CaSE member consultation – regulation post-Brexit

Summary

CaSE members tell us that they view the UK as a world-leader in the development and implementation of progressive scientific regulation. The UK is the current base for the headquarters of the European Medicines Agency (EMA), and UK-based scientific expertise has been extremely influential in developing EU Directives, for example in medicine, ecology, chemical safety and nuclear science. While the UK can continue to be viewed as a powerhouse of regulatory development, there is concern amongst the scientific community regarding the immediate future of the regulatory landscape post-Brexit.

During this consultation, CaSE engaged with our organisational members to capture the expertise of the sector. We received several written submissions from the perspective of sub-disciplines within science and engineering. In addition, CaSE conducted a short survey of attendees at our member workshop event on Brexit in late September, at which Sir Mark Walport was a guest speaker.

This document draws on that consultation to review areas of scientific regulation, pertaining to chemicals regulation, medicine and physics where the UK has been a leader in developing European legislation and directives. Despite the broad spectrum of regulatory environments covered by the consultation, distinct themes were found across the science and engineering community, namely:

- Research collaboration and trade between the UK and the EU will be facilitated by mutual agreement with the regulatory framework set by EU laws and directives
- It will be important for the UK to retain input and influence over EU legislation and directives, should the UK choose to broadly align with EU regulation
- To optimise trade with the EU, the Government must ensure that UK businesses are not subject to additional barriers in a new UK regulatory landscape

CaSE welcomes the opportunity to feed into the wider debate around regulation in a post-Brexit Britain. The purpose of this dossier is to highlight some areas of UK regulation that have been directly applied as a result of EU legislation, and the importance that such UK regulation has on the application of scientific research. Along with discussing some concerns that our member organisations have over the future regulatory environment, we will also explore some of the opportunities that an upheaval in regulatory framework could create for the UK.

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Chemicals regulation is built upon shared data

The EU is an important market and the UK will need to remain compliant with Registration, Evaluation, Authorisation and Restriction of Chemicals (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 Classification, Labelling and Packaging (CLP), Prior Informed Consent (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 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. Analysis from the Royal Society of Chemistry 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 - REACH (Regulation (EC) No 1907/2006); 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. 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

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

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.

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.

UK Government expertise on chemicals regulation is widely dispersed

While the UK's chemical regulatory environment is determined by EU regulation and directives, the UK's responsibilities for chemicals management vary with different statutory instruments and they are spread across different UK government departments as shown in the table below:

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

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.

Future chemicals regulation should support the best interests of UK businesses

The Royal Society of Chemistry have set out a number of key considerations for the future of chemical regulation in the UK, in their recent response to a House of Commons Environmental Audit Committee consultation.

1. 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.
2. Uncertainty on the future of regulation for the longer term could harm UK business.
3. Future UK chemicals regulation needs to support UK businesses both large and small.
4. Future principles of UK chemicals regulation could be harmonised or differ from the EU
5. Regulatory decision making should be informed by scientific evidence.
6. Harmonised chemical classification supports international trade
7. Sharing toxicology data internationally for substances already on the market is vital.
8. UK scientists are highly influential in developing EU regulation via scientific committees.
9. New chemical testing requires accredited test facilities, qualified staff and future-proofing.
10. UK opportunities to lead on new regulation for innovative chemicals and products.
11. Chemicals safety evaluation is on a path to disruptive change.

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.

The UK should seek to retain influence in European Medicines Agency

The European Medicines Agency (EMA) has allowed the UK to provide significant inputs into medical regulations, including streamlining the approval process and regulation of new and existing medicines. Not only does the UK have a leading role in the EMA, the headquarters based in London employ over 600 people. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) works particularly closely with the EMA, for example it[2]:

- led a third of all EU-wide safety reviews since legislation was introduced in 2012
- was a rapporteur or co-rapporteur in 20 centralised procedures that led to granting of a Marketing Authorisation

[2] MHRA (2016) Medicines and Healthcare products Regulatory Agency Annual Report and Accounts 2015/16. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/539679/MHRA_annual_report_and_accounts_2015_to_2016.pdf (Accessed 22 August 2016).

- was appointed Reference Member States (RMS) in 43% of procedures where a UK licence was sought
- held 319 regulatory or advisory meetings to help applicants
- helped shape regulation and approvals through 96 European Scientific Advice meetings

Should the MHRA and EMA no longer be able to collaborate, the UK would lose the ability to influence EU medicines regulatory legislation, and the EU would lose MHRA expertise, increasing the burdens of work the EMA carries out.

Upon consultation with many of our member organisations in the life science sectors and beyond, there is a great deal of discomfort over the uncertainty of the UK's future participation with the EMA, as the EMA falls under the jurisdiction of the European Court of Justice (ECJ), which the UK looks set to leave. Loss of access to the EMA could lead to impacts on the length of time before the UK has access to new treatments, costs of treatments, and it may affect quality and volume of clinical research if drug companies opt to prioritise countries that are part of the EMA. The UK has the opportunity to carve out a role for itself as a global leader for regulation, but divergence from regulation set by organisations such as the EMA could have drastic consequences for businesses and future collaborations. A major concern of the sector, therefore, is that the UK will have to broadly align with EMA regulations, without potentially having any power over the legislative environment. Our members feel that it is imperative that the UK retains access to the EMA, and MHRA can continue to work collaboratively with European counterparts.

Trade of nuclear materials is vital for medical treatments and physics research

EU Directives have great influence over medical physics

The table below gives examples of UK regulations that have been implemented as a direct result of EU Directives.

UK regulation	**Overarching EU Directive**
Ionising Radiations Regulations 1999 (IRR 1999)	European Basic Safety Standards Directive '96/29/Euratom'
The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R 2000)	European Directive 97/43/Euratom (The Medical Exposures Directive) and protect patients.
Control of Electromagnetic Fields at Work Regulations 2016	Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).

With regards to transposition of EU Directives into UK law, the UK Department of Health is currently finalising the following:

- The European Council Basic Safety Standards (BSS) Directive 2013/59/Euratom will shortly lay down in UK law basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repeals the 96/29/Euratom and 97/43/Euratom Directives, plus Directives 89/618/Euratom, 90/641/Euratom, and 2003/122/Euratom
- European Qualifications (Health and Social Care Professions) Regulations 2016, which will transpose the relevant sections of the revised *Mutual Recognition of Professional Qualifications Directive* into the healthcare regulators' governing legislation;
- Commission Implementing Decision (EU) 2016/787 and certain aspects of the *Tobacco Products Directive* 2014/40/EU;
- Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain *technical requirements for the coding of human tissues and cells*;
- Commission Directive (EU) 2015/566 implementing Directive 2004/23/EC as regards *the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells*; and
- Elements of the Falsified Medicines Directive 2011/62/EU (safety feature elements).

The UK has recently introduced the Control of Electromagnetic Fields at Work Regulations 2016. These regulations implement EU *Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields*). The UK was a positive influential partner in developing this Directive. Members of UK institutions, including the Institute of Physics and Engineering in Medicine (IPEM), noted that the original directive would prevent certain medical use of electromagnetic fields. This resulted in the original directive being revoked and replaced. This is an excellent example of how the UK has been an influential, practical and pragmatic partner in developing EU legislation. Without this change, much MRI based healthcare and

innovation in Europe would have had to cease and would likely have been exploited elsewhere in the world.

The UK has had a leading role in developing EU Directives

As well as developing medical technologies, UK healthcare scientists and the UK Department of Health have been influential in the development of their safe regulation. The Medical Devices Directorate (Council Directive 93/42/EEC) harmonised the laws relating to medical devices within the European Union. In order for a manufacturer to legally place a medical device on the European market, the requirements of this Directive have to be met. Products meeting harmonised European standards have a presumption of conformity to relevant safety requirements in the Directive. Products conforming with the Directive must have a CE mark applied. The Directive was most recently reviewed and amended by the 2007/47/EC and a number of changes were made. Compliance with the revised directive became mandatory on 21 March 2010. The Medical Devices Directive is being repealed and replaced by a Medical Device Regulation (MDR). The UK, through the MHRA, has been very influential in significantly improving the original Commission draft, to the benefit of the UK NHS scenario. This new Regulation will likely come into force in the autumn, so will be enacted in UK law.

The UK remains a key innovator of medical technologies. Devices such as medical ultrasound, X-ray CT and MRI) have all been developed in the UK. The UK remains a major world manufacturer of MRI systems with more than 30% of the superconducting magnets in hospitals worldwide manufactured in the UK. As an example, 95% of the magnets made by Siemens Magnet Technology in Oxford are for export. Siemens is now manufacturing new 7 Tesla magnets in the UK. Siemens will partner with universities and hospitals in the UK to further develop this technology and its applications. This development will result in the creation of hundreds of new healthcare science research jobs.

Nuclear Cooperation Agreements are vital for physics research and applications

More broadly within physics, there are concerns arising around the trade of hazardous materials and the legislation thereof. New Nuclear Cooperation Agreements (NCAs) will need to be in place for the trade of nuclear materials to and from the UK to continue after the date at which the UK leaves Euratom, as countries will not trade with the UK unless a new agreement is confirmed. Even with willingness from other countries, the complexity of renegotiating almost all of the UK's NCAs will take time, especially alongside other matters to be settled during the Brexit negotiations. New NCAs must be agreed by the date at which the UK leaves Euratom, or a transitional agreement must be in place to ensure the UK's security of supply in the immediate term. If neither of these options is achieved, the UK will not be able to legally trade nuclear materials with other countries.

Opportunities could arise from regulatory reform

As the UK has been highly influential in the development of rigorous, evidence-driven regulation, there is an opportunity for the UK to position itself as a global leader in scientific regulation. While upholding the high standards currently set by existing regulation, the UK could look towards lowering levels of bureaucracy associated with novel technologies and medical research.

Changes in some medical legislation could help the UK to more effectively implement the outcomes of the Accelerated Access Review[3], or introduce new and innovative medicines into the UK earlier than other nations. Other areas of medical research that can be particularly onerous include clinical trials. The Government, should they choose to do so, could facilitate a quicker and more streamlined setup process for clinical trials, while retaining compliance with global standards to support continued collaboration in international trials. This would set the UK up as a platform for clinical trials, advancing the UK's capability in life sciences industry.

With regards to medical physics regulation, the UK could again seek to position itself as a world leader by some divergence from current EU legislation. There would be an opportunity, for example within the Control of Electromagnetic Fields at Work regulations, to assess which set of legislation and regulations the UK would wish to follow, whether that be existing EU legislation or take directions from the International Commission on Radiological Protection (ICRP). The UK could potentially be a European "test bed" for new developments in areas currently restricted in the EU. However, this would entail a commercial risk if the EU regulations were not relaxed.

[3] https://www.gov.uk/government/publications/accelerated-access-review-final-report

For more information

To find out more about specific pieces of legislation or for more detail on certain issues, please contact james@sciencecampaign.org.uk

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Annex 1: Royal Society of Chemistry regulatory key considerations

1.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.

2. 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.)

3. 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.

4. 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]

5. 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.

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[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

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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]

[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