



Key RIPs and overview of on-going RIPs
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Guidance to Industry



- **Technical Guidance developed in REACH Implementation Projects (RIPs)**
- **Commission focuses at this stage on providing guidance on pre-registration, data sharing and registration**

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2

Overview on-going RIPs



- RIP 2 REACH IT
- RIP 3.2-2: TGD on preparing the CSR
- RIP 3.3-2: TGD on information requirements
- ★ RIP 3.5-2: TGD on Downstream User requirements
- RIP 3.1: Guidance on Registration (IT tool) 1.6.2007
- RIP 3.4: TGD on data sharing
- RIP 3.7: Guidance on preparing an Authorisation Application
- RIP 3.9-2: Guidance on carrying out a Socio-Economic Analysis
- RIP 4.3/4.5: Guidance document on inclusion of substances in annex XIV and guidance document on priority setting for evaluation

Cefic input



- Cefic is giving input to and commenting on the RIPs in Stakeholder Expert Groups (SEG) organised by the Commission.
- Cefic's SEG representatives are supported by RIP shadow groups organised within Cefic
- Mid 2007 there will be a massive amount of Guidance resulting from the different RIPs to be commented on during a short time

Key RIPs



- **RIP 3.1** : guidance on registration, including an IT tool to navigate and link to relevant detailed guidance documents from e.g. RIP 3.10 on substance identification on RIP 3.4 on data sharing, RIP 3.3 on data requirements and RIP 3.2 on Chemical Safety Assessment/Report
- **RIP 2** on **REACH IT** : Roll out of IUCLID 5 (database and tools for submitting REACH dossiers) in May
- **RIPs related to Authorisation** have just started or are on-going e.g. guidance on application for authorisation and on socio-economic analysis

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5

Substance Identity - Some history



- Establishment of EINECS – existing chemicals :
 - reporting of identity based on « EINECS reporting rules »
- Implementation New Substances :
 - principle starting point: comparing of identification parameters
 - « is the substance covered by EINECS or not? »
- Technical Guidance Document (TGD) RIP 3.10:
 - based on REACH definitions and requirements
 - takes over what we learnt from EINECS reporting until now

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6

RIP 3.10: basic elements



Some of the basics (I):

➤ Well defined: mono constituent substances:

- Chemical composition: one main constituent > 80 %
- Chemical identity: based on the main constituent (name, CAS-number, EC-number, etc.)
- Typical concentration and range
- Impurities relevant for classification or present in a concentration ≥ 1 % to be specified

RIP 3.10: basic elements (II)



Main Const.	%	Impurity	(%)	Name
m-xylene	91%	o-xylene	5	m-xylene
o-xylene	87%	m-xylene	10	o-xylene

RIP 3.10: basic elements (III)



Some of the basics (III):

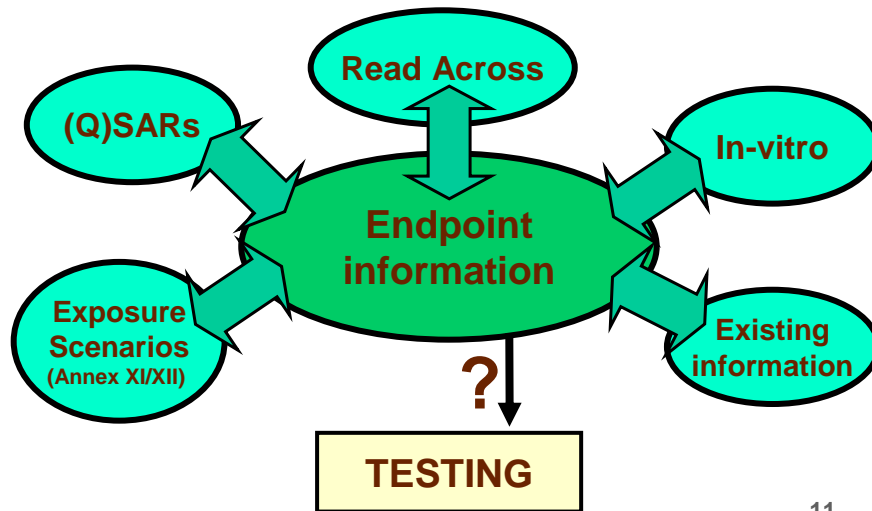
- **Well defined: multi-constituent substances:**
 - **Chemical composition:** mixture of main constituents each between 10-80 %
 - **Chemical identity:** each main constituent (« mixture of ... »)
 - **Typical concentrations and ranges**
 - **Impurities relevant for classification or present in a concentration > 1 % to be specified**

RIP 3.10: basic elements (III)



Main Constituents	Content	Impurity	Content (%)	Name
m-xylene o-xylene	50 45	P-xylene	5	Mixture of m-xylene and o-xylene

RIP 3.3 Integrated Testing Strategies



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11

RIP 3.2 TGD ON Chemical Safety Assessment/Report



- Introduction
- Hazard Assessment (including classification and labelling and DNEL & PNEC derivation)
- PBT assessment
- Development of exposure scenarios
- Exposure assessment
- Risk characterisation
- Preparing the Chemical Safety Report
- Preparing the SDS

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12

How to prepare for REACH Manufacturer/Importer/DU



1. Produce your company inventory of substances and preparations
2. Define for each substance/preparation your own status in the supply chain
3. Determine if your company is the manufacturer, importer of the substance/preparation or purchased by your company from a supplier within the EU
4. Determine if applicable:
 - Non isolated intermediate
 - On-site isolated intermediate
 - Transported isolated intermediate
5. For manufactured and /or imported polymers the monomers they are made from and the other constituents used for manufacturing of polymer

How to prepare for REACH Manufacturer/Importer/DU



6. Establish the annual volume of manufactured or imported substances and the composition of preparations.
7. Identify the CAS# (and if possible the EINICS or ELINCS) of manufactured or imported substances
8. Identify and list your customers per substance and per preparation

How to prepare for REACH Manufacturer/Importer/DU



9. Collect available information

- Intrinsic properties
- Animal testing results owned by company
- C&L
- SDS

10. Ensure there is clarity about the ownership of data

- Arrange formal contract for use and ownership

11. Establish which legal entity is involved as M/I for which substance/preparation

How to prepare for REACH Manufacturer/Importer/DU



12. Identify and list your suppliers per substance and preparation

13. Compile readily available information on uses and conditions of use

- List your customers
- Own workplace and customers
- Industrial, professional, consumer use

14. Identify gaps of information

15. Try to find out if your supplier will register for REACH

Example for template can be found at:

http://mineco.fgov.be/organization_market/Reach/REACH_TOOL_NL.xls - 3785.0KB

How to prepare for REACH Users further down in the supply chain



Overview of substances you work with

- List your suppliers
- Collect exposure information
- Identified use in pre registration?
- Overview of your customers
- Warn customers and suppliers on REACH and future needs