

REACH Evaluation

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REACH Evaluation

What is to be evaluated

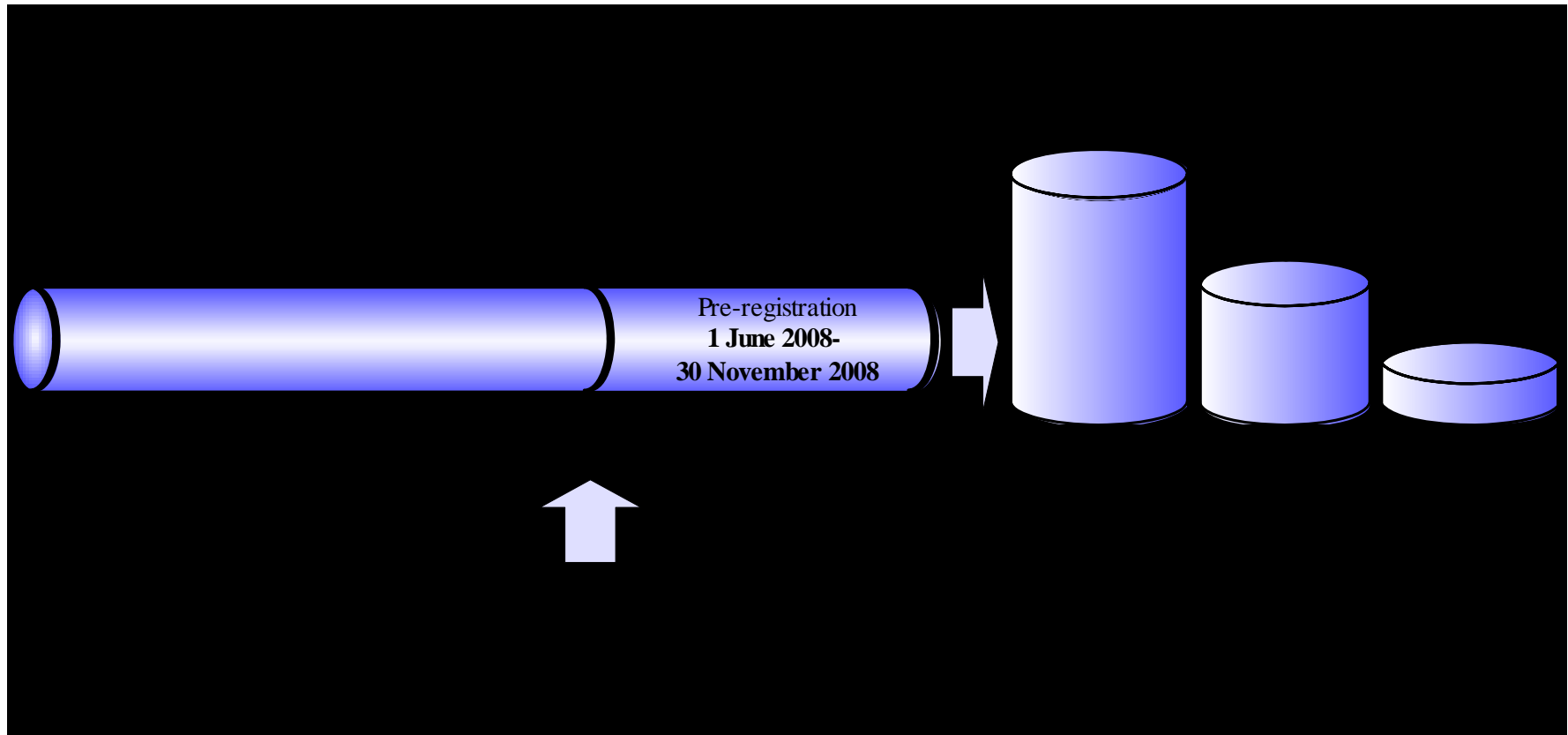
Compliance check

Substance evaluation

Evaluation process and decisions

Testing proposals

REACH - Evaluation



Evaluation

REACH includes two evaluation procedures

1) Compliance check

This is essentially a completeness check of the registration technical dossier

2) Substance evaluation

Full evaluation of the submitted dossier

What is to be evaluated

Registration dossiers submitted by the deadline date

OR

Substances regarded as being registered (Biocides & Plant Pesticides)

OR

Substances that were previously notified - in accordance with 67/548/EEC)

The Agency will also examine all proposals for additional testing

Compliance check

Check that all the required data is included in the submitted dossier in accordance with that specified in Article 10, 12 & 13 and with Annexes III & VI to X

All justifications for adaptations or deviations from the specified data are *acceptable?*

Chemical safety assessments and reports are in compliance

Any explanations have an objective basis

Compliance check

The Agency:

Will inform the Member States of the number of dossiers to be checked.

Within 12 months of starting the check they can request additional information from the registrant.

Will set deadlines for the submission of the new information.

Compliance check

Compliance check carried out by the Agency on no less than 5% of all dossiers submitted from each tonnage band. *Could be more*

Choice criteria:

- **Submission of a separate dossier**
- **Dossier is not complete**
- **Substance is included in the
Community Rolling Action Plan**
- **Information from third party
sources**

Compliance check (Art 41)

On completion, the Agency will notify the Commission and Member states of their decision

Draft decisions prepared

For *non phase* in substances within 180 days of receipt e.g. the registration

For *phase in* substances 3 years after receipt

Substance evaluation (Art 44)

- An in-depth evaluation to be carried out on selected substances
- Agency + Competent Authorities working together.
- Will take a risk based approach.
- Criteria for prioritization
- Hazard information presented in the Technical dossiers.
- Exposure information.
- Aggregate tonnages.

Substance evaluation

Development of a Draft Community Rolling Action Plan.

Include substances which are considered to be a risk to health &/or environment

Agency to send a draft report to the CA, then to be adopted.

An update to be published each year.

To be published on the web site the name of the substance and Competent authority who is responsible for the evaluation.

Substance evaluation

The Agency is responsible for coordination of the evaluation process

The Competent authorities will carry out the evaluations

The CA can appoint another body to carry out the work

MS to choose the which substances they want

2) Evaluation process

CA can request additional data.

Draft decision to include the required information and a deadline for submission.

Drafts to be prepared within 12 months of the publication of the action plan.

Revised draft decision within 12 months of receipt of data.

Evaluation - adoption of the decision

CA to determine how to use the results of the evaluation and inform the Agency of it's decision.

The Agency will then inform the registrants, Commission, other CA's and Downstream Users.

Discussion by all parties of all comments and proposed amendments.

Send to the Member State Committee for the final decision

Registrants can appeal against any decision made

Publication of information

Information and actions taken are made public

Agency to publish progress reports on its web site

To include recommendations to help potential registrants to improve the quality of future registrations

Evaluation of Testing proposals

The Agency will publish on the Web site:

Substance identity.

Hazard end point of the study.

Date the data is required.

**An invitation for third parties to send
in relevant data.**

Priority given to high risk substances

Evaluation of Testing proposals

The Agency will review and come to a decision.

Options:

- **Approve the performance of the study.**
- **Agree to the deadline for completion.**
- **Make changes to the protocol.**
- **Request additional data.**
- **Reject the proposal.**

Evaluation of Testing proposals

- **Where several registrants or Downstream Users have submitted similar testing proposals they are to try to come to an agreement on who will perform the study.**
- **Inform the agency within 90 days.**
- **The Agency can designate one registrant to perform the study on behalf of the all - costs to be equally shared.**

Dossier Evaluation

Where new tests are requested:

Registrants & DU's to agree who will carry out the study and inform the Agency

Cost of the study to be shared equally

Market restrictions can be applied where there is a failure to pay a share

Can be legally enforced

THANK YOU