How Industry can Prepare for

REACH

Workshop on REACH Implementation Project 3
Brussels, Belgium
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European Commission

Overview

1. Recall some basics
2. What are the main steps to go through?
3. What do I do
   - Ø as an EU Manufacturer?
   - Ø as an EU Importer (or non-EU Manufacturer)?
   - Ø as a Downstream User?
   - Ø as “none of the above”?
4. Conclusions

1. Recall some basics (1)

AIM of Registration: Ensure industry adequately manages risks from substances

- **Method**:
  - M/I obtains/generates adequate information
  - Electronic dossier submitted to Agency
  - Information passed down the supply chain to DUs
  - DUs check if they agree.
- **Scope**
  - Substances M/I ≥ 1 tonne/year
  - Exemptions: other law, Annex II/III; polymers (review); PPORD
  - As registered: biocides, pesticides, notified substances.

Industry's responsibility

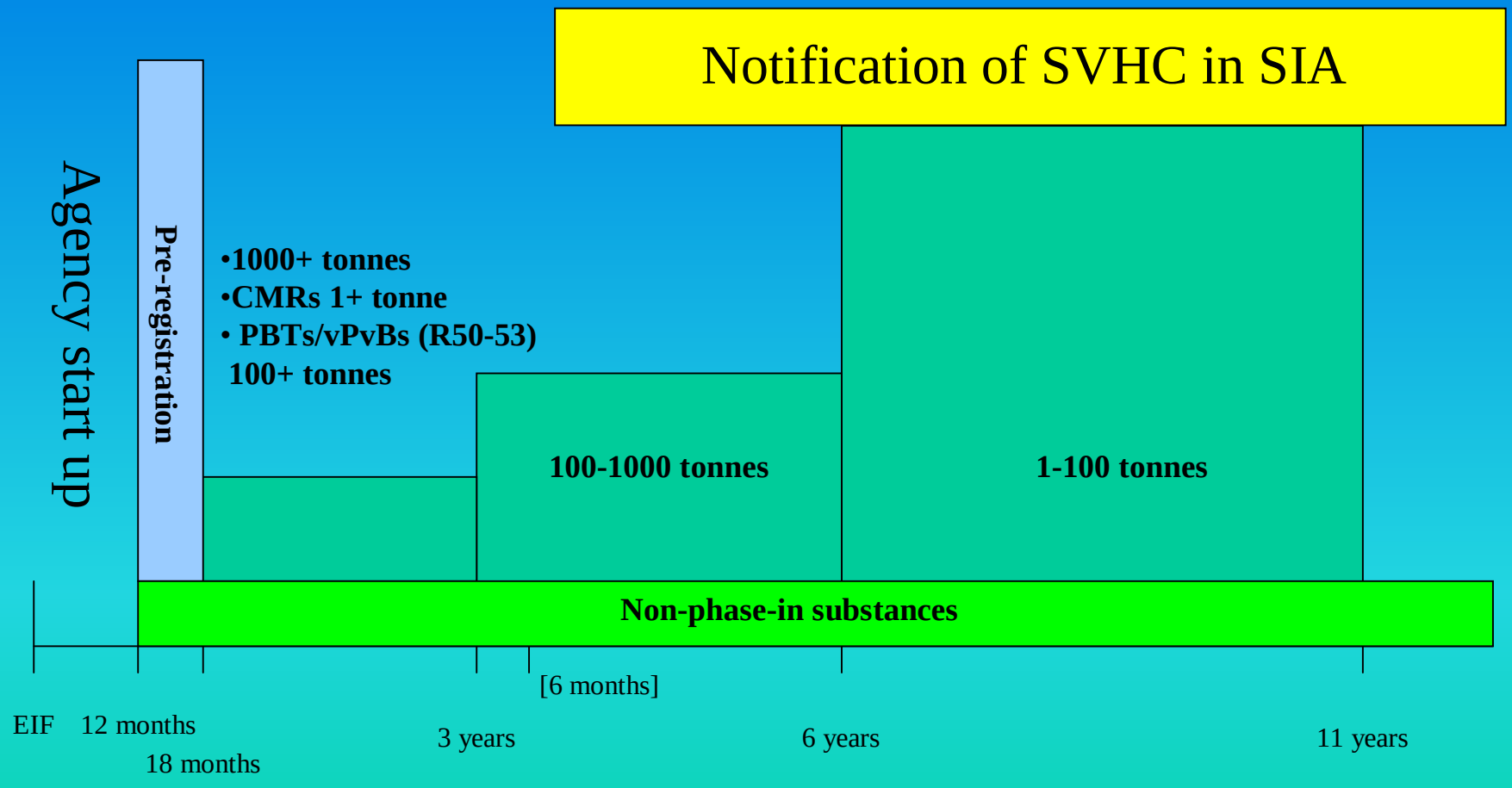
1. Recall some basics (2)

AIM of Pre-registration: Ensure industry shares information and submits joint registrations

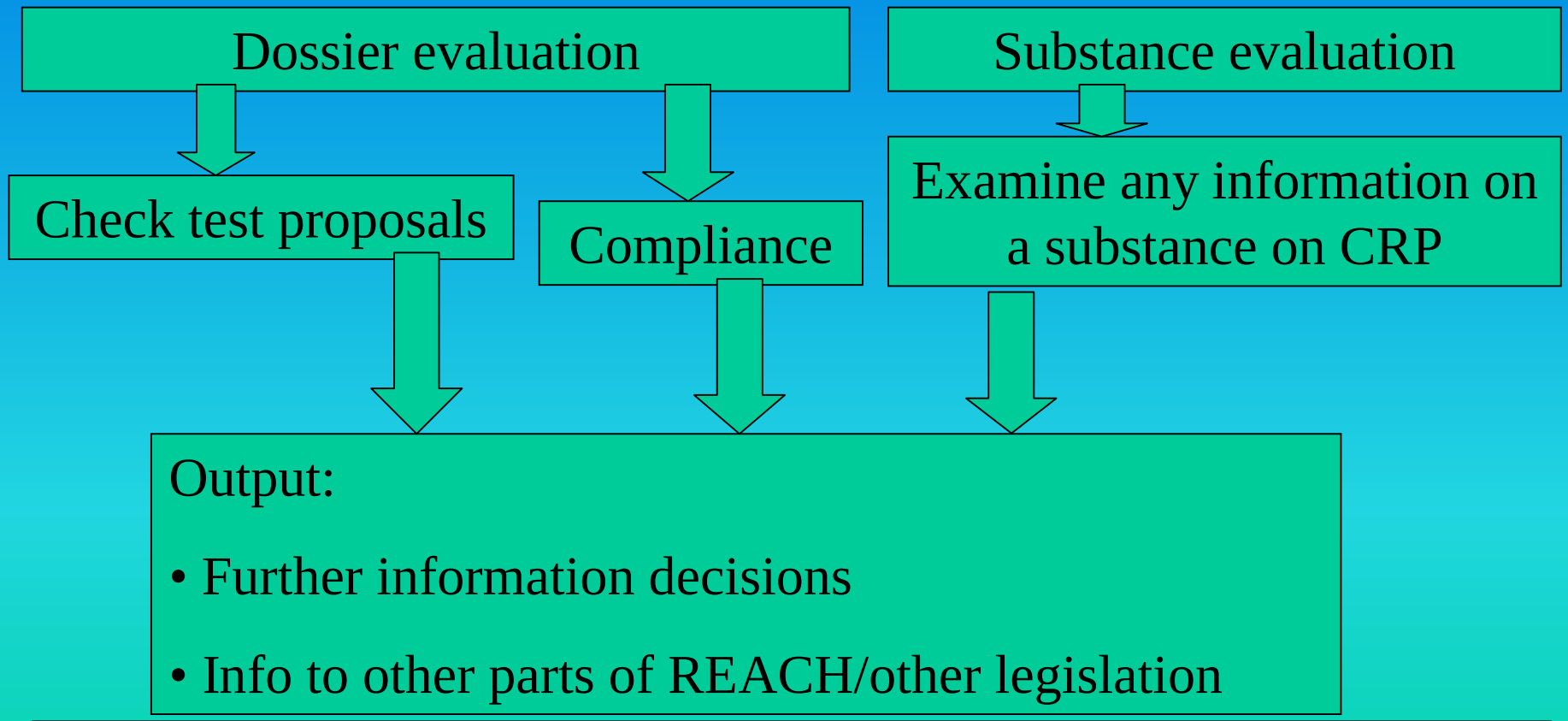
- **Method**:
  - Substance Information Exchange Forum
  - Joint Registrations
- **Scope**
  - Focus on vertebrate animal testing
  - Opt-out possible

Industry's responsibility

1. Recall some basics (3)



1. Recall some basics (4)



1. Recall some basics (5)

Restrictions	Authorisation
• “Don’t call us, we will call you” • Limited number of substances	• Is your substance a candidate? • Limited number of substances

2. What are the main steps for DUs to go through?

Collect Available Information and Locate other relevant information holders:

- Communicate in the supply chain and outside
  - Develop partnerships
  - Discuss how to meet their needs and yours

Also consider:

- Inventarise your substances
- Study guidance developed:
  - http://ecb.jrc.it/REACH/
- Inventorise your operational conditions and management maesures (ES!)
- Plan for the future
  - Discuss with your suppliers, to predict what work will come on you

Start NOW!

2. What are the main steps for M/I to go through? (1)

Collect Available Information and Locate other relevant information holders:

- Inventarise your substances, check identity and uses
- Study guidance developed:
  - http://ecb.jrc.it/REACH/
- Inventorise your operational conditions and management maesures (ES!)
- Communicate in the supply chain and outside
  - Develop partnerships
  - Discuss how to meet their needs and yours
- Plan for the future
  - Don’t leave data generation and assessment too late

Start NOW!

2. What are the main steps for M/I to go through? (2)

Collect Available Information and Locate other relevant information holders:

For example:

Once you know your substances

- Go to ESIS (European Substance Information System):
  - http://ecb.jrc.it/

  and find current EU M/Is, find existing information

  !!!!*For once you are lucky if your substance has already undergone EU work*!!!!!
- Go to OECD:
  - http://www.oecd.org/

  and find current OECD M/Is, find existing information

Contact the Information Owners NOW!

2. What are the main steps for M/I to go through? (3)

Collect Available Information and Locate other relevant information holders:

For example:

Once you know your uses

- Inventorise your exposure scenarios
- Remember, much is not new:
  - Risk assessment for your workers to control the risks!
  - Measures to fulfil your environmental permit conditions
  - Guidance on safe use in the SDS!

} All part of an ES!!!!

- Look around
  - E.g. ESR RARs (http://ecb.jrc.it/)

Start collecting information on ESs NOW!

2. What are the main steps for M/I to go through? (4)

Share Data:

Join the SIEFs, recalling:

- For most HPV Chemicals, data sharing agreements exist, as data submissions have already taken place several times in the past (ESR, ICCA, US HPV, …)
- The will be guidance on data sharing, to facilitate
- If you disagree on who should do a test, the Agency will decide for you!
- Use IUCLID to exchange data, so start early using the format.

Create/Join the SIEFs PREPARED and Early

2. What are the main steps for M/I to go through? (5)

Chemical Safety Assessment and write Chemical Safety Report:

Only > 10 tonnes !!!

Once you have your information

- Carry out the Chemical Safety Assessment
- This is iterative, so may take time and require more information
- Document the assessment in the Chemical safety Report
- There will be guidance and IT support

Identify competence gaps and strategy to fill them

2. What are the main steps for M/I to go through? (6)

Chemical Safety Assessment and write Chemical Safety Report:

Example (relevant for many substance, few “uses”):

- Inventorise your ESs (ie own use steps, ESs at each step)
- Identify which hazards are controlled by the ESs already implemented on site
- Check if all your substances are therefore already adequately controlled

Join/Create the SIEFs PREPARED and Early

2. What are the main steps for M/I to go through? (7)

Compile and submit Registration Dossier:

Once you have your information and CSR

- Compile your technical dossier
  - This will often be done prior to the CSA
  - This will often be built on existing IUCLID data
- The software will be rolled out early next year
- Attach the Chemical safety Report
- There will be guidance and help desks

Start compiling your technical dossier NOW

2. What are the main steps for M/I to go through? (8)

How to prepare for authorisation procedure

- Am I dealing with substances that may be subject to authorisation ?
  - discuss uses and use conditions in the supply chain
  - explore alternatives
- Can I contribute to the process before I may need to apply for autorisation ?
  - use the possibilities to provide information and comments
- NB preparing your registration dossier prepares you for possible authorisation procedure

2. What are the main steps for M/I to go through? (9)

How to prepare for authorisation procedure (cont.)

Possibilities to provide information and comment

- Annex XV dossiers proposing the identification
  - Possible from 1 year after entry into force
  - Notice on Agency website -> possibility to comment the dossier
- Prioritisation of the substances for Annex XIV
  - At the latest 2 years after entry into force, thereafter every 2nd year
  - Agency's recommendation on its website -> especially comments on uses which should be exempted
- Preparation of an authorisation decission
  - Information on applied uses on Agency's website -> provide information on alternatives
  - SEA Committee may require applicant and request 3rd parties to provide information on alternatives

3.1/3.2 What do I do – as an EU manufacturer/importer (1)

- **Main legislative steps of immediate relevance**:
  - Pre-registration
  - Registration
- **Main steps**:
  - Pre-Reg 1: Collect available information
  - Pre-Reg 2: Locate other relevant information holders
  - Pre-Reg 3: Share Data
  - Reg 4: Chemical Safety Assessment and write Chemical Safety Report
  - Reg 5: Compile and submit Registration Dossier
  - Next: Communicate down the supply chain
- **Main Worries**:
  - Will I fulfil my registration requirements?
  - Will I “survive” evaluation?

3.1/3.2 What do I do – as an EU manufacturer/importer (2)

- For pre-registration and registration
  - As a non-phase in (starts April 2008)

    !!!!*You are lucky: except for CSR, much simpler than current NONs*!!!!!
  - As a phase in (Registration starts April 2010 for HPVCs and some others), for HPVCs build on your ESR, ICCA, US HPV and OECD work.
- For CSR see later

3.3 What do I do – as an non-EU producer

- Study obligations of your EU importer
  - REACH registration requirements
  - Guidance developed: http://ecb.jrc.it/REACH/
- Actively communicate with your EU clients to see how their needs can be met and
  - Provide adequate information on the substances
  - Develop and provide exposure scenarios
- Determine: Use “Only representative”
- For CSR see later

3.1./3.2/3.3 - Preparation: Chemical safety assessment

- What are your uses and what are the identified uses?
- How can these best be expressed in (broad) exposure scenarios?
  - M/I: Specific scenarios cost more to prepare but may require less testing and less demanding risk management measures – attractive to DU
  - As a DU, do you wish to identify your use?
- M/I and DU - start talking to each other today!
- Use the flexibility in the proposal
  - ES can be as broad as possible but need to be specific where necessary to communicate appropriate risk management measures

Exposure Scenarios must be developed. Aim of the discussion in the supply chain is to agree on who does what!

3.4 What do I do – as “none of the above”

- Data owners can enter SIEFs
- Cost sharing
- Ownership rights preserved

- Remember: Distributors have to pass information on in the supply chain

4. Conclusions (1): DUs

- Main steps:
  - Collect available information
  - Communicate up and down the supply chain to divide the work on developing Exposure Scenarios and carrying out the Chemical Safety Assessment
  - START NOW!!!!!!!!!!

4. Conclusions (2): M/Is

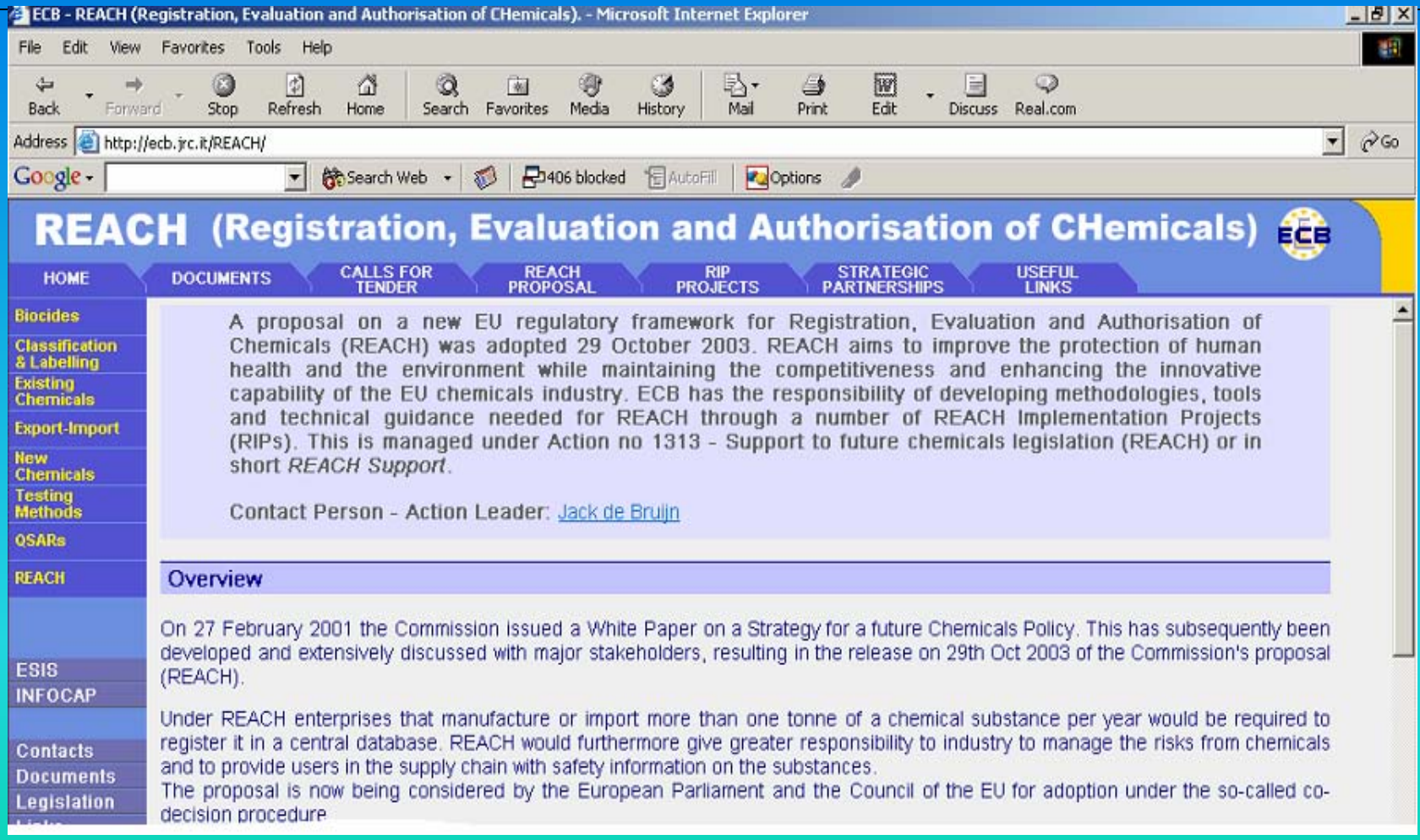
- Main steps:
  - Pre-Reg 1: Collect available information
  - Pre-Reg 2: Locate other relevant information holders
  - Pre-Reg 3: Share Data
  - Reg 4: Chemical Safety Assessment and write Chemical Safety Report
  - Reg 5: Compile and submit Registration Dossier
  - Next: Communicate down the supply chain

  - START NOW!!!!!!!!!!

European Commission - DG Environment

Further information on RIPs

http://ecb.jrc.it/REACH/



Information

EUROPA

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://europa.eu.int/comm/enterprise/chemicals/index.htm