

UK research and the  
European Union  
**Regulation that  
supports research and  
innovation and earns  
public confidence**

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## In a globalised world, global action is needed to keep people safe

Science is a global endeavour. Decisions over how best to conduct research and safely exploit new applications are shared by scientists and governments across the world. Where these may have global impacts, there is value in developing a consistent approach.

### EXAMPLE 1

#### Viruses do not respect borders

Severe acute respiratory syndrome (SARS) is a viral respiratory illness. SARS was first reported in Asia in February 2003. Over the next few months, the illness spread to more than two dozen countries in North America, South America, Europe, and Asia before the SARS global outbreak of 2003 was contained.

### EXAMPLE 2

#### The Biological and Toxin Weapons Convention is informed by scientific evidence and advice from experts around the world

Biological and toxin weapons are biological agents of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. They represent a global threat as they are typically designed with hostile purposes, such as use in armed conflict. The international Biological and Toxin Weapons Convention (BTWC) prohibits the development, stockpiling or production of these weapons and commits states to destroying them except for samples for research purposes.

### EXAMPLE 3



#### Scientists and government around the world will have to consider how to regulate new genetic technologies

New genetic technologies are cheaper, more efficient and more precise than previous genetic technologies and could potentially be used to modify human genes. This is a rapidly evolving policy area.

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“Saving our planet, lifting people out of poverty, advancing economic growth... these are one and the same fight. We must connect the dots between climate change, water scarcity, energy shortages, global health, food security and women’s empowerment. Solutions to one problem must be solutions for all.”

Ban Ki-moon, Former Secretary-General of the United Nations.

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“It’s a collective endeavour, it’s collective accountability and it may not be too late.”

Christine Lagarde, Managing Director of IMF, on climate change.

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1. Centre for Disease Control and Prevention. SARS Basics Fact Sheet. See <https://www.cdc.gov/sars/about/fs-SARS.html> (accessed on 10 April 2018).
2. The Platform is coordinated by academics from the London School of Hygiene and Tropical Medicine, IDS, Sussex, Exeter and Njala University and funded by a grant from the Research for Health in Humanitarian Crises (R2HC) Programme Department for International Development. 2014. New research funding to strengthen ebola response. See <https://www.gov.uk/government/news/new-research-funding-to-strengthen-ebola-response> (accessed 03 May 2018).

## Pooling resources and expertise can streamline regulatory processes

Consistent policy that supports science across multiple countries can facilitate international research collaborations and access to markets. It can also ensure that public safety standards are shared widely and enable regulators to draw on the best available evidence and expertise in a streamlined way. However, poorly designed policy at a national, EU or global level can be damaging, whether applied consistently or inconsistently.

### Chemicals regulation

There are over 300 EU regulations and directives relevant to the UK chemical industry and chemical sciences community. Over 100 of these govern the manufacture, use and distribution of chemicals medicines and other products such as electronics, paint and agrichemicals<sup>3</sup>.

### Medicines can take time to be approved for new markets

Despite having a number of bilateral trade agreements with the EU, it is estimated that Switzerland gains access to new medicines on average 157 days later than the EU. In Australia and Canada new medicines come to market on average 6 – 12 months later than in the EU or USA<sup>5</sup>.

#### CASE STUDY 1

Making new treatments for Duchenne muscular dystrophy available to UK patients.

Duchenne muscular dystrophy (DMD) is a severe type of muscular dystrophy for which there is no cure and limited treatment options available. The number of patients with DMD is estimated at 26,000 in the EU, and 2,500 in the UK. There are several promising treatments progressing through the clinical trials process and a number of these are awaiting authorisation by the European Medicines Agency (EMA). If successful, these medicines could effectively slow down the progression of DMD and result in significant benefits to those affected. Without a UK link to the EMA and considering the small population size and market opportunity for pharmaceutical industries, individuals with DMD in the UK could face lengthy delays in accessing new medicines compared with patients with the same condition living in EU countries<sup>4</sup>.

The UK does not currently have its own pledge under the Paris Agreement. Instead it is covered by the EU pledge to reduce emissions by at least 40% across all 28 Member States by 2030. The EU acts as one party to the UN Paris Agreement, although Member States must also ratify independently. As a party to the Paris Agreement outside the EU, the UK will need to submit its own pledge for action and its own mid-century plan<sup>6</sup>.

### Aviation regulation

The European Aviation Safety Agency (EASA) certifies the safety of aircraft products for use and sale. It also informs standards for R&D projects, environmental regulations and new markets<sup>7</sup>. As a member of EASA, the UK currently benefits from working to a single set of regulations when exporting across Europe, and the bilateral agreements concluded with key markets including the US and Canada

3. Royal Society of Chemistry. 2016 Leaving the EU: implications and opportunities for science and research.

4. Brexit Health Alliance. 2018 Brexit and the impact on patient access to medicines and medical technologies.

5. Brexit Health Alliance. 2018 Brexit and the impact on patient access to medicines and medical technologies.

6. Committee on Climate Change. 2016 Meeting Carbon Budgets – Implications of Brexit for UK climate policy.

7. Parliamentary and Scientific Committee. 2017 Science Priorities for Brexit – Evidence report.

## Working with others can increase the impact of UK research to improve peoples lives in the UK and around the world

UK-based experts help inform national and international policymaking on issues that are important to the lives of people in the UK and around the world.

The UK is a world leader in climate science, and the second largest contributor of expertise to the Intergovernmental Panel on Climate Change (IPCC) process that informs international decision making about climate policies<sup>8</sup>.

### Providing scientific advice to EU policymakers

The High Level Group of Scientific Advisors of the European Commission Scientific Advice Mechanism provides the Commission with high quality, timely and independent scientific advice on specific policy issues where such advice is critical to the development of Union policies or legislation. The advice is based on the best possible scientific evidence. Members currently include Sir Paul Nurse, a Nobel prize-winning researcher currently based in the UK<sup>9</sup>.

### CASE STUDY 2



Current EU policy governing the use of animals in scientific research draws heavily on the pre-existing UK legislation.

At present the use of animals remains the only way for some areas of research to progress. EU policy follows the principle of Three Rs (Replace, Reduce and Refine), which aims to ensure the welfare of animals used for research purposes. The UK has one of the world's strongest regulatory systems in this area and was at the forefront of a number of major advances such as banning cosmetics testing and the use of great apes in the 1990s. EU regulation of this area began in 1986 but inconsistencies in national implementation by Member States led to the publication of a revised Directive in 2010. One of the central aims of the revised legislation was to raise standards of oversight and animal use in other Member States, especially those with a poor record of implementing the previous Directive.

8. Calculated from the annex of author and expert reviewers in the IPCC's Fifth Assessment Report. Total authors and reviewers = 1878, UK based authors and reviewers = 265.

9. European Commission. High level group of scientific advisors. See <https://ec.europa.eu/research/sam/index.cfm> (accessed 10 April 2018).

## The UK is at the forefront of developing innovative approaches to emerging technologies with public confidence

New applications of emerging technologies can make a great contribution to our lives, but to realise these benefits with public confidence, we must navigate significant choices and dilemmas. The UK is respected around the world for its proportionate approach to regulating emerging technologies, such as the application of embryology research to reproductive technologies, in a way that balances emerging scientific understanding and competing values<sup>10</sup>. This has enabled new techniques to be researched and made available to patients in the UK with public confidence and is informing regulatory approaches around the world.

In 2015, UK MPs voted to allow the introduction of mitochondrial transfer techniques into clinics, overseen by the Human Fertilisation and Embryology Authority. This decision was the culmination of many years of scientific and public debate. These treatments, developed in the UK, could reduce the number of children born with rare mitochondrial diseases, and help dozens of families to lead happy and healthy lives. The UK's approach is informing other countries as they consider these new treatments.

### CASE STUDY 3

A world-leading approach to the management and use of data

The UK has a strong history of leadership in machine learning – a technology which shows promise of supporting potentially transformative advances in a range of sectors including healthcare, transport and public services. We are well-placed to develop new regulatory approaches to exploit this technology with public confidence<sup>11</sup>.

### CASE STUDY 4

A new approach to the regulation and use of genetic technologies in plants

The UK has a strong science base in the fields that contribute to the development of genetically modified (GM) applications. However, the length and cost of obtaining EU regulatory approval for GM can discourage the translation of this research into agricultural applications<sup>12</sup>. The UK could adopt a different approach to the EU in this area. For example, considering options to regulate specific agricultural traits or products, rather than the technology by which these are developed, taking into account likely benefits as well as hypothetical risks in regulatory decisions.

10. Mark Walport, Claire Craig. 2014 Innovation: Managing risk, not avoiding it: annual report of the Government Chief Scientific Adviser 2014.

11. Royal Society. 2017 Machine learning: the power and promise of computers that learn by example.

12. The Royal Society. 2014 Submission to the House of Commons Science and Technology Committee's inquiry on GM foods and application of the precautionary principle in Europe. See <https://royalsociety.org/topics-policy/publications/2014/gm-foods-and-precautionary-principle-in-europe/> (accessed 12 March 2016).