REACH Data requirements & Evaluation

Visit of the delegation from Brazilian Ministry of Environment and Institute of Environment and Renewable Natural Resources to ECHA

15 April 2013

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REACH & CLP: information on chemicals & addressing chemicals of concern

- **Pre-registration**
- **Data sharing**
- **Registration**
- **Self-Classification**

Industry gathers information and ensures responsible and well-informed management of the risks

ECHA EUROPEAN CHEMICALS AGENCY

MSs

- **Evaluation**
  - **Dossier evaluation**
  - **Substance evaluation**

ECHA and MSCAs control and request for further info

- **Authorisation**
- **Restriction**
- **Harmonised C&L**

COM, with support of ECHA and MSCAs, applies community wide risk management measures

REACH: Registration

- **Core of REACH**: EU/EEA manufacturers and importers of chemicals collectively obtain information per substance and use knowledge to ensure safe use
- Registration:
  - IUCLID format technical dossier for substances at 1 t.p.a. submitted using REACH-IT
  - Standard **information linked to tonnage**
  - **Testing Proposals for higher-tier studies** (i.e. at 100 & 1,000 t.p.a.)
  - **Chemical Safety Report** for substances at 10 t.p.a.
  - Transitional arrangements, i.e **'phase in' substances registered in 3 stages**

Properties of Chemical Substances

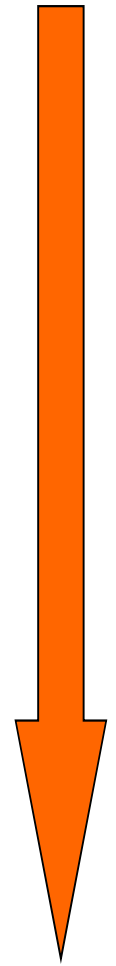
- To define and characterise the substance.
- To identify the hazardous properties for hazard communication.
- To identify and quantify the hazardous properties for risk assessment.
- To obtain parameters necessary for exposure assessment models for risk assessment.
- Physico-chemical, toxicology & environmental (ecotoxicity & environmental fate)

Standard core registration data

Annex	Human Health	Environment
Annex VII (≥ 1 t.p.a.) **Plus physico-chemical tests**	•***In vitro* skin and eye irritation** •**Skin sensitisation** •***In vitro* mutagenicity** •**Acute toxicity (one route)**	•**Short term toxicity (daphnia, algae)** •**Degradation (biotic)**
Annex VIII (≥ 10 t.p.a.)	•***In vivo* skin and eye irritation** •**Further *in vitro* mutagenicity** •**Acute toxicity (2nd route)** •**Short-term RdT (28 days)** •**Reproductive toxicity screening** •**Assessment of toxicokinetics** (not a testing requirement)	•**Short term toxicity (fish)** •**Respiration inhibition test** •**Degradation (hydrolysis)** •**Fate (absorption/desorption)**

Higher-tier data for Testing Proposals

Annex	Human Health	Environment
Annex IX (≥ 100 t.p.a.)	•Further *in vivo* mutagenicity studies (if + results) •Sub-chronic toxicity (90-days) •Reproductive toxicity tests	•Long-term toxicity (invertebrates, fish) •Biotic degradation (simulation studies) •Identification of degradation products •Fate: bioaccumulation in fish, further absorption/desorption •Short term toxicity- terrestrial organisms (invertebrates, micro-organisms, plants)
Annex X (≥ 1000 t.p.a.)	•Further *in vivo* mutagenicity studies (if + results) •Further reproductive toxicity studies • *Chronic toxicity (may)* • *Carcinogenicity (may)*	•Further biotic degradation •Further fate •Long-term effects on terrestrial organisms •Long-term or reproductive toxicity to birds



Increased use of animals and/or costs

Intelligent approach to property evaluation

- **New animal studies are a last resort** for REACH registration.
- **Data sharing** obligations for registrants of the same substance to avoid duplicate testing.
- Registrants must first **collect and assess all existing data**, then **identify data gaps** and consider whether **data waivers** apply or if gaps can be filled by **non-standard data** before deciding on new studies.
- **Data waivers**:

  Impossible to conduct the study for technical reasons.

  'Low' exposure. i.e. '**Substance-tailored exposure-driven testing'** or chemical intermediates under 'strictly controlled conditions'.

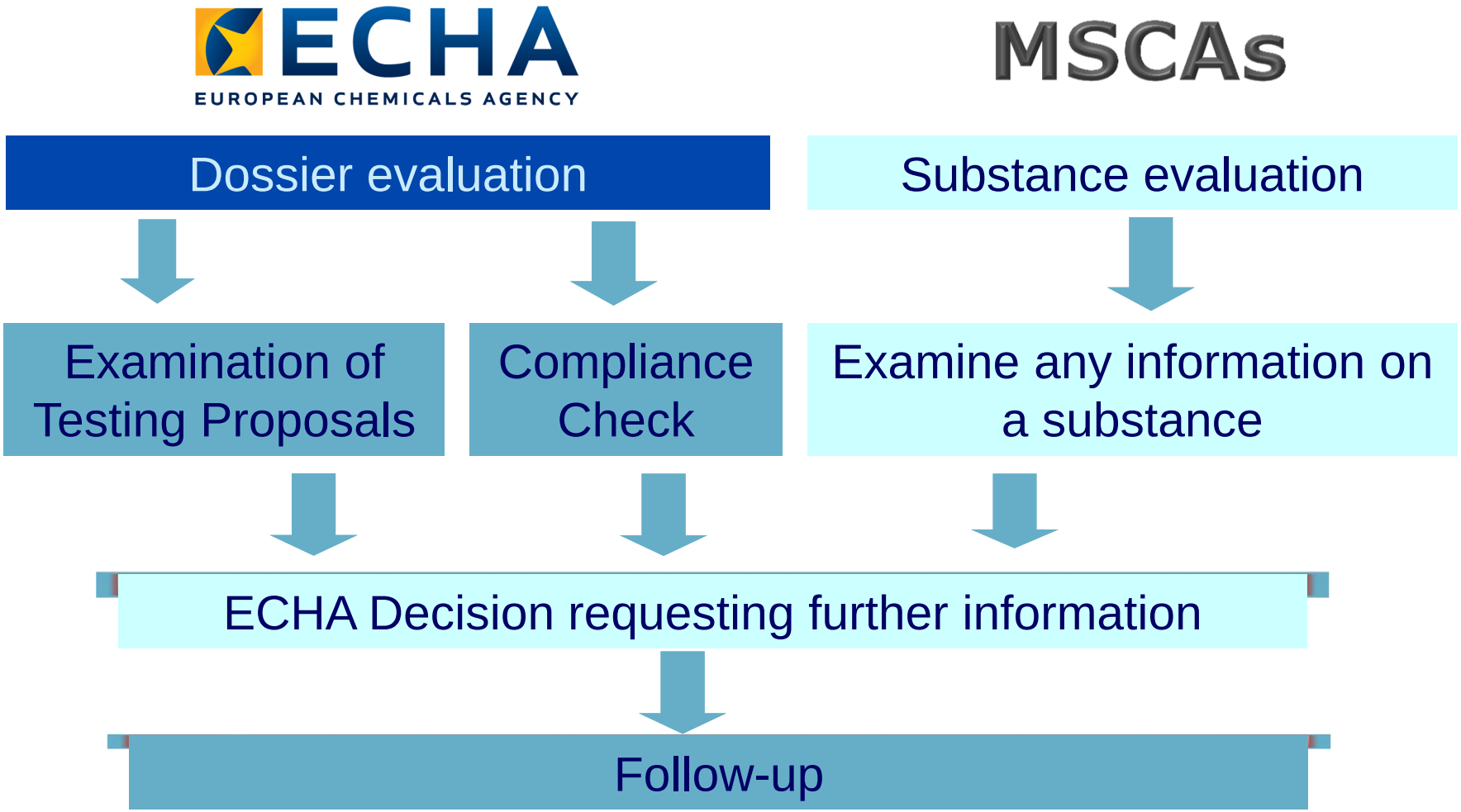
Non-standard Data for use in REACH

- **Annex XI 'adaptation'** of the standard information requirements.
- **Non-standard studies** or non-GLP.
- ***in vitro* studies**.
- Human **epidemiology** data.
- Information from structurally-related substances, i.e. **'read-across' and 'chemical categories/grouping'.**
- Predictions from valid **(Q)SARs**
- **Weight of evidence** (WoE)

Chemical Safety Assessment

- Substances at >10 tonnes per year have Chemical Safety Report (CSR) to record the Chemical Safety Assessment (CSA).
- Assessment if hazardous & if PBT/vPvB.
- 'Exposure scenario' (ES) key output of the CSA process, i.e. a description of manufactured/used as 'operational conditions' (OCs) linked to 'risk management measures' (RMMs).
- Determine 'derived no effect level' (DNELs) for human populations, i.e. level below which adverse effects should not occur, based on toxicity data set using 'assessment factors'.
- Determine 'predicted no effect concentration' (PNECs) for the environmental compartments.
- Exposure assessments are calculated from the ESs for the risk characterisation.
- CSR summarised as an extended Safety Data Sheet (SDS), i.e. essential element of supply chain communication to Downstream Users

Evaluation Overview



MSCA = Member State Competent Authority

Compliance Checks

- Compliance check (CCH) REACH allows ECHA to **verify that the information meets the data requirements**
- Although all registration dossiers must pass the Technical Completeness Check (TCC), there is no assessment of the quality or adequacy of the registration information
- CCHs on at least 5% of registration dossiers for each tonnage band
- 1,200 registration dossiers from 2010 deadline will be checked for compliance by end of 2013
- So far the majority has resulted in an ECHA decision requesting further information
- Quality of many of the registration dossiers can and needs to be improved

Testing Proposal Examinations

- All **Testing Proposals** from registrants for higher-tier studies have to be evaluated
- Over 1,000 testing proposals from 2010 processed but many decisions still to be adopted
- Mostly authorising the testing as proposed or with modifications
- Third parties have only very rarely submitted scientifically valid information or studies making testing unnecessary

Substance Evaluation

- New process under REACH to **clarify potential risk** not identified in the registration (i.e. to get extra hazard &/or exposure data)
- First **Community Rolling Action Plan** ('CoRAP') of **90 substances** as a 'rolling' 3-year list for 2012 to 2014
- Over 30 decisions to take and 46 new evaluations to be monitored from the 2012 list.
- ECHA compiles an annual proposal for CoRAP update by October for adoption by 31 March.
- Member States undertake the substance evaluation within 12 months

ECHA's Strategic Aims

Four strategic aims developed to support prioritisation & guide how ECHA:

- approaches its activities
- allocates resources
- motivates its staff

- Getting better quality data from industry
- Using data intelligently for identifying and addressing chemicals of concern
- Becoming the regulatory science hub
- Using resources efficiently and effectively