

# Data sharing and SIEFs

30 March 2009, Brussels

Sebastian Gil, DG Environment, European Commission



# Contents

- **aims**
- **obligations and rights of SIEF members**
- **external actors' obligations towards SIEF**
- **management and extent of cooperation**

# Aims of SIEF

- to facilitate information exchange for the purpose of registration
- to avoid duplication of studies
- to agree classification and labelling

but: SIEF (data sharing; no opt-out)

≠

Joint registration

(agreement on the choice of studies; possibility to opt-out if disagreement, excessive costs, CBI)

# Obligations of SIEF members

- **provide others - on request and upon compensation - with existing studies involving vertebrates**
- **collectively identify and arrange for missing studies**
  - inquire missing study
  - request such studies if they exist and involve vertebrates
  - conduct only one study if tests involved
  - agree fair, transparent and not discriminatory compensation and/or cost sharing

# Rights of SIEF members

- to obtain, upon compensation paid, requested study (on vertebrates or not) - if not obtained, can proceed with registration
- to be compensated in a fair, transparent and not discriminatory way – ultimately “equal share” (adequate to tonnage requirements)
- ECHA support (see next)

# External actors' obligations towards SIEF

## ■ ECHA:

- guidance on cost sharing
- appointment of a SIEF member to carry out tests on behalf of the SIEF in case of disagreement
- blocking registrations of those who do not share information involving vertebrates
- decides if tests not shared have to be repeated
- gives permission to refer to study submitted by other registrant

## ■ National courts:

- breach of the obligations stipulated by REACH enforceable in national courts and individual contractual agreements between SIEF members

## ■ Member States:

- enforcement of making data available (proof of costs or studies) – penalisation

# Management of SIEFs

- **little regulated by REACH:**

- see rights and obligations, including external actors

- **additional facilitation by ECHA through guidance and REACH-IT:**

- SIEF facilitator functionality (voluntary, does not give a right to SFF to claim leading role against the will of SIEF members)

- communication tools

- data sharing guidance

- **but principally, SIEF members' own arrangements:**

- agreement on the sameness of the substance

- extent and forms of cooperation

# Enhanced cooperation

- REACH foresees certain mechanisms to request studies (“individual route” in data sharing guidance)
- however, SIEFs are free to organise themselves internally in the way that fits best (e.g. “collective route” in the data sharing guidance)
- in case of dispute, they must however guarantee that all SIEF participants can get the relevant studies at a fair price, as foreseen in REACH (i.e. if necessary by individually requesting studies)

# Conclusions

- the aim of SIEF is to enhance data sharing and reduce test duplication (animals and costs); “automatic” membership; no “opt-out”
- members are obliged to communicate (inquire and respond) on studies requiring testing and to share data and costs regarding tests on vertebrates
- members have the right to not be blocked with their registration in case of disagreement on data sharing or performing new tests and to be compensated for data shared
- ECHA and National courts – certain obligations in solving disputes
- management of the SIEF – responsibility of members who choose the way and extent of collaboration
- SIEFs are free to organise themselves internally (including the “collective route”) but members must get the relevant studies at a fair price

**Thank you for your Attention !**

