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Introduction

On 1 January 2021, the UK completed its separation from the European Union with the ending of the transition period which saw the UK withdrawing from following all the rules and institutions of the EU including the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Instead, the UK implemented its own version of REACH, run by Defra and the Health and Safety Executive (HSE). This has huge implications for UK businesses supplying, importing, handling or storing chemicals from European Economic Area (EEA) countries.

It is vital that every UK business in the chemical industry establishes its roles and responsibilities now the changeover has occurred, to ensure the continuity of business and that no-one falls foul of compliance under the new laws.

Worryingly a survey of 91 individuals in the chemicals industry run by Adler and Allan in September 2020 revealed that only 55% were aware of the impending changes to REACH.

Further, only 17% felt fully confident that they understood how the new REACH regulations would impact their organisation and only the same percentage of respondents had discussed the implications of the changes with their suppliers.

With the new rules now in place this paper aims to clear up some of this confusion and give businesses more clarity and confidence in what they now need to do.

We will summarise the key facts surrounding REACH after Brexit, considering what the new UK REACH system will involve and how the changeover will be managed.

We will outline the legal responsibilities of different actors within the supply chain, giving you some guidance on what you need to do when. We will also take a look at the wider likely impact of Brexit on the UK chemical industry, based on recent research and projections.

The survey

Our methodology

Adler and Allan's survey on awareness of changes to REACH after Brexit had respondents made up of individuals from manufacturers, blenders, only representatives (ORs) and downstream users. They were contacted as contacts of Adler and Allan or responded to a link shared on our social media channels.

Of the 91 individuals responding to the survey after email contact, 92% were UK-based and 8% from the EEA (no responses were received from outside the EEA). Some respondents sourced their chemicals solely from the UK, while others source from the EU, a combination of UK and EU, or elsewhere. (Those responding on social media did not give their location/role.) Email respondents completed an online survey of eight questions via Google Forms, and the results were then processed internally by Adler and Allan.



What exactly is REACH?

REACH is a European Union (EU) regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, which came into force on 1st June 2007.

It applies to Member States (MS) of the European Union and to members of the European Economic Area (EEA).

REACH requires manufacturers or importers of chemicals to submit a dossier of information to the European Chemicals Agency (ECHA) to register their chemical substances for use within the EEA. This applies to all substances manufactured or imported into the EU in quantities of 1 tonne or more per year, whether an individual substance, or in preparations or articles.

REACH places the burden of proof on companies. Without this registration you cannot legally manufacture, supply, or bring your substance to market within the EU – the principle is strictly: no data, no market.

Your responsibilities under REACH rules vary according to your position in the supply chain, and the higher the tonnage you deal with, the more stringent the data requirements for registration (the tonnage bands are grouped: 1-10 tonnes, 10-100 tonnes and >100 tonnes).

In general, under REACH you may have one of these roles:

Manufacturer: If you make chemicals, either to use yourself or to supply to other people (even if it is for export), then you will probably have some important responsibilities under REACH.

Importer: If you buy anything from outside the EU/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onwards sale or finished products, like clothes, furniture or plastic goods.

Downstream users: Most companies use chemicals, sometimes even without realising it. You therefore need to check your obligations if you handle any chemicals in your industrial or professional activity. You might have some responsibilities under REACH.

If you are a company established outside the EU (this now includes the UK) then you are not bound by the obligations of REACH, even if you export products into the customs territory of the European Union.

The responsibility for fulfilling the requirements of REACH, such as registration, lies with the importer in the European Union, or with the only representative (OR) of a non-EU manufacturer established in the European Union.

REACH encourages joint registration and data sharing to improve common industry knowledge and accuracy; companies who work together through a Substance Information Exchange Forum (SIEF) and submit a joint registration benefit from a reduced fee.



What is happening after Brexit?

As of 1 January 2021, EU regulations – including REACH – cease to apply in England, Scotland or Wales, and EU registrations for UK-based entities lapsed.

Instead, The Department for the Environment, Farming and Rural Affairs (Defra) and the Health and Safety Executive (HSE) implemented its **own version of** the rules – so-called 'UK REACH'.

[NB: It is important to note that companies in Northern Ireland are still covered by EU REACH according to the 'IE/NI Protocol.']

Registration with UK REACH follows closely the process under EU REACH and as such should not be a major jump for most organisations.

UK companies will have to comply with UK REACH. Their responsibility may shift as they become importers rather than downstream users. If they supply substances into the EU/EEA, the substances will need to comply with EU REACH, but the duty holder is the EU/EEA company who is importing the substance.

The location of the legal entity determines which set of regulations they need to comply with. UK based companies will be treated as a third county outside the EU and can appoint an EU based OR to do the REACH registration for them to continue to supply to the EU27/EEA.

The UK's own version of CLP regulations (Classification, Labelling and Packaging of substances and mixtures) also comes into force, replacing EU CLP regulations regarding classification and labelling.

This is known as GB CLP and replicated EU CLP as it applied on 31 December 2020.

Annex VIII (poison centre harmonised notification) does not apply in England,

Scotland or Wales. However, it is important to note that Annex VIII does apply in Northern Ireland.

It is the responsibility of individual companies to assess their operations, determine any change to their role, and decide whether they need to comply with both the UK and EU REACH regimes, or just one.

UK REACH

From 1 January 2021

The UK established its own substance registration system, mirroring the intention, form and function of EU REACH as closely as possible and upholding its high standards of health and environmental protection. It will echo the principles of "no data, no market", precautionary decision making, animal testing as strictly last resort, and full access to information for workers.

The new UK regime will apply to all chemical substances manufactured in or imported into the UK, and will be overseen by the UK Chemicals Authority (formed by the Health and Safety Executive (HSE) and Defra).

For more information, DEFRA has published detailed online at www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations

A new IT service known as 'Comply with UK REACH' launched on 1 January 2021

Use the 'Comply with UK REACH' service to:

- Transfer your EU REACH registration into UK REACH (also known as 'grandfathering') to continue to have access to the GB market.
- Notify that you're going to continue importing substances from the EU/EEA by submitting a downstream user import notification (DUIN),
- · Submit a new registration for a substance, and
- To transfer your registrations to another legal entity.

You will need to contact the Health and Safety Executive to:

- Validate existing UK-held product and process orientated research and development (PPORDs), and
- Provide information on any authorisation matter, including new authorisation application, grandfathering of existing authorisations, and downstream user notifications of authorised uses.

Overall, the intention is to make the transition as smooth as possible, with a lot of continuity in the required data and the process - for example Safety Data Sheets submitted under EU REACH will remain valid.

You will need to create a Government Gateway account to sign into the 'Comply with UK REACH' service. Find out how to create an account here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/947959/ register_a_business_or_organisation_for_the_Comply_with_UK_REACH_ service.odt



Recognising your EU REACH registrations under UK REACH (grandfathering)

To minimise the impacts of introducing UK REACH, there is a system of 'grandfathering' to ease the transition.

This mean that **if you are a UK entity** with substances currently registered under EU REACH, your registration(s) will be **automatically legally recognised or 'carried over' to UK REACH** on 1 January, and you can continue manufacturing and supplying the chemicals. This applies whether you are a sole, lead, or joint registrant, and applies to any registration made to EU REACH within three years prior to 31 December 2020.

Grandfathering does not incur any registration fees and happens automatically to provide unbroken legal validity. *However*, you will still need to endorse your registration and provide basic supporting information via the UK REACH IT system by 30 April 2021.

Once you have provided the initial information, your UK REACH registration number will be issued to you and you will be able to begin engaging in data sharing negotiations with other (potential) registrants.

You then need to complete a full registration with UK REACH within 2, 4, or 6 years of 28 October 2021, depending on the tonnage with which you are dealing. Just make sure you do not miss the deadlines.

The information required for the registration under UK REACH are identical to the requirements under EU REACH. However, note that UK-REACH requires registrants to hold the rights to refer to substance specific data contained in the registration dossier. If your EU REACH dossier contains information for which your rights to refer have altered as a result of leaving the EU, you will need to create a member dossier from your substance dataset. EU SIEF (substance information exchange forum) participants should verify the scope of their usage rights in relation to the information contained in the REACH registration dossier - and, as the case may be -seek adjustment of existing contracts, based upon their respective contracts. If you have a Letter of Access as proof that you have the right to refer to the data for your EU REACH registration, you will need to determine the conditions under which existing studies may be used for UK-REACH purposes.

For more information, HSE has produced Guidance on Grandfathering EU Registrations which can be found at www.hse.gov.uk/reach/grandfathering-registrations.htm

Downstream User Import Notifications (DUIN)

If you were a downstream user or distributor under EU REACH or were regarded as a downstream user by virtue of an Only Representative (OR) agreement, transitional provisions have been put in place that aim to help minimise disruption to your business.

GB-based companies that were downstream users or distributors prior to the end of the transition period under EU REACH, become importers under UK REACH. Article 127E of the statutory instrument (SI) implementing REACH in the UK provides the transitional provision for these GB-based legal entities.

By submitting a Downstream User Import Notification (DUIN) to the Agency within the first 300 days of the end of the transition period, you effectively defer your registration obligation for up to 6 years plus 300 days after the end of the transition period.

If you opt not to submit a notification, then either a full registration would be due for any substances imported at or above 1 tonne per year, or that import must cease.

How to submit a DUIN

By 28 October 2021 you need to:

- Use the 'Comply with UK REACH' service
 to indicate that you are an existing
 downstream user or distributor. At this
 point your UK REACH DUIN number will
 be issued to you. Note that this step only
 needs to be done once per legal entity
 and covers all substances that you wish to
 continue importing from the EU.
- Populate the additional information spreadsheet with information about the substances that you wish to continue importing. A template can be found at this link www.hse.gov.uk/reach/duinadditional-information.xlsx
 - The spreadsheet should list individually all the substances that you wish to continue importing from the EU, one per line.
 - Where a substance is included in the spreadsheet, it must contain at least one of the following identifiers: substance name, CAS number, EC number.
 - Some information only has to be included if it is available for you.
- Send the completed spreadsheet to the HSE, including your legal entity name and DUIN number in the subject line of the email.

If you wish to continue importing into the UK from the EU, you will then need to submit a new registration to the HSE for each substance that you wish to continue

importing and provide the full information requirement for your tonnage band under UK REACH. The relevant deadline within 2, 4, or 6 years of 28 October 2021, depending on the tonnage and hazardous properties of the substance with which you are dealing.

The first step to creating a new registration is to submit an Article 26 Inquiry. The process for compiling an inquiry dossier is analogous to the process under EU REACH and the requirements are the same and is completed within IUCLID. There is a helpful guide available from ECHA (https://e-cha.europa.eu/documents/10162/22308542/manual_inquiry_en.pdf) and a video (www.youtube.com/watch?v=OnbmY 7evBGE&list=PLOPGDACSd6qyDkdXwP-ua1Fjb5bJksY75k&index=12&t=Os) to guide you through the process. The inquiry dossier can be submitted to the HSE via the 'Comply with UK REACH' service.

Once you have successfully inquired about a substance and received your inquiry number, your contact details, or the details of your appointed Third-Party Representative will be shared with existing registrants, grandfathered registrants, and other successful inquirers. This will enable you to engage in the data sharing process.

For more information, HSE has produced guidance on downstream user import notifications under UK REACH via www.hse.gov.uk/reach/duin.htm



New registrants under UK REACH

Grandfathering does not apply to any new applications; these must be made to UK REACH from the outset.

Registration is not required for mixtures (formulations). However, the substances that comprise a mixture must be registered if the aggregated import volumes for any of those substances reach 1 tonne or more per year.

If you determine that a new registration is required and the provisions for grandfathering and DUIN do not apply to you, a complete registration will be required prior to the manufacture or import into GB reaching 1 tonne per year. In such circumstances, no transitional provisions apply.

For more information, HSE has produced guidance for new registrants under UK REACH www.hse.gov.uk/reach/new-registration.htm

Entities operating out of Northern Ireland are subject to different rules under the Northern Ireland protocol – and EU REACH will continue to apply. For specific support on this the Government has launched a new NI Trader Support Service online – see www.tradersupportservice.co.uk/tss.

The HSE has also produced guidance for GB importers or downstream users of qualifying NI goods registered under EU REACH by a business in Northern Ireland -

www.hse.gov.uk/ reach/northern-ireland.htm



Other related regulations affected by Brexit

Of course, it's not just REACH affected by the UK leaving the EU; all regulations governing the manufacture and trade of chemical substances will be impacted.

The rules around **Poison Centre Notifications** changed in the EU on 1st January 2021, as the deadline for Annex VIII [to the CLP Regulations] harmonised poison centre notifications for consumer and professional use passed. There are no obligatory requirements post-Brexit for GB based suppliers to submit the required information to the EU Poison Centre, as the duty holder is the EU importer. However, a voluntary submission could still be beneficial to avoid the need to provide the full chemical composition of your mixtures to your EU customers.

Annex VIII notifications to the GB poison centre are not required for hazardous mixtures placed on the market within GB, instead voluntary submission of information relating to emergency health response, and preventative measures on hazardous mixtures placed on the GB market, are encouraged. The information is provided by sending the safety data sheet (SDS) to the NPIS. A unique formula identifier, UFI, is not needed, but if available, this should be identifiable on the front page of the SDS.

Annex VIII notifications to the HSE are required for hazardous mixtures placed on the Northern Ireland market. Further information on poison centre notifications can be found at www.gov-.uk/guidance/submitting-chemicals-information-to-the-national-poisons-information-service.

The EU Biocidal Products Regulation (BPR) no longer applies in GB. However, a biocidal product / biocidal product family must be authorised to be made available on the market in Great Britain (GB). Further guidance can be found on the HSE website.

The EU Classification, Labelling and Packaging Regulation (CLP) has been replaced by a UK version - GB CLP. The EU CLP Regulation as amended on 31st December 2020, was retained in GB law. These arrangements mean that GB continues to adopt GHS, independently of the European Union. The GB CLP Regulation applies to GB-based manufacturers, importers, downstream users, and distributors supplying the GB market and the main duties to classify, label and package remain. The existing EU harmonised classification and labelling in force on 31st December 2020 was retained in GB as GB mandatory classification and labelling (GB MCL). There is a duty for GB-based manufacturers or importers to submit a notification to the HSE within one month of placing new substances on the GB market. Notifications already made to ECHA which were included in the ECHA Classification and Labelling Inventory on 31 December 2020 do not need to be re-notified.

The UK switched to its own version of Prior Informed Consent (PIC) regulations on 1st January 2021, so anyone exporting or importing PIC-listed chemicals from or to GB is required to comply with the GB PIC regime. The EU PIC and GB PIC regimes operate independently of each other and there are different procedures for notifying exports under GB PIC.

Rules around Plant Protection Product (PPP) legislation regulating pesticides have also changed. From 1st January 2021 an independent pesticides regulatory regime is in operation in Great Britain and guidance is available on the HSE Website at www.hse.gov.uk/pesticides/brexit.htm





Identifying your new role and responsibilities

Manufacturer, importer, downstream user, or distributor?

A UK-based entity or based in the EU?

Buying and importing from Europe?

Supplying just the UK market, or exporting to the EU?

The responsibilities you carry under UK REACH depends what role you play in the supply chain – i.e., whether you manufacture, import, place chemicals on the market, formulate or mix substances, or facilitate storage for third parties.

Your responsibilities are also affected by where the chemicals you source, sell or store have originated, where your company is based and the size of the quantities you deal with.

Understanding your post-Brexit legal responsibilities means double-checking your role and ascertaining whether it has shifted from 1 January.

You may find you take on a slightly different legal 'label' or hold responsibilities for registration that previously fell to others in the supply chain. You might even have more than one role.

For example, many companies who have always termed themselves 'downstream users' (formulating, transferring, using mixtures, produces or articles) could well find themselves legal 'importers' under the new arrangements – a potentially daunting prospect.

If in any doubt, check with the ECHA or consult an expert - Adler and Allan are happy to provide guidance.

Are you...

A UK-based company manufacturing in the UK and supplying only the UK market?

The transition for you should be fairly straightforward. Assuming you are currently registered under EU REACH, your substance's registration will be 'grandfathered'. You will need to make sure you confirm your registration by 30 April 2021 to get a new UK REACH registration number, and complete full registration by the later relevant deadline (2, 4 or 6 years' time).

Bear in mind that you will need access to technical information you collated for your original ECHA registration. This may involve renegotiating commercial contracts or letters of access you put in place via a Substance Information Exchange Forum (SIEF) for your EU REACH registration – make sure you allow sufficient time for this. Helpfully, Safety Data Sheets created under EU REACH will be valid under UK REACH.

A UK-based company importing from the EU?

If you are UK based but procure or store substances or mixtures from EU/EEA-based suppliers, you must ensure the substances you handle (over 1 tonne per year) are covered by a valid UK REACH registration by one actor within the supply chain. Regardless of the supplier being based in the EU, because the substance is coming into the country it must have a UK registration. You will find you are legally regarded as an importer, even if you previously just saw yourself as a 'purchaser'.

So, make sure you are covered:

- **EITHER** notify the HSE by opening an account on the new UK Comply with REACH IT system and register the substance to be imported before the relevant deadline.
- OR encourage your EU/EEA supplier to appoint a UK-based Only Representative.
- OR change source to a UK supplier so you no longer import from the EU.

Take note – each imported substance only requires one registration – so if your EU/EEA supplier is appointing a UK-based OR you will not need to register the substance.

Also, the principle of "one substance, one registration" applies so if you notify the HSE of your intention to register this will enable you to engage in the data sharing process and to collaborate with other importers.

A UK-based company exporting to the EU?

If you're **UK based but you supply the EU market**, after 31 December 2020 you are no longer able to register a substance under EU REACH. Any existing registration under EU REACH will be regarded null and void and will be revoked. Your EU REACH substance registrations should have been officially transferred to an EU/EEA-based legal entity, most likely an EU Only Representative, through the 'legal entity change' functionality in the REACH IT system before 31 December 2020.

If this transfer has not yet been completed, the EU successor needs to accept the transfer as soon as possible. ECHA have advised that the transfer will be cancelled, and the registration revoked if it is not finalised by 31st March 2021.

Any substances you export after from 1 January 2021 will have to comply with EU regulations as well as UK ones, including EU REACH and EU CLP Regulation.



Is the UK chemical industry ready?

Adler and Allan ran a survey in September 2020 to gauge levels of awareness in the chemical industry of the changes to legislation we've been discussing.

Via email and social media questionnaires, they captured responses from 91 individuals operating in the industry (92% UK-based, 8% EU-based).

Only 55% of respondents said they were aware of the new REACH regulations coming into force. Whilst a small sample size, if this accurately reflects the wider industry it paints a concerning picture regarding the number of organisations who could be unintentionally falling foul of compliance requirements now.

When asked on a scale of 1-5 how confident they felt that they understood how the new REACH legislation would impact their organisation, only 37% of respondents felt confident enough to rate this as 4 or 5.

More positively, 80% of respondents said they were aware of what position they played in the supply chain (although they were not asked if they thought this role might change post-Brexit).

The importance of communication along the supply chain showed less awareness. Only 18% of our respondents said they had discussed the changes to REACH with their suppliers, although a further 37% said they were definitely planning to. A full 20% said they had no plans at all to do so.

Whilst a small-scale survey, this snapshot really does highlight the need to raise awareness of the changes to REACH and provide greater clarity on the requirements and responsibilities falling to individual operators, to ensure companies do not end up accidentally contravening the law.



The impact on the UK chemical industry

Unfortunately, falling foul of compliance isn't the only threat facing UK-based chemical manufacturers and importers. Experts predict worrying trends affecting the industry as many companies reduce or move operations out of the UK due to Brexit.

In a survey of more than 160 chemicals management professionals by Chemical Watch in July 2020, more than one in five (21%) UK-based respondents said their companies will be moving their operations out of the country because of Brexit, and a further 16% said they were considering it. A similar proportion (19%) will be reducing their UK operations and 5% said they were closing their operations altogether because of Brexit (7% considering doing so). This is a significant jump from a survey two years ago when only 5% of UK-based respondents said they were actively organising to move operations out of the UK.

Perhaps unsurprisingly given the complexities of the rules we've been discussing, 7% of UK respondents and 27% of those based outside the UK did not plan to continue registering substances for the UK market after 31 December 2020.

Slightly more encouragingly, when asked about steps they were taking to carry on trading, a quarter (24%) of UK-based

respondents said they were establishing new legal entities in the EU in order to continue business and 59% were using legal entities in the EU to continue business. 28% said they were looking beyond the EU to continue business. And a fifth (21%) said they were still hoping to invest in UK operations.

Asked to indicate what reasons had prompted their intended action post Brexit, the most commonly cited (40% of UK-based respondents) was to gain more regulatory certainty. This was followed by reducing transport costs and delays, improving economic certainty and avoiding bureaucracy. This indicates very strongly that the uncertainty, complexity and additional bureaucracy of the changing rules on REACH (and other regulations alongside) will contribute to a significant loss of trade in our industry.

As an operator, the more clarity and guidance you can get regarding the new regulations the better.



What do you need to do now?

Hopefully after reading this paper you're much clearer on what changes have occurred, and how they will impact you depending on your specific role and situation.

To condense everything down, here's a checklist of key actions over the next few months:

From 1 January 2021 Register for the 'Comply with UK REACH' service when the new UK REACH IT system goes live.

Before 31st March 2021 Ensure your EU successor has completed the transfer of any REACH registrations

By 30 April 2021 Transfer your EU REACH registration into UK REACH (also known as 'grandfathering') to continue having access to the GB market and to obtain a UK REACH registration number.

By 28 October 2021 Submit your DUIN to indicate you were an existing downstream user importing substances from the EU and you wish to continue to import these substances.

Within 2, 4, or 6 years of 28 October 2021

(Depending on your situation), complete a full registration with UK REACH.

Accept that all of this will take time and cost money - set aside planning time and budgets now!

Read Government information (see the links within this document and the section below) and seek advice from industry experts such as Adler and Allan – we have in-house specialists fully versed in everything REACH related, who can answer your queries and provide guidance on requirements, deadlines, and the most up-to-date information as it evolves.

To conclude

The changes to REACH regulations are complex and set to have a major impact on the UK chemicals economy into the future.

Adler and Allan's snapshot of current awareness amongst chemicals professionals shows a concerning lack of comprehension of the changes and poor communication amongst suppliers.

It is crucial that all actors across the industry get a grasp of their defined roles and responsibilities as soon as possible, and understand what is legally required of them in the coming months.

Make sure you are informed and prepared for the changes that affect your business, get advice where needed, and open up conversations with colleagues, competitors, and suppliers.

Let's smooth the path beyond REACH, make sure as many businesses as possible are fulfilling their obligations correctly and confidently, and give a head-start to the UK chemical industry as it navigates a more pressured era.

Further information and contacts

Government advice on how to comply with UK REACH: www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations

HSE REACH information: www.hse.gov.uk/reach/

EHCA 'Brexit' information: https://echa.europa.eu/uk-withdrawal-from-the-eu

Adler and Allan 24/7 advice on compliance: www.adlerandallan.co.uk/environmental-consultancy/consultancy-services/chemical-compliance-and-24-7-chemical-emergency-advice/



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