



“Brexit”: its effect on Chemical Regulations in the UK ... & rest of the EU

Poison Centre Notification in the EU

SCHC Spring Meeting, Las Vegas, NV

Dr. Iain A. MacKinnon, 19th March 2019

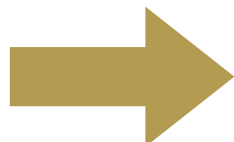
Agenda

- The EU and REACH
- Brexit:
 - What is it ?
 - Potential Consequences for Chemicals Regulation
- Poison Centre Notifications: a new system in the EU

The European Union



- **28 Member States:** sovereign & independent but ...
- ... they have **pooled** sovereignty in certain areas where they have decided to work together with decisions taken at an EU level
- **The Single Market and the Customs Union** allow people, goods, services, and money to move almost as if it were a single country.
- Many Technical, Legal, and Bureaucratic Barriers to trade were removed and common systems instituted
- **Regulation of Chemical Substances** was one such area ...



European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals = **REACH** administered by the European Chemicals Agency, **ECHA**

Brexit – withdrawal of the UK from the EU

- A slim majority of those who voted in a UK-wide referendum in June 2016 were in favour of the UK leaving the EU
- 29 March 2017: Theresa May invokes Article 50 of the Treaty on European Union; in other words, formally gave notice that the UK would be leaving and started a “2 year clock” running.
- A Withdrawal Agreement, which would allow a transition period until Dec 2020, was agreed between the EU and UK Government in Nov. 2018 but ...
- ... it was rejected by the UK Parliament!
- Theresa May is asking EU for further concessions on the Withdrawal Agreement but ...
 - ... they say it is not up for discussion.
- Discussions continue but the default position if no other legislation passed by UK Parliament is that UK will leave the EU on 29th March 2019 without any deal or agreement as to the future relationship between the EU and UK. If there is “no deal”, no Withdrawal Agreement then ...



➔ REACH would **immediately** no longer apply in the UK

What are the options?



The UK leaves with no
Withdrawal Agreement
("no deal scenario")



Withdrawal agreement
ratified

Really only 2 options? *Well, the UK could decide just to stay but despite belated support from the main opposition party for a 2nd or Ratifying Referendum, this is unlikely!*

What are the options?



The UK leaves without a deal (“no deal scenario”)



Withdrawal agreement
ratified

“Brexit Day” is currently set for
29th March 2019 ... it could be
delayed but UK still leaves with
“no deal”

What are the options?



The UK leaves without a deal (“no deal scenario”)

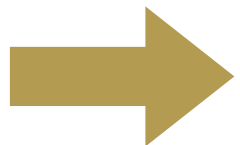


Withdrawal agreement ratified

Even if the withdrawal agreement is ratified and there is a transition period during which REACH will still apply in the UK, there is no guarantee that a deal could be struck covering chemicals regulations (e.g., UK pays a fee and stays within remit of ECHA). If not, then “no deal scenario” would apply from the end of the transition period: Jan. 2021

From REACH to UK-REACH if “no deal”

- ECHA will cancel all REACH registrations by UK companies on 29th March 2019 (or which ever date the UK leaves with “no deal”)
 - No post-Brexit Day transition period
 - Companies need to act in advance if they wish to keep trading into EU
- UK authorities have been preparing for “No Deal”
 - Contingency planning!!
- New regulatory system developed: nicknamed UK-REACH
 - Transposes most of REACH into UK law
 - UK IT system developed but accepts submissions in same format as ECHA’s REACH-IT [IUCLID]
 - Requirements (studies necessary) at each tonnage band are identical to REACH
- New Transitional Arrangements



Companies will need to register twice: UK and EU

REACH Roles with regard to Brexit – *a far from comprehensive list!*

- UK-based REACH lead registrant
- UK-based importer of registered substances from the EU
- UK-based Only Representative (“OR”)
- EU-27-based co-registrant (lead registrant in UK)
- UK-based authorisation holder under REACH
- EU-27 downstream user of an authorised substance
- Manufacturer or formulator outside the EEA whose
 - Current OR is in the UK
 - Current OR is in the EU-27

Your role will dictate what options are open to you.

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UK-REACH: Transition Arrangements

Company status (and wishing to trade into UK):

- **UK-based manufacturers/ORs/importers with a REACH registration:**
 - REACH registration “grandfathered” into UK-REACH
 - Notification to UK authority within 120* days after Brexit
 - 2 years to register (same data package as REACH)
- **UK-based Importers from EU** to provide basic information about the imported chemicals within 180 days after Brexit and full registration within 2 years.
- **UK-based Importers from outside EU:** draft UK legislation is vague as to whether UK importers supplied from outside EU by companies with an EU-based OR will also have 180 days grace period or have to register immediately ... but these are existing supply chains ??!
- **Major flaw** - recognised by UK authorities as intention was to allow all trade based on a current REACH registration to continue. To be resolved ...

*was 60d but recent communications say 120d



UK-REACH: Transition Arrangements

- **Non-UK companies** can appoint a UK-based OR [UK-OR] but transitional timings are bound up with actions of the UK-based customers (i.e., importers into the UK)
 - Draft UK legislation is written from perspective of the UK-based importer
- As written, the legislation looks upon the UK-OR's registration as a "new registration" so they would need to register immediately without notification grace period ... and pay a fee to the UK.
- A non-UK company based in the EU can take advantage of the 180 day grace period offered to its customers (the importers into the UK from the EU):
 - Unclear whether a UK-OR for an EU-based company has in its own right 180 days grace period then 2 years to register
 - Legislation silent on UK-ORs for non-EU/non-UK based companies



➔ Again, clarification required by UK authorities. Their intention was not to disrupt the supply chains, especially from outside EU to UK

... and another thing: Data Rights

- Many REACH registrants do not own the technical data used. They pay for a “Letter of Access” to use the data, normally for “REACH use only”.
- Check the current status of your LoA contracts!
- Are you allowed to also use data which you previously used to register under REACH for a UK-REACH registration ?
 - Do you need to negotiate a new Letter of Access ?
 - Will it cost extra ? UK authorities hope not but it is not within their control
- Note that there is an additional issue in the drafting of the UK legislation:
 - It removes SIEFs* and so the framework for companies to come together to share data is missing
 - could mean that all registrants would need to submit a full dossier with all the technical data sections filled (IUCLID 4-7).
 - This has been challenged by industry but not yet resolved



*Substance Information Exchange Fora; a mechanism used within REACH to make co-registrants come together.

A Summary of Brexit Possibilities

1. UK leaves the EU without a Withdrawal Agreement (“no deal scenario”) so immediately on Brexit Day+1, there would be...
 - Separate regulatory regimes, REACH and UK-REACH
 - **or**
2. UK and EU sign off on Withdrawal Agreement meaning...
 - UK would no longer be a member of the EU but REACH would still apply in UK until the end of a transition period (probably Dec. 2020) during which further negotiations would lead to either...
 - A. UK stays within REACH as administered by ECHA (perhaps as an Associate Member)
 - **or**
 - B. No agreement on UK remaining in REACH and we have separate regulatory regimes, REACH and UK-REACH



Poison Centre Notification PCN

Poison Centres around the Globe

306 Poison centres in **91** countries (=46% of WHO member states)



Source: http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/

Disclosure *versus* Trade Secrets / CBI

- Information transfer / communication of hazard
 - to medical professionals, emergency responders, fire fighters
 - the public!
- Fear of trade secret disclosure
 - Exact Composition
 - Customer related info / tonnage info



PCN in Europe – current status

- Currently, Poison Centre Notifications [PCN] in individual European countries
 - 28 Member States (+ Norway, Switzerland, Liechtenstein)
 - Historic legal requirements
 - Complexity of requirements very different
 - National perspective
- Companies with very international orientation
- PCN on behalf of customers not always possible
- Process not always easy/self-explanatory and only available in national language

PCN in Europe – from 2020

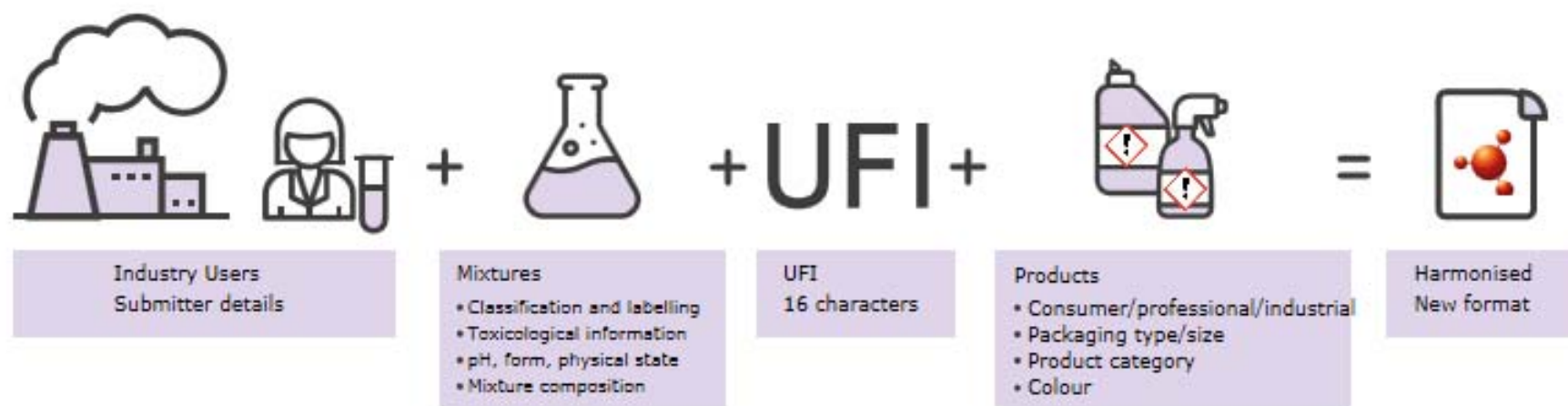
- EU Regulation (EU) 2017/542 Amending CLP-Regulation (EC) 1272/2008 by Annex VIII
 - → CLP Annex VIII
- **Harmonised requirements across EU**
 - XML format
 - What to notify
 - When to update the notification
 - Central notification
- **Unique Formula Identifier (UFI)**
 - a unique 16-character code printed on the label of the product providing ...
 - An “unambiguous link between a product placed on the market and the information ... submitted to poison centres”



PCN in Europe – from 2020

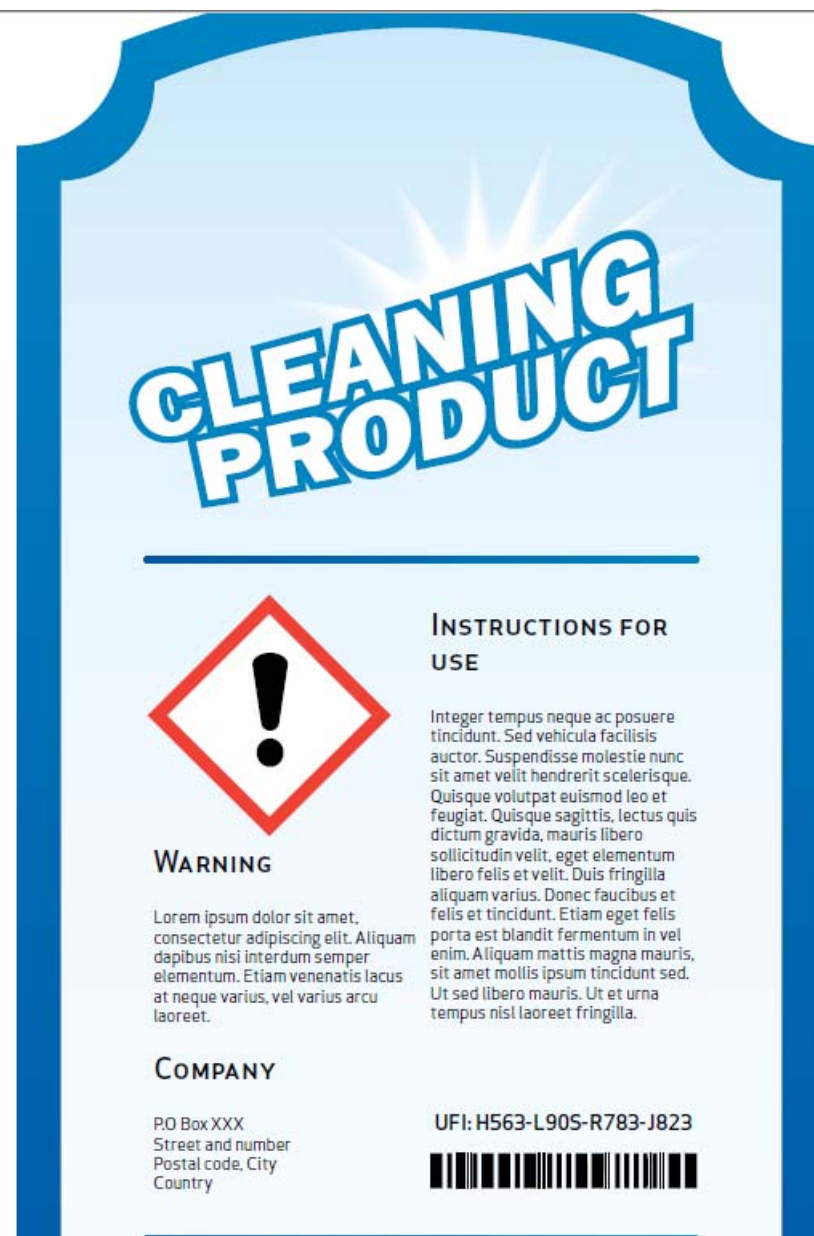
- In scope: mixtures classified for Human Health or Physical Effects (with certain exemptions)
- Duty holders are importers and downstream users placing the mixtures on the market (status of distributors to be clarified)
- Any mixtures notified under national legislation have a transition period until 1st Jan. 2025 to conform.
- Otherwise, for new or “changed” products, deadlines are
 - 1 January 2020 for consumer use
 - 1 January 2021 for professional use
 - 1 January 2024 for industrial use.

PCN Standard Information Requirements



PCN – UFI

- Poison Centre can relate UFI to a product and identify necessary steps to take in event of an incident
- It must be shown on the packaging in future (see timelines)
- It can't be decoded so protects CBI – only Poison Centres know what it refers to.
- UFIs can be communicated in the supply chain so avoiding full formulation disclosure (“mixtures in mixtures”)
- UFIs can be generated “in-house” or via ECHA supported tool



PCN in Europe – from 2020

- A new and harmonised system across the whole of the EU
 - Introduces a new concept, the UFI.
- Poison Centres will have improved access to data on hazardous mixtures
- Companies have reassurance that CBI will not be disclosed



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