



# Brexit – staying compliant with REACH regulations

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# Your presenters



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# About us



Regulatory and science-based services for the chemical, biotechnology and related industries

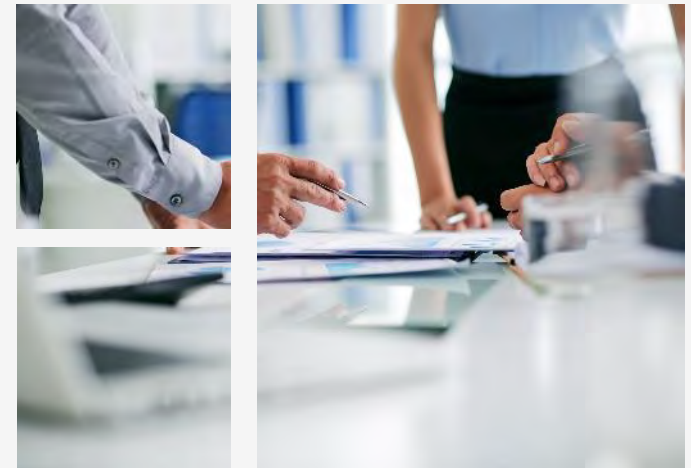
## Experts in:

- Toxicology
- Chemistry
- Biology & microbiology
- Entomology
- Agronomy
- Environmental studies
- Public health
- Public policies

To excel in the provision of scientific, regulatory and registration services to the chemical and related industries

12 European & US offices serving a global market

Established in 1990  
100+ staff globally



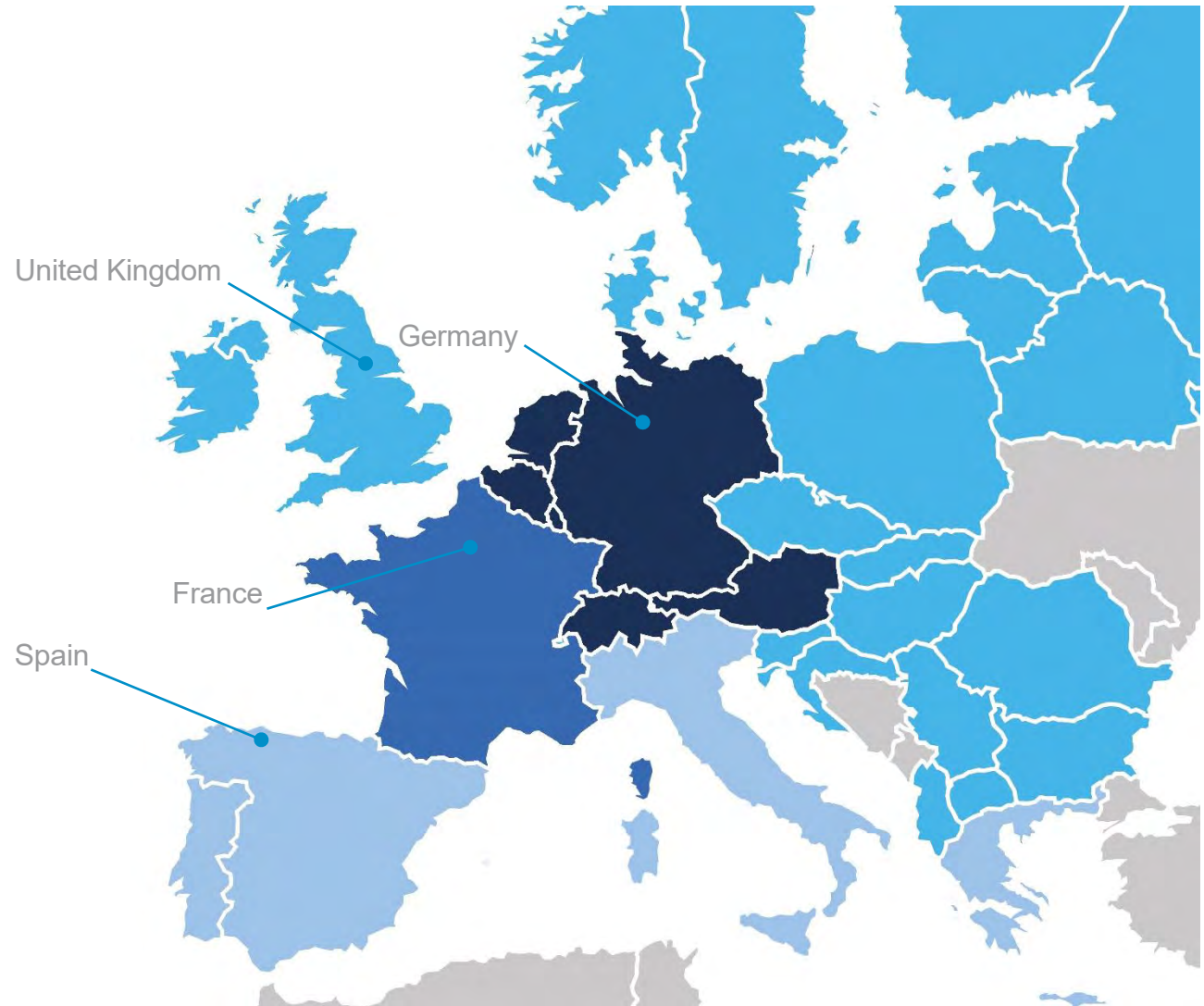
Scientific and regulatory support

## Core values:

- Honest
- Reliable
- Professional

# European offices

- National approvals throughout the EU
- Liaison with regulatory authorities
- Scientific and regulatory support
- Regulatory and technical professionals in all offices
- Full pan-European dossier coverage



Countries coordinated from the following offices

- France
- Spain
- Germany
- UK

# US and Canada offices

- Federal and state services
- Liaison with regulatory authorities
- Scientific and regulatory support



■ TSG North American offices



# Brexit's impact on REACH Regulations

# Current state of play

## Leaving the EU

UK triggered Article 50 on 29 March 2017, which started the 2 year process for withdrawal from the EU

A withdrawal agreement has been arranged by UK and EU27 negotiators

## Rejecting the deal

The draft agreement has been refused in a vote by the UK Parliament

**“The risk of a disorderly exit has increased with this vote”**

Donald Tusk, President of the European Council,  
15 January 2019

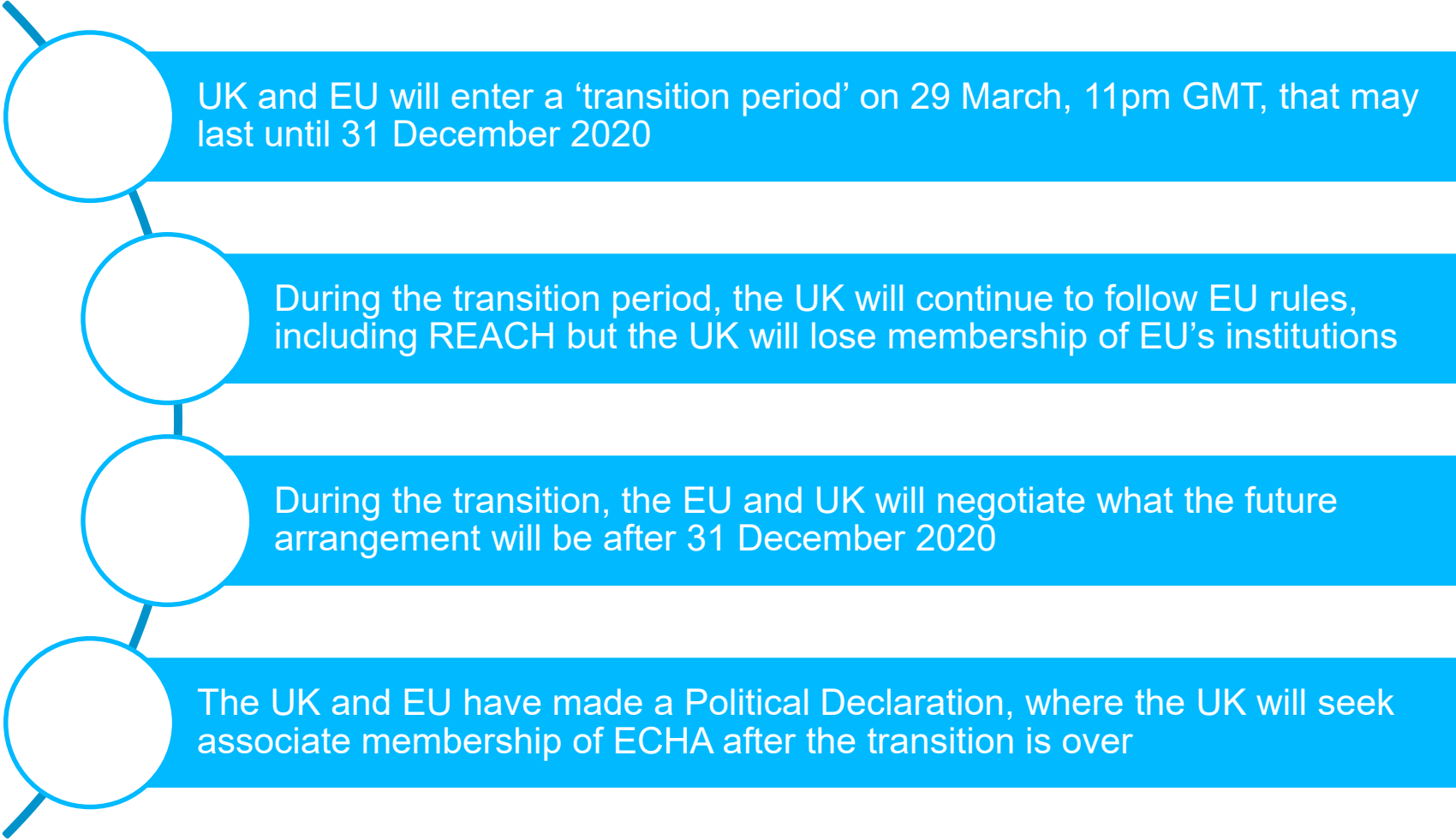
## Uncertain future

UK formally leaves EU on 29 March, 11pm GMT

Without an agreement, the UK becomes a ‘third country’ in EU REACH

*Brexit is a fast moving subject and some details presented in this presentation are likely to change*

# What happens to EU REACH in the UK under the proposed deal?



UK and EU will enter a 'transition period' on 29 March, 11pm GMT, that may last until 31 December 2020

During the transition period, the UK will continue to follow EU rules, including REACH but the UK will lose membership of EU's institutions

During the transition, the EU and UK will negotiate what the future arrangement will be after 31 December 2020

The UK and EU have made a Political Declaration, where the UK will seek associate membership of ECHA after the transition is over



# What happens to EU REACH in the UK if there is no deal?



# No Deal – Maintaining compliance with EU REACH



1. Appoint an Only Representative (OR) in EU

2. Move legal entity and applicable operations to EU

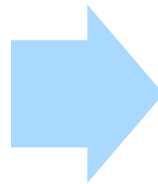
3. Source chemical from an EU-based company

4. EU customers to undertake their own EU REACH obligations

# No Deal – Maintaining compliance with EU REACH

## 1. Appoint an Only Representative (OR) in EU

If a non-EU company has appointed a UK company to act as an OR



Change to an EU27-based OR

If a UK company is a manufacturer or formulator and requires an EU REACH registration, authorisation, or needs to submit a notification to ECHA



Appoint an EU27-based OR

TSG can act as your EU REACH Only Representative in the EU

# No Deal – Maintaining compliance with EU REACH

## 2. Move legal entity and applicable operations to EU

If a UK company holds EU REACH registrations, authorisations or has made notifications to ECHA



Transfer to an EU legal entity  
– Can be done ahead of  
29 March 2019

TSG can help you carry out a legal entity transfer to your EU entity

# No Deal – Maintaining compliance with EU REACH

## 3. Source chemical from an EU-based company

If a UK company currently sources from outside the EU



An EU source could be used to ensure that EU REACH compliance is maintained if it is then re-imported into the EU as a chemical or formulation

# No Deal – Maintaining compliance with EU REACH

## 4. EU companies to undertake their own EU REACH obligations

If a UK company is an importer and not a manufacturer or formulator



Their EU customers could take on these responsibilities for EU REACH registrations, authorisations and notifications

TSG can support your customers in meeting their EU REACH requirements



# Questions & Answers

No Deal – Maintaining  
compliance with EU REACH

# An introduction to UK REACH

- UK REACH may be made law in the UK by the European Union (Withdrawal) Act 2018
- The Act replicates EU REACH, with minor technical modifications, to work outside of the EU
- The Health and Safety Executive (HSE) will act as the lead UK regulatory authority
- UK REACH will be supported by an IT system that is currently in development
- The role your company has in EU REACH may change in UK REACH
- UK REACH will allow 'grandfathering' of EU REACH registrations, PPORDs and authorisations
- Third country manufacturers, formulators and producers of articles can appoint UK-based Only Representatives



## Phased approach for UK REACH compliance

Deadline	Obligation
<b>29 March 2019</b>	UK leaves the EU
<b>29 May 2019</b>	Companies with a valid EU REACH registration, PPORD or authorisation must notify the UK authority to be able to continue access to the UK market
<b>29 May 2019</b>	Companies that are a downstream user of an EU REACH authorisation must notify the UK authority to be able to continue use of that substance
<b>26 September 2019</b>	Companies must notify the UK authority that they wish to submit a new registration
<b>29 March 2021</b>	Companies that submitted a registration notification to the UK authority must now provide a 'full data package'

NOTE: This list is not exhaustive

TSG can support your company in meeting the new UK REACH requirements

# Case study 'Grandfathering' an EU REACH registration into UK REACH

## About your company

You are a UK-based EU REACH registration holder and you wish to place the same chemical onto the UK market

### Scope

- Sole, joint or lead registrant
- Manufacturer
- Formulator
- Only Representative
- Importer

### Steps required

1. Open an account on UK REACH IT
2. Enter basic information on UK REACH IT by 29 May 2019
3. Create an IUCLID dossier containing the specified data requirements
4. Upload the IUCLID dossier on UK REACH IT by 29 March 2021



## Key takeaways



Brexit is a fast moving topic, bringing much uncertainty



EU REACH may be replaced by UK REACH for the United Kingdom market



Take action now to understand what your company needs to do to stay compliant

# TSG's Brexit Package

Keep in-the-know with Brexit news and its impact on chemical regulations

## Six months' helpline

- Up to 20 hours support
- Your Brexit-related regulatory questions answered
- Working with you to help you mitigate your Brexit-related risk

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- What you need to know – and the actions you need to take – when it happens

## Exclusive webinars

- Let's meet again before 29 March 2019



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