

Chemicals Safety Policy post-Brexit

Key points

- The refining sector fully supports the principles behind EU legislation for the protection of health and the environment. The UK Government must ensure management of chemicals safety under the same principles, minimising any additional costs to industry and avoiding any risk of supply chain disruption caused by uncertainties regarding the registration status or safety of chemical substances traded with EU Member States and other countries.
- Duplication of the EU chemicals safety regulatory regime or an alternative would impose additional costs on industry, damaging competitiveness, with risk that companies are not prepared to incur these costs, limiting the range of substances available in the UK market and in formulated products.
- Many of the proposals made in the Technical Notice “Regulating chemicals (REACH) if there’s no Brexit deal” are believed unworkable. The timescales for registration in the UK’s replacement for REACH are unrealistic and the assumption has been made that data and information required for registration is freely available to UK companies, which is not the case. There is also insufficient time available for appointment of EEA-based Only Representatives (ORs) by UK companies wishing to trade with EEA countries, including for those substances where existing ORs are UK-based.
- The only viable option is to negotiate continued regulation of chemical substances under REACH, CLP and related regulations, along with continued access to and funding of the European Chemicals Agency (ECHA).
- UK Companies trading with the EU and other countries recognising REACH registrations will have to maintain existing registrations for substances they trade and register any new substances under REACH, regardless of the trade agreement negotiated by the UK. This will require appointment of an EEA-based OR for companies manufacturing in the UK or where the existing OR is UK-based for substances manufactured outside the UK and EEA.
- The potential for supply chain disruption and uncertainties regarding the registration status of chemical substances must be avoided. Should the supply chain be disrupted, there would be wide-ranging impacts on product availability in both the UK and EU; formulated products such as lubricants, greases, cleaning products, paints and coating and a wide variety of other products, but also for articles that incorporate these products, e.g. automotive components, bearings, electrical switchgear etc. which are essential in supporting day-to-day life in the UK and throughout the EU.

1. Introduction

This briefing paper has been prepared by UKPIA to assess proposals made by the UK Government to maintain chemicals safety legislation under two scenarios, where either the UK leaves the EU without an agreement (the “no-deal” scenario) or where an agreement is negotiated in accordance

with the preferred UK option. The implications for the UK and EU downstream oil industry are also considered.

2. Chemicals safety regulation – “no-deal” scenario

The Government recently published details of their proposals to replace existing EU law relating to chemicals safety in the event that the UK leaves the EU without an agreement on 29th March 2019. The proposals are set out in a Technical Notice “Regulating chemicals (REACH) if there’s no Brexit deal”, published on 24th September 2018¹, with additional guidance published by the HSE (the UK Competent Authority for REACH) on 4th December 2018². Draft legislation³ to bring these proposals into effect was laid in Parliament on 9th January 2018, but is subject to the affirmative decision procedure before it comes into force⁴. Key points are as follows:

- In the event of a “no deal” outcome, whether this be the situation on 29th March 2019 or should negotiations during the transition period be unsuccessful, the UK Government proposes to establish a UK regulatory framework and build domestic capacity to deliver the functions currently performed by the European Chemicals Agency (ECHA, see Section 4). The legislation would preserve the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as far as possible, while making technical changes that would need to be made because the UK has left the EU.
- The new regulatory framework would: enable the registration of new chemicals through a UK IT system that is similar to the existing EU IT system; provide specialist capacity to evaluate the impact of chemicals on health and the environment; ensure sufficient regulatory and enforcement capacity in the HSE, the Environment Agency (EA) and other regulators, enabling them to recommend controls in response to the hazards and risks of substances; and provide for an appropriate policy function in Defra and the devolved administrations.
- In a ‘no deal’ scenario the UK would not be legally committed to medium- or long-term regulatory alignment with the EEA.
- UK Companies with REACH registrations would no longer be able to sell into the EEA market without transferring their registrations to an organisation based in an EEA country. Companies would therefore need to take action to preserve their EEA market access.
- UK companies importing chemicals from an EEA country would face new registration requirements. Under the UK’s replacement for REACH, importers would have a duty to register chemicals. Similarly, UK downstream users of authorisations would no longer be able to rely on authorisation decisions granted to companies in EEA countries.

The UK Government would:

- Transfer existing REACH registrations held by UK-based companies directly into the UK’s replacement for REACH (referred to as “UK-REACH”), legally ‘grandfathering’ the registrations into the UK regime.

¹ See <https://www.gov.uk/government/publications/regulating-chemicals-reach-if-theres-no-brex-it-deal/regulating-chemicals-reach-if-theres-no-brex-it-deal>.

² See http://www.hse.gov.uk/brexit/brexit-chemical-regulation.htm?utm_source=Twitter&utm_medium=social&utm_campaign=EU-Exit&utm_content=Defra.

³ See draft Statutory Instrument “The REACH etc. (Amendment etc.)(EU Exit) Regulations 2019” and Explanatory Memorandum available at http://www.legislation.gov.uk/ukdsi/2019/9780111178034/pdfs/ukdsi_9780111178034_en.pdf and http://www.legislation.gov.uk/ukdsi/2019/9780111178034/pdfs/ukdsiem_9780111178034_en.pdf. An Impact Assessment is also available at http://www.legislation.gov.uk/ukdsi/2019/9780111178034/pdfs/ukdsiem_9780111178034_en.pdf

⁴ When subject to an affirmative decision procedure, draft legislation must be debated in both the House of Lords and the House of Commons, but can only be adopted or rejected, i.e the legislation cannot be amended.

- Set up a transitional light-touch notification process for UK companies importing chemicals from the EEA before the UK leaves the EU, where those companies do not hold a REACH registration. This would reduce the risk of interruption in supply chains for companies currently relying on a registration held by an EEA-based company.
- Carry into UK REACH all existing authorisations to continue using higher-risk chemicals held by UK companies.
- The ECHA candidate list for substances of very high concern (SVHCs) at the point that the UK leaves the EU will be carried into UK law. Annex XIV of the EU REACH Regulation and the substances listed in it will also be retained in the UK REACH Regulation.
- The restrictions currently listed in Annex XVII to the EU REACH Regulation will be carried over into the UK REACH Regulation.
- The powers to update the candidate list, Annex XIV and Annex XVII will remain in UK REACH based on the same legal conditions and criteria as present in EU REACH.

To ensure sufficient information is available to the UK Government to regulate the safe use of chemicals, the UK Government would require companies to take the following actions:

- Companies with existing EU REACH registrations (including authorisations) being automatically grandfathered into UK REACH would have to validate their existing registration and/or authorisation with the UK authority (the HSE), opening an account on the new UK IT system and providing some basic information on their existing registration within 60 days of the UK leaving the EU.
- Companies with grandfathered registrations would have two years from the day the UK leaves the EU to provide the HSE with the full data package that supported their original EU registration and is held on the ECHA IT system.
- Businesses that imported chemicals from the EEA before the UK leaves the EU (but who did not have an EU REACH registration), would need to notify the HSE and provide some basic data on the chemicals within 180 days of the UK leaving the EU, instead of having to undertake a full registration immediately. This would be an interim arrangement for those importers and they would need to move to full registration at a later date following a review of this approach.
- Importing businesses would be responsible for identifying appropriate risk management measures and recommending them to their customers.
- If a business wished to place new chemicals on both the EEA and UK markets, in a 'no deal' scenario, they would have to make two separate registrations, one by an EEA entity to ECHA and one by a UK entity to the HSE. The information and data package needed would be the same for both.

UK companies with existing REACH registrations wishing to maintain EEA market access would need to transfer their registrations to an appropriate EEA-based entity (such as an affiliate or an Only Representative – see below). This would require action before the UK leaves the EU.

UK companies wishing to register new chemicals for the EEA market after the UK leaves the EU would need to register those with ECHA as they do now, but would need to do so via their EU customers or an Only Representative.

In September 2017, ECHA published a series of Q and As on the implications of UK withdrawal from the EU for chemicals safety regulations and registrations, including REACH, CLP and PIC⁵. In the

⁵ See <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu>.

absence of any negotiated agreement for continued participation in REACH, CLP or ECHA, the following considerations apply:

Validity of UK REACH registrations

Article 3(7) of the REACH Regulation states that a registrant must be a manufacturer or importer of a substance or a producer or importer of an article. Article 3(4), (9) and (11) stipulates that registrants must be established in the EU. After 30th March 2019, the UK will no longer be a Member State of the EU. Hence, any existing UK-based registrant will no longer be entitled to hold REACH registrations. For the purpose of the EU's REACH Regulation, any registration by such a registrant will therefore be regarded as non-existent, as registrant will, after the UK withdrawal, be based in a "third country" outside the EU/EEA.

As a consequence, the REACH registration will need to be re-established via one of the following options:

- The substance concerned is re-registered by a registrant located in an EU-27/EEA country.
- The existing registrant relocates to an EU-27/EEA country.
- The existing registrant (if a manufacturer, importer or formulator, not just a trader or distributor) appoints an Only Representative located in an EU-27/EEA country.
- In the case of a UK Only Representative, the non-EU manufacturer will need to appoint an EU-27/EEA-based representative in place of the UK representative.

Compliance with the CLP Regulation

As from the date of UK withdrawal, UK companies will solely be subject to the laws applying in the United Kingdom and will no longer need to comply with the CLP Regulation. However, its provisions may continue to remain valid within the UK on the basis of the European Union (Withdrawal) Act 2018⁶, which will - at least temporarily - convert existing EU law directly into the UK legal system.

Should a company be exporting product to the EU-27/EEA, the provisions of the CLP Regulation (as amended) will continue to apply, along with the requirement for a valid REACH registration.

3. Chemicals safety regulation – preferred UK/EU option

The proposals made under the "no-deal" scenario are very different from the Government's preferred options, which are set out in the White Paper "The future relationship between the United Kingdom and the European Union", published on 12th July 2018⁷. This proposes that the UK should continue regulation in line with the REACH regulation (see Section 2), along with participation in the European Chemicals Agency (ECHA), making an appropriate financial contribution.

The potential for continued participation in REACH has also been recognised in the joint "Political declaration setting out the framework for the future relationship between the European Union and the United Kingdom"⁸ endorsed by the European Council on 25th November 2018. The declaration sets out a number of objectives for "*an ambitious, wide-ranging and balanced economic partnership*" recognising the long-standing economic integration and complexity and integration of supply chains. Regulatory aspects are specifically addressed:

⁶ See <http://www.legislation.gov.uk/ukpga/2018/16/contents/enacted>.

⁷ See

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725288/The_future_relationship_between_the_United_Kingdom_and_the_European_Union.pdf.

⁸ See <https://www.consilium.europa.eu/media/37059/20181121-cover-political-declaration.pdf>.

“While preserving regulatory autonomy, the Parties will put in place provisions to promote regulatory approaches that are transparent, efficient, promote avoidance of unnecessary barriers to trade in goods and are compatible to the extent possible.”

“The Parties will also explore the possibility of cooperation of United Kingdom authorities with Union agencies such as the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), and the European Aviation Safety Agency (EASA).

In this context, the United Kingdom will consider aligning with Union rules in relevant areas.”

Although the detailed arrangements for continuing financial contributions to ECHA and participation in REACH must still be negotiated, the level of political ambition set out in the declaration would fully support continued frictionless trade in chemical substances between the UK and EU countries (and even further afield), if a successful outcome is achieved.

4. Legislative framework

The current legislative framework for chemicals safety regulation was established via Directive 2006/121/EC⁹. This established provisions for the establishment of ECHA¹⁰ and the following key Regulations:

- Regulation (EC) No 1907/2006¹¹, concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)
- Regulation (EC) No 1272/2008¹², covering classification and labelling of substances and mixtures placed on the EU market (CLP)
- The Prior Informed Consent Regulation (EU) 649/2012¹³ concerning the export and import of hazardous chemicals (PIC)

ECHA was subsequently established in 2007 and is based in Helsinki, Finland. It now employs over 500 staff from 27 European countries. A number of further Regulations cover the fees and charges payable to ECHA, data sharing and test methods used under REACH¹⁴.

The REACH Regulation incorporates classification criteria and labelling rules agreed at UN level, the so-called Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances¹⁵. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database. The Regulation also calls for the progressive substitution of the most dangerous chemicals, referred to as "substances of very high concern" (SVHC), when suitable alternatives have been identified. The databases necessary to operate the system are managed by ECHA, who also co-ordinate in-depth evaluation of suspected hazardous substances.

The CLP Regulation is again based on GHS and since 1st June 2015, has been legally binding across the Member States and directly applicable to all industrial sectors. It requires manufacturers,

⁹ See <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0850:0856:EN:PDF>.

¹⁰ See <https://echa.europa.eu/about-us>.

¹¹ See <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&from=EN>.

¹² See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>.

¹³ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:en:PDF>.

¹⁴ Regulation (EC) No 340/2008 (as amended) on the fees and charges payable to the European Chemicals Agency, Regulation (EC) No 440/2008 on test methods used under REACH and Regulation (EU) 2016/9 on data sharing.

¹⁵ Similar regulatory regimes cover biocides (Regulation (EU) 528/2012), plant protection products (Regulation (EC) 1107/2009), food ingredients and packaging and medicines. ECHA carries out similar functions for biocides as covered for chemicals regulated under REACH.

importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

The PIC Regulation administers the import and export of hazardous chemicals, placing obligations on companies exporting these chemicals to non-EU countries. It aims to promote shared responsibility and cooperation for international trade of hazardous chemicals, and to provide developing countries with information on how to store, transport, use and safe dispose of hazardous chemicals.

Regulations forming part of the EU chemicals safety legislation have been implemented directly in the UK as required under various EU treaties.

5. REACH Registrations

Under REACH, any company manufacturing or importing into the EU a substance on its own, in a preparation (mixture of substances), or intentionally released from articles (finished manufactured goods) at or above 1 tonne has been required to register the substance with ECHA.

Registration requires submission of a dossier to ECHA, containing details of the substance, its properties, other relevant information about risks and how these risks can be managed. Under provisions for registration and data sharing, the regulations support formation of substance information exchange forums (SIEFs), where there is more than one manufacturer or importer of a specific substance. SIEFs were initially mandated to operate until 1st June 2018 for “phase-in” (previously existing) substances. Other data sharing provisions applied to new substances, and since 1st June 2018 have applied to all substances.

Within the SIEF, data and information and the costs incurred developing this data can be shared with co-registrants if the substance is within the boundaries of the substance identity profile (SIP) agreed by the SIEF. The SIEF will also usually appoint a ‘Lead Registrant’ to manage compilation and submission of the dossier. Under normal circumstances, data and information is provided to the SIEF under a confidentiality agreement for the specific purpose to support compilation of the dossier and remains the property of the company providing the data and information.

Where a manufacturer located outside the EU wishes to export a substance into the EU by itself or in mixtures or produces an article that is exported into the EU, an ‘Only Representative’ located within the EU may be appointed to be responsible for registration and submission of the dossier. Again, the data and information normally remain the property of the producer.

REACH registration fees are applied by ECHA, depending on the tonnage supplied, subject to a number of factors¹⁶. Although these fees are fairly modest (€1304 to €33699 depending on the tonnage and whether the submission is joint or individual), the costs associated with analysis and hazard evaluation of chemical substances can be very significant at up to €1M or more, especially where associated hazards are identified during toxicological assessment, which can include animal testing.

As of 31st October 2018, there had been 91536 registrations under REACH, covering 21787 unique substances registered by 14262 companies. The UK had the second highest number (12449) of registrations after Germany (22994). The majority of substances have been registered via SIEFs (14789), with 8136 substances registered by an individual company¹⁷.

¹⁶ The fee structure is set out in Commission Implementing Regulation (EU) 2015/864; see <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0864&from=EN>.

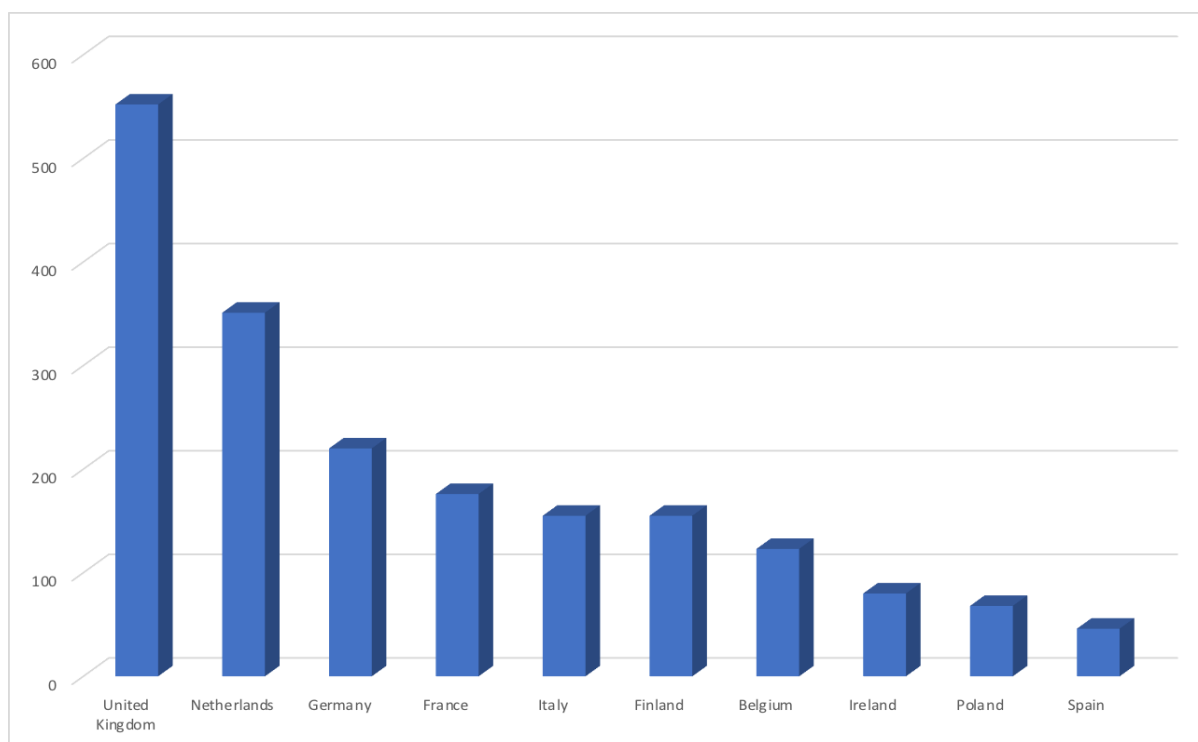
¹⁷ This information is available on the ECHA website at <https://echa.europa.eu/registration-statistics-infograph#> (N.B. The total number of substances is not consistent across all views of the registration statistics, although the reasons for this are not identified).

6. REACH Registrations for petroleum products

There are currently 193 petroleum substances registered within REACH where CONCAWE¹⁸ acts as the SIEF Formation Facilitator. Of these, 11 have a UK-based Lead Registrant (either BP, Esso, Petrolneos, Phillips 66 or Valero). However, the UK also has the highest number of licenses purchased for registration of petroleum substances, 552; most for substances registered by Only Representatives importing these into the UK and Europe from countries outside the EU (Diagram 1). These are used as fuel blending components, but also to formulate lubricants, greases, metal working fluids and other specialised products, where there are over 100 manufacturers located in the UK, many with high margin export business with countries outside the EU.

Petroleum products are derived from crude oil and are characterised in REACH terms as ‘UVCBs’ (substances of Unknown or Variable composition, Complex reaction products or Biological materials). Petroleum substances are both complex and variable and their exact composition can seldom be determined, particularly for heavier substances. Furthermore, the composition varies across different samples of the same product, reflecting the specific refining process they underwent and the crude oils from which they have been obtained.

Diagram 1: Top 10 Registrations and licences for Petroleum Products



Source: CONCAWE

REACH allows grouping of substances into categories and that principle has been developed by CONCAWE for the registration of petroleum substances; the currently registered petroleum substances are grouped into 18 categories. This ‘category approach’ is the most effective way¹⁹ of using hazard data for a substance by applying it with read-across to other substances in the category avoiding unnecessary testing and associated costs.

¹⁸ The technical body for environmental science for the European refining industry – see <https://www.concawe.eu/reach>.

¹⁹ As compared to carrying out 193 separate test programmes.