Dr. Knoell Consult GmbH
A knoell company

Society for Chemical Hazard Communication

knoell worldwide registration

REACH 2018:
How to prepare for registration following ECHA´s roadmap

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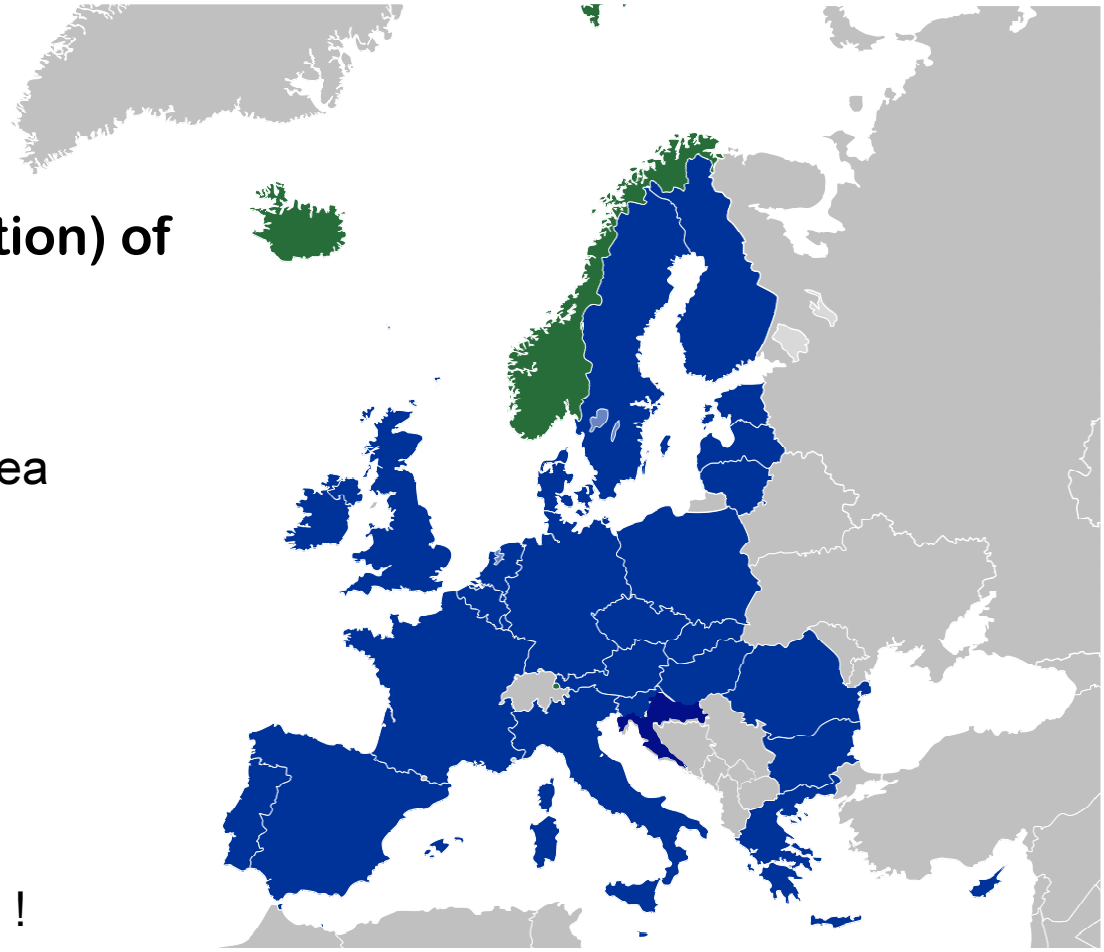
Agenda

- Introduction – REACH basics
- ECHA´s REACH 2018 initiative
- Seven steps to happiness
- Other challenges
- Summary

REACH applies to the EEA

Registration,
Evaluation and
Authorisation (and Restriction) of
Chemicals



- EEA: European Economic Area
- EU member states (28) plus Norway, Iceland and Liechtenstein
- Don´t mix it up with EFTA (European Free Trade Area)
- Switzerland is not part of EU !

REACH in one slide….

All substances (as such or in preparations), **produced** in or **imported** to the European Union in amounts > 1 t/a must be registered at the new European Chemical Agency (EChA) in Helsinki, Finland.

A **technical dossier**, and additionally for substances > 10 t/a, an extensive **chemical safety report**, assessing the risks for humans and the environment, has to be prepared (and both are subject to evaluation).

Substances of very high concern (SVHC) are additionally subject to an authorisation procedure.

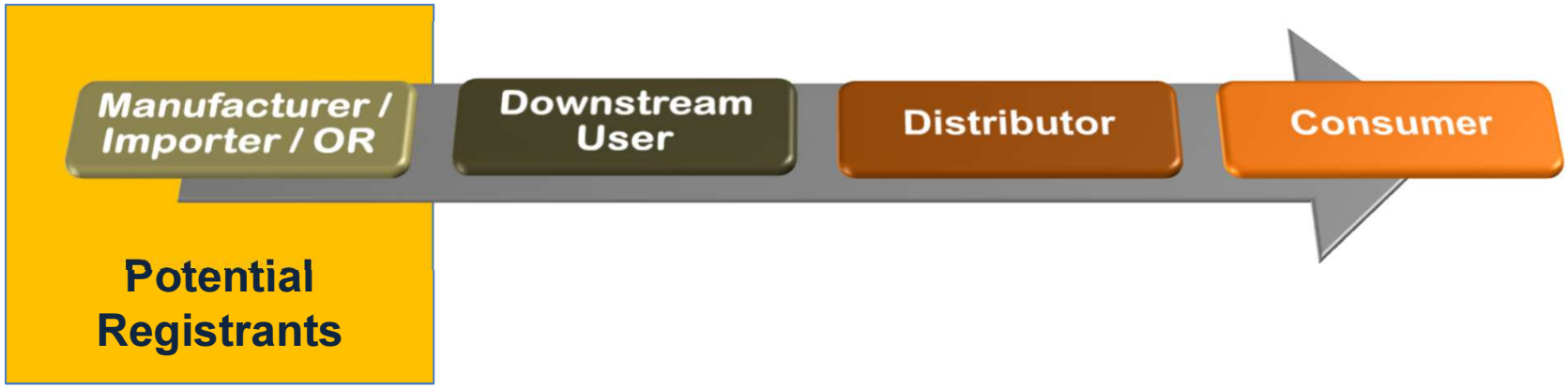
Without registration there will be :

- no production
- no import
- no marketing

„No Data – no Market“ !

(Title II, Article 5)

Actors under REACH



What about US (or other non-EU) companies?

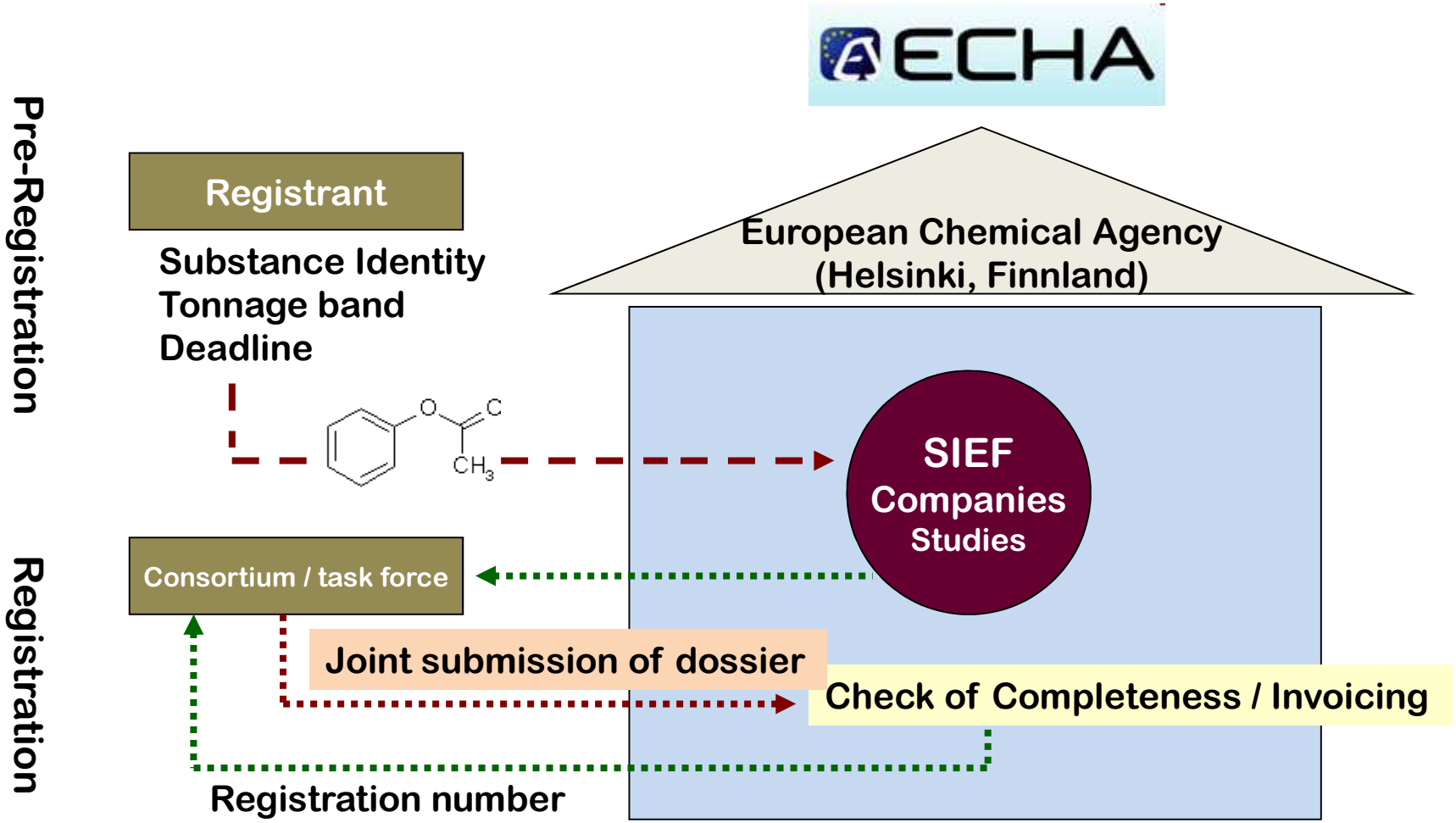
Only Representative under REACH

"According to Article 8(1) of REACH, a natural or legal person established outside of the EU who manufactures substances…., formulates mixtures or produces articles, can nominate an only representative located within the EU to carry out the required registration of their substances that are imported…. into the EU".

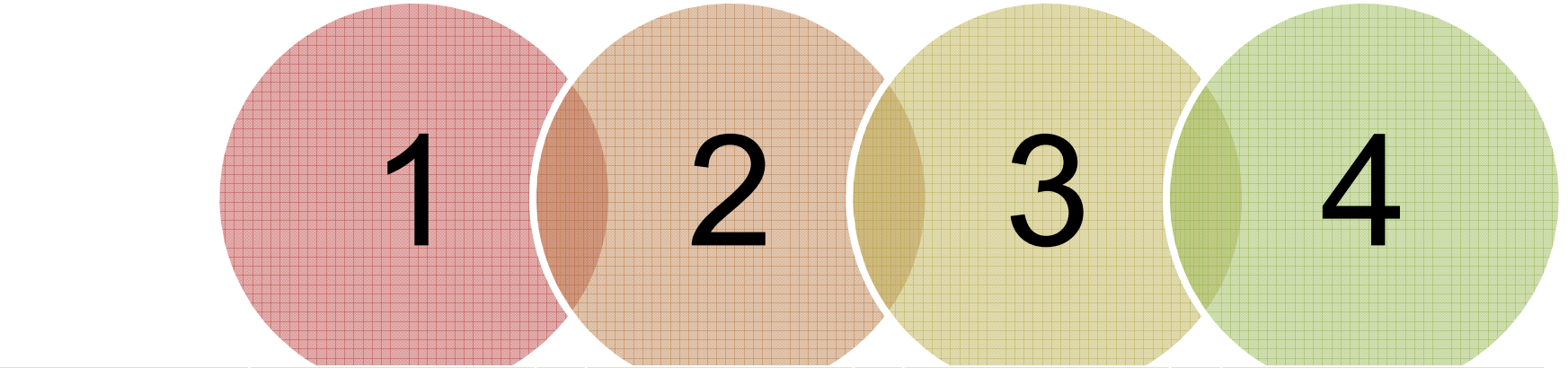
Doing so, the non-EU supplier has to take care of and pay for the registration.
Why should he do that?

- EU importer will prefer a supplier who appoints an OR to avoid registering on its own.
- An importer with its own registration is free to buy anywhere.
- If the composition of a mixture is confidential, the importer is not able to do the registration(s).

Process description



Tiered approach for registrations (article 23)



Tons per year	> 1000		100 – 1000		10 – 100		1 – 10
Deadline	***Nov. 30 2010***		***May 31 2013***		May 31 2018		May 31 2018
CSR	Yes		Yes		Yes		No

Where we are……

- 2.75 Mio pre-registrations
- Initially for 146.000 substances
- 43.972 registrations for 9.032 substances (end of 2015)
- More information available than ever before
- At least additional 20.000 substances are still „waiting“ for registration
- Would be good to have a plan for those…

2018 basics

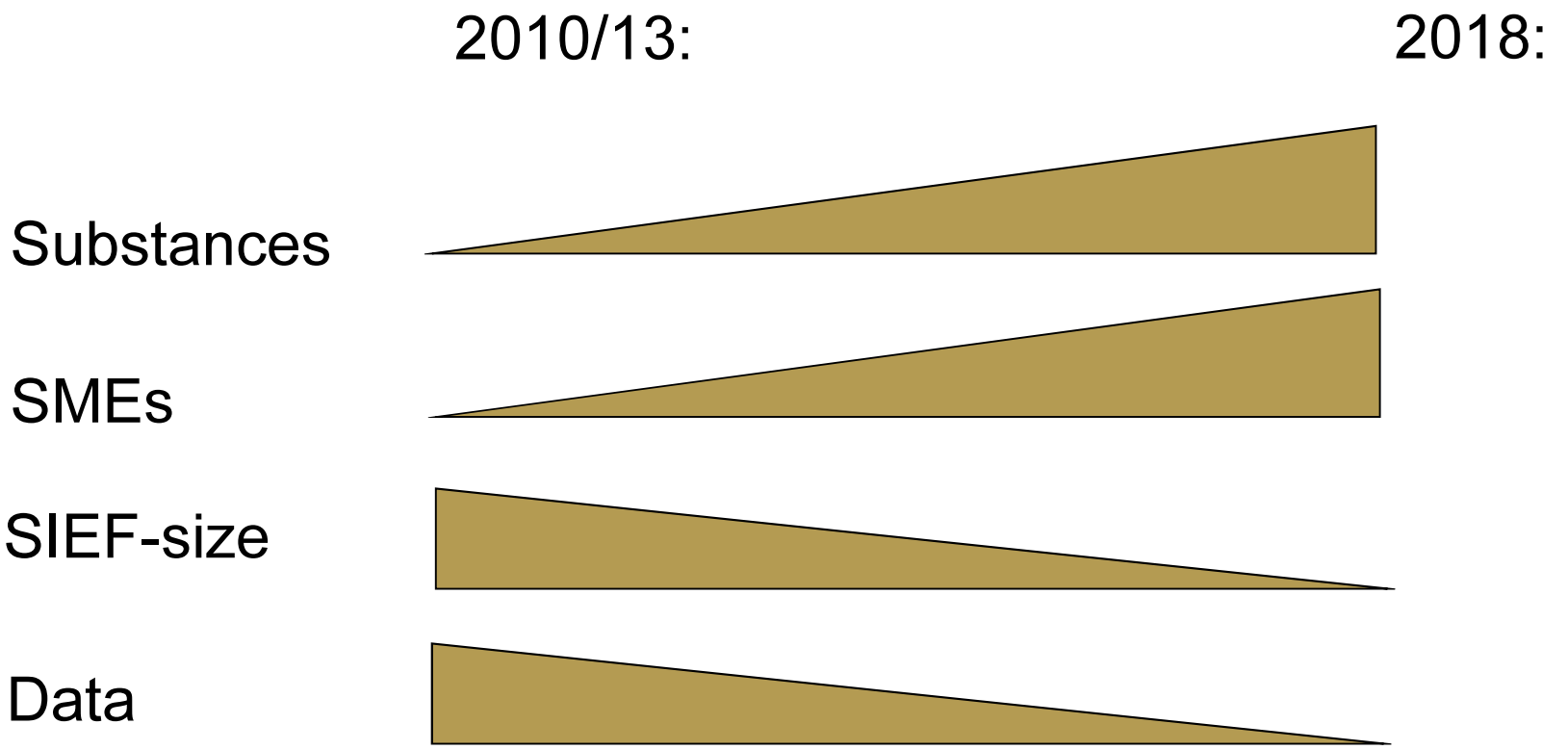
If you have pre-registered substances that you manufacture or import from outside the EU (1-100 t/a) and have not already registered them, the REACH registration deadline of 31 May 2018 concerns you.

If you haven't yet pre-registered your substance (and your first import was within the last six months), late pre-registration may still be an option* until 31 May 2017.

If the 6-months window is already gone or your tonnage is > 100 t/a, you have to submit an inquiry to ECHA and to register your substance before you can start the import into the EU.

*not for CMRs > 1 t/a, their deadline was 2010

What is different in 2018?



Challenging…..but invest in sound planning - and you are half way there

„Wait and see“ or „hide“ ar not sustainable approaches…

Be active !

ECHA´s REACH 2018 initiative

On October 2014 ECHA has launched a set of new web pages related to REACH 2018, which outlines the phases leading to a successful registration. The pages help companies to begin their preparations already now and give them easy access to the current information on ECHA's website.

http://www.echa.europa.eu/reach-2018/

ECHA´s REACH 2018 initiative

ECHA
EUROPEAN CHEMICALS AGENCY

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ECHA > REACH 2018

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REACH 2018

Are you affected by the deadline?

If you manufacture chemical substances or import them from outside the EU above one tonne per year, you may have registration obligations under REACH. Additionally, if you manufacture or import a product (mixture, article), it may contain substances that need to be registered individually.

If you have pre-registered substances that you manufacture or import from outside the EU above one tonne but not more than 100 tonnes per year and have not already registered them, the REACH registration deadline of 31 May 2018 concerns you.

If you haven't yet pre-registered your substance, late pre-registration may still be an option until 31 May 2017.

› More information

Support to understand your tasks

The following pages help you to understand what you need to do and take you through the process step-by-step.

› Share data and costs with your co-registrants

REACH 2018

772
days before the deadline

Support

- Contact your national REACH helpdesk or the ECHA helpdesk
- Contact ECHA's accredited stakeholder organisations for sector specific support
- Are you a small or medium-sized enterprise?
- Are you a non-EU company exporting chemicals to the EU?
- Are you an only representative?
- Are you using chemicals?
- Getting started with EU chemicals legislation

Step 1: Know your portfolio and identify your substances correctly – what should I register?

Sounds trivial, but substance identity is ECHAs fetish, as you may recognize during dossier evaluation ……..

"Unambiguous and correct identification of your substances is essential to a successful and compliant registration. Review that the substance identity information you provided in the pre-registration is still valid".

Particulary, check the composition of your UVCB* substances. If the description is too broad, ECHA will reject it ……..

*UVCB: unknown, variable, complex, biological origin

Step 2: Find your co-registrants

"All co-registrants for the same substance are part of a SIEF (substance information exchange forum). They all have two obligations: to share scientific data and to register jointly".

Find out who intends to register (or has already registered) the same substance.
Many substances have been registered already. A list of already registered substances is published in the registered substances database on ECHA's website.

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

If your substance is already registered…

Find out who the lead registrant is. You probably received emails from that company already. Otherwise, check in the pre-SIEF pages of REACH-IT.

Contact him and confirm that your substance is the same as in the existing registration (check SIP*).

What are the rules for data sharing? What has been submitted jointly (Technical Dossier, Chemical Safety Report, Guidance on Safe Use)? What are the costs for the Letter of Access (LoA)?

Ask for the security token to claim the joint submission in REACh-IT. Prepare and upload your member dossier.

*SIP: Substance Identity Profile

If your substance is not yet registered…

Find the contact details of your potential co-registrants in the pre-SIEF pages of REACH-IT.

Check with all co-registrants that you intend to register the same substance.

If this is confirmed,
the pre-SIEF evolves to a SIEF….

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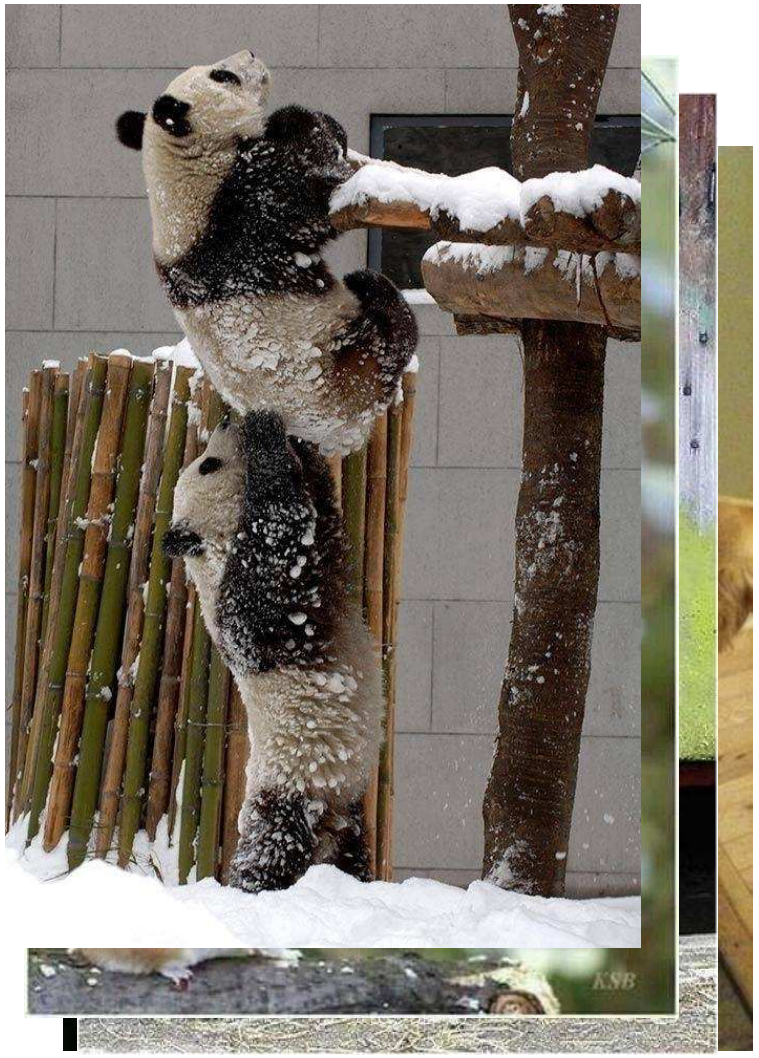
To work together in a SIEF

Cooperation



Step 3: Get organized with your co-registrants

Some 2018 SIEFs are already active (if not: start your own activities anyway):

- Is there a reliable Sief Formation Facilitator (SFF)?
- Already a volunteer for the lead registrant role? If not, consider to claim it for yourself

Start soon !

Step 3: Get organized with your co-registrants (cont.)

Prepare a SIEF agreement. Use „model agreements“ and templates prepared by industry associations like CEFIC*.

Perform a literature search. Compile and share available scientific data and start a data gap analysis.

Reach an general agreement on how to share the cost of data and the cost of SIEF administration (fair, transparent, non-discriminatory).

Appoint the lead registrant.

* Conseil Européen des Fédérations de l'Industrie Chimique (European Chemical Industry Council)

Step 4: Evaluate data and assess hazard and risk

Gather information on uses from the supply chain. Determine Process Categories (PROCs) and Environmental Release Categories (ERCs). Contact your industry association for best practice in your sector.

Based on a data gap analysis, define the strategy to fill in any data gaps (e.g. carrying out new studies, using scientifically solid read across, data waivers etc.); remember that animal testing is the last resort.

No data-gaps, but also no unnecessary testing! Article 5 says "no data – no market", not "no testing – no market"

Based on the hazard data, agree on classification and labelling within the SIEF. Based on uses, clarify the exposure.

Step 5: Prepare your registration dossier in IUCLID (International uniform chemical information database)

http://iuclid.eu/

ECHA has developed supporting IT tools to assist you:

The Validation Assistant plug-in

The Dossier Quality Assistant

The Fee calculation plug-in

The Dissemination plug-in

Step 5: Prepare your registration dossier in IUCLID (cont.)

Lead dossier:

A lead dossier includes the information that co-registrants must submit jointly, such as the classification and labelling (ch. 2) of the substance and (robust) study summaries (ch. 4-7), if applicable.

It is good practice for lead registrants to provide draft basic datasets in IUCLID for members.

As a lead registrant you are strongly advised to prepare your registration dossier well before the deadline, so that your co-registrants have enough time to meet the deadline as well.

Step 5: Prepare your registration dossier in IUCLID (cont.)

If your substance is hazardous, and the tonnage is > 10 tonnes per year, you need to carry out the chemical safety assessment (CSA) and record it in a chemical safety report (CSR).

This includes an exposure-, hazard- and risk assessment. **This needs comprehensive expertise and experience to demonstrate the safe use of your substances.**

Already during the SIEF discussions the co-registrants should decide if the lead registrant will submit the chemical safety report jointly on behalf of the co-registrants or if the individual registrants will submit their own CSR separately.

Step 5: Prepare your registration dossier in IUCLID (cont.)

CHESAR: CHEmical Safety Assessment and Reporting tool

https://chesar.echa.europa.eu/de

Chesar is developed by ECHA to help companies carry out their chemical safety assessments and prepare their chemical safety reports and exposure scenarios (ES) for communication in the supply chain.

Chesar enables registrants to carry out the work in a structured, harmonised and efficient way. This includes the importing of substance-related data directly from IUCLID, describing the uses of the substance, identifying risk management measures if needed, carrying out exposure estimates and demonstrating control of risks.

chesar

It is a tool to be used by experts!

Step 5: Prepare your registration dossier in IUCLID (cont.)

Member Dossier

Dossier includes information specific to your company and your substance. This includes, e.g., information about substance identity (composition, analytical data), your identified uses and your production volumes.

If all the information is at hand and of sufficient quality, a member dossier can be prepared within a few hours.

Critical point: substance identity and analytical reports!

Step 6: Submit your registration dossier

Lead registrant has to:

- Create the joint submission object in REACH-IT,
- Communicate the joint submission name and token generated by REACH-IT to the members,
- Submit the lead registration dossier in REACH-IT.

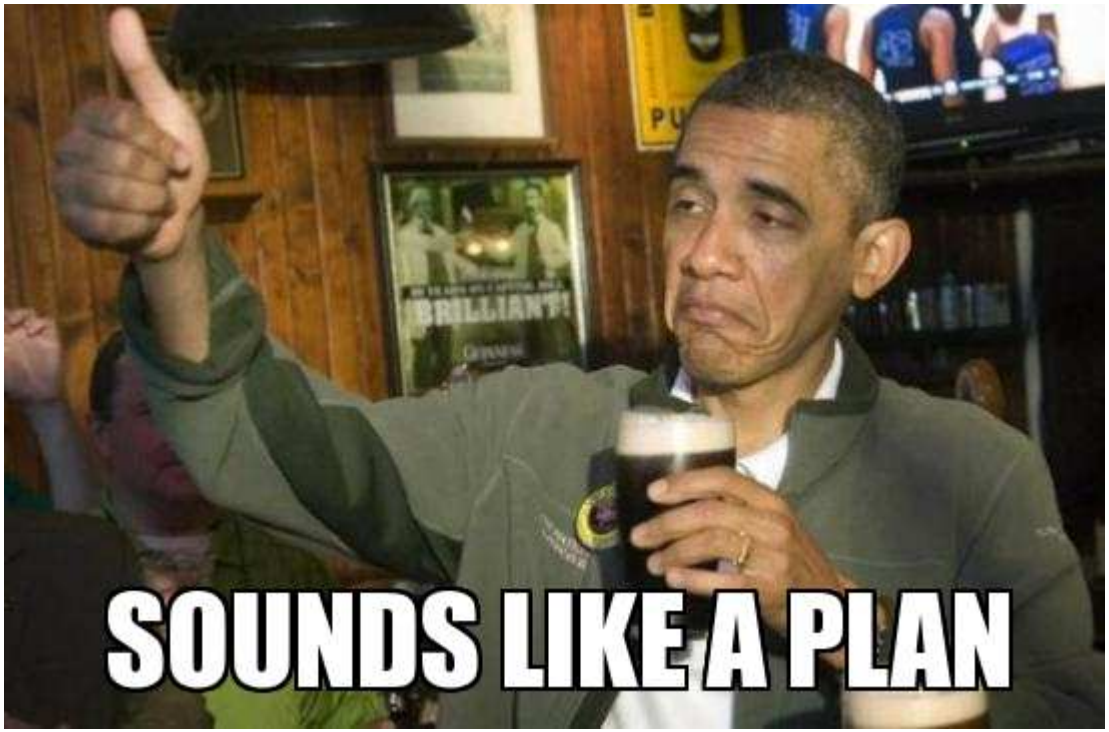
ECHA will check if it can process your dossier (business rules). Only after this check, members will be able to submit their own dossiers.

You are strongly advised to submit your lead dossier well before the end of March 2018.

Step 6: Submit your registration dossier

Member registrants:

- After receiving the joint submission token from your lead, confirm your membership in the joint submission in REACH-IT,
- Check in REACH-IT that the joint registration dossier submitted by the lead registrant has been accepted,
- Submit your IUCLID registration dossier in REACH-IT. ECHA will check if it can process your dossier (business rules). **This is the check you need to pass by 31 May 2018**.


BRILLIANT!
SOUNDS LIKE A PLAN

After submission

Monitor your REACH-IT message box as ECHA will use it to communicate with you on your submission.

Be prepared to pay the fee within the deadline indicated in the invoice that ECHA will send to your REACH-IT message box - **otherwise ECHA will reject your submission**.

Once you have paid the invoice and ECHA has accepted your registration, you will receive a registration number.

If you have any concerns,
please contact the ECHA Helpdesk.

http://echa.europa.eu/de/support/helpdesks

Step 7: Keep your registration up-to- date

ECHA may examine any registration to verify if the information submitted by registrants is compliant with the legal requirements. The selection for compliance check is either random or concern-based (targeted).

Registration under REACH is not just a one time exercise and your legal obligations do not end after you receive a registration number.

Up-to-date information is needed to ensure that chemicals are being used safely.

You should update your registrations whenever new information becomes available. You should also check ECHA's annual evaluation reports.

DOs and DON´Ts

Bad ideas – Don´ts

“Putting on a zebra suit with your buddy and entering an area with freely roaming lions might be considered a bad idea”.

Please don´t…

DON´T take REACH easy – it is not.

DON´T prepare weak dossiers – not sustainable!

DON'T misuse this process to unduly exclude certain competitors.

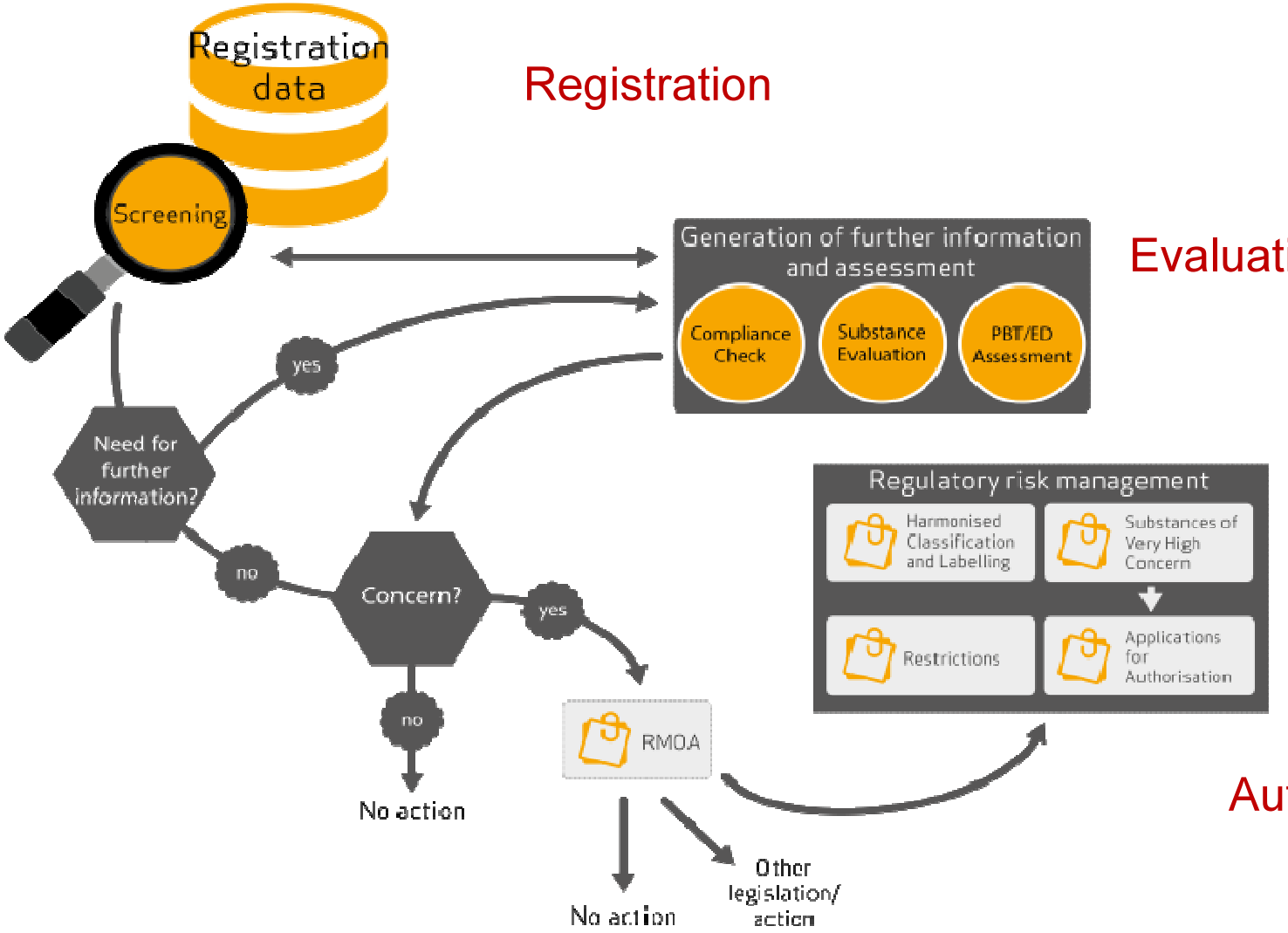
DON'T discuss business related issues that ought to be decided individually by each company.

DON'T exchange non-public sensitive information.

DON'T exchange technical information if this exchange is not necessary under REACH, especially if this exchange of technical information may provide competitors with the ability to align their market behaviour.

Don´t forget other challenges ahead

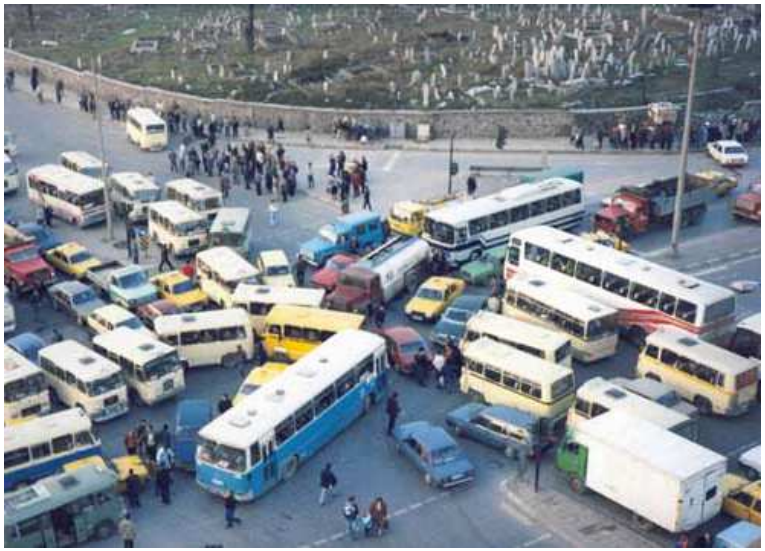
For globally acting companies, REACH is not the only regulation you have to follow…..
Consider also GHS and regulatory requirements in other global target markets like China, Taiwan, Korea, Japan….!


Registration data
Screening
Registration
Generation of further information and assessment
Compliance Check
Substance Evaluation
PBT/ED Assessment
Evaluation
yes
Need for further information?
no
Concern?
yes
no
No action
RMOA
Regulatory risk management
Harmonised Classification and Labelling
Substances of Very High Concern
Restrictions
Applications for Authorisation
Authorization
No action
Other legislation/ action

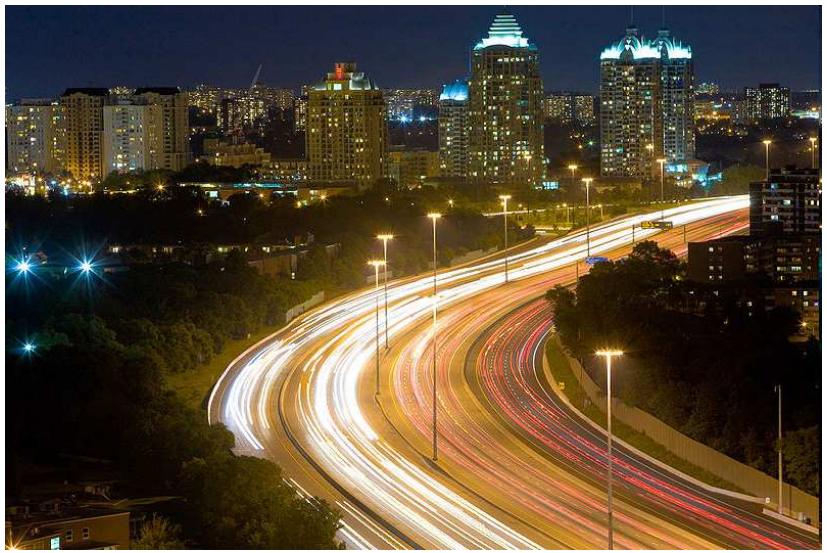
- Be active – communicate!
- Is your Only Representative doing the right things?
- Follow the available recommendations
- Don´t re-invent the wheel
- Assess your own expertise and manpower
- Assess your need for external help
- Start early!

It is for you to decide….

Scenario 1: not prepared



Scenario 2: well prepared



If you are well prepared, finally you will say……..

Many thanks for your attention