



Ethics Assessment in Different Countries

Serbia

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Annex 4.h

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

Deliverable 1.1

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1. Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation in the Republic of Serbia, both for the public and private sector. It 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).

We will begin with providing some basic information about Serbia and the historical development of ethics assessment institutions in the country. With a population of 7,186,862 inhabitants¹ Serbia is situated in the center of the Balkan Peninsula, in Southeast Europe. The northern part of Serbia belongs to central Europe, but in terms of geography and climate it is also partly a Mediterranean country. The Republic of Serbia in its composition also comprises two autonomous provinces: Vojvodina and Kosovo and Metohija.² The official language is Serbian and Belgrade is the capital and the largest city of Serbia.

The Republic of Serbia is not a member of European Union but from January 2014 is in process of accession negotiations with EU. As far as a type of government is concerned Serbia is a republic based on parliamentary democracy.

Serbia is former socialist country and it is still in an economic transition towards market economy. Industry in Serbia is based on production in auto industry, base metals, chemicals, food processing, rubber and plastic and so on. In 2011 Serbia had a gross domestic product (GDP) of 31,472 million Euros.³ In the same year, the gross domestic expenditure on research and development (GERD) as a percentage of GDP was 0.777% which was significantly lower in comparison to the EU27 average (2.03%). Table 1 and table 2 show a breakdown of the GERD, in terms of percentages, by financing sector and performing sector.⁴

Industry	Government	Other national sources	Sources abroad
9.1	63.4	22	5.5

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

Business enterprise	Higher education	Government	Non-profit
9.6	56.6	33.8	n/a

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

After democratic changes in October 2000, Serbia took a decisive step to end its political and economic isolation and embark on a road of European integration. This have had a great

¹ Statistical Office of the Republic of Serbia, "2011 Census of Population, Households and Dwellings in the Republic of Serbia", Belgrade, 2012.

² Since the status of Kosovo is not officially recognised, this report is addressing only to central Serbia and Vojvodina.

³ Statistical Office of the Republic of Serbia, "Statistical pocketbook of Republic of Serbia 2014", Belgrade, 2014.

⁴ Eurostat database, 2011 figures.

influence on regulatory framework created in the past 14 years, including the field of the ethics assessment which was rather neglected in earlier period. As a part of the former Yugoslavia, Serbia has inherited legal basis for ethics assessment mostly in health care domain. General Law on the organisation of health services (1960) stipulated the adoption of Codes of ethics of health-care workers. However, at the time, adopted Code provisions did not directly address ethical decision-making, but only generally stated that the management of professional organisations has the right and duty to ensure the full realisation of the principles of the Code of Ethics. The concept of ethical decision-making was first brought into law by dealing with issues of abortion, primarily in the form of special counselling commission, and later the Ethics boards (Mujović, 2012).

During the 1990s the legal basis of ethical principles in medical scientific research and practice were more widely developed and implemented, but throughout this time Serbia was isolated as a consequence of the breakup of former Yugoslavia. Intensive process of harmonisation with EU legislation began when Serbia was readmitted in UN in December 2001 (following a nine-year break), and after it became a Member of Council of Europe in April 2003 (Stefanović, 2007).

Starting from 2005 all health institutions in Serbia are obliged to establish ethics committees, which was prescribed by Law on Health Care. Currently, the highest body for ethics assessment in Serbia is the *Ethics Board of Serbia* established in 2008.

Apart from national recommendations, the core of the regulations on biomedical research in Serbia is the *Declaration of Helsinki*, defined by the World Medical Association. This declaration often serves as a baseline for the organisations dealing with ethics assessment. Furthermore, the Law on Patients⁵ relies on this declaration in part regarding the patients' rights (including children) involved in medical research. In addition, the *Medicines and Medical Devices Agency* of Serbia (see section 2.1.2) which gives final approval for medical research also calls up on *Declaration of Helsinki*.⁶

Moreover, the Republic of Serbia ratified some important international conventions⁷ that can be the basic for establishing appropriate regulatory framework for ethics assessment.

⁵ http://www.parlament.gov.rs/upload/archive/files/lat/pdf/predlozi_zakona/1283-13Lat.pdf

⁶ <http://www.alims.gov.rs/eng/veterinary-medicines/marketing-medicinal-products/>

⁷ For example: *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*.

2. National government institutions and policies

This chapter will provide a discussion of Serbian national government institutions and policies relating to research and innovation. The following will be examined: The general institutional structure of Serbian government and government-controlled institutions; governmental institutions with a role in ethics assessment; and national laws and policies for ethics assessment.

2.1 General institutional structure

In this section, the general institutional structure of Serbian government and government-controlled institutions, as it relates to research and innovation, will be laid out. The following topics will be included in the discussion: The form of government; the nature of and relations between executive, the legislative and judicial branches; the major ministries and government organisations; and the role of government in research and innovation in private sector.

2.1.1 General structure of government

The government system in the Republic of Serbia is based on a division of power between the legislative, executive and judiciary branches with balanced and mutual control between three branches of power.⁸ The National Assembly is the supreme representative body and the holder of constitutional and legislative power in the Republic of Serbia.⁹ The 250 members of the National Assembly are elected through direct elections on the basis of party-list proportional representation for a four year period. The head of state is the President who is elected through direct elections but the office holds a rather limited executive power. The government is the highest executive authority in the Republic of Serbia¹⁰ since it creates and conducts politics, adopts regulations and other general acts in order to execute laws, proposes bills and other general acts to the National Assembly, and so on. The current government of Serbia consists of 18 ministers, who are heads of 16 specific government ministries. The head of the cabinet is the Prime Minister of the Republic of Serbia, who is usually the leader of the largest party in the government coalition.

The legal system of Serbia is based on the principles of Roman law and continental civil law. Judiciary is formally independent from the executive and legislative branches of government, but in practice there are cases of political pressure on its independency.¹¹

2.1.2 Government organisations relevant to research and innovation

Within government, the *Ministry of Education, Science and Technological Development (Min. ESTD)* is the primary entity responsible for research and innovation policy, it is further responsible for the public research infrastructure and funding of basic research. Its policies are implemented by the agencies and research institutes it provides funding to. There are several

⁸ Constitution of the Republic of Serbia (Article 4.), “Official Gazette of the Republic of Serbia” no. 98/2006. http://www.srbija.gov.rs/cinjenice_o_srbiji/ustav.php?change_lang=en

⁹<http://www.parlament.gov.rs/national-assembly/role-and-mode-of-operation/jurisdiction.501.html>

¹⁰<http://www.parlament.gov.rs/upload/documents/publications/Engleski%20Final.pdf>

¹¹<http://www.diritticomparati.it/2012/12/judicial-independence-and-impartiality-in-serbia-between-law-and-culture.html>

government organisations, associated with Min. ESTD, that are responsible for R&I in Serbia. It is important to mention that the majority of these organisations are rather new, founded in the last five to ten years, mostly as a part of the process of accession negotiations with EU. For example, one R&I related body associated with Min. ESTD is the *National Council for Scientific and Technological development* (Nacionalni savet za naučni i tehnološki razvoj),¹² which was established by Serbian government on May 20th 2010. The purpose of this body is to advice the government and parliament on research, technology and innovation policy with a focus on middle- to long-term research policy issues such are those presented in the document “Strategy of scientific and technological development of Republic of Serbia for 2010-2015 (Official Gazette no. 13/10).¹³

A second important R&I-related body is the *Innovation Fund* (Fond za inovacionu delatnost),¹⁴ established after the adoption of the Innovation law in 2006, although this Fund became fully operational in 2011. The main objectives of the Fund are to provide funding for innovations, to promote innovation in priority areas of science and technology and to support commercialization of technology transfer thus enabling new technologies to reach the market. Another example is the *Center for the promotion of the Science* (Centar za promociju nauke)¹⁵ is government institution established in line with the Law on Scientific research in 2010, as a part of the overall strategic plan for the development of Serbia as a knowledge based economy. The Center conducts numerous R&I promoting activities such as public debates, panels, workshops, exhibitions, projects and so on.

In the area of bio-medical research there are also a few important governmental organisations. One is the *Institute for Public Health of Republic of Serbia* (Institut za javno zdravlje Srbije "Dr Milan Jovanović Batut")¹⁶ which is associated with Ministry of Health Care (Min. HC). The Institute, with almost a one hundred years long tradition, represents an expert institution for public health, which provides advice, support and guidance to the Serbian government and all departments for public health and conducts independent research on issues related to public health in Serbia. Another examples is the *Medicines and Medical Devices Agency of Serbia* (Agencija za lekove i medicinska sredstva Srbije),¹⁷ an independent, government-funded body that is tasked with contributing to the accomplishment of the basic human right for quality, efficacious and safe medicines and medical devices accessibility as well as to promote and enhance public and animal health.

Furthermore, within the *Ministry of Agriculture and Environmental Protection* (Min. MAEP) there is the *Serbian Environmental Protection Agency* (Agencija za zaštitu životne sredine Srbije)¹⁸ founded in 2004. One of this Agency’s main tasks is to ensure the availability of reliable and forehand data and information on the state of the environment which are essential for effective environmental policy realisation.

¹²<http://www.mpn.gov.rs/nauka/tela-i-komisije/545-nacionalni-savet-za-naucni-i-tehnoloski-razvoj>

¹³http://www.apps.org.rs/wp-content/uploads/strategije/Strategija_naucni%20i%20tehnoloski%20razvoj%20do%202015.pdf

¹⁴<http://www.innovationfund.rs/>

¹⁵<http://www.cpn.rs/o-centru/?lang=en>

¹⁶http://www.batut.org.rs/index.php?category_id=122

¹⁷<http://www.alims.gov.rs/eng/>

¹⁸<http://www.sepa.gov.rs/>

The Ministry of Economy (Min E.) is also an important institution for the support of innovation activities and the creation of a national innovation system in Serbia. With regards to this the relevant body is the *National Agency for the Regional Development* (Nacionalna agencija za regionalni razvoj - NARR),¹⁹ which seeks sustainable mechanisms for fostering innovation and the enhancement of innovation in Serbia.

2.2 Governmental institutions for ethics assessment

As we already mentioned main laws, policies and regulation relating ethics assessment and similar activities in Serbia were established in the last decade. Regulatory framework for ethics assessment of R&I is well developed only in the field of biomedical research and innovation i.e. clinical trials, medication testing and experiments on animals,²⁰ while other scientific research areas are only partly regulated or not regulated at all. Only few institutions in other scientific fields have ethics committees or Codes of conduct. Technical (engineering) and social sciences are left without ethics assessment, since there are no laws or by-laws defining the requirements for ethics assessment of research and innovations in these fields.

The following is a list of national governmental and government-funded bodies that have a role in ethics assessment (e.g. in terms of setting standards or providing advice to government) and related areas.

2.2.1 Advisory councils for government policy

- The *National Council for Scientific and Technological development* (See section 2.1)
- The *Health Council of Serbia* (Zdravstveni savet Srbije)²¹ is an independent, government-funded body that provides advice to the government on policy relating to public health and healthcare.²²
- The *Medicines and Medical Devices Agency of Serbia* (See section 2.1)
- The *National council for biosafety* (Nacionalni savet za biološku sigurnost)²³ represents an expert body that, among other activities, monitors the status and development in the field of GMO organisms and provides technical assistance to the authority responsible for GMO.

¹⁹http://narr.gov.rs/index.php/narr_en

²⁰Law on Health Care (Zakon o zdravstvenoj zaštiti) Official Gazette of the RS“ no. 107/05, 72/09, 88/10, 99/10, 57/11, 119/12, 45/13); Law on Welfare of Animals (Zakon o dobrobiti životinja), “Official Gazette of the Republic of Serbia” no. 41/2009. Available only in Serbian; Law on Medicines and Medical Devices (Zakon o lekovima i medicinskim sredstvima), “Official Gazette of the Republic of Serbia” no. 30/2010

²¹<http://www.zdravstvenisavetsrbije.gov.rs/index.php?page=1>

²²<http://www.rvz.net/en/about-the-council>

²³ <http://www.dgsgenetika.org.rs/pdf/Tarasajev.pdf>

2.2.2 National ethics committees

- The *Ethics Board of Serbia* (Etički odbor Srbije-EOS)²⁴ is an independent, government-funded body whose tasks, among others, includes the implementation and monitoring of scientific research and clinical tests of drugs and medical devices in health care facilities; deciding and handing down opinions concerning disputable issues that are of importance for the implementation of results of scientific research, medical experiments, as well as clinical tests of drugs and medical devices; monitoring of decisions' implementation and reviewing of professional issues related to the taking of human tissue for medical, scientific and educational purposes in the health care facilities within Serbia.
- The *Ethics Council for Welfare of Animals used in Animal Testing of Republic of Serbia* (Etički savet za zaštitu dobrobiti ogleđnih životinja Republike Srbije-ESZZ)²⁵ is an independent, government-funded body whose tasks include providing advice in the area of ethics and animal welfare when conducting experiments, genetic modification and manipulation of animals; providing expert opinion on the ethical and scientific justification of the experiments, as well as the cessation of animal tests; providing advice to ensure the harmonisation of the work of ethics commissions for protection of welfare of animals used in animal testing; providing expert opinions on the execution of specific and invasive experiments²⁶ and participating in the development and promotion of alternative methods of conducting the experiments.

2.2.3 Environmental impact assessment agencies

- *The Serbian Environmental Protection Agency* (See section 2.1)
- The *Council for Ecology* (Savet za ekologiju)²⁷ is an independent, government-funded body which provides advisory services with regards to environmental assessment, implementation of international conventions and directives, as well as the promotion of international cooperation and the development of national and international projects in the field of ecology.

2.2.4 Watchdog agencies

- The *Commissioner for Information of Public Importance and Personal Data Protection* (Poverenik za informacije od javnog značaja i zaštitu podataka o ličnosti)²⁸ is an independent, government-funded body who are entrusted with two tasks: those relating to the commissioner capacity as a second-instance authority responsible for protecting the right to data protection in appeal proceedings and those relating to his/her capacity of a supervisory authority responsible for enforcing the law.

²⁴ Law on Health Care - articles 147. and 148.

²⁵ Law on Welfare of Animals – articles 48.-50.

²⁶ Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe impairment of the well-being or general condition of the animals shall be classified as 'severe' (European parliament, Directive 2010/63/EU; personal interview Zoran Todorović, 17/11/2014)

²⁷ <http://www.mpzss.gov.rs/formirano-savetodavno-telo-ministra-za-zastitu-zivotne-sredine/>

²⁸ <http://www.poverenik.rs/en/home.html>

- The *Protector of Citizens (Zaštitnik građana)*²⁹ is an independent, government-funded body that protects and promotes the fulfilment of citizens' rights by controlling whether the bodies and organisations exercising public authority perform their job in a legal and regular manner. In addition to overseeing the formal compliance with laws and regulations, the Protector of Citizens examines, with particular attention, ethics, conscientiousness, impartiality, expertise, expediency, effectiveness, respect of the citizen's dignity and other features that should characterize public authorities and that citizens rightfully expect from those they finance as taxpayers.

2.3 National laws and policies for ethics assessment

In general basic ethical principles regarding R&I in Serbia are presented in the Constitution of the Republic of Serbia (CRS)³⁰ and in the Laws on Scientific Research Activities (SRA law)³¹ and Higher Education (HE law).³²

Autonomy of universities, faculties and scientific institutions (article 72) and freedom of scientific and artistic creativity (article 73) is guaranteed by CRS. Furthermore SRA law stipulates freedom and autonomy of scientific research, publication of scientific research results, scientific and professional criticism, scientific and professional ethical standards in accordance with principles of good scientific practice and responsibility of scientists for consequences of their work. In Article 7 of SRA law ("Scientific freedoms"), it is declared that scientific work shall be free and not subjected to any limitations, except those arising from observing scientific standards and ethical principles in scientific research, the protection of human rights, and environmental protection. HE law stipulates that academic freedoms shall include freedom of scientific research and artistic creativity, including freedom to publish and present to the public the outcomes of scientific research and artistic achievements; and freedom to make a choice of the method of interpretation of scientific and research findings.

There are only two national Ethics committees established by law (see section 2.2). These address biomedical issues (EOS) and animal welfare (ESZZ). Furthermore, from 2005 all health institutions in Serbia were obliged by Law on Health Care to establish ethics committees. However the competences of the ethics committees on the level of research institutions and the EOS are not clearly separated why the responsibilities of these bodies are overlapping (Hajrija Mujović Zornić, personal interview-3/12/2014).

In addition, all public universities in Serbia have some sort of ethics committees but their task is mainly to resolve complains and not to supervise or give approvals for R&I. From the interview with member of Ethics committee of University of Belgrade (the biggest and the most important University in Serbia) we have learned that this committee is quite ineffective and has a great number of unsolved complains (Dragiša Trailović, personal interview - 02/12/2014).

²⁹<http://www.ombudsman.org.rs/>

³⁰The Constitution of Republic of Serbia, "Official Gazette of the Republic of Serbia ", No. 98/06.

³¹Law on Scientific Research Activities (Zakon o naučnoistraživačkoj delatnosti), "Official Gazette of the Republic of Serbia" no. 110/2005 and 50/2006 –corr. and 18/2010. Available only in Serbian.

³²Law on Higher Education (Zakon o visokom obrazovanju) "Official Gazette of the Republic of Serbia", No.76/2005, 100/2007, 97/2008, 44/2010, 93/2012, 89/2013 and 99/2014.

When it comes to ethics assessment policy, there are no frameworks that can be used to define procedures of ethics assessment. Practically every institution in Serbia is left alone to define their Codes of conduct (Zvonko Magić, personal interview - 10/12/2014, Hajrija Mujović Zornić, personal interview-3/12/2014). Two scientific research institutes in the Republic of Serbia – Institute for Oncology and Radiology of Serbia (in January 2001) and Institute for Medical Research (in February 2001) were the first to adopt the Code of Ethics of Scientific Research – Good Scientific Practice (Vučković-Ljubić, 2007). This Code gives recommendations regarding the establishment of research groups, tasks and care for young scientists, quality assurance in laboratory, documentation, data storing and safeguarding, authorship and original nature of scientific publications, intellectual property etc. In the following years this Code has become quite influential and it is used in many other biomedical universities and research institutes as a framework for creating their own Codes of conduct (Miroslava Živković, personal interview - 20/11/2014).

3. Public research and innovation systems

This chapter provides a discussion of ethics assessment of R&I in public research and innovation systems. In the sections below, the following will be discussed, respectively: the general structure and the role of government; the role of industrial national research associations and standard-setting bodies; the role of research funding organisations; and, finally, the role of research performing institutions.

3.1 General structure and the role of government

This section provides an overview of the general structure of the publicly funded and controlled R&I and higher education system. A description of the different organisations and their interrelations will be provided, as well as and the role of government in creating, regulating and funding them.

The key players in steering higher education and research in Serbia at the system level are the government and the academic community. The roles of both and their relationship have changed several times from the end of the 1980s (and the breakup of former Yugoslavia) till the present day. The current state of affairs is primarily the result of the last legislative change which took place in 2005, when the Parliament of Serbia adopted the Law on Higher Education (Law HE) and the Law on Scientific Research Activities (Law SRA).³³ The highest authority responsible for overall education and research policy is the Ministry of Education, Science and Technological Development of Serbia.³⁴ It recommends policy to government, plans the admission regulation for students, allocates financial resources to higher education and research institutions, oversees the overall development of higher education and ensures the execution of decisions of importance.

An advisory but also a governing role, concerning the formulation of advice for the regulatory and obligations and recommendations for the executive bodies, is taken up by the two national advisory bodies that are established by law - the *National Council of Higher Education* (Nacionalni savet za visoko obrazovanje)³⁵ and The *National Council for Scientific and Technological development* (See section 2.1). These bodies do not have long tradition as they came into existence within the last ten years after the adoption of the HE and SRA laws. The councils consist mainly of academics, proposed by the *Conference of Serbian Universities* (Konferencija univerziteta Srbije-KONUS, see section 3.2) and the *Association of Institutes of Serbia* (Zajednica instituta Srbije-ZIS, see section 3.2) and finally appointed by the National Assembly.

Law HE specifies four types of institutional governance entities for all types of higher education systems: the governing body (Board), the professional body (Senate in the case of universities/Council in the case of faculties); the executive officer (Rector/Dean/Director) and

³³<http://www.finhed.org/media/files/FINHED%20System%20report%20-%20HE%20funding%20in%20Serbia%20FINAL%20.pdf>

³⁴http://eacea.ec.europa.eu/tempus/participating_countries/overview/Serbia.pdf

³⁵<http://www.nsvo.edu.rs/>

the student parliament.³⁶ A university is composed of Faculties or Art Academies. Each Faculty is recognised as a separate and independent legal entity, but cannot exist independently, i.e. it needs to be a constituent part of a university. While there is more private than public owned universities only 20% of students attend private institutions of higher education. The main reasons lie in the fact that public universities have longer tradition, better reputation and more diversified network of higher education institutions (i.e. faculties, institutes, and departments). In addition, there are 57 scientific institutes completely independent from universities that are predominantly engaged in research.³⁷ Universities are also obliged to be engaged in research and their staff must have relevant references and to be able to transfer their scientific knowledge and research results in the education process. Traditionally, all university institutions in Serbia have been involved in research through scientific projects granted by the Min. ESTD in three main research programs areas: fundamental science, technological development and interdisciplinary research.³⁸

3.2 National research associations and standard-setting bodies

This section aims at providing an overview of the research associations and standard-setting bodies in Serbia as well as at analyzing their role in ethics assessment. Firstly, we will discuss the main national organisations SANU and ZIS which have role in stipulating general policies for universities and research institutes. Secondly, we will discuss standard-setting bodies and field specific organisations that are involved in ethics assessment.

The research community in Serbia is primarily represented by two national organisations: the *Serbian Academy of Science and Arts* (Srpska akademija nauka i umetnosti-SANU)³⁹ and the *Association of Institutes of Serbia* (Zajednica instituta Srbije-ZIS).⁴⁰ Furthermore, bearing in mind that university teachers are at the same time obliged to perform and publish results of scientific research, the main association that represents them is the *Conference of Serbian Universities* (Konferencija univerziteta Srbije-KONUS).⁴¹

SANU can trace its history back to the Society of Serbian Letters, scientific and literary society founded in 1841. Among other precursors are the Serbian Learned Society (1864) and the Serbian Royal Academy (1886).⁴² Structure, responsibilities and governing capacities of SANU are defined by a separate Law on SANU adopted by National Assembly in 2010.⁴³ The highest administrative body of SANU is the Assembly made up of all of the members, while the Presidency is the executive body. SANU is comprised of eight departments and eight institutes.

³⁶<http://www.finhed.org/media/files/FINHEd%20System%20report%20-%20HE%20funding%20in%20Serbia%20FINAL%20.pdf>

³⁷<http://www.tempus.ac.rs/uploads/documents/2.2%20sistem%20VO%20u%20Srbiji%20eng.pdf>

³⁸ http://eacea.ec.europa.eu/tempus/participating_countries/overview/Serbia.pdf

³⁹<https://www.sanu.ac.rs/English/Index.aspx>

⁴⁰ <http://www.vinca.rs/zis/>

⁴¹ <http://www.konus.ac.rs/>

⁴²https://www.sanu.ac.rs/Novosti/2014STATUT_SANU.pdf

⁴³Law on Serbian Academy of Science and Arts, (Zakon o SANU) Official Gazette of the Republic of Serbia, No. 18/10.

When it comes to establishing the framework for ethics assessment in Serbia the role of SANU is very important since the first national ethics assessment related body was founded as a result of a cooperation between SANU and the Commission for Cooperation with the UNESCO of the Ministry of Foreign Affairs of Serbia. This body was established in 2003 and named the *National Committee for Bioethics of the Republic of Serbia* (see section 5). Today, after establishing two other National Ethics Committees (EOS and ESZZ both formally established by Law), the role of the National Committee for Bioethics is mostly limited to raising awareness of bioethical issues and stimulate exchange of ideas and information, primarily by education in the field of basic natural sciences, particularly genetics and biomedicine.⁴⁴

Another organisation that represents the interests of researchers in Serbia is ZIS, which was founded in 1990 as a legal successor of the Standing Conference of Scientific-Research Organisations. ZIS is an association of 57 accredited R&D institutes from all fields of science. The main tasks of ZIS are laid down in the Law on Scientific Research Activities. Among other, these are: providing expert advice aimed at achieving scientific and research policy and strategy of scientific development of the Republic of Serbia, as well as providing operational assistance to the ministry in achieving their goals regarding research activities in Serbia. ZIS has representatives in the *National Council for Scientific and Technological development*, the *Board for Accreditation of Research Organizations* (Odbor za akreditaciju naučno-istraživačkih organizacija - OANIO) and the *Commission for Acquiring Scientific Titles* (Komisija za sticanje naučnih zvanja).⁴⁵

On the other hand, ZIS does not give recommendations with regards to ethics assessment, neither is this issue mentioned in any of their documents. The fact is that some of the ZIS members do have ethics committees, but this is not due to their membership of ZIS but rather their affiliation with biomedical sciences (Hajrija Mujović Zornić, personal interview-3/12/2014).

A third organisation that gathers researchers in Serbia is KONUS. This association of universities does not have long tradition in the Serbian system of higher education, since it was established ten years ago. KONUS is primarily oriented to coordinating the work of universities in Serbia, defining policy in the higher education field and fulfilling common interests of their members. KONUS is a very important partner to the *National Council of Higher Education* (KONUS proposes more than 50% of its members) and to the *Commission for Accreditation and Quality Assurance* (Komisija za akreditaciju i proveru kvaliteta - KAPK)⁴⁶ whose great majority of members is proposed by KONUS. Furthermore, like ZIS, KONUS also has representatives in the *National Council for Scientific and Technological development*, the *Board for Accreditation of Research Organizations* and the *Commission for Acquiring Scientific Titles*. However, like ZIS, when it comes to ethics assessment there are no signs which could indicate that KONUS has been working on this issue.

We have already mentioned the two most important standard setting bodies in the research area in Serbia - OANIO and KAPK. These bodies' main task is issuing licences for scientific

⁴⁴ <https://www.sanu.ac.rs/English/Bioethics/Bioethics.aspx>

⁴⁵ <http://www.mpn.gov.rs/nauka/tela-i-komisije?lang=sr-YU>

⁴⁶ <http://www.kapk.org/>

institutions in Serbia. After analysing these bodies documents and after the interview with one member of KAPK (Sofija Pekić, personal interview – 12/12/2014) we determined that ethics assessment of institutions when issuing licence is not required nor it is required that these institutions have defined ethics assessment procedures. However, KAPK evaluates whether standards for accreditation of given institution contain mechanisms of internal quality control. This is mainly done by checking the documents but it is not eliminatory, meaning that institution that does not have these mechanisms will not be left without licence.

3.3 Research funding organisations

This section analyses whether research funding organisations include ethics assessment in determining how to spend their funding and their interaction with research performing organisations. We will also address the question whether attention to ethical issues is a condition for basic funding for universities and other public research institutions.

As shown in first chapter of this Report (see table 1.) government is the most important if not the only body that performs systematic funding of scientific research in Serbia. Investments in R&I from public sources are prioritized and budgeted in the framework of multi-annual plans to ensure stability and long term impact. Project financing based on open competition for R&D and innovation projects is a decades-long practice in Serbia.⁴⁷ Every three to five years Min. ESTD announces competitions for research funding in three main research programs: fundamental science, technological development and interdisciplinary research. The last public call for the evaluation and projects funding was announced in 2010 for the 2011-2015 period. In the process of selection, project proposals were subjected to evaluation of national expert bodies as well as to review by three anonymous reviewers, of which one was from Serbia and two were international. For the first time in the process of project proposal selection, within Min. ESTD a three-member, ad hoc, ethics committee was established to assess experimental projects in the biomedical field.⁴⁸ This process was however quite non-transparent since the members of this ethics committee were anonymous and it was unclear which guidelines and criteria they were referring to in the process of ethics assessment. However, project proposals from all other research areas, such as social or technological development research, have not been subjected to any sort of ethics assessment.

Another type of projects - innovation projects that are also funded by Min. ESTD, - are supposed to be realized in a shorter period within smaller time frames (from six months to one year) by innovation organisations in cooperation with research institutions. The aim of this funding program is to support the results of projects with an emphasis on developing commercially validated products, including software, technology processes or innovative services, as well as providing infrastructure support to the innovation activity. These project proposals are not subjected to ethics assessment.

Furthermore, the *Fund for Environmental Protection of Republic of Serbia* (Fond za zaštitu životne sredine Republike Srbije), which was financed from ecological taxes collected from major industrial polluters was an important funding resource for ecological research. This

⁴⁷European Commission, ERAWATCH Country Reports 2012: Serbia, 2013 http://erawatch.jrc.ec.europa.eu/erawatch/export/sites/default/galleries/generic_files/file_0485.pdf

⁴⁸ Internal government document and personal interview with ESTD deputy minister responsible for basic research and development of research staff Nikola Tanić, 25/12/2014.

Fund was however terminated in 2012, but according to announcement of Minister of Agriculture and Environmental Protection it will be reactivated in the second half of 2015. To our knowledge this Fund also did not perform ethics assessment in the process of funding R&I.⁴⁹

3.4 Research performing organisations

Subject of this section are general ethical standards, procedures and organisational units for ethics assessment in research performing organisations. Furthermore we will discuss the role and organisation of research ethics committees, with attention to training and education for ethics.

According to KAPK data from 2011, there were eight public universities in Serbia with 89 faculties and the same number of private universities with 29 faculties.⁵⁰ Most of the public universities have a tradition reaching back more than 50 years, with the notable exception of the University of Belgrade (the biggest and oldest university) whose origin can be tracked to the beginning of the 19th century. On the other hand all private universities in Serbia were founded within the last 10-20 years following the breakup of the former Yugoslavia. It is also important to emphasize that public universities in Serbia are organized as loose organisations of legally independent faculties, whose institutional autonomy is by law at the same level as the one enjoyed by universities.⁵¹ In line with this is the fact that if ethics assessment is performed it will rather be at the level of faculty than at departmental or university level.

Besides universities, Serbian scientists also work at 57 research institutes associated in ZIS. These institutes belong to all scientific fields but only those who perform medical research or animal testing are obliged to have an ethics committee. In other areas of scientific research institutes do not have this obligation, but some institutes have established ethics committees on a voluntary basis. The most recent example is ethics committee established within the *Institute of Social Sciences* (Hajrija Mujović Zornić, personal interview-3/12/2014).

The highest body that deals with ethical issues in Serbia is the *Ethics Board of Serbia* (EOS), established in 2008 in accordance with Law on Health Care (see section 2.2). Although the name suggests that EOS is responsible for ethics assessment in general that is not the case. The mere fact that this body is established by “medical” law is determinant when it comes to the field of this EOS competence.⁵² Furthermore, EOS has a consultative and strategic role (i.e. defines procedures, recommendations and principles for conducting and monitoring ethics evaluations) but no binding power at all. More precisely, all major decisions concerning biomedical research approval and monitoring are made by ethics committees at the level of research institution, whether it is a university, a research institute or a clinical centre. These

⁴⁹<http://www.eko.minpolj.gov.rs/novi-ekoloski-fond-od-septembra/>

⁵⁰ In the meantime two more private universities acquired licences, <http://www.konus.ac.rs/sastav.html>

⁵¹<http://www.finhed.org/media/files/FINHED%20System%20report%20-%20HE%20funding%20in%20Serbia%20FINAL%20.pdf>

⁵² The Law on Health Care stipulates that this Board shall have nine members who shall be elected from the ranks of prominent experts who have major results in the work, as well as contribution in the areas of health care, professional ethics of health care practitioners and of humanistic sciences.

ethics committees were also established by the Law on Health Care. For example, in order to conduct a clinical trial researcher should obtain permission from ethics committee of the Clinic, and if ethics assessment is negative, the research will be suspended. If the researcher is dissatisfied with the assessment he may appeal to the EOS but its appraisal will only be of advisory character. The final decision whether to conduct clinical trial or not is made by the responsible body in the Ministry of Health, such as the Agency for Medicines and Medical Devices of Serbia (see section 2.2).

The same procedure is followed for research that involves animals. At the national level the ESZZ established in 2009 by Law on Welfare of Animals (see section 2.2) has practically the same role as EOS. All major decisions concerning approval of experiments conducted on animals and monitoring are made by ethics commissions at the level of research institution. Furthermore, only institutions which are registered for conducting animal experiments can perform this kind of research.

There is no legal requirement for members of ethics committees regarding training on how to deal with ethical issues. However, there are some training programs created in cooperation between the Faculty of Medicine at the University of Belgrade and the National Committee for Bioethics. These programs have yet to be approved. One of the primary aims of this program will be to harmonize the work of research ethics committees and their procedures (personal interview Hajrija Mujović Zornić, 3/12/2014).

As we have previously stressed, research in other than biomedical sciences remain without serious ethics assessment both at national and level of the research institution. Although most of the public universities do have ethics committees their main task is to deal with complains regarding professional misconduct (see section 2.3).

4. Private research and innovation systems

In this chapter ethics assessment in industry related research will be examined. After describing the industry landscape in Serbia the main attention will be placed on the practice of industry related CSR. The role of industry associations and networks and organisations for accreditation, certification, evaluation and standard setting for industry will be discussed. At the end of this chapter attention will be placed on ethics assessment in large corporations in comparison with SMEs and the role of stakeholders in CSR and ethics assessment.

4.1 General structure and the role of government

This section describes the industry landscape in Serbia, with respect to the major organisations that represent industry. In addition, it discusses government policies and initiatives that support ethics assessment in private industry, including legislation and initiatives in the area of CSR. Furthermore, it analyses the initiatives for public-private partnerships and their support of CSR in Serbia.

The Serbian industry is a typical reflection of a transition economy. A great number of socialist industrial giants are closed and those who are still operational, in the form of public enterprises, lack the resources and capacities to be competitive. The majority of privatized companies are owned by international corporations while large national, privately owned, industrial enterprises are in minority. Serbian industry is burdened with issues such as structural discrepancies, obsolete technology, few investments, high production costs, social functions still being dependent on companies, inefficiency, ecological requirements, but also low exports, incompatibility with EU standards and a lack of comprehension of industrial processes in the EU (Jakopin and Bajec, 2009).

In 2013 Serbia had an employed population of exactly 1.715.163 people, of which close to 20 percent, or 337.285 people, were employed in industry (excluding construction).⁵³ Furthermore, in 2012 the share of industry in the nominal GDP was around 19% (Šojić, 2014). The industry in Serbia is primarily based on the production in the auto industry, of base metals, chemicals, food processing and rubber and plastic.

There are many business associations in Serbia but just a few of them represent industry:

- *Chamber of Commerce and Industry in Serbia* (Privredna komora Srbije-PKS)⁵⁴ - This is an independent, non-governmental, non-budgetary, national association of organisations and individuals who work in registered economic activity. With a more than 150 years long tradition PKS is the largest and most important association of business subjects in Serbia. Within PKS there are many associations and few of them are representing industry:
 - *Association of Chemical, Pharmaceutical, Rubber and Non-Metal Industries*⁵⁵

⁵³Statistical pocketbook of Republic of Serbia 2014, Statistical Office of the Republic of Serbia, Belgrade, 2014.

⁵⁴<http://www.pks.rs/default.aspx?idjezik=3>

⁵⁵<http://www.pks.rs/ONama.aspx?id=240&p=0&>

- *Association of Metalworking and Power Industry, Metal Mines and Metallurgy*⁵⁶
- *Association of Energy and Coal Mining*⁵⁷
- Association of Electronic Communications and Information Society⁵⁸

- *Inovia*⁵⁹ – This is the association of the manufacturers of innovative drugs. Members of the Association are 19 innovative pharmaceutical companies that are doing business in Serbia. The aim of the association is to promote the technological and economic development of the innovative pharmaceutical industry in Serbia. INOVIA is a member of EFPIA, European Federation of Pharmaceutical Industries and Associations, whose Codes of conduct automatically became mandatory for all member companies of the INOVIA Association.

4.1.1 Government and non-government policies and initiatives to support ethics assessment in private industry

In Serbia there is no Ministry or separate organisational unit within a Ministry that deals exclusively with the promotion and development of Corporate Social Responsibility (CSR) or business ethics, but the government, through the Ministry of Labour and Social Policy, has taken steps to establish public policy in this area. The government is also taking measures to incorporate CSR issues in the laws and regulations, as part of the process of accession to the European Union. One of these measures is the adoption of the *Strategy for the Development and Promotion of CSR in the Republic of Serbia for the period 2010 – 2015*.⁶⁰

Furthermore, several laws relating to the protection of the environment includes a requirement for companies to report environmental consequences of their actions.⁶¹ The Strategy emphasises that the majority of companies is, however, not quite aware of the importance of reporting on their environmental impact, with the exception of branches of multinational companies and the companies with predominantly foreign ownership. Thus, the reporting amounts to providing legally required reports and studies to competent institutions and an occasional public announcement on the website of the company, in the media and through other PR activities.⁶²

For now, the leading role in promoting CSR in Serbia has been taken by the non-governmental sector, especially business associations. For example, the Association of

⁵⁶<http://www.pks.rs/ONama.aspx?id=247&p=0&>

⁵⁷<http://www.pks.rs/ONama.aspx?id=238&p=0&>

⁵⁸<http://www.pks.rs/ONama.aspx?id=242&p=0&>

⁵⁹<http://www.inovia.rs/index.php/en/>

⁶⁰http://www.noois.rs/pdf/Strategija_razvoja_i_promocije.pdf

⁶¹ *Law on Environmental Protection* (“Official Gazette of the Republic of Serbia”, No. 135/2004, 36/2009, 36/2009 –state law, 72/2009 –state law and 43/2011 –Constitutional Court’s decision); *Law on Environmental Impact Assessment* (“Official Gazette of the Republic of Serbia”, No. 135/04 and 36/09); *Law on Strategic Impact Assessment* (“Official Gazette of the Republic of Serbia”, No. 135/04); *Law on Integrated Environmental Pollution Prevention and Control* (“Official Gazette of the Republic of Serbia”, No. 135/04).

⁶² http://www.crnps.org.rs/wp-content/uploads/Brifing-003_engl_web.pdf

Corporate Directors of Serbia (see section 4.2.1), which was established on the best international practices, whose members are CEOs or board members of corporations and who commit to an Ethics Code and adopted the OECD Principles of Corporate Governance.⁶³ The Serbian Chamber of Commerce has also adopted Corporate Governance Code to which their members are bound. The UN Global Network also has an active branch in Serbia⁶⁴ and there is also the Socially Responsible Business Forum, the first and most important alliance of socially responsible companies in Serbia.⁶⁵

Furthermore, the *National Alliance for Local Economic Development* (Nacionalna alijansa za lokalni ekonomski razvoj-NALED)⁶⁶, a tripartite business association made up of representatives of business, CSOs and municipalities, promotes CSR as a prerequisite for sustainable development. NALED initiated the CSR certification program (CSR Certification) in 2011 in cooperation with Smart Kolektiv and Balkan Community Initiatives Fund (BCIF). The initiative was supported by USAID through the Civil Society Advocacy Initiative Program in Serbia, implemented by the Institute for Sustainable Communities. CSR Certification establishes the first national standard of CSR in Serbia.

4.1.2 Initiatives for public-private partnerships

Initiatives for public-private partnerships, especially with regard to the ethics assessment or CSR are not developed in Serbia. Just recently the National Assembly adopted Law on Public-Private Partnerships and Concessions ("Official Gazette of Republic of Serbia", no. 88/2011) followed with establishment of the *Commission for Public-Private Partnerships* (Komisija za javno privatno partnerstvo).⁶⁷ This Commission was founded by the government as an inter-departmental, operationally independent public body to ensure technical assistance in implementation of public-private partnerships and concessions. According to the view of the Commission, public-private partnerships should be economically efficient and socially responsible. However, there are not many evidences that this Commission has been involved in promoting CSR in Serbia.

Another governmental body is the *Social and Economic Council* (Socijalno ekonomski savet Republike Srbije)⁶⁸ a tripartite body, appointed by government, and made up of representatives of Serbian government, representatives of associations of employers and representatives of trade unions. This Council does not have a permanent working body that deals with CSR but through other working bodies such as *Working Body on Workplace Safety and Health Issues* it touches upon some CSR related issues.

Furthermore, NALED lead the project "Public-private partnership as development potential" funded by USAID Sustainable Local Development Project. The project is implemented in cooperation with the Ministry of Regional Development and Local Government. The goal of the project was to provide technical assistance for the development of action plans for public-

⁶³http://www.ses.org.rs/eng/ukds-eticki_kodeks.php

⁶⁴https://www.unglobalcompact.org/NetworksAroundTheWorld/local_network_sheet/RS.html

⁶⁵<http://fop.odgovornoposlovanje.rs/home.60.html>

⁶⁶<http://www.naled-serbia.org/>

⁶⁷<http://www.ppp.gov.rs/en>

⁶⁸<http://www.socijalnoekonomskisavet.rs/en/index.html>

private partnership project ideas, thus enabling local governments to participate in such business arrangements with private partners.⁶⁹

There is also the non-governmental *Centre for Public-Private Partnership* (Centar za javno privatno partnerstvo)⁷⁰ of the Belgrade Chamber of Commerce established in 2011, with the aim of informing and educating both public and private sectors about concept of investing - public-private partnership and also to promote its use in Serbia.

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

This section discusses industry associations and networks and accreditation, certification, evaluation and standard setting organisations for industry in the setting and enforcement or promotion of standards and practices regarding ethics assessment and CSR in industry. It also examines the extent industry makes use of independent, external ethics committees to evaluate their R&D, and, if possible, how these committees are set up and governed.

4.2.1 Industry associations

As the largest association of business subjects, the *Chamber of Commerce and Industry of Serbia – PKS* is at the same time the most devoted business association to the establishment and promotion of the CSR principles. The most important activities the PKS carries out in the encouragement of socially responsible business are the CSR National Award, the CCIS Council for CSR and the Global Agreement in Serbia Secretariat. The CSR National Award was established for the first time in 2007 when a total of 55 companies applied. This number has gradually increased as well as the number of firms realizing the importance of this business concept. What makes this CSR National Award unique and separates it from all other CSR awards is the methodology which equally treats different business aspects. The questionnaire involves five main pillars of the CSR: Employment, environment, market, property and community.⁷¹

The *association of the manufacturers of innovative drugs – Inovia*, issued their Code of ethics for the promotion of prescription only medicines and the interaction with healthcare professionals.⁷² This Code seeks to ensure that pharmaceutical companies operate in a responsible, ethical and transparent manner. The aim of this Code is to provide that pharmaceutical companies conduct their promotion and interaction with healthcare professionals in a credible manner, avoiding activities that could lead to a potential conflict of interest among healthcare professionals, while taking into account the political and social environment and the legislative framework related to medicinal products in Serbia.

The *Serbian Association of Corporate Directors* (Udruženje korporativnih direktora Srbije)⁷³ (formally established by a decision of the government) which gathers some of the biggest industrial corporations is very active in promoting ethical corporative behaviour. Two out of

⁶⁹<http://www.naled-serbia.org/en/page/131/Project-%22Public-Private-Partnership-as-Development-Potential>

⁷⁰<http://pppcenter.rs/EIndex.aspx>

⁷¹<http://www.pks.rs/PrivredaSrbije.aspx?id=525&p=0&>

⁷²http://www.inovia.rs/images/publications/inovia_code_2014.pdf

⁷³<http://www.ses.org.rs/eng/ukds-pravilnik.php>

three basic aims that are proclaimed in the Statutes of the Association are related to CSR: the development of efficient and ethical corporative management and the promotion of a management approach guided by economic, social and environmental values. Furthermore this Association has a Code of Ethics⁷⁴ which provides guidance on ethical decision-making by corporate directors, going beyond compliance with laws and regulations and embracing the spirit of the law. In this document, ethical behaviour is considered to be the best practice in corporate governance and it is compulsory for all members of the Serbian Association of Corporate Directors.

4.2.2 Certification, evaluation and standard-setting organisations

In Serbia there are several organisations for industry standard setting but these organisations do not require nor promote ethics assessment or CSR. The *Accreditation body of Serbia* (Akreditaciono telo Srbije)⁷⁵ has some environmentally related standard requirements but this is rather sporadic. Also, the *Institute for standardization of Serbia* (Institut za standardizaciju Republike Srbije) in 2011 published *Guidance on social responsibility* - based on ISO 26000 CSR standard.⁷⁶

4.2.3 External ethics committees

As mentioned earlier, only biomedical research involving human subjects and research based on experiments involving animals require a permit by ethics committees (for human subjects) or ethics commissions (for animal experiments) at the level of research performing institution. The same goes for public and private research funding. Research outside of the bio-medical field is not subjected to any kind of ethics assessment.

4.3 Industry

In this section the industrial sector's engagement in CSR with regard to R&I and ethics assessment of R&I will be examined. In addition attention will be given to ethics assessment in large industrial corporations in comparison with SMEs and on the role of stakeholders in CSR and ethics assessment.

The level of industrial business investments in R&I in Serbia is not significant. In first chapter of this Report (table 1.), we showed that industry participated with only 9% of R&D financing. SMEs are not, to our knowledge, systematically, investing in research and innovation and accordingly they do not perform ethics assessment. On the other hand there are different ownership forms of larger industrial corporations in Serbia and thus their relation to ethics assessment is not at the same level. For example, multinational industrial corporations that are present in Serbia like Holcim, Henkel and Gazprom Neft have their own CSR or ethics assessment policies that are created in their centres and adjusted to national laws, but these corporations are not interested in financing research in Serbia. The exception is the pharmaceutical industry, but their R&I investments are subjected only to external ethics assessment at the level of the institution that conducts research (Miroslava Živković, personal interview - 20/11/2014).

⁷⁴http://www.ses.org.rs/eng/ukds-eticki_kodeks.php

⁷⁵<http://www.ats.rs/en>

⁷⁶http://www.iss.rs/la/standard/?natstandard_document_id=37544

The other type of industrial corporations in Serbia is large publicly owned enterprises such as the Electric Power Industry of Serbia (Elektroprivreda Srbije-EPS).⁷⁷ EPS is involved in the funding of scientific research as a participant in Min. ESTD project cycles in programs regarding technological development research. EPS invests a lot in R&I in the area of environmental protection. EPS have a number of projects in cooperation with scientific institutes and faculties. At the moment projects worth about EUR 120 million are in progress. Furthermore, EPS are planning to invest EUR 1,2 billion in environmental protection by 2015.⁷⁸ The three biggest projects regarding wastewater treatment in Serbia are in fact projects of EPS. As a part of their CSR policy EPS is working on implementing biomass due to a significantly lower emission of CO₂ (their aim is to replace 10% of coal with biomass). In addition they are considering new technologies for environmental friendly transport and storing of ash as well as finding new ways of using it. Although EPS had developed CSR policy,⁷⁹ the company did not establish any sort of ethics evaluation body and there is no practice of ethics assessment of R&I (personal interview, Mihajlo Gavrić, 28/01/2015).

Regarding private national industrial companies, although many of them have developed CSR policies they are not very active when it comes to scientific R&I investments and thus they do not perform internal ethics assessment of R&I (personal interview, Boro Cvijanovic, 29/01/2015).

⁷⁷<http://www.eps.rs/Eng/index.aspx>

⁷⁸<http://www.eps.rs/Eng/Article.aspx?lista=Sitemap&id=12>

⁷⁹http://www.eps.rs/Eng/Documents/Report%20CSR_2013_web.pdf

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

In this chapter the national associations of professionals for ethics assessment and their role in process of ethical assessment of R&I will be discussed. The chapter will not analyse the Serbian Academy of Science and Arts since this organisation has already been discussed in chapter 3.

5.1 National associations for R&D professions

There are numerous national associations for various R&D professions in Serbia, but their involvement in ethics assessment of R&I is rather negligible. Mainly R&D associations from bio-medical area, such as the Serbian Psychiatric Association (Udruženje psihijatara Srbije),⁸⁰ have the Code of Ethics. One of rare examples outside bio-medical area is the Association of Psychologist of Serbia (Društvo psihologa Srbije). Their first Ethical Code has been adopted 15 years ago.⁸¹

On the other hand majority of associations from other R&D areas have the Court of Honour which is concerned with ethical issues primarily in the context of maintaining professional standards and norms or enhancing their members' career opportunities within the profession. For example, the *Serbian Chamber of Engineers* (Inženjerska komora Srbije)⁸² has the Court of Honour which makes decisions on the cases of violation of the professional standards and norms (professional liability), and proposes related penalties. Work of this Court is based on the Code of Ethics which defines the most important ethical principles regarding the professional activities of Chamber members.

5.2 National associations for (ethics) assessors

In Serbia, there are several organisations that govern the debate about ethical issues. The most active are the *Center for the Study of Bioethics*, the *National Committee for Bioethics* as well as the *Bioethical Society of Serbia*.

The National Committee for Bioethics (Nacionalni komitet za bioetiku)⁸³ was founded in 2003 in cooperation with UNESCO and SANU. It was the first association of professionals for ethics assessment at the national level in Serbia. The committee is performing its functions independently with respect to government authorities, scientific research organisations, researchers, medical officers and other individuals and institutions, in accordance with the UNESCO Charter and the present Rules of Order (Marinković and Magić, 2012). The composition and competence of the Committee are determined in accordance with the regulations, conventions and international declarations. The Committee supports all activities focused on enhancing the general level of public awareness and public and private decisions related to bioethics. It cooperates with international organisations in the area of bioethics, as

⁸⁰<http://www.ups-spa.org/en/etics/>

⁸¹ <http://www.dps.org.rs/ethical-code>

⁸² <http://www.ingkomora.org.rs/eng/?id=indexeng>

⁸³<http://www.sanu.ac.rs/English/Bioethics/Bioethics.aspx>

well as national and regional bioethics associations and committees. After establishing the EOS in 2008 the role of the National Committee for Bioethics has mostly been limited to raising awareness of bioethical issues and stimulating the exchange of ideas and information, primarily through education in the field of basic natural sciences, particularly genetics and biomedicine.

The Center for the Study of Bioethics (Centar za bioetičke studije - CBS)⁸⁴ is a recently founded organisation closely related to the University of Belgrade and situated within *The Institute for Social Sciences*. Members of CBS are scientists from different fields, especially social and medical sciences. The purpose of the Center is stimulating scientific debate on the variety of issues bioethics deals with. CBS is organiser of scientific conferences, lectures, round tables and discussions on bioethical issues. Apart from stimulating and engaging in scientific discussions, Center also endeavours to be involved in a broader public debate on issues with bioethical background. CBS envisions to be regional in scope, but with a number of associate members from out of the region (such as Peter Singer, John Harris, Don Marquis, Ingmar Persson, and many others).

The Bioethical society of Serbia (Bioetičko društvo Srbije - BDS)⁸⁵ is founded in 2008 and situated on the *Medical faculty of University of Belgrade*. Its main activities are directed to encourage, help and develop bioethics through bioethical education and research (Radenović et al., 2012). The society gathers researchers who are interested in ethical issues in fields of medicine, healthcare, population politics, animal welfare, food production etc. Main goal of BDS is to stimulate, help and develop bioethics, bioethical education and research. Their primary activity is raising awareness about bioethical issues. In line with that main activity, BDS is organising of public debates, which, at the beginning, were oriented towards students of medical schools. The debates and round tables are now held in Dom omladine (the “Youth club” which is during the last decades recognised as place of important cultural and scientific events).

⁸⁴http://www.csb.eu.com/index_en.html

⁸⁵http://www.mfub.bg.ac.rs/sr/centri/bds/index.dot?host_id=6023

6. CSOs

This chapter describes the role of civil society organisations (CSOs) in ethics assessment of R&I. After discussing the CSO landscape in Serbia, it examines the role of CSOs in ethics assessment.

6.1 The CSO landscape

This section provides an overview of civil sector in Serbia in terms of its history, structure and funding sources. After discussing national legislation and regulation for CSOs, it reviews major CSOs and their societal role as well as their involvement in R&I.

The majority of CSOs in Serbia (75% of around 16000 registered CSOs)⁸⁶ have been established during the last two and half decades, focusing on themes ranging from support to civil society, democracy and human rights, to problems such as sustainable and local development. These organisations are mostly financed from international foundations, with qualified staff, hierarchy and professionalized structure and strong management capacities. Only 5% of CSOs had budget bigger than EUR 100.000 in 2010 (Gradanske inicijative, 2012). The structure of the NGO sector is to a large extent a consequence of the way it emerged – primarily through various mechanisms of international support, and later on with the support of state funds (Vuković, 2013).

The work of CSOs in Serbia is primarily regulated through the Law of Associations (“Official Gazette of Republic of Serbia” no. 51/2009) and indirectly by several other laws such as: Law on churches and religious organisations, Law on political parties, Law on volunteering, and so on. Serbian CSOs’ main areas of interest and ways of financing are shown on figures 1 and 2.

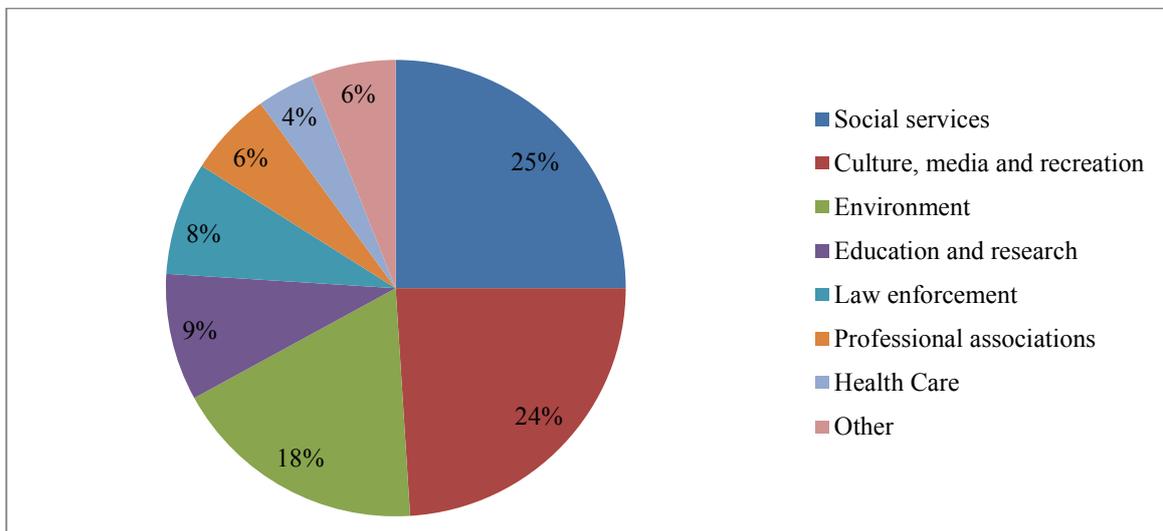


Figure 1: Main areas of interest of Serbian CSOs in 2011. Source: Gradanske inicijative, 2012.

⁸⁶<http://www.gradjanske.org/wp-content/uploads/2014/11/060-OCDsektorSrbija2011.pdf>

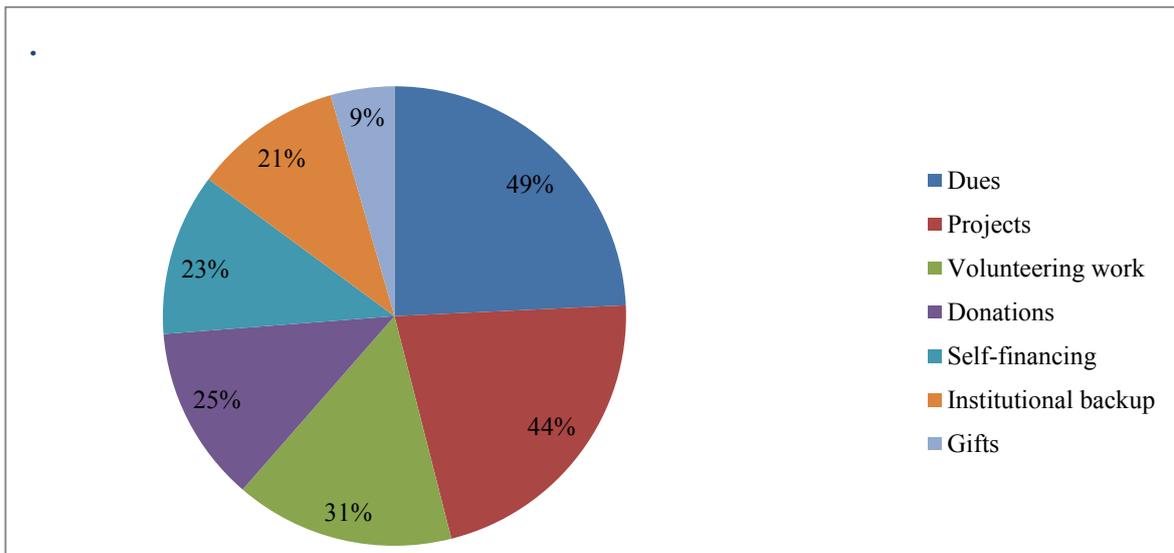


Figure 2. Main ways of financing of Serbian CSOs in 2011. Source: Gradanske inicijative, 2012.

6.1.1 Major CSOs and their societal roles

Religious organisations

- The *Serbian Orthodox Church* (Srpska pravoslavna crkva)⁸⁷ – The great majority of citizens of Serbia are orthodox Christians
- The *Muslim community in Serbia* (Mešihat Islamske zajednice u Srbiji)⁸⁸
- The *Roman Catholic Church in Serbia* (Beogradska nadbiskupija)⁸⁹

Civil liberties/human rights organisations

- The *Belgrade Centre for Security Policy* (BCSP)⁹⁰ is an independent research center dedicated to advancing the security of citizens and a society based on democratic principles and respect for human rights.
- The *Belgrade Centre for Human Rights*⁹¹ is a non-partisan, non-political and non-profit association of citizens concerned with the advancement of the theory and practice of human rights.
- *Equal Opportunities*⁹² is an organisation established with the goal of facilitating equal access for both women and men in using ICT through establishment of permanent mechanisms for bridging the digital and the gender divide.

⁸⁷<http://www.spc.rs/eng>

⁸⁸<http://www.islamskazajednica.org/>

⁸⁹<http://www.kc.org.rs/>

⁹⁰<http://www.bezbednost.org/Bezbednost/2001/English.shtml>

⁹¹<http://www.bgcentar.org.rs/bgcentar/eng-lat/>

⁹²<http://www.e-jednakost.org.rs/en/>

Environmental organisations

- The *Centre for the Environment and Sustainable Development* – CEKOR⁹³ is dedicated to the development of a socially and economically just society with equal opportunities for all citizens, with preserved environment and natural resources for future generations.
- *Environmental Ambassadors*⁹⁴ is a citizens' association, which provides consulting and expert services through its projects in various areas of sustainable development and environmental protection, as well as training in advocacy, lobbying, strategic planning, campaigning, environmental diplomacy and waste management.
- The *Ecological society 'ENDEMIT'*⁹⁵ is aiming to improve state of environment and advocate for sustainable development for benefit of the entire society.

Animal rights organisations

- *ORCA*⁹⁶ is the oldest animal rights organisation in Serbia which, among others, deals with welfare of animals used for experimental and scientific purposes.
- The *Association for Animals Rights and Protection 'Freedom for Animals.'*⁹⁷

Consumer organisations

- The *National Organisation of Consumers in Serbia-NOPS*⁹⁸ is an umbrella consumer organisation with 26 members that includes both local and regional consumer protection organisations from all over the country.

Patient/disabled rights organisations

- The *National Organisation for Rare Diseases*⁹⁹ is an umbrella association for organisations devoted to helping patients with rare diseases.
- The *National Organization of Persons with Disabilities*¹⁰⁰ is the union of organisations focusing on individual disabilities, the organisation of legal advocates of persons with disabilities and the interest organisation gathering persons with different types of disabilities within the territory of the Republic of Serbia.
- *Citizens association 'Onkolog'*¹⁰¹ was founded in 2000 as a humanitarian and non-governmental organisation. It is devoted to gathering citizens interested and willing to

⁹³<http://www.cekor.org/>

⁹⁴<http://ambassadors-env.com/en/>

⁹⁵<http://www.endemit.org.rs/>

⁹⁶<http://www.orca.rs/>

⁹⁷<http://www.sloboda-za-zivotinje.org/sr/udruzenje/o-nama.html>

⁹⁸<http://www.nops.org.rs/>

⁹⁹<http://www.norbs.rs/>

¹⁰⁰<http://www.noois.rs/english>

¹⁰¹<http://www.onkolog.rs/en/>

contribute to the progress of oncological practice, as well as scientists, professionals and other citizens from various fields and professions who can contribute to the general improvement of standards and education in the prevention and treatment of oncological illnesses.

The practice of scientific research financing by CSOs is not well developed in Serbia. There are some organisations, e.g. the *Fund for an Open Society*,¹⁰² who are part of international networks that provide limited funds for conducting scientific research but these are not independent national CSOs. However, even these international networks that operate in Serbia, to our knowledge, do not include ethics assessment in project proposal evaluations. This is partly due to the nature of these project grants which are predominantly planned for social research.

6.2 The role of CSO's in ethics assessment

This section provides a discussion concerning CSOs as stakeholders in public discussion, as participants in ethics assessment panels and procedures, and as agents who engage in ethics assessment themselves. It also analyses the desires of CSOs regarding their role in ethics assessment and problems in playing that role.

With the exception of CSOs that have ethics promotion as one of the basic aims and scopes of their work, CSOs have not been that active in discussions related to ethical issues. Typical example of CSOs involvement in ethics assessment is related to their members' participation in work of ethics committees as representatives of lay people (personal interview Zoran Todorović, 17/11/2014; personal interview Zvonko Magić, 10/12/2014). For example is it customary that activists from animal protection organisations, such as ORCA, participate as laypeople in ethics commissions for experiments on animals (personal interview Zoran Todorović, 17/11/2014). Furthermore, it is often the case that priests are lay people representatives in ethics committees for bio-medical research. This is the common practice in the ethics committee of the Military Medical Academy (personal interview Zvonko Magić, 10/12/2014).

Other than that, CSOs in Serbia take part in public debates on animal welfare, GMO, mandatory vaccination, environmental issues and so on. In this way they are trying to draw the attention of the public and stakeholders to ethical issues. However, the impact of these debates is very limited and the public is not that interested in them. Another problem is that ethics related topics are in many cases approached *ad hoc*, without continuous and competent discussions, often misused for every day political purposes. A recent example was a broad public discussion about GMO.¹⁰³

¹⁰² <http://www.fosserbia.org/>

¹⁰³ <http://www.euractiv.rs/english/6559-gmo-polemics-in-serbia>

7. Discussion

This report elaborated on different aspects of ethics assessment within R&I in Serbia as well as the factors that currently guide and constrain relevant ethics related procedures. For many years ethical issues in R&I in Serbia were associated only with biomedical sciences but even in this field ethics assessment was underdeveloped and without clear guidance (standards, protocols and procedures).

In general, we can identify two processes that gave impetus to the development of ethics assessment practices in Serbia. The first one is the process of accession negotiations with EU which accelerated the harmonization with EU legislation with regards to ethics assessment. The second one is related to the growing importance of ethics issues globally. This resulted in rising awareness about the importance of ethics assessment of R&I as compared with the situation ten years ago (personal interview, Hajrija Mujović Zornić, 3/12/2014). This is also the consequence of a significantly improved legislative framework related to ethics assessment during the last decade.

Furthermore, a new team leading the Min. ESTD is determined to set ethics assessment as one of the top priorities for public funding of R&I (personal interview, ESTD deputy minister responsible for basic research and development of research staff, Nikola Tanić, 25 December 2014).

However, there are still numerous problems which constrain ethics assessment in Serbia. Here we will point out only the most important ones:¹⁰⁴

- The national ethics board appears to be more a formal body, while the real power lies within ethics committees at the level of research performing institutions. This leads to conflict of interest at institutional level since colleagues from the same institution are in a position to assess one another. Furthermore, national ethics board is not authorised to supervise and coordinate the work of ethics committees and resolve potential problems and misconduct.
- EOS is a body founded by *Ministry of Health Care*, so its principal role is to deal with biomedicine issues leaving aside ethics assessment in other scientific and research fields.
- Social and engineering research are not subjected to ethics assessment at all, regardless of the source of financing (private or public)
- CSR is becoming a part of business policy in companies that operate in Serbia, but ethics assessment practically does not exist when it comes to industry investments in R&I. R&I that are financed through private funds are subjected only to the external evaluation and only within biomedical research. There is no kind of ethics assessment in other areas of R&I.

¹⁰⁴ Some of these issues are recognised and discussed by Mujović (2012), Rakić & Bojanić (2011) and Đekić (2012). For other issues we used personal interviews with leading experts for ethics assessment in Serbia (Hajrija Mujović Zornić, Vojin Rakić, Zvonko Magić, Zoran Todorović).

- Universities and institutes have not established common frameworks for ethics assessment. There are no guidelines, procedures or protocols regarding ethics assessment of R&I. Even in obvious cases of plagiarism there is no procedure of determining that fraud had been committed.
- Mentality, which is often based on traditional values, is also a barrier to implementation of ethics assessment in Serbia.

Some possible recommendations to correct these deficiencies could be:

- Implementation of ethics assessment procedures in Law on scientific research and innovations;
- Development of an appropriate legal framework in order to avoid overlapping of responsibilities of different ethics committees.
- Promoting or requiring ethics assessment in social and technical sciences R&I, as well as to expand the jurisdiction of the Ethics Committee of Serbia to these fields.
- Requiring mandatory training for all members of ethics committees.
- Creating common framework for ethics assessment of R&I, with shared standards, procedures, and protocols for all organisations that engage in ethics assessment.

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