



House of Commons Environmental Audit Committee

The Future of Chemicals Regulation after the EU Referendum

Submission by UK Environmental Law Association

About UKELA

1. The UK Environmental Law Association aims to make the law work for a better environment and to improve understanding and awareness of environmental law. UKELA's members are involved in the practice, study or formulation of environmental law in the UK and the European Union. It attracts both lawyers and non-lawyers and has a broad membership from the private and public sectors. UKELA prepares advice to Government and submissions to inquiries with the help of its specialist working parties, covering a range of environmental law topics. Members include practitioners who specialize in advising and handling REACH.
2. UKELA has for some years been taking an active interest in the impact on UK environmental regulation of a possible withdrawal from the EU (Brexit). The Association adopted a neutral position prior to the referendum, but issued a public position statement following the vote (<https://www.ukela.org/UKELAposition>). In particular, UKELA considers it

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imperative that the UK's current environmental legislation is preserved pending proper review, full and open consultation on options for change and the involvement of Parliament as far as possible. The Association considers preservation is critically important in order to ensure ongoing compliance with international law, regulatory stability and continued protection of the environment.

What particular challenges will the UK Government face when it seeks to transpose REACH into UK law through the "Great Repeal Bill"?

Transposition Issues and the Great Repeal Bill

3. If the UK were to remain part of the EEA, REACH would continue to apply as it does to the existing EEA States, and there would be very limited transposition issues. The main difference for EEA States is that while they are entitled to participate in the various institutional bodies established under REACH (notably the management board of the European Chemicals Agency, the Member State Committee, the Committee for Risk Assessment, the Committee for Socio-Economic Analysis, and the Forum for Exchange of Information on Enforcement) and have the same rights and obligations as EU Member States, they have no right to vote – see EEA Agreement, Annex II, p 146.

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4. In the light of the Prime Minister's speech on January 17th, the EEA model looks unlikely for the UK, and so this submission is based on an assumption of an outside EEA model. Any outside EEA model that eventually emerges raises a number of generic legal issues concerning the stability of environmental law in the UK, but there are particular challenges in respect of REACH. The operation of REACH is critical to UK industry. The chemicals industry has been estimated to be the UK's largest manufacturing exporter, with 60% of exports going to the EU. Similarly, huge quantities of the raw materials needed for manufacture within the UK across a range of industries are currently imported from the EU under the REACH regime.

5. As an EU Regulation, REACH has not needed to be transposed into domestic legislation (save for national enforcement measures), and so when the UK leaves the EU (and, it is assumed for the purposes of this paper, the EEA) it will simply cease to apply. If the UK government wants REACH style provisions to continue to apply then it will have to write them into UK legislation. However, because of the way that REACH operates and the terminology used in the Regulation, this could not sensibly be done as simply as by having a line in the Great Repeal Bill deeming REACH to apply in the UK. REACH was written from the perspective of participants being within the EU– with much of it also relating to Member State co-operation and mutual obligations, oversight and controls, and freedom of movement of products.

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6. In addition, as discussed in paragraph 16 below, a number of practical issues, with profound implications for business, will need to be addressed in any such transposition. Establishing the requisite domestic expertise and regulatory capacity to administer any local regime (or securing access to EU bodies or expertise) will also be a key challenge, as discussed at paragraph 14.

What role should the devolved administrations play in setting the regulatory environment in this area? How should any divergences in policy be managed

7. The opportunity for the UK to develop its own national REACH system as discussed below raises devolution issues. The current 2008 REACH national enforcement regulations devolve enforcement responsibilities and post exit will no longer survive since the duties rest on REACH importers who must be based in the EU. Whether devolved administrations would have the legal competence to develop their own REACH equivalent legislation is initially a matter of legal interpretation of the relevant devolution legislation. For instance, under the Scotland Act 1998 essentially environmental issues are devolved while health and safety, and trade issues including consumer protection are reserved, and it will be a question as to where a REACH type system falls. In this context, it is probably relevant that the EU REACH regulation was made under the single market provision of the Treaty rather

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than the environmental provisions. In any event, while one of the general implications of leaving the EU is the likelihood of greater divergences in the environmental laws within the devolved administrations (subject to the constraints of international environmental conventions to which the UK remains a party), the prospect of a system that would permit a particular chemical to be used and marketed, say, in England and not Scotland would be unattractive to say the least. The preferred model is therefore likely to be UK wide legislation with a national body (based on the HSE) responsible for registration and evaluation, but, as with current REACH regulations, enforcement devolved.

What scope is there for the UK to pursue a divergent approach to chemicals regulation from the EU once the process of leaving has been completed?

Exports to the EU and the implications for UK industry

8. REACH will continue to operate in the EU. UK manufacturers who export to the EU market will need to ensure REACH is complied with in order to be able to continue to trade, but it will be the EU importers who will now bear the REACH obligations for those substances going forward. Non-EU companies are entitled under REACH to appoint 'only representatives' (OR) to carry out these obligations. If a UK company did not appoint an OR, then their EU customers would no longer be downstream users under REACH and

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as importers would need to register the substances. As a new importer/registrant they would start by doing an Art 26 inquiry to find out about existing registrations and start the data-sharing process. There would therefore be obligations, administrative burdens and costs for those importers which they did not have previously. Unless the UK company appoints an OR this could prejudice the position of UK companies as suppliers because their customers may choose to go to a different EU supplier to avoid being an importer.

9. The same basic analysis applies to the EU Regulation 1272/2008 on Classification, Labelling and Packaging of Substances which applies the duties on importers and has the same definitions of 'import' and 'importer' as in REACH. A UK industry wishing to export to the EU would need to comply otherwise their importer would be breaching the Regulation.
10. There will be a significant amount of disruption to industry. This is already being seen in the moves to remove existing UK lead-registrants, and the need for UK and other non-EU businesses to start finding and appointing new only representatives in the EU. There will then be the inevitable teething and adjusting to new arrangements. Notably, this will all follow what is predicted to be one of the most intense periods of activity under REACH for the industry – with business now rushing to get certain chemicals they use above the latest phase-in threshold of 1 tonne registered by May 2018.

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11. Other potential constraints on the UK's ability to diverge from REACH after leaving the EU are discussed below – see in particular paragraphs 17 to 21.

How far will the UK's ability to effectively transpose REACH depend on negotiations with other Member States and the nature of the UK's future relationship with the EU

The UK Government's loss of influence within the EU REACH system

12. As a non-EU Member State the UK Government will lose a number of significant legal rights under REACH available only to Member States. For example, absent bespoke agreement (see paragraph 16 below) the UK would not have any access to dossiers being prepared by the European Chemicals Agency (Art 41(2)) nor would the UK competent authorities be notified of any conclusions made by the ECHA. Similarly the UK would lose any rights to influence criteria for prioritizing substances for further evaluation (Art 44). Nor would the UK have the rights under Art 45 to have national competent authorities taking a lead in evaluation since these apply only to competent authorities of Member States. The UK would lose rights to influence the procedures under Title VII of the Regulation for restrictions on placing on the market of dangerous substances, including suggesting substances for restriction – other, possibly, than rights under Art 69(6) for interested parties to comment on proposed restrictions.

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13. As noted above, the EEA Agreement has permitted EEA States to participate in the various institutions established under REACH, though without voting rights. As part of its exit negotiations, it would be sensible for the Government to seek equivalent rights for the UK. Whether that is possible is likely to depend on the extent to which the EU considers that the UK (currently the fourth largest chemical industry within the EU) brings value and insights to the REACH system which would otherwise be lost. We also raise in paragraph 16 the possibility of the UK seeking agreements concerning making use of the REACH system post exit.

Developing a UK REACH System

14. While exports to the EU will need to be compliant with REACH, the EU Regulation will no longer apply to substances produced solely for the UK market. Leaving a void in the UK would be politically and environmentally unacceptable, and it will be necessary to develop a UK equivalent system. This will take time and almost certainly require primary legislation, and the need to build up institutional capacity and business understanding.

How should administrative and enforcement responsibilities, which are currently being carried out by the European Commission or EU Agencies (such as ECHA), be transferred to domestic bodies?

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Does the UK Government have the requisite expertise and resources to take on these tasks?

15. The Health and Safety Executive already has REACH enforcement responsibilities, so has detailed knowledge of the architecture of REACH, albeit no-where near on the scale, or with the depth of technical expertise, of the nearly 600 strong European Chemicals Agency in Helsinki. The Chemical Registration Division team within HSE also has regulatory responsibilities for registration dossiers in relation to biocidal products and pesticides, which have a similar registration process to REACH. There would therefore be expertise within HSE but the resource and time required to set up and administer a UK REACH type chemical registration and regulation system would be considerable.

16. The extent to which a UK system could, at least in a transitional period while it builds up capacity, make use of the EU REACH system post exit would be subject to any agreements that could be negotiated with the EU but with political and budgetary ramifications for both sides. But it raises a large number of practical questions which would have to be addressed, including the following points.
 - a. Existing registration dossiers and how they would be managed going forwards. Will they be grandfathered in and on what basis, and what

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- about substances that are subject to joint registrations involving UK companies and other EU companies?
- b. What about where a UK company is a lead registrant? There are already complex legal discussions taking place for groups with UK lead-registrants who are trying to unwind that position in anticipation of Brexit – with considerable practical and contractual difficulties.
 - c. Where existing EU registrations need to be 'brought across' to the UK system (assuming some means for this are put in place), who will meet the costs of this (and, if industry, how will they share the cost) and how will data-sharing and security issues and conflicts be addressed (much of this chemicals data is extremely sensitive, vital IP)?
 - d. How will the agencies co-operate to avoid duplication of work (both for industry and for the regulators assessing information)?

What principles should a UK chemicals regulation regime follow?

17. There are various considerations that might influence extent to which the UK wishes to or would benefit from developing its own national system that diverges from REACH. This area is exceptionally complex already, and a very significant expense for industry (registration costs for a lead registration under the current system can often be up to £100,000, and there may also be additional testing costs to generate the underlying data for a new substance which can be in the region of £300,000 per substance). If not properly

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managed, a new national regime has the potential to create large-scale excessive cost, duplication and confusion for industry and potentially making the environmental purposes of the regime more difficult to meet. At the same time, the UK will continue to bound by a number of international conventions relating to chemicals – for example, the 1998 Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the 2001 Stockholm Convention on Persistent Organic Pollutants, and the 1987 Montreal Protocol on Substances that deplete the Ozone Layer. Future trade agreements also have the potential to include constraints on derogations from existing environmental standards.

18. Despite these constraints, it is possible to envisage a national system that would have certain advantages. The Royal Commission on Environmental Pollution in its 24th Report Chemicals in Products (2003) was supportive of the overall goals of REACH which was then emerging, but was concerned that traditional approaches of hazard and risk assessment would be excessively time-consuming and cumbersome. It proposed radical new approaches to assessing and managing risks of refined and synthetic chemicals, ways of encouraging substitution of hazardous chemicals with less hazardous chemicals and improvements in administrative arrangements. The Commission recognized that the adoption of new regulatory policies in

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individual Member States would be constrained by EU law. UK's exit from the EU would provide an opportunity to revisit its proposals. The EU REACH regime combined hazard and risk based approaches, while the UK has historically adopted more of a risk-based approach to assessing chemical safety. At the same time, the ability to lobby for changes of regulation simply at UK level would make it easier for a UK industry to obtain derogations/ amendments that met its own needs. This might give certain industries a boost, though would need to be balanced with environmental protection requirements, and with trade/market access requirements. Indeed, lobbying from industry for such derogations may be limited. Many of the larger manufacturers who have been particularly active in lobbying to date export to the EU, and may find such derogations to be prejudicial to their interests, as they would decrease the cost base of their 'domestic market only' rivals, whereas exporters to the EU will still be manufacturing REACH compliant products. As such, there will also be attractions in creating a system that mirrors REACH to a large extent. REACH is now understood by many global players, and recognition that a UK system is acceptable will be important internationally. A system that departs too much from REACH will take time to be accepted. In this context it is worth noting that Switzerland (within EFTA but not bound by REACH) has in place a system for new chemicals which mirrors REACH, as has Turkey (within an EU Customs Union agreement but again not bound by REACH).

19. Any such national system will take time to develop, and there will be challenges in having it in place before the UK exit. One transitional solution

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to deal with the national market and avoid in gap in controls would be to introduce regulations providing that only REACH compliant chemicals could be marketed within the UK. Section 11 of the Consumer Protection Act 1987, for example, allows the Secretary of State to make regulations “with respect to the composition” of goods. This is likely only to be a stop-gap solution since the UK would then be relying totally on an external system over which it have no longer had influence – in effect taking rather than making legislation.

20. Any future trade agreement with the EU is likely to include provision concerning mutual recognition. In respect of product registration, however, it is less likely that any national system that diverges to a significant extent from REACH would support a workable process for mutual recognition. In 2014 during discussions of the US/EU Transatlantic and Trade Investment Partnership (TTIP), the European Commission concluded that the differences in fundamental principle between REACH and the US TOSCA system would make mutual recognition or harmonization impossible. At the same time it recognized there were many areas of regulatory cooperation in this area that could be usefully pursued.¹ It is therefore likely UK exports to the EU would continue to have to be REACH compliant.

¹ European Commission The Transatlantic Trade and Investment Partnership: EU position on Chemicals May 2014

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21. We endorse the UK Government's manifesto pledge to "be the first generation to leave the environment in a better state than it found it". Chemical regulation is hugely important in any system of environmental protection, and the underlying principles of any new system should be to ensure at the minimum the safety level of environmental and health protection to the UK public and the environment as provided by REACH, whilst not prejudicing the UK chemical industry's ability to trade with the EU and other states. But we need to recognize the challenges this imposes. After exit from the EU the UK will be deprived of the administrative facilities and technical resources of the European Chemicals Agency and the European Commission, and any national system may be more susceptible to influence and pressures that could place short-term economic gain over longer-term environmental and health protection.

January 2017

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