

A response from the Royal Society of Biology to the House of Commons Science and Technology Select Committee inquiry into EU regulation of the life sciences

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The Royal Society of Biology is a single unified voice, representing a diverse membership of individuals, learned societies and other organisations. We are committed to ensuring that we provide Government and other policy makers, including funders of biological education and research, with a distinct point of access to authoritative, independent, and evidence-based opinion, representative of the widest range of bioscience disciplines.

The Society welcomes the House of Commons Science and Technology Select Committee consultation on [EU regulation and the life sciences](#). We are pleased to offer these comments which have been informed by specific input from our members and Member Organisations across the biological disciplines and our previous comments on associated topics. The diversity and number of ways in which EU regulation interacts with UK life sciences is significant and we do not attempt to cover this exhaustively in this submission, rather we raise a selection of relevant matters. We recently responded¹ to the House of Lords Science and Technology Select Committee inquiry into the relationship between EU membership and the effectiveness of science, research and innovation in the UK.

Summary

- Life sciences in the UK is a broad and vibrant sector covering human, animal, plant, microbial, synthetic and ecosystem sciences and their application in all settings.
- UK research and innovation endeavour involves a high degree of collaboration, both nationally and internationally, critically involving mobility of researchers.
- Access to EU funding mechanisms and programmes has been beneficial for UK science and established a tradition of collaboration within the EU, with flows of both talent and resources.
- Regulatory mechanisms play significant roles influencing the planning, execution and dissemination of UK life science research, and in defining relevant reporting and governance. There are both regulation specific and implementation dependent effects of EU regulation and a range of consequences for life science.

¹ https://www.rsb.org.uk/images/pdf/RSB_response_to_HoL_consultation_on_science_and_the_EU_FINAL_-_Copy.pdf

Response to consultation questions

What are the key EU regulations and frameworks that govern/influence the conduct of research and innovation in the UK life sciences?

1. The Framework Programmes for Research and Technological Development have been very influential in terms of life science, science and innovation. There have been the eight funding programmes, FP1 to FP7, with the eighth programme, Horizon 2020, currently in operation. With a budget of €74.8 bn that will run until 2020, Horizon 2020 is the largest to date. The Framework Programmes in general support three pillars of excellent science, industrial leadership, and societal challenges, and the UK has been particularly successful in winning financial support. There is a strong link to collaboration and so success is also intertwined with free movement of people and research, as well as harmonised standards in some areas, within the EU. In all funding programme areas with a strong science component, including the ERC, Life Sciences, Marie Skłodowska-Curie and Research Infrastructure (RI) funding the UK research community secured close to double the expected share of total EC income based on the size of the UK economy².
2. EU bioscience funds have steadily increased in successive FP budgets³. Approximately 40% of the UK FP7 competitive science funding was awarded to the biosciences, receiving €2.9 bn to fund over 2,000 projects. Natural and life science projects (encompassing food and agriculture, evolution and ecology, climate change and environmental challenges) received 30% of these awards⁴. The UK led coordination of 20% of the grants awarded in FP5-6. The UK therefore participates in and coordinates a high proportion of the health-related projects by comparison with other EU members⁵.
3. The UK competed well for FP6-7 funded RI projects⁶. These include The European Molecular Biology Laboratory/European Bioinformatics Institute (EMBL-EBI) in Cambridge, which is home to other bioinformatic resources such as, the European Life-Science Infrastructure for Biological Information (ELIXIR), Serving Life-Science Information for the Next Generation (SLING), Impact and BioMedBridges. BioStruct-X is also at the EMBL covering genomics and proteomics research. The Transnational Infrastructure for Plant Genomic Science (transPlant) is also within the EMBL. Imperial College London is home to the Infrastructure for Systems Biology (ISBE) and the Mosquito repository INFRAVEC. The University of Oxford is home to Instruct, the Integrated Structural Biology Infrastructure⁷. Access to EU Infrastructure and

² [The impact of the EU RTD Framework Programme on the UK, \(2010\) Technopolis Group carried out on behalf of the International Science and Innovation Unit within the Department for Business, Innovation and Skills \(BIS\)](#) (p 2)

³ [Budgets:30 years of EU Investment in Research and Innovation](#) (accessed 07/10/15)

⁴ [European Research Council Statistics](#) Country of Host Institution per Domain (accessed 03/11/15)

⁵ [An analysis of subject areas and country participation for all health-related projects in the EU's FP5 and FP6 programmes \(2013\) Galsworthy et al, European Journal of Public Health, 24;3, 514–520](#) (pp 515-16)

⁶ [European Commission Research Infrastructure](#) (accessed 04/11/15)

⁷ [Enabling science, EU support to research infrastructures in the life sciences \(2013\) Directorate General for Research and Innovation Research Infrastructures](#)

Networks offers pan-European platforms for education and training. There is general recognition of a requirement for funding of large Research Infrastructure (RI) projects on a European basis.

4. Funds are also received through Life Science Infrastructure and Marie Skłodowska-Curie Scholarships; with UK life sciences, genomics, biotechnology and sustainable development named as some of the most significant areas to receive funding in terms of volume⁸. For example, the European Regional Development Fund (ERDF) Convergence funding has had a big impact upon the environmental biosciences at the University of Exeter's Penryn Campus.
5. The detail of some funding policy structures is also important, for example long-term (5-year) support is offered by ERC fellowships for both early career researchers and professionals in areas of environmental and ecological sciences that do not have equivalent opportunities in UK funding. Researchers report to us that these EU funds thereby allow researchers to build their own groups and tackle in-depth questions. In a similar vein, plant researchers have suggested that they often lost out to other disciplines in competing for national funding and the EU provided a very valuable additional source of funding for plant researchers in the UK.⁹
6. Without EU membership the UK would not have access to the Innovative Medicines Initiative (IMI) the world's biggest public-private partnership in the life sciences. As an EU led partnership with the European pharmaceutical industry the IMI budget is funded through Horizon 2020 and consortia of EU Pharmaceutical companies with an aim to improve the drug development process¹⁰. Similarly, access to the European Medicines Research Training Network (EMTRAIN) provides a sustainable, pan-European platform for education and training¹¹.
7. EU Regulations are binding laws that come into legal force across the member states simultaneously. More commonly in relation to life science areas, Directives are developed carrying with them a requirement to be transposed into member state law within a defined time and therefore including some flexibility to adapt the instrument to member state existing law or aspiration.
8. Much life-science-relevant EU legislation supports a parity of standards, enabling cross border cooperation for science projects and potentially for products. A high proportion of UK environmental policy and regulation is derived from EU policies and Directives, this enables collaboration with access to European datasets that would otherwise be difficult. Directives support UK-specific implementation and there is improved performance in addressing environmental issues¹². Directives including Water, Birds and Habitats (including the Natura 2000 network of

⁸ [The impact of the EU RTD Framework Programme on the UK, \(2010\) Technopolis Group carried out on behalf of the International Science and Innovation Unit within the Department for Business, Innovation and Skills \(BIS\)](#) (pp 2, 26–27, 30–31)

⁹ [Review of the Balance of Competencies between the United Kingdom and the European Union – Research and Development](#)

¹⁰ The [Innovative Medicines Initiative](#) (accessed 28/10/15)

¹¹ [EMTRAIN](#) (accessed 28/10/15)

¹² [Review of the Balance of Competencies between the United Kingdom and the European Union Environment and Climate Change \(2014\)](#) (p 7)

protected areas) and Marine Strategy provide a framework to prioritise applied research, offering benchmarks to facilitate study design and therefore increasing the impact of research. Directives such as the Environmental Impact Assessment offers guidelines as to why research should be conducted, helping to inform the research questions. The EU regulatory framework on the environment has stimulated a great deal of research, consultancy and compliance activity in the UK, mostly focused on the environment, human well-being and the economy. The Chartered Institute of Ecology and Environmental Management have outlined all of the environmental directives, and indicated how they are implemented in each UK country¹³.

9. The Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes set out to harmonise standards across the EU to support collaboration, remove competitive disadvantage and respond to leading opinion and expertise¹⁴. The Common Agricultural Policy and Common Fisheries Policy have implications across terrestrial, aquatic and marine research, practice and innovation with relevance to environmental, agricultural zoological, plant and agri-tech research among others. Policies on air and water quality, emissions, waste, chemicals regulation, habitats protection and copyright all shape the life science research and innovation space. In addition collectively agreed international arrangements are relevant here, including those under the United Nations Conference on Climate Change (UNFCCC) and the Nagoya Protocol.
10. Very importantly the free movement of people across the EU and within the ERA is a defining feature facilitating the movement of students, researchers and skilled innovators vital to the life science sector.

In what ways do these EU regulations affect the UK life sciences? What are their benefits and the drawbacks?

11. The UK life sciences industry views the European Medicines Agency (EMA)¹⁵, and the Unified Patent Court (UPC), both based in London, as providing beneficial regulation regarding scientific advice on medicinal products. Advanced Therapy Medicinal Products (ATMPs) including cutting edge cell and gene therapies are governed by a European framework for assessment and marketing. Pooled expertise at the European level and direct access to the EU single market are beneficial¹⁶.

¹³ http://www.cieem.net/data/files/Resource_Library/Policy/Policy_work/CIEEM_EU_Directive_Summaries.pdf

¹⁴ [Review of the Balance of Competences between the United Kingdom and the European Union Research and Development \(2014\)](#) (p 44)

¹⁵ [BIA UK Life Sciences Manifesto 2015-20](#)

¹⁶ [BIA Briefing Paper: Advanced Therapy Medicinal Products and Regenerative Medicine](#)

12. A report by the Working Group on Expanding Access to Published Research Findings¹⁷ recommended a reduction of the VAT burden on online access to e-journals. Restricted access to e-publications acts against research efficiency whilst also raising research institute expenditure¹⁸.
13. The Clinical Trials Directive, has benefited from input to counter earlier differing interpretations across states and administrative burden potentially reducing the number of studies; it is now improved and helps to support cross border clinical trials necessary for lower-incidence conditions or highly specific trial criteria. In addition Regulation (EC) No.141/2000 provides incentives for the development of “orphan” medicinal products for the treatment of rare diseases. The European Medicines Agency and harmonised standards means that life science companies do not need to seek 28 different licences across Member States, with advantages for economies of scale and potentially for patients. In addition there are benefits to reporting adverse reactions across the EU.¹⁹ The UK’s MHRA can influence the EMA and provide valued input on health and public health matters.
14. Another example of harmonised standards arises in relation to food and nutrition labelling, and package labelling²⁰ where minimum standards are seen to support development; and harmonised food hygiene standards a health benefit. The European Food Safety Authority²¹ provides evidence-based risk assessments, including around emerging risks, microbiological, pesticide and other hazards. European level assessment and having the capacity to draw on collective European knowledge and expertise provides benefit to national services for assessment and risk management, many of which are under strain, as well as to the European Commission and Parliament.
15. Research on Genetically Modified Organisms (GMOs) is regulated through the Contained Use Directive (2009/41/EC) and subsequent releases within the EU are regulated via the Deliberate Release Directive (2001/18/EC). Under these regulations all GMOs must undergo a risk assessment by the European Food Safety Authority (EFSA) before they can be considered for importation, planting or release in the EU. The European Commission then takes the EFSA assessment into consideration and issues a proposal on the release of the GMO, on which EU Member States vote before a final decision is reached. An independent and robust risk assessment of the release of GMOs is a necessary part of the regulatory framework, and the ecological implications of GMO releases should be understood as thoroughly as possible through a combination of modelling, laboratory work and field trials. Overall risk assessment should consider benefits, and the relative risks of action and inaction. EFSA assessment is a lengthy process and thereafter the Commission decision process often makes little progress, with lengthy delays and uncertainty effectively discouraging new entrants to the process.
16. UK research on genetically modified organisms (GMOs) has led to several innovations in both GM animals and plants, with a range of potential beneficial outcomes including improved crop yields and disease resistance, resistance to transmission of bird flu, and control of insect vectors of viruses such as dengue and

¹⁷ [Accessibility, sustainability, excellence: how to expand access to research publication \(2012\)](#)

¹⁸ [Accessibility, sustainability, excellence: how to expand access to research publication \(2012\)](#) (pp 9, 64)

¹⁹ [Review of the Balance of Competencies between the United Kingdom and the European Union – Health](#) (p7)

²⁰ <http://echa.europa.eu/regulations/clp/labelling>

²¹ <http://www.efsa.europa.eu/>

Zika. However, commercial GM crop R&D in Europe has declined as a consequence of the EU regulatory and market environment.²²

17. A 2015 review²³ of the GMO decision-making process concluded that the legal framework for decision-making on the import and growth of GM *food and feed* should be adapted, and proposed that Member States should be allowed to restrict or prohibit the use of genetically modified food and feed on their territory, despite it being authorised at EU level. More than half of EU member states subsequently decided to opt-out of permitting the cultivation of genetically modified crops. In the UK, this is a devolved issue, with Scotland, Wales and Northern Ireland currently against cultivation of GM crops, whilst England has permitted their growth. The Northern Ireland decision was called in for review by the Office of the First Minister in September 2015. Amendments to allow decision-making about cultivation on a national basis may alter the landscape for research. Inevitably, there is interplay between local market conditions and the research environment, with little incentive to innovate for a market that may not become open.
18. The release of GM insects is also regulated under Directive 2001/18/EC²⁴, alongside guidance on the risk assessment of GM animals²⁵ from the European Food Safety Authority (EFSA). However, the current regulatory framework is not ideally suited to GM insects. Dispersal of GM organisms, will operate differently for GM insects, and there is a low risk of gene flow due to their breeding specificity. A report by the UK Advisory Committee on Releases to the Environment (ACRE) on GM Insects²⁶ explored some of these issues and called for a more holistic approach than available via the Directive, which includes a consideration of the risks of alternative control methods (such as insecticides) and the risks of inaction (continued and increasing disease prevalence as insects develop resistance). The ecological risks and hazards associated with the release of GM insects is 'product' specific; i.e. the GM technology, species, lifecycle, locality, and time of year, will all impact on the ecological consequences of its release. A broad-brush approach to regulation is therefore not appropriate in this context. Assessments would need to be made on a case by case basis, taking into account both the benefits and the risks of the release.
19. At present the timescale for delivery of an EU judgement on gene editing is slipping. There have been rapid developments of gene editing technologies (such as CRISPR-Cas9) in recent years. Typically this process removes specific bases within a genome, but some applications of the technology can also introduce novel sections of DNA. The European Commission has set in motion a "thorough legal analysis" of the definition of 'GM organisms' in its own legislation, and of the criteria for excluding certain technologies. A good deal of discussion around agricultural applications of gene editing is focussed on whether potential products or intermediates should classify as GMOs in the current definition. However, important considerations to be addressed include what are the potential products; what are their potential benefits and harms; where and

²² [Society of Biology response to the Commons Science and Technology Select Committee inquiry into GM foods and application of the precautionary principle in Europe](#)

²³ http://ec.europa.eu/food/plant/docs/plant_gmo_authorisation_communication_en.pdf

²⁴ Deliberate release of genetically modified organisms (GMOs) <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l28130> [Accessed 05.08.15]

²⁵ EFSA Panel on Genetically Modified Organisms (2013) Guidance on the environmental risk assessment of genetically modified animals. EFSA Journal 2013;11(5):3200, 190

²⁶ Advisory Committee on Releases to the Environment (ACRE) Report on the ACRE information gathering workshop on GM insects (2010) London: Advisory Committee on Releases to the Environment, DEFRA.

on whom these might rest; whether and if so what are the ethical implications of producing crops via gene editing etc. Good regulatory policy making will require answers to these questions and more, ideally to avoid stalled regulatory and research pipelines.

How transparent, consultative and evidence-based are EU policy-making processes?

20. The EU commission has committed to reduce bureaucratic load on participants of its programmes, in particular within Horizon 2020²⁷, with explicit plans for the inclusion of better mapping and monitoring²⁸, greater transparency, centralized open-access and equivalent incomes across member states²⁹.
21. There are practical barriers to engaging with EU policy-making processes, primarily around the resource required to engage with policy-makers on the ground and to track the often-lengthy process of policy evolution and iteration. The number of parties involved makes complexity inevitable but collaboration and improved communication among UK groups with an interest in life sciences has greatly improved sector knowledge of processes and identification of opportunities to engage.
22. The UK has frequently been successful in negotiating science based EU rules. Implicit in these are judgements about what levels of risk are appropriate and how these can be balanced against benefits; there are differences across the EU in relation to political and social acceptability of science-based risk/benefit analyses as opposed to other forms of assessment.
23. In 2015 a new Science Advice Mechanism was created to provide science advice to the Commission. The mechanism includes a High Level Group and the overall aim is towards producing independent, transparent, pan disciplinary and context aware advice.³⁰ The process is getting underway and so the outcome of the operation of this new mechanism is difficult to anticipate.

²⁷ [An analysis of subject areas and country participation for all health-related projects in the EU's FP5 and FP6 programmes \(2013\) Galsworthy et al, *European Journal of Public Health*, 24;3, 514–520](#) (p 514)

²⁸ [Horizon 2020 – Impact Assessment Report.\(2011\)](#)

²⁹ [An analysis of subject areas and country participation for all health-related projects in the EU's FP5 and FP6 programmes \(2013\) Galsworthy et al, *European Journal of Public Health*, 24;3, 514–520](#) (p 518)

³⁰ <https://ec.europa.eu/research/sam/index.cfm?pg=about>

To what extent is the UK able to shape regulatory processes at the EU level that affect the life sciences?

24. The UK has played a leading role in shaping EU directives, and harmonisation with national policies removes competitive disadvantage and facilitates easier collaboration. However, the evolution of directives is challenging. The UK is an influential member within the EU, and there is agreement that the UK plays an important role in influencing processes, and through that has additional influence globally³¹ and in multinational legislation, and it is considered important that the UK continues to influence EU agendas. The UK has made the point that commercial benefits of research are often unforeseen and long term, encouraging the EU to maintain capacity to support blue sky research, as it had done through an increase in ERC funding under Horizon 2020.³²
25. The Protection of Animals for Scientific Purposes Directive 2010/63/EU set out to harmonise standards across the EU and the UK played a leading role in developing standards so that harmonisation and improved welfare could be achieved and facilitate collaboration as well as remove competitive disadvantage and respond to leading opinion and expertise³³.
26. Recent development of the General Data Protection Regulation have taken into account the need to accommodate research following engagement by the research community among which UK representatives, researchers and organisations including the Wellcome Trust have played a leading role³⁴. In addition this presented an operational example of EU policy-making process at work in terms of transparency, consultation and use of evidence to inform decision making, albeit over an extended timeframe.
27. The Medical Devices and In Vitro Diagnostic (IVD) Devices Regulations are still in development and a coalition of UK and European organisations³⁵ are active aiming to ensure that access to clinically useful genetic testing technologies, including their wider uptake and use is not restricted by the required genetic counselling process. Again it is hoped that these contributions will influence these decisions.

Is the UK able to depart from the application, standards or timing of such EU regulation?

28. The Davidson Review (2006) considered whether the UK differed from other member states in implementation practice. It reported that, in absolute terms and relative to other EU countries, there was not sufficient reason to believe that inappropriate over-implementation was as big a problem in the UK as often alleged,³⁶ although concerns about 'gold plating' continued. In 2011 the Government introduced *Guiding Principles for EU Legislation* to prevent gold-plating by introducing five transposition principles by

³¹ [Review of the Balance of Competences between the United Kingdom and the European Union \(2012\)](#) (p 7)

³² Review of the Balance of Competencies between the United Kingdom and the European Union – Research and Development

³³ [Review of the Balance of Competences between the United Kingdom and the European Union Research and Development \(2014\)](#) (p 44)

³⁴ <http://www.datasaveslives.eu/>

³⁵ http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/resources/wtp059075.pdf

³⁶ [Davidson Review 2006](#)

which Departments must abide, including the principle that Government will copy out the text of the Directive for transposition where possible, except where doing so would adversely affect UK interests e.g. by putting UK businesses at a competitive disadvantage compared with their European counterparts, or other reasons. In addition the Government has a transposition principle that emphasises the importance of minimising regulatory burdens when implementing EU legislation aiming to ensure that the UK does not go beyond the minimum requirements when transposing EU legislation into UK law.

29. Flexibility around implementation can have positives and negative implications. For example inconsistent interpretation and implementation and enforcement is reported and can be problematic in the area of medicines. Within regulatory frameworks (eg medicines) individual states have *notified bodies* to scrutinise products before release into the market. Because different states have uneven capacity to resource or prioritise this there is a risk of higher or lower quality – with a risk at the lower end. In addition, in some cases guidance to assist even implementation across states may be lacking, leading to confusion and different standards of implementation.

Appendix A – Member Organisations of the Royal Society of Biology

Full Organisational Members

[Academy for Healthcare Science](#)
[Agriculture and Horticulture Development Board](#)
[Amateur Entomologists' Society](#)
[Anatomical Society](#)
[Association for the Study of Animal Behaviour](#)
[Association of Applied Biologists](#)
[Bat Conservation Trust](#)
[Biochemical Society](#)
[Biosciences KTN](#)
[British Andrology Society](#)
[British Association for Lung Research](#)
[British Association for Psychopharmacology](#)
[British Crop Production Council](#)
[British Ecological Society](#)
[British Lichen Society](#)
[British Microcirculation Society](#)
[British Mycological Society](#)
[British Neuroscience Association](#)
[British Pharmacological Society](#)
[British Phycological Society](#)
[British Society for Cell Biology](#)
[British Society for Gene and Cell Therapy](#)
[British Society for Immunology](#)
[British Society for Matrix Biology](#)
[British Society for Medical Mycology](#)
[British Society for Neuroendocrinology](#)
[British Society for Parasitology](#)
[British Society of Plant Breeders](#)
[British Society for Plant Pathology](#)
[British Society for Proteome Research](#)
[British Society for Research on Ageing](#)
[British Society of Animal Science](#)
[British Society of Soil Science](#)
[British Toxicology Society](#)
[Daphne Jackson Trust](#)
[Experimental Psychology Society](#)
[The Field Studies Council](#)
[Fondazione Guido Bernardini](#)
[GARNet](#)
[Genetics Society](#)
[Heads of University Centres of Biomedical Science](#)
[Institute of Animal Technology](#)
[Laboratory Animal Science Association](#)
[Linnean Society of London](#)
[Marine Biological Association](#)
[Microbiology Society](#)
[MONOGRAM – Cereal and Grasses Research Community](#)
[Network of Researchers on Horizontal Gene Transfer & Last Universal Cellular Ancestor](#)
[Nutrition Society](#)
[Quekett Microscopical Club](#)
[The Rosaceae Network](#)

[Royal Microscopical Society](#)
[Science and Plants for Schools](#)
[Society for Applied Microbiology](#)
[Society for Endocrinology](#)
[Society for Experimental Biology](#)
[Society for Reproduction and Fertility](#)
[Society for the Study of Human Biology](#)
[SCI Horticulture Group](#)
[The Physiological Society](#)
[Tropical Agriculture Association](#)
[UK Environmental Mutagen Society](#)
[UK-BRC – Brassica Research Community](#)
[UK-SOL - Solanacea Research Community](#)
[University Bioscience Managers' Association](#)
[VEGIN – Vegetable Genetic Improvement Network](#)
[Wildlife Conservation Society Europe](#)
[Zoological Society of London](#)

Supporting Organisational Members

[Affinity Water](#)
[Association of the British Pharmaceutical Industry \(ABPI\)](#)
[Association of Medical Research Charities](#)
[AstraZeneca](#)
[BASIS Registration Ltd.](#)
[Bayer](#)
[BioIndustry Association](#)
[Biotechnology and Biological Sciences Research Council \(BBSRC\)](#)
[The Donkey Sanctuary](#)
[Envigo](#)
[The Ethical Medicines Industry Group](#)
[Fera](#)
[Forest Products Research Institute](#)
[Institute of Physics](#)
[Ipsen](#)
[Medical Research Council \(MRC\)](#)
[MedImmune](#)
[Pfizer UK](#)
[Plant Bioscience Limited \(PBL\)](#)
[Porton Biopharma](#)
[Procter & Gamble](#)
[Royal Botanic Gardens, Kew](#)
[Royal Society for Public Health](#)
[SynBiCITE](#)
[Syngenta](#)
[The British Library](#)
[Understanding Animal Research](#)
[Unilever UK Ltd](#)
[Wellcome Trust](#)
[Wessex Water](#)
[Wiley Blackwell](#)