UK REACH and GB BPR:

Data Sharing, Disputes and Appeals

Chemical Watch Webinar
8 December 2021

Steptoe

1. Introduction

Today's discussion

SPEAKERS:

Judge Moira Macmillan Lead Environment Judge, First-tier Tribunal, General Regulatory Chamber

Simon Tilling
Partner, Steptoe & Johnson

Darren Abrahams
Partner, Barrister and Avocat, Steptoe & Johnson

TOPICS:

- Why we need to think about data sharing for UK REACH and GB BPR
- Data protection periods
- Data negotiations
- Disputes on data sharing and data sharing appeals
- The appeals process and the role of the First-tier Tribunal, GRC
- Lessons to learn from the EU regime and Board of Appeal decisions

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.
- 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 and UK regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, etc.
- 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.**

Simon Tilling

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"Simon Tilling is super, especially on chemicals regulation"
Chambers UK, 2021

- **Solicitor**, England & Wales and Scotland, partner
- Simon advises international businesses on **UK and EU environmental law,** chemicals regulations and product standards
- With a joint honours degree in chemistry and law, Simon has a particular focus on the **control and regulation of chemicals as substances**, in products and as part of the circular economy
- Simon's experience with both EU chemicals regimes and with UK institutions and legal systems puts Simon in a particularly strong position to **help clients navigate access to the newly independent GB market**

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Firm Overview

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

2. Independent GB Chemical Regimes

The UK's legislative approach: 'lift and shift'

- **The European Union (Withdrawal) Act 2018**, as amended by the **European Union (Withdrawal Agreement) Act 2020**
- EU Directives: EU-derived domestic legislation, as it has effect in domestic law immediately before 11pm UK time on 31 December 2020, continues to have effect in domestic law (section 2(1))
- EU Regulations and judgements of the CJEU: Direct EU legislation, so far as operative immediately before 11pm UK time on 31 December 2020, forms part of domestic law (section 3(1)).
- Ministers given power by regulations to "prevent, remedy or mitigate … any failure of retained EU law to operate effectively, or any other deficiency in retained EU law" (section 8(1)).
- In construing and applying an EU Regulation "…the Court can depart from any retained CJEU case law or any retained general principles. The Court is not bound by such principles and may depart from them if it considers it right to do so." Court of Appeal for England and Wales, *Lipton v BA City Flyer Ltd* [2021] 1 W.L.R. 2545 (March 2021).

The "Lift & Shift" of UK REACH

- UK REACH amended by Statutory Instrument 2019 No. 758 - The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019,
- then amended by Statutory Instrument 2019 No. 858 - The REACH etc. (Amendment etc.) (EU Exit) (No. 2) Regulations 2019
- and by Statutory Instrument 2019 No. 1144 - The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019;
- and by REACH etc. (Amendment etc.) (EU Exit) Regulations 2020/1577;
- and also by the Environment (Miscellaneous Amendments) (EU Exit) Regulations 2020/1313;
- and then UK REACH updated by REACH etc. (Amendment) Regulations 2021/904.

- **None of this 'lifts and shifts' the ECHA-held data.**

The "Lift & Shift" of GB BPR

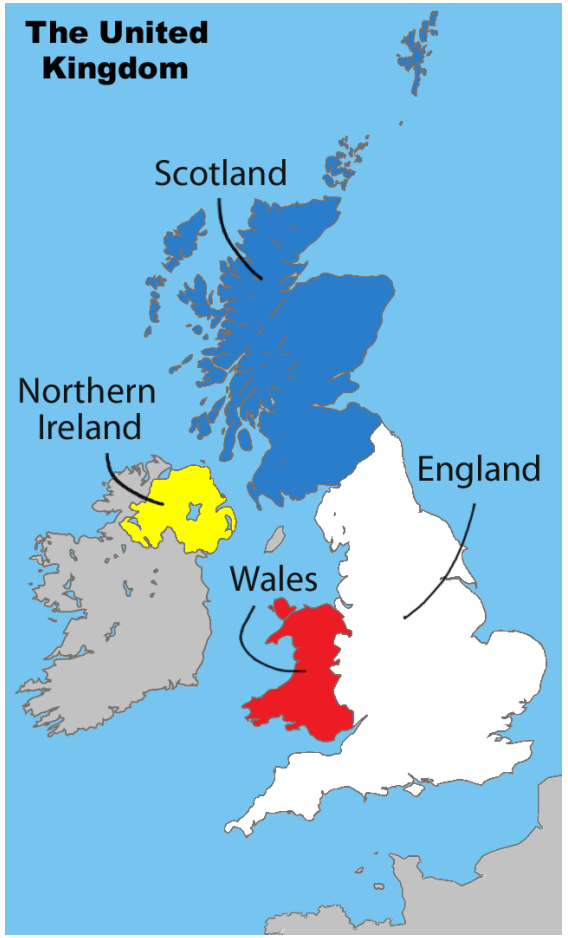
- Statutory Instrument 2019 No. 720 The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, amended retained EU biocides law (BPR, review programme, etc.)
- then amended by Statutory Instrument 2020 No. 1567 The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

- Supplemented by considerable guidance/policy statements from HSE.

Geographical Scope and Devolution

- Complex governance
  - Trade and industry is a reserved competency
  - Health is a devolved competency
  - Workplace safety is a reserved competency
  - Environment is a devolved competency

- Protocol on Northern Ireland
  - Northern Ireland remains under EU REACH, EU BPR

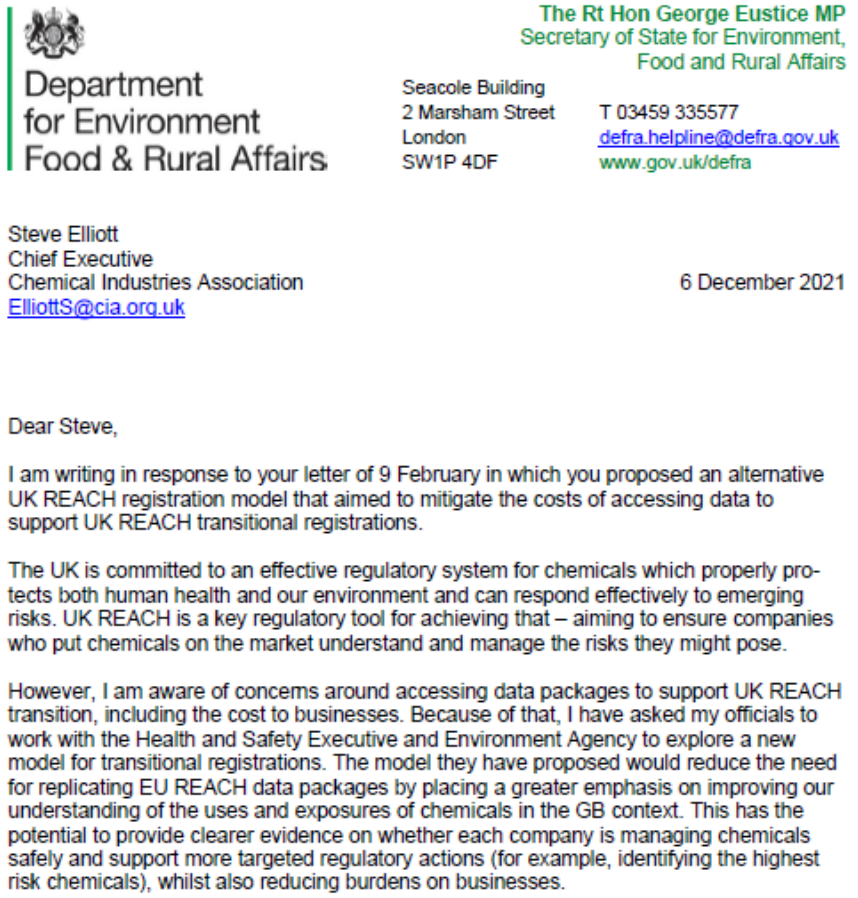


UK REACH as at December 2021

- No data, no access – to the market of Great Britain
- Health and Safety Executive (HSE) steps into the role of the European Chemicals Agency, supported by the national environment agencies
- Secretary of State fulfils the role of the European Commission, with consent of Scotland and Wales
- New UK REACH independent scientific expert pool (RISEP)
- Populate a new database: Comply with UK REACH IT system (no access to ECHA's database)
- Transition period to allow registration (and provide time for data sharing arrangements)
- The First-tier Tribunal, General Regulatory Chamber steps into the role of the ECHA Board of Appeal

George Eustice letter of 6 December

- Work begins to explore a "new model" for transitional arrangements
- "…reduce the need for replicating EU REACH data packages…"
- "…placing a greater emphasis on improving our understanding of the uses and exposures of chemicals in the GB context"
- To allow time to explore this, Defra is "currently minded to extend the 27 Oct 2023 deadline to 27 Oct 2025"



Department for Environment Food & Rural Affairs

The Rt Hon George Eustice MP
Secretary of State for Environment, Food and Rural Affairs

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Steve Elliott
Chief Executive
Chemical Industries Association
ElliottS@cia.org.uk

6 December 2021

Dear Steve,

I am writing in response to your letter of 9 February in which you proposed an alternative UK REACH registration model that aimed to mitigate the costs of accessing data to support UK REACH transitional registrations.

The UK is committed to an effective regulatory system for chemicals which properly protects both human health and our environment and can respond effectively to emerging risks. UK REACH is a key regulatory tool for achieving that – aiming to ensure companies who put chemicals on the market understand and manage the risks they might pose.

However, I am aware of concerns around accessing data packages to support UK REACH transition, including the cost to businesses. Because of that, I have asked my officials to work with the Health and Safety Executive and Environment Agency to explore a new model for transitional registrations. The model they have proposed would reduce the need for replicating EU REACH data packages by placing a greater emphasis on improving our understanding of the uses and exposures of chemicals in the GB context. This has the potential to provide clearer evidence on whether each company is managing chemicals safely and support more targeted regulatory actions (for example, identifying the highest risk chemicals), whilst also reducing burdens on businesses.

UK REACH data submission deadlines… under the current law!

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	

Defra minded to extend to 27 October 2025

Consultation promised on extensions

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

27 October 2021
DUIN notification

GB BPR data submission timelines

- **Article 95 Suppliers List:**
  - 31 December 2022 (if carried over from EU list or)+ UK establishment / representative

- **Existing Authorisation**
  - Possibility for HSE to call in data in within 60 days

- **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

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

3. Data Protection Periods

Data 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 UK 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	27 October 2027 (202X?)
31 May 2013	31 May 2025	27 October 2025 (202X?)
30 November 2010	30 November 2022	27 October 2023 (2025?)

Expiry of data protection before GB latest submission deadline (?)

Free rider issue for first-time registrants in UK or EU

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

Data 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.***

4. How to approach GB Data Negotiations

Tips on negotiations

- 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 for REACH)	No further action	Negotiate terms	Case by case assessment
outside EU by affiliates for other purposes (e.g. GB REACH)	No further action	Negotiate terms	Case by case assessment

Impact on Data Agreements

- **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”)

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

Negotiation Process

- **Essential to set in place standard:**
  - NDA
  - Data sharing agreements
  - Negotiation protocols
  - Cost calculation spreadsheets/baseline data to allow for rapid responses
- **Typical stages in process:**
  - NDA/Confidentiality Agreement
  - Agreement on what is sought (list)
  - (Optional) Delegation of entire process to binding arbitration
  - Exchanges on principles for compensation
  - Review of numbers
  - Review of draft agreement
  - Face to face negotiation
  - Offer to pay

Compensation

Indicative list of issues to consider in negotiations

- Scope of rights
  - Citation or ownership?
  - Geographical spread (EU-27, EEA, EEA, EFTA, EU +GB, EU + US etc?)
  - Purpose (BPR only? BPR + PPP, REACH?)
- Costs
  - Distinction between costs & commercial data value
  - Dossier costs versus raw data costs
  - Actual cost (+ inflation) or replacement cost?
  - Management costs (actual or fixed/variable percentage)
  - Risk premium (compare REACH and BPR risk, and nature of study)?
  - Loss of opportunity?
  - Early market access premium?

Compensation

Indicative list of issues to consider in negotiations

- Dynamic cost formula or static?
  - Reimbursement mechanism?
  - Claw-back for underpaying and updates?
  - EU only considerations or discounts for other jurisdictions?
- Other?
  - Are you being asked for commercial information not required by BPR (use of black box trustees)?
  - Tying data access to supply contracts?
  - Lump sum penalties for change of supplier? Royalty systems to incentivise loyalty to suppliers?

5. When Parties Cannot Agree

Sharing & Disputes

	BPR	REACH
STANDARD (AND BURDEN)	"Every effort" to reach an agreement. Compensation determined in a "fair, transparent and non-discriminatory manner" OR parties may agree to submit matter to binding arbitration (burden on both parties)	"Every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way". *But "such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order."* (burden on both parties)
SUBJECT TO SHARING	Tests or studies on vertebrates Plus all tox., ecotox., env. fate and behaviour studies (for 95 list)	Study involving tests on vertebrate animals
PROCESS TRIGGERED BY	Prospective applicant	Potential registrant's inquiry
DECISION MAKER	HSE	HSE
TIMELINES	No earlier than 1 month after name of data owner provided + 60 day maximum for HSE decision (Prospective applicant must have paid a share of costs before benefitting from Decision)	No earlier than 1 month after receipt, from the HSE, of the name and address of the previous registrant(s).
SUB-LICENSING?	No (Exception under Article 95 to an applicant for authorization in its supply chain)	No (Legal entity specific unless otherwise agreed)
COMPENSATION PRINCIPLES	Proportionate share of the cost	Proportionate share of the costs incurred
REMEDIES AGAINST DECISION	Secretary of State *Suspensive Effect*	First Tier Tribunal *Suspensive Effect*

UK REACH appeals to the First-tier Tribunal

- Article 91 of UK REACH lists the decisions of the HSE that can be appealed to the First-tier Tribunal
  - **Data sharing decisions (Art. 27(6))**
  - Decisions about exemptions from registration for product and process orientated research and development (PPORD) (Art. 9)
  - Dossier completeness check (Art. 20)
  - Dossier evaluation decisions (Art. 51)
  - Substance evaluation decisions (Art. 52)

- Appeal has suspensive effect, and the First-tier Tribunal—

  (a) may dismiss the appeal, or

  (b) if it allows the appeal may—

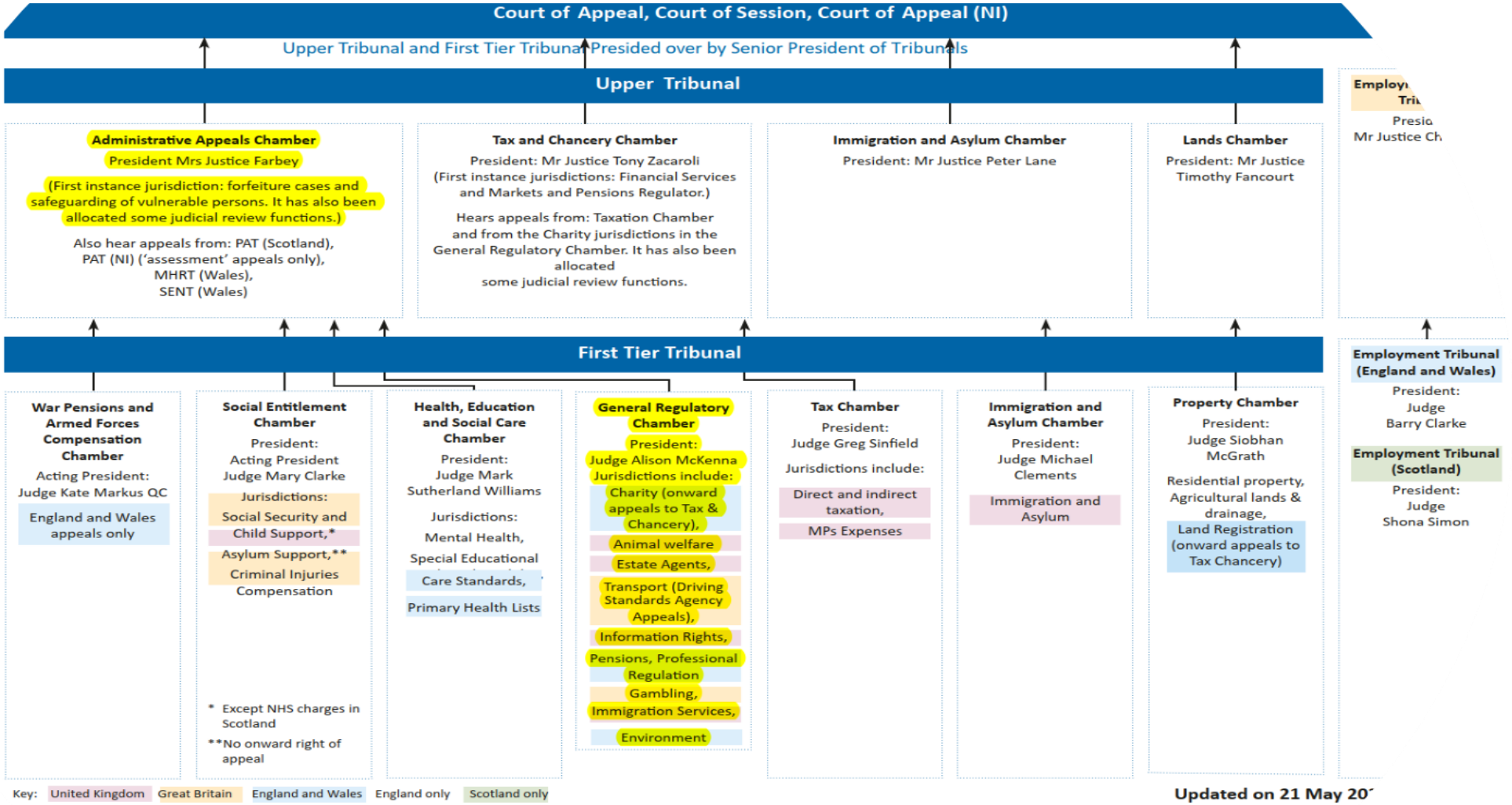
  (i) quash the decision and (if appropriate) remit the matter to the Agency, or

  (ii) substitute for the decision any other decision which could have been made by the Agency

6. Role of the First Tier Tribunal, General Regulatory Chamber

Tribunals, Courts and Enforcement Act 2007

- Simplified statutory framework: existing tribunals and new jurisdictions
- Senior President of Tribunals
- 2 new tribunals – First-tier Tribunal and Upper Tribunal
- 7 FTT Chambers, 4 UT Chambers, each led by a Chamber President
- Chambers may be merged and new Chambers created
- FTT & UT combined: approximately 1 million cases p.a.


Court of Appeal, Court of Session, Court of Appeal (NI)
Upper Tribunal and First Tier Tribunal Presided over by Senior President of Tribunals
Upper Tribunal
Administrative Appeals Chamber
President Mrs Justice Farbey
(First instance jurisdiction: forfeiture cases and safeguarding of vulnerable persons. It has also been allocated some judicial review functions.)
Also hear appeals from: PAT (Scotland), PAT (NI) ('assessment' appeals only), MHRT (Wales), SENT (Wales)
Tax and Chancery Chamber
President: Mr Justice Tony Zacaroli
(First instance jurisdictions: Financial Services and Markets and Pensions Regulator.)
Hears appeals from: Taxation Chamber and from the Charity jurisdictions in the General Regulatory Chamber. It has also been allocated some judicial review functions.
Immigration and Asylum Chamber
President: Mr Justice Peter Lane
Lands Chamber
President: Mr Justice Timothy Fancourt
Employ Tri
Presi
Mr Justice Ch
First Tier Tribunal
War Pensions and Armed Forces Compensation Chamber
Acting President: Judge Kate Markus QC
England and Wales appeals only
Social Entitlement Chamber
President: Acting President Judge Mary Clarke
Jurisdictions:
Social Security and Child Support,*
Asylum Support,**
Criminal Injuries Compensation
* Except NHS charges in Scotland
**No onward right of appeal
Health, Education and Social Care Chamber
President: Judge Mark Sutherland Williams
Jurisdictions:
Mental Health,
Special Educational
Care Standards,
Primary Health Lists
General Regulatory Chamber
President: Judge Alison McKenna
Jurisdictions include:
Charity (onward appeals to Tax & Chancery),
Animal welfare
Estate Agents,
Transport (Driving Standards Agency Appeals),
Information Rights,
Pensions, Professional Regulation
Gambling,
Immigration Services,
Environment
Tax Chamber
President: Judge Greg Sinfield
Jurisdictions include:
Direct and indirect taxation,
MPs Expenses
Immigration and Asylum Chamber
President: Judge Michael Clements
Immigration and Asylum
Property Chamber
President: Judge Siobhan McGrath
Residential property, Agricultural lands & drainage,
Land Registration (onward appeals to Tax Chancery)
Employment Tribunal (England and Wales)
President: Judge Barry Clarke
Employment Tribunal (Scotland)
President: Judge Shona Simon
Key: United Kingdom Great Britain England and Wales England only Scotland only
Updated on 21 May 20

The FTT…

- A specialist jurisdiction
- Composition statements – judge alone/expert alone/2 or 3 person panel
- Chambers vary in size
- Bespoke Procedure Rules - not subject to the CPR
- Decision by the FTT is binding only between the parties to that appeal
- Decisions by the UT and senior courts provide useful authority

The Upper Tribunal…

- A superior court of record – decisions have precedent value
- S11 TCEA – a right of appeal from the FTT to the UT on a point of law, subject to permission
- If the UT decides that the FTT made an 'error of law', the UT will set aside the FTT decision and either re-make the decision or remit the case to be considered again
- 'Error of law' – see *R (Iran) v Secretary of State for Home Department [2005] EWCA Civ 982*

UK REACH appeals in the FTT (1)

- The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009, as amended

- Rules 22(1)(a) & (6)(g) – Notice of Appeal must be sent to the Tribunal within 90 days

- Thereafter, the usual time limits apply:
  - The Respondent (HSE) must respond to the appeal within 28 days (rule 23(1)(b))
  - The Appellant may reply within 14 days, providing further documents (rule 24(1))

- But see Article 93, Regulation (EC) No 1907/2006 as amended:
  - If the HSE considers the appeal to be admissible and well founded, it may rectify the decision within 30 days of the appeal being brought

UK REACH appeals in the FTT (2)

- Early Case Management Hearing: clarify issues and consider expert evidence

- Rule 15(1)(e): the Tribunal may give directions as to…whether the parties are permitted or required to provide expert evidence, and if so whether the parties must jointly appoint a single expert to provide such evidence

- Other case management powers:
  - 5(1)The Tribunal regulates its own procedure
  - 5(1)(d) may require a party or another person to provide documents, information or submissions
  - 5(1)(e) may deal with an issue in the proceedings as a preliminary issue
  - 8(1) & (3) strike out powers

7. Possible lessons from the EU and future GB challenges

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. **Inadmissible challenges: pushing boundaries of what is within decision-maker’s powers.**

Scope of data sharing & “every effort” obligations

5. **Payment of “a share of the costs incurred” - 63(3) BPR – can be made *after* draft ECHA decision.** Recent decisions that the share does not need to be proportionate but must not be “manifestly unreasonable”..
6. **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)
7. **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.
8. **No obligation on Data accessor to agree to terms and conditions that may not be fair, transparent and non-discriminatory.**
9. **Treatment of Affiliates** need to be justified and articulated.

Issues to Consider: UK Data Sharing

Data shared once under EU regime

100% EU compensated

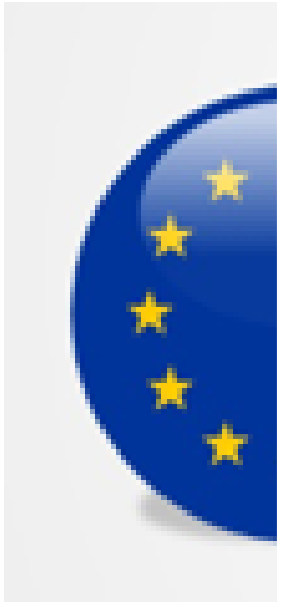
Same data to be shared under UK regime

“New”100% ?

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

Issues to Consider: UK Data Sharing

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 UK regime

Deduction?

"Limited to 50%?

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

Issues to Consider: UK Data Sharing

Data shared once under EU regime

100% EU compensated

Same data to be shared under UK regime

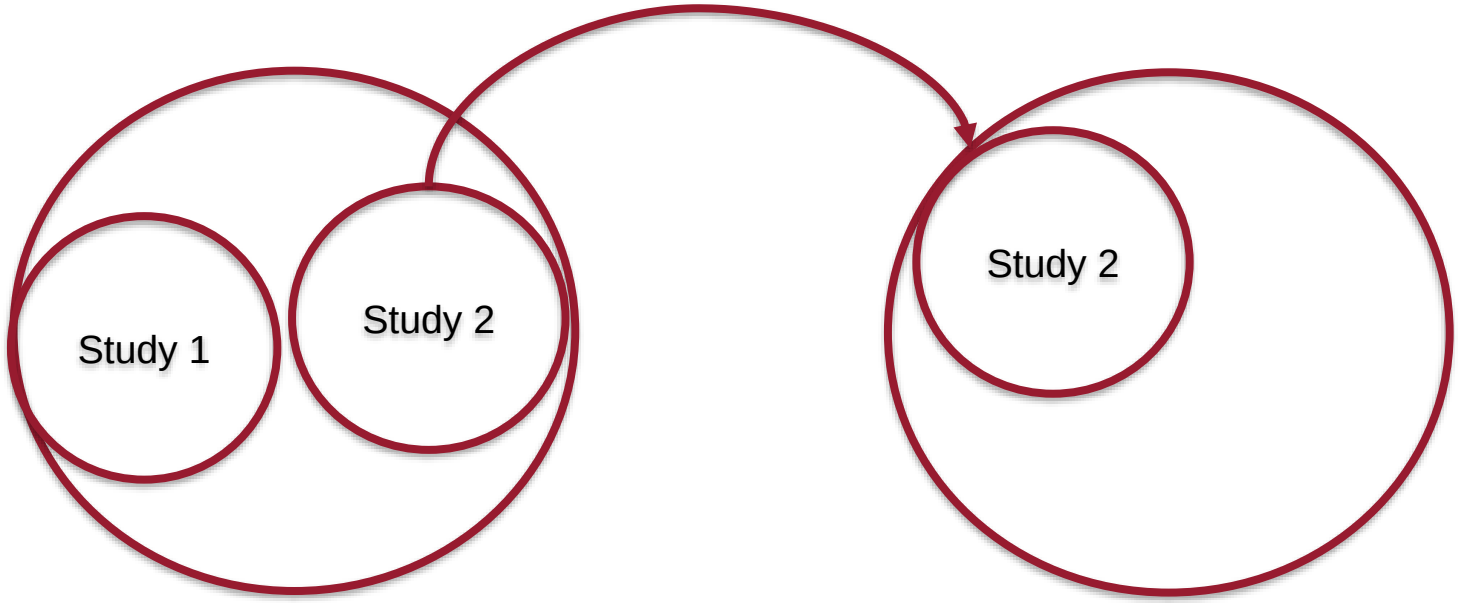
Deduction?

“New”100% ?

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

Extraterritoriality?

Issues to Consider: Effects of Extraterritorial Data Owners



EU REACH

GB REACH

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."

Article 25(1) REACH

"In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.

Article 26(3) REACH

"Studies involving vertebrate animals shall not be repeated."

Any questions?

SPEAKERS:

Judge Moira Macmillan Lead Environment Judge, First-tier Tribunal, General Regulatory Chamber

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Partner, Barrister and Avocat, Steptoe & Johnson