Plan Overview

A Data Management Plan created using DMPonline

Title: Grey areas in the regulation of 'red' and 'green' biotechnology. Towards resilient legislation for rapid technological change

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Template: Data Management Plan v4.5

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Project abstract:

Commissioned by the Netherlands Commission on Genetic Modification (COGEM), we will be investigating how laws and regulations can be designed to keep pace with rapid technological developments (resilient or sustainable regulation). That regulations become outdated due to scientific and technological developments is not unique to genetic modification and a general fact. The emergence of grey or unclear border areas is thus inevitable. Regulations must be sufficiently resilient to move with new developments, while both ensuring safety and not unnecessarily hampering innovation. Current GMO regulations do not seem to do this sufficiently.

The following questions will be answered:

- When, where and how do grey areas arise?
- How does legislation currently deal with them?
- What are the possibilities mentioned in the literature and in the field to deal with them better?

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Grey areas in the regulation of 'red' and 'green' biotechnology. Towards resilient legislation for rapid technological change

General

Please tick the following boxes if you agree to act according to the following terms:

- I will answer all questions truthfully and to the best of my knowledge
- I will discuss the data management plan with my research team
- I will check and, if necessary, update my data management plan a minimum of once a year

Support in writing a data management plan is available through the faculty Data Stewards. Which research support professional is available for you?

- Data Steward of my own faculty - ESL

Scientific research must be conducted in line with existing guidelines on good research practices and integrity. Please tick the boxes if you have read and understand these guidelines and will act accordingly.

- The European Code of Conduct for Research Integrity (ALLEA, 2017)
- The Netherlands Code of Conduct for Research Integrity (VSNU, 2018)

Administration & Project Description

Project title

Grey areas in the regulation of 'red' and 'green' biotechnology. Towards resilient legislation for rapid technological change

Project start date as intended

2024-06-03

Project duration in months as intended

6,5 months

Funding body (if applicable)

Netherlands Commission on Genetic Modification (COGEM)

Grant number (if applicable)

CGM/240530-01

Date of DMP Version 1

2024-09-10

Current DMP - Version [if other than version 1]

Version 2

Current DMP - Date [if other than version 1]

2024-09-19

List the name and affiliation of all members of the research team.
List the researcher responsible for research data management first.
For PhD projects, please indicate the Promotor(s) and/or Daily Supervisor(s) with a (!)

	Name	Email	ORCID	Research Institution
1	Willem-Jan Kortleven	kortleven@law.eur.nl	0009-0001-8515-9517	Erasmus University Rotterdam
2	Lonneke Poort	poort@law.eur.nl	0000-0002-0426-106X	Erasmus University Rotterdam
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Briefly summarize the project background and research question(s) to help others understand the purpose for which the data are being collected or created

Commissioned by the Netherlands Commission on Genetic Modification (COGEM), we are investigating how laws and regulations can be designed to keep pace with rapid technological developments (resilient or sustainable regulation). That regulations become outdated due to scientific and technological developments is not unique to genetic modification and a general fact. The emergence of grey or unclear border areas is thus inevitable. Regulations must be sufficiently resilient to move with new developments, while both ensuring safety and not unnecessarily hampering innovation. Current GMO regulations do not seem to do this sufficiently.
The following questions will be answered:
- When, where and how do grey areas arise?
- How does legislation currently deal with them?
- What are the possibilities mentioned in the literature and in the field to deal with them better?

Specify the research type and briefly describe the methodology, the types of data to be generated and/or collected, and the tools used for data collection

Literature research and case studies. The latter will consist partly of semi-structured interviews with stakeholders, e.g. policy officers, scientists, scientific advisers, representatives of biotechcompanies, representatives of environmental and civil society organisations. Interviews will be conducted live or through MS Teams and will be recorded (using an audio recorder in case of live interviews) and transcribed verbatim. Transcription will be carried out manually. The interview data will be analysed using Atlas.ti.

Specify the (financial and time) resources needed for data management in this project

58 hours (7.884 euros ex VAT) have been reserved for conducting the interviews and 25 hours (1325 euros ex VAT) have been reserved for transcribing interviews by a student assistant. Data storage has not been budgeted, as the data volume is not expected to exceed the limits of available storage space.

Preparation: Legal Arrangements and Policy

1. With whom will you need to make legal arrangements?

- With third parties
- With research participants

2. List the agreements thatyou will initiate and with whom will you make them.

Who	Type of agreement
COGEM	Agreement for the provision of services
Interviewees	Informed consent

3. List the agreements or other data management policies that you need to uphold butdid not initiate. If you are reusing existing data, list the terms of use under which you may re-use them.

Who	Type	Version and Date
EUR	RDM policy of Erasmus University Rotterdam (EUR	Version 1.0 [August 14th, 2020]
EUR	Internet and ICT facilities policy	[July 13th, 2021]
COGEM	Algemene Rijksvoorwaarden voor het verstrekken van Opdrachten tot het verrichten van Diensten	ARVODI-2008, [February 23th, 2009]

4. Do you need to obtain ethical approval for your research project?

- Yes, I am preparing to submit my application

5. If you have obtained ethical approval, list the reference number

Question not answered.

During research: Collecting and analyzing

6. Specify what data you will be collecting and indicate format, estimated size, and whether this is data that you will be generating or existing data that you will be re-using.

Type	Format	Estimated size	Generate	Re-use	Data Classification (optional)
Audio-recorded interviews	.mp3, .mp4, .WMA	1-3 GB	Yes	No	Confidential
Interview transcripts	.docx	<1GB	Yes	No	Confidential
Public documents	.pdf	<1GB	No	Yes	Public

7. Will you be collecting or re-using (sensitive) personal data?

- Yes – Personal data that is non-sensitive -->Consult your faculty’s Privacy Officer
- Yes – Personal data that is sensitive --> Consult your faculty’s Privacy Officer

8. If you collect or re-use (sensitive) personal data, how will you protect the privacy of participants when sharing your data?

- I will pseudonymize the data
- Not applicable - I do not collect or re-use personal data

9. Will you be collecting or re-using non-personal sensitive data?

- Yes

We will perhaps be collecting a little bit of non-personal sensitive data, that is, related to a sensitive policy issue. We will only share these data as far as it is explicitly allowed by those who provided the data, or otherwise avoid sharing the sensitive parts.

10. Where will you store your dataduring the project? You can select multiple options.

- EUR SURF Yoda

12. What hardware and software do you use? Select all applicable options.

- EUR supported hardware [e.g. @wEURk laptop, @wEURk workstation]
- EUR supported software as found in the software catalog

13. If you use private hardware, software, or freeware, please specify what and for what reason:

Question not answered.

14. Are regular backups made of your data?

- Yes, I use only EUR supported tools (as listed in Q12), thus to a limited extent backups are made automatically
- Yes, manually (please specify WHO makes the backups and HOW OFTEN backups are made in the additional information box).

Researcher responsible for RDM will make regular backups manually as often as substantial additions to data collection or data analysis have been made.

15. Who manages access to the data?

- Researcher responsible for research data management

16. Who will have access to the data (during the project)?

- Only researchers as indicated under ‘Administration & Project description’
- Other (please specify in the additional information box).

Student assistant who will transcribe the interviews.

17. How are you going to make sure your data will be accessible in case of staff changes, illness, etc?

- Other (please specify in the additional information box).

Data are accessible to both researchers (and the adviser of the research team, Evert Stamhuis). Should one the researchers fall ill, then the other researcher keeps access to the data. Staff changes during the research project are highly unlikely, given the fairly short time span of the project. Accessibility of the data in case of staff changes etc after finishing the project will be discussed with the research team and/or the departments involved.

18. Have you and your research team agreed on a way to name and order project folders and files?

- No - I have not yet discussed this with the research team

19. Have you and your research team agreed on how to handle versioning of files?

- No - I have not yet discussed this with the research team

Research Publication: Data sharing and re-use

20. What data (and code) will be shared in a research data repository?

- A selection of the data (and code)

21. Please specify why you are unable to share (all) data (and code)

Interviews will be conducted under the condition of confidentiality, otherwise we expect to have difficulty finding respondents willing to participate and/or speak freely as part of the issues we will talk about might be sensitive. Given the purposive selection of respondents because of their role and expertise, such as policy officers and scientists with specific expertise, representatives of biotech companies and representatives of environmental organisations and patients' associations, merely anonymizing transcripts would be insufficient to protect confidentiality, since these transcripts could easily be traced back to specific people. Therefore, we can not go further than releasing selected quotations from the transcripts in the research report (and other publications based on these data), as far as respondents agree with the use of quotes.

22. List the data (and code) that you plan to share in a research data repository. Also list the information / documentation / metadata that you will include to make the data package self-explanatory and re-usable in the future (for other researchers and yourself)

Data	Format	Size
Interview topic list	.pdf	<1 GB
Codebook	.pdf	<1 GB

23. In which repository will you place the metadata, data, and/or code that are associated with your paper?

- EUR Data Repository (EDR)

24. What metadata standard will you use to document your research?

- DCMI [Dublin Core Metadata Initiative] (Note: Default within the EUR Data Repository)

25. Will you place any restrictions on re-using of data?

- Yes, permanent restrictions – Restricted access

Interview data (transcripts and audio) will not be made available for re-use; see the explanation given in response to question 21. Metadata and research materials such as project description and interview topic lists will be made available.

27. Please specify the conditions under which data with restricted access may be re-used:

In principle, these data may only be re-used by members of the research team.

28. Under what license will you make your data available for re-use?

- Creative commons (e.g. CC0 or CC-BY, please specify in Q.29)

29. Please specify which license

Research materials may be re-used under CC BY-NC-ND 4.0 license

After research: Archiving

30. You may be obliged to destroy some data before archiving. Do any of such obligations apply to you?

- Yes - Privacy law [e.g. personal data of participants]

31. List the data and all documentation you will be archiving. These data constitute your archival package.

Data	Format	Size
Topic lists	.docx	<1 GB
Informed consent forms (signed)	.docx, .pdf	<1 GB
Informed consent form (blank copy)	.pdf	<1 GB
Audio-recorded interviews	.mp3	1-3 GB
Interview transcripts	.docx	<1 GB
Contract, project description	.pdf	<1 GB
Data Management Plan	.pdf	<1 GB
Ethical review application & approval document	.pdf	<1 GB
Codebook	.xlsx, .pdf	<1 GB
COGEM Agreement for the provision of services	.pdf	<1 GB
Project description	.pdf	<1 GB
Data management plan	.pdf	<1 GB
Ethical review application & approval document	.pdf	<1 GB

32. Where will you be archiving your data?

- Other --> Specify which in Q.33

33. Please list the name of the archive and link to the archive

Name of archive	Retention period	Link to the archive
EUR SURF Yoda	10 years	https://erasmus-yoda.irods.surfsara.nl/

Planned Research Outputs

Report - "Grijze gebieden in de regulering van rode en groene biotechnologie. Naar veerkrachtige wetgeving voor snelle technologische veranderingen"

Journal article - "Not yet known"

Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Grijze gebieden in de regulering van rode en groen ...		Report	Unspecified	Open	None specified		None specified	None specified	No	No
Not yet known		Journal article	Unspecified	Open	None specified		None specified	None specified	No	No