

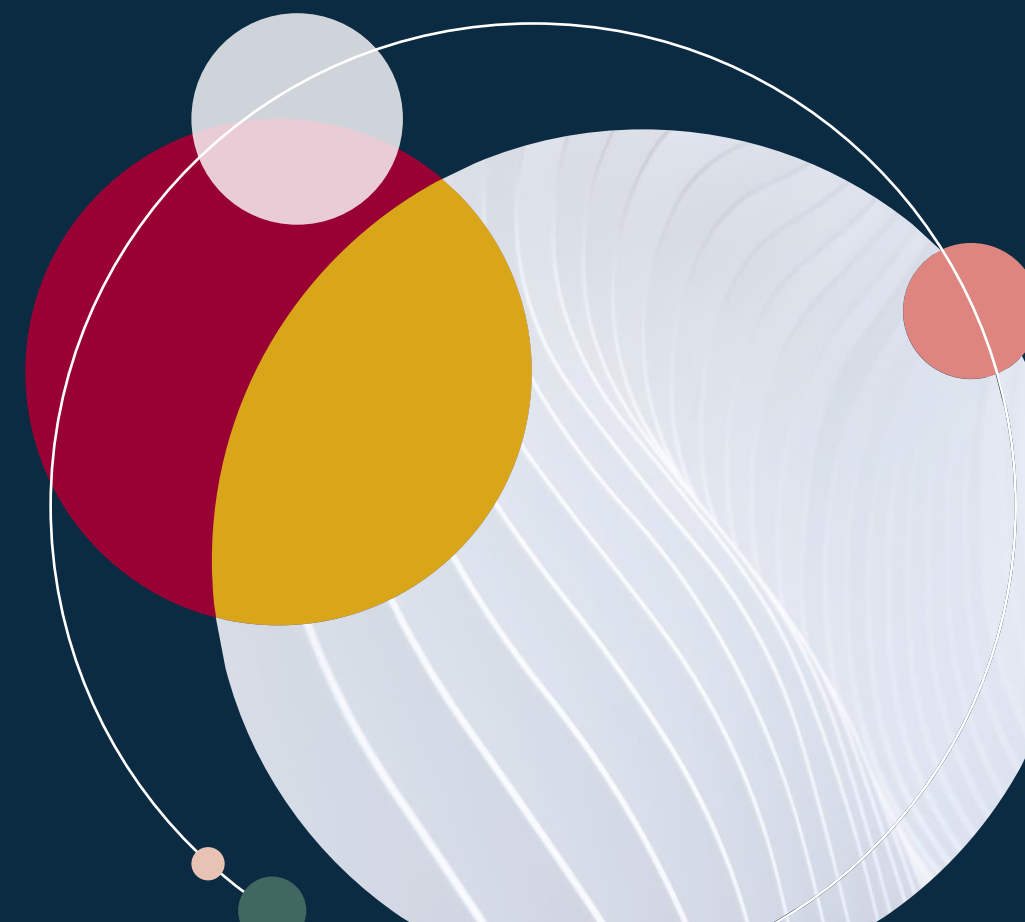
Step toe

Data sharing and global data rights management

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Tom Gillett advises clients on a **wide range of environmental law**, with a focus on **chemicals regulation and product regimes** (including REACH, biocides, food contact, product standards and CE/UKCA marking) in both the EU and the UK.

With a background in complex and technical contentious environmental law (including environmental permitting, pollution incidents and waste regulation), Tom helps clients navigate **regulatory investigations, appeals** (including before the **ECHA Board of Appeal**) and **tribunal hearings**, as well as advising on **regulatory compliance, data sharing, consortium management, and supply chain due diligence**.

The **Legal 500 UK** quotes one client as saying:

"I have worked with Tom Gillett and have found him to be diligent and knowledgeable in this developing area. As well as providing clear advice on a one to one basis, I also find his contributions in seminars and panel discussions useful and valuable."

About Steptoe

Solving our clients' largest, most complex legal challenges

Step toe is known for delivering results for clients around the globe, bringing the right mix of capabilities across the full spectrum of legal services and industries, with a distinct focus on:



Government
Investigations
& Enforcement



International
Regulation,
& Compliance



International
Disputes



Intellectual
Property
Litigation



Regulated
Industries

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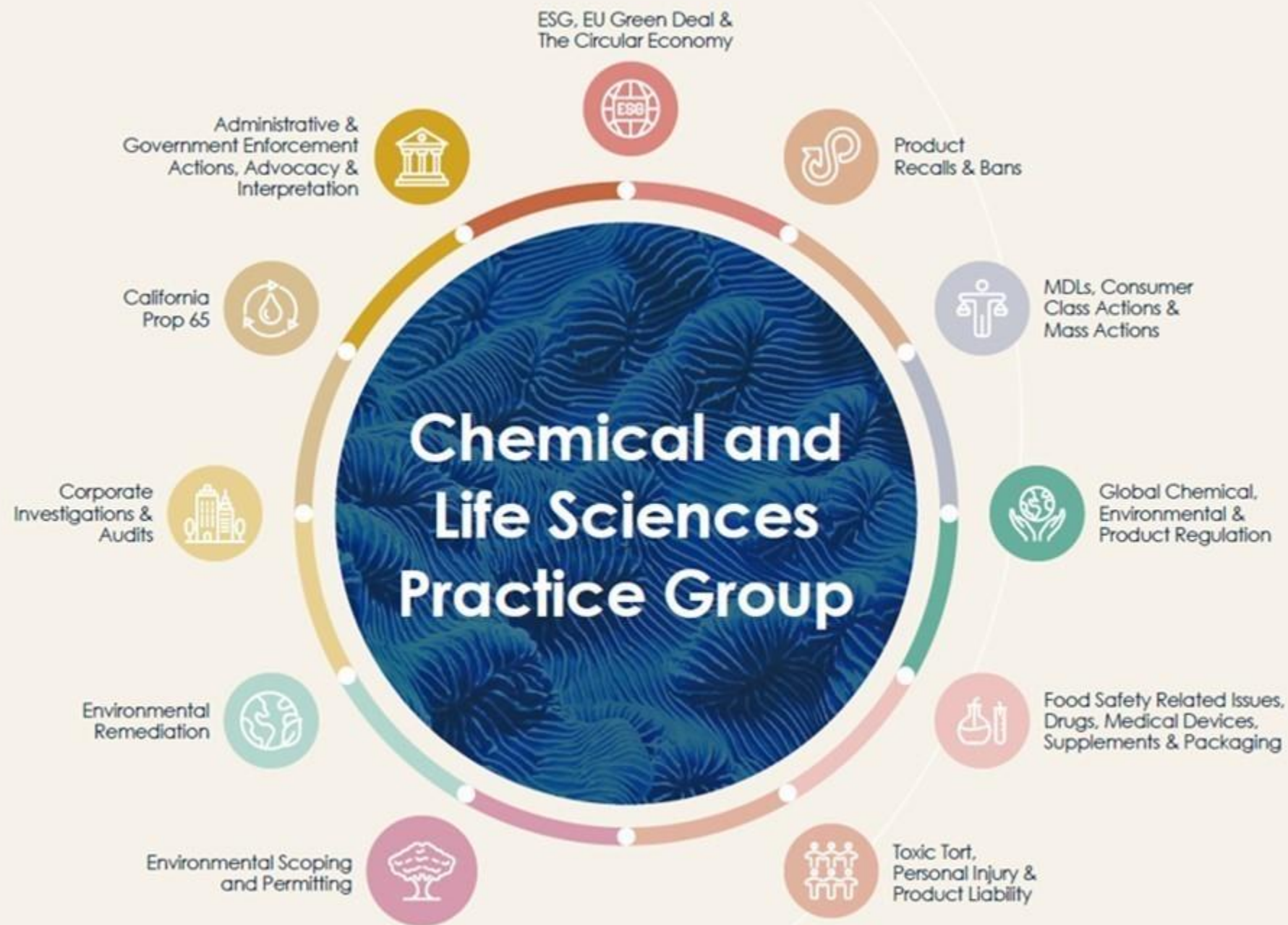
Founded

500

lawyers

9

offices across US,
Europe and Asia

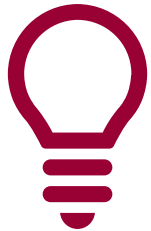


How we can assist you

- Building and executing **strategies for compliance** with chemicals regulation
- **Legal advocacy** before decision makers on legislative, administrative, and policy proposals in order to help shape the general regulatory environment and product-specific regulation
- **Representation** before courts, administrative authorities, and enforcement bodies
- **Assessment and management of compliance and environmental risks**
- **Regulatory monitoring and analysis** to keep abreast of the latest legal developments

To discuss today...

- Data protection: The fundamentals
- Data sharing considerations / negotiation / compensation
- Competition law aspects
- Structuring multi-jurisdictional agreements
- Takeaways



Data protection: The fundamentals

What is data protection?

- The right for authorities to refer to data submitted for x for the benefit of y .
- No necessary link between data protection and confidentiality:
 - Public information can be subject to data protection
 - Secret information may not be subject to data protection
- Data protection applies during period of protection (not open ended).
- Motivated by:
 - Regulatory efficiency
 - Animal welfare

Data sharing considerations

Rules on Existing Data

Make sure you understand jurisdiction-specific rules from the outset:

- Standard (and burden)?
- Data subject to sharing?
- Process triggered by?
- Decision maker?
- Timelines?
- Sub-licensing?
- Compensation principles?
- Remedies?

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)
 - Exchanges on principles for compensation
 - Review of numbers
 - Review of draft agreement
 - Face to face negotiation
 - Offer to pay

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 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 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

- Defining the scope of rights is key.

Compensation

Indicative list of issues to consider in negotiations

- Scope of rights
 - Citation or ownership?
 - Individual endpoints or full dossier
 - Geographical spread (EU-27, EEA, EFTA, EU +UK, EU + US etc?)
 - Purpose (REACH? REACH and BPR? Etc.)
 - Non-confidential Chemical Safety Report
- 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 (cont.)

Indicative list of issues to consider in negotiations

- Dynamic cost formula or static?
 - Fair and transparent model?
 - Reimbursement mechanism?
 - Claw-back for underpaying and updates?
 - Discounts for other jurisdictions?
- Other?
 - Confirmation of EU sanctions compliance of licensee
 - Are you being asked for commercial information not required by chemicals regime (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?

Sharing same data under different regimes

**Data shared once under
EU regime**



100% EU compensated

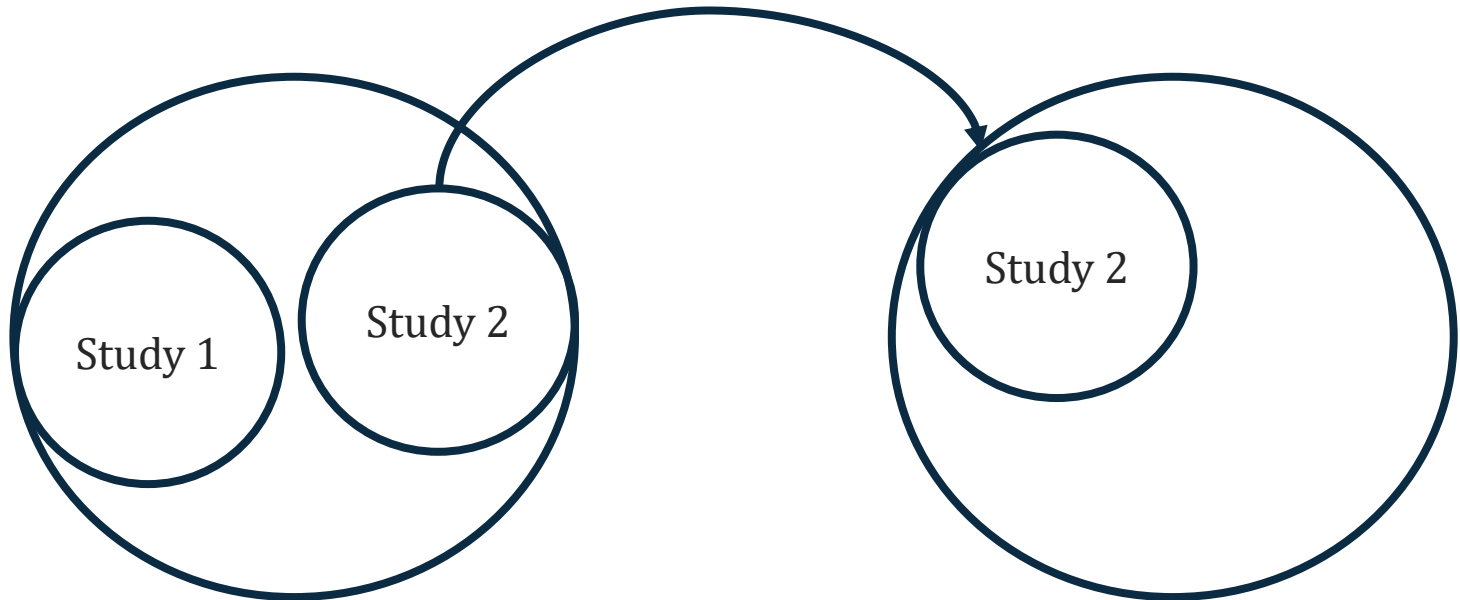
**Same data to be shared under UK
regime**



“New” 100%?

**Are UK rights granted contractually in existing (EU) agreement?
What if data owner remains “offshore”?
Profits possible?**

Effects of extraterritorial Data Owners



- EU REACH/BPR



UK REACH/BPR



Competition law considerations

Competition law considerations

Make sure data sharing negotiations are not used as cover for breaches of Competition law.

- As the parties to data sharing negotiations **DO NOT**:
 - Fix prices or other trading conditions
 - Limit production
 - Share markets or customers
 - Exchange strategic information about your company
- As a data owner **DO NOT**:
 - Charge excessive price
 - Discriminate between applicants
 - Impose exclusive dealing requirements
 - Tie data rights with purchasing other products
 - Refuse providing data rights

Structuring Non-EU or multi-jurisdictional agreements

Consortia & template agreements

Consortia: to form or not to form?

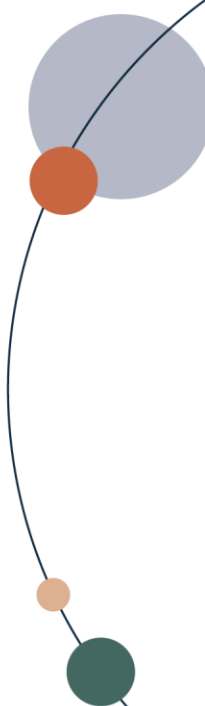
How to form:

- Subgroup
- Free standing
- Internal negotiations – diver giving focus/ interests

Revision of templates for non-EU purposes.

Complexities of data ownership – orphans.

‘Non-EU specific data sharing considerations’



Key messages

Takeaways

- The foundation of all chemicals regulation is data (even if the precise details may be different)
- Understand data ownership, where value may reside, and where there are gaps.
- Understand country specific requirements and considerations
- **The best prepared come out of negotiations on top every time.**

Questions?

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