



## **Ethics Assessment in Different Countries**

### **The Netherlands**

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#### **Annex 4.f**

### **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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**Contents**

1	Introduction.....	4
2	National government institutions and policies.....	6
2.1	General institutional structure .....	6
2.1.1	General structure of government .....	6
2.1.2	Government organisations relevant to public and private research and innovation	6
2.2	Governmental institutions for ethics assessment.....	7
2.2.1	Advisory councils for government policy .....	8
2.2.2	National ethics committees.....	8
2.2.3	Environmental and social impact assessment agencies .....	9
2.2.4	Technology assessment agencies.....	9
2.2.5	Watchdog agencies .....	9
2.2.6	Discussion forums.....	10
2.3	National laws and policies for ethics assessment.....	10
2.3.1	Legal provisions for ethics assessment.....	10
2.3.2	Policies for ethics assessment.....	11
3	Public research and innovation systems.....	12
3.1	General structure and the role of government .....	12
3.1.1	System of higher education and research institutions.....	12
3.1.2	Role of government in the Dutch research and higher education system.....	13
3.2	National research associations and standard-setting bodies.....	13
3.2.1	General research associations and standard-setting bodies .....	14
3.2.2	Field-specific research associations and standard-setting bodies .....	15
3.3	Research funding organisations.....	15
3.3.1	Research and innovation funding organisations .....	15
3.3.2	Conditions for basic funding of Dutch universities and other public research institutions.....	16
3.4	Research performing institutions.....	17
4	Private research and innovation systems .....	20
4.1	General structure and the role of government .....	20
4.1.1	Dutch industry landscape.....	20
4.1.2	Organisations that represent industry .....	20

4.1.3	Government policies and initiatives to support ethics assessment in private industry .....	21
4.1.4	Initiatives for public-private partnerships.....	23
4.2	Industry associations and accreditation, certification and standard-setting organisations.....	23
4.2.1	Industry associations.....	23
4.2.2	Network organisations.....	24
4.2.3	Certification, evaluation and standard-setting organisations.....	24
4.2.4	External ethics committees .....	25
4.3	Industry.....	25
4.3.1	Small and medium-sized Dutch enterprises.....	25
4.3.2	Large multinational Dutch corporations .....	25
5	Professional groups and associations in the R&I field.....	27
5.1	National associations for R&D professions .....	27
5.2	National associations for (ethics) assessors.....	27
6	Civil society organisations .....	29
6.1	The CSO landscape .....	29
6.1.1	National legislation and regulation for CSOs.....	29
6.1.2	Major CSOs and their societal roles .....	29
6.1.3	Role of CSOs in research and innovation.....	31
6.2	The role of CSOs in ethics assessment.....	32
6.2.1	CSOs as stakeholders in public discussions .....	32
6.2.2	CSOs as participants in ethics assessment panels and procedures .....	32
6.2.3	CSOs as agents who engage in ethics assessment themselves .....	32
7	Discussion .....	34

## 1 Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation in the Netherlands, both for the public and the private sector. It will be analysed how the national government has put into place organisational structures, laws, policies and procedures for ethical assessment, how both publicly funded and private research and innovation (R&I) systems address ethical issues in research and innovation, and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs).

We will begin by providing some basic information about the Netherlands and the historical development of ethics assessment institutions in the country. The Netherlands is the main constituent country of the Kingdom of the Netherlands. It is a small, densely populated country, which lies mainly in Western Europe and includes three islands in the Caribbean. With a population of roughly 16,9 million people, as of 2015<sup>1</sup>, the Netherlands is one of the smaller member states of the European Union. The largest and most important cities in the Netherlands are Amsterdam, The Hague and Rotterdam. Amsterdam is the country's capital, while The Hague holds the Dutch seat of government and parliament. The official language of the Netherlands is Dutch; West Frisian, Limburgish, Dutch Low Saxon, English, Papiamentu are recognised as regional languages. The Netherlands is a unitary, parliamentary, constitutional monarchy. Its political system has been described as consociational, consensual, multi-party, and corporatist (Lijphart, 1984).<sup>2</sup>

The Netherlands has a highly developed economy and, as a trade nation, it has played a significant role in the European economy for many centuries. In 2012, it was the world's seventh largest exporting country.<sup>3</sup> Foodstuffs form the largest industrial sector in the Netherlands. Other major industries include chemicals, metallurgy, machinery, and electrical goods. Leading Dutch international corporations include Unilever, Heineken, ING, DSM, AkzoNobel, Shell, Philips, and ASML. In 2011, the Netherlands had a gross domestic product (GDP) of 642.929 million Euros, making it the 17<sup>th</sup>-largest economy in the world and the 10<sup>th</sup> most prosperous in terms of gross domestic product per capita.<sup>4</sup> In the same year, the gross domestic expenditure on research and development (GERD) was 14.597,92 million Euros, which amounted to 2,03 percent of GDP.<sup>5</sup> Table 1 and table 2 show a breakdown of the GERD, in percentage terms, by financing sector and performing sector.

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<sup>1</sup> OECD, "Main Science and Technology Indicators". [http://stats.oecd.org/Index.aspx?DataSetCode=MSTI\\_PUB](http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB)

<sup>2</sup> Lijphart, Arend, *Democracies: Patterns of Majoritarian and Consensus Government in Twenty-one Countries*, Yale University Press, New Haven, 1984.

<sup>3</sup> The World Fact Book, "Country Comparison – Exports". <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2078rank.html>

<sup>4</sup> OECD, op. cit.

<sup>5</sup> Ibid.

Industry	Government	Other national sources	Sources abroad
49,92	35,54	3,65	10,89

**Table 1: A breakdown of the GERD, in percentage terms, by financing sector in 2011<sup>6</sup>**

Business enterprise	Higher education	Government	Non-profit
56,22	32,90	10,88	n/a

**Table 2: A breakdown of the GERD, in percentage terms, by performing sector in 2011<sup>7</sup>**

The practice of ethics assessment of research and innovation in the Netherlands is for the most part decentralised and independent from government. Over the years, successive Dutch governments have established a number of laws on ethics assessment. These laws formally acknowledge the existence of about 45 institutional ethics committees that evaluate scientific research involving human subjects or animal experimentation, and bestow on them the authority to provide legally required permissions for such research. The laws also establish a number of central ethics committees with special powers for oversight and regulation. These committees have as their mission to ensure protection of human test subjects or prevent unnecessary suffering of animal test subjects. Furthermore, at public research institutions in the Netherlands, there are often additional structures for ethics assessment in the form of internal research ethics committees (for research in the social sciences) and scientific integrity counsellors or committees that provide assistance to whistle-blowers and those accused of scientific misconduct. Private industry engages in ethics assessment as well and tends to focus mostly *corporate social responsibility* and “sustainability”. Also, reflective of the *consociational* nature of Dutch politics and governance, a number of public-private partnerships exist concerning ethics assessment, and civil society organisations are represented in various stakeholder dialogues organised on important ethical issues. Finally, a number of government (-associated) bodies engage in activities related to ethics assessment, such as *environmental impact assessment*, *social impact assessment*, and *technology assessment*.

The Netherlands has a rich history in terms of the development of ethics assessment structures. The ethical aspects of scientific research, in particular those pertaining to medical research, started to gain significant attention following the signing of the Helsinki declaration in 1964. This first guideline on the ethical principles for medical research involving human subjects led to the establishment of many institutional medical research ethics committees. In 1990, animal experiments committees were established as well. Then, further institutionalisation of medical research ethics assessment followed in 1999, when the Dutch *Human Subjects Research Act* was signed into law. Over the years, ethics assessment practices have grown to be more participatory. For example, Dutch CSOs and the public at large are currently participating in stakeholder dialogues on the use of (new) technologies, such as hydraulic fracturing and nanotechnology. Finally, it is worth noting that Dutch academia has played, and continues to play, an important role in the development of (ethics) assessment theory, developing such concepts as *constructive technology assessment*.

<sup>6</sup> OECD, op. cit.

<sup>7</sup> OECD, op. cit.

## 2 National government institutions and policies

This chapter offers a discussion of Dutch national government institutions and policies relating to research and innovation. In the next sections, the following will be examined: the general institutional structure of Dutch government and government-controlled institutions; governmental institutions with a role in ethics assessment; and national laws and policies for ethics assessment.

### 2.1 General institutional structure

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

#### 2.1.1 General structure of government

The Netherlands is a constitutional monarchy and a parliamentary democracy. It is described as a *consociational* state (Lijphart, 1984)<sup>8</sup>: Dutch politics and governance are characterised by an effort to reach broad consensus on important issues.

The monarch is the Dutch head of state. Constitutionally, the position is equipped with limited executive power. Instead, executive power is held by the *Council of Ministers*, which initiates law and policy and usually consists of 13 to 16 ministers. Together with a varying number of state secretaries, the ministers constitute the Dutch cabinet. Most of the ministers are heads of specific government ministries. The head of the cabinet and of government is the Prime Minister of the Netherlands, who often also is the leader of the largest party of the government coalition.

The Dutch cabinet is responsible to a bicameral parliament, the *States General*, for government policy and must enjoy its confidence. The States General has legislative powers as well. The 150 members of the lower house of parliament, the *House of Representatives*, are elected in direct elections on the basis of party-list proportional representation. The 75 members of the upper house, the *Senate*, are elected by members of provincial assemblies which, in turn, are elected by the public.

The Dutch judiciary is largely independent of the executive and legislative branches of government. Judges are considered independent and cannot be dismissed by the Minister of Security and Justice. The court system in the Netherlands comprises different areas of law and a variety of bodies.

#### 2.1.2 Government organisations relevant to public and private research and innovation

Within government, responsibility for research and innovation policy is divided chiefly between two ministries: the *Ministry of Education, Culture and Science (Min. OC&W)*, and the *Ministry of Economic Affairs (Min. EZ)*. Both incorporate a number of bodies that have a link with research and innovation. The *Ministry of Finance* is responsible for the provision of

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<sup>8</sup> Lijphart, op. cit. 1984.

funds for publicly funded research and innovation carried out within and outside government institutions, as well as for the relevant fiscal framework.

The Ministry of Education, Culture and Science (Min. OC&W) focuses on scientific research and education. It is responsible for the public research infrastructure and funding of basic research. Its policies are implemented by the agencies and research institutes to which it provides funding. One important R&I-related body within the Min. OC&W is the *Advisory Council for Science and Technology and Innovation (Adviesraad voor Wetenschap, Technologie en Innovatie; AWTI)*<sup>9</sup>, which advises government and parliament on research, technology and innovation policy with a focus on middle- to long-term research policy issues.

The Ministry of Economic Affairs (Min. EZ) is responsible for innovation policy in the Netherlands. It aims to foster knowledge development in companies and collaboration between research institutions and businesses. The Min. EZ implements its programs through various directorates and agencies. An important agency within the Min. EZ is the *Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland; RVO)*, which seeks to stimulate sustainable, agrarian, innovative and international entrepreneurship, by helping businesses apply for grants, find business partners, obtain know-how, and comply with laws and regulations. Another important agency within the ministry is the *Netherlands Bureau for Economic Policy Analysis (Centraal Planbureau; CPB)* which carries out scientific research contributing to the decision-making process of politicians and policymakers on socioeconomic issues.

In addition to Min. OC&W and Min. EZ, other ministries such as the Ministry of Infrastructure and the Environment (Min. I&M) and the Ministry of Health, Welfare and Sports (Min. GW&S) develop and implement specific research policies for their respective sectors. Within the Min. I&M, the *PBL Netherlands Environmental Assessment Agency (PBL)* carries out strategic policy analysis in the fields of the environment, nature and spatial planning. Within the Min. GW&S, the *National Institute for Public Health and the environment (RIVM)* conducts research, advises on policy and helps to implement policy aimed at promoting public health and maintaining a safe and clean environment.

Finally, almost all ministries have their own *Knowledge Forum (Kennisforum)*, which works towards strengthening the interaction between senior civil servants and research institutions.

## 2.2 Governmental institutions for ethics assessment

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

Many of the organisations listed are not strictly part of the Dutch government (and stress their independence from government), but do have a very close relationship with it in the sense that they are funded by it and their primary task is to provide policy advice to government. For this reason, they are included here and not (only) in the chapter on public research and innovation systems (chapter 3).

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<sup>9</sup> Adviesraad voor Wetenschap, Technologie en Innovatie. <http://www.awti.nl/english/item146>



### 2.2.1 Advisory councils for government policy

- The Advisory Council for Science and Technology and Innovation (AWTI) (See section 2.1)
- The *Health Council of the Netherlands (Gezondheidsraad; GR)* is an independent, government-funded body whose legal task it is to advise ministers and parliament on policy in the field of public health and healthcare research. GR usually has about 30 committees that focus on specific areas within the field of public health and healthcare research.<sup>10</sup>
- The *Council for Public Health and Health Care (Raad voor de Volksgezondheid en Zorg; RVZ)* is an independent, government-funded body that provides advice to the government on policy relating to public health and healthcare.<sup>11</sup>
- The *Netherlands Centre for Ethics and Health (Centrum voor Ethiek en Gezondheid; CEG)* is a joint venture of the two preceding organisations, GR and RVZ, whose task it is to identify issues in the field of public health to be put on the government's ethical policy agenda.<sup>12</sup>
- The *Netherlands Commission on Genetic Modification (Commissie Genetische Modificatie; COGEM)* is an independent, government-funded scientific advisory body that advises the government on the risks to human health and the environment of the production and use of genetically modified organisms, and informs the government of ethical and societal issues linked to genetic modification.<sup>13</sup>
- The *Netherlands Advice Committee on Animal Experimentation Policy (Nationaal Comité advies dierproevenbeleid; NCad)* is a government-funded body that provides advice to the government and animal welfare institutions and exchanges knowledge on the procurement, breeding, housing and caretaking of animals used in scientific research and education with the aim of “replacing, reducing and refining” animal experimentation.<sup>14</sup>
- The *Netherlands Advice Committee on the Environment and infrastructure (Adviesraad Leefbaarheid en Infrastructuur; RLI)* is a government-funded body that advises the government on development of the physical infrastructure. In 2015, the organisation published a report on the consequences of technical innovations on the living environment. Another area of focus is sustainable energy supply.<sup>15</sup>

### 2.2.2 National ethics committees

- The *Central Committee on Animal Experimentation (Centrale Commissie Dierproeven; CCD)* is an independent, government-funded body whose legal tasks include reviewing research involving animal experimentation, providing permits for

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<sup>10</sup> Gezondheidsraad. <http://www.gezondheidsraad.nl/en/task-and-procedure/legal-task>

<sup>11</sup> Raad voor de Volksgezondheid en Zorg. <http://www.rvz.net/en/about-the-council>

<sup>12</sup> Centrum voor Ethiek en Gezondheid. <http://www.ceg.nl/en/about-ceg>

<sup>13</sup> Commissie Genetische Modificatie. <http://www.cogem.net/index.cfm/nl/cogem>

<sup>14</sup> Nationaal Comité advies dierproevenbeleid. <http://www.ncadierproevenbeleid.nl/over-het-ncad>

<sup>15</sup> Adviesraad Leefbaarheid en Infrastructuur. <http://www.rli.nl>



such research on a case by case basis, providing official recognition for *animal experimentation ethics committees* (*Dierexperimentencommissies*; *DECs*), and creating guidelines for animal experimentation ethics assessment procedures by *DECs*.<sup>16</sup>

- The *Central Committee on Research Involving Human Subjects* (*Centrale Commissie Mensgebonden Onderzoek*; *CCMO*) is an independent, government-funded body that is responsible for implementing the Dutch *Medical Research Involving Human Subjects Act* (*Wet Medisch-Wetenschappelijk Onderzoek met Mensen*; *WMO*). The *CCMO*'s legal tasks include overseeing the operations of the accredited *medical ethical reviewing committees* (*MERCs*), creating guidelines on assessment procedures by *MERCs* and the selection of members of *MERCs* and reviewing the ethics of research in special cases—that is, in particular fields or in cases where an appeal is filed against a decision by a *MERC*.<sup>17</sup>

### 2.2.3 Environmental and social impact assessment agencies

- The *Netherlands Commission for Environmental Assessment* (*Commissie voor de Milieueffectrapportage*) is an independent, government-funded body that provides advisory and capacity development services with regard to environmental assessment.<sup>18</sup>
- *PBL Netherlands Environmental Assessment Agency* (*PBL*) (See section 2.1)
- *National Institute for Public Health and the Environment* (*RIVM*) (See section 2.1)

### 2.2.4 Technology assessment agencies

- The *Rathenau Instituut* is an institute of the *Royal Netherlands Academy of Arts and Sciences* that promotes the development of political and public opinion on topics relating to science and technology. The institute studies the organisation and development of science systems, produces publications concerning the social impact of new technologies, and organises debates on ethical issues and dilemmas in science and technology.<sup>19</sup>

### 2.2.5 Watchdog agencies

- The *Netherlands Food and Consumer Product Safety Authority* (*Nederlandse Voedsel- en Warenautoriteit*; *NVWA*) is a government agency whose task it is to safeguard public health and animal health and welfare by monitoring the production and consumption of food and consumer products. Institutions conducting animal experiments report to the *NVWA* on their efforts to minimise the suffering of animals. The *NVWA* inspects these institutions and publishes yearly reports on the welfare of lab animals.<sup>20</sup>

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<sup>16</sup> Centrale Commissie Dierproeven. <http://www.zbo-ccd.nl/over-de-ccd>

<sup>17</sup> Centrale Commissie Mensgebonden Onderzoek. <http://www.ccmo.nl/en/tasks-of-the-ccmo>

<sup>18</sup> Commissie voor de Milieueffectrapportage. <http://www.eia.nl/en>

<sup>19</sup> Rathenau Instituut. <http://www.rathenau.nl/en/who-we-are/about-the-institute.html>

<sup>20</sup> Nederlandse Voedsel- en Warenautoriteit. <http://www.nvwa.nl/english/organisation>

- The *Dutch Data Protection Authority (College Bescherming Persoonsgegevens; CBP)* is an independent, government-funded agency that supervises the processing of personal data in order to ensure compliance with the provisions of the Dutch law on personal data protection. It also advises the government on new regulations.<sup>21</sup>

### 2.2.6 Discussion forums

- The *Dutch Forum for Biotechnology and Genetics (Forum Biotechnologie en Genetica; FBG)* is a government-funded body that aims to enhance communication between the government and organisations in the area of medical biotechnology, so as to support the development of balanced opinion and policy. The forum carries out evaluations of new political and administrative developments regarding the extent to which such developments positively or negatively affect the Dutch health care system and public health.<sup>22</sup>

## 2.3 National laws and policies for ethics assessment

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

### 2.3.1 Legal provisions for ethics assessment

On the level of national law, most provisions with regard to ethics assessment in scientific research are fairly abstract, formulated in terms of general values. In part, the abstraction is due to a firm belief in the academic liberty and independence of individual researchers—a belief that is grounded in the Dutch national constitution under the heading of “freedom of expression”.<sup>23</sup> In the Dutch law on higher education and scientific research (WHW), article 1.6 explicitly states that academic freedom is to be valued highly by the research institutes, and that their governing bodies have a mandate to create guidelines with regard to ethical aspects of their work (article 1.7).<sup>24</sup>

Thus, national law does not put many explicit restrictions on research. Notable exceptions include those aspects of research that have ethical significance such as those involving human subjects and animals. Laws that are formulated to regulate these aspects of research form the highest legal framework. These laws include the Medical Research Involving Human Subjects Act (WMO),<sup>25</sup> the Data Protection Act (WBP),<sup>26</sup> the population screening act (WBO),<sup>27</sup> the

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<sup>21</sup> College Bescherming Persoonsgegevens. <http://www.cpb.nl/en/what-does-cpb-do>

<sup>22</sup> Forum Biotechnologie en Genetica. <http://www.forumbg.nl/dutch-forum-for-biotechnology-and-genetics>

<sup>23</sup> Ministry of the interior and kingdom relations, “The Constitution of the Kingdom of the Netherlands 2008”. <http://www.government.nl/files/documents-and-publications/regulations/2012/10/18/the-constitution-of-the-kingdom-of-the-netherlands-2008/the-constitution-of-the-kingdom-of-the-netherlands-2008.pdf>

<sup>24</sup> Dutch parliament, Wet op het hoger onderwijs en wetenschappelijk onderzoek, BWBR0005682. <http://wetten.overheid.nl/BWBR0005682/>

<sup>25</sup> Dutch parliament, Wet medisch-wetenschappelijk onderzoek met mensen, BWBR0009408. <http://wetten.overheid.nl/BWBR0009408>

<sup>26</sup> Dutch parliament, Wet bescherming persoonsgegevens, BWBR0011468. <http://wetten.overheid.nl/BWBR0011468>

<sup>27</sup> Dutch parliament, Wet op het bevolkingsonderzoek, BWBR0005699. <http://wetten.overheid.nl/BWBR0005699/>

act on animal experimentation,<sup>28</sup> and the environmental management act.<sup>29</sup> Moreover, the medical field has strict regulations with regard to the composition and tasks of the 24 accredited *medical research ethics committees (MRECs)* in the Netherlands that review medical/scientific research proposals.<sup>30</sup> Many legal provisions at the national level are direct translations of international or EU legislation.

### 2.3.2 Policies for ethics assessment

In addition to the legal frameworks that are mostly field-specific, much ethics assessment is regulated by statutory organisations. These organisations are authorised to formulate policies for all public research institutes. An overarching body of legislation consists of the four codes that have been established by the *Association of Universities in the Netherlands (VSNU)*, which are the codes on personal data, scientific integrity, animal experiments, and good governance.<sup>31</sup> The code of conduct for scientific research offers five guiding principles for research policies: scrupulousness, reliability, verifiability, impartiality, independence, and responsibility.<sup>32</sup>

In addition to the policies developed by the VSNU, the statutory research funding organisation *Netherlands Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek; NWO)*<sup>33</sup> formulates policies for the regulation of its funding activities. These will be discussed in section 3.3. In addition to regulations on ethics assessment for public research, the Dutch Corporate Governance Code that is primarily stipulated by Dutch labour unions governs several ethical aspects of research by private industry.

Finally, research institutes formulate their own policies on the conduct of their individual researchers. General instances of such policy are university codes of ethics, such as the University of Delft code of ethics.<sup>34</sup> Some of such policies are again rather field-specific like the codes on medical practices by the VUMC/AMC. An overview of the different levels of governance that decide on the regulations with regard to ethics assessment is provided in the Table 3 below.

<b>Level:</b>	<b>General:</b>	<b>Research-specific:</b>
Central government:	National Constitution Law on Higher Education	Human Subjects Act Screening Act

<sup>28</sup> Dutch parliament, Wet op de dierproeven, BWBR0003081. <http://wetten.overheid.nl/BWBR0003081>

<sup>29</sup> Dutch parliament, Wet milieubeheer, BWBR0003245. <http://wetten.overheid.nl/BWBR0003245>

<sup>30</sup> Koeter, G. H. (2012). “CCMO Deskundigheidseisen (WMO-)Leden METC’s”. *Staatscourant*, (13083), 1–7.

<sup>31</sup> Interview with Ed Brinksma, former chair of the steering committee on research and valorisation of the VSNU (Association of Universities in the Netherlands), 21 January 2015

<sup>32</sup> VSNU (2012), “The Netherlands Code of Conduct for Scientific Practice. Principles of good scientific teaching and research”.

[http://www.vsnunl.nl/files/documenten/Domeinen/Onderzoek/The\\_Netherlands\\_Code\\_of\\_Conduct\\_for\\_Scientific\\_Practice\\_2012.pdf](http://www.vsnunl.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code_of_Conduct_for_Scientific_Practice_2012.pdf)

<sup>33</sup> Nederlandse Organisatie voor Wetenschappelijk Onderzoek. <http://www.nwo.nl>

<sup>34</sup> TU Delft, “Code of Ethics TU Delft”.

[http://www.tudelft.nl/fileadmin/UD/MenC/Support/Internet/TU\\_Website/TU\\_Delft\\_portal/Over\\_TU\\_Delft/Strategie/Integriteit/TU\\_Delft\\_Code\\_of\\_Ethics\\_NL\\_.pdf](http://www.tudelft.nl/fileadmin/UD/MenC/Support/Internet/TU_Website/TU_Delft_portal/Over_TU_Delft/Strategie/Integriteit/TU_Delft_Code_of_Ethics_NL_.pdf)

	and Scientific Research	Animal Experimentation Act Environment Act
Statutory organisations:	Codes of The VSNU Protocols of NWO, ZonMw	Field specific policy advice (e.g. concerning genetic modification by COGEM)
Research institutes:	University Codes of Ethics (e.g. University of Delft Code of Ethics)	VUMC/AMC University code of practice

**Table 3: Overview of legal and policy frameworks governing ethics assessment in research**

### 3 Public research and innovation systems

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

#### 3.1 General structure and the role of government

This section provides an overview of the general structure of the publicly funded and controlled R&I and higher education system and the role of the government within this structure. A description of the different organisations and their interrelations will be provided, in addition to an outline of the executive and regulatory powers of the government.

##### 3.1.1 System of higher education and research institutions

The structure of institutions that are involved in policy making in research and higher education can be described with regard to the following categories of organisations: (1) politics & government, (2) advisory bodies, (3) funding organisations, (4) intermediary organisations (5) research institutes and (6) other, supportive organisations.<sup>35</sup> The main decision-making power lies with the research institutes themselves, which is due to the principle of academic self-governance as stipulated in the Dutch law on higher education and scientific research.<sup>36</sup>

The roles that these different categories of institutions have in the Dutch system are executive, regulatory and advisory. Research institutes and funding organisations take up the executive role. The Dutch government, the funding organisations and the intermediary organisations have a regulatory role with regard to agreed-upon regulations for ethics assessment in research and higher education. The Ministry of Education, Culture & Science retains the main

<sup>35</sup> Ministry of the interior and kingdom relations, “The Constitution of the Kingdom of the Netherlands 2008”.  
<http://www.government.nl/files/documents-and-publications/regulations/2012/10/18/the-constitution-of-the-kingdom-of-the-netherlands-2008/the-constitution-of-the-kingdom-of-the-netherlands-2008.pdf>

<sup>36</sup> Dutch parliament, Wet op het hoger onderwijs en wetenschappelijk onderzoek, BWBR0005682.  
<http://wetten.overheid.nl/BWBR0005682/>

governance responsibility for regulating public universities and public research-related organisations. The funding organisations, notably NWO and the *Netherlands Organisation for Health Research and Development (ZonMw)*, stipulate the basic conditions for research institutes to obtain funding for their research. Intermediary organisations, notably the VSNU, make sure that institutions come together to agree upon common regulations of ethics assessment, for example the appointment of an ombudsperson to deal with issues of scientific integrity.<sup>37</sup>

The advisory role for the formulation of advice for both the regulatory and the executive bodies is mostly taken up by the national advisory bodies that are established by law – notably the health council that deals with issues in the medical sciences and the advisory board on science, technology and innovation, which, for example, provides strategic advice with regard to the implementation of the so-called “top sectors”, i.e. areas of research that are of high societal and economic importance.<sup>38</sup> Moreover, internal committees in executive or regulatory bodies (such as the steering committees of the VSNU) take up the advisory role or even other (supportive) organisations like environmental NGOs.

### 3.1.2 Role of government in the Dutch research and higher education system

Research and education have traditionally maintained a high level of independence from the interference of the Dutch central government. The traditional view on science and education puts a strong emphasis on the professional integrity of scientists and educators and barely interferes in matters of social responsibility.<sup>39,40</sup> Dutch scientific institutions receive most of their funding directly from the Ministry of Education, Culture & Science. Recently, however, government policy has shifted in that scientific institutions increasingly receive funding in the form of competitive research grants by funding organisation NWO.<sup>41</sup>

Many of the policies that affect the practices of ethics assessment at the research institutes are made by organisations that are created by government law and are directly funded by government but are nevertheless not part of the central government. The main statutory organisations are NWO (Netherlands Organisation for Scientific Research), TNO (Netherlands Organisation for Applied Research), KNAW (Royal Netherlands Academy of Arts and Sciences) and the KB (Royal Library). The Ministry of Economic Affairs is directly involved in some parts of TNO (TNO Co-funding Program) and NWO (Technology Foundation, STW), with both partly financed by the Ministry of Economic Affairs.

## 3.2 National research associations and standard-setting bodies

This section offers an overview of research associations and standard-setting bodies in the Netherlands and offers an analysis of their role in ethics assessment. Firstly, we will discuss

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<sup>37</sup> Interview with Ed Brinksma, op. cit.

<sup>38</sup> AWTI, *Balans van de topsectoren 2014*, AWTI, Den Haag, 2014.

[http://www.awti.nl/upload/documents/publicaties/tekst/Balans-van-de-topsectoren-2014\\_Def\\_lrs.pdf](http://www.awti.nl/upload/documents/publicaties/tekst/Balans-van-de-topsectoren-2014_Def_lrs.pdf)

<sup>39</sup> Nieveen, N., & W. Kuiper, “Balancing curriculum freedom and regulation in the Netherlands”. *European Educational Research Journal*, 11(3), 2012, pp. 357–368. doi:0.2304/eej.2012.11.3.357

<sup>40</sup> Rip, A., & E. Boeker, “Scientists and Social Responsibility in the Netherlands”, *Social Studies of Science*, 5(4), 2015, pp. 457–484.

<sup>41</sup> Rijksoverheid, “IBO Wetenschappelijk Onderzoek”. [www.rijksoverheid.nl/bestanden/documenten-en-publicaties/rapporten/2014/05/01/ibo-wetenschappelijk-onderzoek/ibo-wetenschappelijk-onderzoek.pdf](http://www.rijksoverheid.nl/bestanden/documenten-en-publicaties/rapporten/2014/05/01/ibo-wetenschappelijk-onderzoek/ibo-wetenschappelijk-onderzoek.pdf)

the main national organisations VSNU and KNAW that have a role in stipulating general policies for universities and research institutes. Secondly, we will discuss field specific organisations that are involved with ethics assessment.

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

The research community in the Netherlands is primarily represented by two national organisations: the KNAW - Royal Netherlands Academy of Arts and Sciences - and the VSNU - the Association of Universities in the Netherlands.

The precursor to the KNAW was established by Royal decree in 1808 in order to bring together the Dutch sciences and arts, to promote Dutch accomplishments in these areas internationally and to incorporate innovations from abroad into the Dutch system of arts and sciences.<sup>42</sup> The academy's formal structure and decision-making powers are laid down in Dutch law on higher education and scientific research.<sup>43</sup> The academy has approximately 500 individual members and is governed by a general board.

With regard to ethics assessment, the KNAW has a role in formulating a national vision on higher education and scientific research and in the provision of advice for more specific ethical issues that are particularly dealt with by the five advisory councils of the academy. An example of the first kind of activity is the formulation of a national position on scientific fraud, instigated by several scandals in Dutch psychology research.<sup>44</sup> Examples of the second activity include advisory documents about the ethics of empirical research in the social sciences and the formulation of a code of conduct for biosecurity.<sup>45,46</sup> A third role of the KNAW is of an executive kind, while the academy directly governs eighteen research institutes that work in different scientific areas. The Rathenau Institute should be mentioned here as it provides assessment and foresight advice regarding the development of the Dutch higher education and scientific research system.

The precursor to the VSNU was established in 1956. The official aim of the association is to represent the Dutch universities vis-à-vis the government and other societal organisations. Moreover, it formulates labour policy for all Dutch universities, as well as common policies on a number of other issues.<sup>47</sup> The organisation is headed by the general board, consisting of

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<sup>42</sup> Weerdesteyn, R., D. Breimer, L. Gelders, & A. Zeilinger, *Evaluatie van de KNAW 2014*, 2014, p. 1.

<http://www.rijksoverheid.nl/bestanden/documenten-en-publicaties/rapporten/2014/03/01/evaluatie-van-de-knaw-2014/evaluatie-van-de-knaw-2014.pdf>

<sup>43</sup> Dutch parliament, Wet op het hoger onderwijs en wetenschappelijk onderzoek, BWBR0005682.

<http://wetten.overheid.nl/BWBR0005682/>

<sup>44</sup> KNAW, "Gesloten datacultuur broedplaats voor wetenschappelijke fraude" 2011.

<https://www.knaw.nl/nl/actueel/nieuws/gesloten-datacultuur-broedplaats-voor>

<sup>45</sup> KNAW, *Een gedragscode voor Biosecurity*, KNAW, Amsterdam, 2007, pp. 1–44.

[https://www.knaw.nl/nl/actueel/publicaties/een-gedragscode-voor-biosecurity/@@download/pdf\\_file/20071069.pdf](https://www.knaw.nl/nl/actueel/publicaties/een-gedragscode-voor-biosecurity/@@download/pdf_file/20071069.pdf)

<sup>46</sup> Soeteman, A., & F. van den Born, *Ethiek van empirisch sociaal-wetenschappelijk onderzoek*, KNAW, Amsterdam, 2007, pp. 1–104.

<sup>47</sup> VSNU. <http://www.vsnu.nl/vsnu.html>



university board members and is assisted in its work by a number of steering committees. Most decisions that are made are based on consensus amongst the board members.<sup>48</sup>

With regard to ethics assessment, three different ways of translating ethical issues into common policies can be discerned: identification of ethical issues at the local level that are transposed to the level of the general board, policy preparations of steering committees and policy based on questions raised by the ministry. Typically, agreed-upon policies are translated into codes and categorised into codes for the use of personal data, scientific integrity, animal experimentation and good governance. Most discussions about these codes revolve around their practical implications rather than their formulation of principles.

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

A number of field-specific research associations and standard-setting bodies are active in the Netherlands. These organisations formulate policies that are specific to assessment in certain fields of research. The greatest array of policies in this respect is formulated by organisations that are involved with medical research. The most significant field-specific organisation is the Central Committee on Research Involving Human Subjects (see section 2.2). Other field-specific organisations in the medical sector with a role in ethics assessment include:

- NFU (The Netherlands Federation of University Medical Centres)<sup>49</sup>
- KNMG (The Royal Dutch Medical Association)<sup>50</sup>
- KNMP (The Royal Dutch Pharmacists' Association)<sup>51</sup>

Some other field-specific organisations exist that mostly involve cooperation structures between universities or research institutes (such as 3TU for the three technical universities in the Netherlands<sup>52</sup>), with specific research settings (such as Fenelab, which deals with laboratory research and the use of instruments<sup>53</sup>) or with specific kinds of technologies (such as Nanonext, which deals with different kinds of Nano technologies and their societal impacts<sup>54</sup>).

### 3.3 Research funding organisations

This section offers a discussion regarding the ways in which research-funding organisations include ethics assessment in determining how to spend their funding. Furthermore, we will examine whether attention to ethical issues is a condition for basic funding of Dutch universities and other public research institutions.

#### 3.3.1 Research and innovation funding organisations

The most important intermediary public research and innovation funding organisations in the Netherlands, in terms of annual research funding expenditure, include the *Netherlands*

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<sup>48</sup> Interview with Ed Brinksma, op. cit.

<sup>49</sup> NFU <http://www.nfu.nl/>

<sup>50</sup> KNMG. <http://knmg.artsennet.nl/Over-KNMG/About-KNMG.htm>

<sup>51</sup> KNMP. <http://www.knmp.nl/>

<sup>52</sup> 3TU. [http://www.3tu.nl/nl/over\\_3tu/](http://www.3tu.nl/nl/over_3tu/)

<sup>53</sup> Fenelab. <http://www.fenelab.nl/>

<sup>54</sup> Nanonext. <http://www.nanonextnl.nl/>



*Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek; NWO)* and the *Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland; RVO)*. Since RVO has stated that it has no rules, procedures or guidelines for dealing with any potential ethical issues in the evaluation of subsidy applications,<sup>55</sup> this section will focus solely on NWO, which *does* have ethics assessment protocols.

NWO regards the ethics of the research proposals it evaluates as an important issue. Its interest in ethics evaluation covers (at least) the following topics: research on animals; informed consent; privacy and data protection; research on human embryonic stem cells; research involving developing countries; and bio-security/dual use.<sup>56</sup> It appears that NWO mainly focuses on ethics topics related to medical research.

Ethics evaluation for NWO grants is not provided in-house, but is outsourced to accredited Dutch ethics committees. NWO funding requests for research involving human subjects and/or animals require a statement of approval by an accredited *medical research ethics committee* (MREC) and/or the *Central Committee on Animal Experimentation* (CCD).<sup>57</sup> Additionally, funding requests may require, by law,<sup>58</sup> a permit from the *Committee on Population Screening* (SPC) of the *Health Council of the Netherlands*.<sup>59</sup> Applicants to NWO funding are themselves responsible for obtaining the necessary statement(s) of approval or permit(s) by the proper ethical committee(s) and/or the SPC.

NWO-funded research projects can only commence once the necessary ethical clearances have been obtained. Funding requests made through the NWO's *STW foundation* for technical research do not explicitly require ethical clearance for project proposals. NWO's *ZonMw foundation* for medical research, on the other hand, is very explicit about requiring such ethics clearance.

### **3.3.2 Conditions for basic funding of Dutch universities and other public research institutions**

A large part of the annual funding of research for Dutch universities and public research institutions is provided by the Dutch ministry of Education, Culture and Science. According to the Dutch law on higher education and scientific research (*Wet op het hoger onderwijs en wetenschappelijk onderzoek*), universities and public research institutions can spend these funds under certain conditions determined by the minister relating to the “quality of the research”<sup>60,61</sup>.

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<sup>55</sup> Telephonic interview with an RVO press officer on 6 October 2014.

<sup>56</sup> NWO. “Rubicon: Grant application form 2015”. [www.nwo.nl/binaries/content/documents/nwo-en/common/documentation/application/nwo/rubicon---application-form/Rubicon+application+form+27+november+2014.docx](http://www.nwo.nl/binaries/content/documents/nwo-en/common/documentation/application/nwo/rubicon---application-form/Rubicon+application+form+27+november+2014.docx)

<sup>57</sup> Ibid.

<sup>58</sup> Dutch parliament, *Wet op het bevolkingsonderzoek*, BWBR0005699. [http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum\\_29-09-2014](http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_29-09-2014)

<sup>59</sup> Ibid.

<sup>60</sup> Dutch parliament, *Wet op het hoger onderwijs en wetenschappelijk onderzoek*, BWBR0005682, Article 2.5. [http://wetten.overheid.nl/BWBR0005682/Hoofdstuk2/Titel2/Artikel25/geldigheidsdatum\\_01-01-2015](http://wetten.overheid.nl/BWBR0005682/Hoofdstuk2/Titel2/Artikel25/geldigheidsdatum_01-01-2015)

<sup>61</sup> Dutch parliament, *Wet op het hoger onderwijs en wetenschappelijk onderzoek*, BWBR0005682, Article 2.6a. [http://wetten.overheid.nl/BWBR0005682/Hoofdstuk2/Titel2/Artikel26a/geldigheidsdatum\\_01-01-2015](http://wetten.overheid.nl/BWBR0005682/Hoofdstuk2/Titel2/Artikel26a/geldigheidsdatum_01-01-2015)

An indication of the scientific quality of research is obtained through self-evaluations by universities and research institutions according to the Standard Evaluation Protocol (SEP). The SEP describes methods for the assessment, once every six years, of research conducted at Dutch universities and NWO and Royal Netherlands Academy of Arts and Sciences institutes, in addition to the aims of such assessment (VSNU, NWO, & KNAW, 2014). In the latest SEP, increased attention is given to the societal relevance of scientific research and scientific integrity.<sup>62</sup>

### 3.4 Research performing institutions

In this section, it will be examined what general ethical standards, procedures and organisational units Dutch research performing institutions contain for ethics assessment. Discussions will be included on the role and organisation of research ethics committees (RECs) and on ethics training and education.

Public sector research in the Netherlands is performed by a number of organisations, including 14 universities, 16 KNAW institutes, 6 NWO institutes, 4 *Large Technological Institutes (GTIs)*, the semi-public *Netherlands Organisation for Applied Scientific Research (TNO)*, and a number of other state-owned research and advisory bodies.

By Dutch law, all scientific research involving human subjects, animal experimentation, or population screening, requires a permit by, respectively, an accredited Dutch medical research ethics committee (MREC) or the Dutch Central Committee on Research Involving Human Subjects (CCMO), the Dutch Central Committee on Animal Experimentation (CCD), or the Committee on Population Screening (SPC) of the Health Council of the Netherlands. A small number of the 24 MRECs are linked to academic hospitals.

MRECs only review studies that fall under the scope of the Medical Research Involving Human Subjects Act (WMO). Research falls under the WMO if (1) it concerns medical/scientific research *and* (2) the participants in it are subject to procedures or are required to follow rules of behaviour.<sup>63</sup> MRECs have a diverse membership that includes ethicists, physicians and lawyers, among others, and draws on ethical principles such as those outlined in the *Helsinki Declaration*,<sup>64</sup> the *Good clinical practice/International Conference on Harmonization (GCP/ICH) guidelines*,<sup>65</sup> and the *Health Research Code of Conduct (Gedragscode Gezondheidsonderzoek)*.<sup>66</sup> The CCMO is the authority that facilitates appeals can be submitted against a negative decision by an MREC. The CCMO also reviews cases of research with specific ethical, legal or social aspects, in addition to cases in fields in which

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<sup>62</sup> KNAW, “Standard Evaluation Protocol 2015-2021”. [https://www.knaw.nl/nl/actueel/publicaties/standard-evaluation-protocol-2015-2021/@@download/pdf\\_file/SEP%202015-2021.pdf](https://www.knaw.nl/nl/actueel/publicaties/standard-evaluation-protocol-2015-2021/@@download/pdf_file/SEP%202015-2021.pdf)

<sup>63</sup> CCMO, “Your research: Does it fall under the WMO?”. <http://www.ccmo.nl/en/your-research-does-it-fall-under-the-wmo>

<sup>64</sup> WMA, Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. <http://www.wma.net/en/30publications/10policies/b3/>

<sup>65</sup> ICH, Guideline for Good Clinical Practice, E6(R1).

[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R1\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf)

<sup>66</sup> Nederlandse Biomedische Onderzoeksgemeenschap, “Gedragscode Gezondheidsonderzoek”.

<http://www.giantt.nl/gedragscode%20gezondheidsonderzoek.pdf>

there is limited expertise.<sup>67</sup> The majority of research proposals, however, are reviewed by MRECs.

The CCD reviews studies that involve animal experimentation, in accordance with the Animal Experimentation Act (WoD). The committee only reviews research performed at institutions that hold a permit to conduct animal experiments, which is provided by the Netherlands Food and Consumer Product Safety Authority. The CCD bases its decision to authorise a project proposal on advice given out by one of 21 accredited Dutch animal experiments committees (AEC). In their evaluation of project proposals, the AECs consider the expertise of the researchers, the wellbeing of the animals, and potential alternatives to the experiments that are more humane. The AECs make ethical judgments by weighing the expected value of the experiment's results against the expected suffering of the animals.

At many universities, and, in particular, at social sciences departments, there are also research ethics committees (RECs) that review research not legally requiring review by an MREC, the CCMO, the CCD, or the SPC. Often, universities require that all research involving human subjects—whether it is medical or non-medical, by staff or by students—be reviewed by the institution's REC before it commences. The RECs examine whether subjects are exposed to disproportional or excessive risks, have consented to the research while being sufficiently informed on any potential risks, and are sufficiently protected by precautionary measures against those risks. These considerations stem from principles such as those outlined in the Helsinki Declaration. Many RECs work with a checklist to determine whether a proposed study can go ahead as planned or whether adaptations need to be made.

In addition to these RECs, scientific integrity counsellors have been appointed at universities and KNAW and NWO institutes to provide assistance to whistle-blowers and those accused of scientific misconduct.<sup>68</sup> The KNAW and some universities also have special scientific integrity committees that investigate complaints about scientific integrity. Furthermore, a national appeals committee exists in the form of the *National Board for Scientific Integrity (Landelijk Orgaan Wetenschappelijke Integriteit, LOWI)* at the KNAW.<sup>69</sup>

Finally, the semi-public *Netherlands Organisation for Applied Scientific Research (TNO)* has a steering committee that evaluates, on an annual basis, the institution's *corporate social responsibility (CSR)* policy. Important aims stated in the policy include the contribution to a better environment and poverty relief and working towards 3R-alternatives—replacement, reduction and refinement—to animal experimentation practices.<sup>70</sup>

Ethics departments of universities may offer ethics training and education to researchers. These departments may teach researchers how to reflect on the moral aspects of their research in scientific, social and political contexts. Training may also be offered on how to deal with

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<sup>67</sup> CCMO. "Reviewing Committee: MREC or CCMO". <http://www.ccmo.nl/en/reviewing-committee-mrec-or-ccmo>

<sup>68</sup> KNAW, "Wetenschappelijke integriteit". <https://www.know.nl/nl/thematisch/ethiek/wetenschappelijke-integriteit> (Dutch only)

<sup>69</sup> Landelijk Orgaan Wetenschappelijke Integriteit. [http://www.lowi.nl/en/national-board-for-research-integrity-lowi?set\\_language=en](http://www.lowi.nl/en/national-board-for-research-integrity-lowi?set_language=en)

<sup>70</sup> TNO, "TNO and its social role". <https://www.tno.nl/en/about-tno/tno-and-its-social-role/>

ethics legislation and complicated procedures relating to human subjects, animal or population research.

## 4 Private research and innovation systems

This chapter will provide a discussion of ethics assessment of R&I and *corporate social responsibility* (CSR) in private research and innovation systems. First, the general structure and role of government will be examined. Then, the role of industry associations and accreditation, certification and standard-setting organisations will be reviewed. Finally, the role of industry itself will be discussed.

### 4.1 General structure and the role of government

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

#### 4.1.1 Dutch industry landscape

Dutch industry is of great economic and social value to the Netherlands. In 2014, the Netherlands had an employed population of around 8.326.000 people, of which roughly 10 percent, or 850.000 people, were employed in industry (excluding construction).<sup>71</sup> Furthermore, the industrial sector generated roughly 24 percent of Dutch gross domestic product in 2013.<sup>72</sup> Foodstuffs form the largest industrial sector in the Netherlands. Other major industries include chemicals, metallurgy, machinery, and electrical goods. Leading Dutch international industrial corporations include Unilever, Heineken, DSM, AkzoNobel, Shell, Philips, and ASML.

#### 4.1.2 Organisations that represent industry

Important Dutch organisations representing industry include:

- the *Association FME-CWM*, which is the largest sector organisation for the technical industry, representing some 2300 Dutch companies in the metal, plastics, electronics and electro-technical industry and related fields;<sup>73</sup>
- the *Federation of Technology Sectors (Federatie van Technologiebranches; FHI)*, which represents the interests of Dutch technology businesses in the sectors of industrial electronics, industrial automation, laboratory technology and medical technology;<sup>74</sup>
- *HollandBIO*, which is the sector association for Dutch biotechnology companies;<sup>75</sup>
- *Nefarma*, which is the sector association for Dutch pharmaceutical companies;<sup>76</sup>

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<sup>71</sup> OECD, “Main Science and Technology Indicators”.

<http://stats.oecd.org/Index.aspx?DataSetCode=STLABOUR#>

<sup>72</sup> Statista, “Netherlands: Size of the employments from 2006 to 2016 (in millions)”.

<http://www.statista.com/statistics/276726/labor-force-in-the-netherlands/>

<sup>73</sup> FME-CWM. [http://www.fme.nl/Over\\_FME/FME\\_Association?lang=en](http://www.fme.nl/Over_FME/FME_Association?lang=en)

<sup>74</sup> Federatie van Technologiebranches. <http://federatie.fhi.nl/> (Dutch only)

<sup>75</sup> HollandBIO. <http://www.hollandbio.nl/hollandbio>

- the *Association of the Dutch Chemical Industry (VNCI)*, which promotes the collective interests of the Dutch chemical industry;<sup>77</sup> and
- the *Confederation of Netherlands Industry and Employers (VNO-NCW)*, which is the largest employers' organisation in the Netherlands.<sup>78</sup>

Other organisations that represent industry include: the *Netherlands Chamber of Commerce*;<sup>79</sup> the *Dutch Federation of Agriculture and Horticulture*;<sup>80</sup> the *Association of Dutch Suppliers in the Oil and Gas Industry*;<sup>81</sup> the *Royal Netherlands Society of Professionals in Shipping Technology*;<sup>82</sup> the *Dutch Association of Subcontracting Industries*;<sup>83</sup> the *Netherlands Defence Manufacturers Association*;<sup>84</sup> the *Dutch Gas Turbine Association*;<sup>85</sup> *Netherlands Maritime Technology*;<sup>86</sup> and the *Royal Association MKB-Nederland* (an association for small and medium-sized enterprises).<sup>87</sup>

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

Dutch policies and initiatives to support ethics practices in private industry mostly concern *corporate social responsibility (CSR)*. The following Dutch legislation relates to CSR:

- The Netherlands has transferred Article 46 of the EU's Fourth Accounting Directive<sup>88</sup> into national law,<sup>89</sup> requiring large companies to include information in their annual report on key non-financial performance indicators, to the extent necessary for understanding a company's development, performance or position.
- According to the Dutch corporate governance code, the management board and supervisory board of Dutch stock listed companies must take into account CSR issues that are relevant to their enterprise (principles II.1 and III.137).<sup>90</sup> Dutch stock listed companies are legally obligated to produce a statement in their annual reports on their

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<sup>76</sup> Nefarma. <http://www.nefarma.nl/english/homepage>

<sup>77</sup> VNCI. <http://www.vnci.nl/english/>

<sup>78</sup> VNO-NCW. <http://www.vno-ncw.nl/English/Pages/default.aspx#.VNhN6yzLlFU>

<sup>79</sup> KVK. <http://www.kvk.nl/english/>

<sup>80</sup> LTO. <http://www.lto.nl/english>

<sup>81</sup> IRO. <http://www.iro.nl/>

<sup>82</sup> KNVTS. <http://www.knvts.nl/> (Dutch only)

<sup>83</sup> NEVAT. <http://www.nevat.nl/en-GB/about-nevat>

<sup>84</sup> NIDV. <http://www.nidv.eu/en-US/pages/1175/Home.aspx>

<sup>85</sup> DGTA. <http://www.dgta.nl/about-dgta/our-organisation/>

<sup>86</sup> Netherlands Maritime Technology. <http://maritimetechnology.nl/en/>

<sup>87</sup> MKB. <http://www.mkb.nl/index.php?pageID=328>

<sup>88</sup> European Council, Fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54(3)(g) of the Treaty on the annual accounts of certain types of companies.

[http://europa.eu/legislation\\_summaries/internal\\_market/businesses/company LAW/126009\\_en.htm](http://europa.eu/legislation_summaries/internal_market/businesses/company LAW/126009_en.htm)

<sup>89</sup> Article 2:391, paragraph 1 of Book 2 of the Dutch Civil Code.

<http://www.dutchcivillaw.com/legislation/dctitle2299aa.htm>

<sup>90</sup> Monitoring Commissie Corporate Governance Code, Dutch corporate governance code – Principles of good corporate governance and best practice provisions. <http://commissiecorporategovernance.nl/download/?id=606>



compliance with the Dutch corporate governance code based on the principle of “comply or explain”.<sup>91</sup>

Additionally, the Dutch government encourages companies to take up CSR in the following ways:<sup>92</sup>

- Every year, the Dutch Ministry of Economic Affairs assesses 500 corporate annual reports concerning companies’ CSR activities and compares scores in what it calls the *Transparency Benchmark*. The company with the highest score is awarded a prize—*The Crystal*.<sup>93</sup>
- The government has established a national knowledge centre and network organisation for CSR—*CSR Netherlands (MVO Nederland)*.<sup>94</sup> Amongst other activities, CSR Netherlands has drawn up a CSR implementation plan<sup>95</sup> to help companies integrate ISO 26000 CSR principles<sup>96</sup> into their operations.
- Companies that comply with the *Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises*<sup>97</sup> are eligible for government financial support for their international trade and investment activities.
- CSR is always on the agenda of Dutch trade missions and companies can only join these missions if they have endorsed the OECD Guidelines.
- The Dutch government has set up the *National Contact Point OECD Guidelines*, which aims to raise awareness of the OECD Guidelines and contribute to the resolution of issues that arise from alleged non-observance of the guidelines in specific instances.<sup>98</sup>
- The Dutch government helped to set up the *Sustainable Trade Initiative (IDH)*, which supports companies in making their international production chains more sustainable for products such as cocoa, cotton, tea, coffee, soya beans and electronics.<sup>99</sup>
- The Dutch government conducts sector risk analyses to identify sectors where problems are most likely to occur, and it subsequently sits down with these sectors to discuss how their CSR efforts can be strengthened.

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<sup>91</sup> Article 2:391, paragraph 5 of Book 2 of the Dutch Civil Code.

<http://www.dutchcivillaw.com/legislation/dectitle2299aa.htm>

<sup>92</sup> Rijksoverheid, “Putting Corporate Social Responsibility (CSR) into practice”.

<http://www.government.nl/issues/corporate-social-responsibility-csr/putting-corporate-social-responsibility-csr-into-practice>

<sup>93</sup> Transparantiebenchmark. <http://www.transparantiebenchmark.nl/en>

<sup>94</sup> MVO Nederland. <http://www.mvonederland.nl/english>

<sup>95</sup> MVO Nederland, “MVO steps”. <http://www.mvonederland.nl/mvo-steps>

<sup>96</sup> ISO, “ISO 26000”. <http://www.iso.org/iso/home/standards/iso26000.htm>

<sup>97</sup> OECD, “Corporate Responsibility”. <http://www.oecd.org/daf/inv/corporateresponsibility/>

<sup>98</sup> Dutch Ministry of Foreign Affairs, “National Contact Point OECD Guidelines”.

<http://www.oecdguidelines.nl/ncp>

<sup>99</sup> IDH. <http://www.idhsustainabletrade.com/>



#### 4.1.4 Initiatives for public-private partnerships

With regard to CSR in the field of research and innovation, there exist a few important public-private partnerships. First, there is the *Social and Economic Council (SER)*, a tripartite body of business associations, trade unions and independent experts appointed by the government, which advises the Dutch government on socioeconomic issues. Through its *Committee for International CSR (IMVO)*,<sup>100</sup> the SER plays an important role in the national and international debate on, and development of, CSR.<sup>101</sup> It was instrumental in the establishment of the *CSR Netherlands (MVO Nederland)* knowledge centre on CSR.

Second, there is the *IDH Sustainable Trade Initiative (Initiatief Duurzame Handel)*, a multinational organisation with representation from public and private sector organisations, which aims to make trade more sustainable through building coalitions of leading multinational companies, civil society organisations, governments and other stakeholders.<sup>102</sup>

With regard to *ethics assessment* in the field of research and innovation, an important public-private partnership is the Forum on Biotechnology and Genetics (Forum Biotechnologie en Genetica),<sup>103</sup> which was established by the Dutch Ministry of Health, Welfare and Sport. One of this organisation's tasks is to analyse and evaluate ethical issues in the area of medical biotechnology and human genetics. Members of the forum are representatives from industry, patient support organisations, government and the Dutch bioethics association.

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

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

### 4.2.1 Industry associations

There is a focus within industry associations on ethics assessment and CSR. The largest industry association, Association FME-CWM, is the most active in this field. It works closely with the Dutch government on the development of industry-specific environmental and CSR policies and it provides information on these policies to its members through its website, brochures, and events. Furthermore, in collaboration with 24 companies and the Netherlands Enterprise Agency (RVO), FME-CWM has developed the *FME Sustainability Compass (FME*

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<sup>100</sup> Sociaal-Economische Raad, "Commissie Internationaal Maatschappelijk Verantwoord Ondernemen". <https://www.ser.nl/nl/raad/commissies/internationaal%20sociaal-economisch%20beleid/internationaal-maatschappelijk-verantwoord-ondernemen.aspx>

<sup>101</sup> Rijksoverheid, "Contribution by the government of the Netherlands to the renewed EU-strategy for CSR". <http://www.rijksoverheid.nl/bestanden/documenten-en-publicaties/richtlijnen/2012/07/05/contribution-by-the-government-of-the-netherlands-to-the-renewed/contribution-by-the-government-of-the-netherlands-to-the-renewed.pdf>

<sup>102</sup> IDH, "About IDH". <http://www.idhsustainabletrade.com/about-idh>

<sup>103</sup> ForumBG. <http://www.forumbg.nl/dutch-forum-for-biotechnology-and-genetics>

*Duurzaamheidskompas*),<sup>104</sup> a handbook with insights, approaches and tools aimed at helping high-tech industrial companies manage their business in sustainable ways. In addition, the association has created the *Quick Scan for Sustainable Business (Quickscan Duurzaam Ondernemen)*,<sup>105</sup> a tool to evaluate and improve a company's sustainability efforts, which takes into consideration a company's level of ambition, scope of CSR implementation and level of communication with stakeholders.

#### 4.2.2 Network organisations

One notable Dutch network organisation is the Dutch Sustainable Growth Coalition. This coalition comprises eight of the biggest Dutch multinational companies—AkzoNobel, DSM, FrieslandCampina, Heineken, KLM, Philips, Shell and Unilever. The organisation works towards a more sustainable way of doing business by promoting the integration of sustainable and responsible entrepreneurship into corporate governance structures and company culture.<sup>106</sup>

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

Certification, evaluation and standard-setting organisations for industry that support private sector organisations in conducting business in an ethical manner focus strongly on CSR and less on other forms of ethics assessment. The *Netherlands Standardization Institute (NEN)* offers CSR implementation guides, best practices, tools, and workshops, which are all based on the ISO 26000 CSR standard.<sup>107</sup> Further, CSR Netherlands (MVO Nederland)—the government-established knowledge centre and network organisation for CSR—promotes CSR by offering market opportunities, practical advice, example cases, implementation tools, contacts, and peer collaboration for CSR to all businesses that enrol in its partnership program.<sup>108</sup> Finally, a number of commercial CSR certification and CSR support organisations offer CSR certification norms, and evaluation and implementation tools. The most important ones of these are the *MVO-Prestatieladder*,<sup>109</sup> the *MVO-Monitor*,<sup>110</sup> and the *MVO-Wijzer*.<sup>111</sup>

- the MVO-Prestatieladder is a CSR evaluation and certification tool, based on the ISO 26000 CSR standard, which evaluates according to five levels of adherence;
- the MVO-Wijzer is another such tool based on the ISO 26000 CSR standard; and
- the MVO-Monitor is a CSR management system with which businesses can implement and monitor adherence to a CSR policy based on self-chosen CSR goals and indicators.

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<sup>104</sup> FME. <http://www.fme.nl/dsresource?objectid=28298&type=org>

<sup>105</sup> FME, “Quick scan duurzaam ondernemen”.

[http://www.fme.nl/Beleidsthema\\_s/Milieu\\_Energie\\_Duurzaam\\_Ondernemen/Content/Duurzaam\\_ondernemen/Content/Quick\\_scan:33555](http://www.fme.nl/Beleidsthema_s/Milieu_Energie_Duurzaam_Ondernemen/Content/Duurzaam_ondernemen/Content/Quick_scan:33555)

<sup>106</sup> Dutch Sustainable Growth Coalition, “Sustainable Innovation”. [http://dsgcpublication.ey.online-magazine.nl/nl/magazine/7739/766919/sustainable\\_innovation\\_game\\_changing\\_solutions\\_for\\_the\\_world\\_s\\_grand\\_challenges.html](http://dsgcpublication.ey.online-magazine.nl/nl/magazine/7739/766919/sustainable_innovation_game_changing_solutions_for_the_world_s_grand_challenges.html)

<sup>107</sup> NEN. “Search: MVO”. <http://www.nen.nl/Searchresults.htm?q=mvo>

<sup>108</sup> MVO Nederland, “About MVO Nederland”. <http://www.mvonederland.nl/english>

<sup>109</sup> MVO-Prestatieladder. <http://www.mvoprestatieladder.nl/en/>

<sup>110</sup> MVO-Monitor. <http://mvo-monitor.nl/mvo-monitor/> (Dutch only)

<sup>111</sup> MVO-Wijzer. <http://de-mvowijzer.nl/index.php> (Dutch only)

#### 4.2.4 External ethics committees

By Dutch law, all medical-scientific research involving human subjects (that undergo procedures or follow rules of behaviour), animal experimentation, or population screening, requires a permit by, respectively, an accredited Dutch medical research ethics committee (MREC) or the Dutch Central Committee on Research Involving Human Subjects (CCMO), the Central Committee on Animal Experimentation (CCD), or the Committee on Population Screening (SPC) of the Health Council of the Netherlands. All organisations operating in the Netherlands, private sector ones included, are bound by these laws and may need to engage with these committees if they plan to carry out research involving human subjects, animal experimentation, or population screening. It seems that these are the only ethics committees that private companies regularly engage with for the evaluation of their R&D practices. Royal Dutch Shell is one Dutch company that stands out in this regard, in that the content of its annual *Sustainability Report* and the process of producing it are assessed by an external review committee of independent experts.<sup>112</sup> Noncompliance of the rules on medical-scientific research involving human subjects, animal experimentation, and population screening can be met with criminal sanctions.

#### 4.3 Industry

This section offers a discussion regarding the ways in which Dutch industrial businesses engage in CSR and ethics assessment, to the extent that these relate to research and innovation. The focus of this section will primarily be on large Dutch multinational corporations, as these generally have extensive and well-documented ethics evaluation systems in place. At the end of this section, a brief example will be presented of a large Dutch company's engagement with CSR and ethics assessment.

##### 4.3.1 Small and medium-sized Dutch enterprises

Smaller Dutch industrial businesses generally do not seem to focus much on ethics assessment and CSR beyond what is required by law. In general, small and medium-sized Dutch enterprises do not structurally and methodically engage in CSR practices (even though they believe CSR is important).<sup>113</sup> The activities they do undertake in this area are mostly restricted to improving basic company-internal processes such as waste management; there is only limited consultation with stakeholders, and topics such as (the impact of research and development on) biodiversity, animal wellbeing, and supply chain sustainability generally receive little attention.<sup>114</sup>

##### 4.3.2 Large multinational Dutch corporations

In contrast, larger Dutch companies focus much more ethics assessment and CSR. Leading Dutch multinational industrial companies are among the world's top performers in the *Dow Jones Sustainability Index*.<sup>115</sup> Most have so-called "sustainability" departments, councils, boards, or committees that engage in ethics (or CSR/"sustainability") assessment, devise

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<sup>112</sup> <http://sustainabilityreport.heineken.com/pdf/other/Dutch-sustainable-Growth-Coalition.pdf>

<sup>113</sup>

<http://www.mvonderland.nl/sites/default/files/media/Rapport%20MVO%20LEEF%20in%20het%20MKB.pdf>

<sup>114</sup> Ibid.

<sup>115</sup> <http://www.duurzaam-ondernemen.nl/nederland-mondiaal-voorbeeld-op-gebied-duurzaamheid/>

CSR/sustainability policies, and report their findings to the executive board. In addition, some of the largest Dutch industrial companies take part in the Sustainable Growth Coalition initiative, produce annual sustainability reports that comply with guidelines of the Global Reporting Initiative (GRI)<sup>116</sup>, have publicly available codes of conduct to communicate their ethical standards, and actively consult stakeholders, such as civil society and government organisations, on ethical issues.

The following is a brief example of a large Dutch company's engagement with ethics, CSR and sustainability:

*Royal Philips N.V.*<sup>117</sup>

Royal Philips views sustainability as an integral part of its overall strategy. It is embedded in the organisation through the *Ecovision* program of sustainability targets and through various codes of conduct. According to Philips, all of its new and existing projects are assessed to determine their social and environmental contribution.<sup>118</sup>

At the corporate level, the *Sustainability Board* acts as an advisory body to the *Executive Committee* and meets every quarter. The Board is chaired by the *Chief Strategy and Innovation Officer*, member of the Executive Committee, who has overall responsibility for the subject. The global head of the *Corporate Sustainability Office* reports to the chair of the Sustainability Board. This Office is responsible for trend analysis, strategy, policy, action plan development, and internal and external reporting on sustainability.

Philips also has a *Professional and Public Affairs* team that manages the company's stakeholder engagement. Furthermore, the *Philips Centre for Health and Well-being* operates a research program that seeks to address key societal issues and solutions on themes such as healthy and active ageing, liveable cities and healthy lifestyle, and brings together experts from academia, practice and politics in think tanks.

Finally, Philips publishes an integrated report that complies with Global Reporting Initiative standards and uses dedicated reporting tools on the various *Ecovision* targets.

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<sup>116</sup> Global Reporting Initiative. <https://www.globalreporting.org/information/about-gri/Pages/default.aspx>

<sup>117</sup> Philips, "Sustainability". <http://www.philips.com/about/sustainability/index.page>

<sup>118</sup> Philips, "How Philips is transforming its business model for sustainability". <http://www.theguardian.com/sustainable-business/how-philips-transforming-business-model>

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

This chapter will provide a discussion of the role in ethics assessment of R&I by professional associations in R&I or the ethics assessment thereof. The chapter will not focus on the Dutch national science academy (KNAW), since this organisation has already been discussed in chapter 3.

### 5.1 National associations for R&D professions

There are a number of Dutch national associations for the various R&D professions, which vary in their level of involvement in ethics assessment of R&D. Some associations focus on enhancing their members' career opportunities within the profession; other, often larger, associations do much more, and engage their members on ethical issues within the profession by organising lectures, facilitating discussions, and creating codes of conduct. Notable examples of such larger associations are the *Royal Dutch Society of Engineers*, and the *Federation of Medical-Scientific Associations*:

- The Royal Dutch Society of Engineers (*KIVI*)<sup>119</sup> is the largest association for engineers and engineering students in the Netherlands. Through its website, KIVI provides codes of conduct and facilitates discussion on engineering ethics topics<sup>120</sup>. It also organises lectures on these topics by experts in engineering ethics. Furthermore, it has an advisory council, called the *Science, Technology and Society Council (Raad Wetenschap, Techniek en Maatschappij)*, which studies societal issues in relation to technology and reports on how technology could contribute to a more sustainable society.
- The Federation of Medical-Scientific Associations (*Federa*)<sup>121</sup> is a large, interdisciplinary, cooperative association of about 10.000 medical researchers. Through its website, Federa provides several codes of conduct relevant to medical researchers, and offers information on how to use them and on the issues that may arise when using them. Further, it provides information and opinions on such topics as Dutch animal experimentation legislation and bio banks.

### 5.2 National associations for (ethics) assessors

There are a number of Dutch national associations for ethics assessment of research and development. They include the *Netherlands Society for Bioethics*, the *Netherlands Association of Medical Ethical Reviewing Committees*, and *Association of Ethicists in the Netherlands*. These organisations generally contribute to ethics assessment practices by promoting, in a variety of ways, reflection and discussion on important contemporary ethics topics among members of the profession and society at large.

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<sup>119</sup> KIVI-NIRIA. <https://www.kiviniria.net/CM/PAG000007804/English-homepage.html>

<sup>120</sup> KIVI-NIRIA, "Blog Ethiek en Ingenieurs". <https://www.kiviniria.net/CM/PAG000007238/Blog--ethiek-en-ingenieurs.html>

<sup>121</sup> Federa. <http://www.federa.org/> (Dutch only)

- The Dutch Society for Bioethics (*Nederlandse Vereniging voor Bio-ethiek*)<sup>122</sup> is an interdisciplinary association for bioethics with both institutional and individual members. The aims of the association are to (1) stimulate bioethical reflection in relevant sectors of science and society at large, (2) enhance the interaction between representatives of different fields, institutions, and organisations that are involved in bioethical issues, (3) sustain the value of open discussion on bioethical issues in science and society, and (4) present academic discussion on bioethical topics to Dutch society at large.
- The Netherlands Association of Medical Ethical Reviewing Committees (*Nederlandse Vereniging van Medisch-Ethische Toetsingscommissies; NVMETC*)<sup>123</sup> aims to contribute to the maintenance and improvement of best practices in the field of ethics assessment of medical-scientific research by medical ethical review committees (MERCs). It does so by establishing contact between MERC members and other ethics assessment professionals, debating the criteria for ethics assessment, enhancing the expertise of MERC members, and publishing a magazine on ethics assessment.
- The Association of Ethicists in the Netherlands (*Vereniging van Ethici in Nederland; VvEN*)<sup>124</sup> aims to initiate discussion among academic ethicists and representatives of other disciplines regarding ethical issues generated by developments that (will) greatly influence society. These discussions take place during the association's annual symposium. The VvEN also aims to stimulate public debate through articles about ethical issues in public life in its quarterly magazine, *Philosophy & Practice (Filosofie & Praktijk)*.

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<sup>122</sup> Nederlandse Vereniging voor Bio-ethiek. <https://nvbioethiek.wordpress.com/> (Dutch only)

<sup>123</sup> Nederlandse Vereniging van Medisch-Ethische Toetsingscommissies. <http://www.nvmetc.nl/> (Dutch only)

<sup>124</sup> Vereniging van Ethici in Nederland; VvEN. <https://verenigingvanethici.wordpress.com/over-de-vereniging/> (Dutch only)



## 6 Civil society organisations

This chapter offers a discussion of the role in ethics assessment of R&I by civil society organisations (CSOs). First, the CSO landscape will be discussed, and then the role of CSOs in ethics assessment will be reviewed.

### 6.1 The CSO landscape

This section will provide a review of the CSO landscape of the Netherlands. An overview will be given of national legislation and regulation for CSOs, major CSOs and their societal roles, sources of funding for CSOs, and the role of CSOs in research and innovation.

#### 6.1.1 National legislation and regulation for CSOs

Legislation and regulation relating specifically to CSOs in the Netherlands includes the following:

- Through the *Medefinancieringsstelsel II* financing system, 67 Dutch development organisations are granted subsidies by the Dutch government.<sup>125</sup>
- The *Mensenrechtenfonds* is a government fund that subsidises organisations promoting human rights internationally.<sup>126</sup>

#### 6.1.2 Major CSOs and their societal roles

The following are the most important Dutch CSOs in the Netherlands with regard to ethics assessment of research and innovation. Organisations with a thoroughly international character, such as *Greenpeace* and the *World Wildlife Fund*, are not included in the list.

*Religious organisations:*

- The *Roman Catholic Church in the Netherlands (Rooms-Katholieke Kerk in Nederland)*—the largest Christian church in the Netherlands with a membership of some 4 million people.<sup>127</sup>
- The *Protestant Church in the Netherlands (Protestantse Kerk in Nederland)*—the largest Protestant Christian church in the Netherlands with a membership of some 1,8 million people.<sup>128</sup>
- The *Netherlands Muslim Council (Nederlandse Moslimraad)*—an umbrella organisation of Muslim organisations that aims to look after the interests of Muslims and Muslim organisations in Dutch society.<sup>129</sup>

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<sup>125</sup> Rijksoverheid, “Medefinancieringsstelsel II”. <http://www.rijksoverheid.nl/onderwerpen/subsidies-voor-ontwikkelingssamenwerking-en-europa/subsidies-maatschappelijke-organisaties/medefinancieringsstelsel-2010-2015-mfs-ii>

<sup>126</sup> Rijksoverheid, “Mensenrechtenfonds”. <http://www.rijksoverheid.nl/onderwerpen/subsidies-voor-ontwikkelingssamenwerking-en-europa/subsidies-maatschappelijke-organisaties/mensenrechtenfonds>

<sup>127</sup> Rooms-Katholieke Kerk in Nederland. <http://www.rkkerk.nl/info.php?id=14> (Dutch only)

<sup>128</sup> Protestantse Kerk Nederland. <http://www.protestantsekerk.nl/overons/protestant-church/Paginas/default.aspx>



*Environmental organisations:*

- *Nature Monuments (Natuurmonumenten)* an environmental organisation that aims to protect Dutch nature reserves.<sup>130</sup>
- *Friends of the Earth Netherlands (Milieudefensie)*—an environmental organisation that focuses on four themes: transportation, food production, natural resources and energy.<sup>131</sup>
- The *Wadden Association (Waddenvereniging)*—an environmental organisation that aims to protect and enhance the quality of the Wadden Sea region of the Netherlands.<sup>132</sup>

*Civil liberties/human rights organisations:*

- The *Dutch Council for Refugees (Vluchtelingenwerk Nederland)*—an organisation that defends the rights of refugees to a fair asylum procedure, adequate housing, education, health care and work.<sup>133</sup>
- *Bits of Freedom*—a digital rights organisation that champions privacy and communications freedom in the digital age.<sup>134</sup>

*Consumer organisations:*

- The *Consumer Association (Consumentenbond)*—an organisation that defends the rights of Dutch consumers.<sup>135</sup>

*Development (aid) organisations:*

- The *Max Havelaar Foundation (Stichting Max Havelaar)*—an organisation that licenses use of the international *Fairtrade Certification Mark* on products in the Netherlands.<sup>136</sup>

*Animal rights organisations:*

- *Animal Protection (Dierenbescherming)*—an organisation that protects animals by offering emergency care to animals and maintaining the wellbeing of animals.<sup>137</sup>
- The *Dutch Society for the Replacement of Animal Testing (Proefdiervrij)*—an organisation that advocates and tries to help realise a future free of animal experimentation.<sup>138</sup>

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<sup>129</sup> Nederlandse Moslimraad. <http://www.nieuwwij.nl/wij-land/nederlandse-moslim-raad-nmr/> (no own website)

<sup>130</sup> Natuurmonumenten. <https://www.natuurmonumenten.nl/over-natuurmonumenten>

<sup>131</sup> Milieudefensie. <https://milieudefensie.nl/english>

<sup>132</sup> Waddenvereniging. <http://www.waddenvereniging.nl/?module=tekstpagina&mid=3&wid=151> (Dutch only)

<sup>133</sup> Vluchtelingenwerk Nederland. <http://www.vluchtelingenwerk.nl/english>

<sup>134</sup> Bits of Freedom. <https://www.bof.nl/home/english-bits-of-freedom/>

<sup>135</sup> Consumentenbond. [http://www.consumentenbond.nl/over/wie\\_zijn\\_we/Missie/](http://www.consumentenbond.nl/over/wie_zijn_we/Missie/) (Dutch only)

<sup>136</sup> Stichting Max Havelaar. <http://www.maxhavelaar.nl/64/english>

<sup>137</sup> Dierenbescherming. <https://www.dierenbescherming.nl/> (Dutch only)

- The *Wakker Dier Foundation (Stichting Wakker Dier)*—an animal welfare organisation whose main purpose is to put an end to “factory farming” practices.<sup>139</sup>

*Disease charity and patient/disabled rights organisations:*

- The *Dutch Cancer Society (KWF Kankerbestrijding)*—an organisation for cancer-related work.<sup>140</sup>
- The *Hartstichting*—an organisation for work related to cardiovascular disease.<sup>141</sup>
- The *Federation of Patients and Consumer Organisations in the Netherlands (Patiëntenfederatie NPCF)*—an umbrella organisation for Dutch patient and consumer organisations, which defends patients’ rights and access to care.<sup>142</sup>
- The *Algemene Nederlandse Gehandicapten Organisatie*—an organisation that promotes the interests of individuals with some disability or chronic illness.<sup>143</sup>

*Labor unions:*

- The *Federation Dutch Labour Movement (Federatie Nederlandse Vakbeweging; FNV)*—a federation of Dutch trade unions.<sup>144</sup>
- The *National Federation of Christian Trade Unions in the Netherlands (Christelijk Nationaal Vakverbond; CNV)*—a federation of Dutch Christian trade unions.<sup>145</sup>
- The *Federation of Managerial and Professional Staff Unions (MHP)*—a federation of Dutch Christian trade unions representing technical and managerial workers.<sup>146</sup>

### 6.1.3 Role of CSOs in research and innovation

Several CSOs, such as disease charities, environmental organisations and animal rights organisations, spend a (substantial) part of their funds on scientific research. The following are some examples:

- In 2013, KWF spent 74,9 million Euros, or about half of its income, on scientific research and education related to cancer.<sup>147</sup> In the same year, the Hartstichting spent 17,6 Million Euros, or 40,6 percent of its income, on scientific research on

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<sup>138</sup> Proefdiervrij. <http://www.proefdiervrij.nl/english>

<sup>139</sup> Stichting Wakker Dier. <http://www.wakkerdier.nl/> (Dutch only)

<sup>140</sup> KWF Kankerbestrijding. <http://www.kwf.nl/english/Pages/The-organisation.aspx>

<sup>141</sup> Hartstichting. <https://www.hartstichting.nl/over-ons>

<sup>142</sup> *Patiëntenfederatie NPCF*.

[http://www.npcf.nl/index.php?option=com\\_content&view=article&id=4164&Itemid=31](http://www.npcf.nl/index.php?option=com_content&view=article&id=4164&Itemid=31)

<sup>143</sup> *Algemene Nederlandse Gehandicapten Organisatie*. <http://www.ango.nl/> (Dutch only)

<sup>144</sup> *Federatie Nederlandse Vakbeweging*. <http://www.fnv.nl/> (Dutch and Polish only)

<sup>145</sup> *Christelijk Nationaal Vakverbond*. <https://www.cnv.nl/> (Dutch only)

<sup>146</sup> VCP. <https://vcp.nl/english/>

<sup>147</sup> KWF, “Jaarverslag 2014”. <http://www.kwf.nl/over-kwf/Jaarverslag/Pages/default.aspx>

cardiovascular disease.<sup>148</sup> In spending their funds, both organisations collaborate closely with research institutions.

- The Dutch Society for the Replacement of Animal Testing (Proefdiervrij) commits money from its research fund (*Fonds Proefdiervrij Onderzoek*) to the development of alternative methods for prevention and treatment of cancer that do not require animal experimentation.<sup>149</sup> In doing so, it collaborates closely with scientists, universities, health organisations and the ZonMw research-funding organisation.

## 6.2 The role of CSOs in ethics assessment

This section will provide a discussion of the roles of CSOs as stakeholders in public discussions, as participants in ethics assessment panels and procedures, and as agents who engage in ethics assessment. CSOs' needs and expectations regarding their role in ethics assessment, and problems in bringing that role about, will also be examined.

### 6.2.1 CSOs as stakeholders in public discussions

Dutch CSOs play an important role in societal debates on the use of (new) technologies such as hydraulic fracturing and nanotechnology. They convey the public's concerns to other stakeholders, while at the same time influencing public opinion through information campaigns, public demonstrations and media appearances.

### 6.2.2 CSOs as participants in ethics assessment panels and procedures

The *Central Committee on Research Involving Human Subjects* (CCMO) has set rules regarding membership of the medical research ethics committees (MRECs) in the Netherlands.<sup>150</sup> Generally, a MREC comprises a number of physicians, a psychologist or psychiatrist, one or two nurses, an ethicist, a lawyer, a pharmacist, one or two paramedics, and sometimes a pastor or priest. Thus, among CSOs, only religious organisations may have some (unofficial) representation in IECs.

However, CSOs *are* well-represented in stakeholder dialogues organised by the Rathenau Institute for technology assessment.<sup>151</sup>

### 6.2.3 CSOs as agents who engage in ethics assessment themselves

CSOs engage in ethics assessment to varying degrees. Although many disease charities often require ethics assessment for the scientific research they fund, they do not engage in it themselves. Rather, they require ethics assessment to be done by medical ethical review committees and animal experimentation committees.

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<sup>148</sup> Hartstichting, "Jaarverslag 2013".

[https://www.hartstichting.nl/assets/jaarverslag2013/pdf/21404010\\_jv\\_jaarrekening%20DEF-2cb3ec82e302502c216f03e5ac32be70.pdf](https://www.hartstichting.nl/assets/jaarverslag2013/pdf/21404010_jv_jaarrekening%20DEF-2cb3ec82e302502c216f03e5ac32be70.pdf)

<sup>149</sup> Proefdiervrij, "Fonds Proefdiervrij Onderzoek".

[http://www.proefdiervrij.nl/onderzoek/fonds\\_proefdiervrij\\_onderzoek](http://www.proefdiervrij.nl/onderzoek/fonds_proefdiervrij_onderzoek)

<sup>150</sup> CCMO, "CCMO Deskundigheidseisen (WMO-)Leden METC's".

<http://www.ccmo.nl/attachments/files/ccmo-richtlijn-deskundigheidseisen-7-2012.pdf>

<sup>151</sup> Rathenau Instituut, "Publieksparticipatie". <http://www.rathenau.nl/organisatie/over-het-instituut/publieksparticipatie.html>

On the other hand, CSOs including animal rights organisations, patient rights organisations and religious organisations often do engage in ethics assessment. The Federation of Patients and Consumer Organisations in the Netherlands, for example, has developed an assessment framework for the evaluation of the impacts of developments in health care on patient welfare (Heldoorn, 2015).<sup>152</sup>

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<sup>152</sup> Interview with Marcel Heldoorn, policy advisor at the Federation of Patients and Consumer Organisations in the Netherlands, 26 January 2015.

## 7 Discussion

There are a wide variety of organisations in the Netherlands that engage in ethics assessment of some sort or promote responsible and ethical research and innovation. Socially responsible research and innovation is on the governmental agenda and on the agenda of a number of major organisations that are important players in research and innovation, such as the Netherlands Organisation for Scientific Research, the Netherlands Association of Universities, the Rathenau Institute, MVO Nederland, and others. Ethical assessment is engaged in by various Dutch organisations, such as the *Health Council of the Netherlands (GR)*, the *Federation of Patients and Consumers Organisations (NPCF)*, *Royal Dutch Shell*, the *Rathenau Institute*, and the *Netherlands Association of Universities (VSNU)*. Other organisations, such as the *Netherlands Organisation for Scientific Research (NWO)*, outsource their ethics assessment.

Dutch universities and publicly funded research institutions have research integrity counsellors and boards. Furthermore, there is a national university code for scientific integrity (which includes social responsibility), in addition to a National Board for Scientific Integrity. Universities increasingly have research projects assessed by research ethics committees. This is the case for medical sciences, and it is increasingly the case for the social sciences, and other sciences. Large corporations usually have a program and office for corporate social responsibility and small and medium-sized companies sometimes adopt initiatives for CSO or responsible entrepreneurship.

The Netherlands has a tradition of political decision-making in which CSOs play an important role in political discussions. In part, as a result of this tradition, the government sometimes organises broad consultations with CSOs and the public when important decisions are to be made regarding the social desirability and ethical permissibility of major advances in research and innovation, or major infrastructural projects. In our interviews with Dutch organisations with a role in the performance, governance or coordination of R&I in the public and private sector, and those who are stakeholders in R&I, it was found that many favour some form of ethics assessment, with participatory, consensus-based approaches to ethics assessment often favoured. The process of adapting ethics assessment procedures to include participation of stakeholders is, however, still in the early stages. The focus of ethics assessment practices among the interviewed organisations is on patient welfare and public health (GR, NPFC), sustainable development (Shell), and scientific integrity (VSNU).

Certainly not all organisations that were studied engage in ethics assessment, or find it important. For example, the Netherlands Enterprise Agency (RVO), the major national organisation for subsidising entrepreneurship does not attach any ethical criteria to its subsidies. Similarly, the Ministry of Economic Affairs, which funds RVO, did not attach any value to ethical assessment. By and large, though, ethics assessment and attention to issues of ethics and responsibility is a visible feature in many R&I-related organisations in the Netherlands, both in the public and private sector, and its significance seems to be increasing.