SME experiences of registration 2016

Chemical Regulations Self Help Group

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Member Registrant process (a)

Actions - make a list of your REACH-liable substances; contact SIEFs .

Problem #1 – finding out who the Lead Registrant is for existing registration

Problem #2 – where no Lead Registrant exists.

Recommendation - if no Lead Registrant, consider whether you need to get involved.

Member registrant process (b)

Problem #3 – communication with a Lead Registrant is slow or non-existent.

Recommendation – communicate several times, giving actions for Lead Registrant with deadlines (keep full records, use registered mail). If there is an unsatisfactory response, consider using dispute resolution process at ECHA on the grounds of slow or no communication.

Member registrant process (c)

Problem #4 – Lead Registrants requiring a confidentiality or secrecy agreement to be signed before issuing a price to purchasers.

Recommendation – a confidentiality or secrecy agreement should not be required for data cost as a whole, or outline cost breakdown. It would only be appropriate if confidential data, such as consultancy rates, name of consultant, or robust study summaries was to be disclosed.

Member registrant process (d)

Problem #4 – price of Letter of Access appears high for level of data, and / or number of registrants requiring data in that tonnage band.

Recommendation – ask for cost breakdown and cost model, and make your own calculations. If you disagree with how costs are compiled, or calculate lower prices, discuss with Lead Registrant. If there is no agreement, consider using the dispute resolution process.

Case study – effects of high LoA costs

SME, turnover £3.6m, net profit £110k, 21 staff. Potentially 8 substances to register.

If Lead (and only) Registrant – estimated costs of £60k per substance, total = £400k

If Member Registrant (assuming one other registrant) – estimated costs of £33k, total =£264k

Case study SME options

Register what they can afford

- 2 Substances as Lead Registrant
- 3 or 4 Substances as Member Registrant

(reduces product range, annoys customers)

Reduce staff numbers to pay for registration
(reduces business capability)

Take out business loan (extra financial risk)

Case Study SME's comments

Unavoidable major impact on our business.

Growth will be affected. Currently have 25 substances just under 1 tonne per annum limit, if want to increase sales of these, it would take 8 years profits to register (as member registrants). (*Relevant data not freely available until 2030*).

Lower LoA costs would reduce impact of REACH significantly.

Member registrant process (e)

Actions: carry out identity and sameness tests for substances being registered.

Problem #5 – identity and sameness tests take longer for complex substances, estimated that 1 in 10 substances are complex, or 1 in 5 for speciality chemicals like dyes.

Recommendation – carry out identity tests as soon as practicable.

Member registrant process (f)

Actions: purchase Letter of Access from Lead Registrant, and submit via REACH-IT, unless partial opt-out registration.

Problem #6 – how to compile IUCLID6 dossier.

Recommendation – get training in using IUCLID6, ECHA guidance is being simplified.

Submit Letter of Access (or IUCLID 6 dossier) via REACH-IT and send payment to ECHA, process ends.

Summary: Member Registrant issues

- Cost of Letters of Access.
- Cost of some LoAs being kept behind confidentiality or secrecy agreements without good reason.
- Lead Registrant issues: finding them, communicating with them, no LR exists.
- Identity and sameness tests can take longer and cost more than “typical” substances.

Lead Registrant process (a)

Actions: Email the SIEF to find out whether there will be any co-registrants to share registration duties with.

Problem #7 – people are waiting for Lead Registrant to step forward and do everything.

Recommendation – don't expect one company to do everything, work together. Get involved as soon as possible, even if not Lead Registrant.

Lead Registrant process (b)

Actions: Email SIEF to confirm they agree with you starting registration process (choice of Lead can happen nearer deadline).

Problem #8 – competition between Lead Registrants to run registration.

Recommendation – if non-credible Lead Registrant, obtain help from Competent Authority and ECHA.

Lead Registrant process (c)

Actions - find experienced consultant to work with on registration.

Problem #9 – good, experienced consultants are getting hard to find.

Recommendation – If you are a new SIEF or individual Lead Registrant, start process as soon as possible.

Lead Registrant process (d)

Actions: Confirm whether co-registrants are willing to share the initial registration cost.

Problem #10 – lack of co-registrants coming forward, LR has to pay full costs upfront.

Recommendation – if you are the Lead, email SIEF regularly with updates, including cost estimates. If you are co-registrant, offer to share costs upfront, and/or offer to help with tasks.

Lead Registrant process (e)

Actions: Set up and maintain SIEF agreements with co-registrants and potential member registrants.

Problem #11 – need for good quality legal advice.

Recommendation – use pro forma CEFIC agreements as templates. If you use a consultant, they may have access to legal advice.

Lead Registrant process (f)

Actions: Agree data strategy and cost share strategy with co-registrants, and keep detailed records.

Problem #12 – ensuring your data and cost strategy comply with current regulations, especially One Substance One Registration.

Recommendation – make sure your cost model complies with the REACH Regulation, as amended in 2016, and findings of ECHA dispute resolution process.

Lead Registrant process (g)

Actions: set up cost model for cost sharing in transparent manner, based on individual tests per tonnage band.

Problem #12 – One Substance One Registration makes cost models more detailed and therefore more complex.

Recommendation – Standardised cost model software would reduce admin costs for Lead, and enable Members to view LoA prices easily. ECHA to host and integrate with REACH-IT?

Lead Registrant process (h)

Actions (with consultant): identify data gaps - request existing data from SIEF, carry out literature review. Consider QSAR, read-across and modelling instead of animal testing. If no alternatives, book any new tests required at laboratory.

Problem #13 – low capacity left for some tests. Example – OECD422 combined repeat dose/reproductive toxicity screening test.

Recommendation – if tests are required, book them as soon as possible.

Lead Registrant process (i)

Compile IUCLID6 dossier (with consultant) and make first registration. Continue to communicate with SIEF, handle quotes, data purchases, and issue LoA tokens. Provide annual summary of costs to SIEF. Process will end, in theory, once data freely obtainable from ECHA (12 years after submission).

Problem #14 administration of SIEFs may be time-consuming and inefficient, increases costs.

Summary: Lead Registrant issues

- Finding co-registrants to share Lead duties and costs with.
- Obtaining agreement from SIEF to start work.
- Finding good consultants to work with.
- Booking any tests required at labs ASAP.
- Ensuring cost model and sharing is up to date and non-discriminatory.
- Managing admin tasks efficiently.

Thank you

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