations on substances to be reported

Criterion	Option	Description	Rec.
1. Definition of the reporting requirement	**a: Hazard based requirements**	Only those substances that fulfil the criterion of being "hazardous substances"[1] are included (refers to the respective "triggers" described in criterion 2a-d).	**+**
	b: Other requirements	Substances are added because of other reporting requirements (e.g. rare earth, conflict minerals, recycling, responsible/sustainable sourcing, etc.)	**0**
2. Definition of the trigger for substance selection/addition/inclusion	**a: Legal approach**	Is the substance regulated[2] globally/regionally (→4) by a governmental agency or authority as a "hazardous substance"[1]? E.g., EU REACH Candidate List (SVHC), California Prop65, China REACH, EU RoHS & China RoHS.	**+**
	b: Proactive legal approach	Is the substance projected to be regulated[3] globally / regionally (→4) by a governmental agency or authority as a "hazardous substance"[5]?	**+**
	c: Risk approach	Is the substance associated with a hazard[4] to human health or the environment, and could its presence in a material or part in an assembly create a significant risk[5] to human health or the environment?	**+**
	d: Hazard approach	Is the substance associated with a hazard[4] to human health or the environment (without currently being covered by 2a-c)?	**0**
	e: Reputation approach	Is the substance not "hazardous" but associated with a significant public discussion which might endanger a company/sector reputation (applicable only if 1b selected)	**0**
3. Definition of the threshold	**a: Threshold by law**	Threshold levels will be based on the global/regional levels required by regulation. The same substance could require different obligations (e.g. thresholds) → Multiple entries/parameters per substance (→4)	**+**
	b: Threshold by own/external data	Threshold levels will be reasonably required by scientific evaluation of own/external data. The same substance could have different requirements (e.g. thresholds) → Multiple entries/parameters per substance (→4)	**0**
4. Definition of the geographic scope of the jurisdiction	**a: Global scope (Best in Class)**	If a substance is regulated differently in individual regions, it results in one SRL entry following the most stringent requirement that is globally applicable.	**+**
	b: Regional scope	If a substance is regulated differently in individual regions, it results in several SRL entries for each individual requirement.	**-**

5. Definition of the scope of the SRL application	**a: Product (=Article) scope**	The substance is expected to be present in a material of an article (incl. spare parts).	**+**
	b: Production scope	The substance is expected to be used in the production processes (non-dimensionals) including the after-sales chemicals (spare-parts).	**0**
	c: Accessories	The substance is expected to be present in brand accessories and related products.	**-**
	d: Pre- & post-production	The substance is expected to be present in mixtures used in the pre- or post-production process outside the core business (e.g. cleaning, office supplies, etc.).	**-**

1 Hazardous substances refers to "substances with properties that are harmful for humans or the environment" (cf. https://echa-term.echa.europa.eu/).

2 Regulated: any requirement on substance restrictions OR on reporting/labelling of substances.
Other types of substance regulations are not relevant (e.g. inventories, registrations, etc.)

3 Projected to be regulated: any official indication of a legal action for a regulated substance (e.g. ECHA PACT, EU RMOA, Registry of intentions for a SVHC/Restriction, Draft legislation, etc.)

4 A hazard means a "property or set of properties that make a substance dangerous" (cf. https://echa-term.echa.europa.eu/).

5 Risk means the "probability that some adverse effect (e.g. skin irritation or cancer) will result from a given exposure to a chemical. The risk posed by a substance depends both on the intrinsic properties of the substance (hazard) and of exposure". (cf. https://echa-term.echa.europa.eu/)

Standard Development Organisations and sector groups are now invited to consider these recommendations in standard stetting activities. The Proactive Alliance has already collected l feedback regarding the recommendations provided by international organisations (see Appendix 5.8.1).

3 Harmonisation of Material Reporting Standards

The second PA approach works towards interoperability between reporting formats by agreeing on a common language and elements. The ultimate aim is to achieve seamless interoperability between different standards and tools.

3.1 Definition of Terms & Scope

The Proactive Alliance analysed the following ways of declaring substance information in products:

- Negative declaration based on any kind of Substance Lists: RSL, DSL (in this document all referred to as Substances Reporting List (SRL))
- Mix of positive (based on allowed substances) & negative declarations (based on regulated or restricted substances)
- Full material declarations based on CAS/EC number or other unique identifiers (biocides?).

Additional information could be provided with the above declaration types, e.g. related to the functionality of a substance. The Proactive Alliance only deals with declarations between trading partners, within proprietary supply chains and taking account of CBI where necessary.

3.2 Business needs for Material Reporting Standards

The PA identified the following business needs related to existing Material Reporting Standards:

1. **A Material Reporting Standard needs to be able to handle all types of statements/information levels**

A cross-industry Material Reporting Standard has to be able to deal with specific formalised declarations like, for example, those explained in Chapter 3.3. This means that a particular piece of declaration information has to be clearly linked to a material and to a list of substances, whether it is a compliance statement (e.g. for the latest version of the EU REACH Candidate List) or a partial or full material declaration. It should be possible to make updates and changes to statements in a reliable way without losing the historical information.

2. **A Material Reporting Standard needs to be able to support data collection for regulatory requirements applicable to all the industries involved**
   In order to ensure the relevance of material data it has to relate to the horizontal term "article" as defined under EU REACH (see also the CJEU judgement of September 2015) and additionally support the legal terminology in specific legislation (e.g. "homogeneous material" in accordance with EU RoHS). In conclusion, the granularity of a declaration needs to support the applicable regulations.
3. **A Material Reporting Standard needs to refer to unique identifiers (substance lists/CAS numbers)**
   It is a crucial requirement that the substances mentioned in a partial or full Material Declaration are linked to a unique identifier, ideally always the CAS number. If there is no clear identification parameter available (no CAS number), another unambiguous identifier has to be provided (e.g. IUPAC or CAS name for substances of unknown or variable composition, complex reaction products or biological materials, known as UVCBs).
4. **A Material Reporting Standard needs to be "future-proof"**
   Future viability of a Material Reporting Standard is enabled by modular approaches that facilitate the update of individual RSLs within the standard. Modular approaches in the Material Reporting Standard provide benefits to manufacturers and suppliers:
   - Different regulations have different legal obligations and require different actions. For example, the REACH Candidate List is a disclosure requirement – information must be communicated if substances are present at more than 0.1% weight by weight of any article. The RoHS and POP regulations and REACH Annex XVII entail restrictions: substances must not be present above certain thresholds unless the material application is covered by a specific exemption.
   - Manufacturers (particularly smaller companies) can start by asking their suppliers to provide material declarations for selected regulations, for example RoHS and the REACH Candidate List.
   - Listing the substances which are included in each regulation enables the supplier to reuse their modular declarations to respond to different requirements from different customers.
   - Modular approaches in the Material Reporting Standard enable suppliers to specify that they are reporting against the latest version of a particular list. An example is the EU REACH Candidate List which is updated every 6 months.

In addition, a standard should be able to support requirements from the (strictest) regulations in a given sector, subject to the SRL criteria developed in Chapter 2. Moreover, a future-proof standard should support reporting of substance categories, article categories and material categories to allow collection of sufficient information for compliance assessments against changing regulatory requirements (such as the EU REACH Candidate List) and to avoid having to update declarations frequently. In this respect a full material declaration (FMD) avoids the need to involve the stakeholders in the entire supply chain when new regulatory obligations or contractual requirements are put in place (see following section).

3.3 Existing Materials and Substance Data Exchange Standards

Industry is committed to disclosing environmental, health and safety information to enable the safe management of chemicals, while respecting justified confidential business information. Manufacturers invest time and effort to collect full material declarations (FMD) from their suppliers. Once they have the FMD data, manufacturers do not need to chase suppliers to provide new compliance declarations every six months when the REACH Candidate list and other regulatory lists are updated. Instead, the manufacturer's IT system can use the materials and substance information in the FMD to calculate compliance against the substance categories in any declarable substances list (GADSL, RoHS, REACH, etc.), both now and in the future, and report them in a compliance declaration. With an interoperability of reporting formats approach in mind, the PA agreed not to create a new standard but to build on existing standards and consider enhancing these where required, e.g. if they show gaps, to produce a harmonised global cross-sector approach. In Autumn 2020, four main standards established by different sectors are used for exchanging data on materials and substances for products in the supply chain (B2B – business to business communication). These standards cover data for automotive, electronics & electrical, and the aerospace and defence industry. The details are provided in Appendix 5.2.

3.4 Brief on Tools

In their mission statement the Proactive Alliance defined that they will focus on standards and not recommend any tools. It is nevertheless interesting to take note of two tools and their formats: the Japanese JAMP chemSHERPA cross-sector initiative which works towards a similar mission as the Proactive Alliance (see section 5.3 in the appendix); and the European SCIP database and their IUCLID format.

JAMP and JGPSSI have merged their tools into a single one, the chemSHERPA tool (stand-alone tool). It supports both composition and compliance declarations based on the IEC 62474 standard. Version 2.0 of this tool was released in October 2019; a new version 2.02 also released in October 2020 to support the SCIP database.

The SCIP database put in place by the European Chemical Agency (ECHA) in 2020 to support the Waste Framework Directive (May 2018) and its Article 9 that has amended the EU REACH Regulation and its Article 33. Manufacturers and importers now have to notify ECHA when their products contain Substances of Very High Concern (SVHC) from the EU REACH Candidate List at more than 0.1% weight by weight in their smallest article. The ECHA SCIP database contains only product notifications on the presence of SVHC against EU REACH article 33. This database cannot be used by companies in business to business (B2B) mode as a repository for their "Substances in Articles" (SiA) data exchange against other regulations or industry standards. The ECHA has decided to use the IUCLID format for the SCIP notification dossier. This is a complex format. Industry standards such as IPC-1752, IEC 62474 and IPC-1754 are not recognised by the ECHA for submitting SCIP dossiers to the SCIP database.

3.5 Recommendations for harmonising reporting standards

The Proactive Alliance identified several ongoing processes that have led to the decision not to develop a new reporting "standard", as industry-specific standards exist for a number of reasons and will continue to evolve:

1. The automotive industry uses a designated tool (IMDS) which is based on a proprietary format.

2. IPC 1752A and IEC-62474 Edition 2 are already quite well aligned, a translator tool is available and interoperability has been achieved.
3. IPC1752B has been published to support new ECHA SCIP reporting and new automotive requirements now that IMDS Recommendation 019 has been deactivated.
4. IPC 1754 1.0 amendment 1 is partly aligned with the above, and specific features go further (process chemicals). It was updated to amendment 2 in March 2020 to support the new SCIP database mandatory data requirements.
5. This IEC 62474 standard was updated in March 2020 to work with any Declarable Substance Lists (DSL), and also supports the new data requirement of the SCIP database.
6. The Joint Article Management Promotion-consortium (JAMP) is promoting its multisector chemSherpa tool for substance reporting in articles and chemicals, which is compatible with the IEC 62474 standard.
7. There is limited public information on the formats and standards used in other industries.

The Proactive Alliance agreed that a realistic first step towards improving the existing standards is to help ensure their interoperability. With a view to gains in efficiency and effectiveness and from a development perspective, the group recommends ensuring that any standard is compatible with an FMD and Regulatory Compliance (RCD) reporting. This harmonisation can probably best be achieved by ensuring the participation of experts from different industries.

4 Cooperation at a global level

The Proactive Alliance has been set up in Europe as a starting point, but the purpose of this initiative is to connect with other similar ones (see Appendix 5.3) and their organisations to reach shared targets. Moving forward to the same medium- and long-terms targets is key to the Proactive Alliance's future vision: reducing the burden of complying with regulations on hazardous substances and creating values. This would require all those initiatives and their stakeholders to synchronise their activities and work together.

This would only be possible if the vision is shared and the targets are established collectively and adopted by most of the stakeholders.

4.1 Proposed Vision

The vision is to reduce the burden related to material related communication efforts with regard to "Substances in Articles" for product manufacturers and importers and instead create business values and a wide range of benefits for all supply chain actors (see Table 1 on Page 1). This can be achieved via a number of objectives (summarised in Figure 1):

- Ensure that any standard is compatible with FMD reporting with a view to gain in efficiency and effectiveness but also supports RCD for just regulatory obligations.
- Emphasise the role of business stakeholders in governance and the creation of standards. As standards are perceived as being "technical", the task of analysis of the business challenge and the proposal of possible standards is frequently shifted to the solution providers (software, database, cloud system etc.) and their experts. In cases where the technical solutions fall short of the reporting requirements stipulated by law, the business stakeholders are faced with additional communication difficulties.

- Put in place simple processes in operations to support the SiA obligations with low costs for small- and medium-sized businesses/enterprises (SMB/SME): e.g. web service companies could subscribe to be informed when SRL and their reference data (exemptions, applications, etc.) are due to change. SRL formats would need to be aligned (Excel and XML) to facilitate exchange and automatic updates.
- Promote system-to-system data exchanges for requesting and collecting the product material declarations in the supply chain. By including cross-sector exchanges, systems would be able to increase the data checks and improve the final data quality.
- Include authorities like the ECHA in order to ensure that authorities publish, notify and adopt the same data exchange formats as the industry when publishing their reference data and collecting their product data.

Figure 1: Objectives to achieve business values

The proposed vision is that most of the activities to support the intended benefits would be performed automatically by ICT (Information & Communication Technology) systems for large companies and only a few of them would remain manual or semi-automatic activities: data checks in special cases, escalation process from requester to supplier when no data are provided by the suppliers or only poor data is available etc.

See appendix 5.4 for an example scenario with an EU REACH Candidate List update for a company to update their IT System and their compliance status for the EU REACH Regulation and its Article 33.

4.2 Roadmaps

In addition to the recommendations given in Chapters 2 and 3, the PA proposes two roadmaps for future developments. Details are given in Appendix 5.5.

5 Appendices

The discussion paper is accompanied by a set of appendices providing context information.

5.1 Reporting criteria description and recommendations

In the following, the reporting criteria and options as well as recommendations mentioned in Chapter 2 are explained in detail.

5.1.1 Criterion 1: Definition of the reporting requirement

The underlying question of Criterion 1 is: *"What is the background of the reporting requirement? Do you want to track hazardous substances only, or do you want to go beyond these substances?"*

5.1.1.1 Overview:

This criterion determines the purpose for a reporting list. Sectors can report hazard-based requirements and/or other requirements.

1 Definition of the reporting requirement	1a: Hazard-based requirements
	1b: Other requirements

Criterion 1a: Hazard-based requirements. Only those substances that fulfil the criterion of being "hazardous substances" are included (refers to the respective "triggers" described in criterion 2a-d).

Criterion 1b: Other requirements. Substances are added because of other (non-hazardous substance-related) reporting requirements, e.g. rare earth, conflict minerals, recycling, responsible/sustainable sourcing, etc. This option covers information needs from the entire value chain including waste operators (e.g. information on substances that cause problems in the recycling process [carbon fibres, copper, etc.], or claims about responsible sourcing of conflict minerals).

5.1.1.2 Recommendations for criterion 1: Definition of the reporting requirement

Generally recommended options for Criterion 1

The PA recommends taking the ***hazard based requirement (only) (Criterion 1a)*** as the default setting for developing an SRL, i.e. only substances that are defined or projected to be defined as being hazardous to human health or the environment should be included (see Criterion 2). High level of acceptance in industry. A high acceptance rate from industry can be expected because management decisions are mainly triggered by legislation and legal measures are likely to be accepted by full global supply chains.

Options to consider for criterion 1

As an alternative or additional criterion to Criterion 1a for defining the reporting requirement, ***other requirements (criterion 1b)*** might be chosen. In this case, substances are added because of other (non-hazardous substance-related) reporting requirements. These can relate to e.g. rare earths, conflict minerals, other issues concerning responsible/sustainable sourcing, and to information needs from waste operators (e.g. information on substances that cause difficulties in the recycling process [carbon fibres, etc.]). In terms of the overall reputation of an industry or company, this holistic approach might be beneficial as it is able to report on substances in the complete value chain. As regulation for other (not related to hazardous substances) reporting requirements is currently not as harmonized as regulation for SoC, SiA reporting (criterion 1a) might serve as pilot case, which can be further developed with additional non-hazardous substance-related reporting requirements. The PA recommends this

option as one to consider. On the one hand it increases the size of the SRL and at the same time may complicate the protection of CBIs but on the other it allows information to be requested and reduces communication loops with suppliers. Depending on the outcome of the Substance of Concern definition, the industry may (have to) accept this option at the interface of chemicals, products and waste.

Criterion	Option	Description	Rec.
1. Definition of the reporting requirement	**A: Hazard based requirements**	Only those substances that fulfil the criterion of being "hazardous substances"[1] are included (refers to the respective "triggers" described in criterion 2).	+
	B: Other requirements	Substances are added because of other reporting requirements (e.g. rare earth, conflict minerals, recycling, responsible/sustainable sourcing, etc.)	0

1 Hazardous substances refers to "substances with properties that are harmful for humans or the environment" (cf. https://echa-term.echa.europa.eu/).

5.1.2 Criterion 2: Definition of the trigger for substance selection

This criterion prompts an answer to the question *"What is the trigger to select/choose a substance for the SRL?"*

5.1.2.1 Overview

In most cases, this trigger derives from a legal regulation (Criterion 2a). The trigger to include a substance on the list can also originate from approaches going beyond legal requirements (Criterion 2b-e). The PA therefore selected five options of relevance for Criterion 2.

2 Definition of the trigger for substance selection	2a: Legal approach
	2b: Proactive legal approach
	2c: Risk approach
	2d: Hazard approach
	2e: Reputation approach

Criterion 2a: Legal approach. Is the substance regulated globally and or regionally by a governmental agency or authority? Whenever legislators in any relevant market have regulated a relevant substance, the substance(s) in question may be added to the SRL.

Criterion 2b: Proactive legal approach. Is the substance projected to be regulated globally and or regionally by a governmental agency or authority? Whenever legislators in any relevant market officially start discussions about a relevant substance obligation, the substance(s) in question may be added to the SRL.

Criterion 2c: Risk approach. Is the substance associated with a hazard to human health and/or the environment, and does its presence in a material or part in an assembly create a significant risk to human health and/or the environment? Besides general producer responsibilities, there is not necessarily a legal substance specific requirement (yet). However, based on an internal or external risk

assessments, the substance is likely to cause a risk to human health or the environment and therefore may be added to the SRL.

Criterion 2d: Hazard approach: Is the substance associated with a hazard to human health and/or the environment? Based on an internal or external hazard assessment, the substance is likely to be hazardous to human health or the environment and therefore is added to the SRL. There is not necessarily a legal requirement, the risk of the substance is not proven and there is no foreseeable future legal requirement. Understanding the hazard of a substance is a prerequisite for a risk assessment but does not necessarily require the substance to be added to an SRL.

Criterion 2e: Reputation approach. Is the substance associated with a significant public discussion which might endanger the reputation of a company/sector and is it not already covered by Criterion 2a? Substances that are associated with a significant public discussion may be added to the SRL even if not considered hazardous. This approach is often used in competition between companies within the same sector to improve their public image.

5.1.2.2 Recommendations for Criterion 2: Substance selection

Generally recommended options for Criterion 2

Based on the main purpose of an SRL of ensuring compliance with the legislation, the group generally recommends always taking the ***legal approach (Criterion 2a)*** as a basis for substance inclusion.

The legal approach meets with high acceptance from industry due to the fact that management decisions are also mainly triggered by legislation and legal measures are very likely to be accepted by full global supply chains.

However, applying the legal approach, i.e. looking solely at current legislation, reduces planning certainty. Subsequently, once a substance becomes legally regulated, efforts for substitution/advocacy will increase while slowing down data collection. These adaption difficulties may endanger future compliance.

The PA therefore recommends choosing additional triggers for substance inclusion. These may be the ***proactive legal approach (Criterion 2b)*** or the ***risk approach (Criterion 2c)*** which are both generally recommended by the PA.

Applying the proactive legal approach as well as the risk approach increases planning certainty by either looking at upcoming legislation or by conducting internal risk assessments and looking at risk substances. Being ahead of legally binding decisions reduces the effort of substitution/advocacy once a legal requirement is officially in place. Data collection is speeded up and compliance ensured. However, this forward-looking approach of considering upcoming legislation involves a risk that substances may be de-listed from the SRL if the regulatory process concludes with no legal action. On the other hand, an internal risk assessment can be very costly and require a high level of expertise, and suppliers' risk assessments must be fully reliable and transparent.

Nevertheless, both options ensure a very proactive character and a high acceptance rate from industry can be expected.

Options to consider for Criterion 2

The ***hazard approach (Criterion 2d)*** is the most proactive and stringent approach, when following the strategy of banning harmful substances from materials. Due to its forward-looking character, planning certainty can be increased, while efforts for substitution/advocacy are reduced. Data collection is speeded up and compliance ensured. However, it is very likely to generate unnecessary effort and to increase the size of the SRL, which complicates maintenance and the protection of confidential business

information. The approach is therefore unlikely to be accepted by industry, mainly due to CBI concerns and the amount of effort to generate and maintain the SRL.

The ***reputation approach (Criterion 2e)*** is assessed as "could be considered". For companies competing in the same sector in particular, this approach provides the possibility of including individual substances (e.g. as a USP) which might improve the company reputation. A high acceptance rate from industry can therefore be expected. However, the reputation approach might lead to company-specific substance additions to the sectoral list. This approach therefore works against the sectoral harmonisation of SRLs and would subsequently generate additional efforts within the supply chain.

Criterion	Option	Description	Rec.
2. Definition of the trigger for substance selection/addition/inclusion	**a: Legal approach**	Is the substance regulated[2] globally/regionally (→4) by a governmental agency or authority as a "hazardous substance"[1]? E.g., EU REACH Candidate List (SVHC), California Prop65, China REACH, EU RoHS & China RoHS.	+
	b: Proactive legal approach	Is the substance projected to be regulated[3] globally / regionally (→4) by a governmental agency or authority as a "hazardous substance"[5]?	+
	c: Risk approach	Is the substance associated with a hazard[4] to human health or the environment, and could its presence in a material or part in an assembly create a significant risk[5] to human health or the environment?	+
	d: Hazard approach	Is the substance associated with a hazard[4] to human health or the environment (without currently being covered by 2a-c)?	0
	e: Reputation approach	Is the substance not hazardous but associated with a significant public discussion which might endanger a company/sector reputation (applicable if 1b selected)?	0

1 Hazardous substances refers to "substances with properties that are harmful for humans or the environment" (cf. https://echa-term.echa.europa.eu/).

2 Regulated: any requirement on substance restrictions OR on reporting/labelling of substances.
Other types of substance regulations are not relevant (e.g. inventories, registrations, etc.).

3 Projected to be regulated: any official indication of a legal action for a regulated substance (e.g. ECHA PACT, EU RMOA, Registry of intentions for a SVHC/Restriction, Draft legislation, etc.).

4 A hazard means a "property or set of properties that make a substance dangerous" (cf. https://echa-term.echa.europa.eu/).

5 Risk means the "probability that some adverse effect (e.g. skin irritation or cancer) will result from a given exposure to a chemical. The risk posed by a substance depends both on the intrinsic properties of the substance (hazard) and of exposure" (cf. https://echa-term.echa.europa.eu/).

5.1.3 Criterion 3: Definition of the threshold

Criterion 3 deals with the thresholds that determine when to report the presence of a substance. The question that should be answered in this case is: *What is the threshold? When defining a reporting threshold, would you like to follow the law or other more stringent sources?*

5.1.3.1 Overview

Thresholds may derive from legal requirements (Criterion 3a) or from one's own or external data (Criterion 3b). The SRL might disclose multiple parameters per substance, depending on the approach.

3 Definition of the threshold	3a: Threshold set by law
	3b: Threshold set by own/external data

Criterion 3a: Threshold set by law. Threshold levels will be based on the global and/or regional levels required by regulation. The same substance could require different obligations (e.g. thresholds), which could result in multiple entries/parameters per substance. Only those thresholds resulting from legal requirements are considered.

Criterion 3b: Threshold set by own/external data. Threshold levels will be reasonably required by the scientific evaluation of one's own/external data. The same substance could have different requirements (e.g. thresholds), which could result in multiple entries/parameters per substance. In cases where legal thresholds are missing or where alternative data is available, other/more stringent thresholds are considered. This option mainly results from option 2d (hazard approach).

5.1.3.2 Recommendations for Criterion 3: Definition of the threshold

Generally recommended options for Criterion 3

When defining threshold levels above which a substance present in an article has to be reported, the PA recommends basing this on ***thresholds set by law (Criterion 3a)***. Even though this approach might be a less proactive approach, it ensures compliance and is easy to enforce in supply chains due to its legal foundation. A high acceptance rate from industry can therefore be expected because management decisions are mainly triggered by legislation. However, this option can result in multiple entries and parameters for one substance, since threshold levels in different geographical regions may differ. In order to keep operation costs for maintaining the SRL low, the PA recommend choosing Criterion 3a along with Criterion 4a.

Options to consider for Criterion 3

Another option for determining thresholds is to rely on ***scientific evaluation of one's own or external data***. This option can be considered in the case that legal thresholds are missing or alternative (more stringent) data is available. It mainly results from option 2d (hazard approach) and is regarded as a very proactive approach as it is not rooted in legal requirements. Companies choosing this option have the possibility of setting individual thresholds (e.g. as a USP) and the approach is highly applicable for self-promotion. Nevertheless, this requires a high level of market power to reach acceptance in the supply chain, mainly due to CBI concerns and the large effort to generate and maintain the SRL. It is therefore unlikely to be accepted by the entire industry.

Criterion	Option	Description	Rec.
3. Definition of the threshold	**a: Threshold by law**	Threshold levels will be based on the global/regional levels required by regulation. The same substance could require different obligations (e.g. thresholds) → Multiple entries/parameters per substance (→4)	+
	b: Threshold by own/external data	Threshold levels will be reasonably required by scientific evaluation of own/external data. The same substance could have different requirements (e.g. thresholds) → Multiple entries/parameters per substance (→4)	0

5.1.4 Criterion 4: Definition of the geographical scope of the jurisdiction

Criterion 4 encourages the definition of a geographical scope. This gives rise to the following main question:

What is the scope of the jurisdiction? Do you mind having one or multiple entries for one substance? Or do you prefer having one entry for one substance, following the most stringent requirement/obligation?

5.1.4.1 Overview

This criterion is decisive for the size and complexity of the SRL. Depending on the approach, the SRL will contain one or multiple entries per substance.

4 Definition of the geographical scope of the jurisdiction	4a: Global scope (Best in Class)
	4b: Regional scope

Criterion 4a: Global scope. If different regions stipulate diverging regulations for the same substance, this still results in one SRL entry reflecting, for example, the most stringent regional requirement. The most stringent requirement may be the lowest threshold or a combination of several parameters (e.g. differentiating use bans combined with thresholds). This entry then applies globally, i.e. without individual entries/parameters for the regions. This option may be applied mainly to companies/industries that are operating globally and want to reduce efforts due to inconsistent regional reporting requirements.

Criterion 4b: Regional scope. If a substance is regulated differently in individual regions, it results in several SRL entries per substance based on individual requirement for the regions. This option may be applied mainly to companies/industries that only operate regionally.

5.1.4.2 Recommendations for Criterion 4: Definition of the geographical scope of the jurisdiction

A large number of companies operate in more than one country. These companies might be faced with the challenge of differing obligations and legal thresholds. If each legal requirement is included in the SRL it becomes longer and managing it more complicated.

Generally recommended option for Criterion 4

The PA recommends following the ***global scope (criterion 4a)***. In this case, regions with the most stringent obligation may set the standard. Opting for the global scope has a very proactive character as it increases planning certainty, reduces the effort for substitution/advocacy, speeds up data collection and ensures long-term compliance. The substance inclusion in the SRL is applicable globally. Consequently, there are no different entries/parameters for regions with their own obligations. Having only one entry per substance makes the SRL easier to manage and maintain and also reduces the effort for substance reporting. This option is recommended mainly for companies/industries that are operating globally and want to reduce the effort linked to different regional reporting requirements.

However, this approach probably causes more effort for the supply chain to meet more specific and detailed requirements (although not legally mandatory). In the case of a regional substance prohibition, this option necessitates the substitution of the substance in all regions and thus creates greater effort. Reaching acceptance within the industry or company might therefore be more challenging, however several large industries are already using this approach, which is therefore likely to be accepted by individual companies or industries.

Generally not recommended option for Criterion 4

The PA advises against following the **regional scope (Criterion 4b)**. For globally operating companies in particular, this option increases the effort for substance reporting, as it results in several SRL entries per substance for each individual regional requirement. The SRL is less clear due to multiple entries for one substance, which creates uncertainty about the completeness of reporting requirements for a specific substance. The regional scope requires increased effort to keep the SRL updated, especially in the case of changes to any regional requirement. This option is not likely to be accepted by individual companies or industries, mainly in order to limit effort and thus costs in the supply chain.

Exceptional cases may exist, for example for companies/industries that only operate regionally. In this case this approach creates less effort for the supply chain to meet regional substance regulation requirements.

Criterion	Option	Description	Rec.
4. Definition of the geographic scope of the jurisdiction	**a: Global scope (Best in Class)**	If a substance is regulated differently in individual regions, it results in one SRL entry following the most stringent requirement that is globally applicable.	+
	b: Regional scope	If a substance is regulated differently in individual regions, it results in several SRL entries for each individual requirement.	-

5.1.5 Criterion 5: Definition of the scope of the SRL application

Criterion 5 determines the scope of the SRL application in terms of the business (processes). It prompts an answer to the question: *Which part of your business should be covered by the SRL (e.g. process chemicals and/or substances in articles and/or…)?*

5.1.5.1 Overview

While the SRL, including the threshold limits to be reported, may often refer to the finished article/product, it can likewise refer to the production process or other processes in addition to the core business.

5 Definition of the scope of the SRL application	5a: Product (=article) scope
	5b: Production scope
	5c: Accessories
	5d: Pre- & post-production

Criterion 5a: Product (=article) scope. The substance should reasonably be expected to be present in the final/cured material of an article, i.e. intentionally added or as a residual substance (e.g. cured paint without solvents). This option includes spare parts.

Criterion 5b: Production scope. The substance should be expected to be used in the production processes (non-dimensionals) including the after-sales chemicals in spare-parts. This option will require each level of the supply chain to report their process chemicals through the supply chain up to the final article manufacturer.

Criterion 5c: Accessories. The substance should be expected to be present in brand accessories and related products (probably produced by third party suppliers). This option will require suppliers from

outside the core business to fulfil the SRL requirements. The scope expands to legislations outside the core business (e.g. branded lunch box --> food contact legislation).

Criterion 5d: Pre- & post-production. The substance should be expected to be present in mixtures used in the pre- or post-production process outside the core business (e.g. cleaning, office supplies, etc.). This option will require suppliers from outside the core business to fulfil the SRL requirements. Each level of the supply chain would have to report their pre- and post-production chemicals through the supply chain up to the final article manufacturer.

5.1.5.2 Recommendations for Criterion 5: Definition of the scope of the SRL application

The SRL might get larger depending on its application scope. In order to keep the maintenance of the SRl to a manageable level, it makes senses to consider the positive and negative benefits of the following approaches.

Generally recommended for Criterion 5

The PA recommends following the ***product (=article) scope (Criterion 5a)*** including spare parts when reporting substances in articles. In this case substances are only considered if they are contained in the final/cured material of an article (e.g. cured paint without solvents). Looking only at the article scope enables the protection of CBI and reduces the effort to maintain the SRL. A high acceptance from all businesses, including the chemical industry, is expected. However, this approach is based on limited business transparency and limited substance traceability.

Options for consideration for Criterion 5

Following the ***production scope (Criterion 5b)*** requires each level of the supply chain to report their process chemicals through the supply chain up to the final article manufacturer. It thus allows greater business transparency and substance traceability and theoretically supports the avoidance of substance obsolescence. As the number of chemicals used in production processes might be a multiple of the substances remaining in the product, maintaining the SRL involves a high level of effort. Following this approach would therefore theoretically require a parallel reporting of process and product chemicals. In this case, disproportionate reporting must be avoided. In addition, transparency entails less protection of CBI and thus a very low acceptance rate is expected from all businesses and especially the chemical industry.

Not recommended options for Criterion 5

Both options, ***accessories (Criterion 5c) and pre- and post-production scope (Criterion 5d)*** also require suppliers from outside the core business to fulfil the SRL requirements. The PA advises choosing these options only in combination with Criterion 5a or 5b.

Selecting the accessories scope implies expanding the scope of the SRL to legislations outside the core business. This approach will broadly increase the scope and size of the SRL while requiring a large effort for maintenance. Due to the limited influence on and power over the non-business supply chain, achieving acceptance within the supply chain is unlikely. In addition, this approach only permits low protection of CBI.

The pre- and post-production scope behaves very similarly. Each level of the supply chain would have to report their pre- and post-production chemicals through the supply chain up to the final article manufacturer. This allows greater business transparency and substance traceability and thus theoretically supports the avoidance of substance obsolescence. However, there is almost no protection of CBI, companies have very limited influence and power over non-business supply chains and it requires a large effort to maintain the SRL.

In both cases a very low acceptance rate is expected from all businesses and especially the chemical industry.

Criterion	Option	Description	Rec.
5. Definition of the scope of the SRL application	**a: Product (=Article) scope**	The substance is expected to be present in a material of an article (incl. spare parts).	+
	b: Production scope	The substance is expected to be used in the production processes (non-dimensionals) including the after-sales chemicals (spare-parts).	0
	c: Accessories	The substance is expected to be present in brand accessories and related products.	-
	d: Pre- & post-production	The substance is expected to be present in mixtures used in the pre- or post-production process outside the core business (e.g. cleaning, office supplies, etc.).	-

5.2 Current status of existing industry standards

This informative appendix provides a brief overview of the state of play within the different standardisation processes. It does not analyse or assess the different standards in terms of the objectives and vision of the Proactive Alliance.

5.2.1 Sectoral DSL/RSL

Brief information on the existing sectoral substances lists either Declarable Substance List (DSL) or Prohibited/Restricted Substance Lists (RSL) or a mixed list:

- Automotive
  - **GADSL**: Global Automotive Declarable Substance List
  - **GLAPS**: Global List of Automotive Process Substances
- Hi-Tech & Medical Devices
  - **IEC 62474** Declarable Substances & Declarable Substance Groups List (has replaced former JIG lists), by IEC TC111
  - **COCIR:** merge of regulatory & industry lists
- Childcare Products
  - **ENPC**: merge of regulatory lists
- Railway
  - **RISL**: UNIFE Railway Industry Substances List
- Cosmetics
  - **COSING**, annex II and III
- Shipbuilding & Offshore
  - **IHM**: Inventory of Hazardous Substances for end of life of ships over 500 Gt, by IMO, Hong Kong 2009 convention
- Aerospace & Defense
  - **AD-DSL:** Aerospace & Defense Declarable Substance List

Figure 2: Overview on existing Declarable Substances List (DSL) and Restricted Substances List (RSL)

5.2.2 Electronics and Electrical

The Electronics and Electrical (EE) sector currently uses two Material Declaration standards for Products: the (1) IPC-1752 and (2) IEC 62474.

5.2.2.1 IPC-1752 Standard

The IPC-1752 standard, governed by IPC under American National Standard Institute (ANSI) procedures, was put in place in 2006 to support the EU RoHS regulation, REACH Candidate List and other regulated substances lists. IPC published the IPC-1752A format in 2010. The new IPC-1752B format was published in 2020 and is influenced by the Proactive Alliance's work since 2018. It is a public standard using an XML schema for the Material Declaration and supports composition declarations at the homogeneous material level required by the RoHS. IPC-1752B covers the article level required by REACH. It has been extended to support the EU REACH Annex XVII Substance Restrictions and any other Declarable Substance Lists (DSL), such as the IEC 62474 DSL. The standard also includes the definitions and references to various DSLs, for example various RoHS with their exemptions and query list, the EU REACH Candidate List and the EU REACH restrictions lists. IPC-1752 offers 4 classes of declarations:

Table 7: Material Declaration Classification (IPC-1752A amendment 3)

Class	Description	Declaration Type	Detailed Requirements
A	Reporting in query/reply format	Query/reply	Supplier provides responses to standard queries and/or optional custom queries.
B	Material class reporting	Material Class	Supplier states the amount of different classes of materials in a product.
C	Substance category reporting at the product level	Substance category compliance declaration	Supplier provides mass and/or concentration of substance category at the product level if above thresholds.
D	Substances reporting at the homogeneous material level	Substance composition disclosure	Supplier provides location, mass and substances at the homogeneous material level.

IPC-1752A Class C Compliance Declarations and Class A Query Statements enable reporting against maintained lists of substance categories for horizontal and vertical legislation modules, which are updated every six months along with the ECHA's updates to the REACH Candidate List.

Horizontal legislation modules

- REACH Candidate List
- REACH Annex XVII substance restrictions

Vertical legislation modules

- RoHS 0508 (six substance categories) and 1506 (four substance categories)
- IEC 62474 declarable substances list
- JIG-101 (obsolete – will not be included in IPC-1752B implementation lists)

The IPC-1752A standard is the most widely used today for material declarations in B2B communication as well as by standard component data providers. Anecdotal evidence from component manufacturers such as Texas Instruments indicates that 90% of material declaration requests from customers specify the IPC-1752 format compared to other industry standard formats.

To help companies collect the necessary information from their supply chains to report to the ECHA SCIP database, IPC developed the IPC-1752B supply chain data exchange standard. This new industry standard

is applicable to products across all industry sectors. It can be used to collect the SCIP numbers for supplier parts in IPC-1752B XML files, so that the supply chain tracking software can enable companies to reuse their suppliers' submissions when making submissions for their products. An extract from an IPC-1752B XML file reporting the SCIP number for a supplier part is provided in the figure below.

```
<IPC-1752B xmlns="http://webstds.ipc.org/175x/1752B/1752B">
  - <Sectional name="IPC-1752B">
        <SubSectional name="A"/>
        <SubSectional name="D"/>
    </Sectional>
  - <Product isArticle="true" numberOfInstances="1" unitType="Each">
      - <ProductID effectiveDate="2019-04-02" requesterItemNumber="OEMCAP123" requesterItemName="20 pf capacitor"
        itemNumber="CAP2345-20" itemName="20 pf capacitor">
            <Amount value="0.12" UOM="g"/>
          - <ArticleCategoryList>
                <ArticleCategoryListID identity="ArticleCategoryList" authority="ECHA"/>
                <ArticleCategory identity="105795" description="853211 - Electrical capacitors, fixed, variable or
                    adjustable (pre-set) > Other fixed capacitors > Tantalum"/>
            </ArticleCategoryList>
          - <SafeUseList>
                <SafeUseListID authority="Supplier"/>
                <SafeUse description="Avoid prolonged direct contact with skin during use"/>
            </SafeUseList>
            <OtherItem identity="f5716c60-d07c-415c-b4c0-c1a796eaaf04/0" authority="ECHA"/>
        </ProductID>
      - <MaterialInfo>
```

Figure 3: IPC-1752B XML file reporting the SCIP number for a supplier part

After its update, IPC-1752B standard is applicable to all products across all industry sectors and has become the most widely used standard to collect data from company supply chains for notifications to the SCIP database.

On 16 December 2020, ECHA reported that, 50 days after the launch of the SCIP database, companies across Europe have submitted a little over 2 million notifications.[3] As highlighted in the database, 97% of these notifications to the SCIP database have used the IPC-1752B standard to collect Full Materials Declarations and Regulatory Compliance Declarations from company supply chains.

You will find IPC-1752B based notifications to the SCIP database from every industry sector. The majority of these SCIP notifications, over 1.4 million notifications (74%), have been made by companies supplying mechanical products. Suppliers in the automotive industry have used IPC-1752B to prepare and submit over 420,000 SCIP notifications (22%) and suppliers in the aerospace industry have used IPC-1752B to prepare and submit over 82,000 SCIP notifications (6%). Any company in any industry sector can use IPC-1752B to exchange information with their supply chains in a format which matches the data requirements of the ECHA SCIP database. Additionally, IPC-1752B based notifications to the SCIP database have been made from companies in every EU Member State in Europe. Companies in every one of the 27 EU Member States have used the IPC-1752B standard to collect supplier declarations and prepare SCIP notifications.[4]

The IPC-1752B standard includes new functionality which enables the reporting of different products with different materials declaration classes in the same XML file. The structure of the IPC-1752B standard mirrors the ECHA SCIP database submission format and enables the supplier to use the newly re-purposed sub-products functionality to report articles in the complex object, provided that the XML file includes declarations for the sub-products.

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[3] https://echa.europa.eu/documents/10162/30160741/20201216_scip_db_growing_fast_en.pdf/aa88392f-35c0-d7ba-12f4-a08df51a876e

[4] Personal communication between PA participant and ECHA as of 16 December 2020

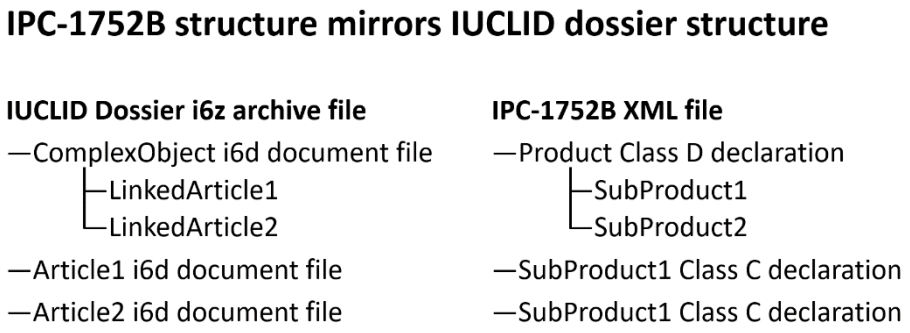

Figure 4: Comparison of IUCLID and IPC-1752B structure

Sub-products can be declared using different declaration classes which provide different levels of detail about the materials in the articles. The example is a complex object A which contains an article X which has a Class C compliance declaration, article Y which has a Class D+C partial composition declaration supported by a compliance declaration, and article Z which has a full substance disclosure. The Class D declaration for the complex object can report these articles as sub-products provided that the same XML file contains a Class C compliance declaration for article X, a Class D+C partial composition declaration supported by a compliance declaration for article Y and a Class D full substance disclosure for article Z.

IPC-1752B has also introduced a new Full Substance Disclosure field to enable companies to comply with new automotive requirements since IMDS Recommendation 019 has been deactivated in 2020. Full Substance Disclosure is defined as a Class D declaration that discloses all substances in the product and their respective masses at the homogenous material level. The isFSD (is Full Substance Declaration) field is mandatory. If the isFSD field is set to "FALSE" then a Class A declaration or Class C declaration for the substance categories within the regulatory scope of the declaration must accompany the Class D declaration. In the automotive industry a Class A declaration is not sufficient. In the automotive industry, if the FSD field is "FALSE", the supplier must provide a Class C declaration, which enumerates the specific substance categories that are present/not present.[5]

5.2.2.2 IEC 62474 Standard

The **IEC 62474 standard** was established by the International Electrotechnical Committee. Its first edition was released in 2012. Edition 2.0 was published in 2018 and is very close to the IPC-1752 revision A. IEC 62474 offers four classes of declarations which are similar to the IPC-1752 classes: Query Lists (4.6.1, similar to an IPC-1752A Class A statement), Material Class (4.5.2, similar to an IPC-1752A Class B declaration), Compliance (4.4, similar to an IPC-1752A Class C declaration) and Composition (4.5, similar to an IPC-1752A Class D declaration). These classes are declared in the standard specification (PDF document) and implemented with an XML schema (XSD file).

[5] http://www.ipc.org/ContentPage.aspx?pageid=Materials-Declaration#1752a

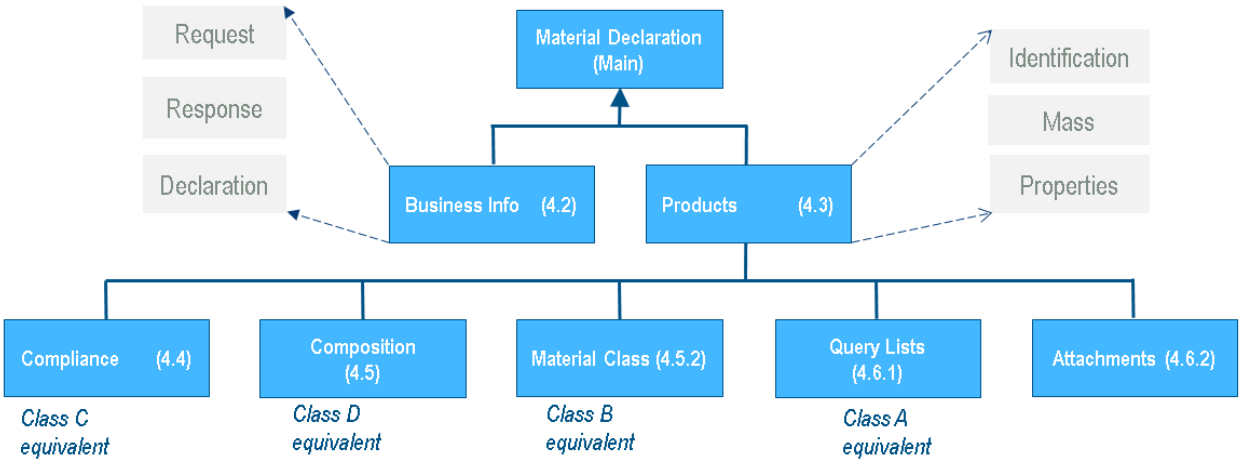

Figure 5: IEC 62474 Edition 2.0 – Conceptual Data Model

The IEC 62474 standard provides their substance list with mandatory and optional substances or substance groups to report the material declaration[6]. This standard also provides a list of reference substances belonging to the substance groups.

The IEC 62474 standard also provides their list of Material Classes to report materials in a product, similar to an IPC-1752A Class B declaration.

Recently, IEC 62474 has issued an exemptions list for RoHS.

All these data are provided in Excel format online in the IEC 62474 material declaration database[7].

Note: The Critical Raw Material (CRM) topic is not addressed by the current IEC 62474 Edition 2.0 and its 8.10 data exchange standard; it is planned to address this.

5.2.3 Automotive Industry

The automotive sector uses the **IMDS** tool with its underlying reporting **standards** to declare (almost) FMD for the products included in a vehicle when it is first put on the market. A tolerance of 10% allows the suppliers' CBI to be protected, except if substances belong to the sectoral GADSL substances list. The IMDS is a private standard used only by the automotive sector; in China another system, CAMDS, is used. Formats used to exchange data with IMDS, either as .DAT or .XML, are also private.

5.2.4 Aerospace and Defence

The Aerospace and Defence (AD) sector has developed the **IPC-1754 standard**, published in version 1.0 in 2018. This standard belongs to the IPC-175x family and has been added to address the specific needs raised by this industry:

- optional material data (AD is outside the scope of RoHS),
- focus on supporting REACH and their sectoral Aerospace and Defence Declarable Substance List (AD-DSL) as a minimum reporting requirement,
- adding reporting of process chemicals for obsolescence management per REACH authorisation & restriction.

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[6] Available online: http://std.iec.ch/iec62474

[7] http://std.iec.ch/iec62474.

The IPC-1752 and IPC-1754 standards belong to the same series and are built on the same foundation as illustrated in Figure 6. The IPC-1751 standard manages the Requester & Supplier data, the Product data, the Declaration Statement and the optional attachment files. It also manages the various sectionals supported by the different IPC-175x standards. The IPC-1755 standard for Conflict Minerals tracks the source of conflict minerals in products and so has a different structure. A modular architecture was defined in June 2019 for all sections of all IPC-175x standards to be included in a single Material Declaration (to be implemented in the next version of each standard).

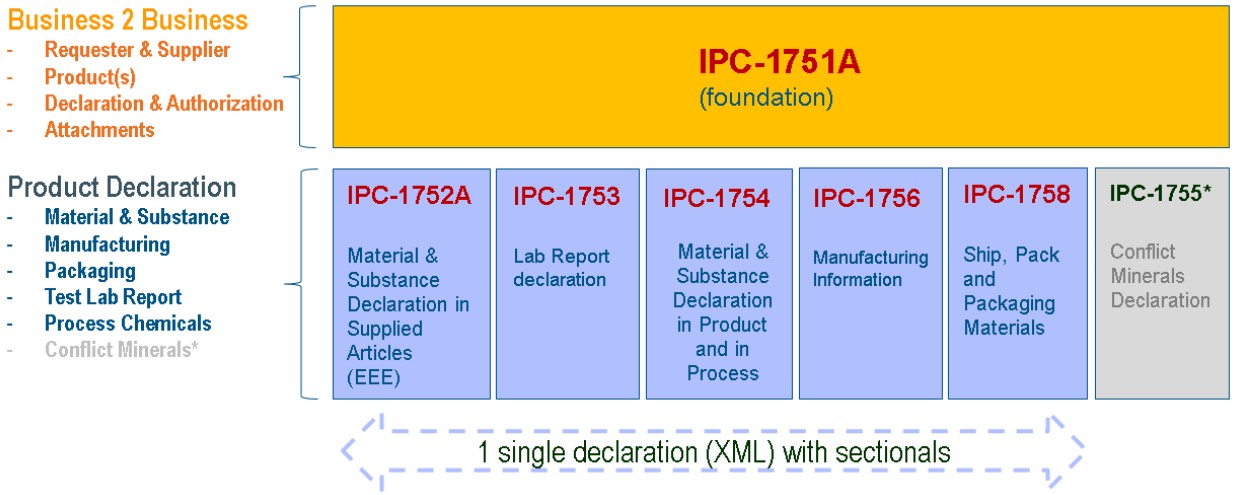


Figure 6: IPC-1751 Foundation

5.2.5 Convergence of existing standards

The IPC-1752 standard and the IEC 62474 standard have been converging for several years:

- The IPC-1752A and IEC 62474 edition 2.0 are similar to each other: they support the same concept and use cases (same four classes). However, their data models have some differences and their XML schemas are different. Most of the solution provider tools implementing the IPC-1752A standard also support the IEC 62474.
- The IPC-1752B implements the new IPC-175x modular architecture, introduces the capability to declare whether a reportable application in a Declarable Substance List (DSL) is applicable to a compliance declaration (example is nickel which is only restricted in skin contact applications), and captures the data fields necessary for reporting to the ECHA SCIP database.
- The IPC-175x series is more agile with a new minor version ("amendment") or a major version ("revision") that could be published every year. The IEC 62474 as an international standard is supposed to be stable for 5 years, even if the database might evolve more frequently, including the XML schema of the Material Declaration and all the IEC 62474 data in Excel.

The IPC-1754 standard released a first amendment at the beginning of 2019 to fix errors in version 1.0. They are currently preparing amendment 2 to include some of the missing features to support the RoHS (exemptions, substances groups). In addition, amendment 2 is trying to address the ECHA SCIP database. This new standard needs to stay stable over four to five years for its first adoption by the Aerospace and Defense sector. The heavy equipment and other industries sector has been part of this standard development for their version 1.0. This sector, represented in the USA by the Association of Equipment Manufacturers (AEM), has stepped back while publishing version 1.0 and amendment 1 with their sector name removed from the title and the scope of this standard. They have decided to adopt the FMD

approach and feel that the IPC-1754 standard, even if supporting the FMD, mainly focuses on declaring substances present in a Declarable Substance List (DSL) like the AD-DSL for the AD Sector.

The IEC 62474 Validation Team (VT) continues to enhance their data, including the IEC 62474 DSL, the Material Classes and a new Exemptions list in 2019. For the time being, they face the issue of supporting the ECHA SCIP database and continuing to converge with the IPC-175x series, without any opportunity to release a new edition for four or five years.

The IEC Maintenance Team (MT) is investigating a dual logo project for the IEC 62474 standard to become an ISO standard applicable to all products in all sectors.

Other IPC-175x standards continue to evolve:

- The IPC-1753 standard focuses on electronic communication of Test Lab Reports in addition to a Material Declaration to ensure good data quality for the presence of RoHS restricted substances in EEE products. A new amendment 2 has been released, and adoption of the new IPC-175x modular architecture is probably the next step.
- The IPC-1755 designed to support US Conflict Minerals with the 3TG (Tungsten, Tantalum, Tin and Gold) sourcing reporting would evolve to support the upcoming EU Conflict Minerals directive that will come into force in January 2021.
- The IPC-1756 supporting manufacturing information is more or less included in the IPC-1752 standard.

5.3 Similar initiatives

The PA is not the only initiative to move forward to a harmonised multi-sectoral data exchange standard on SiA. Other such initiatives have existed around the existing Material Declaration Standards (IPC-175x series and the IEC 62474 standard) for a number of years and others (but not an exhaustive list) are shown in the following map:

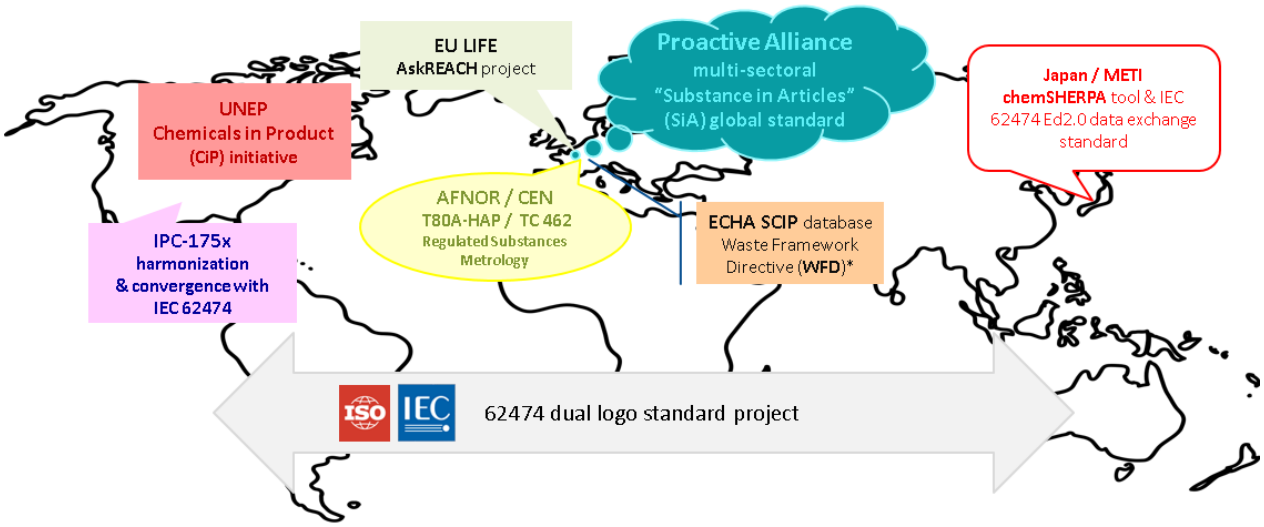


Figure 7: Initiatives moving forward to a harmonised multi-sectoral data exchange standard on SiA

A brief description of each initiative is provided in the following sections.

5.3.1 IPC-175x harmonisation initiative

The most frequently used Material Declaration data exchange standard is the IPC-1752A standard, developed by the electronic sector under the ANSI procedure (USA) of the IPC trade association and also a standard development organisation (SDO).

The IPC-1752 belongs to the IPc-175x standard series that established the IPC-1751 as their foundation and each of the sector-specific standards as add-ons to it. Two years ago, the corresponding IPC E-31 committee decided on a harmonisation initiative with the purpose of reducing the overlap between standards, in particular the IPC-1752A designed for the Electronic & Electrical sector and the IPC-1754 designed for the Aerospace and Defence sector and other sectors (such as Heavy Equipment), both covering the Material Declaration data exchange with different approaches.

Several work packages have been defined and applied. Each standard committee that remains autonomous in terms of their decisions can adopt the outputs of these work packages.

In the meantime, IPC has evolved the IPC-1752B cross-sector standard which is applicable to products across all industry sectors. The IPC-1752B standard is not part of the initiative to harmonize the IPC-1752A Electronic & Electrical standard with the IPC-1754 Aerospace and Defence standard. The IPC-1752A standard can no longer be updated with any new functionality, and so it is unclear whether this harmonization initiative will deliver any practical results.

The figure below outlines a brief description of these work packages and their progress:

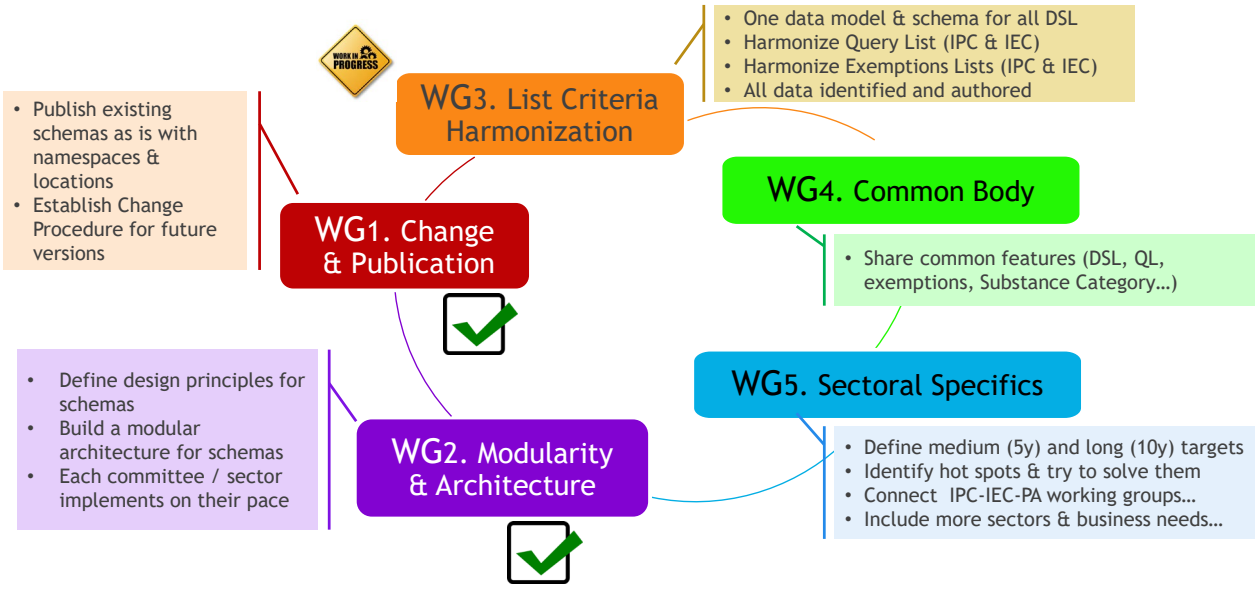
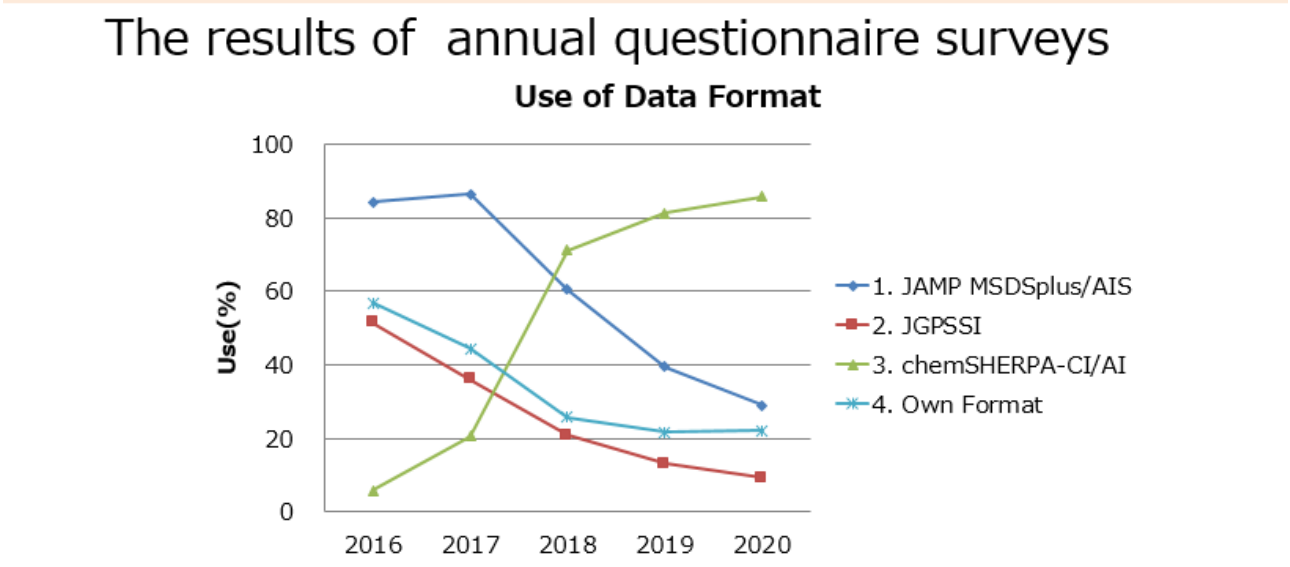


Figure 8: Work packages of IPC E-31 committee's harmonisation initiative for the IPC-1752A and IPC-1754

5.3.2 The JAMP Alliance and chemSHERPA tool in Japan

JAMP (Joint Article Management Promotion-consortium) is a multi-sector Japanese alliance promoting the chemSHERPA tool for substance reporting in chemistry (CI) and articles (AI). There are two versions of this tool[8].

The chemSHERPA tool was released in 2015 to replace multiple formats and tools used previously by various sectors and currently chemSHERPA tool is widely used in Japan.



The chemSHERPA tool uses the IEC 62474 standard, version 2.0 to operate data exchange with a specific configuration. It includes a substance reference list of more than 6,000 substances covering all sectors.

5.3.3 UNEP & OECD "Chemicals in Products" (CiP)

The Chemicals in Products (CiP) Programme is an ongoing activity of the UN Environment Programme on the policy and practical facets of access to information on chemicals contained in everyday products[9]. The activities focus on increasing the availability and access to the information that stakeholders need – throughout the life-cycle of products – so that they can manage those products and the chemicals in them properly.

The main discussion over the past few years has been about Full Material Declaration (FMD) with conflicting positions between NGOs and industry. NGOs prefer the FMD for complete transparency to benefit health and environmental protection, while industry resists this because of confidential business information (trade secrets).

Further topics are to propose a study on developing a Regulatory Database:

- The objective is to build a global database of the regulations and their substance lists
- To ease access to the substance lists and their updates

[8] More information about the chemSHERPA tool here: https://chemsherpa.net/English and https://chemsherpa.net/english/jamp/about

[9] https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/chemicals-products

- With a cross-sectoral approach
- The automotive industry already does this kind of maintenance; objective to share the cost.

5.3.4 EU LIFE AskREACH Project

The AskREACH project aims at enabling access to REACH consumer information rights on chemicals in articles by IT tools. This is an environmental information governance project under the LIFE 16 GIE/DE/000738 programme, funded by EU LIFE Programme. This project incorporates 20 partners from 13 member states.[10]

The AskREACH project involves Business to Consumer (B2C) and Business to Business (B2B) communication about SVHC present in articles identified under REACH. The project has developed a database in which suppliers of articles can fill in information on SVHC in articles. This database is connected to a smartphone application allowing consumers to retrieve information about SVHC in their products (articles), and to create requests for articles not yet contained in the database. The project promotes a supply chain communication approach heading towards FMD that supports suppliers in using material data systems to gather article information along the supply chain. This project was launched before the Waste Framework Directive (2018) established the Substances of Concern in Products (SCIP) database: these are separate initiatives, although the AskREACH project will technically support companies with SCIP duties to easily upload their article information to the AskREACH database by providing an upload option in IUCLID format.

5.3.5 European Content Declaration Open Standard (Eurima initiative)

EURIMA (European Insulation Manufacturers Association) feels the need to develop a European Open Standard to provide information on the chemical substances contained in construction products to customers and downstream users. This would boost healthy buildings and the circular economy by phasing out the hazardous substances from the market and by improving product recyclability. This open initiative is not owned by EURIMA and, in view of this, the initiative will be kept as open as possible.

The European Open Standard will benefit from the HPDc standard (US) and use it as a starting point. The HPDc standard is open, it provides robust guidelines for content declaration (best practices per substance type) and is in active development. For the content declaration, the idea is to align as much as possible with the HPDc standard, in order to benefit from their experience and not to reinvent the wheel. For the hazard identification the objective is to define a method consistent with the EU regulatory framework. The risk assessment of a product is not included in the scope of the standard for the time being.

The European Open Standard is based on a full content declaration in order to facilitate the recycling of the construction products. In this regard, a full disclosure of the content in crucial. Moreover, there are

[10] More information: https://www.askreach.eu/.

likely to be future changes in the assessment of the hazard properties of substances (by the ECHA or other competent scientific authorities). This kind of declaration could be easily integrated in a digital form in a product passport included in the building logbooks and be accessible at the end of life of the building in order to facilitate the process of recycling of building materials.

5.3.6 European Initiatives on Regulated Substances Measurement

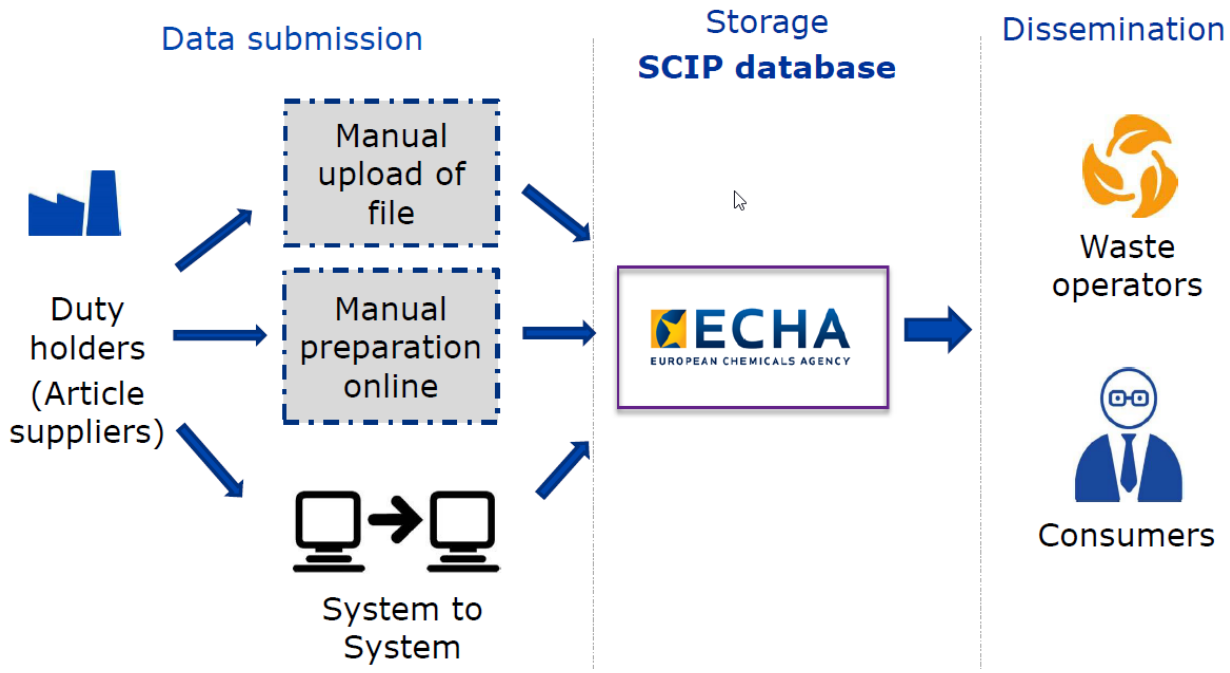
After polycyclic aromatic hydrocarbons (PAH) had been added to the EU REACH Annex XVII as entry 50, the European Commission requested standardisation of PAH measurement under mandate M/556. After an exploratory study (CEN-CLC/BT WG 13 HAP), a new European Technical Committee –TC 462 on "Regulated Substances in Products" – was created as per the AFNOR proposal (France) with the scope of measurement & metrology only; data exchange on substances was present in first draft of the TC proposal but was finally excluded so as not to conflict with the existing IEC 62474 Material Declaration data exchange standard under IEC TC 111.

This TC 462 is mentioned here for completeness of information and to clarify initial ambiguity about the scope of this initiative.

5.3.7 European SCIP database to support EU REACH Article 33

The Waste Framework Directive (WFD, 2018) has established new duties for manufacturers and importers of products regarding the presence of SVHC over the 0.1% mass per mass threshold (w/w). WFD Article 9 thus reinforces EU REACH Article 33: companies must now declare such products to the ECHA in addition to making this information available to their downstream supply chain and end-consumers.[11]

To support this new duty, the ECHA has put in place the SCIP database with data requirements going beyond Article 33: new mandatory and required data need to be included in product notification by companies (manufacturers and importers).



[11] More information here: https://echa.europa.eu/scip-database.

Figure 9: Scope of the SCIP database

This approach raises concerns for those supply chains that have already established a working method in material reporting, specifically those related to REACH Article 33. As these methods represent major investments, it is difficult to understand what the added value of the extra data – such as article categories and a new material categorisation nomenclature – could be in terms of the desired outcome and whether this added value justifies the required investment.

As a consequence – and in addition to the above – the ECHA has selected the existing IUCLIDv6[12] (version 6) data exchange format, used for registering substances and mixtures, for the product SVHC notification. This is a completely new data exchange format with different reference data (product categories according to the TARIC/CN code, new Material Classification, new European Article Number) and targeted at one specific purpose. It is the belief of many industry stakeholders that the success of SCIP would benefit from the support of a selection of relevant exchange formats for SCIP reporting.

The ultimate goal of the SCIP database and B2B product notification collection is to make this information available to the recyclers at the end of life of the products (B2R) and to the end consumers (B2C) so that they can influence the products they buy. Thus, not all information duties exclusively aim to improve the situation of recyclers. It is more likely, that the introduced TARIC codes and the added material category nomenclature could support better browsing of the database by the public.

5.3.8 The IEC-ISO Dual Logo 62474 Project

The IEC 62474 Material Declaration data exchange standard was initiated in 2010 by the International Electrotechnical Committee (IEC) and its Technical Committee (TC) 111 in charge of "Environment Management".[13]

The IEC 62474 inherits from various existing standards, including JIG-101, JGPSSI and the IPC-1752:

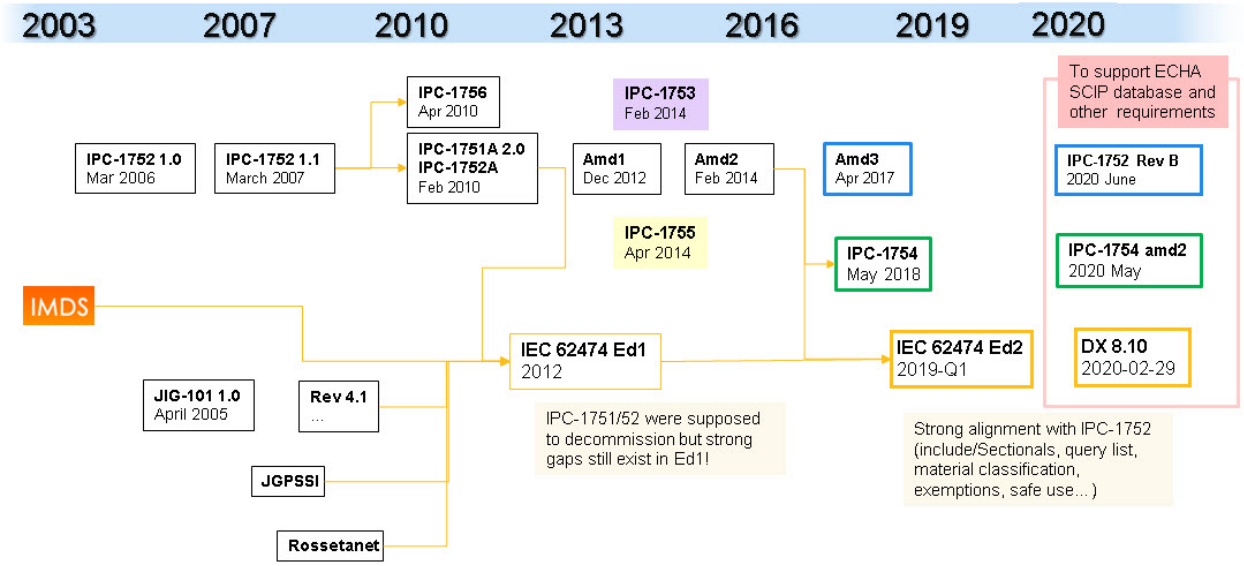


Figure 10: History of IEC 62474 and last version

The IEC 62474 standard includes several elements:

- the standard itself (PDF document) under the responsibility of the maintenance team (MT 62474);

[12] IUCLID: International Uniform ChemicaL Information Database; see https://iuclid6.echa.europa.eu/format.

[13] See: http://std.iec.ch/iec62474.

- additional data and format managed in a separate database under the responsibility of the Validation Team (VT 62474): Declarable Substance List (DSL), Reference Substance List (groups and substance member), Material Classes List (MCL), Exemptions Lists for EU RoHS and China RoHS (EX), Data eXchange Format (EX).

The data and formats are available in a public database available here: http://std.iec.ch/iec62474

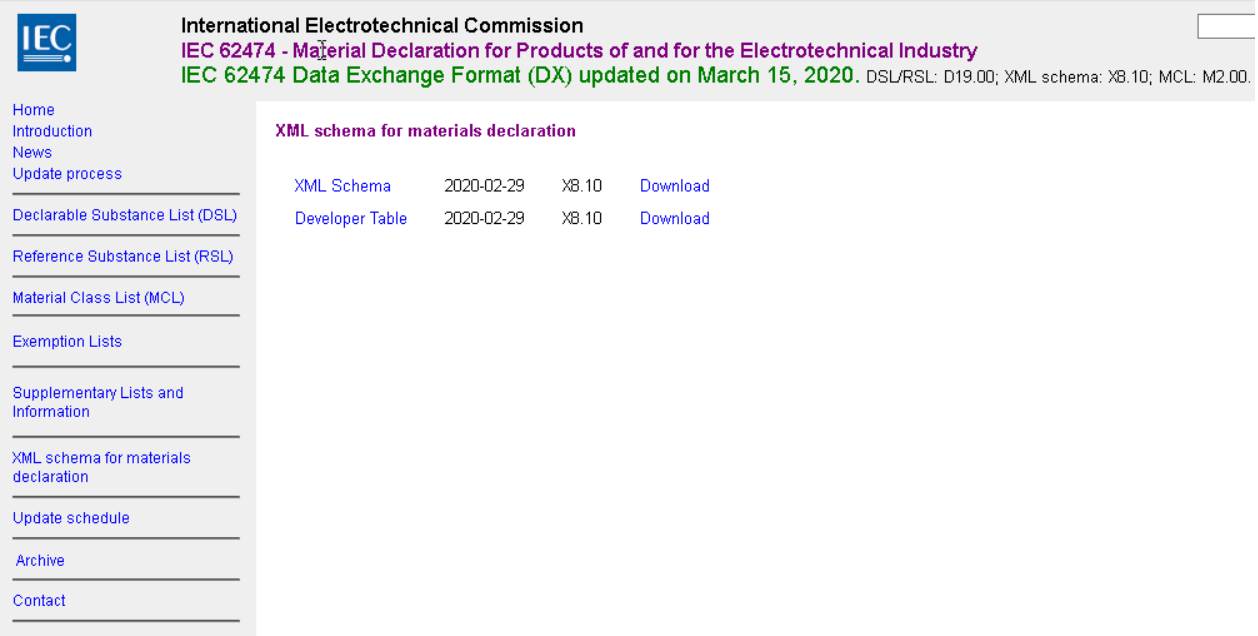


Figure 11: IEC 62474 database managed by IEC 62474 Validation Team (VT)

The IEC 62474 was designed for the Electronic & Electrical sector as an international standard developed under the IEC standardisation procedures. It currently competes with the IPC-1752 standard with a very similar design and supported use cases.

The VT/MT 62474 committees have proposed making their standard usable by any sector and have started to proceed with deleting any reference to their specific IEC 62474 Declarable Substance List (DSL) amended in version 2.0, so that this standard can be used with any other sector specific DSL.

The IEC-ISO 62474 dual logo project aims to achieve the goal of a unique material declaration data exchange standard for all sectors. This project is in the initialisation phase with drafting the IEC and ISO New Work Item Proposals (NP) for their IEC TC 111 and ISO TC 207 committees to approve this project.

5.4 EU REACH Candidate List update scenario as a vision

Here is a possible scenario for large companies, based on the last EU REACH Candidate List update from January 16 2020, and what would be entailed if a vision of this kind were implemented.

It shows the possible benefits of this vision for a large company like an OEM (products manufacturer) if fully implemented as an integrated system to support EU REACH Article 33 compliance. Small- and Medium-sized Enterprises/Businesses (SME/SMB) could also benefit from these recommendations even if adopted with e.g. 50% automatic and 50% manual work. For SMEs/SMBs, the vision is likewise to rely on simple Product Material Declarations and make them available to their customers in the standard format by means of a highly automated data exchange.

Figure 12: EU REACH Candidate List update scenario for large companies

5.5 Proposed roadmaps

In addition to the recommendations given in Chapters 2 and 3, the PA proposes two roadmaps for future developments. Both roadmaps are in line with the PA mission statement and support the goal to develop a global cross-sector standard for SiA communication.

5.5.1 Roadmap 1: Supporting SiA communication based on the IPC 1752 standard

This roadmap recommends the use of the IPC-1752 standard as global cross-sector standard for SiA communication. With support from the Proactive Alliance over the past two years (e.g. at a Chemical Watch webinar on 4 September 2018, the Proactive Alliance provided a presentation on "Why is IPC-1752A a good starting point for a global inter-sector standard for Substances in Articles (SiA)communication?") the IPC-1752 standard has evolved into a global cross-sector standard, which is applicable to products across all industry sectors. In particular, Proactive Alliance members have contributed to the development of IPC-1752B standard, that allows any company in any industry to exchange information with their supply chains in a format, which matches the data requirements of the ECHA SCIP database (cf. section 5.2.2.1).

The IPC-1752B standard has an innovative and advanced architecture, which enables suppliers to report different products with different types of materials declarations (known as declaration classes) in the same XML file. This enables suppliers to report sub-products using different declaration classes that provide different levels of detail about the materials in these articles. This functionality is essential for reporting the range of different types of sub-supplier data, which is received by industry. An example is a supplier who has received FMDs for some sub-supplier parts used in an assembly and regulatory compliance declarations for other sub-supplier parts used in the same assembly. The IPC-1752B standard enables the supplier to roll up these data for their assembly and report all of the FMDs and RCDs in one XML file. Already today (December 2020), 97% of notifications to ECHA SCIP database used the IPC-

1752B standard to collect Full Materials Declarations and Regulatory Compliance Declarations from supply chain actors.

Business benefits of supporting the IPC 1752 proposed roadmap

IPC is a global standards organisation which is accredited by the American National Standards Institute (ANSI) and is known world-wide for its standards. For example, the IPC-1755 global standard is managed jointly with the Japan trade association JEITA.

Companies need a global cross-sector standard that they can use now to collect the necessary data from their supply chains for SCIP reporting and other regulatory requirements. Indeed, the deadline for submissions in the EU to the SCIP database is 5 January 2021 and companies who want to work towards this deadline need a workable solution that they can start using immediately.

Launched in July 2020, the IPC-1752B global standard has already gained industry adoption around the world as a tried and tested standard which is widely used in a range of different industry sectors to report against substance reporting lists in the medical sector, child-care sector, lighting sector and many others. The IPC-1752 standard is the most widely used standard today for material declarations in B2B communication as well as by standard component data providers. The IPC-1752 standard also has the highest level of adoption by solution providers. Moreover, the IPC-1752B standard is used by all the solution providers who provide SCIP compliance solutions recognised by ECHA.

The IPC-1752 standard enables reporting against a modular RSL containing any maintained lists of substance categories for both horizontal and vertical legislation modules. IPC maintains some horizontal lists centrally on behalf of all industry sectors, such as the ECHA REACH Candidate List. A modular RSL which contains separate sections for different regulations provides significant benefits to manufacturers and suppliers:

- Manufacturers (particularly smaller companies) can start by asking their suppliers to provide materials declarations for selected regulations, for example the REACH Candidate List and RoHS
- Listing the substances which are included in each regulation enables the supplier to re-use the modular RSL to respond to different requirements from different customers. For example, some manufacturers do not have an RSL and instead include clauses in their purchasing contracts such as “supplier must comply with the REACH Regulation”.
- Different regulations have different legal obligations and require different actions. For example, the REACH Candidate List is a disclosure requirement – information must be communicated if substances are present > 0.1% by weight of any article. RoHS is a restriction – substances must not be present above certain thresholds, unless material application is covered by a RoHS exemption.

Strategy for supporting the proposed IPC 1752 roadmap

The strategy to implement this roadmap supporting SiA communication based on IPC 1752 is:

1) PA will share this discussion paper with various stakeholders and gain support for this roadmap to promote even greater uptake of the IPC 1752 cross-sector standard for all types of products across all industry sectors.
2) PA participants will provide presentations at webinars and conferences to explain how all industry sectors can use the IPC-1752 standard to exchange material declarations with their supply chains, similar to the Chemical Watch webinar that PA presented on 4 September 2018. For example, the Proactive Alliance will present this roadmap 1 at the Chemical Watch conference on “Chemicals Management Towards 2030 and Beyond” on 19 January 2021 and the Chemical Watch conference on “Enforcement of SCIP database reporting” on 21 April 2021.

5.5.2 Roadmap 2: Supporting SIA communication based on ISO 82474 standard

The roadmap shown below proposes to define a medium-term target with a new global cross-sector material declaration framework, representing all existing standards, based on a new ISO standard (ISO 82474) as the foundation. Other standards (standard 1, standard 2) would need to be evolved and become sectoral extensions in addition to this new ISO standard. This would set the basis for common data demands and alignment between sector-specific standards such as the IPC-1754 standard for the Aerospace and Defence Industry and the IMDS standard for the Automotive Industry.
This ISO standard is drafted today in the context of the IEC-ISO dual logo 62474 project, with the aim of creating the ISO 82474 standard using the existing IEC 62474 standard, edition 2.0, as a starting point.

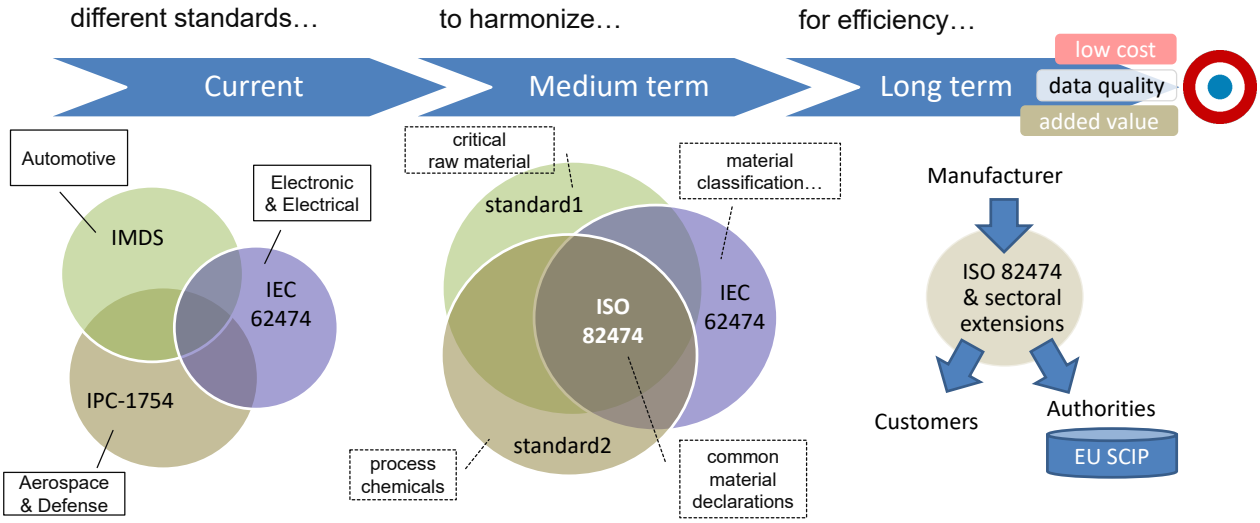


Figure 13: Roadmap proposal based on the ISO 82474 standard

In the long term, additional standard services would be implemented to automate the process to the greatest possible extent and to have dedicated human activities in addition to IT systems to perform high value tasks such as approval, special cases and escalation processes if there is no declaration from suppliers.

This roadmap based on the ISO 82474 future standard (targeted for 2023) needs to be reviewed and agreed with sector-specific stakeholders such as business trade associations and standard development organisations (SDO).

Strategy for supporting the proposed ISO 82474 roadmap

The strategy to establish this ISO 82474 roadmap is as follows:

1. The PA will share their discussion paper with various stakeholders and try to obtain a consensus from them in support of the roadmap to establish the ISO 82474-1 standard as the foundation of the common Material Declaration from the best of existing standards for all sectors (ISO scope).
2. The PA will promote their participants as business trade associations to take part in this standardisation work and to support the IEC-ISO dual logo project, led by the IEC TC 111 and ISO TC 207 SC1 committees that would establish a Joint Working Group, JWG 16, to achieve this. Trade associations could contribute to the National Committees in various countries by becoming members of this JWG 16 or as “liaison members” to the group.
3. Promote an open architecture for the ISO 82474 standard to enable any sector to develop their own additional and specific features, and a standard system to system data exchange for better efficiency.

By considering stakeholders' feedback, the ISO 82474 proposed roadmap and strategy can be adapted if needed.

5.6 Terms of reference

The Proactive Alliance participants agreed to develop Terms of Reference (ToR) for the group to support implementation of the common mission to contribute to the development of a global cross-sector standard for communication on SiA. In order to organise the group and to safeguard the Proactive Alliance's initial objectives, a steering group was established consisting of the PA's founders, formed during the Chemical Watch "Global Business Summit", Amsterdam (NL), in March 2018 with representatives from trade and industry. As the PA secretary, the research group sofia (Society for Institutional Analysis, Haardtring 100, 64295 Darmstadt) was asked to lead the PA in an open, transparent and inclusive manner, in compliance with the applicable law; sofia is the contact point for any third party requests.[14]

In terms of PA participation, the group is open to any industry and trade association that can contribute to the SiA objective. Group participants or the steering group decide on the member status. Industries and trade association can contribute as full participants (voting rights), observers (no voting rights) or guests (occasional participation in technical meetings).

PA participants are expected to be active in the discussions and in providing feedback on documents and issues before PA meetings. Moreover, they are expected to be proactive within their constituencies in promoting awareness of, as well as engaging and participating in, the implementation of the SiA project and in providing advice and approving updates on the Proactive Alliance work on SiA.

Before being welcomed as a participant (full/observer) it is a prerequisite to agree to the PA's ToR and Mission Charter.

The PA holds virtual coordination meetings on a quarterly basis or when deemed necessary to exchange information on ongoing SiA efforts and with clear meeting objectives. The group meets once a year in physical meetings (before the Corona crisis).

The PA is organised into internal working groups. Each working group focuses on a specific issue to meet the group's objectives. Each working group (WG) is coordinated by a volunteer group lead who sets up the (virtual) WG meetings. Subject to the available capacities during these meetings, WGs are open to anyone including non- participants from other organisations and companies.

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5.7 Proactive Alliance participants

	Sector	Trade Association	Organisation
Chair	Scientific Research		Hochschule Darmstadt (University of Applied Sciences), sofia - Society for Institutional Analysis
Proactive Alliance - Participants	Chemical industry	Cefic, European Chemical industry Council - Cefic aisbl	Cefic, European Chemical industry Council - Cefic aisbl
	Chemical industry		Covestro Deutschland AG
	Electronic industry		
	Electrical, Electronic, Mechanical & Metalworking Industries	Orgalim, Europe's Technology Industries	Orgalim
	Retail industry (interior decoration)		Ikea of Sweden AB
	Software Development		BOMcheck.net
	Textile industry		W. L. Gore & Assoc. GmbH
	Industry association	Medical devices and in vitro diagnostics	Medtech Europe
	Industry association	Medical imaging and radiotherapy devices	COCIR
Proactive Alliance – Observer	Automotive industry		Hyundai Motor Europe Technical Center GmbH
	Aerospace industry	ASD Europe - Aerospace and Defence Industries Association Europe (as observer)	ASD Europe (as observer)
	Business association	Amfori BEPI	Amfori BEPI
	Industry association	BDI - Bundesverband der Deutschen Industrie e.V.	BDI
	Chemical industry		Johnson Matthey
	Industry association	EURIMA – European Insulation Manufacturers Association	EURIMA
	Industry association	VDMA e.V. - Mechanical Engineering Industry Association	VDMA e.V.
Participants		Participants are members who have voting rights and are included in the mailing list (referred to in the PA ToR as “full members”).	
Observer		Observers are members of the group without voting rights. Observers are included in the mailing list.	

5.8 Public Consultation: Feedback on Recommendations

The sections below contain feedback regarding the discussion paper from external organisatons. Feedback from PA participants and their member organisations is considered within the recommendations.

5.8.1 Feedback regarding recommended SRL criteria

Organisation	Feedback
ICCA	- Criterion 2b: we are struggling with the prospect of identifying substances "projected to be regulated" as a positive - We see 2D and 2E as minuses, rather than neutral, as they do not take a science- and risk-based approach. - Need for a mechanism to respect global intellectual property rights for proprietary formulations; to be based on objective (not subjective criteria); and to be managed and quality controlled (e.g., audited) by appropriate neutral experts to ensure the integrity, quality, and currentness of the SRL.
ACC	- 2b (should this not be a zero or minus vs plus)? If the process doesn't lead to regulation, what is mechanism to remove from list? To remain on the list forever irrespective of outcome seems wrong in our view. - 2E – should be minus. Paper indicates we want to get away from independent NGO lists like SIN list, but given the descriptor on "reputation" my guess is SIN List (and other NGO drivers) very well would be used as indicator of "significant public discussion" - 2D – should this not be minus vs zero as the hazard only definition is very broad and as indicated in your paper you note the risk approach is recommended?
JCIA	- 2B is necessary: However, it requires a process and schedule management to delete SRL entries in case it does not enter into force the regulation. You also need to clarify the criteria for what is "expected". - 2C risk approach: how do you judge the exposure when considering the life cycle of chemicals, that is, from manufacturing to recycling? - definition of 2E is ambiguous - 3A and 3B, the threshold required by each law should be stated for each SRL entry. If multiple thresholds are set for a chemical, then multiple SRL entries should be avoided. - 4A is a misleading expression. We guess that SRL entries should be created for all regulated substances. How about "If a substance is regulated in any one region, one SRL entry will be generated."?

5.8.2 Feedback regarding the proposed roadmaps

Organisation	Feedback
JEMAI	- Why is PA considering supporting the IPC 1752B as the best approach to realize the dream?
JAMP	**Pro roadmap 2 recommendation** - JAMP operates chemSHERPA compliant with IEC 62474 Ed2 and strongly supports Roadmap 2
Hitachi Hightech	**Pro roadmap 2 recommendation** Promote ISO/IEC82474 series collaborating with other declaration scheme.
Samson Group	**IEC 62474** needs comprehensive improvement before becoming the foundation for a new norm: - Definition of homogenous material - Addition of O5A judgement - Definitions on material level: Classification not practicable - Problem of lists of pure substances as foundation for material declaration formats not addressed

5.8.3 Feedback regarding miscellaneous issues

Organisation	Reference	Feedback
JAMP	General	The standardization of the Material Declaration in a wide range of industries and supply chains is beneficial for industries and is a same goal of JAMP.
JEMAI	FMD	Discuss the definition of the FMD to get comprehension from multi sectors, especially for the industries that produce the products as a short cycle.
Max Klein (tool manufacturer)	FMD	- Make sure the FMD contains a note, which indicates omissions of substance declarations due to business secrets.
JAMP	Sections 3.4 and 5.3.2	- Smaller amendments regarding chemsherpa tool (Brief on tools (section 3.4) and Similar Initiatives (section 5.3.2))