



Risk AssessmenT InnOvatioN for low-risk pesticides

### **Title Third Update of Data Management Plan**

**Deliverable: 7.4.**

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## DELIVERABLE REPORT

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Participant responsible :	University of Thessaly
Main author :	Dimitrios Karpouzas

Nature of the Deliverable		
<b>R</b>	Document, report (excluding the periodic and final reports)	
<b>DEM</b>	Demonstrator, pilot, prototype, plan designs	
<b>DEC</b>	Websites, patents filing, press & media actions, videos, etc	
<b>DATA</b>	Data sets, microdata, etc.	
<b>DMP</b>	Data management plan	✓
<b>ETHICS</b>	Deliverables related to ethics issues.	
<b>SECURITY</b>	Deliverables related to security issues	
<b>OTHER</b>	Software, technical diagram, algorithms, models etc.	

Dissemination level		
<b>PU</b>	Public, fully open, e.g. web (Deliverables flagged as public will be automatically published in CORDIS project's page)	✓
<b>SEN</b>	Sensitive, limited under the conditions of the Grant Agreement	
<b>Classified R-UE</b>	EU RESTRICTED under the Commission Decision No2015/444	
<b>Classified C-UE</b>	EU CONFIDENTIAL under the Commission Decision No2015/444	
<b>Classified S-UE</b>	EU SECRET under the Commission Decision No2015/444	

Quality procedure			
Date	Version	Reviewers	Comments
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## List of partners

Nº	Name	Short name	Country
1	PANEPISTIMIO THESSALIAS	UTH	Greece
2	AIT AUSTRIAN INSTITUTE OF TECHNOLOGY GMBH	AIT	Austria
3	UNIVERSITE CATHOLIQUE DE LOUVAIN	UCL	Belgium
4	METABOLIC INSIGHTS LTD	MI	Israel
5	AEIFORIA HELLAS LTD	AFA	Bulgaria
6	ECT OEKOTOXIKOLOGIE GMBH	ECT	Germany
7	IDRYMA TECHNOLOGIAS KAI EREVNAS	FORTH	Greece
8	INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION	IBMA	Belgium
9	WAGENINGEN UNIVERSITY	WU	Netherlands
10	JULIUS KUHN-INSTITUT BUNDESFORSHUNGSIINSTITUT FUR KULTURPFLANZEN	JKI	Germany
11	HELMHOLTZ-ZENTRUM FUR UMWELTFORSCHUNG GMBH	UFZ	Germany
12	INSTYTUT UPRAWY NAWOZENIA I GLEBOZNAWSTWA, PANSTWOWY INSTYTUT BADAWCZY	IUNG	Poland
13	BIOBEST GROUP NV	BBEST	Belgium
14	INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT	INRAE	France
15	ELLINIKOS GEORGIKOS ORGANISMOS – DIMITRA	HAO	Greece
16	SYNGENTA AGRO GMBH	SYN	Germany
17	WEIZMANN INSTITUTE OF SCIENCE	WI	Israel
18	EUROQUALITY SARL	EQY	France
19	AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	CSIC	Spain
20	BAYER AKTIENGESELLSCHAFT	BAYER	Germany
21	CBC (EUROPE) SRL	CBC	Italy
22	Genolution	Genolution	Korea

## Project summary

This report is part of the deliverables from the project "RATION" which has received funding from the European Union's Horizon Europe research and innovation program under grant agreement No. 101084163.

Low risk pesticides (LRP) including (i) plant extracts (ii) semiochemicals like pheromones and allelochemicals, (iii) microbial pesticides, are gaining ground in the global market, as substitutes of synthetic pesticides. In addition, new microbial solutions (phages, protists, microbial consortia) and ds-RNA pesticides are emerging, low-risk solutions expect to reach the market in coming years. Despite on-going regulatory efforts by the European Commission, we are still lacking a concrete risk assessment (RA) scheme relevant to LRPs, a point which blocks LRPs reaching the EU market. RATION timely comes to address these regulatory constraints and aims to develop a novel RA scheme, supported by the necessary guidance on methods and tools, tailored to the specific characteristics of established and emerging LRP solutions. This main goal will be achieved through a series of interrelated WPs aiming (i) to map the current status of LRPs in Europe and identify main regulatory constraints (WP1). In this quest it will be supported by a stakeholders forum composed of all relevant actors (industry, regulators, academics, farmers, general public); (ii) to develop and validate, through a proof-of-concept exercise, innovative RA (and associated tools) for microbials (WP2), plant extracts, semiochemicals, pheromones (WP3) and, ds-RNA (WP4); and from there (iii) build a harmonized RA for all LRP and determine its socioeconomic impact (WP5), (iv) to effectively communicate and disseminate the new RA knowledge and its associated tools developed by RATION to relevant actors ensuring sustainability beyond project duration (WP6). RATION will benchmark EU regulatory science, uplift blockers holding back LRP uptake by the EU market and motivate research innovation in plant protection. To achieve these goals 22 partners from academia, industry and regulatory bodies, representing 10 member states and 2 non-EU member states, will join forces in a multi-sectoral and multi-disciplinary effort.

## Objective and Executive summary

RATION is set to utilise collected/generated data of diverse structure and format. As a result, the data definition process can be based on the source and the physical format of the data. We note two main aspects: (i) the process under which the underlying data is created/captured, which may include the use of electronic texts documents, spreadsheets, among others, and (ii) the storage format of data, which may include easily accessible formats, such as post scripts (e.g. pdf, xps, etc.), machine-readable formats (xml, html, xhtml, rdf, json, etc.), spreadsheets, (e.g. xlsx, csv, etc.), text documents (e.g. docx, rtf, txt, etc.), compressed file formats (e.g. rar, zip, gzip, etc.) or any other format required by the objectives and methodology of the activity within the frame of which the data is produced.

Key **research data** will be generated within WP1-WP5. The type and formats of the data collected/generated in the context of RATION can be broadly divided into these categories:

- Electronic text documents;
- Spreadsheets, containing tabulated measurements;
- Sequencing data in the FASTA data format, which is a text-based format for representing either nucleotide sequences or amino acid (protein) sequences, in which nucleotides or amino acids are represented using single-letter codes. This format has now become a de facto universal standard in the field of bioinformatics;
- Source code, mainly using the R language for data analysis;
- Resource Description Framework (RDF) databases.

Detailed data summaries per work package for RATION's research activities are attached as an annex at the end of this report.

Moreover, RATION will also generate a set of **operational data** to comply with EC's monitoring and reporting requirements as indicated in the GA, including resource use, expenditure, progress, and schedule (WP7) and public and stakeholders engagement and outreach (WP6). These data are explicitly excluded from the DMP, since they do not fall in the provisions of the Grant Agreement.

## Section 1. FAIR Data

The Guidelines on Data Management in Horizon Europe highlight the importance of making the data produced Findable, Accessible, Interoperable as well as Reusable (FAIR), with a view to ensuring its sound management. This means using standards and metadata to make data discoverable, specifying data sharing procedures and which data will be open, allowing data exchange via open repositories as well as facilitating the reusability of the data. The following sections lay out the approach to be followed by RATION with respect to making data findable, accessible and interoperable, as well as ensuring their preservation and open access, with a view to increasing its re-use.

### 1.1 Making data findable, including provisions for metadata

RATION will enhance the discoverability of the data it processes using metadata that are suitable to their content and format. The project will employ metadata standards<sup>1</sup> to produce rich and consistent metadata to support the long-term discovery, use and integrity of its data.

All the data and associated metadata gathered during RATION will be posted on public repositories such as the [EU Nucleotide Archive](#), [Dryad](#), or [Zenodo](#). Public repositories can enable open access to the project's open data free of charge, supporting all file formats, promoting peer-reviewed openly accessible research, and allowing other stakeholders to explore, download and re-use this data. Moreover, by employing such data repositories, the data produced during the implementation of the project is locatable by means of a standard identification mechanism. In this way we will be able to assign globally resolvable Persistent Identifiers (PIPs) on any data uploaded. An identifier is a unique identification code that is applied to a dataset so that it can be unambiguously referenced. PIPs are simply maintainable identifiers that allow for permanent reference to a digital object. In other words, PIPs are a way of giving digital resources, such as documents, images and data records, a unique and persistent reference number.

### 1.2. Making data openly accessible

The list of datasets that will be made available during the project's activities is provided in the Annex at the end of this document. This list will be updated throughout the project duration to reflect any changes.

RATION emphasises the accessibility of the data collected/generated during the project. No specialised method, software tool and/or documentation is expected to be needed to access the data. Interested parties will have the ability to access the data by simply using their web browser, and entering the persistent identifier of the dataset of interest.

### 1.3. Making data interoperable

Data interoperability refers to the ability of systems and services that create, exchange and use data to have clear, shared expectations for the contents, context, and meaning of that data. RATION will adopt – where applicable the use of metadata vocabularies, standards, and

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<sup>1</sup> See the relevant metadata directory for Life Sciences at <http://rd-alliance.github.io/metadata-directory/subjects/>

methods that will increase the interoperability of the data collected/generated through its activities.

Moreover, RATION will opt for file formats that do not require usage of commercial software or specific operating system, when possible, e.g., open formats (such as csv, pdf, zip, etc.) and/or machine-readable format (such as xml, json, rdf, html, etc.).

## 1.4. Increase data re-use

Without prejudice the Consortium Agreement, RATION, under WP6 (Dissemination, communication, and exploitation of project findings), will actively disseminate, using any available means the openly available data and encourage third parties to access, mine, exploit, reproduce and further disseminate it. RATION will also monitor and report third party access to its open data.

RATION will apply a licence to every open dataset it will make available to ensure that any interested third-party can re-use it. Licences are the instrument which permit a third-party to copy, distribute, display and/or modify the project's data only for the purposes that are set by the licence. Licences typically grant permissions on condition that certain terms are met. While the precise details vary, three conditions are commonly found in licences which are the attribution, non-derivative, and non-commerciality.

RATION will publish its openly available data under the Creative Commons licensing scheme to foster their re-use and build an equitable and accessible environment for them. All candidate repositories provide the opportunity to publish data under one of the five Creative Common licences as follows:

- Creative Commons Attribution-Share Alike 4.0 (CC BY-SA 4.0) according to which any third party can freely copy, distribute, display and modify the datasets for any purpose. Remix, transform, or built upon data, must be distributed under the same license as the original. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made;
- Creative Commons Attribution 4.0 International (CC BY 4.0) according to which any third party can freely copy, distribute, display and modify the datasets for any purpose. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made;
- Creative Commons Attribution-No Derivatives 4.0 International (CC BY-ND 4.0) under which any third party can freely copy, distribute, display and modify the datasets for any purpose. Remix, transform, or built upon data, however, must not be distributed. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made;
- Creative Commons Attribution-Non Commercial 4.0 International (CC BY-NC 4.0) based on which third parties can copy, distribute, display and modify the datasets for any purpose other than commercial unless they get permission by project partners first. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made;
- Creative Commons Attribution-Non Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) according to which third parties can copy, distribute, display and modify the datasets for any purpose other than commercial unless they get permission by project partners first. Remix, transform, or built upon data, however, must not be

distributed. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

In the case a different licensing scheme is needed in the future to better capture the long-term preservation and re-use of the data but also the interests of the consortium, this subsection of the DMP will be updated accordingly.

## Section 2. Allocation of resources

Effective, proper and secure handling of the RATION data collected/generated requires the establishment of specific data management roles within the data management methodology and procedures of the project. These responsibilities are outlined in this section of the DMP as follows:

**Project Coordinator (CO):** The CO (UTH), is responsible for overall data management in the framework of RATION, including the elaboration of the DMP and its updates (when necessary, along with support of all partners). At the same time, the CO is responsible for the elaboration of proper templates for the Data Summary Sheet (see ANNEX I – Data Summary Sheet) to be appropriately adjusted and utilised by project partners. Finally, the CO coordinates with Work Package and Task Leaders to determine whether and how the data collected/generated by the project are shared and become available for re-use, contributes to its quality assurance, and uploads the project's openly available data to the most appropriate repository.

**Project Administrator (PA):** The PA (EUROQUALITY) will be responsible for all communication required and assisting the CO in the implementation of the DMP and its updates, when and if necessary.

**Work Package Leaders (WPL):** The WPLs are responsible for coordinating the implementation of the data processing activities performed under the WPs they are leading. They align with the CO and the respective Work Task Leader on whether and how the data gathered/produced under the tasks that fall within the WP they are leading will be shared and/or re-used. This includes the definition of access procedures as well as potential embargo periods along with any necessary software and/or other tools which may be required for data sharing and re-use. Finally, the WPL are the main responsible for assuring the quality of the data stemming from the activities of the WP they are leading, including assessing their quality and indicating any need for improvement to the respective Work Task Leaders.

**Task Leaders (TL):** The TL act as data controllers of the data collected/generated in the frame of the tasks that fall under their leadership, determining the purposes and means of processing this data as well as safeguarding its appropriate and timely processing. Moreover, they are responsible for completing the Data Summary Sheets for the data sets generated by the task they are leading. Finally, they undertake any necessary actions to prepare the data collected/generated through the tasks they are leading for sharing either within the consortium or openly (including the use of proper naming conventions, the creation of appropriate metadata and documentation, etc.).

**Data repositories:** Data repositories are tasked with the storage and long-term preservation of the project's data. In this respect, they maintain and preserve the openly available data of RATION, enabling its sharing and re-use. They also assign metadata and DOIs to the data, while also taking all the necessary measures to securely back-up the data and be able to restore it, safeguarding its long-term preservation.

## Section 3. Data security

RATION will securely handle any collected/generated data throughout its entire lifecycle as it is essential to safeguard this data against accidental loss.

All project partners are responsible for processing data within their institutional servers and will ensure that this data is protected, and any necessary data security controls have been implemented, to minimize the risk of information loss. The data will be backed up regularly to safeguard their preservation from human error or hardware failure, while also enabling their recovery at any time.

## Section 4. Ethical aspects

RATION will handle personal data in the frame of WP1, Task 1.2. Stakeholders forum. All members of the StaFo will be recruited on a volunteer basis. They have signed a letter of consent and a non-disclosure statement for their participation to the StaFo. As members of StaFo they will be receiving updates and will be given access to the StaFo Intranet Portal. All personal data will be handled as described below for WP5 survey. No other ethical issues are foreseen to be handled by RATION.

### 4.1. Handling of personal data

Human participation in RATION will mainly take place in WP5 through the consumer impact assessment. The Work Package will include interviews, online survey, and workshops. Data collection instruments will include informed consent forms, interview screeners and guidelines, survey questionnaires, and workshop screeners and guidelines. Personal data will be collected, processed, and retained in the form of individual transcribed interview, online survey questionnaires aggregated as datasets, and workshop audio visual recordings and transcripts.

All data collection instruments will be submitted to the Project Coordinator for review prior to being cleared. Personal data will be collected under the principle of minimum impact. Personal data will only be collected for specific, explicit, and legitimate purposes, will be processed fairly and lawfully, and will be adequate, relevant, and not excessive. Data will only be collected, held, and processed to an extent necessary from a quality control, sampling, and analytic perspective. Research participants will be given every assurance that their data will be anonymised and/or will only be dealt with at an aggregated level – i.e., that identifying data will not be reported nor linked to response content. Throughout analysis and reporting, relevant partners will furthermore ensure that the identities of research participants cannot be inferred through the merging of multiple sources.

In accordance with supranational and national regulations, personal data will be conducted through fair and lawful means and with the informed consent of research participants. Consent will be collected during participant recruitment, and will be:

- Free (voluntary and able to be withdrawn at any time)
- Specific (referring to one or more identified purposes)
- Informed (given in full awareness of all relevant consequences of giving consent)

In addition to written data, audio and audio-visual recordings may be collected. The Consortium acknowledges that these constitute personal data and confirms that they will be handled as such.

## 4.2. Data processing

Partners will anonymise all personal data prior to its analysis and its release in the form of deliverables. With respect to qualitative data, anonymisation involves the removal of all names, pseudonyms, specific occupational information, physical or electronic addresses, identification numbers, or other personal identifiers. With respect to quantitative data, anonymisation involves processing, analysing, and reporting results in aggregated form to ensure that specific participants cannot be identified.

In the frame of RATION appropriate technical and organisational measures will be taken to protect all personal data against accidental or unlawful disclosure, access, alteration, destruction, or loss. This will include the design of data collection instruments under the principle of privacy-by-design and -default, the storage of personal data in secure files on secure servers, and the storage of anonymised data and identifiers in separate secure files. The Consortium will furthermore strive to retain data for as brief a period as possible relative to the type of research and the type of participant involved.

## ANNEX I – Data Summary Sheet

<b>I. DATA SUMMARY</b>			
<b>Reference Number</b>	<b>Name of the Dataset</b>	<b>WP (Task)</b>	<b>Date Created</b>
<b>I.1 Principal type of data contained in the data set</b>			
<input type="checkbox"/> Quantitative <input type="checkbox"/> Qualitative <input type="checkbox"/> Numeric	<input type="checkbox"/> Text <input type="checkbox"/> Images <input type="checkbox"/> Audio	<input type="checkbox"/> Video <input type="checkbox"/> Database <input type="checkbox"/> Non-Structured	<input type="checkbox"/> Source Code <input type="checkbox"/> Sequencing <input type="checkbox"/> Other: (Specify)
<b>I.2 Description of Data</b> Please, describe the data, specify the type and provide a short description of every field contained in the data. Moreover, add information about the size of the data set, format, etc [...]			
<b>I.3 Source of the Data</b>			
<input type="checkbox"/> Field work <input type="checkbox"/> Direct measurements <input type="checkbox"/> Surveys <input type="checkbox"/> Simulations	<input type="checkbox"/> Expert knowledge <input type="checkbox"/> Model Output <input type="checkbox"/> Other (please specify):		
<b>I.4 Methodology used to collect the data</b> Please briefly describe the processes or methods which have been used to get the data. [...]			
<b>I.5 Relation of the data with the objectives of the project</b>			
<input type="checkbox"/> Gather fragmented knowledge and guidance on Low Risk Pesticides (LRPs) regulatory process and federate the actors of the crop protection sector to have an objective approach of the stakes and perspectives (WP1); <input type="checkbox"/> Develop and verify a novel, improved Risk Assessment (RA) scheme tailored to the different LRP groups (WP2, 3, 4) <input type="checkbox"/> Develop and verify novel toxicity and ecotoxicity tests and procedures that will pave the way for the sensitive and targeted assessment of LRPs facilitating their rapid placement in the market (WP2, 3, 4) <input type="checkbox"/> Develop and verify novel tools for the identification of RA-relevant Non Target Organisms (NTOs) and for the prediction of environmental exposure of LRPs, as a necessary step for a scientifically sound RA scheme (WP3, 4) <input type="checkbox"/> Set the basis for future standardisation and validation of the developed tools and methods (WP2, 3, 4) <input type="checkbox"/> Propose a harmonized RA scheme encompassing common pathways among LRP groups (WP5) <input type="checkbox"/> Determine and analyse the socioeconomic impacts of implementing the proposed RA in the EU (WP5) <input type="checkbox"/> Disseminate and exploit tools, data and knowledge generated to establish a transparent Risk Assessment process (WP6)			
<b>I.6 Why is this data collected?</b> Please contextualise the data. [...]			
<b>II. IS THE DATA FINDABLE?</b>			
<b>II.1 Metadata Standards</b> Please cite the standard and format use for the data. If any this data set does not follow any standardized format, please provide a formal specification. Link regarding to metadata standard: <a href="http://rd-alliance.github.io/metadata-directory/">http://rd-alliance.github.io/metadata-directory/</a> [...]			
<b>II.2 Documentation stored in the data</b>			

<input type="checkbox"/> Information of the origin of the data	<input type="checkbox"/> Description of Variables
<input type="checkbox"/> Codebook	<input type="checkbox"/> Technical information about files
<input type="checkbox"/> List of abbreviations	<input type="checkbox"/> Other (Please specify):
<b>II.3 Ontologies</b>	
<input type="checkbox"/> External Link:	<input type="checkbox"/> RATION internal Link:
<b>II.4 Potential users and channels to reach them</b>	
<input type="checkbox"/> Public administration	<input type="checkbox"/> Partner webpage
<input type="checkbox"/> Researchers / Research Groups	<input type="checkbox"/> Project webpage
<input type="checkbox"/> Citizens	<input type="checkbox"/> Specialist database
<input type="checkbox"/> Private sector	<input type="checkbox"/> Email of corresponding author
<input type="checkbox"/> NGOs	<input type="checkbox"/> Data access statement in published article
<input type="checkbox"/> Other (specify):	<input type="checkbox"/> Personal networking <input type="checkbox"/> Citation of data set <input type="checkbox"/> Other (specify):
<b>III. IS THE DATA ACCESSIBLE?</b>	
<b>III.1 Accessiblility</b>	<b>III.2 Obligation or intention to share</b>
<input type="checkbox"/> Public data	<input type="checkbox"/> Yes
<input type="checkbox"/> Confidential data	<input type="checkbox"/> No
<b>III.3 If applicable, timeframe to make data open</b>	
<input type="checkbox"/> On collection	
<input type="checkbox"/> Sometime after data collection (specify):	
<input type="checkbox"/> Sometime after the project ends (specify):	
<input type="checkbox"/> To coincide with the publication of the main results	
<input type="checkbox"/> Other (specify):	
<b>III.4 Expected difficulties in making the data publicly accessible</b>	
<input type="checkbox"/> Confidentiality	<input type="checkbox"/> Ownership / licensing
<input type="checkbox"/> Large file size	<input type="checkbox"/> Intended commercialization <input type="checkbox"/> Other (specify):
<b>III.5 Primary storage medium and location</b>	
<input type="checkbox"/> Institutional storage	<input type="checkbox"/> Repository (specify):
<input type="checkbox"/> Secure facility from a data provider	<input type="checkbox"/> Academic research network platform (specify):
<input type="checkbox"/> Physical storage	<input type="checkbox"/> Institutional open data repository (specify):
<input type="checkbox"/> Cloud platform	
<b>IV. DATA INTEROPERABILITY</b>	
<b>IV.1 File Format</b>	
Make sure that the data is available, if possible, in a non-proprietary open format (e.g., CSV as well as of Excel)	
[...]	
<b>IV.2 Methods or software tools needed to access the data</b>	
Please detail any necessary software to manipulate the data, if not standard.	
[...]	
<b>V. DATA REUSE</b>	
<b>V.1 License conditions and restrictions</b>	
<input type="checkbox"/> Copyright	Creative Commons:
<input type="checkbox"/> Open License (specify):	<input type="checkbox"/> CC BY-SA 4.0
<input type="checkbox"/> Other (specify):	<input type="checkbox"/> CC BY 4.0 <input type="checkbox"/> CC BY-ND 4.0 <input type="checkbox"/> CC BY-NC 4.0 <input type="checkbox"/> CC BY-NC-ND 4.0
<b>V.2 If applicable, list of the copyright owners and intellectual property involved.</b>	
[...]	

<b>V.3 If applicable, any access permissions and restrictions</b>			
[...]			
<b>VI. DATA MANAGEMENT</b>			
<b>VI.1 Partner Roles</b>	<b>Collection</b>	<b>Curation</b>	<b>Preservation</b>
UTH (CO, EL)			
AIT (BEN, AT)			
UCLouvain (BEN, BE)			
MI (BEN, IL)			
AFA (BEN, BG)			
ECT (BEN, DE)			
FORTH (BEN, EL)			
IBMA (BEN, BE)			
WU (BEN, NL)			
JKI (BEN, DE)			
UFZ (BEN, DE)			
IUNG-PIB (BEN, PL)			
BBEST (BEN, BE)			
INRAE (BEN, FR)			
HAO (BEN, EL)			
SYNGENTA (BEN, DE)			
WI (BEN, IL)			
EQY (BEN, FR)			
CSIC-INIA (BEN, ES)			
BAYER (BEN, DE)			
CBC (BEN, IT)			
GENOLUTION (AP, KR)			
<b>VI.2 Data curation process</b>			
Please briefly describe the management of data throughout its life cycle			
[...]			
<b>VI.3 Long-term preservation</b>			
Please briefly describe how the data will be preserved after the end of the project.			
[...]			
<b>VI.4 Regularity of Backups and data replication in other locations, if any.</b>			
[...]			
<b>VI.5 File management and versioning</b>			
<input type="checkbox"/> Unnecessary (i.e., overwrite original file) <input type="checkbox"/> Control version software (e.g., GIT) (specify): <input type="checkbox"/> Date/version number in filename or folder <input type="checkbox"/> Other (specify):			
<b>VII ETHICAL AND LEGAL ASPECTS</b>			
<b>VII.1 Ethical Aspects (if known)</b>			
<input type="checkbox"/> No <input type="checkbox"/> Yes (briefly describe):			
<b>VII.2 Legal Aspects (if known)</b>			
<input type="checkbox"/> No <input type="checkbox"/> Yes (briefly describe):			

## ANNEX II – Data Summary per WorkPackage

## Work Package 1. Type of data to be generated during RATION

Dataset No.1	Task No.	Dataset Name	Dataset Description	Type of Data	New/Existing Data	Method of data production	Format of Data	Expected Size	Quality control procedures	Data Utility	Ethical Issues	Type of Access	Chronology
1	1.1	Stakeholders Forum members hip	Names, affiliation and contact details of members of the stakeholders forum	personal details	new	personal communication or via email	xls	100 kb	Standard control processes linked to all steps of the procedure including data analysis	other EU projects, dissemination and communication use	GDPR policy agreement signed, Non disclosure agreement signed	Personal and contact details restricted access to PMB, anonymized analysis of data	1.11.2022, throughout the duration of the project
2	1.1	Stakeholders Forum workshops participation	Names, affiliation of participants in workshops	personal details	new	list of participants from zoom	xls	100 kb	Standard control processes linked to all steps of the procedure including data analysis	Impact assessment analysis by the EC	GDPR policy agreement signed	restricted	23.3.2023, and every six months from then
3	1.1	Stakeholders Forum workshops recordings	Recordings of the 8 workshops of Stafo	video	new	zoom recording	mp4	20 GB	Standard control processes linked to all steps of the procedure	Researchers, Policy makers, Agrochemical Industry	GDPR policy agreement signed	open to members of the StaFo via the intranet portal	23.3.2023, and every six months from then
4	1.1.	Stakeholders Forum – Task Force Events	Names, affiliation and contact details of members of the 3 task	Personal details	new	personal communication or via email	xls	100 kb	Standard control processes linked to all steps of the procedure	Researchers, Policy makers, Agroche	GDPR policy agreement signed	Standard control processes linked to all steps of	M18 until the end of the project

This project has received funding from the European Union's Horizon Europe Research and Innovation programme under Grant Agreement No. 101084163. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Research Executive Agency (REA). Neither the European Union nor the granting authority can be held responsible for them.

			forces (wp2, wp3, wp4)							mical Industry		the procedure	
5	1.1	Stakeholders Forum task forces events participation	Names, affiliation of participants in events	Personal details	new	list of participants from zoom	xls	100 kb	Standard control processes linked to all steps of the procedure including data analysis	Impact assessment analysis by the EC	GDPR policy agreement signed	restricted	M18 until the end of the project
6	1.1	Feedback questionnaires Stafo	Answers on 9-10 questions with gradient of the level of satisfaction	numerical (0 to 5)	new	MSforms link send to participants	xls	100 kB	Standard control processes linked to all steps of the procedure	to EC for impact assessornt	anonymized	open through the website or through google forms	23.3.2023, and every six months from then
7	1.2	Questionnaire addressed to managers in national authorities	Answers to 40 questions about the regulation	Personal details	new	via email	xls	1 MB	Standard control processes linked to all steps of the procedure	to EC for impact assessornt	GDPR policy agreement signed	restricted	April 2023 to July 2023
8	1.3	Regulatory database	Database of regulations and guidance documents	Documents	existing	download from public sources	pdf, doc	100 MB	Standard control processes linked to all steps of the procedure	Reference for all other WPs	N/A	restricted	April 2023 to July 2024

## Work Package 2. Type of data to be generated during RATION

Dataset No.1	Task No.	Dataset Name	Dataset Description	Type of Data	New/Existing Data	Method of data production	Format of Data	Expected Size	Quality control procedures	Data Utility	Ethical Issues	Type of Access	Chronology
1	2.1	Toxicity assessment for humans and mammals data collection	Data required for identifying potential pathogenicity infectivity to humans and mammals summarized by database, genome and literature summary	Summary report	Existing data evaluation	Summary of data of literature and sequence databases	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M42
2	2.1	Toxicity assessment for humans and mammals for microbial approaches with insufficient data	Data collection for in vitro human or mammalian cell or tissue models	Written Report	New	Experimental data and analysis	PDF	10MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	Mammal and human cell lines in accordance with regulations and the aim of minimizing general use	Restricted to Ration partners, open when publication released	M12- M42
3	2.2	Ecotoxicology data collection	Data required for ecotoxicology summarized by database and literature summary	Summary report	Existing data evaluation	Summary of data of literature and subsequent databases	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry,	None	Restricted to Ration partners, open when publication released	M4- M20

									Regulatory bodies		
4	2.2	Ecotoxicological data generation	Results of microcosm and non-standard single species tests with microbial pesticides and microbiome solutions considered only for screening purposes within the remits of the RATION project.	Written Report and Excel files	New	Performing experiments	PDF/XLSX	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None
5	2.2	Adapted ecotoxicology assessments	Selected data collection for model microbial pesticides with selected test organisms for an improved and streamlined ecotoxicological assessment	Written Report	New	Experimental data and analysis conducted according to internationally accepted protocols	PDF	10MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	Animal testing according to guidelines and the aim of minimizing general use

6	2.2.	Meta-analysis of effects of microbial pesticides on the soil microbiome	Meta-analysis on potential effects of microbial pesticides or formulation amendments to soil microbial communities and with emphasis on organisms known for having important ecosystem function	Summary report	Existing data evaluation	Summary of data of literature and sequence databases	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M8-M48
7	2.3	Pipeline for AMR gene detection in microbial pesticides	Evaluation of existing tools for AMR gene detection via WGS (including metatools such as MoPS by EFSA) and adaption/update as well as incorporation into metatools as required	Summary and analysis	New	Literature and Experimental data and analysis; tool development	PDF, fasta, database; <a href="#">html</a>	1000 MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication; and tool released	M12-M36
8	2.3	Pipeline for detection of Secondary Metabolites biosynthesis	Evaluation of existing tools for SM biosynthesis gene detection	Summary and analysis	New	Literature and Experimental data and analysis; tool	PDF, fasta, database, <a href="#">html</a>	1000 MB	Standard control processes	Researchers, Policy makers, Agroche	None	Restricted to Ration partners, open when publication and tool released	M12-M36

		genes on microbial pesticides	via WGS (including meta-tools such as MoPS by EFSA) and adaption/update as well as incorporation into meta-tools as required		development			mical Industry, Regulatory bodies					
9	2.4	New RA for microbial pesticides – proof of concept. 2.4.1. New RA solutions for microbial pesticides	Based on the outcome of T2.1 to T2.3 a new and improved RA scheme for microbial pesticides	Guidance documents; Stepwise approach ; tools tailored for the revised regulations for microorganisms	New	1) Summary of data and procedures, validated tests, and procedures developed in tasks 2.1 & 2. 2) Propose a holistic RA scheme taking in consideration the data requirements in the framework of low risk active substances 3) Development of a stepwise approach	PDF	2MB	Standard control processes. Validation of the RA step wise approach implemented for each of the three model microorganisms products.	Researchers , Policy makers , Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M24-M48

					process based on data generated and data requirement s						
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10	2.4	New RA for microbial pesticides – proof of concept. 2.4.2. Proof-of concept for the RA procedure proposed.	Proof-of-concept and validation of the RA scheme proposed. A pilot RA process will be run for the three model microorganisms proposed.	RA scheme based on the outcome of T2.1 to T2.3. Full report of the RA outcome s of the model microorganism products (virus, bacteria and fungus)	New	1) Summary of data and procedures, validated tests, and procedures implemented for the three microorganism model products. 2) Implementation of the holistic RA scheme taking in consideration the data requirements in the framework of low risk active substances 3) Implementation of the stepwise approach process based on data generated and data requirements.	PDF	2MB	Standard control processes. Validation of the RA step wise approach implemented for each of the three model microorganism products.	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M24-M48

11	2.5	Microbial consortia test data set	Microbial consortia composed of bacteria or fungi with different mode of action example evaluation based on literature, database information and model approach	Written report	New	Literature and Experimental data and analysis	PDF	10 MB	Standard control processes	Researchers , Policy makers , Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M12- M48
12	2.5	New microbial solutions dataset	Bacteriophages example evaluation based on literature, database information and model approach	Written report	New	Literature and Experimental data and analysis	PDF	10MB	Standard control processes	Researchers , Policy makers , Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M12- M48
13	2.5	New microbial solutions dataset	Protists example evaluation based on literature, database information and model approach	Written report	New	Literature and Experimental data and analysis	PDF	10MB	Standard control processes	Researchers , Policy makers , Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M12- M48
14	2.5	Development of guidance supporting	Based on the outcome of T1.4, and on	RA scheme based on	New	Establish a proof of concept for	PDF	2MB	Results will be discussed	WP partners and	None	Restricted to Ration partners, open when	M24- M48

	the RA of new microbiome solutions, new microbials and new application approaches,	the expected risk scenarios, a RA scheme for new novel microbiome applications such as microbial consortia or microorganism s/compounds & bacteriophage s	the outcome of T1.4. Full report of the RA outcome s of the microbiome solutions , new microbial s and new application approach e.	the elaborated RA. Development of a a scheme for new types of microbial applications and the applications of different categories: (a) microbial consortia with different mode of action, (b) microbial consortia with different taxonomic composition, (c) a phage and (d) a microbiome-modulating compound. Applications will be assessed according to the elaborated scheme as		with task partners and stakeholders and based on the outcome a RA guidance will be elaborated (all task partners). workshops involving all task/WP. Standard control processes. Validation of the RA step wise approach implemented for each new microbiome solutions, new microbials and new application approaches.	relevant stakeholders (StaFo) along the entire agricultural food chain.	publication released
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### Work Package 3. Type of data to be generated during RATION

<b>Dataset No.1</b>	<b>Task No.</b>	<b>Dataset Name</b>	<b>Dataset Description</b>	<b>Type of Data</b>	<b>New/ Existing Data</b>	<b>Method of data production</b>	<b>Format of Data</b>	<b>Expected Size</b>	<b>Quality control procedures</b>	<b>Data Utility</b>	<b>Ethical Issues</b>	<b>Type of Access</b>	<b>Chronology</b>
1	3.1	WU-TOX report	Results of ecotoxicity tests (primary aquatic) with plant extracts, focusing on mortality and growth)	Written Report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
2	3.1	WU-AEW report	Results of microcosm and non-standard single species tests with plant extracts and plant derived pure bioactives.	Written Report and Excel files	New	Performing experiments	PDF/XLSX	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
3	3.1	ECT report	Results of ecotoxicity tests (abundance, survival, reproduction, and other endpoints)	Written Report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4-M36

4	3.1	FORTH report	Conducting bioassays on bees and other arthropods for measuring the toxicity of botanical active substances.	Written Report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
5	3.1	MI report	Producing biopesticides and chemical analysis and their properties	Written Report	New	Extraction, purification and chemical analysis	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
6	3,2	CBC report	Background on SCLPs in EU, Scientific knowledge and regulatory knowledge on semiochemicals. French national actions on semiochemicals sharing of data and experience. Regulatory data	Written Report	New	Summaries of data and documentation sharing.	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36

			requirements and Risk assessment knowledge and experience sharing.										
7	3.3	WI report	list of pesticide metabolites in the samples	Written Report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
8	3.3	IUNG report	Biopesticides chemical analysis; biopesticides degradation in soil experiments; biotests; literature research; Physicochemical soil measurement s;	Written Report; Data of pH, organic carbon content, NH4, NO3, chromatograms;	New	Performing experiments: Measurements in air dried soil samples used for our experiments; UHPLC-MS/MS;	PDF	10MB	Standard control processes; chromatography method optimized and validated	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
9	3.3	AFA report	Exposure assessment for plant extracts	Written report/ Exposure assessment tools	New	Summary of data and procedures/ Model design and validation	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry,	None	Restricted to Ration partners, open when publication released	M12 – M48

										Regulatory bodies			
10	3.1	INIA proof-of-concept plant extract and plant derived pure compounds	Proof-of-concept and validation of the RA scheme proposed, a pilot RA process will be run for plant extract	RA scheme. Report of the RA outcome s of the model for one plant extract product	New	1) Summary of data and procedures, validated tests, and procedures developed in tasks 3.1, 3.2 & 3.3 2) Propose a holistic RA scheme taking in consideration the data requirements in the frame work of low risk active substances 3) Development of a stepwise approach process based on data generated and data requirements	PDF	2MB	Standard control processe s. Validation of the RA step wise approach implemented for one model plant extract product and one plant extract product	Researcher s , Policy makers , Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M24-M48

#### Work Package 4. Type of data to be generated during RATION

Dataset No.1	Task No.	Dataset Name	Dataset Description	Type of Data	New/Existing Data	Method of data production	Format of Data	Expected Size	Quality control procedures	Data Utility	Ethical Issues	Type of Access	Chronology

1	4.1	Genolution, dsRNA analysis results	Analysis results of dsRNA produced (e.g. yield, purity and etc)	Written report	New	analysis (confidential)	PDF, excel or word	1 Mb	Standard control processes	For WP4 team	None	restricted to WP4 team	M4 – M24
2	4.1	FORTH report	Development and validation of computational tool to facilitate the early identification of potential non-target organisms	Written report	New	Developing computational pipelines	PDF	2 MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M6 – M30, report M42
3	4.1	WU-AEW report	Results of standard and non-standard single species tests with ds-RNA.	Written Report and Excel files	New	Performing experiments	PDF/XSX	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M4 – M36
4	4.1	JKI/HAO, Plant RNA-seq data	Transcriptome data and/or RT-PCR to detect RNAi enzyme saturation and possible off-targets in plant	digital file	New	Performing experiments	Fasta	1 Gb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M6 – M36,

5	4.1	JKI Insect RNA-seq data	Transcriptome data and/or RT-PCR to detect downregulation level of on-targets and possible off-targets	digital file	New	Performing experiments	Fasta	1 Gb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M6 – M36,
6	4.1	JKI/HAO, Plant bisulfite-seq data	Bisulfite sequencing for DNA methylation analysis in plant loci sharing sequence identity with the dsRNA pesticide	digital file	New	Performing experiments	Fasta	100 Mb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M6 – M36
7	4.1	JKI Insect bisulfite-seq data	Bisulfite sequencing for DNA methylation analysis in insect loci sharing sequence identity with the dsRNA pesticide	digital file	New	Performing experiments	Fasta	100 Mb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M6 – M36
8	4.1	JKI, HAO, BAYER, FORTH report	decision-making roadmap/tool for the selection of	Written report	New	Performing experiments	PDF/XLSX	2MB	Standard control processes	Researchers, Policy makers, Agrochemical	None	Restricted to Ration partners, open	M12 – M36,

			functional and surrogate NTOs						Industry, Regulatory bodies		when publication released		
9	4.2	FORTH report	Novel and advanced ecotoxicity tests for dsRNA-based products in bees	Written report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M16 – M42,
10	4.2	ECT report	Adaptations of existing tests for dsRNA for soil vertebrates	Written report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M16 – M42,
11	4.2	WU-ERA report	Adaptations of existing tests for dsRNA for aquatic organisms	Written report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M16 – M42,
12	4.2	ECT/FORTH/BAYER report	Adaptations of existing tests for dsRNA for bees and	Written report	New	Performing experiments	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical	None	Restricted to Ration partners, open	M16 – M42

			other arthropods							Industry, Regulatory bodies		when publication released	
13	4.3	AFA report	Establishment of and mathematical model to calculate exposure levels of dsRNA in the environment	Mathematical model	New	Model design and validation	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M16 – M42
14	4.3	HAO/UTH Environmental RNA detection data	Soil dissipation data (raw data and DT50s) in 4 soils for dsRNA (naked and formulation). Data to be used for model calibration	Digital file	New	Performing experiments	PDF	1 Gb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M16 – M36
15	4.2 and 4.3.	HAO/UTH Environmental behaviour data	Effects of dsRNA (naked and formulated) on soil microbiota across trophic levels (microbiota, fauna)	Digital file	New	Performing experiment	Fastq Files, pdf	10 Gb	Standard control processes	Research dissemination	None	Restricted to Ration partners, open when publication released	M18 – M42

16	4.4	JKI, BAYER, FORTH, GENO, WU, UTH and HAO report	Proof-of-concept and validation of the RA scheme proposed, a pilot RA process will be run for dsRNA	RA scheme	New	Summary of data and procedures	PDF	2MB	Standard control processes	Researchers, Policy makers, Agrochemical Industry, Regulatory bodies	None	Restricted to Ration partners, open when publication released	M24-M48
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#### Work Package 5. Type of data to be generated during RATION

Dataset No.1	Task No	Dataset Name	Dataset Description	Type of Data	New/Existing Data	Method of data production	Format of Data	Expected Size	Quality control procedures	Data Utility	Ethical Issues	Type of Access	Chronology
1	5.1	Harmonized RA	recommendations for an improved risk assessment	written report	new	collaborative effort within RATION	PDF	2MB	reviewing within RATION and by SAB, StaFo	Researchers, Policy makers, Agrochemical Industry	no	open through the website upon finalisation	M24-48
2	5.2	Questionnaires with consumers	Answers to 40 questions regarding the consumption habits	personnal details	new	economic analysis	xls	100 kB	Standard control processes linked to all steps of the procedure	to EC for impact assessment	anonymized	open through the website	M24-48

3	5.3	Harmonization analysis results	Different forms of harmonization will lead to different valuations on hurdle rates	Results of calculations, rational numbers	New	economic analysis	xls	100kb	Standard control processes linked to all steps of the procedure	Researchers, Policy makers, Agrochemical Industry	no	open access	M36-48
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**Changes made compared to D7.3.**

All changes made are highlighted with yellow. Specifically

WP2.

Chronology changed in Datasets 1, 2, 5, 6, due to be relevant with the progress of the project.

Minor rephrasing in Datasets 7 and 8 to adjust to current data generated

WP4.

Chronology changed in Dataset 7



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