THE ROYAL SOCIETY

The Royal Society submission to the House of Commons Science and Technology Committee inquiry into EU regulation of the life sciences

4 March 2016

Summary

1. Scientific evidence and advice should be at the heart of EU policy, ensuring that it delivers the best outcomes for society. Other factors, such as moral values, play a legitimate role in shaping policy.

2. Cultural contexts and political priorities differ across countries but science is a global enterprise and scientists from all over the globe draw on the same evidence base to provide advice. The Committee asks about the extent to which the UK is able to shape regulatory processes at the EU level. In this response we highlight the importance of having strong science advice mechanisms informing all parts of the EU policymaking process.

3. The UK's world class research base means its researchers and institutions are well placed to make a significant contribution to EU policy through these mechanisms.

4. Different mechanisms of scientific advice across EU institutions can lead to a variety of approaches through which science informs policy at the EU level.

5. In developing EU regulations for the life sciences, policy makers should ensure that:

- Broader legislation does not inadvertently have a negative impact on the life science sector
- Regulations are structured so that they better keep pace with socially acceptable technological developments and enable their rapid and safe realisation
- The application of the precautionary principle takes into account benefits as well as risks, and the consequences of not acting as well as acting
- Policies that support science are implemented consistently.

Introduction

6. The Royal Society is the UK's national academy of science. It is a self-governing fellowship of many of the world's most distinguished scientists. The Society draws on the expertise of the Fellowship to provide independent and authoritative scientific advice to UK, European and international decision makers. This response has been prepared through consultation with experts including members of our Fellowship.

7. The Society is gathering evidence to investigate the impact and influence of EU membership on UK research and innovation. The first phase report of this project, focussing on the role of the EU in funding UK research was published in December 2015[1]. The following two phases, will address the role of the EU in researcher mobility and collaborations, and the impacts of EU policy on UK research. They will be published later this year.

8. In this response we focus on the EU policy-making processes and how best to ensure these are informed by scientific evidence and advice to deliver the best outcomes for research, including the life sciences. We also provide insight into issues that should be considered in developing policy to govern the life sciences at an EU level. We begin with a brief description of the relevant aspects of EU decision-making processes and institutions.

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[1] The Royal Society (2015) UK research and the European Union: the role of the EU in funding UK research : https://royalsociety.org/topics-policy/projects/uk-research-and-european-union/

The development and implementation of EU legislation

EU policy instruments

9. EU regulations cover a number of different policy instruments, including Regulations, Directives and Communications. A distinction should be made between 'Regulations' and 'Directives' implemented by the EU in Member States. Regulations are binding in their entirety and directly applicable in all EU Member States, while Directives bind Member States in terms of the result required to be achieved, but leave the methodology of exactly how to achieve this to the national authority of Member States. Directives are typically transposed into national legislation. In some circumstances, Member States can negotiate certain 'opt-outs' from EU legislation or treaties, and in such cases will not be obliged to participate in associated policy areas.

10. EU institutions can also make binding decisions regarding the actions of Member State governments in relation to existing legislation, and convey specific opinions or recommendations to Member States, which are not binding. For example the European Commission can publish Communications to the European Parliament, which outline a plan of action concerning a specific topic or piece of legislation[2].

11. EU and associated countries receiving research funding from EU Framework Programmes (currently the EU's Horizon 2020 Programme) are subject to specific rules for participation[3]. In some cases, such as for research conducted using animals[4], participating countries are required to comply with specific EU regulations. In other areas of research, for example involving the use of human embryonic stem cells[5], researchers are subject to licensing and control in accordance with the legal framework of the Member States where the research is being undertaken.

The EU policy making process

12. The development and implementation of EU legislation typically involves four main European institutions[6] (see Annex 1):

- The European Commission
- The European Parliament
- The Council of the European Union
- The European Court of Justice

13. Briefly, the European Commission will put together proposals for new legislation. This typically involves consultation[7] with non-governmental organisations, local authorities and representatives of industry and civil society as well as the public. In most cases, these proposals are approved or rejected by a process of co-decision by the European Parliament and the Council, known as the 'Ordinary Legislative Procedure'. The European Parliament and the Council review proposals by the Commission and propose amendments. When the two institutions agree on amendments, the proposed legislation

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[2] An example of this is the EC Communication "Towards a modern, more European copyright framework" : http://ec.europa.eu/newsroom/dae/document.cfm?action=display&doc_id=12526

[3] Regulation (EU) no 1290/2013 of the European Parliament and of the Council of 11 December 2013 – laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[4] See Article 23(10) of EU rules for participation and dissemination in Horizon 2020

[5] See Article 13(2) of EU rules for participation and dissemination in Horizon 2020

[6] http://europa.eu/eu-law/decision-making/procedures/index_en.htm

[7] http://ec.europa.eu/yourvoice/index_en.htm

can be adopted, however either institution can block the process of legislation if an agreement cannot be reached.

14. The EU has areas of competence defined in the Treaties, whereas competences not conferred upon the EU remain with EU Member States[8]. The division of competences between the EU and its Member States takes several forms – it may be exclusive, e.g. common fisheries policy, shared, e.g, environmental policies, or supporting e.g. health where the EU can only intervene to support, coordinate or complement the action of EU countries. In understanding EU regulation of the life sciences, it is important to clarify which aspects of life sciences regulation fall within EU competences.

The importance of scientific evidence and advice in the EU policy making process

15. For the EU to provide an optimal environment for science and innovation, it is essential that the design and implementation of EU policy is informed by appropriate scientific evidence and advice at every stage of the policy making process. The UK Government Chief Scientific Adviser has stated that scientists should expect that "the science is seriously considered, evaluated and communicated as part of the discussion" and "the European Commission needs to strive to ensure rigorous scientific input".[9]

16. This requirement includes both areas where scientific or technical evidence is needed to ensure well-informed decision-making on policies which do not have the promotion of science and innovation as their primary objectives; and where policies and regulation are essential to enable rapid development and application of new science and technologies in ways that best support economic growth and wellbeing. This includes the regulation of research and the operation of the Framework Programmes that fund research.

17. The influence of individual Member States including the UK plays an important role, as does ensuring that the whole process is informed by scientific advice and evidence. The European Commission, European Parliament and Council of the European Union have different mechanisms to access scientific evidence. This creates asymmetry in the way scientific evidence and advice is acquired and used in the different EU institutions. As decisions are made through the co-decision process, involving all of these institutions, this can result in policy decisions that are not adequately informed by the latest scientific evidence. The UK has a strong science base and a reputation for excellence in research and innovation, meaning there is scope for scientists from the UK to play an important role in the provision of advice, together with colleagues across the EU.

18. Science academies from across Europe frequently work together to provide a collective voice, allowing policy to be informed by a broader range of evidence and a more credible scientific input than could be achieved by a single organisation. In this role UK scientists are representing their scientific expertise, not the UK's national interests specifically.

The European Commission

19. The European Commission receives advice from a number of different expert groups and committees, some of which provide scientific advice, and details of these consultative entities are

[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Aai0020

[9] Annual Report of the Government Chief Scientific Adviser 2014 - Innovation: Managing risk, Not avoiding it

published in a Register of Commission Expert Groups[10]. The Commission itself also holds consultations on areas of policy development. Different Directorate Generals (DGs) within the Commission will be involved in different areas of life science policy (see Annex 1) and will receive and use scientific evidence in different ways. The Commission also funds an in-house science service, the Joint Research Centre (JRC)[11]. The Commission has also recently established a new Scientific Advice Mechanism (SAM), which provides a route for scientific researchers (individual, organisations and networks) to input scientific evidence to the Commission to inform policy making decisions (Annex 2).

The European Parliament

20. The European Parliament Research Service (EPRS) functions are similar to the Library services of the UK parliament and the UK Parliamentary Office of Science and Technology (POST). The Scientific Foresight (STOA) unit of the EPRS analyses emerging policy issues and assesses options for MEPs.[12]Informal mechanisms also exist to provide scientific advice to EU policymakers. For example, scientific academies, networks, organisations and researchers can brief relevant MEPs on scientific issues of policy relevance.

European Council of Ministers

21. The European Council of Ministers has no formal internal structures for providing science advice. Council representatives of each Member State therefore rely on their own national institutions and structures[13]. Mechanisms for providing advice vary considerably across different Member States[14].

EU legislation and the life science

22. There are a number of different aspects of the development and implementation of EU legislation that influence life science research and innovation. This response will highlight some of these key issues including; the potential inadvertent impacts of broader policy areas; the importance of flexible regulations that can keep pace with emerging technologies and their applications; the appropriate use of the precautionary principle; the impact of legislation on the rapid and safe realisation of potential future applications of research; and the consistent implementation of sector-specific legislation.

The impact of broader legislation on life science research

23. Non-sector specific areas of EU legislation can have an indirect or unintended impact on life sciences, or other areas of science and innovation. For example, the Single Market legislation on the free movement of people and goods is seen by the CBI to have a positive impact for research in the

[10] http://ec.europa.eu/transparency/regexpert/index.cfm

[11] https://ec.europa.eu/jrc/en/about/jrc-in-brief

[12] EPRS Briefing (2015) Scientific advice for policy-makers in the European Union

[13] EPRS Briefing (2015) Scientific advice for policy-makers in the European Union

[14] Jasanoff, S. (2005) “Designs on Nature: Science and Democracy in Europe and the United States”. Princeton University Press

UK[15]. However, if these potential impacts are not considered appropriately when legislation is being developed, it can have a negative impact on life science research and innovation. Two specific examples of broad EU legislation that impact on the UK life sciences are data protection (Case Study 1) and copyright regulation (Case Study 2).

24. These examples emphasise the importance of embedding science advice at all stages of the policy making process and in all areas of legislation, not just legislation aimed at a specific sector, or at the promotion of science and innovation as its primary objective.

Case Study 1: EU legislation on data access and protection

In January 2012, the European Commission published a proposed General Data Protection Regulation (GDPR) to replace the existing Data Protection Directive, governing the collection and use of personal data of EU citizens[16]. The proposed legislation provided a number of exemptions, when enforced with appropriate safeguards, to facilitate the use of personal data for scientific research purposes.

However, the European Parliament proposed several amendments that would have significantly reduced the scope of the research exemptions meaning health data could be used only for research with the "specific, informed and explicit" consent of data subjects, making it highly problematic to use pseudonymised data, for example from large cohort studies, biobanks, disease registries and routinely collected health data.

In response, the pan-European research community established a long term campaign[17], urging European institutions to find a compromise position to enable vital research to continue. The final text of the Regulation (agreed in December 2014) reinstated research exemptions dependent on proportionate safeguards for the use of personal data.

Case Study 2: EU legislation on copyright and text and data mining

The European Commission is planning legislative proposals to harmonise copyright legislation[18] across Europe as part of their digital single market (DSM) strategy[19]. This could have implications for text and data mining (TDM), a technique to extract and analyse large volumes of text and data at a scale and pace that is not feasible to accomplish manually. This is a critical tool in modern scientific research. For example, TDM has been utilised to identify potential biomarkers for Alzheimer's disease.[20]

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[15] HM Government (2014) Review of the Balance of Competences between the United Kingdom and the European Union : Research and Development

[16] http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

[17] Wellcome Trust (2015) A joint position paper : Ensuring a healthy future for scientific research through the Data Protection Regulation 2012/0011(COD) : http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTP055584.pdf

[18] European Commission Communication (2015): Towards a modern, more European copyright framework.

[19] https://ec.europa.eu/digital-agenda/en/news/towards-modern-more-european-copyright-framework-commission-takes-first-steps-and-sets-out-its

[20] http://translational-medicine.biomedcentral.com/articles/10.1186/1479-5876-10-217

The UK is the only EU country that has adopted an exception for TDM in non-commercial research under the current directive. The upcoming legislation provides an opportunity for this exemption to be extended to all Member States and to all types of research, whether commercial or non-commercial research.[21] Doing so could help facilitate cross-border collaborations and between business and academia.

Currently the Commission has set out its intention for TDM exceptions to "allow public interest research organisations to carry out text and data mining of content they have lawful access to, with full legal certainty, for scientific research purposes".

The need for regulation that can keep pace with socially acceptable technological developments and enable their rapid and safe realisation

Flexible regulation for emerging technologies

25. Research and innovation within the life science sector is rapidly evolving, in both medical and agri-science applications. These applications can raise regulatory and ethical issues so it is important that a regulatory process that has public confidence is in place. To prevent regulation acting as a barrier to applications that have public support, it is essential that EU legislation regulating the life science sector is designed to respond effectively to future challenges and account for fast developing technologies. As new technologies emerge, the scientific community will play a vital role in helping policy makers clarify to what extent existing regulations apply and where new regulations are required.

26. An example of this is the legislation currently in place to govern genetically modified (GM) crops. GM techniques could be an important technological factor in the sustainable intensification of agriculture[22]. The current EU framework on GM regulates the use of organisms in agriculture depending on how they have been developed rather than their novel traits (a so-called 'process-based' approach). However, new traits can be introduced into crops through different approaches, some of which are more heavily regulated than others. This results in inconsistency with some plants with a particular novel trait captured by the legislation whilst others are not[23].

27. Moreover, technological developments quickly outpace regulations and process-based regulations fail to capture these new emerging technologies, resulting in a distinction between regulated and unregulated technologies that is difficult to justify from a risk assessment perspective. The European Commission is currently reviewing whether it should regulate a gene-edited plant that has no foreign DNA, as if it were a genetically modified (GM) organism. It has committed to making its legal analysis public by the end of March[24].

28. A more effective regulatory system would result from a shift in emphasis towards the novel trait that has been introduced, whether by GM, gene-editing or 'conventional' genetic improvement techniques: a 'product-based' approach. This would apply to all crops with a novel trait and would be more resilient to the introduction of new technologies and more likely to deliver environmental protection

[21] Copyright for Knowledge: Priorities for European Union Copyright reform

[22] The Royal Society (2009) Reaping the benefits Science and the sustainable intensification of global agriculture

[23] CST (2014) GM Science Update : A report to the Council for Science and Technology

[24] Nature (2015) *Europe's genetically edited plants stuck in legal limbo* http://www.nature.com/news/europe-s-genetically-edited-plants-stuck-in-legal-limbo-1.19028

and food safety[25]. It is essential that the public are engaged in the development of any new regulatory approach in order to earn and maintain their trust.

Enabling the rapid and safe realisation of potential future applications of research

29. For scientists and investors or funders to see the greatest returns, it is essential that the various regulatory and legal frameworks support rapid and safe exploitation of new developments. This includes, for example, robust frameworks for patents and intellectual property.

30. Decisions may not be directly intended to prevent the realisation of future applications of research but can produce a chilling effect. For example the European Court of Justice (ECJ) ruling in the case of Brustle vs Greenpeace in October 2011 prevents the patenting of technologies that require the prior destruction of embryos. This could potentially jeopardise the ability to commercialise embryonic stem cell-derived products but does not prevent Member States undertaking research using stem cells or developing applications. At the time this ruling led to action in the European Parliament to prevent Horizon 2020 research funding from supporting stem cell research[26]. Research organisations were active in highlighting the risk of cutting funding to promising areas of research.[27]

The precautionary principle

31. When the EU originally adopted legislation to control the use of genetically modified organisms (GMOs) in 1990, the precautionary principle was applied due to the absence of evidence at the time regarding the potential risks to human health and the wider environment. The consensus of scientific bodies is that scientific evidence now no longer justifies using the precaution of controlling GMOs based simply on the technology that generated them (i.e. the process-based approach)[28].

32. In its conventional application, the precautionary principle assesses the risks associated with particular technologies but fails to take into account the potential benefits or the risk of not implementing those technologies. Adequate regulations should include an assessment of potential benefits alongside potential risks[29][30]. The European Commission has stated that the precautionary principal should not be used to address uncertainty that is resolved with risk assessments, but could be used when there are wider, more fundamental evidence gaps[31]. However the precautionary principle is not applied consistently across Member States – an example being regulation of the use of chemical Bisphenol A (Case Study 3).

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[25] EASAC (2013) Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture

[26] Financial Times (2012) *New threat to EU stem cell research*

[27] AMRC, BHF, EGAN, MRC, Parkinson's UK, Wellcome Trust (2012) *Statement supporting funding for stem cell research in Horizon 2020* http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm055496.pdf

[28] CST (2014) GM Science Update : A report to the Council for Science and Technology

[29] The Royal Society (2009) Reaping the benefits Science and the sustainable intensification of global agriculture

[30] Annual Report of the Government Chief Scientific Adviser 2014 - Innovation: Managing risk, Not avoiding it

[31] Communication from the Commission on the precautionary principle (February 2000) : http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l32042&from=EN

33. The implementation of the precautionary principle should also include the reassessment of the need for any restrictions when new evidence becomes available after a reasonable period of time. This would help ensure that any restrictions that are no longer scientifically justifiable are removed, so that the evaluation of valuable technologies is not unduly delayed. These points are echoed in this committee's report on advanced genetic techniques for crop improvement.[32]

Case Study 3 : Risk and precaution in the regulation of bisphenol A[33]

Bisphenol A (BPA) is a chemical used in plastics including, for example, food and drinks containers. BPA can migrate from the material into food and drinks resulting in human exposure. BPA is linked with several negative human health effects, therefore EU legislation is in place to limit human exposure to BPA based on guidelines established by independent expert risk assessments.

The safety of BPA is continually investigated and reviewed by appropriate bodies (such as the European Food Safety Authority). However, some EU Member States have introduced more restrictive controls on BPA, utilising a 'precautionary' approach.

Consistent implementation of policy that supports science

34. In some cases, harmonisation of procedures and operations for researchers across Europe can improve cross-border collaborations and ensure that one Member State is not competitively disadvantaged relative to others. An example of such harmonisation is the case of EU legislation for the protection of animals used for scientific purposes (Case Study 4).

35. If EU regulations that aim to achieve harmonisation of procedures that benefit the conduct of science are implemented in an inconsistent manner across the Member States, this can be detrimental to scientific research and can be slow and difficult to rectify. An example of this is legislation regarding clinical trials in medical research (Case Study 5).

36. Clearly, it is essential that the policies to be applied are themselves well-informed by the latest science, as poorly designed Regulations or Directives will be damaging whether applied consistently or inconsistently.

Case Study 4 : EU legislation for the protection of animals used for scientific purposes

EU legislation for the protection of animals used for scientific purposes (Directive 2010/63/EU) is more comprehensive than the previous legislation that it replaced. It is based on the principle of the Three Rs (replace, reduce and refine) in the use of animals used for scientific purposes[34]. The UK science community has strongly supported this approach[35] and was instrumental in the preparation of the EU Directive, which largely reflects the existing UK legislation. This is seen as having a positive impact as it ensures best practice in animal welfare across Europe and that

[32] House of Commons Science and Technology Committee (2015) Advanced genetic techniques for crop improvement: regulation, risk and precaution, Fifth Report of Session 2014–15

[33] Annual Report of the Government Chief Scientific Adviser 2014 - Innovation: Managing risk, Not avoiding it

[34] http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm

[35] Statement of the Royal Society's position on the use of animals in research : https://royalsociety.org/topics-policy/publications/2015/animals-in-research/

the UK is not put at a competitive disadvantage[36] . The EC will be reviewing the Directive in 2017. It therefore continues to be important for the UK and the other Member States to engage with this process.

Case Study 5 : EU legislation for clinical trials

The Clinical Trials Directive 2001/20/EC13 (CTD) implemented in 2004, had the aim of harmonising authorisation procedures on clinical trials on medicinal products to improve the generation of reliable patient data[37]. However, as reported previously by this committee, the scientific community raised concerns that the CTD had a negative effect on UK medical research due to inconsistent application across Member States[38]. It was noted that the UK had been particularly stringent in its implementation of the CTD compared with other countries, resulting the UK being placed at a competitive disadvantage. Between 2007 and 2011, the number of clinical trials conducted in the UK dropped by 22%[39].

The European Commission ran several consultations on plans to revise the 2001 Directive, during which, organisations representing the medical research community in the UK and Europe strongly articulated their position[40]. A new Clinical Trials Regulation has now been passed and is expected to come into effect in 2017. This is considered by the scientific community to be a considerable improvement on the CTD, addressing many of the previous problems. For example the fact that the new proposal is a Regulation rather than a Directive means that the new legislation will automatically become law across all Member States, reducing the potential for inconsistent interpretation[41].

[36] AMRC (2013) Submission to the government's taskforce on EU regulation : http://www.amrc.org.uk/publications/amrc-submission-to-the-governments-taskforce-on-eu-regulation

[37] http://www.eortc.be/services/doc/clinical-eu-directive-04-april-01.pdf

[38] House of Commons Science and Technology Committee - Third Report on Clinical Trials, September 2013.

[39] House of Commons Science and Technology Committee - Third Report on Clinical Trials, September 2013.

[40]Revision of the EU Clinical Trials Directive - A joint statement from non-commercial and commercial organisation : http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_077460.pdf

[41] House of Commons Science and Technology Committee - Third Report on Clinical Trials, September 2013.

Annex 1 – The four key European Institutions in EU policy making

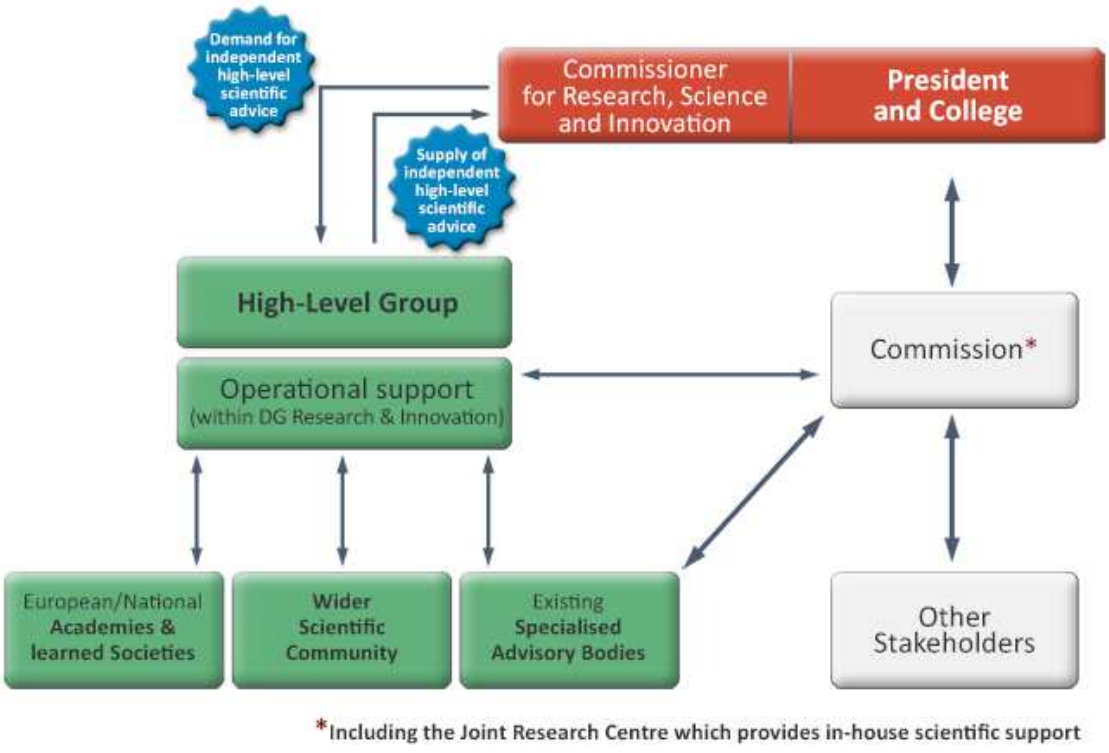
- The **European Commission** (EC) proposes new initiatives initiates and implements and supervise those already approved. The EC consists of a College of Commissioners with a representative from each Member State national government. The Commission itself employs a staff to carry out duties including translation as well as for carrying out scientific research. The Commission is divided into several Directorate-Generals (DGs), some of which play a key role in research and innovation within the life science sector, specifically the DGs for Research & Innovation (DG RTD); Health and Food Safety (DG SANTE) and Agriculture and Rural Development (DG AGRI).
- The **European Parliament** is a directly elected body with legislative, supervisory and budgetary powers. It has a co-legislative responsibility along with the Council, and scrutinises proposed Regulations and Directives, submitting an opinion on these proposals and suggesting amendments. The UK is currently represented in the European Parliament by 73 elected MEPs out of a total of 751.
- The **Council of the EU** negotiates and adopts proposed EU laws, together with the European Parliament, based on proposals from the European Commission. The Council is made up of a representative of each Member State, typically a government minister from each country. The ministers have the authority to commit their governments to the actions agreed by the Council.
- The **European Court of Justice (ECJ)** is often required to interpret EU decisions and makes judgement on issues in the event of a dispute, for example between the different European institutions or between the institutions and an individual Member State. The introduction or implementation of national laws can there be affected by case law resulting from rulings taken by the ECJ.

Annex 2 – The EU Science Advice Mechanism

In May 2015, the European Commission introduced the Scientific Advice Mechanism (SAM) as a means of providing expert science advice to the Commission. The previous Commission included the post of Chief Scientific Advisor to the President of the Commission. Located within the DG RTD, the aim of the SAM is to provide high quality, timely, independent and transparent scientific advice to the Commission to inform better policy making decisions. A key component of SAM is the High Level Group of seven eminent science experts from different EU Member States including the EU.

The organisational arrangement of the SAM and the provision of operational support is summarised in the schematic diagram below.[42] The SAM seeks input from national science academies and European networks of learned societies, specialised advisory boards and the wider scientific community. By institutionalising the role of the European networks of scientific academies to engage with the SAM, and providing financial support to enable them to do so, this new structure could offer a powerful instrument to deliver effective scientific advice to EU policymakers.

The Society will engage with the SAM through its membership of two European academies networks, EASAC (European Academies Science Advisory Council) and ALLEA (All European Academies). As the new system is still in the process of being established, it is too early to assess its effectiveness.



[42] The schematic representation of the science advice mechanism is taken from the European Commission web page : https://ec.europa.eu/research/sam/index.cfm?pg=about