The challenges facing 2018 REACH Registrants

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ReFaC

- Background
- Substance Identity Issues
- Strategies for Registration
- Case Study

Background

ReFaC - Regulatory Facilitation Company a wholly owned subsidiary of the Chemical Business Association (CBA)

- **CBA**
  - UK Trade Association
  - 95% of members are SME in accordance with EU definition
  - Role – 'support the chemical supply chain'
  - Distributors, importers, manufacturers, Only Representatives

- **ReFaC**
  - Regulatory consultants
  - Distributors, importers, manufacturers, Only Representatives
  - SME and large companies – various viewpoints

2018 Registration

- Focus on SME's
- Highlighted by REACH review – SME's will need the most support ahead of the 2018 deadline
  - ECHA encouraged to engage with SMEs further
  - More targeted guidance needed in general
  - Many SMEs unaware of REACH or its potential impact
- SME's have identified the following areas as being of concern for 2018:
    - Awareness of requirements/obligations
    - Cost
    - SIEFs
    - Workload / internal resources

2018 Registration

- REACH from the SME Standpoint:

Is far more complicated for importers than it is for manufacturers

Is considered to be a barrier for market entry

Reduces competition in the market place

May be distorting supply chains

Could be stifling growth

2018 Registration - Costs

- Many SME's faced significant cost burdens in 2010/2013
- Most SME's do not have a large budget for external consultancy
- Cost of LoA:
  - Unpredictable
  - Not always calculated in the same way
  - Some LR charge additional admin fees or increased fees based on unknown number of co-registrants
  - Can be expensive – should registrants only needing Annex VIII requirements pay for access to higher tier studies if used to calculate DNELs??

2018 Registration - Costs

- Data sharing example 2013:
  - Micro enterprise – five employees, turnover < £2 million
  - Two metallic salts in portfolio: controlled by 1 consortium (2 SIEFs)
  - Tonnage band: 100 – 1000 tpa
  - No in house resources – handled through a consultancy
  - Requested a cost estimate for whole process of registration in 2013; cost estimate as follows:

2018 Registration - Costs

- Data sharing example 2013:

	Cost for substance 1	Cost for substance 2
Substance Identity testing and report	£500	£500
LOA to Lead study dossier (€25,065)	£20,888	£20,888
Dossier Preparations (Consultancy)	£2570	£2570
Review of CSR	£1,000	£1,000
ECHA Registration Fee (€863)	£719	£719
Totals	£25,677	£25,677
Grand Total		£51,354

2018 Registration - Costs

- Ideas for reducing cost-burden: Start Now!
  - Identify key substances for your business – ensure you know the chemical identity of these substances!
  - Determine costs LoA / ECHA registration fees and build these into the budget for the next 3 years – don't forget analytical data!
  - Ensure you have correctly fulfilled the criteria for definition of an SME… NB. In 2012 58% of companies who declared SME status were not! Administration charges will add extra cost.

2018 Registration - Costs

- Some costs will be unavoidable, but the following may be considered:
  - In the long-term it might be more cost-effective to outsource some work to ensure it is done correctly
  - Consider whether staff would benefit from additional training (this may also be more costly?)
  - Consider employing a consultant to review the LoA cost: this may help provide a basis for a data-sharing dispute and reduce the overall costs
  - Consider submitting an opt-out dossier if the cost is too high – e.g. if the LR has only used literature but is charging a high fee for access to the data – review the ECHA chem website

  Warning! Be prepared for the dossier to be scrutinised by ECHA

2018 Registration - SIEFS

- Ahead of 2018, different SIEFs may have their own unique problems:
  - SIEF managed by a consortium – easy to access data on LoA costs?
  - Access to LoA costs via an only portal or platform? It may be difficult to get an estimate for your budget
  - No Lead Registrant
  - No SIEF communications
  - SIEF being controlled by a consultant – may be trying to make money from the dossier writing process
  - Substance identity unclear?

2018 Registration - SIEFS

- Some SME's will have to be lead registrants:
    - Great responsibility
    - Additional administration tasks – e.g. SIEF Communications, LoA cost calculations
    - Lack of internal expertise – dossier preparation, testing strategies

2018 Registration - SIEFS

- **ANY SOLUTIONS?**
  - Start Now!
  - Identify your substance and engage the SIEF in communication – know where to find contact details in REACH-IT. Don’t wait to be spoken to!
  - Monitor SIEF communications carefully – don’t ignore emails

2018 Registration - SIEFS

Word of advice regarding substance identity

- An analytical strategy should take into account:
  - Composition and identity of constituents ‘as far as known’
  - Identify unknown constituents using a generic description of their chemical identity
  - Provide typical concentrations and concentration ranges
  - Identify all constituents present at ≥10%
  - All constituents relevant to PBT assessment or classification must be adequately defined – CAS number / IUPAC name

2018 Registration - SIEFS

The time taken to prepare a lead dossier should not be forgotten!

- This is particularly crucial if a lead registrant has not been identified yet
- Labs have advised testing time is typically 5-7 months while for Annex VIII substances it can take 6-7 months
- From start to finish the preparation of a registration dossier could take up to 20 months for an Annex VII substance and 36 months for an Annex VIII substance

2018 Registration – Workload and internal resources

- Most SME's have maybe 1 or 2 dedicated regulatory staff
- Some SME's have dossiers that were submitted in 2010/2013 and need updating
- Additional requirements above and beyond REACH:
  - Monitoring SVHC's
  - CLP
  - eSDS – Implementation of use conditions
  - Other regulations? BPR?

2018 Registration – Workload and internal resources

REACH is an ongoing commitment:

- Plan for updating dossiers at the same time as writing 2018 dossiers
- No definitive end-date for completion of dossier updates – don't wait for these to be finished before moving forward with 2018 substances
- Make use of training courses / webinars – ensure staff are well informed
- Make use of guidance documents / user manuals – ECHA program for SME's
- Consider seeking help! Don't wait until just before the deadline…

2018 Registration – Workload and internal resources

- Ensure you are aware of your suppliers registration intentions
  - Check that your uses will be covered – ensure that you know what your uses are!
  - Ask for evidence of REACH compliance if not provided (registration number)

- Don’t forget about REACH-related issues other than registration
  - Monitor substances that are on Candidate list – respond to consultations and calls for evidence of socio-economic impacts
  - Consider whether you need to apply for authorisation for any substances and make sure any applications are made by the specified date (there is no tonnage limit for substances on the Authorisation list!)

CASE STUDY – COMPANY X

SME – Company X

- Distributor based in the UK
- Planned to register a substance for which they held a pre-registration
- Around the same time, the external consultant appointed to assist with REACH obligations and the company technical director retired

SME – Company X

- Challenge for remaining members of staff to determine what information was available, to find it, and to understand status of registration plans
    - SMEs should have a standardised procedure in place
    - Members of staff not directly responsible for projects should be able to easily access and identify suitable information

SME – Company X

- Some test data was available but on inspection there was no methodology or description of method, only the result – not reliable!
    - Conduct a full Data Gap Analysis
    - Identify what information is available, if it is reliable, what information is still required

SME – Company X

- Substance identity issues: substance was identified as a UVCB substance but investigation showed it may have been a mono-constituent with some impurities
    - Ensure substance identity is correctly defined as early as possible
    - Reliable results should be available to support this identification, if not, conduct new tests!

SME – Company X

- Lessons to be learnt:
  - Important to keep full records of all substances – even if you are a downstream user.
  - Important to know the chemical identity of your substance – perform spectral analyses now! (don't wait)
  - If working with an external consultant – manage the project. Keep a track of timelines / estimates
  - If no lead dossier available – start work now: survey SIEF, perform an initial data gap analysis NB. Test labs are becoming busier and busier especially for basic tests, such as physicochemical testing – don't run out of time!
  - Don't forget about your other obligations – SDS / CLP!
  - KEEP A FULL AUDIT TRAIL!

Timeline – now to 2018

2015

- Check your supply chain and know your obligations
- Define your substances now
- Perform spectral analyses as soon as possible
- Survey the SIEF and find the Lead Registrant
- Get an LoA cost
- If dossier not available:
  - Assess importance of substance – do you need to be the LR?
  - If you are LR – Action needed IMMEDIATELY! DGA, Testing quotes…

Early 2016

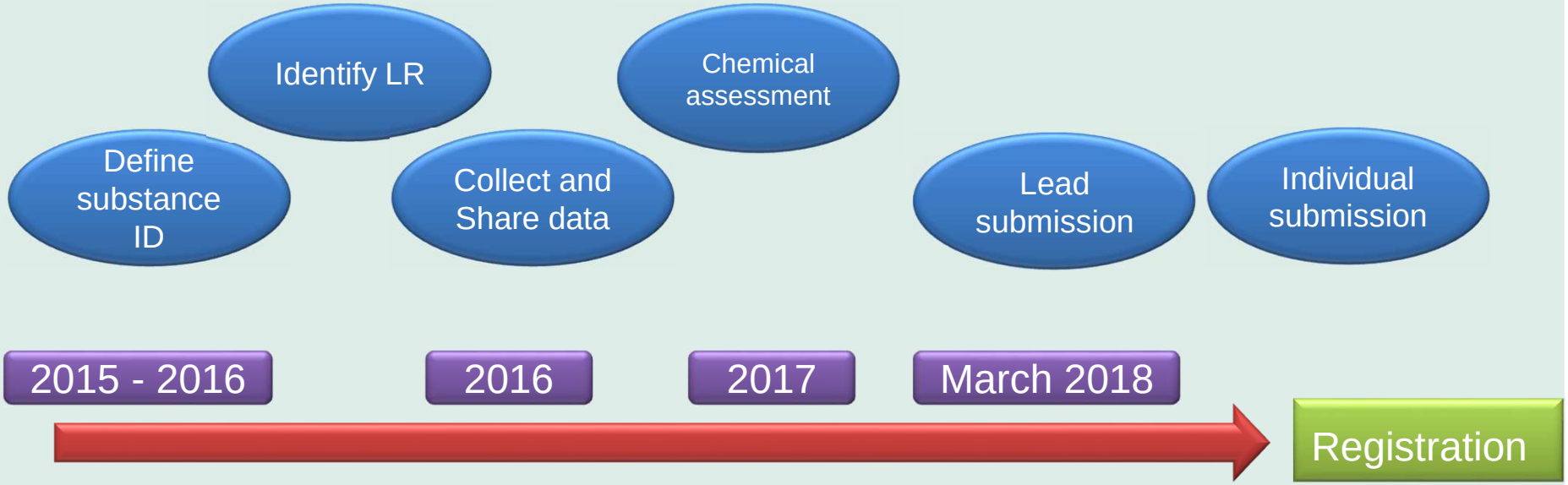
- Expect updates to:

  - REACH-IT - version 3.0 due
  - IUCLID - version 6.0 due
  - CHESAR - version 3.0 due

- Don’t wait for updates – the process of registration can take a long time – START NOW!

Warning! Keep an eye on changes to the guidance

Timeline 2015 to 2018



NB. If testing required (dossier not yet available), the following timelines are estimated based on current test laboratory schedules:

- Annex VI: 5 to 7 months
- Annex VIII 6 to 8 months

Testing should therefore be started at the beginning 2017!

Any Questions?

Information sheets based on this presentation are available at stand RS07!

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