

Key messages for 2013 registration

Lead Registrant Workshop

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Lessons learnt

- SIEF Formation and administration
- Data gathering and data-sharing
- Joint submission
- Dossier submission
- REACH fees and invoicing
- Post registration



SIEF formation and administration

- Get nominated and let ECHA know that you are the Lead Registrant to benefit from our support
 - Also assurance for Downstream Users that registrations of substances of key interest are underway
- Establish SIEF agreement
 - Key document for smooth SIEF management
 - Agree on roles, responsibilities, timelines, liabilities
 - Templates available from industry associations
- Communicate key steps to your SIEF members
 - Let also the passive members know what is going on in the SIEF

Data gathering and data sharing

- Lead registrant has a prominent role in data gathering and in identifying the data gaps
 - ➔ Adequacy of the data and data quality will be scrutinised by ECHA after registration
 - ➔ For data waivers and weight-of-evidence approach a solid justification is required
- Cost sharing must be fair, transparent and non-discriminatory
 - ➔ Detail what your SIEF member gets for his letter of access
 - ➔ Every registrant pays only for data that is required for his own registration

Joint submission

- Create the Joint Submission Object in REACH-IT and invite your members to join
 - Monitor the number of member dossiers submitted
- Advise members that if opting out they still remain members of the joint submission; 'total opt out' (ie. individual submission) is not legally valid
- If you provide a copy of the lead dossier to the members, instruct them to review it and amend fit for their purposes
- Submit lead dossier early enough to allow members adequate time to submit their dossiers

Dossier submission to ECHA

- Prior to submission, check the dossier with TCC plug-in
 - Includes also the most common business rules
- Familiarise yourself with the ECHA submission procedures
 - Data Submission Manual 4
 - IUCLID 5
 - REACH-IT
- Make use of ECHA's support to the registrants
 - Webinars
 - IT tools to check dossier prior to submission
 - Helpdesks (ECHA Helpdesk and 30 national helpdesks)
 - Personal contact for specific submission problems
- If possible, prioritise at least one substance for early submission to learn the administrative process

Prepare for REACH invoicing

- Fees set in the Regulation 340/2008
 - Reduced fees for joint submission
 - Reduced fees for SMEs
 - Fees for confidentiality claims – use the plug-in to calculate the fee before you submit
- Establish internal process for handling invoices
 - Failure to pay means failure of completeness check
- Confirm potential SME status (Rec 2003/361/EC)
 - Declared in REACH-IT when submitting
 - ECHA will check the status to ensure fair competition
 - If wrongly declared, registration fee + administrative fee levied

Prepare for post registration

- Getting the registration number is not the end – the registration dossier must be kept up-to-date
 - Initiative either from the authorities or from the registrant himself
 - Ensure that structures and processes are in place to update the registration dossier and the CSR after registration (e.g. change in tonnage, new uses, C&L, new knowledge of risks etc.)
- Dissemination
 - Use the dissemination plug-in and fee calculation plug-in to see which information will be disseminated and how confidentiality claims affect your registration fee

Conclusions

- Registration is a big but manageable task
- Prepare in a timely manner and keep your SIEF members informed
- Be prepared for post-registration activities prior to the submission
- Make full use of ECHA support to the registrants

Thank You!

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