

UK REACH: Growing pains for the independent UK's chemicals regulation

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One and a half years after the coming into force of UK REACH,² the independent UK's principal chemicals management regulation, there remains a significant degree of uncertainty over both the current transitional arrangements and the ultimate destination for the UK's policy approach to chemicals management. Significant resource is required simply to replicate EU REACH for the market of Great Britain, and stakeholders from all sides of the debate are questioning if 'back to square one' for the registration of chemicals in a separate GB market is the best approach. UK policymakers are actively considering alternatives, but the long overdue UK chemicals strategy is still some way off. Concerns over this tension – between a current, legally binding, UK REACH regime that requires investment to achieve compliance with the letter of the law, and the real possibility of significant changes ahead that might diminish the value of such investment – was well captured in a statement by the head of the National Audit Office on publication of a report into the new responsibilities held by the Health and Safety Executive (HSE) for chemicals regulation:

EU Exit has had a major impact ... it is essential that regulators and policy-makers develop their future strategies as soon as possible to avoid wasting effort on short-term work and to ensure the decisions they make now meet their longer-term goals.³

In this article, we explore these tensions by looking at the current position of UK chemicals management in the UK, the progress that has been made to date, and the challenges to come.

Transition

UK REACH came into force at 11.00 pm UK time on 31 December 2020, creating an independent regulatory framework for the management of chemicals in Great Britain and duplicating many of the obligations (and costs) of compliance for businesses who, over the past decade, had invested significantly in EU REACH. Duplication arises

from the fact that a key feature of REACH is the principle of 'no data, no market': it is for industry (chiefly, manufacturers and importers) to provide robust data about a substance's hazard properties to the regulator before that substance can be placed on the market, in the form of a registration dossier. For the vast majority of existing chemical substances, dossiers have been submitted to the European Chemicals Agency (ECHA) in Helsinki, over a period of nearly a decade, with the final registration deadline as recently as May 2018. On receipt, ECHA maintained the information in a database, and published much of the data online. However, since no agreement was reached between the UK and the EU on sharing the data in the existing EU database, the current law requires companies to submit that data again, to the HSE, to populate a new UK-only registration database.

Clearly, as time is required to populate the HSE's new database, named the Comply with UK REACH IT database, UK REACH provided two 'transitional arrangements'. First, existing EU REACH registrations held, or recently held, by GB-based businesses were carried across directly into UK REACH, legally 'grandfathering' the registrations into the new regime. Although this was a significant benefit to the UK chemicals manufacturing sector, this fix nevertheless only applied to a minority of registrations. Secondly, to protect those UK businesses who were reliant on substances imported into GB under a REACH registration held by an EU or EEA-based company before 1 January 2021, the transitional provisions introduced the concept of the 'protected transitional import'. A protected transitional import allows those businesses who had imported or used a substance in the two years prior to 1 January 2021 to continue importing substances for onward supply or use, provided the current supply comes from an EU REACH compliant supply chain (albeit not necessarily the same supplier). To allow the HSE to have some degree of visibility of such protected transitional imports, the legislation introduced the legal requirement for the GB entity to notify the HSE through a 'Downstream User Import Notification' or 'DUIN' process. The legal deadline under UK REACH for such DUINs was 27 October 2021, but the HSE has made it clear that the window is open for late notifications, notwithstanding the strict legal non-compliance in missing the statutory deadline.

Both the 'grandfathering' and 'DUIN' mechanisms required an initial (relatively light-touch) notification to be made to the HSE during the course of 2021. However, in each case, there remains a 'full registration' obligation still to be completed, which is when the data must be submitted

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² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as incorporated into domestic (UK) legislation pursuant to section 3(1) of the European Union (Withdrawal) Act 2018, and as amended.

³ National Audit Office press release, 18 May 2022, <https://www.nao.org.uk/press-release/regulating-after-eu-exit/>, accessed 1 June 2022.

to the HSE. Under the law as it currently stands (but see further below), depending on the tonnage band and hazard profile of the substance, those relying on transitional provisions would need to be compliant with all applicable registration requirements (and therefore provide all relevant data) within either two, four or six years from October 2021.

These transitional provisions were clearly designed to ensure continuation of the status quo on 1 January 2021, so that widespread concerns about access to key chemicals in the UK would not materialise. However, the UK-centric focus left many EU businesses out in the cold: for those businesses manufacturing in the EU or importing into the EU and supplying GB customers, there were no equivalent arrangements. Although those EU entities could continue to supply those in their customer base who had submitted a DUIN, many downstream users of chemicals did not, and have not done so. Measures were provided to allow EU business to appoint an Only Representative to help customers complete their DUIN obligations, but any such DUINs are only for the benefit of those customers on whose behalf the DUIN has been submitted, and it is not the same as allowing an EU business to hold a DUIN. In practice, it has become a cumbersome short-term fix, causing a good deal of confusion. Most importantly of all, however, is that in a dynamic sector, none of these arrangements allow an EU business to supply a new GB customer: the chilling effect of the DUIN solution was to freeze the market as it was in 2019 and 2020. As at mid-2022, following the global pandemic and during the Ukraine crisis, supply chains already look very different. Those who want to supply new customers from the EU must pay the registration fees to do so, even if the supplies are covered by an EU registration. In the absence of a statutory mechanism to support such businesses, the HSE has taken a pragmatic approach: it has introduced a 'new registration, existing substance' concept (known as NRES) in which, although a registration must be submitted and the appropriate fees paid, the dossier can be submitted with a waiver to say the data will follow. In this way, those obliged to register now can still benefit from the transition timescales for submission of the full data packages set out above. There is, however, no statutory basis for the NRES, it is simply pragmatic enforcement of the rules of UK REACH, and has led to accusations that the UK is somewhat 'making it up as it goes along'.

Consultation on a 'new model'

Industry has estimated that the replication of the EU REACH registration model for the GB market will come at a cost to industry of around one billion British pounds. It is therefore unsurprising that it took just six weeks into the implementation of the new regime (February 2021) for 25 industry associations and downstream user groups to formally propose a lighter touch system where only chemicals of greater concern would need a full registration, in an effort to ease this significant cost of 'replication'.

While the UK Government could no doubt see the advantage of avoiding costs to industry, environmental

NGOs were quick to challenge an approach that moves away from full data sets for all chemicals on grounds that the UK would be lowering environmental protections, undermining legal commitments to a 'level playing field' under the EU-UK Trade and Cooperation Agreement. The NGOs were not against avoiding the costs of replicating the EU database per se, but instead wanted the UK Government to accept that regulatory decisions based on a reduced data set would be less well informed, and therefore to accept that the UK should simply follow EU decisions. Of course, in turn, the NGOs' proposal to follow EU decisions ran against the political imperative to regulate independently, which requires data.

Presumably due to these tensions, as well as other pressures on the department, the Secretary of State for the Environment, Food and Rural Affairs was not quick in coming back with a response. It was only in December 2021 that Secretary of State George Eustice published an open letter to the Chemical Industries Association confirming that he recognised 'industry concerns around accessing data packages to support UK REACH transition',⁴ and the associated cost to businesses. As a result, DEFRA, along with the HSE and Environment Agency, has been tasked with exploring 'a new model for transitional registrations', with the stated objective of 'placing a greater emphasis on improving our understanding of the uses and exposures of chemicals in the GB context'. Despite the lack of detail at this stage, the willingness to explore alternative solutions is a significant development.

Pending the outcome, registrants will be reconsidering the progress of work on new data sharing arrangements for the GB market. This will, in turn, raise concerns for those less able to enjoy transitional arrangements (such as, for example, new entrants to the market), who may find themselves in limbo while they wait for regulatory obligations to fall on their competitors and future co-registrants. To allow time for the new approach to be worked through, the UK Government will consult during summer 2022 on extending the deadlines for submitting the full dossier complete with data. Defra officials have suggested that the first deadline is likely to be October 2026, with the other deadlines to follow in subsequent years, subject of course to the outcome of the consultation. This, of course, extends the period before the HSE receives substantive data on which to make regulatory decisions, causing NGOs to complain that the UK is slipping further behind the EU.

UK chemicals strategy: keeping pace with the EU?

There is no real debate that the regulatory activity in the UK is not keeping pace with activities in the EU: the debate is rather more focused on whether that is a positive or negative. With its Green Deal and chemicals strategy for sustainability (CSS), the EU has set an ambitious agenda and laid out plans for substantive changes to existing EU

⁴ Published 6 December 2021, available at <https://www.gov.uk/government/publications/uk-reach-chemicals-registration-letter-to-industry-leaders>, accessed 1 June 2022.

chemicals regulation. This will likely include an attempt to combine and integrate requirements for chemicals, manufactured products and waste streams, with the aim of achieving circularity. That ambition, in itself, may trigger significant changes to (EU) REACH, as well as product regulations and waste requirements. New concepts are being created: the notions of 'sustainable products' and of 'essential uses'.

It is expected that EU REACH will be amended to allow a streamlined procedure for restrictions for groups of chemicals with newly identified hazard classifications. It is also possible that the EU REACH authorisation process will be amended or even removed altogether, and the restrictions process extended and reinforced. These changes each represent a significant departure from the existing model.

In contrast, the UK is long overdue on its own chemicals strategy, first promised in the 25-Year Environment Plan back in January 2018. Consultations commenced in spring 2022, and unsurprisingly there are many themes in common with the EU's CSS. However, the details of the strategy remain to be seen (and perhaps determined), and with the EU already in the implementation phase for its chemicals strategy, it seems likely that the publication of the UK's chemicals strategy could mark a significant point of strategic divergence between the two markets when it finally arrives.

HSE's work programme and resourcing

As required under the UK REACH legislation, the HSE published its first 'Work Programme' (2021/2022) in June 2021.⁵ The publication of the programme highlighted the challenges faced by the HSE to implement, manage and regulate the new regime – with UK bodies now required to fulfil the full range of roles, tasks and responsibilities currently shared between ECHA, the Commission and 27 EU Member States. By way of an example of the scale of the task, the HSE predicted that 26 per cent of its overall capacity for 2021/2022 would be required simply for training and 'understanding the legislation and associated guidance; learning processes and procedures; developing knowledge of regulatory science, especially in the area of toxicology'.

With limited resources, it is not a surprise that the HSE is taking a risk-based prioritisation approach to its work programme. In 2021/2022, key delivery objectives included work on restriction dossiers for tattoo inks and lead ammunition. Going forward, it has been confirmed that the HSE will assess all EU REACH restriction proposals where the Annex XV dossier has been published, but may also identify priorities from other sources, providing the example of the Regulatory Management Options Analysis on PFAS that the HSE is currently working on with the Environment Agency. It will be fascinating to see how the HSE chooses to deploy its limited capacity in its forth-

coming work programme for 2022/2023, but we anticipate that it will continue with a more focused, risk-based approach, necessarily covering less ground than its EU counterpart.

Substances of very high concern

Another interesting area of divergence was seen in the UK's approach to substances of very high concern (SVHCs). On 9 December 2021, DEFRA published a policy paper entitled 'Approach to including substances of very high concern on the UK REACH candidate list', which received an immediate reaction from NGOs who claimed the UK was not upholding the terms of the EU-UK Trade and Cooperation Agreement on ensuring a 'level playing field', and urging the EU to step in.

The candidate list is a list of SVHCs that may be prioritised for inclusion on the 'authorisation list', the REACH mechanism used for phasing out the use of harmful chemicals. When UK REACH came into force, all substances that were on the EU REACH candidate list were automatically carried over onto the UK REACH candidate list.

The UK REACH work programme for 2021/22 committed to assessing those substances added to the EU REACH candidate list since UK REACH came into force, to consider if it was appropriate to add them to the UK REACH candidate list. To make that assessment, as well as to determine which other substances the UK may wish to add to its candidate list, DEFRA and the Welsh and Scottish Governments have agreed 'interim principles of assessment', confirming that 'a substance should not be proposed for inclusion on the [UK REACH] candidate list unless it is a good candidate for the authorisation list'; and that 'Regulatory Management Options Analysis ... should be used to determine if inclusion on the candidate list is the correct route'.

This UK-specific approach to inclusion on the candidate list differs from the process in the EU. Procedurally, this is somewhat inevitable since, under EU REACH, either a Member State or ECHA (at the request of the Commission) can propose a substance to be identified as an SVHC, followed by input from interested parties and the Member State Committee. UK REACH needs its own process, and the UK system allows the Secretary of State, Welsh ministers, Scottish ministers or HSE to put a substance forward for inclusion on the candidate list, and can only do so if they consider it fulfils one or more of the technical, hazard-based criteria to be considered an SVHC. However, following the latest policy guidance, it appears that consideration must now also be given to whether the substance is a 'good candidate' for phase-out, taking into account other available risk management options. NGOs believe that this will mean that the UK candidate list will be much smaller than the EU's. The NGOs point out that inclusion on the candidate list has legal consequences (such as notification of the presence of SVHC in articles) and encourages substitution – whether or not the substance is a 'good' candidate for subsequent addition to the authorisation list.

⁵ The second Work Programme is due any day, but was not available at the time of writing.

The NGOs have also highlighted that the relevant UK bodies will (presumably) be making any such recommendations (at least in the short to medium term) without much of the hazard data that would be available to their EU counterparts. It has also not gone unnoticed that HSE has only identified four substance groups as priorities (from a significantly longer EU list). The HSE has published a risk-based justification for this smaller list, taking into account factors such as the amount on the UK market, and existing regulatory controls. Industry has welcomed this as pragmatism, but the NGOs disagree.

Impact of the Environment Act 2021

In November 2021, more than 1,000 days after it was first presented with a draft Bill, the UK Parliament has finally passed its first 'Environment Act' in a generation, laying the framework for a significant shift in environmental standards and regulation.

Those grappling with UK REACH should note that the secretary of state has been given powers to further amend UK REACH, to change the 'how' of REACH and adapt it for the GB market. However, as a safeguard, the secretary of state must ensure that any such changes remain consistent with the aim and scope of REACH as set out in Article 1 of the REACH Regulation, and must obtain consent from Scottish and Welsh ministers. Although such powers are not unlimited, the scope for change under these provisions is significant, and should be monitored closely. We have already seen how authorities responsible for chemicals may take different approaches to their EU counterparts – even when applying the same black letter law. Modifications to

the GB decision-making process are likely to accelerate that trend.

Further, the chemicals sector should keep a close eye on the list of substances that the UK nations will monitor when considering the chemical status of its water bodies: wide powers are provided in the Environment Act 2021 to amend the criteria for assessing chemical status including the substances to be monitored. The inclusion of new substances will inevitably increase regulatory scrutiny of the use of chemicals and the supply to the GB market.

Finally, it should be noted that wider powers for repealing laws of EU origin are promised in the forthcoming Brexit Freedoms Bill. REACH was name-checked in Lord Frost's speech to the House of Lords introducing the government's legislative intention to address EU law through such a Bill, and so it is probable that chemicals regulation is an area under scrutiny. Therefore, significant change may well be on the horizon.

Concluding thoughts

REACH was highlighted as being one of the legal regimes that would be most impacted by the UK's exit from the EU, and so it has proved: in the first year and a half, we have seen many of the predictions of challenges and difficulties coming true. Officials working on delivery of chemicals regulation have undoubtedly worked hard to ensure continuity. However, industry and civil society are demanding more, and the demand is the same as the one from the National Audit Office's review: the UK needs a long-term policy backed with clear and certain regulation so that the efforts in addressing the transition to an independent regime are not wasted.