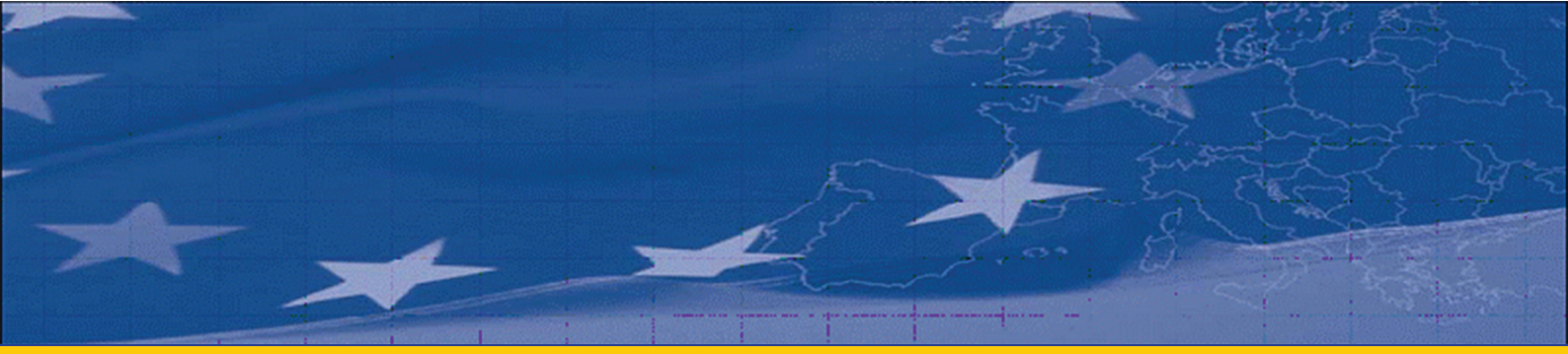

Capacity Building Initiative for Trade Development in India (CITD)

REACH application for Indian companies

Practical guide

EuropeAid/133302/C/SER/IN

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Practical guide REACH application for Indian companies

Prepared by:

Mr. Reimond Willemse
Senior Expert on REACH Regulation

Mr. Dileep Wakankar
Senior Expert on REACH Regulation

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This document has been prepared by the above experts and can in no way be taken to reflect the views of the European Union.

Foreword

This practical guide has been prepared under the framework of the EU funded project "Capacity Building Initiative for Trade Development in India – CITD", delivered by a consortium led by The British Standards Institution (BSI) which began project operations on 10 June 2013 and which will complete on 30 September 2017. This practical guide provides information to companies that want to export substances or products to the European Union (EU) and that want to be informed about the REACH Regulation and its application.

LIST OF ABBREVIATIONS AND ACRONYMS

AAS	Atomic Absorption Spectrometry
APEO	Alkylphenol Ethoxylates
CAS	Chemical Abstracts Service
CITD	Capacity Building Initiative for Trade Development in India
CLP	Classification, Labelling and Packaging of Substances and Mixtures
C&L	Classification & Labelling
CMR	Carcinogenic Mutagenic Reprotoxic
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Substances
ELINCS	European List of Notified Chemical Substances
EU	European Union
EUSES	The European Union System for the Evaluation of Substances
FAQ	Frequently Asked Question
GC	Gas Chromatography
GHS	Global harmonized system
GLP	Good Laboratory Practice
GPC	Gel Permeation Chromatography
HPLC	High Performance Liquid Chromatography
HS	Harmonized system
I	Importer

IR	InfraRed
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
M	Manufacturer
MS	Mass Spectrometry
NLP	No Longer Polymer
NMR	Nuclear Magnetic Resonance
OECD	Organisation for Economic Cooperation and Development
OR	Only Representative
OSOR	One Substance One Registration
PBT	Persistent Bio accumulative Toxic
QSAR	The Quantitative Structure–Activity Relationship. QSAR models are regression or classification models used in the chemical and biological sciences and engineering.
REACH	Registration, Evaluation, Authorisation and Restriction of CHemicals
REHCORN	REACH Help Desk Correspondents' Network
SAICAM	Strategic Approach to international Chemical management
SDS	Safety Data Sheet
SID	Substance Identification
SIEF	Substance Information Exchange Forum
STOT	Specific target organ toxicity
SVHC	Substance of Very High Concern
SWOT	Strengths, Weaknesses, Opportunities, Threats
TPR	Third Party Representative
UV	Ultra Violet
UVCB	Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bio accumulative
XML	Extensible Mark-up Language

01 INTRODUCTION TO THE REACH REGULATION

1.1 REACH in nut shell

- REACH is probably the most important and challenging chemical legislation of all time and was adopted in Europe in December 2006. REACH entered into force on 1 June 2007.
- REACH [EC/1907/2006 of 18th December 2006] is an EU Regulation and therefore mandatory across all EU member states.
- REACH stands for Registration, Evaluation, Authorization (and Restrictions) of CHemicals.

1.2 Understanding REACH

REACH is a regulation of the European Union (EU), adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has an impact on most companies across the EU.

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used, and they must communicate the risk management measures to the users.

If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

1.3 How does REACH work

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances.

Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance.

ECHA receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed.

Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorization.

1.4 REACH's effects on companies

REACH impacts on a wide range of companies across many sectors, even those who may not think of themselves as being involved with chemicals.

In general, under REACH you may have one of these roles:

- **Manufacturer :** If you make chemicals, either to use yourself or to supply to other people (even if it is for export), then you will probably have some important responsibilities under REACH.
- **Importer:** If you buy anything from outside the EU/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onwards sale or finished products, like clothes, furniture or plastic goods.
- **Downstream users:** Most comp anies use chemicals, sometimes even without realising it, therefore you need to check your obligations if you handle any chemicals in your industrial or professional activity. You might have some responsibilities under REACH.
- **Companies established outside the EU:** If you are a company established outside the EU, you are not bound by the obligations of REACH, even if you export their products into the customs territory of the European Union. The responsibility for fulfilling the requirements of REACH, such as pre-registration or registration lies with the importers established in the European Union, or with the only representative of a non-EU manufacturer established in the European Union.

1.5 Purpose of REACH

- To ensure high level of protection of human health & environment.
- To ensure free movement of substances while enhancing competitiveness and innovation.
- To promote development of alternative methods for the assessment of hazards.
- To achieve sustainable development.
- To contribute to fulfilment of the Strategic Approach to international Chemical management (SAICAM).
- To encourage replacement of SVHC (Substances of Very High Concern).

1.6 Documentation of REACH Regulation

REACH Regulation contains almost 850 pages of text and > 6000 pages of Technical guidance.

1.6.1 Titles of REACH Regulation

- Title I: General Issues
- Title II: Registration of Substances
- Title III: Data Sharing and Avoidance of Unnecessary Testing
- Title IV: Information in the Supply Chain
- Title V: Downstream Users
- Title VI: Evaluation
- Title VII: Authorization
- Title VIII: Restrictions on the manufacturing, placing on the market, and use of certain dangerous substances and preparations
- Title IX: Fees & Charges
- Title X: Agency (ECHA – European Chemical Agency)

- Title XI: Classification & Labelling Inventory (CLP – EU GHS)
- Title XII: Information
- Title XIII: Competent Authorities (of Member States)
- Title XIV: Enforcement
- Title XV: Transitional and Final Provisions

1.6.2 ANNEXES OF REACH REGULATION

- Annex I: General provisions for assessing substances and preparing chemical safety reports
- Annex II: Guide to the compilation of Safety data Sheets
- Annex III: Criteria for Substances registered in quantities between 1 and 10 tonnes
- Annex IV: Exemptions from the obligation to register in accordance with Article 2(7)(a)
- Annex V: Exemptions from obligations to register in accordance with Article 2(7)(b)
- Annex VI: Information requirements referred to in Article 10
- Annex VII: Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more
- Annex VIII: Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
- Annex IX: Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
- Annex X: Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more
- Annex XI: General rules for adaptation of the standard testing regime set out in Annexes VII to X
- Annex XII: General provisions for Downstream users to assess substances and prepare Chemical Safety Reports (CSR)
- Annex XIII: Criteria for the identification of persistent, bio-accumulative and toxic substances (PBT) and very persistent and very bio-accumulative substances (vPvB)
- Annex XIV: List of substances subject to Authorization
- Annex XV: Dossiers
- Annex XVI: Socio-Economic analysis
- Annex XVII: Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

1.7 REACH Application

- REACH is applicable only to "Substances" and not "Products". It is applicable for:
- Substances (as such)
- Substances in Preparations (Formulations)
- Substances in Articles (intended for release)
- Being EU regulation, it is applicable to EU companies, who are manufacturing or importing Chemicals.

- Non EU manufacturers or Exporters cannot register substances under REACH themselves. They can however appoint an "Only Representative" (OR) – legal entity in EU, who can register substances on their behalf.
- Non EU merchant exporters cannot register substances under REACH (neither themselves or through OR). Only their EU importers can register substances under REACH.
- The most important guiding principles of REACH are:
- No data no market.
- Every Manufacturer / importer must register or stop manufacture, import or use of substances beyond respective deadlines.
- Reversal of burden of proof from 'Authorities' to 'Industry'.
- Avoidance of fresh vertebrate animal testing.
- Data sharing mandatory (for vertebrate animal testing).
- Substance Information Exchange Forum (SIEF) platform for data sharing.

1.8 ECHA

The European Chemicals Agency (ECHA) is the driving force in implementing the EU's groundbreaking chemicals legislation REACH for the protection of human health and the environment. ECHA was founded in 2007 and is based in Helsinki, Finland.

02 REACH REGISTRATION

2.1 REGISTRATION PRINCIPLES

2.1.1 One Substance One Registration (OSOR) principle

- After pre-registration deadline ECHA has published a list of all pre-registered substances on Internet.
- For same substances 'Substance Information Exchange Forums' (SIEF) to be formed:
- All SIEF members are informed about identity of participants

  Identity can be hidden by nominating 'third party representative' (not to be mixed with 'only representative')
- Technical registration dossiers including exposure scenarios for all 'identified uses' to be prepared for all substances
- One of a group of multiple registrants (the "lead registrant") should submit information on behalf of the others while allowing sharing the burden of the costs
- Joint submission of registration by all SIEF members via lead registrant preferred by the European Commission
- Joint submission and the sharing of information on substances should be provided for in order to:
  - increase the efficiency of the registration system,
  - reduce costs, and
  - reduce testing on vertebrate animals.
- Registrants are manufacturers or importers of a substance
- Each manufacturer or importer need only comply with requirements specified for 'his' volume
- 'Opting out' possible if
  - Costs of joint submission appear too high
  - Confidential business information could be disclosed
  - The 'lead registrant' is deemed unacceptable
- Chemical dossier with basic information for all substances
- Chemical safety report (CSR) obligatory for all substances > 10 t/a:

  Target is to demonstrate that risks identified in CSA are controlled
- CSR comprises chemical safety assessments (CSA) depending on substance properties and is obligatory for substances > 10 t/a
  - human health hazard assessment
  - physicochemical hazard assessment
  - environmental hazard assessment;
  - persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) assessment

- If from the CSA the registrant concludes his substance is to be classified as dangerous he must perform:
  (a) an exposure assessment including the generation of exposure scenario(s) or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
  (b) a risk characterization
- Safety data sheets must be prepared for hazardous substances
- Each company has to pay a registration fee for the registration of each substance.
- Small and Medium-sized Enterprises can benefit from reduced fees under the REACH Regulation. The reductions depend on the company size as defined by the Commission Recommendation 2003/361/EC.

2.1.2 Vertebrate animal Testing:

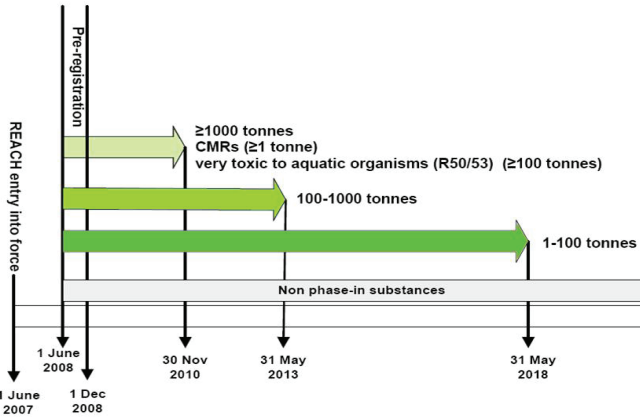
- Among the fundamental objectives of the European Commission is **3R**:
- to replace and thus avoid or minimize,
- reduce or
- refine animal testing.
- Existing 'acceptable' animal tests must not be repeated by the participants of a SIEF (for a specific substance)
- Alternative methods like (Q)SARs have to be used instead of animal testing whenever applicable
- Information related to testing will be published on the Agency website
- Third party is invited to comment, make proposals, make available tests not yet known to registrants and agency

Testing proposals have to be approved by the agency within certain timeframe (2/3/4 years after registration deadlines 2010/13/18).

2.2 REACH Registration deadlines:

REACH registration deadlines are tonnage/annum/legal entity (t/a) based:

- 1st Deadline: 30th November 2010 for
  - substances > 1000 t/a or
  - CMR's (>1 t/a) or
  - toxic to Environment when >100 t/a
- 2nd Deadline: 1st June 2013 for
  - substances >100t/a but <1000 t/a
- 3rd Deadline: 1st June 2018 for
  - substances > 1 t/a but < 100 t/a



2.3 Exemptions from REACH:

2.3.1 Exemptions for REACH registration

- Radioactive substances
- Non-isolated intermediates
- Polymers (but not monomers)
- Biocides
- Fuels, petrol
- Substances like water, sugar etc.
- Gases: hydrogen, oxygen, ,nitrogen, noble gases
- Substances
- in medicinal products for human or veterinary use
- as food additive or flavoring in foodstuffs
- in animal nutrition
- in cosmetic products
- in medical devices
- Non Metals must be registered:
- Exceptions:
- Hydrogen, oxygen: Hazardous but properties 'well-known'
- Nitrogen, noble gases: 'not hazardous'
- Alloys:
- Alloys are preparations under REACH, albeit special ones where the properties of the preparation do not always simply match the properties of the components.
- As preparations alloys do not have to be registered but their components metals must be registered if manufactured/imported ≥1 tonne.

2.3.2 Reduced obligations under REACH (exemptions from only certain Titles of REACH):

- Strictly controlled intermediates: isolated, transported
- Biocides: Registration only for non-biocidal use if applicable
- Substances in articles (see later)
- Polymers: Only monomers must be registered if polymer contains
  >2% of reacted monomer and annual volume exceeds 1 t/a
- ELINCS listed substances are regarded as registered
  and will get a REACH registration number

Note:

(a) if a substance is also used for other purposes it must be registered under REACH

(b) special regulations e.g. regarding biocides or cosmetics must be applied together with REACH

2.4 REACH AND POLYMERS

2.4.1 Polymers and monomers

Polymers have wide application in day to day life such as packaging, building and construction, transportation, electric and electronic equipment, agriculture, medicine, sports goods, textile, paper, leather, coatings and other domestic uses.

Historically polymers are considered to be materials of low concern due to high molecular weight, low reactivity and low bioavailability.

Polymers have been exempted under REACH from Registration and Evaluation

However they may be subjected to Authorization and Restriction based on:

- – Established toxicological criteria
- – Building blocks ….SVHC present ≥0.1%

Article 2(9) of REACH states that the provisions of Titles II (Registration) and VI (Evaluation) shall not apply to polymers.

In other words manufacturers / importers of a polymer are generally not required to provide to the Agency [ECHA], any information related to the intrinsic properties of the polymer itself, with the exception of its Classification and Labelling.

Polymers have reduced obligations. Monomers do not.

Article 6(3) of REACH states that any manufacturer/importer of a polymer shall however submit a

registration to the Agency for the monomer substance(s) or any other substance(s) (such as additives), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

- The polymer consists of 2% w/w or more of such monomer or other substance in the form of monomeric units and chemically bound substances.

  and

- The total quantity of such monomer substance or other substance [i.e. the quantity of these substances ending up in the final polymer as unbound or chemically bound to the polymer makes up ≥1 ton per year.

  While reviewing Polymers for exemptions, one has to first understand the definition of Polymers.

REACH [Article 3(5)]: – criteria for polymer

Substances consisting of molecules are characterized by the sequence of one or more types of monomer units (repetitive units). Such molecules must be distributed over a range of molecular weights, wherein the molecular weight is primarily attributed to difference in the number of repetitive monomer units.

Thus Polymers require two conditions to be fulfilled

- A simple weight majority of molecules containing at least three monomer units (n=3) which are covalently bound to at least one other monomer unit or other reactant.
- Less than a simple weight majority of molecules of the same molecular weight.

In other words:

- >50% of the weight for that substance must consist of polymer molecules, however
- The amount of polymer molecules representing the same molecular weight must be <50 weight % of the substance.

Let us consider a Phenol ethoxylate.

C6H5 –O--(CH2-CH2-O)n – H

Here for this substance to be considered as a polymer following conditions need to be met

1. The product should contain more than 50% of phenol ethoxylate molecules. [An aqueous formulation with less than 50% content of phenol ethoxylate will not be considered as polymeric substance];
2. Degree of ethoxylation should be n≥3. [More than or equal to at least 3 repetitive units];
3. The molecular weight distribution should vary and not more than 50% of the molecules should have same molecular weight (same n). This can be further explained by an example shown in table below.

Table below shows 3 variants of a substance having different molecular weight distributions.

	Example 1	Example 2	Example 3
n=1	-	40%	5%
n=2	10%	20%	30%
n=3	85%	15%	20%
n=4	5%	12%	30%
n=5	-	8%	20%
n=6	-	5%	10%
n=7	-	-	5%
Sum	100%	100%	100%
	No Polymer	No Polymer	Polymer

Example 1

Polymer content is 90% [n=3 + n=4] as against requirement of >50% [neglect n=2].

However this is not a polymer, as molecules with same molecular weight n=3=85% whereas number of molecules with same molecular weight must be <50%.

Example 2

Polymer content is 40% [n=3+n=4+n=5+n=6] [neglect n=1; n=2] as against requirement of >50%. This is not a polymer, though molecular weight distribution meets requirements of molecules with same molecular weight not to exceed 50%.

Example 3

Polymer content is 85% [n=3+n=4+n=5+n=6+n=7][neglect n=1 and n=2] (required > 50%).

Molecular weight distribution OK as n=3; n=4; n=5; n=6 and n=7 are all below 50% each.

Both conditions of polymer content and molecular weight distribution satisfied.

This definition has a great impact.

- Polymer emulsions, solutions or suspensions and polymer based products such as paints, inks, and coatings shall be regarded as "formulations" or "preparations' and not substances or polymers.
- Unbound additives, solvents or emulsion stabilizers (not polymer stabilizers) will have to be registered if manufactured or imported into the EU in quantities > 1 ton/year.
- Additives which are required to stabilize the polymer itself, such as antioxidant will be considered as a part of the polymer itself and need not be registered separately.
- Plastic toys will be considered as articles like plastic furniture or components of car, airplanes etc. [shape to determine the function of the material to a greater degree than its chemical composition].

  Polymer may further be blended with colorants, stabilizers, surfactants, lubricants, thickeners, antistatic agents, compatibilisers, antifogging agents, flame retardants, nucleating agents etc.
- Each of these must also be considered for registration.
- Thus importer will have to know the identity and quantity of each in order to determine its pre-registration and registration requirements.

  Article 6(3)(a): Further additives such as those mentioned earlier the 2% criteria would not apply, because the additives are not chemically bound to the polymer.
- Exceptions to the above rule are unbound heat stabilizers, light stabilizers, and/or oxidants which do not need to be registered, because they are considered to be part of polymer substances.

2.4.2 No Longer Polymers (NLP)

'No longer polymers' is a category of substances that were regarded as polymers at the time that the EU 1967 dangerous substances directive was adopted.

They were therefore not required to be notified to the EINECS (European Inventory of Existing Commercial Substances) inventory.

In 1993, a new definition of polymers (same as that used in REACH above) was adopted that disqualified these substances [more than 700 so far] from being classified as polymers.

Under REACH therefore the exemptions provided to 'Polymers' would not be applicable to NLP and these would have to be treated like substances and would require registration.

However as earlier they were not included in EINECS, they would not be considered as 'Phase-in substances' and would therefore not be able to get the benefit of Pre-registration and extended registration deadlines.

This situation has now been corrected and NLP will be treated as 'Phase-in substances' provided that

- the substances had been placed on the EU market between 18 September 1981 and 31 October 1993;
- they were previously considered to be polymers under the notification rules for EINECS;
- under the seventh amendment of Directive 67548/EEC they meet the criteria for classification as 'no longer polymers'.

A list of 'no longer polymers' has been established. This is non-exhaustive and companies are still able to request inclusion provided they hold the necessary evidence.

Thus potential registrants need to take following steps:

1. Study the chemistries to see if there are repetitive monomeric units in their substances.
2. Undertake GPC (gel permeation chromatography) to study the molecular weight distribution.
3. See if their products meet the definition of Polymers.
4. See if it is included in NLP list.
5. Claim exemptions under REACH if polymeric.
6. Start pre-registration / registration process if NLP
7. In case of exempted polymers ensure that the monomers and other substances are pre-registered/registered by the upstream manufacturer.

2.5 PRE-REGISTRATION:

2.5.1 Pre-registration process

- Pre-registration of substances was possible from 1st June 2008 to 30th Nov 2008 (6 months).
- Pre-registration possible only for "Phase-in Substances" (see explanation below).
- Late pre-registration possible 12 months before deadline for first time manufacture/ import ((30.Nov 2010, 31st May 2013 or 31st May 2018)).
- Pre-registration gives you additional time to organize, collect and assess available data, sharing of existing data and collective generation of missing information.
- Ensures that there will be no interruptions in the supply to downstream users of your substances.
- Provides basis to make existing information on substances e.g.
  - Non-testing information
  - Substance to substance read across data from testing accessible to those who need the information for registration.
- **Allows you to** continue manufacture or import of phase-in substances until relevant registration deadline (30.Nov 2010, 31st May 2013 or 31st May 2018)
- If you do not pre-register, than you cannot manufacture or import material from 1st Dec 2008 onwards until the registration is completed
- If you are a company consisting of several legal entities, manufacturing in EU or importing the same substance, each legal entity has to pre-register separately
- If you do not wish to make contact details available to other registrants than you should appoint Third Party Representative (TPR) who then pre-registers
- Limited data requirements for pre-registration e.g.:
- Identity of manufacturer / importer
- Identity of substance
- Envisaged deadline for the registration + tonnage band
- Proposals for grouping of substances (similar substances)
- European Chemical Agency ECHA has published a list of all pre-registered substances one month after the deadline of November 2008.

2.5.2 Phase-in Substances:

Substances fulfilling at least one of the following criteria may be considered as phase-in substances in accordance with REACH (Article 3(20)):

- Substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- Substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992
- Substances that qualify as "no-longer polymer''

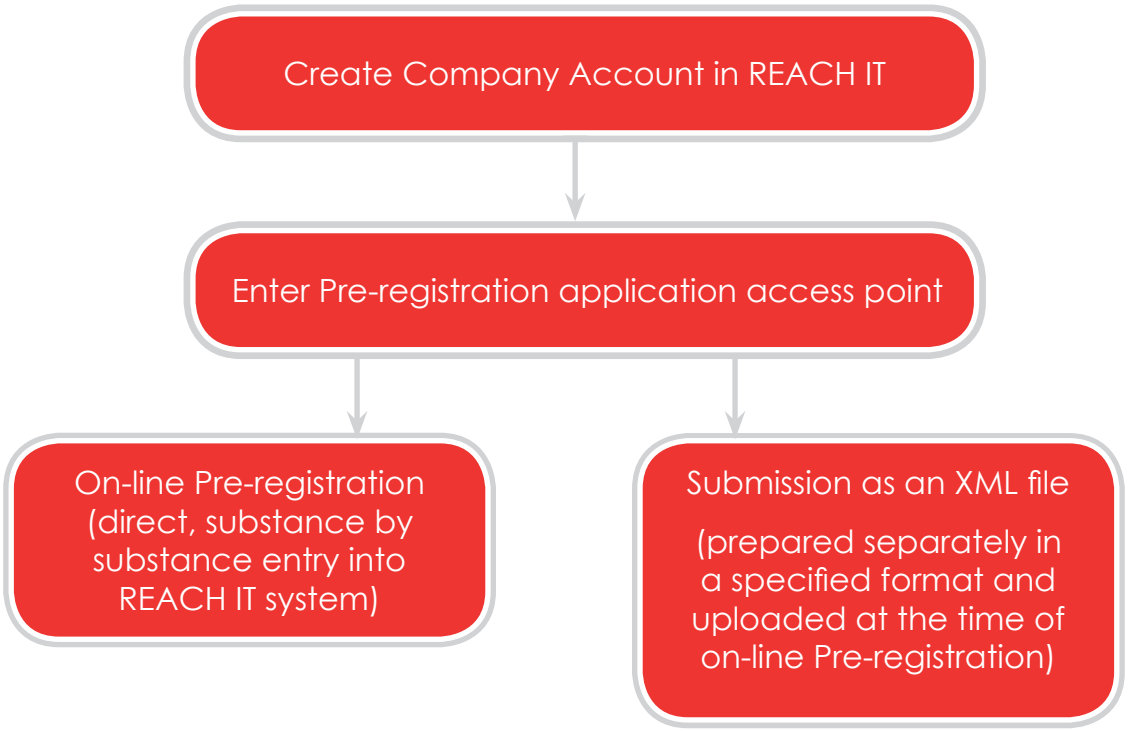
2.5.3 Step-wise process for Pre-registration

- 1st make an inventory of products exported to EU.
- Identify whether the products you export are
- single Substances or
- preparations containing various Substances or
- articles containing Substances to be released
- Identify whether they belong to any of the following lists (polymers, intermediates, substances for product/process development and research, substances in exemption annexures IV or V)
- Collect information on name, CAS Nos., EINECS No. etc. and give correct name as per REACH.
- Check whether the substance is a "Phase-in substance" (having EINECS No, manufactured in EU but not marketed after 01.06.1992 or is a NLP)
- Identify envisaged deadline for registration corresponding to tonnage band and C&L
- Select and appoint an OR (Only Representative)or TPR (Third Party Representative)
- If you are obliged to Register than you are entitled to pre-register

2.5.4 Post Pre-registration:

- The list of all pre-registered substances has been published on the ECHA website after 1st Jan 2009. (Including CAS / EINECS No, other identity code and first envisages deadline for registration).
- This list is open to all.
- Pre-registrants will have access to information about the other registrants for the same substance.
- All pre-registrants for the same substance will become part of Substance Information Exchange Forum (SIEF) and will continue to do so till 1st June 2018. (One SIEF per substance).
- Need to actively participate in SIEF.
- May have financial obligations in relationship to your substances.
- Agreement on cost sharing must be reached before disclosure of information.
- Entire SIEF is the responsibility of the registrant industry. ECHA will play no role in this.

2.5.5 Mode of Pre-registration:



2.5.6 FAQ's for pre-registration:

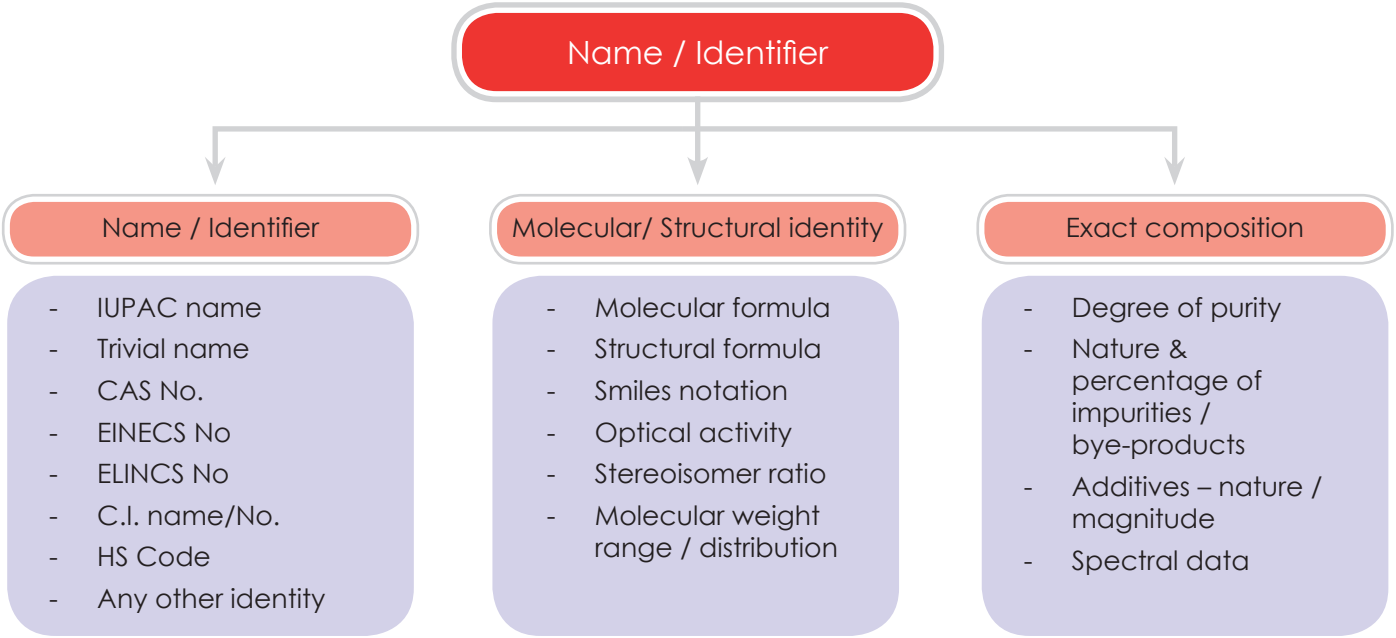
- Is there an obligation to register pre-registered substances?
- Pre-registration does not have to be followed by registration.
- However pre-registrant will continue to be SIEF member and will have to provide information to other SIEF members if they are in possession of such information.
- Who can pre-register?
- M / I of phase-in substances, substances in preparations.
- M/I of articles containing substances intended for release.
- Only representative of non-EU M.
- Who can act as OR?
- Natural or legal person appointed by non-EU M.
- Has to be established in EU.
- Should have sufficient background in the practical handling of substances and information related to them.
- Role of OR?
- Takes up the role of EU importer.
- Fulfils the registration obligation.
- Keep available and up-to-date information on quantities imported and customers sold to (including their uses).
- Meet all obligations to communicate information down the supply chain.
- Obligation of entity appointing OR

- Inform all importers within the same supply chain of the appointment of OR
- An OR can represent several non-EU manufacturers of substances.
- What about quantities below one tonne/year?
- M/I of phase in substances less than 1 tonne/year need not pre-register.
- They can pre-register if they have intention of crossing the 1 tonne/year threshold.
- When the thresh hold is exceeded relevant information has to be provided to ECHA within 6 months from date of exceeding the threshold provided this is at least 1 year before relevant registration deadline.
- What is the period for pre-registration?
- 1st June 2008 to 1st December 2008 (both inclusive).
- What about First time M/I after 1st Dec 2008?
- 1st time of M/I after 1st Dec 2008 can pre-register within six months of exceeding the threshold and at least 1 year before the relevant deadline.
- Thus before:
- 30.11.2009 or
- 31st May 2012 or
- 31st May 2017.
- What if pre-registration is missed?
- Needs to suspend M/I of concerned substances.
- Needs to register these substances at the earliest.
- Enquire with ECHA if the substances(s) are already registered.
- All M/I/use of such substances between period of 1st June 2008 and date of suspension of activities may be subject to penalties.

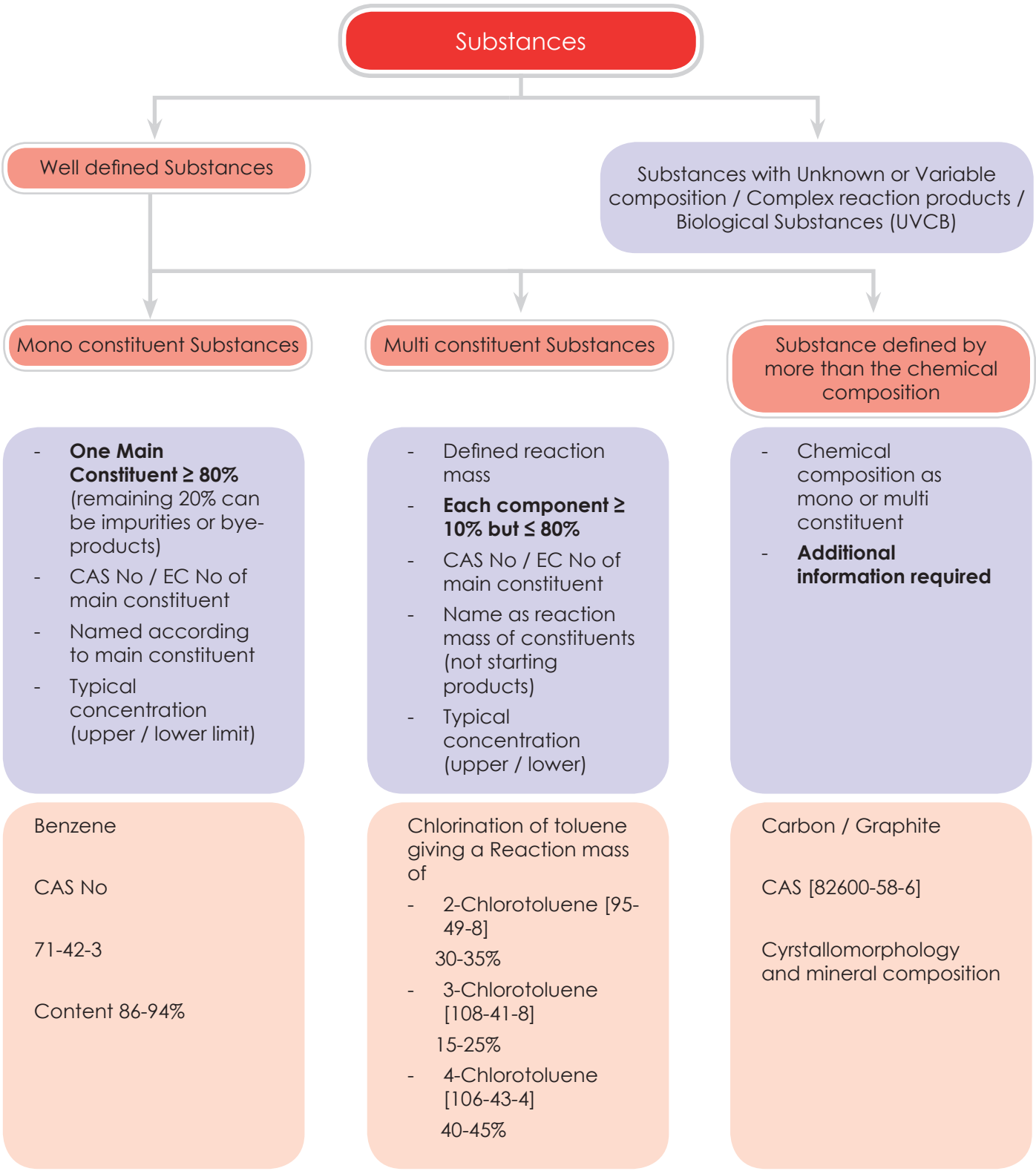
03 SUBSTANCE IDENTIFICATION AND ARTICLES

- **In order to successf**ully complete registration and effectively participate in the right SIEF, Substance identification is very critical
- Erroneous substance identification may lead to confusion about correct SIEF and may affect costs involved. This may also lead to difficulties with concerned Consortia's
- Substance equivalence review shall be an important part before joining the correct SIEF

3.1 Requirements for Substance identification:



3.2 Group of Substances :



Multi constituent substances should not be confused with preparations (mixtures) wherein the latter, the other components are added intentionally and not present as a course of reaction (as bye-products or impurities)

3.2.1 Mono constituent Substances:

One constituent is present at concentration of at least 80% (and which contains up to 20% of impurities).

Naming

Mono-constituent substances are named after the main constituent.

Identifiers

Main constituent must be specified by all parameters. Chemical name, CAS Nos. Molecular and Structural formula, typical concentration / concentration ranges, spectral and analytical information.

Impurities in concentration of ≥1% should at least be specified by Chemical names, CAS Nos. and or Molecular formula).

Analytical information

UV-Vis, IR, NMR, MS, X-Ray diffraction, X-Ray fluorescence, AAS, GC, HPLC

Impurities and additives do not contribute to the naming of the substance.

3.2.2 Multi constituent substances:

Chemical composition is known and more than one main constituent is relevant for the identification of the substance.

Chemical composition is predictable as typical values and ranges.

A substances in which more than one constituent is present in ≥10% and <80%.

Multi constituent substance is the result of a manufacturing process. (Not blending as in case of preparations).

Naming

Named as a reaction mass of the main constituents. (Not the starting materials needed to produce the substance).

Names are to be mentioned in the order of typical concentration percentages starting from the highest.

Only main constituents typically above ≥10% contribute to the name.

Impurities contributing to ≤10% shall not contribute to naming.

Identifiers

Identified by chemical names, quantitative and qualitative chemical composition,

molecular and structural formula.

Impurities present in concentration ≥1% should be specified at least by one of the following –chemical name, CAS Nos, and or Mol formula.

Analytical information

UV-Vis, IR, NMR, MS, X-Ray diffraction, X-Ray fluorescence, AAS, GC, HPLC

3.2.3 Substance defined by more than the chemical composition:

- Such substances in addition to chemical composition need additional identifiers for complete identification.
- Can be treated as mono or multi-constituent substances with additional identifiers.

Kaolin [1332-58-7]

Is composed of kaolinite, potassium aluminium silicate, feldspar and quartz.

Also need morphology and mineral composition to identify the substance unequivocally.

Apatite (Ca5(PO4)3(OH,F,Cl).

Is composed of hydroxylapatite (OH-), fluorapatite (F-) and chlorapatite (Cl-) based on the ions respectively in the crystal lattice.

Naming

Follow principle of mono-constituent or multi-constituent substances.

For inorganic minerals, the minerological names can be used.

Identifiers

Follow principle of mono-constituent or multi-constituent substances.

Other specific main identifiers may be in the form of Elemental composition, crystalline structure, IR, X-Ray diffraction, Swelling index, cation exchange capacity.

Analytical information

Spectral data, plus data mentioned above

3.2.4 Unknown or Variable composition, Complex reaction products or Biological materials (UVCB):

- Cannot be sufficiently identified by chemical composition
- Number of constituents is relatively large and/or
- Composition is to a significant extent unknown and/or
- Variability of composition is relatively large or poorly predictable
- As a consequence other type of information for identification is necessary

When a substance is declared as UVCB the other identifiers are

- "process related" or
- "source related"

Any significant change is "source" or "process" would lead to fresh registration requirements of that substance.

On the other hand if a substance is defined as a " multi-constituent substance" then a substance may be derived from different sources and/or different process as long as the final composition of final substance stays within specified range no fresh registration would be required.

Chemical composition and the identity of the constituents should be given as far as known

Naming

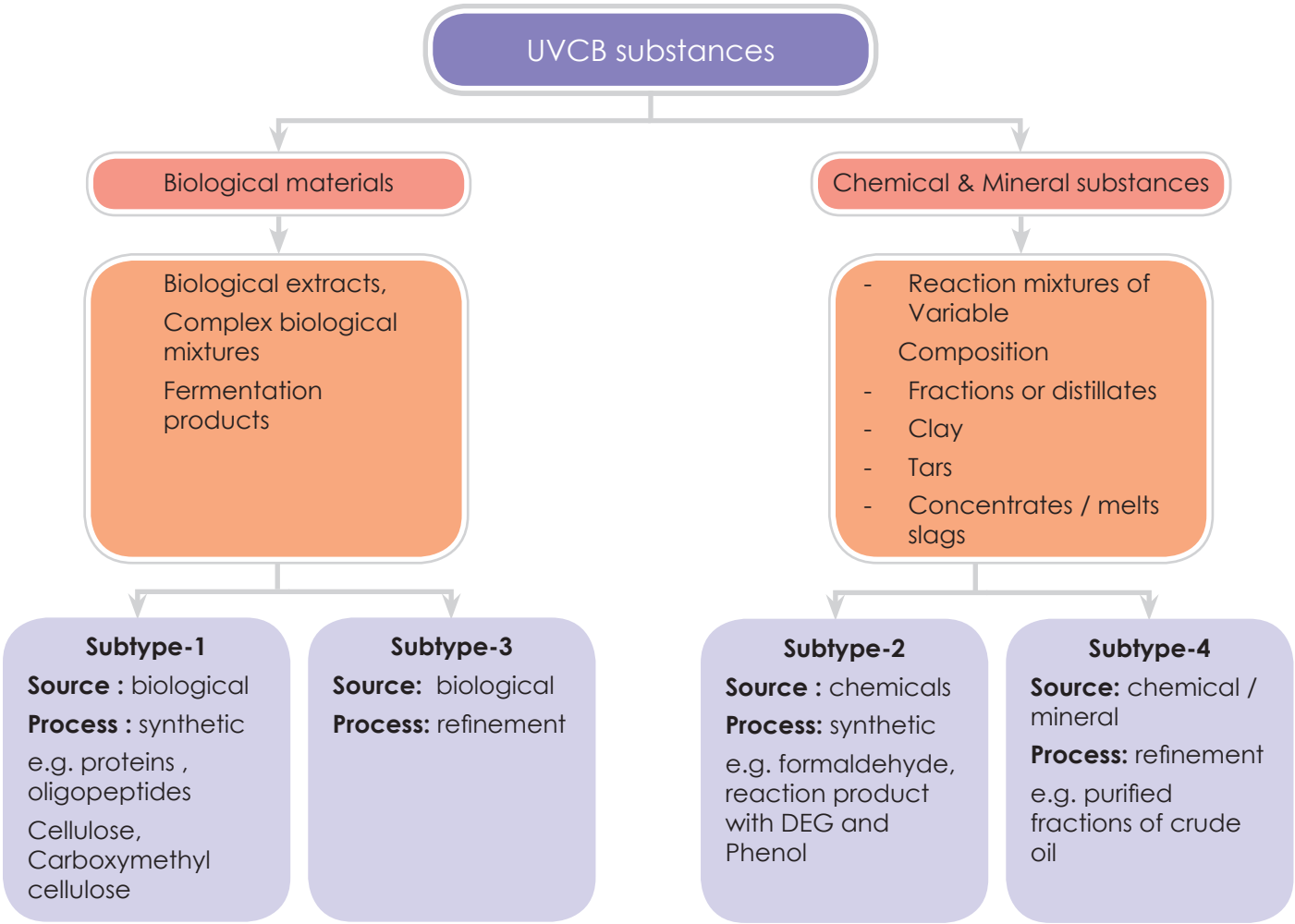
Name of UVCB is a combination of source (1st) and process (2nd) Source biological

A substance derived from biological sources is identified by the name of genus, species and family

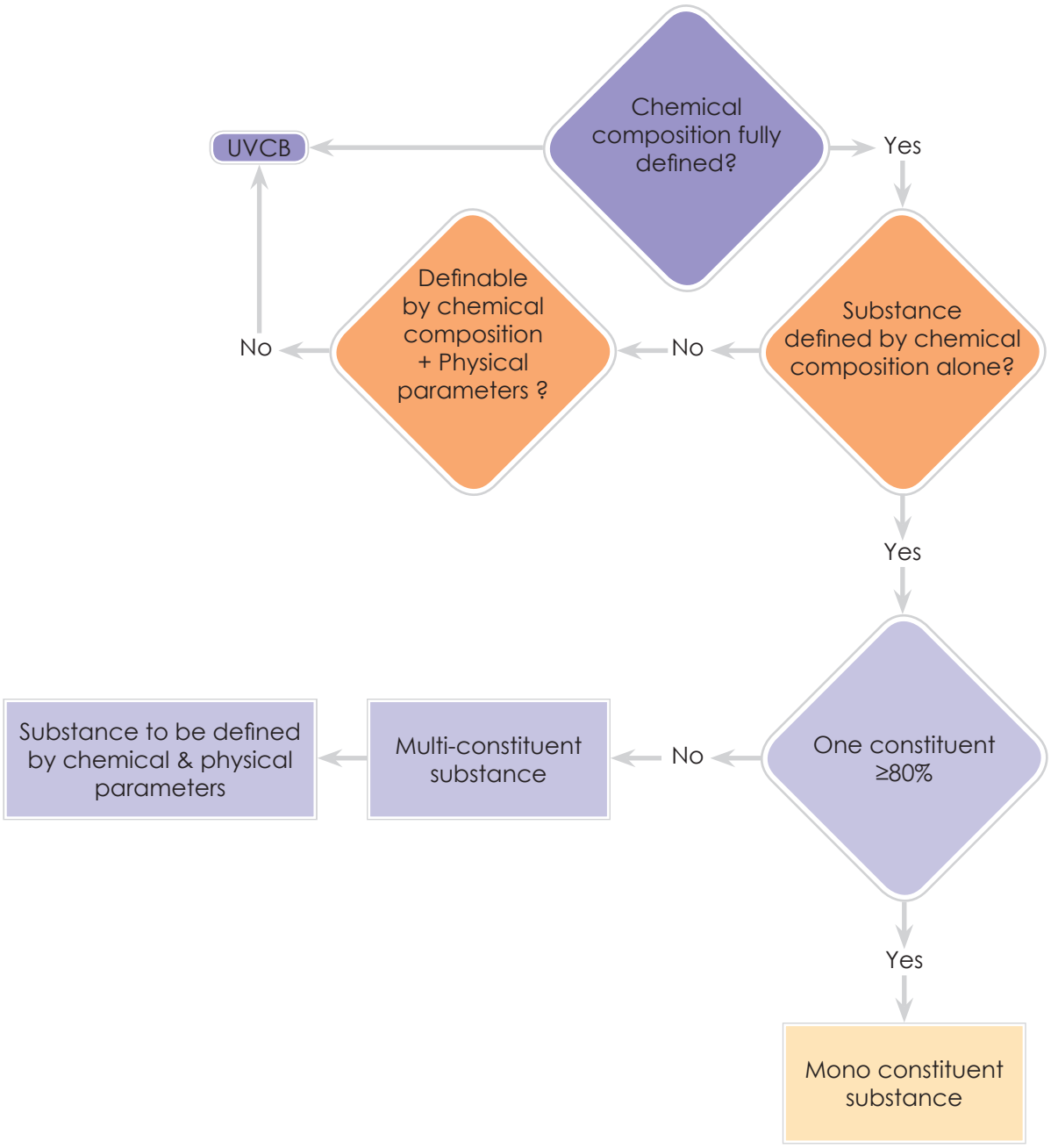
- Lavendar, Lavandula latifolia, ext., sulfurized, palladium salt [EC No. 307-507-9]
- Saccharomyces cerevisae extract [EC No. 283-294-5]
- Extractives and their physically modified derivatives such as distillates, concentrates, absolutes, essential oils, oleoresins, terpenes, terpene free fractions, distillates residues etc. obtained from Saccharomyces (genus) cerevisiae (species) Saccharomycelaceae (family)
- Source chemical or mineral

A substance derived from non-biological sources is identified by the starting materials

- Reaction products of tall oil fatty acids, diethanolamine and boric acid [EC No. 400-160-5]



3.3 Process flow of Substance identification:



3.4 Articles

As mentioned earlier, REACH is applicable to Substances in "Articles".

Before we understand requirements for Articles, we must understand the definition of an "Article".

Article is any object that has definite shape, surface design and specific utility.

REACH defines article as mentioned below:

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

[A shirt is an article as it has definite shape, surface and design. It is meant to cover, protect the wearers' body and for aesthetic / fashion purpose. It does not matter whether shirt is made of cotton, nylon, polyester, rayon, wool etc.]

Thus textile garments, leather shoes, belts, garments, batteries, electronic goods, household articles, handicrafts are few examples of Articles.

Care should be exercised while defining an article - particularly differentiating between an **"article containing substance for intended release" and "container containing substance for intended release"**

[A scented eraser is an 'article containing substance intended for release' viz. the scent/perfume. On the other hand a scent/perfume bottle containing perfume is a container containing perfume. This is not an article. Here the perfume is a substance and needs to be registered.]

Applicability of REACH to articles is subject to **two main conditions** and **both conditions need to be met with simultaneously.**

Article 7.1 of REACH [Registration and notification of substances in articles]:

Registration of Substances in Articles

Any producer or importer of articles must submit a registration to the Agency for any substances contained in those articles, if both the following conditions are met

- The substance is present in those articles, in quantities over 1 tonne per producer or importer per year.
- The substance is intended to be released under normal or reasonably foreseeable conditions of use.

It is important to note that amounts intended to be released as well as amounts not intended to be released, but present in article, need be jointly taken into account for purpose of tonnage bands for registration if above conditions apply.

And even if the above criteria are met, the substance does not have to be registered if it has been registered for that use by up-stream manufacturer.

Notification of Substances in Articles

Article 7.2: Any producer or importer of articles shall notify the Agency, in accordance with para 4 of this article, if a substance meets the criteria in Article 57 [SVHC = i.e. substance is CMR, PBT, vPvB or endocrine disruptor] and is identified in accordance with Article 59(1), if both conditions are met

- The substance is present in those articles in quantities totaling over 1 tonne per producer or importer per year and
- The substance is present in those articles above a concentration of 0.1% weight by weight

Note: Substance concentration threshold of 0.1% applies to the article as produced or imported

Communication of specific information to DU. (Article 33)

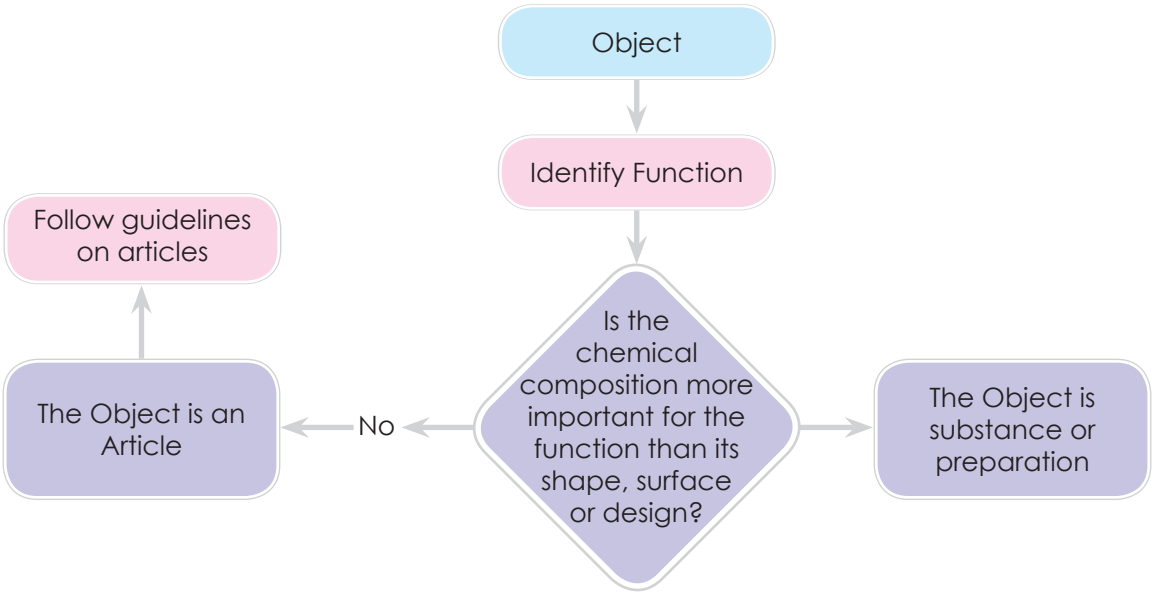
Importers of articles containing SVHC's included in candidate list for authorization in a concentration > 0.1% w/w must provide respective information available to them to the recipients of the articles and as a minimum the:

- name of the substance
- information necessary to ensure safe use of the article

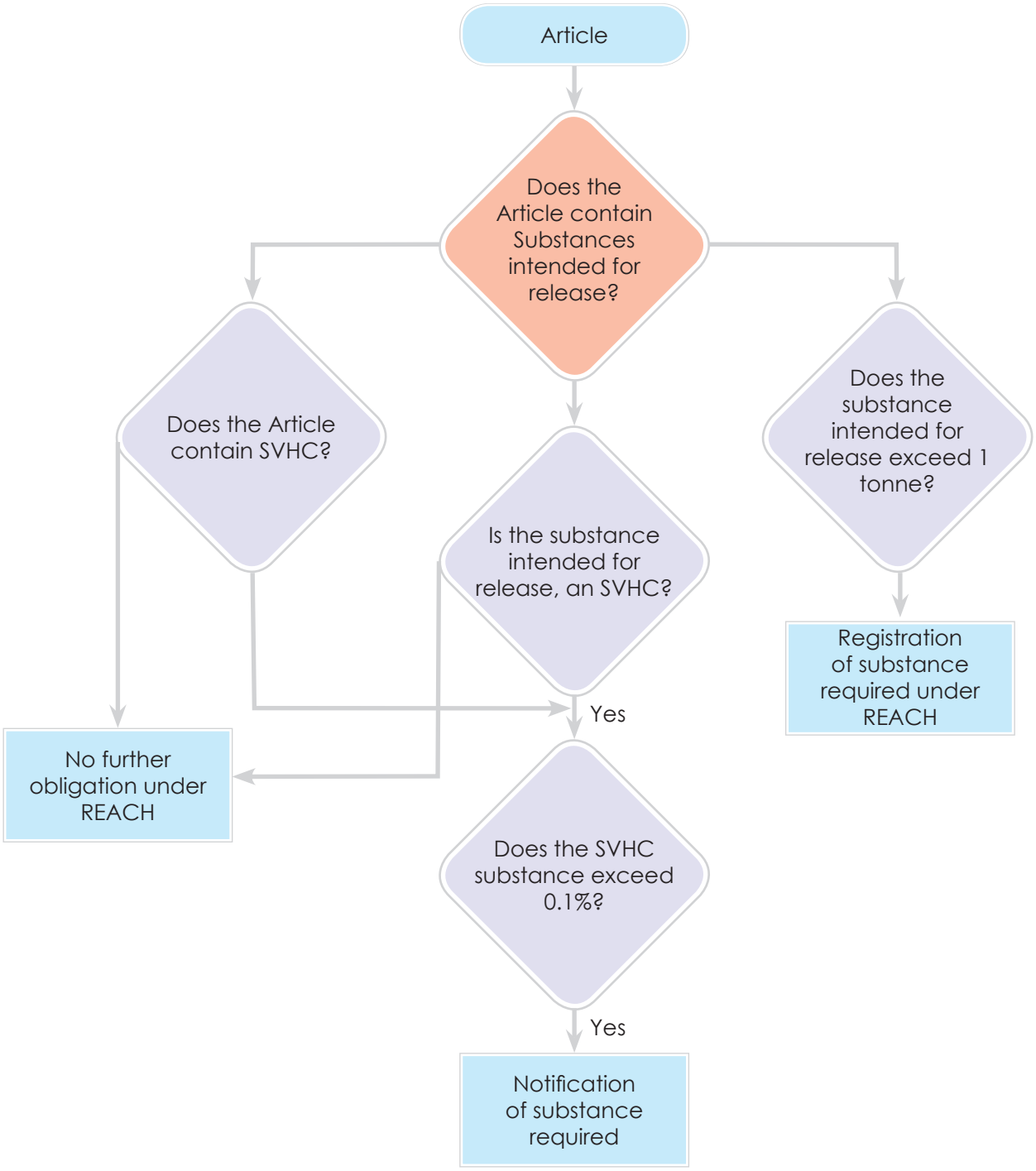
This information has to be provided automatically. There is no tonnage band applicable

Threshold concentration of 0.1% applies to the article as produced, imported or supplied

Flow chart to identify whether a substance meets the definition of Articles.



Applicability of Registration / Notification to Substances in Articles



Thus if a manufacturer or importer of Article is affected by REACH he/she needs to fulfil following obligations:

1. Register and/or Notify Substances in Articles
2. Communicate specific information to the Down Stream User regarding hazards and safe use
3. Comply with REACH restrictions as per annex XVII of REACH

While deciding whether an Article contains 'substances intended for release' the following points should be considered:

1. Intended release for substances as such or in preparations from an article normally applies to an accessory function of an article (i.e. the released substance has certain function of its own)
2. Substances which are released because of ageing of articles, because of wear and tear, as a result of accidents are not intended releases as the release does not provide a function in itself.

A release is not considered as "intended release" in the following cases:

- Release occurring during removal from semi-finished / finished article during production process (before marketing),

  e.g. De-sizing in textile processing is not intentional release
- Release occurring during use or maintenance of the article

  e.g. Washing of clothes by the consumer where remnants of different chemicals (dye, softener, starches etc.) are removed over some washing cycles is not intentional release
- Release of substance formed during chemical reaction

  e.g. ozone released from copying machines, combustion products from articles catching fire is not intentional release.
- Accidental release, (could be forced by undue use or in accident)

  e.g. release of Mercury because of breaking of thermometer is not intentional release.
- If user of articles uses/applies an article in a situation or manner that the supplier has clearly recommended to avoid

  e.g. Do not wash > 30C or keep out of REACH of children, or do not expose to high temperature

One also needs to understand the term "intended release under reasonably foreseeable conditions"

Here the conditions of use /application are not as originally intended by the producer of the article, but which can be anticipated as likely to occur

e.g. Children putting things in their mouth : Intensive use over long durations

04 REACH DATA SHARING

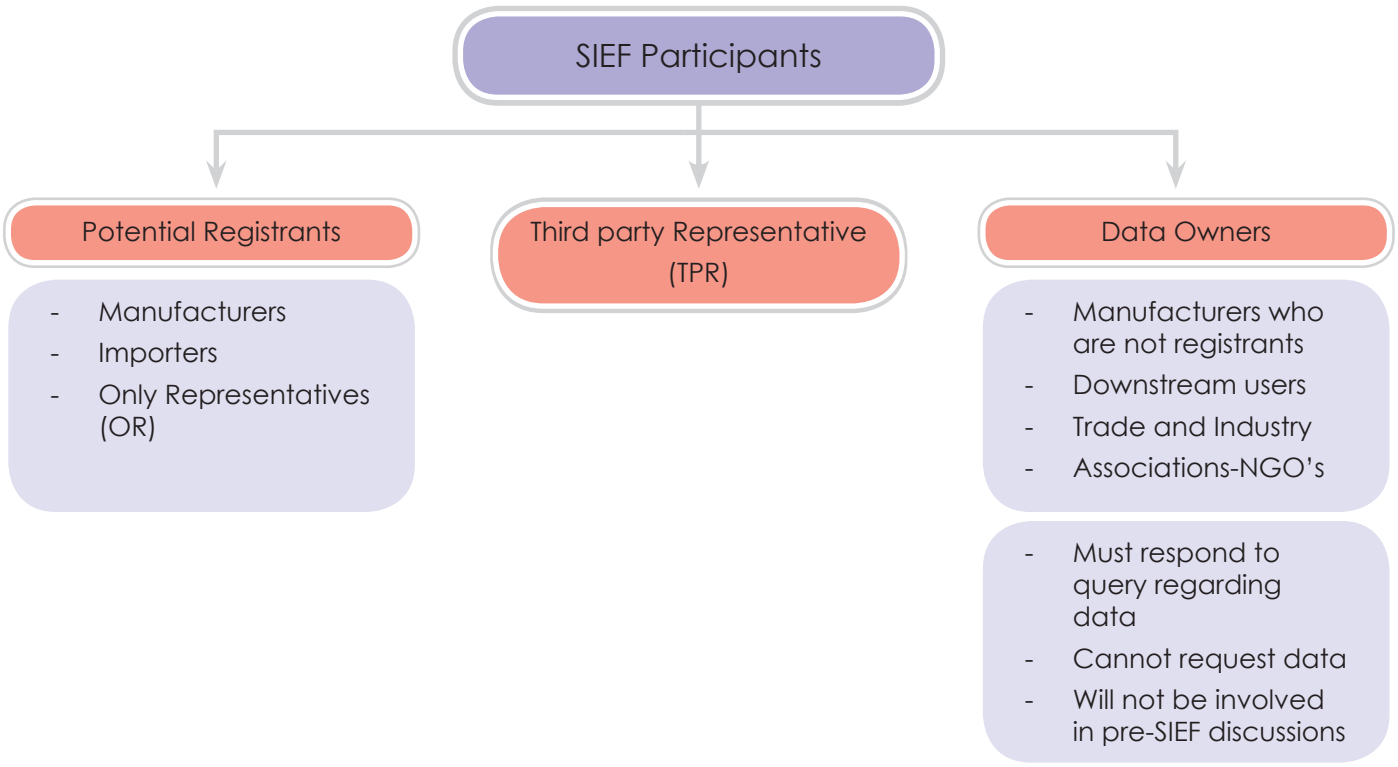
4.1 Data sharing in SIEFs

- Substance Information Exchange Forum (SIEF) – share relevant and available data amongst all Potential Registrants of the same phase-in-substance.
- SIEF would comprise of Manufacturers, Importers, Downstream users and other stake holders
- SIEF will be formed when potential registrants of a substance in the pre-registration list, actually agree that they effectively manufacture, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data (Substance identification process)
- Aims of SIEF:

– Facilitate data sharing for purpose of registration thereby avoiding duplication of studies

– Agree on the classification and labelling of the substance concerned

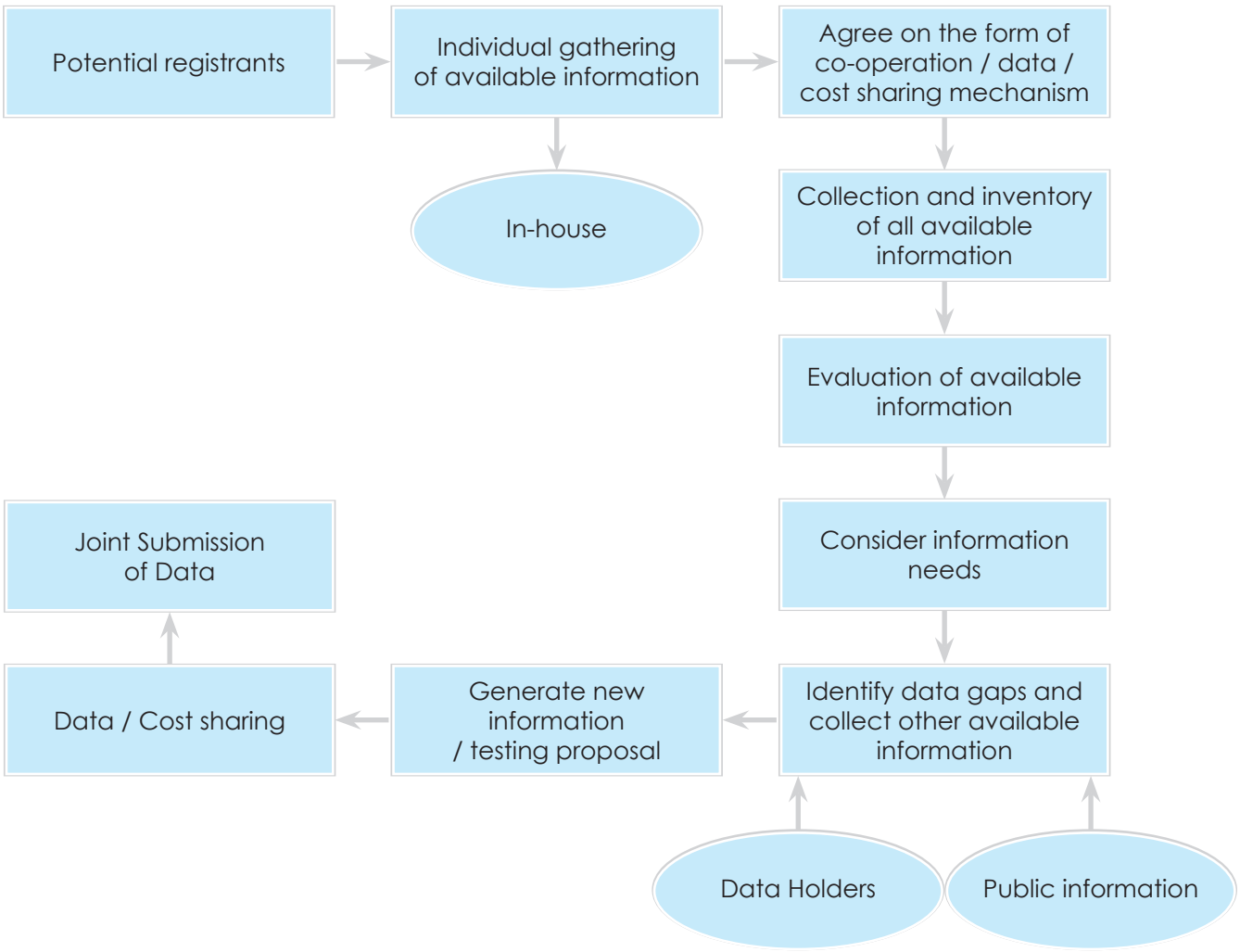
– SIEF is not a legal entity or a consortium. It is a forum to share data



4.2 Obligations of SIEF participants (article 29.3)

- Request missing information from other participants.
- React to request for information from other participants.
- Provide with existing studies upon request.
- Collectively identify needs for further studies.
- Make arrangements to perform the identified studies.
- Agree on classification and labeling.

4.3 Data sharing process:

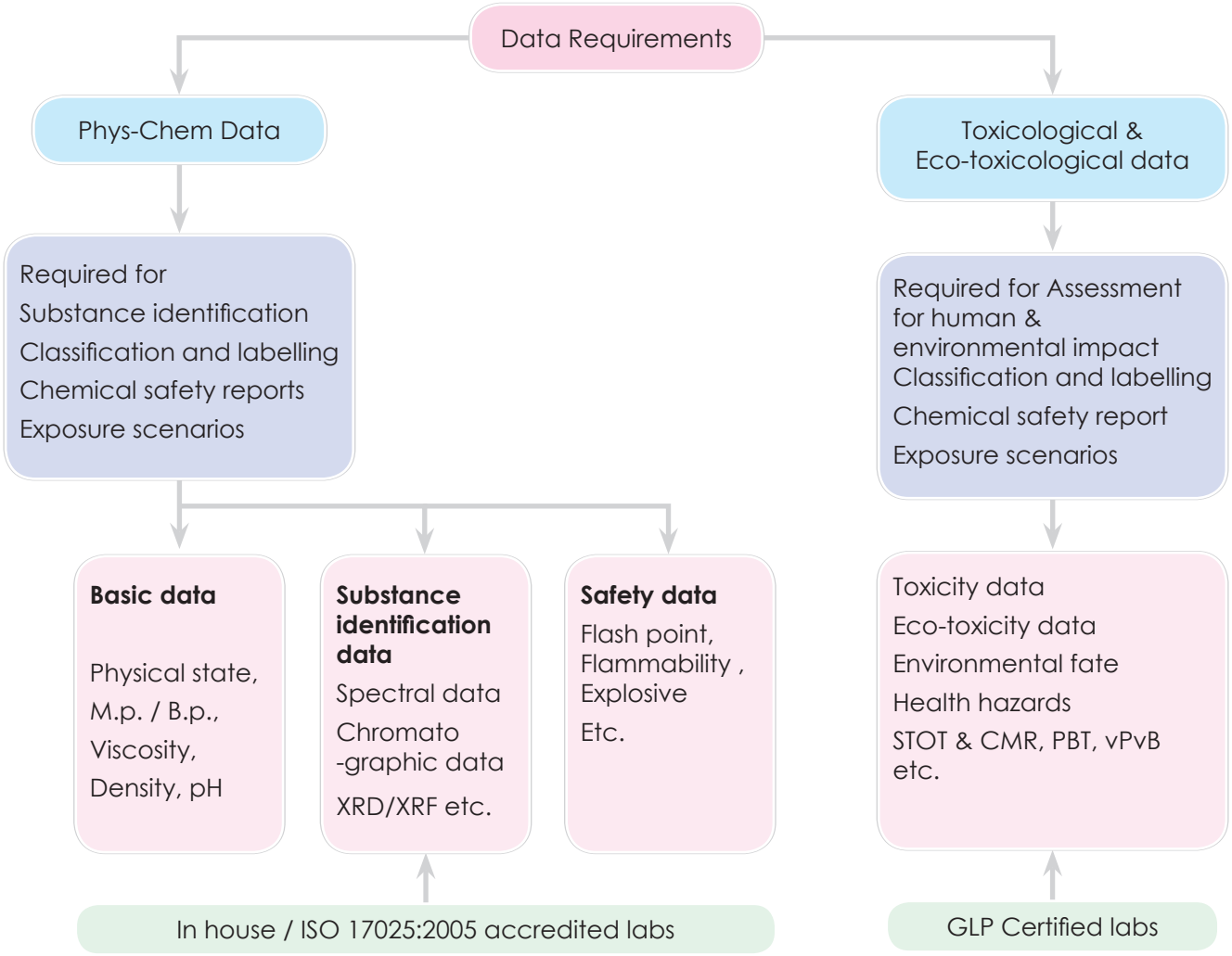


4.4 Gathering information:

- Include data available "in-house" as well as from "other sources", Information on intrinsic properties of the substance.
- Physico-chemical properties,
- Mammalian toxicity,
- Environmental toxicity,
- Environmental fate-including chemical and biotic degradation,
- Non-testing data – QSAR,

- Manufacture and uses – current and foreseen,
- Information on exposure-current and anticipated,
- Information on Risk Management Measures – already implemented and proposed,
- Data gathering should be irrespective of tonnage,
- Registrant must register all relevant and available data – including data for higher tonnage,
- Participants may conduct literature search collectively.

4.5 DATA REQUIREMENTS:



- In line with **OECD** guidance, the process of determining the scientific quality of existing data should take into consideration three aspects.
- Adequacy
- Reliability
- Relevance of the available information to describe a given element
- Klimisch HJ, Andreae E and Tillmann U (1997) addressed the issue of data quality and derived a systematic approach.

- It was a scoring system for reliability, particularly for ecotoxicology and health studies; however it may be extended to physicochemical and environmental fate and pathway studies.
- Klimisch et al. (1997), developed a scoring system which can be used to categorize the reliability of a study as follows:
- 1 = reliable without restrictions: "studies or data...generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline...or in which all parameters described are closely related/comparable to a guideline method."
- 2 = reliable with restrictions: "studies or data...(mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."
- 3 = not reliable: "studies or data...in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."
- 4 = not assignable: "studies or data....which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).
- What studies should be valued?
- From a quality perspective and taking 'Klimisch' ratings as a model, only studies with a reliability rating of 1 or 2 should normally qualify for financial compensation.
- Reports in categories (3) "not reliable" and (4) "not assignable" can therefore effectively be deselected from a valuation procedure whenever higher reliability studies are available.

Data requirements under REACH are tonnage based

<table>
<tr><th colspan="4">DATA REQUIREMENTS</th></tr>
<tr><td>CATEGORY 1-10 t/a</td><td>CATEGORY 10-100 t/a</td><td>CATEGORY 100-1000 t/a</td><td>Category >1000 t/a</td></tr>
<tr><td>Annexure VII</td><td>Annexure VIII</td><td>Annexure IX</td><td>Annexure X</td></tr>
<tr><td colspan="4">Phys-Chem Data</td></tr>
<tr><td>State of substance at 20 and 101.3 kPa</td><td rowspan="11">Same as Annexure VII.
No additional data</td><td rowspan="11">Additional data
Stability in organic solvents
Dissociation constant
Viscosity</td><td rowspan="11">Same as Annexure IX.
No additional data</td></tr>
<tr><td>Melting point /Freezing point</td></tr>
<tr><td>Boiling point</td></tr>
<tr><td>Relative density</td></tr>
<tr><td>Vapour pressure</td></tr>
<tr><td>Surface tension</td></tr>
<tr><td>Water solubility</td></tr>
<tr><td>Log POW</td></tr>
<tr><td>Flash point</td></tr>
<tr><td>Flammability</td></tr>
<tr><td>Explosive properties</td></tr>
<tr><td>Self-ignition</td><td rowspan="3">Same as Annexure VII.
No additional data</td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>Oxidizing properties</td></tr>
<tr><td>Granulometry</td></tr>
<tr><td>CATEGORY 1-10 t/a</td><td>CATEGORY 10-100 t/a</td><td>CATEGORY 100-1000 t/a</td><td>Category >1000 t/a</td></tr>
<tr><td>Annexure VII</td><td>Annexure VIII</td><td>Annexure IX</td><td>Annexure X</td></tr>
<tr><td colspan="4">Toxicological Data</td></tr>
<tr><td>Skin irritation/corrosion (in-vitro)</td><td>Additional Data
Skin irritation (in vivo)</td><td>Additional Data
Sub-chronic toxicity studies (90d)</td><td>Additional Data
Reproduction toxicity</td></tr>
<tr><td>Eye irritation (in vitro)</td><td>Eye irritation (in vivo)</td><td>Reproductive toxicity</td><td>Developmental toxicity</td></tr>
<tr><td>Skin sensitization</td><td>Mutagenicity</td><td>Pre-natal developmental toxicity</td><td>Carcinigenicity</td></tr>
<tr><td>Mutagenicity (Ames test)</td><td>-in vitro cytogenicity (mammalian cells)</td><td>2 generation reproductive toxicity</td><td></td></tr>
<tr><td>Acute toxicity</td><td>-in vitro micronucleus study</td><td></td><td></td></tr>
<tr><td></td><td>In vitro gene mutation</td><td></td><td></td></tr>
<tr><td></td><td>Acute toxicity (inhalation & dermal)</td><td></td><td></td></tr>
<tr><td></td><td>Short term repeat dose toxicity (28d)</td><td></td><td></td></tr>
<tr><td></td><td>Reproductive and development toxicity</td><td></td><td></td></tr>
<tr><td></td><td>Toxico-kinetic behavior</td><td></td><td></td></tr>
<tr><td colspan="4">Ecological Data</td></tr>
<tr><td>Aquatic toxicity (Daphnia)</td><td>Additional Data</td><td>Additional Data</td><td>Additional data</td></tr>
<tr><td>Growth inhibition (Algae)</td><td>Short term fish toxicity</td><td>Long term toxicity (Daphnia)</td><td>Degradation - biotic</td></tr>
</table>

	Activated sludge respiration inhibition	Daphnia reproduction test	Environmental fate
Degradation-biotic(Ready biodegradability	Degradation - abiotic	Degradation - biotic	Effect on terrestrial organisms
	Hydrolysis as a function of pH	-surface water simulation	-long term toxicity on invertebrates
	Environmental fate	-soil simulation	-long term toxicity on plants
	-adsorption /desorption	-sediment simulation	Long term toxicity to sediment organisms
		Identification of degradation products	Long term reproductive toxicity to birds
		Environmental fate	
		-bio-accumulation in fish	
		-further adsorption / desorption	
		Effect on terrestrial organisms	
		-short term toxicity to invertebrates	
		-effect on soil microbes	
		-short term toxicity to plants	

4.6 Cases data requirements

4.6.1 Case (i) : only Klimisch 1 studies available

By contribution of a category (1) report ("reliable without restrictions"), the share of that contributor is considered as paid for the relevant end point. This applies also for any other parties who contribute reports of equal quality. The cost allocation against this end-point is then borne only by the remaining (non-contributory) parties. If any reports are jointly owned by a number of contributors, each would be considered to have met his obligation for that endpoint from a cost share perspective.

4.6.2 Case (ii) : Klimisch 1 & 2 studies available

If reports from both category (1) and (2) ("reliable with restrictions") are available for the same end point, the report with the higher rating will be used as the key study for cost allocation purposes. Contributors supplying a lower rated report contribute according to the difference in value of their study to the key one selected. Other (non-contributory) parties support the cost on the basis of the key study value.

4.6.3 Case (iii) : Only Klimisch 2 studies available

If a report of category (1) standard is not in existence and only one or more reports of category (2) are available, the report with the highest assigned value will be selected as the key study for cost allocation. Contributory members will pay by difference (as above) whilst others will support the cost on the basis of the key study value.

05 INFORMATION ON SUBSTANCES

5.1 Safety datasheets (SDS)

Safety datasheets (SDS or MSDS) are important tool as source of information in the supply chain. The supplier has to provide a SDS to all the downstream users he supplies as soon as the substance on its own or in the preparation falls within one of the following categories:

- is considered dangerous under Directive 67/548/EEC or the preparation containing the substance classified as dangerous under Directive 1999/45/EC
- it is PBT or vPvB
- it is included in the candidate list of substances which may be subjected to authorization (SVHC)

Preparation of a Safety Data Sheet:

- For substance on its own, the Safety Data Sheet has to be prepared for the substance itself
- For a substance in a preparation, the Safety Data Sheet has to be prepared for the preparation

5.2 Registered substances information

As substances are registered under REACH, there is an obligation on registrants to provide information on the substances they manufacture or import. ECHA subsequently has the obligation to make certain of this information publicly available. Here you can find a variety of information on registered substances: for example their hazardous properties, their classification and labelling and how to use the substances safely.

Around 14600 substances have been registered at ECHA (status 25 February 2015), see:

http://echa.europa.eu/information-on-chemicals/registered-substances

5.3 Pre-registered substances information

Pre-registration intentions were submitted to ECHA between 1 June and 1 December 2008. The list may be used to find other potential registrants of your substance so that you can submit a registration dossier jointly, as required by REACH.

More than 140.000 substances have been registered at ECHA, see:

http://echa.europa.eu/information-on-chemicals/pre-registered-substances

06 AUHOTIZATION

Substances of Very High Concern will be subjected to a process of Authorization / Restriction

- Aims for authorization:
- To assure that the risks from Substances of Very High Concern (SVHC) are properly controlled.
- These substances are progressively replaced by suitable alternative substances or technologies
- A Manufacturer/Importer/Downstream User shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV of REACH. (subject to some exemptions)
- This restriction shall not apply to the use of substances, when they are present in preparations
- below concentration of 0.1% by weight.
- for all other substances below the lowest of the concentration limits specified in Dir 1 999/45/EC or Annex I to Dir 67/548/EEC (e.g. Borax 4%)
- Substances to be included in Annex XIV
- Carcinogenic Cat 1 or 2
- Mutagenic Cat 1 or 2
- Toxic to reproduction Cat 1 or 2
- PBT In accordance with Annex XIII
- vPvB In accordance with Annex XIII
- Endocrine disruptors

Currently Annex XIV has 31 substances (as on 11.12.2014)

Substance	EC No	CAS No	Sunset date	Latest Application Date	Exempted categories (or) uses
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	22.01.2019	22.07.2017	

Use or Categories of uses may be exempted from Authorization.

Sunset date is the date from which the substance cannot be placed in market / use unless authorization is granted.

- For inclusion of Substances in Annex XIV the following procedure is followed
- (1) Procedure in Article 133(4) needs to be followed.

- (2) Opinion of Member State Committee is sought.
- (3) Priority is decided (PBT or vPvB properties; wide spread dispersive use or high volumes).

Identification of Substances of Very High Concern (SVHC)

- A Candidate List is established for eventual inclusion in Annex XIV.
- Any member state or ECHA wishing to include a substance in the 'Candidate list' may prepare a dossier for these substances.
- ECHA shall publish on its website a 'Notice' inviting interested parties to comment on this dossier.
- If no comments / objections are received within 60 days the substance shall be included in the Candidate list.
- For substances wherein comments / objections have be received, and if the Member State Committee reaches unanimous decision within 30 days - included in the Candidate list.
- For substances wherein unanimous agreement is not achieved, decision will be taken as per procedure in Article 133 (3)

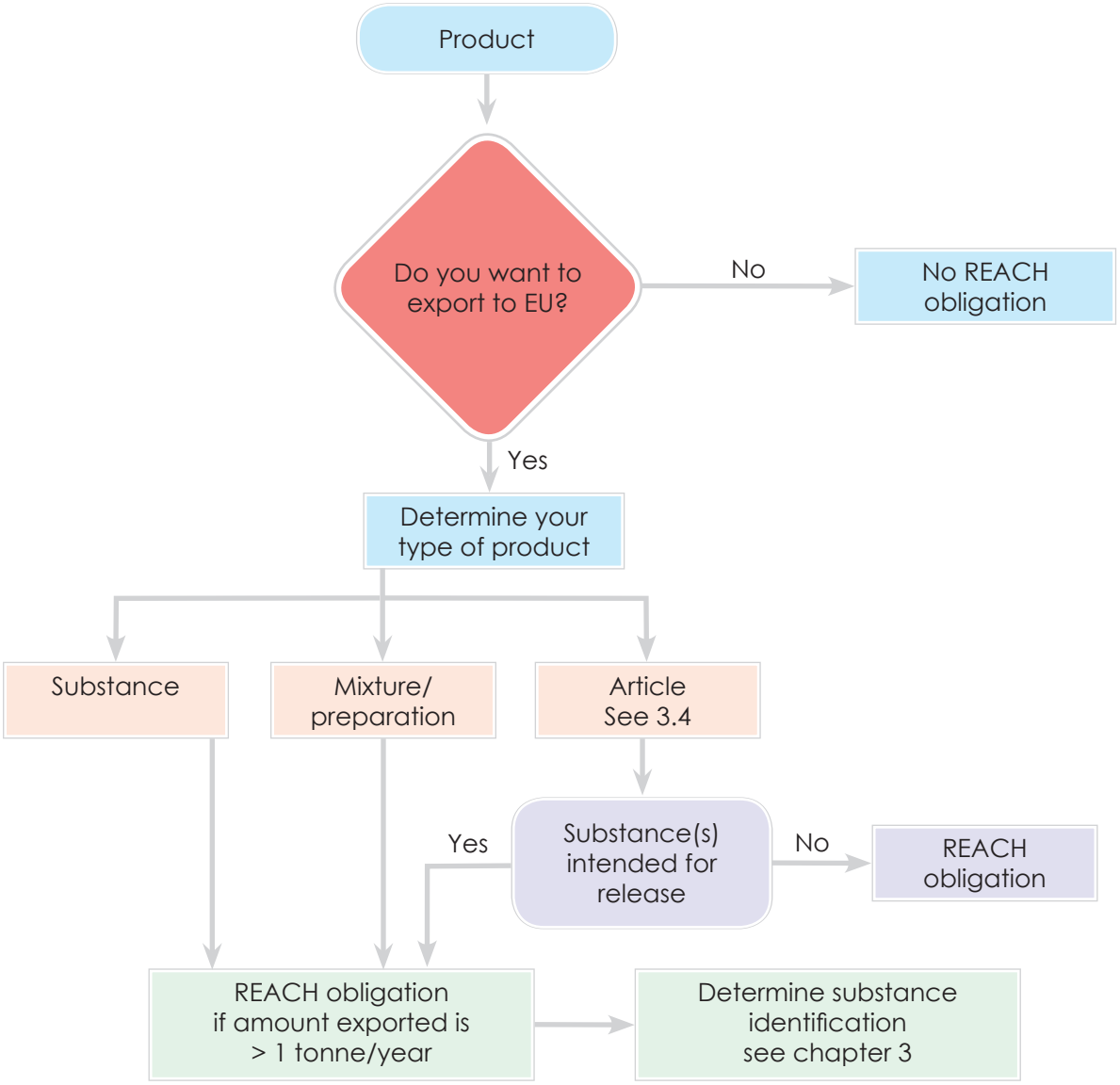
Current Candidate list consists of 155 SVHC's (dated 16.06.2014)

07 RESTRICTIONS

- Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment. A Member State, or ECHA on request of the European Commission, can propose restrictions.
- Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance.
- A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.
- In Annex XVII of the REACH Regulation "RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES" are listed. See also : http://echa.europa.eu/regulations/REACH/legislation

08 IMPACT FOR COMPANIES OUTSIDE EU

8.1 Is REACH applicable for your company?



If there is a REACH obligation for you, this means that substances (or substances present in your products) should be registered within European Union (EU). Only EU companies can do registration of substances. For you as company outside EU there are the following two possibilities:

- Appoint an OR who can do the registration for you (see 1.4)
- Rely on your importer to do the registration for you (in this case you have less influence on process).

As a potential registrant you will have two options

- Do stand-alone registration all by your self
- Submit joint registration through the SIEF (see chapter 4)

If you choose second option, you again have sub-options:

1. Participate in SIEF as an entity. Submit all data for which you are an owner (after due payments), complete the process
2. Join a "Consortia". Here again you have two options

1. Join "Consortia" as a member by paying fees and become 'owner' of data by paying data costs.
2. Get a "Load" from the "Consortia" which allows you to complete your registration without becoming the owner of the data

8.2 REACH Preparation

1. Make a list of products exported to EU and wherein you have decided to proceed with the REACH process
2. If the product is a "Substance" register "as it is"
3. If the product is a "Preparation" or "Mixture" make a list of "Substances in the preparation".
4. These individual substances need to be registered separately.
5. Decide tonnage band for each substance based on percentage composition and exports over last 3 years as well as potential.
6. Once a list of all substances is made, update the list with:
   - CAS No
   - Name of the substance (IUPAC name, Trivial name, etc.)
   - Uses / application of the substance for which it is exported
7. Appoint an "Only representative" and proceed with "Pre-registration" or "Registration" as applicable. Inform your customers of this appointment.
8. Now undertake detailed "Substance identification" studies to know your substance accurately. This involves analyzing the composition with the help of chromatographic / spectroscopic data. Also decide whether your substance is " Mono-constituent, multi constituent, UVCB etc).
9. Make a list of all test data that you posses. This should include the name of parameter, values, units, test method used, lab where data was generated (In-house, ISO 17025 accredited, GLP certified etc.)
10. With the help of "OR" examine all exemptions.
11. Submit all this data to your OR and interact with him regularly till the process is completed

Notes:

- "Phase-in" substances can be pre-registered.
- Non phase in substances have to be registered directly.
- Late pre-registration is now possible only for last deadline till 31st May 2017

IMPACT OF REACH ON VARIOUS INDUSTRY SECTORS IN INDIA

8.3 Textile /Leather Industry

Textile and Leather industry (processing houses, operational units, retailers, brand owners, consumers) are concerned only with "Articles" under REACH as they handle yarns, fibers, fabric, garments, non-wovens, hides, leather, shoes, bags, garments, gloves, belts, purses/ wallets etc. all of which may be defined as "Articles".

Impact of REACH therefore is restricted to "Substances in Articles".

Their concern related to REACH may be divided in three categories

1. Presence of substances 'intended for release'
2. Presence of SVHC's and substances subject to Authorization (Annex XIV of REACH)
3. Presence of Restricted substances (Annex XVII of REACH)

1. Textile containing substances intended for release.

Substances in "Articles" are subject to registration, evaluation and authorization under REACH, only if they are intended for release under normal and foreseeable conditions and exceed 1 tonne per annum.

Majority of the textile articles do not contain substances intended to be released. Here one needs to clearly understand that releases during wash off (denims), wear and tear, improper fastness, fading effects etc. do not fall under "intended releases"

The only types which may be affected. may be certain textiles intentionally coated with substances (free or encapsulated) for certain specific effects such as Vitamin E coatings, antibacterial coatings for control of perspiration odours, coatings for repellant effects etc.

Even in these cases, the quantity of substances (calculated as quantities per square meters) and the total articles per year may not exceed the cut-off limit of 1 tone/annum thereby not requiring registration.

Further such coatings will always be of preparations containing more than one component. Hence calculations have to be done at component levels before deciding on the need for registration.

Wherever these cut-off limits are crossed, registration needs to be done for such substances.

2. Presence of SVHC's

This is of more immediate concern. Textile manufacturers and importers in EU (and non EU exporters) need to constantly keep a tab on list of SVHC's which is ever expanding as more as more substances get incorporated in this list. The current list contains 161 substances (dated 17.12.2014). However as eventually SVHC list will contain all CMR's, vPvB's, PBT's and Endocrine disruptors, this list may blow up to thousands.

It is not necessary and practically and economically viable to test for all SVHC's. The manufacturers need to examine the chemistry, theoretical possibilities of SVHC's and do very selective testing if necessary.

Textile industry needs to get certificates from manufacturers of colourants and auxiliaries that their preparations meet the SVHC requirements of REACH. (not exceeding 0.1%).

Here again it is pertinent to note that cut-off limit may not always be 0.1% as Article 56- 6(b) puts the cut-off limit as –" for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in annex I of Directive 67/548/EC which result in classification of the preparation as dangerous."

To give an example, though Borax is included in the SVHC list (and is present in Enzyme preparations for textile processing), the cut-off limit is 4% and not 0.1%

Some of the SVHC's that may be of concern to Textile & Leather industry

No	SVHC (REACH) (EC No.)	Name	Where likely to be found
1	548-62-9	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	Dyestuff
2	6786-83-0	a,a-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	Dyestuff
3	101-61-1	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	Dyestuff
7	561-41-1	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	Dyestuff
9	75-12-7	Formamide	Auxiliary
10	2580-56-5	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	Dyestuff
13	90-94-8	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	Dyestuff
19	107-06-2	1,2-dichloroethane	Stain removers
22	90-04-0	2-Methoxyaniline; o-Anisidine	Dyestuff
26	25214-70-4	Formaldehyde, oligomeric reaction products with aniline	Tanning agent
30	117-82-8	Bis(2-methoxyethyl) phthalate	Leather finishing
34	7646-79-9	Cobalt dichloride	Dyestuff (metal complex)
38	872-50-4	1-Methyl-2-pyrrolidone	Solvent dyes
42	71-48-7	Cobalt(II) diacetate	Dyestuff (metal complex)
44	110-80-5	2-Ethoxyethanol	Finishing auxiliary
45	109-86-4	2-Methoxyethanol	Finishing auxiliary
50	79-01-6	Trichloroethylene	Stain removers
51	7778-50-9	Potassium dichromate	Dyestuff (metal complex)
54	10043-35-3, 11113-50-1	Boric acid	Enzyme preparations
55	7775-11-3	Sodium chromate	Dyestuff (metal complex)
56	1303-96-4, 1330-43-4, 12179-04-3	Disodium tetraborate, anhydrous	Enzyme preparations
57	7789-00-6	Potassium chromate	Dyestuff (metal complex)
58	79-06-1	Acrylamide	Polymer emulsions
59	1344-37-2	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	
60	12656-85-8	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	
66	84-69-5	Diisobutyl phthalate	Finishing auxiliaries
72	85-68-7	Benzyl butyl phthalate (BBP)	Finishing auxiliaries
73	117-81-7	Bis (2-ethylhexyl)phthalate (DEHP)	Lacquer/lacquer emulsions
79	7789-12-0, 10588-01-9	Sodium dichromate	Metal complex dyes
80	84-74-2	Dibutyl phthalate (DBP)	Lacquer/lacquer emulsions
82	85535-84-8	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	Leather fat liquors
83	120-12-7	Anthracene	Anthroquinone dyes

84	25637-99-4, 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	
85	1163-19-5	Bis(pentabromophenyl) ether (DecaBDE)	Flame retardant
91	-	4-Nonylphenol, branched and linear - substances with a linear and /or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof	Pre-treatment & Dyeing printing auxiliaries (Wetting agents, levelling agents, finishing auxiliaries,)
124	75-56-9	Propylene oxide; 1,2-epoxypropane; methyloxirane	EO-PO black co-polymers
125	64-67-5	Diethyl sulphate	Quaternary products
126	77-78-1	Dimethyl sulphate	Quaternary products
132	95-80-7	4-methyl-m-phenylenediamine (2,4-toluene-diamine)	Dyestuff
133	120-71-8	6-methoxy-m-toluidine (p-cresidine)	Dyestuff
134	92-67-1	Biphenyl-4-ylamine	Dyestuff
135	97-56-3	o-aminoazotoluene	Dyestuff
136	95-53-4	o-Toluidine; 2-Aminotoluene	Dyestuff
139	7440-43-9	Cadmium	Dyestuff
141	335-67-1	Pentadecafluorooctanoic acid (PFOA)	Finishing auxiliary
142	131-18-0	Dipentyl phthalate (DPP)	
143		4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	Pre-treatment & Dyeing printing auxiliaries (Wetting agents, levelling agents, finishing auxiliaries,)
146	573-58-0	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	Dyestuff
147	1937-37-7	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	Dyestuff
148	84-75-3	Dihexyl phthalate	Leather auxiliaries
149	96-45-7	Imidazolidine-2-thione (2-imidazoline-2-thiol)	Finishing auxiliary
156	117-81-7	Di-(2-ethylhexyl)-phthalate	Leather auxiliaries

3. Restricted substances:

This is the most relevant aspect for textile industry.

All restrictions in place, in EU, for Consumer protection/care covered under 76/769/EC and all subsequent amendments covering restricted substances and their limits under different classes of compounds are now clubbed under this Title in Annex XVII in REACH

Thus all previous restrictions on (to name a few)

1. Banned aryl amines [2002/61/EC]
2. Chlorophenols
3. Chlorinated hydrocarbons
4. Phthalates [2005/84/EC; 2004/781/EC]
5. Alkyl phenols and their ethoxylates [2003/53/EC]
6. Polycylic aromatic hydrocarbons
7. Polychlorinated biphenyls
8. Halogenated Flame retardants[2003/11/EC]
9. Dioxins and furans

10. Heavy metals [2004/96/EC]
11. Organotins [2002/62/EC]
12. Short Chain Chlorinated paraffins [2002/45/EEC]
13. Dimethyl fumarates[2009/251/EC]
14. AOX [200/479/EC]
15. ROHS
16. E N71-9

Are now included in Annex XVII of REACH. Textile processors need to ensure that the articles they manufacture or import into EU meet the requirements and the limits of restrictions.

These are also relevant from the Roadmap towards "Zero Discharge of Hazardous Chemicals (ZDHC) of 11 groups of hazardous substances.

8.4 Coatings Industry

Basic Functions of coatings is to provide Aesthetics (visual appeal colour, sheen, gloss, special effects) and Protection (protection of concrete, masonry, wood, metals etc. from weather, sunlight, microbes, corrosion, abrasions etc.).

Generally Coatings are preparations made using several components shown below. (Each component may itself be a preparation). Under REACH, individual 'substances in preparations' have to be registered if they meet the criteria.

- Colorants : Pigments (Inorganic / Organic)
- Solvents : Aliphatic / Aromatic / Water (alcohols, esters, glycols)
- Binders : Oils / Alkyds / Epoxies / Polyurethanes / Acrylics / Silicones
- Additives : Driers (naphthenate and octoate salts of Co, Pb, Mn)
- Rheology modifiers : (cellulose, hydrogenated castor oils, modified urea's etc.);
- Microbicides : (PCP, Organotins, isothiazolinones) ;
- Surfactants : (APEO as well as non-APEO based);
- Defoamers : (Silicone and non silicone)

Important issues that need to be examined may be as shown below

Component	Issue	Concern	
Colourants	Pigments	Banned pigments or banned aryl amines that can be released from pigments	Annex XVII and SVHC
	Pigments	Heavy metals like Pb, Cd, Cr	Annex XVII and SVHC
Solvents	Glycol ethers	Reproductive toxicity of glycol ethers	Annex XVII
Binders	Acrylamide	Residual monomer	SVHC
	Urethanes		Annex XVII
	Plasticizers	Phthalates	SVHC
Additives	Organotins	Catalysts	Annex XVII
Surfactants	APEO based surfactants		Annex XVII and SVHC

Apart from this persistence [PBT's- as pigments are insoluble in water and may persist in environment for extended periods] and Volatile Organic components are of great concern.

8.5 Polymer Industry

Polymers are exempted from certain obligations under REACH. However monomers are not.

For polymer manufacturers it is very vital to first establish that their substances meet the definition of polymers. Thus molecular weight distribution data is of utmost importance.

Monomers need to be registered. As long as one is using /importing monomers that have been manufactured in EU, there is not much of a problem as the Up-stream manufacturer of monomers would have done the registration. However if the monomers are procured from other countries (Saudi Arabia or Japan etc.) then these need to be registered by manufacturer or importer of polymers.

Data on residual monomers such as Acrylamide is important as it is an SVHC. Similarly catalysts used in polymerization process need to be screened.

Surfactants based on APEO's (alkylphenol ethoxylates) should be avoided.

8.6 Perfumery Industry

Ingredients of perfumes can be either synthetic or natural. Natural essential oils used in perfume will be exempted from certain obligations under REACH, if these natural products are not chemically modified.

Manufacturers / exporters must have data regarding name of the substance, source, species, process used for extraction (not involving chemical modification) etc. to claim exemption.

Synthetic perfumes will have to be treated like any other chemical substance.

Sometimes certain Phthalates have been used as carriers of perfumes. These may be affected by SVHC list.

8.7 Inorganic chemicals Industry

Inorganic chemical industry needs to carefully examine various inorganic compounds included in the SVHC list. Toxic heavy metals are of great concern and thus both SVHC and Annex XVII list needs to be constantly monitored

8.8 Natural products Industry

Natural products, if not chemically modified are exempted.

Annex IV list several products which can avail exemption such as:

- Glucose
- Ascorbic acid
- Stearic acid
- Mannitol
- Sunflower oil
- Soybean oil
- Castor oil
- Lecithin
- Fatty acids

- Limestone
- Etc.

Annex V list several products which can avail exemptions such as:

- Substances incidental to storage
- Substances formed due to exposure
- Hydrates of substances whose anhydrous forms have been registered
- Mineral ores, ore concentrates, cement cinders, natural gas, LPG, crude oil, coke coal etc.
- Other natural substances which have not been chemically modified

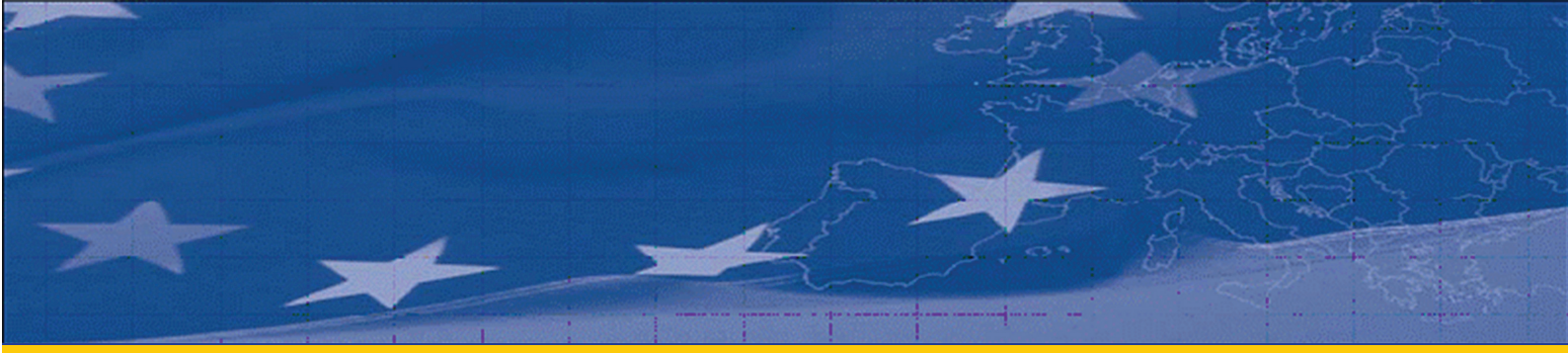
IMPORTANT STAKEHOLDERS WITHIN EU

This page offers website of important links to stakeholders within EU that are publically available and free of charge. They have been provided by ECHA's accredited stakeholders, and are published with the aim to facilitate the implementation of European chemicals legislation.

AISE
International Association for Soaps, Detergents and Maintenance Products
http://www.aise.eu/
CEFIC
European Chemical Industry Council
http://www.cefic.org/
ChemSec
International Chemical Secretariat
http://www.chemsec.org/
CONCAWE
Conservation of Clean Air and Water in Europe
https://www.concawe.eu/Content/Default.asp
ECETOC
European Centre for Ecotoxicology and Toxicology of Chemicals
http://www.ecetoc.org/
ECHA
European Chemicals Agency
http://echa.europa.eu/
ECPA
European Crop Protection Association
http://www.ecpa.eu/
EDANA
The international association for the nonwovens and related industries
http://www.edana.org/
EUROFER
The European Steel Association
http://www.eurofer.org/
Eurometaux
European Association of Metals
http://www.eurometaux.org/
FEA
European Aerosol Federation
http://www.aerosol.org/
FECC
European Association of Chemical Distributors
http://www.fecc.org/fecc/
FEICA
Association of European Adhesives and Sealants Manufacturers
http://www.feica.com/
NIA
Nanotechnology Industries Association
http://www.nanotechia.org/
PISC
Peta International Science Consortium, Ltd.
http://www.piscltd.org.uk/

IMPORTANT STAKEHOLDERS WITHIN INDIA

This page offers websites of important links to stakeholders within India.

AIAI
All India Association of industries
http://www.aiaiindia.com/
AIPIA
All Indian association of plastic industries
http://www.aipia.org/
AIRIA
All India Rubber Industries Association
http://www.allindiarubber.net/
CHEMEXCIL
BASIC CHEMICALS, PHARMACEUTICALS & COSMETICS EXPORT PROMOTION COUNCIL
(Set-up by Ministry of Commerce & Industry, Government of India).
www.chemexcil.in
CII
Confederation of Indian Industry
www.cii.in
ELCINA
ELCINA Electronic Industries Association of India
www.elcina.com
FAFAI
Fragrances and Flavours Association India
http://www.fafai.org/
ICC
Indian Chemical Council
http://indianchemicalcouncil.com/industry-associations.htm
IPA
http://www.aipia.org/
http://www.ipaindia.org/
NABL
National Accreditation Board for Testing and Calibration Laboratories
http://www.nabl-india.org/
NABCB
Quality council of India
http://www.qcin.org/nabcb/
PIAI
Packaging Industry Association of India
http://piai.org/
SIAM
Society of Indian Automobile Manufacturers
http://www.siamindia.com/
TAI
Textile Association India
http://www.textileassociationindia.org/home

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