

SPR Circular Economy

S/999999

Designing Inclusively foR a safe and sustainable circular EConomy Transition (DIRECT)

(proposal number 0046)

Strategisch
Programma
RIVM
2019-
2022



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Commissioner

Commissioner RIVM	Director-General RIVM
Theme / program	Circular Economy
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Other contributions (€)	-

Contractor

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RIVM Centres	VSP, DMG, G&M, VLH, Z&O, GZB
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¹ We have made a planning for the coming two years, with specified tasks and deliverables, as well as an outlook on a possible planning of a consecutive CE SPR 2 year track. Please see section 5.4, page 20 (and further) for specification.

² Project leader = opdrachtcoördinator at RIVM

Introductie

De transitie naar een circulaire economie wordt door velen gezien als noodzakelijk voor het bereiken van de klimaatdoelen, voorzieningszekerheid, en verscheidene duurzame ontwikkelingsdoelen (sustainable development goals, SDG's). De overgang naar een circulaire economie kan hierbij helpen, al is het belangrijk om stil te staan bij het feit dat circulariteit, veiligheid en duurzaamheid niet per se met elkaar samenvallen. Een goed moment om de transitie naar circulariteit duurzaam, veilig en gezond in te richten, is tijdens de onderzoeks- en ontwikkelingsfasen van stoffen, processen en producten (research & development, R&D). Om te beslissen of een ontwikkeling kan worden voortgezet, kijken innovatoren tussen ontwikkelingsfasen in vaak voornamelijk naar technologische aspecten en marktpotentie. Duurzaamheid en veiligheid worden in diverse gevallen niet meegewogen.

Doel(en)

Met dit project willen we bijdragen aan het duurzaam, veilig en gezond inrichten van de transitie naar een circulaire economie door voor twee of drie transitie agenda's (i) de implementatie van duurzaam en veilig circulair ontwerp in innovatieprocessen te stimuleren, en (ii) waar nodig (met kennis) te ondersteunen bij de technische implementatie van duurzaam en veilig circulair ontwerp.

Aanpak

Om circulair ontwerpen veilig en duurzaam te maken, moet het toepasbaar zijn in de praktijk. Daarom vormt een aantal casusstudies de kern van dit project. We starten elke casus met het maken van een veldanalyse en inventarisatie van belanghebbenden. Met of op basis van kennis en behoeften van belanghebbenden ontwikkelen we een of meer scenario's om circulair ontwerp aan te laten sluiten bij de doelstellingen voor veiligheid en duurzaamheid. Deze wordt of worden vervolgens getoetst in een back-casting workshop met een brede groep belanghebbenden. Op basis hiervan specificeren we de scenario's voor specifieke circulaire ontwerpen (conceptueel). We onderzoeken de relevante wettelijke context en voeren geïntegreerde beoordelingen uit van deze scenario's. In een mogelijke tweede fase van het project (M24-48), bekijken we de geïntegreerde beoordeling met als doel om minimale datavereisten en/of proxy's (voorspellende elementen) voor veilig en duurzaam ontwerp te identificeren. Deze beoordelingen leren ons welke sectorspecifieke behoeften en aandachtspunten er zijn, zodat we kunnen toewerken naar maatoplossingen. De generieke lessen brengen we samen in een integraal beoordelingskader (aanpak of instrument).

Verwachte resultaten

De integrale aanpak die uit dit project voortkomt, moet praktisch en toegankelijk zijn voor ontwerpers (nu gericht op CO₂-afvang (moleculen), kunststof medische hulpmiddelen en zonnepanelen). De aanpak dient aan te sluiten op mogelijke andere beoordelingsmethoden die elders in de waardeketen worden gebruikt. De resultaten van DIRECT omvatten het op- of uitbouwen van stakeholdernetwerken om kennis uit te wisselen, het in kaart brengen van (wettelijke) kaders, publiek toegankelijke publicaties en workshops waarin door middel van co-creatie veilige en duurzame beoordelingsmethoden voor circulair ontwerp worden ontwikkeld. De tweede fase van dit project zou een bijdrage leveren aan het vinden van minimale datavereisten voor beoordeling in vroege ontwikkelingsfasen, evenals het vinden van specifieke behoeften en aandachtspunten.

Kernwoorden: veiligheidsbeoordeling, duurzaamheidsbeoordeling, stakeholders, circulair ontwerp, veilig en duurzaam aan de voorkant, innovatie processen, transitie, circulaire economie, praktijkstudies

Designing Inclusively for a safe and sustainable circular Economy Transition (DIRECT)**Introduction**

Many conceive constructing a circular economy as key to values of environmental sustainability, supply security, climate goals, and several of the Sustainable Development Goals (SDGs). Although we expect that the transition towards a circular economy will help solve many disparate problems, circularity is not necessarily identical or even consistent with safety and/ or sustainability. A good place to start the transition to a sustainable, safer and healthier economy, is in research and development (R&D), as this offers ample opportunities for circular design that respects our planetary boundaries. To see if development can continue, innovators conventionally make assessments concerning technology readiness and market potential at the gates between different stages. Neither sustainability nor safety is habitually taken aboard herein.

Objective(s)

Therefore, this project's goals are to contribute to several circular economy transition agendas by (i) filling current knowledge gaps concerning the technical implementation of safe and sustainable circular design, and (ii) stimulating the implementation of safe and sustainable circular design in innovation processes.

Approach

For circular design to be safe and sustainable, it has to be fit for practice. Therefore, a number of case studies staging real-world experimentation form the core of the project. In each case study, we will engage in a process of iterative experimentation in which the same elements recur. Learning from literature and previous (international) project we start with a field analysis for each case study and making a stakeholder map. We then will have a workshop, back-casting circular design to fit safety and sustainability aims to support decision-making. Based on the back-casting, we formulate scenarios of a specific (conceptual) circular design. We investigate the relevant legal context and we conduct integrated assessments with stakeholders. For a potential second stage of the project (M24-48), we would compare and study an early stage assessment and integrated assessment in order to extract minimal data requirements and/ or proxies for safe and sustainable by design in the R&D phase. Also, we would learn from these assessment what sector specific needs and hotspots may be. We will bring generic lessons together in an integral assessment scheme (approach or tool).

Expected results

The integrated assessment scheme that would result from this project should be fit for designers in the area of the case studies performed (now targeted in CO2 capturing (molecules), plastic medical devices and solar panels). The approach should be such that it fits with supplemental assessment methodologies for life cycle stages, further up in the value chain of the circular economy. Results from DIRECT include, building stakeholder networks to exchange knowledge, mapping relevant (legal) frameworks, open source publications and workshops to co-create safety and sustainability assessment approaches for circular design. In a second phase of this project it could contribute with finding minimal data requirements that can be used in early stage assessments (fit for R&D), as well as sector specific needs or hotspots.

Key words: safety assessment, sustainability assessment, stakeholders, circular design, safe and sustainable by design, innovation processes, transition, circular economy, case studies.

4.1 General aim and objectives

When looking at the impacts of our current largely linear model of economic production and consumption on human health, well-being and environmental conditions, it is clear why the call for replacing this with a cyclical one has become a cry¹⁻³. Indeed, many conceive constructing a circular economy as key to values of environmental sustainability, supply security, climate goals, and several of the Sustainable Development Goals (SDGs)^{4,5,3}. In view of that, in 2016 the Netherlands has launched a government-wide program featuring five distinct transition agendas for the circular economy. These focus on (i) biomass and food, (ii) plastics, (iii) solar panels, (iv) the make-industry and (v) consumption goods⁶. As expression of the aforementioned values, the goal was set to close all material cycles by 2050⁷.

Although we expect that the transition towards a circular economy will help solve many disparate problems, circularity is not necessarily identical or even consistent with safety or sustainability⁸. Indeed, each such value might come with its own, potentially contradictory demands on products, processes or services. Evidently, in a circular economy produced and used materials will stay in the loop. This means that any existing or created harmful compound may pose a threat to closed value chains⁹. Apart from dealing with harmful legacy chemicals^{10,11}, circular design generally requires safe and sustainable design to close materials loops without posing a threat to human health and the environment¹².

A good place to start the transition to a more sustainable, safer and healthier economy, is in research and development (R&D), as this offers ample opportunities for circular design that respects our planetary boundaries¹². Presently, however, values of safety and sustainability do not straightforwardly receive the desirable attention in innovation trajectories, for instance because of the complexity of combining these different values in one framework or because, as is the case with chemical engineering, toxicity tests only come into view at the later phases of innovation trajectories, when market launch is nearby¹³. Such trajectories are often described as comprising a number of stages, going from ideation to product launch (see Figure 1)¹³. To see if development can continue, innovators conventionally make assessments concerning technology readiness and market potential at the gates between different stages. Neither sustainability nor safety is habitually taken aboard herein. Therefore, this project's goals are to contribute to several circular economy transition agendas by (i) filling current knowledge gaps concerning the technical implementation of safe and sustainable circular design, and (ii) stimulating the implementation of safe and sustainable circular design in innovation processes. In accordance with

³ Specifically, the circular economy is assumed to contribute to SDGs 3 (good health and well-being), 6 (clean water and sanitation), 7 (affordable and clean energy), 8 (decent work and economic growth), 9 (industry, innovation and infrastructure), 11 (sustainable cities and communities), 12 (responsible consumption and production), 13 (climate action), 14 (life below water), 15 (life on land) and 17 (partnership for the goals).

these goals, the intended end-users (of the project's output) should come from the early development stage of innovation processes e.g. people in R&D or science. Figure 1 presents a schematic innovation process from the idea phase until market launch. Information, data, knowledge and methodologies will be generated throughout this innovation process, which is of utmost importance for the development of an early stage assessment method (ESM) in the R&D phase. All the information, data and knowledge gathered by several value chain parties will be used for safe and sustainable by design implementation, by means of an ESM that we will apply in this project. The ESM applied will not automatically be a new methodology, just as with the integrated full-assessment, it can be one or more method(s), if necessary adjusted to fit circular design.

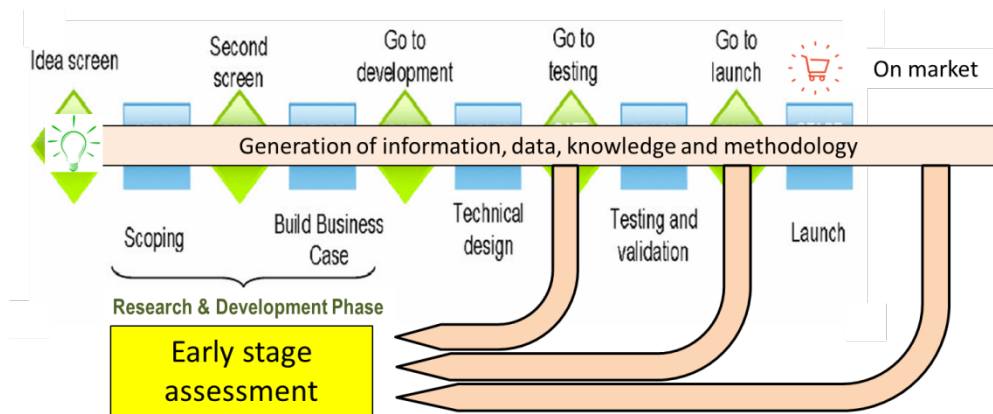


Figure 1: Generation of information, data, knowledge and methodology throughout the innovation process feeding into safe and sustainable by design implementation by means of an early stage assessment in the R&D phase.

We have formulated two main research questions, each of which we have broken down into sub-questions:

1. How can circular design contribute to safe and sustainable design?
 - a) How can an aligned assessment be made of the safety and sustainability of particular circular designs?
 - b) What are the minimal data requirements for such assessment during R&D?
 - c) Are there sector-specific needs that also can be taken into account in the R&D phase?

2. How can the implementation of safe and sustainable circular design in innovation processes in the R&D phase be facilitated?
 - a) In the cases selected for this project
 - i. who are the potential end-users of (a) tool(s) for integrally assessing safety and sustainability in particular circular designs, and
 - ii. which information from the supply chain and the relevant stakeholders is of importance for the R&D phase?
 - b) What are the (potential) end users' needs, wishes, drivers, tools, methods, (perceived) problems and (structural) barriers that one needs to take into account in constructing (a) tool(s) for integrally assessing safety and sustainability in particular circular designs?

Some potential case studies and their properties are summarized in Table 1, with distinction in long versus short and biotic versus abiotic circular cycles, to incorporate a pertinent form of diversity in circular design cases. More specifics can be found in the work package descriptions. As an example, textbox 1 illustrates the outlook of a possible algae case study

The goals and questions formulated here reveal that to realize the transition towards a circular economy, we need both technical-scientific knowledge, social-scientific knowledge and methodologies that enable transdisciplinary knowledge co-construction, including knowledge concerning the facilitation of changes in highly specific innovation systems. This project develops an approach to circularity that integrates issues of safety and sustainability, while also explicitly being geared to understanding and steering goal-directed change in socio-technical systems.

The approach in this study is based on the lessons learned and the methodology of previous SPR project SafeBBE ¹⁴, EU-projects NANoREG and NanoReg2 ¹⁵ and Dutch project NanonextNL ¹⁶. In these projects expertise on safe design, sustainable design and innovation processes is developed. However, the combination of safety, sustainability and circular goals is new to this approach, as well as the applicability for the early phase R&D. Also by performing new case studies, this project will contribute to build knowledge on combining safety, sustainability and circular design.

Textbox 1 Case study on algae as production platform for specialty chemicals.

Genetically modified (GM) algae are assumed to play an increasingly important role as production platform for specialty chemicals. Their recyclability as biomass means algae are generally considered a vital route to a biobased approach to circularity ¹⁷. However, industrial use of algae raises questions concerning environmental safety ¹⁸, sustainable supply chains to algae-based bio-refineries and societal acceptability of GM. Transitions in this field require both technological innovations and technical knowledge on safety and sustainability, and taking into account and relating to legal frameworks, policies and associated (executive) agencies dispersed over numerous layers of governance (from EU through national to water boards, safety regions and more), and accomodating societal perspectives and ethical acceptability.

Table 1: Potential circular design case studies of DIRECT. (For more details, see the work package descriptions below.)

Case	Specification	Transition agenda(s)	Case specific challenges	Possible opportunities
Algae	<i>CO₂ conversion by algae to (platform) molecules, short/ long cyclic, biotic.</i>	<i>Biomass & food/ Consumption goods</i>	<i>Biological safety, societal perception, moral acceptability, legal and regulatory frameworks</i>	<i>Contribution to energy transition and greenhouse gas reduction</i>
Plastics	<i>Medical devices, short cyclic, (a)biotic.</i>	<i>Plastics</i>	<i>Pharmaceutical residues, pathogens, endocrine disruption</i>	<i>Waste reduction, life time extension, bio-based substitution</i>
Solar panels	<i>Nanomaterials used for solar panel application in construction, long cyclic, abiotic.</i>	<i>Make industry/Energy transition</i>	<i>Safety of nanomaterials, possibilities for repair, refurbish and recycling</i>	<i>Contribution to energy transition, design for recycling</i>

(As described in this proposal, the performance of each case study will depend largely on data availability (and stakeholder commitment). If in the first period, one of the above-mentioned themes shows to be too challenging, alternatively, the theme textile will be explored for case study.)

4.2 Project relevance for RIVM's contribution to society

The project strives to become a showcase as regards aligning the demands of high-quality science and needs-driven community service. That is, we aim at developing independent and objective knowledge that is usable in practice by innovators - the prospected end-users of this project's outcomes. To optimally serve this dual purpose for society, we will collaboratively work towards user-friendly and fit-for purpose tool(s) to make integral assessments of safety and sustainability that innovators can use in early phases of their R&D trajectories for developing products, processes or services conducive to the circular economy. Moreover, such tool can also be of interest to regulators and policy-makers, or could be at the basis of products dedicated to these stakeholder groups. To this end, we follow a case-based approach in which we strive to include end-users as co-constructors, and in which pertinent stakeholders will be continuously engaged – be it as key informants (whose needs, wishes (structural) barriers and drivers are studied), as critical peers, or as audience. We select case studies using several criteria, including the priorities set by the CE transition agendas, so as to be aligned with societal challenges and political, industrial and academic work outside the RIVM. Furthermore, we will build on knowledge and lessons learned from international (RIVM) projects that reflect on relevant topics such as responsible research and innovation (RRI, project PRISMA) and SPR Sustainability Development Goals (SDGs), please also refer to work package 1 (lessons from literature and former projects). In doing so, we contribute to the RIVM's strategic positioning in the multi-actor and multi-level dynamics in which the transition to a circular economy takes place.

4.3 Approach, Planning and Design

For circular design to be safe and sustainable, it has to be fit for practice. Therefore, a number of case studies staging real-world experimentation form the core of the project. To this end, we set up a matrix organization (work packages 2-4) that facilitates an optimal interdisciplinary collaboration (with a project manager and cross-case study manager, wp 6), Figure 2.

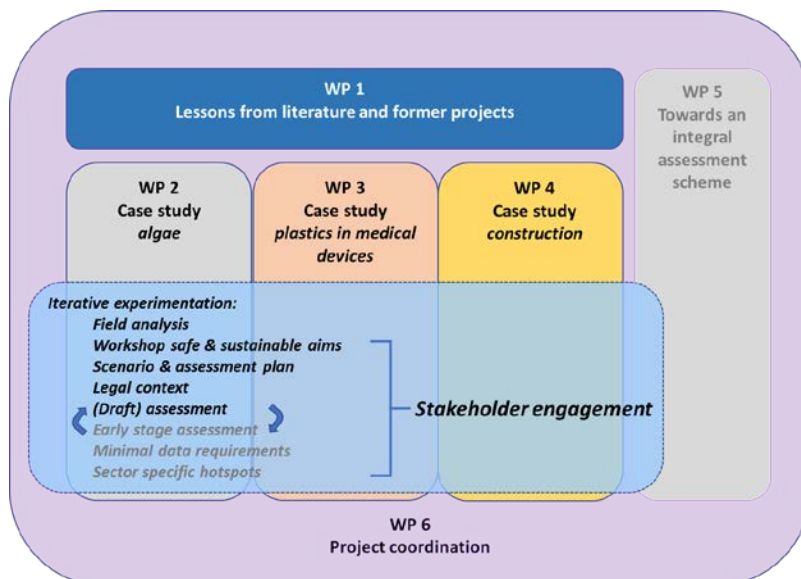


Figure 2: Schematic overview of work packages of DIRECT. Part of the iterative experimentation, as well as most of WP 5, would be optional work for month 24-48 (in grey text).

In this organization, social science elements are as pertinent as are natural scientific ones, as methods for knowledge co-construction play a central role throughout the project. In each case study, we will engage in a process of iterative experimentation in which the same elements recur:

- Before the case studies commence, in WP 1 (see Figure 2) we will draw lessons from the literature and from former projects on how the disparate values of safety, sustainability and circularity can be taken into account when making integral assessments (field analysis). We will combine this with a first inventory of potential relevant parties, making a stakeholder map.
- We then start with a workshop, back-casting circular design to fit safe and sustainable aims to support decision-making. This includes defining the indicators for safety and sustainability.⁴ Together with stakeholders, we delineate individual case study aims and distinguish between what one *needs* to do (minimally), what one *can* do (practically) and what one *desires* to do (ideally)¹⁹.
- Based on the concept of back-casting, we formulate scenarios of a specific (foreseen) circular design with the pertinent stakeholders and make a work plan (stakeholder specific).
- We investigate the relevant legal context and make an inventory of the pertinent assessment frameworks.
- We conduct integrated assessments with stakeholders, this builds on the solution-focused sustainability assessment approach ²⁰. The results will be reported as a fact-sheet with an overview of the (preliminary) assessment. For the potential second stage of the project (M24-48), we would like to apply a full assessment (being e.g. LCA, MCDA, CBA) and also perform an early stage assessment ²¹.
- For a potential second stage of the project (M24-48), we would compare and study an early stage assessment and integrated assessment in order to extract minimal data requirements and/ or proxies for safe and sustainable by design in the R&D phase.
- For a potential second stage of the project (M24-48), we would study (literature and case studies) sector specific needs and hotspots (e.g. landuse for bio-based products ²²).

Based on the case-specific outcomes of WPs 2 – 4, in WP 5 we will bring generic lessons together in an integral assessment scheme (approach or tool), including sector specific needs and proxies, where possible. The integrated assessment scheme that results from this project will not stand alone, it should be construct such that it fits with supplemental assessment methodologies for life cycle stages, further up in the value chain of the circular economy. The case study steps are described in more detail in the WP2 – 4 section. Ideally, there will be a platform (e.g. website) for regulators, authorization holders, industry, academia and consumers where they can find information or assessment strategies throughout each life cycle stage of the circular economy. Depending on the life cycle stage, and for instance a specific sector, tailored assessment approaches will show to help answer the question forehand. This means that we aim to align WP 5 with the other (CE) SPR projects wherein integrated assessments to support safety and sustainability play a role. (We foresee a close collaboration with the SPR CE coordinators for this task.)

WP 6 is responsible for project coordination. This entails practical project management and accountability tasks, as well as scientific coordination and facilitating stakeholder engagement, cross-case study comparisons and learning cycles. As the project strongly depends on stakeholder engagement, building networks in value chains and doing iterative assessments, we feel that two years is too short to set up, execute and report on this full project's aim (also taking into account possible subcontracting to private parties). We are aware that the call is for two years only, with possible outlook for consecutive projects. We have therefore made a planning for the coming two years, with specified tasks and deliverables, as well as an outlook on a possible planning of a consecutive CE SPR track. More information on the planning and deliverables can be found in the WP 6 section of this document, Table 2 lists the deliverables and Table 3 the project's proposed planning.

⁴ This will be done in collaboration with related SPR projects (e.g. QONNECT) where they will also use indicators for safety and sustainability.

4.4 Results and impact

Expected results are workshops, factsheets, reports and/or peer-reviewed articles, new networks, an online platform (48 months plan) with integrated assessment tool(s) and/or approaches for safe and sustainable circular-design (base on a tool data-base with user friendly interface). In the work packages deliverables are described in more detail. In WP 6 we will make a Data Management Plan (DMP) consistent with RIVM's protocol, yet optimally geared towards Open Access. Research data that is not privacy sensitive will be made available open access when possible. The target groups and their involvement, as well as the approach for dissemination and communication strategy, is described in WP 6.

4.5 Co funding and cooperation

Possible relations for funding opportunities can be the National Substances Policy Substitution & Innovation program, Safe Chemicals Innovation Approach Agenda, Safe by Design Program, Circular Economy Program, Dutch Climate Tables, Safe And Sustainable Loops Case assignment. Although programs generally, focus on safety, circularity or sustainability and lack the overall integrated approach as proposed in this project, part of the work of the project coordination of DIRECT is to look for co-funding in these before mentioned related projects, where possible. Opportunities for co-financing might also be found in European funding programs such as Horizon2020 or HorizonEurope. For instance, we are contributing to a submission for a NMBP H2020 call on boosting the efficiency of photosynthesis (biotec-02-2019), in which Safe-by-Design and sustainability considerations are key, and in which microalgae are central experimental platform organisms.

4.6 Facilities and infrastructure

Foreseen specific facilities needed for this project are the use of (external) data bases, the use or design of software for data sharing, stakeholder panels/focus groups, potential participation of CE living labs, Cirkellab networks or similar and setting up/maintaining an (digitally) organised platform.

5.1 Work package 1 - Lessons from literature and former projects

WP leader and expertise: Arianne de Blaeij, VSP (Social Economic Assessments, Costs Benefit Analysis, Environmental Economics)

The aims of this work package are to:

- Explore frameworks to evaluate specific case studies in an integrated manner (people, planet, prosperity), including HERA, LCA, CBA, MCDA approaches;
- Show how different indicators can be structured and presented to facilitate R&D decision making;
- Identify data gaps and plan how to address this in the case studies.

We will review literature on frameworks for the assessment of safety, sustainability and circularity, specifically with regard to the fields covered in the case studies of this project. This also includes how circularity is defined (indicators) by different methodologies (e.g.²³ R-ladder, alternative design (refuse), repair, refurbish, etc.). At least the following frameworks will be explored: Human and Environmental Risk Analysis (HERA), Life Cycle Analysis (LCA), Societal Cost Benefit Analysis (SCBA) and Multi Criteria Decision Analysis (MCDA). Each framework has its benefits and pitfalls²⁴⁻²⁶. For instance, CBA can reveal the relative attractiveness of a scenario, showing its net monetary benefit, but the validity of the monetary valuation for circularity and health or well-being is a serious concern that must be checked. HERA can show whether or not specific safety limits are crossed. Overall, for circular design to be safe and sustainable, a holistic (sometimes tailor made) approach is needed that includes indicators of safety, sustainability, circularity, health/wellbeing and societal expenditure (= financial affordability). Part of this work will focus on what the state of science is for circularity indicators, how these, if relevant, relate to the cascading biomass^{27,28} and the R-ladder²⁹. On top of that, these frameworks may be able to identify (and weigh) the distribution of these indicators (especially gains and losses) among stakeholders and in time (see for example the current political discussion on the climate law in the Netherlands). We will build on knowledge and lessons learned from outside (literature & stakeholder best practices) as well as relevant RIVM projects, amongst which are CleaR (EU), FISSH, Nanoreg2 (EU), PRISMA (EU), SPR Safe & Sustainable Bio-based Economy (SafeBBE), Safe & Sustainable Loops, SPR Sustainability Development Goals and Wat ligt er op ons bord.

Links with other work packages

This work package prepares for the case studies undertaken in work packages 2 – 4.

Deliverables WP1 (brief description and month of delivery)

- D1.1: Study report presenting an overview of existing reports, databases or peer reviewed papers about indicators and different assessment frameworks, including an analysis for applicability within this project (interim version M3, final version M8)

5.2 Work package 2 – 4 Circular Design Case Studies

WP 2 leader and expertise: Korienke Smit, VSP (Synthetic Biology, Science-Policy Interface, Stakeholder Engagement)

WP 3 leader and expertise: Bastiaan Venhuis. GZB (Pharmaceuticals, Health Assessments, Regulatory Compliance)

WP 4 leader and expertise: Joris Quik, DMG (Material Flow Modelling, Circularity Indicators, Environmental fate)

Cross-case studies coordinator of stakeholder engagement and knowledge co-construction methodologies: Pim Klaassen, VSP (Research and Innovation Governance, Transdisciplinarity, Safe-by-design)

Description

The aim of these work packages are to:

- develop aligned assessments of safety and sustainability of particular circular designs;
- align work towards the implementation of safe and sustainable circular design with designers' (endusers') needs, wishes and drivers and to help them overcome (perceived) problems and (structural) barriers.

We selected case studies using the following criteria:

- Pertinent to one or more transition agendas, so as to be aligned with societal challenges and political, industrial and academic work outside the RIVM;
- Both short and long cycles come into view, so as to increase the chance of developing more knowledge generalizable to different fields or sectors;
- Expertise from different centers within the RIVM is called for, so as to stimulate interdisciplinary collaboration;
- Relates to existing knowledge and networks, so as to ensure higher availability of data and bigger chance of uptake.

All case studies will conform to the same project plan, although where necessary or relevant, there can be flexibility in what this means in terms of scheduling tasks and activities. Among other elements, the project plan will encompass a plan for monitoring progress, including several go/no-go assessments. The first go/no-go assessment will take place in month three. If one of the cases does not lead to constructive cooperation and does not progress (e.g. lack of data, not in line with the private-public cooperation guidelines, issues with confidentiality), alternatively the theme textile will be explored as case study. The case studies aim to facilitate mapping possible safe and sustainable ways of designing the specific products of scope circular, identifying hotspots (see Textbox 2) and important indicators. For this to play out, throughout WPs 2 – 4 stakeholders will be engaged in various ways, depending on the phase and its specific aim. The approach will be interactive and adaptive. Together with stakeholders, attention will also be paid to collaboration within the chain and the challenges to be overtaken there like how experts in different fields can effectively communicate and collaborate (also learning from "Integraal Risico's Afwegen" ⁵).

Textbox 2: Hotspot and proxy

The term hotspot in this project DIRECT refers to an important issue or impact that is specific for a certain case or sector. Proxy refers to a specific impact that can be used to predict or represent a wider range of impacts. For instance, landuse can be a hotspot for biobased products and energy can be a good impact to predict greenhouse gas emissions. So, when using energy to also represent greenhouse gas emissions, this does not necessarily mean that it is also a hotspot, where a large impact is to be expected or seen.

⁵ http://wiki.rivm.nl/inwiki/bin/view/Integraal_Risicos_afwegen/WebHome

We foresee three case studies (see Table 1).

1. In this case study, we assess the potential for safe and sustainable use of algae as production platform for specialty chemicals, as well as its role in CO₂ valorization. For a description of the meaning of algae in the context of the biomass and food transition agenda, see Textbox 1. Genetically modified organisms carry with them environmental risks, the assessment of which is a task of the RIVM's GBV (Dutch Bureau Biotechnology "bggo"). Through the bggo, we have many relevant relations with relevant stakeholders, including researchers, companies, national and local policy makers and regulators and civil society organizations.
2. Medical devices are commonly made of plastics components. The type of plastics that are used is determined by patient safety, functionality and costs. Prompted by patient safety, most medical devices are single use only, resulting in a large amount of plastic waste. Reuse, repurposing or recycling of these plastics is challenging given the nature of their contamination (medicines, pathogens, etc.) and their increasing complexity (e.g. multi-polymer layered tubes in avoidance of plasticizers). In this case study we set out to investigate whether there is room for circularity in a highly safety driven environment. We want to identify obstacles and opportunities for circularity in the design, development and waste phase of medical devices. Hospitals, being hotspots for medical devices use, will be the starting point. Results will provide benefit to RIVM in the innovation platforms on medical devices that RIVM participates in (with e.g. MinVWS, Zin, MDCG, EU-COMM) and its role as expert laboratory on medical devices. This WP will reinforce RIVM's ability to make an integrated assessment taking human safety, product functionality, environmental burden and economic aspects into account to support the transition towards a sustainable society.
3. A possible casus, would be the design for circularity of rooftop solar panels. This is currently not elaborated here, but could be done in a potential next phase. Partners (CML, University of Leiden) already exist with relevant experience and network.

For each case study we have a basic approach. This can be adapted if during the process is shown necessary to stay fit for purpose (e.g. to fit end-users needs). The general steps are as follows (see also iterative experimentation, Figure 2) and based on previous SPR project experience and approach (SPR SafeBBE ^{20,21,30,31}):

1. Evaluation of context, and role of circularity within the context
 - ➔ Get insight in the context of the assessment. Developers get insight in the context of the safety and sustainability assessments for circular design (what is the goal of the circular design). Participants get insight in their own- and the other's views on sustainability. The goal is to define what is needed (minimally, e.g. technical or legal needs), what is possible and what not (practicality, implementation) and what is desired (ideally).
2. Question articulation
 - ➔ Specify questions and needs and define such that integral assessments can be matched (and gaps identified). Some of the questions addressed are shown as example, (adapted from SI ²⁰):
 - What is the goal of the assessment? Where should the assessment contribute to?
 - What is the central object of the question (a product, product group, ...)?
 - Which parts of the life cycle should be included?
 - How is circular design defined in the context of the case study?
 - Which sustainability themes are (thus) important to include in the assessment?
 - Which stakeholders that are not yet involved should be involved in this case study?
 - Will they have another view on the questions above then you just answered?
3. Backcasting workshop: Action plans
 - ➔ Action plans are made (steps defined) concerning what assessment (or set of) method(s) is needed, how this will support the decision-making in the R&D phase and how this contributes to circular design. The database of www.sustainabilitymethod.com will be used as a starting point (and updated from WP 1) to find suitable assessments and identify

- knowledge gaps. A time line is made for the case study, with needed data and stakeholders (who should be involved when). (Backcasting)
4. Selection of assessment methodologies
 - ➔ The DIRECT team evaluates and summarizes the outcome of the workshop (steps 1-3), makes a selection of possible assessment methodologies, and identifies possible knowledge gaps.
 5. Inventory of legal context
 - ➔ An inventory of possible relevant legal regulations, directives and guidance for the case studies will be made, on the basis of interviews with experts on legal matters pertinent to the case studies. Experts will both be recruited within the RIVM and in the chains identified in the case studies.
 6. Finalize action plan:
 - ➔ A proposal for approach is presented to the designers who participated the workshop and discussed. The action plan can be made final or refined.
 - ➔ The legal context is presented and reflected on (how this should be included/relevant in the case study).
 7. Drafting first calculations (and qualitative assessments)
 - ➔ The DIRECT team (if possible and relevant together with designers) fulfills the full-assessment method(s) (quantitative and/or qualitative).
 8. Reflect on first results:
 - ➔ Draft results are presented and reflected on (and checked with questions under step 2) together with designers.
 - ➔ Lessons learned identified and see how current methodologies may need to be made fit for practice (for the designer community)
 9. Conclusions and outlook (t=24 months)
 - ➔ **The aim of each case study is to have a preliminary assessment**, including a gap analysis (of the safety and sustainability elements needed and currently missing for circular design). The preliminary assessment will be reported in the form of a factsheet (report). In the kick off meeting of DIRECT a template for such factsheet will be drafted. This will be used during the project to track the progress of the case study and reflect on (together with the reviewers, stakeholders and SPR coordinators).
 - ➔ Identify next steps needed. Next steps could be to update current methodologies (or the interface/ accessibility of the methodologies) to make fit for practice (for the designer community) in order to support safe and sustainable, circular design.

Links with other work packages

These WPs builds on lessons from WP 1 and feeds into WP 5. Coordination between the different case studies undertaken in WP 2 – 4 is managed by WP 6. This helps warrant mutual learning between the case studies.

Deliverables WP 2 – 4

WP2 Case study algae

- D2.1: Stakeholder mapping and field analysis (algae) (M8)
- D2.2: Stakeholder workshop (algae) (M12)
- D2.3: Scenario and assessment plan (algae) (M18)
- D2.4: Legal context of case study algae (M20)
- D2.5: Fact sheets of case study algae (interim version M24, final version M36)
- D2.6: Data collection (algae) (M30)
- D2.7: Report and/or peer-reviewed article of the case study algae (M48)
- D2.8: Report on sector-specific hotspots & data requirements (M42)
- D2.9: Early stage assessment (M48)

WP3 Case study plastics

- D3.1: Stakeholder mapping and field analysis (plastics) (M8)
- D3.2: Stakeholder workshop (plastics) (M12)
- D3.3: Scenario and assessment plan (plastics) (M18)
- D3.4: Legal context of case study plastics (M20)
- D3.5: Fact sheets of case study plastics (interim version M24, final version M36)
- D3.6: Data collection (plastics) (M30)
- D3.7: Report and/or peer-reviewed article of the case study plastics (M48)
- D3.8: Report on sector-specific hotspots & data requirements (M42)
- D3.9: Early stage assessment (M48)

WP4 Case study Solar panels

- D4.1: Stakeholder mapping and field analysis (Solar panels) (M8)
- D4.2: Stakeholder workshop (Solar panels) (M12)
- D4.3: Scenario and assessment plan Solar panels) (M18)
- D4.4: Legal context of case study solar panels (M20)
- D4.5: Fact sheets of case study solar panels (interim version M24, final version M36)
- D4.6: Data collection (solar panels) (M30)
- D4.7: Report and/or peer-reviewed article of the case study solar panels (M48)
- D4.8: Report on sector-specific hotspots & data requirements (M42)
- D4.9: Early stage assessment (M48)

Outcomes

- RIVM's position in the Triple-Helix of Science, Government and Industry is strengthened, as it firmly establishes itself in the network of actors together responsible and required for making the transition to a circular economy.
- Societal problems are tackled, as steps in different socio-technical systems are taken in the transition to a circular economy.

5.3 Work package 5 Towards an integrated assessment

WP leader: Susanne Waaijers, VSP (Environmental Risk Assessment, Sustainability Assessments, Stakeholder Engagement)

Description

The aims of this work package are to:

- Fit, insofar as this is not done yet, the legal minimal requirement within or in parallel to the integrated assessment (desired safe and sustainable design targets). Also addressing the minimally, practically and ideally achievable requirements;

- Fit the assessment methodologies to stakeholder practice (e.g., fit methodologies to innovation stages);
- Provide guidance/structure for safety and sustainability indicators and preconditions in themes (people, planet, prosperity) and in scenario definition (setting scope of studied boundaries). These indicators and precondition can be used to assess the impact, limits, advantages, etc. of new innovations;
- Align with other CE SPR projects (alignment and harmonisation framework for different stages in the supply or life cycle chain).
- Combine these aspects in a practical tool (e.g. a website, (interactive) integrated assessment scheme), developed together with end-users.

Based on the case-specific outcomes of WPs 2 – 4, in WP 5 we will bring generic lessons together in an integral assessment scheme, including sector specific needs and proxies, where possible. Such integrated assessment scheme does not necessarily mean developing a new methodology. The integrated assessment scheme may also be an update of existing ones (incl. those reviewed in WP 1). Alternatively, the available and applicable R&D assessment methodologies can be structured and made fit for purpose.

The integrated assessment scheme (or approach) that results from this project will not stand alone, it should be construct so as to fit supplemental assessment methodologies for life cycle stages further down circular economy value chain. Accordingly, in WP 5 we will pursue alignment with the other (CE) SPR projects that work on integrated assessments to support safety and sustainability – in close alignment with the SPR CE coordinators. Ideally, there will be one online platform for regulators, authorization holders, industry, academia and consumers where they can find information or assessment strategies throughout each life cycle stage of the circular economy. Depending on the life cycle stage, and for instance a specific sector, tailored assessment approaches will prove to help answer question early on in innovation trajectories.

Links with other work packages and planning

This WP builds on lessons from WP 1 through 4 and potentially feeds back into WP 1. It also links with other SPR CE projects. We have made a planning for the coming two years, with specified tasks and deliverables, as well as an outlook on a possible planning of a second part of the project for the consecutive CE SPR, any deliverables that are part of this outlook are in grey.

Deliverables WP5

- D5.1: Meetings with other CE SPR projects (M6, M18, M24, M36)
- D5.2: Inventory of end user needs for platform development of integrated assessment (M24)
- D5.3: Beta version of online platform (M36)
- D5.4: Focus group (M40)
- D5.5: User-centered online platform (possibly update/build on an existing one) where various stakeholders can find information or assessment strategies that facilitate designing safely and sustainably for circularity (M48)

5.4 Work package 6 Project Management

WP 6 leader 1 and expertise: Susanne Waaijers, VSP (Environmental Risk Assessment, Sustainability Assessments, Stakeholder Engagement)

WP 6 leader 2 and expertise: Pim Klaassen, VSP (Research and Innovation Governance, Transdisciplinarity, Safe-by-design)

Description

The aims of this work package are to:

- To conduct an efficient management process, ensuring that the project is carried out as planned;
- To warrant throughout the entire project duration that high quality research is carried out, leading to useful products that will prove to make an impact;
- To facilitate each collaborator's obligations;
- To explore additional financial support to sustain this project (Min. EA, Min. I&W, EU H2020, NWO);
- To disseminate project approach and results;
- To effectively communicate with SPR coordinators and to see to it that SPR's strategic goals are attained.

Together with the coordinator of the "stakeholder engagement"-track in WP 2 – 4, the project manager will set up an Advisory Board (AB) containing relevant stakeholders and experts, plan and organize regular meetings with the AB and safeguard that follow-up actions on advice given by the AB.

The project manager will write management reports, monitor budget, expenditures and compile financial reports, and coordinate the submission of deliverables and reports, see Table 2 for the list of deliverables of this project and Table 3 for the DIRECT Gantt chart. Moreover, in this WP we will make a Data Management Plan (DMP) consistent with RIVM's protocol, yet optimally geared towards Open Access. Research Data that is not privacy sensitive will be made available open access when possible. We will also make an plan for dissemination activities, in cooperation with the communication department. The plan will distinguish between facilitating (external) communication and dissemination ensuring practical impact and application. These different goals require different actions in the project's timeline. In the first months of the project, the project leaders will draft a communication plan with the communication department, this will be updated and reflected on during the project. A final dissemination plan will be delivered in month 18.

Stakeholder involvement

Figure 3 shows the expertise of involved RIVM and external parties (non-profit, network organizations, knowledge institutes) of this project. This will be used as a starting point for the stakeholder engagement. The stakeholder engagement will also be in close alignment with other relevant SPR (CE) project leaders and the coordinators.

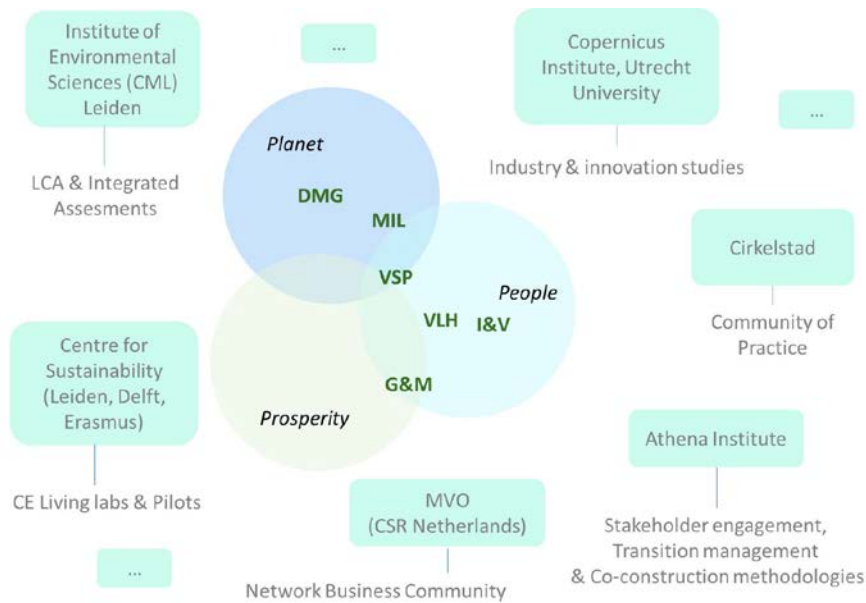


Figure 3: Expertise of involved internal (RIVM) and external (non-profit, network organisations, knowledge institutes) partners of DIRECT. The expertise shown here reflects the relevant expertise of the partners for the project, with expected input and scope. The field of research may be wider than reflected here, for each of the shown stakeholders.

We aim at developing independent and objective knowledge that is usable in practice by innovators - the prospected end-users of this project's deliverable. These end-users will of course be one of the stakeholders or even co-constructors. Additional end-users might be e.g. licensing authorities or educational institutions. However, many other parties may be involved, for example researchers, companies, national and local policy makers and regulators and civil society organizations. These stakeholders will be continuously engaged, be it as key informants (whose needs, wishes (structural) barriers and drivers are studied), as critical peers, or as audience. Also, as a part of every case study, a stakeholder mapping and field analysis will be performed and a stakeholder workshop will be organized.

In the first months of the project the different goals of stakeholder participation will be formulated after which a stakeholder analysis, based on the various goals, will be done. As the goal of the involvement of the end-users differs from other stakeholders, the way that they will be involved in the project will also be different.

Links with other work packages

WP 6 will coordinate the different research teams across project activities; the choice of case studies conducted in WPs 2-4 and inter-case learning cycle WPs 2-4. Moreover, in WP 6 overall performance of the project will be monitored to oversee that quality standards are met and timely submission of deliverables is achieved. This includes making risk analyses and, where necessary, contingency plans.

Deliverables WP6

- D6.1: Case study monitoring plan (go/no go criteria, reflecting on progress) (M3)
- D6.2: Open data management plan (M6)
- D6.3: Dissemination plan (M18)
- D6.4: Management review (with potential evaluation for second stage of the project) (M24)
- D6.5: Final management review (M42/48)

Table 2: List of deliverables (outlook for potential second stage of the project M24-48 in grey)

Number of deliverable	Title	Short description	Date of delivery
D1.1	Inventory of indicators and assessment frameworks	Study report presenting an overview of existing reports, databases or peer reviewed papers about indicators and different assessment frameworks, including an analysis for applicability within this project	Interim version M3 Final version M8
D2.1	Stakeholder mapping and field analysis (algae)	Identification of stakeholders, based on previous expertise, projects and D1.1	M8
D2.2	Stakeholder workshop (algae)	Identification of user needs and barriers for the case study algae.	M12
D2.3	Scenario and assessment plan (algae)	Based on results of the workshop and D1.1, a selection of assessment frameworks will be recommended to be applied within each case study	M18
D2.4	Legal context (algae)	Inventory/ overview of the legal context relevant for the algae case study.	M20
D2.5	Fact sheets of case study algae	Short presentation in a fact sheet of a (preliminary) safety and sustainability assessment performed for the case study algae	Interim version M24 <u>Final M36</u>
D2.6	Data collection (algae)	Collect additional data for final integrated assessment for the algae case study	M30
D2.7	Report and/or peer-reviewed article of the case study algae	Report presenting the (potential) end users' needs, wishes, drivers, (perceived) problems and (structural) barriers including an integral assessment of safety and sustainability in particular circular designs for the case study algae	M48
D2.8	Report on sector-specific hotspots & data requirements (algae)	Report describing hotspots and data requirements which are needed for early stage assessment	M42
D2.9	Early stage assessment for algae case study	Report on minimal data needs	M48
D3.1	Stakeholder mapping and field analysis (plastics)	Identification of stakeholders, based on previous expertise, projects and D1.1	M8
D3.2	Stakeholder workshop (plastics)	Identification of user needs and barriers for the case study plastics.	M12
D3.3	Scenario and assessment plan (plastics)	Based on results of the workshop and D1.1, a selection of assessment frameworks will be recommended to be applied within each case study	M18
D3.4	Legal context (plastics)	Inventory/ overview of the legal context relevant for the plastics case study.	M20
D3.5	Fact sheets of case study plastics	Short presentation in a fact sheet of a (preliminary) safety and sustainability	Interim version M24

		assessment performed for the case study plastics	Final M36
D3.6	Data collection (plastics)	Collect additional data for final integrated assessment for the plastics case study	M30
D3.7	Report and/or peer-reviewed article of the case study plastics	Report presenting the (potential) end users' needs, wishes, drivers, (perceived) problems and (structural) barriers including an integral assessment of safety and sustainability in particular circular designs for the case study plastics	M48
D3.8	Report on sector-specific hotspots & data requirements (plastics)	Report describing hotspots and data requirements which are needed for early stage assessment	M42
D3.9	Early stage assessment for plastics case study	Report on minimal data needs	M48
D4.1	Stakeholder mapping and field analysis (solar panels)	Identification of stakeholders, based on previous expertise, projects and D1.1	M8
D4.2	Stakeholder workshop (solar panels)	Identification of user needs and barriers for the case study solar panels.	M12
D4.3	Scenario and assessment plan (solar panels)	Based on results of the workshop and D1.1, a selection of assessment frameworks will be recommended to be applied within each case study	M18
D4.4	Legal context (solar panels)	Inventory/ overview of the legal context relevant for the solar panels case study.	M20
D4.5	Fact sheets of case study solar panels	Short presentation in a fact sheet of a (preliminary) safety and sustainability assessment performed for the case study solar panels	Interim version M24 Final M36
D4.6	Data collection (solar panels)	Collect additional data for final integrated assessment for the solar panels case study	M30
D4.7	Report and/or peer-reviewed article of the case study solar panels	Report presenting the (potential) end users' needs, wishes, drivers, (perceived) problems and (structural) barriers including an integral assessment of safety and sustainability in particular circular designs for the case study solar panels	M48
D4.8	Report on sector-specific hotspots & data requirements (solar panels)	Report describing hotspots and data requirements which are needed for early stage assessment	M42
D4.9	Early stage assessment for solar panels case study	Report on minimal data needs	M48
D5.1	Meetings CE SPR projects	Meetings with other CE SPR project to harmonize terminology (content) and layout (interface) of foreseen platform/ dissemination	M6, M18, M24, M36
D5.2	Inventory of end user needs for platform development of integrated assessment	Integration of identified end user needs, described in D2.2, D3.2 and D4.2	M24
D5.3	Beta version of online platform	Implement content in online platform (beta version)	M36
D5.4	Focus group	Focus group with end users in order to make	M40

		the interface user friendly	
D5.5	Online platform	User-centered online platform (possibly update of an existing one) where various stakeholders can find information or assessment strategies that facilitate designing safely and sustainably for circularity.	M48
D6.1	Case study monitoring plan	Formulating go/no go criteria to reflect on progress of case studies throughout the project	M3
D6.2	Open data management plan	Report describing an open data management plan for this project	M6
D6.3	Dissemination plan	Report presenting the dissemination plan of the project results	M18
D6.4	Management review	Review & potential evaluation for M24-48	M24
D6.5	Final management review	Final management review	M42/M48

Table 3: DIRECT Gantt chart, with go/no-go evaluation planned at month 24.

			Year 1									Year 2												Year 3												Year 4														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
TASK	START	END																																																
Work package 1	1	8																																																
D1.1	1	3-8																																																
Work package 2	4	48																																																
D2.1	1	8																																																
D2.2	4	12																																																
D2.3	4	18																																																
D2.4	9	20																																																
D2.5	9	24-36																																																
D2.6	25	30																																																
D2.7	25	48																																																
D2.8	25	42																																																
D2.9	37	48																																																
Work package 3	4	48																																																
D3.1	1	8																																																
D3.2	4	12																																																
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D3.9	37	48																																																
Work package 4	4	48																																																
D4.1	1	8																																																
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6 Budget and authorization



6.1 Budget calculation

Budget required for 24 months is 475,000 euros, for 48 months would be 950,000 euros. No budget is required from the additional programs “Nieuwe methodieken en meetmethoden” and “Perceptie en gedrag”. The required budget (5%) for communication and dissemination activities will be reserved. The detailed budget calculation is submitted separately in IPB-format.

6.2 Statutory regulations and required permits

The foreseen required RIVM regulation at this point is the public private partnerships (PPS) guidelines, potentially subcontracts and a data management plan.

6.3 Authorisation

(Signatures are only required once the project plan has been approved by the RIVM management board)

Project leader (=RIVM opdrachtcoördinator)

Date

SPR coordinator(s)

Date

Head of RIVM Centre

Date

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