



2021 Chemicals Workshop Webinar Series

UK REACH – Its Implementation and Challenges and the EU Chemicals Strategy for Sustainability

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Welcome





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UK REACH – Its Implementation and Challenges, and the EU Chemicals Strategy for Sustainability



Dave Gordon



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Background – EU REACH



EU REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals (EU Regulation 1907/2006).

- Registration EU manufacturers and importers substances over 1 tonne p.a.
- Non-EU manufacturers can appoint an "only representative" (OR) in the EU to take on importer registration duties (OR does not need to import itself).
- Downstream users benefit from the registrations higher up the supply chain.
- Evaluation review by European Chemicals Agency (ECHA) of submitted dossiers.
- Authorisation substances of very high concern (SVHC) after review banned unless specifically authorised for limited uses.
- Restriction prohibitions on specific uses of certain substances.



UK REACH



- UK REACH is a stand-alone 'version' of EU REACH.
- UK REACH has applied since 1 January 2021.
- More appropriate name would be GB REACH ... because EU REACH continues to apply in Northern Ireland.
- HSE as regulator.
- Actions needed to comply with UK REACH, and maintain compliance with EU REACH for:
 - GB companies with EU REACH registrations.
 - GB downstream users buying chemicals from EU/EEA suppliers.
 - GB companies relying on EU REACH authorisations.
 - GB companies importing chemical under EU REACH Only Representative arrangements.

UK REACH – existing registrants



- GB manufacturers, importers or only representatives (ORs) are subject to "grandfathering", so existing registrations will be carried across into UK REACH (regardless of whether they have been/are being transferred to an EU entity to be retained under EU REACH).
- Companies had to provide basic information to HSE by 30 April 2021 about the registered substances.
- Full registration dossiers need to be submitted by the relevant phase-in date (but no registration fee as not considered to be a new registration).
- Also to maintain EU/EEA market access needed to transfer EU REACH registration to an EU entity before 31 December 2020 (manufacturers or ORs to an EU OR, or transfer of GB import business to an EU entity).

UK REACH – new importers



- Companies that were previously downstream users under EU REACH, without registration obligations, are now importers.
- Two main options:
 - The GB company submits a Downstream User Import Notification (DUIN) to the
 HSE by 27 October 2021. It will then have to submit a full registration dossier for each substance according to the same timetable as existing EU REACH registrants.
 - The non-GB manufacturer/formulator may, instead, appoint a GB OR to take on the registration duties of importers.
- These are considered new registrations so fees will apply (no fee for DUIN).
- Sensible to submit DUINs on a protective basis, even if supplier has said it will appoint an OR.
- Also consider EU REACH aspects for sales from GB importers/formulators into EU/EEA.
- Importers from outside EU, previously relying on an EU REACH OR that is not in GB will also be new importers.

What are the deadlines?



DEADLINE	OBLIGATION
30 April 2021	Last date for GB holders of EU REACH registrations to provide basic data to HSE
27 October 2021	Last date for DUIN submissions to HSE
28 October 2023	 Registration of: All substances manufactured/imported at 1000 tonnes or more per year Carcinogenic, mutagenic or toxic for reproduction (CMR) substances manufactured/imported at 1 tonne or more per year Very toxic to aquatic organisms (acute or chronic) substances manufactured/imported at 100 tonnes or more per year All candidate list substances (as at 31 December 2020)
28 October 2025	 Registration of: All substances manufactured/imported at 100 tonnes or more per year All candidate list substances (as at 27 October 2023) (i.e those added since December 2020)
28 October 2027	Registration of all substances manufactured/imported at 1 tonne or more per year

UK chemicals regime outpaced by the EU



- The EU's Chemicals Strategy is developing rapidly and there is now a Chemicals Strategy for Sustainability – Ken will deal with this shortly.
- In contrast, the UK is playing catch-up.
- It took a number of legislative changes simply to achieve parity with EU REACH post-Brexit
- The REACH etc. (Amendment) Regulations 2021 was the fifth amendment to UK REACH to account for updates to REACH brought into force by the EU during 2019 and 2020.
- In February 2021, 25 industry groups wrote to ministers to propose that only chemicals of greater concern would need full registration, using the evaluation work of ECHA (and others) as a guide.
- This would require new primary legislation.
- Adopting a risk-based approach in the UK is likely to be resisted by NGOs and may even result in EU officials reaching for the provisions on levelplaying fields in the EU-UK Trade and Cooperation Agreement.

UK REACH: A substantial shift on the horizon?



- The long-awaited Environment Bill will provide ministers with wide-ranging powers to change the "how" of UK REACH. However, these powers are not unlimited.
- DEFRA has just started working on the UK's Chemicals Strategy.
- These interventions have been timed to influence the future of UK chemicals regulation. Manufacturers, suppliers and users of chemicals in the GB market will need to monitor developments closely.



Further guidance



- HSE guidance, including different scenarios https://www.hse.gov.uk/brexit/reach-guidance.htm
- HSE Brexit guidance pages also cover CLP, PIC & Biocides
- gov.uk "How to Comply with REACH Chemical Regulations": health%20or%20the%20environment.
- SPB UK REACH Roadmap: <u>https://www.squirepattonboggs.com/en/insights/publications/2020/11/revised-uk-reach-roadmap-are-you-ready-for-the-new-uk-chemical-regulation</u>
- The REACH etc. (Amendment) Regulations 2021 (legislation.gov.uk)

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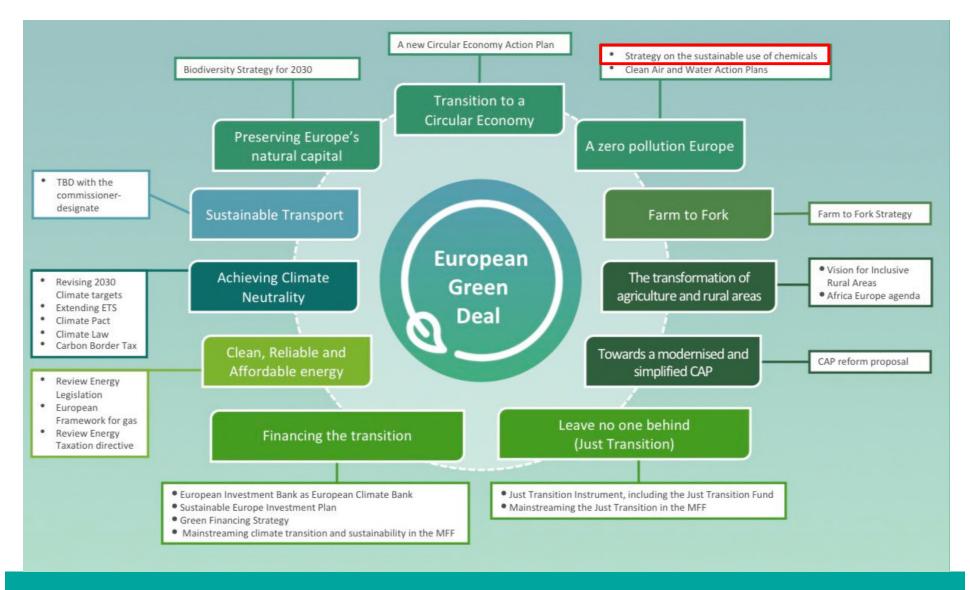
Ken Huestebeck



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The CSS in the context of the European Green Deal





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Motivation for the CSS: Implementation of REACH



Registered under REACH

 Roughly 22.000 substances (Source: <u>ECHA's REACH</u> <u>Registration Statistics</u>)

Candidate List (Article 59(10) of REACH)

219 substances

Authorisation List (Annex XIV to REACH)

54 entries

Restrictions
(Annex XVII to REACH)

• 70

CSS: Main elements



Safe and sustainable by design

Non-toxic material cycles

Innovating industrial production

Chemical pollution in natural environment

Strengthening EU's open strategic autonomy

Protection against most harmful chemicals

Endocrine Disruptors

Chemical mixtures

PFAS

Coordinate and simplify chemicals legislation

Zero tolerance for non-compliance

Information requirements

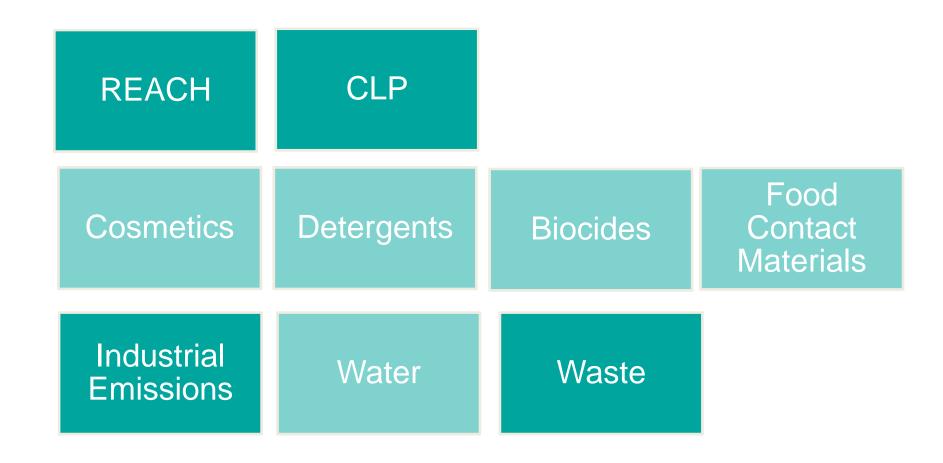
Methodologies and data

Science-policy interface

International leadership

CSS: Affected legislation (selection)





CSS: Implementation



- October 2020: Adoption of the Strategy
- March 2021: Call for applications for High-level roundtable (expert group)
- March 2021: Announcement of the members of the High-level Roundtable
- May 2021: First meeting of the High-level Roundtable
- May 2021: Publication of the inception impact assessments for the revision of REACH and CLP
- August 2021: Launch of public consultation on CLP revision
- Q1 2022: Public consultation on REACH revision planned

CSS: What does it mean for you?



No start from scratch with a new regulatory system – but CSS heralds most significant changes to EU chemicals regulation in 15 years → 'watch this space'

Impact (of course) depends on the substances manufactured/imported/used; spans from compliance (e.g. testing/reporting) costs to restricted market access

Existing rules: Implementation in parallel to the CSS





Actions to prepare







Compliance

Prepare for enforcement and inspections



Horizon scanning

Monitor regulatory changes



Getting involved

Through stakeholder engagement and voluntary initiatives



Sustainable chemistry

Integrate analysis of alternatives, substitution strategies, green chemistry



Innovation

Digital and green transition



Supply chain

Share chemical information

Welcome





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CLE



For those of you who require CLE credits please note the following states have been approved for CLE in AZ, CA, CT, NJ, NY and TX. The program is pending CLE in CO and OH.

Please write down the following affirmation code [UK1110]

A couple business days after today's session you will receive an email with a copy of the *uniform certificate of attendance* and *program evaluation* to complete and SUBMIT to Robin Hallagan at robin.hallagan@squirepb.com.

Questions?





