Chemical Regulation post-Brexit: EU *v* UK

Chem Academy
8 November 2021

Darren Abrahams

Steptoe

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.**

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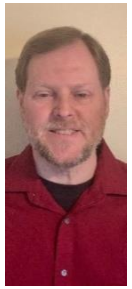

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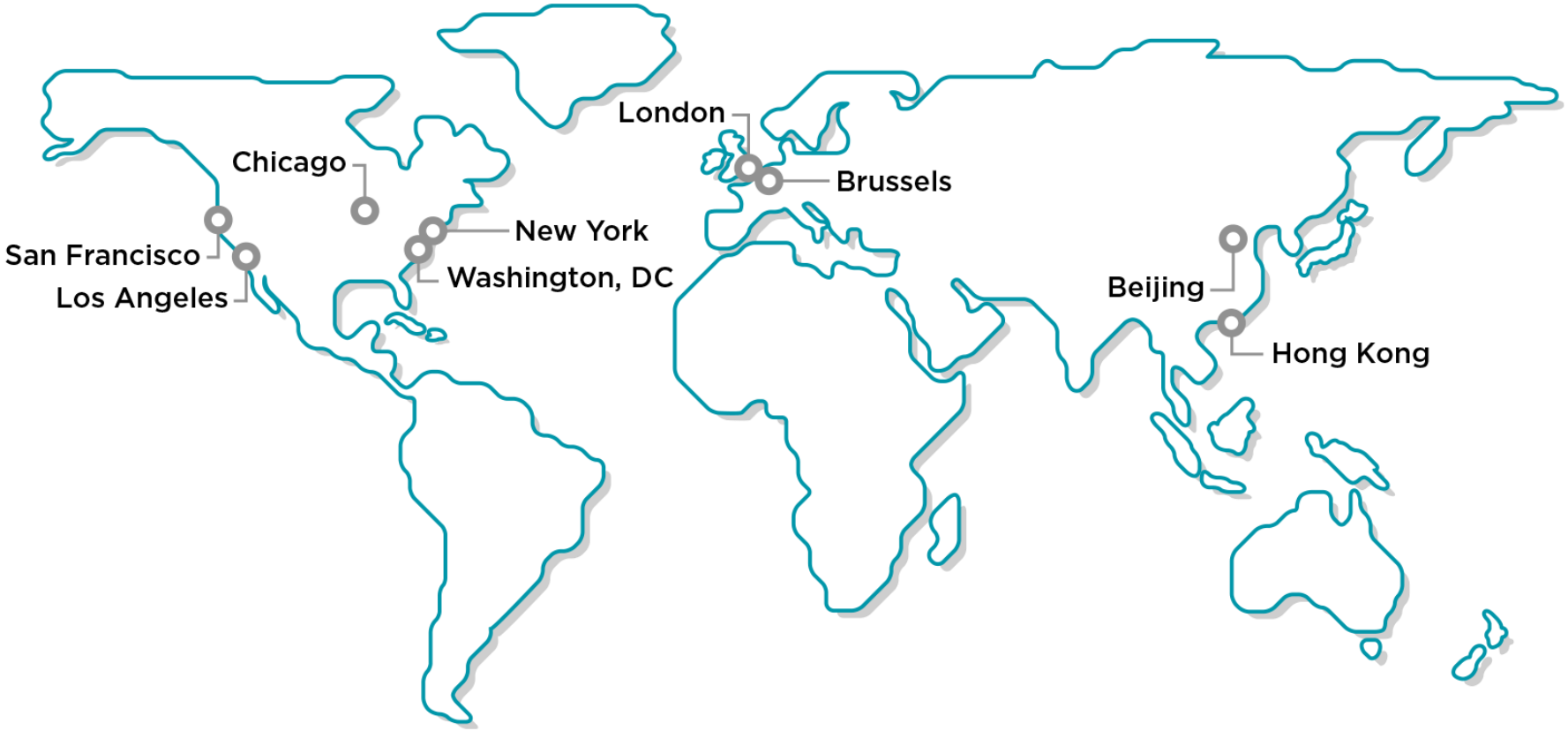
Firm Overview

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



Outline

- Introduction
- How and where UK REACH system works
- Registration Timelines
- Data Protection Periods
- Data Costs
- Data Gaps & Duplication
- Fees
- SVHC list (Candidate list for inclusion in Annex XIV)
- Authorisation list (Annex XIV)
- Applications for authorisations
- Restrictions list (Annex XVII)
- Proposed restrictions
- Regulatory divergence
- HSE Work Programme
- Take away messages

How & Where the UK REACH System Works: "Lift & Shift"

- **REACH regime applicable in England, Scotland and Wales ("Great Britain"). Separate Northern Ireland Protocol arrangements.**

- **UK European Union (Withdrawal) Act 2018, as amended, 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,

- **REACH:** Statutory Instrument 2019 No. 758 - The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, as 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; REACH etc. (Amendment etc.) (EU Exit) Regulations 2020/1577; REACH etc. (Amendment) Regulations 2021/904

- **Similar measures for CLP, Biocides, PIC etc.**

Transitional Rules: Registration Submissions

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 and data owner re-submits.

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 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.

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

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

Strategic Issues

- 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. GB REACH)	No further action	Negotiate terms	Case by case assessment

Issues to Consider: UK Data Sharing

Data shared once under EU regime

100% EU compensated

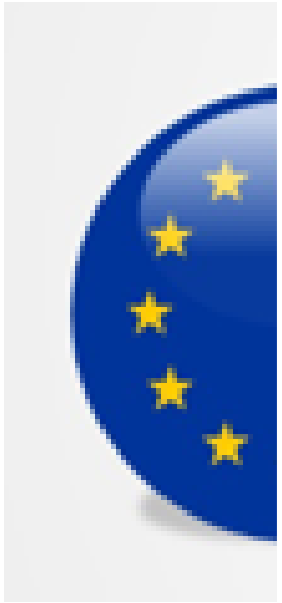
Same data to be shared under UK regime

“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

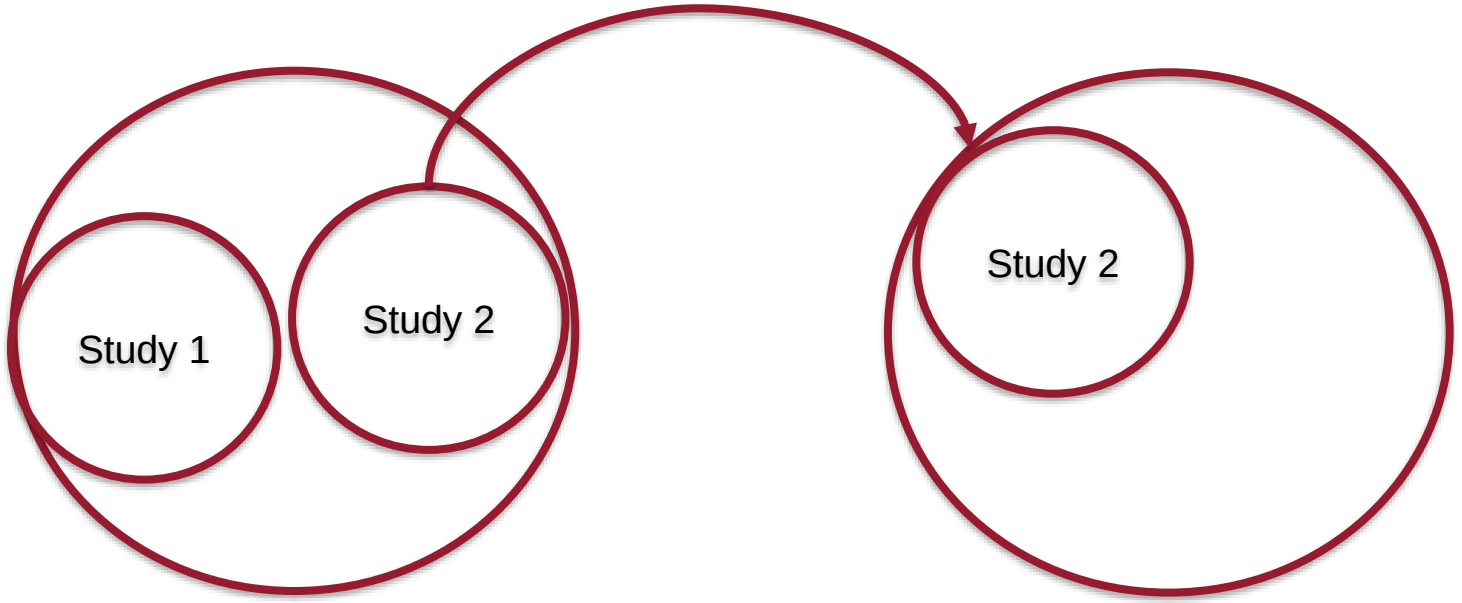
Deduction?

“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

Data Gaps & Duplication

- If data gaps: risk of duplication?

Article 25

"Objectives and general rules

1.

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

"Duty to inquire prior to registration

…

3. "Studies involving vertebrate animals shall not be repeated."

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

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

Issues to Consider: Regitsration Fees

Fees for registrations submitted under Article 6, 7 or 11 of Regulation (EC) No 1907/2006

Table 1

Standard fees

	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	EUR 1 739	EUR 1 304
Fee for substances in the range 10 to 100 tonnes	EUR 4 674	EUR 3 506
Fee for substances in the range 100 to 1 000 tonnes	EUR 12 501	EUR 9 376
Fee for substances above 1 000 tonnes	EUR 33 699	EUR 25 274

Fees for registrations submitted under Articles 6, 7 or 11 of UK REACH (full registrations)

Table 1: Standard fees

	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	£1,518	£1,138
Fee for substances in the range 10 to 100 tonnes	£4,080	£3,061
Fee for substances in the range 100 to 1 000 tonnes	£10,913	£8,185
Fee for substances above 1 000 tonnes	£29,419	£22,064

EU REACH

GB REACH

Issues to Consider: Authorisation Fees

Charges for the review of an authorisation under Article 61 of Regulation (EC) No 1907/2006

Table 1

Standard charges

Base charge	EUR 54 100
Additional charge per use	EUR 10 820
Additional charge per substance	EUR 10 820

Fees for applications for an authorisation under Article 62 of UK REACH

Table 1: Standard fees

Base fee	£47,229
Additional fee per substance	£9,446
Additional fee per use	£42,506

EU REACH 

GB REACH 

Transitional Rules: Annex XIV Authorisation List Carried Over

EU "Authorisation list" (Annex XIV) retained (54 entries – including split group entries) under UK REACH Authorisation List as at the end of the Transition Period on 31 December 2020:

- **Mostly same latest application dates** (LADs) and **sunset dates** (SDs) apply.

	Substance name Note: Group entries are split in different rows.	Description	EC No.	CAS No.	Entry No.	Sunset Date	Latest application date	Intrinsic property(ies) referred to in Article 57	Exempted (categories of) uses
2	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)		201-329-4	81-15-2	1	21/08/2014	21/02/2013	vPvB (Article 57 e)	
3	4,4'- Diaminodiphenylmethane (MDA)		202-974-4	101-77-9	2	21/08/2014	21/02/2013	Carcinogenic (Article 57a)	
4	Hexabromocyclododecane (HBCDD)	and all major diastereoisomers identified	-	-	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
5	Hexabromocyclododecane		247-148-4	25637-99-4	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
6	gamma-hexabromocyclododecane		-	134237-52-8	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
7	1,2,5,6,9,10-hexabromocyclododecane		221-695-9	3194-55-6	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
8	alpha-hexabromocyclododecane		-	134237-50-6	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
9	beta-hexabromocyclododecane		-	134237-51-7	3	21/08/2015	21/02/2014	PBT (Article 57 d)	
10	Bis(2-ethylhexyl) phthalate (DEHP)		204-211-0	117-81-7	4	21/02/2015	21/08/2013	Toxic for reproduction (Article 57c)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or

- **Extended LADs to 30 June 2022** (18 months) where application made before LAD but not granted before 31 Dec 2021.

Transitional Rules: Carrying Over Authorisations

- **Holders of an existing EU authorization:**
  - established in GB (with a "*relevant connection with Great Britain*")
  - submitted by 1 March 2021 "*the required technical information relating to the authorization*".

  Authorisation holders who submitted the information are included as grandfathered authorisations on the List of UK REACH authorisations – granted and applications in progress.

- **DUS of carried over existing EU authorisations:**
  - DU established in GB
  - Had to notify HSE of their status before 31 Dec. 2020, by 1 March 2021 to continue to reply on that authorization.

Transitional Rules: Carrying Over Applications

- **Existing applications for EU authorization in progress at the "final decision stage"**
  - established in GB
  - ECHA RAC and SEAC opinions adopted but Commission had not made a final decision by 31 December 2020.
  - Notified Secretary of State of existence of application & provided required information by 30 June 2021.

Transitional Rules: Carrying Over Applications

- **Existing applications for EU authorization in progress NOT at the "final decision stage" (awaiting ECHA opinion)**
  - EU application was still under consideration (ECHA RAC and SEAC opinions NOT issued and NO Commission final decision)
  - EU Latest Application Date (LAD) fell before 1 January 2021 and EU application had been made before
  - EU sunset date was on / after 29 March 2017
  - established in GB
  - Notified Agency & provided required information by 30 June 2022

Market Assess Issues

- Beyond what you do: Ensure that **upstream actors** who currently fulfil regulatory compliance will continue to do so. Supply chain analysis is key.

- Requirement of being **established** in the territory (UK or EU)

- Avoid
  - **becoming "accidentally"** responsible for regulatory compliance (e.g. treated as importer under REACH"), or

- Even if not taken by surprise:
  - **short timelines** for action under future GB system, and
  - **data rights access** complexities.

Compare: REACH Regulation – SVHC and Authorisation

SHVC – Candidate List

- ECHA decision to add 8 new substances to the Candidate list (July 2021), incl.:

Annex XIV Inclusion

- ECHA's 10th Annex XIV recommendation (April 2021)

Draft recommendation		
#	**Substance name**	**EC**
1	*Octamethylcyclotetrasiloxane (D4)*	209-136-7
2	*Decamethylcyclopentasiloxane (D5)*	208-764-9
3	*Dodecamethylcyclohexasiloxane (D6)*	208-762-8
4	*Terphenyl, hydrogenated*	262-967-7
5	*Dicyclohexyl phthalate (DCHP)*	201-545-9
6	*Disodium octaborate*	234-541-0
7	*Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)*	209-008-0

Compare: UK REACH Regulation – SVHC and Authorisation

SVHC – Candidate List

- UK REACH Candidate List
- HSE Work Programme:

Table 8: Substances that HSE, the Environment Agency, and the Appropriate Authorities will consider for SVHC identification in 2021/22

	For consideration as SVHCs	EC No.	CAS No.
1	Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivatives, and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	-	-
2	Bis(2-(2-methoxyethoxy)ethyl) ether; tetraglyme	205-594-7	143-24-8
3	Resorcinol; 1,3-benzenediol	203-585-2	108-46-3
4	2,2-Bis(bromomethyl)propane1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative, 3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)		
5	Glutaral	203-856-5	111-30-8
6	2-(4-Tert-butylbenzyl)propionaldehyde and its individual stereoisomers		
7	1,4-Dioxane	204-661-8	123-91-1
8	Orthoboric acid, sodium salt	237-560-2	13840-56-7
9	Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from propene oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)		
10	4,4'-(1-Methylpropylidene)bisphenol; bisphenol B	201-025-1	77-40-7

Annex XIV Inclusion

- Draft recommendation of priority substances to be included in Annex 14 (list of substances subject to Authorisation) of UK REACH 2021 for
  - Disodium octaborate
  - Dicyclohexyl phthalate (DCHP)
- Public consultation until 30 November 2021

Applications for Autorisations

- “The **process** for applying for an authorisation under UK REACH is **very similar to the EU process and much of the ECHA guidance and templates can be used.** There is information on the ECHA website on how to identify whether you need to apply for authorisation and how you can prepare.

- If you think you will need to apply for UK REACH authorisation you should contact the Agency in **the first instance to notify your intention at ukreach.authorisation@hse.gov.uk**, using the subject "notification of intention to submit an application for authorisation".

- The following information should be provided:

- Foreseen submission date
- The Substance(s) and use(s)for which the application will be made
- The applicant(s) and role(s) in the supply chain
- Contact details”

UK REACH – Restrictions

- HSE to "*assess all EU REACH restriction proposals where the Annex 15 dossier has been published – but we may identify priorities from other sources and workstreams*"
  - Recent public consultation on two restriction proposals:
    - Questions for the call for evidence for the lead shot ammunition until 22 October 2021
    - Call for evidence: substances in tattoo inks and permanent make-up (PMU) until 2 November 2021

- "*Assessment of an EU REACH restriction proposal may lead to the initiation of a UK REACH restriction proposal with a different scope that we believe is more appropriate to addressing a risk*"

- *RISEP: REACH Independent Scientific Experts Pool will be used in the assessment of applications for authorisation within the workplan activities and will first support the formation of opinions on restriction in in 2022/23.*

EU REACH – Potential future restrictions

Proposed restriction on **Per- and polyfluoroalkyl substances (PFAS):**

- Content

  "PFAS in the scope of this restriction intention have the following structural formula:
  X-(-CF2-)n-X' with n equal to or larger than 1 and X, X' not being H (thus including X-CF3),
  meaning fluorinated substances that contain at least one aliphatic carbon atom that is both, saturated and fully fluorinated, i.e. any chemical with at least one perfluorinated methyl group (-CF3) or at least one perfluorinated methylene group (-CF2-), –), including branched fluoroalkyl groups and substances containing ether linkages, fluoropolymers and side chain fluorinated polymers."

- Status
  - Restriction Intention submitted by Germany, Denmark, the Netherlands, Norway and Sweden on 15 July 2021
  - Call for Evidence consultation until **17 October 2021**

UK REACH – Potential future restrictions

- Regulatory Management Options Analysis **(RMOA) on PFAS** foreseen for 2021-2022 in the HSE Work Programme:
    - HSE „*will produce an RMOA to characterise and understand the risk posed by PFAS and to assess the likely effectiveness and efficiency of various potential regulatory measures*.“
        - As part of broader assessment of EU Annex 15 dossiers
    - Prioritisation activity to “*identify and assess further substances for potential regulatory action under UK REACH or alternative legislation*. “

Procedural differences

- EU REACH
  - Draft Opinions (on restrictions and authorisations) prepared by ECHA's
    - Committee for Risk Assessment (RAC) and
    - Committee Socio-Economic Analysis (SEAC)
  - Ultimate decision by European Commission

- UK REACH
  - HSE develops draft opinions
  - Challenge Panel
    - "to provide a critical voice" and
    - "*scrutinising and challenging draft opinions*"
    - REACH Independent Scientific Expert Pool (RISEP)
      - ≠ scientific advisory committee but pool of independent experts

  - Ultimate decision by Secretary of State

HSE Work Programme 21/22

Objective	Target
Complete the processing of UK REACH authorisation applications within the statutory deadline.	100%
Complete the processing of UK REACH registrations for previously unregistered substances within 3 weeks of submission (i.e. technical completeness check).	100%
Produce UK REACH Annex 15 restriction dossiers.	2 – (tattoo inks and lead ammunition), due in Q4
Helpdesk - provision of high-quality advice to helpdesk enquiries; answering 90% within 10 working days of receipt.	90% in 10 days
Produce a draft Annual report for 2021/22 and a draft Work Programme for the operation of the Agency for UK REACH in 2022/23.	31st March 2022

Matters relating to strategic policy and further development of the UK REACH framework are addressed by Defra and the Scottish and Welsh Governments. They are outside the scope of this plan. However, we will assist Defra and the other Appropriate Authorities by providing technical support as required.

HSE Work Programme 21/22

Table 3: HSE's CRD resources for 2021/22

Activity in 2021/22	%	Staff hours	FTE
Helpdesk and engagement.	15	5800	3.56
Registration, notification, product and process orientated research and development (PPORDs).	14	5400	3.31
Dossier Evaluation, including compliance checks and testing proposals.	10	3880	2.38
Priority setting and the analysis of regulatory options, including consideration of EU REACH regulatory dossiers (e.g. restriction and SVHC proposals) and preparatory work for substance evaluation.	5	2000	1.23
Substance evaluation	0	0	0
Authorisation: identification of SVHCs for the Candidate List, the prioritisation of substances for Annex 14, and processing applications.	12	4650	2.85
Restriction, specifically generation of Annex 15 dossiers for tattoo inks and lead ammunition.	5	2100	1.29
Technical support to policy departments, including international activity.	5	2000	1.23
Management: planning, reviewing, reporting, information sharing, general governance.	7	2750	1.68
Total on delivery	***74***	***28580***	***17.73***
Training: understanding the legislation and associated guidance; learning processes and procedures; developing knowledge of regulatory science, especially in the area of toxicology.	26	10135	6.22
Total	**100**	**38715**	**23.95**

Compliance Checks

- 20% aim
- Initial focus on the registration dossiers of 'novel' substances, i.e. not registered previously under EU REACH prior to the end of the EU exit transition period (31 December 2020).
- Affected by the transitional provisions in UK REACH which set out the data submission requirements for grandfathered registrations and "downstream user import notifications". It is possible that many UK registrations will have little data in them before the submission deadlines in November 2023, November 2025 or November 2027.

Chemicals Strategies: Movement

EUROPEAN
COMMISSION

Brussels, 14.10.2020
COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

{SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 248 final} -
{SWD(2020) 249 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}

UK's new Chemicals Strategy.

Take Away Messages

- Duplication of regulatory compliance obligations (EU and GB)
    - Risk of divergence
- Verify supply chains: Which entities hold obligations?
- Different procedures might warrant different strategies