

RIVM & BIPRO

CleaR



Clean material Recycling project

European Commission – DG Environment, Brussels
Directorate B, Circular Economy & Green Growth
ENV.B.2 – Sustainable Chemicals

CleaR



Clean material Recycling project

Study for the development of an evidence-based approach
as support to regulators when assessing how to manage the
presence of substances of concern in recycled materials -

proposed by the Dutch National Institute for Public Health and the Environment (RIVM) and BiPRO (part of the Danish Ramboll group).



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



Part of Ramboll Environ

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Contents

1	Clean material recycling (CleaR) project introduction — 5
1.1	Introduction to the consortium — 6
1.2	Approach taken in this project and consortium objective — 13
1.3	Project plan and rationale — 14
2	Task 1: Selection of appropriate hazard categories and test substances — 17
2.1	Context — 17
2.2	Methodology — 17
2.3	Output and deliverables — 21
3	Task 2: Mass Flow — 22
3.1	Context — 22
3.2	Methodology — 22
3.3	Output and deliverables — 29
4	Task 3: Exposure — 30
4.1	Context — 30
4.2	Methodology — 30
4.3	Output and deliverables — 34
5	Task 4: Socio-economic impacts — 35
5.1	Context — 35
5.2	Relevant methodologies — 35
5.3	Output and deliverable — 40
6	Task 5: Framework — 41
6.1	Context — 41
6.2	Methodology — 42
1.2.	Output and deliverables — 46
7	Task 6: Standard flow chart — 47
7.1	Context — 47
7.2	Methodology — 47
7.3	Output and deliverables — 51
8	Task 7: Variable parameters for setting limit values — 52
8.1	Context — 52
8.2	Methodology 53
9	Main deliverables and overall planning — 56
9.1	Timing of actions by task — 56
9.2	Deliverables — 56
11	Management structure and procedures — 58
11.1	Project management — 58
11.2	Managing procedures — 59
11.3	Reports and meetings — 60
11.4	Risk management — 61

12 Annex 1: References — 63

1 Clean material recycling (CleaR) project introduction

To achieve a circular economy it is essential to recycle substances, materials and products created by that economy. Recycling, however, becomes more difficult when said materials and products contain substances that are so hazardous that their use is restricted. Potential conflicts may arise during the waste stage, under the Waste Framework Directive, and under the REACH Regulation when recycled material is brought on the market again.

The purpose of this project is CleaR: clean material recycling. The project team will build on previous know how and expertise gathered on similar topics, e.g. how to distinguish material streams, which SVHCs occur in which material streams, whether removal of SVHCs is possible or whether it is possible to set certain limits. The objective is clear: an evidence-based framework assessing how to manage the presence of substances of concern in waste and recycled materials and their potential adverse effects on human health and the environment.

Just recently the new head of the European Chemicals Agency (ECHA) Bjorn Hansen stated that regulating chemicals in recycled materials is a key challenge for ECHA in his inauguration address. He questioned whether we want exactly the same standards for recycled materials, or do we want higher levels of exemption in order for recycling to occur? Industry¹ and NGO's² both have their different views on circular economy and there is a need for an objective, transparent, framework to assess the pro's and con's of recycling materials containing hazardous substances in order to support policy makers.

The interface between waste and REACH is on the European policy agenda and has been on the Dutch policy agenda since 2013 when the Netherlands submitted a discussion paper to CARACAL12. BiPRO carried out a study on certain waste related issues on POPs already in 2005. This interest resulted in a number of reports produced in our Centers and in input in the REACH and POP frameworks on this topic. RIVM currently carry out work focusing on similar topics, e.g. how to distinguish material streams, which SVHCs occur in which material streams, whether removal of SVHCs is possible or whether it is possible to set certain limits for the Dutch Human Environment and Transport Inspectorate and the Dutch Waste registration at Rijkswaterstaat.

RIVM and BiPRO have a strong combined knowledge of waste regulation, risk management of hazardous substances, environmental and human health risk assessment, circular economy and sustainability, life cycle analysis, and socio-economic impacts. In addition, the Dutch Competent Authority (CA) for REACH is based at the RIVM as well. This provides the project team with insights on current discussions about the interface between waste and REACH and will add to the practical implementation

¹ <https://chemicalwatch.com/57958/cefic-reach-and-clp-appropriate-for-regulating-circular-economy>

² <https://chemicalwatch.com/59609/greenpeace-premature-circular-economy-threatens-detox-campaign>

of the proposed framework. In addition, RIVM has first-hand experiences as Dossier Submitter and Rapporteur for several REACH restriction dossiers.

1.1 Introduction to the consortium



**National Institute for Public Health
and the Environment**
Ministry of Health, Welfare and Sport

The **National Institute for Public Health and the Environment** (RIVM) is a recognised leading centre of expertise in the fields of health, nutrition and environmental protection. RIVM shares its knowledge with governments and supranational bodies around the world. The results of our research, monitoring, modelling and risk assessment work are used to underpin policy on public health, food, safety and the environment. The RIVM Act guarantees the scientific independence of the institute. In this regard, it is important to note that Ministers cannot issue instructions as to how research is conducted or reported. A Supervisory Committee monitors the scientific quality at RIVM. We employ over 1400 employees, many of whom work in multidisciplinary fields.

In 2015 RIVM published 149 reports and 802 scientific publications in leading international journals, of which 119 reports and 759 articles in English. RIVM has a proven track record regarding the execution of EU funded projects. Our researchers are members of more than 200 international expert committees of the EU, WHO, OECD and other international organizations and provide scientific advice for policy development. RIVM regularly performs research and provides advice to EU agencies such as EFSA, EEA, ECDC and EMA.

Within RIVM, the **Centre for Safety of Substances and Products** (VSP) is a major expert centre for the risk assessment of chemicals for the Dutch government. VSP is complementary in many research areas and co-ordinate and execute legal Tasks on risks of chemical substances. Within a multidisciplinary setting, information and knowledge is combined to advice governmental departments and international organisations. The centre also cooperates with other institutes in this field in the Netherlands to develop a public network of knowledge and information on chemicals. VSP includes Bureau REACH, which act as the Dutch CA for the REACH and CLP regulations and which host the helpdesk for both regulations.

Relevant key expertise:

- Human and environmental risk assessment of chemical substances
- Consumer and product safety
- Safe by design
- Innovation and substitution activities
- Industrial chemicals
- Biocides and pesticides
- Bio-based and circular economy
- Socio-economic analysis
- Stakeholder participation
- Legal frameworks

Within RIVM, the **Centre for Sustainability, Environment and Health** (DMG) uses its knowledge on the impact of environmental quality for improving the health and wellbeing of people and ecosystems. The centre works for the sustainability of our society so that presently and in the future, sustainable use can be made of our environment. The environment can then be used as optimally and sustainably as possible for the long-term quality of life. This includes sustainable use of natural resources such as raw materials, energy sources, and material and energy cycles. In addition, we analyse the effectiveness of environment and climate change measures to support the government in focusing policy on these issues.

Relevant key expertise:

- Impact directed policy on sustainability, air, drinking water and noise
- Impact of environmental measures on the health and welfare of people and the ecosystem
- Sustainable use of resources and ecosystems
- Methodology development to assess measures and deviation from standards
- Epidemiological and toxicological research on the health impacts of environmental burden
- Experience studies in relation to impact of environmental factors
- Health impact assessment and integrated considerations
- Contributing to government information on environment, public health and ecosystem services
- Knowledge platforms bringing different stakeholders together
- Solution focused sustainability assessment (incl. Life cycle analysis, e.g. ReCiPe)

RIVM is well connected to the European REACH network in general and also well informed about the process of submitting a REACH Restriction dossier in particular. Staff from RIVM VSP and Bureau REACH, on behalf of the Ministry of Infrastructure and Water Management, executes tasks within all REACH and CLP processes since the adaption of these Regulations. With regard to regulatory management and specifically restrictions, the experience started already under the Existing Substances Regulation (Regulation 793/93/EEC) and the Limitations Directive (Directive 76/769/EEC). RIVM's relevant work for restrictions include screening activities the results of which are discussed in the Risk Management Expert Meeting (RiME). RIVM performs multiple screening

activities to identify potential restriction candidate substances such as looking for SVHC restriction candidates in the framework of the SVHC roadmap, organizing, coordinating and analysing signals (e.g. by enforcement agencies) on newly emerging risks (environment, worker, consumer) and analysing the need for restriction as a follow-up from substance evaluation, compliance check or harmonized classification and labelling .

RIVM has experience as an early restriction dossier submitter for N-Methyl-2-pyrrolidone (NMP), a restriction that has now been decided upon at policy level. Currently, RIVM, in cooperation with ECHA, is working on a restriction proposal on polycyclic aromatic hydrocarbons (PAHs) in rubber granules used on synthetic turf pitches. This dossier is highly relevant within the scope of this tender as it focusses on end-of-life tire recycling and deals with all relevant risk related issues and socio-economic issues that are typical for many recycling cases. In the context of RAC and SEAC involved RIVM staff has experience in reviewing many other relevant restriction proposals in which exemptions for recycling were considered such as the recent proposal on lead stabilizers used in PVC materials and the restrictions for decaBDE and PFOA and its related compounds. For these dossiers RIVM also contributes to the decision making in REACH Committee by providing policy advice and representing the Netherlands on behalf of the Ministry of Infrastructure and Water Management.

In a range of projects for the Ministry of Infrastructure and Water Management and Rijkswaterstaat (responsible government body for the implementation of national waste legislation) RIVM currently carries out work on the interface between REACH and waste. In these projects, the focus is on the identification of SVHCs in waste streams and whether removal of SVHCs is possible or whether it is possible to set certain limits for the Dutch inspectorates and the waste registration. We are working in close contact with the Ministry of Infrastructure and Environment and have provided them with relevant policy advice for the NL-CA intervention in the scope of the Commission 2017 public consultation of the Chemicals, Products and Waste interface. We also have many years of experience in executing NL tasks in the scope of the POP Regulation and Stockholm convention. In addition, our experts are involved in the ECHA Restriction Efficiency Task Force.



Part of Ramboll Environ

BiPRO (www.bipro.de) was founded in 1999 in Munich as „Beratungsgesellschaft für integrierte Problemlösung“ (consultancy for integrated solutions). Since June 2016 BiPRO is part of the Danish Ramboll group and supports the global business sector Environment & Health, Ramboll Environ.

BiPRO provides support to national and international ministries, authorities, trade associations and companies with respect to environmental and health related affairs. The German Environmental Agency (UBA), European Commission (EC), European Chemicals Agency (ECHA), and European Central Bank (ECB) can be mentioned as most important clients. Moreover, BiPRO supports the Environment Program of the United Nations (UNEP) and United Nations Industrial Development Organization (UNIDO) as well as the World Bank (WB). Another focus of activity is the strategic and technical support of various industrial companies and associations.

Public and industry clients appreciate that we deliver a wide range of services within complex thematic fields, interdisciplinary, quick and efficient yet sound and reliable and with a high quality standard. We successfully support and elaborate solutions and policy recommendations related to technical, economical-technical and technical-ecological questions in several languages and are accepted in different regions and cultures all over the world as service provider. For several years BiPRO closely collaborates with Ramboll Environ and on June 23, 2016 Ramboll has acquired BiPRO GmbH. The merger of BiPRO, which is kept as part of Ramboll Environ until further notice, and Ramboll Environ is the logical consequence of the close and long-term collaboration. For the herein offered consultancy service the collaboration with Ramboll Environ is envisaged as well.

Ramboll Environ (www.ramboll-environ.com) is a global consultancy offering highly skilled consultancy services with regard to a variety of technical, scientific and strategic questions in the context of environmental and health topics. With more than 2,100 specialists around the world, thereof 100 in Germany, Ramboll Environ elaborates innovative solutions in the field of Environment & Health. The focus of consultancy is placed on the fields Chemistry, Pharmacy, Automotive, Facilities and Private Equity.

Ramboll, which is privately owned, is the leading engineering, design and consultancy company in Northern Europe with the head office located in Copenhagen. With more than 13,000 employees and 300

offices in 35 countries the Danish group is one of the largest international consultancy groups. Ramboll combines local expertise and global know-how in the business units Buildings & Design, Transport & Infrastructure, Urban Planning and Design, Water, Environment & Health, Oil & Gas and Management Consulting. In Germany, Ramboll is now employing 400 specialists in 10 offices.

Within the context of the project at hand, it is relevant to note that BiPRO:

⇒ **Has in-depth knowledge in risk management and hazard assessment of POPs and other chemical substances regulated under REACH**

Members of the project team have been involved in various projects and activities with respect to hazard and risk assessment of chemical substances in the past years. Examples are projects on the elaboration of risk profiles and management option dossiers and other documents in the frame of the EU Commissions international work on POPs for several substances such as for PFOA, its salts and related compounds, PFOS and related substances, SCCPs, HCBd, PCN, PCP, Endosulfane, Trifluralin, commercial octa-BDE, chlordecone and hexabromobiphenyl as well as evaluation of risks resulting from PCB contamination in food and feed material (including European sampling and measurements) and two projects related to implementation of limit values for POP in the EU POP Regulation. Members of the project team have also experiences in elaborating safety reports related to chemicals in the scope of Council Directive 96/82/EC (Seveso II Directive). Since 2015 BiPRO consults the Norwegian Environment Agency in the frame of several projects with respect to the management of DecaBDE containing waste regarding Norway's activities under the Stockholm and Basel Conventions. A current project concerns assistance of the Norwegian Environment Agency in data collection and analysis related to the proposal to list PFHxS under the Stockholm Convention [Ref. 3]. BiPRO is expert in the field of POPs and POPs candidates, including risk management and phasing-out of intentionally produced POPs, and drafting of proposal of actions to be taken at EU level for implementation of Stockholm Convention and POP Regulation requirements. The first POP related projects realised by members of the project team have been carried out almost 20 years ago. Members of the project team have been involved in numerous projects and activities with respect to POPs. This includes the collection of available data, development of mass flows for the assessment of individual life cycles and process steps, discussion of limit values for POPs in environment and waste, sampling and analyses of certain POPs and impact assessments. BiPRO has been closely involved in preparation of previous projects concerning releases, sources, environmental levels and fate of POPs and POP candidates [See Annex 1, ref. 6, 17, 25, 27, 30, 43, 48, 50].

⇒ **Has excellent experience with collection, compilation, management and analysis of data and drafting and critically analysing statistics for EU legislative targets**

The project team has shown in various projects that it has excellent experience in critically analysing statistical data, including the analysis and quality check of data from Eurostat and further data bases. In many projects team members were responsible for data collection, compilation of statistics and also analyzing existing statistics including data quality checks. Several of such projects concerned POP waste and content limits [Ref. 54, 43, 39]. Furthermore, the project “Ratification of the Minamata Convention by the EU – complementary assessment of the mercury export ban” for the European Commission is highlighted as it included critically analysing and comparing of mercury export data to check the quality of the data and identify possible data gaps and illegal exports [Ref. 29].

⇒ **Has excellent expertise in EU waste legislation and waste management**

BiPRO has carried out a large number of projects regarding the implementation of waste legislation at European scale including all 28 EU Member States and has profound knowledge and vast experience with administrative, legal, technical and economic issues of waste management. BiPRO has actively contributed to support the correct implementation of the environmental EU acquis, in particular in the waste sector throughout several assignments by means of assessing the implementation at EU-Member State level, legal analysis, expert workshops and information exchange events, preparation of guidance documents on EU waste legislation and expert contribution to and participation in twinning projects and the IMPEL network. BiPRO performed studies as regards the implementation of the Waste Framework and the Landfill Directive, the Waste Shipment Regulation, the WEEE Directive, several Decisions and assignments as regards the POPs Regulation, Chemical EU legislation, the Minamata Convention and others.

BiPRO led several EC Framework contracts issuing waste legislation and waste management (2007-2012 EC FWC on ‘Advice and services related to accompanying measures for implementation of waste legislation’, 2009-2011 EWC on ‘Assessment and guidance for implementation of EU waste legislation in Member States’, since 2013 FWC on ‘Assistance to the Commission on the assessment of Waste Management Plans and on compliance monitoring and support of the implementation of the Waste Framework Directive’ and since 2014 also the FWC on ‘Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation’ [Ref. 34, 46].

⇒ **Has experience in drafting recommendations for EU and national legislative targets and legal requirements, most notably, in the field of EU POPs legislation.**

The development of a set of recommendations for policy makers on EU and national level are an integral part of the project work BiPRO is realising.

Many of the projects carried out by the project team included the analysis of information and subsequent drafting of possible solutions and recommendations. Examples are listed in Annex 1 e.g. “Evaluation of monitoring data for POPs, candidate POPs and their substitutes in order to better explain reasons, pathways and trends of their occurrence in the environment” [Ref. 25], “Contribution to the implementation of the objectives of the Stockholm Convention (restriction and elimination) from relevant applications of specific POPs – “Implementation of the Stockholm Convention in Germany” [Ref. 9], “Assistance to the Commission in view of the EU becoming a party to the Minamata Convention on Mercury” [Ref. 35], “Ratification of the Minamata Convention by the EU – complementary assessment of the mercury export ban” [Ref. 29].

The projects “Investigation on POP containing waste and recyclates – proposal of POP limit values” [Ref. 39] on behalf of the German Environment Agency and “Study on waste-related issues of newly listed POPs and candidate POPs” [Ref. 43] and “Study to facilitate the implementation of certain waste related provisions of the Regulation on Persistent Organic Pollutants (POPs)” [Ref. 54] realised on behalf of the European Commission were all related to the task to derive and propose appropriate POP-content levels.

⇒ **Has experience in stakeholder consultations, exchange with stakeholders’ experts, workshop organisation and proceedings of questionnaires**

Stakeholder consultation has been part of many projects carried out by BiPRO. Members of the project team hold know how of the different procedures of carrying out surveys and consultations either by questionnaires, targeted telephone interviews or commenting rounds (commenting on prepared documents). This includes the preparation of stakeholder lists to be included in the consultation/survey and the preparation of follow-up templates in order to track the provided information, the preparation and conduction of such consultations/surveys and the post-processing. The project team uses different ways to make sure that the information is wide spread and enough feedback is received. Recent projects where stakeholder consultations were performed are the assessment of all documents, opinions, questionnaires and records of conferences for revising the circular economy package [Ref. 55] and a consultation for the official EU guidance documents on the classification of hazardous waste [Ref. 33] including beside authorities, companies, associations and operators.

BiPRO has successfully organised many workshops for different topics, e.g. about 50 information exchange and awareness-raising seminars on landfill of waste, shipment of waste and waste management planning/waste prevention. Another series of 10 workshops has been realised within the project on the ‘Support to Member States in improving waste management based on assessment of Member States’ addressing the national Ministries of Environment, other authorities and involved stakeholders and a high level meeting in Brussels.

1.2 Approach taken in this project and consortium objective

According to our understanding, the general context of this study concerns the intersection of the EU's efforts to ensure a high level of protection for health and the environment from exposure to substances of concern and its efforts to facilitate the recycling of waste as part of its 7th environmental action programme (7th EAP) and its circular economy action plan.

In its 7th EAP the EU has set itself a priority objective to safeguard the Union's citizens from environment-related pressures and risks to health and well-being. As a sub-objective, the EU has decided to set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products.³ The Commission has translated these aims into concrete policy actions through various legislative efforts concerning, inter alia, persistent organic pollutants in products and waste (POP regulation), hazardous substances in electric and electronic equipment (RoHs Directive) and the registration, evaluation, authorisation and restriction of chemicals (REACH regulation).

On the other hand, the 7th EAP sets another priority objective of turning the Union into a resource-efficient, green and competitive low-carbon economy. One of the sub-objectives in this regard is the development of the European market for secondary raw materials.⁴ More specifically, the Commission has laid down the concrete policy actions for this aim in its circular economy action plan. A key ambition of the Commission in this regard is the stimulation of recycling of key waste streams. This ambition has been translated into initiatives related to, inter alia, the aim to set new recycling targets and the development of quality standards for secondary raw materials, as well as proposals on the improvement and clarification of rules on the 'end-of-waste' status (in the legislative proposal, part of the Circular Economy Package).⁵ In the same action plan, the Commission recognizes the importance of addressing the issue of substances of concern in recycled materials for the uptake of secondary resources in the economy. The Commission therefore concludes in its action plan that it will "develop an analysis and propose options for action to overcome unnecessary barriers while preserving the high level of protection of human health and the environment."

The described intersection between the EU's aims of a non-toxic materials cycle and the circular economy has been raised in further detail in the Roadmap on the interface between chemical, product and waste legislation (CPW interface).⁶ Most notably, the Roadmap mentions two obstacles related to the substances of concern in recycled materials:

³ Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (7th EAP), annex, par. 50

⁴ Ibid, annex, par. 40

⁵ Closing the loop - An EU action plan for the Circular Economy (CEAP), Brussels, 2.12.2015 COM(2015) 614 final, p. 12

⁶ Roadmap - Analysis of the interface between chemicals, products and waste legislation and identification of policy options, European Commission, Brussels, 27.01.2017

1. Limited information is available about the presence of substances of concern in articles, material streams and recycled materials which affects the ability to monitor compliance of recovered materials (and articles produced thereof) with relevant legislative requirements
2. Currently there is no general framework to deal with the presence of substances of concern in recycled materials and in articles made thereof and, in particular, no agreed methodology to determine the overall costs and benefits for society of the use of recycled materials containing such substances compared to disposal of, or energy recovery from, the waste and the impacts of production of virgin materials in case recycling is prevented.

Recent studies and projects, issued by the Commission or other stakeholders have already addressed aspects of the described obstacles. In particular, these studies and projects concerned issues such as the tracking of hazardous substances under REACH, the promotion of non-toxic product innovations and priority materials and sectors to drive the circular economy.

According to our understanding, this study should aim to combine the focus and findings of previous studies and projects and to complement any knowledge and focus gaps, in order to provide the Commission and Member States a solid scientific basis for addressing the key obstacles described in the Roadmap on CWP interface.

1.3 Project plan and rationale

In figure 1.5 the link between the different tasks set out in the call for tender is shown.

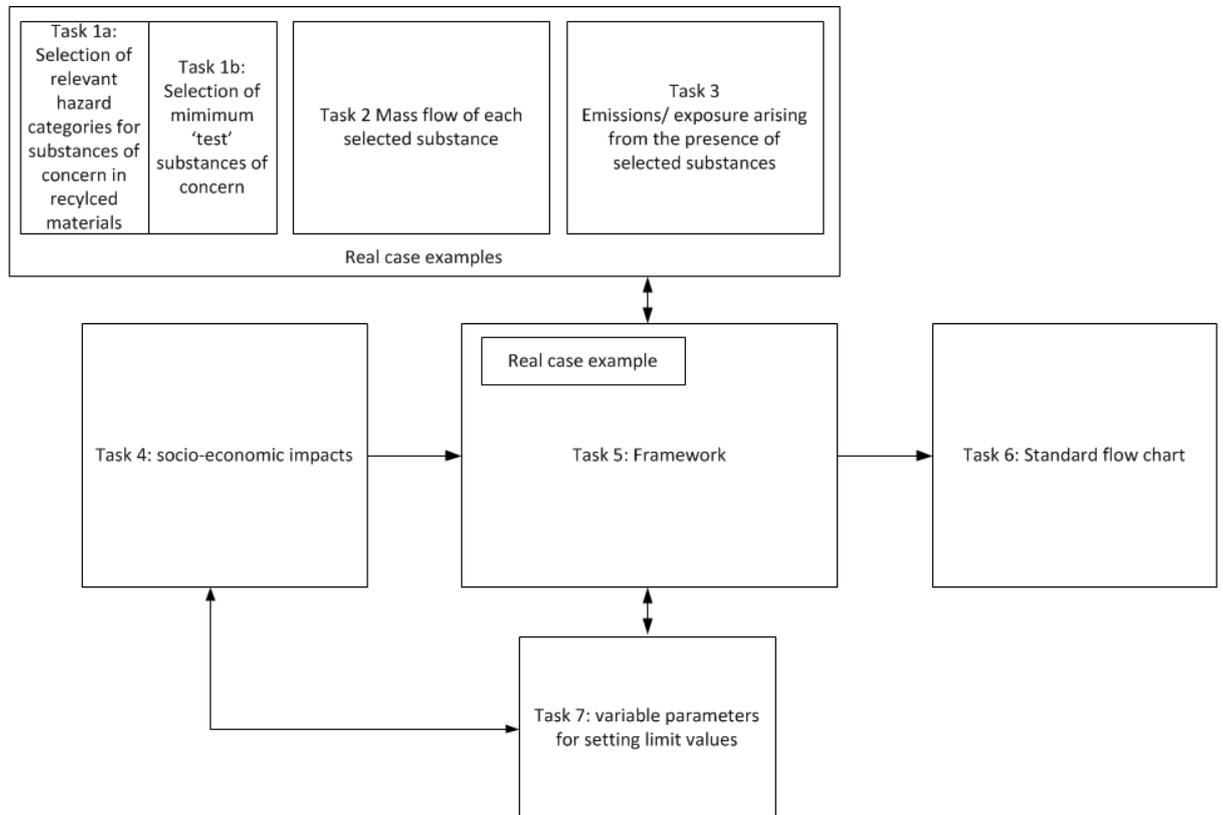


Figure 1.5: Linkage of the different tasks

In the first three tasks in-depth knowledge will be obtained about the presence and fate of substances of concern in products, waste and recyclates. This will improve the Commission’s knowledge base about substances of concern in material flows. The information collected in **task 1-3** will also feed into **task 5**; the development of a framework that will enable regulators involved in the preparation REACH restriction proposals to carry out an evaluation of the need for a potential derogation to allow some use of recycled material containing the substance of concern. This framework will contain strict criteria based on the socio-economic elements identified **task 4**, the type of variables that could be used for setting limit values in **task 7** and other elements that need to be considered (e.g. enforceability, control and confinement possibilities). If a recycling derogation would be considered when preparing a restriction dossier, **task 6** will develop a flow-chart for the dossier submitter, taking into account all information generated in the previous tasks.

The offered cooperation between RIVM and BiPRO with regard to the current tender offers various combinations of knowledge and skills which ensure an accurate, thorough and well-substantiated execution of the envisaged tasks.

1. Governmental and consultant: RIVM and BiPRO offer the combination of the policy-oriented and academic-based approach of a governmental research institute as RIVM with the industry-specific and practice-oriented approach of BiPRO. As such, this combination will be able to offer the required balance between policy goals and practical

achievability, which will be essential for the simultaneous attainment of the goals of circular economy and toxicant-free material cycles.

2. In-depth knowledge of hazardous substances and waste management practices: both parties of this consortium offer extensive experience and deep practical knowledge with regard to important areas of risk management, hazard assessment and waste management practice and regulation. Together, the parties of this consortium cover a wide range of relevant substances such as POPs and metals. In addition, both parties have gained highly relevant experience with regard to waste management and recycling practices and policies through their work for government organisations within the context of the EU's legal framework on waste management and, more specifically, the circular economy.

3. Case-specific and EU-wide knowledge: this consortium combines national and case-specific knowledge of hazardous substances and recycling of RIVM with a more general EU-wide overview of BiPRO. This will enable the consortium to identify relevant data and case studies which will feed into the various tasks.

2 Task 1: Selection of appropriate hazard categories and test substances

2.1 Context

Reuse and recycling (next to safe and circular design) of products are key elements in a circular economy. Previous studies showed that a great number of material streams contain various hazardous substances, which may hamper safe recycling options for these materials (European Commission 2011; Janssen, Spijker et al. 2016; Janssen and van Broekhuizen 2016; Wassenaar, Janssen et al. 2017; Wassenaar, van Leeuwen et al. 2017). Examples for some of the priority materials and sectors are organotin as additive in plastics, flame-retardants in plastics, dyestuffs and pigments in textile, and heavy metals in agricultural waste streams.

The future European waste policy aims to overcome unnecessary barriers for a circular economy, while preserving the high level of protection of human health and the environment. Managing substances during safe recycling makes knowledge on the presence of substances in products or material streams, the impact of waste treatment processes on these substances and the corresponding legislation of paramount importance.

It is difficult to get a complete overview of hazardous substances in material streams, because their application may vary among different sectors, as well as in time, and information on the actual concentrations in waste is often lacking (European Commission 2017). The heterogeneity of material streams and used waste treatment processes make a generic approach challenging. If hazardous substances are monitored or removed during the waste treatment process, this is often only done when specifically relevant upon waste becoming a new product. At that interface the material leaves the area of the European waste legislation and enters that of the REACH regulation or other relevant product legislation.

Task 1 entails:

- The selection of hazard categories
- The selection of test substances of concern per hazard category

2.2 Methodology

Step 1.1: Selection of hazard categories

First step in the development of an evidence-based approach for safe and sustainable recycling is to identify appropriate hazard categories and to select test substances.

Appropriate hazard categories for substances in material streams are proposed as identified in article 57 of the REACH regulation. These hazard categories are considered to be most relevant for the interface between chemical, product and waste legislation, because the ultimate aim is to substitute and/ or eliminate substances in products with these hazard categories. Next to vPvB and PBT substances (as mentioned in the tender specifications), substances with carcinogenic, mutagenic

and/or reproductive effects category 1A and 1B are considered to be relevant as well. A variety of hazard categories is recommended as different categories may have specific issues during and after recycling. During recycling occupational and environmental health related end points may be specifically relevant, whereas after application, during the use phase, consumer exposure may be more prominent. We propose to start the project with substances from the hazard categories vPvB, PBT, carcinogenic (cat. 1) and/or reprotoxic (cat. 1). Their negative health and environmental effects may be enhanced during multiple life cycles in a circular economy. For instance, persistent chemicals may build up in concentration during multiple life cycles. To prevent discarding potential valuable resources containing persistent chemicals, adequate risk management is required specifically for such hazard categories. The proposed hazard categories vPvB, PBT, carcinogenic (cat. 1) and reprotoxic (cat. 1), as well as additional categories and explanation on their relevance is given in Table 2.1. This table can be used as a starting point for discussion with the Commission to select relevant hazard categories and substances (together with Table 2.2).

Table 2.1: Endpoint hazard categories, their properties and relevance in a circular economy.

	Hazard category	Threshold (T)/ Non-threshold (NT)	Acute (A)/ Chronic (Ch)	Rationale
	Persistent, Bioaccumulative & Toxic, PBT	T & NT	A & Ch	Because of the intrinsic physical-chemical properties of PBT substances, these chemicals may persevere in certain materials and material streams. PBT substances may exert their negative environmental and health effects during multiple life cycles and are therefore of particular concern in the circular economy.
Environment	very P & very B, vPvB	NT	Ch	Very persistent and very bioaccumulative chemicals will remain or even build up (depending on processing techniques used) during multiple life cycles and can form a risk if, for example, plastic material streams are recycled.
	Persistent and Mobile Toxicants (PMTs) or Persistent Mobile Organic Compounds (PMOCs)	NT	Ch	Potential new hazard category under discussion with various international regulators mainly due to perseverance of persistent (and toxic) substances in water supply chains.
Human	Carcinogenic (H350)	T & NT	Ch	The presence of non-threshold carcinogenic or mutagenic compounds can pose a threat (during and) after recycling, as low concentrations may still have negative health consequences.
	Mutagenic (H340)	T & NT	Ch	
	Reprotoxic	T	A & Ch	Keeping reprotoxic chemicals in the loop is

	Hazard category	Threshold (T)/ Non-threshold (NT)	Acute (A)/ Chronic (Ch)	Rationale
	(H360)			a serious concern (during and) after recycling as they can have negative impact on multiple generations. The effects may well be indirect or retarded, irreversibly influencing the next generation, even beyond the one exposed.
	Specific target organ toxic, STOT RE, SE (H372, H370)	T	Ch	Chemicals that are toxic to specific target organs after repeated exposure may be of concern in the circular economy. If they are kept in the loop, repeated dosing is more likely to occur with each life cycle.
	Neurotoxic	T & NT	Ch	Several metals (Mercury and Lead) are neurotoxic at low doses and are present in current material streams.
	Endocrine disruption, ED	T & NT	Ch	Keeping endocrine disrupting chemicals in the recycling loop is of serious health concern as the health and environmental consequences can be large and impact multiple generations. There are various uncertainties around EDC and the effects may well be indirect or retarded, irreversibly influencing the next generation, even beyond the one exposed.

Step 1.2: Selection of test substances of concern per hazard category

The project offers the possibility to choose substances already covered by restriction or authorisation under REACH or substances with emerging and newly identified concerns. We suggest focusing on already covered substances initially, as **data** on mass flow, exposure and socio-economic impact are likely to be present and these may deliver the general principles in developing an evidence-based framework (cf page 20 of the tender specifications).

We recommend selecting both **organic and inorganic substances** for this project. Removing metals from a matrix uses different techniques and encounters different problems compared to removing organic hazardous substances from material. In contrast to organic substances, metals cannot be irreversibly transferred. Once present in the technosphere, there are limited options for disposal.

Core in the REACH regulation is ensuring a **high level of protection of human health and the environment** from risks arising from the application of substances. Starting point in the protection are the limit values set for the presence of various substances in new mixtures or products. For a number of substances a derogation for recycling is granted, for some other substances this has not been the case. In case of a derogation various considerations may play a role. Costs and benefits of the derogation are weighed, the derogated application should be clear and it should be relatively narrow defined and the derogation will be allowed for a limited time and may include a review clause. In the case of legacy substances present in waste, application of the

criteria from 'normal' derogations may be more complicated by the fact that the influx of the substance depend on the life cycle of the material containing the substance of concern. A selection of substances for which dossiers under REACH have been prepared should provide a good starting point for the study.

The ultimate aim of European policy is to minimise and finally eliminate vPvB, PBT and CMR substances. So, total volume of a material stream, as well as the substances' concentration is **relevant** in setting priorities and thus in selecting substances for this study, but should be combined with potential applications and exposure to the recycled material. Small material streams with substances causing relevant exposure are interesting in terms of measures, but large material streams where the concentrations in new applications stay under the limit values may be interesting as well. We propose to discuss some relevant substance/material streams/sector combinations in the kick off meeting. Building on our knowledge and expertise, the project team will propose several substances of concern relevant for the REACH-waste interface, which have been or are (potentially) prioritised for either restriction or authorisation. Some examples are provided in Table 2.2.

Table 2.2: Non exhaustive list of examples of possible substances to be selected in order to develop an evidence-based approach to manage the presence of substances in recycled materials

Hazard category	Substances	Material stream	Sector
PBT	Brominated Diphenyl Ethers (BDEs) (commercial Penta, and OctaBDE)	Plastics	Transport, Electronic and electrical equipment, Furniture,
	Hexabromocyclododecane (HBCDD)	Plastics	Building and construction, Electronic and electrical equipment, Textiles
Persistent	Perfluorooctanesulfonic acid (PFOS)	Plastics	Packaging, Furniture
	Perfluorooctanoic acid (PFOA)	Wood and paper	Packaging, Furniture
vPvB	Short-chain chlorinated paraffins (SCCPs)	Plastics (Rubber)	Transport, Building and construction
	Short-chain Per- and Polyfluoroalkyl Substances (PFASs)	Plastics, wood and paper	Packaging, Furniture, Textiles,
PMT	Cadmium or Lead	Plastics (PVC)	Building and construction
Carcinogenic	Poly aromatic hydrocarbons (PAHs)	Plastics (Rubber)	Transport, Building and construction
	Mineral oil aromatic hydrocarbons (MOAH)	Paper and paperboard	
Mutagenic	Lead	Plastics (PVC)	Building and construction
Reprotoxic	PFOS	Plastics,	Packaging, Furniture, Textiles
	PAHs	Plastics (Rubber)	Transport, Building and construction
	Diethylhexyl phthalate (DEHP)	Plastics (Soft PVC)	

The project team is open to discuss with the Commission whether some newly identified substances of concern in recycling, such as cobalt in

chemical and ceramic uses, mineral oil aromatic hydrocarbons (MOAH) in paper and organotin in plastics (PVC), could be addressed as well and be used as input in task 6 and 7. The final identification of the substances, relevant material streams and sectors to be selected will take place in collaboration with the Commission in the kick off meeting. To summarize, during the selection of the most relevant hazard categories, substances and material streams with the commission, we propose that the following criteria will be taken into account:

1. A variety of hazard categories is recommended, as different categories may have specific issues during and after recycling.
2. A variety of type of substances is recommended, as different physical-chemical properties will result in different behaviour during and after recycling and different perspectives for risk management.
3. Variation in material streams and sectors is desired, as a substance can cause a problem in a particular material stream, but not necessarily in all.
4. Differentiate in available processing or recycling techniques; as these may influence the risk that a substance will pose.
5. The volume (EU, produced, imported, foreseen) of a particular substance and the material stream is very relevant for potential risks (exposure) and risks measures.
6. Potential applications of the recovered material; as next to volume, chosen applications and category of use will determine exposure as well.
7. Finally, data availability is addressed to ensure the feasibility of task 1 and the project.

2.3 Output and deliverables

Task 1 will provide:

- Proposed list of hazard categories, substances and material streams to be discussed at the kick off meeting. At the kick off meeting a selection will be made, in cooperation with the Commission. The selection will be minimally two substances per selected hazard category.
- Selected hazard categories, substances and material streams as focus point of the project. After the kick off meeting, the selection will be refined and complemented with available data where necessary.

3 Task 2: Mass Flow

3.1 Context

The development of a framework as described under task 5 of this tender, as well as the exposure and socio-economic impact assessments, will require knowledge of occurrence and fate of each selected substance of concern in products, waste and recyclates based on the identified priority materials and sectors for that test substance. Mass flows provide an effective tool for the compiling and schematising such information per selected test substance.

Task 2 entails:

- The identification of required information and data sources.
- Supplementing identified information with questionnaires
- The compilation of the identified information
- Establishment of mass flows

3.2 Methodology

Step 2.1: Identification of required information and data sources

The structure of required information and results will be established and appropriate information sources will be identified in order to enable a systematic and objective driven collection of data and transparent reporting of results. The information has to be structured according to the information needs of the mass flows and can be categorised as follows:

- data on occurrence and levels in different wastes, recycled articles/materials and articles in use
- data on types of articles recycled or produced from recycled material, extent of recycling, environmentally sound waste management and potential associated releases
- data on occurrence and levels in articles/materials that might be recycled in future
- data on existing concentration limits in waste
- data on processes using the selected substances
- data on recycling and other management operations for the selected substances
- data on concentrations of selected substances in production processes (current and historic) and options for the environmental management of their operation and potential related releases

The project team will establish a proposal for a detailed draft information structure within the first 2 weeks after the project start in order to discuss the structure with the responsible Commission personnel already during the kick-off meeting. The proposed information structure will also enable the start of the drafting of questionnaires as described in step 2.2. As an outcome of the kick-off meeting the information structure will be adjusted and improved correspondingly until week 5 (inception report) of the project running time and will at the same time provide essential input for the questionnaires.

In addition to the identification of information needs, it is essential to identify the relevant information sources. To this end in a first step, available databases, statistics and reports will be identified. Additional input is expected from the evaluation of the feedback to the questionnaire. The following is an indicative list of selected information sources for databases, statistics and reports:

- Information that is available at international Conventions, such as the Stockholm convention, the Basel Convention, etc.
- Relevant reports and any other material available at the EU Commission or other European institutions such as the EEA, Eurostat or the European Chemicals Bureau
- If relevant, information accessible via national and international emission inventories (e.g. PRTR) in particular those established as a consequence of CLRTAP
- National and international waste statistics, databases / reports from the Member States and international institutions (such as UNECE, UNEP, FAO, WHO, OECD, IARC, IFCS)
- Information from industry associations and individual industry stakeholders
- Stockholm Convention BAT-BEP Guidelines and other relevant documents from the Stockholm or Basel Convention websites
- BREF documents for the relevant industry sectors
- EEA databases for emission and waste
- ISWA country reports
- Other

Step 2.2: Questionnaires

The main objective of this step will be the collection of information from competent authorities, scientific institutions and other relevant experts via questionnaires. More specifically, the questionnaires aim to supplement the information collected under step 2.1 and address any information gaps. The project team will draw from previous experience with contacting stakeholders within the context of previous studies on waste containing POPs on EU level (see Ref. 54, 43) and national level for the German EPA (see Ref. 39), as well as, questionnaires carried out within the context of other relevant studies concerning REACH and/or waste management projects.

Based on experience in previous studies on POPs waste (refs. 54, 43, 39) and bearing in mind the varied characteristics, occurrence, industrial application and waste treatment operation for the selected substances; the questionnaires will be adapted to the envisaged respondent. This will enable the project team to collect specific or technical information in a more effective manner. In addition, the number of questions can be limited to the ones most relevant for the addressed respondent. Consequently, this approach would create two main forms for questionnaires:

- A questionnaire e.g. for competent authorities and scientific institutions, containing questions related to all (or at least most of the) selected substances. To this end, the project team will draw from questionnaires which have been used in previous project and which can be adapted according to the specific project needs.

- A questionnaire for individual companies, industry associations and specialized scientific institutions, containing more specific questions, geared towards the collection of industry-specific information on specifically one or more of the selected substances.

All questions will be drafted in close cooperation with the Commission. The project team will provide first drafts of the questionnaires to the Commission for comments.

With regard to the relevant Member State institutions, the project team will make sure that all responsible ministries and/or other relevant national authorities will have the chance to provide answers to the questionnaires, as well as other relevant information if necessary.

Relevant Member State institutions

- Responsible Ministries
- Competent enforcement authorities
- National (research) institutes

As for other stakeholders, the selection of respondents for the questionnaire will include an adequate number per following categories:

Scientific institutions and research bodies

- Relevant universities
- Research bodies of international organisations

Relevant industry representative bodies and specific industry actors

- Representative bodies of industries
- Specific industry actors with key knowledge/information

NGO's

- For example. EEA, Greenpeace, Zero waste Europe, Chemical watch

With regard to the selection of specific respondents from scientific institutions, relevant industries and NGO's, the team will draw from the list of respondents used for previous EU and national studies on POP waste and Other relevant studies concerning REACH and/or waste management. This list will be complemented with new stakeholders, connected to the selected substances. A draft list of stakeholders will be shared and coordinated with the Commission to ensure that all relevant stakeholders are covered. Individual experts who are identified in the course of the research and who are able to deepen the existing information and fill data gaps will be selectively contacted.

The replies of respondents will be documented (also telephone interviews), analysed and compared to available literature and other information sources, compiled as part of step 2.1.

Contradicting/complementary sources will be highlighted and information gaps will be identified. If necessary, follow-ups with stakeholders will be carried out for additional information and elaboration on sources of interest. A summary of the answers of respondents will be included in the final report of this study.

Step 2.3: Compilation of information

All identified information sources and the questionnaires will be compiled and evaluated. The evaluation will, among other information sources, serve as input into mass flows, as well as the exposure and socio-economic impact assessments and the establishment of variable parameters. Thus, this step will form a crucial part of the project work. Compilation will be structured by source sector and topic and will concentrate on the compilation of all relevant information as regards technologies and activities that are relevant for the use, occurrence and recycling of the selected substances. In particular, it will comprise the aspects:

- Occurrence and levels of selected substances in different waste categories, recycled articles and articles in use, namely articles that might be recycled in future
- Types of articles recycled or produced from recycled material, extent of recycling, environmentally sound waste management and potential associated releases
- Processes using selected substances
- Recycling and other management operations for selected substances in articles
- Concentrations of selected substances in production processes
- ESM options, recycling operations and potential related releases
- Data on existing concentration limits in waste

Information will be compiled in Excel matrixes by substance and activity and will focus on information such as generation factors (waste/ton process activity), contamination data (compilation of data, averaging) and activity data (EU statistics for source sectors). Emission factors into waste/product will be used if available.

In addition, information will be compiled on activities and technologies relevant for generation/dissemination of selected substances. This will be a compilation of all processes (source sectors) that significantly contribute to the generation of waste and recycled articles containing selected substances including details on the corresponding technological characteristics as far as possible. This step serves as basis for the mass flow analysis and helps to identify the probability that relevant wastes have not been taken into account in the mass/waste flow model in order to enable to further improve the coverage ratio in the future. Such assessment will be based on a comparison of potential source sectors with data availability. The results are to be summarised in a chapter on waste streams not covered.

Finally, the compilation will include a rough assessment of the present and expected importance of the relevant activities and an assessment of typical "substance emission factors" or "waste generation factors" for activities according to the range of size and capacity of activities. The compilation of activities will finally include simplified process schemes for the technologies and activities.

Step 2.4: Mass flows

The final part of this WP will be to conduct an analyses for the establishment of mass flows for relevant substances (in the following designated as "substance flows") in wastes, recycled articles and articles in use (in the following designated as "material flows"). Depending on

the availability of relevant data, mass flows will be established at European scale for different waste categories, recycled articles and articles in use containing selected substances. The mass flows will be investigated and presented by source sectors in relevant industries, i.e. technologies and activities that significantly contribute to generation of waste containing selected substances or to further dissemination in recycled articles and articles in use and substance/ substance group. The mass flows will be done separately by substance and activity and indicate:

- The volume of waste, recycled article or article in use
- The typical range of selected substance concentration

The information on the occurrence of the relevant substances/ substance groups and the corresponding substance and mass flows enable conclusions on substantial points:

- Relevance of certain selected substances and materials for the path waste, product and recycle
- Comparison of the relevance of different selected substances and related materials
- Comparison of the relevance of different source sectors
- Comparison of the relevance of waste treatment and recovery options for the different selected substances and related material flows
- Comparison of the relevance of possible input of the selected substances into the environment (due to the handling of waste: energy recovery or disposal, respectively material recovery)
- Availability of information and identification of knowledge gaps especially regarding the presence of the selected substances in products, waste and recyclates

The applied mass flow model will follow the principle of the preceding studies on POP waste which were already successfully performed by the project team [Ref. 54, 43, 39], and will differentiate to have a macro dimension (overall mass balance) and a micro dimension (inputs and outputs at process level) where possible. The project team will aim at using data representative for the situation in the European Union. Information on the data sources used and assumptions made will be provided.

Starting point in the mass flows is the generation of the waste and the material recycling of contaminated material. Articles in use containing the relevant substances are a third group of activities that could be investigated. Finally, there will be an illustration of processes related to the use selected substances.

The mass flows will be calculated by means of a computer based system as done in previous projects [Ref. 43]. Main input parameters are activity data (such as historic and current production and/or consumption volumes), waste generation factors (including information on the lifetime and life-cycle of relevant articles) and specific contamination data for solid residues and/or recycled materials in EU Member States as far as accessible in international data bases and literature plus unpublished data directly communicated by industry associations, scientific experts or NGOs. Based on these data figures on annual quantities of the various substances in residues from important

source sectors and articles will be calculated. Calculation will be done on EU 28 level.

The overall mass flows (macro-dimension) indicate the relative importance of annual flows to wastes, articles and recycling to materials in relation to emissions to the environment established on EU level. The calculation is based on average values and Member State specific values will be made available if possible. Extrapolations will be used when necessary. Information on the data sources used and assumptions made will be provided.

The following example figure shows the comprehensive principle of substance and material flow on macro-level. The figure has been adapted to indicate the most relevant flow of selected substances through the product, waste and recycling phases. Key aspects have been coloured red.

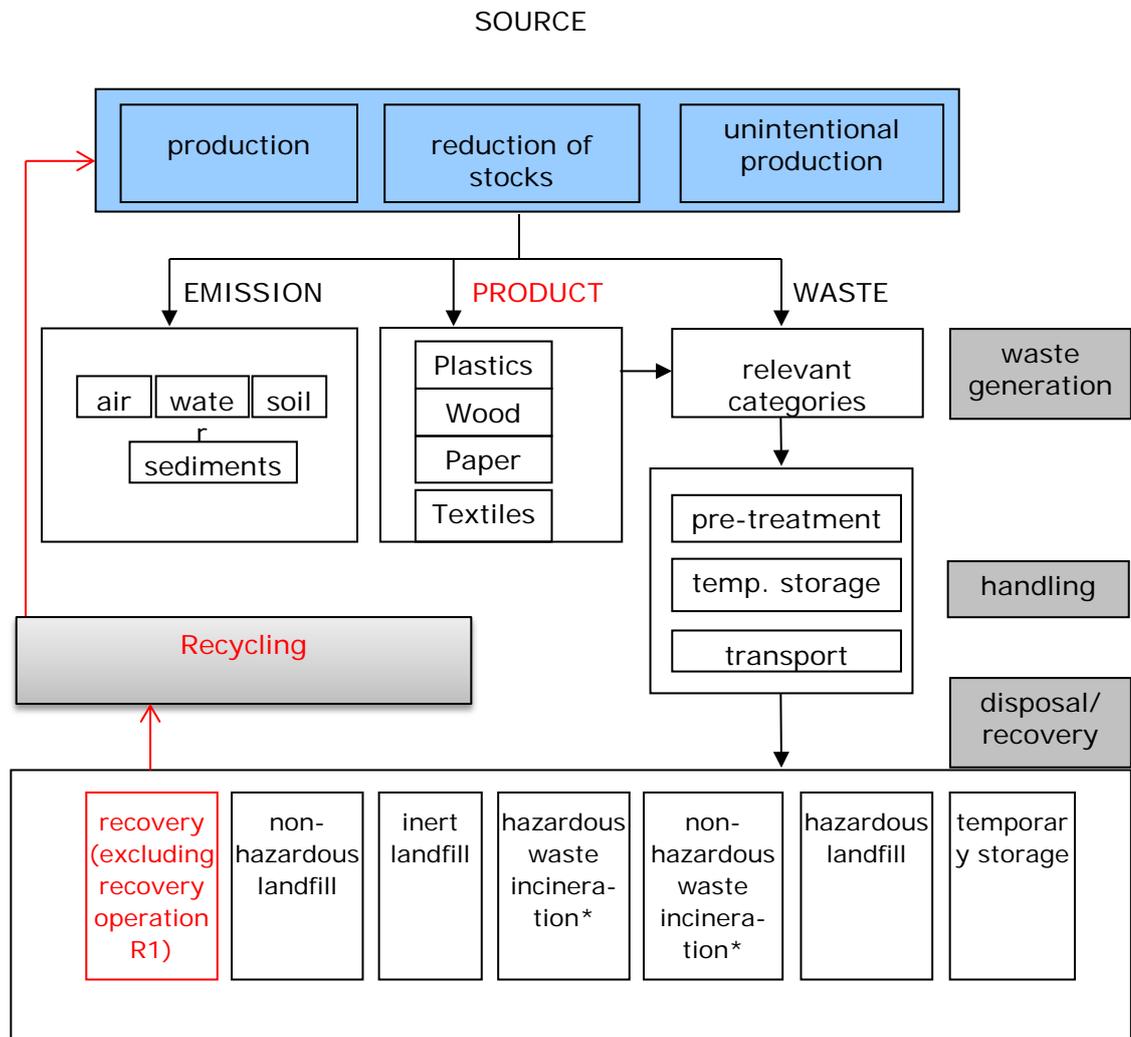


Figure 2.1: Principle of substance and material flow on macro-level

For the different selected substances, the project team can create mass flows which single out more/most relevant parts of the overall macro-mass flow. This could be one activity within the comprehensive mass

flow which requires specific attention. The following example figure shows a mass flow by substance and source/treatment method as envisaged for previous POP waste studies. Bearing in mind the objectives of this tender, the mass flows for substances by activity in the current study will focus on activities relevant for the flow of selected substances into the product cycle.

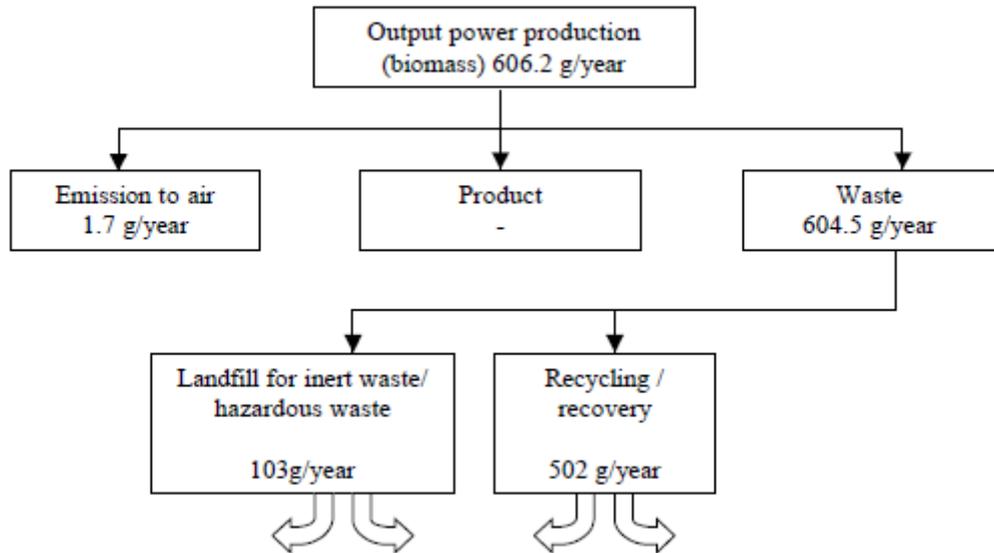


Figure 2.2: A mass flow by substance and source/treatment method as envisaged for previous POP waste studies

Together with the macro dimension, there can be a "micro dimension" focusing on relevant inputs and outputs at process level. This will include the internal flow charts of the processes of the macro dimension. The following figure shows the principle of a mass flow on a micro-dimension level for a selected substance (example taken from a study on POP waste [Ref. 43]). Bearing in mind the objectives of this tender, the micro-level mass flows for the current study will be focussing on the flow of selected substances into recycled material and products after recycling.

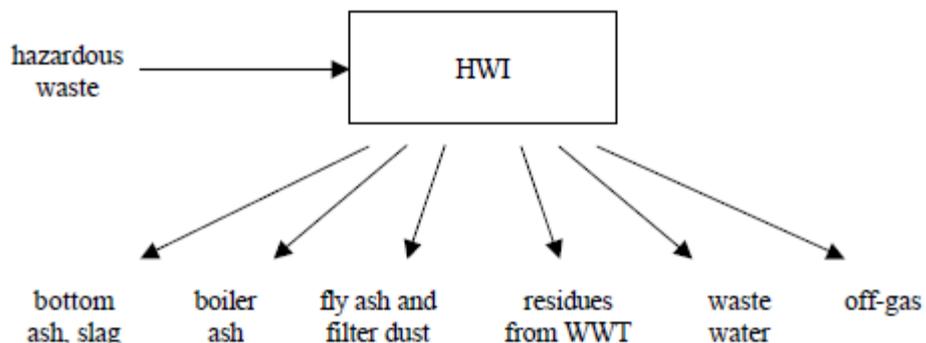


Figure 2.3: The principle of a mass flow on a micro-level

The micro dimension will provide information on capacities, on relevant inputs and outputs and statements on the likelihood and the range of output streams containing selected substances including mass volumes and concentrations to the extent possible. Based on detailed mass flows the importance of source sectors for releases of selected substances into waste and recycled material can be quantified and illustrated. Such quantification forms a valuable basis for task 3 and task 4.

As in the previous studies on POPs waste [Ref. 39, 43, 54], the results of the substance and material flow, as well as their elaborations, will be used to extend and specify the data gathered during the preliminary research. Based on more specific substance and mass flows and additional relevant information on the occurrence of the selected substances in products and waste as well as on their treatment, an overview can be generated which shows the sectors in which the substance flows typically occur and which risks arise from the corresponding waste and recyclates. The product lifecycle time of the relevant products and currently applied waste treatment and recycling operations will also be taken into account including possible degradation of the substance of concern during these processes.

3.3 Output and deliverables

Task 2 will provide:

- Macro-level mass flows per selected substances and materials
- Relevant micro-level process related mass flows for selected substances and materials
- Overview showing the sectors and materials in which the substance flows typically occur and which risks may arise from the corresponding waste and recyclates

4 Task 3: Exposure

4.1 Context

Investigation of the emissions and exposure arising from the presence of each selected substance of concern in products, waste and recyclates will primarily be based on a generic life cycle assessment (LCA) methodology. LCA is an analytical tool for the (comparative) environmental assessment and covers the entire life cycle. All relevant resource consumption and emissions are quantified with respect to an 'functional unit' (FU), and the related potential impacts on a number of categories (e.g. human health, ecotoxicity, etc.) are estimated. In order to make results of task 3 more relevant, the project team will complement the LCA with a risk assessment (RA) methodology, which will identify actual emissions and exposure in specific situations. By using a RA methodology, the likelihood of harmful consequences can be identified and the need for risk management options to avoid or limit the impact of chemicals will be assessed. The endpoints covered by LCA are typically defined more holistically than the test species or ecosystems protected in ERA. Task 3 aims to cover both aspects and to provide relevant data for the selected test substances.

Task 3 entails:

- Setting up the methodology.
- Literature research and data collection
- Interpretation of result

4.2 Methodology

Step 3.1: Setting up the methodology

Step 3.1 is dedicated to the elaboration of an **appropriate methodology to investigate the emissions and exposure** of the selected test substances. As requested in the tender, specification of the methodology will be based on a generic life cycle assessment methodology, for which we will use ISO 14044 norm adapted for the specific needs within the present project. In order to ensure a reliable and useful approach the project team will start with defining the goal and scope of the assessment as first logical step to determine the boundaries of the assessment (e.g. cradle-to-gate or cradle-to-grave). This means in particular to identify in which impact categories should the inventory feed into and which functional units (performance characteristics) are relevant, to identify system boundaries based on the substance and waste stream (scale definitions – which units process to be included in the study) and to define the data scale (generic data, site specific data, etc.). In this regard it is extremely important to align the work with the work carried out in task 2 and 4 of the present project. The mass flows as well as the impacts to be assessed will influence the choices in task 3 and will help to set up appropriate cut off criteria to decide which inputs are included in the assessment.

In parallel, the project team will set up a risk assessment approach, which starts with hazard identification, the setting up of a dose (concentration) – response (effect) assessment, the actual exposure assessment and the final risk characterisation. In the dose

(concentration) – response (effect) assessment, the predicted no-effect concentration (PNEC) is developed or identified. Together with the identified / modelled exposure data the risk can be calculated and assessed.

The assessment starts subsequently with the **inventory step** in which data will be collected, and process flow diagrams showing the involved processes and their relationship will be drawn up. Any data necessary for the risk assessment will be considered as well.

Generally, for life cycle assessments, energy, raw material, ancillary and physical inputs, products, by-products and waste as well as release to air, water and soil and other environmental aspects will be identified and discussed. For the present project we suggest placing specific emphasis on products, by-products and waste as well as release to air, water and soil and any other environmental aspect. However, the final selection will be done after consultation with stakeholders and in particular task 4 in order to ensure consistency. As the project aims at providing a framework to be used mainly for the preparation of future REACH Restrictions, the project team suggests considering in particular the aspects addressed by ECHA. Following agreement on the aspects the project team will identify the related required data.

Various methods are available for categorizing and characterizing the life cycle impact of the flows to the environment. In addition, many agreed and commonly used impact categories (human toxicity, acidification, ecotoxicity, depletion etc.) are available. The project team is actively involved in the development of various LCIA methodologies, such as ReCiPE

(http://www.rivm.nl/en/Topics/L/Life_Cycle_Assessment_LCA/ReCiPe)

Usetox (<http://www.usetox.org/>) and PEF (and OEF)

(<https://www.openlca.org/project/pef/>). Furthermore, the team has long-standing experience with exposure assessment of chemical substances: Ramboll/BiPRO have developed numerous life-cycle trees and use descriptions for both REACH registrations (more than 150 chemicals) and Applications for Authorisation (AfA) under REACH (more than 50 AfAs), and elaborated the corresponding exposure scenarios and risk characterisations. Both human health and environmental impacts were assessed in detail.

In addition, all unit processes will be described in detail together with any factors influencing inputs and outputs and related flow data will be collected. In order to perform the task in a structured way, the project team will set up a dedicated spreadsheet file (e.g. MS Excel) in which all data requirements are entered. In the spreadsheet several general columns will be added (e.g. for indication of the reference, indication of person having entered the data, etc.) to ensure reliability and traceability. It is expected that some data can be used from work carried out in task 2 (mass flows) as a basis of further elaborations. Any further necessary data will be collected by means of literature review and stakeholder interviews (see working step 3.2). As soon as data collection is finalised relevant information will be entered in the spreadsheet.

As soon as all relevant unit processes are described, the project team will identify relevant life cycle stages where a risk assessment seems useful and of added value. This step will be carefully discussed with Commission Services before a risk assessment is carried out.

Step two in a life cycle methodology is usually dedicated to the **life cycle impact assessment**, which will provide answers to the question “what do the data from step 1 mean?” More precisely, the data identified for the inventory will be analysed for specific impacts by the project team. This task is mainly done in task 4. Any preparatory steps will be considered in task 3. The life cycle impact assessment will be finalised with the characterisation step, i.e. the calculation of the indicator results. All methods used for calculating indicators will be documented including any assumptions made or value choices.

Step 3.2 Literature research and data collection

The literature search will start for every selected substance with a scoping exercise trying various combinations of search terms and Boolean operators to determine the most useful search algorithms that will yield reasonable number of identified references, among most of which are relevant for this service. In addition, a set of eligibility (inclusion/exclusion) criteria will be established during the scoping exercise.

The next step focuses on the identification of the data sources in order to retrieve the information required for the present project. Data sources to be used will be the following: [1] literature databases (e.g. PubMed, Google Scholar, Open Grey), [2] chemical databases (e.g. eChemPortal, TOXNET, PubChem), [3] LCA databases (exiobase, USDA, eco-invent, agrifootprint (as far as freely accessible) etc.) or [4] websites as well as published documents or reports from organisations and authorities (e.g. ECHA, EU Commission). Such reports can serve as reference tools to identify key studies/references for this service. If searches in free data bases are unsuccessful, Web of Science or STN have the potential to reveal also leaching, fate, and other data.

The outcomes of the scoping exercise will provide a preliminary understanding of the existing information on the relevant aspects, however, in addition the project needs to assess whether the outcomes of the scoping exercise provide sufficient and scientifically robust data. Following the aspects above the project team will start the actual literature search. Each identified reference will undergo title/abstract screening and selection process using the eligibility criteria established before. The screening and selection process will follow a two-tiered approach. First, the screening of the identified references will be done by title and abstract, and inclusion of the references for data extraction and analysis will be determined using the eligibility criteria established. If the title and abstract of certain references do not provide enough information to determine their eligibility for data extraction, then the second screening will follow with full-text retrieval and review for their eligibility. The relevant references along with their full-texts will be organised and managed by the project team using a reference managing programme. Finally, the project team will evaluate and extract the data from the eligible references selected during the screening process. The first step is to retrieve the full texts of these eligible references for data evaluation. Next, in order to facilitate the data analysis and synthesis, the relevant data will be extracted during full-text review and be compiled in in the aforementioned Excel file. During this step, any uncertainty observed, or assumptions made in the evaluated references

will be documented accordingly. For the assessment of study quality (e.g. data robustness, risk of bias), an evaluation strategy along with a ranking system will be developed and implemented by the entire project team. As soon as possible data will be cross checked – if possible - by relating of data to unit processes and by relating data to reference flows of any unit. The evaluation of the results is crucial in order to ensure confidence and reliability. For this, the project team will carry out and document completeness, sensitivity check as well as consistency checks.

In parallel to the literature search, the project team will conduct stakeholder consultations in order to fill data gaps but also to verify and check literature data. The project team will start the stakeholder consultation with the identification of potential stakeholders. For each of the selected substances the team will indicate key stakeholder groups that need to be consulted. A focus will be given on industry and, potentially, public sector organisations (e.g. municipal recyclers, waste dump operators, STP operators, as appropriate), NGO representatives or scientists that will be approached directly by the project team. In order to discuss the list of stakeholders with Commission Services, information on likely issues to discuss/obtain will be added. The proposed candidates will be discussed with Commission Services before any contacts are made. As soon as an agreement on potential persons to contact is reached, the team will identify the most appropriate techniques and methods to communicate with the different stakeholders. From our experiences it is very useful to establish the first contact by phone informing the stakeholder briefly on the project and the discussion points. Subsequently the discussion points/ questions are sent by email or a link to an online questionnaire (e.g. via the survey monkey tool) is provided. As soon as first feedback from the stakeholder is provided a second phone call will be used to discuss the provided information. A crucial aspect to consider is that consulting stakeholders entails an implicit “promise” that, at least some of their views/ data will be considered. It is therefore essential to be very clear in what can be considered, and which aspects are already fixed. Each consultation will be documented accordingly and in case necessary sent for a final check to the relevant stakeholder.

It is expected that stakeholders may be able to contribute actual emission data, e.g. concentrations of target substances in wastewater, off-air, etc., to allow modelling of emissions/substance-flow into potentially affected environmental compartments. Concentrations in relevant environmental compartments (to be identified depending on substance properties and emission pathways) are envisaged to be calculated using sophisticated distribution models. It is noteworthy that standard chemical risk assessment tools as used for REACH registrations (e.g. EUSES) typically provide very conservative and generic estimates of environmental concentrations. We therefore expect that extended/modified calculations may be necessary, taking into account actual stakeholder data.

Depending on the respective substance properties, realistic site- or landscape-specific estimation of environmental concentrations may be desired using fugacity-based fate and transport models (e.g. FlowEQ),

geographical information systems (GIS) or similar approaches, as appropriate.

Depending on the identified impact categories and substance properties, estimation of human exposure at the workplace or of consumers via the food chain may be necessary, as appropriate. The suitability of standard models as used under REACH and in other regulatory contexts (ECETOC TRA worker, ECETOC TRA consumer, ART, MEASE, RISKOFERM, etc.) will be evaluated and exposure estimates will be generated using the selected modelling tool. Special attention is given to the identification of suitably confined and strictly controlled uses for recovered materials that contain substances of concern in the priority material streams.

Step 3.3 Interpretation of result

Step 3.3 is related to the **interpretation of the results** from the steps before. The project team will consider the results of the life cycle inventory as well as the life cycle impact assessment (in close cooperation with task 4) as well the results of the risk assessment jointly to reach conclusions, to explain limitations and to elaborate recommendations. The project team will start this task by addressing any significant issue identified during the assessment. The interpretation should in particular reflect the issue that the life cycle impact assessment is based on a relative approach and indicate potential environmental effects rather than actual impacts. However, the risk assessment is performed to find out whether the use of an individual chemical can be considered safe, i.e. not resulting in a deleterious impact on the environment or human health. Both assessment complement each other and will lead to valuable results. Furthermore, any methodological choices and value choices made will be addressed in this working step as well as any issues identified regarding completeness, sensitivity or consistency (see working step 3.2). Based on this the project will elaborate conclusions and recommendations for each test substance.

4.3 Output and deliverables

Task 3 will provide estimations on the emission and exposure of the selected test substances resulting from the handling of products, waste and recyclates. The results will be based on a generic life cycle methodology and data collection via literature research and stakeholder consultation. We see task 3 as closely linked to the work in task 2 and will carefully consider alignment with task 4 in order to be compliant with endpoints taken into account for the socio-economic analysis. Related to task 5, key aspects to be considered regarding transferability of the approach to the framework will be addressed.

5 Task 4: Socio-economic impacts

5.1 Context

The aim of Task 4 is to determine the relevant elements to consider in the trade-off between a complete ban of recycling of products and waste with substances of concern (i.e. a non-use scenario) and of a potential derogation. By weighting up the pros and cons in a socio-economic analysis, one aims to estimate whether recycling waste with substances of concern is assumed to be an appropriate policy scenario for society as a whole. The challenge is to recycle safely and sustainably, weighing between a complete ban on recycling if necessary or if possible safe and efficient re-use of feedstock, saving primary resources. Not compromising on safety, social, economic and environmental aspects need to be taken into account and weighed. The answer on the questions whether substances of concern are allowed for recycling will depend on the impacts, which are also influenced by the different applications and end of life scenarios.

Task 4 entails:

- Setting the scope by describing the scenarios.
- Identification of the relevant impacts.
- Indicators to assess the relevant impacts.
- Identification of welfare effects to make aggregation of impacts possible.

5.2 Relevant methodologies

The elements to consider in assessing the socio-economic analysis will focus on the difference in efficiency and equity between the scenarios of use and non-use of recycled material streams that contain substances of concern, conform the ECHA guidance explaining the REACH obligations with respect to socio-economic analysis for the implementation of restrictions (ECHA 2008) - and in an updated version as guidance document for authorisations (ECHA 2011), the Impact Assessment Guidelines of the European Union of 2009⁷, as well as Chapter 3 about Impact Assessment in the better regulation guidelines of the EU (Commission 2017). According to the ECHA guideline (ECHA 2008) "..... The SEA facilitates a systematic and comprehensive comparison of different risk management options (RMOs) and/ or of the relevant costs/ benefits of continuing to use a substance compared to the conditions of the proposed restriction. ... " This approach has already been widely applied in practice for the context of REACH, e.g. in several case studies of different complexity and sometimes sparse data, both from an ex-ante and ex-post perspective (Greßmann 2014).

In this task, the aim is to investigate which impacts are relevant to take into account when making the comparison between a ban on recycling or derogation for recycling. The REACH context of restriction as well as authorisation is very similar to the situation to be evaluated in this project, since the "applied for use scenario" of an authorisation with a

⁷ http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf

fixed and limited time horizon of 4, 7 or 12 years corresponds to a derogation with a similar time limit, and the “non-use scenario” taking effect from the latest application date corresponds to a complete recycling ban.

To make it possible to assess, it would be necessary to aggregate and weigh the different type of indicators. We propose to apply welfare economic principles, more specific reflected in the Cost Benefit Analysis (CBA) to identify all possible relevant social-economic impacts of a potential derogation for recycling within the EU, compared to a complete ban. The CBA is a systematic approach to analyse the strengths and weaknesses of alternatives, what is the effect on the social welfare of a country, or in this Task, on the EU. Based on this, we propose 4 steps to investigate the elements to consider, see Figure 5.1 and 5.2;

Step 4.1: Setting the scope by describing the scenarios

Step 4.2: Identification of the relevant socio-economic impacts (people, planet, prosperity)

Step 4.3: Indicators to assess the relevant impacts

Step 4.4: Identification of welfare effects to make aggregation of impacts possible (including equity issues)

Figure 5.1: Summary of the steps to devise the elements to consider as socio-economic impacts.

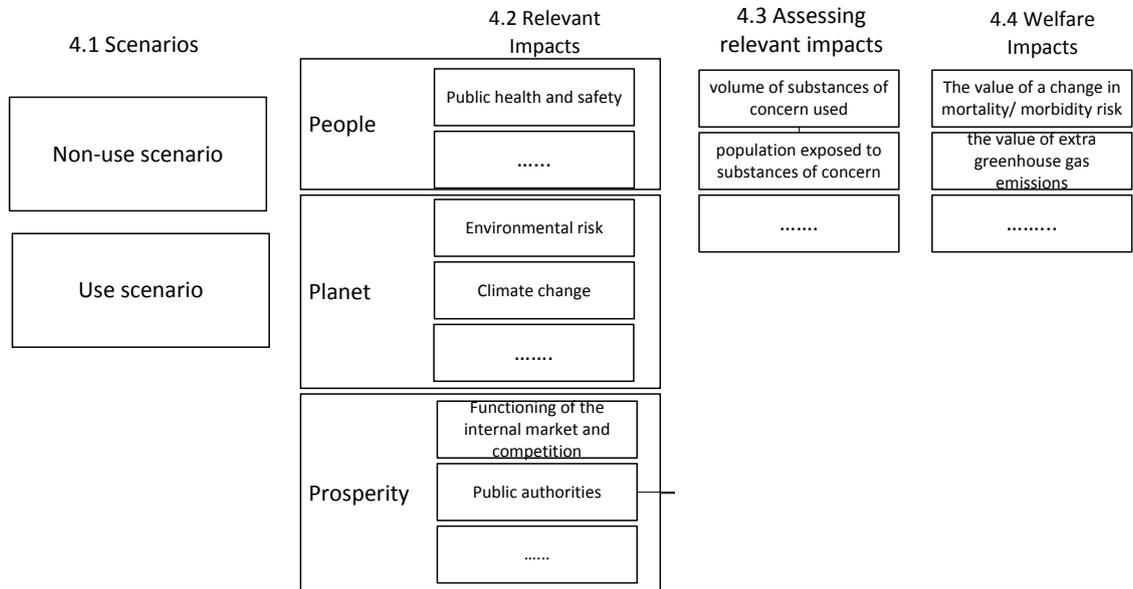


Figure 5.2: Illustrative examples of elements to consider in assessing the trade-off between recycling and a ban on recycling of substances of concern

Step 4.1: Setting the scope by describing the scenarios

To assess the socio-economic impacts, the policy decision context has to be clear. In essence, the two scenarios are;

- i) a complete ban on recycling of materials that contain substances of concern in the (proposed) restricted application (non-use scenario), which thus means incineration or landfill of the material;
- ii) a potential derogation for recycling in the proposed restriction (use-scenario).

For both scenarios, not only the complete supply chain of a product, but the total life cycle of the substances of concern will be the scope. The global, time trajectory and life-cycle boundaries defining the scenarios should be carefully chosen in order to have the complete and relevant scope for the assessment.

For example, when describing the scenarios it is important to take into account what happens with the waste in case of a ban (Scenario i), what is the response of the market (are there alternatives for incineration and landfill?). An example in case of scenario ii, what is the effect of recycling on the market of virgin material? While doing this, it is important to realize that different European stakeholders can have a different view on what is considered to be a favourable scenario and what should be take into account when deciding on which scenario is favourable.

Within our team we have extensive experience with socio-economic analyses carried out in the context for REACH restrictions and authorisations (dossier submitter as well as reviewer) and with the fate of substances in the waste phase, and stakeholder consultations for sustainability assessments. The project team will make a first

description of the context, which can be discussed with relevant stakeholders if deemed feasible.

Step 4.2: Identification of the relevant impacts

The main aim is to devise the relevant elements to consider in assessing the socio-economic impacts associated with recycling. The project team is familiar with the ECHA guidance on Socio-Economic Analysis for restrictions (ECHA 2008) and the Annex XV restriction dossier template (ECHA 2016). ECHA (2008) distinguish five different categories of effects; Human health, environmental, economic, social and wider economic impacts. Within each category, various impacts might be relevant. As starting point for the identification we will make use of the impacts mentioned in appendix G in the ECHA guidance on socio-economic analysis (ECHA 2008) and of the impacts mentioned in the ECHA guideline for authorisations (ECHA 2011).

As different scopes, and different ways to categorise sustainability impacts exist a further fine-tuning of the default REACH SEA guidance impact categories may be necessary to include all relevant elements associated with recycling. To do this, we will perform a desk study on related relevant impacts and categorisation. Examples of other relevant literature are the sustainability goals of the UN⁸, and the integrated reported initiative of the International Integrated Reporting Council⁹. Additionally, we will build on the expertise of the project team, who are well experienced and up to date with the latest developments in sustainability assessments, including a harmonised life cycle impact assessment method named ReCiPE (Huijbregts, Steinmann et al. 2017), and the development of the Product Environmental Footprint (PEF) and Organisation Environmental Footprint (OEF)¹⁰ (Broeren, Zijp et al. 2017; Zijp, Waaijers-van der Loop et al. 2017).

Also within Member States and ECHA there is already some experience with submitting restriction dossiers that have considered derogation for recycling, or where the need for derogation was discussed within the RAC or SEAC opinion making process. We will involve these experiences in fine-tuning relevant impact categories in the REACH SEA guidance. In this step 4.2, the relevant impacts will be structured per impact category. The project team will identify the main impacts, which can be discussed with relevant stakeholders if deemed feasible (as in step 4.1).

Step 4.3 Indicators to assess the relevant impacts

Here we focus on how the impacts per relevant impact category can be assessed: which indicators should be used. Per relevant impact, the method to assess differs. There are different indicators to express an impact, from abstract to specific. For example, potential human health effects can be expressed in terms of changes in risk (abstract) and in changes in actual impacts (specific). Next to this, a trade-off to decide at which level to express the impact is needed for the assessment. This can be due to data-availability, but also based on what is proportional in the context of the question.

⁸ <https://sustainabledevelopment.un.org/>

⁹ <http://integratedreporting.org/>

¹⁰ http://ec.europa.eu/environment/eussd/smgp/dev_methods.htm

Per relevant impact, we will investigate the possible indicators to measure the impacts. These indicators should be able to link the option to recycle and the substance of concern in recycled materials to the welfare effects of a ban on substances of concern. These impacts will occur at different places in the life-cycle of the product, and at different spatial, temporal and technical scales. To know who will be affected by an impact, to make it possible to set target values (decision-rules), and to make it possible to aggregate the different effects via a cost-benefit approach, indicators are needed.

In this task we propose to make a list of indicators based on the indicators used Task 3 to measure emissions/ exposure. We will also make use of Camboni, Footitt et al. (2016) who developed indicators for environmental and health impacts to assess the beneficial impact of EU legislation and policies specific to the EU chemical sector. Examples of effect indicators mentioned in Camboni, Footitt et al. (2016) are: volume of substances of concern used, type of use, population exposed to substances of concern in the recycled material. In addition, we will look at indicators used in REACH restriction dossiers and applications for authorisation. To identify the impacts, it is necessary to assess the targeted group. Therefore, the description of the scenarios (step 4.1) is important. The use of the material will determine the affected population, e.g. vulnerable groups such as infants expecting women, or patients.

The project team will investigate the main relevant sustainability metrics to be used to describe the recycling trade-off, which can be discussed with relevant stakeholders if deemed feasible (as in step 4.1 and 4.2).

Step 4.4: Identification of welfare effects to make aggregation of impacts possible

To aggregate and weigh the different type of indicators, we propose to apply a cost-benefit approach to include all social impacts of the derogation within the EU, compared to a complete ban. The aim of this Task 4 is not to carry out the complete CBA, but to identify the relevant welfare impact, as elements to consider in the socio-economic assessment. In Step 4, we have to investigate the possible welfare effects related to the impacts identified in step 2 and assessed in step 3. What is the change in welfare for the (different groups of) affected population?

The first group of actors affected is the sector of companies. Different branches of companies might be affected in different ways, think of companies recycling products and waste with substances of concern, the waste processing companies and companies producing alternative products and will profit of a ban. Due to a ban, these companies can lose producer surplus. Knowledge about these impacts is relevant for addressing equity issues as well.

By looking at the social costs (and benefits) of both scenarios, all impacts affecting human welfare will be considered, independent whether these are traded effects on markets. Examples of considered impacts the value of a change in mortality risks and the value of extra

greenhouse gas emissions due to extra virgin material use in case of a total ban compared to an derogation option.

We will make use of the Guidance on Socio-Economic Analysis – Restrictions (ECHA 2008) relevant for REACH restriction dossiers. We will look for relevant policy and vision documents in the EU, such as the Dutch CBA guideline (Romijn and Renes 2013), possible comparable dossiers from outside the EU and recent scientific and relevant grey literature.

The project team will identify the main expected welfare effects. These can be discussed with relevant stakeholders if deemed feasible (as in Step 4.1, 4.2 and 4.3).

5.3 Output and deliverable

The output of Task 4 will be a list of elements to consider, and a short note explaining the relevance of the different elements and the relationships between the elements of an integral assessment framework. The deliverable of this Task will be a chapter in the final report written for this project. The main topic of this chapter will be the list of elements to consider is assessing the socio-economic impacts of a complete ban of recycling compared to derogation. The output of Task 4 will be used as input for Task 5 and 6

6 Task 5: Framework

6.1 Context

The aim of Task 5 is to develop a framework, including a decision tree, for assessing whether exemptions for recycling should be considered in a REACH Restriction dossier. Figure 5.1 depicts again the relationship of Task 5 with the other tasks of this project. The figure illustrates that the assessment takes not only potential risks on humans and the environment into account, but also relevant socio-economic elements. An actual choice in (a) certain derogation value(s) leads, via a change in recycling practices in the market, to different impacts.

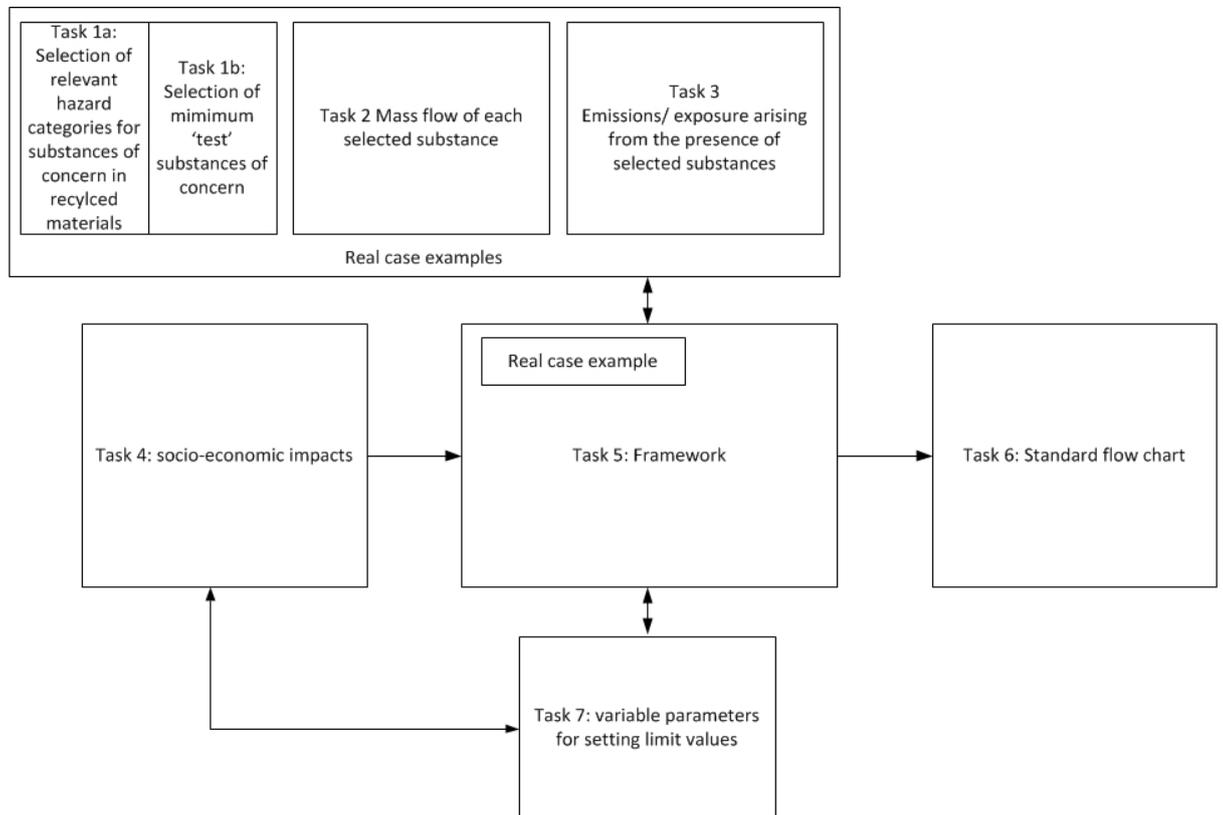


Figure 5.1: Linkage of the different tasks

The developed framework shall enable regulators preparing REACH restriction dossiers to carry out an evaluation of the need for a potential derogation to allow some use of the recycled material in the restriction proposal. Currently, such an evaluation is not a standard step when preparing a restriction dossier. Arbitrary inclusion of derogations for recycling between restriction proposals is undesirable and therefore the project team will propose evidence-based criteria to objectively assess whether a derogation for recycling could be justified.

The project team has substantial experience with such an iterative integral assessment of circular economy options in general, and recycling options in particular, having a keen eye for the level of detail of information that is needed at any part of the assessment process, avoiding information overload at early phases of the assessment. An example is RIVM's 'Safe Loops' project (Janssen, Spijker et al. 2016; Janssen and van Broekhuizen 2016), in which broader framework is being developed for the integrated assessment of recycling of waste streams that may contain SVHCs. In this integrated framework, risk assessment is combined with life cycle assessment and 'circularity' indicator (Broeren, Zijp et al. 2017; Zijp, Waaijers-van der Loop et al. 2017).

Task 5 entails:

- Literature review.
- Drafting the framework and decision tree
- Example case in the decision tree
- Final framework

6.2 Methodology

Step 5.1: Literature review

In this step the relevant standards in non-REACH regulations and international commitments are determined and the Restriction Efficiency Task Force note on the approach of Dossier Submitters, Committees and approach to the public consultation on several issues related to restrictions will be evaluated.

Various product and environmental regulations, as well as international agreements have already laid down standards with regard to the presence of specific substances of concern. As part of this task, the project team will carry out a legal mapping of the relevant legislation which contains such standards. Examples of non-REACH regulations can be:

- POP regulation (EC) No 850/2004
- RoHs Directive 2011/65/EU
- Fertilizer regulation (EC) No 2003/2003
- Regulation on pesticide residues animal feed (EC) NO 396/2005
- Directive on undesirable substances in animal feed 2002/32/EC
- Ozone depleting substances (ODS) regulation
- Regulation on cosmetic products (EC) No 1223/2009

The project team estimates that many of the existing international commitments of the EU and Member States have already been implemented in EU legal acquis. Nevertheless, the project team will assess whether additional commitments can be found in international treaties and agreements. If relevant, any case law restricting exemptions or establishing and/or explaining norms will be taken into account under this step.

As part of the framework under this task, the project team will draw up a table of the most relevant standards which regulators can use as a basic tool when assessing an exemption while preparing REACH Restriction dossiers. This table can list, for example:

- The relevant legislation
- The products and/or streams and/or sectors it covers
- The relevant standards to be taken into account

The Restriction Efficiency Task Force note on the approach of Dossier Submitters, Committees and approach to the public consultation on several issues related to restrictions will be assessed for relevant information concerning this framework. The project team is familiar with the Restriction Efficiency Task Force and will contact the ECHA secretariat for the final version. At the moment of writing this proposal the final paper was not available at the ECHA secretariat.

Step 5.2: Drafting the framework and decision tree

Based on the information gathered in the step 5.1 and the information from tasks 1-4 a framework will be developed by the project team. Figure 5.2 shows a schematic representation of the position of the framework and the other relevant tasks in this project.

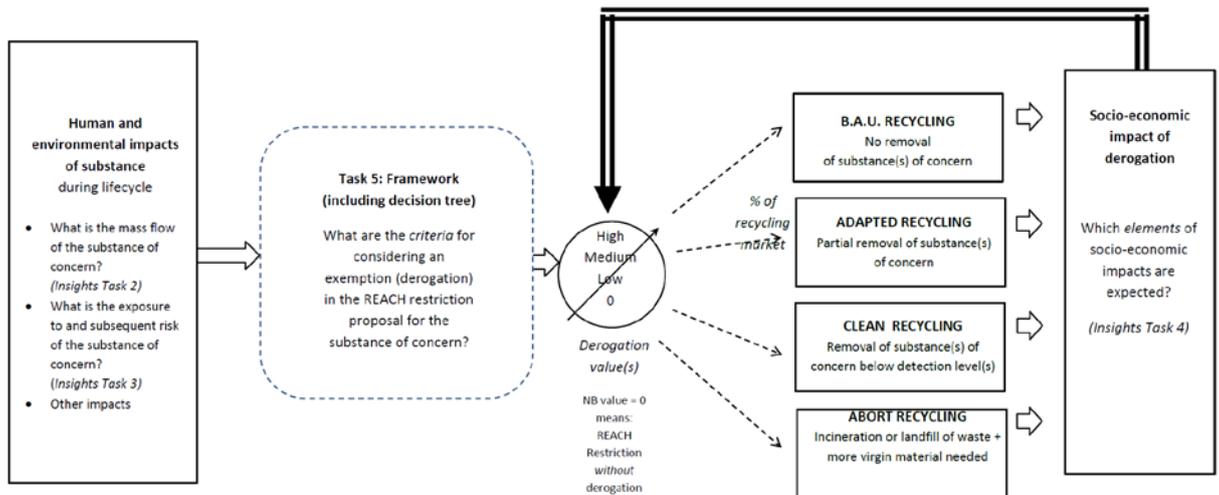


Figure 5.2: Schematic representation of the framework

This framework includes a decision tree to assess whether exemptions for recycling should be considered in a REACH restriction dossier. Figure 5.3 depicts an illustrative example for such a decision tree. The elements of the decision tree should at least consider the following (not excluding others):

- The determination whether the substance, as specified in the restriction, will be subjected to current or foreseeable recycling practices in the EU, i.e. relevant to the scope of the restriction. It would only be feasible and relevant to include an exemption if currently, or in the near future, applications subject to the restriction are actually being recycled. Foreseeable recycling refers to processing techniques at technology readiness level (TRL) 4 minimally (technological validation in the lab).
- A consultation of any other relevant legislation or international commitment that may prohibit, restrict or specify conditions for recycling. These should be addressed and, unless fully restricted,

safe recycling options should be examined within compliance.

This will be included in elements of the decision tree, as

important aspects of setting the conditions for safe recycling.

- Another element of the decision tree is to consider the technical and economic feasibility of removing the substance of concern at the end of its life cycle. If stakeholders indicate that removal of the compound subject to restriction is economically and technically feasible or currently performed, it is preferable to strive for elimination. Removing a substance of concern from entering a new life cycle enables safe and sustainable recycling for multiple loops. When the substance is removed, no exemption is needed.
- The project team will develop objective criteria based from the previous tasks. Criteria for impact on sustainability issues will be included, by examining environmental impacts of different end of life scenarios. Comparisons will be made considering the whole life cycle to account for different end of life options, such as disposal (landfill), incineration, or recycling (up/down). Unless the material is infinitely recyclable, a decision as to its fate in the waste phase will always be needed. This unavoidable end fate of most materials should be considered. Previous tasks will provide input on the aspects to be included, especially the identified elements from task 4.
- An important aspect to consider when developing the framework will be the additional burden on the dossier submitter to gather the information necessary to make the assessment whether an exemption to allow some use of the recycled material should be considered. Guidance shall be provided on how to deal with missing data for the identified criteria.

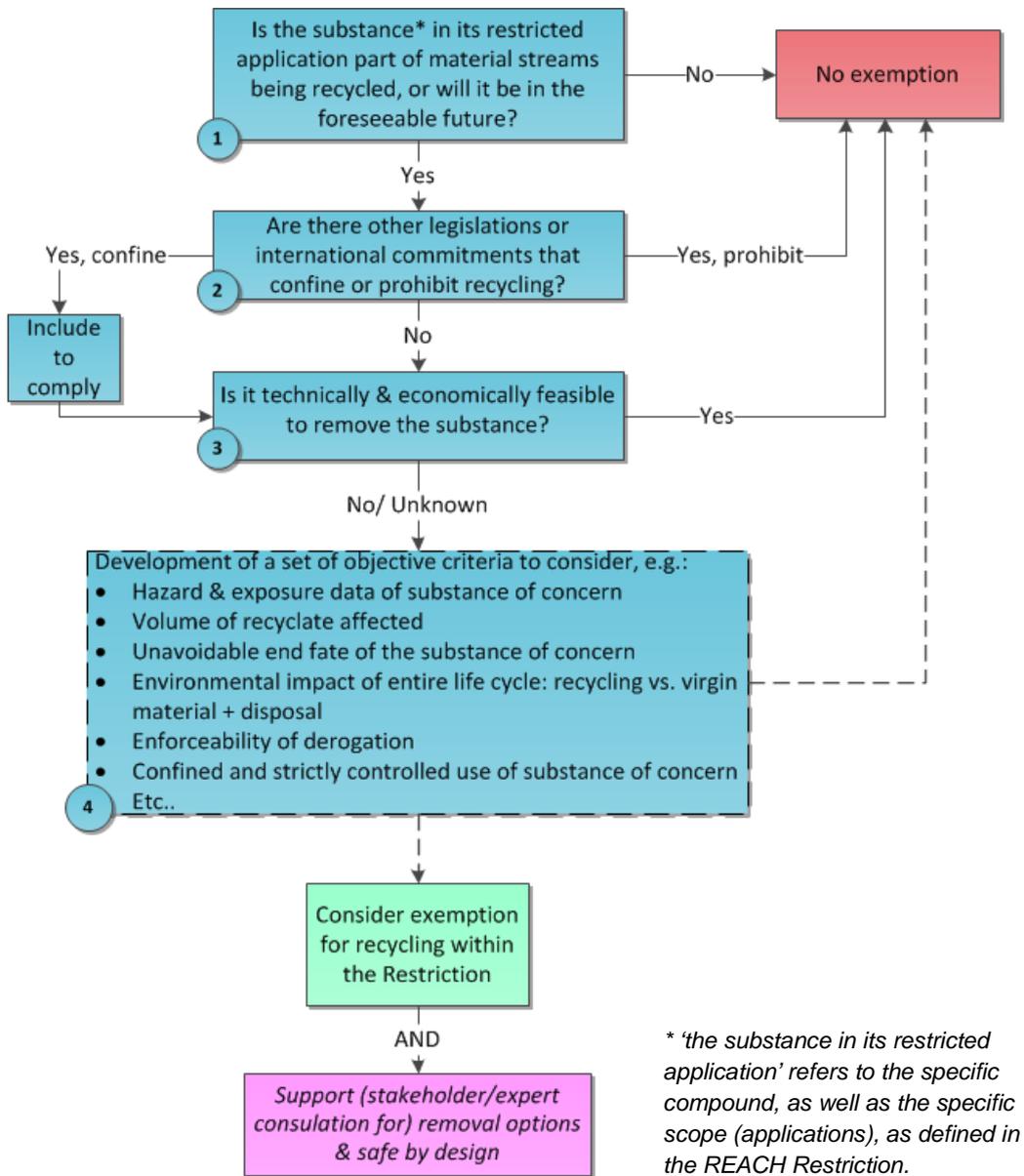


Figure 5.2: Schematic approach of an illustrative decision tree when assessing whether to consider an exemption for recycling within a REACH Restriction dossier.

An option in the framework could be to inform stakeholders to actively keep pursuing removal options even when considering an exemption for recycling because minimization of emissions for specific hazard categories such as PBT/vPvB is required under REACH. In addition, an exemption can be process-limited (use is allowed within a certain process, or by utilizing a specific technique), time-limited (use is allowed only for a certain period of time, within which industry will have to introduce changes or develop alternative methods), progress limited (the exemption is contingent towards the development of alternatives) or a combination of those. The project team will also assess whether there should be an option included in the restriction proposal to review recycling possibilities in the future if no exemption is justified in the

present situation, for instance if other legislation is adapted or new recycling techniques will become available. Inclusion of such recycle review option would allow for innovations in the future.

Step 5.3: Example case in the decision tree

In collaboration with the Commission, the most relevant test substance from task 1-3 or a case study from a previous restriction dossier will be selected in order to demonstrate its function in practice. If needed, the decision tree will be adapted based on the results of the example case study

Step 5.4: Final framework

Step 5.2 and 5.3 will provide the information for the draft framework and decision tree. In step 5.4 the project team will seek feedback on the draft framework from stakeholder. Consultation on the draft framework is sought from at least three different types of stakeholders:

- The Commission (as policy maker)
- Dossier submitters and RAC/SEAC members (as practitioners)
- The recycling and industry interest groups (as information providers)

Various different types of consultation could be provided; the project team is experienced in stakeholders' consultation meetings and questionnaires. Furthermore, the project team has excellent relationships with all three types of stakeholders. The project team will provide an overview of the main issues discussed or raised during the consultation. Based on the feedback from the stakeholders the project team will finalize the framework

1.1. Output and deliverables

Task 5 will provide:

- A framework, including a decision tree, which will allow regulators preparing REACH Restriction dossiers to assess whether, in certain exceptional cases, an exemption to allow some use of the recycled material should be considered in the restriction proposal.
- A case study demonstrating the function of the decision tree in practice
- Stakeholder consultation on the draft framework, including an overview of the main issues discussed or raised during the consultation

7 Task 6: Standard flow chart

7.1 Context

The assessment framework, as developed in Task 5, helps dossier submitters to determine whether to consider a derogation for recycling. When it is justified to consider such derogation, further consultation of stakeholders and information gathering is started. This information is required to evaluate the derogation conditions in a socio-economic assessment and so optimize the net welfare change for society thereby justifying the derogation. Task 6 will propose a standard flow chart that depicts the different stages the dossier submitter is recommended to follow in preparation of such a derogation. Therefore, the flow chart needs to be developed in a way that eases implementation in the Annex XV restriction dossier template (ECHA 2016) that provides the different stages of the development of a restriction proposal.

Task 6 entails:

- Literature review, restriction dossier process analysis and interviews.
- Preparing a draft version of the flow chart.
- Finalization of the flow chart.

7.2 Methodology

Step 6.1: Literature review, restriction dossier process analysis and interviews.

In this step the project team will briefly study of the Annex XV restriction dossier template, the ECHA guidance for the preparation of an Annex XV dossier for restrictions (ECHA 2007), the ECHA guidance on Socio-Economic Analysis for restrictions (ECHA 2008) and current restriction dossiers containing a derogation for recycling. The project team has already experiences working with these guidances and templates during the preparation and evaluation of restriction dossiers. The focus will be on information gathering relevant for the elements identified in task 4 will be described and the key stages in the development of a restriction proposal, such as the public consultation.

In addition, Member States and ECHA have experience with submitting restriction dossiers that have considered a derogation for recycling, or where the need for a derogation was discussed within the RAC or SEAC opinion making process. It is valuable to learn from these experiences. To that aim, the project team, in consultation with the Commission, will study the submission (and opinion-making) process for relevant dossiers (e.g. for phthalates used in articles, lead as stabilizer in PVC, DecaBDE, nonylphenol ethoxylates, PFOA and related compounds in textile). Interviews with the dossier submitters are foreseen and the analysis of dossiers will focus on: i) what the dossier submitter has proposed (and the information that has been submitted to substantiate a derogation), ii) what new information has been added during the public consultation and additional requests during RAC/SEAC opinion making and iii) how the RAC/SEAC opinions were used in the final decision making. This analysis would only look at the kind of information that is provided and

will not verify or assess the information or policy statements made in the process.

Part of the analysis is a desk study (documents, internet), part of it will consist of consulting the persons that were actively involved in submitting the dossiers. The literature review, process analysis and consultation will focus on the relevant stages to distinguish and which information is needed and feasible to acquire in each stage. Special attention shall be paid to the additional burden on the dossier submitter to gather the necessary information.

Step 6.2: Preparing a draft version of the flow chart

Based on the information from step 6.1, a draft version of the flow chart will be created. The flow chart will make clear what type of information is required and at which point in the preparation phase of the dossier. The elements identified in Task 4 will determine the information needed, e.g. information on risks for man and the environment, and socio-economic impacts (including impacts on environmental aspects). An important aspect to take into consideration is timeframe of any recycling exemption to ensure that an exemption lasts only as long as necessary. The standard flow-charts from the ECHA guidance for the preparation of an Annex XV dossier for restrictions (ECHA 2007) could be used as a starting point (see figure 6.1 and 6.2).

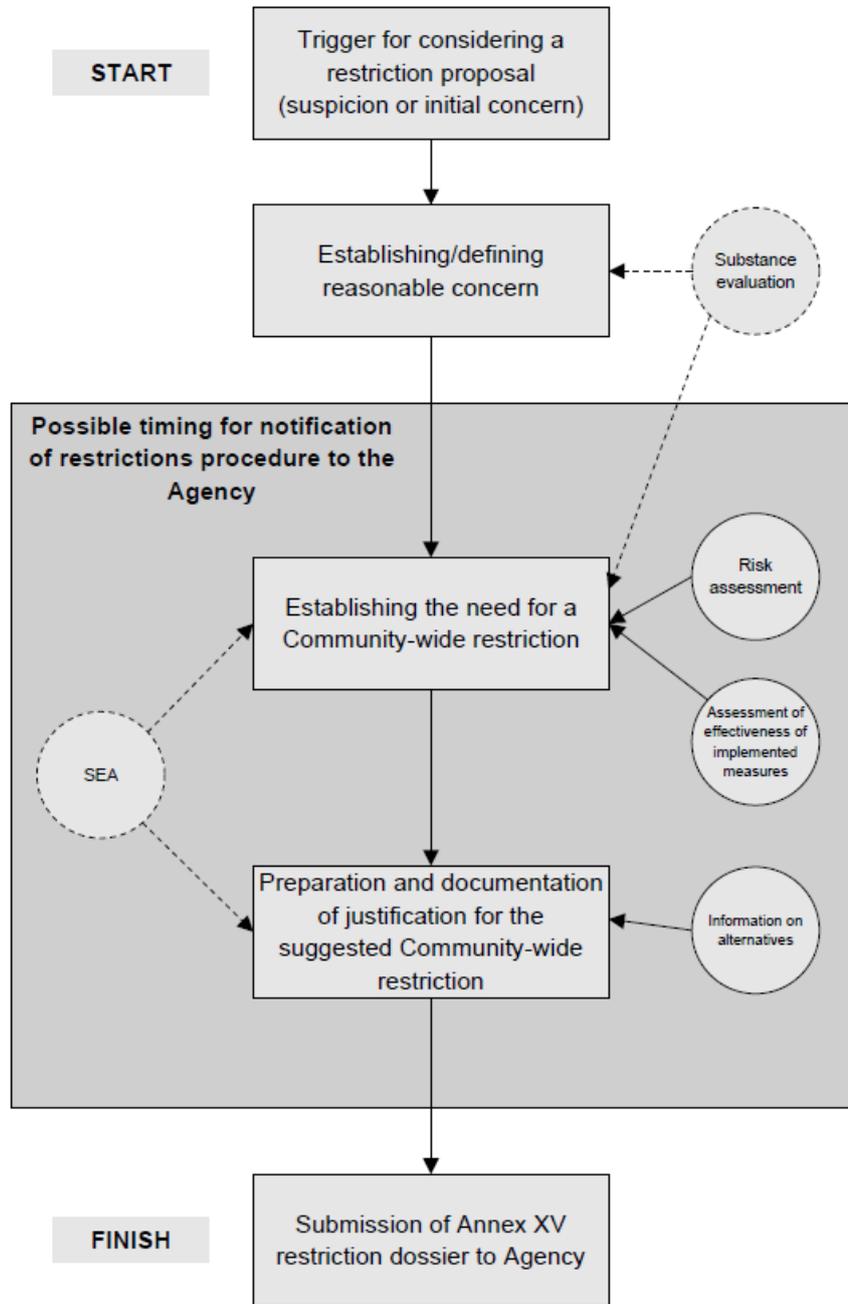


Figure 6.1: Overview of actions for the Dossier Submitter throughout the preparation of a restriction proposal (as presented in ECHA 2007)

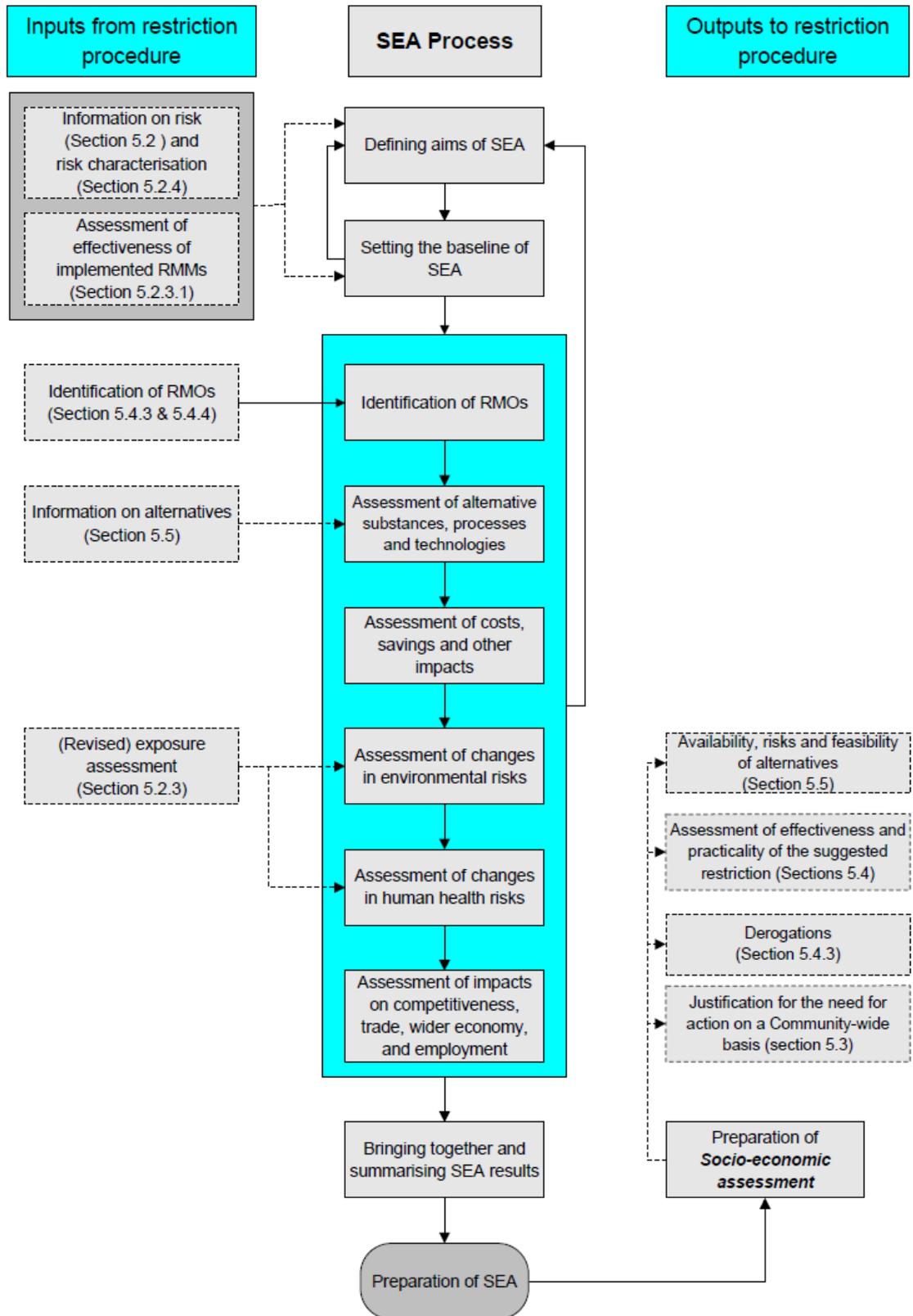


Figure 6.2: Links between the overall SEA in a restriction dossier, including derogations, and the preparation of the restriction proposal (as presented in ECHA 2007)

Step 6.3: Stakeholder consultation on draft version of the flow chart

It is foreseen that stakeholders will be consulted to test the applicability of the framework, to learn from their experiences and views, and to get their support. In collaboration with the Commission the project team will assess the need for such stakeholder consultation and if needed, propose the most relevant stakeholders to consult. If desired, this can be a stand-alone stakeholder meeting or a side event at a set meeting (e.g. SEAC, RAC, Network of REACH SEA and Analysis of Alternatives practitioners (NerSAP), Restriction Efficiency Task Force meetings, workshops hosted by ECHA related to restriction or circular economy etc.). Input from stakeholders on the draft flow chart will be actively sought to create a broad support among regulators and other stakeholders from different European regions and to increase the quality and applicability of the framework.

Step 6 4: Finalization of the flow chart

Based on the input from step 6.3 and the Commission, the flow chart will be finalized.

7.3 Output and deliverables

The output of Task 6 will be a standard flow chart that depicts the different stages a dossier submitter is recommended to follow in preparing that derogation. It will include all the relevant information elements that are necessary to assess the net welfare benefit for society in case a derogation would be justified.

8 Task 7: Variable parameters for setting limit values

8.1 Context

During the last decade we have seen scientific underpinning of the limit values developed for instance for the POP concentrations in waste followed by negotiations on the feasibility and authorisations or restrictions under REACH where a specific exemption was provided for the recycling of legacy materials. This was the case for instance for DEHP in soft PVC, cadmium in rigid PVC and nonylphenoethoxylate in textile. Proposals for specific exemptions for decaBDE in plastics, and PFOA in recycling textiles were not granted, whereas the assessment of recycling of rigid PVC containing lead stabilisers is still in process. Under the POP regulation, the recycling of commercial pentaBDE and octa-BDE containing plastics was allowed.

The setting of limit values for the presence of specific substances of concern in recycled material has major implications for the balance between the EU's two aims of limiting the presence of substances of concern in material streams and the stimulation of recycling of waste streams. In essence, the chosen limit value determines the quantity of a material which is included and excluded from re-entering the economic cycle .

The concentration in the recyclate is basically determined by the concentration in the waste material and the percentage of recycled material in the new product. That is precisely the reason why either separate limit values were adapted for recyclate under REACH or why exemptions for recyclate were derogated. Examples are cadmium in rigid PVC up to a concentration of 1000 mg/kg compared to 100 mg/kg in virgin material and the recycling of POP-BDE containing plastics was allowed by setting a derogated value of 1000 mg/kg compared to 10 mg/kg in virgin plastics. Mirroring these limit values in mixtures or products, setting values in waste material has a comparable effect as is illustrated in the figure below.

The following figure 7.1 illustrates the effect of limit values in waste material in the case of POP waste, where the effect of two limit values on the recycling is depicted. Assume the blue limit value = 100 g/kg and the red one 1000 mg/kg. The effect of the limit value heavily depends on the actual concentration in the delivered material and on the variation of the concentration in that material.

Task 7 entails:

- Identification and description of key parameters.

Amount of recycling

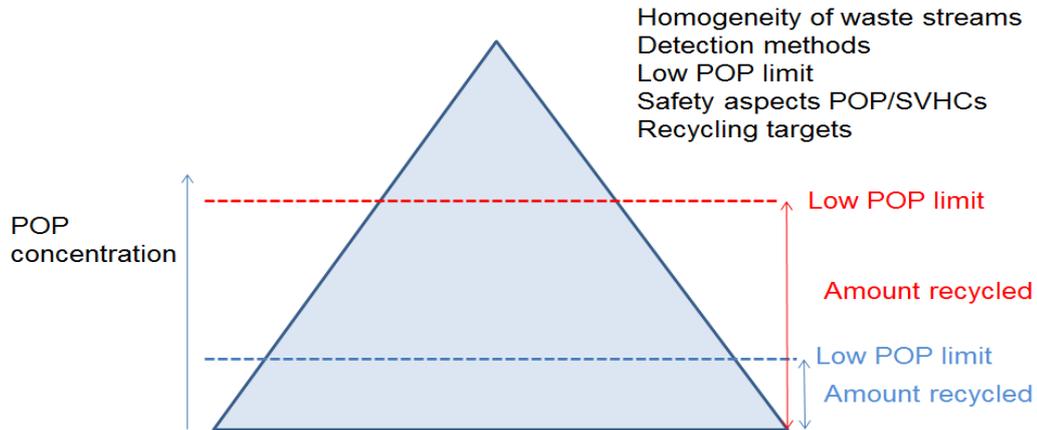


Figure 7.1: The effect of limit values in waste material in the case of POP waste

8.2 Methodology

Step 7.1: Identification and description of key parameters

To our understanding the parameters established in this task will be used to determine a value limit for specific test substances of concern in a material stream which has been recycled. Such an approach entails several similarities to the one used to establish a concentration range between lower and upper POP content levels for POP waste. For example, task 7 under the ToR seems to describe the setting of limit values by way of parameters which “zoom” in on a defined range of possible limit values.

The project team would therefore propose that it establishes the relevant parameters for such approach, bearing in mind the methodology for the proposal of value limits for POP waste, as applied in its previous studies on POP waste [Ref. 54, 43, 39]. This methodology can be adapted to the specific needs of the current tender. In this regard, the project team is fully aware that the current task concerns the setting of limit values for certain substances in recyclates and not in waste, as set in previous studies on POP waste. The final methodology for which variable parameters will be applied shall be established in close cooperation with the Commission.

The selected parameters represent data which provide lower and upper limits for a range of possible limit values. For example, the available detection methods will limit the lowest possible limit value. Previously established legal limit values will most likely pose an upper limit value. By using different parameters, the applicant of the methodology can “zoom in” on a specific limit value for a substance.

The following figure 7.2 illustrates the resulting range of options for a limit value after application of lower and upper limitation criteria.

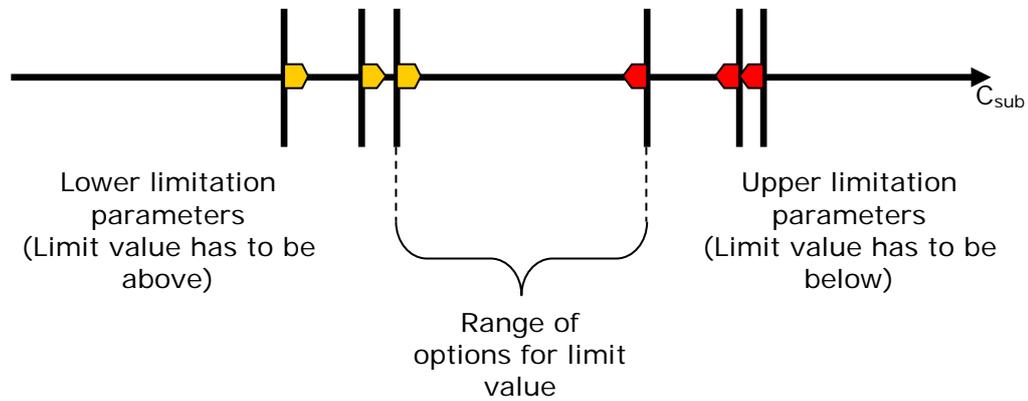


Figure 7.2: Range of options for a limit value after application of lower and upper limitation criteria

The resulting range of feasible limit values will differ for selected substances and different results can be expected for different material streams. In order to derive specific proposals for limit values it will be necessary to reduce the range of possible options for a limit value to an implementable proposal for one specific value. For this purpose the methodology foresees the use of two decision tools. This approach is applied in decision theory in order to reduce the range of potential options. The selected decision tools will be established in close cooperation with the Commission. The following figure 7.3 illustrates the tool for decision on selected substance limit value in the range between upper and lower limitations.

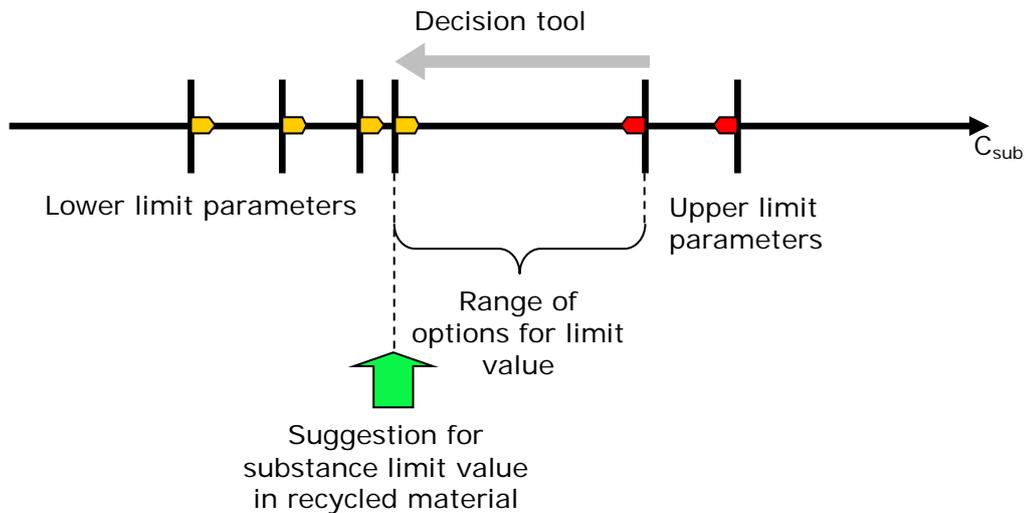


Figure 7.3: Decision tool on selected substance limit value in the range between upper and lower limitations

For the selected substances within this project, a set of lower and upper limitation criteria will be established, with which a possible range for the limit values can be determined. These criteria can be considered to be the requested variable parameters under task 7 of the ToR. The selection may comprise parameters such as the desirability and feasibility of other options for waste treatment (value of recycling versus final disposal), the risk of exposure of a certain application (adequately controlled conditions), the possibility to monitor the application and to collect the waste at the end of life, and the concentration development of the substance in the recyclate over time (review clause). The latter will heavily depend on concentrations and the turnover time of the material containing the substance and thus on the waste stream considered. The project team assumes that the work generated in the tasks 1 to 6 will provide input for properly accomplishing task 7.

Possibly, a number of the developed parameters will be similar to the ones used for the establishment of limit values for POP waste, as these parameters, such as “economic feasibility” and “worst case scenario for human health risks” are closely connected to the parameters mentioned above and can also be deduced from the data collected from task 1 to 6 of this tender.

During the described process of establishing parameters, a “brainstorming session” could be organized by the project team for the most relevant stakeholders, during which the most relevant parameters could be discussed and placed within the context of real case examples. Such a brainstorming session can be discussed with the Commission during the kick-off meeting or at another suitable stage of the project.

Output and deliverables

Task 7 will provide:

- A list of key parameters relevant in proposing one or more limit values for the presence of the test substance of concern in recycled material taking into account the output of tasks 1-6 and the output of the brainstorm session if feasible.
- Description of these parameters, their relationships and how they affect the limit values.

9 Main deliverables and overall planning

9.1 Timing of actions by task

In table 9.1 an overview is given on the planning of the different tasks, the foreseen progress meetings and deliverables.

Table 9.1: Time line of various tasks, meetings and deliverables.

Month		Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Deliverable
<i>Contract signed</i>									
1	Kick-off								Inception report
2									
3	First pm								Interim report
4									
5									2e interim report
6	Second pm								
7									
8									Draft final report
9	Third pm								
10									
11	Fourth pm*								Updated draft final report*
12									
	Final meeting								Final report

Foreseen time frame for drafting task

Foreseen time frame for finalising task

* Depending on the progress and comments received on the draft final report an additional progress meeting and updated draft report can be planned.

9.2 Deliverables

The following report related deliverables will be prepared and submitted:

- An inception report reflecting the outcome of the kick-off meeting, detailing the proposed approach to the study and including an updated work program.

Deadline: 2 weeks after the kick-off meeting

- Two interim reports:
 - o summarising the obtained results until that moment
 - o raising issues encountered with sufficient information to enable reorientation if appropriate and required
 - o describing what preliminary conclusions can be drawn
 - o providing a clear overview including planning of the work to be carried out during the rest of the period to complete the tasks

Deadline:

- o First interim report- Three months after signature of contract.
- o Second interim report- Five months after signature of contract.
- A draft final report containing all deliverables as set out under Tasks 1 to 7.
Deadline: Eight months after signature of contract
- The final report taking into account comments made by the Commission on the draft final report. The final study report shall include an abstract of no more than 200 words and an executive summary of maximum 6 pages in English.
Deadline: Twelve months after signature of contract

All reports and meeting minutes are drawn up in English.

10 Management structure and procedures

10.1 Project management

RIVM, as the Project Coordinator, is responsible for the overall project management and deals with all DG Environment contacts, both for technical and administrative/financial matters. The Project Manager (PM) at RIVM receives administrative, financial and legal support from experts within the RIVM organisation that has a vast experience in the administration and management of national and international collaborative projects. At the implementation level, task leaders manage the execution of the technical development per task.

RIVM has a proven track record regarding the execution of EU funded projects. Our researchers are members of more than 200 international expert committees of the EU, WHO, OECD and other international organizations and provide scientific advice and support for policy development. RIVM continuously performs research and advises EU agencies such as ECHA, EFSA, EEA, ECDC and EMA. In 2016, 128 reports and 808 scientific publications were published in leading journals. These publications represent a major scientific contribution by RIVM to decision-making processes in the Netherlands and abroad.

It is important to note that RIVM has strict quality assurance procedures in place. The RIVM Scientific Advisory Board has been tasked with monitoring the scientific quality of RIVM's work. The Board monitors and advises on the standards and quality of research implementation, as well as contributions to and continuous development of the quality assurance system at RIVM. In that context, the Board plays a key role in monitoring and improving various fields of science. Based on its findings, the Board releases an annual statement regarding the quality of research at RIVM and the RIVM quality assurance system. In 2014, a scientific audit was carried out on risk assessment and policy advice on substances and products. The audit reiterated the excellent quality of RIVM's risk assessment and policy advice related to chemicals. More specific on the project level, all deliverables are always checked for clarity, consistency, content and presentation by senior members or staff and each report is checked and approved by the responsible director. RIVM maintains an evolving set of written procedures (standard operating protocols) which cover a wide range of issues from our policies to safety, environment, and quality and all have an impact on our quality of work and efficacy of operation.

For this particular project, the Project Manager will supervise the projects progress, ensuring that the project's deliverables and milestones are completed within time and budget, while at the same time meeting required quality criteria. This will be achieved through continuous detailed, systematic, team-involved assessment of progress through the deliverables, resulting in immediate response to any possible changes in the project's course (see Figure 10.1).

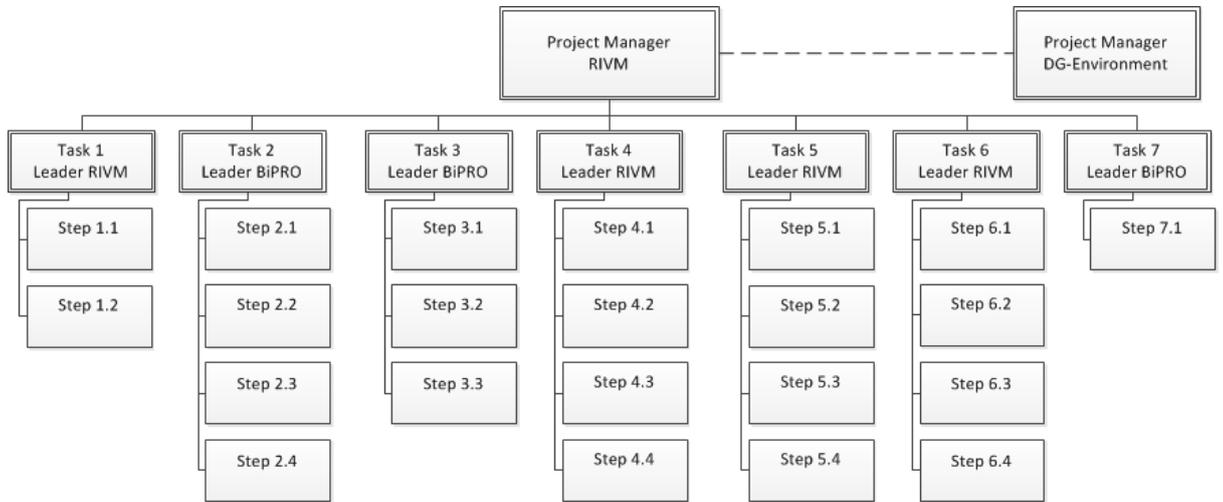


Figure 10.1: Project management structure and responsibilities

In close collaboration with the Task leaders and DG-Environment project manager, the Project Manager performs the day to day management of the project on the executive level, resolves conflicts and monitors the work progress with respect to the project plan. Actions to be performed are:

- Overall technical project management
- Supervision of legal issues
- Organisation of reporting to DG-Environment and interaction with BiPRO
- Financial monitoring and tracing
- Monitoring the working process and ensure that the project's deliverables and milestones are completed within time and budget

All tasks involve multiple members of the project team, which in fact will function as a safety net in case of unforeseen absence of members of the team by providing back-up staff. Next to that, the centres of the RIVM participating in this project consist of over 100 experts. Most of these experts have overlapping expertise with those that are relevant for the project. Unforeseen absence of project team members can therefore be filled by relevant experts within the RIVM and BiPRO. In addition, the composition of the project team is chosen in such a way that the necessary broad spectrum of expertise is on board. RIVM and BiPRO have both extensive experience with the EU chemical policy, waste regulation, waste management, life-cycle analysis and socio-economic impacts. As both BiPRO as RIVM have experts with similar profiles, both parties act as reviewer of each other's work, thereby increasing consistency and the overall quality. The Task Leaders deal with the technical developments and will watch over the overall coherence and implementation of project outputs.

10.2 Managing procedures

Our internal procedures for ensuring an adequate product in terms of quality include a number of distinct activities:

- Two senior experts review the product independently
- The report is checked upon at least the following elements:
check on the correctness and completeness of key parameters;
consistency of terminology used and traceability of references;
use of the appropriate methodologies and correctness of used
figures and calculations; the logic, justification and correctness of
conclusions
- The report is challenged on the appropriateness and usefulness
of the content in relation the objectives of the client; the
technical-scientific coherency; overall quality and language.

The work of each task will be managed by the task leaders to accomplish the specific objectives as defined in the work plan in accordance with time and budget. Each task leader will be responsible for the execution of the respective Work Package while the cooperation and interaction between the various work packages and the follow-up after finalisation will be checked by the Project Manager. The progress of the project will be monitored by the project manager by email or telephone conferences.

The project manager will coordinate the project meetings, (interim) deliverables, the (interim) reports and the final report and presentation. In addition to the deliverables, the project manager can deliver monthly progress reports, in the form of reports sent per email (if requested by DG Environment) containing the following:

- Activities provided during this period;
- Potential obstacles/risks to be tackled (if any);
- Proposed solution how to tackle those obstacles/risks;
- Planned activities until the next progress report.

Cost control is implemented by means of SAP cost control software. SAP calculates the actual spent budget and provides insight to manage and control the planning for the remaining part of the project. The project manager has direct access to these data and will monitor actual spending versus scheduled spending.

10.3 Reports and meetings

As specified in the call for tender, five meetings with the Commission of this study will be planned. All meetings will take place on Commission premises in Brussels. The following meetings are anticipated:

- a kick-off meeting at the beginning of the study – about two weeks after the start of the contract;
- a first progress meeting – after delivery of the first interim report;
- a second progress meeting – after delivery of the second interim report;
- a third progress meeting- after delivery of the draft final report;
and
- a final meeting – after delivery of the final report.

The project team will propose an agenda for the meetings and all documents on the agenda of the meetings with the Commission will be made available at least five full working days before the meeting takes

place. The project team will prepare minutes of the meetings and provide them to the Commission.

The kick-off meeting will allow a discussion of the setup of the tasks and work plan. During the kick-off meeting the appropriated hazard categories and subsequent test substances specified in task 1 will be selected in collaboration with the Commission. The progress meetings will allow an in-depth discussion of the interim draft reports and draft final report and enable alignment of requirements for the completion of the final report.

10.4 Risk management

Risk Management is the continuous process of recognition, assessment and control of uncertainties that may result in schedule delays, cost overruns, performance problems, not achieving Tasks objectives and other undesired effects. The objective of risk management is to ensure delivery of the system according to the requirements in time. One important risk arising in the envisaged project might be that experts of the project team leave or are for any circumstances no longer available for the project work. Replacement options within the company have been discussed internally and are agreed upon even though we try to prevent any changes to the team as initially proposed for the specific contract. The Project Manager will perform the risk management activities in coordination with the project team. An initial risk assessment has been performed during proposal preparation and the results will serve as a baseline for the project. Table 10.1 provides the initial risk assessment, how potential risks for the project might be identified and lists the options for mitigation. Identified risks can be both technical as procedural. The table will be continuously updated and will be attached to the interim reports and discussed during the progress meetings.

Table 10.1: Identified risks and mitigation plan

Risk Identification	Responsible Person	Mitigation Plan
Continuity in case of absence	Project manager	<p>Regarding the absence of the project manager, a deputy project manager is appointed (who is to be constantly informed and can take over the tasks of the project manager in case of absence).</p> <p>Regarding unforeseen absence of other team members of all categories it may be possible that other team members (of the same or higher category) take over the tasks of the absentee temporarily. In case substitution is needed, a pool of experts is available to step in. Both BIPRO as RIVM have a broad pool of experts with the</p>

Risk Identification	Responsible Person	Mitigation Plan
		expertise requested in this project.
Incoherently written documentation	Project manager/task leader	Early internal deadlines set to allow for revision and senior staff members available for review.
Proposed methodology does not fit the needs of the Commission or Regulators	Project manager/task leader/DG ENV	Two interim meetings are planned with the Commission to allow for sufficient face-to-face interaction for feedback and discussion on the proposed methodology. Consultation of previous dossier submitters of restriction proposals are part of the proposed project plan.
Clarity is needed on the format and content of deliverables	Project manager/DG ENV	Two interim meetings are planned with the Commission to allow for sufficient face-to-face interaction for feedback on draft task reports as well as the proposed methodology. Deadline for draft report is sufficient to allow for implementation of feedback from the Commission.
Data availability of selected test substances	Project manager/task leader/DG ENV	Data availability is discussed during the kick-off meeting with the Commission to select the test substances. Anticipated data availability is balanced between the selected test substances.
Extra discussion in finalisation stage is needed	Project manager/DG ENV	An extra face-to-face meeting or telephone conference can be planned for in the four month finalisation period when needed
The progress of one or more tasks can be delayed	Project manager/ task leader	In case if one or more tasks get behind schedule a solution will be searched for by both institutes in providing extra staff and management effort to overcome the delay

11 Annex 1: References

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