The Impact of UK REACH and GB CLP on Chemical Compliance in Europe

James Lloyd

SCHC Annual Meeting 2021

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THE IMPACT OF UK REACH AND GB CLP ON CHEMICAL COMPLIANCE IN EUROPE

11/05/2021

James Lloyd, Brexit Lead – H2 Compliance

AGENDA

1. **H2 BACKGROUND**
2. **UK REACH – SIMILARITIES**
3. **UK REACH - DIFFERENCES**
4. **GB CLP**
5. **KEY FOCUS AREAS**
6. **Q&A**

H2 COMPANY BACKGROUND

- Established in 2006 with offices in Ireland, UK, Poland, USA, plus partners internationally
- Full-service consulting firm supporting our clients with their continued market access in the UK, EU and other Rest of World markets
- Since acquisition by the Landbell Group in 2016, further expanding into Circular Economy activities
- Trusted by > 200 active clients across all sectors of business
- As part of expansion of our global footprint, established UK Legal Entity 2019
- Come and visit us at our booth!

UK REACH

JURISDICTION AND APPLICABILITY

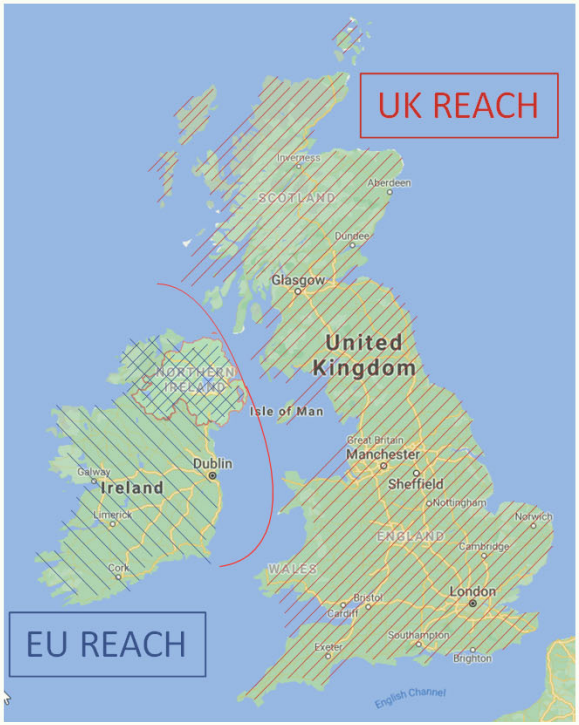
- EU REACH only applies in the EU to EU-based companies…

- UK REACH only applies in the UK* to UK* based companies

H2 COMPLIANCE

UK REACH only applies to GB

EU REACH continues to apply in NI



JURISDICTION AND APPLICABILITY

- EU REACH only applies in the EU to EU-based companies…
- UK REACH only applies in the UK* to UK* based companies
- US (and other non-GB) companies have **NO OBLIGATIONS** under either regulation
  - Your customers probably do…
- Appoint a UK-based entity to take on obligations of your customers.
  - **TAKE CONTROL** of your UK market access
  - **REDUCE** regulatory and cost burden on your customers

UK REACH – WHAT'S DIFFERENT?

- Added transitional provisions
- All references to the EU removed
- Defra and HSE
- No ECJ, no European Commission
- Independent scientific advice procedures

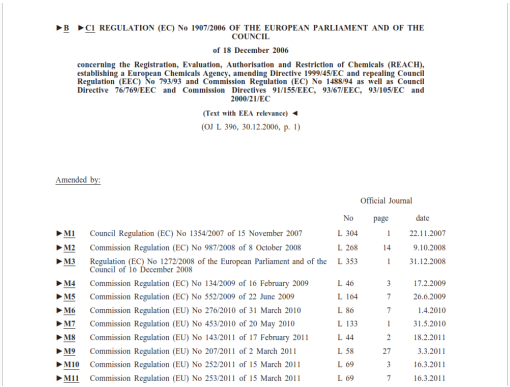
- **LISTS**
  - Candidate List of Substances of Very High Concern (SVHC)
  - Authorisation List: 2 new in GB (already on EU)
  - Restriction List: 2 proposals

UK REACH – WHAT'S THE SAME?

- **ALMOST EVERYTHING** is retained – including:
  - Registration

Ctrl + C

EU REACH



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of 18 December 2006

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(Text with EEA relevance) ◄

(OJ L 396, 30.12.2006, p. 1)

Amended by:

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►M1	Council Regulation (EC) No 1354/2007 of 15 November 2007	L 304	1	22.11.2007
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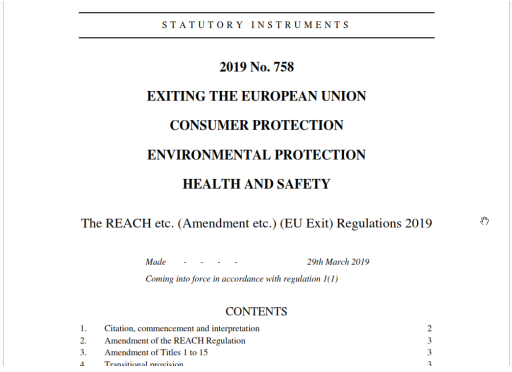

STATUTORY INSTRUMENTS

2019 No. 758

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

ENVIRONMENTAL PROTECTION

HEALTH AND SAFETY

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

Made - - - - 29th March 2019

Coming into force in accordance with regulation 1(1)

CONTENTS

UK REACH – REGISTRATION

- **REGISTRATION is required in the UK**

- EU registrations are **not valid** in the UK

- Import from the EU that was previously covered **now requires registration**

- Duplication of cost
- Duplication of effort
- Minimal benefit to human health and the environment?

UK REACH – WHAT'S THE SAME?

- **ALMOST EVERYTHING** is retained – including:
  - Registration
  - Only Representation
  - **EXEMPTIONS**

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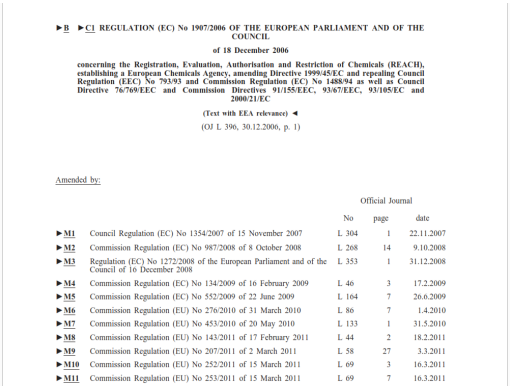
EU REACH



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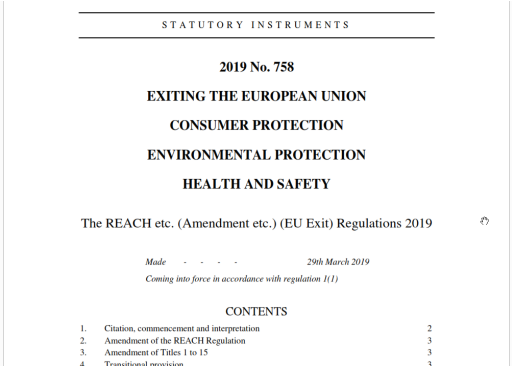

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UK REACH - EXEMPTIONS

- UK REACH retains all the same exemptions as EU REACH, notably:
  - Re-import e.g., UK → US → UK or UK → EU → UK
  - Annex IV
  - Annex V
  - Medicinal products
  - Polymers (monomers to be registered)
  - SRD

UK REACH – WHAT'S THE SAME?

- **ALMOST EVERYTHING** is retained – including:
  - Registration
  - **EXEMPTIONS**
  - SDS
  - Authorisation
  - Restriction
  - Lists…. At first
  - Joint submission
  - Data sharing…. For now

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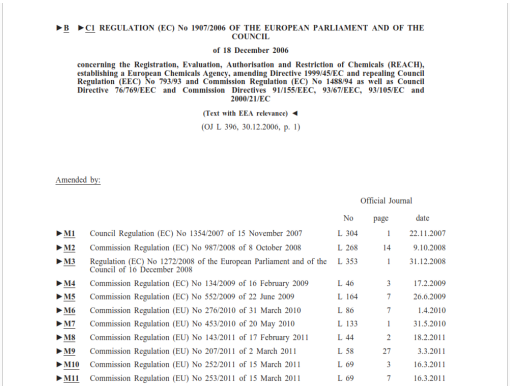
EU REACH



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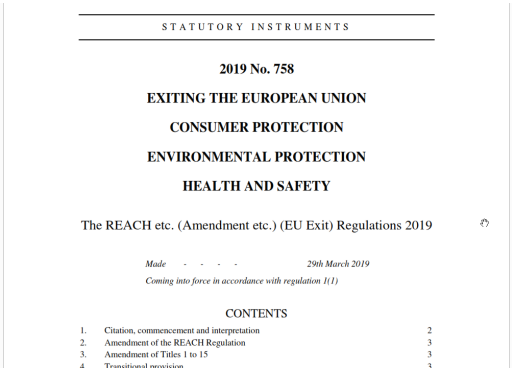

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UK REACH – WHY IS IT THE SAME?

- Brexit caused a vast legislative change across the entire UK

- Almost everything introduced via *Secondary Legislation*
  - Removes the need for parliamentary debate on *every piece* of the 10000 pieces of legislation
  - ***SPEED***
  - Comes with conditions: **no policy changes**
  - Prioritise “lift and shift” with fixes for “inoperability”

- Much of REACH was deemed “operable”, with the addition of transitional provisions…. …. ….

TRANSITIONAL PROVISIONS - EXPIRED

- Grandfathering
  - For existing GB-based registrants — End of April 2021
  - Continuation of registration, no loss of investment
  - (Also for authorisation holders – niche)

- DUIN
  - For downstream users and distributors
  - For continuation of import from the EU (and wider via OR) — End of October 2021
  - For substances registered in the EU

Neither of these are/were pre-registration

DEADLINES

- If you grandfathered – supply data
- If you notified or are covered by a supplier OR notification (DUIN) – submit registration

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	

- 28th October 2023
- 28th October 2025
- 28th October 2027

HSE WORK PROGRAMME 2021/2022

- No resource allocation for Substance Evaluation
- New SVHC candidates
- New restriction proposals
  - Tattoo inks (already active in EU)
  - Lead in firearms (proposed in EU also)

UK SVHC - DIVERGENCE

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

→ Added in EU Jan 2021

→ Not on ECHA

→ Candidate List

→ Added in EU Jul 2021

Industry-initiated:

- Account management of new registration
- Processing applications for Product & Process Orientated Research and Development (PPORDs)
- Testing proposal evaluation
- Applications for authorisation
- Helpdesk; Enforcement

Demand-led (from legislative requirements):

- Compliance check
- Recommendation for additions to the authorisation list
- Reports

Government-initiated:

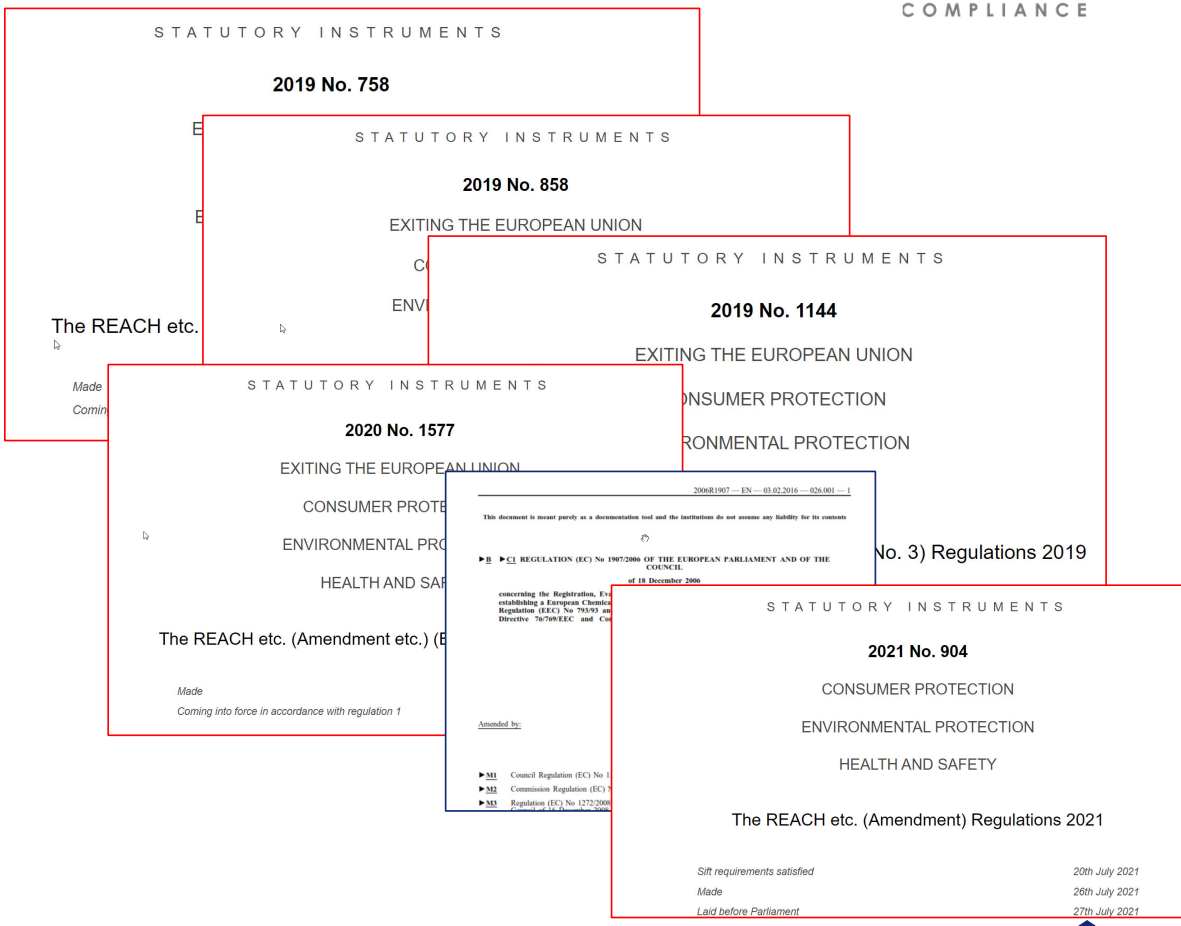
- Substance evaluation
- Regulatory Management Options Analysis (RMOA) & prioritisation activities
- Identification of substances of very high concern (SVHCs)
- Restriction
- Enforcement

Other:

- Drafting & maintaining website guidance
- Stakeholder engagement
- Independent scientific advice
- Training & Development (of HSE & Environment Agency staff)

WHERE TO FIND OUT MORE

- Complicated mess of legislation
- legislation.gov.uk… 1,2,3,4,5
- Defra
  - https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations
- HSE
  - https://www.hse.gov.uk/reach/index.htm



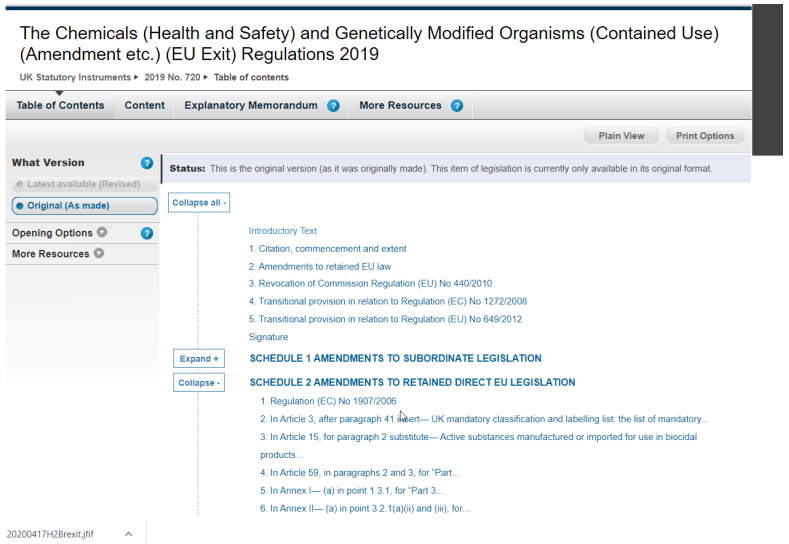
SUMMARY

- UK REACH = EU REACH, with some small changes
- Exemptions still apply – re-import, medicines, polymers, naturally occurring…
- If you availed of transitional provisions – deadlines for compliance (similar to pre-registration but not)
- Registration in the UK = duplication
  - Of effort **and cost**

GB CLP

GB CLP – THE GB IMPLEMENTATION OF GHS

- Another “Copy-and-paste” or “Lift-and-shift”
- Only 45 amendments!
- HSE are policy lead **and** operational delivery
- C&L Notifications
- Harmonised Poison Centre Notifications (PCN)



MANDATORY CLASSIFICATION AND LABELLING (MCL)

- Equivalent to 'harmonised classifications' under EU CLP

- The same rules apply, but the list may change
  - More potential diversion over time…

- Keep up-to-date via:
  - GB CLP e-Bulletin from HSE
  - Publications table

THE LIST

Using the GB mandatory classification and labelling list (GB MCL List)

The GB MCL List (.xlsx) gives information on the classification and hazard labelling of the substance and is legally binding in GB.

RULES FOR NOTIFICATION (AND EXEMPTION)

- Essentially the same rules as the EU…
  - But applicable to GB-based manufacturers and importers
  - NI Protocol

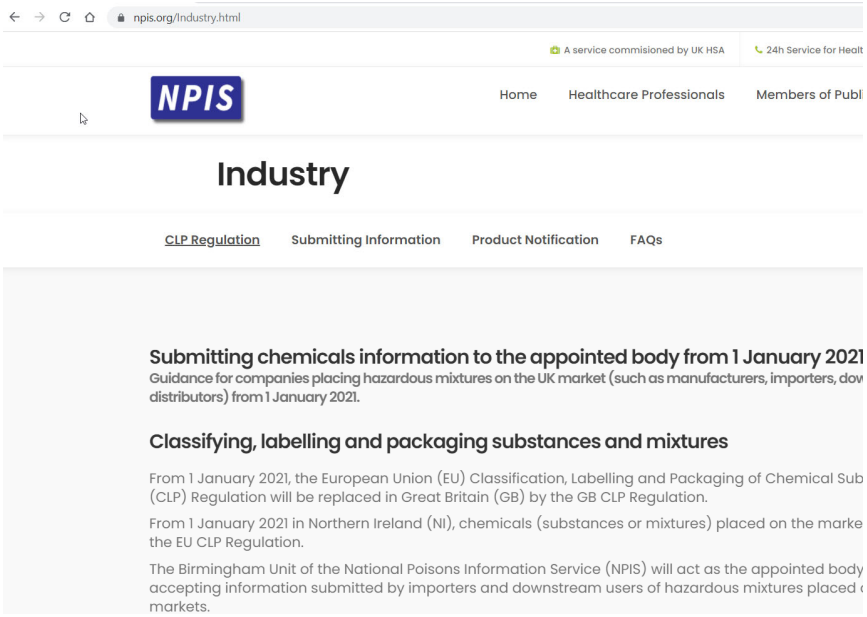
Also applies to NI-based manufacturers, distributors and DU directly supplying the GB market with NI goods.

In addition to any obligations under EU CLP.

- Minimising unnecessary notifications:
  - Notified prior to 1st January 2021
  - Part of a supply chain where notification was completed prior to 1st January 2021
  - UK REACH registration is in place
  - New supply chains from 1st January 2021
  - Change in classification

ARTICLE 45 AND ANNEX VIII

- NO POISON CENTRE NOTIFICATIONS FOR GB
  - No need for a UFI
- Pre-Brexit system remains:
  - Voluntary submission to NPIS
- However, PCN **is** required for NI
  - More complicated – cannot use the portal
  - UFI required
  - Submit IUCLID file to NPIS



KEY FOCUS AREAS

UK REACH – NRES

- New Registration of Existing Substances

HSE inform you that this process is applicable.

Should be available to any substance that was registered in the EU

- **THIS IS A NEW REGISTRATION**
  - Inquiry dossier first
  - Submit registration dossier
  - Pay registration fee
  - No data required - waiver

- Data is expected to be provided (or LoA purchased) by the relevant deadline

UK REACH tonnage bands and hazard profiles

Deadline (last date for dossier submission)	Tonnage	Hazardous property
27 October 2023	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)
27 October 2025	100 tonnes or more per year	Candidate list substances (as at 27 October 2023)
27 October 2027	1 tonne or more per year	

Same deadlines as for grandfathering and DUINs

UK REACH AND GB CLP – LABELS AND SDS

- EU REACH applies to EU-based manufacturers, importers, downstream users, distributors – *suppliers*
- UK REACH applies to GB-based manufacturers, importers, downstream users, distributors - *suppliers*

The definitions have changed as a consequence of the new regulations

- **Label elements may need to change**
  - A GB-based formulator shipping to the EU is no longer an EU supplier. The "supplier" for CLP is the EU-based importer.
  - An EU-based importer shipping to GB is not a GB supplier. The "supplier" for CLP is the EU-based importer.

We published an article with the International Chemical and Regulatory Law Review (ICRL) on this issue!

- Same regarding SDS – "details of the **supplier**"

Practical Solutions to Challenges Associated with Safety Data Sheets and Labelling in the EU-27 and the UK Following the UK Withdrawal from the EU

As a consequence of the UK withdrawing from the European Union, it is becoming more difficult to comply with the labelling and safety data sheet (SDS) aspects of REACH and CLP. Such difficulties have also begun to shine a light on compliance in those areas more widely across the EU – regardless of the impact of Brexit. Correspondingly, authorities are ramping up enforcement across the EU and ECHA's Enforcement Forum is undertaking an enforcement project currently focusing on this area. Fortunately for duty holders in the EU and UK, and those exporting into those jurisdictions, the majority of the obligations are the same. Primary differences are due to legal entity changes – downstream users becoming importers, and the subsequent change this requires in legal entity details on labels and in SDS. What follows is an introduction to this issue, an outline of the obligations required in each jurisdiction, problems encountered when attempting to achieve compliance, and practical solutions to these problems. We hope that this document can be used to support your continued market access and minimise the chance of enforcement action against your business, and that of your customers.

*James Lloyd, Olena Krychevska and Adam Hedley**

I. Introduction

The European Union's REACH[1] and CLP[2] regulations have long been intertwined. REACH relies heavily on CLP to determine how substances should be classified, and often the applicability of some exemptions and derogations such as those in REACH, Annex V. They also frequently form part of larger REACH processes to help determine whether:

– there is adequate risk to justify evaluation of sub-

GB CLP – LISTS

- Divergence between UK and EU means keeping track of extra lists…

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→ Added in EU Jan 2021

→ Not on ECHA

→ Candidate List

→ Added in EU Jul 2021

THANK YOU FOR YOUR ATTENTION

Q&A

Related H2 Services

- Planning and Gap Assessment
- Only Representation in both EU and UK
- New Registration
- Data negotiation and SIEF services
- C&L Notification
- New Registration Services

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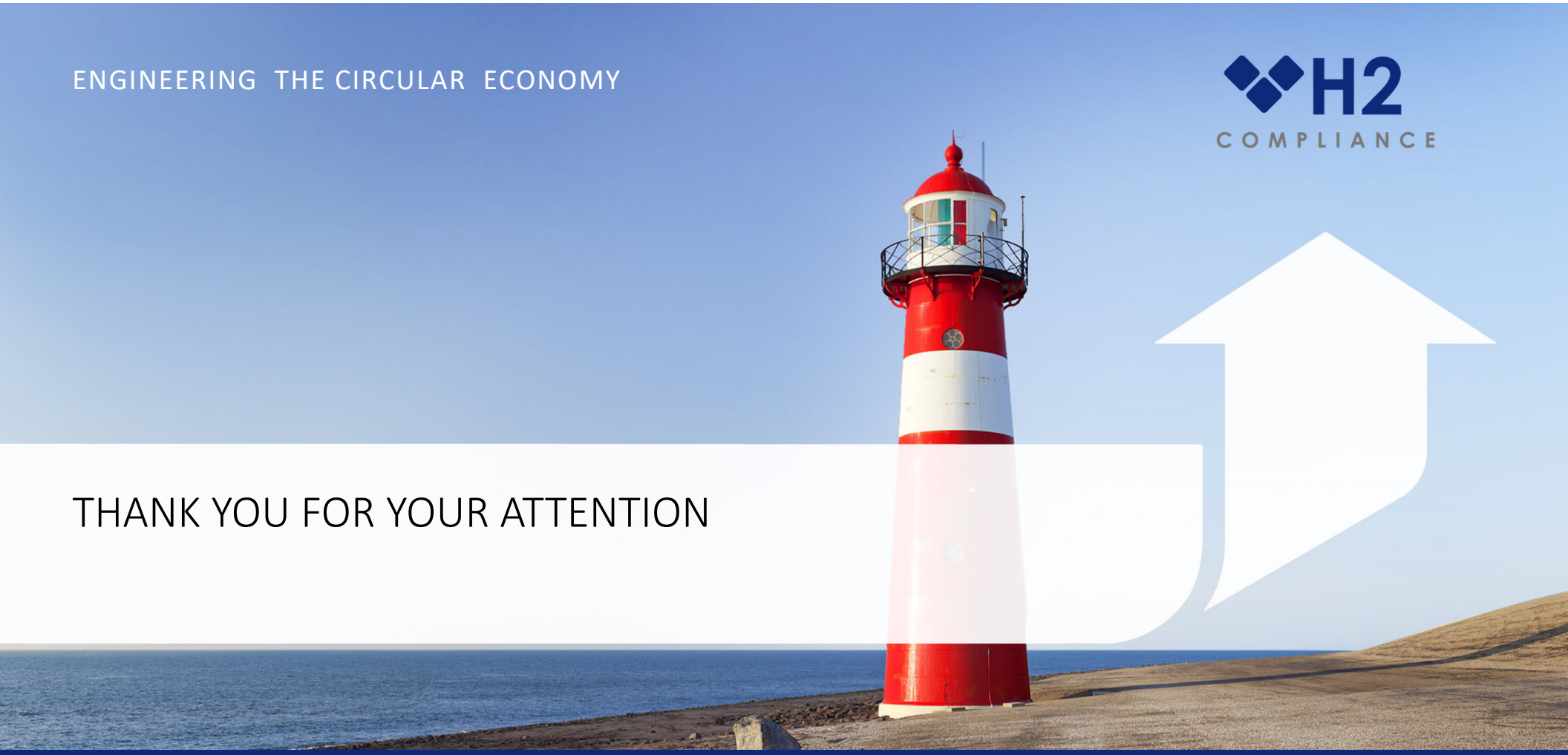
ENGINEERING THE CIRCULAR ECONOMY

H2 COMPLIANCE



THANK YOU FOR YOUR ATTENTION

European Recycling Platform

H2 COMPLIANCE

prodigentia® information technologies, s.a.

LANDBELL®

DS Entsorgungs- und Dienstleistungs- GmbH

green ALLEY