



Ethics Assessment and Guidance at the European Union Level

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Annex 5.a Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

Deliverable 1.1

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1 INTRODUCTION

The aim of this report is to provide an analysis of the existing structures and agents for the ethical assessment of research and innovation in the European Union (EU), both for the public and private sectors. The report focuses on EU-level structures only and not those at the national level. The report describes how organisational structures, laws, policies and procedures for ethical assessment have been put in place at the EU level; the ways in which publicly funded and private research and innovation systems address ethical issues in research and innovation; and the role of ethical assessment in the activities of professional groups and associations for research and innovation. The report has been compiled using data gathered from public sources such as organisational websites, books, and articles, in addition to interviews carried out with representatives of some organisations mentioned here. The discussion section draws on insights from some of the SATORI stakeholder interviews.

We begin by offering a general picture of ethics assessment of R&I in the EU with regard to the general state of affairs and the institutional division of responsibilities for ethics assessment across the public and private research and innovation systems.

Ethics assessment of research and innovation (R&I) in the European Union is well organised across the public research and innovation system. The European Commission has a well-established structure of ethics review for research funded by the Commission. Ethics review requirements are supported by EU level research funding organisations that include ethics assessment in determining how to spend their funding. At a higher level, the Commission puts an emphasis on the contribution of ethics expertise in guiding its policies and legislation with regard to ethics in science and new technologies. Moreover, both the Commission and the European Parliament place importance on the role of scientific expertise in evidence-based policy-making, in which assessment of ethical issues may also play a role. To that end, independent scientific advice is provided for both in-house and by external experts. The foundation for ethics assessment of R&I has been well established in EU law and policy mechanisms. EU-level research associations and standard-setting bodies develop policies, issue best practice guidelines, provide advice and collaborate with similar organisations or other actors on ethics topics via events, platforms and other mechanisms. The private research and innovation system in the EU also plays a role in the ethics assessment landscape; corporate social responsibility is considered “important for the sustainability, competitiveness, and innovation of EU enterprises and the EU economy”¹, and there are government policies and initiatives to support CSR in private industry. Industry associations help members to comply with ethical and professional standards by developing codes of practice, guidelines, strategies and offering training. Finally, professional groups and associations in the R&I field work to coordinate ethics assessment of their respective areas and uphold ethical and professional standards across their EU members. In addition, these associations work to facilitate and enhance ethics assessment at national level.

¹ European Commission, “Corporate social responsibility”. http://ec.europa.eu/growth/industry/corporate-social-responsibility/index_en.htm

2 EUROPEAN INSTITUTIONS AND POLICIES

2.1 INSTITUTIONAL STRUCTURE OF GOVERNMENT

This section briefly outlines the EU government and government-controlled institutions: nature of and relations between executive, legislative and judicial branches, major ministries and government organisations (especially those relevant for R&I), and the relation between the EU and national governments.

The EU has a unique institutional set-up in which:

- the EU's broad priorities are set by the European Council, which brings together national and EU-level leaders
- directly elected Members of the European Parliament (MEPs) represent European citizens in the European Parliament
- the interests of the EU as a whole are promoted by the European Commission, whose members are appointed by national governments
- governments defend their own country's national interests in the Council of the European Union.²

The European Council sets the EU's overall political direction – but has no powers to pass laws. It is led by a President and comprises the national heads of state or government and the President of the Commission.³ There are three main institutions involved in EU legislation:⁴

- The European Parliament, representing the EU's citizens and directly elected by them;⁵
- The Council of the European Union, representing the governments of the individual member countries.⁶ Its Presidency is shared by member states on a rotating basis.
- The European Commission, representing the interests of the Union as a whole.⁷

Together, these three institutions produce, through the 'Ordinary Legislative Procedure', the policies and laws applicable throughout the EU. In principle, the Commission proposes new laws, and Parliament and Council adopt them. In most cases, the Commission makes proposals in order to meet its obligations under the EU treaties, or because another EU institution, country or stakeholders has requested it to act.⁸ The Commission and the member countries implement legislation, and the Commission ensures that the laws are properly applied and implemented. Note that, according to the subsidiarity principle, "the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level" (Treaty on European Union (TEU) Article 5).⁹

² Europa.eu, "EU institutions and other bodies". <http://europa.eu/about-eu/institutions-bodies/>

³ <http://www.consilium.europa.eu/en/european-council/>

⁴ <http://europa.eu/about-eu/institutions-bodies/>

⁵ <http://www.europarl.europa.eu/portal/en>

⁶ <http://www.consilium.europa.eu/en/homepage/?lang=en>

⁷ http://ec.europa.eu/index_en.htm

⁸ Ibid.

⁹ Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on European Union - Protocols - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007, *Official Journal C 326*, 26/10/2012 P. 0001 – 0390.

Two other institutions that play vital roles are the Court of Justice of the EU¹⁰ (which interprets EU law to make sure it is applied in the same way in all EU countries and settles legal disputes between EU governments and EU institutions), and the European Court of Auditors¹¹ which checks the financing of the EU's activities. The EU has a number of other institutions and inter-institutional bodies¹² that play specialised roles.¹³

The EU has decentralised agencies (located across the EU) that carry out technical, scientific or managerial tasks that help the EU institutions make and implement policies.¹⁴ They support cooperation between the EU and national governments by pooling technical and specialist expertise from EU institutions and national authorities. Examples include: the European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice (EU-LISA)¹⁵, the European Aviation Safety Agency (EASA)¹⁶, the European Chemicals Agency (ECHA)¹⁷ and the European Environment Agency (EEA).¹⁸ Agencies under the Common Security and Defence Policy include: the European Defence Agency (EDA)¹⁹, the European Union Institute for Security Studies (EUISS)²⁰ and the European Union Satellite Centre (SatCen)²¹. There are also executive agencies (set up for a fixed period) that help the European Commission manage EU programmes e.g. the European Research Council Executive Agency (ERC Executive Agency)²², the Consumers, Health and Food Executive Agency (CHAFEA)²³ and the Research Executive Agency (REA)²⁴. EURATOM agencies and bodies support the aims of the European Atomic Energy Community Treaty (EURATOM).²⁵

The European Institute of Innovation and Technology (EIT), based in Hungary, is an independent EU body seeking to promote Europe's ability to develop new technologies, by pooling its best scientific, business and education resources.²⁶

¹⁰ http://curia.europa.eu/jcms/jcms/Jo2_6999/

¹¹ <http://www.eca.europa.eu/en/Pages/ecadefault.aspx>

¹² http://europa.eu/about-eu/institutions-bodies/interinstitutional-bodies/index_en.htm

¹³ I.e. European Central Bank, responsible for European monetary policy; the European External Action Service (EEAS) which assists the High Representative of the Union for Foreign Affairs and Security Policy; the European Economic and Social Committee which represents civil society, employers and employees; the Committee of the Regions which represents regional and local authorities; the European Investment Bank finances EU investment projects and helps small businesses through the European Investment Fund; the European Ombudsman who investigates complaints about maladministration by EU institutions and bodies; the European Data Protection Supervisor (EDPS), the independent supervisory authority that protects personal data and privacy and promotes good practice in EU institutions and bodies; the Publications Office that publishes information about the EU; the European Personnel Selection Office that recruits staff for the EU institutions and other bodies; and the European School of Administration which provides training in specific areas for members of EU staff.

¹⁴ http://europa.eu/about-eu/agencies/index_en.htm

¹⁵ <http://www.eulisa.europa.eu/>

¹⁶ <https://www.easa.europa.eu/>

¹⁷ <http://echa.europa.eu/>

¹⁸ <http://www.eea.europa.eu/>

¹⁹ <http://www.eda.europa.eu/>

²⁰ <http://www.iss.europa.eu/>

²¹ <http://www.satcen.europa.eu>

²² <http://erc.europa.eu/about-erc/organisation-and-working-groups/executive-agency>

²³ <http://ec.europa.eu/chafea/>

²⁴ http://ec.europa.eu/rea/index_en.htm

²⁵ <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:11957A/TXT>

²⁶ <http://eit.europa.eu/>

2.2 GOVERNMENTAL INSTITUTIONS FOR ETHICS ASSESSMENT

The following section offers a description of EU-level governmental and government funded/controlled organs and institutions, agencies and advisory bodies and their role in ethics assessment (e.g., standard setting, advice to government, etc.) and related areas such as technology assessment and impact assessment.

The organisations and institutions described here have been categorised according to their role and/or location within the European Commission and the European Parliament.

The European Commission

The European Commission places particular importance on the role of scientific expertise in policy-making. To that end, a number of expert groups, committees and organisations - both external and in-house - have been established. Some of these groups carry out explicit ethics assessment, i.e., ethics assessment or review is a clear aspect of their mandates, while others may encounter ethical issues and discussion in the course of carrying out different kinds of assessment, i.e. ethical issue are *among* the issues investigated in assessments.

Mechanism for scientific advice at the European Commission

In 2011, the role of Chief Scientific Adviser (CSA) was established under Commission President Jose Manuel Barroso.²⁷ Professor Anne Glover was appointed as the Commission's first Chief Scientific Adviser in January 2012, aimed at ensuring more evidence-based European Union policy-making, in addition to promoting the uptake of science and technology in society, including an improved transfer of knowledge from the scientific world to industry.²⁸ One of the functions of the CSA was to interact with high-level advisory groups including the European Group on Ethics in Science and New Technologies (see section below).²⁹ On the expiry of the term of office of President Barroso on 31 October 2014, the mandate of the CSA expired and was not renewed by the current Commissioner President Juncker, a move that has been both praised and criticised.³⁰ In mid-May 2015, Juncker's Commissioner for Research, Science and Innovation, Carlos Moedas, made a recommendation - endorsed by President Juncker - to set up a mechanism for high quality, timely, independent scientific advice.³¹ The future mechanism will draw on the wide range of scientific expertise in Europe through a close relationship with national academies and other bodies, coordinated by a High-Level Group of Independent Scientists.³²

Joint Research Centre

The Joint Research Centre (JRC) is the European Commission's in-house science service which employs scientists to carry out research for the provision of independent scientific

²⁷ <http://www.sciencecouncil.org/content/what-next-science-european-union>

²⁸ http://europa.eu/rapid/press-release_IP-13-168_en.htm

²⁹ <http://www.academies.fi/wp-content/uploads/2015/04/future-directions-for-scientific-advice-in-europe-v5a-online-version-26042015.pdf>

³⁰ The move was criticised by many in the science community as a backward step, out of line with the broader emphasis on evidence - informed policymaking. Other commentators felt that it was a welcome admission that the diversity of political cultures across Europe could not be served adequately by a UK-style science adviser.

³¹ http://europa.eu/rapid/press-release_IP-15-4970_en.htm

³² Ibid.

advice and support to EU policy.³³ The JRC works in close cooperation with policy Directorates-General and addresses key societal challenges while stimulating innovation through the development of new methods, tools and standards, and sharing its knowledge and skills with Member States, the scientific community and international partners.³⁴ In President Juncker's Commission, the JRC is under the responsibility of Tibor Navracsics, Commissioner for Education, Culture, Youth & Sport, rather than the Directorate General for Research and Innovation, as it was previously.³⁵

The European Political Strategy Centre

The European Political Strategy Centre (EPSC)³⁶ provides strategic analysis and policy advice to the President of the Commission on matters related to policy priorities and outreach to decision-makers, think tanks and civil society at large. The EPSC provides the Secretariat of the European Group on Ethics in Science and New Technologies (EGE).

The *European Group on Ethics in Science and New Technologies (EGE)* was established in 1991 and is an independent, pluralist and multidisciplinary body advising the European Commission on ethics in science and new technologies in connection with Community legislation or policies.³⁷ Since its founding, the EGE has adopted Opinions on issues ranging from nanotechnology, novel food legislation, animal welfare, embryo research, genetically modified organisms, CAP revision, climate change, global trade, digital agenda, research and innovation policy, to food security, internet governance, energy and security and surveillance technologies. Opinions are initiated at the request of the Commission President.³⁸

The EGE is a core component in a wider set of coordinated activities with the aim of, first, embedding EU policymaking on science and new technologies within a firm ethical foundation and, second, enhancing global cooperation on ethics.³⁹ These include the Inter-service group on Ethics and EU Policies which coordinates Commission activities in the fields of bioethics and ethics of science and new technologies; cooperation with the international organisations whose responsibility it is to examine the ethical implications of science and new technologies (the UN and its agencies, OECD, Council of Europe); and the organisation of the European Commission's International Dialogue on Bioethics, a platform bringing together the National Ethics Councils from 97 countries (EU-G20 forum and beyond).⁴⁰

The *Science and Technology Advisory Council (STAC)*, also led by the EPSC, is a permanent Commission expert group, established in January 2013, comprising a group of science and technology experts from academia, business and civil society, covering a broad range of disciplines and uniting expertise from across the European Research Area.⁴¹ The mission of STAC is to provide advice to the President of the Commission regarding how to create a proper environment for innovation by shaping a European society that embraces science,

³³ <https://ec.europa.eu/jrc/>

³⁴ Ibid.

³⁵ <https://ec.europa.eu/jrc/en/about/people/commissioner>

³⁶ <http://ec.europa.eu/epsc/>

³⁷ http://ec.europa.eu/epsc/ege_en.htm

³⁸ Ibid.

³⁹ http://ec.europa.eu/epsc/ege_en.htm

⁴⁰ Ibid.

⁴¹ http://ec.europa.eu/archives/commission_2010-2014/president/advisory-council/index_en.htm

technology and engineering.⁴² The Council advises on the opportunities and risks that derive from scientific and technological progress.⁴³ Moreover, the Council will advise on the best means of communicating such opportunities and risks in order to foster informed societal debate and to ensure that Europe remains a global leader in cutting-edge technologies.⁴⁴

In October 2014, STAC presented a report to President Barroso entitled “The future of Europe is science”.⁴⁵ This foresight report outlines some key opportunities for Europe that could be provided by science and technology, looking ahead to the year 2030.⁴⁶ The report is structured around citizens’ priorities, as identified by the Eurobarometer survey on “Public perceptions of Science, Research and Innovation” which was published on the same day.⁴⁷

Directorate General for Research and Innovation

Through its Directorate General (DG) for Research and Innovation, the European Commission develops EU policies in the field of research and technological development and contributes to the international competitiveness of European industry.⁴⁸ The Ethics and Research Integrity Sector at DG Research and Innovation⁴⁹ is responsible for organising ethics assessment of proposals submitted to the Commission for funding.

The *National Ethics Councils Forum (NEC Forum)* is a European Commission expert group for which DG Research and Innovation is the lead DG.⁵⁰ The NEC Forum is an independent network of representatives of the National Ethics Councils for the exchange of information, experience and best practices on issues of common interest in the field of ethics and science.⁵¹ The NEC Forum has held meetings since 2001 with practically all Council rotation Presidencies which also function to initiate national discussion regarding issues of major significance in bioethics.

The European Parliament

Many of the issues that come before the European Parliament have a scientific or technological dimension to them. The European Parliament defines its position on these issues through reports prepared by its Committees.⁵² If Committees decide that expert, independent assessment of the various scientific or technological options in the policy sectors concerned would be helpful to their policy-making role, they can make use of the services of STOA.⁵³

⁴² <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2908>

⁴³ Ibid.

⁴⁴ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2908>

⁴⁵ <https://ec.europa.eu/programmes/horizon2020/en/news/report-pres-barrosos-science-and-technology-advisory-council-stac-future-europe-science-oct2014>

⁴⁶ Ibid.

⁴⁷ http://europa.eu/rapid/press-release_IP-14-1092_en.htm

⁴⁸ <http://ec.europa.eu/research/index.cfm?pg=dg>

⁴⁹ http://ec.europa.eu/research/dgs/pdf/organisation_en.pdf

⁵⁰ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1806>

⁵¹ Ibid.

⁵² <http://www.europarl.europa.eu/stoa/cms/home/about>

⁵³ Ibid.

STOA is the Parliament's *Science and Technology Options Assessment* unit. STOA provides policy advice to decision-making bodies concerning the impact of science and technology on EU policy. While STOA is an official organ of the European Parliament, its work is carried out in partnership with external experts, including research institutes, universities, laboratories, consultancies or individual researchers contracted to help prepare specific projects.⁵⁴ Round-table expert discussion and conferences and workshops with associated or relevant studies are increasingly made use of by STOA.⁵⁵ Various stakeholders including Members of Parliament and invited experts from EU institutions, international institutions, universities, specialist institutes, academies and other sources of expertise worldwide can jointly participate in the analysis of current issues at these events.⁵⁶

Operational responsibility for STOA lies within Directorate C (Impact Assessment and European Added Value) of the Directorate General for Parliamentary Research Services (DG EPRS).⁵⁷ Specifically, staff in the Scientific Foresight unit carry out STOA's programme.⁵⁸ The EPRS's service in the fields of Impact Assessment and European Added Value help to enhance the capacity of the European Parliament to undertake scrutiny and oversight of the executive, particularly through *ex ante* and *ex post* evaluation of EU legislation, i.e. before and after it is adopted by the Union's institutions and to analyse the need for, or, effectiveness of, action at European level.⁵⁹ The European Added Value Unit supports committees in their work on legislative initiative reports through the provision of 'European Added Value Assessments' of parliamentary proposals, the preparation of 'Cost of Non-Europe Reports' and the identification of the added value of existing EU policies.⁶⁰ *Ex ante* impact assessment involves the identification of the foreseeable economic, social, environmental and other effects of proposed legislation, including the analysis of alternatives available to achieve defined policy goals.⁶¹ *Ex post* impact assessment work supports committees in their work on implementation and highlights the state-of-play in relevant fields through regular briefing notes.⁶²

2.3 EU LAWS AND POLICIES FOR ETHICS ASSESSMENT

The following section sets out the major laws, policies and regulations relating to ethics assessment and related activities such as impact assessment, evaluation of R&I, including requirements for ethics review, and participatory processes in R&I. Policies and initiatives for Responsible Research and Innovation (RRI) are also discussed here. As legislation for specific areas of R&I is described in another SATORI deliverable - D3.1 *Part 1: A report on the legal frameworks that guide or constrain ethical procedures within research within the*

⁵⁴ <http://www.europarl.europa.eu/stoa/cms/home/about>

⁵⁵ Ibid.

⁵⁶ <http://www.europarl.europa.eu/stoa/cms/home/about>

⁵⁷ <http://epthinktank.eu/>

⁵⁸

<http://www.europarl.europa.eu/stoa/cms/cache/offonce/home/about;jsessionid=7FEBF4F8A4683DA3B4F5A255BED07823>

⁵⁹ <http://www.europarl.europa.eu/EPRS/EPRS-Impact-Assessment-European-Added-Value-presentation.pdf>

⁶⁰ Ibid.

⁶¹

<http://www.europarl.europa.eu/stoa/cms/cache/offonce/home/about;jsessionid=7FEBF4F8A4683DA3B4F5A255BED07823>

⁶² Ibid.

EU⁶³ - this section provides a more general description of the legal and policy landscape in the EU.

Ethics is an integral part of all research activities, from beginning to end, funded by the European Union, and ethical compliance is viewed as pivotal to the achievement of real research excellence.⁶⁴ Ethical research conduct implies the application of fundamental ethical principles - including the principle of proportionality, the right to privacy, the right to the protection of personal data and human health protection - and legislation to scientific research in all domains of research, including biomedical research, the natural sciences and the social sciences and humanities.⁶⁵

All activities carried out under the EU research funding programme Horizon 2020⁶⁶ must comply with ethical principles and relevant national, EU and international legislation, for example, the Charter of Fundamental Rights of the European Union⁶⁷ and the European Convention on Human Rights.⁶⁸ The Charter of Fundamental Rights of the European Union (2010/C 83/02)⁶⁹ sets out the rights, freedoms and principles of the citizens of the EU Member States. The core values of the Union are described as human dignity, freedom, equality and solidarity. The Charter contains several principles which are relevant in the context of research.⁷⁰ These principles form the basis of important ethical guidelines but also support the conduct of research.⁷¹ They include the right to the integrity of the person (Article 3), respect for private and family life (Article 7), protection of personal data (Article 8) and freedom of the arts and sciences (Article 13). Importantly, the incorporation of the Charter into the Lisbon Treaty in 2009 means that the Charter is fundamentally binding and has the same status as primary EU law.

The *European Convention on Human Rights* and the relevant case-law of the European Court of Human Rights, especially regarding Article 8 (Right to Respect for Private and Family Life)⁷² is also an important point of reference for ethics review.

Ethics in Horizon2020

Ethics is dealt with extensively in the Horizon 2020 legislation. Article 14 on Ethics review in the Horizon 2020 Rules for Participation⁷³ stipulates that the Commission shall systematically carry out ethics reviews for proposals raising ethical issues and make the process of the ethics review as transparent and efficient as possible. Article 19 on Ethical Principles of Horizon 2020 - Regulation of Establishment⁷⁴ stipulates the kinds of ethical principles that should be complied with in research activities, in addition to those areas of

⁶³ See <http://satoriproject.eu/media/SATORI-Deliverable-3.1-.pdf>

⁶⁴ http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

⁶⁵ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics>

⁶⁶ These requirements also apply to the Seventh Framework Programme. As Horizon2020 is the current funding programme, requirements are discussed in relation to this programme.

⁶⁷ http://www.europarl.europa.eu/charter/pdf/text_en.pdf

⁶⁸ http://www.echr.coe.int/Documents/Convention_ENG.pdf

⁶⁹ http://www.europarl.europa.eu/charter/pdf/text_en.pdf

⁷⁰ http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

⁷¹ Ibid.

⁷² http://www.echr.coe.int/Documents/Convention_ENG.pdf

⁷³ http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf#page=10

⁷⁴ http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf#page=11

research that should not be financed, e.g. research activity aimed at human cloning including both human reproductive cloning and the cloning of embryos for research purposes. Article 34 on Ethics of the Model Grant Agreement⁷⁵ sets out a number of conditions and issues including the obligation to comply with ethical principles, activities raising ethical issues, activities involving human embryos or human embryonic stem cells and the consequences of non-compliance.

The Ethics Appraisal Procedure in Horizon2020⁷⁶ concerns all activities funded in Horizon 2020 and includes the Ethics Review Procedure, conducted prior to the start of a project, in addition to Ethics Checks and Audits.⁷⁷ Applicants are required to conduct an Ethics Self-Assessment by completing an ethics issues table which sets out the most frequent ethical issues seen in the ethics review.⁷⁸

A scientific evaluation is carried out initially and all proposals above threshold and considered for funding will undergo an Ethics Review carried out by independent ethics experts working in a panel.⁷⁹ The Review begins with an Ethics Screening, and, if appropriate, a further analysis called the Ethics Assessment is carried out.⁸⁰ The Ethics Review can lead to ethics requirements that become contractual obligations.⁸¹ The Ethics Review Procedure centres on compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of research methods and applicants' awareness of the ethical aspects and social impact of the planned research.⁸²

The Ethics Sector at DG R&I has a standard pool of ethical experts who are identified and selected through a database – experts database – which is open and free for participation to all those who consider themselves capable of carrying out the task regarding the review or the evaluations.⁸³ A common database exists for both the scientific and ethics reviews. Experts are chosen from this database. In addition, experts are chosen from their own networks and people from the national ethics committees and research ethics committees are invited to register with this database - a selection is made from these sources. The Ethics Sector has a list of approximately 200 experts – the list is valid for a year, after which time they renew some of the people on the list. The ethics panels are composed of experts selected from this list. This list of experts is publicly available.

Policy for public engagement

The European Commission's 2001 communication "European governance - a white paper"⁸⁴ advanced the participation of citizens in the drafting and implementation of policies as a principle of good governance. Public engagement in policy-making in the European Commission is an important mechanism that aims to engender mutual understanding, co-

⁷⁵ http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf#page=70

⁷⁶ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics>

⁷⁷ Ibid.

⁷⁸ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics>

⁷⁹ <https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics>

⁸⁰ Ibid.

⁸¹ <https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics>

⁸² Ibid.

⁸³ This information was garnered in an interview with an ethics review expert from the European Commission.

⁸⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0428&qid=1434019836499&from=EN>

create research and innovation outcomes and provide input to policy agendas.⁸⁵ Policy for public engagement in Horizon2020 implies the establishment of participatory multi-actor dialogues and exchanges - including researchers, policy makers, industry and civil society organisations, NGOs and citizens - to foster mutual understanding, co-create research and innovation outcomes and provide input to policy agendas.⁸⁶ Public engagement is viewed as facilitating the creation of space for ethical, value-laden issues to be explored.⁸⁷ Public engagement in Horizon 2020 can be called for either directly by the European Commission to help feed its own policy agenda-setting processes or promoted through calls for proposals, so that it may be taken up by project consortia and other external actors.⁸⁸

Responsible Research and Innovation (RRI)

The concept of Responsible Research & Innovation (RRI) is supported in the H2020 regulation, namely in Article 14.1 (l) which mentions responsible research and innovation including gender as a cross-cutting issue⁸⁹ and in its Annex 1, Part V, which states that “The aim of the specific objective ‘Science and with for society’ is to build effective cooperation between science and society, to recruit new talent for science and to pair scientific excellence with social awareness and responsibility”.⁹⁰ Under the Science with and for Society objective, projects and actions will seek to promote RRI both on the level of the individual researcher or research project and more systematically on the level of institutions and their practices, in order to work towards broader and more lasting impact.⁹¹

Impact assessment

Before the European Commission proposes a new initiative, it assesses the need for EU action and the potential economic, social and environmental impacts of alternative policy options.⁹² The Commission does this by making use of impact assessments for initiatives that are anticipated to have significant impacts, including economic, environmental or social or impacts.⁹³ Initiatives include legislative proposals, non-legislative initiatives (white papers, action plans, financial programmes, negotiating guidelines for international agreements) that define future policies and implementing and delegated acts.⁹⁴ Impact assessment (IA) is a smart regulation tool that operates at the early stage of the policy cycle, when proposals are being developed.⁹⁵ IA “contributes to the quality of policy-making by ensuring that Commission initiatives and proposals for EU legislation are prepared for on the basis of transparent, comprehensive and balanced evidence on the nature of the problem to be addressed, the added value of EU action and the economic, social and environmental costs

⁸⁵ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=engagement>

⁸⁶ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=engagement>

⁸⁷ Ibid.

⁸⁸ <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=engagement>; A call topic may be specifically designed to solicit public engagement in research and innovation. Such a dedicated call may take on the form of either a Research and Innovation Action (RIA) or a Coordination Support Action (CSA).⁸⁸ One kind of CSA - a Mutual Learning Action Plan (MML) of which SATORI is one - is particularly suited towards fostering multi-actor and public engagement in research and innovation. Public engagement may also be plugged in to a much larger initiative such as a Joint Programming Initiative as a separate work package or sub-project.

⁸⁹ http://inea.ec.europa.eu/download/legal_framework/regulation_12912013_establishing_h2020.pdf

⁹⁰ Ibid.

⁹¹ <http://www.euroscientist.com/ec-implementing-rri-institutional-change/>

⁹² http://ec.europa.eu/smart-regulation/impact/index_en.htm

⁹³ Ibid.

⁹⁴ http://ec.europa.eu/smart-regulation/impact/index_en.htm

⁹⁵ http://ec.europa.eu/smart-regulation/impact/docs/iag_pc_questionnaire_en.pdf

and benefits of alternative courses of action for all stakeholders.”⁹⁶ An IA may lead the Commission to make substantial amendments to a legislative proposal, scale it down or even drop it altogether.⁹⁷ IA includes environmental impact assessment (EIA) and social impact assessment (SIA) as important sub-sets of assessment.⁹⁸ SIA is the most closely related type of impact assessment to ethical assessment as it concerns societal values.⁹⁹

3 PUBLIC RESEARCH AND INNOVATION SYSTEMS

This section centres on different organisations at EU level within the public research and innovation system and their roles in ethics assessment and ethics guidance.

3.1 EU-LEVEL RESEARCH ASSOCIATIONS AND STANDARD-SETTING BODIES

This section reviews some key EU-level research and university associations and associations of science academies that have a role in representing public R&I institutions and in coordinating their activities. It also looks at accreditation, certification and standard-setting organisations for publicly funded research. Each of these organisations engage in a variety of activities relevant to ethics assessment: e.g. providing advice, promoting ethical values and principles, developing ethical guidelines and best practice, networking and information sharing, and standard setting and quality assurance. Each organisation is further discussed below.

Euro-CASE

The European Council of Academies of Applied Sciences, Technologies and Engineering is an independent non-profit organisation of national academies of engineering, applied sciences and technology from 22 European countries.¹⁰⁰ Euro-CASE has issued *Guidelines on advising policy makers and society* applicable to itself, policy advisory bodies, its experts, and its clients.¹⁰¹

European Science Foundation (ESF)

The European Science Foundation currently has 66 Member Organisations from 29 European countries.¹⁰² It promotes the following values: excellence, openness, responsiveness, rising above national interests, and ethical awareness and human values.¹⁰³ The ESF’s *European Charter for Researchers and Code of Conduct for the Recruitment of Researchers* are best practice guidelines designed to promote equal rights and obligations for individual researchers throughout Europe by specifying the roles, responsibilities and entitlements of researchers, as well as those of funders and/or employers of researchers. The Scientific

⁹⁶ Ibid.

⁹⁷ <http://www.euractiv.com/sections/science-policymaking/when-science-meets-politics-eus-impact-assessment-review-307765>

⁹⁸ See SATORI D1.1 report (Annex 1.a). Conceptual cross-comparison of the ethical technology assessment and ethical impact assessment with the broader fields of technology assessment and impact assessment).

⁹⁹ Ibid.

¹⁰⁰ <http://www.euro-case.org/index.php/about-eurocase.html>

¹⁰¹ <http://www.euro-case.org/images/stories/pdf/position-paper/Euro-CASEguidelines2013.pdf>

¹⁰² <http://www.esf.org/esf-today/values.html>

¹⁰³ Ibid.

Review Group for the Biomedical Sciences (SRG-MED) covers (along with other fields) bioethics, clinical trials, open access and research involving animals.¹⁰⁴

European University Association (EUA)

The EUA representing universities in Europe, with 850 members across 47 countries represents universities' interests and lobbies on their behalf in the development and revision of European policies, programmes and funding instruments; formulates evidence-based policies, studies and reports - using information collected from members – as input to policy debates on crucial issues for universities; organises a wide range of mutual learning activities – including projects and events; keeps members informed about activities and European developments; and promotes global partnerships and EU visibility via dialogue, projects, and events. While the EUA does not offer its own set of guidelines regarding ethics, it does facilitate events and opportunities to be more specific about the sharing of best practices.¹⁰⁵ As part of the project *The Shape of Things to Come*, the EUA Council for Doctoral Education (EUA-CDE)¹⁰⁶ held a focus group meeting on research ethics in doctoral education on 20 March 2015 where managers of doctoral education discuss the issue of integrating the ethics dimension in the training of future researchers.¹⁰⁷ Research ethics will also be a major theme of the EUA-CDE Annual Meeting at the Technische Universität München in Munich, Germany on 18-19 June 2015.

European Academies' Science Advisory Council (EASAC)

EASAC was formed by the national science academies of the EU Member States to enable them to collaborate with each other in providing independent science advice to European policy-makers.¹⁰⁸ EASAC issued a statement on *The use of non-human primates in research* (2008)¹⁰⁹ which urges EU Institutions and Member States to recognise the case for the use of non-human primates in research, while ensuring their use is carefully regulated. EASAC also published a report on *Realising European potential in synthetic biology: scientific opportunities and good governance* (2010).¹¹⁰

All European Academies (ALLEA)

ALLEA, the federation of All European Academies, brings together 58 Academies in more than 40 countries from the Council of Europe region. Member Academies operate as learned societies, think tanks and research performing organisations.¹¹¹ ALLEA's mission includes: promoting the exchange of information and experiences between Academies; fostering excellence and high ethical standards in the conduct of research, as well as inter-, trans-, and multidisciplinary approaches in all scientific endeavours etc. The core of the scientific work of ALLEA is performed by the five Working Groups: Intellectual Property Rights, Science

¹⁰⁴<http://www.esf.org/hosting-experts/scientific-review-groups/biomedical-sciences-med/scientific-review-group-for-the-biomedical-sciences.html>

¹⁰⁵Insight from interview with a EUA representative.

¹⁰⁶ The EUA Council for Doctoral Education aims to contribute to the development, advancement and improvement of doctoral education and research training, in addition to internationalisation issues and the tracking of students and graduates.

¹⁰⁷ http://www.eua.be/News/15-04-09/Research_Ethics_in_Doctoral_Education.aspx

¹⁰⁸ <http://www.easac.eu/about-easac/what-is-easac.html>

¹⁰⁹ http://www.easac.eu/fileadmin/PDF_s/reports_statements/Use.pdf

¹¹⁰ http://www.easac.eu/fileadmin/PDF_s/reports_statements/Synthetic%20Biology%20report.pdf

¹¹¹ <http://www.allea.org/Pages/ALL/4/731.bGFuZz1FTkc.html>

and Ethics, Science Education, E Humanities (digital humanities) and Social Sciences and Humanities.¹¹² The Permanent Working Group on Science and Ethics (PWGSE) is concerned with a wide range of problems, 'internal' (within the scientific community) and 'external' (relations between science and society).¹¹³ The PWGSE thematic meetings address issues such as: scientific integrity and research misconduct, research on human embryos, quantitative evaluation of research, ethical aspects of risk, education in ethics. The ALLEA Standing Committee on Science and Ethics works with the European Science Foundation, European Union organisations dealing with scientific/research integrity, and on a national level, with government organisations, academies of science and universities. ALLEA's ethics-related publications include: ALLEA Statement on Education à l'éthique des sciences¹¹⁴, ALLEA Statement on Enhancement of Open Access to Scientific Publications in Europe¹¹⁵, ALLEA Statement on Ethics Education in Science¹¹⁶, and *The European Code of Conduct on Research Integrity*¹¹⁷.

Academia Europaea

Academia Europaea is a functioning European Academy of Humanities, Letters and Sciences, composed of individual members (currently 2,800),¹¹⁸ that seeks to promote a wider appreciation of the value of European scholarship and research and encourage interdisciplinary and international scholarship in all areas of learning relevant to Europe. Academia Europaea published a special issue on *Research 'Values' in the Humanities: Funding Policies, Evaluation and Cultural Resources* in January 2015.¹¹⁹ It issued a Joint Statement along with ALLEA, EASAC, Euro-Case and FEAM in support of European Directive 2010/63/EU on the protection of animals used for scientific purposes.

EURASHE

EURASHE is the European Association of Institutions in Higher Education that offer professionally-orientated programmes and is engaged in applied and profession-related research within the Bologna cycles.¹²⁰ Since 2001, EURASHE has been an official consultative partner to the Bologna Process¹²¹ and, in particular, a consultative member of the Bologna Follow-Up Group (BFUG) and member of the E4-Group, a partnership of European associations involved in quality assurance activities (ENQA, ESU, EUA and EURASHE). EURASHE is engaged in the development of policies on key issues for professional higher education in the areas linked to the Mission of Professional Higher Education, Quality of

¹¹² Ibid.

¹¹³ <http://www.allea.org/Pages/ALL/19/228.bGFuZz1FTkc.html>

¹¹⁴ http://www.allea.org/Content/ALLEA/2014_03_04-Statement_Ethics_Edu_french.pdf

¹¹⁵ http://www.allea.org/Content/ALLEA/Statement_ALLEA_Open_Access_2013-11.pdf

¹¹⁶ http://www.allea.org/Content/ALLEA/SC%20Science%20Ethics/Statement_Ethics_Edu_web_final.pdf

¹¹⁷

http://www.allea.org/Content/ALLEA/Scientific%20Integrity/A%20European%20Code%20of%20Conduct%20for%20Research%20Integrity_final.10.10.pdf

¹¹⁸ http://www.ae-info.org/ae/Acad_Main/About_us/What_are_we

¹¹⁹ http://www.ae-info.org/ae/Acad_Main/News/Special%20Issue%20Humanities

¹²⁰ <http://www.eurashe.eu/about/faq/>

¹²¹ The Bologna Process is a collective effort of public authorities, universities, teachers, and students, together with stakeholder associations, employers, quality assurance agencies, international organisations, and institutions, including the European Commission. http://ec.europa.eu/education/policy/higher-education/bologna-process_en.htm

Higher Education, Modernising of Professional Higher Education within a diversified Higher Education, and Research, Development and Innovation.

European Association for Quality Assurance in Higher Education (ENQA)

ENQA is an umbrella organisation which represents quality assurance organisations from the European Higher Education Area (EHEA) member states.¹²² ENQA promotes European co-operation in the field of quality assurance in higher education and disseminates information and expertise among its members and towards stakeholders in order to develop and share good practice and to foster the European dimension of quality assurance.¹²³ The *Standards and Guidelines for Quality Assurance in the European Higher Education Area* (ESG) were produced by ENQA, in co-operation and consultation with its member agencies, the E4 Group (ENQA, EUA, EURASHE and ESU)¹²⁴, BUSINESS EUROPE, Education International, and the European Quality Assurance Register for Higher Education (EQAR). These were adopted by the Ministers responsible for higher education in 2005.

3.2 RESEARCH FUNDING ORGANISATIONS

The following section offers a description of EU-level research funding organisations and a brief discussion of the role of ethics assessment in how these organisations determine how to spend their funding.

Research funding organisations at the EU level include the European Commission and the European Research Council. At European level, research funding organisations have established ethics requirements as conditions for research funding. In particular, the European Commission is keen to emphasise the importance of ethics throughout the whole research process.¹²⁵

The European Commission Framework Programmes

The Framework Programmes for Research and Technological Development, also called Framework Programmes, are funding programmes created by the European Union and European Commission to support and foster research in the European Research Area (ERA).¹²⁶

The Framework Programmes for Research have two main strategic objectives:¹²⁷

- to strengthen the scientific and technological base of European industry
- to encourage its international competitiveness, while promoting research that supports EU policies

¹²² <http://www.enqa.eu/?s=ethic>

¹²³ <http://www.enqa.eu/>

¹²⁴ The E4-Group is an informal cooperation between key stakeholders of higher education involved in matters of quality assurance.

¹²⁵ http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

¹²⁶ http://en.wikipedia.org/wiki/Framework_Programmes_for_Research_and_Technological_Development

¹²⁷ http://ec.europa.eu/research/fp7/understanding/fp7inbrief/what-is_en.html

The 7th Framework Programme for Research and Technological Development (FP7) was the European Union's research and innovation funding programme for 2007-2013.¹²⁸ Horizon 2020 is the follow-up programme to FP7 and is the largest EU Research and Innovation programme with nearly EUR 80 billion of funding available over 7 years (2014 to 2020).¹²⁹ As mentioned in the previous section, the Ethics Appraisal Procedure is used to assess and address the ethical dimension of activities funded under Horizon 2020.

The European Research Council

The European Research Council (ERC) was established in 2007 as the first pan-European organisation for funding research.¹³⁰ The ERC's mission is to encourage the highest quality research in Europe through competitive funding and to support investigator-driven frontier research across all fields, on the basis of scientific excellence.¹³¹ The ERC complements other funding activities in Europe such as those of the national research funding agencies.¹³² Moreover, the ERC is a flagship component of Horizon 2020.¹³³ All research activities in Horizon 2020 must respect fundamental ethical principles.¹³⁴ For this reason, ERC grants are subject to the Ethics Review mechanism (see section 2.3). The Standing Committee on Conflict of Interest, Scientific Misconduct and Ethical Issues (CoIME) is responsible for formulating guidelines on conflict of interest, fraud and ethical matters related to any aspect of the competences of the ERC, clarifying criteria and considering any particular instances or situations in which ethical concerns may arise.¹³⁵ The ERC strategy is based on the assumption that host institutions of ERC applicants and grant holders have primary responsibility for the detection of scientific misconduct and for the investigation and adjudication of any breaches of research integrity.¹³⁶ However, all concerns about potential scientific misconduct or suspected breaches of research integrity regarding an ERC applicant or project will be addressed by the ERC within the appropriate legal and procedural framework.¹³⁷

Science Europe

Science Europe is an association of European Research Funding Organisations (RFO) and Research Performing Organisations (RPO) established to promote their collective interests.¹³⁸ Science Europe works with other entities such as the European Universities, the European Academies, the European Scientific Intergovernmental Organisations and the European Commission in order to develop a coherent and inclusive ERA.¹³⁹ Science Europe's Working Group on Research Integrity focuses on three main areas, namely promoting research integrity, preventing misconduct and increasing transparency when investigating cases of

¹²⁸ http://ec.europa.eu/research/fp7/index_en.cfm

¹²⁹ <https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020>

¹³⁰ <http://erc.europa.eu/about-erc/history>

¹³¹ <http://erc.europa.eu/about-erc/mission>

¹³² Ibid.

¹³³ <http://erc.europa.eu/about-erc/mission>

¹³⁴ <http://erc.europa.eu/glossary/8/lettere>

¹³⁵ <http://erc.europa.eu/about-erc/organisation-and-working-groups/standing-committees/Conflict-of-Interests-Scientific-Misconduct-and-Ethical-Issues>

¹³⁶ http://erc.europa.eu/sites/default/files/document/file/ERC_Scientific_misconduct_strategy.pdf

¹³⁷ Ibid.

¹³⁸ <http://www.scienceurope.org/about-us/about-us-full/>

¹³⁹ Ibid.

misconduct.¹⁴⁰ The activities of the Working Group build on and advance previous work conducted in relevant initiatives such as the ESF-ALLEA Forum (2008-2010) and the resulting European Code of Conduct.¹⁴¹

4 PRIVATE RESEARCH AND INNOVATION SYSTEMS

The following section offers a general description of the private research and innovation system at EU level, namely research and innovation funded and developed by industry, with regard to major EU organisations that represent industry, government policies and initiatives to support ethics assessment in private industry and the role of EU industry associations in ethics assessment and guidance.

The *State of the Innovation Union* report, outlines that despite the deep economic recession, “research and innovation remains alive and well in Europe”.¹⁴² While it suggests that the “European economy is transforming into a knowledge-based Innovation Union”, “the path from ideas to market is still not a smooth one”, and “there is still much to be done both at the European and at the national level.”¹⁴³ This is the case for reform of research and innovation systems as well as for funding. The EU still lags behind major players such as the US, Japan and South Korea in terms of R&D investment relative to GDP. There are also large differences between EU Member States in funding and innovation performance”. It also reports:

Overall, European enterprises have slightly increased their investments in R&D as a share of GDP since 2008. They also expect to increase their investment in R&D globally by an annual average of 4% over the period 2012 – 2014. However, there are large differences between Member States and between industrial sectors and actors. Some countries are suffering cuts in R&D investment by the private sector, in particular by SMEs. Larger international corporations tend to increase their level of investment but not necessarily in their country of origin, confronting innovation leaders with the challenge of knowledge specialisation and cluster building on a global scale. As regards sectors, many countries have seen an increase in R&D intensity in more traditional medium-tech industries (metals, rubber and plastics, food products) and in growing markets that are influenced by societal challenges such as waste treatment and the need for clean energy and water.¹⁴⁴

¹⁴⁰ <http://www.scienceurope.org/policy/working-groups/Research-Integrity>

¹⁴¹ Ibid.

¹⁴² European Commission, Research and Innovation performance in EU Member States and Associated countries Innovation Union progress at country level, 2013. http://ec.europa.eu/research/innovation-union/pdf/state-of-the-union/2012/innovation_union_progress_at_country_level_2013.pdf

¹⁴³ Ibid.

¹⁴⁴ European Commission, Research and Innovation performance in EU Member States and Associated countries Innovation Union progress at country level, 2013. http://ec.europa.eu/research/innovation-union/pdf/state-of-the-union/2012/innovation_union_progress_at_country_level_2013.pdf

4.1 GENERAL STRUCTURE AND THE ROLE OF GOVERNMENT

This section addresses major EU organisations that represent industry, and government policies and initiatives to support CSR in private industry.

Major EU organisations that represent industry

The *2014 EU Industrial R&D Investment Scoreboard* (the Scoreboard) contains economic and financial data for the world's top 2500 companies ranked by their investments in research and development (R&D).¹⁴⁵ The Scoreboard suggests, “companies based in Germany, the top R&D investor, continued to increase R&D in 2013, at 5.8%, above the world (4.9%) and EU (2.5%) averages. Companies based in the UK showed also a significant increase of R&D (4.9%) and French companies, on the contrary, reduced R&D investment by 3.3%. The largest wealth creation efficiency (ratio of value-added to costs of employees and depreciation) is found in Pharmaceuticals and biotechnology, three times more ‘efficient’ than the Electronic & Electrical Equipment sector”.¹⁴⁶ The top eight sectors identified in the report are: aerospace and defence; automobiles and parts; chemicals; electronic and electrical equipment; industrial engineering; pharmaceuticals and biotechnology; software and computer services; and technology and hardware equipment.

Government policies and initiatives to support CSR in private industry

The European Commission “believes that CSR is important for the sustainability, competitiveness, and innovation of EU enterprises and the EU economy. It brings benefits for risk management, cost savings, access to capital, customer relationships, and human resource management”.¹⁴⁷ The Commission defines CSR as, “the responsibility of enterprises for their impact on society. CSR should be company led. Public authorities can play a supporting role through a smart mix of voluntary policy measures and, where necessary, complementary regulation”.¹⁴⁸ The Commission suggests companies can become socially responsible by “following the law and integrating social, environmental, ethical, consumer, and human rights concerns into their business strategy and operations”.¹⁴⁹ The Commission promotes CSR in the EU and encourages enterprises to adhere to international guidelines and principles. The EU’s policy is built on an agenda for action to support this approach.¹⁵⁰ The new EU CSR agenda (2015-2019) will move from compliance to innovation.

The Guidelines and Principles that the Commission’s CSR strategy is built upon include the United Nations Global Compact, the United Nations Guiding Principles on Business and Human Rights, ISO 26000 Guidance Standard on Social Responsibility, the International Labour Organization Tripartite Declaration of Principles concerning Multinational Enterprises on Social Policy, and the OECD Guidelines for Multinational Enterprises. The European Commission tracks national CSR policies in its CSR Compendium published in

¹⁴⁵ Hernández, Héctor, Alexander Tübke, Fernando Hervás, Antonio Vezzani, Mafii Dosso, Sara Amoroso, Nicola Grassano., *The 2014 EU Industrial R&D Investment Scoreboard*, European Commission. 2014. <http://iri.jrc.ec.europa.eu/scoreboard14.html>

¹⁴⁶ Ibid.

¹⁴⁷ European Commission, “Corporate social responsibility”. http://ec.europa.eu/growth/industry/corporate-social-responsibility/index_en.htm

¹⁴⁸ Ibid.

¹⁴⁹ http://ec.europa.eu/growth/industry/corporate-social-responsibility/index_en.htm

¹⁵⁰ http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm

2014¹⁵¹ and uses the European CSR awards to encourage responsible partnerships between businesses and non-business organisations. Additionally, it has published a *Recommendation on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations*.¹⁵²

Directive 2014/95/EU on disclosure of non-financial and diversity information by certain large undertakings and groups¹⁵³ requires companies concerned to disclose in their management report, information on policies, risks and outcomes as regards environmental matters, social and employee aspects, respect for human rights, anticorruption and bribery issues, and diversity in their board of directors. This will provide investors and other stakeholders with a more comprehensive picture of a company's performance. This Directive is relevant for the European Economic Area (EEA). The new rules will only apply to some large companies with more than 500 employees and includes listed companies as well as other public-interest entities, such as banks, insurance companies, and other companies that are so designated by Member States because of their activities, size or number of employees. The Directive entered into force on 6 December 2014. EU Member States have two years to transpose it into national legislation.

4.2 INDUSTRY ASSOCIATIONS & ACCREDITATION, CERTIFICATION & STANDARD SETTING ORGANISATIONS

This section discusses the role of industry associations that represent various types of R&D industries in the EU and their role in ethics assessment and guidance.

There are a large number and variety of associations representing various types of R&D industries at the EU level, for example:¹⁵⁴

- AeroSpace and Defence Industries Association of Europe (ASD), representing the aeronautics, space, defence and security industries in Europe¹⁵⁵
- Alliance for a competitive European industry (ACEI), representing 11 major European industry sector associations and BUSINESSEUROPE¹⁵⁶
- Bureau Européen des Unions de Consommateurs Fédération (BEUC), representing independent national consumer organisations from 31 European countries (EU, EEA and applicant countries)¹⁵⁷
- Eucomed, representing the medical technology industry in Europe¹⁵⁸
- European Chemical Industry Council (CEFIC), representing the European chemical industry¹⁵⁹
- European Council for Automotive R&D (EUCAR)¹⁶⁰

¹⁵¹ <http://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=7726&visible=1>

¹⁵² European Commission, Recommendation 2014/179/EU of 9 April 2014 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations, 09.04.2014.

¹⁵³ European Parliament and the Council, Directive 2014/95/EU of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups, *OJ L* 330, 15.11.2014, p. 1–9. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0095>

¹⁵⁴ This is not an exhaustive list.

¹⁵⁵ <http://www.asd-europe.org/>

¹⁵⁶ <http://www.business-europe.eu/Content/Default.asp?PageID=605>

¹⁵⁷ <http://www.beuc.org/>

¹⁵⁸ <http://www.eucomed.com/about-us>

¹⁵⁹ <http://www.cefic.org/>

- EuropaBio, the European Association for Bio-Industries¹⁶¹
- European Association of Remote Sensing Laboratories (EARSeL)¹⁶²
- European CRO Federation (EUCROF), representing the interests of EU clinical research organisations¹⁶³
- European Federation of Pharmaceutical Industries and Associations (EFPIA) representing the research-based pharmaceutical industry in Europe¹⁶⁴
- European Industrial Research Management Association (EIRMA)¹⁶⁵
- European trade association of Research and Technology Organisations (EARTO)¹⁶⁶

Role in the setting and enforcement or promotion of standards and practices w.r.t. ethics assessment and CSR

Industry associations help members comply with ethical and professional standards by developing codes of practice, guidelines etc. Eucomed, for instance, has developed a *Code of Ethical Business Practice*¹⁶⁷ and a *Procedural Framework* (grounded on the Code) based on principles of autonomy, proportionality, speed, due process, fairness and transparency. It provides consistent principles and enforcement structures for Europe, building on the existing processes at national level. The EFPIA *Code of Practice* lays down fundamental rules for members on the promotion of medicines to, and interactions, with healthcare professionals and recognises the importance of voluntary control of advertising medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.¹⁶⁸ The code is enforced at national level, through EFPIA member associations, which in some cases goes beyond existing laws and regulations.¹⁶⁹ ENCORDER has a *Sustainable Development Charter* setting out basic principles for good employment practices, contacts with the local community, transparency and ethical standards, amongst other things.¹⁷⁰

Associations develop specific strategies on relevant aspects, such as sustainable competitiveness.¹⁷¹ EUCROF has a working group on 'Clinical Trials Legislation' (WG CTL).¹⁷² Some organisations investigate, discuss and raise awareness about ethical issues among their members. For instance, BEUC investigates EU decisions and developments likely to affect consumers, with a special focus on eight areas identified as priorities by its members, namely, Financial Services, Food, Digital Rights, Consumer Rights, Sustainability, Safety, Health and Energy. It publishes position papers, factsheets, reports, brochures, EU

¹⁶⁰ <http://www.eucar.be/>

¹⁶¹ <http://www.europabio.org/>

¹⁶² <http://www.earsel.org>

¹⁶³ <http://www.eucrof.eu/>

¹⁶⁴ <http://www.efpia.eu/>

¹⁶⁵ <http://www.eirma.org/>

¹⁶⁶ <http://www.earto.eu/>

¹⁶⁷

http://www.eucomed.org/uploads/Modules/Publications/110504_eucomedcebp_broch_210x297mm_v20_pbp.pdf

¹⁶⁸ <http://www.efpia.eu/topics/building-trust/codes-of-practice>

¹⁶⁹ Ibid.

¹⁷⁰ <http://www.encord.org/?p=553#more-553>

¹⁷¹ http://www.eccredi.org/navigation/library_set.html

¹⁷² <http://www.eucrof.eu/index.php/eucrof/working-groups/119-list-of-working-group/28-clinical-trials-legislation>

Presidency Memos etc.¹⁷³ EFPIA partners in EU Research programmes, such as the IMI (Innovative Medicines Initiative), Europe's largest public-private partnerships.¹⁷⁴

5 PROFESSIONAL GROUPS AND ASSOCIATIONS IN THE R&I FIELDS

This section offers a description of associations of professionals in research and innovation, or in ethics assessment (and related fields) and their role in ethical assessment or guidance of R&I. The discussion centres on the role of these organisations in ethics assessment and in upholding ethical standards, in addition to their relation to national organisations. Representative associations for specific areas within the social sciences, humanities, engineering and life sciences are described here.

The European Federation of Psychologists' Associations is the leading federation of national psychology associations, providing a forum for European cooperation in a wide range of fields of academic training, psychology practice and research.¹⁷⁵ EFPA includes 36 member organisations representing approximately 300,000 psychologists, including practitioners, in addition to academic and research psychologists.¹⁷⁶ Member organisations in EFPA are concerned with promoting and improving psychology as a profession and as a discipline, with a particular focus on applied settings and on the training and research associated with such practice.¹⁷⁷ The EFPA has developed a Meta-Code of Ethics which provides guidance for the content of the ethical codes of its members associations.¹⁷⁸ The Meta-Code of Ethics stipulates that the ethical codes of member associations should be based upon the ethical principles specified therein.¹⁷⁹

The European Association of Archaeologists (EAA) is an association for professional archaeologists in Europe and beyond with over 11,000 members from 60 countries worldwide working in prehistory, classical, medieval and later archaeology.¹⁸⁰ In addition to promoting the development of archaeological research and the management and interpretation of European archaeological heritage, EAA works to promote proper ethical and scientific standards for archaeological work.¹⁸¹ The EAA Code of Practice aims to establish standards of conduct for members of the EAA to follow in fulfilling their responsibilities, both to the community and to their professional colleagues.¹⁸² The Code stipulates that members of the EAA must adhere to high standards of ethical and professional conduct in their work, and must refrain from conduct which could bring the profession into disrepute.¹⁸³

The European Federation of National Engineering Associations (FEANI) is a federation of professional engineers that brings together national engineering associations from 32 European countries and represents the interests of over 3.5 million engineers in Europe.¹⁸⁴ FEANI aims to develop a single voice for the engineering profession in Europe, to develop

¹⁷³ <http://www.beuc.org/about-beuc/who-we-are>

¹⁷⁴ <http://www.efpia.eu/our-work>

¹⁷⁵ <http://www.efpa.eu/about>

¹⁷⁶ Ibid.

¹⁷⁷ <http://www.efpa.eu/about>

¹⁷⁸ <http://ethics.efpa.eu/meta-code/>

¹⁷⁹ Ibid.

¹⁸⁰ <http://e-a-a.org/about.htm>

¹⁸¹ Ibid.

¹⁸² http://e-a-a.org/EAA_Code_of_Practice.pdf

¹⁸³ Ibid.

¹⁸⁴ <http://www.feani.org/site/index.php?id=8>

the professional identity of engineers and to strengthen the position, role and responsibility of engineers in society.¹⁸⁵ The 2006 FEANI position paper on Code of Conduct: Ethics and Conduct of Professional Engineers sets out a universal statement for the conduct of professional engineers in Europe.¹⁸⁶ This pan-European statement on engineering ethics and conduct is promoted as being best implemented through the codes issued by national engineering associations.¹⁸⁷ National codes reflect national circumstances and enable additional objectives to be added as required by national practice.¹⁸⁸

The European Molecular Biology Organization (EMBO) is an organisation of more than 1,700 leading life scientists.¹⁸⁹ EMBO aims to support talented researchers at all stages of their careers, stimulate the exchange of scientific information and to help create a stimulating European research environment. EMBO helps to shape science policy by seeking input and feedback from the community and closely following the trends in science in Europe.¹⁹⁰ EMBO established a Science Policy Programme in 2011 in order to investigate concerns emerging from advances in scientific research, with a focus on life sciences in Europe.¹⁹¹ The programme focuses on the governance of new technologies for advancing science and the implications of the use of new technologies for the public.¹⁹² Responsible conduct of research is one area of interest and EMBO is involved in work to understand the dimensions of the responsible conduct of research and to communicate this work to scientists.¹⁹³ Their work centres on the activities of scientists at the bench, issues of research integrity in the writing and publication of research results and the roles of scientists in society.¹⁹⁴

The European Association of Centres of Medical Ethics (EACME) is, an international research and communication network that aims to “promote research, education and consultation in the field of (bio)-medical ethics by way of exchange of information, support of students, teachers and researchers, and organisation of annual conferences”.¹⁹⁵ It seeks to “promote and reinforce debate on moral values and ethical theory in relation with health care practice, biomedical research and healthcare systems, from an individual, social and legal point of view” including the development of methods and concepts to implement ethical deliberation into daily medical and health care practice.¹⁹⁶ EACME endorses “the cooperation with other societies and associations in the field of bioethics, philosophy of medicine and social medicine, both at a national and international level, particularly in regard with ethical deliberation and policy-making”. EACME states it “focuses on the development of the debate

¹⁸⁵ Ibid.

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http://www.feani.org/site/index.php?eID=tx_nawsecured1&u=0&file=fileadmin/PDF_Documents/Position_papers/Position_Paper_Code_of_Conduct_Ethics_approved_GA_2006.pdf&t=1432694203&hash=c51ac342dac66c3fb6c6917134e8f335a6eb7b9a

¹⁸⁷ Ibid.

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http://www.feani.org/site/index.php?eID=tx_nawsecured1&u=0&file=fileadmin/PDF_Documents/Position_papers/Position_Paper_Code_of_Conduct_Ethics_approved_GA_2006.pdf&t=1432694203&hash=c51ac342dac66c3fb6c6917134e8f335a6eb7b9a

¹⁸⁹ <http://www.embo.org/about-embo>

¹⁹⁰ Ibid.

¹⁹¹ <http://www.embo.org/science-policy>

¹⁹² Ibid.

¹⁹³ <http://www.embo.org/science-policy>

¹⁹⁴ <http://www.embo.org/science-policy/responsible-conduct-of-research>

¹⁹⁵ <http://www.eacmeweb.com/uploads/files/Mission%20Statement%20EACME.pdf>

¹⁹⁶ Ibid.

in and institutional forms of (bio)-medical ethics especially in Eastern and Southern Europe”.¹⁹⁷

6 DISCUSSION¹⁹⁸

Ethics assessment and guidance of research and innovation takes place across both private and public research and innovation systems in the EU. Ethics review is well organised at European Commission (the ‘Commission’) level and is supported and enhanced by European research funding organisations. In addition, there are a variety of organisations at both the European Commission and European Parliament that carry out ethics assessment/guidance as part of their mandate, or encounter ethical issues in other kinds of assessment activities.

One ethics expert at the Commission offered their observations regarding ethics review and the role of the EU in ethics assessment. The expert noted that, while the quality of ethics review at the Commission is quite high, there is room for improvement, for example, in inviting the participation of non-governmental organisations and civil society organisations in the ethics review process. Moreover, there is also interest in having experienced researchers (primarily from the natural sciences, as the majority of proposals that go through ethics review derive from the natural sciences) participate in the Commission’s review panels. The expert also commented on the importance of ethics assessment at EU level in terms of having mechanisms to achieve what cannot be achieved at member state level. While most Member States have established ethics procedures that function well for biomedical research and other areas of research, the approach is not homogeneous. Moreover, ethics procedures are not in place in all member states. For this reason, it is necessary to have ethics panels at European level. In addition, there are issues that still require in-depth analysis and approval at European level, for example, human embryonic stem cell research. However, for all other areas of research, if the ethics structures are in place, it will only be necessary for the Commission to verify that the structure works, as opposed to verifying individual research projects. The respondent feels that this will be possible but it will take time, given the need for choices to be made at institutional level and for priorities to be made.

Specific laws and policy mechanisms set a solid base for ethics assessment of R&I, public engagement activities, RRI, and related activities such as impact assessment. The incorporation of the European Charter of Fundamental Rights into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights at EU level and the work of advisory bodies such as the EGE, in particular. Ethical expertise at EU level is an important input to evidence-based decision-making. However, one expert involved in the area was keen to emphasise that decisions made by politicians are guided by many different, conflicting issues and not only ethics. Thus while their decisions may be ethical, recommendations issued by various expert groups may not be taken up. Indeed, political requirements may modify their decisions and needs and “should” do so, according to the respondent.

EU-level research associations, standard-setting bodies, industry organisations and professional groups and associations in the R&I field have an important role to play in developing policies and issuing guidelines and best practices. Moreover, collaboration between national and European branches of these organisations appears to be strong. For

¹⁹⁷ <http://www.eacmeweb.com/uploads/files/Mission%20Statement%20EACME.pdf>

¹⁹⁸ This section includes insights from interviewees interviewed for SATORI.

example, the British Psychological Society interacts with the European Federation of Psychologists' Association (EFPA), particularly with regard to the EFPA's Meta Code of Ethics.

Private research and innovation systems and actors also have a key role in contributing to the ethics assessment sphere, primarily through CSR initiatives and mechanisms. Interviews with EU level industry respondents offered some insights into CSR in Europe. CSR has different meanings and permutations across sectors and industries. CSR is viewed by companies as creating value, enabling organisations to go beyond legal compliance, as a philanthropy tool (collaboration in social initiatives), and as a means of improving quality of life through the promotion of social technology.