

REACH 2018 

Gospodarska
zbornica
Slovenije 
Chamber of Commerce
and Industry of Slovenia
Association of Chemical Industries

REACH 2018 SME workshop - road to successful registration

Running a SIEF



Marko Grčar, chairman
CCIS, Association of Chemical Industries,
Section of REACH and CLP

Vienna, March 9, 2017

Belinka Perkemija



- Experience since 1948
- Biggest Sodium Perborate producer in the world
- One of only 8 producers of Hydrogen Peroxide in the EU

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Belinka Perkemija

A member of the European Helios Group

- Among the top ten coating companies in the European market
- Sales 2016: more than € 370 Mio.
- Employees: approx. 2,000
- Production sites in: Austria, Germany, Italy, Slovenia, Croatia, Russia, Serbia and Ukraine
- Production area: 145,000m² (covered area)

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Belinka Perkemija

Hydrogen Peroxide - REACH reg. in 2010 (co-registrant)
Sodium Perborate - REACH reg. in 2010 (lead registrant)
Peracetic Acid - REACH reg. in 2018 (co-registrant)
Carbon Dioxide - REACH exemption
Hydrogen - REACH exemption
Demineralised water - REACH exemption

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Content

What is a SIEF
SIEF Activities (New SIEF/ Existing SIEF)
Agreements (SIEF/ Consortium/ Data sharing/ LoA)
Communication
Experiences from practice
Conclusion

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SIEF

Substance

Information

Exchange

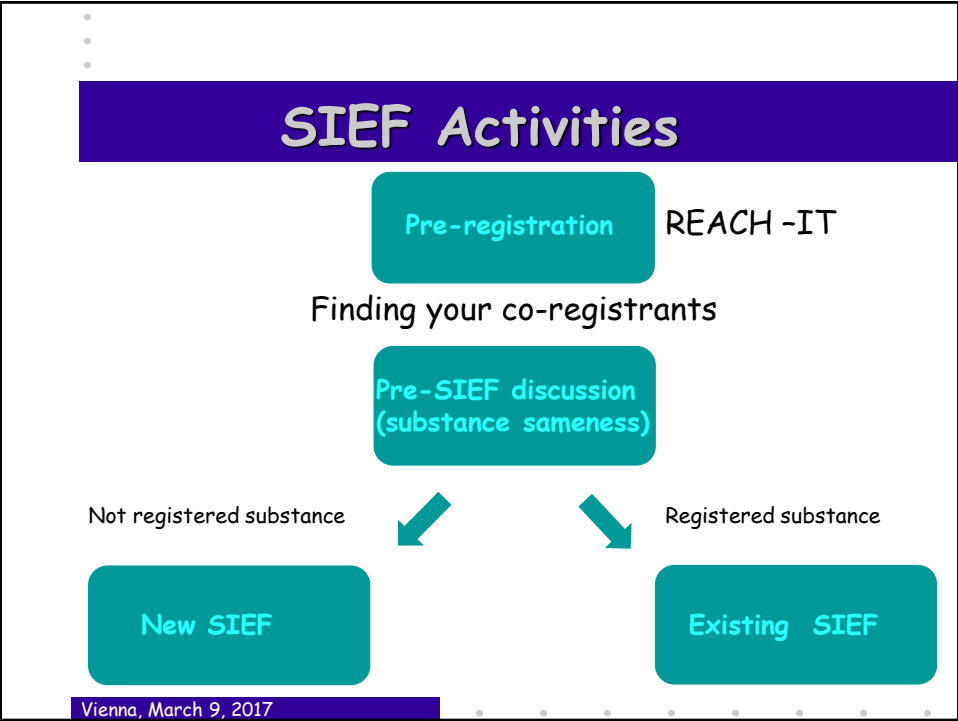
Forum



One Substance - One Registration

One SIEF always covers One Substance

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New SIEF

Substance identification	Facilitator contact information	Pre-SIEF summary	Information from the SIEF formation facilitator/nominated lead registrant
Name: 2-ethylanthraquinone EC number: 201-535-4 CAS number: 84-51-5	Contact details: J. REACH Manager @ REACH-IT@solway.com T: +322842988	Entered registration date: 19/01/2017 Highest tonnage: > 1000 tpa Number of active members: 152 Number of inactive members: 32	

Pre-SIEF members

Member	Status	Participant 1 - Reference number	Contact person
Belinka Perlempa d.o.o.	Active - Potential Reg.	09-2116450595-40-0000	Marko Grčar +386 3026
Solway Chemie B.V.	Facilit. - Potential Reg.	09-2114399405-0000	REACH Manager @ REACH-IT@solway.com +322842988
Chemours	Active - Potential Reg.	09-2110540439-34-0000	Tamara Van Moortel tamara@chemoursna.be +32 31 33 30 89

Status in SIEF

Core Data Exchange

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SIEF Activities

SFF – SIEF Formation Facilitator
 Communication with all SIEF Members - The role of the SFF is totally voluntary and does not entail any specific obligations

LR – Lead registrant
 (Member registrants - who intent to register)

SIEF Agreements
 Participation in a SIEF can be combined with the signature of a formal SIEF agreement or not

Important legal point of view!

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Existing SIEF

You know who is your first contact

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Agreements

Consortium Agreements

A consortium is a voluntary grouping of companies who have decided to work together to prepare the registration material for one or several substance(s)

It is recommended that parties who will cooperate within a SIEF agree in advance in writing at least on the main rules of data sharing, on the ownership of the studies jointly developed and on the sharing of costs.



Ref. Cefic

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Agreements

Data Sharing Agreements

The mechanisms for compensation must meet the following conditions:

- It must be acceptable to SIEF members

- The method must be fair, transparent & non-discriminatory and allow for flexibility

- Comply with competition law

Letter of Access

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Communication

Create REACH communication person or team
It could be created to develop a communications strategy, both internal and external

Internal
Which substance do you intend/ needs to be registered?
Purchasing/ sales department, R&D
Prepare your own data gap analysis

External
Communication with SIEF, Consortium, etc... which data you need exactly?

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Experience from practice

We do not know where we should start!
No responsible person, too little knowledge of regulatory requests, management does not support this activity, additional costs, etc..

Where can we find relevant information?
Which available data exists? Where you can find it? Are there any SIEF, Consortium, Lead Registrant, etc...

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Experience from practice

There is no reply from SIEF members!

You would like to be active in SIEF and you call all pre-SIEF members to co-operate, however, only 50% or less reply - what now? In practice certain members of SIEF reply too late, after everything was already agreed

Agreement about the communication?

Despite the fact that SFF is determined, there is communication in all possible ways.

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Experience from practice

Which data do you have/ need?

Do we, in company, have any studies, which of studies do not need to be purchased, since company has its own or studies are publically available

LoA - take it or leave it?

If there is already existing SIEF or consortium, you usually already get a LoA proposal with estimated cost - with no possibility to negotiate

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Experience from practice

Time frame!

Communication within big SIEF take place very slowly - just to sign a contract it can sometimes take more than a month

Problems with little issues?

Many times important content issues are being solved relatively quickly, however, little things can become issues - e.g. determination of analytical method or concentration limit with determination of substance identity.

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Experience from practice

Legal point of view is important!

Contract as legal base (SIEF or consortium) is very important - it is necessary to determine exactly who owns what, to whom who can sell what, what can who sign, what is the situation regarding new members or withdrawal of co-members during the preparation of contracts...

Important is risk for the company?

It is important to include experts (legal and economic) in the process of making any kind of decisions.

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Conclusion

Every SIEF is unique!

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Thank you for your kind attention 😊

Questions?

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