

# Brexit and the Implications on Supply and Use of Chemicals in Irish Businesses

1<sup>st</sup> November 2018



Rialtas na hÉireann  
Government of Ireland



# Brexit – possible impact on the European (Irish) Chemical & BioPharma industry

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# “UK out of REACH scenario”

- The impact of Brexit on REACH registration compliance as a “licence” to operate
  - Classification Labelling & Packaging Regulation
  - Biocidal Products Regulation
  - Prior Informed Consent
- This presentation is based on a briefing note produced by Cefic & the Chemical Industries Association that is aimed at supporting businesses across Europe in preparing for the potential effects Brexit may have on REACH compliance

# Three considerations/implications will be addressed:

1. Maintaining access to EU single market:  
considerations for UK-based businesses
2. Considerations for EU-based companies with  
UK supply and trade relationship
3. Implications of a future UK REACH for UK and  
EU27/EEA companies

# Maintaining access to EU single market: considerations for UK-based businesses

- UK based chemical manufacturers will need to interface with EU-based only representatives (ORs) for their substances - such as companies' affiliates or consultants, or to relocate to the EU or to allow EU based importers to register under REACH on their behalf
- UK based importers and traders would need to establish themselves in the EU/EEA, as they won't be able to appoint EU-based ORs. Under REACH, only non-EU manufacturers of substances, formulators of mixtures and manufacturers of articles can appoint an OR
- UK based companies currently acting as OR under REACH on behalf of non-EU manufacturers won't be able to continue with their role. The non-EU manufacturer will need to appoint an OR based in the EU/EEA

# Maintaining access: Practical considerations I

- Identify substances/mixtures impacted – also consider the role of your company in the supply chain
  - If a substance is manufactured by a UK legal entity as well as by an EU legal entity of the same company and both hold valid registrations, the EU entity could act as importer of the UK product
  - The EU legal entity's existing registration would need to be updated to indicate the additional volume being imported in the dossier
  - An OR would not need to be appointed in this case and transfer of registrations would not be required

# Maintaining access: Practical considerations II

- The scenario of transferring of registrations is already envisaged under specific circumstances that are not necessarily related to Brexit, e.g. for changing OR, partial total asset transfer, mergers, spin-offs, splits (please see [ECHA guidance](#) for further information)
- The ECHA website currently states that a possibility to transfer existing registrations “immediately” before the withdrawal date will be put in place in the case of registrations held by UK manufacturers, and practical steps will be clarified in due course

# Maintaining access: Practical considerations III

- ECHA is currently advising to set up a contractual agreement to appoint an OR, which contains a suspensive conditional clause stipulating that the appointment takes effect on the date when the UK withdrawal from the EU takes effect
- In the case of UK importer registrations, according to ECHA *“it is not possible to transfer a registration of a UK importer to a newly appointed Only Representative. In this case, non-EU manufacturers may appoint an EU-based Only Representative of the substance. However, the EU-based Only Representative would then need to submit a new registration for the substance”*.
- No information is available at present on whether UK traders will be able to transfer individual registrations to EU legal entities that would act as importers post Brexit



# Maintaining access: Practical considerations IV

- review your contractual conditions of SIEF/consortia agreements in order to prepare for the potential future transfer of dossier rights to an EU subsidiary or representatives so they can take over the EU registration
- In the case of mixtures, UK formulators may need to track raw materials imported from the EU to confirm future “re-import” to EU status (REACH registration exemption)

# Considerations for EU-based companies with UK supply and trade relationship I

- Check the list of your actual suppliers and approved suppliers of your substances and mixtures
- Identify substances and mixtures that are sourced from UK suppliers
- Please bear in mind that registrations are per legal entity, not per company
- Check whether UK suppliers plan to appoint an EU legal entity that will act as EU based OR post Brexit to ensure continued supply in the EU or if they can use a legal entity that has registered in the EU27/EAA countries and that can become EU importer

# Considerations for EU-based companies with UK supply and trade relationship II

- If you are already importing a substance and at the same time you have a registration under your company name, you can continue to be supplied from the UK source as you can be covered by your own registration. Your dossier would need to be updated in due course once the UK leaves REACH, to indicate the additional volume being imported in the dossier

# Considerations for EU-based companies with UK supply and trade relationship III

- If there are other suppliers in the EU-27/EEA countries, or other non-EU suppliers covered by an OR in the EU/EEA, they may be able to support you. If they are not approved yet by your company, you may have to initiate the process of approval of a new supplier, which may be rather cumbersome and time consuming in some cases

# Considerations for EU-based companies with UK supply and trade relationship IV

- If the other options are not available or you are not sure, you have to reflect on whether registering substances on their own or in mixtures as EU importer post Brexit may be a way forward (if import into the EU reaches 1 tonne or more per year)
- A registration as importer would allow importing from different non-EU sources if the substance is the same and if allowed by your quality system and your requirements for approving new suppliers

# Implications of a future UK REACH for UK and EU27/EEA companies

Worst case scenario under no deal Brexit would mean:

- UK based companies with existing REACH registrations need to notify the UK authority within 60 days from 30 March 2019 at 0h CET, 29 March 2019 23h UK time and then resubmit registration data in the UK within 2 years (by 30 March 2021) for products already registered under REACH
- UK companies (currently downstream users) that source products from EU suppliers will become UK importers under UK REACH and may be subject to a UK REACH registration scheme. A notification within 180 days from 30 March 2019 at 0h CET, 29 March 2019 23h UK time is required as an interim arrangement, with full registration expected at a later date

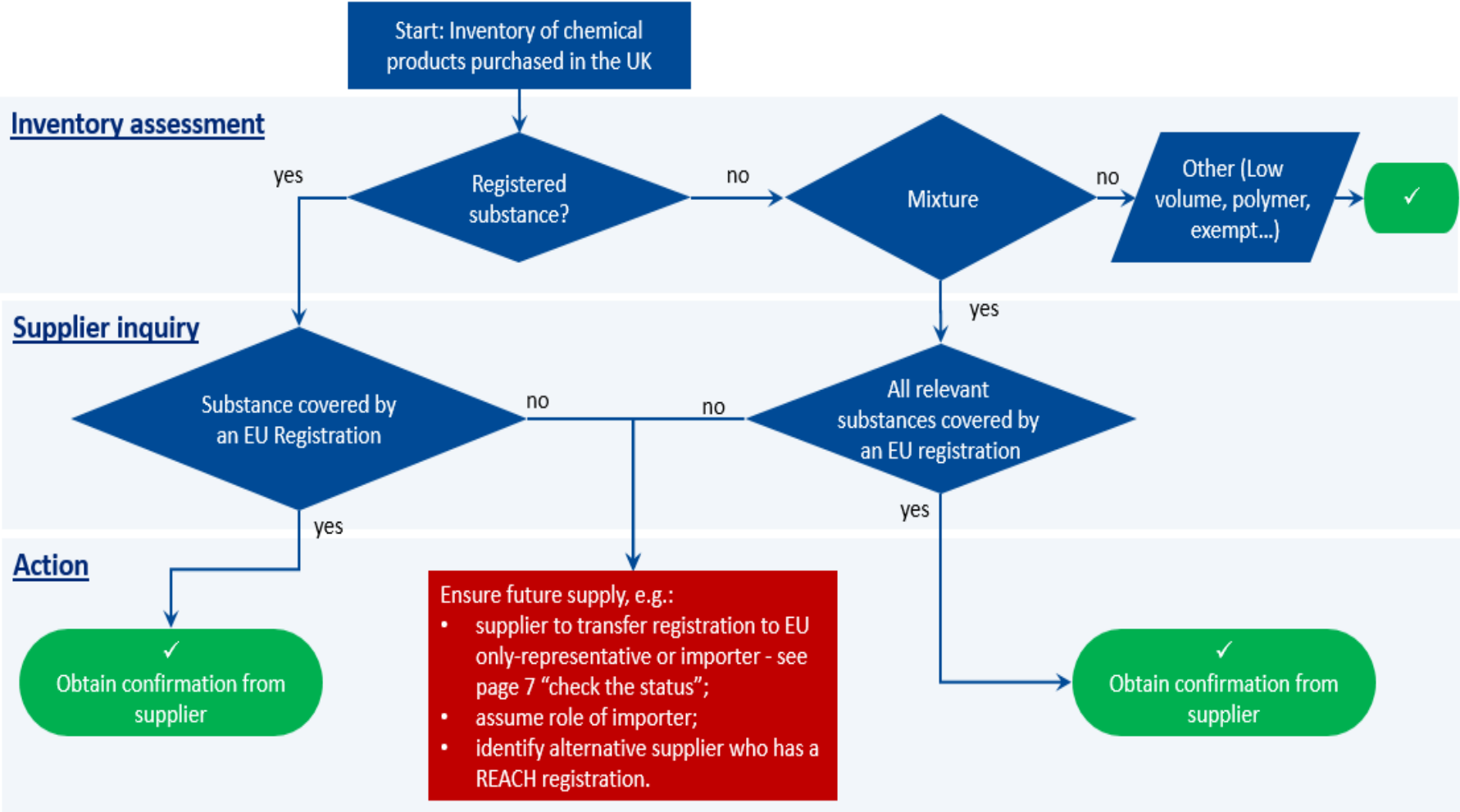
# In summary

Looked at three considerations/implications:

1. Maintaining access to EU single market: considerations for UK-based businesses
2. Considerations for EU-based companies with UK supply and trade relationship
3. Implications of a future UK REACH for UK and EU27/EEA companies

A technical notice on regulating chemicals under a no-deal scenario has been published by the UK Government and is available [here](#)

# BREXIT – “no deal” preparedness





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# **UK withdrawal preparedness - challenges for ECHA and its stakeholders**

**Brexit and the Implications on Supply and Use  
of Chemicals in Irish Businesses**

1 November 2018


Outi Tunnela  
Regulatory Advice team  
European Chemicals Agency

**Where are we today?**



## The progress of a withdrawal: Article 50 of the Treaty of the European Union

Today	30 March 2019 Withdrawal	31 December 2020
Acquis	Acquis + Full Alignment No decision making No trade agreements	Provisions of Agreement
Membership	Transition	Future Relations
TEU Negotiation and ratification of Withdrawal Agreement by Council and EP	Withdrawal Agreement + transitional arrangements + outline of the framework for future relations  Negotiations of future relations only possible with a "third country"	Agreement depends on ratification by EU-27 Member States (mixed agreement)



# No agreement at EU summit 17 Oct

No advances

The UK and EU still have another chance for a deal, at an EU summit on 13 and 14 December.

Negotiators consider extending the transition period.

# Impact on supply chains

If the UK is no longer part of EU REACH, then

UK Registrants or Authorisation holders will no longer be EEA companies

Downstream companies in the EEA suddenly become chemical importers

Putting new REACH registrations and authorisations in place will take years

This will affect 10,000's of chemical products, including mixtures

New importers may choose NOT to register or authorise due to time/cost

Users of affected chemical products may have disrupted supply

Long-lifecycle products with high safety standards heavily impacted

E.g. Aerospace and Nuclear



# Transition period in EU and UK

## Transition period

Acquis applies to UK as if MS (similar to EEA), including four freedoms

As “third country”, UK not part of decision-making; not in institutions (bodies or agencies)

EU regulatory, supervisory, enforcement instruments apply

No UK trade agreements

EU trade partners to agree

## Implementation period

- UK Withdrawal Bill converts EU acquis into UK law
- No deviation from acquis during transition period
- Devolved responsibilities
- Domestic debate on transition and final accord (“Customs Union” v. “Global Britain”)
- Industry: customs union



# **ECHA's preparedness**

Wide scope of actions underway

Working assumption:

UK withdrawal on 30 March 2019

No Withdrawal Agreement concluded / ratified  
(for now)





We do not have any role in the negotiations – but we cannot sit and wait, either



# Principles for preparations

- Central coordination since June 2016 (towards Commission, press enquiries, helpdesk enquiries)
- Sole current legal basis: Triggering of Article 50 – two-year withdrawal period
- ECHA is not party to the negotiations
- Alignment with European Commission
  - Task Force 50
  - Directorate for preparedness (General-Secretariat)
  - DGs GROWTH, ENV, SANTE (Brexit contact persons)

# What do we need to do?

- Regulatory preparations
- Review of IT-tools
- Prepare guidance for companies
- Prepare ourselves...

# Regulatory preparations



## The 'new normal' after the UK withdrawal\*

\*companies may benefit from transition period; immediate impact on authorities

Being in a third country, UK companies will

- see their REACH registrations, authorisations granting access to the EU market becoming non-existent
- need to change, by e.g. appointing an Only Representative etc., to retain access to the EU market
- if OR for third country companies, need to change to EU-based OR

UK authorities will

- No longer participate in EU regulatory processes
- No longer have access to ECHA databases
- No longer be part of or send experts to ECHA bodies
- No longer need to have a REACH/BPR/CLP helpdesk

## **Regulatory preparations:** **Withdrawing regulatory tasks from the UK authorities (1)**

- February 2018 -> no more UK rapporteurs
- Transfer of evaluation work to other MSCAs
  - REACH: as of March 2018 substance evaluations
    - Succession decided at CARACAL
  - BPR evaluating or reference MS
    - On-going consultation on Draft delegated Regulation amending 1062/2014 (active substances/product-type combinations for which the UK has been designated as the evaluating competent authority)

## **Withdrawing regulatory tasks from the UK authorities (2)**

Impact on various regulatory processes: *e.g.*, fate of testing proposals from UK, SEV decisions issued to UK companies

Participation of UK experts in ECHA Committees ends 30 March 2019

Ending UK participation in ECHA expert groups

- UK experts no longer to take part in working groups (PBT, ED, Nano, etc.)

## **Excluding UK actors from ECHA's networks**

Security Officers Network

Helpdesks network (HelpNet)

Risk Management and Evaluation platform (RiME)

Accredited stakeholder organisations (monitor relocation to EU-27/EEA)



## **How to still retain some of the expertise...?**

Forum: possibly inviting UK to attend during transition period

Could we invite UK experts to join as observers in e.g. HelpNet?

**And all this affects you how...?**

# Effects on companies (1)

## **REACH, joint submissions**

See ECHA's advice on taking over role of "disappearing" LR ahead of UK withdrawal date

## **REACH, dossier evaluation decisions issued to UK companies**

Member registrants to be involved in conjunction with new addressee policy

## **Substance evaluation decisions, surrogates**

Requesting surrogate companies by UK withdrawal date

## Effects on companies (2)

### Fate of REACH authorisations from the UK

- UK manufacturer -> OR
- EU27 DU -> change of supplier unless OR takes over, own AfA

### Data-sharing and disputes

### Flag UK-sourced data on ECHA website?

# Effects on companies (3)

## C&L notifications

UK submissions will become invalid -> new notification (if C&L is not in REACH registration)

**BPR** – suppliers, applications...

<https://ec.europa.eu/info/files/qa-biocidal-products>

# Review of IT-tools



# Re-tooling IT-tools

## ECHA

Submission tools (REACH-IT, R4BP3, ePIC, PCN)

Helpdesk network tool

Enforcement co-op tools

Dissemination Portal

Internal tools

...

## UK

- Developing own IT-tools
- “BREACH-IT” and other submission functionalities
- No coordination with ECHA

## Discontinuing access by UK authorities to ECHA's databases

Shutting down access to databases

Monitoring downloads

Access of UK to co-operation fora





# Preparing guidance for companies



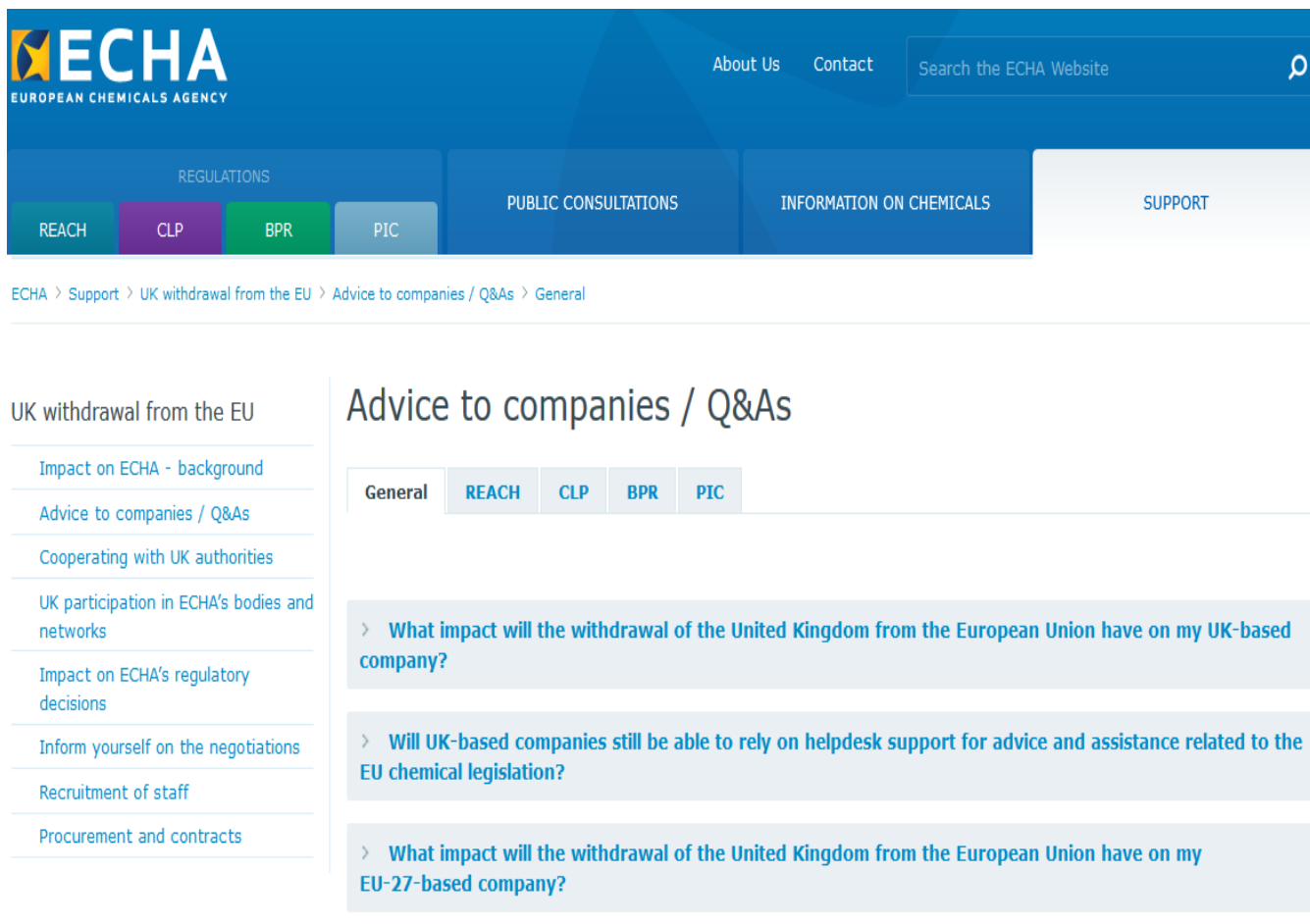
## Webpage: “The UK’s withdrawal from the EU”

Logic: Prepare for withdrawal date: 30 March 2019!

<https://echa.europa.eu/uk-withdrawal-from-the-eu>

 <p>Impact on ECHA – Background information</p>	 <p>Advice to companies / Q&amp;As</p>
 <p>Cooperating with UK authorities</p>	 <p>UK participation in ECHA’s bodies and networks</p>
 <p>Impact on ECHA’s regulatory decisions</p>	 <p>Inform yourself on the EU-UK withdrawal negotiations</p>
 <p>Recruitment of staff</p>	 <p>Procurement and contracts</p>

# ECHA's webpages for reference

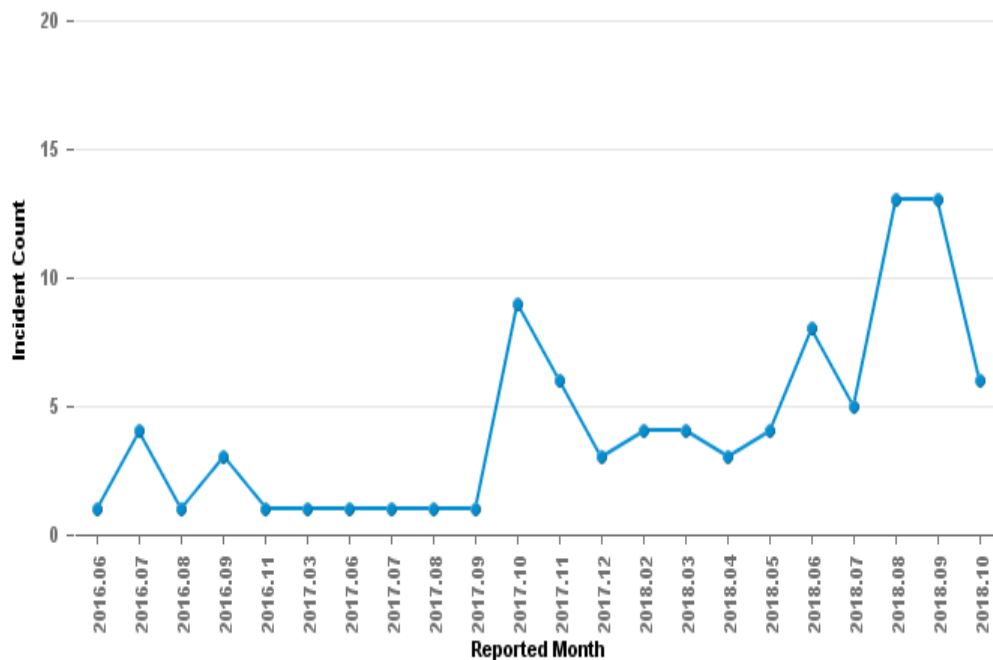


The screenshot shows the ECHA website interface. At the top left is the ECHA logo and name. To the right are links for 'About Us' and 'Contact', and a search bar labeled 'Search the ECHA Website'. Below this is a navigation menu with categories: 'REGULATIONS' (containing REACH, CLP, BPR, and PIC), 'PUBLIC CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The breadcrumb trail reads: 'ECHA > Support > UK withdrawal from the EU > Advice to companies / Q&As > General'. On the left side, there is a sidebar menu for 'UK withdrawal from the EU' with links to 'Impact on ECHA - background', 'Advice to companies / Q&As', 'Cooperating with UK authorities', 'UK participation in ECHA's bodies and networks', 'Impact on ECHA's regulatory decisions', 'Inform yourself on the negotiations', 'Recruitment of staff', and 'Procurement and contracts'. The main content area is titled 'Advice to companies / Q&As' and has a sub-menu with 'General', 'REACH', 'CLP', 'BPR', and 'PIC'. The 'General' tab is selected, showing three questions with expandable arrows: 'What impact will the withdrawal of the United Kingdom from the European Union have on my UK-based company?', 'Will UK-based companies still be able to rely on helpdesk support for advice and assistance related to the EU chemical legislation?', and 'What impact will the withdrawal of the United Kingdom from the European Union have on my EU-27-based company?'.

# Upcoming re-vamp

- More visibility
- Structured by role of company
- Better accessibility of Q&As

# Questions to ECHA helpdesk on Brexit



# The future EU-UK partnership



## **Future partnership can only be negotiated with non-EU country**

First, the Withdrawal Agreement

Withdrawal Agreement can only include “overall understanding on the framework for the future relationship”

No other linkage between Withdrawal Agreement and future relations

Negotiation after conclusion of the Withdrawal Agreement and after withdrawal per 30 March 2019 can take years

## **Transition arrangement (draft withdrawal agreement)**

### Article 121: Transition period

There shall be a transition period, which shall start on the date of entry into force of this Agreement and end on 31 December 2020.

### Article 122: Scope of the transition

Unless otherwise provided in this Agreement, Union law shall be applicable to and in the United Kingdom during the transition period.



**Would apply generically to all EU institutions and agencies!!**

## Article 123 (5): Institutional arrangements

By way of derogation from paragraph 1 and from Article 6, during the transition period, representatives or experts of the United Kingdom, or experts designated by the United Kingdom, **may, upon invitation and on a case-by-case basis**, exceptionally **attend meetings** or parts of meetings of the committees referred to in Article 3(2) of Regulation (EU) No 182/2011, of Commission expert groups, of other similar entities, or of bodies, offices or agencies where and when representatives or experts of the Member States or experts designated by Member States take part, provided that one the following conditions is fulfilled:

- (a) the discussion concerns individual acts to be addressed during the transition period to the United Kingdom or to natural or legal persons residing or established in the United Kingdom;
- (b) the presence of the United Kingdom is necessary and in the interest of the Union, in particular for the effective implementation of Union law during the transition period. During such meetings or parts of meetings, the representatives or experts of the United Kingdom or experts designated by it shall have no voting rights and their presence shall be limited to the specific agenda items that fulfil the conditions set out in point (a) or (b).

# A role for ECHA?

## UK White Paper of February 2016:

A number of EU agencies, including **the European Chemicals Agency (ECHA)**, are responsible for enforcing particular regulatory regimes, or for pooling knowledge and information sharing. **As part of exit negotiations the Government will discuss with the EU and Member States our future status and arrangements with regard to these agencies.**

## EU negotiation guidelines, 29 April 2017:

Preserving the **integrity of the Single Market excludes participation based on a sector-by-sector approach. A non-member** of the Union, that does not live up to the same obligations as a member, **cannot have the same rights and enjoy the same benefits as a member.**

**Time is running short –  
but there's still a long  
road ahead.**

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# Questions and Answers

## Session 2



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# Closing remarks



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