The Future of Chemicals Regulation after the EU Referendum

A response from the Royal Society of Chemistry to the House of Commons Environmental Audit Committee

Executive Summary

The UK needs a clear, simple and enforceable regulatory framework relating to chemicals that balances the needs of research, innovation and trade with protecting citizens, wildlife and the environment. Regulation aims to ensure continued environmental protection from hazardous chemicals that can have harmful effects. Regulation must also enable industry to innovate and develop new products, using existing and new chemicals as raw materials, all of which can be traded internationally.

The EU is an important market and the UK will need to remain compliant with REACH if UK businesses are to continue to export to the EU market. Compliance with EU regulation is likely to continue to be important once we leave the single market.

It is important to recognise that REACH and other EU chemicals regulations (such as CLP, PIC and product-specific regulations) are linked and cross-reference each other, relying on common data.

If the UK developed its own regulations, it is likely that data requirements would be broadly similar but future policies could be based on differing principles. The following principles should be considered: precautionary principle, risk principle, innovation principle and the harmonisation principle.

Scientific evidence, in the forms of data generated to high standards and of high level expertise in the interpretation of data, is vital to informing regulatory chemical safety decisions, where the degree of risk and precaution can be balanced to enable innovation and ensure environmental protection goals.

The UK is strong and active in all areas of science that currently underpin chemical regulation and is involved in new areas of science that will change the way safety assessment is performed in the future. It is important that the UK maintains and invests in a strong scientific base for chemicals regulation whether we remain involved in a EU regulatory framework or need to implement our own

To ensure a thriving economy through chemicals and product innovation, it is vital that UK scientists continue to work actively and internationally to stay at the forefront of providing sound evidence into chemicals regulation, in the UK and globally.

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Background – Current EU Chemicals Regulation & UK Approach

1. EU REACH regulations are only one area of EU regulation relating to chemicals

Since 2006 when EU REACH was enacted, the UK has gradually shifted to an operating model of chemicals management where the European Chemicals Agency (ECHA) acts as the main centre of technical expertise, hosts a central data resource for safety data on thousands of chemicals and acts as the enforcement agency for REACH. In considering the UK's future approach to chemicals regulation, it is important to consider that REACH and other chemicals regulations (such as CLP, PIC and product-specific regulations) and directives are linked and cross-reference to each other, as the data and decisions captured within REACH are used to inform other regulations. One example of this (see below) is that the classification of a substance within CLP, based on data collected within REACH, is carried through to implementation in the SEVESO III directive. Due to the interconnected nature of EU chemicals regulations, the data within REACH is relevant to many other regulations and directives.

Our analysis shows that there are at least 300 regulations and directives relating to chemicals, under the following themes:

A) Manufacture, Import & Export of Chemicals as 'Substances' and 'Products'
There are over 100 regulations and directives that govern the manufacture, use and distribution of chemicals as both 'substances' and 'products' (terms defined specifically within the regulations[1]), where the main EU regulations for chemical 'substances' (including mixtures) are

- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Regulation (EC) No 1907/2006)
- Classification, Labelling & Packaging (CLP) Regulations (Regulation (EC) No 1272/2008).
- Prior Informed Consent (PIC) (Regulation (EU) 649/2012)

Within the context of these regulations, there are some important points to recognise as to how these regulations work together and support other chemicals regulations. To illustrate:

i) GHS: A globally harmonised system (GHS) of hazard classification has been developed by the United Nations (UN), to support international trade and provide consistency of terms.
Data collated within the REACH process is used by the EU Risk Assessment Committee (RAC) within ECHA to classify the hazards of chemical 'substances' according to CLP regulations. The EU CLP regulations are where the principles of the UN GHS become legally binding for the UK via EU law.

ii) Product Specific regulations: REACH and CLP regulations controlling manufacture, use and shipping of chemical substances influence the innovation and design of finished products e.g. consumer goods, foods, pesticides, biocides, cosmetics, electronics, paints, and medicines etc. Classifications within CLP, based on data within REACH, can often mean the ban or restricted use of a substance in products. Such products are manufactured and sold according to product-specific EU regulations and directives, as specific substances may pose different risks for specific use scenarios of a finished product. These risks are assessed by scientific committees like the *Scientific Committee on Consumer Safety* who advise the European Commission on the safety of products based upon all the safety data available.

iii) SEVESO/COMAH for dangerous substances: Industries that manufacture and handle dangerous (highly toxic or explosive) chemical substances must also comply with the UK Control of Major Accident Hazards Regulations 2015 (COMAH 2015), which implements the EU SEVESO III Directive. In turn, this Directive relies on hazard identification and classification information on substances from CLP and on data within REACH.

iv) Prior Informed Consent (PIC) regulation controls chemical exports of hazardous chemicals to non-EU countries and implements the *Rotterdam Convention* at EU level. This convention was agreed at UN level 'to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm'. Hazards are defined via REACH and CLP.

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B) Chemical Pollution Prevention & Control

There are many types of environmental protection standards, directives and regulations relating to chemicals in air, land, water and waste. Specific examples are the EU Ambient Air Quality Directive, EU Water Framework Directive and the EU Waste Framework Directive. Pollutants can be derived from natural or anthropogenic sources. Data on toxicological hazards from REACH and CLP evaluations are used to inform environmental standards set through some of these regulations and directives.

2. UK Government Approach to Chemicals Regulation

European regulations (e.g. REACH, CLP and PIC) are enforced at EU level by ECHA and the European Commission. *European directives* are implemented in UK law and enforced by UK government agencies. Chemicals are currently managed in the UK via both EU regulations and directives. In recent years, some key directives (e.g. relating to cosmetics, biocides) have been transitioned to regulations. The UK's responsibilities for chemicals management vary with different statutory instruments and they are spread across different UK government departments (Table 1).

Table 1 Different government bodies and departments and an illustration of regulations relating to chemicals within their remit

Government body	Government Department	Regulation*
Health & Safety Executive (Chemicals Regulation Directorate)(Great Britain) Health & Safety Executive Northern Ireland	Department of Work and Pensions (DWP)	REACH, CLP, PIC COMAH/SEVESO Pesticides
Environment Agency – England & Wales Scottish Environmental Protection Agency (SEPA) Northern Ireland Environment Agency	Department of Environment Food & Rural Affairs (Defra)	REACH, CLP; environmental pollution prevention and control regulations; agricultural regulations; waste.
Foods Standards Agency (England, Wales) Foods Standards Scotland Foods Standards Agency (Northern Ireland)	Non-Departmental Body	Product-specific food contamination; novel foods regulation; pesticides residues; food waste. (Information from other chemicals regulations informs hazard evaluations)
Public Health England	Department of Health	Toxicological assessments to support all chemicals regulations, and provision of health advice (Draw upon REACH and CLP data held at ECHA)
Local Authorities**	Department of Business, Energy, Innovation & Skills (BEIS)	Consumer Product-specific regulations; REACH, CLP, PIC relevant to Industry. Industrial wastes.
	Department for Transport	Transport Emissions

*illustrative not exhaustive; **Local authorities are also responsible for enforcing UK land quality regulations.

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The need for chemicals sciences data and skills in different government bodies varies accordingly. This fragmentation can make it challenging to work on a coordinated chemicals management plan for the UK. Chemicals management should aim to consider the use and safety of chemicals in all regulatory contexts in a consistent manner as efficiently as possible.

3. Chemicals regulation needs high quality data and excellent data interpretation

At EU level, ECHA defines the data requirements for REACH and industry must pay for, generate and submit the data to meet those requirements. Such data generation is defined in REACH technical guidance[2], including:

- chemical properties, (e.g. boiling point, water solubility, flammability etc.)
- analytical/monitoring of chemicals (e.g. in biological fluids and environmental media)
- exposures estimates (modelling and measurement e.g. mg/kg intakes; ug/m^3 in air)
- human and environmental toxicology (multiple endpoints to OECD guideline tests)
- epidemiology (e.g. observed adverse effects in populations)
- occupational hygiene (e.g. personal protective equipment used in workplaces)
- risk assessment (e.g. determination of derived no effect levels as guidance values)

Data collection must be performed to agreed standards: for toxicology data using globally harmonised OECD test guidelines and good laboratory practice (GLP); for chemistry data by accredited analytical laboratories such as the UK accreditation service (UKAS). These types of standards and principles related to data generation operate across all chemicals regulation. Data, even generated to high technical standards, can be open to different scientific interpretation and different technical assumptions and choices even within test guidelines. In order to make chemical safety decisions, data interpretation is performed by scientific specialists and risk assessors. Hence, it is important that the UK maintains and invests in a strong scientific base for chemicals regulation whether we remain involved in a EU regulatory framework or need to implement our own.

4. UK Government access to technical scientific expertise

As chemicals regulation is split across several different government departments, it is difficult to build a comprehensive picture of the technical expertise that exists across the current UK chemicals management framework. It is unclear how the government currently receives and utilises technical expertise in chemicals regulation. This can be through the deployment of technical experts within relevant government departments and associated bodies, through the scientific committees linked to government or through external routes (e.g. consultants). Understanding the current status of this will be essential in exploring the UK's future capability to develop an alternative chemicals regulatory framework.

The Future of Chemicals Industry and UK Chemical Regulations

5. The EU is an important market and the UK will need to stay compliant with REACH if UK businesses are to continue to export to the EU market. The UK will still need to comply with and respond to changes in EU chemicals regulations controlling EU imports (REACH and CLP) and exports (PIC) if UK businesses still wish to export to the EU. This would still likely be the case once we leave the single market.

6. Uncertainty on the future of regulation for the longer term could harm UK business. Whilst the proposals to move the *acquis* into UK law provides some level of certainty for the day the UK exits the EU, uncertainty remains over the longer-term regulatory framework e.g. in terms of having a mechanism for updating or modifying regulation as new evidence arises. Care is also needed to avoid unintended consequences of action in one regulation that can impact another (e.g. banning a pesticide can have implications for food production.)

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7. **Future UK chemicals regulation needs to support UK businesses both large and small.** The burden to generate regulatory safety data and register REACH substance dossiers with ECHA falls to industry. This can be technically complex and generating data is reliant on scientific input from specialists in the chemical sciences and regulatory professionals. The costs of REACH registration can be business-critical for smaller enterprises[3]. As data underpins the development and enforcement of chemicals regulation, access to skills to collect and interpret this data, and the associated administrative burden for those collecting it (e.g. small and medium enterprises), needs to be considered in any future UK regime.

8. **Future principles of UK chemicals regulation could be harmonised or differ from the EU**
In considering future UK chemicals regulations, data requirements will likely be similar but future policies can be based on differing principles. The following principles should be considered:

    - precautionary principle [4,5]
    - risk principle[6]
    - innovation principle[7]
    - harmonisation principle[8]

9. **Regulatory decision making should be informed by scientific evidence.** Scientific evidence helps to inform decisions that balance risk and precaution, supporting the ability to innovate with protection of the environment and human health, alongside necessary social and economic considerations. Principles around international harmonisation (EU or global) need a common and agreed scientific basis underpinning the regulations.

10. **Harmonised chemical classification supports international trade**
Upon leaving the EU, CLP may no longer apply and the UK would need to have some mechanism for implementing GHS for chemical substances to provide industry with clarity around classification for supporting international trade. The UK could either adopt EU classification decisions or if the UK disagreed with these decisions, the UK could develop its own classifications based on UK interpretation of safety dossiers that still align with GHS. However, such deviations would require technical resources and whilst potentially allowing for different decisions to be taken for chemicals and products imported from and exported to non-EU countries, could adversely impact the UK's trade with the EU.

11. **Sharing toxicology data internationally for substances already on the market is vital.**
In particular, *in vivo* toxicology data performed over many decades on legacy chemicals should be shared internationally to avoid unnecessarily repeating animal testing. Summary data from industry is held within the REACH databases at ECHA but terms of access may need to be negotiated to maintain UK access to the full data as supplied by industry into REACH.

12. **UK scientists are highly influential in developing EU regulation via scientific committees**.
UK scientists (from government departments and academia) sit on the majority of EU scientific committees that inform the development of EU chemicals regulation. The UK has a strong and active science base and if we wish to trade with the EU going forward and influence EU regulations, it is unclear whether UK scientists could continue to participate in committees as they do now.

    Scientific committees are generally advisory but some are more aligned to ECHA's legislative and enforcement responsibilities, for example, the ECHA Risk Assessment Committee (RAC) and ECHA Biocidal Products Committee, where UK government scientists (from Health & Safety Executive and Environment Agency) represent the UK's interests.

13. **New chemical testing requires accredited test facilities, qualified staff and future-proofing.**
If new safety testing and evaluation is required, the UK has hundreds of private sector test facilities and contract research organisations (CROs). However, the extent of UK capabilities in terms of accreditation, operating standards, level of qualified and trained staff and sustainability of our current skills base for meeting potential future needs of a UK regulatory regime, is unclear and will depend upon the future regulatory system that we adopt.

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14. **UK opportunities to lead on new regulation for innovative chemicals and products**. There are scientific advances and regulatory knowledge gaps that could present possible future world-leading opportunities for the UK. One example is nanotechnology, progressing rapidly in the UK; this is a topic where international nanosafety regulatory consensus has been difficult to achieve in the context of REACH, as more science is needed. Other areas of regulatory development are safety testing for endocrine disrupting chemicals (EDCs) and safety evaluation of chemical mixtures. The UK's strong scientific research base combined with our approach towards the use of scientific evidence in the development of regulation could present an opportunity to coordinate a way forwards in developing regulations for these rapidly evolving areas of research across the world.

15. **Chemicals safety evaluation is on a path to disruptive change**. The years ahead will result in key developments of new science for chemicals regulation. New approaches to safety testing involving the chemical sciences are being developed for future implementation in chemicals regulation. For example:

    - Adverse outcome pathways (OECD, US EPA, EU)[9]
    - Chemical read-across (OECD, US EPA, EU)[10]
    - Exposomics (EU, USA research collaboration)[11]
    - European Human Biomonitoring Initiative
      (26 countries, 170 EU organisations: including Horizon20:20 funding)[12]

    The UK is active in all of these areas of science that will change the way safety assessment is performed. It is vital the UK continues to actively work internationally in these areas to stay at the forefront of chemicals regulation.

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in our response in more detail. Any questions should be directed to Dr Camilla Alexander-White, alexanderwhitec@rsc.org, 01223 432438.

About us

With over 50,000 members and a knowledge business that spans the globe, the Royal Society of Chemistry is the UK's professional body for chemical scientists, supporting and representing our members and bringing together chemical scientists from all over the world. Our members include those working in large multinational companies and small to medium enterprises, researchers and students in universities, teachers and regulators. See www.rsc.org

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[1] REACH Regulation (EC) 1907/2006
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&from=EN

[2] Guidance on information requirements and chemical safety assessment
https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[3] REACH registration costs and fees . Chemical Inspection and Regulation Service.
http://www.cirs-reach.com/REACH/REACH_Registration_Fees.html

[4] The Precautionary Principle: Policy & Application. Paper by the United Kingdom Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA) published on the HSE website. http://www.hse.gov.uk/aboutus/meetings/committees/ilgra/pppa.htm

[5] The Precautionary Principle. Europa. Eur-Lex http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l32042

[6] Risk Management. Guidance from the HSE website. http://www.hse.gov.uk/risk/index.htm

[7] Innovation Principle. European Risk Forum website. http://www.riskforum.eu/innovation-principle.html

[8] A new approach to technical harmonisation. Europa EUR-Lex-I21001a. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l21001a

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[9] Adverse Outcome Pathways, Molecular Screening and Toxicogenomics, OECD.org http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[10] Cronin M, Madden J, Enoch S, Roberts D (2013) Chemical Toxicity Prediction: Category Formation and Read-Across. Book published by Royal Society of Chemistry, Print ISBN: 978-1-84973-384-7, PDF eISBN: 978-1-84973-440-0, DOI:10.1039/9781849734400

[11] Exposomics Project http://www.exposomicsproject.eu/

[12] European Human Biomonitoring Initiative (HBM4EU) https://ec.europa.eu/research/conferences/2016/hbm4eu/index.cfm

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