BREXIT UPDATE

PHARMACEUTICAL EHS COUNSEL ROUNDTABLE

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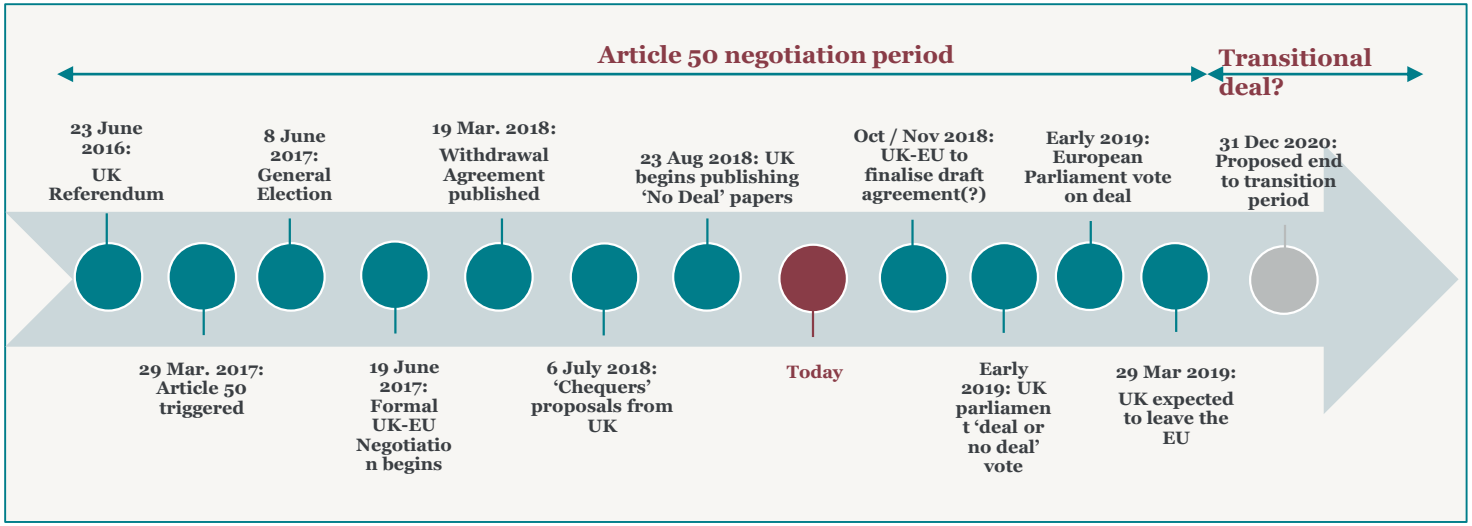
25 September 2018

DAYS SINCE THE REFERENDUM:
824

DAYS UNTIL EXIT DAY:
185

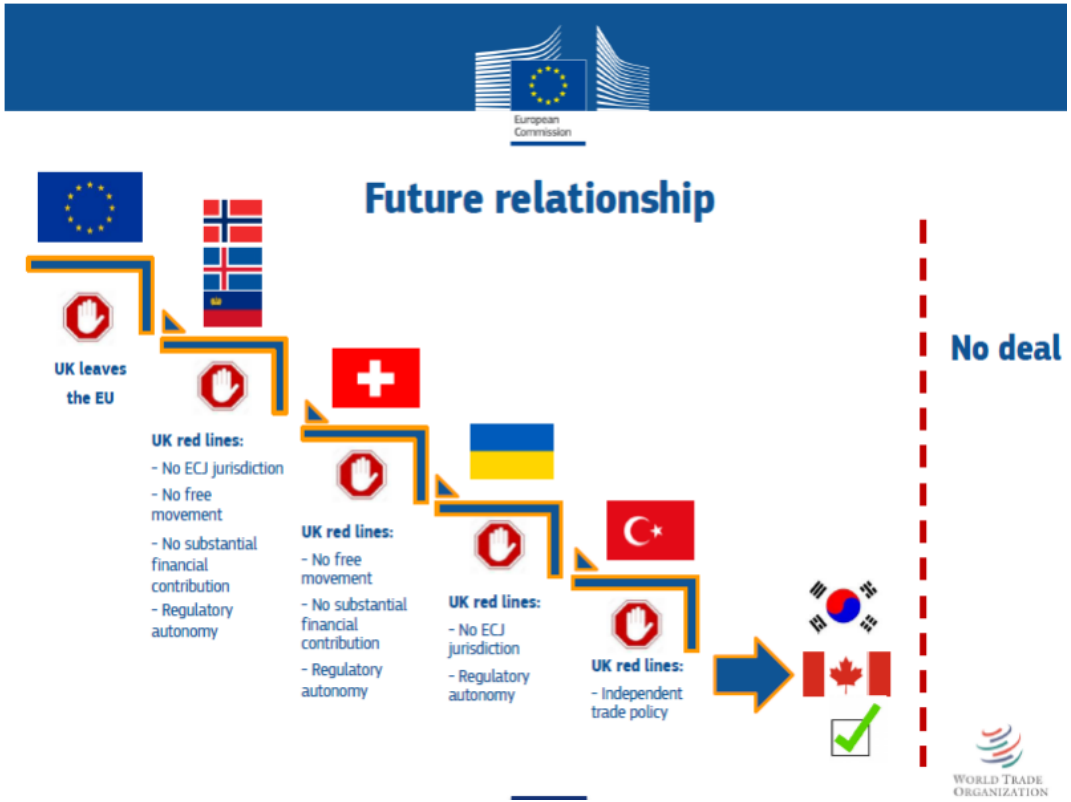
Where are we now?



- Draft withdrawal agreement published (includes transition period) – but important elements outstanding, including Irish border 'backstop'. Doesn't cover future relationship
- Current talks focused on future relationship (and Irish 'backstop') – intent is to have principles agreed at exit, with detailed agreement to be settled in the transition period

Key dates to reaching agreement…

- **23-26 Sept**: Labour Party Conference – support for a second referendum?
- **30 Sept - 3 Oct**: Conservative Party Conference – curtains for May?
- **18-19 Oct**: EU Summit
- **November**: emergency EU Summit(?)


European Commission
Future relationship
UK leaves the EU
UK red lines:
- No ECJ jurisdiction
- No free movement
- No substantial financial contribution
- Regulatory autonomy
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- No ECJ jurisdiction
- Regulatory autonomy
UK red lines:
- Independent trade policy
No deal
World Trade Organization

Future relationship: Trade –vs- Sovereignty

Chequers Proposal

- 'Official' UK government position – but dead in the water following EU Salzburg summit (EU counter-proposal awaited) / UK government splits
- Proposed a high degree of regulatory alignment in goods (not services) via a 'common rulebook' - UK would maintain a "level playing field" in e.g. environment

'Canada Plus' Model

- Favoured by many in the UK government
- 'Outcome equivalence' rather than full regulatory alignment (giving UK more flexibility in its own laws) with a system of 'mutual recognition' to smooth cross-border trade

No Deal

- Maximises UK legislative flexibility - but also trade barriers…

Potential impacts to the legislative landscape?

Some areas are less of a concern…

- for 'traditional' environmental regulation, domestic UK laws expected to remain largely the same, at least in short to medium term
- for example, the UK will 'bring down' current EU requirements around point source emissions, water quality, habitats etc. without excessive difficulty (esp. where EU Directives)
- pre-existing 'UK only' regimes (e.g. contaminated land, carbon corporate transparency regimes) set to continue (and potentially grow)

…than others

- potential enforcement gap in absence of EU Commission and ECJ
- risk of 'zombie laws' – particularly where based on EU Regulations, cross references to other EU regimes or dependent on EU surveillance / regulatory infrastructure – market access, products and trade set to be esp. impacted

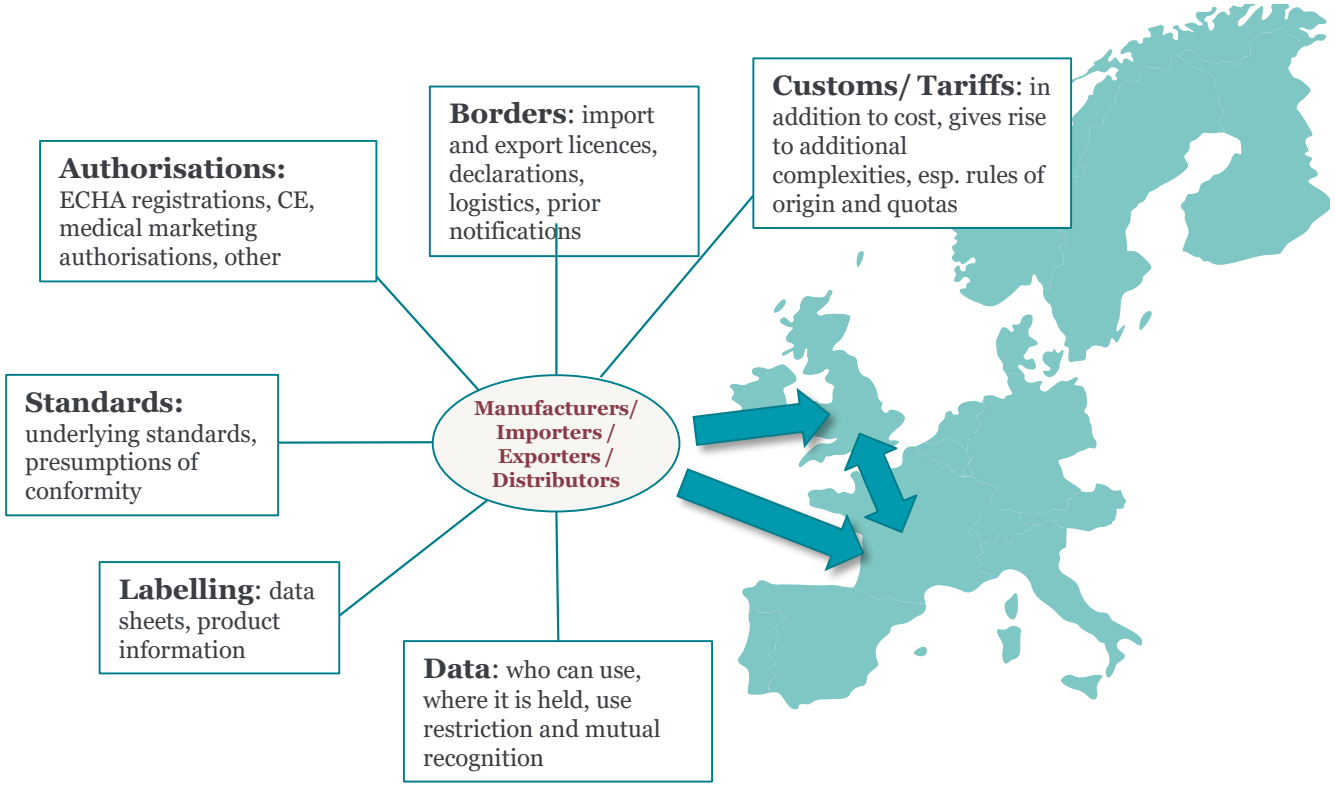
Areas of environment law likely to be most affected?

Higher Impact

Higher Impact

	Soil & Water	Emissions	Conservation	Carbon	Products
Soft Brexit	Minimal change - UK regimes largely domestic. Water quality likely to track EU developments	Minimal change - UK likely to (formally or informally) adopt EU laws	Minimal change - UK likely to (formally or informally) adopt EU laws / designations	Likely to remain within the EU ETS 'UK-only' laws already relatively prominent in this area (e.g. CRC) and will remain	Depending on precise nature of exit, could be various logistical changes to accommodate continued harmonisation / mutual recognition
Hard Brexit / No Deal	As above – but may be some divergence around water quality in the long term	Standards likely to remain broadly aligned – potentially some UK simplification / new guidance or 'BREFs'	Over time changes in designation, processes and assessment relating to habitats / certain species to be anticipated	UK could exit the EU ETS - query whether there will be, and form of, successor	Significant impacts – products to potentially meet different standards, obtain new authorisations Difficulties around quotas, proof of origin and market access

Impact on the trade of products?



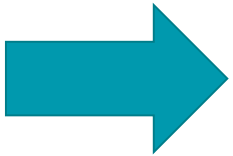
Will I need a new product authorisation to sell to UK/EU?

		Pharma / Medical Devices	Consumer Electronics	Chemicals
ACCESS TO UK MARKET	For current products, will my existing product authorisation be sufficient?	**Low risk** At present, appears existing 'EU' marketing authorisations will be grandfathered	**Low risk** Existing CE marks likely to continue to be recognised	**Medium risk** At present appears ECHA registrations will be grandfathered, but complex UK/EU interface, data issues etc. will need to be resolved
	For future products, will a new UK product authorisation also be required?	**Medium-high risk** If no 'EEA' or Swiss type outcome, could need additional UK authorisation (though may simply be duplicative of EMA process)	**Medium-low risk** Additional UK recognition could be required, at least in some areas. Is precedent (UK plugs). But would be surprising if CE mark not still recognised	**Medium-high risk** Highly uncertain. Much will depend on UK-EU agreement. However, outside an EEA-style agreement, full mutual recognition seems unlikely (and would be novel)
	Will underlying standards remain aligned?	**Medium-low risk** Risk mitigated by increasing internationalisation in standards	**Low risk** Degree of harmonisation may depend on future standing / influence of the BSI. Seems relatively unlikely UK will impose higher standards	**Medium risk** Some suggesting a more 'risk-focused' approach (cf. TSCA), but given industry links to EU would be a surprise
ACCESS TO EU MARKET	What if my existing product was manufactured and/or 'authorised' in the UK?	**Medium risk** May need to transfer authorisation to EU. Change in notified body adds complexity. May also be issues if UK supply chain, e.g. additional active ingredient 'importation' requirements	**Low risk** Nature of regime designed to accommodate manufacture, testing and compliance functions taking place overseas. Responsibility will shift to EU 'importer' however	**Medium-low risk** May need to transfer registration to EU (and/or appoint EU Only Representatives there) – must adhere to EU market access rules

Supply Chain?

Issues

- Availability and disruption
- Cost impact – increased custom tariffs on feedstock / components – new EU export tariffs
- Quotas?
- Potential for additional registrations and authorisations – evidence files, conformity testing and proof of origin
- Tax and business efficacy for UK manufacture / assembly (or not)
- Regulatory risk



Next Steps

- Supply Chain Mapping
- Contingency Planning
- Contractual Options

YOUR BREXIT RESPONSE STRATEGY

With "Brexit day" (29 March 2019) six months away, contingency planning is now essential. But considerable uncertainty remains – making the task of preparing for Brexit all the more challenging. So what should you do?

Plan for the transition

If the UK leaves the EU with the benefit of a transition period relatively little should change immediately. But businesses still need to consider their exposure if some international agreements between the EU and third countries cease to apply during the transition.

Plan for a hard Brexit

Increasingly, an immediate hard Brexit cannot be ruled out. Our view is that businesses should hope for the best, but plan for the worst. This means making contingency plans for a hard Brexit – just as you would make plans for other eventualities that you hope will never happen (such as a serious fire at your premises).

Plan for the end of the transition

Under the draft Withdrawal Agreement, the transition is scheduled to end on 31 December 2020. In practice, we think the UK will need to ask for an extension – but if those negotiations were to fail (which can't be ruled out), businesses would effectively face a hard Brexit from January 2021.

How can we help?

Our 'Brexit response programme' will help you understand where your business is most vulnerable to adverse impacts from Brexit and what you can do about it. Time is short – so we will focus only on the material risks and move swiftly from information-gathering and analysis to actionable recommendations and implementation.

Our environmental work on Brexit

- Working with UK Environmental Law Association on various Brexit representations to UK Government
- Working with UK Government's Environmental Audit Committee on Brexit inquiries
- Hosting International Environmental Law Network seminar focused on Brexit
- Regular Brexit roundtable events with clients and government ministers
- Advising various clients on impacts of Brexit, including regular tailored progress updates

Top EMEA environment & regulatory ranking

of any UK law firm

Who's Who Legal 2017

Douglas Bryden

Thought Leader:

Who's Who Legal 2017

Band 1: Environment

Chambers UK, 2018

Owen Lomas

Senior Statesman

Chambers UK, 2018

"Notable expertise in regulations governing the production and distribution of chemical and electrical products in Europe"

Chambers 2018