

Regulatory divergence in the UK chemical industry

A Royal Society of Chemistry briefing

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Following the UK's departure from the European Union (EU) on 31 January 2020, the impact on the future of chemicals regulation in the UK must be considered, alongside the possibility of divergence from EU regulations. At the same time, the government is developing a new Chemicals Strategy as part of its 25 Year Environment Plan, and its formulation will partly depend on how the chemicals regulatory landscape evolves after Brexit. The Royal Society of Chemistry (RSC) has set out a vision for the key pillars of such a strategy in our document '[A Chemicals Strategy for a Sustainable Chemicals Revolution](#)', and one of the most important pillars is the future regulatory regime.

The government is starting from a negotiating position that there will be no dynamic alignment with EU regulations in a new UK-EU trade deal, and has indicated that there will be scope for divergence. There is also no stated intention from the government to seek close cooperation with the European Chemicals Agency (ECHA). Regulatory divergence has the potential to produce both positive and negative outcomes for public health and environmental protections. It is therefore important that, as the UK forges its own path, the government approaches divergence in the right way and is conscious of all possibilities:

- **Divergent sources of data:** harmful divergence could occur if the evidence-base is not harmonised; a new legal agreement is needed in order to continue to share commercially sensitive data between UK authorities and the European Chemicals Agency (ECHA).
- **Positive outcomes of divergence:** Well-informed regulatory divergence could lead to improvements in standards and levels of protection.
- **Negative outcomes of divergence:** Hurried divergence could lead to lowered environmental protections and increased risk to public health, and have negative consequences for our ability to trade products with the EU.

If divergence is to be considered and implemented, we are calling on government to:

- a) Maintain harmonisation of the evidence-base between the UK and the EU
- b) Put chemicals safety science at the heart of regulatory decision-making
- c) Look at regulation in the context of a longer-term UK chemicals strategy
- d) Make regulatory decisions based on a set of defined and transparent principles
- e) Ensure decision-making frameworks are transparent and have clear accountability

Divergent sources of data: Different data can mean different decisions

1. During the transition period the UK has become legally 'a third country'. This means the UK does not have access to the same EU databases and the 98,000 plus dossiers of commercially sensitive safety and technical data for more than 22,000 substances. Our regulatory professionals are not sat in complex technical discussions in the EU that underpin regulatory decisions on substances of concern that are important for UK industry.

2. When scientists and technical review panels cannot see the same scientific data and cannot discuss the data with scientific counterparts in EU, inevitably different decisions could be drawn. Government needs to be mindful of this, and our regulatory authorities must seek to gain access to all of the available data for chemicals from the EU and the rest of the world, in order that important chemicals safety decisions can be taken in full knowledge that all of the evidence is shared, accessible and understood by all.
3. The UK must seek to retain full access to ECHA databases, and as a minimum remain part of the EU REACH registration process, in order that all data can be shared legally. The government should seek to have UK regulatory scientists participate in joint UK-EU working groups, to share knowledge, discuss the same data and ensure that all available data is fully understood by all parties. A harmonised evidence-base will facilitate the best possible decision-making both in the UK and the EU, to the benefit of UK-EU trade, and also for the benefit of leading and harmonising standards globally.

Positive outcomes: Divergence could lead to improvements in standards and levels of protection

4. Divergence could present an opportunity for the UK to show global best-practice leadership, through the application of the best science and evidence in regulatory decision-making and through pragmatic approaches of risk-based decision-making where the UK has good chemical exposure and monitoring data.
5. For example, if there were scenarios in the UK where the evidence indicated that there were adverse impacts on public health and environment, specific to substances of national concern, then divergence from EU regulations leading to quicker and impactful action for the benefit of UK society and public health would be an appropriate situation for divergence. Ideally, if seeking to tackle national issues by regulatory divergence then the UK can lead and influence by example, such that others with similar issues can follow in improving global standards. The UK should use a defined and defensible set of principles by which the government would make divergent decisions, including defined implementation of the precautionary principle.

Negative outcomes: Divergence could lead to lowered regulatory standards, risks to public health, and difficulties trading products internationally

6. In a divergent regulatory system, the government must be careful to avoid any lowering of our current high standard of environmental protections and increasing risk to public health, solely for the purpose of quick short term economic international trade wins or rapidly rolled-out innovations. Innovating new substances without performing the necessary safety studies would not be acceptable divergence.
7. The UK should maintain the spirit and approach of EU REACH, of being proactive and pre-emptive, and using regulation to prevent harm based on scientific evidence. In preparation for no-deal, which could still arise at the end of 2020, the government is developing a UK REACH. It should regulate those substances that are known to be hazardous, and expect data to be generated for new substances whose safety is unknown. Where new data generation is required, the UK should furthermore seek to implement the “3Rs” principles: reduction, refinement and replacement of animal testing by adopting new approach methodologies where appropriate.

8. The UK should not diverge to a regulatory philosophy that involves innovating, delegating responsibility for safety entirely to industry, and then punishing pollution; ie. by applying legal action and fines after a pollution or product contamination incident has occurred. This is a system of operating that can lead to real public health issues (e.g. chromium VI contaminated water) and has led to the recent concern around [poly fluoroalkyl substances \(PFAS\) in water](#), which are biopersistent, unregulated substances in the USA but are now regulated under the EU POPs Regulation (2019) and EU REACH, with specific authorisations of use.
9. Furthermore, a divergent chemicals regulatory system in the UK will bring additional cost burdens to businesses, and if standards are lowered or untrusted will bring consequences to the ability to trade products with the EU.

If divergence is to be considered and implemented, the government should:

10. **Maintain harmonisation of the evidence-base between the UK and the EU**, so that even if the ultimate decisions taken are different, it is transparent as to the reasons why. This includes ensuring UK regulators can access the same data as the EU, and keep their seat at the table for in-depth discussions between UK-EU scientists and regulatory counterparts in order to ensure proper understanding of the data.
11. **Put chemicals safety science at the heart of regulatory decision-making**. The government must use the latest science and evidence to define a 'long list' of the UK's 'substances of concern' to lead and work together with the EU and globally to ensure regulatory action is harmonised for the most impactful actions on substances of concern.
12. **Consider regulation in the context of a UK chemicals strategy**, based on the four pillars of education, innovation, circular economy and regulation. It must seek to present clear and transparent regulatory decisions and actions to a scientifically literate society, and provide assurances that innovations are safe, and that the risks, benefits and value of chemicals in use are fully understood.
13. **Make regulatory decisions based on a set of defined and transparent principles**. The precautionary principle, risk & impact principle, innovation principle and mutual recognition principles could be used to make pragmatic and risk-based decisions for chemicals, based on best practice and the best evidence, as per the RSC's recommendations in '[Principles for the Management of Chemicals in the Environment](#)'.
14. **Base any divergence on transparent decision-making frameworks with clear accountability**, either ministerial or agency-led, to approve and authorise hazardous chemicals based on evidence and an explanation of the underpinning rationale for the decision in full.

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in this briefing in more detail. Please direct questions to Camilla Alexander-White or Matt Davies at policy@rsc.org.

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