

UK and EU – What is new and what is different?

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UK's withdrawal from the EU

- The UK left the EU on 31st Dec 2020
 - At that point, all existing EU law, including that related to chemicals, was transcribed into “UK” law
- These new laws apply in Great Britain
 - UK REACH, GB CLP, GB BPR, etc.
- Special arrangements for Northern Ireland
 - NI still under EU Regs for chemicals



UK REACH

Established by The REACH etc. (Amendment) Regulations

- “Lifted and shifted” EU Regulation into UK law
 - only applies in GB, NI still in EU REACH
- Shifted responsibility from the Commission and ECHA, to the UK Secretary of State and HSE as the UK REACH Agency
- Transitional arrangements to allow companies to comply with requirements for registration , authorisation, etc
- Set up UK versions of EU lists (Candidate List, Authorisation List, Restrictions List, SVHC Proposals, Registry of Restriction Intentions)
- Set up parallel technical processes for registration, for updating regulation, etc.
- Consolidated text, as on exit day, now available at <https://www.legislation.gov.uk/eur/2006/1907/contents>

Practical differences for Registrations

GB 'Comply with REACH' portal very different to EU REACH IT

- DEFRA REACH-IT videos
 - [How to set up a REACH IT account](#)
 - [Parent-child account](#) (for ORS, etc)
 - [New substance registration](#)

Transition periods to allow industry to get together

- For now, most registrations are NRES
- Expectation of industry to use EU data sets
- Data access arrangements

No numbering process equivalent to 'EC list numbers' for new substances

- Can submit an EU CLP notification to get one though!

UK Divergence from EU REACH

In theory, technical detail of UK REACH is exactly the same as the EU, but.....

- EU continues with regular updates programmes for Candidate List, Annex XIV, Annex XVII
- UK will not automatically adopt these decisions, but review and decide whether to adopt
 - Systems still playing catch-up
 - HSE work programme

Changes to the Candidate List of SVHC

EU Candidate List updated
4 times

- 19 Jan 21 – 2 new entries
- 8 Jul 21 – 8 new entries
- 17 Jan 22 – 4 new entries
- 10 Jun 22 – 1 new entry

UK list has not been
updated since exit day

- UK published [interim principles](#) for adding new substances to Candidate List
4 substance groups identified for RMOA
- As yet, no entries on the [SVHC proposals list](#)

Annex XIV Authorisation List

Regulation (EU) 2022/586
added 5 substances to Annex
XIV (Authorisation List)

- Reaction mass of DOTE and MOTE
- 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
- Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)
- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol
- Tetraethyllead

UK Authorisation List not
updated since exit day

- 2 substances recommended for inclusion so far
 - Dicyclohexyl phthalate (DCHP)
 - Disodium octaborate

Annex XVII Restrictions List

EU REACH

- Adopted
 - Tattoo Inks
 - N,N-dimethylformamide
- Proposals in development include
 - Lead and its compounds
 - Microplastics
 - Skin sensitisers
 - Formaldehyde releasers
 - MCCP
 - Perfluoro compounds
 - D4/D5/D6
 - Dechlorane Plus
 - PAH
 - Bisphenols

UK REACH

- Proposals for
 - Lead ammunition
 - Tattoo inks
- RMOAs for
 - PFAS
 - Microplastics
 - Formaldehyde releasers
 - Bisphenols in thermal paper
 - Hazardous flame retardants

HSE Work Programme

- HSE Work Programme 2022/23 includes:
 - Completing 5 RMOA to identify priorities for restriction and SVHC identification
 - Initiating 3-9 RMOA to identify priorities for restriction, SVHC identification, inclusion on Authorisation List
 - Completing up to 4 dossiers for substances to be included on the Candidate List

<https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-in-2022-to-2023/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2022-to-2023>
- Plus all the “usual work” on managing registrations, authorisations, dossier evaluations, testing proposals, etc.

Other EU Changes: SDS format

- Regulation (EU) 2020/878 (changes to SDS by end Dec 2022) not adopted into UK REACH
 - UK format still as set out in Regulation (EU) 2015/830
 - UK Gov a bit coy as to if/when they may adopt
 - In the meantime, enforcement likely to be pragmatic
 - No issues with additional info included such as nano/ED as long as it's useful and not confusing
 - Changes to section headings, section 9, are minor and not likely to cause any confusion of the safety messages

Other EU Changes: Update of Annexes VI-X

- Regulation (EU) 2022/477
 - Clarification of testing requirements for mutagenicity, reproductive toxicity, environmental toxicity
 - ORs to disclose information on non-EU manufacturer
 - Clarification of substance identification requirement, including new reporting requirements for nanoforms, UVCBs
 - Applies from 14 Oct 2022

Other EU Changes: Intermediates

- European Court judgment on Acrylamide Case C-650/15 P
 - Interpretation of what is intermediate use - 3 conditions to meet:
 - Intended purpose at the time of manufacture and use
 - Transformed through a synthesis process
 - Confined to a controlled environment
 - SCC not required for exemption from Authorisation or Restriction, though some controls are required
- ECHA updating guidance as a transitional measure in light of this judgement
- COM considering changes to legal text to clarify intermediate uses and that SCC apply to derogations from Authorisation and Restriction

Forthcoming EU Changes: EU Green deal and CSS

- Ambitious plans to overhaul chemicals regulations (and product and waste regulations)
- Additional information on use and exposure
- Polymers registration
- Mixture assessment factors

More on these tomorrow from Chris Cullen!

Other activities in the EU pipeline

- Revisiting idea of standard electronic format for SDS in the supply chain
 - Making electronic format mandatory? Dual systems? Restarting ENES?
- Update Annex VII (physico-chemical properties) to better align with GHS & latest test methods
- Further development of test methods and guidance for nanoforms

Forthcoming changes – UK REACH

- Consultation on delays to transitional registration just ended
 - Extending registration deadlines by up to 3 years
- 25 year environment plan (2018) committed to the development of a new UK Chemicals Strategy
 - Work has started, but no publication date yet
- Dual Regulatory Regimes for NI?
 - Option to choose to comply with either UK or EU REACH?

GB CLP

- Established by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations
 - “Lifted and shifted” EU Regulation into UK law
 - only applies in GB, NI still in EU CLP
 - Shifted responsibility from the Commission and ECHA, to the UK Secretary of State and HSE as the UK CLP Agency
 - Creates new GB Mandatory Classification List (GB MCL) to replace CLP Annex VI Table 3, new GB CLP substance notification scheme
 - Consolidated text as on exit day (excludes 14th & 15th ATPs):
<https://www.legislation.gov.uk/eur/2008/1272>

Practical differences – CLP Notification

- Simple system for GB CLP
 - No need for Comply with REACH accounts, simple web form on [HSE website](#)
 - Requirements to notify same as EU CLP, BUT
 - Derogation for substances already notified to EU before 1 Jan 2021
 - Derogation where UK importer was part of an EU supply chain before 1 Jan 2021, and a notification had been made as part of that supply chain
 - If classification changes, or supply chain changes, new notification is needed
 - Data requirements are the same as for EU
- No publicly available list of notified classifications

Divergence – ATPs implementing RAC Opinions

EU ATP status in GB CLP

- 14th & 15th ATPs were included in GB CLP and came into force Oct 21 and Mar 22 respectively
- 16th ATP (clarification of notes related to CMRs) published after UK exit, not included
- 17th ATP (2019 RAC opinions) & 18th ATP (2020 RAC opinions) published after UK exit, not included in GB MCL

UK approach

- UK aims to review RAC Opinions within 6 months of publication of RAC opinion
- After a slow start, HSE catching up fast
- Not all HSE Technical Reports agree with RAC opinions!
- Aim is to produce annual updates to GB MCL

Example differences

Substance Name	RAC Opinion	HSE Opinion
d-Limonene	Flam. Liq. 3 H226 Skin Irrit. 2 H315 Skin Sens. 1B H317 Asp. Tox. 1 H304 Aquatic Acute 1 H400 (M=1) Aquatic Chronic 3 H412	Flam. Liq. 3 H226 Skin Irrit. 2 H315 Skin Sens. 1B H317 Asp. Tox. 1 H304 Aquatic Acute 1 H400 (M=1) Aquatic Chronic 1 H410 (M=1)
Lithium Carbonate [1] Lithium Chloride [2] Lithium Hydroxide [3]	Repr. 1A H360FD Lact. H362	Repr. 1A H360Df Lact. H362

Poison Centres

- UK did not intend to implement Annex VIII as it came into force after UK exit
- HOWEVER it appears to have been accidentally copied across into UK law ...
 - Consultation anticipated on whether to retain Annex VIII
- What to do in the meantime??

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Industry

As of 3rd February 2022 this section is under review.
Please check back later for updated guidance.

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Poison Centre Notifications - what to do?

Options:

1. Do nothing
2. Send voluntary SDS, as previously requested
3. Send dossiers in new i6z format (as required if placed on NI market)

Forthcoming EU Changes: EU Green deal and CSS

- Ambitious plans to add new hazard classes
 - PBT/vPvB
 - Endocrine disruptors
 - PMT/vPvM
 - Immunotoxicity
 - Neurotoxicity
- Aiming to get these added to the GHS – INF paper presented in July

More on these tomorrow from Chris Cullen!

Other activities in the EU pipeline

- New ATPs
 - 19th, 20th ATPs drafts in consultation
 - New notes/rules for mixtures containing reprotoxins (borates and 2-EHA)
 - 21st ATP (2021 RAC opinions) in development
 - Lead and lithium salts entries generating lots of comments!
 - Implementation of GHS 8th and 9th Rev Eds
 - Has been delayed due to lack of resources
- Update to Annex VIII
 - Legal clarifications, mainly in relation to standard formulas

SCIP

- Not transposed into UK law as came into force after UK's exit from the EU
- Doesn't apply in NI (not part of the NI protocol)
- DEFRA considering UK options for tracking chemical to reduce recycling barriers
 - May be included in UK Chemicals Strategy?

Keep up to date

- CHCS Newsletters (accessible to all SCHC members through the SCHC website)
- HSE bulletins
- ECHA news

- UK-EU regulatory divergence tracker (high level overview across all areas, not just chemicals)
<https://ukandeu.ac.uk/research-papers/uk-eu-regulatory-divergence-tracker/>
- CARACAL (documents for discussion at past and future meetings) <https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98>

Any questions?

