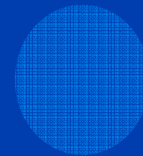
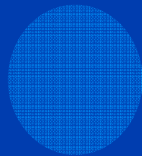
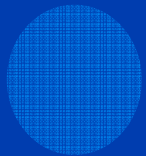


Frequent challenges observed in SIEF

Genevieve Hilgers
Procter & Gamble
September 11, 2009



P&G

1. Challenges in SIEFs

- **Complex:** REACH text and guidance anticipated simple approach to SIEF work...but in practice, it is very complex, very time-consuming and expensive
- **Many other tasks than safety:** So far our toxicologists spent 95% of their time to deal with everything except safety i.e admin., organizational, legal , IT, etc...
Lack of guidance on many aspects e.g. data sharing
- **“Cow-boys” SFF...** an unexpected issue which created big confusion , significant additional workload to industry & very important delay in Registration preparation...and now we start to see “cow-boys” LR

- **Two types of approach: Consortia & SIEFs**
and within these, there are several variations:
 - > good & inclusive organization
 - > poor & almost secretive organization
 - > Some consortia pretend to be open to new members but in reality they are not
- **Still many SIEFs with Registration due after Dec 2010 without SFF/LR**
Could be an issue as LR could facilitate
 - > Classification agreement in SIEF
 - > Preparation of Classification Notification due by Dec 1, 2010 when no Registration is submitted by that time



- If CSR is performed by SIEF, sharing of Use descriptors through the supply chain is needed
 - > DUs have not received a lot of Use descriptors from their suppliers so far...and when they have it is not always aligned with DU's uses
 - > M/I are invited to utilize Use Descriptors already developed by DU sector groups e.g.

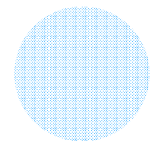
Detergents and cleaning products: <http://www.aise.eu/reach/exposureeass.htm> ; Cosmetics: <http://www.colipa.eu/use-and-exposure-information.html>

CEPE (paints): http://www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&eas:dat_im=101AED

Construction chemicals: http://info.vci.de/user_cc/default.aspx Adhesives and sealants: <http://www.feica.com/reach.htm#use>

Chemical distributors: <http://www.fecc.org/fecc/committees/safety-health-a-environment-she/171-mapping-of-uses-of-the-chemical-distribution-sector>

- > ECETOC TRA tool based on RIP 3-2 to get Exposure information is very conservative for
 - a) Consumer use / Human health &
 - b) Workplace / Environmentand might lead to “**unsafe use**”.
- > Exposure Scenario refinement might be required by M/ I & DU on many Registration dossiers



2. Requests to Lead Registrants & ECHA

Background information

- > Expert Resources in industry are scarce and timing is very very tight
- > Only way to survive & to make REACH a success is:
 - a. to focus on real need & aim of REACH i.e. safety
 - b. to be very pragmatic and simplify the procedure when possible
 - c. to minimize drastically unnecessary work

Four Requests to Lead Registrants

a. Streamline admin. Work / discussions in SIEFs

Use standardized templates already developed

e.g. CEFIC templates on sameness, consortia & SIEF model agreements, to share uses through supply chain

<http://cefic.org/en/reach-for-industries-documents-and-tools.html>

b. Generate High Quality Registration dossier

Select highest quality data & established scientifically sounded DNEL, PNEC, correct EU classification & relevant ES

Why is it so important?

- It is in the interest of the whole supply chain i.e M/I/DU
- Once defined, these parameters will be used everywhere & forever
- DU are impacted by different legislation's than chemical manuf. (e.g. Cosmetic & Detergent Regulations etc..)
- Some of these above parameters may not have impact on the Chemical manuf. but may have huge impacts on DUs
- If DU's are in trouble, Chemical manuf. might be in trouble



c. Use reliable services and tools

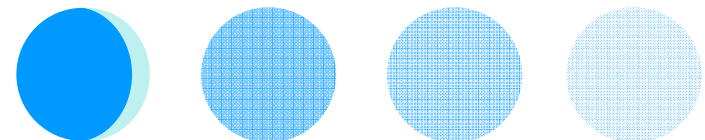
- ✓ If you need external support, use reliable service provider
- ✓ Use secured web-sites to exchange information in SIEF and store them for 10 years

d. Ensure dossier is completed before submission to ECHA

- ✓ If the Joint submission part of the dossier is not completed after the “2nd chance” ...
the LR will be out of the market until new dossier is submitted....and all the other registrants as well



- ✓ Completeness check by ECHA contains 3 key steps:
 - 1) Meet the Business Rules Validation
 - 2) Pass the Technical Completeness Check
 - 3) Pay Registration fees within deadline set by ECHA



d. Ensure dossier is completed before submission to ECHA

5 Actions required by LR to ensure the dossier is complete

1. Read ECHA guidance on “how to complete Registration dossier”
(Data Submission Manual 4 and 5) http://echa.europa.eu/reachit/registration-it_en.asp
2. Ensure that your dossier complies with Business Rules validation described in the ECHA guidance
(Data Submission Manual 8) http://echa.europa.eu/reachit/registration-it_en.asp
3. Conduct Technical Completeness Check software on your dossier once available
4. Ensure in your Company that the payment of the Registration fees is made in due time (time allocated to pay the fees is short)
(Industry User Manual-Part 8) (http://echa.europa.eu/reachit/registration-it_en.asp)
5. Update the consortia/SIEF agreement, if needed, to ensure that the LR will submit its dossier by Sept 30, 10

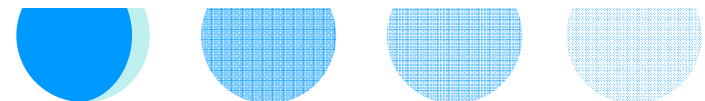
Six requests to ECHA

a. Get the Technical Completeness Check Tool very quickly

- ✓ Critical for industry to understand what they are expected to deliver to ECHA
- ✓ **Why?** To avoid waste of time for both industry & ECHA i.e.
 - >to avoid re-drafting dossiers already drafted
 - >to avoid endless correspondences between industry & ECHA to make dossiers completed
 - > To avoid stop of manuf/import if we miss the 2nd chance

b. When dossier is incomplete, give enough time to industry to update the dossier

- ✓ If we fail to provide missing data within deadline set, industry **will have to stop manuf/import the substance** until a new dossier is submitted and new fees are paid
- ✓ Please ensure that the deadline is “reasonable” & broad enough as defined in Art 20(2)



c. Get Lead Registrant box in ECHA SIEF-page

- ✓ SFF have a box but not LR, while their role will be much more important in SIEF
- ✓ LR box is critical to facilitate communication in SIEF
- ✓ Solution proposed : rename “ SFF box” as “SFF/LR box”

d. Read-across

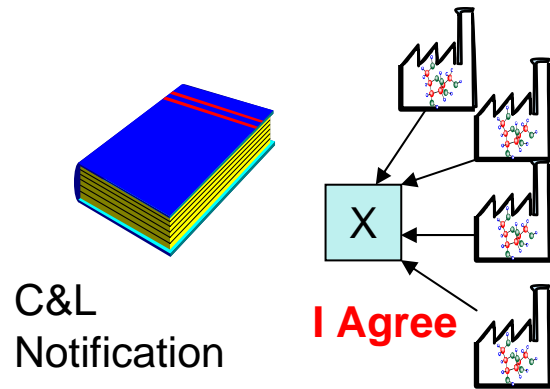
- ✓ Facilitate use of read-across to minimize use of animals
- ✓ Critical to the success of REACH

e. Use Descriptors

- ✓ Please issue updated R12 guidance on Use descriptors as soon as possible
- ✓ Inform DU about Dec 1, 09 deadline for communicating their Uses to their suppliers on Registrations due by Dec 1, 10

f. On Classification & labelling Notification:

- ✓ To get the possibility to submit only one dossier per substance .
This is allowed by the CLP Regulation



- ✓ To allow all companies who have the obligation to submit such a dossier
 - a) to review the Notification already prepared
 - b) and agree with it by clicking on a box instead of submitting a full notification again

Benefits:

- 1) win/win for both industry and ECHA i.e drastic decrease of
 - a) workload for industry and
 - b) # of notifications received by ECHA, without any compromise on safety
- 2) will streamline the number of different classifications per substance (less confusing for industry and less work for ECHA to maintain/update the inventory)



Thank you for your attention

