

SunChemical®

a member of the DIC group



SIEF's and Consortia

2009 GlobalChem Conference
Baltimore, MD
Robert C. Mott

April 6-8, 2009

working for you.



SIEF – preamble to the Regulation.

A group of entities with an agreement that one or more substances will be considered together for the purposes of a test plan.

- ...a system should be established
- ... avoid duplication of work...
- ... avoid duplication of testing...
- ...exchange of information on the substances that have been registered...
- ...all relevant actors submitting information...
- ...potential registrants...
 - ...who must provide and be supplied with any information...
 - ...other participants, who may receive financial compensation for studies...
-smooth functioning of that system...

Substance Information Exchange Forum (SIEF) - Definition

SIEF – Article 29

1. All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15, for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline set out in Article 23(3), shall be participants in a substance information exchange forum (SIEF).

2. The aim of each SIEF shall be to:
 - (a) facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between potential registrants, thereby avoiding the duplication of studies; and
 - (b) agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.

3. SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of paragraph 2(a) and arrange for such studies to be carried out. Each SIEF shall be operational until 1 June 2018.

Agreement on registration substance identity

- Purity
 - “80% rule”
 - Exceptions
 - < 80%
 - Similar physico-chemical properties
 - Same hazard profile as substances meeting the 80% rule
 - only occasionally \leq 80%, but overlaps
 - Main substance ranges
 - Impurity ranges

- By-products
 - Different processes
 - Different control measures
 - Different process capabilities

- Impurities
 - Raw materials
 - Side reactions
 - Isolation techniques

Must Share of all Vertebrate test results

- Existing
- Planned
 - Read across and grouping
 - Use of QSAR's to avoid animal testing
- Newly performed only after ECHA approval

Should Consider Sharing Non-Vertebrate test results

QSAR's to fill data gaps

Consortia – This is not a REACH requirement

What is a Consortium?

“a group formed to undertake an enterprise beyond the resources of any one member.”

Why form one?

- Allows efficient management of REACH registration requirements

Recommendations

- Agreement on registration substance identity
- Agreement on use pattern
- Agreement on interpretation of test results
- Keep contract simple

Problems

The SIEF is described differently

- Scope – a defined group vs. all inclusive
- Purpose – develop test plan vs. communicate up and down
- Function – exchange data vs. registration

Other SIEF Issues

- Administration of a SIEF is not addressed
- No mechanism for management or control is specified
- Leadership roles are not defined
 - SIEF Facilitator
 - Lead Registrant

Problems

The Consortia relationship to SIEF

- Restrictive vs. Inclusive
- Multiple substances
- Contract
- Administrative costs



Questions?

Resources

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

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en08500856.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf

<http://echa.europa.eu/>

<http://www.opsi.gov.uk/si/si2005/20051524.htm>

- “GUIDANCE FOR SUBSTANCE IDENTIFICATION AND NAMING IN REACH”; ECHA