Steptoe

UK REACH: Authorisation & Restrictions

Chemical Watch - UK Chemicals Policy & Regulation
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Darren Abrahams & Hannah Widemann

Darren Abrahams

dabrahams@steptoe.com

"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

hwidemann@steptoe.com

- ***Advocaat* at the Brussels Bar** and Associate at Steptoe.
- 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**

European Team

Ruxandra Cana
rcana@steptoe.com
+32 2 626 0571

Darren Abrahams
dabrahams@steptoe.com
+32 2 626 0500

Dr. Anna Gergely
agergely@steptoe.com
+32 2 626 0542

Eléonore Mullier
emullier@steptoe.com
+32 2 626 0563

Simon Tilling
stilling@steptoe.com
+44 20 7367 8000

Hannah Widemann
hwidemann@steptoe.com
+32 2 626 0595

Zanda Romata
zromata@steptoe.com
+32 2 626 0591

Lukasz Gorywoda
lgorywoda@steptoe.com
+32 2 626 0518

Glen Rosini
grosini@steptoe.com
+1 312 577 1233

Outline

- Introduction
- SVHC list (Candidate list for inclusion in Annex XIV)
- Authorisation list (Annex XIV)
- Applications for authorisations
- Restrictions list (Annex XVII)
- Proposed restrictions
- 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 <u>and</u> data owner re-submits.

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 authorisation:**
  - 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.

- **DSU 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

Applications for Authorisations

- "*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

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: EU 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

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*"
  - Currently 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*"

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

Take Away Messages Questions