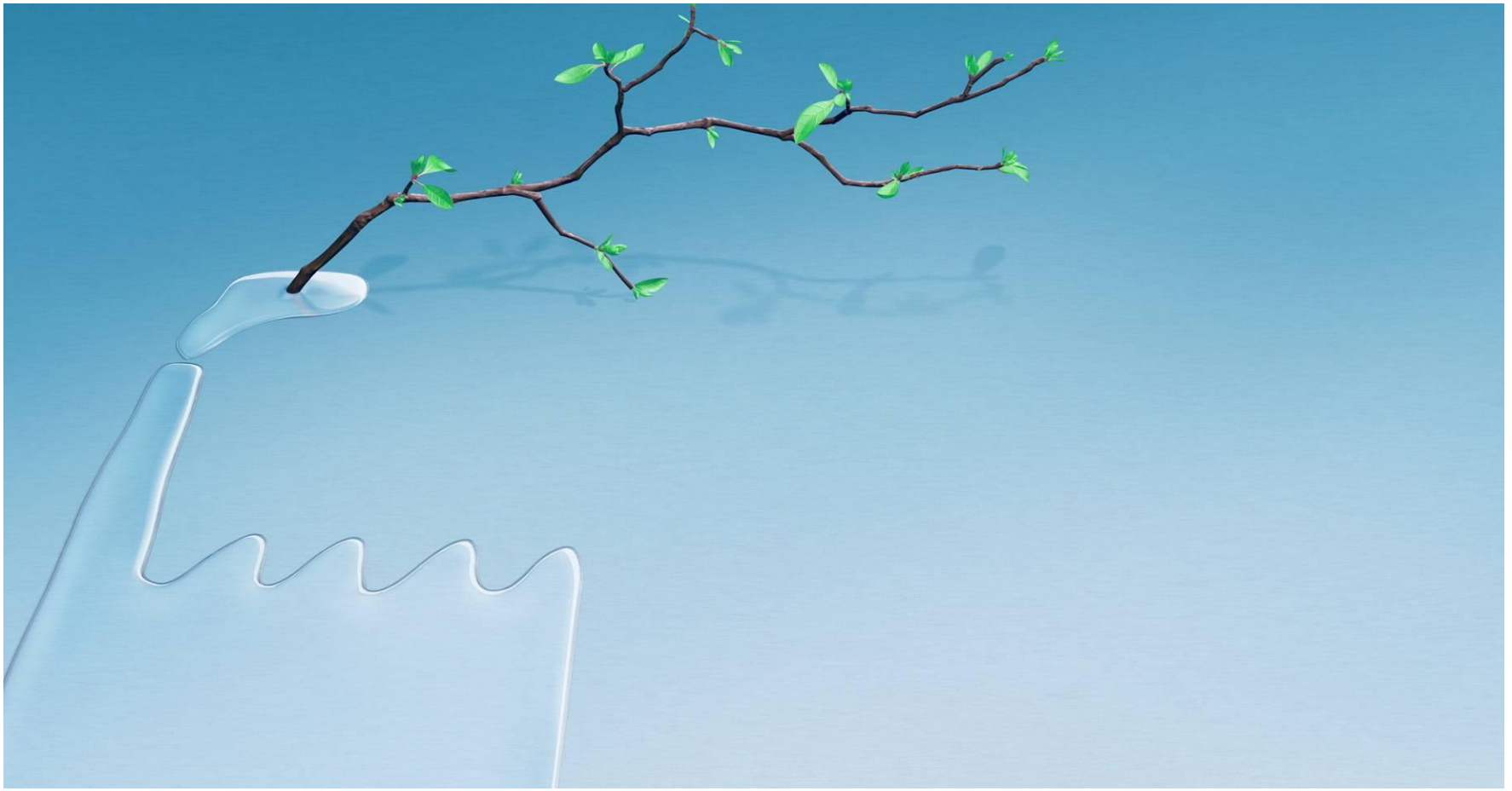

FORMATION OF ALUMINIUM SALTS SUPER-SIEF

Webinar for all pre-SIEF members
3. March 2010 at 13:00 – 14:30 CET

Water is the connection kemira

Agenda

13:00	Opening and introduction	H. Huttunen, Kemira Oyj
13:10	Substance Identification Profiles	H. Huttunen C. Rietveld, Akzo Nobel T&E
13:30	Letter of Access	B. Vandenbulcke, ReachCentrum
13:50	Results of the 2nd SIEF survey	M. Silvennoinen, Kemira Oyj
14:00	Next steps for SIEF formation	H. Huttunen, C. Rietveld
14:20	Practical aspects	
14:30	Review of questions submitted via the web conferencing tool	Participants
14: 45	Closure	

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Introduction to SIEF formation

All potential pre-SIEF members to be contacted and the SIEFs officially formed after substance sameness agreed

Three waves of SIEF communication:

- 1st wave in January – August 2009: pre-SIEFs - done
- 2nd wave ongoing: SIEF formation - ongoing
- 3rd wave: SIEF collaboration
- 4rd waves: Dossier submissions in 2010, 2013, 2018
- 5th wave: Maintenance (until at least 2022)

Substance Identitification Profiles (SIP)

The Substance Identification Profile (SIP) is developed to represent the Identification parameters of the Substance described in line with the Substance Identification requirements of REACH Annex VI and relevant Guidance's for the purpose to identify the substance sufficiently to meet the REACH registration requirements under the same joint submission.

The content of the SIP is developed by KEMIRA, discussed and agreed upon within the **Consortium PI236 Alu salts** to the best of their knowledge to be used for the purpose of substance identification and sameness checking process in the (pre-)SIEF and as base for being part of the same joint registration dossier under REACH.

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Three generic categories of soluble aluminium salts:

SIP
Aluminium chloride hydroxy sulphate (generic)

$Al(OH)_xCl_{(3-x)}(SO_4)_y$,

where $0.6 < x < 2.5$ and

$0.05 < y < 0.5$ and

$(x+y/2) < 2.4$

SIP
Aluminium Sulphate (generic)

$Al_2(OH)_x(SO_4)_{(3-x/2)}$,
where $0 \leq x \leq 3$

SIP
Aluminium chloride, basic (generic)

$Al(OH)_xCl_{(3-x)}$,
where $0 < x < 2.7$.
When x=0,
aluminium chloride is in aqueous solution.

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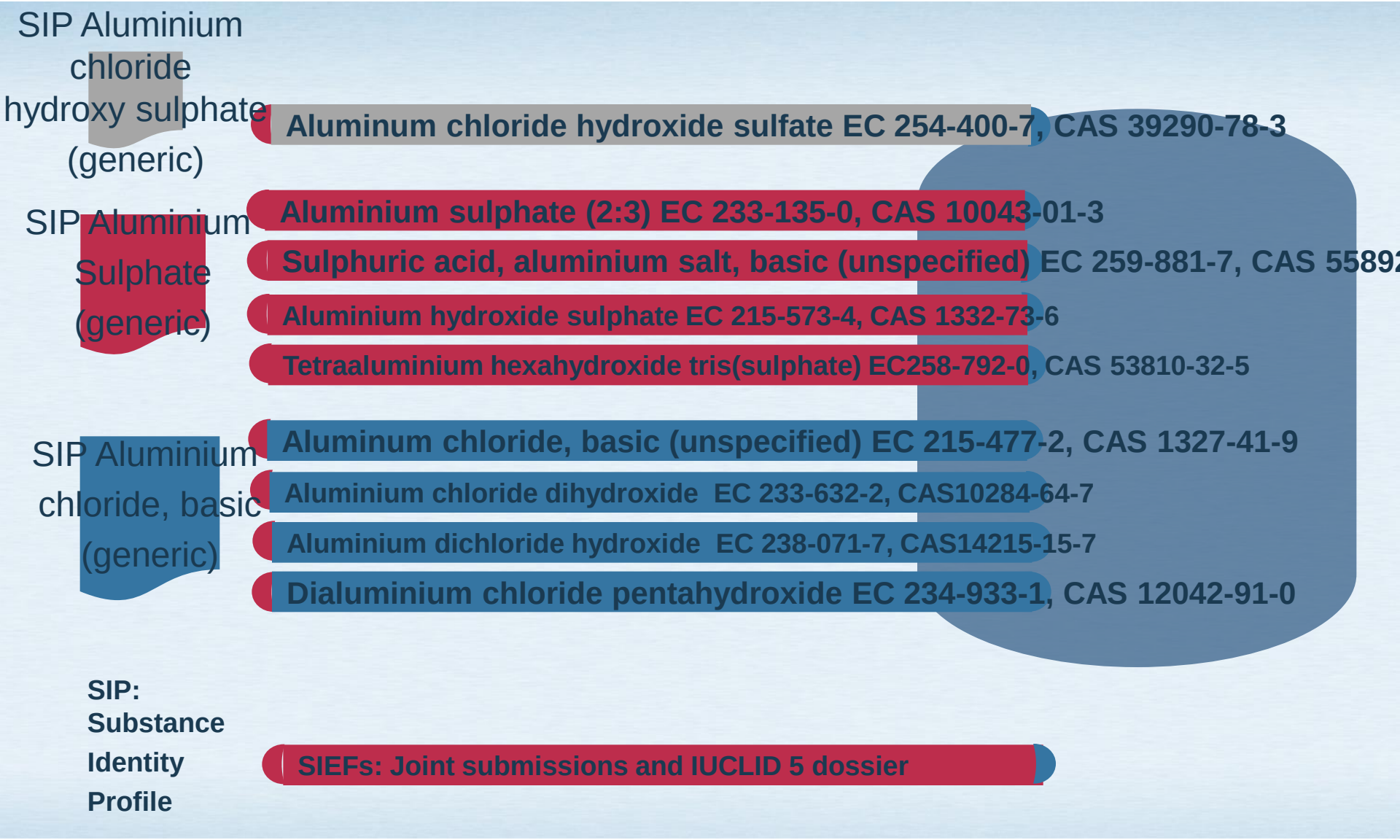
Proposed Registration Approach



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Aluminium substances covered by the ALFE REACH Consortium

SIPs, 1st phase

Aluminum chloride hydroxide sulfate EC 254-400-7, CAS 39290-78-3

Aluminium sulphate EC 233-135-0, CAS 10043-01-3

Sulphuric acid, aluminium salt, basic (unspecified) EC 259-881-7, CAS 55892-56-3

Aluminum chloride, basic (unspecified) EC 215-477-2, CAS 1327-41-9

Dialuminium chloride pentahydroxide EC 234-933-1, CAS 12042-91-0

SIPs. 2nd phase (backup)

Aluminium sulphate (2:3), EC 233-135-0, CAS 10043-01-3

Aluminium hydroxide sulphate EC 215-573-4, CAS 1332-73-6

Tetraaluminium hexahydroxide tris(sulphate) EC 258-792-0, CAS 53810-32-5

Aluminium chloride dihydroxide EC 233-632-2, CAS10284-64-7

Aluminium dichloride hydroxide EC 238-071-7, CAS14215-15-7

SIPs recommended to be merged under other SIEFs

Sulfuric acid, aluminum salt (3:2) EC 233-329-5, CAS 10124-29-5

Sulfuric acid, aluminium salt (3:2), tetradecahydrate, EC 605512-3, CAS 16828-29-5 (*

Aluminium sulfate hexahydrate, CAS 51306-13-9 (*

(* For hydrates, the water free form should be registered

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Next steps: How to select the correct SIP 1(2):

The problem: 3 generic SIPs but 5…9…12 ”old” CAS and EC-numbers on the market for aluminium sulphate and aluminium chloride not properly matching with REACH

Options:

- **Continue using the CAS and EC-number used for the pre-registration?**
- **Change to a generic CAS and EC-number?**

ECHA has been contacted for clarification on 12. November 2009. Based on an intial feedback, each specific aluminium:acid moiety molar ratio may need to be registered separately, but it was recognised that also unspeficied definitions exist. A basic form of a substance shall not be regarded as the hydrate of the substance.

Specific provisions exists in Annex V (6) of the REACH regulation for enabling a registrant to cover hydrated forms of a substance under the unhydrous equivalent.

Please see a position paper: Substance Identification Approach for Aluminium salts on SIEFreach for more information.

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How to select the correct SIP 2(2):

- The 3 generic SIPs will be published now in SIEFreach for all 9 substances for commenting and approval. Each SIEF member will decide which SIEFs they join in. A Joint Submission for 5…9 EC/CAS-numbers can be prepared on request of the SIEF members.
- Each and every registrant (Legal Entity) to make their substance identity analyses to verify how they fit into these SIPs and SIEFs
- Test method recommendation has been published in SIEFreach
- New SIEF surveys will be conducted in late March – April for deciding the SIEFs needed for the Joint Submissions
- SuperSIEF agreements will be released in April – May via Kemira's SIEF communication tool (an url address will be delivered separately at that stage)

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Letter of Access

- content
- estimated costs
- planning for 2010, 2013 and 2018 registrations

SIEF Survey Results

- Extracted from SIEFreach
- Results handled and archived per survey
- Master list created consisting all SIEF members (status 1-4), their current SIEF status and registration deadline
    - Based on the results of second SIEF survey
    - Updated according to email requests sent by pre-SIEF members

Results of the 2nd SIEF survey (20.2.2010)

Name / Synonym	Pre-SIEF members	Answers in Total	Answer %	LR agreed	Animal Tests
Al					
Aluminum chloride hydroxide sulfate	120	18	15	18	0
aluminium chloride dihydroxide (*	53	24	45,3	24	0
aluminium dichloride hydroxide	49	23	46,9	23	0
aluminium sulphate	906	102	11,3	102	0
Aluminum chloride, basic	437	53	12,1	53	0
dialuminium chloride pentahydroxide (*	300	39	13	39	1
Sulfuric acid, aluminum salt, basic (*	58	14	24,1	14	0
Name / Synonym	Pre-SIEF members	Answers in Total	Answer %	LR agreed	Animal Tests
Substances for which Kemira is not SFF					
Tetraaluminium hexahydroxide tris(sulphate) (**	30				
Sulphuric acid, aluminium salt (***	79	28	35,4	28	0

The questionnaire was sent to all pre-SIEF members, and contain also answers of ALFE Consortium members. For the future, separate lists for Consortium and SIEF Members need to be maintained.

Next Steps for SIEF formation

- A SuperSIEF agreement will be prepared by Kemira using the CEFIC template
- One Aluminium Salt SuperSIEF agreement grants access to any of the 3…9 substances
- The Agreements will be distributed via Kemira's SIEF tool as SIPs have been approved for any SIEF member to join in (via a simple electronic process)
- Foreseen timing for release: April – May (as SIPs have been agreed)

Planned workflow and timeline

Status overview of AN TE activities 2010

	Activities	Deliverables	Ultimate date due Week Year	Status*
7.	Test protocol approval & testing Phys-chem, Tox and Ecotox	Approved protocols & test reports	04/15 2010	Not begun
8.	Hazard assessment; DNEL & PEC/PNEC determination	Draft hazard assessment	16 2010	In progress
9.	Use and exposure scenario comilation	Draft Generic Exposure Scenarios	18 2010	In progress
10.	Risk assessment, risk reduction measures	Draft Risk Assessment & proposals for RRM	21 2010	Not begun
11.	Chemical safety report	Report	26 2010	Not begun
12.	Classification and labeling proposals	C&L proposals	30 2010	Not begun
13.	Extended SDS	Draft proposals for SDS	35 2010	Not begun
14.	Post Registration Testing plan	Draft Annex IX&X testing plan	22 2010	Not begun
15.	Dossier finalization, technical & company specific dossier in IUCLID5	Final versions of above	35 2010	Not begun
15.	Dossier archiving and distribution	DVD	46 2010	Not begun

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Formation of ALFE Super-SIEFs – next steps

Task	Document	Implementation	Week
2. pre-SIEF collaboration and communication	• 3rd SIEF communication letter	• Kemira (emails)	8
3. Substance sameness check	• update of Consortium advertisement	• RC (ALFE web), Kemira (SIEFreach public)	8
	• Substance Identity Profiles	• Kemira/AN T&E (SIEFreach)	8
4. SIEF Agreement/ Opt-out	• testing method recommendation	• Kemira (SIEFreach)	8
	• 3rd, 4th, … SIEF surveys	• Kemira (SIEFreach)	12…
5. JS Object and Token creation, confirmation of membership	•Super-SIEF agreements (incl. NDA)	• Kemira (SIEFreach + other SIEF tool)	14… 21
6. SIEF Payments	• 4th, 5th, … SIEF communication letter on progress of dossier status, data and cost sharing, C&L proposals, JS schedule, ES and CSRs, PNEC and DNELs	• Kemira (emails/other SIEF tool)	20… 26
7. LoA and Token delivery			
8. LR Dossier submission	• JS names, tokens, email communication	•Kemira (REACH-IT + other SIEF tool/email)	33
- -	• invoices, LoA, i5 html dossiers, Word-CSRs (if sufficient)	• Kemira (other SIEF tool/email)	34
11. CoR subsequent submission			

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Practical aspects

ALFE Consortium webpage: www.reachcentrum.eu > Consortium management > Aluminium and iron salts

SIEFreach public website: https://www.siefreach.com/wps/portal > Public SIEF information

SIEF communication tools:

- SIEFreach system Reachlink admin [admin@reachlink-eu.com]
- Another SIEF communication tool (link to be provided later)

SIEF email contacts: newly launched email addresses based on the EC number of a specific substance

- i.e. iron sulphate 231-753-5@kemira.com
- To be used for all SIEF communication by Kemira and towards Kemira
- Organized archiving (per quarter year) as advantage

Consortium contact: are@reachcentrum.eu

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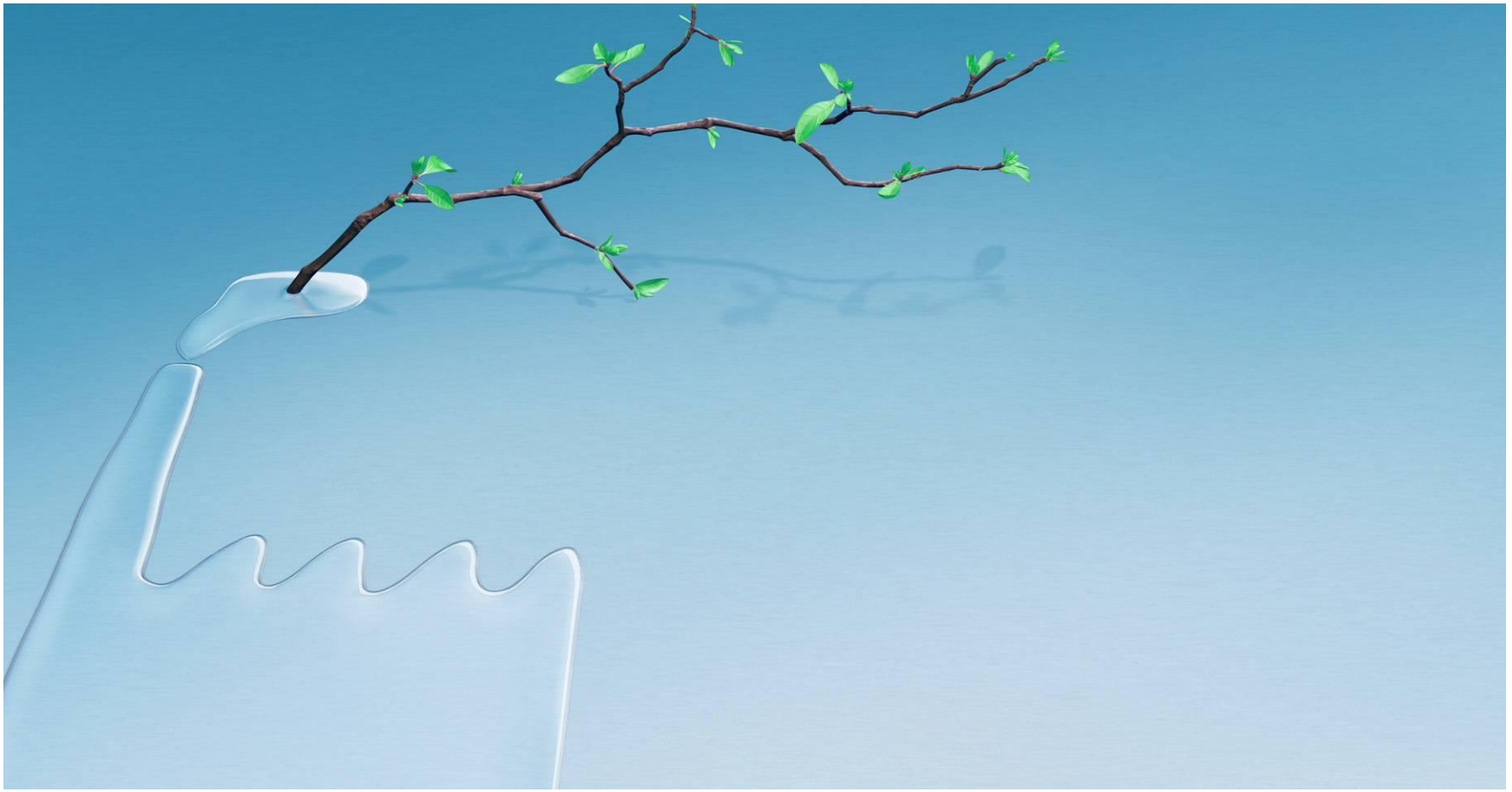
Legal Disclaimer in any SIEF communication

"No representations or warranties are made and no liability will be accepted for damages of any nature whatsoever resulting from the action of the Lead Registrant or the results generated by it, as long as there is no contractual arrangement in place between a SIEF member and the declared Lead Registrant."



Thank you for your attention!
Please type in your questions on the webconf tool