CHEMSERVICE

Annual Conference & Networking Lunch
REACH&CLP

REACH 2018
Registration Deadline

Dr. Dominik Kirf (ERT)
CHEMSERVICE S.A.

Luxembourg, 8 December 2016

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CHEMSERVICE Group

- Consulting company founded in 2007 by Dr. D. Drohmann, > 40 experts from the Chemical Industry, CROs and Academia
- Main Offices in Luxembourg, Germany and Korea
- Comprehensive Service Provider in the area of REACH, International Chemical Control Legislation, Toxicology, Risk Assessment, Environmental Sciences and Advocacy to the Chemical Industry and its value chain
- Broad in-house expertise (Chemists, Chemical Engineers, Toxicologists, Environmental Scientists, Biologists, Agronomists, Veterinarian, Regulatory Specialists, etc.) enabling interdisciplinary problem solving

„You can do your business. We remove the regulatory roadblocks."

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Our Regulatory Services

- REACH, Korean-REACH & GHS
- Non-EU Manufacturer representation in EU (e.g. OR)
- International Chemical Control Legislation Consulting
- Global Food Contact Notifications
- Biocides (Active Substances and Formulations)
- Cosmetics & Medical Devices
- Hazard Communication (e.g. CLP, SDS)
- Risk Assessments
- EH&S Consulting
- Consortia, SIEF Management
- Advocacy
- *…*

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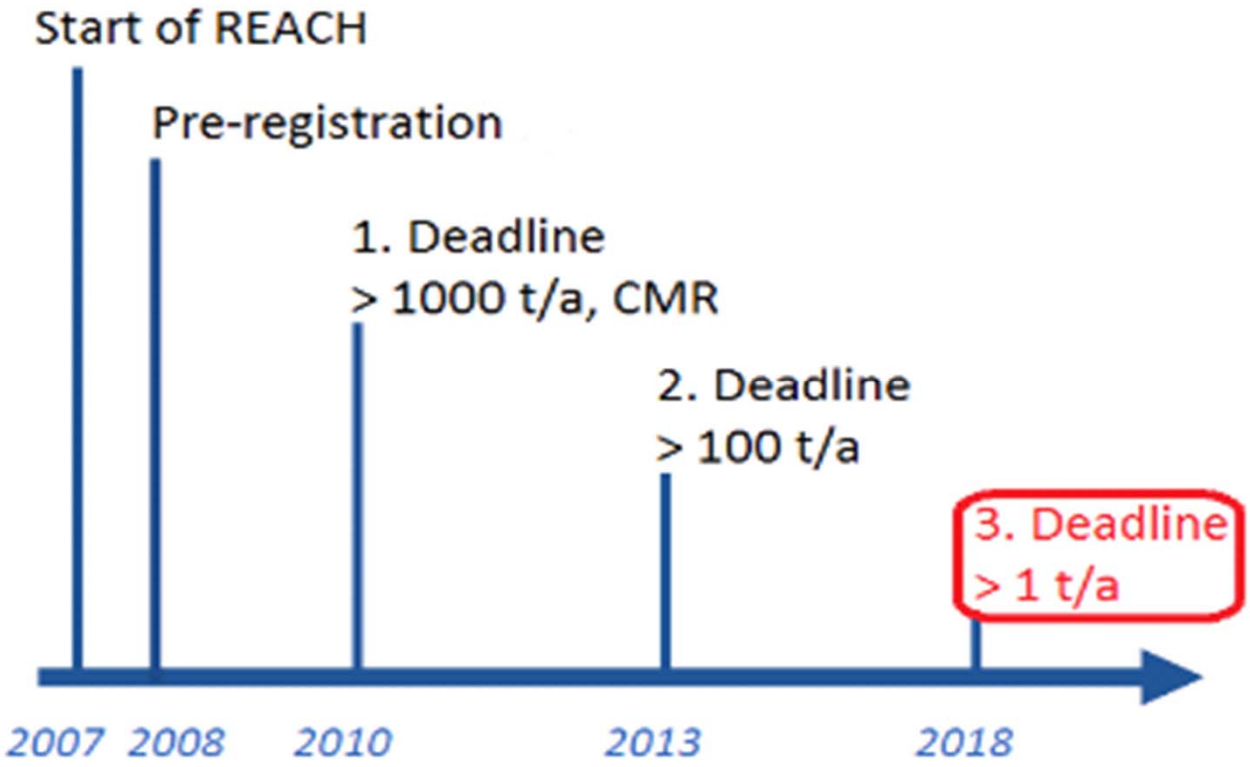
REACH 2018 Registration Deadline

537 days before the deadline
on 31.05.2018

ACT NOW

REACH 2018 Registration Deadline

For “Phase-in substances” following pre-registration



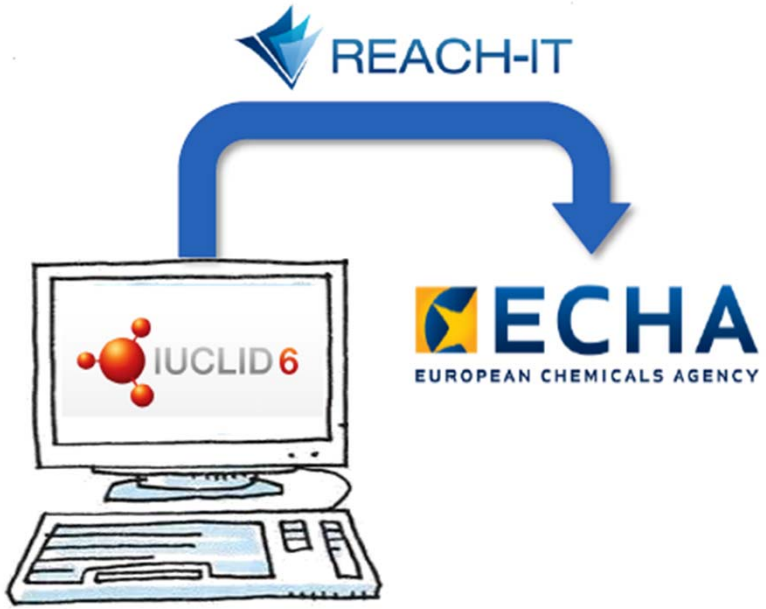
REACH 2018 Registration Deadline

What needs to be registered?

– Manufactured or imported substances at volumes ≥ 1 t/a (several exemptions may apply)

Where

How



REACH 2018 Registration Deadline

Who needs to register?

- EU-manufactures and importers of substances (as such or in mixtures)
- EU-based Only Representatives (on behalf of a non-EU manufacturer or formulator)
- Producer and/or importer of articles, only if the article contains the substance > 1 t/a and is intended to be released during use

Who doesn't?

- Downstream users
  - → Formulators
  - → Re-fillers
  - → End users…

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REACH 2018 Registration Deadline

Joint Registration - Lead & Member Registrants

- REACH requires joint registrations, if the same substance is registered by more than one company

  One Substance, One Registration - "OSOR principle"

- Main aim: Avoid generating redundant testing data

  especially for animal studies

- Co-registrants for the same substance become part of a virtual cooperation group:

  SIEF (Substance Information Exchange Forum)

- Here, a Lead Registrant will be elected/agreed upon
- Lead Registrant takes care of data requirements, prepares & submits the complete registration dossier
- Remaining Member Registrants purchase access to the dossier und submit limited substance & company related information only

REACH Registration Deadline 2018

Some figures…

	2010	2013	2018
Substances	~ 3,400	~ 3,000	up to 25,000
Dossiers	~ 20,000	~ 9,000	up to 60,000

Dossier information as of May 2016:

- 70 % for substances produced outside the EU
- 15 % SME
- Top three countries: *Germany (31%), UK (14%), Netherlands (9%)*
- Luxembourg: 171 substances, 293 dossiers

Source:
https://echa.europa.eu/regulations/reach/registration/registration-statistics

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Challenges for "Small and medium-sized enterprises" (SME)

- Determining registration needs and obligations
- Lead registration or member registration?
  - Full lead registration: Take care of data requirements asap!!!

    1-10 t/a: *Annex VII requirements (exemptions possible)*

    10-100 t/a: *Annex VIII requirements*

    (time & cost intensive studies necessary)

  - Member registration: Cooperation with the SIEF

    Communications with the Lead Registrant

    Agreeing on Substance ID

    Data sharing negotiations

    Cost sharing (fair, transparent and non-discriminatory)

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Standard Information Requirements - REACH 2018 Deadline

Annex VII: 1-10 t/a, Annex VIII: 10 – 100 t/a (+CSR)

(waiving may apply according to column 2 and Annex XI)

Physicochemical data:

Physical state, melting point, boiling, point, density, granulometry, vapour pressure, surface tension, LogPow, water solubility, flammability data, reactivity data….*(sufficient if Annex III criteria are not met)*

Environmental fate and ecotoxicology:

Biodegradation screen, short-term tox to aquatic invertebrates, tox to algae, short-term tox to fish, tox to microorganism, hydrolysis, adsorption desorption

Toxicology:

Acute tox oral, skin irritation/corrosion (in vitro), eye damage (in vitro first), skin sensitisation (in vitro first), mutagenicity in vitro with bacteria,

additional acute tox test (dermal or inhal.), mutagenicity in vitro with mammalian cells, toxicokinetic info, subacute repeated-dose tox (28-day), repro-developmental tox screen

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REACH Registration Deadline 2018

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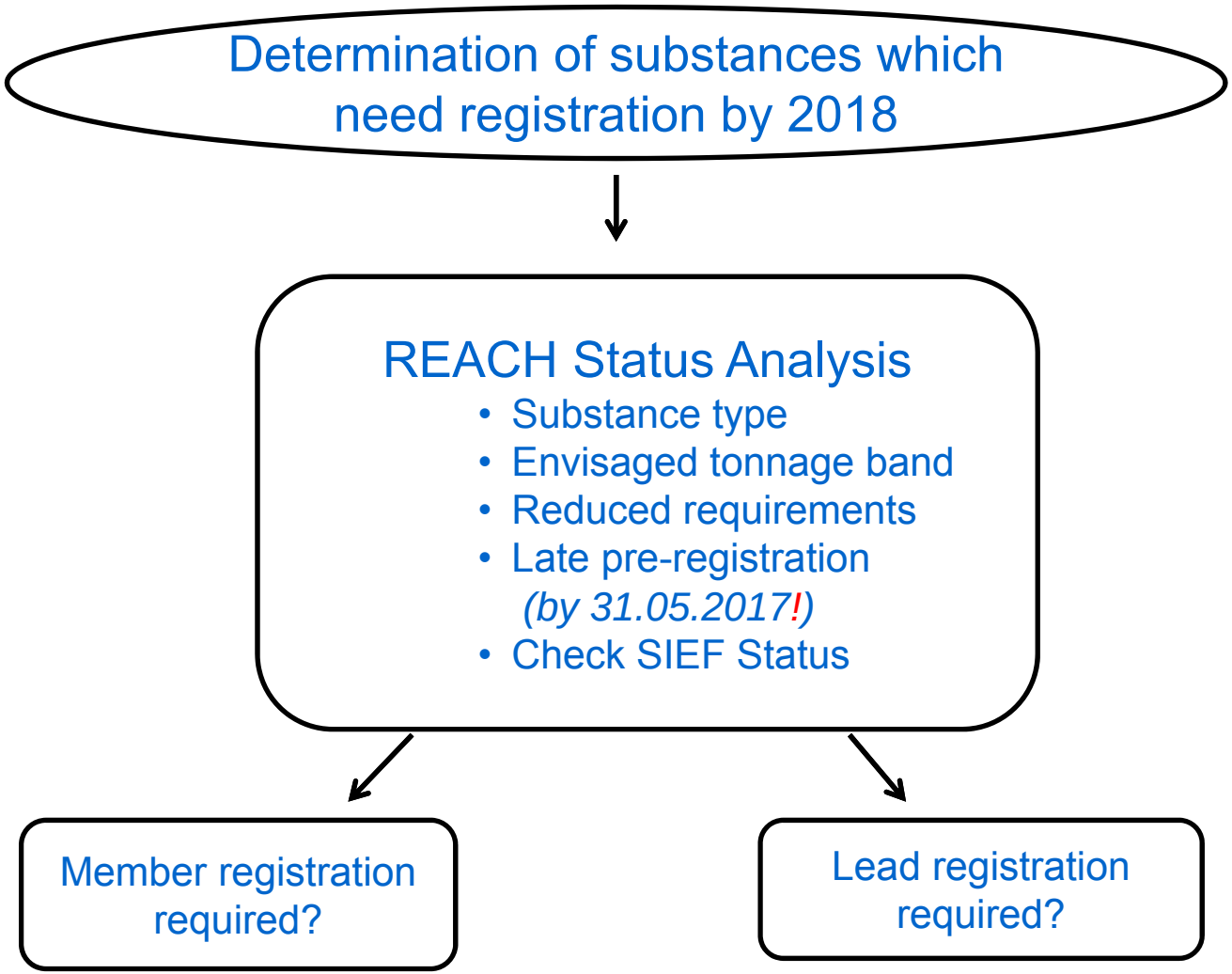
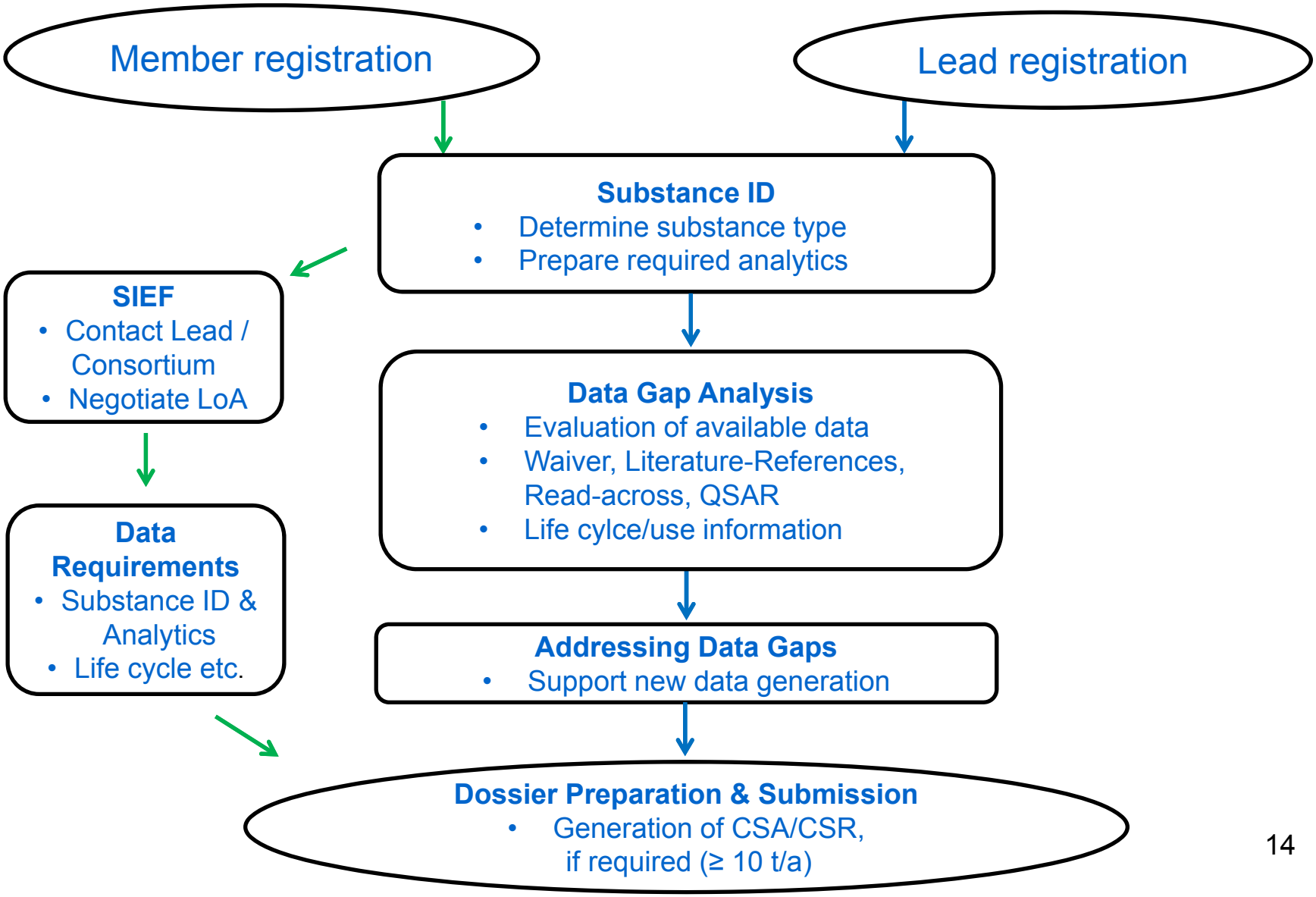
2018 REACH Deadline – Practical Tips



2018 REACH Deadline – Practical Tips



REACH 2018 Registration Deadline

Summary & key points

- Only 1.5 years until the deadline
- Act now!
- Determine your registration obligations
- Submit pre-registration (deadline 31.05.2017)
- Contact the SIEF
- Lead or member registration needed?
- Start the registration process

…. Seek for professional support, if needed

Contact us

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Thank you for your time & attention

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