

**REACH**→**LAW**

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8.2.2018 | REACHLaw

# Meet the REACH 2018 Deadline

Webinar by REACHLaw

# *Welcome*

## Presenter:

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# Webinar: Meet the REACH 2018 Deadline

## Agenda

1. REACHLaw in Brief
2. The REACH 2018 deadline
3. Lead Registrants for 2018
4. Co-Registrants for 2018
5. What if you miss the deadline?
6. Q&A
7. Contact

**Duration: ca. 60 min**

**1. REACHLAW IN BRIEF**

**2. THE REACH 2018 DEADLINE**

**3. LEAD REGISTRANTS FOR 2018**

**4. CO-REGISTRANTS FOR 2018**

**5. WHAT IF YOU MISS THE DEADLINE?**

**6. Q&A**

**7. CONTACT**

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EU REACH & CLP

TURKEY KKDİK

CHINA REACH & GHS

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# REACHLaw Market Access Services

## For Chemical Products

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- ONLY REPRESENTATION
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- REACH AUTHORISATION
- SVHC ADVOCACY
- CLP & GHS SERVICES
- GLOBAL CHEMICAL REGULATIONS (*KKDIK, KOREA REACH ...*)
- LEGAL & TECHNICAL SERVICES
- CONSULTING
- TRAINING *...and more*

# REACHLaw Market Access Services

## Some "REACH like" Chemical Regulations around the World

EU REACH & CLP

Turkey KKDİK  
& SEA & GBF

South-Korea  
"K-REACH"

China "REACH"  
& GHS

Swiss ChemO

Taiwan Existing  
Substance Inventory  
Available

USA TSCA and Safe  
Chemicals Act

Malaysia Voluntary  
Registration of  
Hazardous Substances

Japan Chemical  
Substances Control  
Law

Russia "REACH"

Thailand National  
Inventory

*... and more is coming*

***Chemical Regulations is our Core  
business, it doesn't have to be yours***



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**May 31<sup>st</sup> 2018 will be the last REACH  
Registration deadline for smaller volume  
1 - 100 t/a (non SVHC\*) substances**

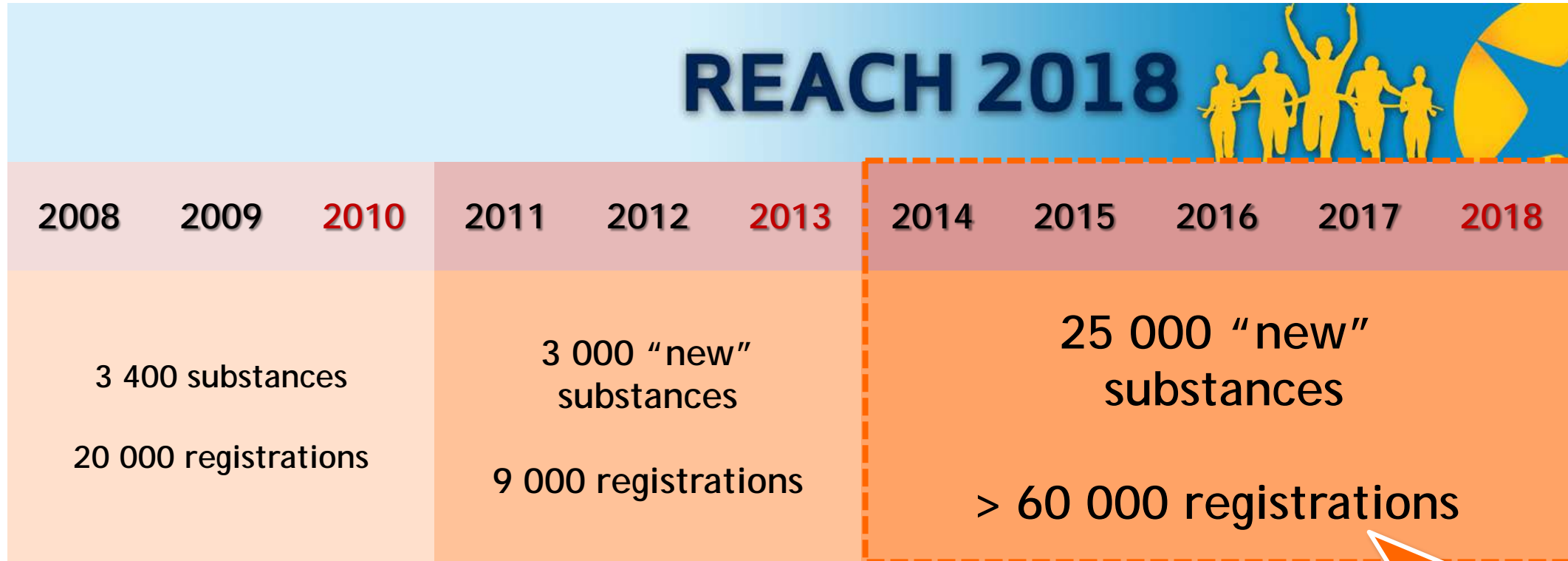
*\* Substances of Very High Concern at 1 t/a or more had their REACH Registration deadline at 30<sup>th</sup> of November 2010*

***Therefore, as of June 2018, all substances  
on the EU/EEA market at  $\geq 1$  t/a must be  
REACH Registered \****

*\* Unless specifically exempted from REACH Registration*

# The REACH 2018 Deadline

## What will the Deadline Look Like?



- As of February 2018:
  - Registrations: **67 664** *(this incl. smaller volumes of already registered substances)*
  - Unique substances: **17 687**

...ECHA has noted that these are not targets but predictions based on pre-registration and notifications to ECHA etc.

# The REACH 2018 Deadline and

## 2018 Deadline, Current status *(January 19<sup>th</sup>, 2018, newest available data)*

- Currently of the 2018 substances:
  - 6 403 out of ca. 25 000 unique substances have been registered
  - These are covered by 14 578 registrations (*out of ca. 60 000*)
- Out of these 14 578 registrations\*:
  - 75 % Registered as full registration (→ 10 976)
  - 25 % Registered as intermediates (→ 3 664)
  - 85 % Registered by Large company (→ 12 404)
  - 15 % Registered by SME (→ 2 174)
  - 28 % Covered by an Only Representative (→ 4 118)
  - 43 % Covered by EU/EEA importer (→ 6 242)
  - 24 % Covered by EU/EEA manufacturer (→ 3 433)
- On average, there are 4 members in the SIEF  
(1 LR + 3 Co-registrants)

Where are all the rest of the SME's?

\* Any combination of one up to three different types can be covered. This is why the numbers do not add up to the total number of registrations.

***We have less than 4 months to go and we still have ca. 18 500 unique substances to register, covered by ca. 45 000 dossiers still to be submitted based on ECHAs statistics...***

*...that's only ca. 25% done of the estimated  
number of Registrations*

# The REACH 2018 Deadline

## Supply Chain Implications (*Related to Registrations*)

- It is expected that substances will **fall of the market** by the 2018 registration deadline due to the following reasons:
  - Lack of knowhow
  - Not enough Resources
  - No solid business case → *No point in registering a substance for a lot of money if revenues are not supporting the costs*
  - Carelessness
  - ...
- This is especially true for **low volume, small market share chemicals** (*typically specialty chemicals*)





***No-one knows what will happen after  
REACH 2018 in the Supply Chain.***

***We will see in 6 months...***

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# Lead Registrants for 2018

## Reminder to the Lead Registrant

- **You** have the responsibility to:
  1. Manage / lead the Joint Submission work, *and*;
  2. Prepare the Joint Submission Dossier (Lead dossier) on behalf of the Joint Submission
- **You** will be the contact point for the authorities and ECHA with regards to the Lead dossier and its content.
- **You** could be **liable**\* towards the Co-Registrants (*and your customers*) in case of problems submitting a proper lead dossier on-time
- **You** need to **submit on time** so that your co-registrants also can submit their Co-Registrations (*as members of the Joint Submission*)
  - At a minimum the *Business Rules Check* has to be passed by the lead dossier in order for the Co-registrants to be able to submit their dossiers

*\* The responsibilities of the lead registrant towards the co-registrants, would likely be determined based on the applicable national civil/commercial law.*

# Lead Registrants for 2018

## Where should the Lead Registration work be at this point?

**Note:** If you haven't started yet, it's already too late to start with a REACH 2018 Lead Registration, mostly due to testing capacity limitations (*especially true for 10-100 t/a substances*)

- For on-going lead registration work for the 2018 deadline, you should as of the beginning of February 2018 have done the following:
  1. Identified and agreed on the substance identity within the (pre-)SIEF
  2. Know all relevant uses of the substance
  3. Collected available information on the substance to satisfy end-point requirements
  4. Ordered and completed the necessary Annex VII and Annex VIII related tests
  5. Received at a minimum the final draft test results back from the laboratories
  6. Populated most of the required sections of the lead dossier in IUCLID 6
  7. Drafted the first proper version of the CSR including Exposure Scenarios (applies for 10-100 t/a substances and hazardous 10-100 t/a substances respectively)
  8. Communicated with SIEF members about the registration timetable and how to Joint the Joint submission (*SIEF/LoA agreement etc.*)

# Lead Registrants for 2018

## What can be done if the Lead Registration work is running late?

- **Case 1: Test data not being available on-time for inclusion into the Lead dossier**
  - Industry may, in spite of their best efforts, have some difficulties in providing data required in Annex VII and Annex VIII in due time to include in the lead dossier on-time.
  - In these cases, if companies have ordered tests in a timely manner but have not received the results in due time, ECHA may take this into consideration when setting a reasonable deadline to complete their dossier.
  - In order to take advantage of this possibility, the lead registrant should to follow the following procedure:
    1. Contact ECHA before submitting the dossier as instructed on the DCG webpage ("*DCG issue 10.3*"): <https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues>
    2. Document you best efforts (*lab contract dated and ordered latest by end of March 2018, communication with the lab etc.*)
    3. Follow ECHA's advice and timeline

# Lead Registrants for 2018

## What can be done if the Lead Registration work is running late?

*[...Case 1 cont'd]*

- When the Lead registrants submits the incomplete dossier, it will **fail the Technical Completeness Check (TCC)**
- However, because the Lead Registrant contacted ECHA before, they will give more time based on the communication and reasoning (*maybe 2 - 3 months depending on the case*) to update the dossier and pass the *TCC (the second time)*.
  - Co-Registrants can submit their dossiers, when the Lead Registrant dossier has passed the *Business Rules* check.
- A registration number **will not be issued** for incomplete (lead- or Co) registration dossiers

# **Note:**

***Registrations will not be complete until all ECHA / REACH-IT checks have been passed successfully for the lead dossier and the subsequent Co-registration dossier and you have received a registration number by ECHA***

# Lead Registrants for 2018

## What can be done if the Lead Registration work is running late?

- **Case 2: Lead Registrant not doing their job**
  - This means the Lead registrant is not fulfilling its legal obligations pertaining to the lead registration for the 2018 REACH deadline.
  - If this is the case, the Co-registrants need to take action quickly to **elect a new lead registrant** that will take over the responsibilities of the old lead registrant (*with or without its consent*)
    - It is also highly recommended to **contact ECHA** in these cases to get their support (*e.g. in releasing the Joint Submission object ion REACH-IT to the newly elected Lead Registrant*)
  - The old Lead Registrant will revert back to a Co-registrant with this action and still be responsible for their own Co-registration.



*As a Co-Registrant, make sure your lead Registrant for the 2018 deadline substance truly is progressing with their lead registration work and that they will successfully submit the lead dossier preferably during March 2018*

# Lead Registrants for 2018

## What can be done if the Lead Registration work is running late?

- **Case 3:** Follow-up to Case 2 of where the Lead registrant has submitted an incomplete registration and fails to correct it within the completeness check deadline
  - In order to take advantage of this possibility, a new lead registrant has to have been elected (view Case 2) and the Co-registrants should to follow the following procedure:
    1. Contact ECHA before submitting the dossier as instructed on the DCG webpage ("*DCG issue 20.1*"): <https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues>
    2. Follow ECHA's advice

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## Lead Registrants for 2018

What can be done if the Co-Registration work is running late?

*... absolutely nothing! Don't be late!*

- Check “*WHAT IF YOU MISS THE DEADLINE?*” of this presentation for other options.

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***As of June 1<sup>st</sup> 2018 all substances  
(≥ 1 t/a) on the EU/EEA market  
(manufactured / imported) should be  
REACH Registered (unless exempt from  
REACH or the registration obligation)***

# What if You Miss the Deadline?

## State of Play

As of June 1<sup>st</sup>, 2018, the REACH regulation has reached a business-as-usual state where no further transitional schemes will apply for substances that require registration.

- By this time, companies have either:
  1. Registered their substances successfully, *or*;
  2. The submitted incomplete dossier has been granted an additional extension by EHCA to complement and resubmit the dossier, *or*;
  3. Submitted the registration dossier but it has been rejected and not resubmitted by the deadline (*31<sup>st</sup> of May 2018 for 1 to 100 t/a*), *or*;
  4. Not registered at all.

# What if You Miss the Deadline?

## Options for the (Co- and Lead) Registrants

If you miss the 2018 registration deadline, it means that you cannot manufacture or import a substance ( $\geq 1$  t/a) in the EU/EEA starting June 1<sup>st</sup> 2018.

- However, REACH gives you the option to **always register any substance at any time after 31<sup>st</sup> of May 2018**.
- **Pre-registrations will no longer be valid after 31.5.2018** and therefore to Co-/Lead register, you will first have to submit an **inquiry to ECHA** with information about your substance identity so that ECHA can put you in contact with the proper Lead Registrant (*if available*).
- **Only once ECHA has accepted the inquiry, can the REACH registration be submitted.**
  - Adding the inquiry step to the registration process easily means (depending on the substance type) a **1 - 3 month delay in the registration process**.



# What if You Miss the Deadline?

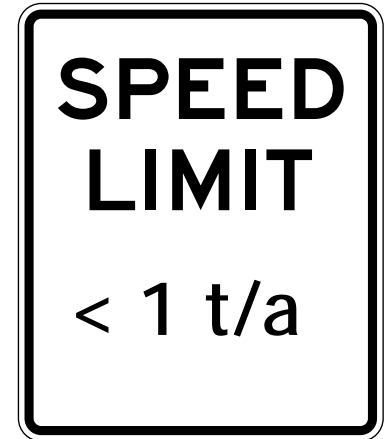
## Other Options for the (Co- and Lead) Registrants

- Albeit not very viable business alternatives, but:

- **Lower** the annual volume to less than 1 t/a,

*or;*

- **Cease** business activities regarding the non-complaint substance.



# What if You Miss the Deadline?

## Special case of “Pre-registered Stocks”

According to ECHA, in agreement with the EU Member States, substances may **exceptionally be sold onwards and used in the EU/EEA after May 31<sup>st</sup> 2018 without a registration** under the following conditions:

Role in the supply chain:	Condition(s) to continue activity:
Manufacturers and importers required to register	<ol style="list-style-type: none"><li>1. The substance has been <b>validly pre-registered</b>; <i>and</i></li><li>2. The substance is <b>manufactured or imported before 31.5.2018 in quantities of <math>\geq 1</math>-&lt;100 tonnes per year * , <i>and</i></b></li><li>3. The manufacturer or importer <b><u>ceases</u> manufacture or import and simply acts as a supplier for the pre-registered stocks after 31.5.2018.</b></li></ol>
Actors down the supply chain not required to register	The substance manufactured and imported as detailed above has been <b>supplied to them before 31.5.2018.</b>

\* *“Per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years.” - REACH Article 3(30).*

Calculation examples can be found in the ECHA Guidance on Registration, available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>

# Important note:

To continue supply of pre-registered substances after 31.5.2018 and avoid the burden of an inquiry with the associated business disruption, manufacturers, importers and ORs are required to register by 31.5.2018. EU/EEA customers will demand proof of registration after 31.5.2018.

The special case of “pre-registered stocks” should only be used as a last resort.

***To avoid disruptions in business, make sure to REACH register ahead of the last deadline of 31st of May 2018***

***Understand that REACH is a journey,  
not a destination!***

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# *Questions & Answers*

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