Steptoe

GB Brexit: First Experiences – Tips, Tricks and Pitfalls

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Darren Abrahams

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"exceptional expertise on EU regulations on chemicals…and a great ability to understand the complexity of businesses."
"When it comes to things like REACH and chemical law, he is the best"
Chambers & Partners Europe, 2019 and 2020

- **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.
- Chambers & Partners **Europe-wide** Regulatory (2020): **Agro/Food and Environment** Legal Rankings: **top tier practitioner in both, and Steptoe listed as a band 1 firm.**

Hannah Widemann

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- **Belgian-qualified associate**, ***Advocaat*** **at the Brussels Bar.**
- She advises clients on **EU regulatory compliance** questions in the areas of **chemical** and **product regulations**, including **REACH**, **CLP**, **biocides**, **plant protection products**, and **fertilizers**.
- Her work includes **product defense** and **litigation strategies** before the European Court of Justice and the Board of Appeal of the European Chemicals Agency (ECHA), as well as supporting clients with (data sharing**) negotiations**, **contracts**, and **potential disputes**.

Topics

- **Data Protection & Sharing**
  - Supply Chain Obligations
  - Assessment of Data Rights & Protection Periods
  - Rights management: contractual & regulatory
  - Every effort negotiations
  - Remedies

- **Consortia & Taskforces**
  - Practical considerations

- **Regulatory Divergence**
  - Asymmetrical data sets
  - Data duplication

- **Takeaway Messages**

Data Protection & Sharing

Supply Chain Obligations

- **What is my role (per AS/BP)?**

Regulatory	Supply Chain
• Art. 95 supplier	
• AS RP Participant • Supporting AS renewal	• AS manufacturer or purchaser
• Supporting BP (re-)authorisation • BP Authorisation holder	• BP formulator or purchaser • UK importer of Ass, BPs and treated articles
• Data owner and/or accessor	
• Consortium/TF member	

- **What upstream compliance is ensured?**
- **What do downstream actors require from me?**

Requires up and downstream supply chain communications and undertakings.

Supply Chain Obligations

- **Article 95 Suppliers List:**
  - 31 December 2023 + UK establishment / representative

- **Resubmission for Pending AS approvals/renewals, and Pending Product authorisations**:
  - 31 March 2021 if UK was eCA / refMS /receiving CA
  - 29 June 2021 if UK was not eCA /erfMS / receiving CA

- Pending Nat. Auths / simplified / same / change or amendment: 31 March 2021.

- **Existing Authorisation**
  - 31 December 2021 UK establishment requirement / no "representative" option
  - Possibility for HSE to call in data in within 60 days
  - Remains valid until expiry date.

Ultimately requires submission of (i) full dossier to HSE or (ii) LoA and data owner re-submits.

Supply Chain Obligations: Co-formulants (REACH)

Deadline Post 28 October 2021	Tonnage	Hazardous Property
2 years from 28 October 2021	1000 tonnes or more per year	• carcinogenic, mutagenic or toxic for reproduction (CMRs) - 1 tonne or more per year • Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year • Candidate list substances (as at 31 December 2020)
4 years from 28 October 2021	100 tonnes or more per year	Candidate list substances (as at 27 October 2023)
6 years from 28 October 2021	1 tonne or more per year	

30 April 2021 *basic notification had to be submitted to carry-over registrations*

27 October 2021 *DUIN notification*

Ultimately requires submission of (i) full dossier or (ii) LoA <u>and</u> data owner re-submits.

Assessment of Data Rights

- Data agreements typically split into three categories based on *position* entity:
  - Data holder
  - Data accessor
  - Part of task force/consortium
- Companies should not 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 BPR/REACH	No further action	Negotiate terms	Case by case assessment
outside EU by affiliates for other purposes (e.g. GB BPR/REACH)	No further action	Negotiate terms	Case by case assessment

Assessment of Data Rights & Protection Periods: Biocides

All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95)

ACTIVE SUBSTANCE (AS)	BIOCIDAL PRODUCT (BP)
Approval of a NEW AS **15 years** from the first day of the month following the date of adoption of AS approval decision (i.e. adoption of Implementing Regulation) of each AS/product-type combination	**BP with a NEW AS** **15 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
Approval of an EXISTING AS **10 years** from the first day of the month following the date of adoption of AS approval of each AS/product-type combination If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) **December 31, 2025.**	**BP with ONLY EXISTING AS** **10 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
RENEWAL/REVIEW of an AS approval **5 years** from the first day of the month following the decision on renewal/review of a the approval of an AS	**RENEWAL/AMENDEMENT OF BP AUTHORIZATION** **5 years** from the first day of the month following the decision on the renewal/amendment of a BP authorization

Under GB BPR where products already "authorised in the United Kingdom prior to exit day" time runs from then "as it had effect immediately before exit day" i.e. ***you do not start counting again but time continues to run.***

Assessment of Data Rights & Protection Periods: REACH

Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least 12 years previously can be used for the purposes of registration by another manufacturer or importer (Art. 25(3) REACH)

Calculation from date of submission to ECHA (under Directive 67/548/EEC or REACH):

- NOT earlier date of generation of the study
- NOT potentially later date of publication on ECHA's website.

*Under GB REACH inserts additional start date: "or under EU REACH before exit day" i.e. time runs from EU REACH submission and you **do not start counting again.***

Latest EU Submission Date	Latest EU/GB Protection Expiry	Latest GB Submission Date (from 28 Oct 2021)
31 May 2018	31 May 2030	28 October 2027
31 May 2013	31 May 2025	28 October 2025
30 November 2010	30 November 2022	28 October 2023

Expiry of data protection before GB latest submission deadline.

Subsequent data calls post-registration: 12 year rules applies.

Data Rights Management: Contractual

Data shared once under EU regime

100% EU compensated

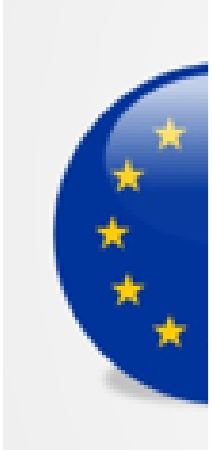
Same data to be shared under GB regime

"New"100% ?

Are GB rights granted contractually in existing (EU) agreement?

Data Rights Management: Regulatory

Data shared once under EU regime



Only 50% EU compensated

Case A-001-2016

BoA held ECHA was not entitled to examine the cost formula which data owner proposed during the negotiations, but could only make an assessment of the parties' efforts: ECHA "*…went beyond its scope of assessment in concluding that the division of costs by two was manifestly unfair…*" and "*overstepped its role*".

Same data to be shared under GB regime

Deduction?

Limited to 50%?

If not granted contractually: Is there a rule against "profit"?

Data Rights Management: Regulatory

Data shared once under EU regime

Same data to be shared under GB regime

What if data owner <u>does not plan to use data in GB for itself?</u> Extraterritoriality?

Scope of data sharing & "every effort" obligations

1. **Look carefully at NDA/Confidentiality/ "Every Effort" Agreement for terms which are not necessary:** e.g. technical equivalence or chemical similarity and agreements not to negotiate is not demonstrated.
2. **Focus on demonstrating your "efforts"** (arguably more important than your substantive position – even if wrong in law).
3. **Recent tend to focus more on the substantive fair, transparent and non-discriminatory (FTND)** conditions - esp. REACH - (not just efforts – but the dividing line is not always clear as to when the calculation *methods* employed are being evaluated.
4. **Justification for study values** (e.g. proof of costs or invoices) an important part of a transparent approach but a global sum decoupled from the individual study values also requires consideration (efforts assessment)
5. **Arbitration body alternative route is not mandatory**, so openness to submission to one cannot be construed as a substitute for the obligation to make every effort to reach a data sharing agreement.
6. **No obligation on Data accessor to agree to terms and conditions that may not be fair, transparent and non-discriminatory.**

Contrasting Remedies Post-HSE Decision: GB REACH and BPR

GB REACH	GB BPR
First-tier Tribunal (a) may dismiss the appeal, or (b) if it allows the appeal may (i) quash the decision and (if appropriate) remit the matter to the Agency, or (ii) substitute for the decision any other decision which could have been made by the Agency. **Suspensory effect** **Reference to fee deleted**	**Secretary of State** **Suspensory effect** **Fee may be payable**

Consortia & TaskForces

Consortia & TaskForces: Practical Considerations

- **Will <u>all</u> EU consortia members want to submit data to the HSE?**
  - Existing Data (individually owned)
  - New Data (generated and owned jointly)

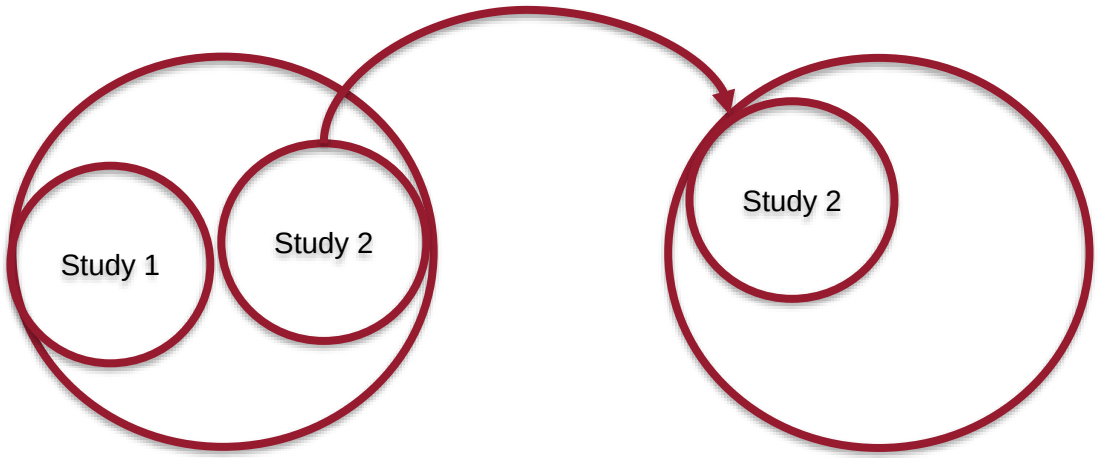
- **Different deadlines for:**
  - Member companies, their Customers, Third Parties
  - Submission on BP dossiers (containing AS data)

- **New consortia (or subgroups) for GB market:**
  - Biocidal Products
  - AS evaluations (ongoing)
  - AS renewals

- **LoAs:**
  - Costs
  - Wording (entities, submission of actual data etc.)

Regulatory Divergence

Effects of Extraterritorial Data Owners



Effects of Extraterritorial Data Owners

- If data gaps: risk of duplication?

Article 62(1) BPR

"In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation."

- Risk of less favourable results? Sufficient time to generate (if possible)?

- EU and GB regimes may be making assessment based on different data sets.

Takeaway Messages