Ethics assessment and Guidance in Different Types of Organisations

Industry

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Annex 3.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 and compare how ethics assessment and ethical guidance of research and innovation, with a particular focus on Corporate Social Responsibility (CSR) strategies, is performed by industry in the European Union, the United States and China. The study analyses practices of multi- and transnational corporation (MNCs and TNCs), small and medium sized enterprises (SMEs), chambers of commerce, consultancy firms, research institutes and NGOs engaged in the topic of human rights and business. Furthermore, various sectors of industry are taken into consideration.

The report is based on online and offline documentation, previously published reports, and interviews with representatives of organizations in ten different countries and at the EU and global international level. Eight representative European countries have been singled out for in-depth study, including seven EU members and one candidate for EU membership: Austria, France, Germany, the Netherlands, Poland, Serbia (an EU candidate country), Spain and the United Kingdom. In the report, it will be investigated how companies are organized in these countries, in China, the US and at the EU and global international level. The situation in other EU member states and candidate countries will be considered as well. It will be studied how organizations of this type are institutionally embedded, how they perform ethics assessment and guidance and with what aims, and what are the perceived strengths and weaknesses of their participation in ethics assessment and guidance.

Ethics assessment, in the context of this report, is any kind of assessment, evaluation, review, appraisal or valuation of research or innovation that makes use of ethical principles and criteria. Ethical principles are criteria that aim to determine whether certain actions or developments are right or wrong. They define individual rights like rights to freedom and privacy, and include principles of justice and principles that say that harms to individuals and society should be avoided and benefits for them should be promoted. Ethical guidance is different from ethics assessment in that it does not concern an evaluation of practices and products of research and innovation that have already occurred, but rather presents rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere.

2. Industry: Basic Characteristics and Distribution

Companies are legal entities engaged in commercial activities, usually with a for-profit motive. Companies vary depending on their size. As defined in EU law (EU recommendation 2003/361), small and medium-sized enterprises (SMEs) are companies with less than 250 employees and a turnover of less than €50 million. Corporations are companies with a legal personality and recognised as agents separate from their owners – shareholders, whose liability is limited to their investment. A multinational corporation is a corporation that owns or controls production of goods or services in one or more countries other than their home country, as the result they fall under multiple jurisdictions. One type of multinational corporations is the transnational corporation which in contrasts with the multinational corporation, which is a national company

with foreign subsidiaries, does not identify themselves with one national home. The focus of this report is on companies that engage in R&I, which prominently include industrial companies, which are companies that engage in manufacturing and technical production.

In the modern economy, there are various industry classifications, which are typically grouped into larger categories called sectors. Two examples of these classifications are the *Industry Classification Benchmark*[1] and the *Global Industry Classification Standard* (GICS).[2] Following the GICS classification, consisting of 10 sectors, 24 industry groups, 67 industries and 156 sub-industries,[3] there are particular sectors and industry groups that are related to R&D processes. The table below indicates in bold industrial sectors that are particularly related to R&D ("research intensive"):

Sector	Industry Groups
Energy	**Energy**
Materials	**Materials**
Industrials	**Capital Goods**
	Commercial & Professional Services
	Transportation
Consumer Discretionary	**Automobiles & Components**
	Consumer Durables & Apparel
	Consumer Services
	Media
	Retailing
Consumer Staples	Food & Staples Retailing
	Food, Beverage & Tobacco
	Household & Personal Products
Health Care	**Health Care Equipment & Services**
	Pharmaceuticals, Biotechnology & Life Sciences
Financials	Banks
	Diversified Financials
	Insurance
	Real Estate
Information Technology	**Software & Services**
	Technology Hardware & Equipment
	Semiconductors & Semiconductor Equipment
Telecommunication Services	**Telecommunication Services**
Utilities	**Utilities**

Table 1. *Global Industry Classification Standard* (GICS).[4]

Companies from a particular industry sector are supported by Business and Industry Associations (also known as trade organisations and industry trade groups). They usually work as not-for-profit organisations providing information, training and education programs to companies in

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[1] http://www.icbenchmark.com/Site/ICB_Structure;
http://www.icbenchmark.com/ICBDocs/Structure_Defs_English.pdf
[2] https://www.msci.com/gics
[3] https://www.msci.com/gics; Note: The classification is regularly updated. See e.g.
https://www.msci.com/resources/pdfs/GICS_Consultation2015.pdf
[4] https://www.msci.com/gics

their sector. Moreover, Business and Industry Associations facilitate networking and collaboration between companies, arrange advertising and promotional programs for the industry, and lobby to influence governmental policy. They are also involved in setting industry standards and help companies to meet these standards. In addition, there are Chambers of commerce, which are local, regional or national business associations that are not limited to a particular sector, and that represent business interests in a particular area. They strive for improvement of the economic and regulatory environment in which companies operate, and help their members prosper. Since industry associations and chambers of commerce are often involved in the promotion of standards and quality of service, they may as such be involved setting ethical standards.

3. Ethics Assessment by Industry: Prevalence and Aims

In the business sector, many companies are engaged in research and innovation processes. Many large corporations have separate R&D divisions that are a driving force behind the company's success. Most corporations nowadays have policies, and officers, or divisions, for Corporate Social Responsibility (CSR). CSR policy is intended to function as a self-regulating mechanism for business to ensure its compliance not just with laws, but also with the spirit of the law, with international norms and with ethical standards. An important element of CSR is social accounting, which is the communication of social and environmental effects of a company's actions to stakeholders and to society at large. CSR may also include ethics training within the company. For companies that focus heavily on R&D activities, CSR will naturally focus to a significant extent on the company's R&D activities, and will normally consider ethical aspects of this activity.

Ethical assessment by industry is closely related to the in the business world well-established concept of CSR. In general, CSR refers to *responsibility*, hence duties and obligations or motivation and opportunities of the companies towards society. Despite the fact that most of large multi- and transnational corporations (MNCs and TNCs) have developed CSR strategies, there is a critique towards the motivation of companies, and the understanding and using CSR by some companies in a "symbolic" rather than "substantive" manner.[5] Moreover, the perception of "responsibility" varies, from general responsibility (a duty to act with a due-diligence), accountability (a process of the assessment of one's behaviour) and liability (legal consequences of one's conduct).[6] The interviews conducted for the SATORI project also confirm some differences between the understanding of the role of a company and fall within the two opposing approaches. On the one hand, almost all bigger corporations (this is not valid for SMEs) have developed their CSR strategies including codes of conduct and engage in CSR initiatives in order to develop positive impacts in the society and minimize risks due to their business. For instance, a pharmaceutical company from the Central-Eastern European country that wishes to remain anonymous, one of the largest manufacturers of generic pharmaceuticals in the region, explicitly

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[5] See discussion e.g. in Luis A. Perez-Batres et al., "Stakeholder Pressures as Determinants of CSR Strategic Choice:
Why do Firms Choose Symbolic Versus Substantive Self-Regulatory Codes of Conduct?", pp. 157–172 in *the Journal of Business Ethics*, 110, 2012.
[6] See the differentiation e.g. in Ivo Giesen, François G.H. Kristen, "Liability, Responsibility and Accountability: Crossing Borders", in the Utrecht Law Review, Volume 10, Issue 3, June 2014.

states that the need to implement a social responsibility strategy is an indispensable element of operating in the pharmaceutical industry which has to do with human life. Sustainable development has also become a guiding principle of the company.

On the other hand, a number of business representatives from the Western European countries[7] share Milton Friedman's argument that "there is only one and only one social responsibility of business – to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition, without deception or fraud"[8] and that CSR is against shareholders' interest.[9] For example, an industry association from the Western European country interviewed for SATORI that wishes to remain anonymous, allows Friedman's approach, arguing that the main responsibility of a company is to make profit, provide work place, and pay taxes to the state. If a company is successful, then it is also responsible. This dichotomy triggers questions about the real substance of what companies claim to do.[10] However, one common parameter might be the role of shareholders who are more and more targeting the large companies to integrate CSR in their strategy since that minimizes the risk of lower financial performances. Therefore, the two different approaches to CSR might also depend on the 'interpretation' and expectations on CSR coming from the shareholders.

Currently, there is a visible shift in industry of omitting the notion 'social' and using the term 'corporate responsibility'. This change of the language expresses the intention to broader the understanding of CSR and include not only responsibilities regarding society, but also the environment, human rights, etc. Other alternative terms that are nowadays in use include 'sustainability' or 'sustainable development,' 'business ethics,' 'corporate social performance' and 'corporate citizenship'. Due to the complexity and multi-faceted issues related to CSR, a unique and generally accepted definition of CSR is lacking. However, there is a growing awareness and interest in CSR, and some common principles are now acknowledged. The concept of CSR varies depending on the actor defining the notion. International organisations, companies, NGOs, activists, consultants, and lawyers have very different understanding of CSR.[11] The focus depends on the profile of an organisation, enterprise or NGO.

In 1979, Archie B. Carroll proposed a four-part definition of corporate social responsibility embedded in a conceptual model of corporate social performance (CSP):

> The social responsibility of business encompasses the economic, legal, ethical, and discretionary expectations that society has of organizations at a given point in time.[12]

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[7] Based on SATORI interviews.

[8] Milton Friedman, "Capitalism and Freedom: Fortieth Anniversary Edition", University of Chicago Press, 15 February 2009, [p. 133], available online.

[9] Crane A., Matten D. Spence L.J., (ed.), Corporate Social Responsibility: Readings and Cases in a Global Context, Routledge 2008, [p. 49].

[10] Ibid.

[11] Amao O., "Corporate Social Responsibility, Human Rights and the Law: Multinational corporations in developing countries", Routledge, 2011, [pp. 67-68].

[12] Carroll A. B., "A Three-Dimensional Conceptual Model of Corporate Social Performance' in *Academy of Management review*, 4: 497-505, [p.500].

Carroll's definition is known as 'pyramid of CSR' and can be visualised in the following figure (Figure 1):

Responsibilities of a firm – Pyramid of CSR/CSP

Figure 1 Carroll's Pyramid of CSR *Source:* André Martinuzzi, Barbara Krumay & Umberto Pisano, *European Sustainable Development Network, "Focus CSR: The New Communication of the EU Commission on CSR and National CSR Strategies and Action Plans" in ESDN Quarterly Report December 2011. http://www.sd-network.eu/?k=quarterly%20reports&report_id=23*

According to Carroll, the first and foremost social responsibility of business is economic responsibility, so responsibility to produce goods and services that the society wants to buy and to sell them at a profit.[13] The second responsibility of business is the legal responsibility, which is based on the expectations of the society towards business to fulfill its economic mission within the framework of legal requirements.[14] The third part of the definition is ethical responsibility. As Carroll explains "(a)lthough the first two categories embody ethical norms, there are additional behaviors and activities that are not necessarily codified into law but nevertheless are expected of business by society's members. (…) Suffice it to say that society has expectations of business over and above legal requirements."[15] The last element is discretionary (or volitional) responsibility understood as voluntary activities of business that engages in social roles.[16]

Carroll's definition has gained a worldwide acceptance due to its simplicity[17] and has become the starting point for further discussion on the nature of CSR by academics and professionals. For instance, Georges Enderle, an expert in Corporate Ethics and Social Responsibility, modifies Carroll's approach and claims that companies have three responsibilities to society: economic,

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[13] Carroll A. B., "A Three-Dimensional Conceptual Model of Corporate Social Performance' in *Academy of Management review*, 4: 497-505, [p.500].

[14] Ibid.

[15] Ibid.

[16] Ibid.

[17] Although not without a critique, e.g. that the model is less relevant for the national context outside the US. See e.g. Maignan, I., "Consumers' perception of corporate social responsibilities: a cross-cultural comparison", pp. 57-72 in Journal of Business Ethics, 30 (1/1), 2001. Therefore, Carol together with Schwartz have updated the model using three domains rather than four.

social and environmental.[18] His claim is particularly interesting, as he emphasized that CSR is not only a domain of transnational corporations, and SMEs can have an important role in this respect.[19] There is a great number of theories and a wide array of understanding the responsibility of a company. CSR can be perceived instrumentally (instrumental theories), as a strategic tool with the economic objective (e.g. Friedman's view); from the political perspective CSR is about the power and position of business in regard to its interactions and connections with other actors (e.g. Corporate Citizenship); and lastly a group of integrative theories can be identified, which argue that business existence, continuity and growth depends on society and therefore companies should operate in accordance with social values.[20]

4. Institutional Setup of Ethics Assessment

The level of institutionalisation of ethics assessment in industry varies greatly across different countries and particular companies. The ethics assessment and ethical guidance in the context of industry is related to companies CSR strategies. CSR tools include standards, principles, codes of conduct, and reporting initiatives to provide quantitative data on social responsibility performances. This section provides a number of CSR standards and initiatives including their classification. As far as individual companies codes of conduct are concerned, these voluntary/self-regulation instruments demonstrate companies' commitment to a more responsible behaviour towards the society and environment. Therefore, the study intends to find common approaches to CSR based on the analysis of the interviews conducted for the purposes of the project. The analysis does not however refer to specific codes of conduct, however the details can be found in the Appendix. The CSR principles are presented in section 6 of this study, although the principles are closely related to CSR instruments a company adheres to.

The institutional setup of CSR strategies can be divided into:

I. Firstly, depending on the geographical scope:

    1. Global level
    2. Regional level (e.g. European level)
    3. National level

II. Secondly, from the legal point of view, the CRS frameworks can be divided into:

    1. hard-law instruments
    2. soft-law/voluntary/self-regulation instruments

III. Thirdly, depending on a types and a number of organisations engaged:

    1. Sectoral level

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[18] Georges Enderle, "Global competition and corporate responsibilities of small and medium-sized enterprises", pp. 51-63 in *Business Ethics: A European Review*, Volume 13 Number 1, January 2004.
[19] Ibid.
[20] Garriga E. and Melé D., "Corporate Social Responsibility Theories: Mapping the Territory", pp. 74-104 in Crane A., Matten D. Spence L.J., (ed.), "Corporate Social Responsibility: Readings and Cases in a Global Context", Routledge 2008.

2. Individual company level
3. Governmental level
4. Multi-stakeholder initiatives

IV. Lastly, the initiatives may also focus on a particular principle, human right, or ethical issue; for example: discrimination, security, environment, groups, human trafficking and forced labour in global supply chains, freedom of association.

CSR is an internationally recognised concept, acknowledged at the international, regional and country level. Key examples of global initiatives focusing on CSR or being a reference point for CSR include:

- Universal Declaration on Human Rights (and Charter of Fundamental Rights of the European Union and the European Convention on Human Rights),
- United Nations Guiding Principles on Business and Human Rights,
- United Nations Global Compact,
- OECD Guidelines for Multinational Enterprises (OECD Guidelines),
- The ILO Tri-partite Declaration of Principles on Multinational Enterprises and Social Policy, and the ILO Core Conventions and the Declaration on Fundamental Principles and Rights at Work (Instruments of the ILO).

CSR is a recognised concept in Europe since 1993, when the European Commission President Jacques Delors called European business to recognise European structural problems of unemployment, restructuration and social exclusion and appealed to adopt a European Declaration against Social Exclusion.[21] Nine years later, in 2002 the European Commission adopted its first communication on CSR (*Corporate Social Responsibility: A business contribution to Sustainable Development*[22]), influenced by the Lisbon Appeal on CSR and a wide consultation (green paper).[23] This time the Commission has defined CSR as "a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis",[24] because companies are increasingly becoming aware that responsible behaviour leads to sustainable business success.[25]

In the latest Communication on CSR from 2011 (*A renewed EU strategy 2011-14 for Corporate Social Responsibility*[26]), the European Commission redefines CSR as 'the responsibility of

[21] CSR Europe, The European Business Network for Corporate Social Responsibility, *CSR in Europe Policy*, available at: http://www.csreurope.org/csr-eu-policy
[22] European Commission (former Commission of the European Communities), Communication, concerning Corporate Social Responsibility: A business contribution to Sustainable Development , Brussels, 2.7.2002 COM(2002) 347 final, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0347:FIN:en:PDF
[23] CSR Europe, The European Business Network for Corporate Social Responsibility, *CSR in Europe Policy*, available at: http://www.csreurope.org/csr-eu-policy
[24] European Commission (former Commission of the European Communities), Communication, concerning Corporate Social Responsibility: A business contribution to Sustainable Development , Brussels, 2.7.2002 COM(2002) 347 final, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0347:FIN:en:PDF
[25] Ibid.
[26] European Commission, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: A renewed EU strategy 2011-14 for Corporate Social Responsibility, Brussels,

enterprises for their impacts on society'.[27] It observes that the respect for applicable legislation, and for collective agreements between social partners is crucial for meeting this responsibility.[28] The European Commission emphasizes the need to 'integrate social, environmental, ethical, human rights and consumer concerns into their [enterprises] business operations and core strategy in close collaboration with their stakeholders'.[29] Furthermore, companies' CSR policies should aim at 'maximising the creation of shared value for their owners/shareholders and for their other stakeholders and society at large'[30] and 'identifying, preventing and mitigating their possible adverse impacts'.[31] The European Commission has developed its CSR strategy based on the following guidelines and principles: the United Nations Global Compact; the United Nations Guiding Principles on Business and Human Rights; ISO 26000 Guidance Standard on Social Responsibility; International Labour Organization Tripartite Declaration of Principles concerning Multinational Enterprises on Social Policy; and the OECD Guidelines for Multinational Enterprises.[32] The European Commission refers to these documents as "an evolving and recently strengthened global framework for CSR".[33] The Commission's CSR agenda strives for:

1. Enhancing the visibility of CSR and disseminating good practices
2. Improving and tracking levels of trust in business
3. Improving self- and co-regulation processes
4. Enhancing market reward for CSR
5. Improving company disclosure of social and environmental information
6. Further integrating CSR into education, training and research
7. Emphasising the importance of national and sub-national CSR policies
8. Better aligning European and global approaches to CSR.[34]

Global, international protocols are setting overarching key principles for responsibility and ethical behaviour of all kind of organizations (including industry). EU policy initiatives are aimed to stimulate companies to endorse CSR initiatives.

Besides these actions, a key role in the diffusion of CSR policies in industry has been played by multi-stakeholder initiatives, that in the last two decades supported the definition of shared practices and methodologies (standards) to define, apply, measure and report CSR actions and performances. Standardization plays an important role in companies' activity, as it provides clear requirements on development and implementation of management strategies. The advantage of

25.10.2011   COM(2011)   681   final,   http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF
[27] Ibid.
[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] Ibid.
[32] http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm
[33] European Commission, "An Analysis of Policy References made by large EU Companies to Internationally Recognised CSR Guidelines and Principles", March 2013, http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr-csr-guide-princ-2013_en.pdf
[34] http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm

the standard system is its compatibility and applicability in every organisation regardless of sector or size.[35]

Two key examples of multi-stakeholder initiatives are:

- The Global Reporting Initiative (GRI)
- The ISO 26000 Guidance Standard on Social Responsibility (ISO 26000)

GRI is an international independent organisation that developed in the late 1990s a methodology for reporting CSR and sustainability performances of industry, in close relationship with the work of UN global compact. The GRI is one of the most widely used standards for CSR at industry level. GRI is a voluntary tool, and monitoring of compliance with GRI requirements can be done by self-evaluation or assessment by a third party (certification).

The International Standard Organisation is an international standard setting body including representatives of regional and national standard bodies of more than 160 countries. ISO 26000[36] is the first ISO standard entirely devoted to social responsibility. It was published in 2010, after several years of consultation with more than 400 stakeholders worldwide, including government, industry, and Civil Society Organisations (CSOs).

ISO 26000 is intended to provide guidance for organisation regarding social responsibility and sustainable development, based on transparency and ethical principles. It does not include measurable indicators and criteria, and therefore is not a management standard (such as the GRI) that could be certified. This approach underlines how social responsibility should be considered, first of all, as an internal (voluntary) process of the organisation.

The core subjects of ISO 26000 provide a reference to the various concepts underlying social responsibility:

1. Organizational governance
2. Human rights
3. Labour practices
4. The environment
5. Fair operating practices
6. Consumer issues
7. Community involvement and development

The study conducted for SATORI confirms companies' commitment to implementation of ISO 26000, but also the following standards have been mentioned by the industry interviewed:

- Social Accountability 8000[37] (focusing on workers' rights and workplace conditions);

- OHSAS 18001[38] (regarding health and safety of employees and minimizing the risk of accidents);

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[35] Konstantinos Iatridis, "Identification of CSR tools related to RRI principles", published 27 March 2015, Deliverable for the Responsible Industry Project, http://www.responsible-industry.eu/dissemination/deliverables
[36] www.iso.org/iso/home/standards/iso26000.html
[37] http://www.sa-intl.org/sa8000

- ISO 14001 and Eco-Management and Audit Scheme (EMAS)[39] (on environmental management).

Lawyers, academics and business people constantly discuss the question of effectiveness of institutional setup of CSR as a transnational regime. The effectiveness of this regime needs to be assessed taking into consideration its characteristics as a global governance mechanism. The main arguments in the discussion focus on a dichotomy between hard-law and soft-law. Most of the CSR standards, principles, codes of conduct, and reporting initiatives have a soft-law character, it means that they are not binding and a company may voluntary commit to adhere to these instruments through e.g. developing their own code of conduct based on the aforementioned instruments. The voluntary character of these instruments raises questions regarding the boundaries between public and private spheres, law and politics,[40] and relations of "power, authority, legitimacy, social practices, democracy and how organisations work".[41] Definitely, hard-law regulation provides certainty, credibility of commitments, and accountability in case of breach of the rules.[42] Nevertheless, the binding character of hard-law entails legal consequences as it restricts actors' behaviour and even their sovereignty and therefore actors are reluctant to pay these costs.[43] From the normative perspective, hard-law regulations while 'requiring commitment to a background set of legal norms including - engagement in established legal processes and discourse - legalization provides actors with a means to instantiate normative values.'[44] The effects of legalization can be perceived through normative standards and processes, but also self-interested calculation.[45] The success of law lies on both interests and values.[46]

Soft-law 'begins once legal arrangements are weakened along one or more of the dimensions of obligation, precision, and delegation.'[47] On the one hand, the voluntary character of CSR instruments is widely criticized for having no effect, because it lacks an independent judiciary that supports enforcement powers.[48] Nevertheless, this criticism is also relevant to a great extent to the whole international law. From a more normative perspective, common creation and dependence on soft-law instruments 'might destabilize the whole international normative system

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[38] http://www.ohsas-18001-occupational-health-and-safety.com/

[39] http://www.iso.org/iso/catalogue_detail?csnumber=31807

[40] Mario Vinkovic, "The Role of Soft Law Methods (CSR) in Labour Law", [p. 4], http://mta-pte.ajk.pte.hu/downloads/mario_vinkovic.pdf

[41] Ulrika Mörth, "Soft Law and New Models of EU Governance – A Democratic Problem?" Paper presented in Darmstadt, November 2005, [p. 4], http://www.mzes.uni-mannheim.de/projekte/typo3/site/fileadmin/research%20groups/6/Papers_Soft%20Mode/Moerth.pdf

[42] Abbott, Kenneth W., Snidal, Duncan, "Hard and Soft Law in International Governance", pp. 421-456 in *International Organization*, Vol. 54, No. 3, Legalization and World Politics, Summer 2000, [p. 422].

[43] Agata Gurzawska, "From Commitment to Compliance, From Compliance to Practice – the Effectiveness of the Voluntary Principles on Security and Human Rights", unpublished thesis for the European Master's Programme in Human Rights and Democratization (E.MA), [pp. 51-52]. 2012-2013

[44] Abbott, Kenneth W., Snidal, Duncan, "Hard and Soft Law in International Governance", pp. 421-456 in *International Organization*, Vol. 54, No. 3, Legalization and World Politics, Summer 2000, [p. 422].

[45] Ibid.

[46] Ibid.

[47] Ibid.

[48] Ibid.

and turn it into an instrument that can no longer serve its purpose.'[49] The discussion regards also the question whether soft-law is only a mean, an interim step to achieve hard-law regulation or whether it is an ultimate goal as such. On the other hand, soft-law has a number of advantages, namely related to practicalities. Firstly, soft-law is less controvertible, more likely, faster and easier to be achieved, because it 'facilitates compromise, (…) between actors with different interests and values, different time horizons and discount rates, and different degrees of power.'[50] Secondly, it 'offers more effective ways to deal with uncertainty, especially when it initiates processes that allow actors to learn about the impact of agreements over time'[51]. Thirdly, while adoption of the hard-law mechanisms by all stakeholders with various interests may be a long, tedious and sensitive process, in many cases soft-law regulation emerge as a quick reaction for current problems. Lastly, participation in the soft-law instruments can have a positive effect on companies' reputation, but also a content wise on their behaviour combining competitiveness with a responsible business.

5. Procedures for Ethics Assessment

Companies do not use the term "ethics assessment". The most common assessment procedure that companies implement is impact assessment (IA). Impact assessment (IA) is a process of identifying the future consequences of a current or proposed action (impact prediction/forecasting), and an assessment of the social significance of those impacts (impact evaluation).[52] The "impact" (or "effect") is the difference between what would happen with the action and what would happen without it.[53] IA is a tool helping to make the best possible decision about the action using the best available information in a systematic and proper manner.[54] The impact assessment may concern the effects of actions on environment, society, or more specifically on ecology, biodiversity, human rights, health, culture, gender, etc. There are therefore different types of impact assessment, e.g., environmental impact assessment (EIA) and social impact assessment (SIA), but also in existence are human rights impact assessment, health impact assessment, gender impact assessment, etc.

Environmental impact assessment (EIA) and social impact assessment (SIA) are the most common assessment procedures among companies. Furthermore, organisations engaged in human rights and business (national human rights institutions, NGOs) emphasized the importance of human rights impact assessment, which recently has received a wider recognition as an assessment procedure. The human rights impact assessment has been incorporated by the European Commission,[55] Equator Principles,[56] OECD[57] and FAO.[58] Some of these organisations

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[49] Ibid.
[50] Ibid.
[51] Ibid.
[52] The International Association for Impact Assessment, http://www.iaia.org/iaiawiki//History.aspx?Page=impactassessment&Revision=1
[53] The International Association for Impact Assessment, http://www.iaia.org/
[54] IAIA, "Impact Assessment in the Corporate Context", http://www.iaia.org/publicdocuments/special-publications/Bi1%20pdf.pdf
[55] Recognized not without a critic, see e.g. "Draft recommendation of the European Ombudsman in the inquiry into complaint 1409/2014/JN against the European Commission", claiming that "The Commission should conduct a comprehensive and participatory HR impact assessment.", http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/59398/html.bookmark

have developed their own human rights impact assessment tools, e.g. Human Rights Impact Assessment and Management (HRIAM) by the International Finance Corporation;[59] and tools created by the Danish Institute for Human Rights - a "Quick Check" and a Human Rights Compliance Assessment (HRCA) tool (since Spring 2015 both of the tools are publicly available).[60] Furthermore, a number of interviewed companies have also developed their own impact assessment tools. For instance, an applied research company from Southern European country that wishes to remain anonymous, has developed a tool to promote and measure the social impact of its projects. This tool includes six dimensions that are evaluated (economic capital, social capital, cultural capital, well-being, ecological capital, relational capital) with indicators in each category.

More traditional tools are also being used as the assessment procedure, such as risk assessment and cost-benefit analysis. Risk assessment[61] is a well-known procedure, particularly in engineering, and medicine, focusing on e.g. environmental, ecological, or public health risk assessment, but also regarding general financial decisions. Cost-benefit analysis of investment projects[62] helps to predict whether the benefits of a project or investment outweigh its costs.

The assessment of companies' behaviour, including impact assessment and compliance with the applicable laws and regulations is conducted both internally (in-house) and externally, by independent auditors, e.g., a consultancy firm or an organisation working on human rights and business. The assessment normally focuses on the adherence to international human rights standards (see section 4 Institutional Setup of Ethics Assessment) and applicable laws (national/regional; hard law/soft-law instruments).

The assessment is related to the development and implementation of the CSR strategy. The literature provides various examples of the steps within this process. For instance, Bryan Husted and David Bruce Allen propose a seven-step model of corporate social strategy:[63]

> Step 1. Analyze social issue opportunities, competitive environment, and nonmarket stakeholders (environmental analysis) including potential creation of competitive advantage;

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[56] CSR Wire, "The New Equator Principles III Amplify CSR For Financial Institutions", 12 June 2013, http://www.csrwire.com/blog/posts/885-the-new-equator-principles-iii-amplify-csr-for-financial-institutions

[57] OECD, "OECD Guidelines for Multinational Enterprises", 25 May 2011, http://www.oecd.org/daf/inv/mne/oecdguidelinesformultinationalenterprises.htm

[58] CFS, "Principles for Responsible Investment in Agriculture and Food Systems", approved by CFS on 15 October 2014, http://www.fao.org/cfs/cfs-home/resaginv/en/

[59] http://www.ifc.org/wps/wcm/connect/Topics_Ext_Content/IFC_External_Corporate_Site/Guide+to+Human+Rights+Impact+Assessment+and+Management

[60] https://hrca2.humanrightsbusiness.org/

[61] See e.g. http://www.hse.gov.uk/risk/controlling-risks.htm; or for more specific research related to CSR and risk https://www.kpmg.com/NL/en/Issues-And-Insights/ArticlesPublications/Documents/PDF/Sustainability/CSR-Sector-Risk-Assessment.pdf

[62] See e.g. European Commission, Directorate General Regional Policy, "Guide to cost-benefit analysis of investment projects", Structural Funds, Cohesion Fund and Instrument for Pre-Accession, 2008 http://ec.europa.eu/regional_policy/sources/docgener/guides/cost/guide2008_en.pdf

[63] Bryan Husted and David Bruce Allen, "How Do We Build Corporate Social Responsibility", pp. 451-472 in Crane A., Matten D. Spence L.J., (ed.), "Corporate Social Responsibility: Readings and Cases in a Global Context", Routledge 2008.
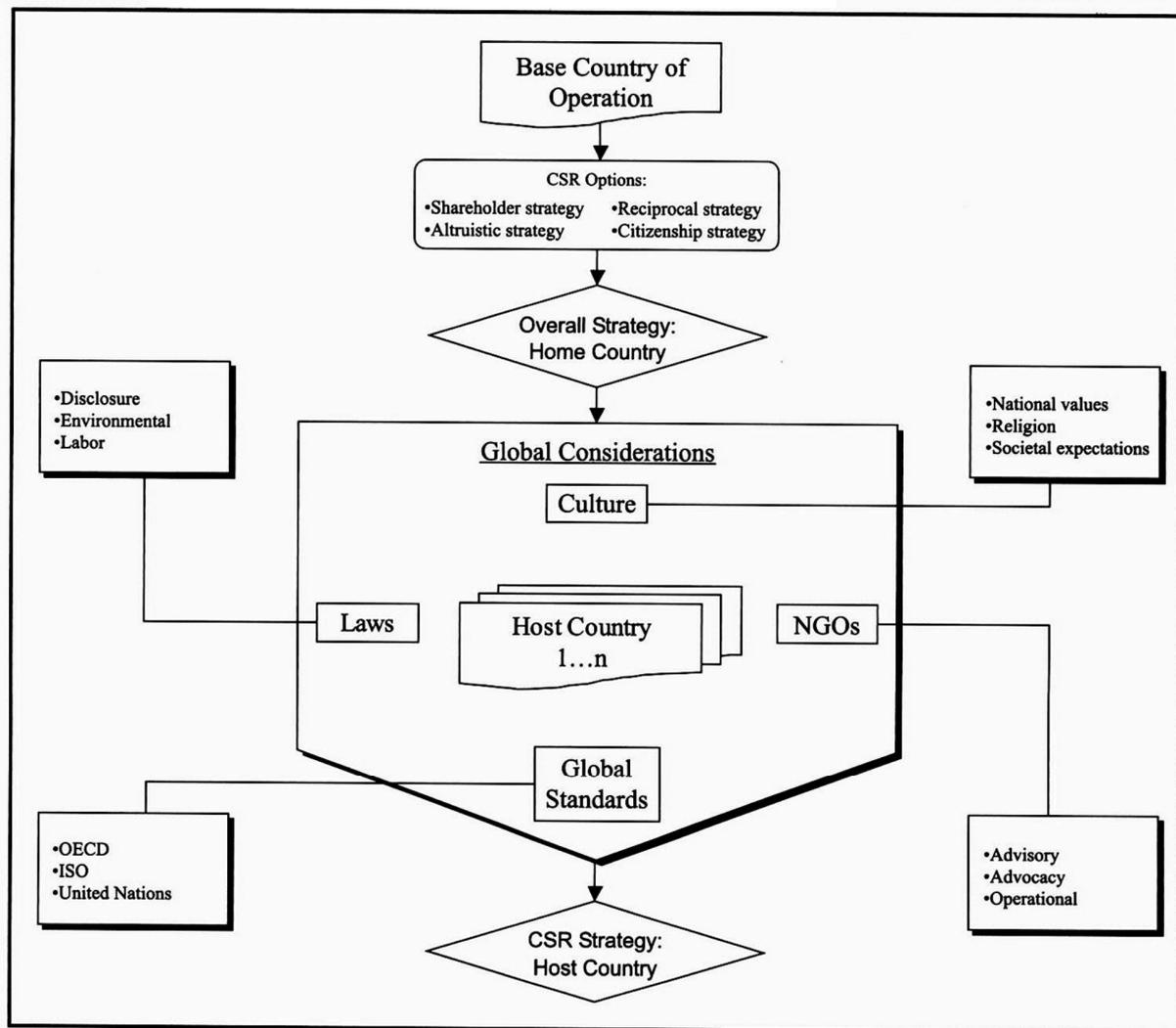
Step 2: Analyze firm resources and capabilities to see whether the firm can take advantage of those opportunities;

Step 3: Evaluate firm identity (corporate culture, values, etc.) in terms of social needs and opportunities;

Step 4: If the firm does have the requisite resources and capabilities, determine the means and cost of acquiring them. Frequently, alliances and other forms of collaboration are necessary;

Step 5: Create a plan integrating issues, stakeholders, identity, resources, competitive environment and expected outcomes;

Step 6: Implement the plan;

Step 7: Measure and evaluate performance.[64]

The assessment procedure is particularly challenging due to multi- and transnational character of companies and globalisation of their activities. The challenges include various aspects, such as local cultures, regulatory environment, and adherence to global standards in a specific local context. The overall principle is that a company operating in a host country should perform due-diligence in any aspect of their activity. Jeremy Galbreath specialising in CSR and strategic management offers a scheme of potential relations between a company, home and host country, and NGOs, in the local context including the aforementioned considerations (Figure 1).[65]

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[64] Ibid., [p. 453].
[65] Jeremy Galbreath, "Corporate Social Responsibility Strategy: Strategic Options, Global Considerations", pp. 472 – 487 in Crane A., Matten D. Spence L.J., (ed.), Corporate Social Responsibility: Readings and Cases in a Global Context, Routledge 2008.

Figure 1. Consideration for CSR strategy in a global context
Source: Jeremy Galbreath, "Corporate social responsibility strategy: strategic options, global considerations", pp. 175-187 in Corporate Governance of International Journal of Business in Society, Vol. 6 No. 2, February 2006, [p. 184].

An important mechanism for companies striving for transparency is reporting, e.g. in the form of an annual report. In many countries, companies are legally obliged to disclose their financial performance. This tool reflects issues of transparency, anti-corruption and tax-avoidance. Nevertheless, non-financial disclosure on the environmental and social impacts is receiving a wider acceptance in the business world. Recently, companies are more willing to provide this information voluntary as a part of their annual report and by participating in such initiatives as Global Reporting Initiative (GRI).[66] To give an example of such companies that report on their environmental and social performance, two of the companies interviewed use this practice – BMW and Novartis.

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[66] https://www.globalreporting.org/Pages/default.aspx

According to the BMW Group, the company's Sustainable Value Report (SVR) 2014 has been published to provide stakeholders with comprehensive information about the company's sustainability strategy and the progress made in integrating sustainability into its corporate processes.[67] As we read in the report, it has been compiled in accordance with the Global Reporting Initiative (GRI G3.1) guidelines; and at GRI level A+ it meets the maximum requirements detailed in the GRI guidelines.[68] Moreover, the report makes references to the Global Compact principles.[69] According to Novartis, the company has a strong history of corporate responsibility activities, and transparent reporting is a central part of Novartis commitment to corporate responsibility.[70] The company has publicly reported on its performance in this area since 2000 through Novartis Annual Report and several online and printed materials.[71] The 2014 Novartis Corporate Responsibility Performance Report (CR Performance Report) consolidated information previously published in Novartis separate Global Reporting Initiative (GRI); Health, Safety and Environment; and United Nations Global Compact reports.[72] The content of this report was structured in accordance with the GRI the GRI's fourth generation (G4) of CR reporting guidelines launched in May 2013.[73]

Furthermore, in the European context the Directive 2014/95/EU on disclosure of non-financial and diversity information by certain large undertakings and groups,[74] requires companies "to disclose in their management report, information on policies, risks and outcomes as regards environmental matters, social and employee aspects, respect for human rights, anticorruption and bribery issues, and diversity in their board of directors."[75] The Directive is applicable for large companies with more than 500 employees, and other public-interest entities, such as banks and insurance companies. The scope includes approx. 6,000 large companies and groups across the EU.[76] The effectiveness of the Directive depends however on its transposition to the national legal systems.

In the opinion of a number of companies from the Western European countries, the Directive may have a negative impact on companies' innovativeness, because the Directive forces firms to report, but also to make an effort in these areas. This is perceived as additional bureaucracy and not all companies, especially SMEs, can handle its costs. On the other hand, non-corporate interviewees from the Western European countries, a human rights institution and a human rights research institute that wishes to remain anonymous, consider the Directive as useful tool, particularly regarding transparency. Although, the human rights research institute feels the

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[67] BMW Group, "Sustainable Value Report 2014", [p.146], http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[68] Ibid., [p.147].
[69] Ibid.
[70] Novartis, "CR Performance Report", https://www.novartis.com/about-us/corporate-responsibility/reporting/cr-performance-report
[71] Ibid.
[72] Novartis, "Corporate Responsibility Performance Report 2014", [p.8]; https://www.novartis.com/sites/www.novartis.com/files/cr-performance-report-2014.pdf
[73] Ibid.
[74] Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0095
[75] http://ec.europa.eu/finance/accounting/non-financial_reporting/index_en.htm
[76] Ibid.

Directive itself is not that strict, there is therefore a risk that the Member States will not to make it so ambitious and strict.

The most advanced and challenging reporting for the companies is the full integration of CSR into the annual company financial assessment and report, which is commonly called the Integrated Financial Report. A unique reporting of both financial and social responsibility performances to shareholders could support the alignment of financial strategic decision with CSR strategies, aiming to integrate financial stability and sustainable development.[77]

Let us finally turn to a discussion on the relation between CSR and ethics assessment. On the basis of the research and interviews that were conducted, we can conclude that CSR strategies and activities can be perceived as a form of ethics assessment, however CSR is broader than ethics assessment of R&I. It is because CSR does not exclusively relate to companies' R&I activities, but it should be perceived as a business strategy that in the most broad sense:

> (…) is integrated with core business objective and core competencies of the firm, and from the outside is designed to create business value and positive social change, and is embedded in a day-to-day business culture and operations.[78]

This holistic approach to CSR covers all aspects of a company's activity, including R&I. CSR is in large part a form of ethics assessment that emphasizes impacts on society. Furthermore, companies that also do human subjects research and/or biomedical research will often have an additional ethics assessment of this research in the form of assessment by a research ethics committee or ethics officer for consideration of ethical aspects. So in practice, ethics assessment of R&I in companies is either part of CSR or a combination of that part of CSR that is concerned with R&I and ethics assessment for biomedical or human subjects research.

6. Principles and Issues for Ethics Assessment

The most discussed issues related to CSR are: sustainability, sustainable development, environmental management, philanthropy and community investment, environmental and social impacts, ESIA (Environmental and Social Impact Assessment), stakeholders' engagement, business ethics, worker rights and welfare (including suppliers' workers as well), human rights, corruption, corporate governance, legal compliance, and animal rights.[79] Notwithstanding the variety of approaches to CSR, human rights are one of the crucial reference points in a company's CSR strategy. The core international documents on CSR make a clear reference to human rights (see Section 4: Institutional Setup of Ethics Assessment). CSR principles should be embedded in

> an organisational corporate culture, a vigilant and constant awareness of the possibility of wrongdoing, a personal ethic of care, and an responsibility for the consequences of one's actions.

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[77] See the work of the International Integrated Reporting Council (IIRC) - http://integratedreporting.org/the-iirc-2/
[78] http://claridenglobal.com/programs/CGArticle_CSRLeadership.pdf
[79] Murray A., and Dillard J., "Deciphering the Domain of Corporate Social Responsibility", in Kathryn Haynes, Alan Murray and Jesse Dillard (ed.), *Corporate Social Responsibility: A Research Handbook*, Routledge, 2013, [pp. 10-27].

This includes an organisational commitment to ensure that companies not only *conform* with the law and regulatory obligations, but *perform* to a higher standard than that which is required by law.[80]

The overall principle in CSR is acting with a due-diligence, e.g. human rights due-diligence.[81] Guiding Principle 17 of the *Guiding Principles on Business and Human Rights* states:

> In order to identify, prevent, mitigate and account for how they address their adverse human rights impacts, business enterprises should carry out human rights due diligence. The process should include assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed.[82]

Human rights due-diligence is therefore a process of understanding specific human rights risks - the risks of having an adverse impact on human rights; and taking actions to prevent and mitigate these risks.[83]

Companies that have highly developed CSR strategies consider their responsibility internally and externally. The internal level focuses on employees and the workplace, e.g. non-discrimination, occupational health and safety, freedom of association and the right to collective bargaining, workforce's well-being, own environmental performances and CO2 impacts, but also business ethics, including integrity. The external level is about the impact a company has on society and the environment, e.g. accountability and transparency through social and environmental reporting, relations with stakeholders, local community, consumers, suppliers, clients, and the home and host countries. When considering the research and innovation process, a key principle is excellence, including such aspects as developing competences and encouraging innovation as well as quality and creating value for partners.

A regular survey undertaken on a large sample of industry active in different type of sectors and industry[84] shows that there is a number of common and acknowledged global CSR priorities across different industries. These include:

- Respect of human rights;
- respect of workers' rights and occupational health and safety;

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[80] KPMG, "Corporate Social Responsibility is more than just donating money", 2011, [p. 1], https://www.kpmg.com/dutchcaribbean/en/Documents/KPMG%20Article%20Canto%20-%20Corporate%20Social%20Responsibility%20(CSR)%20is%20a%20strategic%20issue%20and%20must%20be%20on%20every%20Corporate%20agenda.pdf

[81] See e.g. United Nations Human Rights Office of the High Commissioner, "The Corporate Responsibility to Respect Human Rights - An Interpretive Guide", New York and Geneva, 2012, http://www.ohchr.org/Documents/Publications/HR.PUB.12.2_En.pdf; or Institute for Human Rights and Business, 'The "State of Play" of Human Rights Due Diligence Anticipating the next five years', 2011, http://www.ihrb.org/pdf/The_State_of_Play_of_Human_Rights_Due_Diligence.pdf

[82] United Nations Human Rights Office of the High Commissioner, "Guiding Principles on Business and Human Rights. Implementing the United Nations "Protect, Respect and Remedy" Framework", New York and Geneva, 2011; http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf

[83] United Nations Human Rights Office of the High Commissioner, "The Corporate Responsibility to Respect Human Rights - An Interpretive Guide", New York and Geneva, 2012, [p.31]; http://www.ohchr.org/Documents/Publications/HR.PUB.12.2_En.pdf;

[84] BSR and GlobeScan, "State of Sustainable Business report", 2014.

- Sustainability, including efficient access and use of resources (in particular water) along the supply chain, environmental performances and climate change (prevention, mitigation, adaptation);
- Professional (business) ethics and responsibility toward all stakeholders.

Key challenges/drivers in CSR approaches include: integrating sustainability issues into the core business of an organisation (promoting a culture of CSR within the company), increasing transparency on business and collaborating and engaging with stakeholders. In the opinion of STMicroelectronics Italia, "the return of CSR and sustainability strategies should be seen in the medium to long term, and might not be easily measurable. It is a continuous process that aims to work on the attitude and mind set of people."

All of these aspects have been identified as highly relevant in the interviews conducted with industry.

Besides common themes, there are principles and issues for ethics assessment that are specific of the sector considered. Examples on the materials and chemicals, a sector with an impact on several other industrial areas (being at the beginning of the supply chain), and on other three sectors referring to the industry interviewed, are reported below:

Sector: Materials, particularly chemicals:

– Ethical principles, values and issues: Professional integrity (business ethics), dealing with risks and anticipating social and environmental impacts, animal testing, implication for distributive justice, implications for individual and civil rights, implications for quality of life, outsourcing of research and/or innovation to developing countries.

Key areas of concerns include:[85]

- Greenhouse gas emissions (production of chemicals)
- Environmental damage (e.g. soil, water) linked to production activities
- Use of resources (in particular energy and water)
- Use of, exposure and disposal of substances
- Dangerous substances and critical raw materials
- Environmental risks linked to the transport of dangerous goods
- Chemical waste (in the production process)
- Land use in vulnerable areas (e.g. oil and agro commodities)
- Impact of chemicals and chemical products on human health
- Compromising of animal welfare (e.g. in animal testing)
- Unhealthy working conditions in the production process
- Unsafe working conditions (personal and process safety)
- Breach of the right to free association/forming of trade unions (also among suppliers)
- Deprivation of the right to a clean, safe and healthy living environment (locally and abroad)
- Depletion of natural resources (e.g. oil, gas and minerals)

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[85] Based on KPMG, "CSR Sector Risk Assessment Considerations for dialogue", September 2014, [p. 61-71] and the interviews conducted by SATORI partners.

- Land grabbing/non-respect of land rights (e.g. in the extraction of raw materials and the use of land for factories)

Sector/industry: Energy:

Ethical principles, values and issues:
- Professional integrity (business ethics), dealing with risks and anticipating social and environmental impacts, implication for distributive justice, implications for individual and civil rights, implications for quality of life, outsourcing of research and / or innovation to developing countries

Key areas of concerns include:[86]

- Greenhouse gas emissions and CO_2 footprint (in energy production, distribution and storage)
- Land use in vulnerable areas (e.g. in the case of coal and biomass)
- Use of biomasses for energy production from crops, in competition with human nutrition
- Radioactive waste (e.g. nuclear energy)
- Unsafe and unhealthy working conditions in energy production, distribution and storage (personal and process safety), in particular with respect to extraction of coal
- Breach of trade union laws and the right to free association (abroad)
- Child labour in the extraction/production of coal (abroad)
- Depletion of natural resources (e.g. coal, gas, rare metals)
- Land grabbing/non-respect of land rights (coal and biomass)

Serbian energy company, Electric Power Industry of Serbia-EPIS, focuses on environmental impacts and social responsibility. When it comes to environmental protection EPIS invests in research and innovations projects, including a number of projects in cooperation with scientific institutes and faculties. EPIS is working on implementation of biomass, because the emission of CO_2 is significantly lower (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 and using it for other purposes.

One of the Western European oil and gas company that wishes to remain anonymous, refers to equality/non-discrimination, implications for civil rights, implications for health and/or safety, and environmental impacts. Furthermore, the company implemented a strategy on sustainability in the shared value chain, focussing on human rand natural resources. The strategy consists of different stands related to health, safety, security and environment (HSSE), business ethics, human rights, diversity, stakeholder engagement, skills to succeed, eco-efficiency and eco-innovations. The notion of HSSE relates to measures in relation to the employees' safety, security and health. Regarding business ethics, it mainly relates to anti-corruption measures.

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[86] Based on KPMG, "CSR Sector Risk Assessment Considerations for dialogue", September 2014, [p. 87] and the interviews conducted by SATORI partners.

Sector: Electronics/Information technologies

Ethical principles, values and issues:

- Professional integrity (business ethics), dealing with risks and anticipating social and environmental impacts, implications for individual and civil rights (in particular privacy, rights to freedom of movement, autonomy, authenticity and identity, integrity and dignity, including bodily integrity), dual use

Key areas of concerns in industrial production include:[87]

- Use of resource in industrial processes and production (e.g. water scarcity and pollution, raw materials, etc.)
- Use of, exposure and disposal of substances and dangerous substances
- Greenhouse gas emissions linked to production, transportation, use of products
- Electronic wastes
- Impact of chemicals and chemical products on human health
- Working conditions in production plants
- Depletion of natural resources in the country of origin (e.g. critical raw materials)
- Breach of trade union laws and the right to free association (production abroad)
- Forced/migrant work (production abroad)
- Low wages/underpayment (production abroad)
- Child labour (production and waste processing abroad)
- Excessively long working hours (production abroad)
- Breach of women's rights (production abroad)
- Deprivation of the right to a clean, safe and healthy environment (mining)

Examples of areas of concerns in the use of ICT products include:[88]

- Privacy and data protection, in applications and systems for data storage, analysis and transmission systems (e.g. big data, social networking techniques, etc.)
- Autonomy, authenticity and identity in applications using human machine interaction (e.g. robotics, brain computer interfaces)
- Integrity and dignity, Rights to freedom of movement in real time surveillance systems using environmental sensors monitoring citizens, users, patients through sensing systems (e.g. for healthcare and security)

STMicroelectronics Italy, part of the STMicroelectronics corporation, adheres to the principles of professional integrity, equality/non-discrimination, implications for civil rights, social responsibility, implications for health and/or safety, implications for quality of life, environmental and social impacts. The principles and values for sustainable excellence, officially stated in a publicly available document signed by the company CEO, are integrity, people and excellence. Moreover, professional (business) ethics, respect of human rights, responsibility toward all stakeholders and the environment are considered mandatory aspects.

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[87] Based on KPMG, "CSR Sector Risk Assessment Considerations for dialogue", September 2014, [p. 123] and the interviews conducted by SATORI partners.
[88] Based on KPMG, "CSR Sector Risk Assessment Considerations for dialogue", September 2014, [p. 123] and the interviews conducted by SATORI partners.

Sector/industry: Healthcare

Ethical principles, values and issues:
- Scientific and professional integrity, human subjects research (patients/human safeguard), law abiding experiments and clinical tests, treatment of animal in experiments), safety in the work place, environmental protection.

Key areas of concerns include:
- Biomedical and clinical research (and respect of concerned principles and regulations)
- Involvement of patients in clinical trials
- Transparency in the publication of results of clinical trials (scientific integrity)
- Patient safety and pharma co-vigilance (responsibility to monitor adverse events of drugs)
- Confidentiality and data protection (e.g. use of health data of patients)
- Licensing of Intellectual Properties of pharmaceuticals toward poor countries (distributive justice)
- Access to treatments related to Orphan drugs
- Abuse/misuse of pharmaceuticals products (e.g. doping)

For example, a pharmaceutical company from the Central-Eastern European country that wishes to remain anonymous, adheres to the following principles: scientific integrity, justice/fairness, professional integrity, implications for health and/or safety, human subjects' research, implications for quality of life, treatment of animals in R&I, environmental impacts, social impacts, social responsibility. A health care research company from the Southern European country that wishes to remain anonymous, bases its activity on professional integrity, and refers to confidentiality and data protection, value transfer, payments to professionals (transparency), privacy, patient safety and pharmacovigilance, management of information, transparency in the publication of results, and clinical trials (protocols and both positive and negative results are published), Health and Safety at work, environment and sustainability.

Some of the interviewed pharmaceutical companies are members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Industry. Their codes of good practice guide the actions of the company and pharmaceutical industry in general. The Code of Good Practices for the Pharmaceutical Industry is the set of common ethical standards on human medicines to be governed both in the field of promoting medicines for human use and in the interaction with Healthcare Professionals, Healthcare Organisations and Organisations of patients, with the aim of ensuring that these activities are carried out in compliance with the highest ethical principles of professionalism and responsibility.

Tethis S.p.A. is a privately held company active in the bio-and nanotechnology fields. Because a large part of the company's activity is bound to health care, the attention to ethical issues is part of the everyday routine. It is implicit in the company culture and in what the company does. The attention is on scientific and professional integrity, patients safeguard, experiments and clinical tests, safety in the work place, environmental protection, quality, and ethics associated to the

person. Nevertheless, the interviewee emphasized that as oppose to large corporations, Tethis is a small entity, with limited resources, therefore a structured approach to social responsibility is a challenge.

7. Problems and Developments

Responsible Research and Innovation (RRI) vs. Corporate Social Responsibility (CSR)

Some of the problems regarding the understanding and implementation of CSR have been already mentioned in the previous sections. For the purposes of SATORI, an interesting point should be made regarding companies' approach to responsible research and innovation (RRI), which is a term that has often been used in EU policy and academic studies to refer to research and innovation that is ethically acceptable and societally desirable.[89] The study based on 25 interviews conducted with business shows that companies are not aware of the concept of RRI or they do not have a structured approached focused on R&I phase of their business. This does not necessarily mean they do not behave in a responsible way. As was presented in the sections above, most of big corporations have developed their corporate responsibility strategies; therefore (excluding the discussion on motivation and realization) they do recognise their responsibility towards society and environment.

CSR is generally applicable to all company activities, and thus also research and innovation, but are not specifically designed for the various R&I phases (from applied research, to engineering and testing and product development). Companies with intense R&I activities are starting to consider specific actions, often in connection with aspects related to quality and environmental performances. Examples include internal recognition (awards) of design processes and innovations leading to energy saving during production and addressing other sustainability issues (e.g. eco-design).

The RRI concept might be an opportunity to increase awareness for companies of the specific ethical and responsibility aspects related to research and development (very early stage of product development). It should be seen as a step beyond compliance with standards and regulation ("above the baseline of the law"). RRI is about quality of R&I and providing evidence of quality (effectiveness, usefulness, desirability of R&I processes and products).

However, the political language and academic concept of RRI is still not well understood by companies. Companies avoid using the term "ethical". Preferably, they refer to responsibility, responsible behaviour, sustainability and sustainable behaviour. In this regard companies refer to "innovating and doing research in a responsible way". The assessment conducted by companies is not however an "ethical assessment", but it rather focuses on aforementioned applicable CSR instruments.

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[89] See e.g.: Von Schomberg, R. (2013). "A vision of responsible innovation". In: R. Owen, M. Heintz and J. Bessant (eds.), Responsible Innovation. London: John Wiley, 2013; Van den Hoven et al. (2013). Options for Strengthening Responsible Research and Innovation: Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation; Owen et al. (2012). Responsible research and innovation: From science in society to science for society, with society; Sutcliffe (2011) – A report on Responsible Research & Innovation; Stilgoe, J., et al., Developing a framework for responsible innovation. Res. Policy (2013).

Despite clear differences between the concepts of CSR and RRI, some convergent points can be addressed. In Table 2, RRI dimensions are mapped onto corresponding topics in CSR that should be further discussed.

RRI dimension	CSR dimension
Engagement Involvement of society in R&I	Stakeholder engagement (Multi-stakeholder approach/Multi-Stakeholder Initiatives (MSIs))
Gender equality	Worker Rights; Human Rights
Science Education	Sustainability, Sustainable Development, Welfare, Community Investment, Human Rights, Social Impacts
Open Access Transparency	Sustainability, Sustainable Development, Stakeholders Engagement, Philanthropy, Welfare, Human Rights, Corruption (Transparency)
Ethics	Business Ethics
Governance	Corporate Governance, Legal Compliance, Business Ethics
A proactive approach to R&I benefits	Sustainability, Sustainable Development, Community Investment, Stakeholders Engagement, Welfare, Human Rights
Anticipation and reflection	Sustainability, Sustainable Development, Environmental management/environmental impacts, Social Impacts, ESIA, Business Ethics

Table 2. Correspondence between RRI and CSR dimensions
Source: Based on research by Agata Gurzawska, for the Responsible Industry Project, Deliverable "Systematic review of industry relevant RRI discourses", published on 19 August 2014, [p. 25], http://www.responsible-industry.eu/dissemination/deliverables

In the opinion of an applied research company from a Southern European country that wishes to remain anonymous, consensus needs to be reached on what CSR, ethical practices and responsible research mean for its sector (R&D&I). On this basis, a series of both regulatory and self-regulatory tools can be created, in particular:

- Definition of minimum standards that become pre-requisite for EC financed projects
- Certification for socially responsible research, and real recognition of this certification
- European Awards for social research and real visibility for these awards.

With regard to the improvement of ethical practices in R&D in industry, according to the interviewee, self-regulation can only work, if industrial stakeholders are aware of the need and the benefits of ethical practices (as well as sustainable innovation and production). Especially regarding ethical aspects, the application of regulatory tools might be the only effective approach. Another interviewee representing the industry association from the Western European country that wishes to remain anonymous suggests self-regulation might work better than regulation. Some companies are aware of the need to retain public support and based on that do their best to improve CSR/ethical practices. Following the discussion on hard-law/soft-law instruments, according to a human rights institution that wishes to remain anonymous, both solutions are needed, regulatory and self-regulatory measures. The interviewee emphasized that

laws and regulations for companies are needed, because companies will be forced to actually do something. There is a risk of a lawsuit and potential punishment; therefore people will obey the law. However, in some countries there are laws in place, but they are not enforced. In these cases, the interviewee thinks the industry measures might be useful. An interviewee representing a human rights research institute that wishes to remain anonymous, noticed that soft-law instruments have limitations. Until there is some external pressure on companies to act responsibly, they will do act responsibly. However, when it comes to incentives, in most cases the profit is the most important incentive. Therefore, if higher profit depends on being less responsible and it is an option to act less responsibly, this is what companies would do. In that sense, the hard law has the advantage over the soft-law. According to the interviewee, soft-law instruments have some impact on consciousness, awareness within a company, on developing policies and processes, but in practice the profit motive will always win.

In the opinion of a health care company from the Southern European country that wishes to remain anonymous, the belief that ethical behaviour is not a cost but a profitable investment could promote the adoption of ethical practices, but clear and precise rules could certainly also help. The company prefers them, though besides the rules to be followed, they adopt also internal self-regulatory tools that can strengthen an ethical behaviour and with a long-term perspective could help to anticipate eventual future problems.

An oil and gas company from the Western European country that wishes to remain anonymous, feels a European approach could be helpful. However any possible guidelines need to leave room for manoeuvre, as companies need to be able to build their own strategies. Furthermore, in the opinion of an industry association from the Western European country that wishes to remain anonymous, innovation requires research based on freedom, therefore additional constraints such as additional ethical standards could limit the creativeness of firms.

Small and Medium Enterprises (SMEs)

Regarding SMEs, typically they do not have CSR structured strategies, tools and reporting at all. That does not mean that SMEs manage their business without responsibility; however there is no evidence and possibility to depict trends and behaviours about their positive/not positive role in the society. A number of interviewees generally agreed that SMEs do not have enough resources for having people dedicated solely to this task. According to Tethis S.p.A., sometimes certain problems could be overlooked or not timely addressed. The creation of a company vision, with written policy on this matter, could help to overcome this problem.

That is even more relevant for the RRI. In fact research and disruptive innovations are more and more 'produced' by SMEs and start-ups, e.g. refer to the Information Technology and Telecommunication sectors where start-ups are playing a key role in disrupting value chains and in the consumers' behaviours with new solutions in the market and in the society (refer to Facebook at early stage, UBER, WhatsApp, and a myriad of services and applications going in the ICT market and accessible to everybody in the world via internet).

Furthermore, another important trend is the increasing way to make innovation through collaborations among large industries and SMEs, where: SMEs bring mainly creativity and new skills; large companies bring capability to make industrialization, reliability and scalability in the global market. Such conjunction points very much focused on collaborating on innovation offers

the opportunity to embrace and involve SMEs in structured CSR thanks to large industries commitment. However, the role and impact of SMEs in the CSR, and more specifically in RRI, is an open point that should be part of new assessment models.

Annex: Ethics Assessment and Guidance in Specific Companies/Industry Association/Business related organisation

This Annex contains 8 reports on particular surveyed organisations. The research is based however on 22 studies on particular surveyed organisations. Additional 2 reports are based on a desk-study research. The reports that are not included are confidential. For each organisation that was surveyed, basic data is provided about the organization, its mission, structure, and role in ethics assessment and/or ethical guidance, and its procedures for assessment and guidance.

	Country/Region	Name in English	Organisation type
1.	South European Country	Confidential	Applied research company
2.	Western European Country	Confidential	Industry association/nuclear industry
3.	Northern European Country	Confidential	Human rights institution,
4.	Spain	Lilly	Pharmaceutical company
5.	Western European Country	Confidential	Oil and gas company
6.	Italy	STMicroelectronics	Semiconductor company
7.	Italy	Tethis S.p.A.	Bio- and nanotechnology
8.	South European	Confidential	Health care sector
9.	Global	Royal Dutch Shell	Global group of energy and petrochemical companies
10.	Serbia	Electric Power Industry of Serbia	Energy company
11.	Serbia	Court of Honor of Serbian Chamber of engineers	National industry organisation/Professional Association
12.	Western European Country	Confidential	Industry association
13.	Central Europe	Confidential	Pharmaceutical company
14.	Global/Southern European Country	Confidential	Professional services for enterprises
15.	Germany/Global	BMW	Automotive company
16.	Switzerland/Global	Novartis	Pharmaceutical company
17.	Northern European Country	Confidential	Telecommunication company
18.	Western European Country	Confidential	Human Rights research institute
19.	Western European Country	Confidential	Industry association
20.	Western European Country	Confidential	Pharmaceutical company
21.	Western European Country	Confidential	Biotechnology company
22.	Global	Confidential	Chemical company
23.	Finland	Industrial Biotechnological Cluster Finland (IBC Finland)	Biotechnology cluster

Name of organization	STMicroelectronics Italia
Type of organization	Industry
Country	Italy
Website address	General: http://www.st.com/ Main page(s) on ethics assessment: http://www.st.com/web/en/about_st/sustainablity_strategy.html.
Basic description (organization and mission)	STMicroelectronics Italy is part of the STMicroelectronics corporation. ST is one of the world's largest semiconductor companies with net revenues of US$ 7.40 billion in 2014. Offering one of the industry's broadest product portfolios, ST serves customers across the spectrum of electronics applications with innovative semiconductor solutions by leveraging its vast array of technologies, design expertise and combination of intellectual property portfolio, strategic partnerships and manufacturing strength.
Interest in research and innovation	A relevant part of the company business is linked to research and innovation and all R&I activities need to respect and comply with sustainability principles and targets.
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	The company has in place a sustainability governance framework, defining how activities on sustainability (and Corporate Social Responsibility) are managed within the company
Name and description of ethics unit(s)	A specific corporate unit is in charge of deploying and monitors the company sustainability strategy and programs at central level (all sites in the world).
Aims and motivation for ethics assessment	The company sustainability mission is to: „*be recognized as a world leader in innovation for sustainable development through excellence in our people, our products, the environment and the community".*
Objects and scope of assessment	The sustainability strategy, promoted and regularly monitored by the top management, contributes to the overall vision, objectives and "culture" of the company, and therefore has an impact on all company activities. A relevant part of the company business is linked to research and innovation and all R&I activities need to respect and comply with sustainability principles and targets. In particular, the principle of excellence is underpinning all R&I activities of the company. Within the sustainability strategy, relevant examples of initiatives for R&I are in the products and community pillars (see below)
Beneficiaries of assessment	The company employees, stakeholders and shareholders
Ethics assessment unit: appointment process	A specific corporate unit is in charge of deploying and monitors the company sustainability strategy and programs at central level (all sites in the world). The unit refers directly to the Managing Board of the company. Global company sustainability themes and initiatives are managed centrally. Local activities are instead performed at site level. The sustainability corporate unit interacts with the Sustainable Excellence Coordinators Community, a network having representatives in the different company sites around the world.
Procedure for ethics assessment: before	The strategy comprises four pillars: - people (employees as primary stakeholders for the success of the company) - products (create high-quality, innovative, eco-designed and responsible products that help improve the quality of life of final customers)

	Priorities include: customer satisfaction, innovation management, product stewardship, conflict-free minerals; • environment (minimizes impact on the environment) Priorities include: management of water, energy, chemicals, waste, transport and logistic, greenhouses gases emissions; • community (creating value for stakeholders through constructive, transparent engagement and collaboration) Priorities include: sustainability in the supply chain, business ethics & compliance, local impacts, Partnership in R&D and education, public affairs and industry networking
Procedure for ethics assessment: during	Each site is responsible for collecting both quantitative indicators (mainly related to health and safety and environmental aspects) and outcomes of other sustainability/CSR initiatives and to report them to the Corporate unit (that prepares the annual report). In our site, a Sustainable Excellence Committee meets regularly during the year to share initiatives and results and agree on information to be included in the report to the corporate unit. The company sustainability strategy is in line with several international guidelines and standards, including: International Labor Organizations Conventions, United Nations Global Compact Principles, United Nations Guiding Principles on Business and Human Rights, OECD Guidelines for Multinational Enterprises, Electronic Industry Citizenship Coalition Code of Conduct, ISO 26000 - OHSAS 18001, ISO 14001, EMAS, ISO 50001, ISO 14064, QC 080000. Regarding ethical assessment, one of the most relevant initiatives is the *Electronic Industry Citizenship Coalition*. The company adheres to the Coalition and assesses its "ethical" performance following the EICC methodology. Assessments are made on a regular basis both at corporate and manufacturing sites level.
Procedure for ethics assessment: after	The company regularly monitors and evaluates its sustainability strategy, and results are condensed in the sustainability report published each year. The company adheres and complies with the Electronic Industry Citizenship Coalition Code of Conduct. Quantitative parameters on ethical performances of the company are regularly provided basing on the EICC assessment scheme (see above). A rating on ethical performances for member companies is provided in the EICC website.
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [x] professional integrity [x] implications for health and/or safety [ ] human subjects research [x] implications for quality of life [ ] treatment of animals in R&I [x] environmental impacts [ ] human dignity [x] social impacts [x] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [x] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [ ] other, specify: [x] social responsibility

	Commentary: The principles and values for sustainable excellence, officially stated in a publicly available document signed by the company CEO, are *integrity*, *people* and *excellence*. All companies activities and employees shall take in due account these principles in their areas of competences. Professional (business) ethics, respect of human rights, responsibility toward all stakeholders and the environment are considered mandatory aspects.
Self-assessments, strengths and weaknesses	The return of CSR and sustainability strategies should be seen in the medium to long term, and might not be easily measurable. It is a continuous process that aims to work on the attitude and mindset of people. It is a challenge to keep high the attention of the management and employees on these topics, even in period where there are other urgency or challenges to be faced and therefore people tend to focus only on core business issues. In general, commitment of the top management is paramount for the success of CSR in a company. As far as regards shareholders (and customers) the situation is quite heterogeneous. Some are committed and interested in sustainability and CSR, others are not.
Other	

Name of organization	Tethis S.p.A.
Type of organization	Industry
Country	Italy
Website address	*General:* www.tethis-lab.com *Main page(s) on ethics assessment:* http://www.tethis-lab.com/company-mission.html
Basic description (organization and mission)	Tethis S.p.A. is a privately held company active in the bio-and nanotechnology fields. It employs some 20 people and its mission is to become a solution provider leader for In Vitro Diagnostics (**IVD**) devices and tools development and production through its internal R&D, proprietary technologies and product development capabilities. Tethis technological and scientific background is based on two platforms - nanomaterials and biotechnology. The technologies at the basis of Tethis activity allow the precise production and manipulation of nanoparticles in gas phase and their easy integration in devices. Tethis also offer customers the possibility to have access to some of the nanomaterials production methods developed by the company, through the commercialization of a set of lab-scale equipment. Customers can have access to Tethis R&D experiences through its technical consulting and services
Interest in research and innovation	Research and innovation in the bio-and nanotechnology fields.
Ethics assessment and/or guidance	Assessment [x] Guidance [ ] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	Social responsibility, ethical issues related to the development of company products (e.g. medical devices)
Name and description	See below

of ethics unit(s)	
Aims and motivation for ethics assessment	The need for social responsibility is certainly well present at Tethis. Also because a large part of our activity is bound to health care, the attention to ethical issues is part of the everyday routine. It is implicit in the company culture and in what the company do. We cannot avoid it to have access and succeed on the market. The bottom line of the company depends from a correct approach to this aspect. However Tethis is a small entity, with limited resources and there is not the possibility, as it happens with big companies, to have a structured approach, let alone a dedicated function/unit to take care of ethics assessment.
Objects and scope of assessment	The attention is on scientific and professional integrity, patients safeguard, experiments and clinical tests, safety in the work place, environmental protection, quality, ethics associated with the person. Tethis is sometimes involved in projects funded by the EU and when this implies the use of sensitive data or particular specimens, there are normally specific European rules/norms related to ethics that must be respected. We follow them. In these cases it's the EU itself that asks for ethics assessment to decide whether the project goes ahead or not. All partners are involved and are equally responsible. Furthermore, when we are interacting with public health care institution, such as hospitals, for testing or selling products or equipment, we have to comply with the indication provided by the Ethics Committees that assist the regional Health Agencies that supervise at these structures. In several cases, for ethics assessment, we have to deal with existing external organisms, either at EU level or locally, such as the above mentioned Ethics Committees or other organisms that regulate the sector in which we operate. In conclusion, at Tethis we are aware of the need of ethics assessment and we try to address timely the relevant issues involved, though without a structured approach.
Beneficiaries of assessment	All company stakeholders, including in particular all employees and customers.
Ethics assessment unit: appointment process	The discussion involves all people working within the company, but the matter is under the particular responsibility of those people that are in charge of the planning and guide the activities.
Procedure for ethics assessment: before	See object and scope of the assessment
Procedure for ethics assessment: during	See object and scope of the assessment
Procedure for ethics assessment: after	See object and scope of the assessment
Principles and issues in assessment / guidance	[x] scientific integrity [ ] justice / fairness [x] professional integrity [x] implications for health and/or safety [x] human subjects research [x] implications for quality of life [ ] treatment of animals in R&I [x] environmental impacts [ ] human dignity [x] social impacts

	[ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [ ] other, specify: [x] social responsibility Commentary:
Self-assessments, strengths and weaknesses	The major problem in ethical assessment for companies like Tethis is their dimension. Generally, SMEs do not have enough resources for having people dedicated solely to this task. Sometimes certain problems could be overlooked or not timely addressed. The creation of a company vision, with written policy on this matter, could help to overcome this problem.
Other	

Name of organization	**Royal Dutch Shell**
Type of organization	Assessor / industry
Country	World-wide
Website address	*General: http://www.shell.com/*
Basic description (organization and mission)	Shell is a global group of energy and petrochemical companies.
Interest in research and innovation	"Our commitment to technology and innovation continues to be at the core of our strategy. As energy projects become more complex and more technically demanding, we believe our engineering expertise will be a deciding factor in the growth of our businesses. Our key strengths include the development and application of technology, the financial and project-management skills that allow us to deliver large field development projects, and the management of integrated value chains."
Ethics assessment and/or guidance	Assessment [x] Guidance [] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary: Impact Assessment "We contribute to sustainable development by working to deliver benefits through our projects and our operations, while helping to reduce their impacts. Impact assessments help us to do this. They outline the steps needed to help reduce the impacts on people and the environment. The systematic assessment of the potential environmental, health and social impacts is a fundamental part of the way we design our projects or any changes to

	existing facilities.
	An impact assessment looks to identify the positive and negative impacts that can arise from our activities.
	We familiarise ourselves with the environmental setting and regulations, consult with affected and interested parties, and plan from the earliest stages how we can reduce any impacts to an acceptable level and optimise the delivery of benefits.
	We capture the goals we set in the impact assessment process in a management plan and must implement and track these through the life of the project or operation.
	During operations we work to maintain good relations with communities and other interested parties and to find ways to continually improve our social and environmental performance."
Terminology for ethics assessment / guidance	N.a.
Name and description of ethics unit(s)	Unknown
Aims and motivation for ethics assessment	"Our strategy seeks to reinforce our position as a leader in the oil and gas industry while helping to meet global energy demand in a responsible way. Safety, environmental and social responsibility are at the heart of our activities."
Objects and scope of assessment	5 areas of responsibility (see beneficiaries) Shell employees share a set of core values – honesty, integrity and respect for people. Sustainable development
Beneficiaries of assessment	Shareholders, consumers, employees, "those with whom we do business," society
Ethics assessment unit: appointment process	unknown
Procedure for (ethics) assessment: before	unknown
Procedure for ethics assessment: during	unknown
Procedure for (ethics) assessment: after	Unknown
Principles and issues in assessment / guidance	[] scientific integrity [] justice / fairness [x] professional integrity [] implications for health and/or safety [] human subjects research [] implications for quality of life [] treatment of animals in R&I[x] environmental impacts [] human dignity [] social impacts [] equality / non-discrimination [] outsourcing of R&I to developing [] autonomy / freedom countries with lower ethics standards

	[] implications for civil rights [] dual use (possible military uses) [] implications for privacy [] other, specify: [x] social responsibility Commentary: Sustainable development is usually based on 3 p's: people, planet, profit. Shell is committed to all three. Shell General Business Principles: http://www.shell.com/global/aboutshell/who-we-are/our-values/sgbp.html
Self-assessments, strengths and weaknesses	As an oil and gas company, Shell is criticized for their impact on society and the environment (see: http://www.theguardian.com/environment/2015/mar/09/what-is-fossil-fuel-divestment). Shells self-reported oil spills in Nigeria were also underestimated according to Amnesty International (https://www.amnesty.org/en/articles/news/2012/04/shell-s-wildly-inaccurate-reporting-niger-delta-oil-spill-exposed/)
Other	N.a.

Name of organization	Electric Power Industry of Serbia
Type of organization	Non-assessor – major national company
Country	Serbia
Website address	General: http://www.eps.rs/Eng/Article.aspx?lista=Sitemap&id=10 Main page(s) on ethics assessment:
Basic description (organization and mission)	Prevailing activity of EPIS is electricity supply whereas electricity generation, electricity distribution and distribution system management, production, processing and transport of coal, generation of steam and hot water in combined processed is performed in subsidiaries. EPIS mission is secure electricity supply to all customers, under the most favorable market conditions, with continuous upgrading of the services, improvement of environmental protection and welfare of the community. The Vision of the EPIS is to be a socially accountable, market-oriented and Profitable company, competitive on the European market with a major impact in the region, recognized as a reliable partner among the local and international companies.
Interest in research and innovation	When it comes to environmental protection EPIS invests a lot in research and innovations. There are a number of projects in cooperation with scientific institutes and faculties. The biggest tree projects regarding wastewater treatment are in fact projects of EPIS. EPIS is working on implementing biomass because the emission of CO_2 is significantly lower (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 and using it for other purposes.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [x] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ]

	Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	
Objects and scope of assessment	
Beneficiaries of assessment	
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [ ] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [x] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [ ] other, specify: [x] social responsibility Commentary:
Self-assessments, strengths and weaknesses	
Other	

Name of organization	Court of Honor of Serbian Chamber of engineers
Type of organization	Non-assessor / industry national organization
Country	Serbia
Website address	*General:* www.ingkomora.org.rs *Main page(s) on ethics assessment:*
Basic description (organization and mission)	The Law on Planning and Construction (*Official Gazette of the Republic of Serbia*, 47/2003 and 34/2006) regulates the establishment of the Serbian Chamber of Engineers (SCE) with its seat in Belgrade. The Chamber was established to improve the conditions for performance of the professional work in the field of the spatial and city planning, design and construction, and in other fields of relevance for planning and construction; protect the general and individual

	interests in these fields; organize rendering of services in these fields, and also to achieve other objectives set by the Chamber Statute. The Code of Ethics defines the most important ethical principles regarding the professional activities of members of the Chamber: Adherence to legal and other regulations and standards, scientific and professional postulates, rules of the Chamber and ethics standards; Acknowledging the cultural and historical heritage of the environment; Safety, health and well-being of people and the protection of the natural environment and material goods; Responsibility and fairness in work; The improvement of professional knowledge and the development of general and technical education.
Interest in research and innovation	Research and development in Serbian industry practically do not exist. They use European standards and technology, since there is no money for scientific research and innovations
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [ ] None [x] Commentary: If assessment/guidance is undertaken: In-house [ ] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	One of the main tasks of the Court of Honor is to make opinions on ethical behavior of its members. Court investigates and gives judgments about cases of braking ethical principles.
Objects and scope of assessment	
Beneficiaries of assessment	
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [ ] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards

	[ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [ ] other, specify: [ ] social responsibility Commentary:
Self-assessments, strengths and weaknesses	
Other	

Name of organization	Lilly Spain
Type of organization	Industry
Country	Spain
Website address	*General:* N/A *Main page(s) on ethics assessment:*
Basic description (organization and mission)	This company works to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. Its mission is to make medicines that help people live longer, healthier, more active lives. The company works on three core values: integrity, excellence and respect for people; this values mark all their practices: exercise of ethics business; as a healthcare research company respects the Principles of Medical Research and, it is actively committed to the welfare of people and the environment.
Interest in research and innovation	Pharmaceutical company.
Ethics assessment and/or guidance	Assessment [ ] Guidance [ ] Other [x] None [ ] Commentary: The company's ethical framework is marked by the Red Book (business and legal ethical code of conduct applicable to all employees worldwide) and the Code of Good Practice for the Pharmaceutical Industry approved by the European Federation of the Pharmaceutical Industry Associations (EFPIA). On the other hand it is subjected to compliance with applicable regulations regarding biomedical research and clinical trials, as well as data protection and respect for the environment. The evaluation process is continuous through audits to confirm that ethical criteria are met. If assessment/guidance is undertaken: In-house [x] Outsourced [ ] Other [ ] Commentary:
Terminology for ethics assessment / guidance	corporate social responsibility
Name and description of ethics unit(s)	Ethics and Compliance Commission. This commission is independent of local management teams and reports directly to the Central Company. In every department the highest risk areas are identified and are audited monthly. The findings are presented in the Management Committee and corrective measures are established when needed. The Commission also performs training. This training is based on cases, a very practical method because it has a much greater impact on behaviour change. The people who make up this committee have a common ethical framework of values, dictated by the company, for its assessment and monitoring, also based on the compliance with the law. As a general rule they follow the most demanding

	framework. This gives little room for personal interpretation
Aims and motivation for ethics assessment	In the company ethical evaluation is performed not only in the specifics aspects of research but also on the behaviour of company employees and their relationship with others. The company is strongly committed to train properly its staff in good practices policies. Within the sector the company has been one of the first to adopt these measures to ethics and compliance policies and incorporate corporate social responsibility, both with workers, patients and employees, donations... Many aids are given to the community where the company is located, through environmental activities, volunteering, committees of social donations to help developing countries (diabetes), help to treat drinking water in India… Not all donations necessarily have to do with the business of the company.
Objects and scope of assessment	In the company ethical evaluation is performed not only in the specifics aspects of research but also on the behaviour of company employees and their relationship with others. The company is strongly committed to train properly its staff in good practices policies.
Beneficiaries of assessment	
Ethics assessment unit: appointment process	The members of the commission are employees of the company of a senior level, so they can assume this responsibility.
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [x] professional integrity [ ] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [ ] environmental impacts [ ] human dignity [ ] social impacts [ ] equality / non-discrimination [ ] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [ ] implications for privacy [x] other, specify: confidentiality and data protection, value transfer, payments to professionals (seeking transparency, any payment to external professionals is published), privacy, patient safety and pharmacovigilance; management of information, transparency in the publication of results, and clinical trials: protocols and both positive and negative results are published; issues of Health and Safety at Work, Environment and sustainability [ ] social responsibility Commentary:

Self-assessments, strengths and weaknesses	In general the problems are not critical, they are minor findings. No cases of violation of the Standards of Good Clinical Practice occur. No major weaknesses, thanks to the launch of the Commission on Ethics and Compliance and the training through the analysis of real cases. The training system is highly standardized so that each worker knows the procedures to be performed and training aims to reinforce learning.
Other	Evaluation measures have a very positive impact on the company. They have some organizational costs, but they are contributing to improving the quality of the company. The proceedings are binding and failure to comply is punishable. Closer interaction is with Farmaindustria, the National Business Association of the Pharmaceutical Industry established in Spain, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Industry. Their codes of good practice guide the actions of the company and pharmaceutical industry in general. The Code of Good Practices for the Pharmaceutical Industry is the set of common ethical standards on human medicines to be governed both in the field of promoting medicines for human use and in the interaction with Healthcare Professionals, Healthcare Organizations and Organizations of patients, with the aim of ensuring that these activities are carried out in compliance with the highest ethical principles of professionalism and responsibility.

Name of organization	**BMW Group**
Type of organization	Industry
Country	International
Website address	*General:* http://www.bmw.com/com/en/ *Main page(s) on ethics assessment:* • BMW Group Responsibility: http://www.bmwgroup.com/com/en/responsibility/index.html
Basic description (organization and mission)	The BMW Group is an international company, represented in over 140 countries around the globe. At the end of 2014 it employed 116,324 people.[90] The BMW Group consists of the three brands, BMW, MINI and Rolls-Royce Motor Cars having its sights set firmly on the premium sector of the international automobile market.[91] BMW Group declares that they are committed to the very highest in quality for all its products and services, starting from research and development to sales and marketing,[92] The company develops new mobility solutions and its mission statement up to the year 2020 is defined: *the BMW Group is the world's leading provider of premium products and premium services for individual mobility.*[93]

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[90] BMW Group, "Sustainable Value Report 2014",
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[91] BMW Group, http://www.bmw.com/com/en/insights/corporation/bmwgroup/content.html
[92] Ibid.
[93] The BMW Group, "Company portrait",
http://www.bmwgroup.com/bmwgroup_prod/e/0_0_www_bmwgroup_com/unternehmen/unternehmensprofil/strategie/strategie.html

Interest in research and innovation	The company perceives innovation as one of the BMW Group's success factors.[94] The BMW Group's provides innovative premium products, and the driving force behind these products are the approximately 9,300 people who jointly constitute the BMW Group's global research and development network.[95] According to the company, "efficient development processes and a deeply rooted, day-to-day innovation culture create the prerequisites for the success of the three premium brands"[96] giving the company a strong position in the automotive industry with its products and its manufacturing processes.[97] The company engages in research and innovation through its large research and innovation network, with 12 locations in five countries around the world.[98] Currently, its production network comprises 30 locations in 14 countries.[99]
Ethics assessment and/or guidance	Assessment [ ] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [x] Other [ ] Commentary: The company does not use the term ethics assessment.
Terminology for ethics assessment / guidance	In terms of terminology, the BMW Group does not use the term ethics assessment or guidance, the company however refers to responsibility and sustainability. In the opinion of the company sustainability is capable of making a positive contribution to the long-term business success of the company, and claims that social and environmental responsibility is an integral part of how they perceive themselves as a company.[100] The company's "Sustainable Value Report 2014" focuses on sustainability in the following areas: Sustainability Management; Product Responsibility; Group-wide Environmental Protection; Supply Chain Management; Employees; and Corporate Citizenship.[101]
Name and description of ethics unit(s)[102]	The company declares that sustainability is a component of the BMW Group's corporate strategy. For this reason, the company's Sustainability and Environmental Protection department has been directly incorporated into Corporate Planning and Product Strategy unit since 2007, under the mandate of the Chairman of the Board. This unit is responsible for the sustainability strategy and sustainability management worldwide. The entire Board of Management is represented on the Sustainability Board, which makes decisions on the long-term alignment of the sustainability-related areas of action of Strategy Number ONE. The heads of central Corporate Communications and Sustainability and Environmental Protection are also members of the Sustainability Board.
Aims and motivation for ethics assessment	The BMW Group claims that they aim at creating innovations with tangible benefits for society.[103] According to the company, the BMW Group sustainability

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[94] BMW Group, "A Look at Development",
http://www.bmwgroup.com/bmwgroup_prod/e/0_0_www_bmwgroup_com/forschung_entwicklung/ein_blicke_in_die_entwicklung/ueberblick.shtml
[95] BMW Group, "An Insight into Development",
http://www.bmwgroup.com/bmwgroup_prod/e/0_0_www_bmwgroup_com/forschung_entwicklung/ein_blicke_in_die_entwicklung/portal_zukunft/BMWGroupPortalZukunft143014.html
[96] Ibid.
[97] Ibid.
[98] BMW Group, "Sustainable Value Report 2014",
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[99] Ibid.
[100] Ibid.
[101] Ibid.
[102] Based on BMW Group, "Sustainable Value Report 2014", [p.14],
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8

	approach "is holistic, focused on implementing sustainability throughout the value chain" and ensuring that sustainability is firmly entrenched within the company's structures and practised by its employees.[104] To achieve this, the company claims it is gradually refining its sustainability strategy and setting long-term objectives in defined areas of activity including the reduction of fleet CO2 emissions with the BMW Group's Efficient Dynamics technology strategy and efficient use of resources.[105] Furthermore, the BMW Group declares its commitment to international conventions such as the ten principles of the UN Global Compact.[106]
Objects and scope of assessment	The BMW Group declares they believe that long-term thinking and responsible action are the basis for its business success.[107] In addition to business aspects, other integral parts of the BMW Group's strategy that the company claims to take into consideration are environmental and social criteria along the entire value chain, product responsibility in all areas as well as a clear commitment to resource efficiency.[108] According to the company, the BMW Group's corporate strategy is based on the four pillars, where sustainability is an integral part of each of the four pillars and is one of the company's core principles:[109] – **Growth:** Develop products and services that lead the way and tap into new markets and customer groups. – **Shaping the future:** Design new concepts for individual mobility and develop new business fields along the entire value chain. – **Profitability:** Be a leader in innovation in the area of individual mobility and leverage potential efficiencies along the entire value chain. – **Access to technologies and customers:** Access new technologies and enable customers to experience the company as well as its products and services. Furthermore, the company has set its Sustainability Leadership goals characterized by four principles: Entrepreneurial innovation; Impact on society; Alliances; and Scale Effects.[110]
Beneficiaries of assessment	N/A
Ethics assessment unit: appointment process	N/A
Procedure for ethics assessment: before	The company claims that social responsibility is an integral part of the BMW Group.[111] They declare their commitment to adhering to the Organisation for Economic Co-operation and Development guidelines for multinational companies

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[103] BMW Group, "Sustainability at the BMW Group",
http://www.bmwgroup.com/com/en/responsibility/sustainability/index.html
[104] BMW Group, "Sustainability at the BMW Group",
http://www.bmwgroup.com/com/en/responsibility/sustainability/index.html
[105] Ibid.
[106] Ibid.
[107] BMW Group, "Sustainable Value Report 2014",
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[108] Ibid.
[109] Based on BMW Group, "Sustainable Value Report 2014", [p.11],
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[110] BMW Group, "Sustainable Value Report 2014",
http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8
[111] Ibid., [p.40].

	and the contents of the ICC Business Charter for Sustainable Development, as well as the United Nations Environment Programme Cleaner Production Declaration.[112] The company's due diligence process for human rights is modelled on the UN Guiding Principles on Business and Human Rights, and the BMW Group claims they are used to reflect on the company's processes and to ensure the observance of human rights within the company and along the value chain throughout its sphere of action and influence.[113] According to the company, the BMW Group requires its employees to respect human rights and protects them in their daily actions.[114] Furthermore, as the company said it obliges its business partners to comply with human rights.[115] According to the BMW Group, they provide a sustainability training for its managers and employees.[116] Moreover, the company declares they are committed to lawful and responsible conduct.[117]
Procedure for ethics assessment: during[118]	The company declares that: Sustainability has been established at the BMW Group since 2009 as a strategic corporate objective based on specific targets and key performance indicators. Sustainability is therefore an explicit component of the BMW Group's management system. This means on the one hand that every major project must be measurable in terms of "Sustainability" as a corporate objective, ensuring that, in addition to economic factors, environmental and social aspects are also accounted for in the decision-making process. It also means that sustainability as a corporate objective is broken down to the level of business areas and divisions. As a result, the personal targets set for managers include sustainability aspects and criteria which have an effect on their performance-based remuneration. Furthermore, the company claims they engage in ongoing dialogue with its stakeholders at all its locations and in relevant markets.[119]
Procedure for ethics assessment: after	The company publishes the BMW Group's Sustainable Value Reports annually (see The BMW Group's Sustainable Value Report 2014). As we read in the latest report from 2014, it has been compiled in accordance with the Global Reporting Initiative (GRI G3.1) guidelines and at GRI level A+ and it meets the maximum requirements detailed in the GRI guidelines.[120] Moreover, the report makes references to the Global Compact principles.[121]
Principles and issues in assessment / guidance	[ ] scientific integrity [ ] justice / fairness [x] professional integrity [x] implications for health and/or safety [ ] human subjects research [ ] implications for quality of life [ ] treatment of animals in R&I [x] environmental impacts [x] human dignity [x] social impacts [x] equality / non-discrimination [ ] outsourcing of R&I to developing

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[112] Ibid., [p.27].

[113] Ibid.

[114] Ibid.

[115] Ibid.

[116] Ibid.

[117] Ibid., [p.34].

[118] Based on BMW Group, "Sustainable Value Report 2014", [p.14], http://www.bmwgroup.com/com/en/_common/_pdf/BMW_Group_SVR2014_EN.pdf#page=8

[119] Ibid.

[120] Ibid., [p.147].

[121] Ibid.

	[ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [x] social responsibility Commentary: Based on the BMW Group "Sustainable Value Report 2014".
Self-assessments, strengths and weaknesses	N/A
Other	

Name of organization	Novartis
Type of organization	Industry
Country	International
Website address	*General:* https://www.novartis.com/ *Main page(s) on ethics assessment:* • Novartis Corporate Responsibility https://www.novartis.com/about-us/corporate-responsibility • Novartis Research & Development https://www.novartis.com/our-work/research-development • Novartis Innovation https://www.novartis.com/our-work/innovation
Basic description (organization and mission)[122]	Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland. Novartis' mission of caring and curing underscores their work, their values and their efforts around the world. More than 119 000 people of 150 nationalities work at Novartis. Novartis' strategy is to deliver better outcomes for patients through science-based innovation. They aim at leading in growing areas of healthcare. Novartis is a full member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).
Interest in research and innovation[123]	According to Novartis, they provide innovative healthcare solutions that address the evolving needs of patients and societies. Novartis offers a diversified portfolio to meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. These three leading divisions are supported by Novartis research organisation, the Novartis Institutes for BioMedical Research (NIBR) and a centralized services group, Novartis Business Services, to facilitate collaboration across their divisions, and drive efficiency and productivity gains. Novartis is expanding their presence in the emerging markets of Asia, Africa and Latin America, where there is fast-growing demand for access to high-quality medicines and healthcare. Novartis spends almost 20 percent of their revenue on research and development,
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [ ] None [ ] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [x] Other [ ] Commentary:
Terminology for ethics	Novartis has developed its corporate responsibility strategy. The company

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[122] Based on Novartis, https://www.novartis.com/
[123] Based on Novartis, https://www.novartis.com/

assessment / guidance	declares that the assessment focuses on the principles stated in Novartis Code of Conduct; other Novartis internal principles and standards on a particular activity, e.g. clinical trials; and relevant international laws and regulations. Novartis claims that the company recognises its responsibility to do business in a responsible and ethical way.
Name and description of ethics unit(s)	According to the company, responsibility is a core part of Novartis' business strategy. Novartis recognises its corporate responsibility in the following areas: access to health; transparent reporting of annual targets and long-term objectives; efficient use of natural resources and minimizing the environmental impact of its activities and products; doing business responsibly and ethically; promoting the well-being of Novartis' associates, and supporting communities through volunteerism and philanthropic activities. The company claims that its shared commitment to corporate responsibility rests with every Novartis associate.
Aims and motivation for ethics assessment	Novartis declares that they focus on discovering and developing new medicines to treat disease and improve human health with research priorities at the intersection of unmet medical need and strong science. The company claims they strive for developing new therapies to treat and prevent infectious diseases and virally induced cancers, and building scientific capabilities in developing world countries. According to Novartis, the company recognizes ethical questions, such as those involved in animal welfare, stem cell research, Investigator-Initiated Trials or clinical trials in developing countries.
Objects and scope of assessment	Novartis says that the objects of assessment include research results, the clinical trial designs, and innovations, which reviewed by the research ethics committees. The company added that individual medicines are also reviewed for cost-benefit profiles, impact on patient health as well as environmental impact. In terms of behaviour of scientists, according to the company Novartis code of conduct and its values also apply to scientists and innovators within the company.
Beneficiaries of assessment	The users of Novartis assessment include the research and development board of Novartis board of directors, who oversees all of Novartis research and development; and the external institutions or clinical research group that Novartis would be working with. Moreover, Novartis claims they are committed to meet the expectations of five key stakeholder groups: Novartis' patients, associates, shareholders, healthcare partners and society at large.[124]
Ethics assessment unit: appointment process	Novartis does not have one ethical assessment unit. The assessment depends on their activity, and therefore for various activities there are different ethical assessment committees or individuals who do the assessment.
Procedure for ethics assessment: before	Novartis has developed its Code of Conduct applicable globally to all Novartis' employees. The Code of Conduct includes Novartis' core principles: • Patients: Patient benefit and safety is at the heart of everything Novartis does • Associates: Novartis treats its associates fairly and respectfully • Shareholders: Novartis is committed to outstanding and sustainable performance with integrity • Healthcare: Novartis strives to be a trusted healthcare partners partner • Society: Novartis aspires to be a good corporate citizen Furthermore, the company declares they support the United Nations Universal

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[124] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/standards-integrity

	Declaration of Human Rights and was one of the original signatories of the United Nations Global Compact. Currently, Novartis is updating its position on human rights. Regarding Novartis' research and development, the company claims it is based on the Declaration of Helsinki setting ethical principles regarding human experimentation, and principles of Good Clinical Research Practice. The company operates globally, therefore they claim to strive for responsible procurement. According to Novartis, they expect their suppliers to aspire to the standards defined in its Supplier Code, which is based on the United Nations Global Compact and other international standards or accepted good practices. The Supplier Code is aligned with the Novartis Code of Conduct.
Procedure for ethics assessment: during	According to Novartis, ethical conduct results from a culture of integrity. Novartis claims that the culture of integrity is built around a Code of Conduct, which as they say is a fundamental part of the terms of employment for all associates of Novartis Group companies.[125] Novartis declares also that they expect their managers to lead by example through reflecting ethical considerations in business planning and decisions, training associates to make responsible decisions, and encouraging associates to speak up when ethical issues arise.[126] In terms of capacity building, according to the company all Novartis Group company employees are required to complete integrity and compliance training.[127]

Novartis declares that they require associates to report even suspected violations of the Code of Conduct. Employees and people outside of Novartis can report any misconduct to the Business Practices Office (BPO). The BPO is responsible for investigation of all complaints, and escalating any substantiated cases of misconduct to management for appropriate action.[128] Novartis informs that the majority of cases investigated by the BPO involve fraud, such as fraudulent expense reporting.[129]

Novartis is active globally, and therefore at the global level the Global Integrity & Compliance Function designs and implements compliance programs associated with the Novartis Code of Conduct, Anti-Bribery and Professional Practices Policies.[130] The company declares that each Novartis division has a Global Integrity and Compliance Officer who drives the implementation of these programs throughout their divisions striving for achieving ethical business practices by all associates.[131] Moreover, Novartis has an extensive network of suppliers worldwide, and therefore has developed its Responsible Procurement (RP) strategy based on the Novartis Global Procurement Policy and the Novartis Supplier Code. According to Novartis, RP "means working closely with these suppliers, whose contribution is crucial to the Company's success, to ensure that |

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[125] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/standards-integrity
[126] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/standards-integrity
[127] Ibid.
[128] Ibid.
[129] Ibid.
[130] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance
[131] Ibid.

	goods and services are ethically sourced. By making sure we "buy responsibly," we are able to protect our patients, our people, and our business."[132] In terms of engagement of stakeholders in the ethical assessment, the company admits it would not be often that Novartis consults with the general public. Nevertheless, according to them e.g. in cardiovascular area Novartis would typically consult with medical experts within the field. However, the company claims they make all of their research results available for the public.
Procedure for ethics assessment: after	Novartis claims they are committed to transparent reporting. Novartis Annual Report serves as a primary reporting mechanism for corporate responsibility, and since 2000 Novartis has published a combined financial and Corporate Responsibility report.[133] According to the company, Corporate Responsibility Performance Report consolidates the company's CR reporting and reflects the Global Reporting Initiative's G4 Guidelines and the 10 principles of the UN Global Compact.[134] Novartis claims they track annual performance against key performance indicators (KPIs) on access, people and ethics, and environmental sustainability.[135] Novartis declares its participation in public policy debates affecting healthcare and Novartis business and recognizes a responsibility to share their perspective, scientific knowledge, technical expertise and fact-based information with policymakers and regulatory authorities.[136]
Principles and issues in assessment / guidance	[ ] scientific integrity [x] justice / fairness [x] professional integrity [x] implications for health and/or safety [x] human subjects research [x] implications for quality of life [x] treatment of animals in R&I [x] environmental impacts [x] human dignity [x] social impacts [x] equality / non-discrimination [x] outsourcing of R&I to developing [ ] autonomy / freedom countries with lower ethics standards [ ] implications for civil rights [ ] dual use (possible military uses) [x] implications for privacy [ ] other, specify: [x] social responsibility Commentary: Novartis claims they are committed to conducting all business activities at a minimum in compliance with existing labour, environmental, tax and other laws and regulations, and where these are not consistent with their values often at a higher standard. As the company said, Novartis values and standards are set out in their Code of Conduct and Corporate Citizenship guidelines, which define the Novartis approach and give affiliates' associates guidance in their daily work. Furthermore, Novartis declares they strive for anti-bribery and anti-corruption in their operations[137] and claim to be dedicated to responsible marketing practices.[138]

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[132] https://www.novartis.com/news/novartis-responsible-procurement-launch-%E2%80%93-taking-our-ethical-sourcing-practices-next-level
[133] https://www.novartis.com/about-us/corporate-responsibility/reporting
[134] Ibid.
[135] https://www.novartis.com/about-us/corporate-responsibility/reporting/key-performance-indicators
[136] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/public-policy-advocacy
[137] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/anti-bribery-anti-corruption

Self-assessments, strengths and weaknesses	According to Novartis, the company has an Internal Audit team responsible for monitoring management processes and adherence to integrity standards. Moreover, the company declares that monitoring is also conducted by the external auditors. The company declares it's Enterprise and Risk Management team regularly assesses any risks that may arise from noncompliance, and they benchmark Novartis programs against other companies.[139] The Audit and Compliance Committee of the Board of Directors holds final authority for all ethical matters at Novartis.[140] Novartis claims that if there is an issue, the Committee works with a particular group and makes changes that need to be made to address a certain issue, depending on how significant the issue is.
Other	In the opinion of the interviewee, more companies should agree and subscribe to a common set of principles such as the UN Global Compact in order to ensure more ethical corporate behaviour. An interesting point of the interview was that while the interviewee does not see the need for guidelines specific for the pharmaceutical industry because they are to a great extent covered by Good Clinical Practice and Declaration of Helsinki, but setting minimum standards, a tool kit or conduct of ethical research across industries or groups that engage in research could be helpful.

Name of organization	Industrial Biotechnology Cluster Finland (IBC Finland)
Type of organization	Industry association
Country	Finland
Website address	*General:* http://www.ibcfinland.fi/ *Main page(s) on ethics assessment:*
Basic description (organization and mission)	"Industrial Biotechnology Cluster Finland promotes sustainability and bioeconomy in the Finnish industry by means of industrial biotechnology. IBC Finland builds novel biotechnology solutions and products through project cooperation between companies and research institutes. We offer industry the opportunity to achieve sustainable processing and production of biobased products, chemicals, materials and fuels, from renewable raw materials using biotechnology." (//www.ibcfinland.fi/)
Interest in research and innovation	Organization's aim is to "identify industrial needs and based on them, to establish new innovative cooperation projects to create novel biotechnology solutions". IBC Finland have specific activities to endorse this function: it supports the members in planning and preparing research and R&D projects; it organizes idea mill workshops in critical research areas identified by the industry; communicates with all stakeholders; and keeps the member organisations up-to-date with global trends in industrial biotechnology.
Ethics assessment and/or guidance	Assessment ☐ Guidance ☐ Other ☒ None ☒ Commentary: The organisation is not explicitly involved with ethical impact assessment, but ethical aspects are taken into account in the ideation sessions organized with the industry. If assessment/guidance is undertaken: In-house ☐ Outsourced ☒ Other ☐ Commentary:
Terminology for ethics	The basic approach in the IBC Finland is to approach the ethical aspects as

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[138] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/marketing-practices

[139] https://www.novartis.com/about-us/corporate-responsibility/our-actions/ethics-compliance/standards-integrity

[140] Ibid.

assessment / guidance	internal issues of member organisations. There are standard ethical guidelines and regulation that govern the laboratory practices in companies etc. The overall view is that ethical aspects are internal issues of the companies.
Name and description of ethics unit(s)	-
Aims and motivation for ethics assessment	The organisation is not explicitly involved with ethical impact assessment, but ethical aspects could be taken into account in the ideation sessions organized with the industry.
Objects and scope of assessment	Depends on the nature of ideation sessions
Beneficiaries of assessment	Companies and stakeholders in the field of Finnish industrial biotechnology.
Ethics assessment unit: appointment process	There is no separate ethics assessment unit or procedure in the organisation. The discussion on ethics assessment is realised in the industry ideation sessions. The organisation generally follows the outlines and directions of the ethics assessment organisation in Finland: National Advisory Board on Biotechnology (http://www.btnk.fi/en/); The Board for Gene Technology (http://www.geenitekniikanlautakunta.fi/en/); National Animal Experiment Board (Eläinkoelautakunta, ELLA); The National Advisory Board on Social Welfare and Health Care Ethics – ETENE (http://www.etene.fi/en); The Sub-Committee on Medical Research Ethics (TUKIJA) (http://www.tukija.fi/en); The Cooperation Group for Laboratory Animal Sciences (KYTÖ); The National Advisory Board on Research Ethics (http://www.tenk.fi/) (for more details, see the separate interview literation).
Procedure for ethics assessment: before	Ibid.
Procedure for ethics assessment: during	Ibid.
Procedure for ethics assessment: after	Ibid.
Principles and issues in assessment / guidance	☐ scientific integrity ☐ justice / fairness ☐ professional integrity ☐ implications for health and/or safety ☐ human subjects research ☐ implications for quality of life ☐ treatment of animals in R&I ☐ environmental impacts ☐ human dignity ☐ social impacts ☐ equality / non-discrimination ☐ outsourcing of R&I to developing ☐ autonomy / freedom countries with lower ethics standards ☐ implications for civil rights ☐ dual use (possible military uses) ☐ implications for privacy ☐ other, specify: ☐ social responsibility Commentary: No separate ethics assessment procedure in the organisation. IBC Finland is an industry association.
Self-assessments, strengths and weaknesses	The organisation identifies the potential need for ethical assessment. The interviewee had view that the discussion on ethical issues is mainly on-going inside companies. As the interviewee noted, the ethical discussion has become integrated in the general corporate culture of biotech companies. This is a result of the development that has been on-going some ten to fifteen years. This internal company discussion is mostly linked with potential economic impacts of certain

	risks, like use of novel technologies in the production.
Other	An interesting point in the interview was the comment that in Finland the industrial community was so small and dense that it protects the awareness of potential ethical misconducts from leaking into the public consciousness. The background for this viewpoint was the notion that professions form strong circles that protect one another. This is why the discussion on ethical issues has remained fairly stable in Finland. This also reflects the general decision-making culture in Finland which is quite heavily bent on consensus. The interviewee connected this to the particular protestant culture in Finland. The interviewee noted that the emerging applications in neuroscience should be set under ethical evaluation. Also, the interviewee saw that there would be a specific need for future-oriented ethical impact assessment that realises the assessments in the context of specifically built future scenarios considering e.g. emerging technologies.