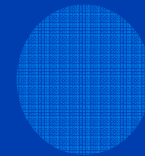
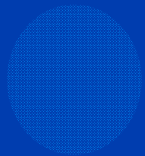
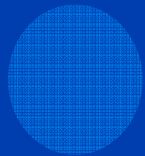
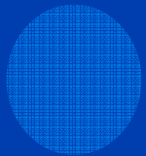


Good and bad experiences with pre-SIEF / SIEF

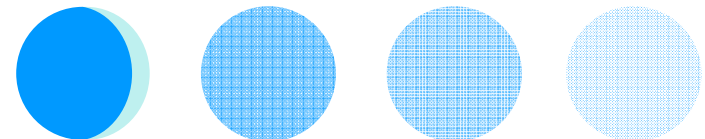
Genevieve Hilgers
Procter & Gamble
March 30, 2009



P&G

Company's background

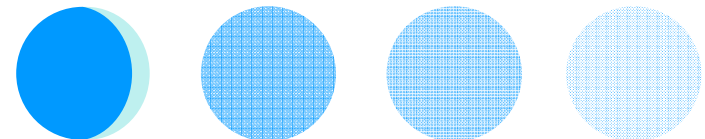
- Have submitted several thousands of pre-registrations
- Between 50-100 Registrations to be submitted by Dec 2010 and many others for 2013 and 2018
- We are involved in growing number of consortia



Experience in Pre-SIEF:

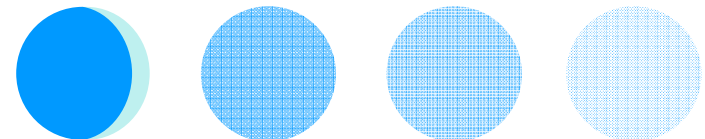
1. REACH-IT

- Very slow start due to REACH-IT issue in Jan 09
- Since Feb 09, we have not faced any REACH-IT issue anymore



2. SFF

- In general very slow progress
- Still many pre-SIEFs without SFF
(In our Company, we have contacted/will contact key suppliers & key Manuf. to strongly encourage them to nominate themselves)
- When there are any progress, it is because either:
 - > Consortia already in place
 - > or SFF is a big manuf.



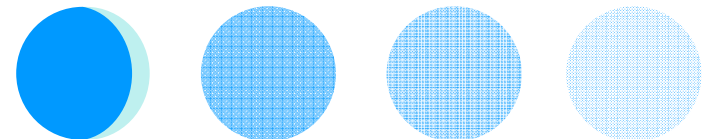
2. SFF

- Many SFF are consultants or small companies:

a) Slow

-> either they initiate the work slowly

-> or SFF does not start the work and
often does not reply to any e-mails we sent them

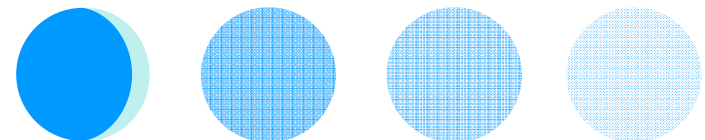


2. SFF (con't)

b) Raise trust issue

- Some Industry associations seem to contribute to further slow down the “sameness” process for trust reason

-> recommend to their members not to reply to SFF which are unknown company or consultants



2. SFF (con't)

c) Sometimes go beyond what is required by the law

- SFF as Consultant often:

- > send standardized questionnaire

- *Status in SIEF?

- (Leader, Involve, Passive, Dormant)

- *Type of Registration

- *Information on the substance

- (Monoconstituent, multiconstituent etc...)

- *Do you own data?

- > Many of them do not ask for confidential information

- * except some ask for UUID number and

- * some of them have been able to extract UUID from REACH-IT and contact SIEF member with this number



2. SFF (con't)

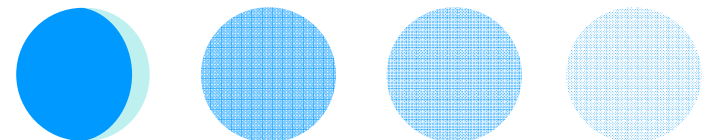
c) Sometimes go beyond what is required by the law (con't)

-> Some of them ask to sign a legal statement before replying to their questionnaire:

Extract: *“Users shall only use xxx for REACH related activities and only those (from pre-SIEF after entering into ECHA REACH-IT for the purpose of activities such as data sharing, classification & labelling, designation of the lead registrants, preparation of the joint submission etc). ...”*

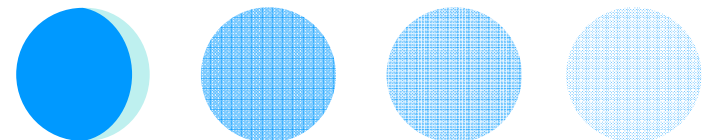
-> SFF we have seen so far have not asked for financial contribution

d) Many SFF have poor knowledge in chemistry



3. Other issue in pre-SIEF

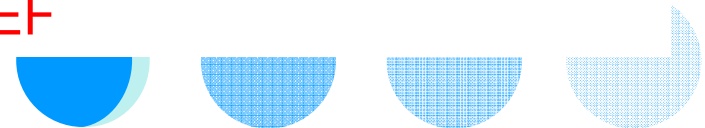
- Some substances have Registration deadline of Dec 2010 while based on market knowledge no manuf. or import are at >1,000t/y
- > Explanation? Some Companies (SME's) did not put a deadline in pre-registration dossier
->in this case Dec 2010 is put by default?
- > Csq: Force all SIEF members to speed-up the SIEF process until they will find-out that none of SIEF members plan to register at >1000t/y



4. Issue with data sharing

a) Between Consortia and other SIEF members

- > Interactions between consortia and other SIEF members are in general poorly defined in consortia agreement
- > In some cases, consortia work already finalized when pre-SIEF has been formed early 2009
- > Some Consortia's language: "take it or leave it" and not open to take into account potential relevant data available which could further increase dossier quality
- > CEFIC is currently drafting work process which indicate that SIEF members should have the possibility to check data collected by consortia and provide his data if relevant for SIEF



4. Issue with data sharing

b) Published data

-> Inclusion of Published (e.g., in scientific journals subject to copyright, HPV program data) and non published data as a key study for the purpose of registration requires always a letter of access from data owner

-> In many cases, data requesters will have to ask permission to use data to data owner

-> Menu provided in IUCLID 5 very misleading
(proposed correction)

- Data submitter is data owner
- Data submitter has Letter of Access
- Data no longer protected
- Data published **and legitimate possession**
- Not applicable
- Other

-> Menu as currently provided in IUCLID 5 gives the false impression to many industry that all published data can be use for free



5. Issue with data compensation

Between Consortia and data owners

- > Registration at >1,000t/y
- > Carcinogenicity data is available
- > Consortia members want only to compensate data owner for 91-Day even though a carcinogenicity study is required based on REACH criteria
- > Letter of Access will state that only 91-day has been compensated
- > Will ECHA review LoA in details and indicate to consortia members that Carcinogenicity study is needed and LoA to Carcinogenicity test is needed?

