# Ethics Assessment in Different Countries

## Germany

*Saskia K. Nagel, Michael Nagenborg, Wessel Reijers - University of Twente*

*Rok Benčin, Gregor Strle, Boštjan Nedoh - Scientific Research Centre of the Slovenian Academy of Sciences and Arts (ZRC SAZU)*

June 2015

**Annex 4.e**
**Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries**
***Deliverable 1.1***

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI* - which received funding from the European Commission's Seventh Framework Programme *(FP7/2007-2013)* under grant agreement n° 612231

**Contents**

# 1 Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation in Germany, both for the public and private sector. We will analyse how national and regional governments have put into place organisational structures, laws, policies and procedures for ethical assessment, how both publicly funded and private research and innovation systems address ethical issues in research and innovation, and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs).

Firstly, we will provide some basic information about Germany and the historical development of ethics assessment institutions in the country. Germany is a federal state comprising 16 regional states (a German state is called *Land*), situated on the North European Plain (with the neighbouring countries Austria, Belgium, Czech Republic, Denmark, France, Luxembourg, the Netherlands, Poland and Switzerland). It is one of the larger European states and is the second-most populated (after Russia) with approximately 81 million inhabitants, as of 2014. Germany's capital city is Berlin, the main seat of the federal government; other major cities are Hamburg, Munich and Cologne. The only official language is German, and the major ethnic groups are Germans (91,5%) and Turks (2,4%). Germany is a predominantly Christian country, with equal shares of people of Protestant and Catholic denominations (both 34%), a relatively small share of Muslims (3,7%) and 28,3% being of other denominations or unaffiliated to a religion[1]. Germany is a decentralised, federal, parliamentary state with a strong judicial review (Germany has a constitutional court) and a multi-party, consensus democracy[2].

Germany has a highly developed economy, backed up by a highly skilled labour force, and plays a major economical role at the European and global level. Its economy ranks as the fifth largest in the world and the largest one in Europe. Its gross domestic product is € 2,9 trillion (in 2014), its GDP per capita is € 35.200 (in 2014). Germany's economy strongly relies on export; it is one of the leading exporting countries of machinery, vehicles, chemicals, and household equipment. With regards to the gross domestic expenditure on research and development (GERD), 66,531 billion Euros have been spent in Germany in total in 2011. The biggest financing and performing sector of R&D is the German business and industry sector. Below, an overview is given of the shares of different sectors in both financing and performance of R&D[3].

[1] Central Intelligence Agency, "The World Factbook 2013-14." Washington D.C., 2013. https://www.cia.gov/library/publications/resources/the-world-factbook/index.html
[2] Lijphart, A., *Patterns of democracy*, Yale University Press, New Haven, 1999.
[3] OECD MSTI database, 2011 figures. https://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB

| Industry | Government | Other national sources | Sources abroad |
|---|---|---|---|
| 65,63 | 29,83 | 0,35 | 4,18 |

**Table 1: A breakdown of the GERD, in percentages, by financing sector in 2011**

| Business enterprise | Higher education | Government | Non-profit |
|---|---|---|---|
| 67,65 | 17,81 | 14,54 | n/a |

**Table 2: A breakdown of the GERD, in percentages, by performing sector in 2011**

The practice of ethics assessment in Germany is organised at different levels of government (federal and regional) and is partly decentralised; medical research projects e.g. financed by the *Deutsche Forschungsgemeinschaft*, must be assessed by the legally competent RECs. Some areas of research, especially medical research and research involving human subjects are extensively legally regulated. The regional governments of the German Länder have their own legal provisions for ethics assessment of research and innovation and establish regional ethics committees. Important players in the German research culture are the non-university research institutes that fund a great portion of public research and innovation. The German Research Foundation (*Deutsche Forschungsgemeinschaft*, DFG) is the main standard-setting body for public research in Germany. German policies and initiatives to support ethics practices in private industry do not aim at ethics assessment strictly but mostly concern *corporate social responsibility* (*CSR*) as an element of *sustainable development*. Standard setting in German industry is mostly organised through network organisations. CSOs in Germany do not influence decision making in the area of ethics assessment, though they do actively shape the public discussion; notably on issues concerning bioethics.

Germany has a relatively long history in development and implementation of ethics assessment. Already in 1900, the Prussian Ministry for Religious, Educational, and Medical Affairs was the first known law requiring that medical experiments be done only with "informed consent" of a patient. Following the World Medical Association Declaration of Helsinki for Ethical Principles for Medical Research Involving Human Subjects in 1964[4], the first research committees were established in the 1970s[5]. As with most countries in which ethics assessment became an established practice, a significant share of the developments in Germany happened in the fields of medical and environmental ethics. The German Medical Products Acts (1976) and the Animal Protection Act (1972) laid the basis for the inclusion of ethical standard for clinical trials with human subjects or animals. Following EU legislation stipulated in the 1980s, the Environmental Impact Assessment Act (1990) was implemented. More recently, ethical issues concerning genetics and embryonic stem cell research have been strictly regulated, and a national ethics council (*Deutscher Ethikrat*) was installed in 2007 to

[4] http://www.wma.net/en/30publications/10policies/b3/17c.pdf
[5] Vollmann, J., *Healthcare Ethics Committees in Germany: The Path Ahead,* H E C Forum, 2001, p.255.

propose topics for ethical consideration[6]. During the last decades, ethics assessment practices have extended from medical and environmental issues to issues of data protection and governmental CSR strategies such as "CSR in Germany[7]" that was adopted in 2010.

In this country report, we provide an overview of the existing organisations and structures that govern the ethics assessment of research and innovation in Germany. Firstly, we will provide an overview of national government institutions and national policies on ethics assessment of R&I. Secondly, we will discuss the ways public research is conducted and national innovation systems are organised. Fourthly, we will provide a similar analysis for private research and innovation systems, and fifthly we will provide an overview of professional groups and associations as well as CSOs that are involved in ethics assessment of R&I.

# 2 National government institutions and policies

This chapter will provide a discussion of German federal government institutions and policies relating to research and innovation. The following will be examined: the general institutional structure of the German federal government and government-controlled institutions; governmental institutions with a role in ethics assessment; and national laws and policies for ethics assessment. Moreover, we will shortly discuss regional structures for ethics assessment in Germany.

## 2.1 Institutional Structure of government

In this section, we will provide an overview of the structure of the German federal government and government controlled institutions that relate to research and innovation. Firstly, we will provide an overview of the form of government, followed by a discussion on the relation between the executive, legislative and judicial branches and an overview of the major ministries and government organisations. Secondly, we will discuss the role of the German federal government in research and innovation in the public and private sectors.

### 2.1.1 General structure of the German government

Germany is a federal, decentralised state, which implies a strong separation of powers and functions between the national, federal government (the *Bund*) and the regional states (the *Länder*, 16 in total). This also means that both levels of governance have their own executive, legislative and judiciary branches; although a typical imbalance exists in Germany as the legislative branch is primarily placed at the federal level and the administrative branch is mostly situated at the regional levels[8]. Because of the federal structure of government, Germany has a bicameral system that consists of the Bundesrat with 69 delegates of the

[6] The *Deutsche Ethikrat* follows the *Nationale Ethikrat*, which was active from 2001 to 2007, with a new name and a changed legal basis, the *Gesetz zur Einrichtung des Deutschen Ethikrats* (EthRG, 01.08.07).
[7] https://www.csr-in-deutschland.de/en.html
[8] Schneider, H., *The federal republic of Germany*, Forum of Federations, 2008.

Länder that are appointed by the regional governments and the Bundestag, the lower house that consist of 631 nationally elected parliamentarians.

Both chambers are represented in the Federal Convention, which is a body endowed with the task of electing a federal president. The main executive power lies with the Chancellor of Germany, who is elected by an absolute majority in the first 2 voting steps of members of the Bundestag and appointed by the president. The chancellor is the head of the Federal Cabinet, consisting of an undefined number of ministers (under the current government of Chancellor Angela Merkel, Germany has 15 ministers[9]).

Germany has a powerful federal constitutional court (established in 1951) and furthermore has regional courts for Penal Law, Civil Law, Administration Law, Labour Law. The Länder have a system with a hierarchy of courts[10]. The judiciary power is vested in the professional judges of these courts. The German constitution can only be altered by a two-thirds majority of both the Bundesrat and the Bundestag. However, a legal provision conditions such alterations by a-priori rejecting any restriction on the essential contents of a basic right[11].

### 2.1.2 Government organisations relevant to research and innovation

With regards to governmental structures for research and innovation, different organisations are responsible for both horizontal and vertical processes of governance. We will discuss the governance at the regional level in section 2.4 of this country study. On the federal level, the main legislative body that is involved in research and innovation, which "deliberates on items such as draft laws, motions and briefings referred to it by the plenary"[12] is the Committee on Education, Research and Technology Assessment. This committee focuses on creating recommendation documents for the parliament.

The three main executive bodies at the federal level are the Federal Ministry for Education and Research, the Federal Ministry of Economics and Technology and the Federal Ministry of Health. The main activities of the first include the creation and implementation of policies in the context of research and funding and supporting public research as well as R&D projects at public or private research institutions. For example, the Federal Ministry for Education and Research since 1997 programmatically funds research on ethical, legal, and social aspects of the life science. The main activities of the Federal Ministry of Economics and Technology are promotion of cooperation between organisations in the field of research and innovation. Moreover, it is responsible for certain institutes for research and innovation, which are federal services (e.g. National Metrology institute). The responsibility for drug research and research on medicinal devices – about 53% of all medical research projects lies with the Federal Ministry of Health. Some other ministries are also involved in R&I, though generally only in specific aspects of it (e.g. the ministry of finance setting the budgetary working conditions).

---

[9] http://www.bundesregierung.de/Webs/Breg/EN/FederalGovernment/Cabinet/_node.html
[10] Böttcher, H., *The Role of the Judiciary in Germany,* Legal Culture, 2001.
[11] Sweet, A. S., "Constitutional Courts and Parliamentary Democracy", *West European Politics*, 25 (1), 2002, pp. 77–100 [p. 91].
[12] Braun, M., "Country Profile : Germany," *Private Sector Interaction in the Decision Making Processes of Public Research Policies*, 2010, pp. 1–16.

Both at the federal and at the regional levels of government, joint commissions coordinate the drafting and implementation of new policies. Generally, common policy issues on R&I are discussed by the Commission for educational planning and research promotion. Another joint body is the Standing conference of the ministers of education and cultural affairs of the Länder in the Federal Republic of Germany, which unites all the regional ministers in the fields of education and culture.

## 2.2 Governmental institutions for ethics assessment

In this section, we will describe national governmental and government-funded/controlled organs and institutions, and their role in ethics assessment. Federal governmental institutions, most notably the German Ethics Council, provide recommendations on ethical issues and legislation. Several governmental and parliamentary agencies, councils and commissions study environmental and societal impacts of R&I. Established and/or funded by the government, most of the institutions listed below are declared as independent advisory bodies.

### 2.2.1 Advisory councils for government policy:

- **German Ethics Council** (*Deutscher Ethikrat*). The German Ethics Council was established in 2007. Its 26 members are appointed for a four-year term by the president of the German Bundestag on the proposals of the Bundestag and the Federal Government. Members are experts with scientific, medical, theological, ethical, social, economic and legal backgrounds representing a wide spectrum of opinion. The mandate of the Council is to "pursue the questions of ethics, society, science, medicine and law and the probable consequences for individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity".[13] Among its most important duties are: "informing the public and encouraging discussion in society, engaging the various social groups"; "preparing opinions and recommendations for political and legislative action".[14]
- **The German Reference Centre for Ethics in the Life Sciences** (*Das Deutsche Referenzzentrum für Ethik in den Biowissenschaften* - DRZE). The DRZE is a national documentation and information centre on ethics in biomedicine. The DRZE's mission is "collecting, presenting, and providing information of the different scientific areas that matter to the various current debates concerning bioethics in science, society, and politics".[15]
- The **German Bundestag** establishes "**study commissions**" (*Enquete-Kommissionen*) on the request of its members "for the preparation of decisions on wide-ranging and significant issues".[16] Composed of parliamentarians and external experts, such commissions as "Law and Ethics in Modern Medicine" (1999-2001 and 2003-2005) have been established in the past.

[13] http://www.ethikrat.org/about-us/our-mandate.
[14] Ibid.
[15] http://www.drze.de/about-us.
[16] https://www.bundestag.de/htdocs_e/bundestag/bodies/study.

- **The Council of Science and Humanities** (*Wissenschaftsrat*). It advises the government on the development of science and higher education systems.[17]

### 2.2.2 Technology assessment agencies:

- **The Office of Technology Assessment at the German Bundestag** (*Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag* - TAB). TAB is an independent institution offering advice on research and technology to the Bundestag, based on scientific assessments of technologies' impacts, considering its opportunities and risks.[18]
- **Nano Action Plan** (*Nano-Aktionsplan*). This long-term government project (2006-2015) aims to assess risks and opportunities of nanotechnology through wide stakeholder dialogue.[19]

### 2.2.3 Environmental and social impact assessment agencies:

- **Ethics Commission "Secure Energy Supply"** (*Ethikkommission Sichere Energieversorgung*). The government founded the Commission in 2011 to establish a wide stakeholder discussion on the risks of nuclear power and transition to renewable energies.[20]
- **The Federal Environment Agency** (*Umweltbundesamt* - UBA). The UBA assesses environmental risks and provides governmental bodies with policy support on environmental issues and regulations.[21]
- **Federal Agency for Nature Conservation** (*Bundesamt für Naturschutz* - BfN). The BfN provides scientific advice to the government on environmental issues.
- **The German Advisory Council on the Environment** (*Sachverständigenrat für Umweltfragen* - SRU). The SRU is an "expert advisory body whose mission is to describe and assess environmental conditions, problems, and political trends and to point out solutions and preventive measures".[22]
- **German Advisory Council on Global Change** (Wissenschaftliche Beirat der Bundesregierung Globale Umweltveränderungen - WBGU). The WBGU analyses global environment and development problems and reviews and evaluates research in the field of global change.[23]
- **The German Council for Sustainable Development** (*Rat für Nachhaltige Entwicklung*). The Council's mission is to advise the government on its sustainable development policy and to foster social dialogue on the issue of sustainability.[24]

---

[17] http://www.wissenschaftsrat.de/en/about/function.html.
[18] http://www.tab-beim-bundestag.de/en/about-tab/tasks-and-goals.html.
[19] http://www.bmub.bund.de/en/topics/health-chemical-safety-nanotechnology/nanotechnology/the-nanodialogue/.
[20] http://www.bundesregierung.de/Content/DE/Lexikon/StichworteAZ/E/ethikkommission.html.
[21] https://www.umweltbundesamt.de/.
[22] http://www.umweltrat.de/EN/TheGermanAdvisoryCouncilOnTheEnvironment/Council/mission_node.html.
[23] http://www.wbgu.de/en/about-us/mission/.
[24] http://www.nachhaltigkeitsrat.de/en/the-council/.

### 2.2.4 Watchdog agencies[25]:

- **The Robert Koch Institute** – The Public Health Institute for Germany. The institute serves the government as a central scientific institution in the field of biomedicine, combining risk research with political advice.[26] Its activities include dual use risk assessments in life sciences. Within the institute, *Central Ethics Committee for Stem Cell Research* reviews and evaluates applications for import and use of human stem cells.[27]
- **The Paul Ehrlich Institute (**Paul-Ehrlich-Institut – Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, PEI**)**. The PEI is as a federal agency a subordinate to the Federal Ministry of Health and a medical regulatory body. It is the German federal institute for vaccines and biomedicines. It is a WHO Collaborating Centre for quality assurance of blood products and in vitro diagnostic devices.
- **The Federal Institute for Risk Assessment** (*Bundesinstitut für Risikobewertung* - BfR). The BfR is a federal scientific agency, responsible for expert reports on food, products and substances safety.[28]
- **The Federal Office of Consumer Protection and Food Safety** (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* - BVL). The BVL detects and manages risks related to consumer safety (food, products, genetic engineering) by relying on scientific knowledge.[29]
- **Federal Commissioner for Data Protection and Freedom of Information** (*Bundesbeauftragter für den Datenschutz und die Informationsfreiheit* - BfDI). The BfDI independently monitors data processing in public authorities (and private companies) and advises on data protection issues; it is not strictly entitled to ethics assessment but gives advice and develops reviews.[30]

## 2.3 National laws and policies for ethics assessment

This section provides an overview of major German federal laws, policies and regulations on ethics assessment and related activities. Both the legal framework and organisational policies—in the form of codes of conduct or protocols—will be discussed.

### 2.3.1 Legal provisions for ethics assessment

The main legal provision on research and innovation in Germany is in article 5 of the German Basic Law (*Grundgesetz* - the constitution, which consists of constitutional laws, stating, "arts and sciences, research and teaching shall be free"[31]. Hence, the main principle with regards to

---

[25] The following institutions are more authorities by their character.

[26] http://www.rki.de/EN/Content/Institute/Profile/.
[27] http://www.rki.de/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell-content.html.
[28] http://www.bfr.bund.de/en/the_federal_institute_for_risk_assessment__bfr_-572.html.
[29]http://www.bvl.bund.de/EN/07_TheFederalOffice/02_Duties/01_Range_of_duties/Range_of_duties_node.html
[30] http://www.bfdi.bund.de/DE/BfDI/Artikel_BFDI/AufgabenBFDI.html.
[31] Basic Law for the Federal Republic of Germany (Grundgesetz für die Bundesrepublik Deutschland), 23.05.1949. English:
http://www.gesetze-im-internet.de/englisch_gg/basic_law_for_the_federal_republic_of_germany.pdf;

academic science and education is one of scientific freedom that is framed by the rights safeguarded by the constitution and that allows researchers to enjoy a considerable level of autonomy regarding the contents of their research.

At the level of federal law, legislation regulates the performance of research, both relating to the use of human subjects and animals. The Medicinal Products Act[32] and the Medical Devices Act[33] regulate research on human subjects. The Medicinal Products Act and Medical Devices Act stipulate that research involving clinical trials of medicinal products or medical devices need to be submitted to a review of a competent ethics committee (which is asked to issue a favourable opinion) and to the competent Federal Authority for an approval. The ethics committee in question functions on the basis of States law (*Landesrecht*), which guaranties its independence, its multidisciplinary composition and requires bylaws to be approved by the States government. Research involving animal experiments needs to be subjected to a consultation by competent authorities on the regional state level of a committee on animal experimentation; according to the Animal Protection Act[34].

The major legal provisions for legislation on impact assessment are laid down in the Environmental Impact Assessment Act[35], which is mainly a transposition of European Directives on the regulation of environmental impact. An area of research that is considerably regulated is any kind of research involving the use of embryonic stem cells (regulated by the German Stem Cell Act[36]) or the use of genetic testing (regulated by the Genetic Diagnosis Act[37]). The Federal Data Protection Act regulates the use of personal data in research.[38] As to research integrity, provisions are laid down in criminal law (in the German criminal code[39]) and in the German Act on Copyright and Related Rights[40].

---

German: http://www.gesetze-im-internet.de/bundesrecht/gg/gesamt.pdf

[32] Medicinal Products Act (*Gesetz über den Verkehr mit Arzneimitteln*), 24.08.1976. English: http://www.gesetze-im-internet.de/englisch_amg/medicinal_products_act.pdf
German: http://www.gesetze-im-internet.de/bundesrecht/amg_1976/gesamt.pdf

[33] Medical Devices Act (*Gesetz über Medizinprodukte*), 02.08.1994, Unofficial English translation: http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze_und_Verordnungen/GuV/M/MPG_englisch.pdf

[34] Animal Protection Act (Tierschutzgesetz), 24.07.1972. http://www.gesetze-im-internet.de/bundesrecht/tierschg/gesamt.pdf

[35] Environmental Impact Assessment Act (*Gesetz über die Umweltverträglichkeitsprüfung*), 12.02.1990. http://www.gesetze-im-internet.de/bundesrecht/uvpg/gesamt.pdf

[36] Stem Cell Act (*Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen*), 28.06.2002. http://www.gesetze-im-internet.de/bundesrecht/stzg/gesamt.pdf

[37] Genetic Diagnosis Act (*Gesetz über genetische Untersuchungen bei Menschen*), 31.07.2009. http://www.gesetze-im-internet.de/bundesrecht/gendg/gesamt.pdf

[38] Data Protection Act (*Bundesdatenschutzgesetz*), 20.12.1990. English: http://www.gesetze-im-internet.de/englisch_bdsg/federal_data_protection_act.pdf; German: http://www.gesetze-im-internet.de/bundesrecht/bdsg_1990/gesamt.pdf

[39] German Criminal Code (*Strafgesetzbuch*), 15.05.1871. English: http://www.gesetze-im-internet.de/englisch_stgb/index.html. German: http://www.gesetze-im-internet.de/bundesrecht/stgb/gesamt.pdf

[40] Act on Copyright and Related Rights (*Gesetz über Urheberrecht und verwandte Schutzrechte*), 09.09.1965. http://www.gesetze-im-internet.de/bundesrecht/urhg/gesamt.pdf

### 2.3.2 Policy provisions for ethics assessment

Next to research and innovation that has been strictly regulated by means of federal law, further policy provisions and soft law instruments exist that impact research practices in Germany. The most important soft law regulations in the form of codes of conduct have been based on the recommendations issued by the German Research Foundation (*Deutsche Forschungsgemeinschaft*; DFG) in 1998[41]. These recommendations lay down principles for scientific practice (e.g. proper documentation, a critical attitude towards one's own findings) as well as recommended organisational structures. Professional organisations and universities across Germany have implemented the policy recommendations of the DFG.

Apart from the recommendations issued by the DFG, some policies exist that are field-specific. An important code of conduct in this respect is the Code of Deontology for the German Medical Profession drafted by the German Medical Assembly[42] that is part of the Central Committee for the Protection of Ethical Principles in Medicine, attached to the Federal Medical Association, as advisory board. The German Medical Assembly is only entitled to accept a proposal for the Code of Deontology. The Code of Deontology becomes legally binding by decision of the Medical Associations in the States (*Landesärztekammern*) and by approval of the States government.

The German Ethics Council drafts soft-law regulations for the specific issue of dual-use (the issued opinion "Biosecurity – Freedom and Responsibility of Research"[43]) and a collaborative drafting by the DFG and the National Academy of Sciences Leopoldina ("Scientific freedom and scientific responsibility; Recommendations for handing security-relevant research"[44]). Next to the soft law and regulative policies, a substantial part of the ethics assessment is organised at the regional state level and at the level of research institutes. We will discuss this in the next section.

## 2.4 German regional institutions and policies

While Germany is a federal state, a considerable share of the ethics assessment of research and innovation is organised and implemented at the regional level. For this reason, we will briefly focus on the specific institutional structure of the German regional states, its Länder, and the laws and policies that are formulated on this level of governance.

---

[41] DFG, *Sicherung guter wissenschaftlicher Praxis*. Wiley VCH Verlag, Denkschrift, 2013. doi:10.1002/9783527679188

[42] For more information: http://www.bundesaerztekammer.de/page.asp?his=4.3569

[43] German Ethics Council (Deutsche Ethikrat), *Biosecurity – Freedom and Responsibility of Research*, 2014. http://www.ethikrat.org/files/opinion-biosecurity.pdf

[44] German Research Foundation (*Deutsche Forschungsgemeinschaft*), Academy of Sciences Leopoldina (Nationale Akademie der Wissenscahften Leopoldina), *Scientific Freedom and Scientific Responsibility. Recommendations for Handling Security-Relevant Research,* 2014. http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf

### 2.4.1 Organisations and institutions of the Länder

Structurally, significant differences can be identified between the federal government in Germany and the regional states as well as between the regional states amongst each other. First of all, the legislature at the regional level is more flexible than at the federal level, with all Länder showing opportunities of *direct democracy* (explicated by Lijphart as an indicator of the opportunity of constitutional change)[45]. Politically, the German Länder are fairly heterogeneous, with some states such as Bavaria showing strong features of majoritarian political structures and decentralisation while states such as Berlin show features of a consensus and centralised political system. A shared feature of the Länder vis-à-vis the federal government is that both levels enjoy territorial autonomy (having fixed borders) and government autonomy (by having their own constitutions)[46]

Within the Länder the governance level of the communes is included (municipalities and districts), which are to be seen as an integral part of the regional structure rather than as a third level of governance[47]. While the local legislation is dealt with at the regional level, the communes do have a mandate for self-administration and a democratically chosen representative body.

With regards to regional state legislation, the principle in Germany is that unless basic law states differently, state functions ought to be integrated in regional laws and policies. A difference exists between exclusive responsibilities of the federal government, the concurrent responsibilities that are shared with the federal government and the competences of the Länder[48]. Some important responsibilities of the regional states are public welfare, economic affairs, social security, education, cultural affairs, technology and environmental law. Some Länder have their own research and innovations programs that often reflect the regionally dominant sectors and target groups such as the "LOEWE" program in Hesse[49] and the *Elitenetzwerk* in Bavaria[50].

### 2.4.2 Regional laws and policies on ethics assessment of R&I

A substantial part of the legislation and administration of the ethics assessment of research and innovation is dealt with at the regional state level. First of all, the Länder initiate regulations in the field of education, for example in the form of university laws. Secondly, the Federal Medicinal Products Act and the Act on Medical Device explicate that the ethics committees are asked to give their favourable opinion on that research that involves human clinical drug trials are to be responsible under Landesrecht[51].

---

[45] Freitag, M., & A. Vatter, "Patterns of democracy: A sub-national analysis of the German Länder", *Acta Politica,* 44, 2009, pp. 410–438.
[46] Schneider, H., *The federal republic of Germany,* Forum of Federations, 2008.
[47] Ibid. p.4
[48] Schneider, op. cit., 2008, p.6.
[49] https://www.cased.de/en/about/loewe.html
[50] https://www.elitenetzwerk.bayern.de/elitenetzwerk-home/elitenetzwerk-home/
[51] Medicinal Products Act (*Gesetz über den Verkehr mit Arzneimitteln*), 24.08.1976. English: http://www.gesetze-im-internet.de/englisch_amg/medicinal_products_act.pdf; German: http://www.gesetze-im-internet.de/bundesrecht/amg_1976/gesamt.pdf

The creation of ethics committees in the states is done by means of the stipulation of States legislation (for example as is the case with "the Act on the Establishment of the Ethics Committee of the State of Berlin"[52]). Such regional state legislation stipulates the scope of the committee (e.g. which kinds of trials have to be assessed and the procedures to be followed. Moreover, the Länder are responsible for the consultation of Committees on Animal Experiments in the case animal trials are involved in a research. Regarding data protection, bio bank regulations are largely left to the Länder as well (e.g. in some of them private data cannot be exchanged between hospitals, in some of them it can).

A further note on RECs: RECS have been established in Germany since the early seventies by Faculties of Medicine or Universities, by the Medical Associations, and by the States of Berlin, Bremen, and Sachsen-Anhalt. The latter 3 RECs are only competent for research on medicinal products and medical devices, whereas all other RECs are competent for all kind of biomedical research (see section 3.4). The above-mentioned RECs function, as far as a research on drugs or medical devices is considered, on the basis of States law.

Research on medical products and medicinal devices constitutes only about 53% of biomedical research in Germany. Only for this kind of research the decision of a REC is legally binding. All other research has also to be assessed by RECs, which are established on States law (see above). The researcher is obliged to seek the opinion of these RECs by intramural right of Universities or by the legally binding Code of Deontology of the Medical Association in that State. In these cases the opinion of a REC is an advice to the researcher.

# 3 Public research and innovation systems

## 3.1 General structure and the role of government

In this section, we will introduce the publicly funded and controlled research & innovation and higher education system. Due to a Humboldtian tradition, research and higher education systems in Germany are strongly connected and form a single research and education system, based on the so-called *Forschung und Lehre* principle promoting the unity of research and teaching.[53]

### 3.1.1 System of higher education and research institutions

The role of government in research and education policy and funding is shared between the Federal Ministry of Education and Research and 16 Länder Ministries of Education and

[52] *Gesetz zur Errichtung einer Ethik-Kommission des Landes Berlin* (Act on the Establishment of the State of Berlin), 07.09.2005. https://www.berlin.de/imperia/md/content/lageso/gesundheit/ethik/errichtungsgesetz_ek_berlin_2012.pdf?start&ts=1355325476&file=errichtungsgesetz_ek_berlin_2012.pdf

[53] Liessmann, Konrad Paul, *Theorie der Unbildung: die Irrtümer der Wissengesellschaft*, Paul Zsolnay Verlag, Vienna, 2006, pp. 50–73.

Research[54]. The Federal Ministry of Economics and Technology is responsible for some specific research areas, such as aerospace, energy and transport research.[55] Finances are also shared between Federal government and Länder. The German Parliament has a permanent Committee on Education, Research and Technology Assessment that approves the budget proposed by the Ministry of Education and Research and Ministry of Economics.[56] Finances for employments coverage in public research and education institutions are generally guaranteed from Länder budgets. The Joint Science Conference[57] is the only body to coordinate the research policy between State and Länder. Due to a quite strong responsibility of the Länder in decision-making processes in research and education policy, there is little strategic operation on the federal level. The only body that performs some of these aspects is the German Council of Science and Humanities (*Wissenschaftsrat*) with representatives from federal and Länder level, having an advisory and evaluative role.[58]

The German Research Foundation (*Deutsche Forschungsgemeinschaft)* plays a central role in the funding of basic research in Germany. Although it receives the large majority of its grants from Länder as well as from the State, it nevertheless remains a self-governing organisation under private law. The membership consists of university as well as non-university research institutions, other scientific associations and Academies of Science and the Humanities.[59] Its funding principle is to complement the institutional funding for basic research with project-type funding.[60] Erawatch reports that "[m]ost publicly funded R&D programmes are administered and managed by a range of implementation agencies (*Projektträger*), which are mostly located in large research centres."

The DFG is also advisory: "The DFG gives policy advice to parliaments, governments and public institutions on scientific issues. As the voice of science in political and social discourse, it counsels and partakes in political decision making processes with scientific expertise".[61]

### 3.1.2 The role of government in publicly funded research

Most institutions performing basic research are supported by public funds (State and Länder), while most of the applied research is sustained by funds from the private sector. The function of national academies of sciences and humanities such as Leopoldina (National Academy of Science) or acatech (National Academy of Science and Engineering) as well as eight other academies in the Unit of German Academies of Science and Humanities "include providing guidance and advice to policymakers and society as a whole relating to general and specific

[54] European Commission, *Country profile: Germany*. http://ec.europa.eu/invest-in-research/pdf/download_en/psi_countryprofile_germany.pdf
[55]http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/de/country?section=Overview&subsection=StrResearchSystem
[56] Ibid.
[57] http://www.gwk-bonn.de/english/
[58] http://www.wissenschaftsrat.de/en/about.html
[59] http://www.dfg.de/en/dfg_profile/mission/who_we_are/index.html
[60]http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/de/country?section=Overview&subsection=StrResearchSystem
[61] http://www.dfg.de/en/dfg_profile/mission/policy_advice/index.html

areas of research. They organise symposia and public events, with which they make a valuable and research-based contribution to the dialogue between research, society and industry".[62] Other important publicly funded basic research organisations are the Helmholtz Association of German Research Centres, the largest German research institution, comprising 18 scientific-technical and biological-medical research centres, "whose mission is to set up, operate and further develop large research infrastructures, such as particle accelerators, research vessels and aircraft"[63]; Max Planck Society (MPG), which includes 83 institutes to complement research projects at universities[64]; and the Fraunhofer-Gesellschaft with 67 institutes, which "conducts applied research for both private and public enterprises, as well as for the general benefit of the public".[65]

## 3.2 National research associations and standard-setting bodies

In this section, we will introduce the national and major regional research and university associations and science academies and their role in ethics assessment and standard setting for research performing organisations. The R&D infrastructure in Germany supports different types of publicly funded research institutions: universities, universities of applied sciences, non-university research institutes, and federal, as well as Länder (state) institutions. The *German Council of Science and Humanities*[66] (*Wissenschaftsrat*, WR) presides over the Länder and various research societies and associations in their engagement (typically in form of umbrella organisations, e.g. *Helmholtz Society* (HGF), *Max Planck Society* (MPG), *Fraunhofer Society* (FhG), *Leibniz Science Association* (WGL), and *Deutsche Forschungsgemeinschaft* (DFG)) in public research funding and cooperation activities. Nevertheless, the societies and associations are highly independent in defining research policies, setting priority research topics and allocating funds accordingly. They moderate a continuous dialogue with policy makers and society, and issue guidelines, recommendations and statements.

### 3.2.1 General research associations and standard-setting bodies

The German Research Foundation (*Deutsche Forschungsgemeinschaft,* DFG) is the central self-governing national research foundation. It provides policy advice to parliaments, governments and public institutions, and makes recommendations concerning fundamental issues in science and responsible application of scientific findings in society.[67] The Joint Committee is DFG's main decision-making body. It is made up of 39 members of the DFG's Senate (majority vote), representatives from the Federal Government (16 votes), 16 state

[62] http://www.research-in-germany.org/en/research-landscape/research-organisations/academies-of-sciences-and-humanities.html
[63] http://www.research-in-germany.org/en/research-landscape/research-organisations/helmholtz-association.html
[64] http://www.research-in-germany.org/en/research-landscape/research-organisations/max-planck-society.html
[65]http://www.research-in-germany.org/en/research-landscape/research-organisations/fraunhofer-gesellschaft.html. For a good overview on "Private Sector Interaction in the Decision Making Processes of Public Research Policies", see: http://ec.europa.eu/invest-in-research/pdf/download_en/psi_countryprofile_germany.pdf.
[66] WR is under Federal Ministry of Education and Research (*Bundesministerium für Bildung und Forschung,* BMBF; http://www.bmbf.de/)
[67] Deutsche Forschungsgemeinschaft (DFG). *Safeguarding Good Scientific Practice.*

representatives and 2 representatives from the Donors' Association for the Promotion of Sciences and the Humanities in Germany.[68] DFG provides advice to research institutions, makes research-policy decisions, issues research-oriented standards, handles transparent project application procedures, publishes recommendations (on good scientific practice, security-relevant research, equal opportunities, diversity, etc.), gives out Leibniz Prize awards, and decides on cases involving scientific misconduct.

The DFG and German National Academy of Sciences Leopoldina (*The Deutsche Akademie der Naturforscher Leopoldina*) published recommendations "Scientific Freedom And Scientific Responsibility[69] aimed at individual scientists and research institutions. The recommendations discuss issues of self-regulation, dual use dilemma, conditions and training measures for ethically responsible research, and the development ethics rules for handling security-relevant research that go beyond compliance with legal regulations. They propose establishing special committees for Ethics in Research to implement these rules and to advise scientists.

### 3.2.2 Field-specific research associations and standard-setting bodies

*Leopoldina* is an association of scientific and medical scholars, funded by the Federal Government (Ministry of Education and Research, BMBF) and the Land of Saxony-Anhalt. Leopoldina cooperates with other academies (from the Union of German Academies of Sciences and Humanities/*Union der Deutschen Akademien der Wissenschaften*), societies and associations (e.g. DFG) on science-based advice for policy-makers. Permanent standing committees comprise of scientists and representatives from industry and society to respond to policymakers' requests and provide policy advice on health, demographic change, digitised society, life sciences, climate and energy, environment, science and ethics, etc. Leopoldina's working groups tackle various areas of research (e.g., Clinical Trials of Medicinal Products on Humans, Predictive Genetic Diagnostics, Animal Testing, Dual Use - *Umgang Mit Sicherheitsrelevanten Forschungsergebnissen*, Science and Society) and consult with independent experts in the peer review processes. Leopoldina publishes statements and recommendations[70] on politically and socially relevant issues, such as research practice and responsibility[71], animal experimentation research, synthetic biology, genetic engineering, stem cell research, etc.

*Acatech - the National Academy of Science and Engineering* is a non-profit association funded by the Federal government and Länder. The main aim of acatech is to give advice on

[68] http://dfg.de/en/dfg_profile/statutory_bodies/joint_committee/index.html
[69]DFG & Leopoldina, *Recommendations "Scientific Freedom and Scientific Responsibility*". Recommendations for Handling Security-Relevant Research (2014).
[70]DFG & Leopoldina, "Statements & Recommendations." http://www.leopoldina.org/en/policy-advice/statements-and-recommendations/; Clinical Trials with Medicinal Products on Humans, 2014. http://www.leopoldina.org/en/publications; http://www.leopoldina.org/en/policy-advice/statements-and-recommendations/
[71]Freiheit und Verantwortung der Wissenschaft: Rechtfertigen die Erfolgschancen von Forschung ihre potentiellen Risiken? (2015). Dokumentation des Symposiums der Nationalen Akademie der Wissenschaften Leopoldina, der Deutschen Forschungsgemeinschaft und des Deutschen Ethikrates am 3. November 2014. http://www.leopoldina.org/en/dualuse-diskussion

future-oriented scientific and technology issues to policy makers and society through analyses and recommendations, in compliance with acatech guidelines[72] on science-based, independent and non-partisan research. It has a dual role, as working academy and as science and business network, to facilitate transfer of knowledge arising from practical applications in industry[73]. As an academy, acatech mainly represents technical disciplines that engage in applied research and delivers recommendations[74] on the core issues within a techno-political context: Biotechnology and Bioeconomy, Materials Science and Engineering, Energy and Resources, Nanotechnology, Healthcare Technologies, Product Development and Production, Information and Communication Technology, Safety and Security, Mobility, Logistics and Aerospace Engineering, Society and Technology. Scientific project groups are established to work on these issues, and results are published in annual reports and the three series of acatech monographs. *Position Statements*[75] – "acatech takes a position" is the format of brief statements on current issues from the fields of technical sciences and technology politics. *Project Reports* – "acatech reports and advises" present results of studies by interdisciplinary working groups in give specific recommendations for action, and *"acatech debates"* share opinions on a wide range of topics, reports about symposia, workshops and other projects not conducted by acatech.

## 3.3 Research funding organisations

This section provides a discussion on how research-funding organisations include ethics assessment in determining how to spend their funding. Furthermore, it will examine whether attention to ethical issues is a condition for basic funding of German universities and other public research institutions.

### 3.3.1 Research and innovation funding organisations

In Germany, most of the public funding for research and innovation is organised through organisations that are partly independent from the German government and usually organised as foundations or associations. A typical feature of the German research system is that non-university research institutions conduct a large portion of the overall research[76]. The major research funding organisations are the *Fraunhofer-Gesellschaft*, the *Helmholtz Association*, the *Leibniz Association*, the *Max Planck Society*, the *Alexander von Humboldt Foundation*, the project management agency at *DLR* (German Aerospace Center), the German Academic

[72] http://www.acatech.de/uk/home-uk/organisation/guidelines.html
[73]Mission Statement of the National Academy of Science and Engineering. http://www.acatech.de/uk/home-uk/mission-statement.html
[74]acatech, *Recommendations for implementing the strategic initiative INDUSTRIE 4.0*, Final report of the Industrie 4.0 Working Group, 8 April 2013.
http://www.acatech.de/fileadmin/user_upload/Baumstruktur_nach_Website/Acatech/root/de/Material_fuer_Sonderseiten/Industrie_4.0/Final_report__Industrie_4.0_accessible.pdf
[75]acatech, "acatech Takes a Position: Strategy for promoting interest in science and engineering".
http://www.acatech.de/de/publikationen/stellungnahmen/kooperationen/detail/artikel/strategy-for-promoting-interest-in-science-and-engineering.html
[76] DFG, *Funding Atlas 2013*, Deutsche Forschungsgemeinschaft, Bonn, 2012.

Exchange Service (DAAD), and the German Research Foundation (DFG), which is the central, self-governing research funding organisation in Germany[77].

Some of these associations are fairly specialised in certain branches of research (e.g. the Helmholtz association focuses on six research areas) while others focus on a widely diverse range of subjects (e.g. the *Leibniz Association*). Moreover, some of these organisations are primarily concerned with fundamental, basic research (e.g. the DFG) while others deal with applied research (e.g. *Fraunhofer-Gesellschaft*). The major agenda setting organisation in Germany seems to be the DFG, in which the federal and regional government are involved in its government on a minority basis together with a majority of representatives of the scientific community.

In the recommendations on basic rules of good scientific practice[78], the DFG states:

> In the rules for the use of funds granted, the principal investigator shall be obliged to adhere to good scientific practice. When a university or research institute is the sole or join grantee, it must have rules of good scientific practice and procedures for handling allegations of scientific misconduct[79].

Generally, the research institutes have followed up on and incorporated the DFG guidelines on these issues in their own policies.[80] Hence, it should prove sufficient to deal with the DFG policies as typical for the German conditions for research funding.

In assessing research proposals for the assignment of funding, the DFG uses field-specific review boards whose members are elected on a four-yearly basis by the entire German research community on the basis of their expertise. The field-specific review board issues advice and the joint committee of the DFG, which members are partly elected by the members of the DFG (the German universities) and partly appointed by government ministries, makes the eventual decision on whether to fund research or not.

In case the research involves experiments with human subjects or human tissue, an ethics vote of a research institution's ethics committee is required for the approval needed to fund the research. Apart from research involving human subjects or human tissue, the only substantial ethical issue that is dealt with by the DFG is scientific integrity. Hence, most of the provisions in the recommendations issued by the DFG relate to authorship issues and data storage. Arguably, a downside of the way that review of research for funding is organised in Germany is the field specific outlook of the review committees; which has the implication that most of

---

[77] Deutscher Akademischer Austauschdienst, *German Funding Programmes for Scientists and Researchers.* Bonn, 2014.
[78]German Research Foundation (*Deutsche Forschungsgemeinschaft*), *Proposals for Safeguarding Good Scientific Practice* (1998). http://www.izw-berlin.de/tl_files/downloads/self_regulation_98.pdf
[79] Ibid.
[80]For example, the Alexander von Humboldt Foundation lists of good scientific practice, legal regulations and general obligations in section IX of its documents on the regulations for the use of its funds (Alexander von Humboldt Foundation, *Research Group Linkage Programme – Regulations on the Use of Funds*), 2014.

these focus on field-specific requirements rather than consulting each other on possible cross-disciplinary concerns[81].

### 3.3.2 Conditions for basic funding for universities and public research institutes

Most of the funding organisations in Germany are organised as collaborations between researchers, research institutes and the federal and regional governments. The funding of these organisations predominantly consists of government funding, which is typically based on a 50:50 division between the federal state and the regional states, with some exceptions that are based on a 90:10 division (the *Fraunhofer Society* and the *Helmholtz Association*)[82]. Because the funding organisations have their own statutes and a high level of independence, they function as "inter-mediate policy makers". Hence, there is no direct government requirement for funding of non-university research institutes; at least so far as the research itself is concerned (and therefore, no requirements on ethics assessment). The basic funding of universities is organised at the level of the regional states[83], though they receive a substantial part of their research funding from the non-university research institutes (e.g. the DFG).

## 3.4 Research performing organisations

This section will examine what general ethical standards, procedures and organisational units German research performing institutions use for ethics assessment. Discussions will be included on the role and organisation of research ethics committees and on ethics in training and education.

Public sector research in Germany is performed by numerous organisations, including universities, non-university institutes (such as the *Max Planck Society*, Germany's largest research organisation that performs basic research with 80 institutes, as well as the *Leibniz Association* as an umbrella organisation of 82 non-university research institutes), moreover institutions run by federal or state authorities, and companies. There is an estimated number of almost 1000 public and publicly funded institutions for science, research and development, as well as more than 500 research and innovation networks and clusters.

According to German law, all scientific medical research involving human subjects (including application of methods directly on humans, using human bodily tissue) requires a permit by a research ethics committee (REC). Germany has a total of 53 RECs.[84] 33 of those are attached to Faculties of Medicine/Universities, 17 to Medical Associations (*Ärztekammern*) in the states and three (Berlin, Bremen, Sachsen-Anhalt) attached to state governments.[85] In Germany, RECs are the only legally competent ethics committees to assess all kind of

[81] Interview with Anke Reinhardt, representing the DFG (*Deutsche Forschungsgemeinschaft*), 3 March 2015.
[82] Braun, M., "Country Profile : Germany." *Private Sector Interaction in the Decision Making Processes of Public Research Policies*, 2012, pp. 1–16.
[83] Hartwig, L., *Funding Systems and Their Effects on Higher Education Systems.* Bavarian State Institute for Higher Education Research and Planning, November 2006.
[84] http://www.eurecnet.org/information/germany.html
[85] The three RECs attached to states governments are restricted to assessing drug research and research on medicinal devices.

biomedical research including drug research. The 53 committees differ regarding their structure while all are composed from multiple disciplines: some work on the basis of parity, others follow community review involving e.g. lawyers, ethicists, and theologists, and there are expert-laymen committees.

Free or commercial research ethics committees are not legally competent to assess any kind of research, as any research has to be assessed by a committee established in accordance with the states law (*Landesrecht*). For research studies outside a university, the REC of the regional Medical Association (*Ärztekammer*) is legally competent. Ethics committees in hospitals have an advisory role but there is no legal regulation regarding their competence. Their role is seen in the decision whether a research project, approved by an authority, with favourable opinion by a REC, may be carried out at that specific hospital.

In universities ethics committees of the faculty of medicine or of the university assess research projects. Some universities require that their ethics committees review all research involving human subjects. These committees examine whether subjects are exposed to disproportional or excessive risks, will give their consent to the research while being sufficiently informed on any potential risks, have been informed about the right to leave the study at any time, and are sufficiently protected by precautionary measures against risks. The criteria for considerations concern scientific quality, legality, and ethical acceptability – the latter based on principles outlined in the Belmont Report[86] and the Declaration of Helsinki[87]. Oftentimes, ethics committees employ checklists to determine whether a proposed study can proceed as planned or whether adaptations need to be made. In most cases, the responsible researcher is invited for a short discussion to explain the project, but is excluded from decision-making. The RECs attached to the medical associations and to the States Berlin, Bremen, and Sachsen-Anhalt do their assessment on the same basis as University RECs.

At present, there is no national ethics committee for medical research in Germany. Medical researchers are obliged by the professional code (*Ärztliche Berufsordnung*), which, in the German States is a legally binding instrument, and/or by the 'Intramural Right' of Universities to submit any biomedical research project to the REC of a Medical Association or of the University. Notably, a decision of the REC in this field is an advice - not an allowance or a prohibition – in contrast to drug research and research on medicinal devices.

However, in practice, often a favourable opinion serves as an approval. The Central Ethics Committee of the German Medical Association ('*Zentrale Ethikkommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten bei der Bundesärztekammer*') gives opinions on general ethical issues and on request may give advice that is not binding to the Research Ethics Committees of the Medical Associations. Consultancy for the public, governments and parliaments is provided by the independent Permanent Working Party of Research Ethics Committees in Germany ('*Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland*'[88]), allowing exchange of information of the regional RECs.

[86] http://videocast.nih.gov/pdf/ohrp_appendix_belmont_report_vol_2.pdf
[87] http://www.wma.net/en/30publications/10policies/b3/

[88] http://www.ak-med-ethik-komm.de.

The working party offers training for REC members on national and regional level and regularly publishes report of its meetings.[89]

Animal experiments for research purposes are always subject to report or approval by regional authorities, the Animal Protection Committee (§15 Animal Protection Act[90]). Institutions at which animal experiments are conducted are required to appoint an animal welfare officer with appropriate qualifications and authority.

To safeguard good scientific practice and to prevent dishonesty in research, the *Deutsche Forschungsgemeinschaft* (DFG) as the main research funding body in Germany, in 1998 published *Recommendations for Safeguarding Good Scientific Practice*[91] to complement other professional or legal norms or codes of conduct, offering a general frame for the key aspects to be included in rules of good scientific practice. In line with these recommendations, all universities and research institutions in Germany have implemented their own guidelines as requested in the DFG document. The DFG created the office of ombudsperson[92], and most universities have an ombudsperson as independent authority to advise and assist scientists in questions of good scientific practice.

# 4 Private research and innovation systems

This chapter will provide a discussion of ethics assessment of R&I and Corporate Social Responsibility (CSR) in private research and innovation systems. First, the general structure and the role of government will be examined. Then, the role of industry associations and accreditation, certification and standard-setting organisations will be reviewed. Finally, the role of industry itself will be discussed. As Germany is a federal republic, its member states (*Länder*) are largely autonomous in regard to their internal organisation and retain limited sovereignty. This report focuses on the role of the Federal Government.

## 4.1 General structure and the role of government

In this section, the following topics will be discussed: the German industry landscape; major German organisations that represent industry; German government policies and initiatives supporting ethics assessment and CSR in private industry; and German initiatives for public-private partnerships with regard to ethics assessment and CSR.

### 4.1.1 German industry landscape

In 2014, Germany had an employed population of around 42 million people, of which roughly 20 percent, or 8,5 million people, were employed in industry (excluding construction).[93]

[89] http://www.coe.int/t/dg3/healthbioethic/activities/02_biomedical_research_en/guide/Guide_EN.pdf
[90] http://www.gesetze-im-internet.de/bundesrecht/tierschg/gesamt.pdf
[91] http://www.dfg.de/en/dfg_profile/structure/statutory_bodies/ombudsman/index.html
[92] http://www.ombudsman-fuer-die-wissenschaft.de/
[93] http://stats.oecd.org/Index.aspx?DataSetCode=STLABOUR#

Furthermore, the industrial sector generated roughly 26% of German gross domestic product in 2014.[94] Major industries include machinery, chemicals, foodstuffs, electrical goods, and metallurgy. Leading German international industrial corporations include Volkswagen AG, Daimler AG, Siemens AG, BASF, and BMW.[95] 99% of all companies in Germany are small- and medium-sized enterprises, SMEs (*Mittelständische Unternehmen*, with less than 250 employees).[96] 10% of these SMEs belong to the industry sector. 85% of the German industries are family-owned. [97]

### 4.1.2 Organisations that represent industry

Important German industry-representing organisations include:

- The *Federation of German Industries (Bundesverband der Deutschen Industrie e.V., BDI)* is the association of (German) industrial sector associations. The BDI has 36 member federations and represents the interests of 100.000 businesses with 8 million employees. Not all members are "industry only" associations.[98]
- The Association of German Chambers of Commerce and Industry (*Deutscher Industrie- und Handelskammertag*, DIHK) is the central organisation for 80 local Chambers of Commerce and Industry (*Industrie- und Handelskammern*, IHKs) in Germany. In total, the IHKs have more than three million members, since all German companies registered in Germany (exceptions: handicraft businesses, free professions, and farms) are required by law to join a chamber.[99]
- The *German Association of the Automotive Industry* (*Verband der Automobilindustrie*, VDA) which represents 600 members (500 members, mostly SMEs, supply parts and accessories);[100]
- 1.600+ companies have joined the *German Electrical and Electronic Manufacturers' Association* (*Zentralverband Elektrotechnik- und Elektronikindustrie e.V.*, ZVEI).[101] They employ around 90% 102of the employees and staff of the electrical industry in Germany.[103]
- The Federal Association for Information Technology, Telecommunications and New Media (*Bundesverband Informationswirtschaft, Telekommunikation u. neue Medien e.V.*, BITCOM) represents 2.200+ businesses in the IT and telecommunications industry and in new media. These includes 1.000 SME as well as almost all global players.
- The Federation of the German Waste, Water and Raw Materials Management Industry (*Bundesverband der Deutschen Entsorgungs-, Wasser- und Rohstoffwirtschaft e.V.*,

[94] http://de.statista.com/statistik/daten/studie/36846/umfrage/anteil-der-wirtschaftsbereiche-am-bruttoinlandsprodukt/# (German only)
[95] http://de.wikipedia.org/wiki/Liste_der_größten_Unternehmen_in_Deutschland (German only)
[96] http://en.wikipedia.org/wiki/Economy_of_Germany; http://www.bdi.eu/Industrieller-Mittelstand.htm
[97] http://www.bdi.eu/Industrieller-Mittelstand.htm
[98] http://www.bdi.eu/BDI_english/index.htm
[99] http://www.dihk.de/en
[100] https://www.vda.de/en/association/members.html
[101] http://www.zvei.org/en/association/Pages/default.aspx
[102] http://www.bitkom.org/en/about_bitkom/42611.aspx
[103] http://www.zvei.org/en/association/tasks-and-objectives/Pages/default.aspx

BDE) represents 750 companies, which collect and recycle around 60% of household waste and 70% of industrial waste produced in Germany.[104]

Other industry-representing organisations, such as the Association of Research-Based Pharmaceutical Companies (vfa)[105] and the Federation of German Food and Drink Industries (BVE),[106] are on the membership list of the Federation of German Industries (BDI).[107]

### 4.1.3 Government policies and initiatives to support ethics assessment in private industry

German policies and initiatives to support ethics practices in private industry mostly concern *corporate social responsibility* (*CSR*) as an element of *sustainable development*. While sustainability has been recognised as a guiding principle by the Federal Government, it sees, for example, "no need to make sustainability reporting a legal obligation."[108]

The Federal Government appointed the German Council for Sustainable Development *(Rat für nachhaltige Entwicklung, RNE)* in 2001, which advises the government on its sustainable development policy.[109] The chancellor appoints the 15 members for a three-year term.[110] Current members include the Chairwoman of the board of *Berliner Gaswerke AG* and the Chairwoman of the Sustainability Council at *Henkel AG & Co. KGaA*.[111]

The *National Sustainable Development Strategy (NSDS)* was first presented at the UN World Summit on Sustainable Development in Johannesburg in 2002. The strategy has been updated by three extensive reports. In the most recent report (2012)[112] special attention has been given to the "green economy" and CSR. More specifically, the German government "supports small and medium enterprises in their CSR activities; pools the information available on CSR and the support available from individual ministries; raises the awareness of the general public; devised a concept 'CSR – Made in Germany'; integrates CSR into education, training, academic work and research; steps up the importance of CSR at international level and in the development context."[113]

The German Council for Sustainable Development has also published "The Sustainability Code" (2nd completely revised edition 2015), which at times is also referred to as "German

---

[104] http://www.bde-berlin.org/wp-content/uploads/2014/06/bde_voeb_en.pdf
[105] http://www.vfa.de/en/about-us-member-companies
[106] http://www.bve-online.de/english/english-aboutbve
[107] http://www.bdi.eu/BDI_english/485.htm
[108] The Federal Government, *National Sustainable Development Strategy, 2012 Progress Report*, p. 124. For an elaborate analysis of the specifics of the German stance in corporate responsibility, see: http://www.sowi.rub.de/mam/content/lsip/cornellpaper_kindermann.pdf
[109] http://www.nachhaltigkeitsrat.de/en/the-council/fact-sheet/
[110] http://www.nachhaltigkeitsrat.de/en/the-council/mandate-given-to-the-german-council/
[111] http://www.nachhaltigkeitsrat.de/en/the-council/council-members/
[112] http://www.bundesregierung.de/Content/DE/_Anlagen/Nachhaltigkeit-wiederhergestellt/2012-06-07-fortschrittsbericht-2012-englisch-barrierefrei.pdf?__blob=publicationFile
[113]http://www.bundesregierung.de/Content/EN/StatischeSeiten/Schwerpunkte/Nachhaltigkeit/2013-10-23-progress-report-2012_en.html

Sustainability Code (GSC)."[114] At the time of writing, 80+ companies have submitted declarations of conformity, which have been published online.[115]

A National CSR-Strategy (*Aktionsplan CSR*) was adopted in 2010. The National CSR forum (*Nationales CSR Forum*) advises the government on this strategy. Members of the National CSR forum include Federal ministries, the German Council for Sustainable Development and representatives from industry such as the Federation of German Industries *(BDI)*.[116] The National CSR forum adopted a declaration on the shared understanding of CSR in Germany (2009), which became part of the National CSR-strategy.[117] It also recommended the introduction of the CSR Award of the Federal Ministry (*CSR-Preis der Bundesregierung*). There are four categories for the prize (small, medium, large, and very large companies), which has been awarded by Federal Ministry of Labour and Social Affairs (BMAS) since 2013.

### 4.1.4 Initiatives for public-private partnerships

The German Global Compact Network (*Deutsche Global Compact Netzwerk*, DGCN) has a membership of 150+ companies. These include SMEs as well as 24 of the 30 major German companies trading on the Frankfurt Stock Exchange (Dax 30).[118] The network also includes NGOs and representatives of the Federal Government. The DGCN receives financial support from the Federal Government and representatives from German ministries are members of the steering group (*Lenkungskreis*).[119]

The Federal Ministry of the Environment, Nature Conservation and Nuclear Safety and econsense (the sustainable development forum of the German economy, see below) jointly published Corporate Sustainability Management (*Nachhaltigkeitsmanagement im Unternehmen*)[120] in 2007.[121] The manual includes recommendations for the R&D management.

The *German Sustainability Award* has been established in 2008. The Federal Government is represented on the board of trustees of the German Sustainability Award Foundation. The

[114]http://www.deutscher-nachhaltigkeitskodex.de/en/the-code/the-code.html. A "comparison of the German Sustainability Code with the principles of the UN Global Compact, the OECD Guidelines for Multinational Enterprises and ISO 26000 09.01.2012" can also be found at this web page.
[115] http://www.deutscher-nachhaltigkeitskodex.de/en/database/database.html
[116]http://www.bmas.de/SharedDocs/Downloads/DE/PDF-Publikationen/a397-csr-empfehlungsbericht.pdf (German)
[117] http://www.csr-preis-bund.de/fileadmin/user_upload/doc/Aktionsplan-CSR.pdf (German)
[118] The Federal Government, *National Sustainable Development Strategy. 2012 Progress Report*, p. 122. See also: http://www.globalcompact.de/themen/deutsches-global-compact-netzwerk (in German). On the "Dax 30": http://en.wikipedia.org/wiki/DAX
[119] http://www.globalcompact.de/themen/lenkungskreis
[120] http://www.bmub.bund.de/fileadmin/bmu-import/files/pdfs/allgemein/application/pdf/nachhaltigkeitsmanagement_unternehmen.pdf (in German)
[121] The Federal Government, *National Sustainable Development Strategy. 2012 Progress Report*, pp. 122-123.

awards ceremony is the highlight of the German Sustainability Conference (*Deutscher Nachhaltigkeitstag*).[122]

The Federal Ministry for Economic Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*) has initiated a specific program for Public-Private Partnerships in German development cooperation: Development partnerships with the private sector.[123] It aims to encourage "companies to conduct their business activities in a responsible manner and fulfil their special role in the creation of a more equitable form of globalisation."[124]

## 4.2 Industry associations and accreditation, certification and standard-setting organisations

This section will provide a discussion of the role of industry associations and networks, as well as the role of accreditation, certification, evaluation and standard-setting organisations for industry, in the setting and enforcement or promotion of standards and practices with regard to ethics assessment and CSR in industry. The extent to whether industry makes use of independent, external ethics committees to evaluate their R&D will also be examined.

### 4.2.1 Industry associations

The most visible contributions from industry associations are within network organisations. To give an example for an activity from an individual industry association: The *German Electrical and Electronic Manufacturers' Association* (ZVEI) has designed its own code of conduct, which "is intended as a model for enterprises' own declarations to their customers, or for requests to suppliers for equivalent declarations."[125] A list of companies who have adopted the code is available at the ZVEI web site.[126] The adoption of the code is voluntary.

### 4.2.2 Network organisations

*Econsense* is a corporate network initiated by the *Federation of German Industries* (BDI) in 2000. Econsense aims "to provide a dialogue platform and think tank, with the dual objectives of advancing sustainable development in business and assuming social responsibility."[127] The network has 32 members from various industries (including the leading German industrial corporations such as Volkswagen AG, Daimler AG, Siemens AG, BASF, and BMW).

[122] https://www.nachhaltigkeitspreis.de/sonstige/english-summary/, https://www.nachhaltigkeitspreis.de/app/uploads/2014/02/german_sustainability_award-1.pdf
[123] http://www.developpp.de/en/content/developpde
[124] http://www.developpp.de/en/content/opportunities-development-cooperation
[125] http://www.zvei.org/en/subjects/society-the-environment/Pages/ZVEI-Code-of-Conduct-english.aspx
[126] http://www.zvei.org/Themen/GesellschaftlundUmwelt/Seiten/Anerkennung-des-ZVEI-COC.aspx
[127] http://www.econsense.de/en

Around 400 companies from the German mechanical engineering industry have joined the Blue Competence initiative[128] and have adopted the 'Blue Competence Sustainability Code'.[129]

*CSR Germany* is the CSR Internet portal of Germany's four leading business organisations (including the *Federation of German Industries* and the *Association of German Chambers of Commerce and Industry*).[130] The portal "offers companies the possibility to link up with a network in order to promote the exchange of experience; present their CSR activities to a wider public; obtain information about backgrounds, recent developments and trends."[131]

Besides the already mentioned German Sustainability Conference, the German CSR-Forum – International Forum for Sustainability and Futureability is an important annual event and networking platform.[132]

### 4.2.3 Certification, evaluation and standard-setting organisations

The *German Institute for Standardisation* (*Deutsches Institut für Normung e.V.*, DIN) has adopted ISO 26000 CSR norms as DIN ISO 26000 in 2011.[133]

As pointed out in the previous section CSR initiatives in Germany emphasise the voluntary nature of the implementation of CSR guidelines. Obligations to report on relevant aspects, etc., thus stem from commitment made by industry to international initiatives such as the UN *Global Compact*.

### 4.2.4 External ethics committees

Medical research by industry in Germany is regulated in the same way as medical research in any other sector.[134] Ethics committees outside this domain are rather uncommon. A notable exception (even though it is discussed whether it is an ethics committee in the stronger sense) has been the *Ethics commission on "safe energy supply"* ('Sichere Energieversorgung'), which had a mandate for three months in 2011 and produced only one, ably influential report.[135] The commission had been appointed by the Federal Government to provide advice on the feasibility of the *Energiewende*, the transition "to an energy portfolio dominated by renewable energy, energy efficiency and sustainable development. The final goal is the abolition of coal and other non-renewable energy sources."[136]

---

[128] http://www.bluecompetence.net/en/home
[129] http://www.bluecompetence.net/web/bluecompetence/article/-/articleview/3216770
[130] http://www.csrgermany.de/www/csr_cms_relaunch.nsf/id/home-de
[131] http://www.csrgermany.de/www/csr_cms_relaunch.nsf/res/csrgermany_english_overview.pdf/$file/csrgermany_english_overview.pdf
[132] http://www.csrforum.eu/en/
[133] http://de.wikipedia.org/wiki/ISO_26000 (German)
[134] http://de.wikipedia.org/wiki/Ethikkommission
[135] http://www.bundesregierung.de/Content/DE/Lexikon/StichworteAZ/E/ethikkommission.html
[136] http://en.wikipedia.org/wiki/Energy_transition_in_Germany

## 4.3 Industry

In this section, we discuss how German industrial businesses engage in CSR and ethics assessment, to the extent that these relate to research and innovation. Again, the voluntary nature is central to Germany's stance.[137]

### 4.3.1 Small and medium-sized German enterprises

As stated in section 1.1, CSR and related activities of SMEs are a central topic of the *National Sustainable Development Strategy*. In line with the National strategy, the project *Gesellschaftliche Verantwortung im Mittelstand* (Social responsibility of the *Mittelstand*) has been initiated by the *Federal Ministry for Labour and Social Affairs*. The project was funded by the European Social Fund (2012–2014).[138] 1305 SMEs have been included in the project and a total of 3500 SMEs have been reached. The successful evaluated program, thus, has demonstrated the general interests of SME in CSR. However, only one of the enterprises in the project (Nanogate AG) had a clear focus on R&D.[139]

A clear focus on R&D is also not obvious for the nominees and winners of the *CSR Award of the Federal Ministry* (CSR-Preis der Bundesregierung) in the categories "small" and "medium."

### 4.3.2 Large and very large German Enterprises

In contrast, large and very large corporations focus much more ethics assessment and CSR. 24 of the 30 major German companies trading on the Frankfurt Stock Exchange are members of the *German Global Compact Network*.

BASF serves as an example: In 2014, the company had 10700 employees in R&D worldwide and EUR 1,88 billion in R&D expenditures. It filed 1.200 patents and has been the No. 1 in the Patent Asset Index.[140] BASF has established a *Corporate Sustainability Board*. The *Sustainability Core Team* supports the Corporate Sustainability Board to drive the implementation of CSB decisions. The *Sustainability Communities* are cross-divisional and cross-regional teams, which implement the sustainability strategy in their businesses.[141] BASF is a member of various networks, for example, Chemie³, the Conference Board, CSR Europe, econsense, Global Compact, and GRI.[142] BASF's 2014 report[143] combines the financial and nonfinancial information on the company and follows the GRI's G4 "comprehensive" international guidelines for the sustainability reporting. The BASF Report 2014 also served as

[137] See for more information: http://www.sowi.rub.de/mam/content/lsip/cornellpaper_kindermann.pdf
[138] https://www.csr-vernetzung.de/
[139] http://www.csr-vernetzung.de/nc/gute-beispiele/unternehmen/detail/nanogate-ag-2.html (in German)
[140] https://www.basf.com/en/company/research.html
[141] https://www.basf.com/en/company/sustainability/management-and-instruments/structure.html
[142] https://www.basf.com/en/company/sustainability/responsible-partnering/networks.html
[143] http://report.basf.com/2014/en/

a progress report on BASF's implementation of the ten principles of the United Nations Global Compact.[144] A third party audits the report.[145]

# 5 Professional groups and associations in the R&I field

## 5.1 National associations for R&D professions

In this section, we will discuss associations of professionals in either research & innovation or in ethics assessment. German associations in R&D focus on knowledge transfer and networking among publicly or privately funded research institutions and SMEs, promotion of innovation on international level, as well as on the career development of its members. Moreover, larger associations also issue practical guidelines, recommendations and act as standard-setting bodies. Notable examples are the Association of German Engineers (*Verein Deutscher Ingenieure, VDI*), the German Federation of Industrial Research Associations (*Arbeitsgemeinschaft industrieller Forschungsvereinigungen*, AiF) and the German Medical Association (*Bundesärztekammer*):

- The Association of German Engineers (VDI)[146] is the largest association for engineers, technology scientists and IT professionals, with over 150,000 members. Through its website, VDI provides advisory information for policy decision makers (on energy, environment, transport, education and innovation as well as the education and promotion of young engineers codes of conduct and facilitates discussion on engineering ethics topics). It also provides technical and professional recommendations[147] and studies[148], and issues Fundamentals of Engineering Ethics / *Ethische Grundsätze des Ingenieurberufs*[149]. It organises lectures on these topics by experts in engineering ethics. Furthermore, it has a Scientific Advisory Council and a Professional Affairs Advisory Council.
- The German Federation of Industrial Research Associations (AiF)[150] promotes R&D in all industrial sectors on behalf of small and medium-sized enterprises (SMEs). AiF is a network of 100 industrial research associations from all sectors (industry and service sector) with 50,000 affiliated companies (above all SMEs). The AiF promotes R&D for SMEs in several ways: organisation of joint industrial research for the benefit of entire industrial sectors, administration of programmes for governmental R&D support measures, promotion of R&D through open innovation processes, networking within and between industrial sectors and politics. However, AiF does not issue code of ethics or professional standards, these are issued by individual associations under the AiF umbrella.

[144] http://report.basf.com/2014/en/about-this-report/content-and-structure.html
[145] http://report.basf.com/2014/en/about-this-report/audit-and-evaluation.html
[146] http://www.vdi.eu
[147] http://www.vdi.eu/studies/recommendations-preparing-for-future-manufacturing/
[148] http://www.vdi.eu/studies/publication-and-downloads/
[149] https://www.vdi.de/bildung/ethische-grundsaetze/
[150] http://www.aif.de/en/about-aif.html

The German Medical Association (*Bundesärztekammer*)[151] is the central organisation in the system of medical self-administration in Germany. As the joint association of the State Chambers of Physicians (*Landesärztekammern*), it represents the interests of over 470,000 physicians in matters relating to professional policy, and plays an active role in opinion-forming processes with regard to health and social policy and in legislative procedures. It has a special Department for Science, Research and Ethics, and issues Professional code (*Berufsordnung*)[152], regulating the ethical and professional obligations of physicians and speciality training regulations (*Weiterbildungsordnung*)[153], which define the content, duration and objectives of speciality training and specialist designations. Notably, the Bundesärztekammer can only propose, without having decision force. All the fields that are mentioned above lie in the legal competence of the States.

### 5.2 National associations for (ethics) assessors

- **Permanent Working Party of Research Ethics Committees in Germany (***Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland Inc.*): This independent Working Party was established in 1983 as an association of research ethics committees (RECs) in the States with the view to harmonise the work of the committees and work on common assessment procedures.[154] Regular meetings are organised where ethical and legal issues are discussed by members and invited experts. The Working Party also organises trainings for RECs' members.[155]
- **Technology Assessment (TA) Network** (*Netzwerk Technikfolgenabschätzung* - NTA): The NTA was established in 2004 as an association of technology assessment institutions in German-speaking countries (Germany, Austria, Switzerland) to establish a platform for cooperation among TA experts and to promote TA in science, politics, business and the public.[156]
- **The German Network for Business Ethics** (*Deutsches Netzwerk Wirtschaftsethik* - DNWE): The DNWE is the German chapter of the European Business Ethics Network.[157]

## 6 Civil society organisations

### 6.1 CSO landscape

Notwithstanding the fact that the German political system is based upon a shared responsibility between Federal state and Länder, federal laws mostly regulate the legal and organisational forms as well as financial activities of CSOs.[158] There are various legislative

[151] http://www.bundesaerztekammer.de
[152]Professional Code for Physicians in Germany, http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf
[153] http://www.bundesaerztekammer.de/downloads/MWBO_Englisch_210113_FINAL_aktualisiert171214.pdf
[154] http://www.ak-med-ethik-komm.de/organisation.html.
[155] http://www.eurecnet.org/information/germany.html
[156] http://www.openta.net/netzwerk-ta
[157] http://www.ihi-zittau.de/cms/en/280/DNWE-(Business-Ethics)
[158] http://www.cof.org/content/germany#Applicable_Laws

acts that regulate their legal and organisational forms and financial status. Foundations and activities of CSOs are guaranteed by the German Constitution (*Grundgesetz*) and further regulated by the German Federal Civil Code (*Bürgerliches Gesetzbuch*) and Law on Associations (*Vereinsgesetz*).[159] CSOs are usually considered as non-profit organisations acting for the purpose of public and common benefit or church-related purposes, therefore "exempted from Germany's corporation tax (*Körperschaftsteuer*), commercial tax (*Gewerbesteuer*), and gift and inheritance tax (*Erbschaft-und Schenkungsteuer*). Sections 52-54 of the Fiscal Code (*Abgabenordnung)* describe these exempted purposes".[160]

CSOs are active in many spheres in civil society (such as religion, environment, development, human rights, animal rights, trade unionism etc.). Many CSOs in Germany are also international organisations and/or act beyond the borders of Germany. The most important are the following:

- Religion: Protestant Church (includes 22 member regional churches and 23.4 million member); Catholic Church (includes 24.2 million members)[161]. Further, there are church-related Stiftungen (funding provided by the Federal Ministry for Economic Cooperation and Development): *Brot für die Welt*/Bread for the World is the Protestant Development Service, the globally active development and relief agency of the Protestant Churches in Germany: 2011 budget of €181 million, including €119 million from the Federal Ministry for Economic Cooperation and Development. *MISEREOR* is the German Catholic Bishops' Organisation for Development Cooperation: 2011 budget of €181 million; received €107.4 million in German federal grants. In 2012, *Misereor* received €113.8 million in German federal grants; "it does not list its partners"[162].
- Human Rights: The oldest German human rights-NGO is the *Deutsche Liga für Menschenrechte* (German League for Human Rights). The *European Centre for Constitutional and Human Rights* engages in innovative strategic litigation, using European, international, and national law to enforce human rights[163]; the *European Centre for Minority Issues* conducts research into minority-majority relations in Europe; the *Vereinigung der Opfer des Stalinismus* (Association of Victims of Stalinism) formed by vicitims of Stalinism, *EarthLink* is active for harmony between people and nature.
- Environment: *Naturschutzbund Deutschland*[164] (NABU) and *Bund für Umwelt und Naturschutz Deutschland*[165] *(BUND)* are the biggest environmental organisations in Germany with around 500,000 members each.
- Animal Rights: *German Animal Welfare Organisation* is an umbrella association, representing a large number of animal rights organisations and activists.[166]

[159] http://www.cof.org/content/germany#Applicable_Laws
[160] http://www.cof.org/content/germany#Applicable_Laws
[161] http://www.dbk.de/en/katholische-kirche/katholische-kirche-deutschland
[162] http://www.ngo-monitor.org/article/germany
[163] http://www.ecchr.de/
[164] https://www.nabu.de/
[165] http://www.bund.net/
[166] http://www.tierschutzbund.de/organisation/selbstdarstellung.html

- Trade Unions: The *Deutsche Gewerkschaftsbund* is the largest trade union federation with 6.2 million members;[167] *Industriegewerkschaft Metall and Vereinte Dienstleistungsgewerkschaft* respectively have 2.3 and 2.2 millions of members.[168]
- Development: VENRO, the *Association of German development non-governmental organisations* (NGOs), is the umbrella organisation of about 120 independent and church related NGOs working in the fields of development cooperation, emergency assistance, development education, and advocacy.[169] It acts as political stakeholder for NGOs working in the field of development policy. The *Deutsche Stiftung Weltbevölkerung* (this foundation operates offices in Ethiopia, Kenya, Tanzania, Uganda, Berlin and Brussels, Belgium. It supports projects focused on sexual and reproductive health, HIV/AIDS and other issues); *AWO International* (domestically, the *Arbeiterwohlfahrt)* is best known for organising job training to professionals and vacation getaways for children. Internationally, AWO provides humanitarian aid in response to natural emergencies and crises); the *Malteser Hilfsdienst* is a Catholic charity that helps to provide disaster relief, first aid training and sanitation around the globe. *Ärzte für die Dritte Welt* (Doctors for the Third World) sends physicians on an unpaid, volunteer basis to developing countries in order to treat patients. The *Welthungerhilfe* focuses on nutrition, food security and agricultural development as well as on humanitarian aid. The *Kindernothilfe* is one of the largest Christian organisations in Europe for children's aid with programmes and projects, which help vulnerable and marginalised children.[170]

The *Bundesnetzwerk Bürgerschaftliches Engagement* (National Network for Civil Society) is a nationwide network linking organisations and associations from the third sector (non-profit organisations) and civil society, aiming to improve the general legal, organisational and institutional conditions for civic involvement.[171]

The CSO landscape is very heterogeneous in Germany, sizes and structures differ a lot, such that information about the funding situation is difficult. A recent report on CSO financing in Germany by the *Körber-Stiftung* and *Zivilgesellschaft in Zahlen* (ZiviZ) has found that the membership fees are the most important source of income for CSOs. Other funds are generated on the market (fees for services and events), with state and public funding (especially in social and environmental services) and through private donations.[172] Among different funding sources for CSOs, there are also political foundations or Stiftungen, affiliated with political parties in the Bundestag. Stiftungen "are funded based on electoral results, with budgets reflecting the proportion of the corresponding party in Parliament following each election".[173]

[167] http://www.dgb.de/uber-uns/dgb-heute/organisation-und-bundesvorstand
[168] http://www.igmetall.de; http://www.verdi.de
[169] http://venro.org/english/whoweare/
[170] https://www.devex.com/news/top-german-global-development-ngos-a-primer-74980
[171] http://www.b-b-e.de/bbe-english/
[172] http://www.ziviz.info/fileadmin/download/ZiviZ_2015_Finanzierung_Zivilgesellschaft_kurz.pdf
[173] http://www.ngo-monitor.org/article/germany

## 6.2 The role of CSOs in ethics assessment

CSOs are not directly involved in ethical assessment councils or research ethics committees. However, there are initiatives to involve civil society in bioethics debates to obtain. *Aktion Mensch*[174] organised an on-line public discussion forum on bioethical issues, 1000fragen.de, which was active from 2002 to 2009. More than 100,000 comments from citizen were recorded and are still accessible on the project's website.[175] The forum generated a lot of interest and was also academically studied.[176] Several other CSOs and initiatives are active in the field providing information and developing positions on ethical issues, especially in biomedicine and genetics, e.g. *Gen-ethische Netzwerk*,[177] *Interessen Gemeinschaften Kritische Bioethik Deutschland.*[178]

CSOs in Germany strive for more influence on research agendas, especially on subjects related to environmental protection and sustainable development. *ForschungsWende* is a civil society platform for environmental organisations and agencies for discussion of research and innovation policies.[179] Its aim is to "enable CSOs of all kinds – social organisations, environmental organisations, transparency (Germany), consumer protection organisations, religious groups, development groups to engage in research and innovation system and to be advocates for their special themes, such as biodiversity, climate change, consumer protection, etc."[180] *ForschungsWende* assesses R&I budget plans and provides feedback and recommendations to the Parliament and the Ministry of Education and Research. Its goal is to push societal and environmental challenges higher up the research agenda.

Several environmental CSOs engage in research-based environmental impact assessment of technologies. Some of them, such as *NABU* (*Naturschutzbund Deutschland*) and *BUND* (*Bund für Umwelt und Naturschutz Deutschland*) are officially recognised by the government and must be consulted on environmental issues and policies.[181] A number of other CSOs issue position statements on environmental, societal or developmental impacts of new technologies, e.g. *INKOTA*'s position paper on biofuels.[182]

# 7 Discussion

There is a plethora of organisations in Germany engaging in ethics assessment and promoting responsible and ethical research. Socially responsible and ethically acceptable research is a political goal. During the last decades, ethics assessment practices have extended from medical and environmental issues to issues of data protection and governmental corporate

[174] https://www.aktion-mensch.de/
[175] http://www.1000fragen.de/
[176] http://www.1000fragen.de/projekt/ueber/index.php
[177] http://gen-ethisches-netzwerk.de/
[178] http://www.kritischebioethik.de/
[179] http://www.forschungswende.de/
[180] SATORI interview with Dr. Steffi Ober, leader of the project.
[181] http://en.wikipedia.org/wiki/Naturschutzbund_Deutschland;
http://en.wikipedia.org/wiki/Bund_f%C3%BCr_Umwelt_und_Naturschutz_Deutschland.
[182] SATORI interview with INKOTA representative. *Cf.* http://www.inkota.de/.

social responsibility (CSR) strategies. CSR initiatives in Germany strongly emphasise the voluntary nature of the implementation of CSR guidelines. In international comparison, social outcomes are high given Germany's high regulatory density and works councils; at the same time there is a complex, historically developed ambivalence towards CSR in German companies.[183] Today, German policies and initiatives to support ethics practices in private industry mostly concern CSR as an element of sustainable development.

Recently, there has been increased involvement and participation of the public in the discussions of ethical issues. Some interviewees suggested that more public engagement should be developed to allow more work on "science in society", e.g. for questions around dual-use or research with vulnerable populations. Moreover, it was recommended that CSOs become more involved in the process of technological development.

In Germany, one of the key values in the ethical debate (in particular the public debate) is human dignity, which has a prominent place in the German Constitution. There is a tendency for deontological argumentation, focusing on the autonomy of persons. Notably, moreover, Germany's history significantly impacts the argumentation in ethics, in particular on topics around human or animal life. Some interviewees refer to Germany's history as strongly influencing its ethics assessment until today.

The German Research Foundation (*Deutsche Forschungsgemeinschaft*), as the central self-governing national research foundation, plays a key role in funding of basic research and states basic rules of ethical conduct and good scientific practice. German universities and publicly funded research institutions have counsellors for research integrity. Research ethics committees that are legally competent assess research projects with human subjects in the medical sciences including drug research. A choice between committees ("committee hopping") is not possible as the researcher's institution is responsible for the ethics assessment by law. There is no national ethics committee for medical research such that there is heterogeneity among federal states. There is continuous effort to improve this; the same holds for the maintenance of independence of the RECs and regulations concerning the scope of topics for RECs. Ethics training for researchers is widely lacking (except for the training offered by the *Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland* for members of RECs[184]), and further capacity building is desirable.

The National Ethics Council makes recommendations on ethical issues and legislation. It is independent and has a considerable influence on the discussions in politics. However, as the Bundestag and the Federal Government propose the members, and politics is not bound to the Council's advice, the impact on actual decision-making is not always predictable.

---

[183] http://www.sowi.rub.de/mam/content/lsip/cornellpaper_kindermann.pdf (including interviews with relevant stakeholders), & Zeidler, Max, "Corporate Social Responsibility: Imagepolitur oder neuer Gesellschaftsvertrag im Entstehen?" in Daniel Dettling and Max von Bismarck (eds.), *Marke D: Das Projekt der naechsten Generation, Leske und Budrich,* Opladen, 2003, pp. 139-146.

[184] For RECs in the field of biomedical research, capacity is ensured via infrastructure, technical equipment, and qualified personal.

The German Reference Centre for Ethics in the Life Sciences provides information on ethically relevant topics, and the Office of Technology Assessment at the German Bundestag as an independent institution offers advice on research and technology to the Bundestag. The Bundestag establishes “study commissions” to prepare of decisions on wide-ranging and significant issues.

There is a general demand for more public engagement as well as for capacity building both in interdisciplinary fields in academia and for the communication between scientists and other stakeholders involved in the process of assessment, e.g. NGOs. There is also a need for improved transparency regarding assessment criteria and objects.

Currently, political discussion and legislation is needed with respect to diverse issues in the field of research ethics. As a lot of ethics assessment is done via recommendations and voiced opinions, the immediate impact, e.g. a legislative change, is often hard to assess.