Steptoe

Brexit and Biocides

Practical tips and tricks: *what companies need to do now*

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"exceptional expertise on EU regulations on chemical…and a great ability to understand the complexity of businesses."
Chambers & Partners Europe, 2019

- **English barrister, *Avocat* at the Brussels Bar**, partner resident in Brussels.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.

Firm Overview

- International law firm, particular strengths in regulatory issues and litigation
- Over 500 professionals in the US, Europe and China

Complex Litigation & Discovery Center

EU Team: Chemical Regulation, Environment & Life Sciences

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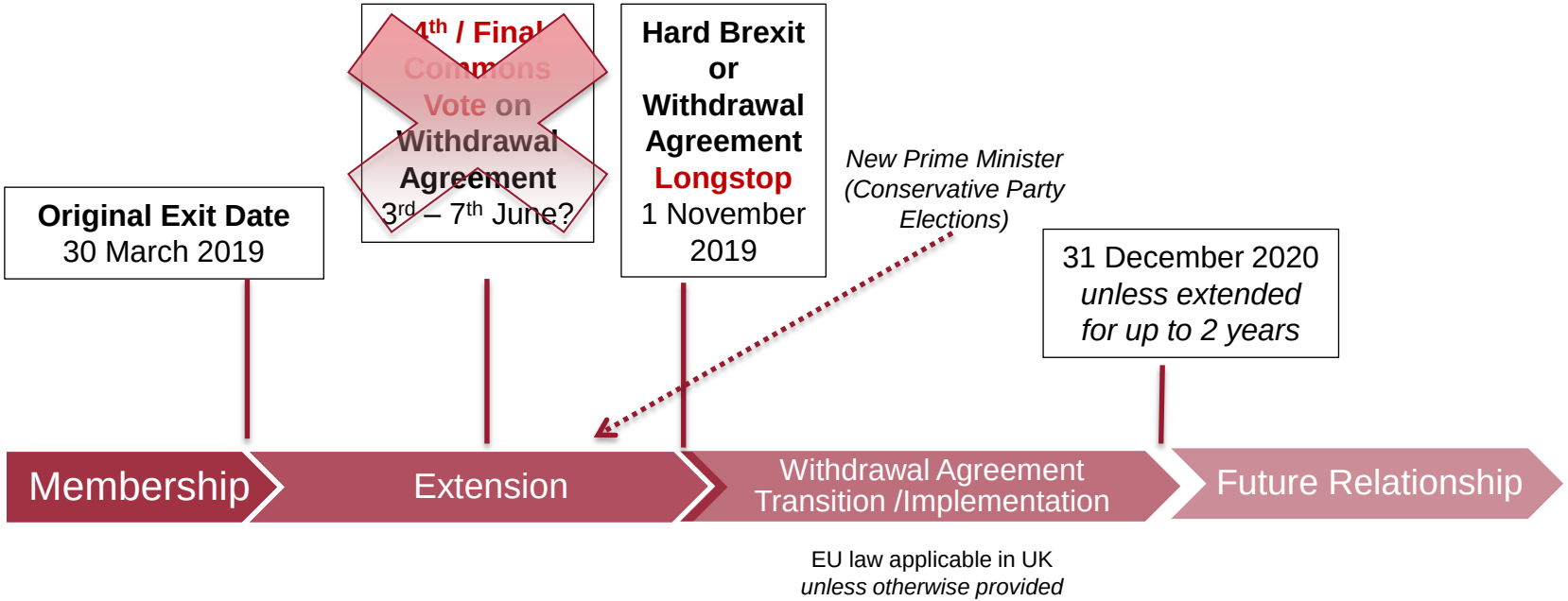
Brexit & Biocides: Today's Topics

1. Overview on Brexit status
2. Direct Impacts for EU Biocides Regime
3. Direct & Impacts for Future UK Biocides Regime
4. Data sharing for Biocides (and other chemicals regimes)
5. Take away messages

1. OVERVIEW ON BREXIT STATUS

Timelines

- UK becomes a third country
- Impact will depend on (i) existence and (ii) content of Withdrawal Agreement



Hard Brexit

- No agreement reached by exit date:

  "*All Union primary and secondary law **ceases to apply** to the United Kingdom…" from withdrawal date* (EC Notice to Stakeholders)

- UK third country:
  - WTO tariffs will apply
  - Trade deals to be negotiated
  - No mutual recognition (certifications, authorizations, standards for circulation of goods)

Hard Brexit

- UK European Union (Withdrawal) Act 2018 applies:
  - Repeal of 1972 European Communities Act
  - Retention of existing EU law
  - Mechanism to deal with "deficiencies" - during a 2 year period UK must enact legislation covering areas formerly governed by EU law, e.g.:
    - S.I. 2019 No. 720 **The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019**, amending the:
      - Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;
      - Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013;
      - Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015;
      - EU BPR and its EU Implementing Regulations & EU REACH

2. DIRECT IMPACTS FOR EU BIOCIDES REGIME

Direct impacts on EU Biocides Regime

- HSE Role
- Pending Approvals (AS)
- Article 95 list
- Biocidal Product Authorisations

HSE Role: EU applications for approval/authorization

- Even if Soft Brexit (withdrawal agreement):
  - *"During the transition period, the United Kingdom shall not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union or of Member States acting jointly referred to in [the BPR]"*
  - *"The United Kingdom shall transfer without delay to the competent authority of a Member State (…) all relevant files or documents in relation to assessments, approvals and authorisations ongoing on the day before the date of entry into force of this Agreement and led by a United Kingdom competent authority in accordance with Regulation (EU) No 528/2012 (…)"*

EU Pending approvals (AS)

- Evaluation of existing AS/PT combinations in the review programme is attributed by law to "a Member State"
- Delegated Regulation 2019/227 amending the Review Programme Regulation (Regulation (EU) No 1062/2014)
  - Transfer of 18 active substance dossiers
  - MS may request fees *"Notwithstanding the stage of evaluation of the application"*
    - Applicant informed at the latest by 30 April 2019
    - Application rejected if the participant fails to pay the fees
  - Deadline to submit conclusions and assessment reports: at the earliest 31 December 2020
- Application for renewal
  - No obligation for initial eCA to act as eCA for renewal
- New applications for approval, location of applicant not restricted to EEA

EU Article 95 list

- Article 95: "*unless either the substance supplier or the product supplier is included in the list*"
  - Substance supplier*: "A person established within the Union who manufactures or imports a relevant substance"*
  - Product supplier*: "A person established within the Union (…) who manufactures or makes available on the market a biocidal product "*
  - Need to transfer "in due time"
  - EU representative?

EU Biocidal product authorisations

- Authorisation Holder (AH)
  - *"the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorization"*
  - Need to transfer existing Auths. before exit date

EU Biocidal product authorisations

- Possibility for Mutual recognition
    - EU-27 MS recognition based on national authorisation delivered by the UK
        - Before the exit date – *unaffected*
        - After the exit date – *no longer possible*

EU Biocidal product authorisations

- How to approach applications for EU-27 Authorisations (with UK):
  - New
  - Pending
  - Change
  - Renewal

3. DIRECT & INDIRECT IMPACTS FOR FUTURE UK BIOCIDES REGIME

Article 95 List UK

Grandfathering Article 95 list by drag and paste, but then….

2 years (from exit day) to secure rights:

- UK establishment
- Submit (assuming no data protection and data obtainable to UK):
  - complete substance dossier for the relevant substance; or
  - LoA to complete substance dossier and the data owner has submitted the data to the competent authority and the competent authority holds the data after exit day.

Product Authorisations UK

Grandfathering of Authorisations - will remain valid until expiry date subject to:

- the authorisation holder being established in the United Kingdom within **365 days** after exit day; and
- supplying the competent authority with scientific and authorisation data:
  - by the date of any application for renewal or amendment; or
  - within **60 days** on request by competent auth.

AS Transitional Procedures UK

Pending AS <u>application</u> on exit day, maintained by applicant if **within 90 days**:

- resubmits the application and any supporting data to the competent authority; or
- LoA supported by resubmission of application + data owner resubmits the data.

Pending AS <u>renewal</u> – same principles and timelines (except if UK was not priori eCA in which case **180 days** submission deadline).

Product Transitional Procedures

Pending BP <u>applications</u> for mutual recognition on exit day, maintained by applicant if **within 90 days**:

- resubmits the application and any supporting data to the competent authority; or
- LoA supported by resubmission of application + data owner resubmits the data.

Same principles and timelines if UK was not RefMS but only a concerned Member State, in which case **180 days** submission deadline (and also mirrored for renewals).

Direct Biocides impacts – UK

Overall Result is Duplication of:

- authorization holders – for both UK and EU purposes
- data rights to support duplication ("*same information as was previously submitted*")

4. DATA SHARING

Data Rights Essentials

- Data agreements typically split into three categories based on *position* entity:
  - Data holder
  - Data accessor
  - Part of task force/consortium

- Companies should <u>not</u> need to ask for permission to use *all* data rights – categorize/map agreements (drilling down for each data category):

USE	Clearly allowing for use	Clearly excluding use:	Ambiguous
in EU by affiliates (or OR) for REACH	No further action	Negotiate terms	Case by case assessment
outside EU by affiliates for other purposes (e.g. UK REACH)	No further action	Negotiate terms	Case by case assessment

Data Rights Essentials – Negotiations

- **For use of EU access rights in the EU27 – no changes:**
  - Same rules on mandatory sharing and compensation: scope and fair, transparent and non-discriminatory test
  - Same remedies – ECHA data sharing disputes
  - Non-duplication vertebrate animal studies
  - Contractual rules (may benefit related entities)

Data Rights Essentials – Negotiations

- **For use of EU access rights in the UK…**
  - EU (Withdrawal) Act indicates - same rules (generally) + mechanism to deal with "deficiencies" (but differing disputee mechanism fora)
  - Could mean very similar *system* but:
    - Extraterritoriality (when data owner not in UK market)
    - Will payments already made under BPR + REACH be discounted?

For all regimes: Impacts on contracts – EU and UK

- **Scope of data rights**
  - Transfer / Affiliates
  - Limitations on assignability
  - Scope limited to (EU) BPR
  - Geographical scope (“European Union”)
  - Required establishment in EU
  - Use limitations (specific concern for “existing data”)

- Ot**her types of agreements**
  - Sale, supply, services,…
  - New agreements with Brexit clause

5. TAKE AWAY MESSAGES