

REACH: Implications for IPIA and its Member Companies

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Why I am here

- The REACH Centre (www.thereachcentre.com) and
- PTK Ltd (www.ptkltd.com): consultancy on regulatory chemicals issues (e.g. REACH, GHS)
 - Individual companies, trade associations, academic institutions
 - Special Advisor to EU Presidency (Government of Finland), 2006
- **DG ENTR (until September 2004)**
 - author (1 of) of REACH
 - co-decision process (Council & EP)
 - implementation of GHS in EU
- **UK government (HSE): international chemicals policy**
 - policy on chemicals strategy White Paper
 - author (1 of) of GHS: IOMC drafting group
 - Acting head of UK delegation to IFCS III
- **DG ENV chemicals unit (94 – 97)**
 - NONS, ESR, C&L

Presentation

- Why REACH is important to you
 - **Cultural Change**
- REACH Overview
- Registration
 - **Scope**
 - **Pre-registration**
 - **Substance identity**
 - **One substance one registration (OSOR)**
 - **Substances in articles**
 - **Non-EU manufacturer**
 - **Only representative**
- Information through the supply chain
 - **Downstream users**
- IUCLID 5

Why REACH is important to you

- **REACH will impact chemical use and supply globally**
- **Withdrawal of substances inevitable; in your supply chain?**
- **Greater information will affect liability**
- **Exports to EU; importers and customers will require help (scientific, technical etc)**
- **Opportunities as well as threats**
- **Costs and benefits**

Cultural Change

- **Most health, safety and the environment (HSE) legislation is largely ‘technical’ in nature**
- **Usually delegated to HSE departments and professionals**
- **REACH is different...**
- **Organisations have to think differently and across all operations**

Cultural Change

- 1. No data = No market**
 - Not an 'open' market but a tightly regulated one
- 2. Pre-manufacture, not pre-marketing**
- 3. Responsibility placed on industry and manufacturers/importers (M/I) in particular**
- 4. Role of national authorities 'one step' removed**
- 5. Greater sharing of information on substances in products (preparations and articles), including to customers**

Cultural Change

- 6. 'Forced' cooperation between companies (OSOR, data sharing)**
- 7. 'Forced' communication along the supply chain (e.g. on properties, identified uses, risk management measures (RMM))**
- 8. Business decisions feeding into technical areas and vice versa (e.g. uses to support, relationship with customers and suppliers)**
- 9. Legal considerations (how work together, confidentiality, supply contracts)**
- 10. Ongoing/continuous obligation (i.e. not a one-off 'fix')**

REACH in a Page

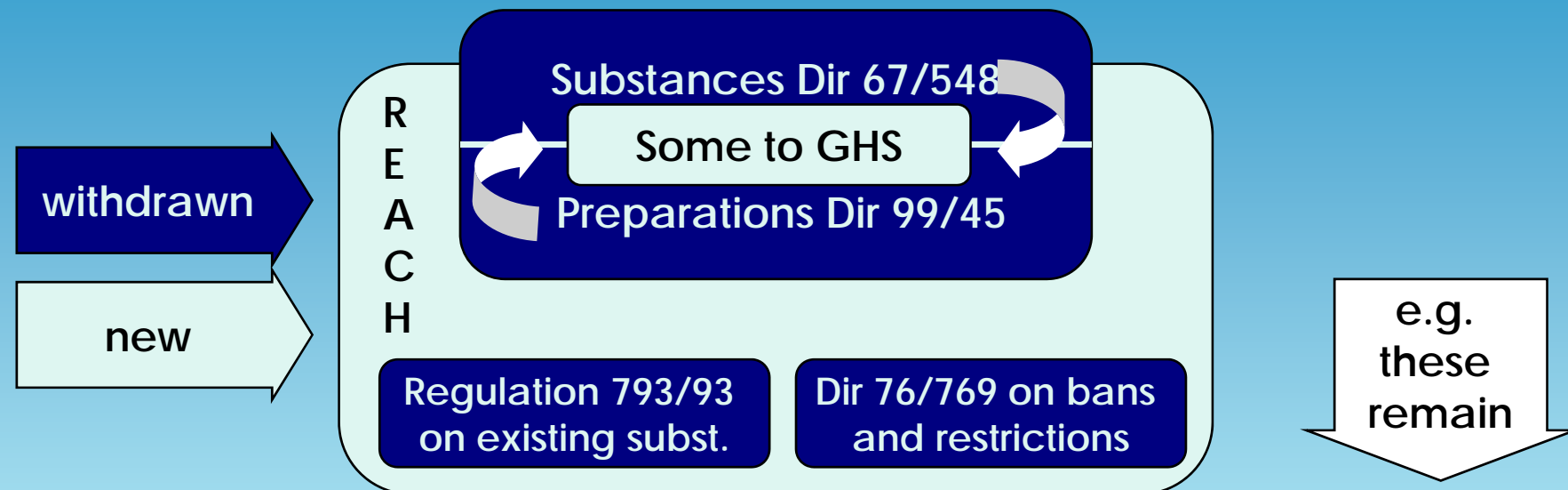
REACH = Registration, Evaluation and Authorisation of Chemicals

High level of health and environmental protection with the goal of achieving sustainable development.

- Single coherent system for new (non phase-in) and existing (phase-in) chemicals
- Elements:
 - **Registration** of substances ≥ 1 tonne/yr (staggered deadlines)
 - **More information and better communication** through the supply chain
 - **Evaluation** of some substances by European Chemicals Agency (MS support for substance evaluation)
 - **Authorisation** only for 'Substances of Very High Concern' (SVHC)
 - **Restrictions** - the safety net
 - **Agency** to manage system
- Focus on priorities:
 - high volumes (early deadline)
 - greatest concern (CMRs and high volume R50/53 early)

A Tiered Approach

Replaces part of EU Chemical Legislation



medicines	food, feed, food additives	biocides	Plant Protection Products
fertilizers	cosmetics	detergents	product safety
transport of dangerous goods	Seveso	worker protection	liability
international conventions	waste	environmental protection	

Scope of REACH

- **Applied to substances**
 - as such
 - in preparations
 - in articleswithin a life cycle
- **Applied to**
 - manufacture
 - import
 - placing on the market
 - use

Substance – means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (see RIP 3.10).

Preparation – means a mixture or solution composed of two or more substances.

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 .

Chemical – not defined in the Regulation - appears only in the name of the Regulation. In normal language means substances and preparations.

General Exemptions

- **REACH does not apply to**
 - Waste: not considered to be a substance, preparation or article
 - radioactive substances
 - substances in customs supervision under specified conditions
 - non-isolated intermediates
 - transport of dangerous goods
 - MS discretion: substances used for defence purposes
- **Worker and environmental legislation applies without prejudice to REACH**
- **A lot of other exemptions: e.g. on Registration, Evaluation, Authorisation and Downstream user obligations**
- **Scope to be reviewed by 1 June 2012**

Actors

Manufacturer – means any natural or legal person established within the Community who manufactures a substance within the Community

Producer of an article – means any natural or legal person who makes or assembles an article within the Community

Importer – means any natural or legal person established within the Community who is responsible for import

Downstream user – means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user

Distributor – means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties

European Chemicals Agency: Agency established by REACH-Regulation in Helsinki

Competent Authorities of the Member States: to be appointed or established by EU Member States

Enforcement authorities of the Member States: to be appointed or established by EU Member States.

Consumer: REACH Regulation does not set obligations to consumers, but will improve access to information on substances

A company has to identify its role/roles within REACH

Scope of Registration

- **New notified substances considered to be registered**
- **Uses as (approved) pesticide or biocide component regarded as being registered**
- **Exemptions from Registration**
 - Uses covered by sectoral legislation (e.g. medicinal uses, food additives)
 - Identified individual substances (Annex IV)
 - E.g. some organics, cellulose pulp
 - Categories of substance (Annex V). For example:
 - Ores, ore concentrates, minerals, cement clinker, liquid petroleum gas (LPG), crude oil, coke, coal (which occur in nature) exempted unless chemically modified.
 - Substances occurring in nature unless chemically modified and unless meet the criteria for classification as dangerous.
- **Review of Annexes IV and V by 31 May 2008**

MOST IMPORTANT NOW!!

Pre-registration

****Pre-registration****

- **Timing? 1 June 2008 – 1 December 2008**
- **Why?**
 - To allow phase-in substances (EINECS listed substances on own, in preparations, intended to be released from articles) to take advantage of the phase-in deadlines
 - To enable all registrants of the same substance to prepare a single hazard data-set (= OSOR)
 - To agree classification and labelling
- **Who?**
 - Potential registrant (M, I, ‘only representative’)

Pre-registration

- **What?**

- Substance name
- Potential registrant details (or 3rd party representative)
- Deadline for registration
- Similar substances (for read-across).

- **How?**

- Agency form on website
- Agency publishes list of information on website
- Pre-registrants put in touch

- **Next?**

- ‘Pre-SIEF’: **sameness check**. One SIEF may require several SIEFs in practice
- Start of the SIEF (Substance Info Exchange Forum); can also include DUs and other non-registrants
- SIEF works out how it operates; few rules (**consortium?**)

IPIA Role

- ***Third party representative?***
 - *Act as or recommend*
 - *Necessary for pig iron?*
 - *Additives/ingredients?*
- ***Identifying whether pig iron as pre-registered requires several SIEFs to be established and setting out their parameters (e.g. impurities present and ranges).***

Why is Pre-registration so Important?

- **First duty for most**
- **Vital for all**
- **Take advantage of phase-in deadlines**
- **Importer: have to pre-register 'all' substances, substances in preparations and substances 'intended to be released' from articles**
- **Manufacturer: have to pre-register 'all' substances**
- **Downstream User: have to ensure the substances supplied to you are registered (threat of substance withdrawal)**

Pre-registration: Notes

- Identify substances essential to you as a downstream user (as well as for your own pre-registration)
- Identify substances 'intended to be released' from articles – few (**RIP 3.8 interpretation...**)?
- Consequences of failure to pre-register
 - Withdrawal of substance from market?
 - No registration no market
 - Early registration; from 1 June 2008 (**1 December 2008 in practice**)
 - Uncertainty
 - N.B. possibility of DUs being able to react to list of pre-registered substances
- Some substances 'regarded as being registered' so no need to pre-register (but can presumably operate in the SIEF)
- **If in doubt (e.g. substance identity, registration strategy) pre-register (buys you time but also duties)**

Consortia

- **Not mentioned in REACH**
- **Legal platform for cooperation ('SIEF with a contract') including:**
 1. Substance identity check
 2. Management of SIEF
 3. Organise exchange of data
 4. CBI management
 5. Ownership of data
 6. Liability
- **Pre-register => SIEF but can decide not to be in a consortium**

IPIA Role

- ***Establishing and managing, directly or through an agent, a consortium of IPIA members to undertake REACH tasks***
 - *cost-effective and efficient*
 - *many trade organisations have organised consortia*
 - *depends partly on activities of others...*
 - *IPIA role set-out in a contract or agreement to support or manage the work of the consortium*
- ***Consortium must adhere to European Competition Law and not violate WTO rules***

IPIA Member Companies

- *Identify substances (pig iron and potentially others) that require pre-registration*
- *Decide on registration strategy per substance to pre-register (EU manufacturers, importers or only representatives)*
- *Decide whether a third party representative is needed*

IPIA Member Companies

- *SIEFs will operate from January 2009*
- *Companies should be prepared to operate effectively (in some cases this will mean an active role and in others a ‘watching brief’) in SIEFs from this date.*
- *Register pig iron by end November 2010 (assuming >1000t/yr)*
 - *need to be active immediately the SIEFs are formed*

Identification & Naming of Substances

- At pre-registration, substance identification does not require full identification; potential registrant to give the name of the substance including its EC-number and CAS-number, if available.
- RIP 3.10 => naming rules.
- Registration to include substance identity.
- If not technically possible, or scientifically necessary, to give information on a substance parameter a justification is needed.

Substances: subdivision, RIP 3.10

Well defined substances

- Mono-constituent substances
- Multi-constituent substances

UVCB substances

- substances of Unknown or Variable composition, Complex reaction products or Biological materials

Well Defined Substances

Mono-constituent substances

Chemical composition: one main constituent > 80% (substance identity according to the main constituent)

Multi-constituent substances

mixture of main constituents each between 10 - 80% (substance identity by each main constituent)

For substances defined by more than the chemical composition, for example crystal forms, substances are also identified by physical or characterisation parameters: e.g. crystallography

Mono-Constituent Substances

- **Pig iron** and some **alloys** have a primary component present above 80%.
- Substance identity on the basis of the >80% component?
- The naming conventions in RIP 3.10 indicate that the remaining (up to) 20% are impurities:
“all constituents (except additives) which are not the main constituent(s) in the mono-constituent...substance are considered to be impurities”
- Impurities are *“an unintended constituent present in a substance, as produced. It may originate from the starting materials...not intentionally added”* (RIP 3.10).
- Hard to argue for most alloys, but OK for pig iron?

UVCB Substances

- *Biological substances*
 - Plant or animal species and family.
 - Part of plant/organ of known or generic composition.
 - Chromatographic and other fingerprints
- *Chemical and mineral substances with poorly defined, complex or variable composition (UVC)*
 - Known or generic composition
 - Chromatographic and other fingerprints
 - Reference to standard index

Substance Characterisation

Is crucial for **SIEF** formation and **Grouping**

- Should contain same main constituents
- Impurity profile may define use of data
- If similar enough data sharing possible

This requires expert judgement

Examples:

- Hydrates and water free substances may be one substance
- Acids or bases and their salts are different
- Branched vs linear, saturated vs unsaturated are deemed different

Registration: general

Registrant collects information, assesses risk(s) and implement/recommend relevant control measures

- **Scope**
 - substances manufactured/imported ≥ 1 tonne/year (per M/I)
 - Isolated intermediates: reduced requirements.
 - Exemptions e.g. PPORD, polymers, non-isolated intermediates
- **Tasks of the registrant (manufacturer/importer (only rep.)):**
 - obtain adequate information (inc (Q)SAR and existing data)
 - perform CSA for substances > 10 tonnes/year (demonstrate adequate control per use)
 - send information to Agency by deadline (and to clients)
- **Single hazard data-set per substance (OSOR)**

No formal acceptance - industry retain responsibility

IPIA Role

- ***Cannot take over the pre-registration and registration responsibilities for its member companies***
- ***The exception to this would be if IPIA was appointed as an OR by one or more non-EU manufacturers.***
- ***However, industry associations can provide valuable assistance to registrants in preparing registration dossiers, and can help co-ordinate the process.***

IPIA Role

- *Submit data on the substance to the SIEF?*
- *Appointed to represent a registrant in discussions with SIEF members on preparation of the joint submission of hazard data?*
- *Act as third party representative?*
- *SIEFs can include non-EU enterprises and other organisations who, even though having no direct registration obligations, can provide information and assistance.*
- *Set-up and manage, directly or through an agent, a consortium of potential registrants to prepare the material for registration by all members of the consortium.*

Timetable- Phase-in Substances

Volume of substance manufactured (EU) or imported (into EU) (per manufacturer or importer per year*)	Registration deadlines for phase-in substances 1 June 2008 start registration. Pre-registration 1/6 – 1/12/08.
≥ 1,000 tonnes or CMR ≥ 1t or PBTs/vPvBs (R50/53**) ≥ 100t	End Nov 2010
100 – 1,000 tonnes	End May 2013
10 – 100 tonne	End May 2018
1 tonne	End May 2018

* average of last 3 years

**very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment

Registration: OSOR

- Shared hazard data-set per substance
- **No mandatory sharing of use information**
- Pre-registration: 1 June to 1 Dec 2008
- Data sharing
 - Animal data always shared
 - Non animal data shared on request
- Joint data set - mandatory with opt outs:
 - Disproportionate cost
 - Commercial secrets
 - Disagreement on selecting data

IPIA Role

- **Only Representative:**
 - *help non-EU manufacturers make decisions about whether to appoint an OR?*
 - *identify suitable ORs?*
- **Act as the OR (if the resources and expertise are available)?**
- **Opt outs from SIEFs:**
 - *advisory role on whether opt-outs could apply and were advisable?*
 - *prepare justifications, required by ECHA, if required?*

OSOR



Production or Import



Analysis and identification



Pre-registration



**Substance Information
Exchange Forum SIEF**



Consortium formation



Data sharing



Joint Submission

Reg. Dossier: who will submit what?

Art. 10 and 11

<u>Lead registrant:</u>	<u>Optional:</u>	<u>Each registrant separately:</u>
<ul style="list-style-type: none">• C&L* (proposal)• (robust) study summaries• testing proposal• assessor indication	<ul style="list-style-type: none">• guidance on safe use (extension of SDS**)• CSA/R***	<ul style="list-style-type: none">• identity of the registrant• substance identity• mfg & use information use & exposure categories• 1-10 t/a: exposure information• assessor indication

Possession of or permission to refer to full study report

Copy of full study report can be requested by evaluating MS

* classification and labelling

** safety data sheet

*** chemical safety assessment/report

Generation of Information

- (Q)SARs*
- Use of category approaches
- Analogs, read across
- Available data (non-EU, GLP**, non-GLP)
- Historical human data
- Data sharing (existing and new)
- Testing (*in vitro*, *in vivo*) as a last resort

See Annex XI = FLEXIBILITY !

- **Information requirements may also be waived**
 - because testing can't be done on a substance
 - for some tests (mainly in Annexes IX and X) because of no/limited exposure (exposure based waiving)

* Quantitative Structure Activity Relationships

** Good Laboratory Practice

Pig Iron

3 'substances'

Basic, haematite and nodular

- High potential for read-across
- Hazard information may already be available for most components
 - *Need to consider how this may relate to the substances*
 - *Use of transformation/dissolution tests?*

Dominic will discuss more

IPIA Role

- **Gathering, assessing, evaluating and valuing available information? On behalf of:**
 - *individual IPIA member companies,*
 - *groups of companies, or*
 - *the SIEF as a whole.*
- **Holder of data on behalf of its members**
 - *establish who owns the data (only the owner of the data can input data into the SIEF and gain compensation for its use)*
- **Supporting the relevant SIEF(s) in assessing the quality and value of data?**
- **Recommending how the relevant costs could be shared between members of the SIEF?**

Registration: 1 – 10t

- Special rules apply
- All: physicochemical properties of Annex VII (+ available information)
- New substances: full Annex VII
- Screening by registrant:
 - likely CMR*, PBT** or vPvB***, or
 - Dangerous for health and environment plus wide-spread exposure?

=> full Annex VII

* carcinogen, mutagen, reproductive toxicant

** persistent, bioaccumulative and toxic

*** very persistent and very bioaccumulative

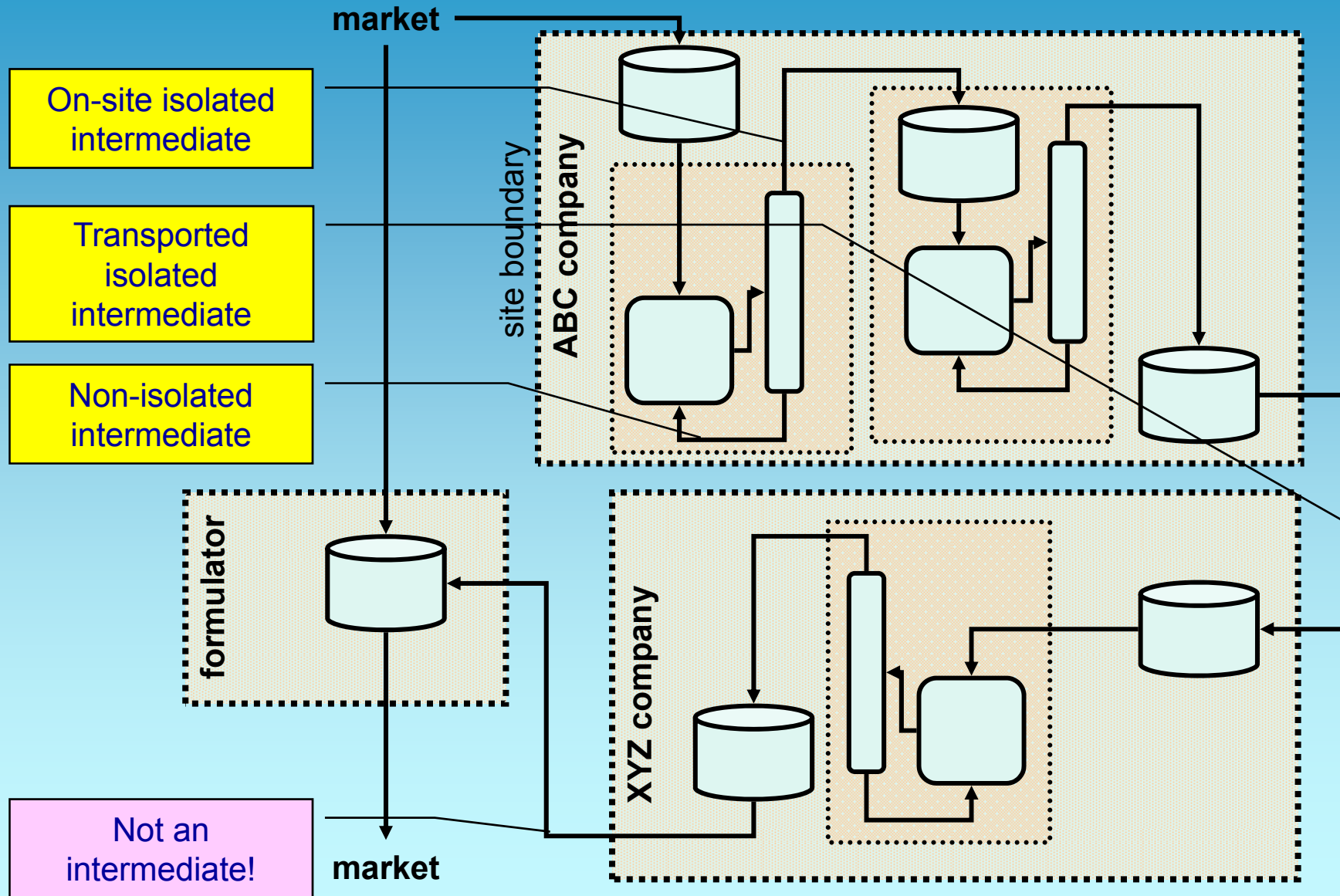
Registration: Notes

- **Volume for registration is per manufacturer or importer (average of last 3 years)**
- **An importer may import the same substance in several different products; aggregate quantities**
- **Total quantity for substances in articles (SIA), not quantity intended to be released**
- **Operate in SIEF regardless of registration deadline**
- **No signal within three weeks of registration carry on...does not mean however that it is a valid registration**

Intermediates

- **Non-isolated: exempt**
- **On-site limited isolated: reduced registration**
- **Transported isolated: reduced registration**
- **Satisfy definition and strictly controlled conditions apply (Art 17)**
- **N.B. SYNTHESIS!**

Intermediates



Registration: Substances in articles (1)

- Registration of substances intentionally released (Art. 7.1)
 - applies to all substances in articles (SIA); i.e. no requirement to meet criteria for classification as dangerous
 - deadlines and thresholds as other substances

Registration:

Substances in articles (2)

- **Notification of 'substances of very high concern' (SVHC) (Art. 7.2) if:**
 - present above a concentration limit of 0.1%,
 - exposure of the public or the environment during the full life cycle cannot be excluded,
 - it is present above 1 tonne
- **Applies 6 months after substance listed on authorisation candidate list – i.e. commences 1 June 2011**
- **N.B. 'candidate' list of SVHC due late 2008/early 2009 (98% already known...)**

Registration:

Substances in articles (3)

- **Agency can request registration of any notified substance contained in articles, when:**
 - Substance is present over 1t; AND
 - Suspects that the substance is released and that release presents a risk to human health or the environment; AND
 - Substance is not subject to Art. 7.1

Substances in Articles: Notes

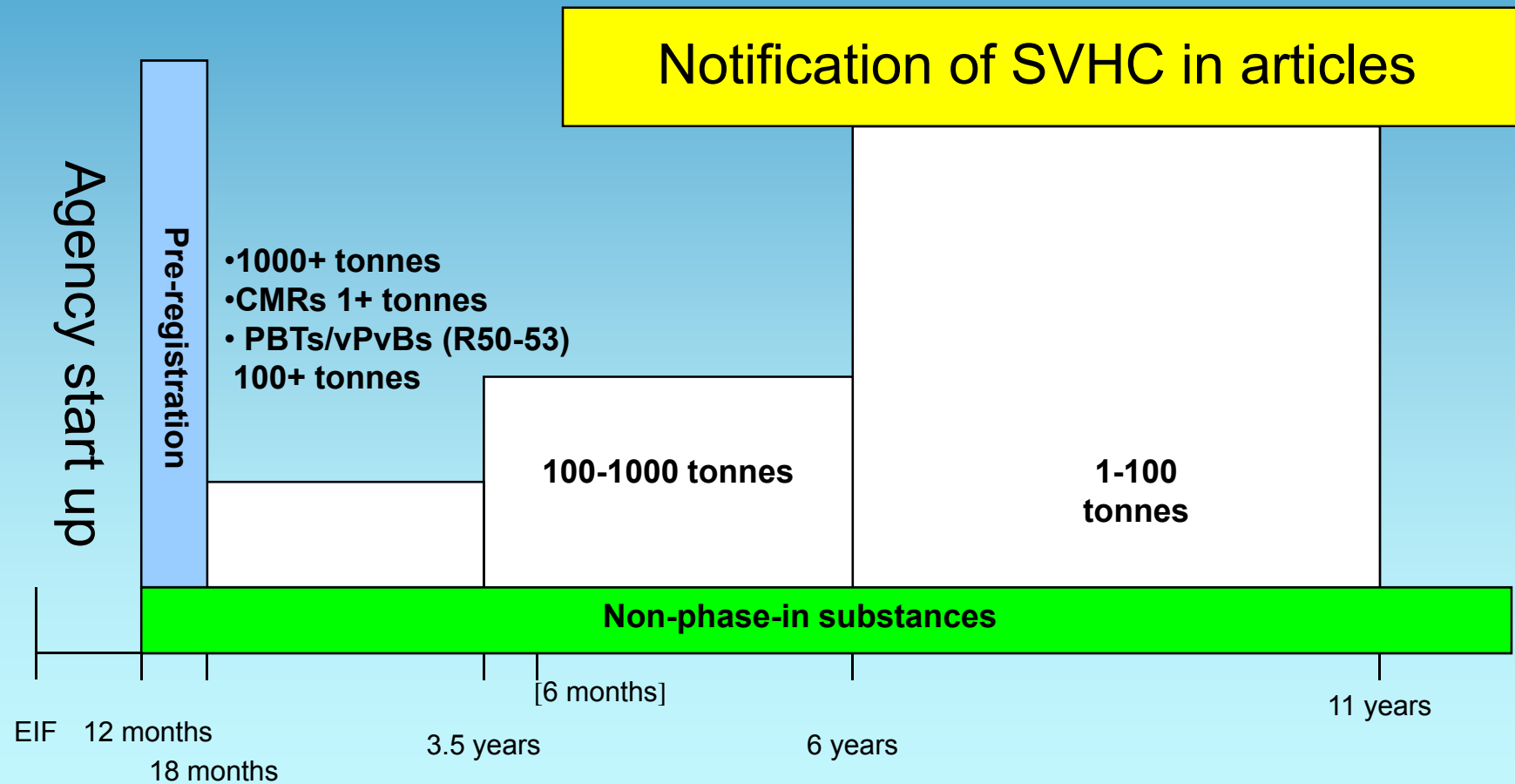
- Identify any articles that will be imported into the EU
- Need to identify all substances in these articles if possible (identify SVHC if not)
- Any likely SVHC in the articles?
- Assess % SVHC in articles as imported into the EU
- Time to remove SVHC that can be substituted or removed?
- Agency guidance to industry on application of rules for SIA
- Time is short to understand your supply chain(s) (N.B. Mattel and toys case)

SIA: Update

- **Subject to furious debate in the EU**
- **Symptom of ‘bad law’...**
- **RIP 3.8: containers = articles, chemicals in them substances/preparations (S/P) => registration**
- **Leaves few articles containing substances ‘intended to be released’**
- **More articles subject to potential notification**
- **Problem is when is a container of S/P and when a substance is an integral part of an article**
- **Homogeneous vs whole article debate over? whole article counts (COM LS* view)**

* European Commission Legal Service

Registration: Overview



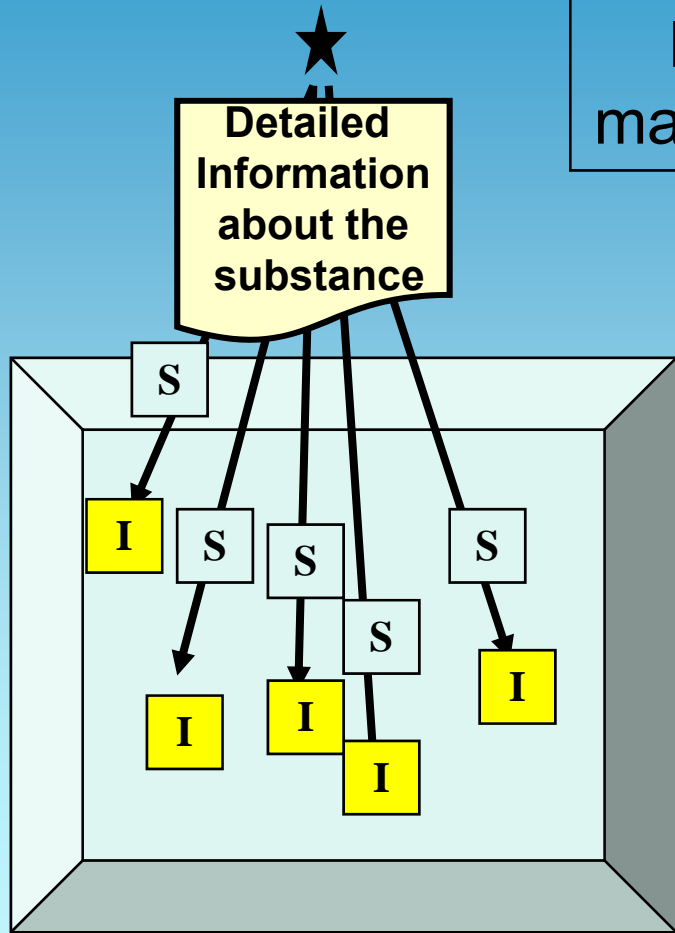
Non-EU Manufacturer

What are the obligations for a non-EU manufacturer, exporting the substance to the EU?

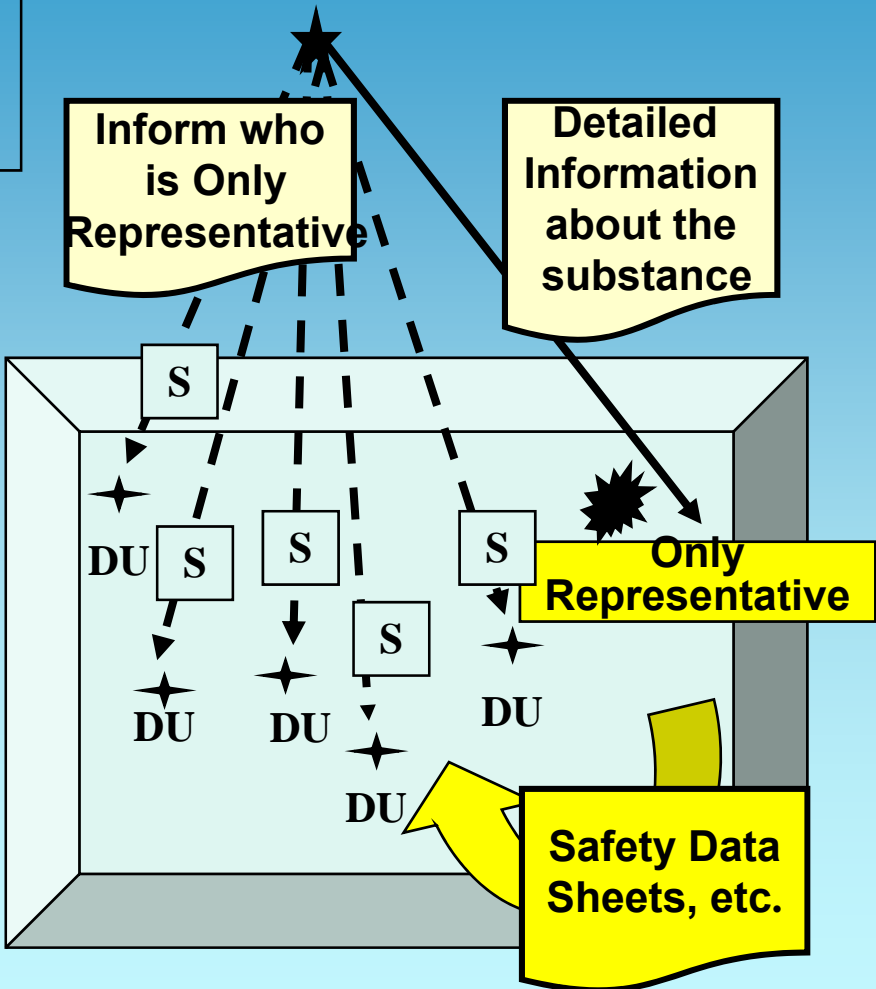
- **the non-EU manufacturer has no obligations under REACH;**
- **When exporting a substance to the EU, they need a legal representative (importer or “only representative”):**
 - the legal representative must be based in the EU and has the legal responsibility to comply with all relevant obligations under REACH

Export to the EU – two options

Option 1



Option 2



Non-EU Manufacturer

- There are no differences in obligations between:
 - the legal representatives of companies exporting substances to the EU (importer or “only representative”);
and
 - EU based manufacturers of substances;
- Some obligations might require additional effort e.g.:
 - obtaining information (e.g. use / exposure scenario) from supplier or downstream users (DU);
 - the representative has to be fully informed (e.g. composition of the substance) which brings an additional layer of communication

Only Representative

- “Only representative of a non-EU manufacturer” (Article 8):
 - EU-based
 - appointed by a
 - **manufacturer**
 - **formulator or**
 - **article producer**outside the EU
 - to fulfil the registration obligations of importers

Only Representative

- Importers are considered downstream users to the “only representative”;
- If multiple importers of the same substance this approach limits the number of registrations to one
- ...but tonnage is aggregated;
- ‘Only representative’ needs to have “sufficient background in the practical handling of substances and information related to them”.

Only Representative: Examples

1. One 'only representative' for 1 non-EU manufacturer, with 5 legal EU entities (importers) receiving the substance:

- The tonnage should be aggregated and the data-requirements based on this figure; **one registration**.

2. One 'only representative' for 2 non-EU formulators of the same substance:

- The tonnage should be aggregated. This case will result in **one registration** with the registration tonnage being for both formulators; analogous to an EU importer with several non-EU suppliers

IPIA Role

- ***Option 1 - OR for some or all non-EU manufacturers.***
- ***Option 2 - identify a legal entity to act for some or all non-EU manufacturers as their OR.***
- ***Option 3 – all importers (I) to act independently (OR or I)***
- ***Options 1 and 2 - cost effective as costs shared and the tonnage band would not change (assuming it would be 1000t anyway for one or more non-EU manufacturers).***
- ***All options - IPIA (or appointed representative) manages consortium of pig iron manufacturers and importers***
 - *efficient and effective way of managing the duties REACH places on pig iron manufacturers and importers.*

Importer: Example

Same substance imported in different forms (e.g. substance, in preparations) needs to be aggregated.

An example: If a company imports 10 tonnes/year of substance A on its own and two preparations containing the same substance:

- **Preparation 1: Annual import of 100 t/yr**
 - Component A 90% (= 90t)
 - Component B 5%
 - Component C 5%
- **Preparation 2: Annual import of 10 t/yr**
 - Component A 70% (= 7t)
 - Component P 10%
 - Component Q 20%
- **They have to do 1 registration for component A at 100+ tonnes (10+90+7 = 107 tonnes)**

Information through the supply chain

Improve risk management

- **What:**

- Expanded SDSs with information from Chemical Safety Reports (CSR) - **exposure scenarios for identified uses**
- Information on risk management, authorisations, restrictions, registration number etc.
- Information up the supply chain on new hazards
- SDS for all SVHCs (concentration limits apply)
- **Information to recipients of articles on SVHC (>0.1%)**
- **Information to consumers on SVHC in articles (>0.1%), on request**

IPIA Role

- ***Stress the importance of communicating with their suppliers; ensures that they are confident that substances they depend on will continue to be supplied.***
- ***If there is any concern over continued supply alternative suppliers and/or substances should be identified.***

Exposure Scenarios

An exposure scenario (ES) is a set of information and/or assumptions that describe how the substance is manufactured or used during its life-cycle, including the waste stage. It also sets out how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

Exposure Scenarios

Information could include:

- relevant characteristics of the substance; e.g. physical state (powder, liquid, gas) and vapour pressure (ability to evaporate),
- technical description of use and control,
- process description,
- tasks of the operator (description, duration, frequency of exposure),
- risk management measures (process control, storing/handling and personal protective equipment)

Chemical Safety Assessment: Notes

- **Iterative**
 - Demonstrate adequate control
 - Refine with data and exposure scenario
- **Generic vs specific uses**
 - Cost consideration
 - Business benefits
 - Impact on associated uses
- **Industry responsibility**
 - First 'bite at the cherry'
- **Targeted**
 - Key end-points only
 - Not comprehensive (uses or effects)
- **Exposure scenarios**
 - Communicated to users
 - Likely to be 'off-the-shelf' for vast majority of uses

IPIA Role

- *Preparing CSAs is a complex technical and scientific task.*
- *IPIA could have a key role in identifying the uses (including EU manufacture) of pig iron and in helping in the preparation of CSAs and ES in particular.*
- *Most uses of pig iron are well known and common to many if not all pig iron manufacturers and importers.*

IPIA Role

- *It does not make sense for all IPIA members to do these assessments individually.*
- *IPIA could manage the process for the preparation of exposure scenarios for all IPIA members for common uses.*
- *IPIA could have a role in developing exposure scenarios and CSAs for key uses of pig iron for use by all relevant members in their registrations.*

Downstream Users (DU)

- **Manufacturer/importer CSR to cover all uses identified by downstream users.**
- **DU benefit from choice of:**
 - supplier carrying out assessment, or
 - for confidentiality reasons doing own assessment.
- **If using suppliers CSR just have to:**
 - implement supplier's RRM for identified uses
- **If carrying own CSR (>1t) will have to:**
 - perform assessments only for 'unidentified uses' (using supplier hazard information)
 - inform Agency of 'unidentified uses'

DU Rights

- **To make their uses known to M/I => “identified use”**

[N.B. sufficient data needed by M/I to perform CSA]

- **To carry out their own CSA**
- **To contribute to SIEFs**

[e.g. cost sharing, confidence in substance availability – cost?]

Published Information

- **Published on web, free of charge:**
 - Information on substance identity,
 - classification,
 - physicochemical data,
 - results of toxicological and ecotoxicological studies,
 - DNELs*, PNECs**,
 - guidance on safe use,
 - analytical methods.

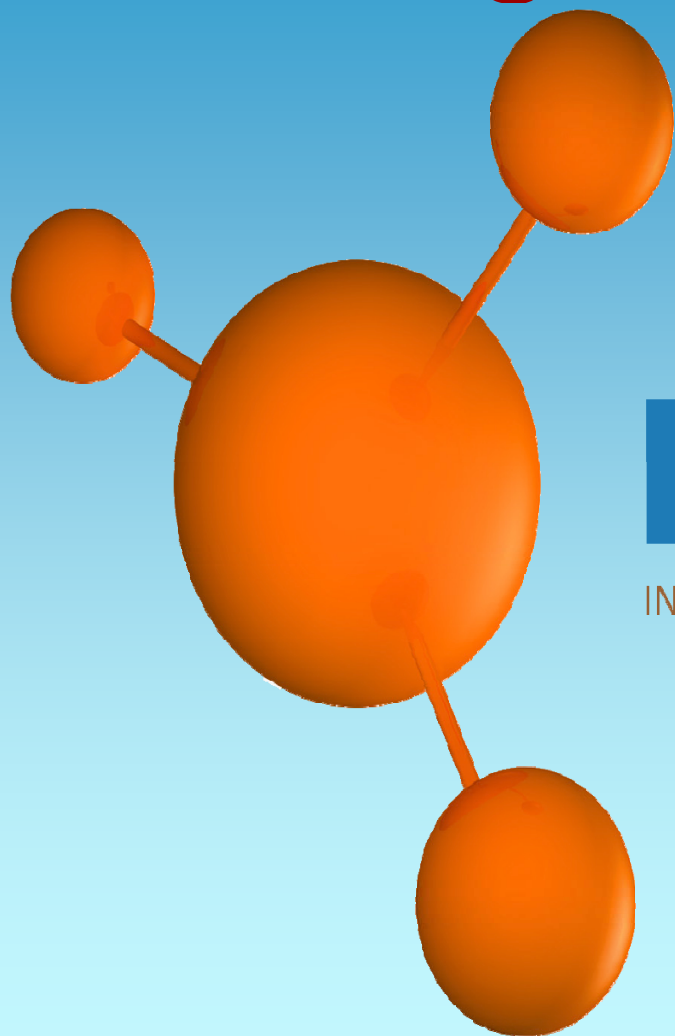
* derived no effect level (human health)

** predicted no effect concentration (environment)

Published Information

- **Published on web, free of charge, unless companies justify otherwise:**
 - information on tonnage bands,
 - impurities,
 - information in the SDS (unless above)
 - study summaries/robust study summaries.
- **Normally not published to protect commercial interests:**
 - composition of a preparation
 - precise use, function or application
 - precise tonnage
 - links down supply chain

Registration Format



IUCLID 5

INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

Harmonised Datasets

- **IUCLID 5 is based on OECD Harmonised Templates.**
- **Developed by OECD, industry and authorities**
- **IUCLID is used for other programs and legislation (Biocides Directive, Pesticides Directive, OECD existing chemicals program, ICCA HPV Initiative, US EPA HPV Challenge Program and for REACH).**
- **Every endpoint (intrinsic properties) has specified entry fields (e.g. test type, method, species, number of animals, route, control group, result, value, free tests...)**
- **Fields for free text**
- **IUCLID gives different views depending on objective (e.g. Annex VII for 1 - 10t)**
- **See all fields per end-point**

Submission

Technical dossier + Chemical Safety Report

- **Technical dossier (data to IUCLID database)**
 - company identity & substance identity
 - manufacture & uses; guidance on safe use; C&L; exposure information if applicable
 - study summaries; robust study summaries; proposals for testing
 - various statements
 - Chemical safety report (>10 tonnes)
- **Chemical safety report: document (pdf);**
 - document created and edited outside IUCLID, but can be incorporated by attachment

IPIA Role

- ***Understanding of IUCLID is vital to an effective and efficient implementation of REACH***
- ***IPIA could have a role in arranging training for its members in, and support for, the use of IUCLID 5.***

RIPs and Guidance

ECHA website:

http://ec.europa.eu/echa/reach_en.html

- 1. REACH Implementation Projects (RIPs)**
- 2. Explanations on REACH (processes, scope, obligations)**
- 3. IT-Tool (Navigator)**

REACH: Key Elements

- **Better information**
- **Joined up supply chain**
- **Industry responsibility for safe management**
- **Not a once only exercise**
- **Cultural change**
 - Legislation
 - Duty holders
- **Winners and losers**
- **Plan and manage carefully**

Summary: IPIA Role???

- **Establish and manage a consortium**
- **SIEF management**
- **Only representative (OR)**
- **Chemical Safety Assessments (CSA) and Exposure Scenarios (ES) common to all/most members**
- **Data collection, evaluation and valuation**
- **Independent 3rd party**
- **3rd party representative**
- **Training and advice**

Good Luck!

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