REACH
New European Chemical Legislation

Requirements – Costs
Preparation
Business Continuity Risks

Alan Looney Managing Director NCC Group
President European Association of Chemical Distributors
President of Chemical Distribution Ireland

FECC

Chemical Distribution Ireland

- **European Association of Chemical Distributors**
- Represent Over 1,200 companies
- Total annual sales amount to approx. € 30 bn
- More than 40,000 employees
- Supply over 1 million downstream users
- Most member companies are SMEs
- Many are importers of chemicals from outside EU

CDI

- Chemical Distribution Ireland
- Member of FECC & IBEC
- Close Working Relationship with Pharmachem Ireland
- 19 Members (Irish & Multinational)
- Promote Best Practice
- Manage Responsible Care Programme
- Will assist Members implement Good Trade Distribution Practice
- Will assist members comply with REACH
- Will assist members in assisting their customers comply with REACH

Topics

- What is REACH – a general overview
  - Intention
  - Elements
  - Time Schedule
- Requirements in detail
  - Testing
  - Information Exchange
  - Costs
- How to deal with REACH
- Business Continuity Risks

Intention – „ Reasons and Objectives“

- …ensure that substances are used safely at all stages in their life cycle
- …failure to register means that the substance **cannot** be manufactured or imported
- …oblige downstream users to consider the safety of their uses of substances
- …ensure non-confidential information on chemicals is available [to public]
- reverted burden of proof

extracted from the European Council resolution of Dec. 18th 2005

Scope

- **All substances** produced in or imported into the EU
- **registration for all substances** on their own or in preparations or contained in and purposefully released from articles at volumes of **above 1 t/a**
- exemptions for substances that are dealt with in other major regulations
- exemptions for polymers*
- exemption for goods in transit (under customs control)

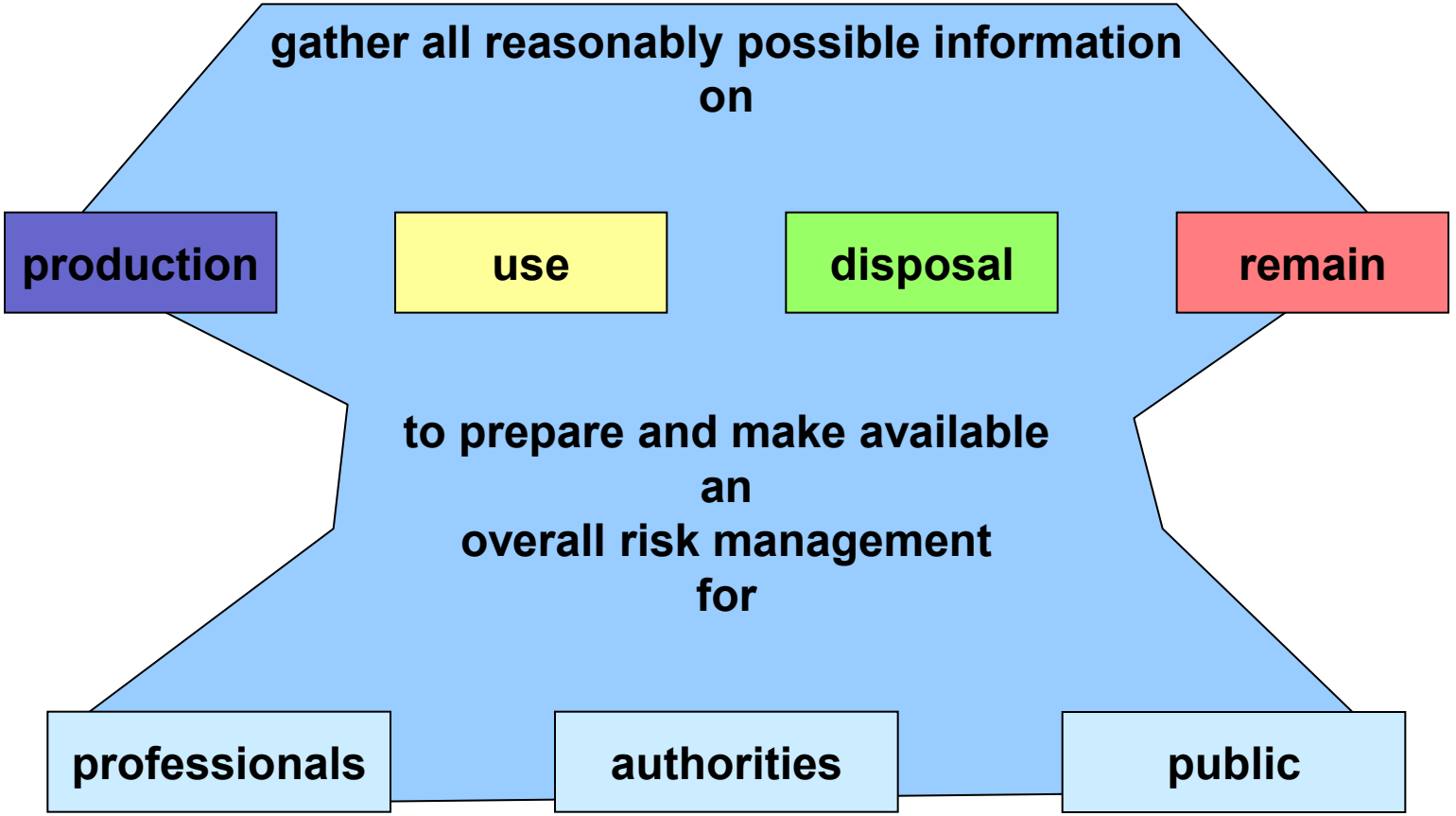
Exemptions
Polymers

- only if monomers are registered
- non registered monomers have to be registered under REACh
- additives are dealt with like a substance in a preparation
- the exemption is only valid with regards to the registration other requirements of the regulation have still to be fulfilled

Exemptions
< 1 t/a

- the exemption is only valid with regards to the registration other requirements of the regulation have still to be fulfilled
- the exemption is not valid if the substance belongs to the group of substances of special concern (CMR etc.)

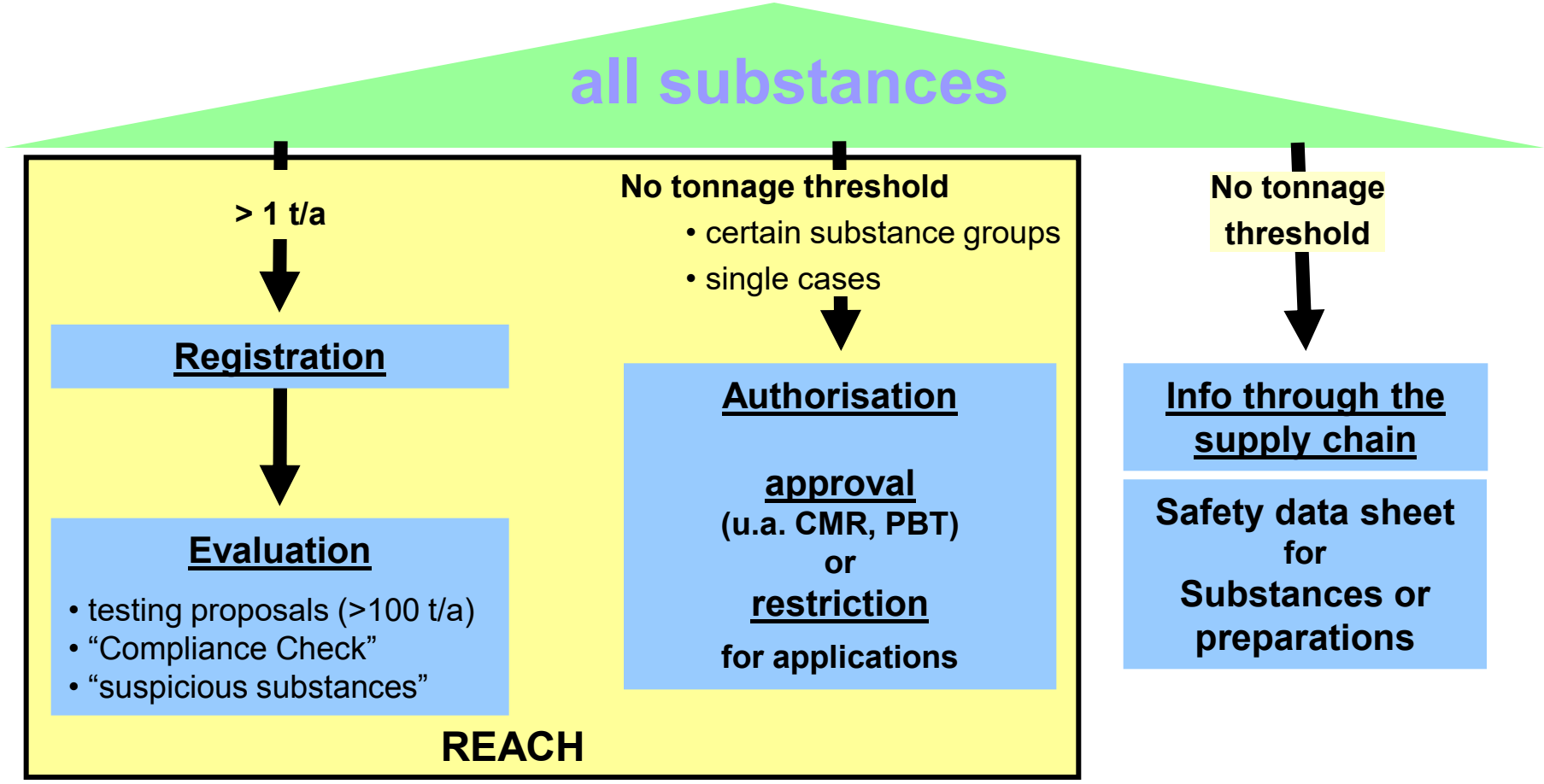
Overall Requirements



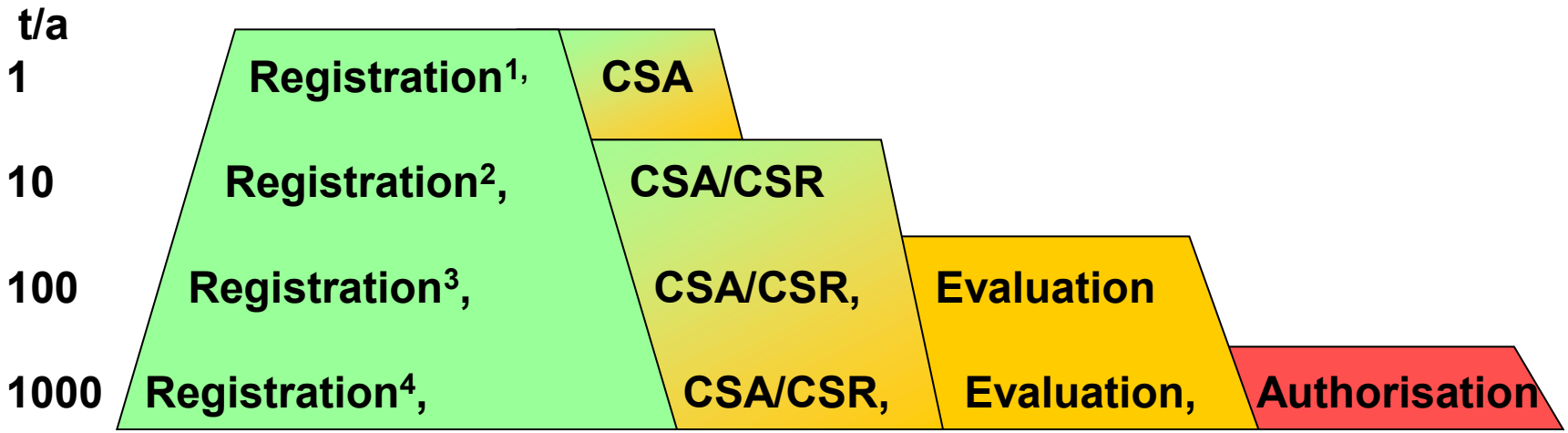
Elements 1

- **No Registration – No Marketing**
- **Registration**
  - physico/chemical, toxicological data, ecotoxicological data
  - use/application data
- **Evaluation**
  - to be initiate by authorities for volumes < 100 t/a
  - compulsory for volumes > 100 t/a
- **Authorisation**
  - compulsory for CMR, BPC and volumes > 1,000 t/a
  - to be initiate for “substances of special concern”
- **Information through the supply chain**
  - **C**hemical **S**afety **A**ssessment / **C**hemical **S**afety **R**eport
- **Reverted burden of proof**

Elements 2


all substances
> 1 t/a
Registration
Evaluation
• testing proposals (>100 t/a)
• “Compliance Check”
• “suspicious substances”
No tonnage threshold
• certain substance groups
• single cases
Authorisation
approval
(u.a. CMR, PBT)
or
restriction
for applications
No tonnage threshold
Info through the supply chain
Safety data sheet
for
Substances or preparations
REACH

Elements 3

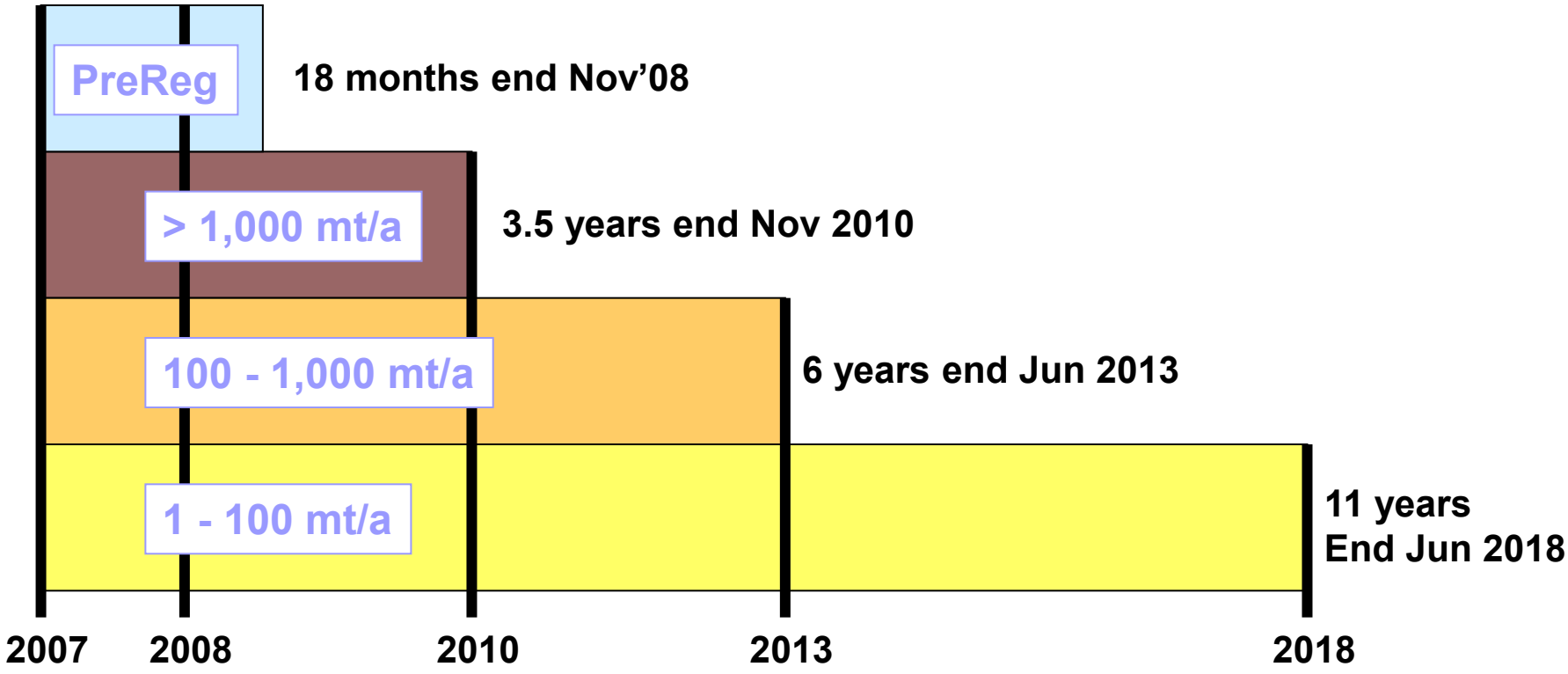


1 – data acc. to annex V
2 – data acc. to annex V +VI
3 – data acc. to annex V, VI + VII
4 – data acc. to annex V,VI,VII+VIII

Time Schedule
legislative Procedure

- 2000 White Book „Future Chemical Policy…“
- 2003 1st official draft and I-net consultation
- 2004 1st lecture in EP
- 2005 Elections
  - Oct. 1st lecture and resolution in the new EP
  - Nov. 1st resolution from the Counsel
- *2006 2nd course through EP and Counsel*
  - *final resolutions Nov 2006*
- *2007 came into force July*

Time Schedule
Registration Procedure



Transitional periods only apply to "phase-in substances" and only if they have been preregistered !

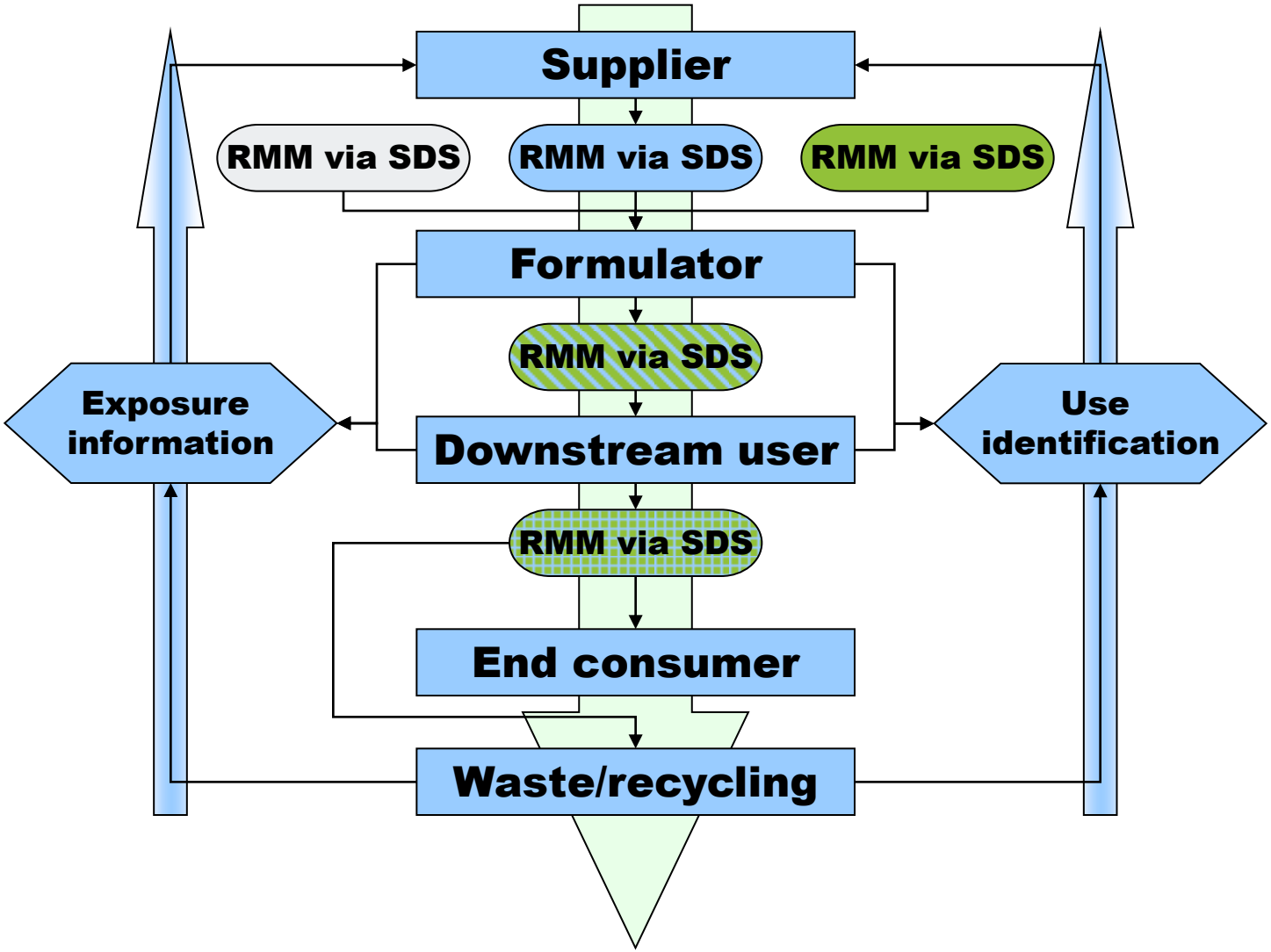
All dates and time frames calculated from the date of coming into force of the directive

REACH Preparation

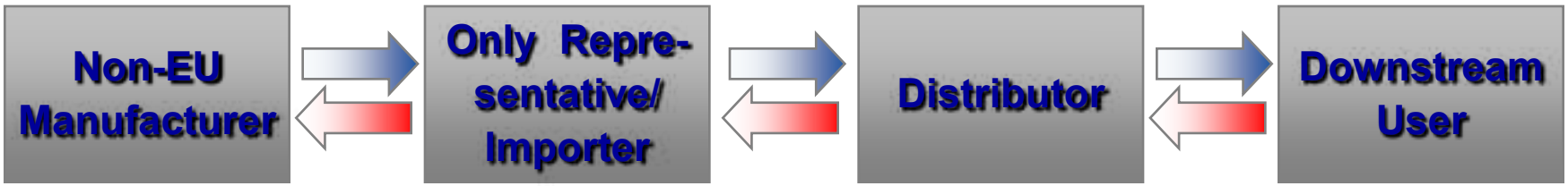
Chemical Distribution Ireland

- Roles & Obligations under REACH
- Compiling an Inventory
- Pre Registration
- Communicating up and down the supply chain – Recommendations
- Role of Distributors & Trade Associations
- Considering Alternatives
- Down Stream User Guidance RIP 3.5.2

Communication up&down the value chain is the essence of REACH



Actors in Supply Chain



- **Manufacturer or Importer**
  - Registers substances and identified uses
  - Prepares chemical safety report (CSR), exposure scenario and risk management measures (RMM)
- **Only Representative**
  - Appointed by to carry out the registration and thus coequal to an importer
- **Distributor**
  - Up- and downstream supply chain communication
- **Downstream User**
  - Should follow advised RMM
  - Should inform supplier about use and exposure
  - In case of non-identified use (> 1 t/a) : registration + CSR

REACH Implementation Phases

- **Preparation Phase**
  - Audit of product portfolio
  - Review of marketing, operations and procurement strategies
  - Adapting business models, offers and supply arrangements
  - Development of new work processes to integrate REACH into the day-to-day work
- **Intermediate Phase**
  - Organizing and managing SIEF (Substance Information Exchange Fora), consortia participation and data collection
  - Preparing Pre-Registration, Registration and Authorization dossiers
- **Implementation Phase**
  - Filing of dossiers
  - Monitoring of the REACH processes
  - Legal rights and remedies

REACH

- Major challenges to all including Down Stream Users (DSU)
- Distributors are often Manufacturers, Importers, Formulators, distributors and down stream users (DSU's)
- 80/20 rule applies Distributors supply 20% of volume to 80% of down stream users so we are the major DSU interface
- Estimate 15% of distributors products are imported from outside of EU
- **Estimate 5-20% of products will not be registered as not economically justified and will disappear from market**
- **Reduced Competition, higher prices ?**

Next Steps – re. Suppliers

- Distributor/DSU audits portfolio of principals
- Identifies products from EU and non-EU manufacturers
- Are there early indications for product phase-outs?
- Distributor/DSU involves the suppliers
  - Are they aware or REACH?
  - Identify contact person at supplier
  - How are suppliers approaching REACH implementation?
  - What is their status regarding availability of data?
  - Distributor contacts principals in EU and non-EU countries
  - DSU contacts Distributor for sourcing help REACH@NCC.ie for products of concern

Communicate with Suppliers

- Communicate with your suppliers – Standard Questionairre

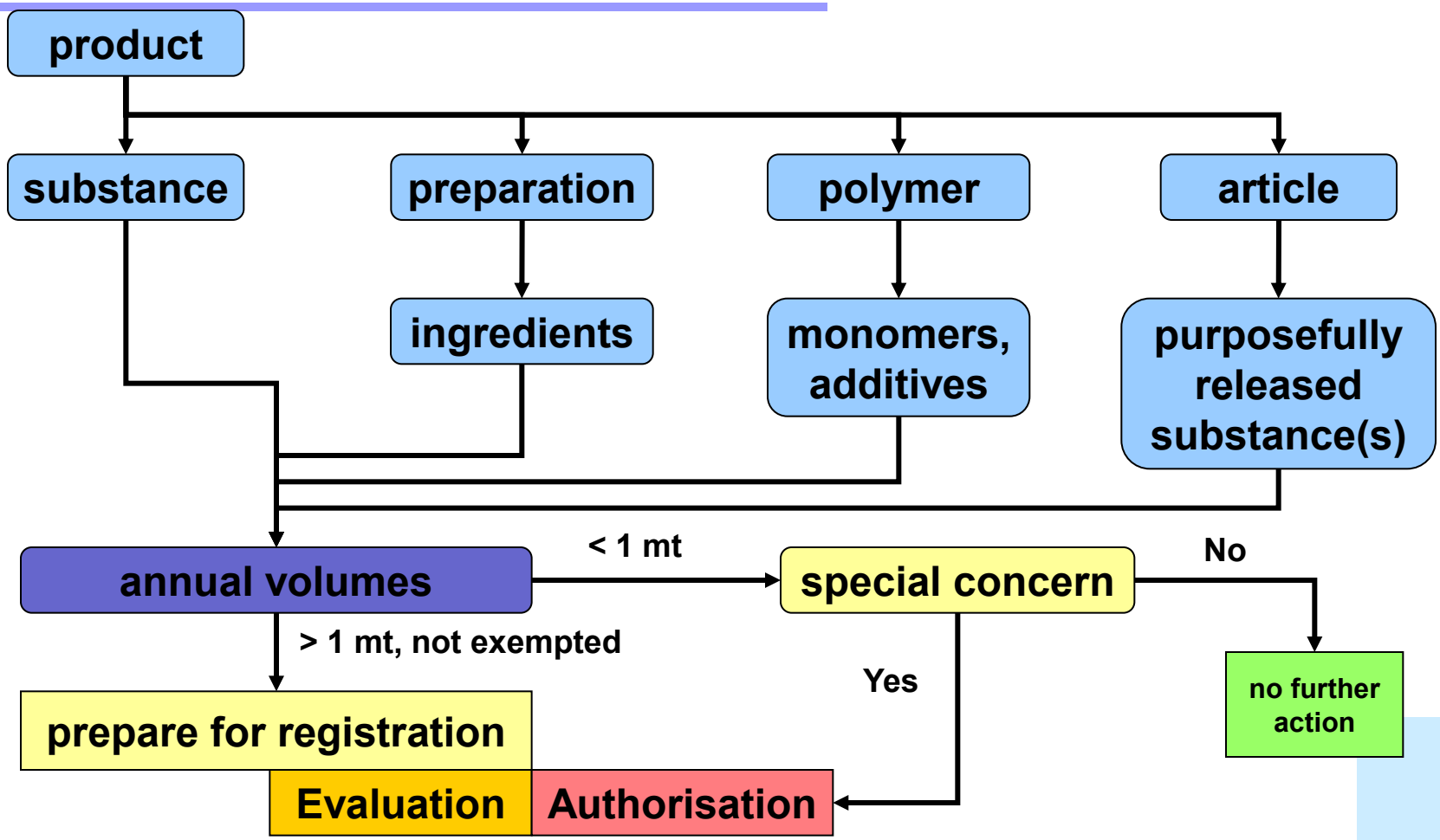
  1. Can we assume that the substances, which are contained in the product above and require registration, will be **pre-registered** by your company or by your upstream supplier?

  2. Can we assume that the substances, which are contained in the product above and require registration, will be **registered**?

  3. Regarding the substances that are contained in the product and require registration – please mark the crucial REACH registration deadlines for those substances which are decisive for the product properties.

  4. Contact details. Please provide full contact details for the person in your company responsible for REACH issues

Check product status products/raw materials



REACH Inventory

- Compile inventory by substances and preparation.
- Include Material Safety Data Sheets and Specifications
- Manufacturer/Importer or Downstream user
- For polymers M/I monomers and additives they contain.
- Annual volumes
- CAS numbers of substances and EINECS or ELINCS number.
- Customers & Suppliers per S/P
- Which legal entity
- industrial use, professional use, consumer use ?
- In final product or final product subject to qualification or approval - Prioritise **REACH Inventory.xls**

Next Steps – Customers

- Customer contact re specific use and exposure scenario
- Use must be registered to ensure continued supply
- Supplier not informed may not register use
- CEFIC/FECC Supplier and Customer Questionairres to be finalised following RIP completion
- Web based IT tool being developed for use by larger suppliers to invite customers to report uses on line
- Distributors can assist customers identify products at risk of non registration assist alternate sourcing or substitution by a safer product

Pre Registration

- DU may help secure sourcing ,benefit from phase in period and ensure substance is registered for their use through SIEF.
- ECHA establish dedicated webpage as soon as a substance is first pre registered
- Pre Registrants notified as further pre registration of the substance occurs
- All pre registrants have access to list of pre registrants or their third party representative showing deadline and tonnage band
- Full list of pre registered substances published 1st Jan. 2009
- DU can check if own substances listed and advise ECHA if not and current supplier details
- ECHA may invite new suppliers to register this substance
- If in doubt pre register , a lot to gain nothing to lose

REACH and pharma

With regard to the exemption from **registration**, **downstream user obligations, evaluation** and **authorisation**:

- **only the quantities used in the medicinal product are exempted from registration**. If the same substance is manufactured/imported for other uses, those quantities must be registered/authorised (if applicable)!
- The exemption applies **both to active ingredients and excipients**
- It is the **final substance used in the medicinal product that is exempted**, not all substances used in the production of it or precursors of the substance that is finally used in the medicinal product. If a substance is used in the production of a medicinal product, but itself is not used in that medicinal product, then the exemptions do not apply.

REACH and Food

A substance is **exempted from registration, downstream user obligations, evaluation** and **authorisation** if it is used in food or feeding stuff in accordance with the Food Safety Regulation 178/2002.

Am I covered by the Food Safety Regulation?

- This Regulation covers "*all stages of production, processing and distribution* of food and feed."
- Food means "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonable expected to be ingested by humans*".

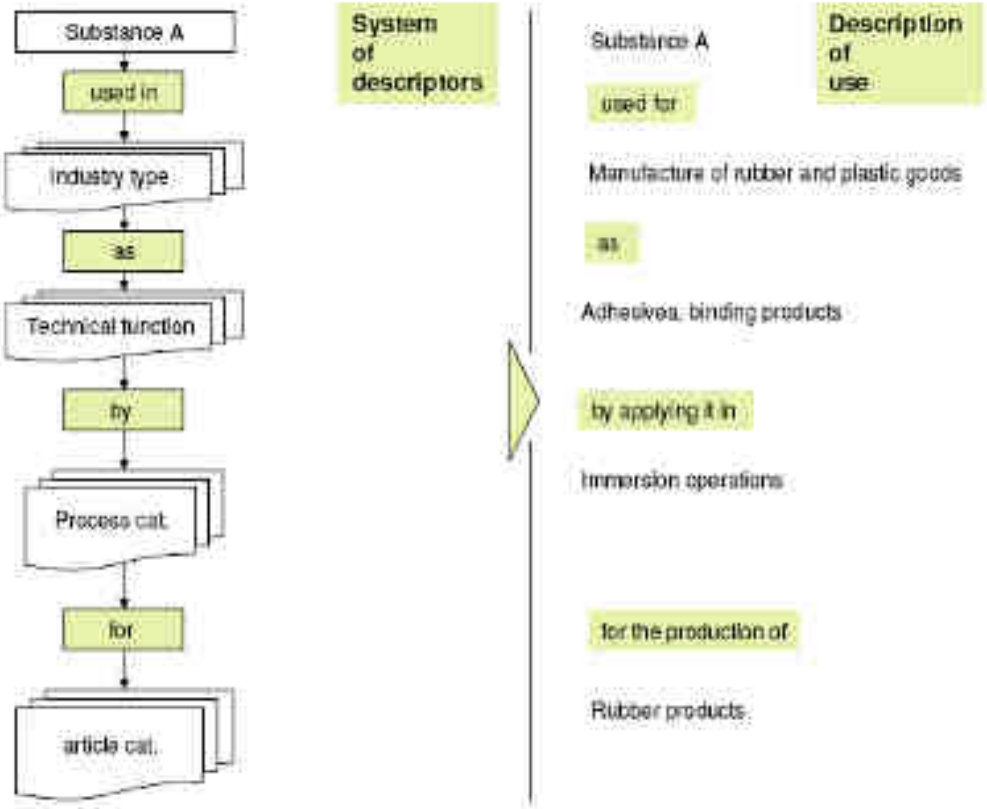
REACH and Food

- With regard to the exemption from **registration**, **downstream user obligations, evaluation** and **authorisation**, **only the quantities used in food or feeding stuff are exempted**. If the same substance is manufactured/imported for other uses, those quantities must be registered/authorised (if applicable)!
- The food or feedingstuff in the finished state (intended for final user) and the uses listed in article 2 (6)(d) are **exempted** from the provisions of Title IV (**Information in the supply chain**)

Reach Implementation Project 3.5-2

- Technical Guidance Document on DU requirements
  - REACH and roles and obligations
  - Uses
  - Exposure Scenarios
  - Information requirements in supply chain
  - Confidential Business Information
  - FECC participating
  - Drafts being reviewed
  - Completion anticipated Nov'07
  - Will be available on line as part of REACH IT System

Use Identifier System RIP 3.5.2



Exposure Scenario

- Exposure scenario: means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate. (Definition 35)

Exposure Scenario

- Exposure Scenario - an (understandable) definition

  ‘An Exposure Scenario (ES) describes the conditions under which a substance (as such, in a preparation or in an article) or a group of substances can be safely used.’

- REACH requires
  - Description of ES for hazardous substances.
  - Communication of ES in the annex of the SDS of hazardous substances and preparations.

Exposure Scenarios

- **Conditions for use**:

- Process description (incl. quantity used)

- Operational conditions (incl. frequency and duration of specified operations)
- **Risk Management Measures**

– process control (e.g. closed system and lo
– emission control
– personal protective equipment
– good hygiene / working practice
– etc.

- Other relevant information

Requirements testing

- **up to 88 parameters**
  - physico chemical
  - toxicological
  - ecotoxicological
- **4 tonnage bands**
  - > 1 to 10 t/a Annex V
  - >10 to 100 t/a + Annex VI
  - > 100 to 1,000 t/a + Annex VII + Evaluation
  - > 1,000 t/a + Annex VII + Authorisation

Distributors Challenges

- Increased complexity in communicating chemicals safety information.
- Our role as Downstream User (DU)
  - Downstream Users inform us about the use of substances
  - Distributor informs the supplier about the use by DU's
- Under REACH the Safety Data Sheet will be expanded by an annex containing 'Exposure Scenarios'
- '…Distributors role is vital with regard to supply chain communication.' and stimulating competitive marketplace

Costs - Overview

Requirements :

provide all data according to annex V to VII (up to 88 parameters) under GLP

Costs per registration of a substance including 5 applications in 1000 €							
Volume	Internal Costs					Fees	Sum
(t p.a.)	Testing	Exposition	Research	Administration	Sum		
1 - 10	45	5	15	6	71	2	73
10 - 100	135	15	20	16	186	5	191
100 - 1000	325	30	40	31	426	31	457

from the supplement to BDI/ADL-study on the economical impact of REACH

Costs Estimates

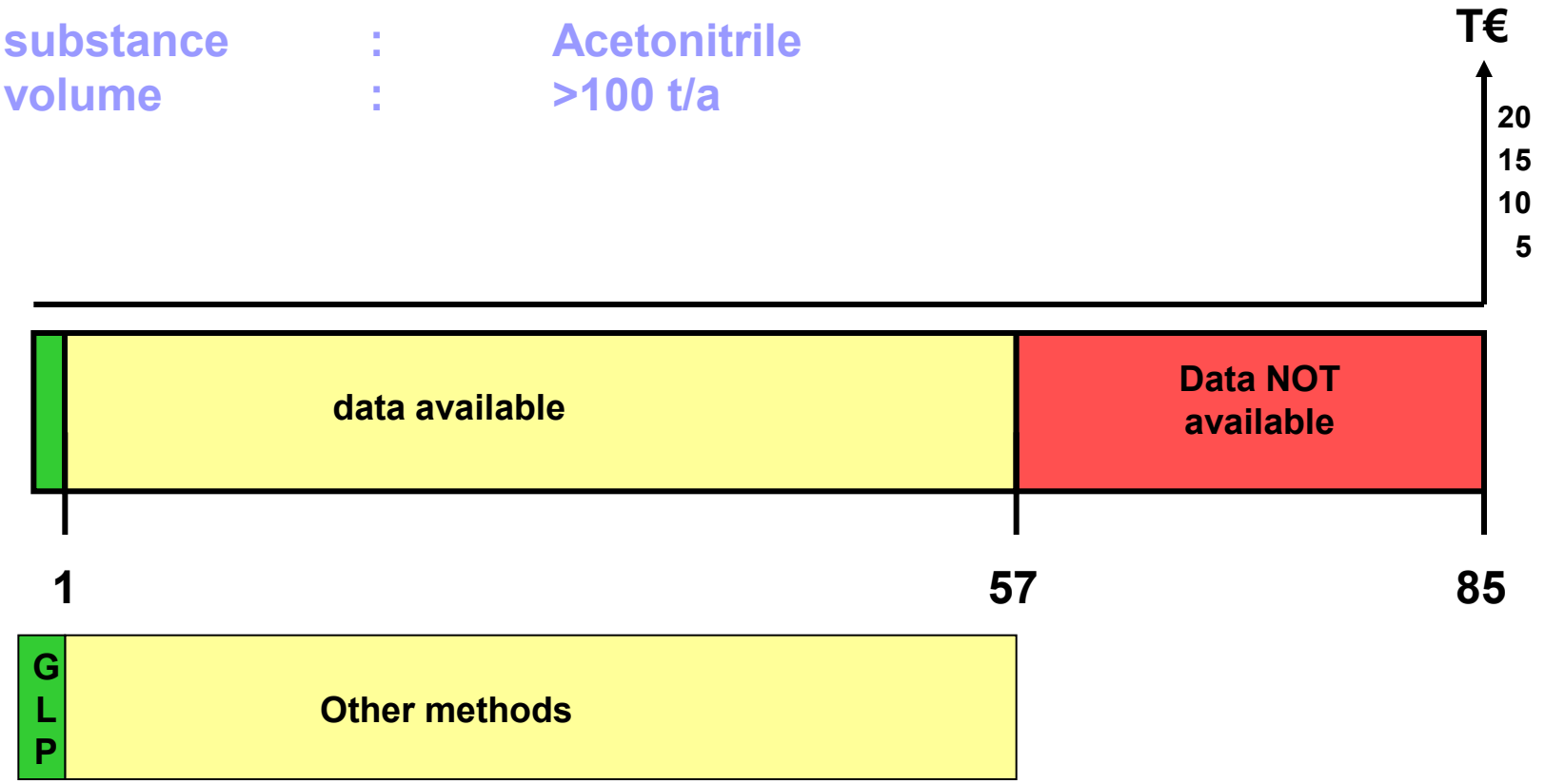
	Commission	Council	EP
1 – 10 t/a	50,000 €	25 – 40,000 €	20 – 35,000 €
10 – 100 t/a	350,000 €	250,000 €	200,000 €
100– 1,000 t/a	450,000 €	400,000 €	400,000 €
> 1,000 t/a	0.5 – 2.0 mio. €	0.5 – 2.0 mio. €	0.5 – 2.0 mio. €

included :
testing, registration dossier, administration, chemical safety report

not included :
possible weaving, existing data (phase-in-substances)

Costs Profile

substance : Acetonitrile
volume : >100 t/a



Sourcing Alternatives

- Purchasing Criteria
  - Availability, Quality, Price
- Will the dynamic change ?
- Dual sourcing becomes more important
  - Allocate at least 20% to 2nd Supplier
- Costs of Registration may change dynamic and lead some to exit market
- Lower number of Suppliers with higher costs may impact on prices
- Distributors may help source new suppliers and advise on substitution

Summary

- Customers need to tell Distributors how their chemicals are used. We need to start an open discussion with suppliers and customers
- e-SDSs will need to contain REACH information.
- Information on Expose Scenarios will be needed (but wait for the industry-wide questionnaire).
- Distributors will have to pass Use and Exposure Scenarios up-stream.
- Chemical Safety Reports will have to contain information from the supplier and downstream user.
- **REACH is not final nor are most RIPs! But don't wait to prepare**

Advice

- Complete your Inventory
- Communicate with Suppliers
- Consider Communicating with Customers
- Identify products at risk of supply
- Identify alternatives
- Help available !
  - IBEC Helpdesk info@reachaid.ie tel.: 01 6051519
  - Suppliers helpdesks such as reach@ncc.ie and ICMA members
  - HSA HelpDesk reachright@hsa.ie locall 1890 289 389
- **REACH Guidance is not final But don't wait to prepare**

Thank You for your Attention !

Registration Content

- identity of the producer/importer
- identity of the substance/preparation
- volumes, production process
- all „**identified uses**“ (Art. 35)
- assumptions for classification and labelling
- advise for safe use of the product
- summary and „**robust study summaries**“
- information on animal testing
- **Chemical Safety Report** for all substances > 10 t/a (Art. 13)

Requirements Testing

General Requirement :

GLP generated data

or adequately validated non GLP-data

Annex V

Requirements
Testing

Annex V – physico-chemical data

- physical state
- melting point
- boiling point
- rel. density
- vapour pressure
- surface tension
- solubility in water
- flash point
- flammability
- explosivity
- self ignition properties
- oxidative properties
- granulometry

Requirements
Testing
Annex V – toxicological data

- skin irritation
  - evaluation of existing data from animals and humans
  - determination of acidic and alkaline reserve
  - in-vitro test skin corosivity
  - in-vitro test skin irritation
- eye irritation
  - evaluation of existing data from animals and humans
  - determination of acidic and alkaline reserve
  - in-vitro test eye irritation
- sensitisation via skin contact
  - evaluation of existing data from animals and humans
  - in-vitro test
- mutagenicity
  - in-vitro test on bacteria for genetic mutations
- acute toxicity
  - test for oral pathway

Requirements
Testing
Annex V – ecotoxicological data

- aquatic toxicity
  - short time exposition test on splineless species (Daphnia)
  - groth inhibition of Algae
- degradeability
  - biodegradebility

Requirements

Annex VI

Requirements
Testing
Annex VI – physico-chemical data

no further requirements

Requirements
Testing
Annex VI – toxicological data

- skin irritation
  - in-vitro skin irritation test
- eye irritation
  - in-vitro eye irritation test
- mutagenecity
  - in-vitro cytogenicity test
  - in-vitro gene mutation test on mamalian cells
- acute toxicity
  - inhalation
  - dermal exposition
- toxical properties of multiple exposure
  - short time toxicity test (28 days)

Requirements
Testing
Annex VI – ecotoxicological data

- aquatic toxicity
  - short time toxicity test on fish
  - activated sludge respiration inhibition test
- Fate and behavior in the environment
  - absorption/desorption screening study
- degradebility
  - abiotic
    - hydrolysis as afunction of pH

Requirements

Annex VII

Requirements

Testing

Annex VII – physico-chemical data

- Stability in organic solvents and identity of the degradation products
- dissociation constant
- viscosity

Requirements
Testing
Annex VII – toxicological data

- toxicity on multiple exposure
  - extended short term toxicity test (28 days)
  - extended test on sub chronic toxicity (90 days)
- reproduction toxicity
  - prenatal development study
  - two generation test

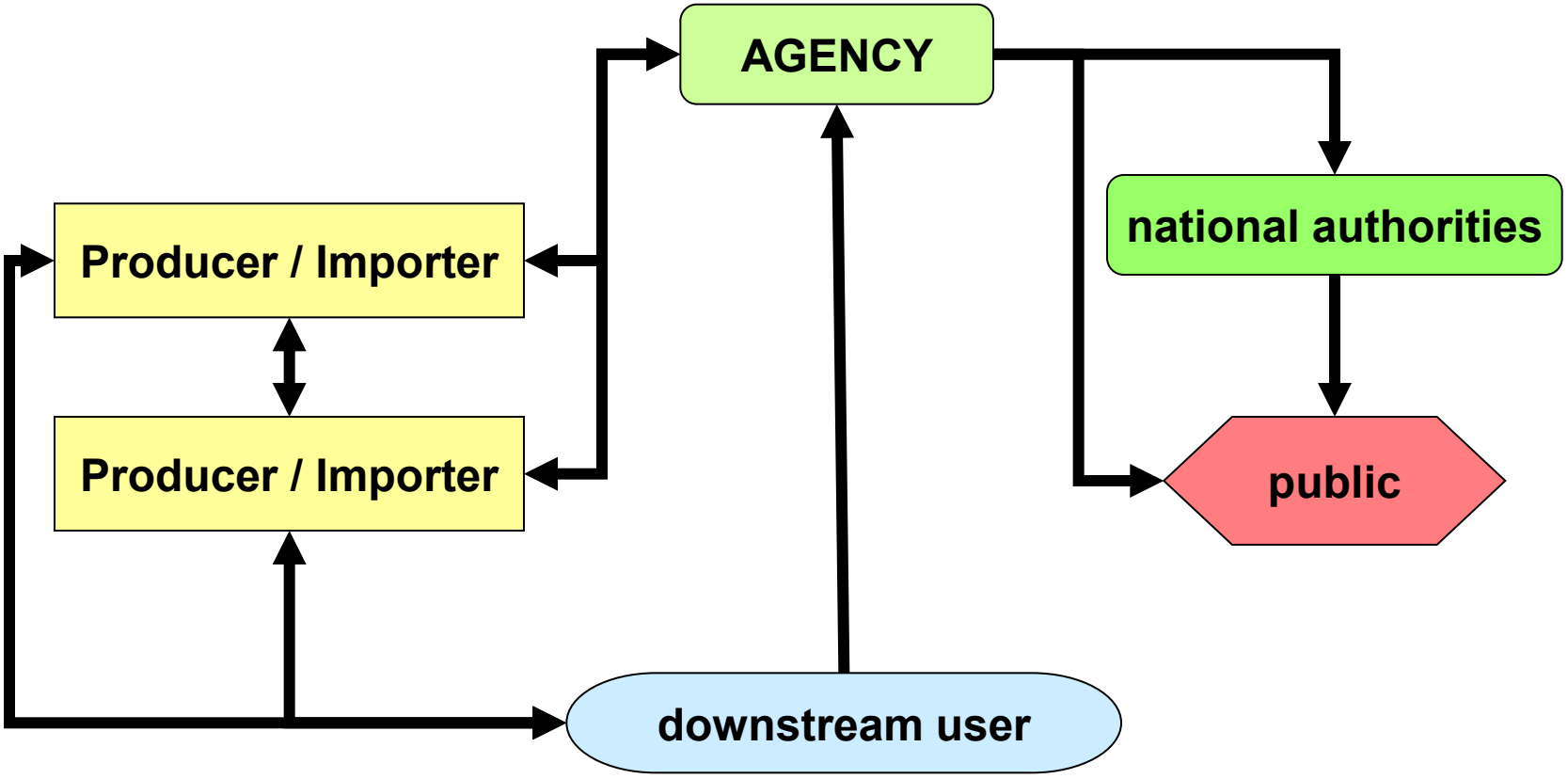
Requirements
Testing
Annex VII – ecotoxicological data

- Aquatic toxicity
  - long term toxicity test on invertebrates
  - long term toxicity test on fish
  - early development study on fish
  - fish embryonic toxicity
  - growth study on young fish
- Degradability
  - biotic
    - simulation of long term degradation in surface water
    - simulation of long term degradation in soil
    - simulation of deposition in sediments
    - identification of degradation products

Requirements
Testing
Annex VII – ecotoxicological data

- Fate and behaviour in the environment
  - bio accumulation in aquatic organisms
  - extended studies on absorption / desorption
- Effects on terrestric organisms
  - short term toxicity test on invertebrates
  - effects on soil microbes
  - short term toxicity test on plants

Information Exchange Overview

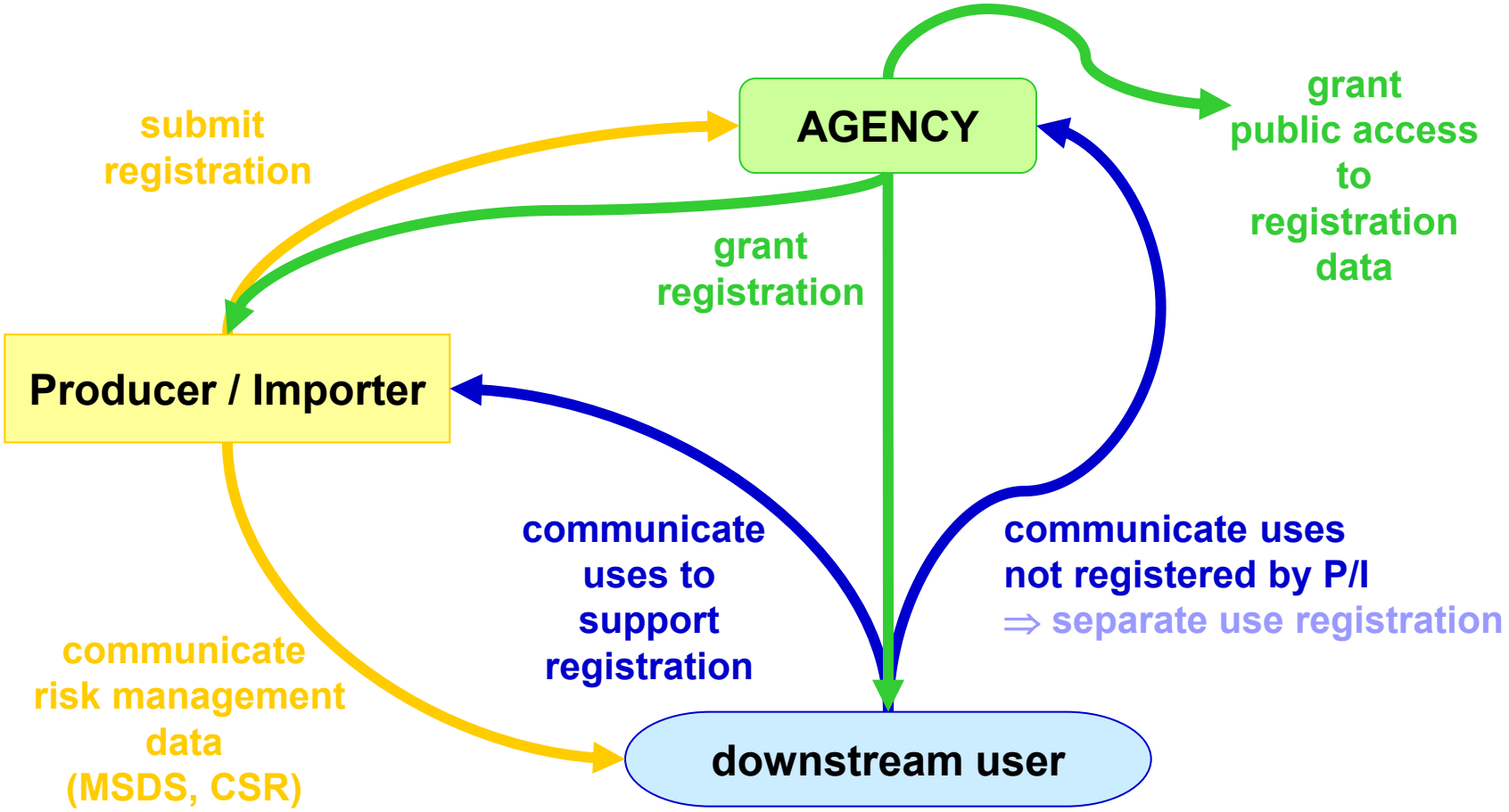


Information Exchange

- information access regulations grant access for competition, other market players and the public
- requirement for data sharing for the preparation of a registration

  ⇒ OSOR
- information access via national authorities according to national legislation

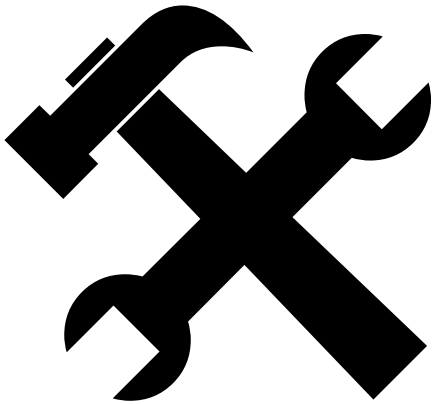
Information Exchange



Missed Cost Reduction opportunities

- omitting tests if not reasonable for the product
  (e.g. irritation test for known corrosives)
- omitting tests if not required due to non existing exposition pathways
- omitting tests that are already covered by other tests that have to be performed (e.g. short term toxicology is usually also covered by long term studies)

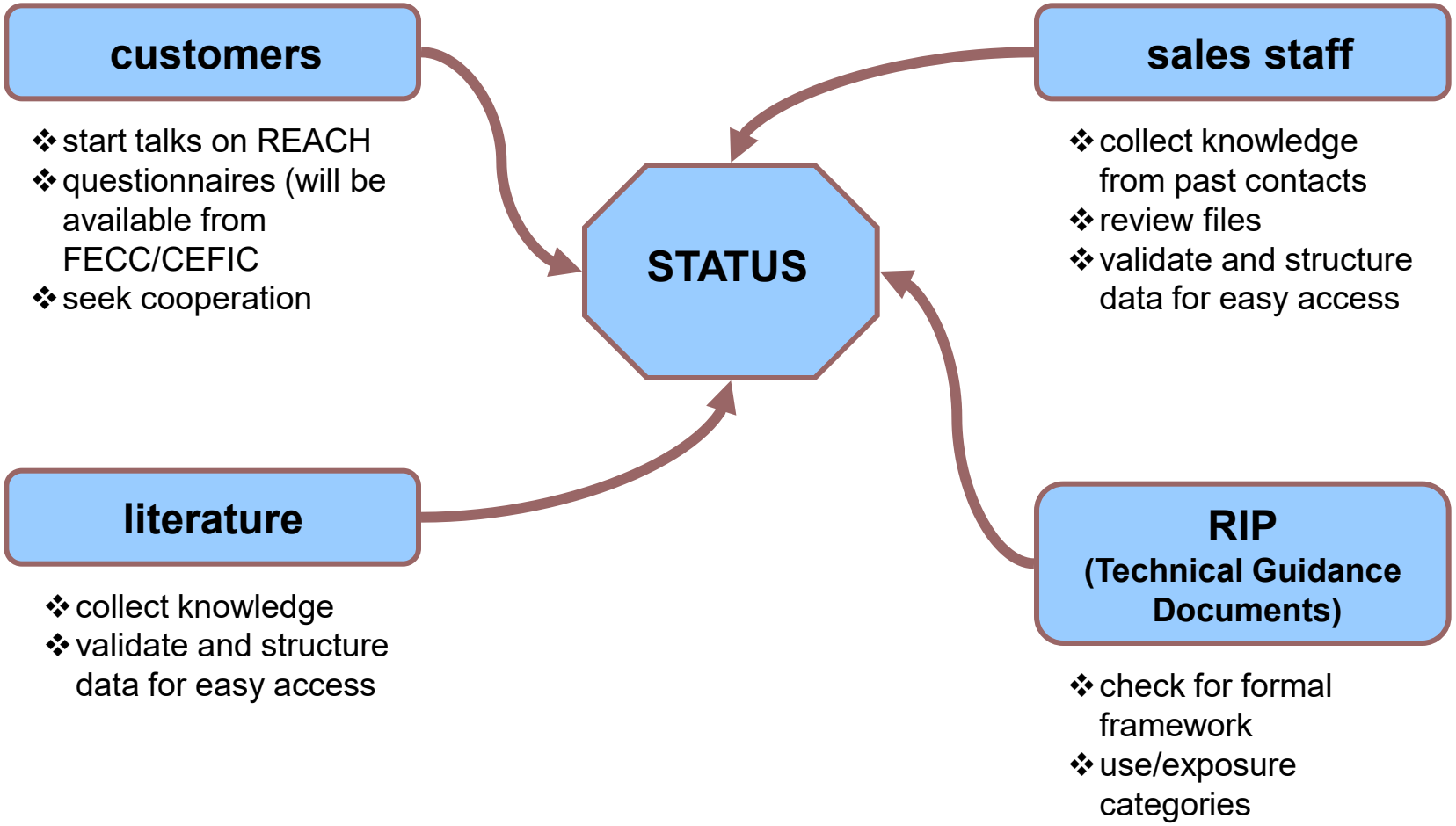
How to deal with REACH



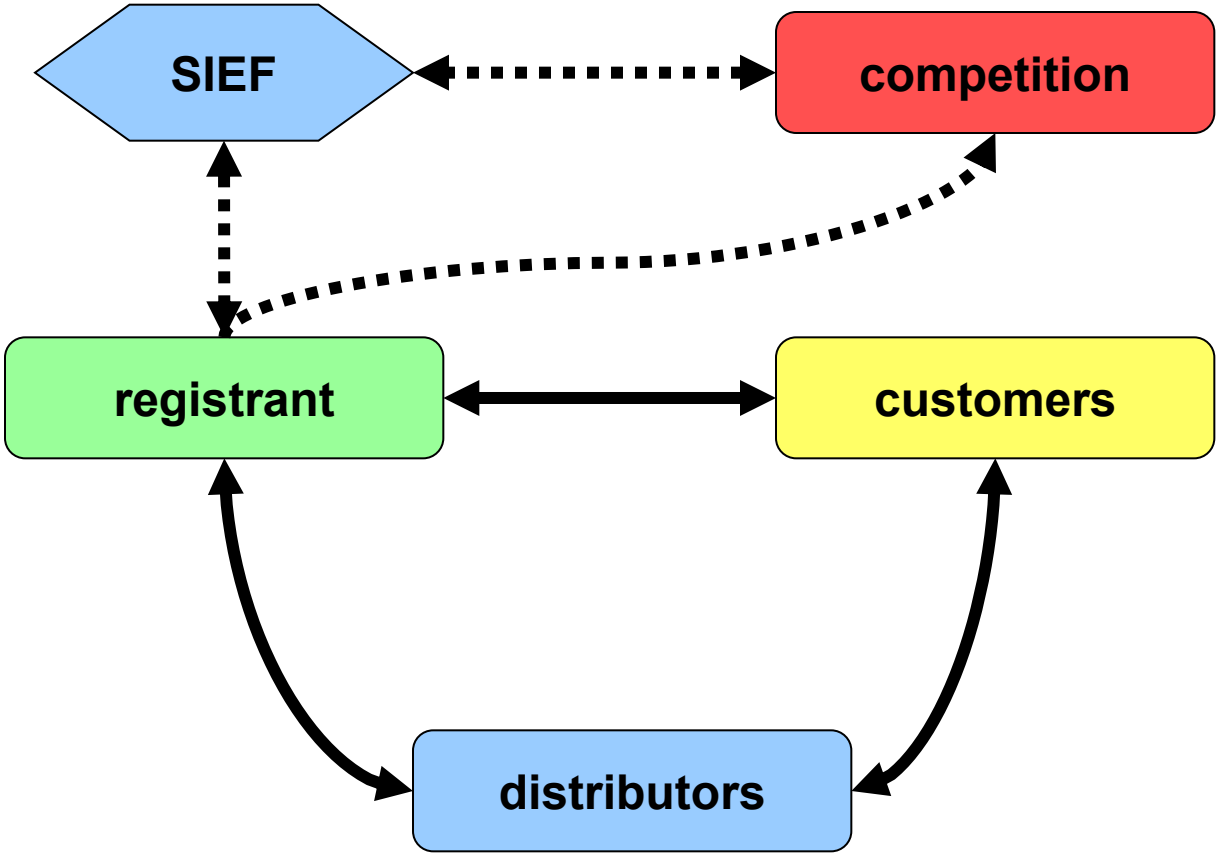
YOU NEED TO BE PREPAIRED

START NOW!!

Check customers knowledge about uses



Check possible cooperation opportunities



Discussion points

Consortia

- SIEF
  - IT based platform at the agency
  - easily find unknown collaborators (competition)
- data sharing
  - a chance to substantially ease burdens
  - risk to lay open business secrets
- cost sharing
  - a chance to substantially ease burdens
  - risk of endless discussions and legal actions

Summary

- extreme financial efforts for existing products
- high burdens for new products before marketing (import or production)
- high risk for new products
- difficult investigations on applications/uses
- long term engagement for administrative and sales personnel
- difficult integration of producers/raw materials from outside Europe