UK research and the European Union

The role of EU regulation and policy in governing UK research

THE ROYAL SOCIETY

The UK's strong research base means that its researchers and institutions are well-placed and well-regarded to make significant contributions to policymaking.

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UK research and the European Union: the role of EU regulation and policy in governing UK research

EU policy making offers an opportunity to implement consistent policy that supports science.

A referendum on the United Kingdom's membership of the European Union will take place on 23 June 2016. This report provides an insight into the role of the EU in developing EU and global policies that influence research conducted in the UK. It provides an overview of how EU policy is made and a number of case studies illustrating the development and implementation of EU and global policy that govern UK research. It attempts to show where scientific advice and evidence are drawn on throughout these processes although does not claim to be comprehensive. It does not attempt to assess the value of these policymaking processes or the impact of the policies themselves.

This is the third part of a phased project gathering evidence about the influence of the UK's relationship with the EU on research. It is intended to inform debate. Previous phases have looked at the role of the EU in funding UK research and its role in researchers' international collaboration and mobility.

Research is a global endeavour and researchers are highly collaborative. In 2015 over half of the UK's research output was the result of an international collaboration[1]. UK researchers successfully collaborate with researchers in the EU and around the world. Many of these researchers will be based in countries that have different policies governing research. This does not prevent collaborations but can make them more complicated.

Policy that influences research can be divided into two types; policy that is intended to govern research; and broader policy that has impacts for research practice.

EU policymaking offers an opportunity to implement consistent policy that supports science across multiple countries. This can facilitate international research collaborations and inform decisions over where to invest or locate research. However poorly designed policy at a national, EU or global level can be damaging, whether applied consistently or inconsistently.

Taken together, the case studies in this report illustrate that EU policymaking can result in policy that supports science. Where this is achieved, the research community has actively engaged with the policymaking process. For example, the EU's General Data Protection Regulation that has recently been adopted sets out to regulate the way that personal data are collected and shared across the EU. Following engagement with and by the research community, it will do so while allowing research that accesses personal data to go ahead safely. Where policy is damaging to research, as for example in the first EU Clinical Trials Directive, active engagement by the research community has informed welcome revision of the policy.

Scientific evidence and advice is not the only factor shaping EU policy. Variations in cultural contexts, political priorities and public opinion in Member States can also influence policymaking that affects research. For example, scientists have helped shape EU authorisation procedures for genetically modified organisms (GMOs) but high levels of public concern mean that a limited number of GMOs have been authorised for cultivation and food and feed within the EU. This has consequences for research in this area.

The UK's strong research base means that its researchers and institutions are well-placed and well-regarded to make significant contributions to policymaking. In places, the UK plays a leading role in this, for example current EU policy governing the use of animals in scientific research draws heavily on the pre-existing UK legislation. A number of formal mechanisms exist for EU institutions to access scientific advice. These are not the only way, however, that scientific evidence and advice can inform EU policymaking. The case studies show that informal mechanisms play a considerable role, with individual researchers, coalitions and organisations, such as the UK's National Academies, proactively engaging with EU policymakers. UK researchers often engage directly with policymaking at a global level as well as through EU mechanisms.

This report provides examples of where EU policymaking has resulted in a number of different outcomes for science, but cannot illustrate what would happen if the UK's research community and legislators were no longer to be engaged in EU policymaking. If the UK chooses to leave the EU, decisions would need to be made over where the UK might want, or need, to remain consistent with EU policy, and where it might wish to develop its own domestic policy. Whatever decisions are made, it is possible that EU policy would still exert a strong influence over the UK – for example EU policy governing animal research is a condition of all countries that wish to access Horizon 2020 funding, whether or not they are EU Member States. EU science advice mechanisms ensure that scientific advice is part of the EU policymaking process, but UK-based researchers may be less likely to utilise these formal and informal mechanisms and UK legislators would have little or no formal input if the UK chooses to leave the EU.

If the UK chooses to leave the EU, decisions would need to be made over where the UK might want, or need, to remain consistent with EU policy, and where it might wish to develop its own domestic policy.

How is policy developed in the European Union?

The current European Commission, which came into office in November 2014, has pursued a "better regulation" agenda, aiming to streamline legislation and cut red tape.

What are the EU institutions and how do they make policy?

Policymaking is the process of developing ideas or plans that are then put in place through legislation, creating a regulatory system.

Policymaking in the European Union (EU) takes place across four EU institutions[2]:

- the European Commission;
- the European Parliament;
- the Council; and
- the European Court of Justice (See Fact Box 1).

Member States such as the United Kingdom (UK) have several opportunities to feed into this policymaking process through their representation in the European Parliament (elected representatives of the European Parliament) and the Council (representatives of national governments).

EU policy (See Fact Box 2) can be developed and new policy introduced for a number of reasons and in a number of ways. The European Commission continually works to identify where policy development may be needed, or existing legislation requires review. At the same time, the Presidency of the Council rotates every six months and each country will have priorities for their Presidency that may require policy development[3].

Many factors can drive new policy development including social need and technological progress, meaning legislation is no longer fit for purpose. The current European Commission, which came into office in November 2014, has pursued a "better regulation" agenda, aiming to streamline legislation and cut red tape. The stated intention is to create a clear, consistent framework which promotes better jobs and growth[4]. There is a strong focus on improved impact assessment, which as yet does not include scientific issues.

How is policy made in the European Union? (See Figure 1)

To begin policy development, the European Commission develops proposals. It does this by inviting input from citizens, stakeholders and experts through consultations and expert committees to develop these.

If a proposed Commission policy is expected to have 'considerable economic, social and environmental impacts', the preparation of an Impact Assessment (IA) is required. This applies to both legislative and non-legislative initiatives as well as delegated acts and implementing measures, where the Commission can make more technical changes and amend non-essential aspects of legislation[5].

IAs must verify the existence of a problem, identify its underlying causes, assess whether EU action is needed, and analyse, quantifying where possible, the advantages and disadvantages of different approaches. Commission guidelines specify that IAs are usually not required when, 'there is little or no choice available for the Commission (for instance when the Commission is implementing previous policy decisions already subject to an IA); impacts cannot be clearly identified (for instance, in the case of broad policy communications); or impacts are small (for instance, the repeal of a redundant act)'[6].

The proposal then undergoes a process of scrutiny and debate by MEPs from the 28 EU Member States and representatives from the governments of each state in the Council.

Policymaking in the EU typically takes place by 'ordinary legislative' procedure. This procedure involves the Commission, Parliament and Council, who aim to come to agreement on the final legislation.

FACT BOX 1 The four main European Union institutions[7]

1. **The European Commission** is the executive body of the European Union responsible for managing the day-to-day business of the EU. This includes proposing legislation, implementing decisions and upholding the EU treaties. It is made up of 33 Directorate Generals (DG) departments covering a wide remit of areas such as research and innovation, health, environment, communication, and budget. This is overseen by a College of 28 Commissioners, one from each Member State, each nominated by their respective national governments to serve five year terms.
2. **The European Parliament** is an elected body, made up of 751 Members (MEPs) elected to represent constituencies in the 28 member states. The United Kingdom has 73 MEPs.
3. **The Council of the European Union** is made up of representatives of the national governments of the 28 Member States. The representative from each national government attending Council is typically the Minister who represents a portfolio relevant to the topic being discussed.
4. **The European Court of Justice** interprets EU law to ensure that it is implemented equally across EU Member States. It settles legal disagreements between the EU institutions and between the EU institutions and Member States and responds to cases brought by relevant individuals. The Court of Justice is made up of three bodies: the Court of Justice, the General Court and the Civil Service Tribunal. One judge from each EU member state sits on the Court of Justice, and 11 Advocates General; one judge from each EU member state sits on the General Court; and seven judges sit on the Civil Service Tribunal. Judges and advocate generals are appointed by national governments to serve a renewable 6-year term. Each Court has a President, selected by the judges to serve a renewable 3-year term[8].

FACT BOX 2 Types of European Union policies[9]

Under the rules of the treaties the European Commission develops policy proposals for different types of legislation:

Directive A legislative decision made by the European Union that requires Member States to achieve the outcome as outlined in the Directive, but allows some variation in how they implement this[10].

Regulation A legislative decision made by the EU, which must be implemented in the same way by all Member States[11].

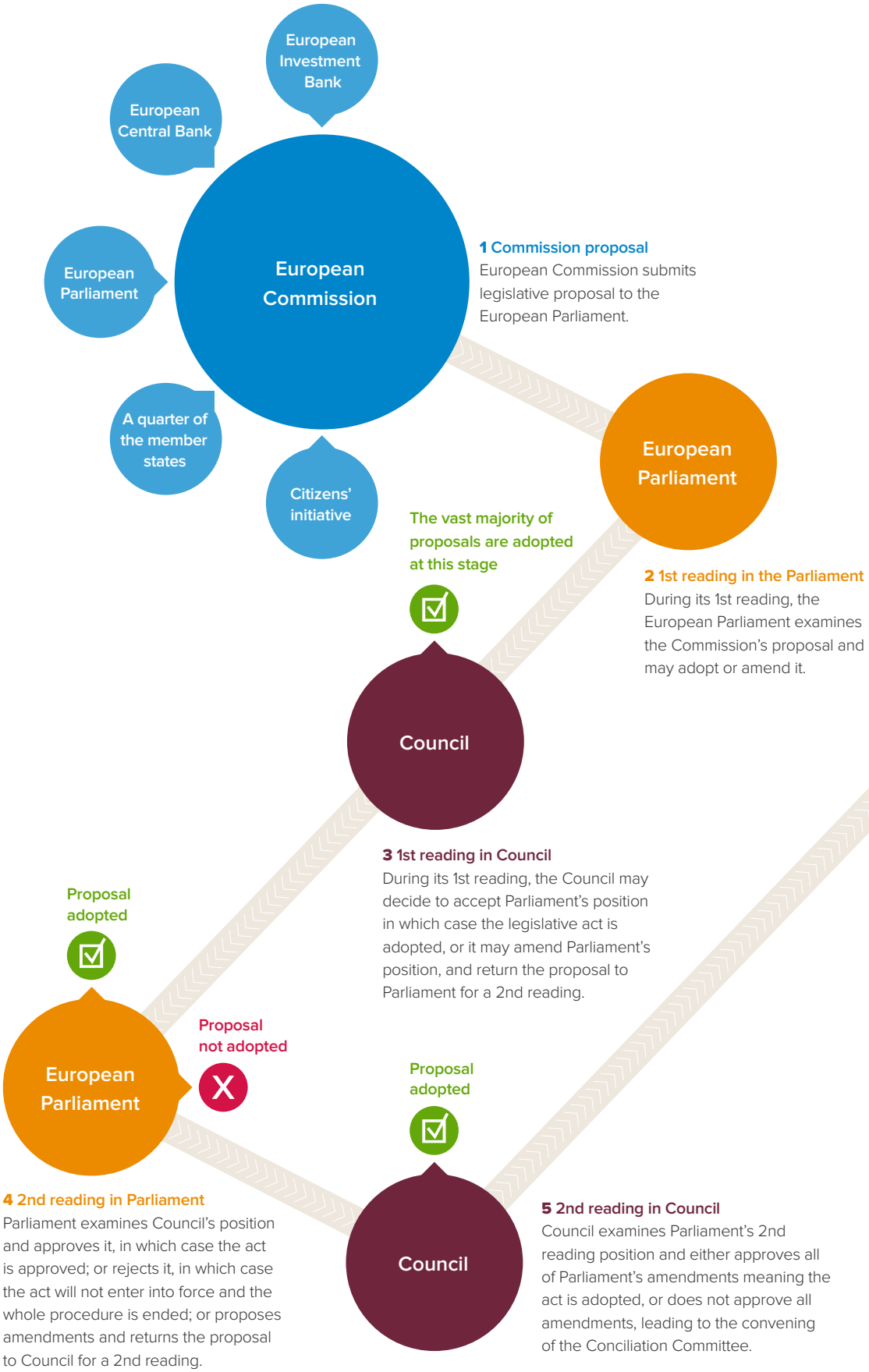
Decisions A legislative decision aimed only at specific organisations and individuals, made clear in the Decision.

Recommendation Non-binding, it allows the EU institutions to express an opinion on a specific issue, and to recommend a way forward.

Opinion A non-binding instrument on a specific issue that can be issued from three of the institutions (Commission, Council and Parliament), or from the (consultative) Committee of the Regions and European Economic and Social Affairs Committee. These can be issued whilst legislation is being developed by the EU. An example of this is a 2014 opinion by the Committee of the Regions on "A Policy Framework for Climate and Energy in the period from 2020 to 2030"[12].

FIGURE 1

How is policy made in the European Union?



This figure has been adapted from a diagram provided on the European Parliament website.

6 Concilliation

The Conciliation Committee, composed of an equal number of MEPs and Council representatives, tries to reach agreement on a joint text. If unsuccessful, the legislative act will not enter into force and the procedure is ended. If a joint text is agreed, it is forwarded to the European Parliament and Council for a 3rd reading.

7a 3rd reading in Parliament

The European Parliament examines the joint text and votes in plenary. It cannot change the wording of the joint text. If it rejects it or fails to act on it, the act is not adopted and the procedure is ended. If it is approved by Parliament and Council, the act is adopted.

7b 3rd reading in Council

Council examines the joint text. It cannot change the wording. If it either rejects or does not act on it, act will not enter into force and the procedure is ended. If it approves the text and the Parliament also approves it, the act is adopted.

Proposal adopted

Once both European Parliament and Council have approved the final text of a legislative proposal, it is jointly signed by the Presidents and Secretaries General of both institutions. After signature, the texts are published in the Official Journal and become official.

- Regulations are directly binding throughout the EU as of the date set down in the Official Journal.
- Directives lay down end results to be achieved in every member state, but leaves it up to national governments to decide how to adapt their laws to achieve these goals. Each directive specifies the date by which the national laws must be adapted.
- Decisions apply in specific cases, involving particular authorities or individuals and are fully binding.

Proposal not adopted

If a legislative proposal is rejected at any stage of the procedure, or the Parliament and Council cannot reach a compromise, the proposal is not adopted and the procedure is ended. A new procedure can start only with a new proposal from the Commission.

Ordinary Legislative Procedure

The European Commission proposal is considered by the co-legislators: the European Parliament and the Council. This is the 'first reading' of the proposed policy.

In the Council, proposals are considered by specialised working groups which go over the texts to agree as far as they can and report upwards to senior officials and then to national ministers in Member States. How far ministers are directly involved – whether in Member State capitals or in Brussels – depends on the issues and how far they generate controversy among Member States. The Council may agree on a 'general approach' before the Parliament has agreed on its position, to give them an idea of the Council's general view of the Commission's policy proposal.

In the European Parliament a specialist Committee of MEPs is assigned to lead in scrutinising, debating and developing amendments to the proposed policy. The Committee also agrees a negotiating team for discussions with the Council[13]. One MEP from this Committee is elected *rapporteur*. They will lead the development of a committee report, suggesting any amendments they think should be made to the Commission's policy proposal. This report is presented to the rest of the Parliament and an overall Parliamentary position is developed. This will form the basis of the Parliament's position to debate with the other co-legislator, the Council.

As a co-legislator, the Council can choose to agree with the Parliament's position, or suggest amendments. Any amendments must be debated with the Parliament through further 'readings' of the text until an agreement is reached.

'Trilogue' meetings can also be arranged between the members and representatives of Commission, Parliament and Council as an informal way of engaging and facilitating agreement in addition to the formal agreement process.

A Conciliation Committee (made up of an equal number of Council representatives and MEPs) reaches agreement on the final joint text. This Committee must agree in order for the policymaking process to continue. The policy is adopted when Parliament and Council approve the text after a 'third reading', where they cannot make any further textual changes.

The Presidents and Secretary-Generals of both institutions sign the text and it becomes official once it is published in the Official Journal of the European Union.

Once a piece of policy is in place, it can be reviewed and adapted at certain times if necessary. This may be to take into account changes in an area of legislation due to technical and scientific advances, for example the revision of the Medical Device Directives in 2012[14]. The Commission can propose a reform of an existing policy which is passed to the Parliament and Council for agreement through ordinary legislative procedure.

Once it has been adopted, EU legislation may be subject to challenge in the national and European court systems. Legislation can be annulled by the European Court of Justice if it infringes upon EU treaties or fundamental rights. The European Court of Justice can also enforce the law against national governments if they do not comply with EU law[15].

Image
Scientist inspecting oilseed rape.
© Andreas Reh.

Do EU institutions have access to the latest scientific advice and evidence?

The European Commission announced the creation of a Scientific Advice Mechanism (SAM) in May 2015.

In the development of policy proposals and the legislative process, EU institutions and agencies draw on evidence and advice. This is a complex and diverse picture and there are a number of ways that they do this, including through expert advisory groups and various consultative processes. However, at the current time, there is no cross-institutional mechanism for developing and delivering scientific evidence and advice throughout the policymaking process; it varies according to EU institution or agency. National governments also draw on their domestic arrangements for seeking scientific advice.

The European Commission

The European Commission has an in-house science service, the Joint Research Centre (JRC), which runs seven scientific institutes across the EU and responds to requests from other Directorate Generals for scientific analysis[16].

For the period 2012 – 2014, the President of the European Commission appointed a Chief Scientific Adviser supported by a relatively small team.

Following a review of scientific advice mechanisms in 2015, the European Commission announced the creation of a Scientific Advice Mechanism (SAM) in May 2015. This SAM consists of three new elements:

1. **A high level group** of seven scientific advisers to provide high quality scientific advice to the Commission on specific pieces of policy or legislation where scientific advice is particularly necessary.
2. **A stronger relationship** with the academies' networks: Academia Europaea[17], All European Academies (ALLEA)[18], European Academies Science Advisory Council (EASAC)[19], Euro-CASE[20] and Federation of European Academies of Medicine (FEAM)[21].
3. **A dedicated secretariat** in DG Research.

There are over 1000 expert advisory groups which advise the European Commission. They provide the Commission with advice and expertise in the drafting of policy proposals including legislation, preparing delegated acts, and implementing existing EU legislation, programmes and policies. This can include, but is not limited to providing scientific input[22]. Experts in relevant fields are selected by the European Commission and can be invited to apply through public calls for advisors. Commission expert groups can be permanent or temporary.

Many Directorates General (DGs) have Advisory Committees focused on providing scientific advice. For example, in DG Health and Food Safety, the Commission can draw on four scientific committees: the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[23], the Scientific Committee on Consumer Safety, the Scientific Committee on Health and Environmental Risks and the Inter-Committee Coordination Group. These committees provide scientific opinions in response to specific requests, and can also consult with other scientists and experts.

The European Commission also employs external consultants to undertake project work, which can include scientific analysis.

The European Parliament

The European Parliament has its own scientific advisory bodies, but they are structured differently to those in the European Commission. The European Parliamentary Research Service (EPRS) provides analysis and scientific evidence on specific issues, along similar lines to the UK Parliament's House of Commons and House of Lords Libraries. MEPs can use the services of STOA (Science and Technology Options Assessment) which carries out foresight projects, and acts both proactively and reactively to requests from MEPs[24].

There are many less formal mechanisms through which MEPs may access scientific information including through contact with their constituents and campaign groups.

Council of the European Union (Council)

Given that the Council is made up of representatives from EU Member States, Ministers attending draw on their own national science advice mechanisms, rather than use a collective mechanism. These systems will vary across Member States.

Within the Council, the Committee of Permanent Representatives of the Governments of the Member States to the European Union (Coreper) brings together senior officials who prepare meetings of ministers drawing on the prior work of some 150 working groups and committees. These can be standing groups or established by Coreper to deal with a specific issue. The Working Party on Research considers research and innovation issues and legislation before these are discussed at Competitiveness Council meetings (meetings of national ministers with relevant portfolios and relevant Commissioners); it does not provide scientific advice *per se*[25].

EU Agencies[26]

EU agencies also seek scientific advice and expertise, and can provide it when relevant to their area of operation.

For example, the European Medicines Agency (EMA) is based in London and its purpose is to evaluate and oversee the use of medicines across Europe with the intention of protecting and promoting public and animal health. It also provides scientific evaluation of applications to market medicinal products in Europe[27]. Member States or the Commission can request a scientific opinion on medicine from the EMA. Another EU agency relevant to research is the European Food Safety Authority, based in Italy, which provides scientific opinions on a number of EU policy areas, including GMOs[28].

Many scientists input through these established EU and national mechanisms. In addition, scientists, like all EU citizens, can engage with the European institutions outside the formal scientific advice mechanisms outlined above. They can contact EU officials and Members of the European Parliament on their own initiative.

It is important to recognise that providing scientific evidence and advice does not guarantee that it will be taken into account in the development of policies. Other factors may play a legitimate role in shaping policy, including social norms, tradition and moral values.

Scientists, like all EU citizens, can engage with the European Institutions outside the formal scientific advice mechanisms.

Which countries do EU policies apply to?

Certain policy areas in Member States may be governed exclusively by legislation developed at an EU-level.

EU Member States

Policy made at the EU level generally applies to all 28 Member States of the EU, unless any have negotiated 'opt outs' or exemptions, which mean that they do not have to implement certain policies, or particular clauses in legislation.

EU policy is implemented in Member States according to the type of policy proposal. For example, a Directive will give a set time period in which Member States integrate it into their own domestic legislation (a process called 'transposition') and apply it to their national law. A Regulation must be applied in its exact form in all Member States in a given time period, and typically forms part of national legislation once the Regulation has entered into force. Certain policy areas in Member States may be governed exclusively by legislation developed at an EU-level. For example, this will be the case for the UK when the Clinical Trials Regulation (see Case Study on P20) comes into force.

Non-EU Countries

EU policy can also apply to non-EU countries, depending on the arrangements they have with the EU. For example, Norway, Iceland and Liechtenstein are members of the European Economic Area (EEA), but not the EU. These countries participate and trade in the European Single Market, and sign up to some EU laws, those focused on the European Union principles of free movement of goods, persons, services and capital[29]. These EEA countries contribute to the EU budget and are subject to EU jurisprudence applied through the European Free Trade Association (EFTA) Surveillance Authority[30]. Some other countries, such as Switzerland or Turkey, also have bilateral agreements that commit them to implementing some EU laws. None of these countries has direct representation in the EU institutions.

Non-EU countries can also sign agreements with the EU to participate in specific programmes[31]. These agreements may require compliance with relevant EU policies. For example, Associate Countries of Horizon 2020 must comply with specific EU regulations governing research conducted with animals. Research must also comply with any relevant domestic legislation in the country where it is being conducted[32].

The size of the Horizon 2020 Budget and its strategic priorities are decided by the European Parliament, Commission and Council (through ordinary legislative procedure), at which non-EU countries are not represented.

What can the EU make policy on?

EU membership does not mean all of a Member State's policy will be developed at an EU level. Some areas of policy remain national 'competences', while some may be shared with the EU and others are in the exclusive competence of the EU – meaning that the EU makes policy in this area rather than each Member State individually.

Research and technological development is a 'shared competence', which means that both Member States and the EU can make policy in this area. Member States are only able to make policy in the area where the EU has not already done so or where it will no longer do so[33].

Would the UK have to remake research policies if it left the EU?

Were the UK to vote to leave the EU, the shape of its future relationship would depend upon the withdrawal agreement. Some EU agencies play a role in domestic law. Negotiations for this withdrawal agreement could include access to agencies that play a role in UK domestic law such as the European Medicines Agency[34]. Similarly in international agreements where the EU acts en bloc for the UK, such as on climate change, the UK's responsibilities are currently met through EU legislation.

Should the UK not want to access the European Single Market, then, broadly speaking, it would no longer be required to comply with EU legislation, such as biological standards and data protection. In theory, it could choose to draw up its own new legislation.

However, to negotiate, trade and do business with the EU as a non-EU country, the UK would have to comply with a number of EU regulations[35]. For example, under the terms of participation, UK researchers wishing to access Horizon 2020 funding would have to comply with EU animal research regulation, regardless of whether the UK is a Member State of the EU.

Based on the current bilateral agreements between the EU and non-EU countries, those agreements that provide increased access to the Single Market require the non-EU country to comply with relevant EU regulations, the free movement of people, and to make a financial contribution[36].

Non-EU countries are not represented in the Parliament and Council, but some do have opportunities to comment on developing legislation, depending on the agreed relationship they have agreed with the EU[37].

Research and technological development is 'shared competence'

Image
Europe from space. © MarcelC.

How does EU policymaking influence UK research?

A number of areas that are within the EU's competence to make policy can influence research, for example the use of animals in research, the governance of clinical trials, data protection, patents and copyright.

Policy that influences research can be divided into two types:

1. policy that is intended to govern research; and
2. broader policy that has impacts for research practice.

Both types may influence research in a number of ways. Policy may directly govern how research is conducted, or it may influence the rapid and safe realisation of potential future applications. For example, if the development of commercial applications of research is restricted, this may discourage further investment in research.

Research is highly collaborative. In 2015 over half of the UK's research output was the result of an international collaboration and while the US continues to be UK based researchers' single most frequent partner country, the number of UK based researchers collaborating with EU partners is increasing at a faster rate[38]. Consistent implementation of policy that supports science can facilitate these cross-border collaborations. However poorly designed policy can be damaging whether applied consistently or inconsistently.

The following case studies illustrate the development of EU policy in a number of areas that impact on UK research. They show how scientific evidence and advice has been provided and has influenced the process, and where other factors such as social norms, tradition, moral values and global events have influenced the outcome. They illustrate how the scientific community engages with the policymaking process through both formal mechanisms and more informal engagement.

Policy may directly govern how research is conducted, or it may influence the rapid and safe realisation of potential future applications.

Image
Binary code. © ahlobystov.

General Data Protection Regulation (GDPR)

What is this?

Data protection policy regulates the way that personal data are collected and shared across the EU. It is a shared competence between the EU and Member States.

Data protection policy has evolved in the EU since the development of the 1995 EU Data Protection Directive 95/46/EC[39]. In January 2012, the European Commission published a proposal for a General Data Protection Regulation (GDPR) to replace the existing Directive[40], and noted that while its objectives and principles were sound, the original Directive had not ensured a harmonised system of personal data protection across the EU[41].

The new Regulation was developed to bring data protection laws in line with rapid technological developments that have transformed the way data are collected, accessed, used and transferred. This aimed to create a single, technologically neutral and future-proof set of rules across the EU[42].

How has scientific evidence and advice been used in the development of this policy?

Throughout the development of the GDPR, the research community engaged with the policymaking process. The original draft of the proposed Regulation set out a proportionate mechanism for protecting privacy, while enabling research using personal data, for example in health and social sciences, to continue through specific exemptions[43].

During the legislative process, several amendments were proposed[44] that would have negative consequences for research[45]. For example, the amendments would mean that, while Member States could pass a law permitting the use of pseudonymised health data (i.e. data that cannot be attributed to a particular individual) for research purposes without consent, the criteria for allowing this would be very narrow and restrictive. The use of fully identifiable health data without consent would have been prohibited.

In practice, this would have made it problematic to use data concerning health, for example from large cohort studies, biobanks and disease registries, without specific consent[46], which could have prevented valuable health research that is currently legal and already tightly regulated[47].

The research community across the EU established campaigns, urging EU institutions to find a compromise position to enable vital research to continue[48]. Activity included interaction with MEPs and the Council of Ministers, through briefings and meetings[49] as well as articulating positions through statements[50] and open letters[51].

The European Commission held a number of conferences[52] and consultations[53] on the use and protection of personal data, which gave stakeholders the chance to express their views formally.

After considerable input from the European research community, the final text of the new GDPR did not include the proposed amendments and ensured that the legislation maintains a proportionate balance between facilitating research and ensuring safeguards to protect individuals[54].

How does this impact on research in the UK?

As a Regulation, the GDPR will apply directly in all 28 Member States, however, some aspects, such as safeguards and exemptions for research are delegated to Member States.

It is difficult to assess the impact of this Regulation on UK research, as it has not yet been applied into UK law. The European research community is confident that this will not prevent research which accesses personal data from going ahead. However, this will be dependent on exactly how different Member States implement the Regulation in research and how this approach varies across the EU.

There is rapid technological development in the handling and analysis of data meaning that it is likely that this legislation will need regular review to ensure governance practices are fit for purpose.

2018

May 2018
The EU General Data Protection Regulation will apply to all Member States from 25 May 2018.

2016

May 2016
Publication of the official Regulation text, which comes into force on 24 May 2016.

Apr 2016
Adoption of the formal text by the European Parliament and Council of Ministers.

Dec 2015
The EU General Data Protection Regulation is agreed in trilogue, rejecting the proposed amendments to impose restrictions on data used for research purposes.

Autumn 2015
Trilogue negotiations take place between the European Parliament, the Council and the European Commission, to agree a compromise position.

Jun 2015
The Council agrees its general approach on the Regulation.

2014

Mar 2014
European Parliament adopts amendments to Articles 81 and 83 of the regulation that would severely restrict the use of personal data for scientific research purposes without specific consent.

Sep 2013
Key organisations representing the scientific community hold a roundtable meeting at the European Parliament entitled 'Data Protection Regulation: Keeping Health Research Alive in the EU'.

Oct 2012
Council holds a debate on proposed changes to data protection laws.

Jan 2012
The European Commission publishes a proposal for a comprehensive reform of EU data protection law, outlining plans for a new Data Protection Regulation.

2012

Oct 2011
The Commission publishes a Communication: 'A comprehensive approach on personal data protection in the European Union' for public consultation.

Nov 2010
European Commission sets out new strategy on how to protect individuals' data in all policy areas, and sets out proposals on how to modernise the EU framework for data protection rules.

2010

Jul – Dec 2009
A consultation is held on the legal framework for the fundamental right to the protection of personal data.

May 2009
The European Commission holds a conference on the use and protection of personal data, and examining new challenges for privacy.

Jul 1998
The European Union Directive 95/46/EC is transposed into UK law through the 1998 Data Protection Act.

Dec 1995
The European Data Protection Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data comes into force.

1995

Image
Patient undergoing general anesthesia.
© kupicoo.

Clinical Trials Regulation[55]

What is this?

Policy to regulate clinical trials in the EU aims to ensure high and harmonised standards for conducting clinical trials across the EU. However, the introduction of the Clinical Trials Directive (CTD) 2001/20/EC[56] in 2001 did not achieve the harmonisation sought, and furthermore the legislation made it particularly difficult to perform certain clinical trials in several Member States (see below). In the UK, the number of clinical trials dropped by 22% between 2007 and 2011[57].

In 2012, the Commission proposed a revised Clinical Trials Regulation EU No 536/2014[58], which entered into force in 2014. As a Regulation, this must be implemented in the same way by all Member States. The Regulation aims to simplify authorisation procedures, creating a more favourable environment for conducting clinical trials, with the highest standards of patient safety in all EU Member States.

How has scientific evidence and advice been used in the development of this policy?

Recognising problems with the implementation of the 2001 Clinical Trials Directive, the European Commission ran consultations on plans to revise it[59,60]. During this period, organisations representing the medical research community in the UK and other Member States strongly articulated the need for legislation that would create a supportive environment for conducting research involving clinical trials. In the UK, sixteen organisations including Cancer Research UK, the Wellcome Trust and the Academy of Medical Sciences produced a statement welcoming the revision of the Clinical Trials Directive[61]. The Commission and the European Medicines Agency held a conference[62] to facilitate a dialogue on clinical trials legislation between the Commission and stakeholders from industry and academia.

The new Clinical Trials Regulation[63] has now been adopted and came into effect in May 2016. This is considered by the scientific community to be a considerable improvement on the Clinical Trials Directive, addressing many of the previous problems. 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.

How does this impact on research in the UK?

The Regulation has been formally adopted by the EU and is in the process of being implemented in Member States. It is envisaged that the Regulation will have a positive effect on the system of conducting clinical trials in the UK. The UK has been particularly stringent in its implementation of the Clinical Trials Directive compared with other EU Member States, resulting in high standards in the UK but placing the UK at a competitive disadvantage. In the development of the new Clinical Trials Regulation, the research community has been effective in influencing the debate to ensure the administrative burden and increased cost of conducting clinical trials is addressed. Issues arising from the inconsistent interpretation of the current Clinical Trials Directive should be addressed by the fact that the new piece of legislation is a Regulation[64] (see Fact Box 2).

2016

May 2016
Clinical Trials Regulation EU No 536/2014 will become applicable no earlier than 28 May 2016.

2014

Jun 2014
Clinical Trials Regulation EU No 536/2014 on clinical trials on medicinal products for human use enters into force.

2012

Jul 2012
The European Commission publishes a Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, that would repeal the Clinical Trials Directive 2001/20/EC. Ordinary legislative procedure begins.

Feb 2011
The European Commission publishes a concept paper for public consultation, outlining a legislative proposal to revise the Clinical Trials Directive 2001/20/EC.

2010

Mar 2010
A summary of the responses to the public consultation paper are published by the European Commission.

Oct 2009
The European Commission issues the Public Consultation Paper 'Assessment of the Functioning of the Clinical Trials Directive (2001/20/EC)'.

2008

Feb 2009
A report produced by the EU FP7-funded project 'The Impact on Clinical Research of European Legislation (ICREL)' notes the level of concern from stakeholders about the impact of Directive 2001/20/EC on clinical trial research was 'intense and widespread'.

Dec 2008
The Commission announces that an assessment would be made of the application of the Clinical Trials Directive 2001/20/EC.

2006

Dec 2006
The EC Pharmaceutical Committee endorses a report expressing a concern that experience with implementation of the clinical trials legislation varies between EU Member States.

Oct 2007
The European Commission and European Medicines Agency hold a conference on the operation of the Clinical Trials Directive (2001/20/EC) and perspectives for the future.

2004

May 2004
Clinical Trials Directive 2001/20/EC is transposed into UK law through the UK Medicines for Human Use (Clinical Trials) Regulations.

2002

2000

Apr 2001
Clinical Trials Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use is adopted.

Image
Tomatoes © ZoiaKostina.

Genetically Modified Organisms (GMOs)

What is this?

Modern biotechnology can use techniques that are not naturally occurring to modify the genetic material of organisms. The EU has established a legal framework which aims to ensure the safe and responsible development of these GMOs across the EU. The framework is intended to establish:

- high standards of safety;
- harmonised risk assessment and authorisation procedures;
- clear labelling;
- traceability for GMOs.

This framework comprises a number of Directives and Regulations supplemented by a number of implementing rules, recommendations and guidelines on more specific aspects[65].

How has scientific evidence and advice been used in the development of this policy?

To take into account scientific and technical developments in biotechnology, the European Commission established a New Techniques Working Group[66] to assess what falls within the scope of EU legislation. Similarly, the European Food Safety Authority (EFSA) has a Scientific Panel on GMOs[67] to provide scientific advice on the safety of GMOs in the food chain such as plants, animals and micro-organisms. This comprises 18 scientists from across Europe, covering wide areas of expertise.

Two reports were prepared between 2009 and 2011 evaluating the EU legislative framework in the field of cultivation of GMOs focusing on GMO cultivation and GM food and feed[68].

The Joint Research Centre (JRC) also plays a role in the development and implementation of EU GMO legislation. Sitting within the JRC, the EU Reference Laboratory for GM Food and Feed[69] provides the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorisation procedure. It also coordinates the National Reference Laboratories for GMOs in the Member States.

When the EU originally adopted legislation to control the use of 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 controlling GMOs based simply on the technology that generated them (i.e. the process-based approach)[70].

Alongside the scientific evidence, public opinion is very important. High levels of public concern over the use of GMOs[71] and different attitudes across EU Member States have limited the number of GMOs authorised for cultivation and food and feed.

To date, one GM crop, a pest resistant variant of maize, is commercially cultivated in the EU. Although this crop has EU-wide approval, it is only grown in five Member States[72].

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 organism.

How does this impact research in the UK?

The UK has a strong science base in the fields that contribute to the development of GM applications. However, the prohibitive length and cost of obtaining EU regulatory approval for GM products is a factor that may discourage the translation of this research into agricultural applications[73]. This can deter investors and drive research to other countries with more permissive regulation such as the US, Canada or emerging economies like Brazil and China[74]. In the UK, England, Scotland, Wales and Northern Ireland can each choose to restrict or prohibit the cultivation of GMOs that have been approved by the EU. In Autumn 2015 Scotland, Wales and Northern Ireland chose to do so.

Mar 2015
Directive (EU) 2015/412, amends Directive 2001/18/EC introducing an option for EU Member States to restrict or prohibit the cultivation of EU approved GMOs in their territory.

Feb 2015
A UK House of Commons Science and Technology Committee report warns that the EU's process-based regulatory system for novel crops cannot account for advances in technology and could prevent new products from reaching the market, both in the UK, in Europe and the developing world.

2015

Mar 2011
A report by the European Policy Evaluation Consortium (EPEC), commissioned by the European Commission provides an evaluation of the legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003. The report concludes that the legislative framework is not meeting needs or expectations, or its own objectives.

May 2009
Directive 2009/41/EC on the contained use of genetically modified micro-organisms is adopted and comes into force in June 2009.

2010

Dec 2008
A meeting of the Council on GMOs concludes that is 'necessary to look for improvement of the implementation of this legal framework in order to better meet the objective of the EC legislation'.

Sep 2003
Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is adopted, coming into force in April 2004. This set out the procedures for evaluation and authorisation of GM foods. Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of GMOs and their derived products is adopted. This amended Directive 2001/18/EC.

2005

Oct 2002
Directive 2001/18/EC comes into force.

Feb 2002
The European Food Standards Agency (EFSA) is established. EFSA's core role in GMO legislation is to independently assess risks posed by GMOs towards human and animal health and the environment.

Mar 2001
Directive 2001/18/EC on the deliberate release into the environment of GMOs is adopted, repealing Directive 90/220/EEC.

2000

Dec 1996
The Commission publishes a report identifying a number of problem areas with the implementation of Directive 90/220/EEC and state an intention to amend this Directive.

1995

Oct 1991
Council Directive 90/220/EEC on the deliberate release into the environment of GMOs comes into force.

Apr 1990
Council Directive 90/220/EEC on the deliberate release into the environment of GMOs is adopted.

1990

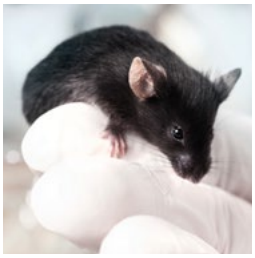


Image
Laboratory mouse.
© anyaivanova.

The use of animals in scientific research

What is this?

At present the use of animals remains the only way for some areas of research to progress[75]. EU policy follows the principle of Three Rs (Replace, Reduce and Refine), which aims to ensure the welfare of animals used for research purposes. 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.

How has scientific evidence and advice been used in the development of this policy?

The UK Bioscience sector – consisting of a united coalition of academic, industry, small and medium-sized enterprises (SMEs), funding, charity and patient bodies - played an active role in providing evidence and advice to inform the revision of the Directive. For example, the bioscience sector published position statements, responded to consultations of the Home Office[76] and House of Lords European Union Select Committee[77] and provided briefings for Parliamentary debates[78]. This formed a powerful collective voice that shaped the UK's negotiating position at the Council.

Throughout the process of revising the Directive 86/609, the Commission sought the opinions of Scientific Expert Committees on a number of issues relating to the use of animals in experiments[79]. The Scientific Committee on Animal Health and Animal Welfare (SCAHAW) provided input on the welfare of non-human primates used in experiments[80] and a Technical Expert Working Group (TEWG) was assembled by the European Commission's Directorate General Environment to include expertise from industry, academia and animal welfare organisations[81]. A public stakeholder consultation[82] on the use of animals in experiments and ways to improve their welfare included both citizen and expert questionnaires.

How does this impact on research in the UK?

The UK has one of the world's strongest regulatory systems in this area[83]. 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. For the majority of UK researchers there has subsequently been little change to the governance of research using animals.

The UK Bioscience sector has expressed concerns that the Directive is being implemented inconsistently across Member States, and that this could negatively impact on collaboration between Member States and other countries[84]. The Directive will be reviewed in 2017.

2017
The Directive will be reviewed as part of the EU's normal legislative review process.

2015

Jan 2013
The Directive is formally applied across the EU.

Nov 2009
The House of Lords European Union Select Committee publishes its report into 'The revision of the EU Directive on the protection of animals used for scientific purposes'.

May 2009
The European Parliament adopts its first reading of the document.

Sep – Nov 2010
The Directive is finalised, signed and enters into force. Member States are given 24 months to adopt and publish national legislation to transpose the provisions of the new Directive.

Nov 2008
Ordinary legislative procedure begins: Commission adopts a proposal to revise Directive 86/609/EEC.

2010

Oct 2008
The UK Bioscience sector publishes its perspective on the revision of the EU Directive.

Jun – Aug 2006
The Commission carries out a public stakeholder consultation on the different options for a revision of the Directive.

Nov 2005
The Animal Health and Animal Welfare Panel (AHAW) of European Food Safety Authority publishes a scientific opinion on questions in relation to the revision of the Directive.

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is launched – a public-private partnership between the Commission, European trade associations from various industry sectors, and individual companies to promote the development and implementation of methods to replace, reduce and refine animal testing.

Nov 2003
DG Environment organises a Technical Expert Working Group (TEWG) from industry, science, academia and animal welfare organisations to collect scientific and technical evidence for the revision of the Directive – reports are published.

2005

Jan 2003
European Court rules that the Netherlands has failed to fulfil its obligations under Council Directive 86/609/EEC.

Dec 2002
The Scientific Committee on Animal Health and Animal Welfare (SCAHAW) publishes an opinion on the welfare of non-human primates used in experiments.

Nov 2002
The European Parliament's Committee on the Environment, Public Health and Consumer Policy publishes a report calling for the revision of Directive 86/609/EEC.

Jul 2002
The House of Commons Select Committee Report on Animals in Scientific Procedures describes the UK's Animals (Scientific Procedures) Act as 'the tightest system of regulation in the world'.

2000

Nov 2001
The European Commission announces that it intends to review and revise the Directive 86/609/EEC.

Apr 1996
European Court rules that Luxembourg has failed to fulfil its obligations under Council Directive 86/609/EEC.

Nov 1986
Council adopts Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. This is transposed into the 1986 UK Animals (Scientific Procedures) Act.

1985

How do the UK and EU interact in the development of international polices that govern research?

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.

Due to its world-class research base, the UK's researchers and institutions are well-placed to inform international policy that governs research. There are many ways to do this including through scientific networks, national governments, the EU and international bodies such as the UN.

The following case studies illustrate two areas of scientific progress where countries are working together to ensure these are exploited safely, highlighting the UK and EU role in these.

Image
Earth from space showing North and South America.

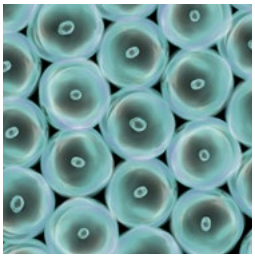


Image
Human cells.
© Shing Lok Che.

Human Genome Editing

What is this?

New genetic technologies are cheaper, more efficient and more precise than previous genetic technologies and could potentially be used to modify human genes. Scientists and governments around the world are, or will have to, consider how to regulate the use of these new technologies[85].

Is the UK engaged?

The UK's long standing and established regulatory systems have made us a leader in the regulation of new technology. The Human Fertilisation and Embryology Authority (HFEA) is dedicated to licensing and monitoring of all UK research involving human embryos and permits researchers to undertake genome editing of human embryos for research purposes on a case by case basis. In February 2016, the HFEA approved a research application from researchers at the Francis Crick Institute to use new gene editing techniques on human embryos (up to 14 days)[86].

The United States (US) National Academies of Sciences and Medicine are convening discussions on the issues. In December 2015, the UK's Royal Society co-hosted an International Summit on Human Gene Editing with the Chinese Academy of Sciences, the US National Academy of Sciences and the US National Academy of Medicine.

Is the EU engaged?

An independent advisory panel to the President of the European Commission, the European Group on Ethics in Science and New Technologies (EGE), issued a statement in January 2016 on genome editing[87]. European networks of scientists are engaging with the issue at a global and national level and beginning to define the scientific questions.

At a European level, the Federation of European Academies of Medicine (FEAM) held a meeting conference on 28 April 2016 on the regulation of human genome editing across Europe. The findings from the FEAM meeting will also provide evidence for the US National Academies of Sciences and Medicine's forthcoming report.

How was scientific evidence and advice used in the development of the policy?

As a rapidly evolving policy area, scientists are in the process of presenting evidence on human genome editing.

Nov – Dec 2016
US National Academies of Sciences and the US National Academy of Medicine publishes a consensus report on human genome editing.

Apr 2016
The US National Academy of Sciences and the US National Academy of Medicine hold a second meeting on human genome editing in Paris.

Apr 2016
FEAM holds a meeting to provide an overview of the regulation of human genome editing across Europe.

Feb 2016
HFEA grants a license for the use of gene editing on human embryos in research[88].

Jan 2016
European Group on Ethics in Science and New Technologies (EGE) issues a genome editing statement.

2016

Dec 2015
Progress Educational Trust holds an Annual Conference on 'From Three-Person IVF to Genome Editing: The Science and Ethics of Engineering the Embryo'[89].

The Council of Europe Committee on Bioethics publishes a statement on Genome Editing Technologies[90].

Dec 2015
The Royal Society, the US National Academy of Sciences, the US National Academy of Medicine and the Chinese Academy of Sciences hold a Human Gene Editing Summit.

Nov 2015
Health Council of the Netherlands (GR) and The Netherlands Commission on Genetic Modification (COGEM) holds a symposium on human genome editing. This symposium will inform the Trend Analysis Biotechnology 2015. This report will be used to advise the Dutch government and Parliament[92].

Nov 2015
A case of leukaemia in the UK is cured with somatic cells that have been edited[91].

Oct 2015
UNESCO calls for a ban on human genome editing[93].

Sep 2015
Parliamentary Assembly of the Council of Europe, working with the Committee of Social Affairs, Health and Sustainable Development, holds a moderated debate about heritable genetic engineering in human embryos[94].

2015

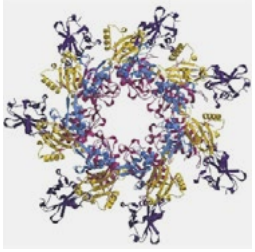


Image
ANTHRA 1. Image credit: R. John Collier, Harvard Medical School. Licensed under Public Domain via Wikimedia Commons.

Biological and Toxin Weapons

What is this?

Biological and toxin weapons are biological agents 'of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes[95]. 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.

As of 2015, there are 174 State Parties (who have ratified the Treaty) and 9 Signatory States (who have signed the Treaty but not ratified it)[96].

Is the UK engaged?

The UK signed the BTWC in 1972 and ratified it in 1975. The UK is one of 41 member nations of the Australia Group, which was established in 1985 to limit the spread of chemical and biological weapons through export controls on chemical precursors, equipment, agents, and organisms[97]. In March 2005, to mark the 30th anniversary of BTWC ratification, the UK, the US, and Russia issued a joint statement to reaffirm their strong support for the Convention and called on all remaining countries not party to the BTWC to implement and comply with the convention[98].

Is the EU engaged?

The Council of the European Union adopted a common position in 2015 outlining its role in the BTWC. The EU will focus its efforts on four broad areas: 'building and sustaining confidence in compliance; supporting national implementation; supporting the United Nations Secretary General's mechanism for investigation of alleged use of biological weapons and agents; and promoting universality'.

The EU has adopted four action plans to support the BTWC, and also supports the World Health Organisation (WHO) in bio-safety and bio-security.

Since 2006 the EU has provided financial support to encourage participation in BTWC activities, such as workshops, and to support implementation of the BTWC in countries both party and not yet party to the Convention[99].

How was scientific evidence and advice used in the development of the policy?

A review conference takes place every five years to discuss the BTWC, its development and implementation. A preparatory meeting takes place in April of the year of the review conference to agree what should be discussed. Since 2003, inter-sessional meetings (annual Meeting of Experts and Meetings of State Parties) take place twice a year in the years in between the review conference, where the changing nature of the issues are discussed, such as scientific and technological advancements.

The Royal Society, the US National Academy of Sciences and the Polish Academy of Sciences led work for the InterAcademy Panel (IAP) Biosecurity Working Group to help the State Parties in their preparation for the 8th BTWC Review Conference in December 2016 by reviewing the trends in science and technology with implications for the BTWC[100].

Dec 2016
Eighth Annual Review Conference of BTWC.

Sep 2015
IAP hosts a conference on Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention to assist the State Parties in Preparing for the Eight Review Conference[101].

Dec 2015
Meeting of the States Parties: IAP side event.

2011
Seventh Review Conference.

Oct – Nov 2010
The US National Academy of Sciences publishes a report on the International Workshop in Beijing on 'Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention' to feed into the Seventh Review Conference[102].

2010

Mar – Apr 2008
IAP, InterAcademy Medical Panel, International Union of Biological Sciences, International Union of Microbiological Societies and Internationl Union of Biochemistry and Molecular Biology organises the 2nd International Forum on Biosecurity[103].

2006
Sixth Review Conference: IAP hosts a side event.

2006
Royal Society/ Inter-Academy Panel/ International Council for Science holds a workshop on science and technology developments relevant to the Biological and Toxin Weapons Convention, to provide independent international scientific advice to the Sixth Review Conference.

Nov 2005
InterAcademy Panel (IAP) publishes a statement on Biosecurity[104].

Jun 2005
Royal Society publishes 'Issues for discussion at the 2005 Meeting of Experts of the Biological and Toxin Weapons convention[105].

Mar 2005
InterAcademy Panel in cooperation with International Council for Science (ICSU) and InterAcademy Medical Panel (IAMP), organise International Forum on Biosecurity[106].

2001
Fifth Review Conference of BTWC.

2000

1996
Fourth Review Conference of BTWC.

1991
Third Review Conference of BTWC.

1990

1986
Second Review Conference of BTWC.

Mar 1980
BTWC hold Review Conference in Geneva.

1980

Feb 1975
UK completes ratification process.

Jan 1975
Soviet Union ratifies Geneva Protocol and BTWC.

Dec 1974
US ratifies Geneva Protocol and BTWC.

Feb 1974
'Biological Weapons Act' becomes UK law.

1970

Apr 1930
UK ratifies Geneva Protocol.

1930

1928
Geneva Protocol enters international law.

1925

1925
The Geneva Protocol for the Prohibition of the use in Warfare of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare is signed.

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