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

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Proposal for a tiered modular framework to assess options for material recycling

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RIVM Report 2018-0173

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Synopsis

A blueprint for safe and sustainable material loops in a circular economy
A proposal for a tiered modular framework to assess options for material recycling

RIVM has laid the foundations of a framework to assess whether raw materials from waste can be used safely and sustainably. In this integral approach, the risk assessment of a substance is compared with the benefits of its reuse for the environment, e.g. how much CO_2 emissions are reduced. By making both explicit, it becomes clear what is needed to adequately limit the risks to man and the environment and what that effort will contribute towards sustainable development. On the basis of this information, both industry and policy makers can make an assessment of the use of recovered raw materials. Other values, such as economic costs and social acceptance, have not yet been taken into account.

The framework integrates legally established rules, existing risk limits and new methods into one coherent, tiered system. In this way, it supports the Dutch government's basic principle of dealing efficiently with raw materials and reducing the burden on the environment. Safety for man and the environment is a precondition for the transition to the circular economy; an economy which maximizes the reuse of materials from waste streams wherever possible. Material that is recycled may present risks to the environment if it contains substances of very high concern (ZZS), drug residues, pesticides or pathogens. Legislation and policy frameworks protect against some of the risks but are not comprehensive enough to prevent the risks currently presented by recycled material. For example, while the regulations prohibit the use of substances in new products, such as fire retardants, there is no legislation available for products which were made before the prohibition was enforced. In addition, regulations may be missing, such as those for controlling drug residues. The framework has been tested with three cases: recovering phosphate from waste water, recycling polystyrene foam and using rubber granulate from old car tires. RIVM would like to discuss the practical application of the framework, and its further development, with the government and industry. By expanding the framework with other safety and sustainability themes, it will become more widely applicable.

Keywords: circular economy, recycling, environmental impact, material circularity, chemical safety, biological safety, SVHC, sustainability, pathogens, pharmaceutical residues

Publiekssamenvatting

Blauwdruk voor veilige en duurzame kringlopen in een Circulaire Economie

Het RIVM heeft de basis gelegd voor een raamwerk om te beoordelen of grondstoffen uit afval veilig én duurzaam kunnen worden gebruikt. Met deze integrale benadering wordt de risicobeoordeling van stoffen naast de voordelen van hergebruik voor het milieu geplaatst, bijvoorbeeld hoeveel uitstoot van CO_2 wordt bespaard. Door dit allebei inzichtelijk te maken wordt duidelijk wat nodig is om de risico's voor het milieu voldoende te beperken en wat die inspanning oplevert aan duurzaamheid. Op basis van deze informatie kunnen zowel de industrie als beleidsmakers een afweging maken over het gebruik van teruggewonnen grondstoffen. Andere waarden, zoals economische kosten en sociale acceptatie, zijn nog buiten beschouwing gebleven.

Het raamwerk voegt wettelijk vastgestelde regels, bestaande risicogrenzen en nieuwe methoden samen tot één samenhangend, getrapt systeem. Het ondersteunt zo het uitgangspunt van de Nederlandse overheid om efficiënt om te gaan met grondstoffen en het milieu minder te belasten. De veiligheid voor mens en milieu is een randvoorwaarde voor de overgang naar de circulaire economie, waarin zo veel mogelijk materialen uit afvalstromen opnieuw worden gebruikt.

Materiaal dat wordt gerecycled, kan risico's voor het milieu met zich meebrengen wanneer het bijvoorbeeld zeer zorgwekkende stoffen (ZZS), geneesmiddelresten, bestrijdingsmiddelen of ziekteverwekkers bevat. Wetgeving en beleidskaders voorkomen de risico's gedeeltelijk. De huidige regelgeving is echter nog onvoldoende ingericht op het gebruik van gerecycled materiaal. Zo kan de regelgeving het gebruik van stoffen in nieuwe producten verbieden, zoals brandvertragers, terwijl ze in afvalstromen zitten van producten die zijn gemaakt toen het verbod nog niet gold. Daarnaast kan regelgeving ontbreken, bijvoorbeeld voor geneesmiddelresten. Het raamwerk is met drie casussen getest: fosfaat terugwinnen uit afvalwater, piepschuim recyclen en het gebruik van rubbergranulaat uit oude autobanden.

Het RIVM wil met de industrie en de overheid in gesprek over de praktische toepasbaarheid van het raamwerk en de verdere uitwerking ervan. Door het raamwerk uit te breiden met andere veiligheids-en duurzaamheidsthema's, wordt het breder toepasbaar.

Kernwoorden: circulaire economie, recycling, milieu impact, circulariteit, chemische veiligheid, biologische veiligheid, duurzaamheid, Zeer Zorgwekkende Stoffen, pathogenen, geneesmiddelenresten

Contents

Samenvatting

Deel 1: inleiding SSL raamwerk
Dit rapport gaat over het snijvlak tussen het beleid voor de transitie naar een circulaire economie en dat voor stoffen en producten. Hiertoe is een nieuw raamwerk ontwikkeld voor het veilig en duurzaam sluiten van materiaalkringlopen, dat we de naam Safe and Sustainable Loops (SSL) hebben gegeven. Het SSL raamwerk is bedoeld voor overheid en bedrijfsleven en heeft tot doel de informatie over risico's en voordelen van diverse manieren voor het sluiten van kringlopen transparant te maken. Daarmee ondersteunt het SSL raamwerk (beleids-) beslissingen voor het efficiënter omgaan met grondstoffen en het verlagen van de milieudruk, met de bedoeling de veiligheid voor mens en milieu te waarborgen en onvoorziene consequenties in de toekomst te voorkomen. Dit zijn randvoorwaarden voor de transitie naar een circulaire economie.

Reststromen kunnen verschillende risico's met zich meebrengen, zoals de aanwezigheid van zogenaamde zeer zorgwekkende stoffen (ZZS), medicijnresten of pathogenen (ziekteverwekkers) die kunnen vrijkomen in het milieu, zodat ecosystemen of mensen eraan blootgesteld worden. Deze risico's worden gedeeltelijk beheerst door wetgeving en beleidskaders. Echter veel regelgeving is nog onvoldoende gericht op gebruik van secundaire grondstoffen zoals gerecycled materiaal en reststromen, waar stoffen met bepaalde gevaren in kunnen voorkomen die geen rol spelen bij primaire grondstoffen. Ook kan regelgeving de toepassing van stoffen verbieden in nieuwe producten, zoals sommige brandvertragers, terwijl deze nog voorkomen in afvalstromen van producten die gemaakt zijn toen het verbod nog niet gold. Waar het ontbreekt aan regelgeving, zoals voor medicijnresten in secundaire grondstoffen, kan dit het hergebruik hinderen en vertragen, bijvoorbeeld doordat er alsnog per secundaire grondstofstroom beoordeeld moet worden of het veilig is.

De ambitie van Nederland om tot een volledig circulaire economie te komen, met een volledig gebruik van afvalstromen en productieresiduen, vraagt dus om extra aandacht voor de mogelijke risico's van gebruik van reststromen, zoals ook de Gezondheidsraad onderschrijft (Gezondheidsraad, 2018). Dit moet gebeuren zonder de voordelen van dit gebruik voor mens en milieu uit het oog te verliezen. Daarom maakt het SSL raamwerk de voordelen van recycling van materialen expliciet door het beoordelen van de "circulariteit" en "milieu-impact". Omdat SSL primair bedoeld is voor het maken van afwegingen van milieuveiligheid en duurzaamheid, blijven mogelijke andere voordelen, zoals nieuwe werkgelegenheid of economische kansen, buiten beschouwing. Het SSL raamwerk is ontwikkeld om op een transparante en gestructureerde manier om te gaan met de complexiteit rond beoordeling van hergebruik van secundaire grondstoffen. Een verwaarloosbaar risico op schadelijke gevolgen voor de menselijke gezondheid en het milieu is in het Nederlandse beleid een harde randvoorwaarde voor het toelaten van secundaire grondstoffen en daaruit verkregen producten (I&M, 2017).

Belangrijke principes van het SLL raamwerk zijn 1) dat er een duidelijke afbakening moet zijn van de aspecten waar de beoordeling over gaat, 2) dat de beoordeling transparant moet zijn over welke gegevens worden gebruikt en 3) dat een systematische aanpak en presentatie van uitkomsten een consistente besluitvorming vergemakkelijkt.

Deel 2: technische uitwerking

Het SSL raamwerk bestaat uit een aantal modules voor afzonderlijke veiligheids- en duurzaamheidsthema's, met een stappenschema om de relevante modules te selecteren en voor elke module een praktische invulling van de beoordelingsmethode. De volgende thema's zijn in modules geoperationaliseerd: circulariteit, milieu-impact, zeer zorgwekkende stoffen (ZZS), medicijnresten, bestrijdingsmiddelen, pathogenen en antibioticaresistentie. De methoden die in deze modules zijn opgenomen, zijn gebaseerd op de huidige stand van de wetenschap en bestaande beoordelingen van materialen voor recycling (Ehlert *et al.*, 2016; Quik *et al.*, 2016; Schmitt *et al.*, 2017; Wassenaar *et al.*, 2017; van der Grinten and Spijker, 2018; Lijzen *et al.*, 2019). Daarvoor is waar mogelijk voor elke module ook het relevante beleids- en wetgevingskader gebruikt. Zo zijn bijvoorbeeld de restricties en autorisaties binnen REACH een belangrijk onderdeel van de ZZS module.

Elke module is zoveel mogelijk opgezet volgens een getrapte benadering. Dit betekent 'eenvoudig als het kan, grondiger indien nodig'. Voor elke hogere trede is meer gedetailleerde informatie vereist, maar een trede wordt alleen uitgevoerd wanneer de voorgaande trede niet resulteert in een duidelijk antwoord.

De uitkomst van elke module wordt afzonderlijk gerapporteerd, maar gezamenlijk gepresenteerd in een 'materiaalveiligheids- en duurzaamheidsinformatieblad' (*Figuur* 1). De beoordeling wordt dus op niveau van een module gedaan. De afweging van de uitkomsten van de verschillende modules maakt geen deel uit van het SSL raamwerk.

Figuur 1. Materiaal veiligheids- en duurzaamheidsinformatieblad als overzicht van uitkomst Safe & Sustainable Loops (SSL) raamwerk. De grijze vlakken krijgen afhankelijk van de uitkomst van de betreffende module een kleur: groen, oranje of rood.

De modules. Het sluiten van materiaalkringlopen is een cruciaal onderdeel van de circulaire economie. Met de circulariteitsmodule kan de bijdrage hieraan worden beoordeeld. Dit wordt in eerste instantie gedaan met de Europese lijst met schaarse ruwe grondstoffen en in tweede instantie door drie circulariteitsindicatoren: 1) de efficiëntie waarmee materialen worden teruggewonnen, 2) de bijdrage van secundaire materialen aan de vraag en 3) de toekomstige recycleerbaarheid. Omdat het voordeel van recyclen voor duurzame ontwikkeling niet alleen in het efficiënt omgaan met grondstoffen zit is een module voor beoordelen van de milieudruk relevant. Dit wordt gedaan door het recycling scenario en een basis scenario op te stellen. Deze worden vergeleken in termen van CO_2 footprint of energie- en landgebruik. Dit zijn goede indicatoren voor veel andere effectcategorieën die een negatieve impact op het milieu, hebben, zoals vermesting en ozonafbraak (Steinmann *et al.*, 2017). Verder kunnen de andere modules gericht op veiligheid worden gebruikt om stof of pathogeen gerelateerde schadelijke gevolgen voor mens en milieu te beoordelen.
De module voor zeer zorgwekkende stoffen is belangrijk gezien het frequent voorkomen van deze stoffen in (oudere) materialen en producten waarin de stoffen inmiddels wettelijk niet meer toegepast mogen worden. De eerste trede maakt gebruik van de generieke grens van 0.1 gewichtsprocent, maar er wordt ook rekening gehouden met specifieke regelgeving voor persistente organische stoffen. In de tweede trede wordt in eerste instantie beoordeeld of de ZZS kan worden verwijderd. Daarna volgt de vergelijking met specifiekere risicogrenswaarden, die onder meer gelden in bestaande product- en afvalregelgeving. Vervolgens wordt ingeschat of de verdere aanwezigheid van ZZS in de materiaalketen door beoordeling van de blootstelling acceptabel is, rekening houdend met de toepassing (m.n. of er sprake is van onacceptabele blootstelling aan mensen en ecosystemen).
In de module voor medicijnresten zijn in de eerste trede meerdere methoden toegepast om triggerwaarden voor verdere beoordeling af te leiden. Verder zijn criteria opgesteld voor het afleiden van een lijst met indicatorstoffen als basis voor de beoordeling van medicijnresten.
De module voor bestrijdingsmiddelen is gebaseerd op een bestaande beoordelingsmethode voor reststromen die toegepast worden als covergistingsmateriaal in biogasproductie, inclusief het gebruik van het digestaat als meststof. Hier is al veel ervaring mee en verschillende reststromen zijn op deze manier al goedgekeurd.
In de pathogenenmodule zijn de treden opgehangen aan de aan- of afwezigheid van specifieke controlestappen, zoals steriliseren, waarvan bekend is dat de risico's voor blootstelling aan pathogenen verwaarloosbaar worden. Als de effectiviteit van een processtap in het reduceren van de aanwezigheid van micro-organismen onbekend is kan een specifieke test gedaan worden om deze te bepalen.
In de module voor antibioticaresistentie wordt voor de beoordeling doorverwezen naar de methode toegepast in de medicijnrestenmodule en de pathogenenmodule. Daarbij moeten expliciet antibioticaresten meegenomen worden in de beoordeling, omdat dit samen met de aanwezigheid van micro-organismen een belangrijke oorzaak is van de ontwikkeling van antibiotica resistente bacteriën.

Deel 3: case studies en analyse SSL raamwerk
Om de werking en doelmatigheid van het huidige raamwerk te testen zijn drie cases bestudeerd: het winnen van struviet uit afvalwater, het recyclen van piepschuim en het toepassen van rubbergranulaat uit oude autobanden. Deze voorbeelden zijn gekozen omdat zij aansloten op binnen het RIVM uitgevoerd onderzoek waarbij de thematiek zeer geschikt was om de werking van het raamwerk te testen.

In alle drie de voorbeelden was het effect van de optie terugwinning of hergebruik gunstig voor het thema duurzaamheid, vanwege energiebesparing ten opzichte van het referentiescenario van verwerking. Dit is van belang, omdat het alleen zinvol is om de risico's voortkomend uit nieuwe verwerkingsprocessen te beschouwen als er een duidelijke winst is qua grondstoffenreductie en/of milieu-impact.

Het toepassen van rubbergranulaat op kunstgrasvelden scoort minder goed op het thema circulariteit, omdat er nog geen goede recyclingoptie is nadat een kunstgrasveld na de gebruiksfase afgedankt wordt. Ook werd duidelijk dat, hoewel er geen reden is voor zorgen over veiligheid voor de mens, het milieu wel potentieel risico loopt.

Bij het recyclen van piepschuim konden zorgen omtrent potentiele risico's van de brandvertrager HBCDD weggenomen worden door HBCDD te verwijderen met behulp van de solvolyse techniek. Bij herwinning van het fosfaatmineraal struviet uit afvalwater zijn potentiële risico's geïdentificeerd met betrekking tot medicijnresten die mogelijk in het struviet kristal kunnen zitten. Het aantal meetgegevens is te gering voor een definitief oordeel, zodat het advies was om meer gegevens te genereren in een hogere trap van de SSL beoordeling.

Conclusies en aanbevelingen
Uit de case studies is gebleken dat met het SSL raamwerk de voordelen goed kunnen worden beoordeeld en een duidelijk beeld ontstaat voor verdere handelingsperspectieven. Om het SSL raamwerk toe te passen wordt de hoeveelheid benodigde informatie voor een beoordeling in balans gebracht met de moeite vereist voor het verzamelen hiervan. Door het integreren van de beoordeling van de voordelen met de beoordeling van de risico's wordt duidelijk of, als extra stappen voor het opschonen nodig zijn, dit nog steeds voordeel oplevert.

De aanpak gebruikt in eerdere risicobeoordelingen die het RIVM heeft uitgevoerd voor secundaire materialen komt nu samen in de systematische methoden geïmplementeerd in de modules van het SSL raamwerk, zodat deze ook voor nieuwe gevallen weer gebruikt kunnen worden. Ondanks deze vooruitgang zijn er nog verschillende uitdagingen om vooral de praktische toepasbaarheid van het raamwerk te verbeteren. De volgende drie acties zullen daar aan bijdragen:

1. Verbetering van de methoden voor het beoordelen van de verschillende thema's die al geïmplementeerd zijn in het SSL raamwerk.
2. Uitbreiding van de toepasbaarheid van het SSL raamwerk door extra modules toe te voegen, zoals aangaande fysieke veiligheid (bijvoorbeeld voor beoordeling licht radioactief materiaal).

3. Het optimaliseren van de wisselwerking tussen stakeholders die het SSL raamwerk gebruiken.

Uiteindelijk kan de meer integrale aanpak van het SSL raamwerk dergelijke beoordelingen binnen wetgevende kaders verder stroomlijnen. Zo bevat het Derde Landelijke Afvalbeheerplan (LAP3) criteria voor het omgaan met ZZS en stelt een methode voor om de milieudruk van recycling opties in te schatten. Dergelijke methoden en criteria zullen baat hebben bij de stapsgewijze aanpak, zoals uitgewerkt in het SSL raamwerk. Ook op Europese schaal is dit relevant voor de Kaderrichtlijn afval en het EU-actieplan voor de circulaire economie.

De industrie heeft een belangrijke rol in verdere uitrol van dit raamwerk aangezien zij vaak gezien worden als de partij die het meeste gaat bijdragen aan de transitie naar een circulaire economie. Daarom moet het SSL raamwerk geschikt gemaakt worden voor het onderzoek- en ontwikkeltraject (R&D) van bedrijven om zo de ontwikkeling van veilige en duurzame (secundaire) materialen en producten te ondersteunen.

Summary

Part 1: Introduction of the SSL framework
This report deals with the interface between the policy for the transition to a circular economy and the policy for substances and products. To this end, a new framework has been developed for the safe and sustainable closing of material loops or cycles, which we have named Safe and Sustainable Loops (SSL). The SSL framework is intended for government and industry and aims to make the information about the risks and benefits of various ways of closing material cycles transparent. In this way, the SSL framework supports (policy) decisions for the more efficient use of raw materials and the reduction of environmental pressure, while ensuring safety for people and the environment and preventing unforeseen consequences in the future. These are preconditions for the transition to a circular economy.

Residual material or waste streams can present various risks, i.e. those related to the presence of ‘substances of very high concern’ (SVHCs; in Dutch ZZS), pharmaceutical residues or pathogens that can be released into the environment, thus leading to the potential exposure of ecosystems or people. These risks are partially controlled by legislation and policy frameworks. However, many regulations still insufficiently focus on the use of secondary materials such as recycled materials and residual materials, particularly in instances where substances or agents carrying certain hazards occur that are not present in primary materials. Legislation can also prohibit the application of specific substances in new products, such as some flame retardants, while these substances still occur in waste streams from products that were made when the ban did not yet apply. Where clear legislation is lacking, such as for presence of pharmaceutical residues in secondary raw materials, this can impede and slow down circular initiatives, such as when risks need to be assessed separately for each secondary material.

It is the ambition of the Netherlands government to achieve a circular economy, with full use of waste streams and production residuals. This ambition requires extra attention to be given to the potential risks of using residual flows (Gezondheidsraad 2018), without losing sight of the benefits of a circular economy for people and the environment. For this reason, the SSL framework makes the benefits of recycling materials explicit by assessing "circularity" and the "environmental impact". Because SSL focusses on assessing environmental safety and sustainability, other potential benefits are not taken into consideration, such as new opportunities for employment or the development of the economy. The SSL framework has been developed to deal with the complexity of the assessment of secondary materials and their use in a transparent and structured manner. In Dutch policy, a negligible risk of an adverse impact on human health and the environment is a precondition for allowing the use of secondary materials and the products derived from them (I&M, 2017).

Important principles of the SLL framework are 1) that there must be a clear scope set for the topics included in the assessment, 2) that the

assessment must be transparent about the used data and 3) that a systematic approach and presentation of outcomes should support decision-making.

Part 2: Technical description of modules
The SSL framework consists of a number of modules for separate safety and sustainability themes, with clear guidance for selecting the relevant modules. For each module a practical description of the assessment method is given. The following themes have been operationalized in such modules: circularity, environmental impact, substances of very high concern (ZZS), pharmaceutical residues, pesticides, pathogens and antimicrobial resistance. The methods included in these modules are based on the current state of science and experience with the assessment of materials for recycling (Ehlert, Van Wijnen et al. 2016, Quik, Mesman et al. 2016, Schmitt, Blaak et al. 2017, Wassenaar, Janssen et al. 2017, van der Grinten and Spijker 2018, Lijzen, Grinten et al. 2018). Wherever possible, the relevant policy and legislative framework was included. For example, the restrictions and authorizations within REACH are an important part of the ZZS module.

Each module is set up as much as possible using a tiered workflow. This means 'simple when possible, more thorough when necessary'. For each higher tier, more detailed information is required, but a tier is only invoked when the previous tier does not result in a clear answer. The outcome of each module is reported separately and presented jointly in a 'material safety and sustainability data sheet' (Figure 1). The assessment is done at the level of a module. A combined assessment of the outcomes of the different modules, e.g. by weighing their outcome, is not part of the SSL framework.

Figure 1. Material safety and sustainability data sheet as an overview of the outcome of the Safe & Sustainable Loops (SSL) framework. Depending on the outcome of the module in question, the grey areas get a colour: green, orange or red.

The modules. Closing material loops is a crucial part of the circular economy. The circularity module assesses the degree to which material loops are closed using a particular recycling or recovery option. This is initially done with substances on the European list of critical raw materials and in the second instance by quantifying three circularity indicators: 1)

the efficiency of the materials recovery process, 2) the contribution of the secondary materials to the materials-market demand for such materials and 3) future recyclability (second loop recycling). Because the advantage of recycling for sustainable development includes not only the efficient use of raw materials, a module for assessing environmental impact is also relevant. Therefore a recycling scenario and a baseline scenario are defined. These are compared in terms of CO_2 footprint (or energy demand) and land use. These are good indicators for many other impact categories that have a negative impact on the environment, such as eutrophication and ozone degradation (Steinmann, Schipper et al. 2017). Furthermore, the other safety-oriented modules can be used to assess substance or pathogen-related harmful effects on people and the environment.
The module for substances of very high concern (ZZS) is important in view of the frequent occurrence of legacy substances in materials and products. The first step uses the generic limit of 0.1% w/w, but specific regulations for persistent organic substances are also taken into account. In the second tier, the question of whether the ZZS can be removed is assessed. This is followed by the comparison with more specific risk limits, which apply, among other things, to existing product and waste regulations. Subsequently, it is estimated whether the presence of ZZS in the material cycle is acceptable, taking into account the application (i.e. potential exposure of people and the environment).

In the module for pharmaceutical residues, several methods are applied in the first tier to derive trigger values for further assessment. Furthermore, criteria have been drawn up for deriving a list of indicator substances to serve as a basis for the assessment of pharmaceutical residues. The module for pesticides is based on the existing method for assessing residual flows that are used as co-digestion material in biogas production, including the use of the digestate as fertilizer. There is already a lot of experience with this method and several residual streams have been approved in this way. In the pathogen module, the tiers use the presence or absence of specific control steps, such as sterilization, to indicate that the risk of exposure to pathogens is negligible. If the effectiveness of a process step in reducing the presence of microorganisms is unknown, a specific ‘challenge test’ can be done to demonstrate this. In the module for antimicrobial resistance, the assessment is based on the methods applied in the pharmaceutical residues module and the pathogens module. In addition, antibiotic residues must be included explicitly in the assessment because this, together with the presence of microorganisms, is a major cause of the development of antibiotic-resistant bacteria.

Part 3: Case studies and analysis of the SSL framework
To test the feasibility and efficiency of the current framework, three cases have been studied based on previous research at RIVM: the recovery of phosphate in the form of struvite from waste water, the recycling of expanded polystyrene foam and the use of rubber granulate from old car tyres.

In all three examples, the effect of the recovery or recycling scenario was favourable for the theme of sustainability, because of energy savings compared with the baseline scenario. This is important, because it only makes sense to assess the risks arising from new secondary materials if there is a clear gain in terms of resource efficiency and/or reduction in environmental impact.

The application of rubber granulate on synthetic turf pitches scores lower on the theme of circularity, because there is still no good recycling option after a synthetic turf pitch is discarded at the end-of-life phase. It has also become clear that, although the use is safe for humans, the environment is potentially at risk.

When recycling polystyrene foam, concerns about the potential risks of the fire retardant HBCDD could be removed by extracting HBCDD using the solvolysis technique. When recovering the phosphate mineral struvite from wastewater, the potential concern was identified and linked to pharmaceutical residues that may be present in the struvite crystal. The number of measurement data is too small for a final assessment, so the advice was to generate more data in a higher tier of the SSL assessment.

Conclusions and recommendations

The case studies showed that the SSL framework allows for a proper assessment of the benefits of recycling, providing a clear view of the potential management options. In order to apply the SSL framework, the amount of information required for an assessment needs to be balanced with the effort required for collecting it. By integrating the assessment of the benefits with the assessment of the risks, it becomes clear whether this still results in a net benefit when, for example, extra steps for clean-up are required. The approaches used by RIVM in previous safety assessments of secondary materials is combined with the systematic methods used within the modules of the SSL framework. This ensures that lessons learned can be applied again in new cases.

Despite this progress, there are still several challenges, mainly to improve the practical applicability of the framework. Three actions will contribute to this:

1. Improving the methods for assessing the different themes already implemented in the SSL framework.
2. Extending the applicability of the SSL framework by adding extra modules, such as physical safety (e.g. for assessment of slightly radioactive material).
3. Optimizing the interaction with stakeholders using the SSL framework.

Ultimately, the integrated approach of the SSL framework can streamline such assessments within legislative frameworks. For example, the Netherlands' LAP3 waste management plan contains criteria for dealing with ZZS and proposes a method to estimate the environmental impact of recycling options. Such methods and criteria will benefit from the step-by-step approach, as elaborated in the SSL framework. This is also relevant on a European scale for the Waste Framework Directive and the EU action plan for a circular economy. Industry also has an important role to play in the further roll-out of this framework, since they are often seen as the party that will contribute the most to the transition to a circular economy. That is why the SSL framework should be made suitable for the research and development process (R & D) of companies in order to support the development of safe and sustainable (secondary) materials and products.

Part 1: Introduction of the SSL framework

1 Introduction

The transition to a circular economy (CE) is a major policy goal in the Netherlands and in the EU (Rijksoverheid, 2016; The European Parliament and The Council of the European Union, 2018). The transition is necessary to decouple material use from environmental impact and is closely related to reducing CO_2 emissions (IRP, 2018). In the CE it is necessary for materials and resources to be recycled or reused and not incinerated or landfilled. This can be done by smart design and use of products, by extending their lifespan or by the application of the materials contained in them (Figure 1-1). Discarded materials or waste should be recycled or reused. When landfilling or incineration were needed for the disposal of materials, in particular when they are contaminated, there is now a clear demand for a different approach, whereby the recycling and reuse of materials becomes possible by controlling the risks. To decide on use of current waste streams as secondary materials, not only the contribution towards sustainable development needs to be considered, but also the risk to human health and the environment.

Smart use and design of products	R0 Refuse	Make product redundant by abandoning its function or replacing it with a radically different product
	R1 Rethink	intensifying product use (eg by sharing products, or multi-function products)
	R2 Reduce	Producing a product more efficiently. Less resources and materials in the product, or in its use.
Extending lifespan of products	R3 Reuse	Reuse of discarded, still good, product in the same function by another user
	R4 Repair	Repair and maintenance of broken product for use in its old function
	R5 Refurbish	Refurbish or modernize old product
	R6 Remanu-facture	Use parts of discarded product in new product with the same function
	R7 Repurpose	Use of the scrapped product or parts of it in a new product with a different function
Useful application of materials	R8 Recycle	Process materials into the same (high) or lower quality.
	R9 Energy Recovery	Incineration of materials with energy recovery

Figure 1-1. Classification of approaches to reducing material and resource use, from high (R0) to low (R9) reduction in resource use or contribution to the circular economy. Adapted from PBL & RLI (Potting et al., 2016).

Safely closing material loops requires additional effort for the development, assessment and control of new recycling options for materials. This effort needs to be balanced with the benefits of material recycling. These benefits consist of a reduction in virgin material consumption and environmental impact, coupled with an increase in the economic value of the waste stream; in other words, an increase in natural and economic capital. These are two elements of sustainable development (Farley and Smith, 2013). The preservation of natural capital can be seen as a precondition for the transition towards a CE. In the Dutch government-wide CE programme, this is emphasized by the following:

"*It is about an economy that meets needs without unacceptable environmental pressures and without depleting natural resources. This requires not only a relative decoupling of resource use and economic growth, but also an absolute decoupling of economic growth and environmental impacts. Safeguarding the natural capital, from the point of view of securing supply and sustainability, is a precondition for this.*" (Rijksoverheid, 2016).

Closing material loops may present problems, e.g. with substances of very high concern. The flame retardant HBCDD used in foam insulation material (expanded polystyrene) is an example of a Substance of Very High Concern (SVHC) that must be controlled in the waste phase. This fire retardant is now banned, but has been used extensively over the last 30 years and waste streams containing HBCDD will occur in the decades to come. These can now be processed with the solvolysis extraction technique that reduces the concentration of fire retardant in the recovered polystyrene to an acceptable level (Bodar *et al.*, 2018). This shows that the presence of SVHC initially present in materials does not necessarily lead to an additional risk to human health and the environment when the SVHC can be extracted. Even better is the prevention of the need for such steps by following principles for the safe and sustainable design of new products. Unfortunately, this will not solve the safety concerns due to legacy substances being present in materials.

This report describes the assessment of the recycling or reuse of materials by combining the assessment of risks to human health and the environment and the sustainability benefits, see Figure 1-2. By addressing both of these issues, information is provided that helps decision makers to balance sustainability benefits (e.g. a reduction in CO_2 emissions) with the efforts required to control risks, i.e. due to exposure to substances of concern in waste. The ultimate goal is to control the risk, which could involve, say, control measures such as clean-up with associated energy costs, while still realizing sustainability benefits. The optimal outcome is depicted in the top-left panel of Figure 1-2. When, after an assessment using the SSL framework, the risk for man and the environment are identified (right panels), it only makes sense to put effort into controlling the risks when there is a clear benefit. By controlling the risks, the outcome would shift from the right to the left panels following the arrows. Additionally, optimization of the recycling process could result in added benefits, e.g. moving from modest to high benefit (bottom panel to top).

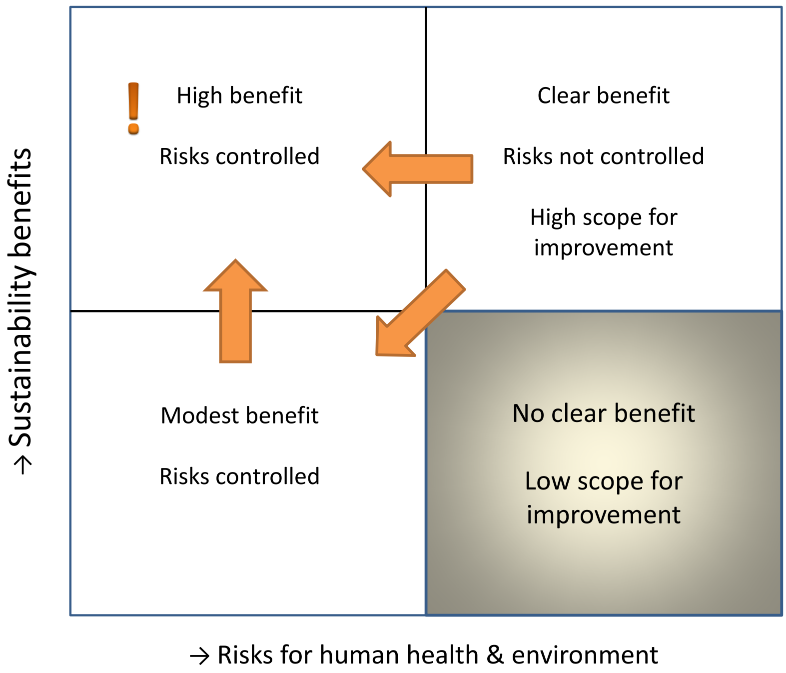


Figure 1-2. Approach to optimizing recycling with respect to sustainability benefits and risks for human health and the environment.

The risks of recycled material can have various causes, such as the presence of SVHC, pharmaceutical residues or pathogens that are released into the environment or that could affect people.

To control these risks, various relevant laws apply, such as those regulating chemicals (REACH), products (e.g. food packaging materials and construction products) or waste.

In many cases, a safe circular economy requires a review and possibly also an adaption of current risk assessment procedures. Inherent to the type of legislation, emphasis is placed on different parts of the material cycle; from design and use up to the end-of-life phase of a product. This also causes differences in the assessment of risks. For some products and substances, the risk is assessed in relation to an application or product, taking into account the positive properties. This happens, for example, for the active ingredient in medicines, for which the risk to the environment is not taken into account. This means that the risk of the substance has not been assessed for a possible new application of the material flow in which it is present.

A transparent and systematic approach is helpful for dealing with the increased complexity; different legislative frameworks (more than already mentioned) and multiple risk factors are at play. There is also a need for a practical approach to make the benefits of using secondary material explicit. For instance, when the safe use of a secondary material is only possible if a hygiene-promoting step is present due to bacterial contamination, the potential impact on climate needs to be taken into account as well, because such a step costs energy. A practical method should be able to demonstrate that the overall sustainability benefits are or are not large enough to make an envisaged recycling process preferable.

A methodology is presented to assess the material circularity, environmental impact and safety of using secondary materials based on the following principles:

- The scope of an assessment needs to be clearly defined. This concerns: (i) the source material/waste used, (ii) the recycling process, (iii) the secondary material produced and (iv) its application.
- Assumptions and underlying data are made explicit to increase transparency. This concerns, for instance, the use of risk limits, quality criteria or material characteristics.
- A systematic and consistent approach. This should create a level playing field where the method of assessment is clear.
- The outcome of different topics assessed should be presented in a harmonized way to support decision makers.

Based on these principles and needs, a modular framework has been developed for assessing the safety and sustainability of applying secondary material flows. This framework is called the safe and sustainable loops (SSL) framework. The SSL framework is meant to assist governing bodies and companies in tackling issues related to the safety and sustainability of secondary materials and their efforts to contribute to the transition to a circular economy and sustainable development. By using the SSL framework, the decision-making process can include information on safety concerns, the contribution to the circular economy and the reduction of environmental impact.

The SSL framework consists of several modules for different safety and sustainability themes, with a scheme to select the relevant modules. Each module is made up of a practical assessment method using tiers. The practical application of the framework is illustrated by applying it to three case studies.

1.1 Readers guide

This report consists of three parts.

Part 1 consists of the introduction and set-up of the SSL framework (Chapter 2).

Part 2 consists of the modules describing the approaches used to assess different topics (Chapters 3 – 9). These topics were selected based on their previous relevance for the assessment of secondary materials (Ehlert *et al.*, 2016; Quik *et al.*, 2016; Schmitt *et al.*, 2017; Wassenaar *et al.*, 2017). The currently selected topics are:
Chapter 3: Material circularity
Chapter 4: Environmental impact
Chapter 5: Substances of Very High Concern (ZZS)
Chapter 6: Pharmaceutical residues
Chapter 7: Pesticides
Chapter 8: Pathogens
Chapter 9: Antimicrobial resistance

Part 3 consists of a description of three case studies (Chapter 10), their analysis and further discussion of the SSL framework (Chapter 11). The SSL framework is tested using case studies on struvite recovery (10.1), Polystyrene foam recycling (10.2) and recycling of End-of-Life Tyre rubber granulate (10.3).

2 Description of the SSL framework

2.1 Overview

The SSL framework is meant to assist governing bodies and companies in tackling issues related to safety and sustainability in order to contribute to the transition to a circular economy and sustainable development. The processing of a waste stream into new materials or products involves many steps that can influence the assessment for safety and sustainability (Figure 2-1).

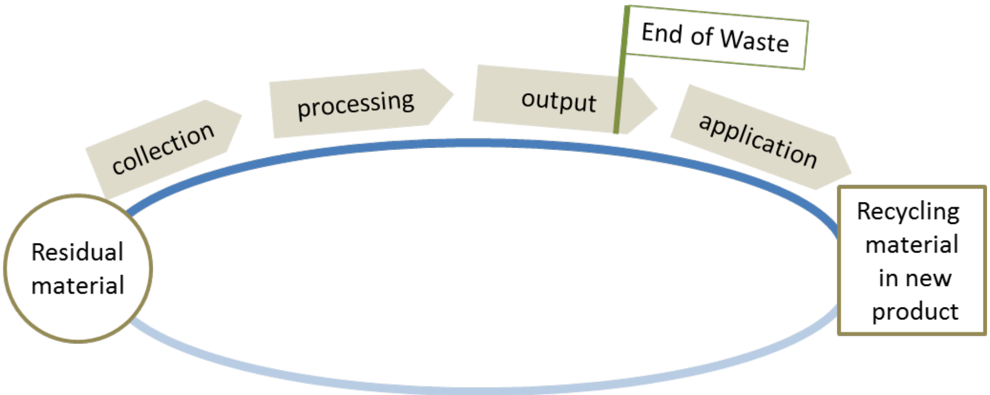


Figure 2-1. The recycling process, subdivided in assessment steps for safety and sustainability. 'End of waste' is a legal definition of the point at which the processing of waste results in a new material and waste legislation no longer applies. End-of-waste decisions can also be made for earlier processing steps.

The SSL framework is based on a tiered approach. Tier 0 consists of a screening for potential concern, based on the composition and origin of the waste stream. This results in a selection of 'safety' modules to assess various risk themes to man or the environment, e.g. the health risks of flame retardants in certain plastics or the health risks of pathogens in manure. These modules in themselves are tiered by their complexity, easy when possible, thorough when required. Each module leads the user to conclusions about safety and sustainability. Where Tier 1 is mostly concerned with material and hazard properties, Tiers 2 and 3 are progressively targeted to a quantification of actual risk and benefit, i.e. the result of both hazard and exposure.

The following themes have been incorporated in the SSL framework: Circularity and environmental impact, Substances of Very High Concern (SVHCs / ZZS), pharmaceutical residues, pesticides, pathogens and antimicrobial resistance. The methods incorporated in these modules are based on the current state of the art, existing methods and tools. This is further elaborated in each chapter (Chapters 3 - 9). The relevant policy and legislation frameworks are used, such as REACH (European Commission, 2006) for the module on substances of very high concern. This module is based on a risk analysis report 'ZZS in waste' (Zweers *et al.*, 2018).

2.2 Sustainable development

Closing material loops, hereafter referred to as circularity, is an important part of the transition towards a circular economy. This increase in resource use efficiency should generate benefits in the areas of economy, social and environmental sustainability and geopolitics. Some assessment methods for sustainability are available that cover aspects of the SSL framework, such as 'Omgevingswijzer' that is used to take sustainability decisions in infrastructural projects and spatial planning (Rijkswaterstaat, 2015). Within the Dutch national waste management programme (LAP), methods were developed to perform an extended sustainability analysis for three life cycles of a material stream (CE Delft *et al.*, 2017; van Ewijk *et al.*, 2018). This shows that a wide variety of methods is available, from qualitative to quantitative, for the assessment of sustainability. However, none are optimized for use in an integrative approach for assessing the safety and sustainability of materials and their application. For this reason, two approaches for assessing the sustainability-benefits have been introduced. Firstly, an approach to assess the circularity of a material loop related to a new application (Material Circularity module, Chapter 3) and, secondly, an approach to quantify the environmental impact of the new application (Environmental Impact module, Chapter 4).

The tiered workflow in these modules follows the same principles followed for the safety focused modules, progressing from simple to more complex.
The contribution of novel approaches for the recovery of resources or the recycling of materials to sustainable development and the circular economy is often assumed to be self-evident. This is not always the case, specifically when there are safety concerns and risk control measures are needed.

The circularity module is currently limited to strategies aimed at recovery, recycling and reuse options at the material level, e.g. not including lifetime-extending or smart design strategies. The module provides insight in terms of material conservation.
The environmental impact module provides insight into the positive effects or reduced environmental impact relative to a 'business as usual scenario', but also shows unintended impacts in the life cycle of the new application, e.g. an energy-intensive hygienization step in the production process.

2.3 Defining the opportunity for recycling

The definition of which recycling issue is at stake is very important and should be documented as early as possible; examples can be found in Zijp et al. (2017).
It is beneficial for the start of the assessment with relevant stakeholders that are involved from the start (Tier 0) to identify available knowledge, views and interests. Depending on the case, this could involve those providing source residual/waste material and those processing it (e.g. waste sector), policy advisers and, if necessary, government. Waste handlers and producers of recovered (secondary) materials have information on the recycling process, materials, required energy and products and their applications.

Tier 0 is designed to use the information from stakeholders on the source and composition of the waste stream in order to identify any human health or environmental safety concerns. The flow diagram for Tier 0 shows that the fact about whether waste streams are biotic or not greatly defines the relevance of specific safety themes (Figure 2-2). The ubiquity of the presence of substances of very high concern (ZZS) in current waste streams makes it difficult to rule out the relevance of the ZZS module for specific waste streams. Although there are options or circumstances where waste streams remain uncontaminated, until this is common practice such exclusions would need to be addressed in a case-by-case Tier 0 assessment.

To further define the benefits and potential risks of specific recycling operations, the SSL framework highlights the following questions:

- What secondary material and its application are assessed, and what material or application does it replace as a reference?
- In what aspects does the new product or material differ from the reference situation as defined earlier?
- Which material streams are part of the analysis, does it involve a single stream of several or even an entire product chain?
- What is the scope of the assessment in terms of spatial or temporal scale, life cycle stages and steps in the recycling process (Figure 2-1)?

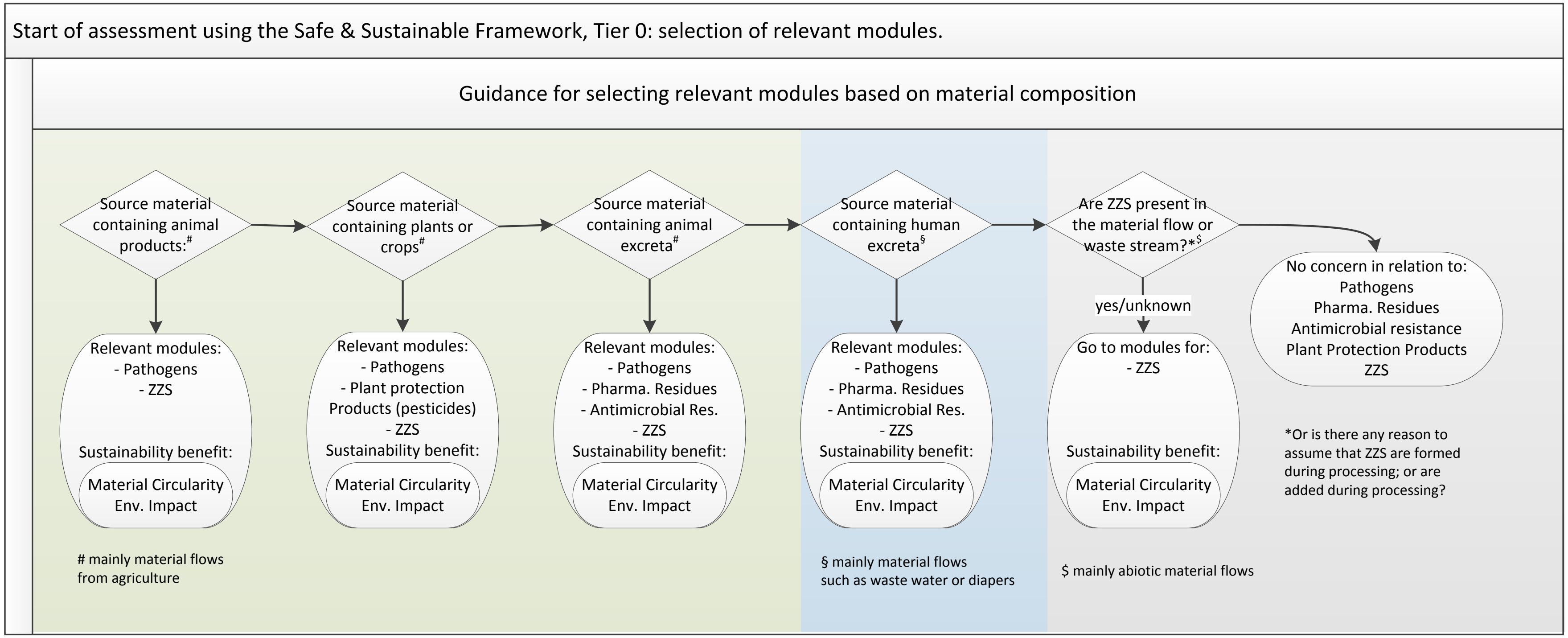


Figure 2-2. Guidance for selection of relevant modules based on the composition of the source residual/waste material.

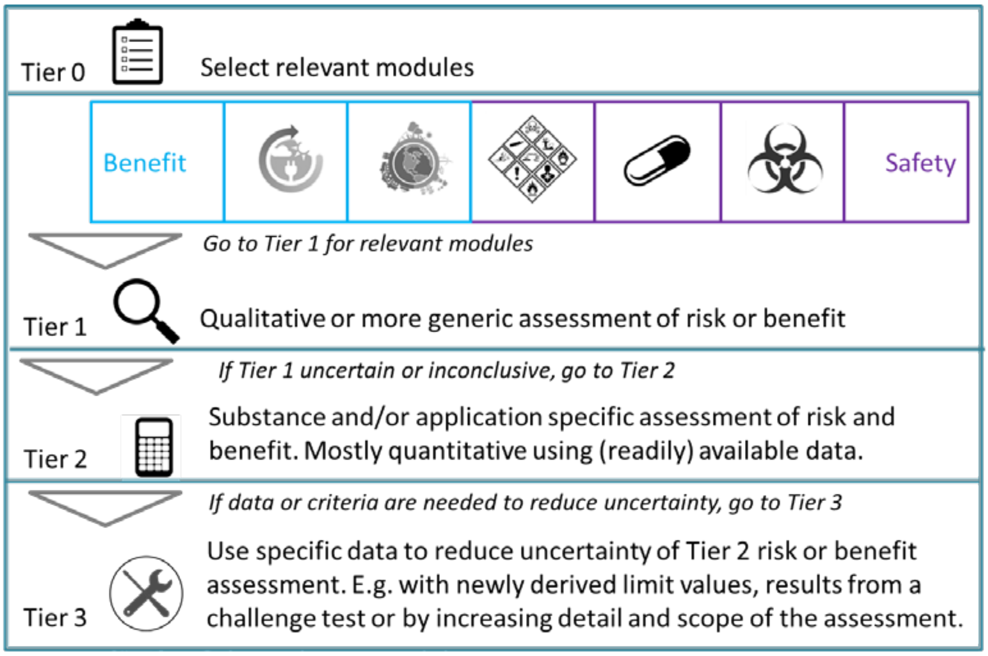


Figure 2-3.Overview of workflow of the safe and sustainable loops assessment framework using Tiers, where the first one (Tier 0), is used to select the relevant modules: substances of concern (ZZS), pharmaceutical residues, pesticides, pathogens, circularity and sustainability.

2.4 Tiered approach

The SSL framework uses a tiered approach – simple where possible, more complicated if needed. Each tier requires more information than the previous one, but is only invoked if the previous tier did not result in a clear answer, e.g. due to a lack of data on which to base a decision; higher tiers offer more detailed methods for dealing with such data gaps (see Figure 2-3).

As described in Section 2.3, each assessment starts with an inventory of the material flows, a problem definition, and a selection of the various sustainability and risk modules in Tier 0. In Tier 1, each module generates a conclusion based on limited available information and semi-quantitative criteria on the potential benefits and risks.
Tier 2 continues if Tier 1 is indecisive, based on more detailed quantification and the application of criteria derived from existing legislation. Tier 3 is tailor-made, adjusted to the circumstances of specific cases. It usually involves generating new data and possibly new criteria in the absence of legally binding ones. The SSL assessment ends with a summary of the results for each module and tier that was triggered (Section 2.5).

2.4.1 *Tiers 1 to 3*

The Tier 1 assessment is based on information that is readily available and only done for risk themes that are selected in Tier 0. Based on available criteria for assessment, one of the following conclusions can be drawn:

- Safety concern or not and sustainability benefits or not, and no further assessment is needed.

- More information is needed to make a robust decision on potential benefits or safety concerns, go to Tier 2.

It is possible to iterate Tier 1 if, for example, the process or material input into the process changes.

In Tier 2, additional information is gathered and documented during the assessment:

- Quantitative data (measurements, indicators, relevant literature data, etc.).
- Additional qualitative information.
- Information on assessment criteria (legally binding, non-legally binding, trigger values, reference values, etc.) for health, environment and sustainability.

In Tier 2, where available, more specific criteria for assessment are used to draw the following potential conclusions:

- Safety concern or not and sustainability benefits or not and no further assessment is needed.
- More information is needed to make a robust decision on potential benefits or safety concern, go to Tier 3.
- Decision to end the assessment, e.g. due to a lack of potential sustainability benefits. This can be done even though there is no definitive answer on the robust outcome of the safety assessment.

It is possible to iterate Tier 2 if, for example, the process or material input into the process changes.

Tier 3 is a tailor-made approach used to gather more information or to generate new data on potential benefits, risks and criteria. If quality criteria are lacking, additional research may be needed to test whether the envisioned new applications show options for risk management.
It may also be possible to perform additional testing in order to show that a recycling process or recycling step can reduce potential risks, e.g. by extracting substances of concern or sterilizing a biotic waste stream. Another approach could be to assess specific applications of materials or products for relevant exposure to man or the environment, which usually requires more elaborate risk assessment methods. Depending on the availability of relevant exposure scenarios, it may be possible to estimate the risk of exposure due to the use of regenerated materials or products.

2.5 Outcome of the framework

The overall outcome of the different modules is presented in an overview, see Figure 2-4.
This presentation is called a safety and sustainability data sheet. For each module, the final tier of the assessment is listed with the conclusion. This is of course based on an extensive report for each module in the SSL framework, including the outcome of each tier.
Optionally, it is possible to indicate the contribution to relevant Sustainable Development Goals (SDGs) (UN, 2015) or other policy goals. For instance: it could be indicated how much a recycling option contributes to CO_2 emission reduction targets.
The SSL framework does not weigh the different outcomes of the modules into a single number or indicator. The main outcome of the

assessment is presented at the bottom with a colour code. Green is used to indicate control of risk or a clear benefit, orange is used when the outcome is indecisive and red when the outcome of the module clearly shows a safety concern or lack of benefit.

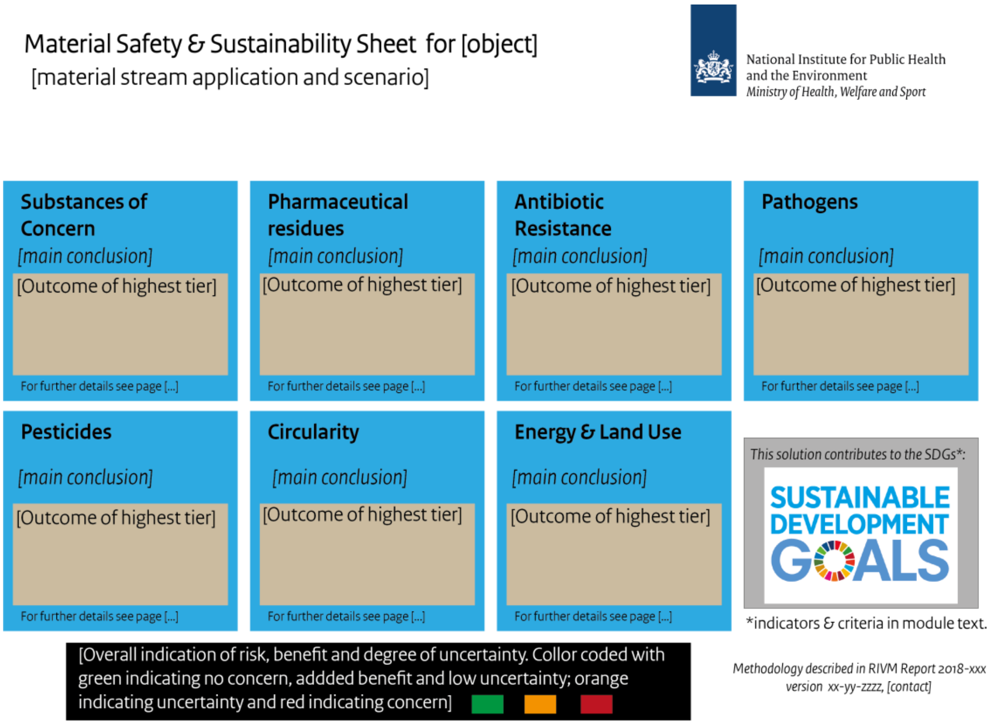


Figure 2-4. Generic material safety and sustainability data sheet to present the overall outcome of the SSL framework.

2.6 Extending the framework

The SSL framework is meant to explore and communicate the effects of recovered materials on sustainability, health and the environment. Because the approach is modular, additional sustainability or risk themes can be added when required, such as socio-economic effects. Current topics of concern are the effects of microplastics, released intentionally or unintentionally, nanomaterials and radioactivity. Individual modules can also be extended or simplified when needed. An additional field of interest is ‘safe and circular by design’, where alternative or new technologies are assessed for sustainability and safety during development and before actual production starts. With the required adaptations, the SSL framework could be useful for the design phase as well.

Part 2: Technical description of modules

3 Material Circularity

Closing material loops, hereafter referred to as circularity, is an important part of the transition towards a circular economy. With this module, the circularity of a material loop related to a new application can be assessed. The circularity module is currently limited to strategies aimed at recovery, recycling and reuse options at the material level, e.g. not including lifetime-extending or smart design strategies. The module provides insight into the contribution of the application to the transition towards a circular economy in terms of material conservation. The basic set-up of this module is given in Figure 3-1.

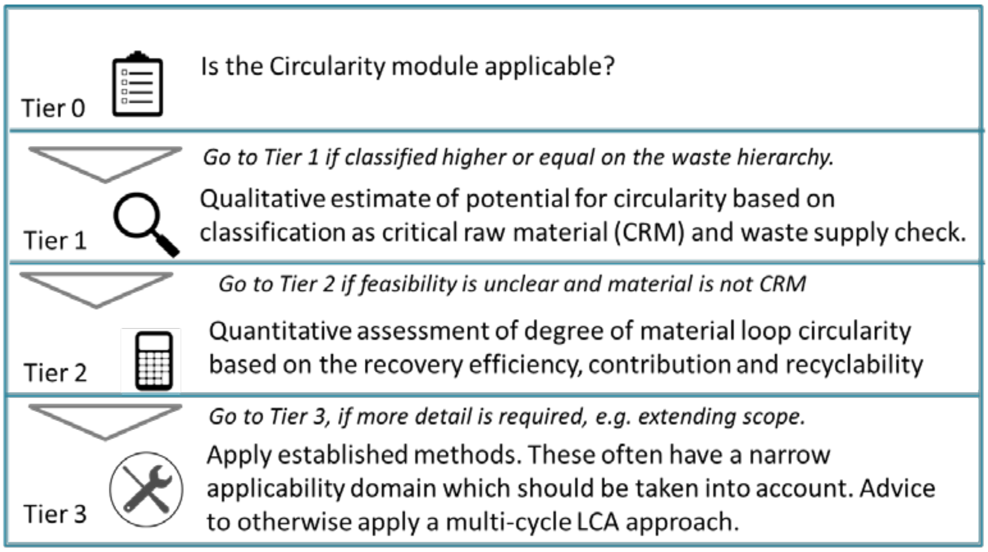


Figure 3-1. Overview of circularity module.

3.1 About the Circularity module

The use of this module should give an initial estimate of the degree of circularity increase. This assessment of circularity is aimed at the use (or processing) of waste streams (or material flows in general) for certain applications. Circularity is all about the efficient and smart use of materials to prevent resource depletion; in other words, increasing the efficiency of resource use. This can be done by re-using or recycling our resources as much as possible and extending the lifespan of products, components and materials for as long as possible. This means preserving feedstock supply and preserving the value of resources for as many life cycles as possible.

This assessment module of circularity is based on the scarcity of resources, the recovery efficiency, the contribution of this recycled resource to a new application and its availability for recycling afterwards. This module falls within the scope of the SSL framework, meaning that it is used for assessing novel applications of material flows and, as such, does not include other circularity principles that are higher up the R ladders, such as extending product life or smart design (Figure 1-1).

In Tier 1 we mainly indicate high potential benefit if the recycling option is for an EU critical resource (European Commission, 2017) and if the potential indirect impact of a shift in resource use is limited, i.e. the intended application will consume a negligible fraction of the market of the source material. If this is not the case, it is advised that a more detailed assessment of circularity be performed in Tier 2. The indicators applied here were chosen after the evaluation of several existing indicators (De Jonge Milieu Advies, 2014; Stevense and van Dalen, 2014; Metabolic, 2015; Schoenaker and Delahaye, 2015; European Environment Agency, 2016; Potting *et al.*, 2016; CE Delft *et al.*, 2017; Optimal Planet, 2017; Biobased, 2018; Maatschappelijk Verantwoord Ondernemen Nederland, 2018; Planbureau voor de Leefomgeving *et al.*, 2018).
The result were three main indicators aimed at different sections of the material cycle. These are aimed at assessing (i) the recovery efficiency, (ii) the contribution of the recovered resource to the total demand and (iii) recyclability, which is the fraction of the resource to reach a next recycling step.
These three indicators are all based on information on the amount of material used, lost and recovered, combined with a classification of the quality of the recovered resource. This quality classification is based on the policy rule developed for use in the Dutch waste management plan (CE Delft *et al.*, 2017; Ministerie van Infrastructuur en Waterstaat, 2017). Further details on assessing these indicators are given below in Section 3.3.
This Tier 2 method to assess the degree of circularity results in a score between 0 and 1, which is a score related to this material loop (SSL scenario). For an indication of the added benefit over the current practice, the circularity score of the baseline scenario should be assessed as well. To estimate this potential benefit, the module should also be applied to the current practice, a reference scenario, see Section 4.2. After comparing the two scenarios, the benefit can be estimated. For more details, see the workflow in the following sections.

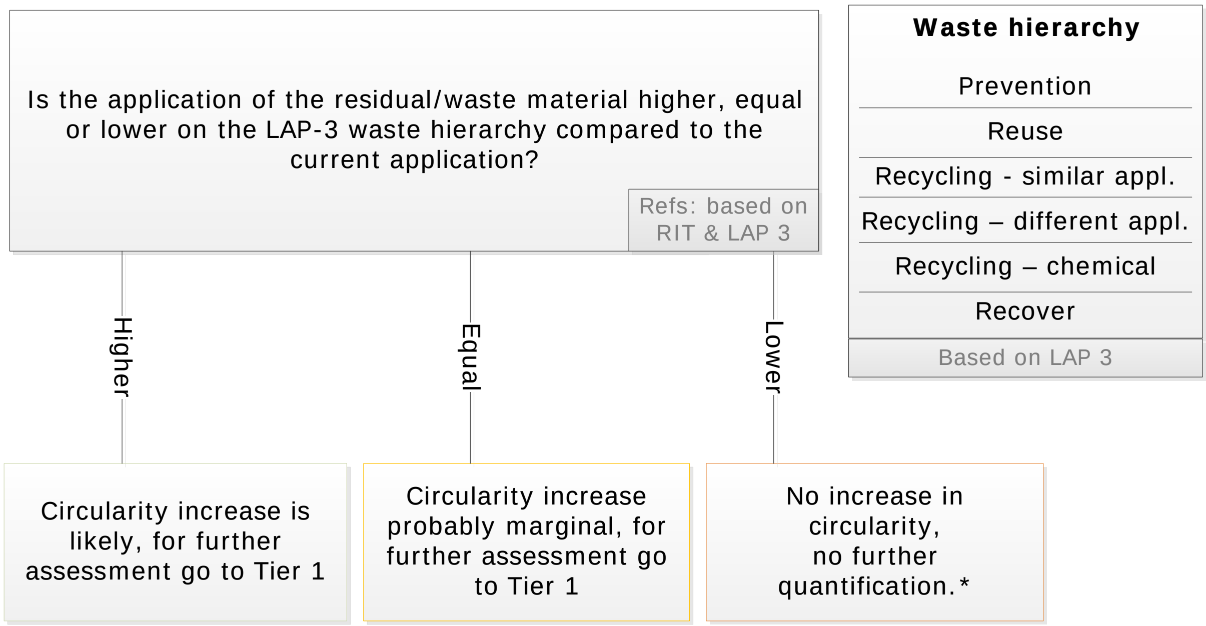
Tier 3 assessment is currently not a defined method. This tier should be versatile and can be fulfilled by one of the available comprehensive assessment methods. These are often specific for different material cycles (e.g. building materials (De Jonge Milieu Advies, 2014) or food (Vellinga *et al.*, 2016)) and can potentially include the use of a novel multi-life cycle analysis (mLCA) aimed at improving circularity while taking environmental impact into account (CE Delft *et al.*, 2017).

3.2 Relevant material flows and product cycles

This module is deemed applicable to all material flows or waste flows. However, it is foremost designed to fit assessments of a waste stream with a foreseen application. This can be a particular product or any intermediate product or building block. Currently, the module is being tested in two case studies: the application of sewage waste to produce struvite (see Section 10.1) and the application of end-of-life tyres to produce infill material for artificial turf (see Section 10.3).

3.3 Assessment work flow

3.3.1 Relevance of module



**Tiers 1 and 2 include indicators aimed at measuring the material circularity of recycling or higher.*

Figure 3-2: Tier 0 – Circularity, a flow chart to identify the applicability of this module and to assess the potential contribution to circularity. At the upper right, the waste hierarchy is presented as used in LAP3 (Ministerie van Infrastructuur en Waterstaat, 2017).

The aim of this module is to assess the potential benefit in terms of increased resource efficiency. Here, in Tier 0, we indicate that this module is only relevant if the novel application of the material flow has an expected net positive effect. For this reason, in Tier 0 the leading question is whether the *intended* application of the material flow will be higher, equal or lower in the waste hierarchy compared with the *current* application (Metabolic, 2015; Potting *et al.*, 2016; Ministerie van Infrastructuur en Waterstaat, 2017), see Figure 3-2. The hierarchy in circularity strategies (R ladder) applied here is defined in six steps, although there are versions with up to 9 levels. This module is aimed at those levels that are directly relevant to waste or residual material use and applies the approach implemented in the current Dutch Waste Management plan (LAP 3). The upper level, prevention (or 'refuse'), is seen as the ultimate form of circularity and the lowest, recovery, is seen as the final option, to recover energy (see text box below for definition of the different levels). As a rule of thumb, the resource savings are greater, the higher the application is in the hierarchy of circularity (Potting *et al.*, 2016). The circularity module Tiers 1-3 are deemed relevant if the answer to the main question is a higher or equal level. Although the methods in Tier 1 and higher tiers could be applicable to any recycling option, it is advised to report only the Tier 0 outcome if the SSL scenario considers a lower step in the hierarchy compared with the baseline. However, if the classification in Tier 0 is uncertain or a contribution to circularity is still expected, then a continuation through the next tiers anyway is advised. This should be done while taking into account the limitation that the methods used in Tiers 1 and 2 are not developed for energy recovery processes (R0 in Figure 1-1), as then the material is lost. It should also be noted that, even though potentially no added circularity benefit is shown, that assessment of other aspects, such as environmental impact, may show a benefit. It is known that the waste hierarchy does not include all types of trade-offs and the environmental impact module and safety modules can be used to support arguments for deviation from this waste hierarchy. For instance, the chemical recycling of insulation foam (EPS) with the flame retardant HBCDD is preferred over recycling of the material in the same quality and application because, in the first option, HBCDD is largely removed. See Section 10.2 for more information.

Definitions of the terms used in Tier 0, Figure 3-2:

Application is the intended use or utility. This can be at different stages in a product material cycle: a building block or end product, e.g. a particular volume of mown road-side grass or a specific polymer.

Residual or waste stream is the source material flow containing the raw material or product to be used.

Prevention is an alternative scenario, such that the application is not needed. For instance, if toddlers were to be potty-trained at a younger age, diaper waste could be prevented.

Re-use (in the R ladder) is using product or components for the same purpose, without introducing virgin material and without dismantling or separating it into separate materials, such as the re-use of furniture on the second-hand market or wood pallets.

Recycling – same application is the application of materials from the previous use cycle to the same or similar application type for the next cycle using material of a similar quality; e.g. glass recycling.

Recycling – different application is the application of raw materials from a previous use cycle that replaces primary material use, but which are not recovered in their pure form. The material replaced does not need to be the same as the recycled material. For instance, PET ending up in a mixed plastics fraction that replaces wood.

Recycling – chemical is the application of raw materials from a previous use cycle at the substance level, e.g. precious metal extraction from mobile phones.

Recover is the recovery of energy from the material or waste stream.

3.3.2 *Tier 1: critical raw materials and source supply check*

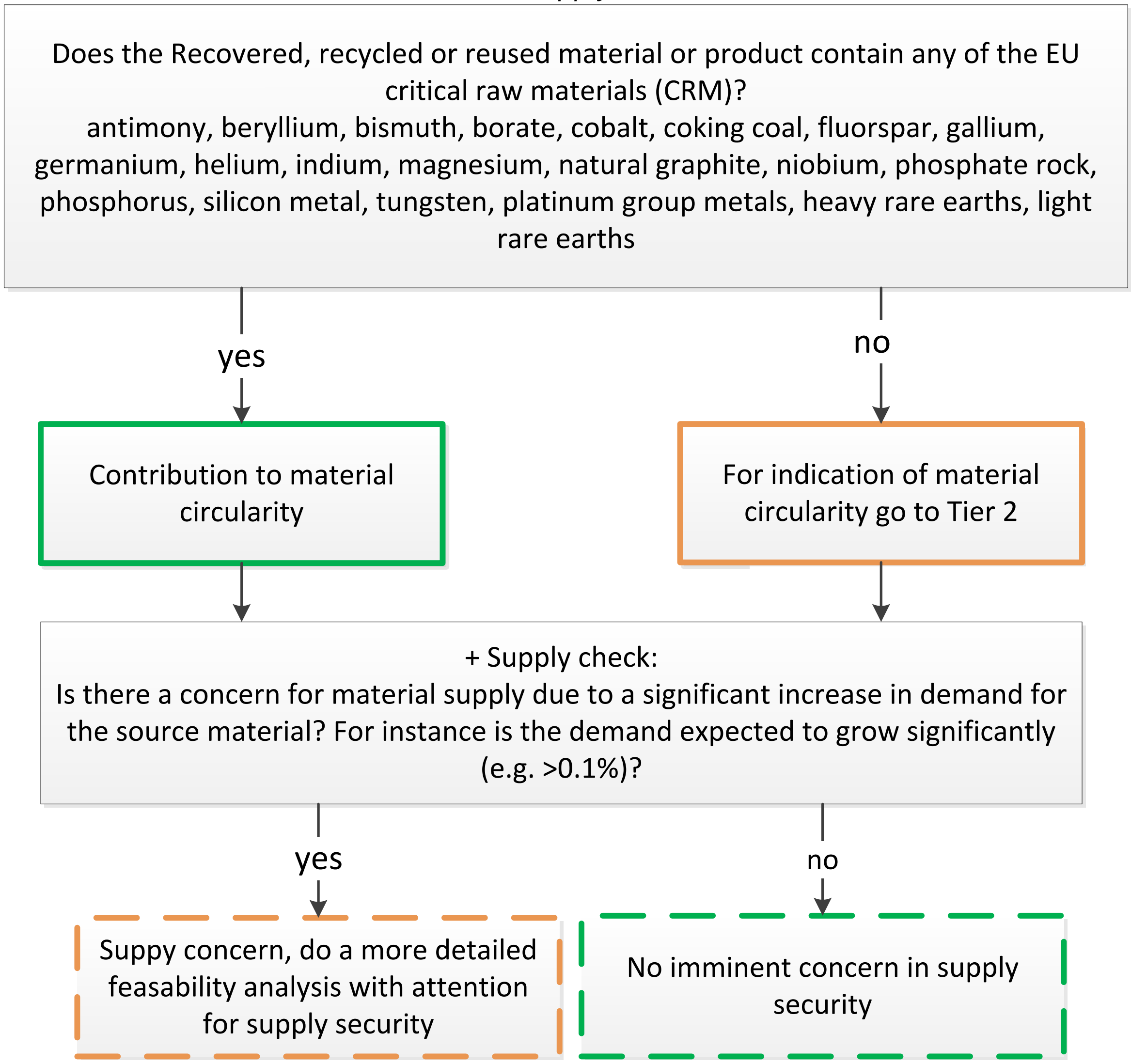


Figure 3-3. . Tier 1 –Flow chart to make a first estimate of circularity based on the presence of critical raw materials (CRM) and to conduct a check of source residual material supply. This is to check whether the source material flow required for the intended processing step is readily available.

The first-tier checks whether the resource recovered from a material flow is relatively scarce or has low supply security and whether the material flow itself is sufficiently available (supply check). If the resource is scarce, this is deemed to be enough to contribute positively towards circularity. The supply check then should show whether there are any concerns in relation to supply and demand for the source material under consideration

This means that in Tier 1 (see Figure 3-2) the first question is whether the intended resource recovered contains any Critical Raw Materials (CRM). We advise using the EU list of critical raw materials (Commission, 2017). The second question is an initial semi-quantitative indicator to check the stock supply of required material. It asks whether there is already a demand for the source material flow required for the processing step. This means that it has already been applied or processed somewhere else. If there were a demand, it could be that the proposed application would not increase the demand significantly. For example, when less than 0.1% of the total yearly available material flow will potentially be used. This 0.1% is an arbitrary limit and can, of course, be adjusted based on things such as available feedstock or mass flow balances. Spatial scale can also be important here, e.g. the supply in one town or in the whole of the Netherlands. This check is important in order to make sure that the application does not require more feedstock than can be provided or is available for the particular application. For instance, the use of waste water for struvite recovery does not indicate problems with the supply of waste water. The struvite is recovered at the existing wastewater treatment plant and there is currently no other demand for waste water as a source material. Phosphate in struvite is a CRM. This indicates a clear contribution to circularity. Evidently, demand and scarcity can vary over time and it is therefore recommended to check regularly for updates on the CRM list, as well as to keep track of changes in stock supplies, etc., and to repeat this Tier 1 assessment if needed. The positive contribution seems clear in that case. For a more thorough assessment, proceed to Tier 2. Tier 2 is required when the recovered resource is not on the CRM list. If there is concern related to the supply of source material, this should be assessed separately. Furthermore, it is advised to apply Tier 2 also to the currently most demanding application for the material under consideration in order to compare the potential increase in material circularity with the novel application under consideration.

Definitions of the terms used in Tier 1, Figure 3-3:

Application is the intended use or utility. This can be at different stages in a product material cycle: a building block or end product, e.g. a particular volume of mown road-side grass or a specific polymer.

CRM is a critical raw material. These elements are raw materials that are crucial to Europe’s economy and have a high risk associated with their supply (Commission, 2017).

Supply check is the assessment of the availability of the relevant source waste streams to be recycled.

Residual or waste stream is the source material containing the raw (secondary) material or resource to be applied, e.g. in a product.

3.3.3 Tier 2: Recovery efficiency, contribution and recyclability

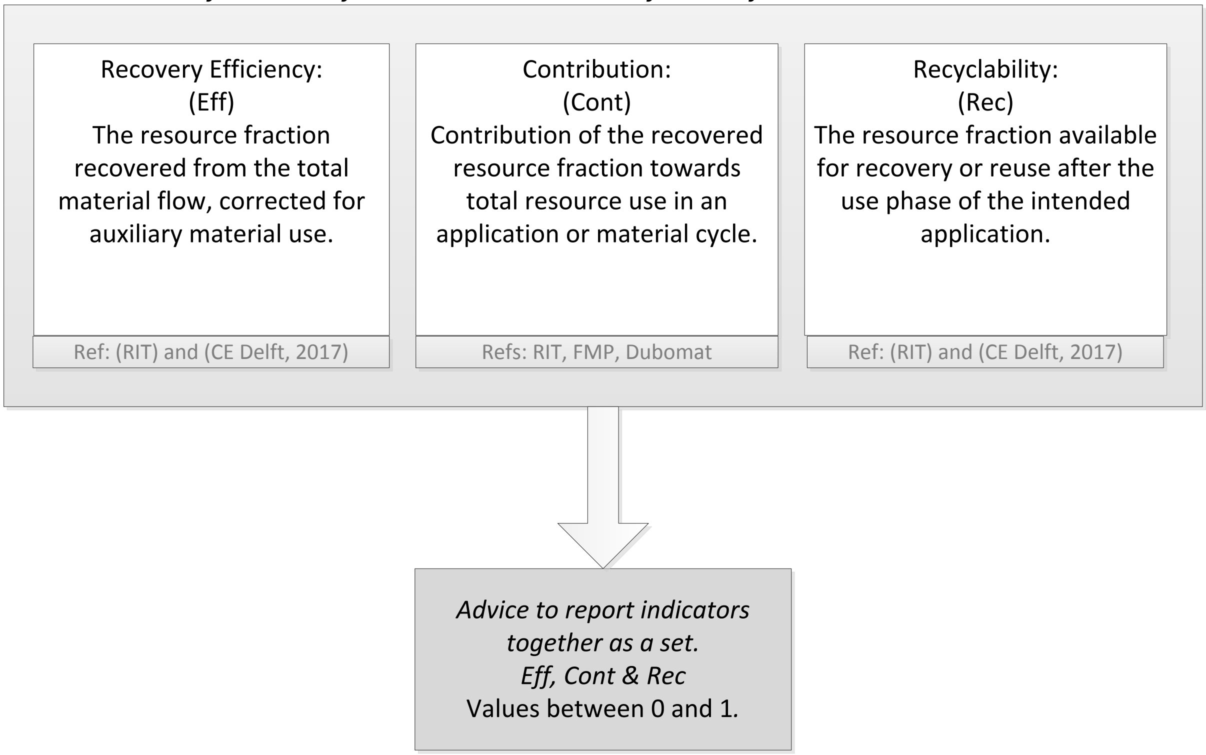


Figure 3-4. Tier 2 – Scheme illustrating the assessment of circularity based on recovery efficiency (Eff), Contribution (Cont) and Recyclability (Rec).

In Tier 2, a quantification of material circularity is performed using indicators for the efficiency of resource recovery, the contribution of recovered resources to the intended product or application and the recyclability after the use phase (Figure 3-4). These indicators are calculated based on a basic material flow analysis and essentially require knowledge about the composition of a waste stream, the recovery process and the composition of its application. The approach to quantify these indicators is given below.

Recovery efficiency
The recovery efficiency is based on the recovery of a resource or secondary material from the total of materials contained in the waste or residual material flow, e.g. clean polystyrene from building insulation material. This recovery is done using a recycling or refurbishing process, which inherently encounters some losses (large or small). These losses are accounted for here. Anything not recovered is not available for a subsequent material cycle. Furthermore, additional raw materials might be required for recycling purposes, which may counteract the material circularity benefits. Therefore the indicator corrects for auxiliary raw/virgin materials. This leads to the following equation for recovery efficiency:

$$Eff = \frac{Rx}{Rtm} * \frac{Rx}{Maux + Rx}$$

Whereby:
Eff = Recovery efficiency [-]
Rx = recovered resource, x [kg]
Rtm = total resource in the source (waste) material flow [kg]
Maux = raw/virgin auxiliary materials used for production of resource [kg]

The functional unit of the total resource should be the same for the recovered resource, e.g. total mass of P (phosphorus) in waste water (Rtm) and total mass of P in recovered phosphate in the form of struvite (Rx).
Auxiliary materials included in Maux are the help materials needed for recovery of a resource, e.g. water (if not reused within the recycling process), catalysators, coagulants and solvents. Materials that make up the processing machinery or that are required for transport are not included here. This has been done in order to focus on the primary recycling process and its efficiency in terms of material use and yield. Transport and energy use in general are part of the module on assessing environmental impact.

This approach produces an 80% recovery efficiency for the recycling of old tyres to rubber granulate (RecyBEM and ARN, 2011). This process does not include any auxiliary materials, as this is a purely mechanical process and thus *Eff* equals 0.8. For P recovery from waste water via struvite, about 23% to 47% of total P can be recovered. However, a significant amount of auxiliary materials are used to precipitate P in the struvite mineral. This results in *Eff* of between 0.06 and 0.24.
The current approach for taking auxiliary materials into account is rather crude because this is done purely on a mass basis. For instance, the use of MgCl or NaOH salts for the recovery of struvite are now added to the total amount of P in waste water, whereas these are totally different materials in different material cycles. It is recommended to include a quality factor in order to take these differences in material into account. This factor could be based on the economic worth or the cumulative energy demand of the materials under consideration. Due to time restrictions, this was not worked out further here, but the resulting formula would be as follows:

$$Eff = \frac{Rx}{Rtm} * \frac{Rx}{Qxa * Maux + Rx}$$

Whereby:
Qxa = Factor indicating the quality of the auxiliary materials compared to the recovered resource

Contribution
This indicator is aimed at quantifying the degree to which a recovered resource can fulfil demand within a defined geographical market (worldwide, in Europe, national, regional or local). It is about the contribution of the recovered resource towards the reduction of virgin, raw material use in an application or material cycle. For instance, if worldwide all P is recovered from waste water, it can only replace a fraction of demand for P. This means that, for closing the loop, other

sources are needed. The contribution indicator is based on the fraction of total applied materials in the intended application or materials cycle that is substituted by the recovered resource. This includes other materials required for the system to support the intended function. For example, there is enough rubber granulate from end-of-life tyres (ELT) to fulfil the demand, e.g. for infill materials in artificial turf pitches. This can be calculated using the following equation:

$$Cont = \frac{Rx}{Rta}$$

Whereby:
Cont = contribution [-]
Rta = Total resource required for the intended application [kg]

In reality, the contribution indicator for ELT granulate as infill material is 0.9 because, in previous years, about 90% of synthetic turf used ELT granulate as infill in the Netherlands.

Recyclability
The recyclability indicator is aimed at quantifying the potential for the recovered resource to be recycled or reused after the current use phase. This consists of two measures:
1. The amount of material available after the current use phase, so after subtracting the losses, e.g. due to wear and tear.
2. The quality of the recovered materials in combination with their current application compared with the source material. This is based on the quality indicator as used in the policy decision rule (CE Delft *et al.*, 2017) because, in assessing circularity of material flows, the degree of contamination or value for future application needs to be accounted for. Combining these two measures leads to the following equation:

$$Rec = \left(\frac{Rret}{Rta}\right) * Qr$$

Whereby:
Rec = recyclability [-]
Rret = Resource returned for recycling or reuse [kg]
Qr = Quality classification factor between 0 and 1.

To assess the quality classification factor, it is advised to follow the approach reported in (CE Delft *et al.*, 2017). In summary, the quality factor is divided into three classes:

1) First, the recovery of material at the same functional level as the source of the material flow.
2) Second degree is the (target) resource recovered, but contaminated with non-target materials or characteristics of the material deteriorated such that it cannot again be used to fulfil a comparable function. This results in a lower grade material.
3) Third is the recovered material mixed with non-target materials in such a way that only long-term application in another domain is possible, e.g. use as a substitute for building materials or filler material.

The weights given to these classes are 1, 0.5 and 0.25, respectively, for each degree from first to third (CE Delft *et al.*, 2017). These were chosen

in order to make a clear distinction between recycling options relative to each other. Although their values are arbitrary and might be changed, they have shown to be functional in two studies with this method (CE Delft *et al.*, 2017; van Ewijk *et al.*, 2018). Furthermore, it is advised that a Qr of 0 is used when the material is landfilled or incinerated.
The classification of the quality of the recovered resource uses the source material product cycle as its reference. For example, rubber granulate from tyres being used again for the production of tyres would get the highest score of 1. However, if the rubber granulate is contaminated with substances that are not up to current quality standards, the Qr is reduced to a score of 0.5.

Aggregation of circularity indicators
Although the three indicators can be aggregated by calculating an average or by multiplication, we advise the use of them separately and a discussion of them together in order to pay individual attention to these three aspects of closing a material loop and increasing circularity. If any of these indicators is low or 0, the loop is not closed. For example, if the recovery efficiency and recyclability are both high, but this material flow is only very small compared to demand, then the material loop is not closed. If recyclability is low, the material loop is not closed because a lot of material is lost in the use phase. If recovery efficiency is low, a lot of material is wasted or ends up in another material loop.

Further experience is needed with applying these indicators in practice, e.g. in novel applications for which data might be scarcer. Some further work and development is needed to show that these indicators work in practice to properly distinguish between different scenarios that contribute in different degrees towards the efficient use of resources as part of a circular economy. For a detailed account of the use of this module, see the cases presented in Chapter sections 10.1 and 10.4.
Circularity is only aimed at reducing material use, which is only a limited indicator for environmental impact. For this reason, there is a separate module aimed at assessing environmental impact, see Chapter 4.
Assessing material circularity or resource efficiency in more detail using more specific and realistic data on materials and production processes is possible, but it is advised not to limit such efforts in data gathering to material circularity only and also to use it for assessing environmental impact.

3.3.4 Tier 3
When a Tier 2 analysis of material circularity is not deemed adequate, a Tier 3 analysis can be performed. This can be relevant when there is still uncertainty in the assessment of one of the material circularity indicators. Other methods aimed at specific types of materials could help in this regard.

Several methodologies exist to assess (qualitatively and quantitatively) more aspects of recycling and other aspects of circularity suited for a Tier 3 approach (Metabolic, 2015; Vellinga *et al.*, 2016; CE Delft *et al.*, 2017). For instance, those specifically for building materials (De Jonge Milieu Advies, 2014) or the food cycle (Vellinga *et al.*, 2016)). A helpful overview might be found in Kok and Zijp's (2017) review on methodologies for circular procurement.

As this module is primarily aimed at assessing material circularity and resource efficiency, ultimately this increase in resource efficiency should lead to lower environmental impact. Environmental impact can be assessed using the next module, using energy or CO_2 and land use as indicators. When methodologies for the purpose of assessing circularity become rather complex and require a lot of similar data compared to an LCA, it is recommended that this type of method be used to compare scenarios. LCA is a much more extensive method to assess environmental impact. This is especially true for the multi-cycle LCA method, as developed for use in the Dutch national waste management plan (LAP3). That approach offers a good way to combine the analysis of increased resource efficiency with an assessment of environmental impact (van Ewijk *et al.*, 2018). A recent evaluation of this multi-cycle method was done on different recycling options for recycling 5 different materials or products (van Ewijk *et al.*, 2018).

3.4 Data sources

For Tiers 0 and 1, if no data on the mass flows are present, the module can also be used qualitatively based on basic knowledge of the source residual material and the recycling process. For Tiers 2 and 3, however, specific data on the material flow and the application (mass and content) are needed for the calculation of the indicators or the use of another quantitative method.

3.5 Criteria

In Tier 0, the approach to assessing circularity is related to the waste hierarchy. This classification can be seen as a qualitative criterion. Although the criterion of a change of 0.1% in demand is mentioned as an example, this criterion is the preferred level in CLP legislation below which no meaningful use is indicated (ECHA, 2017). So there is an argument for applying this 0.1% and asking for a feasibility study otherwise. For the material circularity indicators introduced in Tier 2, there are no practical criteria. These indicators show the degree of circularity, on a scale between 0 and 1, with 0 meaning linear and 1 meaning fully circular. The governmental policy of the Netherlands is aimed at a transition to a circular economy, with the ambition of realising a reduction in the use of primary raw materials by 50% in 2030 and full circularity in in 2050 (Rijksoverheid, 2016). It remains unclear how these percentages should be interpreted, but the indicators introduced here could help, e.g. a minimum score of 0.5 for each indicator in 2030. These indicators can be tested further in future case studies.

3.6 Possibilities for intervention

It is clear that a useful approach to intervening in terms of circularity is to go up the R-ladder or waste hierarchy. Furthermore, in the future exact circularity goals can be used to check or intervene in certain business plans or processes. Circularity goals can be set, such as setting the recycling targets at the EU level within the Waste Framework Directive (The European Parliament and The Council of the European Union, 2018). These should also support the smart design of processes and products in order to reduce resource use and losses in a material/product life cycle.

3.7 Recommendations

This module is currently based mainly on a mass-flow-based approach to recycling efficiency, contribution and recyclability. Although some quality aspects, such as those for auxiliary materials, are included, the scope of the method should be extended to other circularity strategies (R0-R7). This is related to the following elements:

- Investigate the inclusion of lifespan, e.g. closing a material loop with a short lifespan is likely to score differently from one with a long lifespan.
- Further update the method for including the net use of auxiliary materials (avoided and added) in a consistent manner. For instance, develop an approach to quantify the quality factor (Qxa) as part of the recovery efficiency indicator.
- Improve the output of Tier 2 to better inform decision makers, e.g. compare the outcome to a baseline scenario or in relation to a set goal or limit.

Overall, this method needs to be applied in practice in order to further develop its applicability in terms of data availability and the refinement of output. It is currently aimed at assessing material flows previously not used for recycling or resource recovery. This application domain should be expanded, e.g. for assessing design and remanufacture practices.

4 Environmental Impact - Energy and Land use

The environmental impact module provides insight into the positive effects or reduced environmental impact relative to a business-as-usual scenario. But it also provides insight into unintended impacts in the life cycle of the new application, e.g. an energy-intensive hygienization step in the production process. The module consists of a method using cumulative energy demand and land use as indicators for environmental impact (Figure 4-1). This is implemented in Tier 2. Currently, no qualitative method has been proposed as a part of Tier 1. Tier 3 is required when a more precise assessment is deemed necessary, using other existing tools and methods to apply a life cycle assessment (LCA) approach.

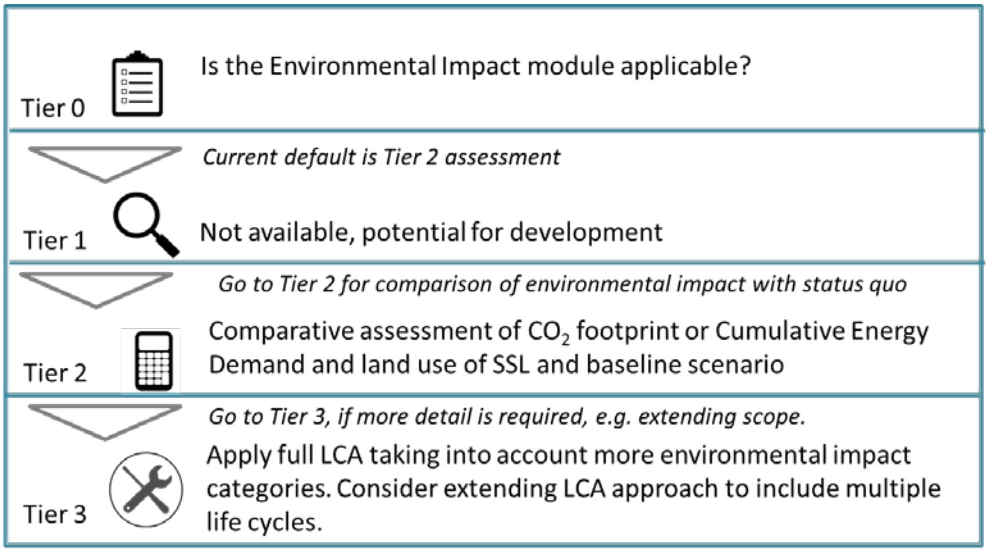


Figure 4-1. Overview of environmental impact module.

4.1 About the Environmental Impact module

Sustainability covers a plethora of environmental, social and economic issues. It is unfeasible and impractical to include all these issues in decision-making at the same time. There are two ways to cope with this complexity. The first is to make a well-informed decision on a selection of issues that matter most. The second is to choose indicators that correlate well with a large set of issues. Various studies, published in well-established journals, show that energy indicators and land use indicators together show a close correlation with damage to human health and biodiversity loss (Huijbregts *et al.*, 2010; Steinmann *et al.*, 2016; Steinmann *et al.*, 2017). In other words, many damage pathways – e.g. via climate change, air quality, eutrophication – are well covered by two indicators: energy and land-use. An exception is made for toxicity (Steinmann *et al.*, 2017). This is why, as a basis, we propose an Energy and Land use indicator as a proxy for environmental impacts that come with new technologies and products. Using this approach in the environmental impact module makes it simpler and less data intensive compared with a full Life Cycle Assessment (LCA). Using this module in addition to the safety-related modules and the circularity module resolves the main drawback of using only energy and land use, which has the poor correlation with toxicity, and the exclusion of the impact on other types of resources, such as critical materials. For example, there are still concerns related to substances present in rubber granulate, but as an infill for artificial pitches it shows a decrease in energy use compared with other infill materials. Here we suggest using the cumulative energy demand or emission of CO_2 equivalents as indicators for energy use. CO_2 is more frequently assessed than cumulative energy demand and therefore data might be easier to collect in order to perform this module. It should be kept in mind that the results from this method, similar to a standard LCA, should only be used for the defined goal and scope.

4.2 Scope definition and baseline scenario

The goal is to assess the sustainability impact of a new method for resource recovery over an existing or business-as-usual method. For this reason, energy or CO_2 eq. and land use are assessed in comparison with the present situation. Most of the time, the recovered resource and its application will replace an existing product. But first the following questions have to be answered:

A. What material flows and/or resulting products are assessed?
B. What is the reference product that is replaced by the new application of the non-virgin material?
C. What are the system boundaries: the spatial scale, temporal scale and the life cycle stages (cradle to gate, to grave or multicycle)?

For example, in the case of struvite (A), struvite replaces phosphate from mining in manufactured fertilizer (B). This means that the recovered product should be defined in a comparable manner to the reference product. In this case, struvite should be compared with rock phosphate in terms of the same effectiveness in soil fertilization. For reasons of practicality, some simplifications of such a comparison are required. For example, struvite contains three types of nutrients – P, N and Mg – whereas phosphate from mining is in the form of di-ammonium phosphate, containing another P:N ratio and no Mg (see the struvite case in Section 10.1). For this reason, the focus on the critical raw material phosphate is used for comparability, meaning that the assumption is made that 1 kg of P in struvite has the same fertilizing capacity as 1 kg of P in di-ammonium phosphate.

The system boundaries (C) should be defined and applied in the same way to both products (struvite and phosphate rock). It is important to explicitly and transparently state the defined system boundaries and specifically the life cycle phases and the spatial and temporal scale.

- Life cycle phases: a cradle-to-grave approach is advised. Alternatively, when for example the use and end-of-life phases of the compared products/materials are similar, a cradle-to-gate approach can be applied (more details given below).
- Spatial scale: is based on the definition of the life cycle phases included and the source and destination of the material flows being assessed. For example, for struvite versus phosphate rock,

the spatial scale for struvite is related to the Waste Water Treatment Plant (WWTP) and, for phosphate rock, this is the mine and phosphate purification plant in combination with transport to the factory that makes the final manufactured fertilizer product. Additionally, location-specific or more generic data can be used, e.g. including differences in phosphate rock from the US, China or Morocco.

- Temporal scale: is based on
  a) the wish if long-term effects should be included. That is, for example, the inclusion of expected changes in the quality or quantity of the material flow or changes in the demand for the original and new product. And
  b) whether the present pilot scale situation should be assessed or an extrapolation to the envisioned full scale should be made.

The proposed default for the system boundaries is:
Life cycle phases: Cradle to grave. Deviation from this default can be sensible. Relevant considerations for deviating from cradle to grave are given below (see 8.2.3).
Spatial scale: use location-specific foreground data (case-specific data for the new production process: amounts of energy, material) and generic background data (from existing databases for, as an example, the cumulative energy demand (CED) or CO_2 footprint of the energy source and materials); when variability in foreground data and variation between different sources of background data are known, this can be used for sensitivity analyses. This improves the quality of the assessment because the range of results can be shown instead of one number.
Temporal scale: Assume constant material flow (stable quantity and quality) and extrapolate for use in a full-scale scenario.

The definition of the system boundaries and scope should result in at least two scenarios for the assessment of energy (or CO_2 eq. emission) and land use. Firstly, the novel scenario for the production of a product from a material flow under consideration within the whole SSL framework. Secondly, the baseline scenario for the production of the reference product (e.g. present situation). For a fair comparison, the costs and benefits of each scenario need to be accounted for in a certain way. This can be done based on several allocation methods. For the purpose of this type of assessment, it is recommended that a system expansion is used as the allocation method. A system expansion means that the benefit of process steps that are not included in the alternative scenario (negative CED or CO_2 footprint) are added to the alternative scenario and vice versa (Figure 4-2). For instance, the application of recycled or reused material (SSL scenario) saves the use of raw material (baseline scenario). Therefore, in the baseline scenario, virgin materials for product B should be included. Likewise, the Energy Recovery from the baseline scenario should be added to the SSL scenario. Note that, specifically for energy recovery, this is only recommended when, in the end-of-life phase of the second life cycle, energy recovery is no longer possible.

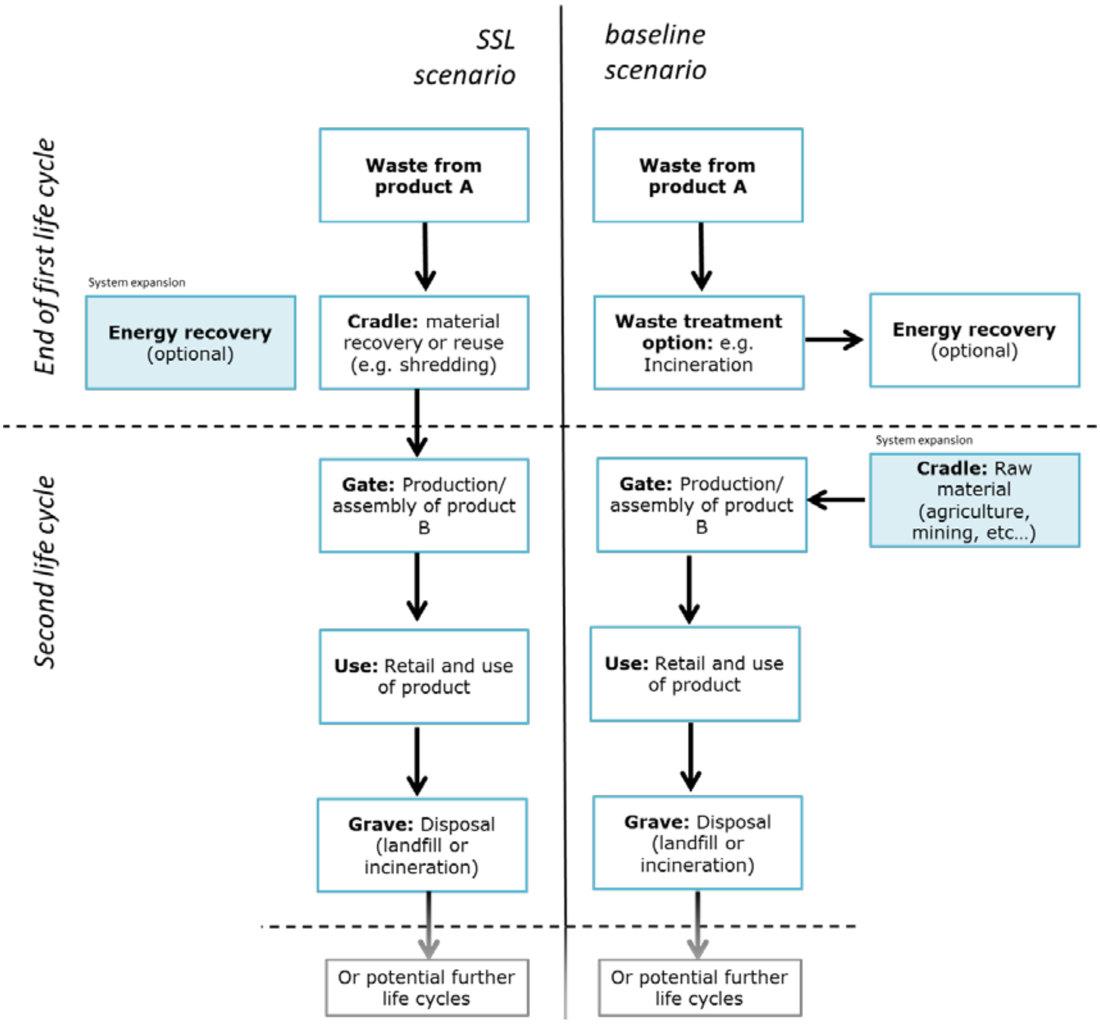


Figure 4-2. Schematic overview of the SSL and baseline scenario for the assessment of the environmental impact. The application of recycled or reused material (SSL scenario) saves the use of raw material (baseline scenario). Therefore, material for the production of the product B is added in the baseline scenario. Likewise, potential Energy Recovery is optionally added to the SSl scenario because this is a benefit of the baseline scenario. This is called system expansion (indicated by the shaded boxes). The 'use' and 'grave' life phases only have to be included when they differ between the two scenarios.

Cradle to grave and cradle to gate

As a default, a cradle-to-grave perspective should be applied in order to prevent unforeseen impacts. This is applicable when a specific product is foreseen, e.g. jeans. However, when the use and end-of-life phases are identical for the new application and the product it replaces (e.g. fossil-based lactic acid versus a green-waste-based lactic acid), a cradle-to-gate analysis will do. Furthermore, in some situations there is a lack of knowledge on the application of the product, e.g. because there are many potential applications, as is the case for lactic acid: will it be used for soap or for plastic cups? Finally, the grave (disposal or end-of-life) phase can be neglected when the product keeps its energetic value and is disposed in a way comparable to the reference situation. At least in the Netherlands, incineration is the reference situation for most materials that are discarded, except for fully abiotic/non-carbonaceous materials, e.g.

electronics. But, when a material is used as material instead of fuel, it keeps its energetic value. Energy retrieval by incineration is therefore not seen as a benefit, but rather as the last stage of every possible scenario for the material flow, which can thus be neglected when comparing scenarios. An exemption should be made when a significant fraction of the volume of the material is lost during the production or use phase of the new application compared with the baseline, e.g. compost. This means that incineration is not an option after the second life cycle or is an option, but for only a fraction compared with the baseline scenario. Another exemption should be made for biogas. Organic material and sludge are often used to produce biogas before further application of the material (digestate), such as fertilization or incineration. The influence of the new application on the production of biogas should be a part of the assessment. In these types of scenarios, the energy recovery by incineration should be a part of the assessment.

Multiple cycles
When there is enough confidence in further reuse and/or recycling options after the SSL scenario, the assessment can include additional life cycles. The benefits of the additional (multiple) cycles compared with the reference situation are then calculated. Deriving inventories for multicycle LCAs is not yet very common. Examples can be found in (CE Delft *et al.*, 2017; van Ewijk *et al.*, 2018) .

4.3 Assessment work flow

4.3.1 Relevance of module & selection of relevant indicators for Environmental Impact

In order to get an indication of the environmental impact or benefit, cumulative energy demand should always be assessed. When a production process does not request additional energy compared with the present production process (it is an existing by-product), the module is still relevant because the difference between the energy use of the new application and the product it replaces is an indication of the benefits of the new application. In most cases, the information for this module will be readily available, as energy cost is often already an integral part of product and process development. In the past, safety concerns of secondary material use were often assessed after such information on the energy requirements of the production process was known. Also, regarding a business case, investors often already ask for carbon footprints, which are based on essentially the same information.

In the SSL framework (Figure 4-3), assessing land use, is required when:

- the reused or recycled material replaces a virgin product from agriculture or forestry, e.g. cellulose vs wool-based insulation.
- the production process includes input from agriculture/forestry in the form of an auxiliary material or substance, e.g. virgin cellulose.

When the assessment method is used for new materials not based on waste, land use should also be taken into account when:

- bio-based products (from agriculture or forestry) are compared to products from either fossil-based or alternative bio-based sources.

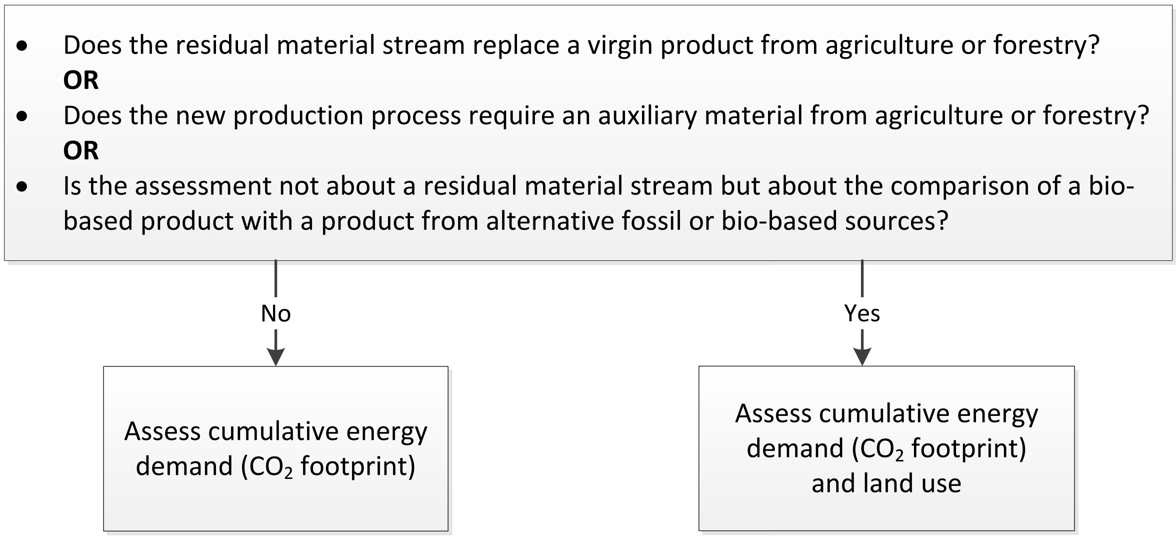


Figure 4-3. Diagram of Tier 0 to identify whether land use should be assessed in addition to the cumulative energy demand or CO_2 footprint as indicators for environmental impact.

4.3.2 Tier 1

At present, there are tools that use qualitative indicators to estimate environmental impact. These indicators are related to the production process. Those qualitative tools often use questions such as: “is there an added sanitation step?” or “is a renewable energy source used?”. These tools, however, are meant as hotspot analyses that indicate which parts of the process design could be further improved to make it more sustainable. This type of qualitative assessment is currently addressed here further because quantitative data is often available anyway. For instance, often in considering a business case, quantitative data (at least estimations) on energy use are already available in the stage where an application for a permit for the use of a waste flow is made. Also, investors often ask for things such as the carbon footprints of innovations, which requires the same type of data and thus, in most cases, these data will be available for the application for a permit as well. Regarding the assessment of land use, considerable data on land use are required for a variety of materials. Assessing these is less common, in practice, than carbon footprints and CEDs, but when a material balance is available, the translation to an estimation for land use should not take much time. Therefore, for this module it is assumed that a Tier 1 is not necessary and is therefore excluded: from Tier 0, the user goes directly to Tier 2.

When, after application of this module in more cases, quantification of CED and land use (tier 2) is shown to be less readily available than we assume here, a qualitative step can be developed. Another option is that this tier might be operationalized by CED in the future and land use profiles made per type of material and application as an initial indication for environmental risks and benefits. These profiles can be designed based on experiences with the method.

4.3.3 *Tier 2*

The Tier 0 assessment resulted in a selection of CED only or both CED and land use, depending on the role of products from agriculture or forestry. In Tier 2, the cumulative energy and land use are calculated based on an overview of used energy and materials and compared to the reference situation (Figure 4-4).

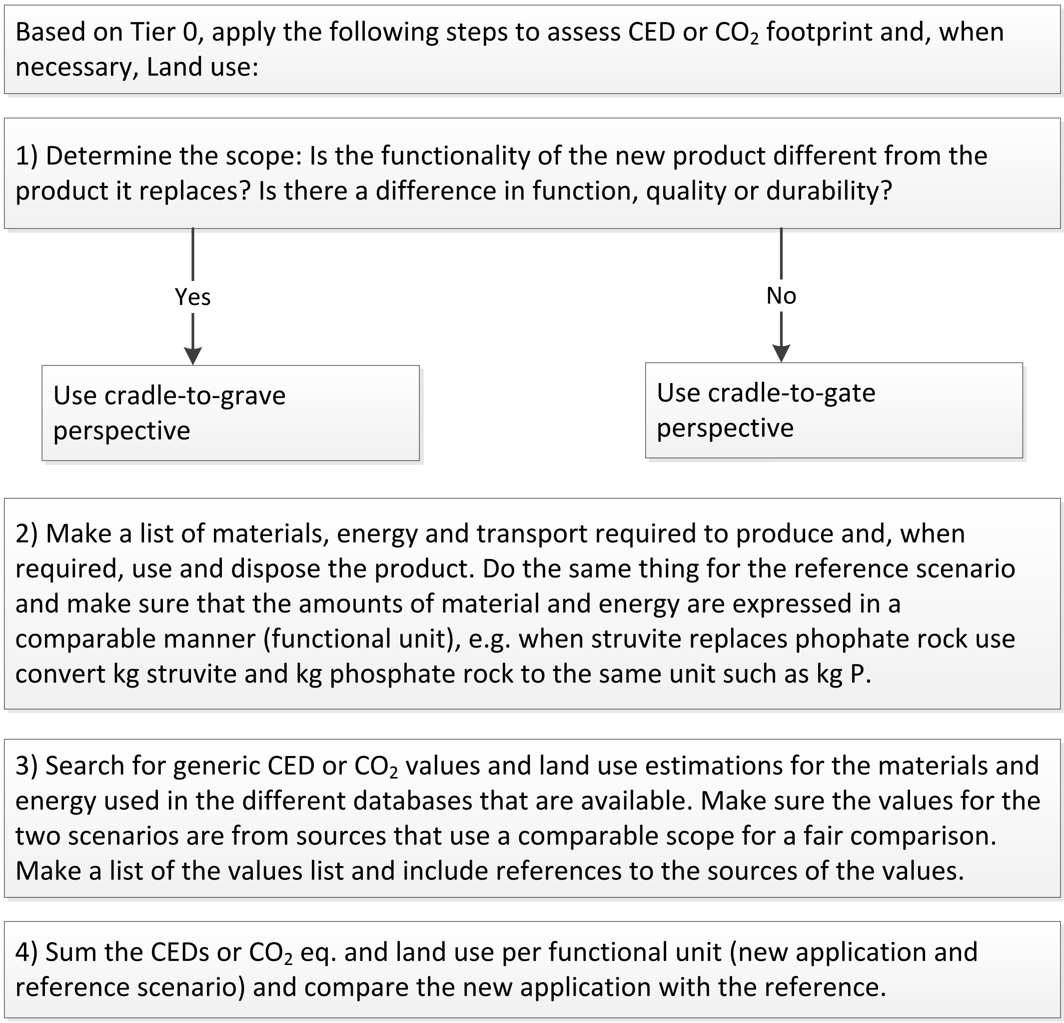


Figure 4-4. Tier 2 – Work flow to calculate if the new application results in benefits or counter benefits in terms of energy demand (or CO_2 footprint) and land use as indication for (reduced) impact on the environment.

Calculate the CED for the production of the product

NB: when CO_2 data is easier to collect, CED can be replaced by CO_2 eq. below.

CED is expressed in Joule per functional unit (for example: 1 ton of product). It is the sum of:

- the CED of the energy used at the production plant.
- the CEDs of the materials used to produce and, depending on the scope, apply and dispose the product.
- the CEDs of the transport of these materials.

CED is not the same as electricity use, because the amount of energy needed to produce electricity depends on the energy source (e.g. solar, biomass or crude oil) and the way of transport and co-occurring losses. RVO and Idemat provide the CED (RVO, 2018) of most common electricity-sources and the net caloric values (NCV) of the most common fuels and materials. Other sources are existing databases such as ecoinvent and Agri-footprint.

Calculate the CED (or CO_2 footprint) for the reference product (baseline scenario)
It is the sum of:

- the CED of the energy used at the reference production plant.
- the CEDs of the materials used to produce and, depending on the scope, apply and dispose the product.
- the CEDs for the transport of these materials.

The land use for the production of the product and the reference product
Total land use is the sum (km^2) of the land surface area required to produce the virgin materials needed to produce the product per functional unit, e.g. hectares of agricultural land. For example, a permit is applied to extract cellulose from waste water to produce packaging material. In that case, the question is what other ingredients are used when the packaging is produced. For example, when 25% of the packaging material is cellulose from waste water and the remaining 75% is from new (virgin) cellulose, the land used for growing the new cellulose should be assessed as a land use indicator expressed in the same functional unit as CED.

Optionally, the land use required for assembly (recycling plant), mining, infrastructure and energy production can be added as well, but the focus for land use is on agricultural products because, per kg of bio-based product, the area land needed for agriculture is often the hotspot (De Valk *et al.*, 2016; Steinmann *et al.*, 2017). For bio-based waste materials, the land use is zero, because the bio-based material –now wasted- was not the original goal for which the land was used. Hence, the land-use benefit of using waste material instead of virgin bio-based material is expressed as avoided land use (which is the land use needed for the replaced product).

Results
The resulting CED and the land use of the product and its reference product are compared. Is it less or more energy and land demand?

4.3.4 Tier 3
In the third tier, the calculations of the first tier can be improved by using values of the materials used in the production process that are supplier-specific. Instead of using generic numbers found in literature or databases, suppliers in the production chain are asked to perform a CED and land-use assessment or to provide the data required for this. Also, as described in Tier 3 of the circularity module (Section 3.3.4), a multi-life-cycle analysis (mLCA) can be used that is focused on CED and land use.

4.3.5 LCA

A full LCA can also be performed or perhaps data from an LCA that is relevant to the material and application under consideration is already available. As mentioned in Tier 3 of the circularity module (Section 3.3.4), a multi-life-cycle analysis (mLCA) can be used. This would obtain sufficient information on the environmental impact. Part of the data required for an LCA is already gathered together in Tier 2, but the inventory will have to be complemented with more detailed data in order to quantify other impact categories, such as mineral depletion and eutrophication.

4.4 Data sources

Various existing LCA databases can be used as background data to perform the assessment. Inventories such as ecoinvent (www.ecoinvent.org), Agri-footprint (www.agri-footprint.com/). Details on the method to translate LCI data to CED using the 'Cumulative Energy Demand method' version 1.09 (available in LCA software, e.g. OpenLCA). Idemat (www.ecocostsvalue.com) and RVO (https://www.rvo.nl/file/ger-waarden-en-co2-lijst-februari-2018xlsx-0) provide ready-made datasets in spreadsheet format.

4.5 Possibilities for intervention

The analyses of the CED also reveal the hotspots of where in the life cycle most energy is used and hence where intervention is most profitable. This is information on the energy source used in different parts of the life cycle or the transport distances, which can be changed. Other interventions could be the replacement of an energy and/or land-use intensive auxiliary material or potential to increase the recycled content, or to provide opportunities for multiple life cycles.

4.6 Recommendations

It is important to complement the list of CEDs for Tier 2 with materials for which such information is not yet available and to keep it up to date.

Toxicity is covered by the other modules, but not from a life cycle perspective. In other words, the module's focus is on the use of a product, but not on the toxicants used in the whole life cycle of a product. This could be added in this environmental impact module as an addition to energy and land use or by a adding life cycle perspective to the toxicity modules. This would mean that a baseline scenario would also be included in those assessments which give insight into the potential increase or decrease of safety or risk.

A database of the CED and land use of reference scenarios could be drafted per product group. This will make the assessment easier for the user, but it does require maintenance to keep the references up to date.

5 Substances of Very High Concern: ZZS module

Source materials (waste or residual) intended for recycling and reuse potentially contain chemical substances that pose a high concern with respect to human health and the environment. This module presents a method to assess the acceptability of substances of very high concern in material streams in recycling. The basis for this module is the Dutch policy on hazardous chemicals, which particularly focuses on Dutch substances of very high concern: the so-called ZZS, in Dutch: Zeer Zorgwekkende Stoffen (Wassenaar *et al.*, 2017; Zweers *et al.*, 2018). Due to the legacy of use of ZZS in the past, it is expected that this module will be relevant for many material flows and product cycles, and therefore needs to be taken into account by default (Figure 5-1). The first tier assesses the material flow based on a generic ZZS limit value of 0.1% w/w, taking into account the specific regulation in place for POPs. In Tier 2, the assessment focuses in more detail on the feasibility of separation of ZZS from the material to be reused by recycling and the acceptability of the presence of ZZS in the material, taking the new application(s) into account. The third tier forms an additional step in the process, which is only needed when the feasibility or acceptability of ZZS in the material cannot be assessed yet and additional generation of data should be considered.

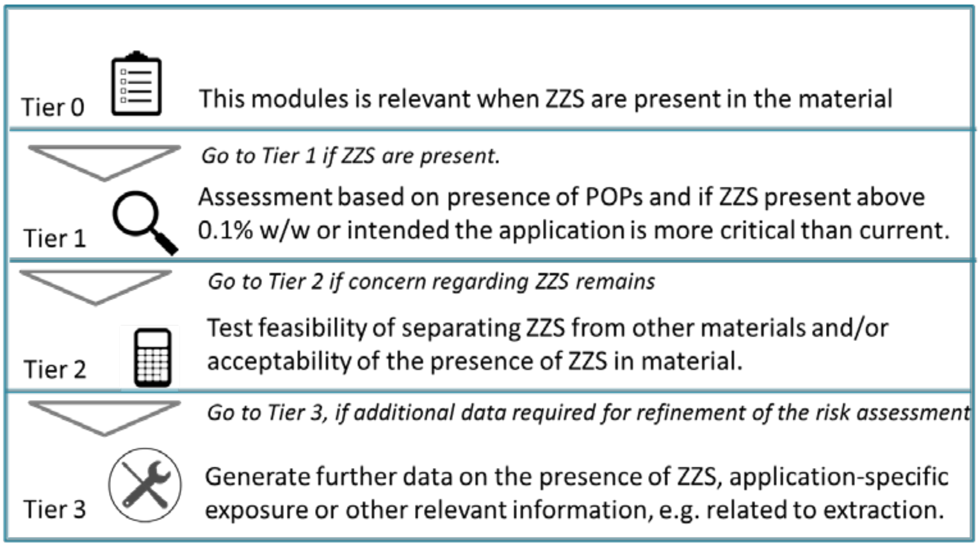


Figure 5-1. Schematic overview of tiered workflow in ZZS module.

5.1 About module ZZS

Within the Netherlands, national policy on hazardous chemicals is particularly focused on Dutch substances of very high concern, hereafter referred to as ZZS. The ZZS module is developed to assess the risks related to ZZS in waste/material streams.
These substances are of very high concern since they can seriously harm man and the environment. The ZZS cover a much broader range than the substances of very high concern (SVHC) under REACH (Figure 5-2). ZZS are identified based on the same hazard criteria as SVHC (i.e. REACH

article 57 (1907/2006)). Substances meeting one of the following criteria are considered as ZZS:

- Carcinogenic category 1A or 1B according to Regulation 1272/2008/EC.
- Mutagenic category 1A or 1B according to Regulation 1272/2008/EC.
- Toxic for reproduction category 1A or 1B according to Regulation 1272/2008/EC.
- Persistent, Bioaccumulative and Toxic in accordance with the criteria set out in REACH Annex XIII.
- Very Persistent and Very Bioaccumulative in accordance with the criteria set out in REACH Annex XIII.
- Substances for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to the criteria listed above.

Furthermore, substances are identified as ZZS if they are placed on one of the following lists:

- Substances on the Candidate list for REACH Annex XIV.
- Substances listed in the POP Regulation 850/2004/EC.
- Priority Hazardous substances according to the Water Framework Directive 2000/60/EC.
- Substances on the OSPAR list for priority action.

For ease of reference, a non-limitative list[1] is compiled, which is updated twice a year. Currently it contains over 1,400 substances which comply to the ZZS criteria (Dutch National Institute for Public Health and the Environment (RIVM), 2017). The ZZS in this list can be categorized in different classes (e.g. according to functionality, origin or chemical structure). Within the Netherlands, the ZZS policy focuses on the minimization of the emission of ZZS. This can be done by minimizing or preventing emissions or by the substitution of these substances by less harmful alternatives.

[1] ZZS-list: https://rvs.rivm.nl/zoeksysteem/ZZSlijst/Index

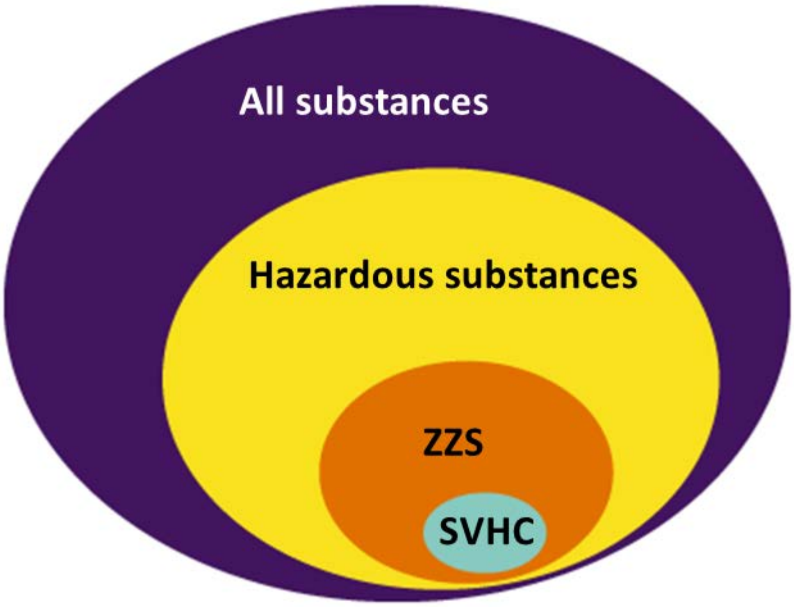


Figure 5-2. Illustration of the categorization of substances, indicating the Substances of Very High Concern (SVHC) which comprise only a part of the Dutch list of very hazardous substances (Zeer Zorgwekkende Stoffen(ZZS)) in the Netherlands(Wassenaar et al., 2017).

Application and presence of ZZS

The ZZS module is relevant when ZZS are present in a material flow or waste stream. In order to decide whether it is necessary to include this module, information on the ZZS content of the material flow or waste stream needs to be gathered. As ZZS covers a wide variety of chemical and functional classes (e.g. lubricant, intermediate, flame retardant), it is expected that the ZZS module will be relevant for many material flows and product cycles, including both biotic and abiotic materials. Information on the potential presence of ZZS in general waste streams can be found in RIVM report 2017-0071 (Wassenaar *et al.*, 2017). This report covers the following waste streams: waste water, production residues as a potential base for fertilizers and co-digestion, as well as plastic, rubber, cathode ray tube glass, construction materials, paper and paperboard, textile, and diaper waste streams. In addition, a report on the presence of ZZS in waste streams (Hofstra, 2018) can be consulted.

5.2 Assessment work flow

5.2.1 Relevance of module

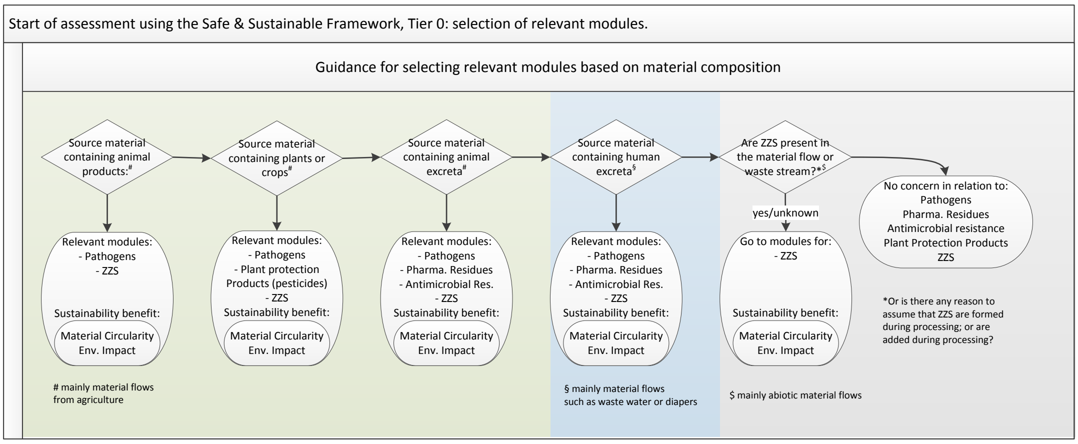


Figure 5-3. Selection of modules in the general workflow showing the ZZS module by default in all waste streams considered here.

Tier 0 is a first check, whether or not the ZZS module is relevant for a specific material or waste stream (Figure 5-3). When no information is available on the exact composition of the material or waste stream, an assessment of ZZS content should be conducted. A useful tool for this is the ZZS navigator (RIVM, 2018). Furthermore, it is advised to consult the reports mentioned in Section 5.1: (Wassenaar *et al.*, 2017) and (Hofstra, 2018).
Due to the wide variety of chemical and functional classes covered by ZZS, and the wide variety of material streams, the resulting check list is considered to be too complicated for a Tier 0 assessment. In the general workflow to select relevant modules (see Chapter2), it is therefore assumed that the ZZS module is applicable by default and will lead to a Tier 1 assessment, unless ZZS content can be ruled out.

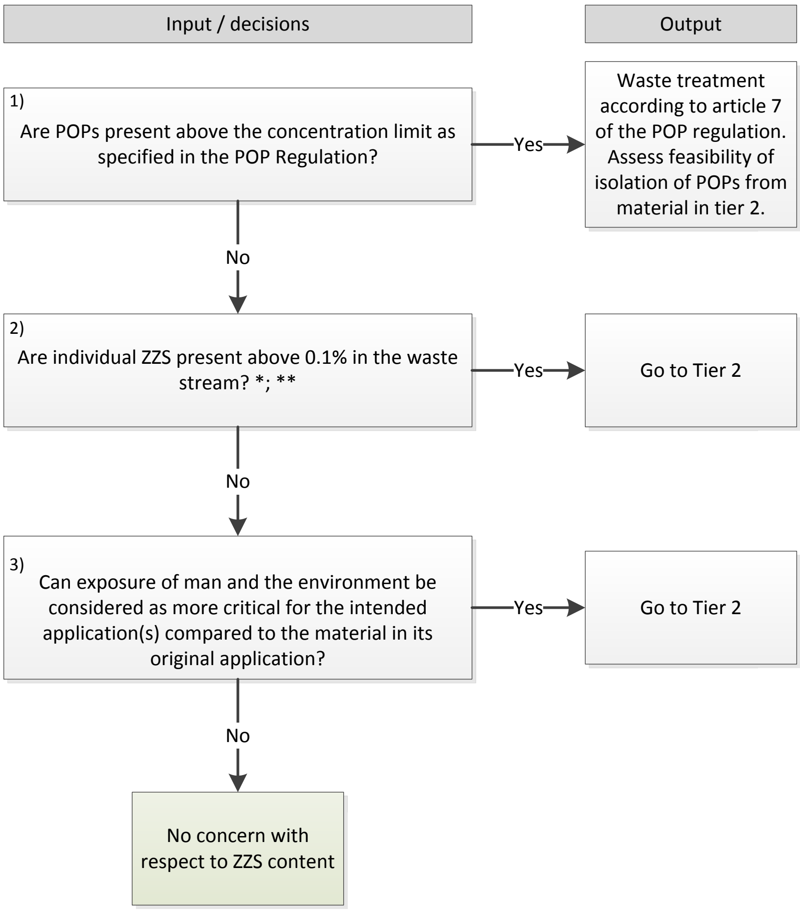


*Figure 5-4. Tier 1 of the ZZS module. The concentration limit values as included in Annex IV of the POP Regulation are included in Annex I. *or is there any reason to assume that ZZS are formed during processing up to a concentration above 0.1%; or are ZZS added during processing up to a concentration above 0.1%?. **several more stringent substance-specific concentration limit values, as adopted by CLP Annex VI, need to be considered (see Annex II).*

5.2.2 Tier 1

Within Tier 1, a decision scheme is presented (Figure 5-4). In this tier, a basic risk analysis is done, based on limited data, with respect to ZZS content. If the level of risk remains unclear, a more in-depth assessment is necessary to conclude whether there might be a risk or not (i.e. go to Tier 2). Tier 1 of the ZZS module is derived from the decision scheme in RIVM report 2017-0099 for the Dutch national waste management programme (LAP3) (Wassenaar *et al.*, 2017). Sections 5.3 to 5.5 provide additional details on data, criteria, etc., relevant to this tier.

The first question addresses the derogation, based on the POP Regulation, which is aimed at their destruction. Within this regulation, it is required to isolate the POP from the waste or material flow for subsequent disposal. This can be done based on the methodology described in Tier 2. However, methods used to remove POPs from a material should have regulatory acceptance, an example is the removal of HBCDD from EPS, see Chapter 9 for more details. The origin of the second question “Are individual ZZS present above 0.1% in the waste stream?” is described in more detail in Section 5.4. When the individual

ZZS concentration (or concentration range) is not known, a worst-case assumption should be made (i.e. ZZS > 0.1%). The third question addresses new foreseen applications, if any. If a new foreseen application of the ZZS-containing waste stream is the same as the origin of the waste stream, no concern with respect to ZZS-content is assumed. If the new application is expected to be more critical in terms of an increase in (the level of) the exposure of humans (including workers, consumers or humans indirectly exposed via the environment) and the environment, Tier 2 should be conducted.

5.2.3 *Tier 2*

When a ZZS is present above 0.1 % w/w or the intended application potentially leads to increased exposure compared with the original application, Tier 2 should be consulted (Figure 5-6). Within Tier 2, a more in-depth analysis is conducted based on all available data. Information on two different options needs to be gathered:

- “is separation of the ZZS from the material flow or waste stream (technically and economically) feasible?”, and
- “is keeping the ZZS-containing material or waste stream in the system acceptable?” ().

The information on these aspects has to be weighed in order to decide on the acceptability of the application for the material flow or waste stream. Based on this analysis it can be concluded that:

1. separation of the ZZS is feasible and required, which will result in no concern regarding the ZZS content;
2. there is no concern when preserving the ZZS in the system, but given the feasibility, separation and destruction of the ZZS is needed to minimize the emission of and exposure to ZZS;
3. removal is not feasible and there is a concern when preserving the ZZS in the system; or
4. removal is not feasible, but the risk of keeping the ZZS in the material stream is considered acceptable.

When it is not possible to draw a conclusion based on available data, Tier 3 should be followed.
Tier 2 of the ZZS module is comparable to the decision scheme as proposed in RIVM report 2017-0168 for inclusion in the Dutch national waste management programme (LAP3) (Zweers *et al.*, 2018). This specific report (in Dutch) details how to assess and weigh these different aspects. Within this report, the essential aspects are specified and explained below.

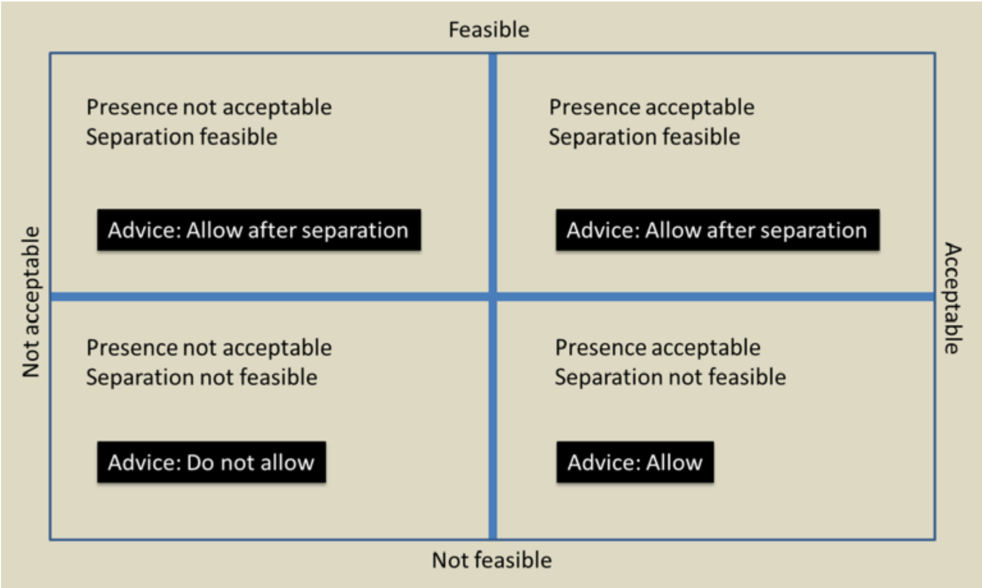


Figure 5-5. Two principle factors to be assessed: acceptability of the presence of ZZS in the material and the feasibility of removal/separation of ZZS from the material. Four outcomes are illustrated, combined with a general concept to follow regarding the safety of ZZS in material for recycling.

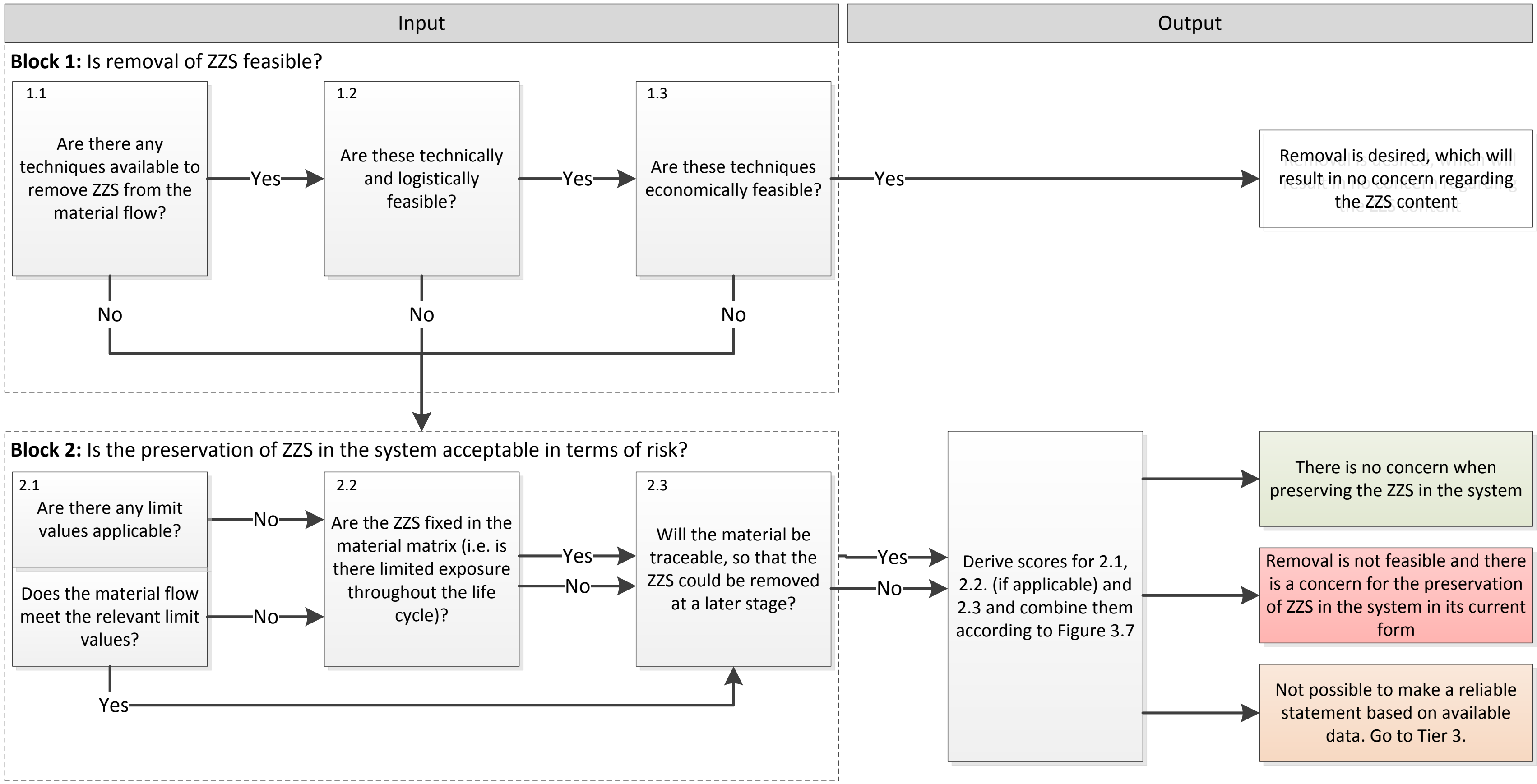


Figure 5-6: Tier 2 of the ZZS module. A description of the underlying sub-questions that should be considered for deriving scores for blocks 2.1, 2.2 and 2.3 can be found in text. More details can be found in Zweers et al. (2018).

Block 1 of Tier 2: Removal of ZZS

Within Block 1 of Tier 2 (Figure 5-6) it is assessed whether it is technically and economically possible to remove the ZZS from the material stream. This block has been sub-divided in three blocks concerning: gathering of data on available removal techniques (1.1); an extensive analysis of technical and logistic feasibility (1.2); and an extensive analysis of economic feasibility (1.3). Because technical and economic feasibility are difficult to assess in the absence generally accepted methodology, only Block 1.1 needs to be assessed at first. As a rule of thumb, it can be stated that, when removal techniques are available, they should be applied. If this is not feasible from a technical, logistic or economic perspective, then Blocks 1.2 and 1.3 should be assessed in more detail before Block 2 can be considered. In Zweers *et al.* (2018), an extensive description is provided on how these blocks can be assessed.

- *Questions and outcomes related to Block 1.1:*
  - *Question 1:* Are there any techniques in use in Europe to remove the ZZS from the material?

    If question 1 is answered with 'yes', the following questions need to answered.

  - *Question 2:* Is the removal of the ZZS technically and logistically feasible and is the current processing capacity of this technique sufficient for the material flow? Or is expansion within the foreseeable future possible?

  - *Question 3:* Which reduction in ZZS concentration can be achieved with the removal technique and is it sufficient in comparison with the relevant ZZS limit value(s) (see Block 2.1 of Tier 2)?

  - *Outcome:* When question 1 is scored as 'yes' and the concentration of ZZS is to be sufficiently reduced, it is considered technically and economically feasible to remove the ZZS from the material. This will then be the overall conclusion of Tier 2,and no further analysis is necessary. The ZZS (-containing stream) should be removed accordingly. When no removal technique is available (i.e. removal is not technically and economically feasible), the assessment needs to be followed by the assessment of Block 2 of Tier 2.

Block 2 of Tier 2: Risk analysis

Within Block 2 of Tier 2, it is assessed whether or not the risk is acceptable when the ZZS-containing material or waste stream is recycled in the system (Figure 5-6). This block has been sub-divided in three blocks concerning: ZZS limit values (2.1); fixation of ZZS to the material (2.2); and traceability of the ZZS-containing material during the life cycle (2.3). The scores of Block 2 of Tier 2 are expressed as traffic light colours (i.e. green, orange or red) and are combined in order to obtain an overall outcome of Tier 2 (see Figure 5-7).

- *Steps and outcome related to Block 2.1: Limit values*
  - *Step 1:* The first step is to gather all relevant limit values that apply to the ZZS in the material and to the intended application(s). In Section 5.3, an overview of relevant chemical legislation is presented.
  - *Step 2:* Assess if and which relevant ZZS limit values have been exceeded.
  - *Step 3:* Determine the corresponding consequences of exceeding the limit values.
  - *Outcome:*
    - When none of the relevant limit values have been exceeded (i.e. outcome of Step 2), Block 2.1 is scored ‘green’ and one should continue with Block 2.3 (see Figure 5-7).
    - When no limit values are applicable to the ZZS and the intended application (i.e. outcome of Step 1), one should continue with Block 2.2. In that case, Block 2.1 will be scored ‘orange’, since it remains unclear whether the general concentration limit value of 0.1% is sufficiently protective.
    - When a relevant limit value is exceeded, which results in a use restriction, Block 2.1 will be scored ‘red’.
    - When a relevant limit value is exceeded that results in other, less restrictive measures (e.g. classification and labelling or notification), Block 2.1 will be scored ‘orange’.

    When the final score in Block 2.1 is ‘orange’ or ‘red’, one should continue with Block 2.2. The corresponding consequences of exceeding the limit value(s) will be taken into account when weighing all scores of Block 2 of Tier 2.

- *Questions and outcome related to Block 2.2: Potential exposure*
  - *Question 1:* Are the ZZS released during processing/recycling at the end of the life phase?
    - Yes or unknown. Block 2.2 will be scored ‘red’.
    - No or limited, proceed with Question 2.

  - *Question 2:* Is there a legislative framework for the intended application which provides migration or emission limits (e.g. food contact materials or construction materials)?
    - If ‘Yes’, test according to legislation. When the ZZS migration/emissions meets the criteria as laid down in the applicable legislation, Block 2.2 is scored ‘green’. Otherwise this block is scored ‘red’.
    - If ‘No’, proceed with Question 3.

  - *Question 3:* Can existing measurement methods and criteria from adjacent legislative frameworks be used for the intended application?
    - If ‘Yes’, go back to Question 2.
    - If ‘No’, proceed with Question 4.

  - *Question 4:* Can it be assumed that the ZZS can be released from the material? For example, by evaporation (in the case of volatile substances), weathering or decay of the material (e.g. in the case of rubber), or during the processing of the material.
    - If 'No', Block 2.2 will be scored 'green'.
    - Limited (in the range of limit values of adjacent legislative frameworks). Block 2.2 will be scored 'orange'.
    - If 'Yes', Block 2.2 will be scored 'red'.

- *Questions and outcomes related to Block 2.3: Traceability*
  - *(Essential) Question 1:* Is there a legally required designation or labelling of the products / objects / materials made from the ZZS-containing material? *As a rule of thumb, classification and labelling based on hazardous properties fulfils this criterion, on the condition that it is relevant for the (new) application.*
  - *(Essential) Question 2:* Is there a recovery system, so that it is guaranteed / encouraged that the products / objects made from the ZZS-containing material are handed in? *As a rule of thumb, an isolated waste stream or the possibility for separation (mechanically or chemically) fulfils this criterion.*
  - *(Additional) Question 3:* Does the volume of the ZZS-containing material remain the same during the use in the intended application (i.e. there is no increase or decrease in volume during its lifetime)? *In the case of a decrease in stream volume (e.g. due to (bio)degradation), the ZZS concentration could increase if ZZS is not lost or degraded in that stream. In the case of an increase in volume, it can be the result of better waste treatment (= acceptable) or the mixing of waste (= not acceptable).*
  - *(Additional) Question 4:* Are the products / objects / materials produced from the ZZS-containing material exclusively used for industrial and/or professional applications (i.e. it is not intended for the general public = consumer use)? *As soon as the products or materials are used by the general public, it is considered that ZZS-containing waste can no longer be contained and properly managed.*
  - *(Additional) Question 5:* Is it possible to monitor the ZZS-containing products during the next lifetime and in the next waste phase? *If the ZZS-containing products or waste crosses the border, this is not the case. If the number of applications is limited and on a large scale, the ZZS is better traceable than when this is not the case.*
  - *Outcome:*
    - When both essential questions are answered with 'yes', as well as one of the additional questions, Block 2.3 will be scored 'green'.
    - When one of the essential questions is answered with 'yes' and at least one of the additional questions with 'yes', Block 2.3 will be scored 'orange'.
    - If both essential questions or all the additional questions are answered with a 'no', Block 2.3 will be scored 'red'.

When relevant limit values are not exceeded (see Block 2.1), but ZZS concentrations are just below the relevant concentration limit values (with less than a factor of 10 below as an indication), the following scores will be applied for Block 2.3:

- A 'red' score is applied in the event of wide-dispersive use, indicating that ZZS are still present in certain material cycles and not traceable, e.g. in generic plastic recyclate.
- A 'green' score is applied when wide dispersive use is not applicable.

The individual results of Blocks 2.1, 2.2 and 2.3 have to be combined in order to obtain an overall outcome for Block 2 of Tier 2. If at least two of the aspects (2.1, 2.2 (if relevant), or 2.3) score 'red', this means that the risks cannot be adequately controlled (see Figure 5-7). Therefore, the outcome of Tier 2 will be: "Removal is not feasible and there is a concern for the preservation of ZZS in its new application". When no 'red' scores are provided, and only 'green' or 'green and orange' scores are applicable, this means that the risks can be considered acceptable (see Figure 5-7). In this case, the outcome of Tier 2 will be: "There is no concern for preserving the ZZS in its new application". If one of the aspects scores 'red' or all aspects score 'orange', this may indicate that the risks are not adequately controlled or that there are too many data gaps to sufficiently score this Tier (see Figure 5-7). In this case, the outcome of Tier 2 can either be: "Removal is not feasible and there is a concern for the preservation of ZZS in the material streams/flows in its current form" or "Not possible to make a reliable statement based on available data. Go to Tier 3".

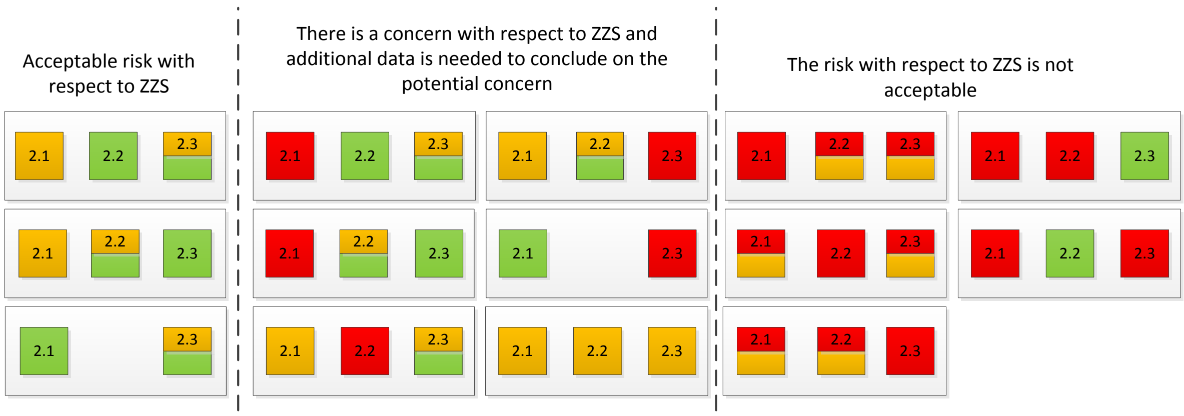


Figure 5-7: Weighing of the scores of Block 2 of Tier 2. On the left side are the possible combinations that are considered to be acceptable in terms of risk. On the right side are the possible combinations that are considered to be a concern and not acceptable, and in the middle possible combinations are presented that are related to either a concern. Additional data is needed to conclude on the potential concern. The two-coloured blocks indicate that the score for that block may be green as well as orange, or red as well as orange.

5.2.4 *Tier 3*

When specific information is missing in order to conclude on the acceptability of the use of a ZZS-containing material flow or waste stream for a specific application, Tier 3 should be followed (Figure 5-8). For instance, there might be uncertainties with respect to the ZZS

content of a material flow, the (potential) exposure of the intended application or other information, such as the removal or separation possibilities which are considered relevant for Tier 2.
Under specific conditions, it can be decided to define a pilot phase for a restricted time span in order to obtain relevant additional data or change the processing or application of the recyclate in order to iterate the assessment. In this way, the potential beneficial applications of secondary materials are not totally hampered by a lack of data. Though, in such a pilot phase, safety should be guaranteed by setting case-specific conditions.
The purpose of the new generated data is to refine the risk analysis of Tier 2, Block 2 to see if orange (or red) scores can be refined. These refined scores can be taken into account in the risk analysis to see whether the adjusted combination of scores for the new application is acceptable or not in order to come to a final decision (see Figure 3.7).

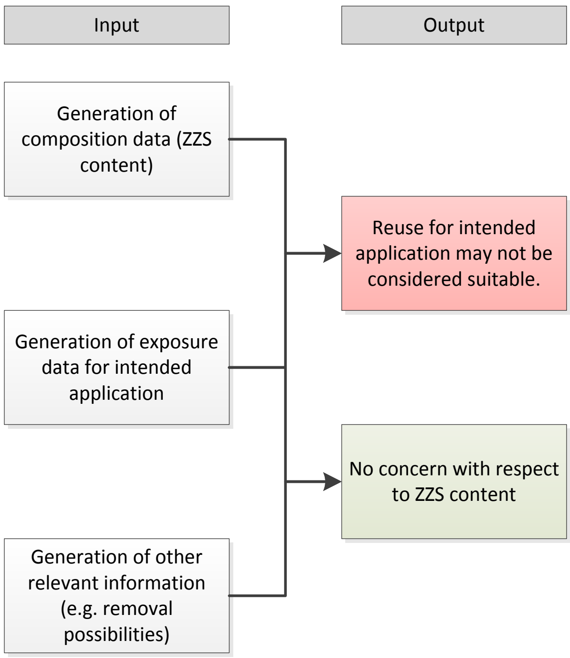


Figure 5-8: Tier 3 of the ZZS module.

5.3 Data sources

Data requirements for conducting the different tiers vary in complexity from Tier 0 (simple) to Tier 2 (very complex), and Tier 3 (case-specific). Information on the ZZS content is necessary for all tiers, though requirements differ in their level of detail. For Tier 0, only information on the (expected) presence of ZZS needs to be obtained. In Tier 1, the concentration needs to be specified for all ZZS (above or below 0.1%) and in Tier 2 the exact concentration (range) is necessary. How such information can be gathered is described in Section 5.1.
Furthermore, for Tier 1 and Tier 2 information on the intended application is necessary, as is information on substance- and/or application-specific concentration limit values. More information on regulations that include relevant limit values (Zweers *et al.*, 2018) are described in Section 5.4.

Moreover, for Tier 2 very specific information is necessary. This includes information on ZZS removal possibilities and on the technical and economic feasibility of the techniques. In addition, data on the fixation of the ZZS in the material matrix and data on the separation possibilities of the material with ZZS from other materials after end-of-life are necessary. In Zweers *et al.* (2018), more details are provided on how these questions can and should be addressed.

5.4 Criteria

The use of limit values as criteria to assess the risk of the presence of ZZS is always related to a certain substance in combination with a certain application. However, for a first screening in Tier 1, a generic limit value of 0.1% is applied (together with the assessment of whether exposure will be more critical in the new application). The assignment of this 0.1% cut-off value (i.e. 1000 mg/kg) is based on the most stringent general concentration limit value for the classification of mixtures according to the CLP-legislation (1272/2008/EC). This lowest limit value is also applicable for the classification of waste as hazardous according to the waste directive (2008/98/EC).
It should be noted that there are a few exemptions in the CLP-legislation, in which a more stringent concentration limit value is provided for some specific substances (see Annex II). These need to be considered as well (as also described in Tier 1, Figure 5 4).
Furthermore, POP limit values, as included in the POP-regulation, are relevant to Tier 1 (see Annex I). When a POP exceeds this concentration limit, the waste stream needs to be treated and disposed of according to Article 7 of the POP-regulation (850/2004/EC).
In Tier 2, information on substance- and/or application-specific concentration limit values are required. Some relevant regulations, including limit values, are described in Table 5-1. Several of these regulations, with relevant limit values for ZZS, are listed and described in Zweers *et al.* (2018).

5.5 Possibilities for intervention

In Tier 2, two intervention strategies are mentioned already. First is the removal of the ZZS from the material stream(s). When this is not possible, the prevention of exposure by the prevention of leaching from the matrix might be a solution. In cases when the overall outcome of the ZZS module indicates that recycling in its proposed form or application is not acceptable, some adjustments can be made to the process or the intended use. In particular, the adjustment of the application may change the overall outcome. For instance, applications with no direct exposure (closed-applications) might be of lower concern in comparison with wide, dispersive use applications (i.e. consumer uses).

Table 5-1: Overview of regulations containing concentration limit values or migration limit values relevant for ZZS.

Regulations	Limit values	Consequences
REACH restrictions[2]	Varying (also <0.1%)	Restriction in use
REACH candidate list[3]	0.1% (for PBT/vPvB/C/M substances) 0.3% (for R substances) With a number of possible exceptions (e.g. see Annex II)	Notification- and communication- (and upon release) registration obligation
REACH authorization list (conform CLP)[4]	0.1% (for PBT/vPvB/C/M substances) 0.3% (for R substances) With a number of possible exceptions (e.g. see Annex II)	Authorization must be applied for
CLP[5]	0.1% (for PBT/vPvB/C/M substances) 0.3% (for R substances) With a number of possible exceptions (e.g. see Annex II)	Classification & labelling
POP regulation[6]	Varying (also <0.1%)	General restriction on production and placing on the market
Food contact material regulations[7]	Varying (also <0.1%)	Restriction in use
Toys Directive[8]	Varying (also <0.1%)	Restriction in use
Cosmetics Directive[9]	Varying (also <0.1%)	Restriction in use
RoSH Directive[10]	0.1 or 0.01%	Restriction in use
NL Fertilizer act[11]	Varying (expressed in mg/kg fertilizing ingredient)	Restriction in use
NL Soil Quality Decree[12]	Varying (also <0.1%)	Restriction in use

[2] REACH restrictions
[3] REACH candidate list
[4] REACH authorization list
[5] CLP
[6] POP-Regulation
[7] Food contact material directive
[8] Toys Directive
[9] Cosmetics Directive
[10] RoSH Directive
[11] Fertilizer Act
[12] Soil Quality Decree; Soil Quality Regulation

6 Pharmaceutical residues module

This module aims to assess the human and environmental safety of pharmaceutical residues in the source (waste) materials used for the production of secondary materials. This method contains several novel approaches because there is currently no legislation that imposes specific quality standards for pharmaceutical residues in waste. In Tier 1, a method is used for assessing the safety of pharmaceuticals based on a selection of trigger values. These are conservative limits that are used to trigger further assessment in higher tiers. In Tier 2, indicator compounds are selected and the expected concentrations in secondary materials and source materials are estimated. Refined risk assessment using Tier 3 can be required when (additional) quality standards need to be derived or measurements of effect are the best option.

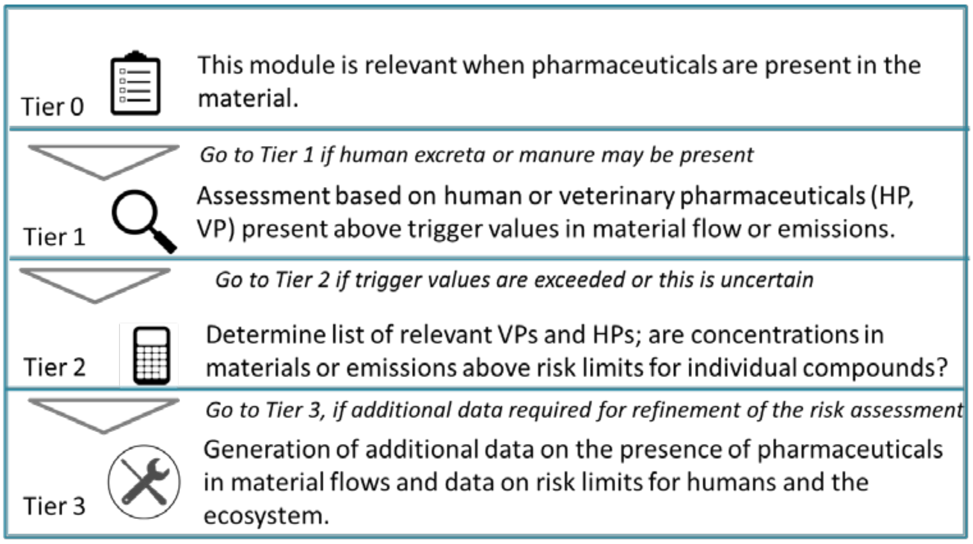


Figure 6-1. Schematic overview of the tiered workflow in the Pharmaceutical residues module

6.1 About the pharmaceutical residues module

Human pharmaceutical residues (HPRs) and veterinary pharmaceutical residues (VPRs) are present in different waste streams. Most HPRs and VPRs will have entered through human or veterinary excreta and by washing off dermal medication (e.g. gels and creams). Recycling such waste streams may result in human or environmental exposure to HPRs and VPRs. This module helps to assess those risks. Risks to humans and the environment comprise endocrine disruption, antimicrobial resistance (AMR), toxic effects and carcinogenic, mutagenic or reprotoxic properties (CMR) (e.g.(Moermond *et al.*, 2016)).

Products made of or made with materials containing pharmaceutical residues should be safe. However, there is no legislation that imposes specific quality standards for pharmaceutical residues in waste streams.[13] This module describes a standard approach to assess the safety of secondary materials with regard to pharmaceutical residues. The basis for this method is the safety assessment for struvite and diapers, which contain pharmaceutical residues (van der Grinten and Spijker, 2018; Lijzen *et al.*, 2019).

The standard approach in this module assesses whether the presence of pharmaceutical residues in a waste stream can be expected (Tier 0) and, if so, what their concentrations are relative to reference values (Tier 1). Ideally, sufficient information is available in Tier 1 to assess whether there are concerns about pharmaceutical residues in the outgoing products, materials or streams. However, if the necessary information is lacking, a higher Tier is invoked. The higher Tiers describe actions to be taken to obtain the missing information. Once this information is obtained, it feeds back into Tier 1 for the risk assessment.

6.2 Assessment work flow

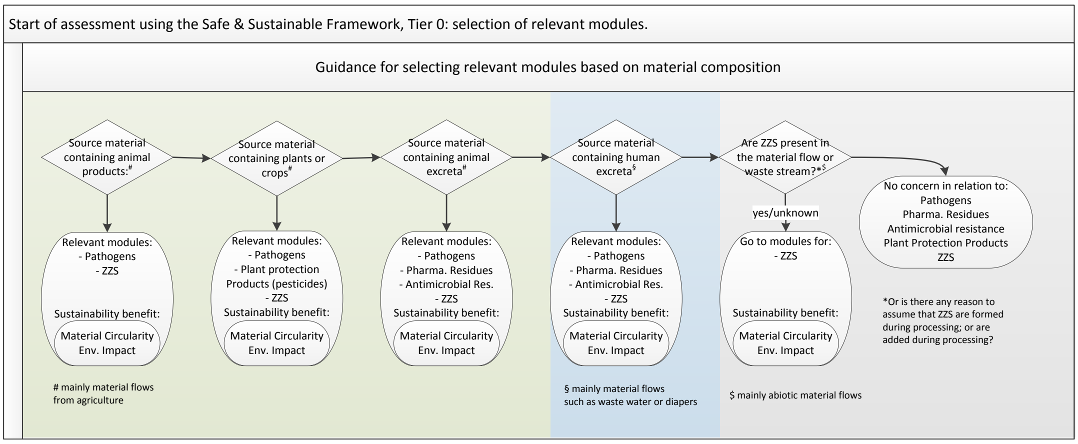


Figure 6-2. Selection of the pharmaceutical module, triggered primarily by the presence of human or animal excreta, animal waste streams or household waste flows (see text).

6.2.1 Relevance of module

In Tier 0, it is assessed whether the material flow might contain pharmaceutical residues based on the nature and origin of the material (Figure 6-2). Pharmaceutical residues are expected to be present in materials that originate from various streams related to waste water, manure, solid waste or other residual materials of biological origin:

- domestic waste water containing human excreta and residues from creams/gels that are washed off the skin or out of clothes, where mainly human pharmaceuticals that are used in the household are present;
- waste water from hospitals or care facilities, which may contain more specific pharmaceuticals that are used for in-patients;
- manure that contains veterinary pharmaceuticals;
- solid waste[14], including diapers, incontinence materials or any other solid waste containing human excreta, which may contain specific pharmaceuticals used by children and the elderly;

[13] Certain VPs excepted that are also used as plant protection products
[14] Unused pharmaceuticals entering garbage bins are currently beyond the scope of this module.

- animal waste such as animal (by-)products, or residual biotic streams (e.g. food slurries) containing veterinary pharmaceuticals;
- plant- or crop-related waste streams, which may contain veterinary pharmaceuticals (after application of manure); however, currently, there are no indications that pharmaceutical residues are an issue in these waste streams, although this insight could change in future.

If the material to be recycled is demonstrated to be unrelated to the above sources, no further assessment is needed. For all other materials, assessment in Tier 1 is required. If there is uncertainty about the nature, origin or constancy of the ingoing material, assessment in Tier 1 is also required.

6.2.2 *Tier 1*

Tier 1 assesses the HPRs or VPRs in the ingoing and outgoing materials (see Figure 6-3). Actual concentrations of pharmaceutical residues are required for comparison to appropriate quality standards.

Tier 1 consists of:

a. Identification of relevant VPs and HPs
Because of the large number of potential pharmaceutical residues in ingoing materials (active substances, metabolites and degradation products), it may not be feasible to determine their presence and concentrations in all ingoing and outgoing material flows.[15] Therefore, relevant pharmaceuticals (indicator compounds) can be selected based on the nature and origin of each ingoing material. If recyclers lack a standard approach for identifying indicator compounds, Tier 2 is invoked.
b. Retrieve data on indicator compound concentrations[16]
Indicator compound concentrations should become known for ingoing and outgoing material flows. If the indicator compound concentrations in the ingoing and outgoing material flows are below detection limits, then the conclusion is that there is no concern (see also (Leerdam et al., 2015)). In all other cases, Tier 2 is invoked. If hormones are expected to be present, Tier 3 is invoked for an effect assessment.
c. Comparing concentrations with quality standards.
The indicator compound concentrations in ingoing and outgoing material flows are compared to quality standards (safe concentrations). If concentrations of the indicator compounds are below the quality standard, then there is no further concern for that indicator compound and the related compounds.

For most pharmaceuticals, quality standards (or safe concentrations) are not readily available. To enable risk assessment of pharmaceutical residues in general, specific quality standards may be replaced by general trigger values, which may be used as a first screening level for

[15] Current standard analysis packages of commercial laboratories do not necessarily suffice.
[16] The chemical analysis and detection limits should meet current best practices with a state-of-the-art analysis system. It should also be tailored to the specific material in which these might be present. Data for one matrix cannot necessarily be extrapolated to another matrix.

pharmaceuticals in Tier 1, like the trigger values used in the environmental risk assessment for marketing authorization ((EMA, 2006) for HPs (aquatic) and (EMA, 2000)for VPs (soil)). When these trigger values for further assessment are exceeded, specific quality standards should be searched for (Tier 2) or derived in Tier 3.

- For the water phase of ingoing or outgoing streams, it is expected that there are no risks when the surface water concentration is lower than the trigger value for further assessment of 0.01 µg/l (or 0.1 µg/l in effluent) (EMA, 2006). Exceeding that value triggers the need for further risk assessment. The trigger value does not apply to hormones, which should always be further assessed (See Tier 3).
- For sludge or manure, a trigger value of 100 µg/kg dry weight for further risk assessment is available (EMA, 2000). This value does not apply to hormones and antiparasitic compounds; these substances should always be evaluated (see Tier 3). For hormones, an effect assessment method applies. For antiparasitic compounds, further assessment may be performed using the general methodology and specific quality standards for these compounds should be used.
- For the human risk assessment of materials, trigger values for further assessment may also be derived from the indicative Acceptable Daily Intake and the methodology for Food Contact Materials (FCM) (Lijzen *et al.*, 2019).

The trigger value approach does not apply to residues of hormones and antiparasitic compounds. These pharmaceuticals are a concern at very low concentrations below the trigger values. If these residues might be present, Tier 3 is invoked.

If the above does not apply or if trigger values are exceeded, further assessment in Tier 2 is required. If the quality standard is exceeded, the recycling process must be adapted, the intended purpose of the product must be changed, or further refinement of the risk assessment should take place.

Conclusion on concern
When measured relevant concentrations in the ingoing and outgoing streams and products are below trigger values for further assessment or quality standards, the outcome of the Tier 1 assessment is ‘no concern’. If VPRs or HPRs (in outgoing flows or materials) are sufficiently removed or reduced during the recycling process (see Tier 2) to concentrations below trigger values, then the assessment also concludes with ‘no concern’.
The exceedance of trigger values or a lack of information on concentrations or quality standards triggers Tier 2; the potential presence of endocrine-disrupting hormones or antiparasitic compounds triggers Tier 3.

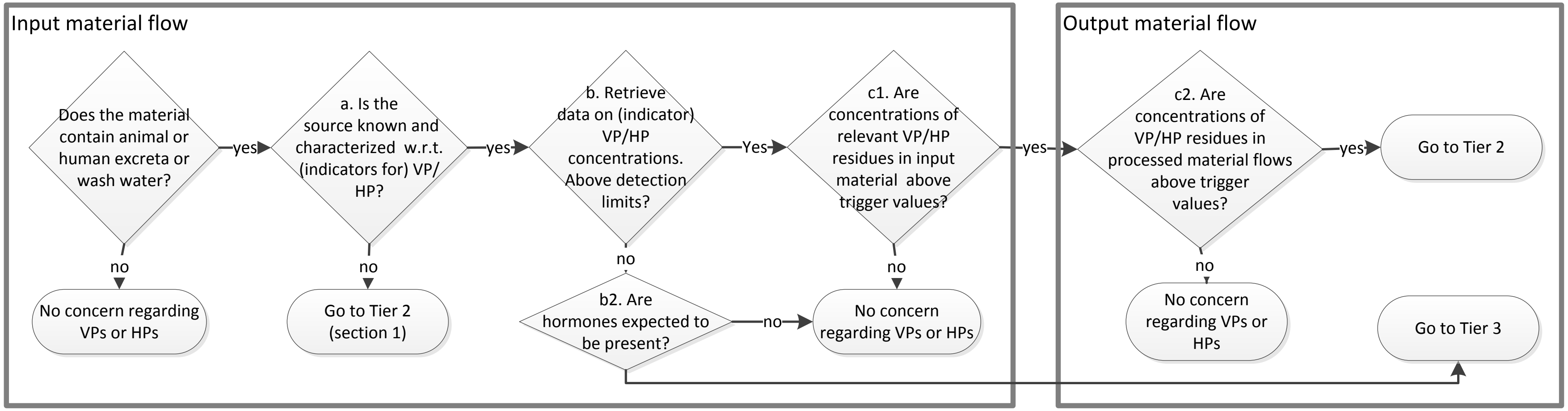


Figure 6-3: Tier 1 of the pharmaceutical residues module. The determination of the relevant pharmaceutical residues in the ingoing and outgoing material(s) are important steps.

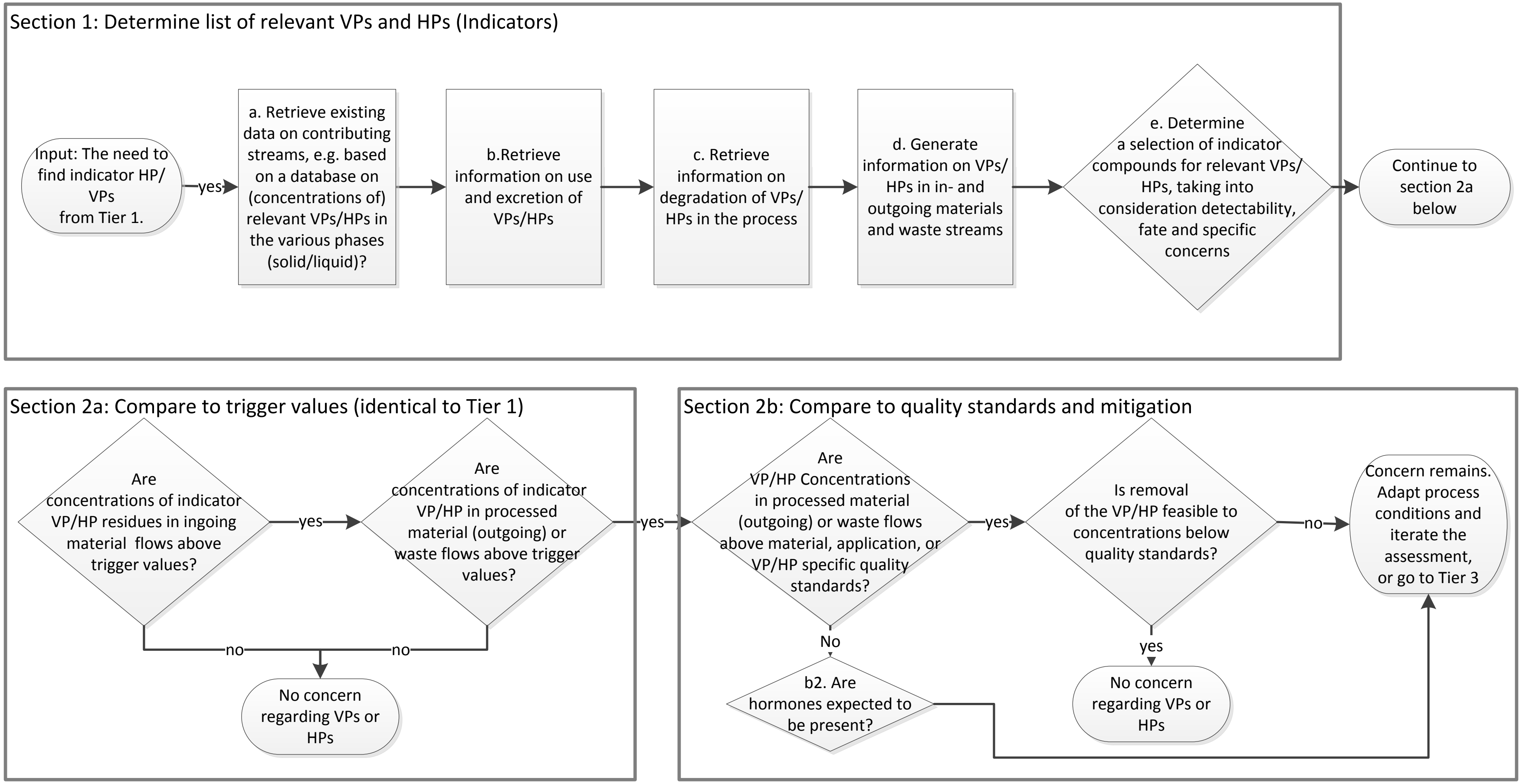


Figure 6-4. Tier 2 of the pharmaceutical residues module, focusing on a procedure to select relevant indicator substances in various waste streams.

6.2.3 *Tier 2*

In Tier 2, the recycling process is reviewed to determine a) the relevant HPRs and VPRs for measurements and b) the streams or products in which these should be measured.

Selection of relevant human and veterinary pharmaceuticals as indicator compounds

In the Netherlands, pharmaceutical residues of >1,000 active ingredients are marketed which could be present in waste streams that are to be recycled. Tier 2 describes an approach to arrive at a manageable number of indicator compounds for further assessment. Indicator compounds preferably contain different types of pharmaceuticals (e.g. antibiotics, hormones, analgesics, etc.) with different physico-chemical characteristics (in particular, low degradation rates). Various procedures to identify indicator substances are described in previous case studies ((van der Grinten and Spijker, 2018; Lijzen *et al.*, 2019)). These procedures aim to select indicator compounds that give adequate representation.

Tier 2 (see Section 1 in Figure 6-4) consists of:

a. *Retrieving existing data on contributing streams*
   If relevant data is available on pharmaceutical residues in streams that contribute to the ingoing materials, these may be used to select relevant indicator compounds. For instance, data on waste water in waste water treatment plants (WWTP) is available for the production of struvite (van der Grinten and Spijker, 2018) and [http://www.emissieregistratie.nl.](http://www.emissieregistratie.nl) (see also 6.3.2)
b. *Retrieving existing information on use and excretion profiles*
   If relevant data is not available on pharmaceutical residues in streams that contribute to the ingoing materials, then they can be estimated from relevant use and metabolism. For HPs and VPs, the quantities sold over-the-counter (OTC) must be accounted for in addition to the quantities dispensed at the pharmacy, veterinarian, hospital and veterinary clinic (see Section6.3, Data sources). Pharmaceuticals that are extensively metabolized are considered less suitable as an indicator compound (see Section 6.3, Data sources).
   In general, the 10 most used human pharmaceuticals (kg active pharmaceutical ingredient) and the 10 with the largest user group should be taken into consideration for the appropriate streams contributing to the ingoing material (see Section6.3, Data sources). OTC medicines should be taken into consideration too, although sales volumes are usually not publicly available. The most important contribution by OTC medicines is expected from analgesics (NSAID)(Lijzen *et al.*, 2019). For veterinary pharmaceuticals, the volume of use and the frequency are often unknown. Some estimates are available in scientific literature (see Section6.3, Data sources).
c. *Retrieving existing information on degradation during the recycling process or in the environment*

HPR and VPR levels may decrease and increase[17] in the recycling process. In the case of diapers, the treatment process involves heat treatment. Therefore, indicator compounds were partly selected for resistance to heat treatment. If a process could liberate the unchanged pharmaceutical from a conjugate, that would also be a reason for selection as an indicator compound (see Section6.3, Data sources). Environmental degradation may be considered as well. When this is slow, a pharmaceutical is more suitable as an indicator substance (see Section6.3, Data sources).

d. *Generating information on HPR and VPRs in ingoing and outgoing streams and materials.*
   If insufficient information is available on HPRs and VPRs, this should be generated to feed into the next section of Tier 2, see Figure 6-4. It is most important to acquire knowledge about the identity of the HPRs and VPRs, their concentrations, their fate, and their distribution over the outgoing streams and materials. To determine whether endocrine-disrupting effects could be an issue, this may be investigated using the Calux assays (see Tier 3).
   To assess the fate of pharmaceutical residues under process conditions, a degradation test should be carried out. Such a test requires[18] the ingoing materials to be spiked with the selected indicator compounds; and sufficient knowledge of analytical issues and extractability must be demonstrated (further details in Lijzen et al, in prep. 2018). Please note that pharmaceutical residues may unevenly distribute over streams and materials. For hormones, a degradation test may be carried out using very high spiking concentrations should that sufficiently improve detectability.

e. *Selection of indicator compounds*
   From the list of relevant pharmaceuticals generated in the above sections, a list of indicator compounds may be selected. The selection process should take into consideration: detectability, fate, and specific concerns. (Spijker *et al.*, 2016; Lijzen *et al.*, 2019).

   Specific concerns that should be addressed are:
   - Substances that are highly ecotoxic have a higher priority if waste streams are emitted from the process to the environment, e.g. via sewage treatment plants.
   - Antibiotics, with emphasis on preferential treatment of common infections (airways, urinary tract (e.g. Amoxicillin, Clarithromycin, Trimethoprim)
   - Endocrine disruption, e.g. steroid hormones (e.g. Estriol and Estron)
   - Cytostatics for cancer treatment (e.g. 5-Fluoro-uracil).

When a final set of indicator compounds has been identified and both their fate and distribution are known, a conclusion with respect to

[17] By concentration steps or by liberating the unchanged pharmaceutical from conjugates.
[18] In processes where spiking of the ingoing material is technically impossible (e.g. in continuous flow systems) a degradation test is not required and the recycler should assess the risks of the outgoing streams and materials.

concern can be drawn. As processes may change over time, indicator compounds should be updated to reflect the actual situation.

Conclusion on concern
After deriving the final list of indicator VPs or HPs, their concentration in ingoing flows should be compared to generic trigger values for further assessment, or to specific quality standards when available (see Section 2 in Figure 6-4). This regards quality standards for relevant environmental compartments, as well as quality standards for products and/or specific applications. If estimated concentrations in processed materials (outgoing) and waste flows exceed these trigger values or quality standards, then a degradation test may be performed. Based on the results of this degradation test (laboratory, pilot scale or full-scale), the concentrations in the processed materials (outgoing) and waste flows can again be compared to these trigger values (the same as used in Tier 1) or quality standards for individual indicator compounds.

When measured VPs or HPs are below trigger values or quality standards, there is no concern. When trigger values or quality standards are exceeded, concern remains. This means that the recycling process must be adapted, the intended purpose of the product must be changed, or further refinement of the risk assessment should take place in Tier 3.

6.2.4 Tier 3
In Tier 3, quality standards are determined for the relevant outgoing materials or the receiving environmental compartments and effect measurements can be performed.

a. *Generating quality standards*
   Quality standards (also called risk limits or safe concentrations), below which no risks are to be expected, may be found in literature (Predicted No Effect Concentrations or PNECs; Environmental Quality Standards or EQSs) or derived using toxicity data. Information on how to obtain these risk limits is provided in Section 6.4. Trigger values may differ over the intended purpose of the stream or material and over existing legal frameworks.
   When a final set of quality standards is generated, this information feeds into Tier 2 (Section 2b in Figure 6-4). These specific quality standards may then replace the general trigger values. If quality standards cannot be derived or are exceeded, then further risk assessment is necessary or the recycling process must be adapted (see Section 6.5)
b. *Effect measurements*
   If the presence of certain pharmaceuticals cannot be excluded, then risks may (to a certain extent) be determined using bioassays. This effect measurement is additional to Tier 1b because, for certain pharmaceuticals (especially hormones), effects are observed below the detection capability of chemical analysis. Bioassays generally show a combined effect of the mixture of all substances that exert same effect. When an effect exceeds a reference value (response compared to the response of a reference compound), hormonal activity is a concern. A high-

throughput method may be used to identify the compound(s) of concern. More information is provided in 6.4.2.

If adequately conducted effect measurements show there is a concern, further risk assessment is necessary or the recycling process must be adapted (see Section6.4)

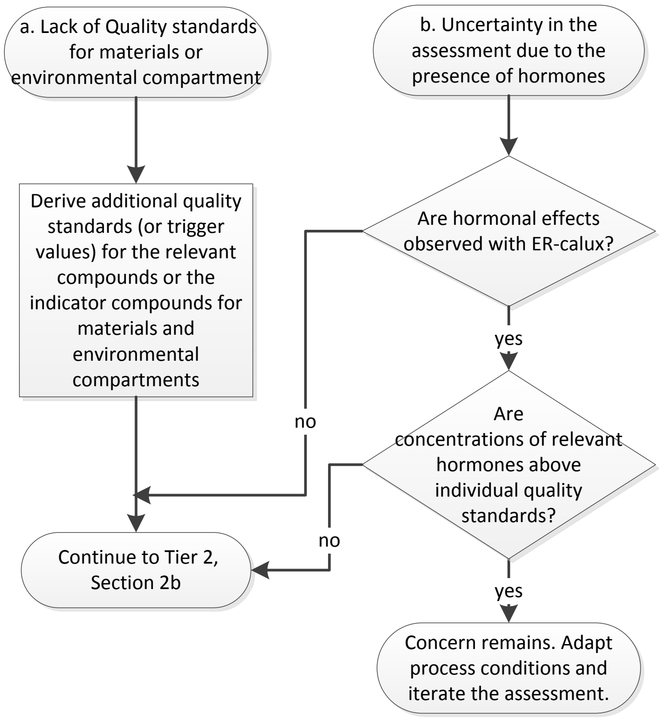


Figure 6-5. Tier 3 of the pharmaceutical residues module focusing on additional quality standards (risk limits) for indicator VP or HP or effect assessment for hormones.

6.3 Data sources

6.3.1 Use of pharmaceuticals

Via data on the use of pharmaceuticals, an estimate can be made of the substances that potentially will be present in the waste stream. For pharmaceuticals, it is important to note that not only the load (in kilogrammes) may be important, but also the number of daily doses prescribed. The latter reflects the potency of a pharmaceutical – the most potent compounds are prescribed in very small amounts, but they may also be potent in the environment and cause effects at very low concentrations.

Data on medicine use can be divided between three categories:

1. Medicines available over the counter (OTC medication), which can be obtained without a prescription.
2. Medicines used in hospitals and care facilities.
3. Medicines that are obtained at the pharmacy on prescription.

The amounts of prescribed pharmaceuticals (cat 3) is recorded in the GIP databank (Genees- en hulpmiddelen Informatie Project; www.gipdatabank.nl). No public record is kept on pharmaceuticals that are sold over the counter at drugstores and supermarkets (e.g. pain medicine being an important part of them). In hospitals and care facilities, in-house pharmacists keep their own records. The use of veterinary pharmaceuticals (except for antibiotics) is not recorded publicly (http://edepot.wur.nl/392237;Moermond et al., 2016.).

The scale of human medicines dispensed by public pharmacies can be estimated from the GIP database (https://www.gipdatabank.nl/). This database also allows for the identification of relevant patient groups (e.g. children or the elderly).

The use of antibiotics, as a specific group of compounds that is of concern because of antibiotic resistance, is published annually by the MARAN (http://www.wur.nl/nl/Expertises-Dienstverlening/Onderzoeksinstituten/Bioveterinary-Research/Publicaties/MARAN-Rapporten.htm).

In a study about pharmaceuticals in diapers and incontinence pads, a selection of pharmaceuticals was made for babies and the elderly (Spijker et al., 2016). In the report on the assessment of the recycling of diapers and incontinence pads, the most relevant pharmaceuticals for the elderly and children were selected (Lijzen *et al.*, 2019).

6.3.2 Measured concentrations

In the Watson database of the emission registration, concentrations of pharmaceuticals in the influent and effluent of wastewater treatment plants are available. (http://www.emissieregistratie.nl/erpubliek/erpub/wsn/default.aspx). Measured concentrations for the Netherlands may also be found in the waterkwaliteitsportaal (https://www.waterkwaliteitsportaal.nl/). However, often only influent concentration will be useful for the current assessment, since most recycling processes will happen before the water is discharged.

6.3.3 Metabolism

Data on metabolism can be found in the Farmacotherapeutisch Kompas (www.farmacotherapeutischkompas.nl). Also, a summary of the marketing authorization dossier ((European) Public Assessment Report or (E)PAR) contains this information. The EPARs can be found on the site of the European Medicines Agency (www.ema.europa.eu). The PARs can be found on the site of the College ter Beoordeling van Geneesmiddelen (https://www.cbg-meb.nl/). If a maximum residue limit (in meat or dairy products) has been determined for a veterinary pharmaceutical, data on metabolism may also be obtained via the (E)PAR, Section 6.4.3.

6.3.4 Physico-chemical properties and toxicity; quality standards

Physico-chemical properties and data on (eco)toxicity may be obtained via public literature. The data that are used for the marketing authorization should be publicly available according to the Arhun convention (Montforts and Keessen, 2007), but often this is not the case or these data are very hard to find. This may depend on the member state that has performed the assessment of the authorization dossier.

Other data sources are:

- http://www.fass.se. A database with results of the marketing authorization in Sweden. If available, PNECs are published in this database as well;
- www.wikipharma.org. A database with an overview of ecotoxicity studies on pharmaceuticals;
- www.ema.europa.eu. The EPARs (see above) may be obtained through this website. EMA may also be contacted directly with a request for environmental information on pharmaceuticals that have been authorized via a centralized procedure;
- www.astrazeneca.com. This pharmaceutical company publishes environmental data on their compounds on their website;
- https://rvs.rivm.nl/normen. Database with Dutch national safe concentrations, with a note on whether they are officially set or not;
- https://echa.europa.eu/information-on-chemicals/registered-substances. The database of the European Chemicals Agency. Especially for compounds with multiple uses, data can also be found here.

6.4 Quality standards

6.4.1 Environmental quality standards

If trigger values for further assessment are exceeded (Tier 1c) , the estimated concentration in the relevant environmental compartment(s) should be compared to quality standards (risk limit, safe concentration). This does not apply to hormones or anti-parasitic compounds, which should always be further assessed.

Quality standards in the environment may be:

- PNECs (Predicted no Effect Concentrations) from the authorization dossier;
- EQCs (Environmental Quality Criteria);
- EQSs (Environmental Quality Standards) from public literature or EQSs from https://rvs.rivm.nl/normen (See(Moermond *et al.*, 2016)).
- Minimal Risk Levels (MRL) for human consumption of food may be found in the (E)PARs (see above).

If no PNECs or EQSs are available, they may be derived using the method of the EQS derivation within the Water Framework Directive (EC, 2011). Analogous to fertilizers, the Commissie Deskundigen Meststoffenwet has a protocol to determine risks to the environment (CDM, 2016). According to this protocol, the negligible risk level (VR; verwaarloosbaar risiconiveau)) may not be exceeded one year after application. The VR is set at the level of the MPR (maximal Permissible Risk level)/100. The MPR is similar to the PNEC or EQS (see Section 6.3). The derived levels, supported by ample relevant scientific literature on environmental effects, can be used in Tier 1.

For materials also, a trigger value for further assessment was derived based on an indicative Acceptable Daily Intake and the methodology for Food Contact Materials (FCM)(Lijzen et al., in prep.) This is derived in Tier 3, but could serve as a trigger value of Tier 1. If this trigger value is

exceeded for an individual substance, Tier 3 should be used to verify whether the estimated exposure is lower than the indicative ADI. The risk assessment of materials in specific products is possible, but does not fall within the scope of this framework. Such a tailored approach can be carried out within the responsibility of the producer.
This principle could also be applied to pharmaceuticals that could end up in fertilizer applications. In the report about struvite (van der Grinten and Spijker, 2018), detection limits for pharmaceuticals are used as criteria for the assessment because the aforementioned risk levels are lacking.

6.4.2 *Effect measures or bioassays*

The presence of some substances or substance groups may be difficult to determine analytically at relevant concentrations. This is especially the case for hormones, which are able to exert an effect at very low concentrations. Bioassays may detect effects at these low concentrations. Although bioassays detect the effects of the mixture of pharmaceuticals and their metabolites (known and unknown), there are no bioassays that are generally applicable to all pharmaceuticals (e.g. bioassays to identify endocrine disruption cannot be used to identify the presence of antibiotics).

The Calux system is a validated method to detect hormonal activity. Even within the Calux assays , there is no ‘one size fits all’. Amongst other things, the ER-Calux assay detects estrogenic activity, the AR-Calux detects androgenic activity, the anti-AR Calux detects anti-androgenic activity, the PR-Calux detects progesterone activity and the GR Calux detects glucocorticoid receptor activity. Thus, to obtain a good indication of the presence of hormones, several of these assays need to be performed.

If the availability of hormonal activity is demonstrated, it may be necessary to identify the compounds causing this activity. To do this, a screening method may be used, such as the high-throughput effect directed analysis (HT-EDA) developed by the Waterlaboratorium in the Netherlands (Jonker, 2015; Houtman *et al.*, 2018). Using this method, the sample is fractionated into different fractions, for which Calux assays are then performed. The samples showing hormonal activity are then analysed using UPLC-MS, so individual substances exerting the effect can be identified and possibly quantified. For these substances, an individual risk assessment may then be performed. In time, the recycling process then only needs to be monitored periodically and this screening may help to identify whether it is still the same fraction causing the effect.

In this way, chemical analyses and bioassays may complement each other, especially when material flows contain many different compounds making it impossible to measure them all. An additional benefit of using bioassays is that they can be used to exclude possible effects. Other frameworks also make use of bioassays (e.g. the ESF-tox approach, in which 12 bioassays are combined with chemical monitoring, was developed by STOWA for the water system analyses (STOWA, 2016)).

6.4.3 *Risks to human health*

For groundwater (as a source for drinking water), no legal risk limits are available. A precautionary generic trigger value of 0.1 µg/L may be used for groundwater (as is used for pesticides). When there is a possibility that the pharmaceuticals may end up in food crops, the expected concentration in the crops should be compared to the Maximal Residue Level (MRLs) for human consumption. MRLs for the human consumption of food may be found in the (E)PARs (www.ema.europa.eu). Only for some veterinary pharmaceuticals are ADI (Acceptable Daily Intake) values available, but for most HPRs and VPRs this is not the case. If no ADI's are available, the lowest registered therapeutic dose of pharmaceuticals, with an assessment factor, may be used as an indication. This approach was applied for the assessment of groundwater/ drinking water (Versteegh *et al.*, 2003; Moermond, 2014). The choice of assessment factors is discussed in scientific literature (e.g.(Faria *et al.*, 2016). As a first screening, a trigger value for further assessment may be set at 1/10,000 of the lowest registered therapeutic dose. When this is exceeded, an ADI may be derived based on toxicological data (Lijzen et al., in prep).

6.5 Options for recyclers

Recyclers that make use of materials containing HPRs or VPRs may reduce their burden by a) being selective towards the source of the ingoing material[19], b) using optimal process conditions for destroying pharmaceutical residues (as evidenced by a degradation test, see Tier 2), and c) developing materials or products that have minimal contact with humans or the environment. Obviously, the future exposure and fate of new materials and products should be considered. An example is the production of insulation from recycled cellulose instead of application to soil.

6.6 Recommendations

- It is recommended that the relevance and practically of the trigger values for use in Tier 1 be improved. These trigger values should be specific for water, soil/sludge/manure and materials (e.g. plastic, cellulose).
- For the most relevant/prioritized individual pharmaceuticals, quality standards for water and soil should be derived.
- Furthermore, it is useful to develop methods for measuring the adverse effects of groups of pharmaceuticals and to relate their outcome to reference values in order to assess safety.

[19] A Dutch chain approach aims to reduce the amount of pharmaceutical residues entering the water cycle (see e.g. https://jamdots.nl/view/239/medicijnresten-uit-water).

7 Pesticides module

This module describes the safety assessment of waste streams that potentially contain residues of plant protection products (PPP). This can be extended in the future to biocides. One waste stream and application combination is worked out in detail: plant- or crop-based organic waste streams that are used as fertilizer or co-digester substrate. In the Netherlands, a legal framework is in place that contains a safety assessment of this reuse option, which is the basis for this module. An overview of the tiered workflow is given in Figure 7-1. In Tier 1, a relatively simple check is done based on previous assessments or if the origin is organic farming. In Tier 2, the safety for soil and groundwater after reuse is assessed. In the ideal situation, analytical measurements of the active substances of the plant protection products used on the plant or crop in the waste stream are used for the assessment. If analytical data are not available, a list of substances potentially present in the waste stream material is drawn up. This list can be used to estimate maximally expected levels of substances in the waste stream, or to target the performance of analytical measurements as part of Tier 3.
This module should be extended with safety assessments of PPP for other applications of plant/crop waste streams when needed. This also holds for waste streams with PPP residues consisting of other material, e.g. water or soil.

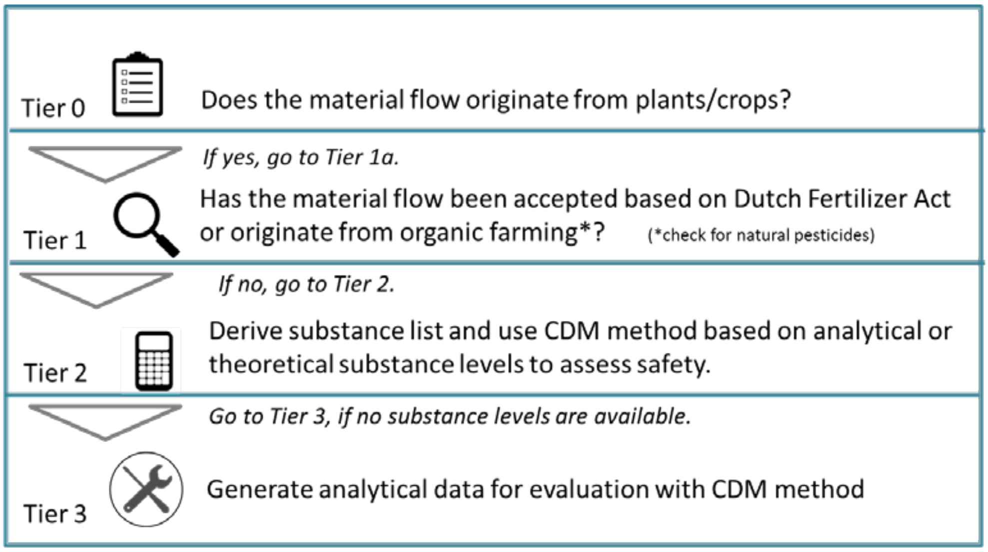


Figure 7-1. Schematic overview of tiered workflow in Pesticide module. ' CDM method' refers to the Expert Committee Fertilizer Act, abbreviated CDM in Dutch(CDM, 2016).

7.1 About module pesticides

This module applies to waste streams that potentially contain residues of pesticides. The goal of this module is to assess the safety of humans and the environment related to residual biomass used that contains pesticides, but for now limited to plant protection products. We note here that the active substances in plant protection products and biocides can both be called pesticides as, in general, their purpose is to treat or kill a pest. A general distinction between PPPs and biocides is that PPPs are largely applied on plants, mostly (but not exclusively) crops, while biocide uses cover a very diverse range of applications, such as disinfection (e.g. hospitals, offices, food and feed producing facilities, stables), preservation (e.g. in paints, glues, adhesives, wood, fibres, building materials, liquid cooling), antifouling, rodenticides, insecticides (e.g. against ants, treatment of manure storage), etc.
PPP use will result in plant/crop material waste streams containing PPP residues, in addition to other possible types of streams (Section 7.2.2). Biocide use will less often result in a plant/crop material waste stream containing biocide residues. Given the scope of the application of residual biomass flow only as a fertilizer, only PPPs are considered. A further extension of the method would be required in order to also make it fit for use with biocides, which would include additional applications, e.g. related to consumer products with the relevant regulatory frameworks to be considered.

This method is currently developed for the application of residual biomass flows to soil to function as fertilizer or as substrate in co-digesters, whereby the digestate functions as fertilizer. This specific reuse stream and destination is worked out here since a safety assessment procedure is established within the Netherlands (CDM, 2016) for 'waste used as fertilizer', which is legally embedded under the Dutch Fertilizer Act (Anonymous, 2005). The methodology of the CDM framework is applied here to the plant/crop waste stream that is potentially contaminated with PPP residues. There are many other potential reuse goals for waste streams that potentially contain PPP residues, e.g. the production of plastic or biofuel. These other waste streams can be considered in the future.

In the current quantitative safety assessment, three principal decision criteria apply:

- The concentration of the PPP active substance shall not exceed the maximum permissible concentration in furrowed soil (MPC_{soil}) directly after soil application of the fertiliser (CDM, 2016).
- The second criterion is that the concentration of the active substance in soil should be reduced to (at least) the negligible concentration in soil (NC_{soil}) due to degradation within one year. Both environmental risk limits, MPC_{soil} and NC_{soil}, are defined at the Dutch national level (Van Vlaardingen *et al.*, 2007; CDM, 2016).
- The third criterion is the groundwater limit for individual PPPs. Each individual substance shall not exceed the negligible concentration for groundwater ($NC_{groundwater}$). If an $NC_{groundwater}$ is not available, the limit value in water intended for human consumption, which derives from EU Directive 98/83/EC (EU, 1998), applies.

The relevant legal framework is the Dutch Fertilizer Act (*Meststoffenwet*;(Anonymous, 2005).

7.2 Assessment work flow

7.2.1 Relevance of module

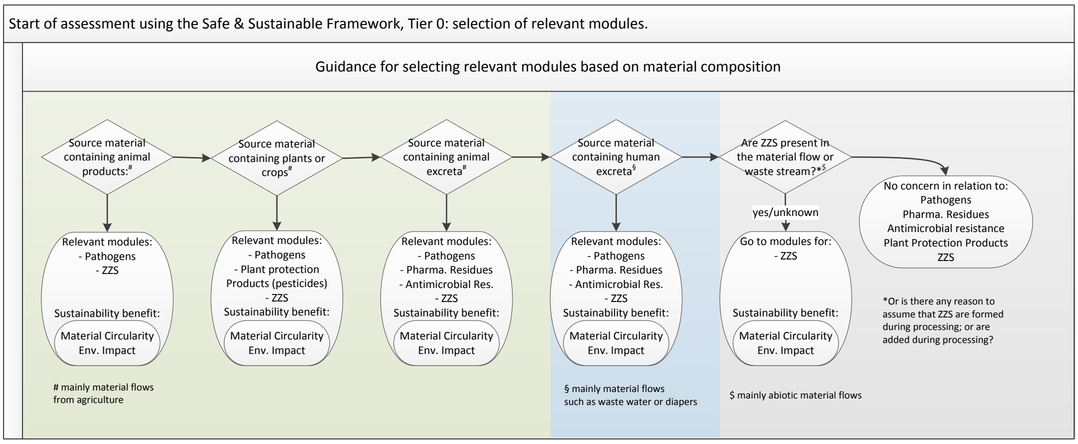


Figure 7-2. The PPP module is triggered by streams originating from plants or crops

Tier 0 is triggered when material originating from plants or crops is processed, on which PPP could have been used (see general workflow, Figure 7-2).

Any waste stream that originates from agriculture, horticulture, herbal cultivation or forestry (both in private and public) can potentially contain residues of plant protection products.
Waste streams originating from plants or crops from agricultural origin cover all – non-edible – parts of crops that are produced for human consumption, such as vegetables, fruits, herbs, nuts, etc., as well as crops produced for animal feed production, such as grass and maize. Waste parts from agricultural crops produced for other purposes, such as clothing, rope, etc., can also potentially produce waste streams containing PPP residues.

The module described in this report currently deals with only one type of waste stream, plant/crop material, coloured blue in Figure 7-3. The basis for this module is the existing method, falling under the Dutch Fertilizer Act, for assessing 'plant/crop material' originating from a source where plant protection products have been applied with the direct reuse destination is fertilizer or is used for fertilizer production. A well-known example in the latter process are (co)-fermenters. Compost as a waste stream is not considered here, as a different regulation applies to it under Dutch law (Anonymous, 2005). The compost quality before application has to meet maximum level restrictions for eight heavy metals.

A non-exhaustive overview of sources / types of waste streams that fall under this category are:

- Vegetation from forests, parks, road verges, ditches, etc. (from areas or situations where PPPs have been applied): pruning wood, leaf waste, cutting waste, etc.;

- Land and (greenhouse) horticultural crops (national and abroad) and related flows;
- Crop residues after harvesting the product: e.g. tomato plant residues from greenhouse horticulture, straw;
- Waste of non-consumable parts of products from industrial or non-industrial processing (households, restaurants, various types of care facilities): peels/skins or other residues of products (citrus fruits, potatoes, carrots, onions, bulbs, residual streams of animal feed, cocoa pods, chaff of grain);
- Waste streams of processed or non-processed (animal) consumption products or consumable parts of (animal) consumption crops: over-the-date products, biomass waste from food manufacturers (industrial, restaurants, etc.), rejected products, surplus after food preparation.

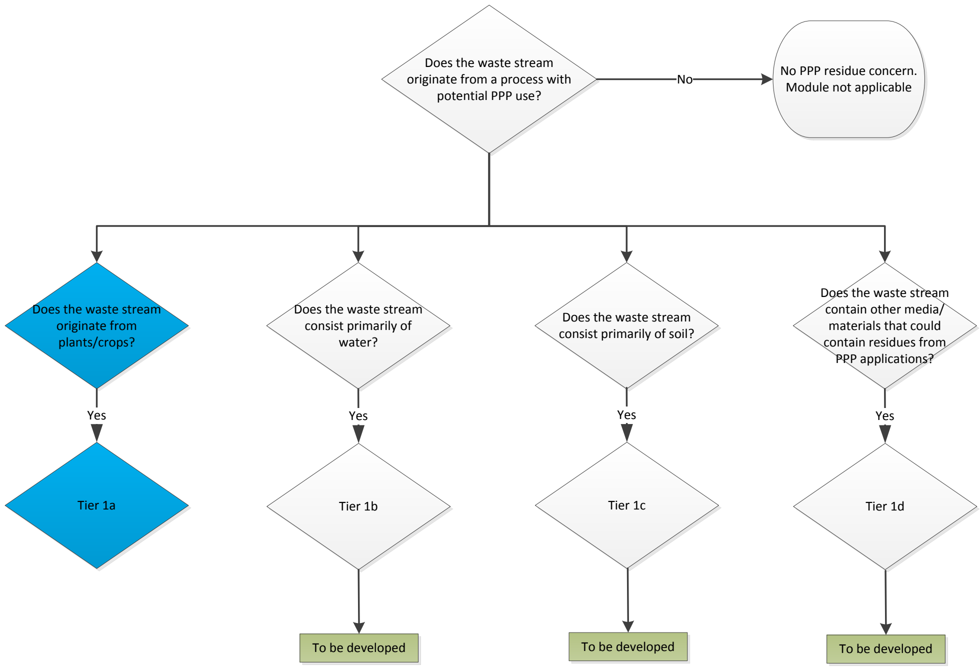


Figure 7-3. Detailed flow scheme for Tier 0, specified to applicability domain of the pesticide module, currently aimed at Plant Protection Products (PPP) originating from plants/crops.

7.2.2 *Tier 1 – Water, soil and other materials*

In addition, other waste streams from processes in which PPPs are used are possible. For now, water, soil and 'other materials' have been identified. An example for water are the options for water cycle closure for greenhouse hydroponic cultivation, as explored in the project '*Glastuinbouw Waterproof*', e.g. (Balendonck *et al.*, 2012). The reuse of effluent from waste water treatment plants is another example. An example of the waste stream category 'soil' is soil tare resulting from, for example, beet and potato cultivation (Beltman *et al.*, 2014). The category 'other media/materials', may cover streams like mushroom cultivation substrate, fertilizers, e.g. digestate of (co)-digestion and compost.

Assessment schemes for the other three categories of waste streams have not been developed for this report. However, if the emission route of these waste streams would lead to exposure of the soil compartment, the assessment described in Tier 2 is, in principle, applicable.

The current module only partly addresses the indirect exposure of humans. The soil standards described in Section 7.4.1 (MPC_{soil} and NC_{soil}) do cover, in principle, human consumption of crops grown on the composted field and consumption of milk and meat derived from cows feeding on grassland soil.

Exposure routes for humans that are currently not covered in this module include the use of plant/crop material waste streams as feed for animals whose meat, milk or eggs may be used for human consumption. A second example (not covered) is the production of clothing from crops (e.g. cotton, hemp, flax, nettle).

7.2.3 *Tier 1a – Quick scan for plant/crop material*

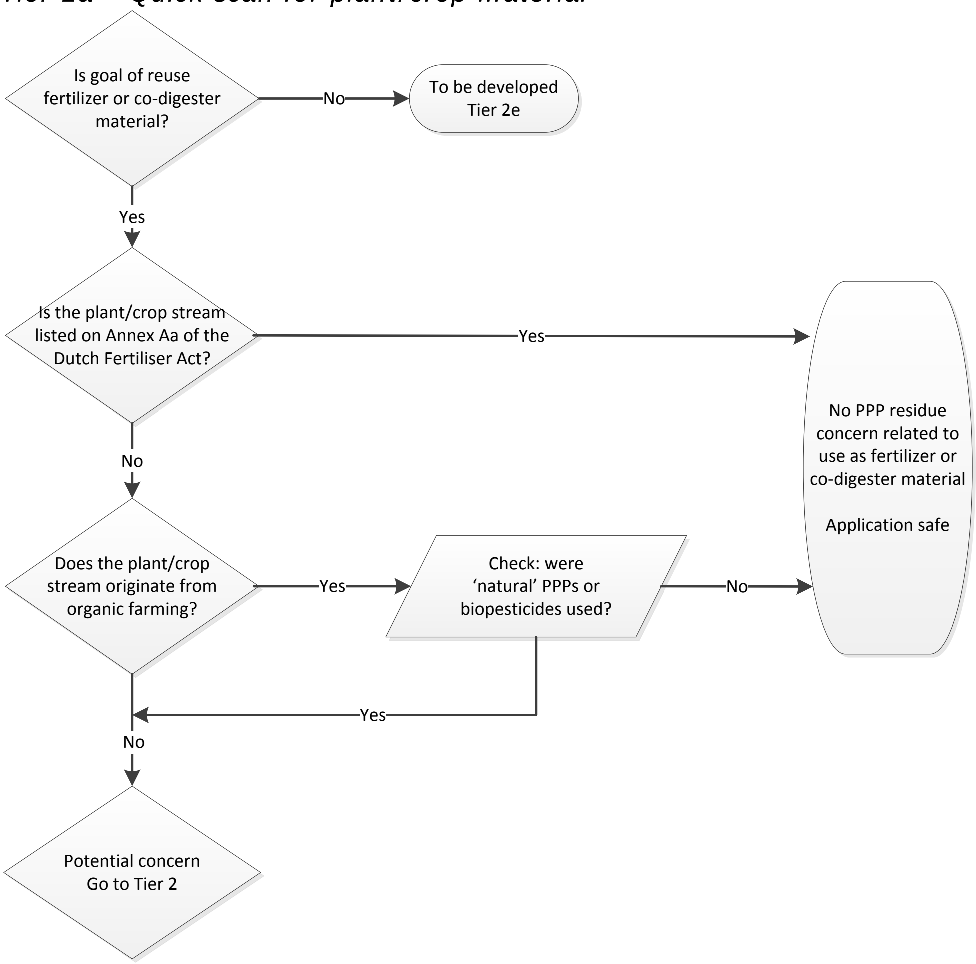


Figure 7-4. PPP module. Flow scheme for Tier 1a.

This module is currently drafted only for the reuse destinations of fertilizer of co-fermenter material with organic plant/crop material as the waste stream. There are various other reuse destinations for this stream, examples of which are the production of biofuel and plastic production. Environmental safety assessment of these and other reuse destinations is currently not covered in this module.

The safety assessment in this module stops if the waste stream under investigation is on the positive list of the Dutch Fertilizer Act (*Meststoffenwet*). The positive list is Appendix Aa to this Act (Anonymous, 2005); it contains those fertilizer materials for which no objections exist for their use as fertilizer from both environmental and agricultural viewpoints.

A second 'stop' in the applicability of this module is when it is established that the waste stream originates from a farm or company that is applying organic principles, i.e. crop culturing is performed without the use of PPPs. Care should be taken, however, since products with 'natural ingredients' or biopesticides may have been used on farms adhering to organic principles and these products could still contain PPP active substances or their residues. Examples are 'natural' products based on pyrethroids or copper use on potatoes against *Phytophthora*.

If the presence of PPP residues in the waste stream cannot be excluded and data on chemical analysis of the batch are not (yet) available, then the next step is to assess which PPPs may have been used on the original crop. This is done in Tier 2.

A minimum data set needed for the performance of the safety assessment is requested (CDM methodology, Chapter 4 (CDM, 2016)). This comprises, amongst other things: identity of the waste stream owner, name of the stream, production volume, process description, description of intended use and a basic chemical analysis.

7.2.4 Tier 2 – Assessment

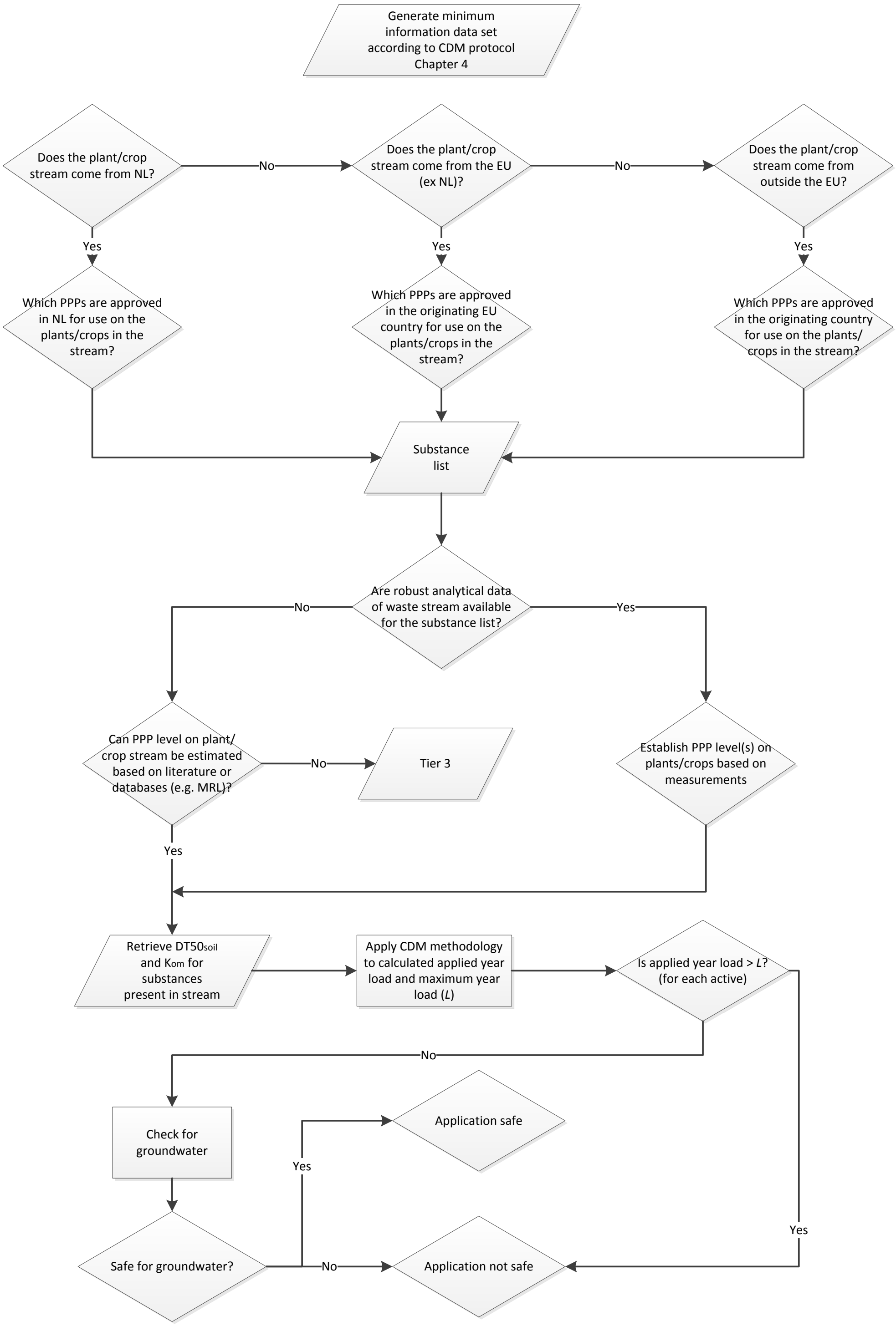


Figure 7-5. PPP module. Flow scheme for Tier 2.

List of substances present in the waste stream

As a first step, it is necessary to determine from which country the stream originates. Different countries have different lists of authorized products for a specific crop:

- If the waste stream originates from the Netherlands, the database of the Dutch Board for the Authorization of Plant Protection Products and Biocides (Anonymous, 2017) can be used to retrieve the possible active substances present in a given crop in the Netherlands.
- If the waste stream consists of crops originating from outside the Netherlands, but from within the EU, the EU pesticides database (European Commission, 2017) should be consulted.
- For waste streams consisting of crops imported from outside the EU, the combination of crop type and PPP active substances regularly used on that crop – in the country from which the waste stream originates – is sometimes known. An important source is the Codex Alimentarius of the World Health Organization (WHO, 2017). This is a database of Maximum Residue Limits (MRL) that can be disclosed per commodity. An MRL is a substance-specific, human toxicological risk limit. Searching the database per commodity thus results in a list of substances for which MRLs have been derived. The substance-MRL list can be taken as the list of possible active substances that could have been used on a given crop. At present, information to further narrow this list down (e.g. by a country-specific list of authorized actives per crop) should be gathered by consulting the Internet, e.g. information provided by competent authorities.

After performing the above steps, *a list of substances potentially present in the waste stream* has been drawn up. The next step is to establish whether *robust analytical data on PPP residues* in the waste stream are already present at this stage. If no robust analytical data are present, a generic assessment can be applied to estimate the concentration of active substances in the waste stream, see Section 7.2.4.2. From these concentrations, the applied yearly load of the residual material to soil is calculated (see Section 7.2.4.3 for details and calculation). If this is higher than the maximum yearly load based on the NC_{soil}, application is not advised. If robust analytical data[20] are available, the procedure described in Section 7.2.4.3 applies.

No robust analytical data available

The expected level of PPP residues present in plant/crop waste can be inferred using data on PPP use per crop, maximum crop residue levels and historical measurements. This approach is also part of the CDM methodology, but depends a lot more on expert judgement and is semi-quantitative in nature. The following sources can be used for estimating the applied load without analytical data:

- Usage data for crops in NL or EU: Which PPPs on which crops (RIVM / WUR reports, EU reports) at which crop concentration.

[20] Robust in this context means that the applied analytical methods are adequately validated by following appropriate guidelines specified in the CDM protocol (CDM, 2016). For example, crops may be treated with different PPP products during a growing season. This means that sampling of the waste stream should be performed such that the possible variation in the PPP residues is covered.

- Usage data for crops outside EU: Which PPPs on which crops. NB Pay attention to PPPs with a high-risk profile that may not be approved in EU. Perform a literature check for specific waste streams coming to NL.
- PPP standards for crops/products. The most appropriate standard for this use are likely MRLs. These are maximum residue levels on crops - EU database (European Commission, 2017). For the substances potentially present on the plant/crop stream, twice the MRL level can be used as a worst-case approximation of the concentration expected.
- MRLs are set for the Raw Agricultural Commodity (RAC) and apply to food items intended for human consumption. In addition to MRLs, residue limits for feed (intended for animal consumption) are derived. These risk levels are SMTR (supervised trials median residue) or HR (highest residues). If no MRLs are available, the OECD Feed calculator can be used to infer which crops are consumed by which animal category. This may help in identifying the target animals and food products (meat, milk, eggs, etc.) that are relevant for human exposure to PPP residues.
- Measurement data from statutory product controls (NVWA reports food products)
- Measurement data in specific waste streams. Intended are project-based measurements; these will be relatively limited data sets, so search for literature for specific streams.
- See, amongst others, Ehlert et al. (2016) for a list of 21 waste materials reviewed for their suitability as fertilizer or substrate for co-digestion.

Using the estimated concentration(s) of active PPP substances in the waste stream, the applied yearly load of the substance is calculated. See Section 7.2.4.3 for details.

Quantitative safety assessment

The methodology of the assessment is described in the CDM protocol (CDM, 2016). The protocol text serves as a guide and is cited here in brief steps for illustrative purposes.

First, the maximum (allowable) yearly load of the waste stream needs to be calculated. Two substance-specific environmental fate parameters are needed: $DT50_{soil}$, which is the half-life for dissipation of the active substance in aerobic soil, corrected to a temperature of 10°C[21] and the organic matter, normalized adsorption coefficient in soil, K_{om}, for calculating the concentration in groundwater. See Section 7.3.3 for data sources on these parameters.

The $DT50_{soil}$ is used to calculate the maximum yearly load (L) as:

$$L = \frac{NC_{soil}}{A} \cdot M_{soil}$$

L maximum yearly load

[21] if a dissipation half-life value at 20°C is available, the half-life value at 10°C is calculated by multiplying the DT50 at 20°C by 2.58 (CDM, 2016).

NC_{soil} negligible concentration in soil
A accumulation factor
M_{soil} dry mass of 1 hectare of 20 cm soil with a dry bulk density of 1.5 kg L^{-1}.

with:

$$NC_{soil} = \frac{MPC_{soil}}{100}$$

$$A = \frac{r}{1-r} = \frac{1 - e^{(-253 \cdot DT50_{\text{soil}})}}{e^{(-253 \cdot DT50_{\text{soil}})}}$$

$$M_{soil} = 3 \times 10^{6} \text{ kg dry soil}$$

The calculation above is based on the mixing of the fertilizer in furrowed soil over 20 cm deep and on one soil application event per year. The potential degradation or accumulation of the active substance in soil is taken into account over a 10-year period. The result of the calculation is a yearly load (L) that leads to a soil concentration that is both ≤ MPC_{soil} and reduced to ≤ NC_{soil} within one year. This is, however, limited to substances with a DT50 < 55 days. For a substance with higher DT50 values, L should be adjusted such that NC_{soil} is reached within one year.

In a second step, the *applied* yearly load of the waste stream is calculated. This load is limited by the concentration of one of eight components of the waste stream: P_2O_5, N, K_2O, neutralizing value, organic matter, MgO, SO_3 and Na_2O. Limit values in kg ha^{-1} are set for each of these components. The component for which the limit value is reached first is used to calculate the yearly load, using the expected or measured concentration of active substance in the waste stream.

If the yearly load exceeds the maximum yearly load (L), application of the waste stream is not allowable. If the yearly load is lower than L, the concentration in groundwater is calculated.

The model PEARL[22] is used to calculate the concentration in groundwater at 1 m depth in a representative, vulnerable agricultural soil. Both the maximum yearly load (L) and the DT50 and K_{om} values collected above are used as model input. If the predicted groundwater concentration exceeds the groundwater standard, L should be reduced to such a level that the groundwater criterion is met. If the (re) calculated concentration in groundwater at 1 m depth is > 0.01 µg/L and < 0.1 µg/L, it should be recommended that the fertilizer application is not done in groundwater abstraction areas.

The above procedure should be run for each of the PPP active ingredients expected or measured in the waste stream.
If the destination of the waste stream is an application as co-digester material, the CDM protocol offers an extra calculation step in which the potential anaerobic degradation of the active substance(s) are taken into account before the calculation of the load. This step is not detailed here. Consult the CDM protocol for more details.

[22] A model developed for simulation of pesticide behaviour in plant-soil systems, used in regulatory assessment of plant protection products to predict the leaching of active substances and metabolites to groundwater.

7.2.5 Tier 3 – Generation of new data

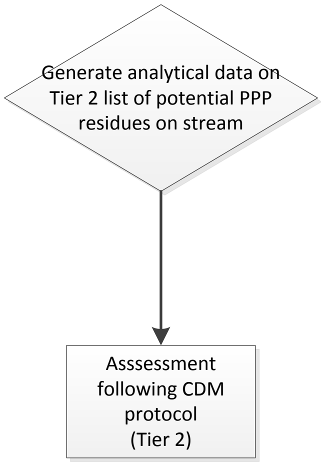


Figure 7-6. PPP module. Flow scheme for Tier 3.

If it is not possible to estimate levels of PPP active substances in the waste stream (Tier 2), chemical analysis should be performed in Tier 3. The chemical analysis is focused on a limited number of heavy metals and expected organic micro pollutants listed in Chapter 4 of the CDM protocol. Although this list does cover PPP residues, the protocol explicitly states the list of PPPs analysed is dependent on the specific stream. The Expert Committee on Fertilizers (CDM) will request a list of PPPs that have potentially been used during the cultivation of the crops from the waste stream supplier. This list has been generated in Tier 2.

7.3 Data sources

7.3.1 Data sources for MRLs and residue concentrations

- EU database with maximum residue levels on crops (European Commission, 2017).
- Codex Alimentarius of the World Health Organization (WHO, 2017).
- Ehlert et al. (2016). Review of 21 waste and by-products for use as co-digestion material.
- Results of pesticide residue monitoring in food items. For the Netherlands, periodic reports can be found on the website of the Netherlands Food and Consumer Product Safety Authority (NVWA, 2018).

7.3.2 Data sources for MPC_{soil} and NC_{soil}

Although MPC_{soil} values for PPP active ingredients have been derived in the Netherlands, these risk limits have not been consistently archived or made public. MPC_{soil} values for PPPs have not been formally approved by the responsible Ministry. Nevertheless, risk limits for soil have been derived in the past, e.g. by order of the Dutch Board for the Authorization of Plant Protection Products and Biocides (Ctgb) or for the purpose of projects setting environmental quality standards. If an MPC_{soil} and/or NC_{soil} is needed, a question should be addressed to the helpdesk of the Dutch website *Risico's van stoffen* (RIVM, 2017). If an MPC_{soil} is available, it will be retrieved and provided by the helpdesk.

If no MPC_{soil} exists, an *indicative* environmental risk limit may be derived using the methodology described by De Poorter et al. (2015). Data that can be used in the derivation of an indicative risk limit may be found in active substance evaluations performed at European level. Expert judgment is needed to establish how information in these dossiers can be used in risk limit derivation. Access to active substance evaluations is provided via the EU-pesticides database (European Commission, 2017). Finalized risk assessments for PPP active substances are published in the EFSA journal, accessible via EFSA's website (EFSA, 2017).

7.3.3 *Data sources for $DT50_{soil}$ and K_{om}*

For the calculation of the maximally allowable soil load, data on the dissipation half-life (DT50) of the active substance in soil and on the adsorption coefficient to soil organic matter are needed. Data sources for these parameters are:

- the Ctgb database (Anonymous, 2017), in which these parameters are specified in the so-called lists of endpoints, which are part of the authorization files.
- the EU pesticide database (European Commission, 2017)
- the EFSA journal, accessible via EFSA's website (EFSA, 2017), in which lists of endpoints are included of finalized EU-level active substance evaluations.

7.4 Criteria

7.4.1 *Criteria applied in the described method*

The criteria used in the environmental safety assessment are the:

1. maximum permissible concentration in soil (MPC_{soil}).
   The concentration in soil directly after application of the fertilizer to soil shall not exceed the MPC_{soil};
2. negligible concentration in soil (NC_{soil}).
   The concentration of the substance in soil shall be (at least) below the NC_{soil} due to degradation within one year after application.
3. concentration in groundwater at 1 m depth;
   The concentration in groundwater at 1 m depth at the calculated maximum yearly load shall not exceed 0.1 µg/L. For groundwater collection areas, a limit of 0.01 µg/L applies.

These standards are substance-specific environmental quality standards. The MPC_{soil} is derived based on available ecotoxicological data, according to a standardized methodology. The NC_{soil} is derived as the maximum permissible concentration in soil divided by a factor of 100:

$$NC_{soil} = MPC_{soil} / 100$$

The groundwater limit values are generic values that are applicable to individual substances.

If an MPC_{soil} is not available, then it needs to be derived. Section 7.3.1 addresses the appropriate steps to be taken.

7.4.2 *Other relevant criteria*

To safeguard food quality, safe concentrations in crops are derived for active substances of plant protection products: MRLs or maximum residue limits. MRLs are based on human toxicological limit values. In the currently described module, MRLs are used in Tier 2 to qualitatively estimate concentrations in crop-based waste streams. In future modules describing other reuse destinations of waste streams that contain PPP residues, MRLs may have a potential use for human health safety assessment.

7.5 Possibilities for intervention

Options for intervention could include the processing of the waste stream before land application in order to reduce PPP residues. An example is co-digestion. In any case, a reduction of the concentration of PPP residues after processing should be confirmed. It should be realized that this may give rise to metabolite formation.

7.6 Recommendations

- In Tier 0, three waste streams potentially containing PPP residues are identified that were not worked out in this module. We discerned three categories: water, soil and other media/materials (e.g. activated carbon, sewage sludge, etc.). Modules for these other waste streams should be developed when the need arises.
- For the waste stream 'plant/crop material', reuse destinations other than fertilizer or fermenter material may be applicable. Two examples given are the production of biofuel or plastic. Emission scenarios and an accompanying safety assessment should be developed for these other reuse destinations. An overview of the many possible waste streams containing PPP residues and their reuse options seems to be lacking. Before developing new PPP-related modules, it seems worthwhile to map currently existing routes, including existing initiatives for reuse.
- Explore the need for extending the module for material flows that contain both PPP and biocide residues. For example, preservatives that may be applied during storage of an organic waste stream. This may also be relevant when material streams are mixed, e.g. manure and plant material.
- Add a module or extend the current one for the assessment of waste streams for which the primary concern is related to biocide residues.
- Extend this module with sub-modules that better cover indirect exposure of humans to waste streams containing PPP residues. This should be developed in cooperation with human exposure modellers/toxicologists.
- Currently in Tier 2, a list of possible PPP residues present in the stream should be drawn up when concentration measurements of pesticides in the waste stream are absent. This can be problematic for non-experienced users of the module. A more user-friendly method could be developed, which requires listing of crop-product active ingredients per country. It seems possible to generate such lists, but this will require cooperation with the competent authorities, which means the Ctgb for the Netherlands. For other EU member states, research into the availability of crop-product active ingredient lists per country would be needed. For non-EU countries, a list of databases or handbooks covering crop-product active ingredients would need to be drafted.
- The addition of an additional criterion for surface water should be considered in an update of the module.

8 Pathogens module

Pathogenic viruses, bacteria, fungi, parasites and their metabolites and toxins are microbiological hazards. Also prions can be considered as a microbiological hazard. Exposure to these hazards results in a microbiological risk. Although, in theory, microbiological hazards can be present in and on all types of products, the most likely source of hazards are products of biological origin. Safety assessments of material flows in the Biomass and Food sector should take this aspect into account. Packaging used for Biomass and Food also has a relatively high potential for introducing pathogens in material flows. This is assessed in the pathogens module by identifying potential risk-reducing steps and assessing their effectiveness, see Figure 8-1. If this is not possible based on existing data, a challenge test can provide this information.

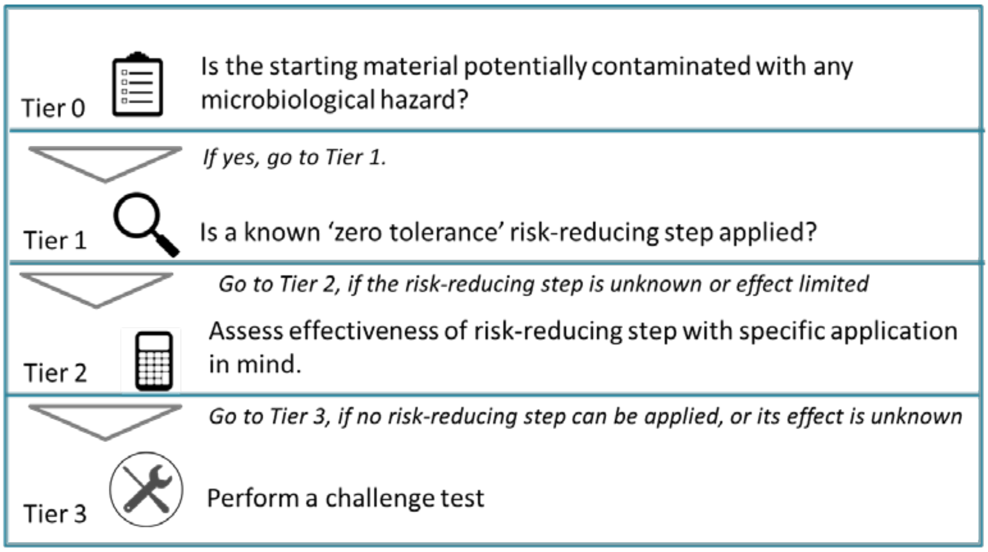


Figure 8-1. Schematic overview of tiered workflow in Pathogen module.

8.1 About module pathogens

Any risk is the result of the likelihood of exposure x severity. This module describes a method aimed at assessing the risk of illness from pathogens by using residual material flows. Viruses, bacteria, fungi and parasites (pathogens) and their metabolites (including toxins) are considered microbiological hazards. Also prions can be considered as a microbiological hazard. This module focuses only on the pathogens: viruses, bacteria, fungi and parasites. The risks of exposure to metabolites and prions are not further elaborated, as these 'chemical' hazards behave differently from pathogens.

As further defined below, the risk of illness depends on the level of exposure and the severity of an infection. In cases of microbiological hazards like pathogens and their metabolites, the level of exposure (likelihood or frequency of occurrence) depends on the prevalence of a hazard (number of contaminated batches of a product), the concentration of a hazard in a contaminated batch and the frequency of contact with such a contaminated batch. Exposure can occur via various routes: via food, the environment (air, water, soil), humans or animals. The route of exposure for infections can be orally, respiratory or via skin wounds. Although pathogens and other hazards can be present in a wide variety of residual material flows, the most likely source of human microbiological hazards are material flows of biological origin.

Besides the level of exposure, the risk of illness also depends on the severity of the consequences of infection. This depends on the host and the type of pathogen. Specific host groups, the so-called YOPI (young, old, pregnant and immune-compromised person), are at higher risk than the general population. Some (low virulent) microbiological hazards only cause mild, short-lasting symptoms like vomiting and nausea. Other (high virulent) hazards can cause very serious symptoms like kidney failure, paralysis and even death. So, besides the level of exposure and the host, the risk of illness also depends on the type of hazard, and on the severity of the consequences of exposure to microbiological hazards.

Among the various microbiological hazards are:

- Bacteria: e.g. Salmonella, Legionella, Shigella, Clostridium, *Vibrio cholera*, Campylobacter, *Coxiella burnetii*, pathogenic *E. coli*;
- Viruses: e.g. Hepatitis A and E virus, norovirus, rotavirus, enterovirus, reovirus, astrovirus, calicivirus;
- Parasites: e.g. Cryptosporidium, Giardia, Entamoeba, *Toxoplasma gondii*; worm eggs: e.g. Ascaris (tapeworm like), Toxocara.
- Harmful metabolites: an example of harmful metabolites formed by pathogens is aflatoxin, a well-known toxin produced by *Aspergillus flavus*, a fungus that can be found on peanuts.
- Prions: bovine spongioform encefalophaty (BSE, mad cow disease) and Creutzfeldt-Jakob disease in humans are well-known examples of diseases caused by prions.

To control microbiological hazards in waste material flows, processing steps should be identified where the number of pathogens in the final product can be controlled, reduced or even eliminated. Cold storage is a way to control the outgrowth of microorganisms. Heat treatment can reduce or even fully eliminate any pathogen present.
Unlike chemical hazards, the concentration of pathogens in a product can increase during processing, storage or transport as a result of growth. Additionally, if waste processing does not lead to full elimination, there is a risk of a post-processing spreading of pathogens to an environment where their number can increase, e.g. in agricultural areas or in food. Therefore, when judging the safety of a circular process, it is not only relevant to identify processing steps where the number of pathogens can be controlled, reduced or eliminated, it is also important to consider their growth possibilities, especially in processes that do not lead to full elimination. This risk shall be considered when setting microbiological criteria for the final product.

Waste material flows can also harbour microorganisms that can be resistant to antimicrobial agents. This chapter can also be used to assess the risk of exposure to such antimicrobial resistant microorganisms. Well-known examples of antimicrobial resistant (AMR) microorganisms are MRSA-bacteria and ESBL-producing bacteria. AMR microorganisms are not by definition pathogenic, but if they are, this module is relevant. For the risks linked to non-pathogenic AMR microorganisms, Chapter 7 is relevant.

8.2 Assessment work flow

8.2.1 *Relevance of module: Should the microbiological hazard be assessed?*

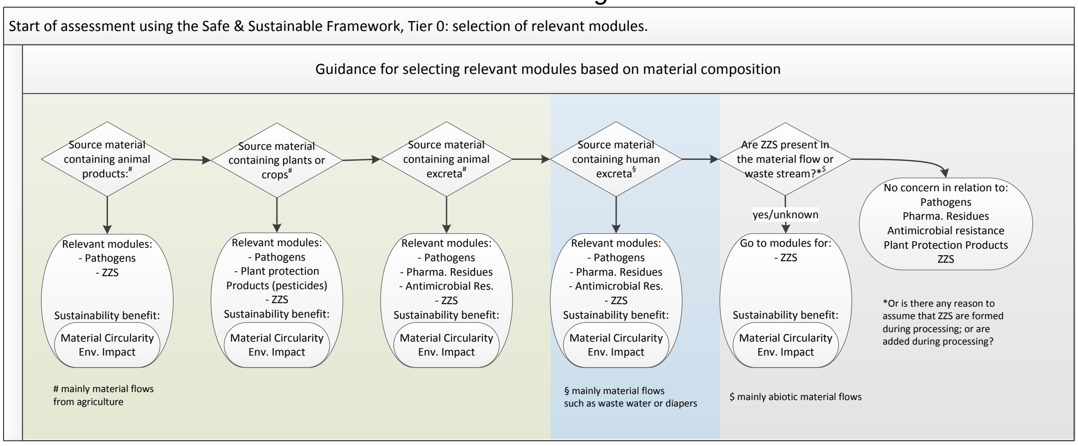


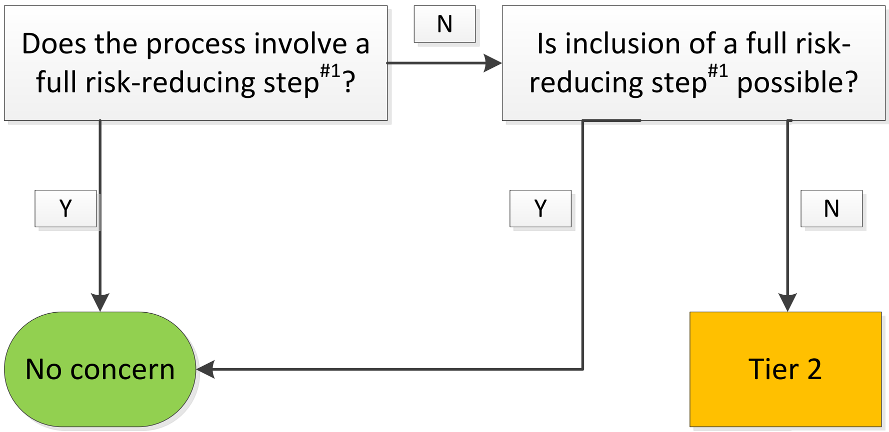
Figure 8-2. Triggering of the Pathogens module

In order to decide if further assessment of risk due to pathogens is necessary one needs to answer the basic question: ‘Is the starting material potentially contaminated with any microbiological hazard?’ This primarily depends on the biological nature of the material flow.
Some hazards, such as viruses, can be transmitted from human to human. Other hazards can also originate from animals, the so-called zoonotic hazards. Transmission of zoonotic hazards can occur by direct contact with animals, but also by contact with animal products (such as meat and manure). And, as manure is used as fertilizer for the cultivation of fruits and vegetables, transmission of zoonotic hazards can also occur via faeces-contaminated agricultural products of non-animal origin. Other pathogens can originate from soil.
Basically, pathogens need material of biological origin for growth and multiplication. The first question to be answered in Tier 0 therefore is: does the starting material contain products of biological origin? This is split up in four different types of biological material: animal products, plant or crops, and animal or human excreta (Figure 8-2). If the answer is yes for the presence of any of the four types of biological material, there is a potential for contamination with pathogens and further assessment in Tier 1 is needed.

8.2.2 *Tier 1 – checklist risk-reducing steps*

If starting material is potentially contaminated with a microbiological hazard, its processing should be checked for the presence of a risk-reducing step. Such a step is often referred to as a critical control point (CCP). Various technologies have a risk-reducing effect, such as heating, drying or chemical treatment. Their efficacy varies from partial to full risk reduction.
Some bacteria can transform into so-called spores. Such bacterial spores are very resistant to risk-reducing treatments like heating or drying. When a high number of spore-forming microorganisms can be expected, their full elimination requires a moist heat cycle of 30 minutes

at 121 °C, which is prescribed for the sterilization of specific hospital waste in the Netherlands (Anonymous, 2008). If such or an equivalent full risk-reducing step is present, there is no concern (Figure 8-3). If not, is its inclusion feasible? If the answer is “Yes”, there is “No concern” when included. If the answer is “No”, the further assessment in Tier 2 is necessary.



[#1]:full risk-reducing means a step, like a heat treatment of 30 min at 121 °C (eliminating all microbiological hazards, including heat resistant spores).

Figure 8-3. Tier 1 of the pathogen module.

8.2.3 *Tier 2 – risk-reducing step assessment*

Tier 2 is relevant for processes in which the inclusion of a full risk-reducing step is not feasible (Figure 8-4). The central question then is: is a full risk reduction step necessary? This depends on the type of microorganisms that are present in the source material and on the application. Spore-forming microorganisms are more resistant to risk reduction steps such as heating than non-spore-forming microorganisms. For starting material in which spore-forming microorganisms are potentially present and that does not receive a full risk-reducing step, there remains a concern in relation to its safety. For starting material in which only non-spore-forming organisms are present, full risk reduction can now be achieved with a less intensive treatment (e.g. pasteurization: a heating process of 10 sec at 72 ^{o}C or equivalent; Figure 6-3), because such organisms are less resistant to risk-reducing treatments. See Section 6.5 for further information on risk-reducing steps.
Full reduction is safest, but a zero-tolerance policy for microbiological hazards is not always feasible or might not be necessary. Therefore, a potential risk can also be reduced to a level that complies with a given criterion that does not require full elimination. Compliance with such criteria results in no concern. When it is clear that the existing control step does not reduce the risk to an acceptable level, the possibility of incorporating an additional control step should be considered. If inclusion of such a step is not feasible due to technical or economic

limitations or if the level of risk reduction is unknown, a challenge test is required (Tier 3).

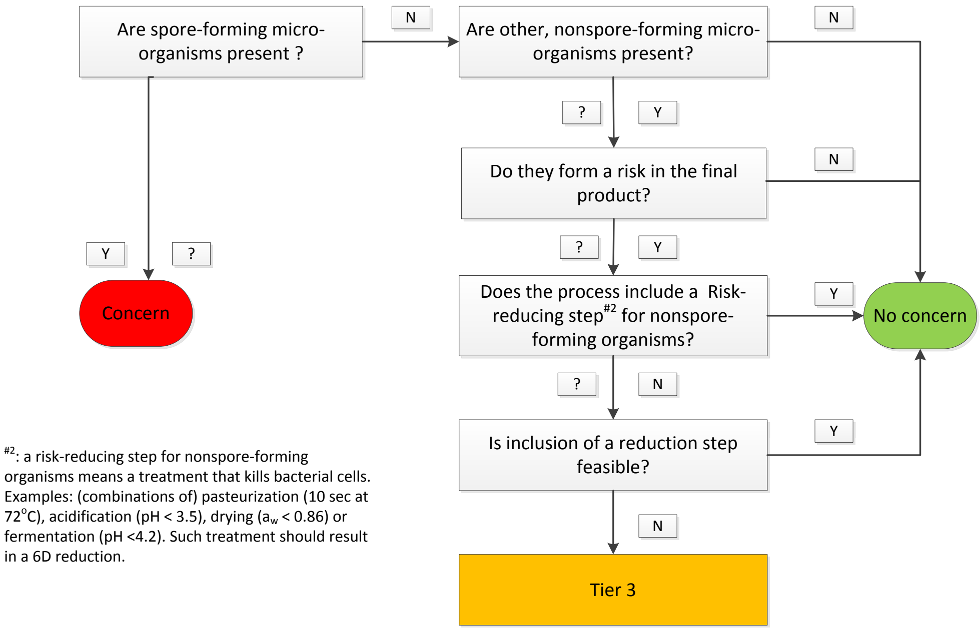


Figure 8-4. Tier 2 of the pathogen module.

8.2.4 *Tier 3*

When a potential microbiological risk is present, but the overall effect of a process on the final risk/number of pathogens is unknown, a challenge test is required to establish the microbiological safety of the production process and its final product. Challenge testing involves inoculating starting material or using a specific challenge device with a known concentration of a relevant microbiological hazard to determine what happens to it during production, processing, distribution or subsequent handling (Anonymous, 2008). The resistance of the microbiological challenge should be similar to the resistance of the microbiological contamination present or expected. If exact simulation is not feasible, an extrapolation of the results to the efficacy of the process should be made. The level of reduction is assessed using a challenge test. Comparing the reduction achieved with set criteria (see Section 6.4) will indicate if this is enough and the outcome is either concern or no concern. The challenge test must be performed with relevant, representative species under process conditions.

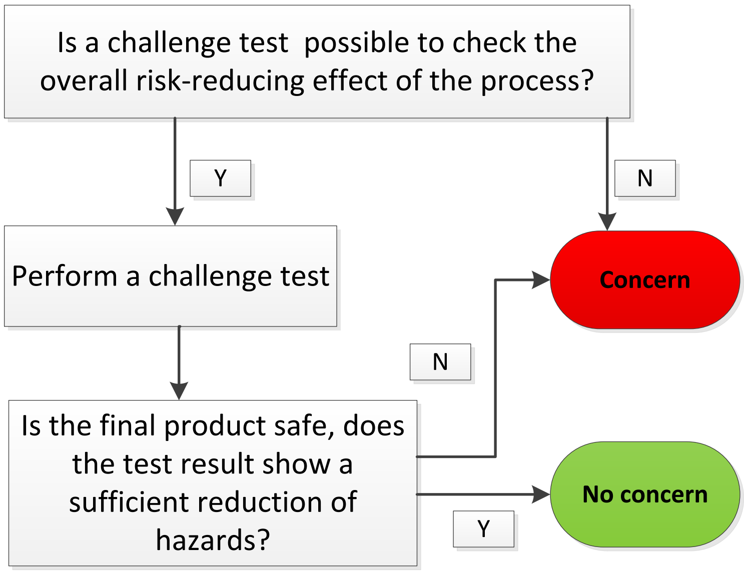


Figure 8-5. Tier 3 of the pathogen module.

8.3 Data sources

The approach that is used in this module is based on the Hazard Analysis and Critical Control Points as described in the Codex Alimentarius Committee document 1 (1969). More information that is used in this pathogen module is present in the scientific literature and in textbooks on microbiology and food processing (example: Handbook of Food Preservation, 2nd edition (MS Rahman (ed), CRC Press, Boca Rotan, London, New York). Information is also available, for instance, on indicators for the presence of pathogens in treated waste water (e.g. source of struvite) and in plant and animal by-products (e.g. used as ingredients of feed). For sterilization of hospital waste, a guideline is available in the Netherlands, specifying acceptable processes with considerable safety margins (Anonymous, 2008).

8.4 Criteria

'Is the level of risk reduction sufficient?' is a question to be answered in Tier 2. Sufficient means that the result of a risk-reducing step is in compliance with a criterion, with full elimination as the strictest criterion. Setting criteria requires a protection target (e.g. a number of people ill per year). In its absence, a target should be set and a product criterion derived (e.g. material flow shall not contain more than 1 pathogen per m^3). Before doing this, the rationale for such a microbiological criterion should be made clear, e.g. by epidemiological evidence and/or by the result of a risk assessment indicating that the product under consideration represents a significant public health risk and that a criterion is meaningful for consumer protection.
In their guidelines for drinking-water quality, the WHO (2017) uses health-based targets to set criteria. This can be a health outcome target (e.g. tolerable burden of disease), a performance target (e.g. log reduction of specific pathogens) or a specified technology target (e.g. application of a defined treatment process). Combined with a full quantitative microbiological risk assessment (hazard identification, exposure assessment, hazard characterization, risk characterization),

such a target will give a criterion for the maximum number of pathogens in a specific product. By comparing the number of pathogens in starting material and this maximally acceptable number of pathogens in the final product, process parameters can be set. For example: to assure that no person becomes ill from using a specific product (target), Salmonella should be absent (criterion) in the final product. To meet this criterion, the product should receive a heat treatment of at least 10 sec at 70 ^{o}C (process parameters) ensuring sufficient reduction of the number of pathogens.
When establishing microbiological criteria, a variety of approaches can be used, depending on the risk management objectives and the available level of knowledge and data. Approaches can range from developing microbiological criteria based on empirical knowledge related to Good Hygienic Practices (GHP), to using scientific knowledge of product safety systems such as hazard analysis and critical control points (HACCP, see Figure 8-6), or conducting a risk assessment (EFSA, 2017). However, performing a full quantitative microbiological risk assessment requires a considerable amount of data and is time-consuming and costly. Therefore, a preventive approach, such as HACCP, is preferable in combination with good hygiene practices because hazardous pathogens can be difficult to detect as they can be present in low concentrations and non-homogeneously distributed.
HACCP (Figure 8-6) can be applied to identify critical steps in the process (such as heating, cooling and drying) that control (prevent, reduce, eliminate) the number of pathogens – these steps are called Critical Control Points (CCPs).

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

Figure 8-6. Principles of the HACCP system (CAC/RCP, 1969).

In the HACCP approach, process parameters are set (Principle 3, Figure 8-6) at risk-reducing steps (CCPs, Principle 2, Figure 8-6). For a heating step, limits shall be established for the minimum temperature and duration at this temperature. Monitoring (Principle 4, Figure 8-6) process parameters (*in casu* time and temperature) should be used to show that microbiological risks are under control.
If residual/waste material is submitted to a risk-reducing step, the number of pathogens will gradually decrease during such a step.

However, it is not always known whether or not a process step causes sufficient reduction of the number of pathogens, especially since the initial number of pathogens in the source material can fluctuate considerably. But not only the initial contamination level and the reduction achieved should be considered, the possibility of (post-processing) outgrowth of surviving hazards should also be taken into account. The intended use of the recycled product shall be taken into consideration. Intended uses can vary from packaging material for food products and fertilizer to an ingredient of concrete. Microorganisms can grow and produce toxins in or on products whose pH (parameter for acidity) varies between 3.8 and 9.5 in situations in which sufficient water is available (water activity, a_W > 0.86) and in which the temperature is neither too low (>5 °C) nor too high (< 45 °C). The possibility of post-processing outgrowth should result in stricter criteria with respect to hygiene and the level of risk reduction.

8.5 Possibilities for intervention

Different hazards have different levels of resistance to applied intervention strategies. In our Tiered approach, we distinguish for instance between spore- and non-spore-forming hazards because the resistance characteristics of these two types differ strongly. However, within the group of non-spore-forming hazards, the characteristics of resistance to different treatments can also vary. Therefore, when deciding upon the suitability of a risk reduction strategy, it is key to first identify the type of hazards that can be present and need to be controlled.

To reduce the number of microbiological pathogens, various interventions and techniques are possible. They include:

- a heat treatment;
- chemical treatments with oxidizing agents (e.g. chlorine, ozone, peracetic acid and $H_2O_{2)}$, or volatile fatty acids (such as g. lactic acid, acetic acid or formic acid);
- drying;
- fermentation;
- combinations (so-called hurdles) of above-mentioned points.

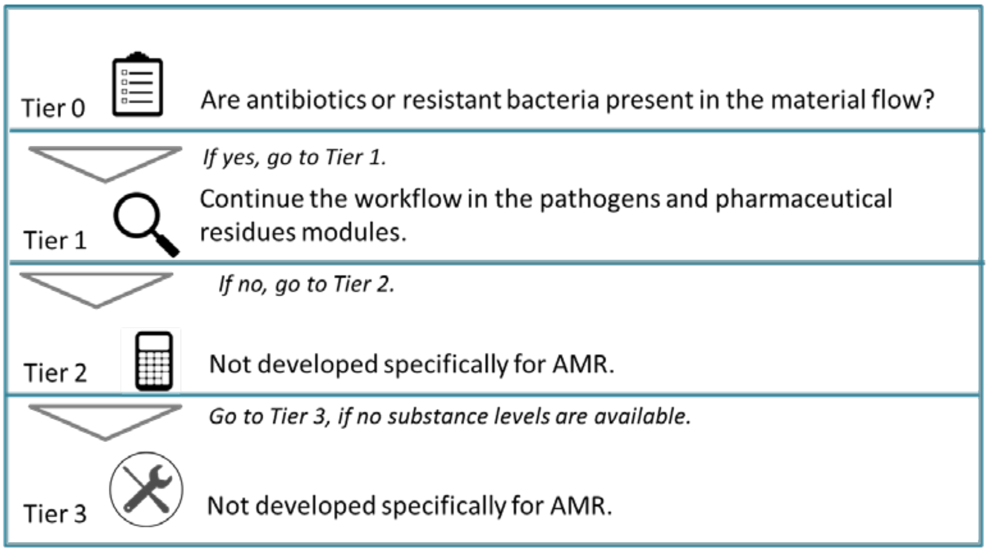
More detailed information can be found in textbooks on food processing, such as the Handbook of Food Preservation (2nd MS Rahman (ed) CRC Press, Boca Rotan, London, New York).

8.6 Recommendations

As pathogens can be present in low concentrations and non-homogeneously distributed in very large product flows, a preventive approach to guarantee the safety of products is preferred. In the food industry, this involves a combination of good hygiene practices and HACCP in every part of the chain. The combination of good hygiene practices and HACCP is also an appropriate method to control hazards in processes that transform waste streams into useful products.
The implementation of HACCP and understanding and controlling microbiological risks requires specific knowledge. When such knowledge is not present, help and advice should be sought.

9 Antimicrobial resistance

An added concern in relation to pathogens is microbial resistance to antibiotics. Worldwide there is an increasing resistance of bacteria to these types of pharmaceuticals, which means that for certain infections treatment becomes more difficult. This issue can play an important role in material flows where antibiotics and resistant bacteria are present. This means the potential health impacts are largely related to waste streams such as waste water, manure and other livestock waste flows (Schmitt et al., 2017). Although Antimicrobial resistance is a separate aspect of human safety that is part of the SSL framework, the methods to assess its impact on human safety are largely similar to the methods used for Pathogens and Pharmaceutical residues. Therefore, for Tiers 1 to 3, this module follows their approach (Figurel 9-1).



Figurel 9-1, Schematic overview of tiered workflow in antimicrobial resistance module.

9.1 About the antimicrobial resistance module

This module describes a method aimed at assessing risks of using secondary material flows regarding antimicrobial resistance (AMR). AMR is caused by resistant bacteria, bacterial DNA coding for antibiotic resistance, and antibiotic residues. Therefore, this chapter briefly discusses information regarding AMR and refers to Chapter 4 for further assessment on antibiotic residues and Chapter 6 for further assessment on (resistant) pathogens. AMR is defined here as bacterial resistance to antibiotics. Other forms of resistance exist, such as fungal resistance to fungicides.

AMR mainly originates from humans and animals, in particular from faeces. From there, transmission of AMR to humans could occur, for example, through the emission of (treated) wastewater or the application of manure. High levels of resistance are found globally in bacteria that cause health care associated infections (WHO, 2014). Thus, some infections can’t be treated with the antibiotics of first choice and treatment can incur higher costs. In the Netherlands, the number of resistant bacteria in humans has been more or less constant over recent years (de Greeff and Mouton, 2017).

In order to tackle AMR, it is important for the use of antibiotics to be kept as low as possible. In the Netherlands, the use of antibiotics in livestock has decreased with over 60% since 2009 (de Greeff and Mouton, 2017). The Netherlands has a very strict policy regarding the use of antibiotics in health care compared to other countries.

With respect to the circular economy, it has been found that large amounts of residues and resistant pathogens are being emitted in the Netherlands through waste water (Schmitt *et al.*, 2017). Currently, RIVM is investigating, in close collaboration with national and international partners, the extent to which this is leading to public health risks and/or disease burden. Resistant bacteria and antibiotic use are also present in animal manure, as frequently documented and as investigated in the Netherlands in national and international research projects.

9.1.1 Bacteria

Bacteria originating from humans and livestock are being emitted to the environment via faeces. In 2017, the World Health Organization (WHO) published a list of most critical, high and medium priority resistant pathogens (WHO, 2017):

- Critical:
  - *Acinetobacter baumannii* (carbapenem-resistant);
  - *Pseudomonas aeruginosa* (carbapenem-resistant);
  - *Enterobacteriaceae* (carbapenem-resistant, ESBL-producing).
- High:
  - *Enterococcus faecium* (vancomycin-resistant);
  - *Staphylococcus aureus* (methicillin-resistant, vancomycin-resistant);
  - *Helicobacter pylori* (clarithromycin-resistant);
  - *Campylobacter* spp. (fluoroquinolone-resistant);
  - *Salmonellae* (fluoroquinolone-resistant);
  - *Neisseria gonorrhoeae* (cephalosporin-resistant; fluoroquinolone-resistant)
- Medium:
  - *Streptococcus pneumoniae* (penicillin-non-susceptible);
  - *Haemophilus influenzae* (ampicillin-resistant);
  - *Shigella* spp. (fluoroquinolone-resistant)

In the Netherlands, several of these pathogens have been classified as ‘Bijzonder Resistent Micro-organisme’, which are a serious threat for hospitals and care homes (RIVM, 2017). Of these bacteria, several have been documented to occur in waste water or manure, including Enterobacteriaceae, *Enterococcus faecium*, Campylobacter and Salmonella.

Furthermore, non-resistant bacteria may play a role in the distribution and development of AMR through gene transfer. That is, genetic information is transferred between pathogenic microorganisms, but also between pathogenic and non-pathogenic bacteria, which thus form a reservoir of resistance.

As resistant bacteria have a mostly similar behaviour to pathogens, the reader is referred to Chapter 6 for more background information regarding risks due to pathogens.

9.1.2 Antibiotic residues

Antibiotic residues originate from unused and/or non-degraded antibiotics excreted with animal or human faeces or urine. When these residues interact with bacteria, resistance may develop – however, it is still unclear which concentrations of antibiotic residues are needed to trigger this effect. Assessment of antibiotic residues is part of the pharmaceutical residues module, so the reader is referred to Chapter 4 for more background information on the risks due to the presence of pharmaceutical residues.

9.2 Assessment work flow

As mentioned above, resistant bacteria are a subgroup of all bacteria and antibiotics are a subgroup of pharmaceuticals. Materials that may contain resistant bacteria (i.e. animal manure or human faecal matter / waste water) are likely to contain bacterial pathogens and pharmaceuticals as well. Currently, there are no guidelines related to AMR that specify safe levels of resistant bacteria or resistant pathogens. Also, there are no guidelines for the residues of antimicrobial substances that address the risk that antimicrobial substances might trigger the development of resistant bacteria or select for existing resistant bacteria (Larsson *et al.*, 2018). These selective effects are currently starting to be scientifically investigated. However, it is known that processing steps that are able to reduce concentrations of pathogens and pharmaceuticals will also reduce the levels of AMR. While awaiting more scientific support for the formulation of guidelines for resistant pathogens / bacteria and/or antibiotic residues within the approach of 'safe and sustainable loops', the risks of AMR are currently being addressed through the modules of pathogens and pharmaceuticals. This is based on the assumption that a product that is safe with respect to presence of pathogens and pharmaceuticals also does not pose the risks connected with the presence of resistant bacteria. This might change because this assumption should be tested once specific guidance on resistant bacteria or antibiotics becomes available.

9.2.1 *Relevance of module*

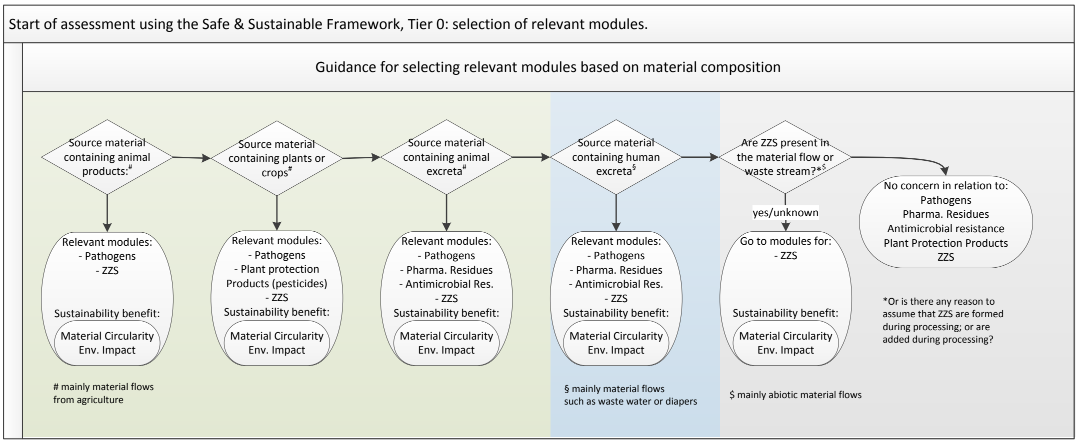


Figure 9-2. Triggering of the antimicrobial resistance (AMR) module.

A simple workflow is presented here which shows the link with more detailed assessment at higher tiers in the modules for pathogens and pharmaceutical residues.
If the module for pathogens does not indicate risks due to the presence of pathogens, it is initially assumed that the risks for transmission of resistant pathogens are also acceptable. Similarly, if the module for pharmaceuticals does not indicate a risk, it is initially assumed that the concentrations of antibiotics are not sufficiently high to select for antibiotic resistance.
If the module for pharmaceuticals does indicate a risk and antibiotics are among the pharmaceuticals potentially present in the product, then selection for antibiotic resistance cannot be ruled out. However, no clear target concentrations have been established for which selection of resistance is assumed to be negligible. For orientation, concentrations as described under 7.4 (Criteria) might be used.

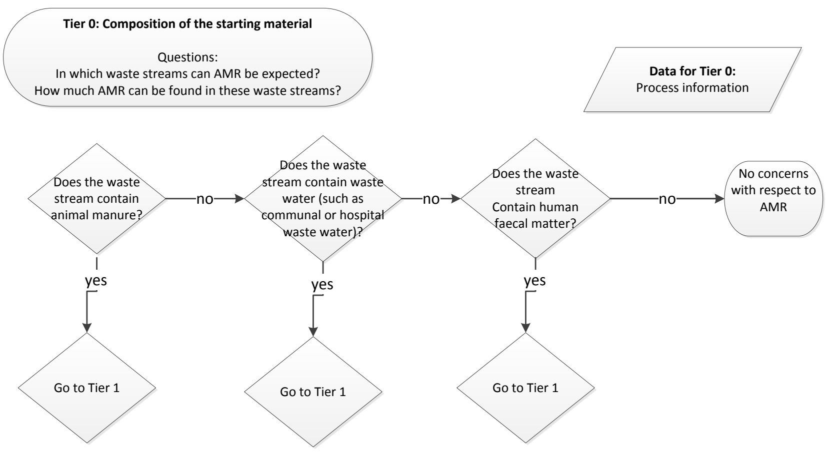


Figure 9-3. Schematic overview of link with other modules.

According to this workflow, the module for pathogens and pharmaceutical residues is invoked if either animal manure or animal/human waste water or faecal matter is a constituent of the product. See Tiers 1 to 3 within the pathogen / pharmaceutical residues module.

9.3 Data sources

Upon conducting the other modules with interest in AMR, the following data sources can be of value. The prevalence of resistant bacteria in the Netherlands is published each year in part 1 of the NethMap/MARAN report (de Greeff and Mouton, 2017). The use of antibiotics is published yearly in part 1 of the NethMap/MARAN report (Veldman *et al.*, 2016). Recently, Schmitt et al. (Schmitt *et al.*) published an environmental surveillance study on AMR (pathogenic bacteria, resistance genes and residues) in Dutch waste water.

9.4 Criteria

Due to the lack of specific criteria for resistant bacteria, criteria for pathogens are taken as a surrogate (Chapter 8 (pathogens)). With respect to antibiotic residues and their possible effects on the development and selection of resistant bacteria, there are no legal quality standards either. However, recently, PNEC levels have been derived for the selection of resistant bacteria by antibiotic residues by Bengtsson-Palme et al.(2016) based on the sensitivity of non-resistant (‘wild type’) bacteria to antibiotics, which could have been used as an initial approximation of concentrations that are expected not to trigger the selection of resistance (see also Chapter 6 on pharmaceutical residues).

9.5 Possibilities for intervention

For resistant bacteria, interventions such as those mentioned for pathogens (including heat treatment, specific chemical treatments, drying, and fermentation and combinations thereof) are generally also effective for reducing the levels of resistant bacteria. Other techniques effective for reducing levels of resistant bacteria include techniques applied during manure treatment, such as composting and (anaerobic) digestion. These are partially also effective for reducing antibiotics, although to variable extents (Youngquist *et al.*, 2016; van Leuken *et al.*, 2017).

For further information, also see Chapter 6 (residues) and Chapter 8 (pathogens).

9.6 Recommendations

Most prominently, risks connected with the presence of antibacterial resistance can only be assessed once specific guidance on safe levels becomes available. This, in turn, is hindered by the lack of precise data on the health impacts of resistant bacteria and on the relationship between exposure levels and health effects (dose-response curves)(Schmitt *et al.*, 2017). As for antibiotics, their role in the development of resistance at very low concentrations (such as expected in products after interventions) is also not yet completely known and is at the centre of recent research.

Part 3: Case studies and analysis SSL framework

10 Cases studies

10.1 Struvite from waste water

10.1.1 Background

Domestic waste water contains phosphate, which is considered as a critical resource (CRM). In the Netherlands, this waste water is treated in Waste Water Treatment Plants (WWTP) and effluent is discharged mainly on surface waters. The resulting waste stream sludge is incinerated. In the treatment plant, phosphate is mainly removed to comply with WFD requirements for maximum nutrient concentrations in surface water. The traditional technique for removing phosphate does not allow reuse.

Currently, attempts are being made to recover and reuse phosphate in pilot cases. Different recovery techniques are being investigated here. Besides recovering phosphate from the ashes of incinerated sludge, techniques are being developed to recover phosphate from the wet sludge stream. Recently in the Netherlands, different techniques for forming struvite, a phosphate crystal, have been applied in some pilot WWTPs. The product of these techniques can be used to produce artificial fertilizer for agricultural use or as a secondary raw material in artificial fertilizers. Different techniques of recovering phosphate by the formation of struvite crystals are being studied in these pilot cases. For example, the Airprex system uses a reactor in which the crystallization of a mineral phosphorus product occurs directly in the sludge, while the Pearl system is applied to the process water after sludge dewatering by mechanical solid-liquid separation similar to centrifugation. The purity, e.g. expressed as total organic content, differs substantially between these techniques.

Besides the recovery of a critical material, the traditional treatment process has also been improved. This is because dewatering is less energy-demanding with the addition of the struvite recovery techniques. There are also lower maintenance costs for WWTPs with struvite recovery. Van der Grinten and Spijker (2018) describe the details of this case in relation to the request for the End-of-Waste status by the waterboard Waternet, for their struvite produced using the Airprex method.

In this section, the process for the recovery of struvite by Waternet (using the Airprex technique) will be assessed as a test case for the different topics currently addressed in the Safe and Sustainable Loops framework. The purpose of the framework is to assess potential environmental benefits and address the human and environmental safety issues of a product or recovered resource as an integral part of the development of a novel material application and business model. In this exercise with the SSL framework, the modules of circularity, environmental impact (Energy and land use), ZZS, pharmaceutical residues, pathogens and antimicrobial resistance were used (based on Tier 0).

10.1.2 *Modules*

Circularity

For the circularity and energy-demand assessment, we use the following scope: recovery of struvite from domestic waste water (in general) intended for application in artificial fertilizer. Here we focus only on the recovery of phosphate, as present in struvite, although struvite can also be a source of nitrogen and magnesium for fertilizer products. The source of phosphate is the decentralized recovery from domestic waste water due to its treatment in a WWTP. Where applicable, the comparison is made between struvite and the use of phosphorus from mining. Because of the focus on phosphate as a resource, a brief comparison is also made to a more centralized phosphate recovery from fly ash produced during sludge incineration, where relevant.

Circularity - Tier 0

Tier 0:
Will the intended application of the residual material or waste stream be higher, equal or lower on the LAP-3 waste hierarchy compared to the current application?

Higher. Using the waste hierarchy, the recovery of struvite results in a higher classification compared with the traditional way of waste water treatment, resulting in sludge and effluent with no particular use for the phosphate fraction in the Netherlands. Although in several other countries the sludge fraction is applied to soil as fertilizer, this is not the case in the Netherlands. Furthermore, it should be mentioned that struvite production from waste water also prevents the clogging of pipes as a side-effect, saving maintenance work.
This clearly shows that an increase in circularity is likely, so we continue on to Tier 1.

Circularity - Tier 1

Tier 1:
1. Does the material under consideration contain any of the EU critical raw materials?
2. Supply check: Is there a concern for material supply due to a significant increase in demand for the source material?

1. Phosphate is one of the EU critical raw materials (CRM) that was added to the 2014 list based on the review of 78 raw materials in 2017 (European Commission, 2017). The inclusion of phosphate in the list is due to (I) the reliance on imports of phosphate in the EU, (II) the difficulty of using another material as a substitute and (III) the negligible recovery from waste compared with the EU demand for phosphorus.
2. Supply check: there is no current market application for domestic waste water, so its use for the recovery of struvite would likely not depend on the availability of this material flow. In principle, decentralized recovery at a WWTP means that the recovery facility can be scaled in such a way that there would be no change in the availability or demand for domestic waste water as a resource on the WWTP scale. However, it is known that recovery of other resources contained in domestic waste water, such as alginate or cellulose fibres, are being investigated. So in

the future, this potential for competition for the same source material might need to be taken into account. When struvite is recovered at a WWTP, this will decrease the amount of phosphate that can be recovered from the sludge using the more centralized method based on fly ash from incineration. It can be concluded that no supply problems are currently foreseen on the scale of a WWTP, but on the national scale some extra attention might be needed for a case where phosphate is recovered from fly ash.

Overall, the Tier 1 analysis indicates a significant contribution to the circular economy because phosphate is a CRM. Although a user of the circularity module could stop here, a more refined analysis of material circularity is given below to illustrate the use of the method in Tier 2.

Circularity - Tier 2

Tier 2:
1. Recovery efficiency: The resource fraction recovered from the total material flow, corrected for auxiliary material use.
2. Contribution: Contribution of the recovered resource fraction towards total resource use in an application or material cycle.
3. Recyclability: The resource fraction available for recovery or reuse after the use phase of the intended application.

For struvite from domestic waste water influent, this depends on the method of struvite extraction used, in this case for the extraction at the WWTP with or without the WASSTRIP method applied. The variability of these methods for struvite recovery at the WWTP were found to vary between 23% and 47% of total P in the influent (STOWA, 2016). Alternatively, the extraction of P from the fly ash produced during sludge incineration is estimated to be about 82% of total P in the influent (STOWA, 2016).
For struvite recovery, magnesium chloride and sodium hydroxide are used as auxiliary materials, see Table 10-1 On the contrary, in a WWTP with struvite recovery, the use of Iron (III) Sulphate and polyelectrolyte for dewatering of sludge is reduced.

Table 10-1 Inventory of material flows for two methods of struvite production at a WTTP, source: Tables 4.10, 4.11 and 4.12 (STOWA, 2016). Annual material flows based on 100,000 inhabitant equivalents

	Rejection water method	**Rejection water and WASSTRIP method**
Auxiliary material $MgCl_2$	31 ton $MgCl_2$ or 8 ton Mg	55 tons $MgCl_2$ or 14 tons Mg
Auxiliary material NaOH	0 – 3 tons NaOH	0 - 10 tons NaOH
Produced struvite	84 tons	205 tons
Recovered P	24 tons P_2O_5 or 12 tons P	59 tons P_2O_5 or 26 tons P
Recovered N	5 tons N	12 tons N
Recovered Mg	8 tons Mg	20 tons Mg
Avoided Iron(III)sulphate	-94 tons $Fe_2(SO_4)_3$ or -31 tons Fe	-84 tons $Fe_2(SO_4)_3$ or -31 tons Fe
Avoided polyelectrolyte	-3.8 tons Polyacrylamide	-6.8 tons polyacrylamide

The recovery efficiency indicator is calculated by correcting the reported recovery efficiency for the amount of auxiliary materials used. We calculate a conservative (23%) and best-case recovery efficiency (47%).

Best case: $$Eff = 0.47 * \frac{59\ tons\ P_2O_5}{0\ ton\ NaOH + 55\ tons\ MgCl + 59\ ton\ P_2O_5} = 0.24$$

Conservative: $$Eff = 0.23 * \frac{24\ tons\ P_2O_5}{3\ tons\ NaOH + 31\ tons\ MgCl + 24\ tons\ P_2O_5} = 0.092$$

This shows that correcting for auxiliary material use can considerably reduce the overall indicator for recovery efficiency. The current calculation assumes the same quality or worth in terms of circularity for the auxiliary materials compared to the recovered resource, (Qax = 1, for equation see Chapter 0). This is not the case – e.g. MgCl is not a CRM, phosphate is. Additionally, given the scope of a full WWTP, as used below for the energy-demand calculation, auxiliary materials are also avoided due to the recovery of struvite (Table 10-2). Currently, such avoided materials are not included in the indicator for recovery efficiency. The simplest solution could be to use the recovery efficiency indicator without taking into account any auxiliary materials, e.g. 0.47.

Contribution

Only a fraction of the final fertilizer product on the market consists of phosphate sourced from struvite. Currently this is estimated to be 1% P_2O_5 from struvite, substituting phosphate from a virgin source. This gives a contribution indicator (Cont) of 0.01. But if the contribution of phosphate from struvite is to be extrapolated to the global phosphate demand, the contribution to artificial fertilizer on the global scale was estimated to be 2-5% as early as 2010, with a potential to grow up to 11 % by 2100 if all available waste water was to be used for phosphate recovery (Lwin *et al.*, 2017).

Recyclability

Assessing the recyclability of phosphate flows is not a straightforward assessment. In theory, the same nutrient cycle applies to nutrients from

secondary sources. This means there is no direct change in recyclability compared to any other fertilizer type. However, the quantification using the recyclability indicator, as proposed in Chapter 0, can be calculated, at least on a national scale for the Netherlands. To do this, we need to know the fraction of phosphate returned to the WWTP for potential recovery. In the case of phosphate, we simply use the total amount of phosphate in influent of the WWTP in the Netherlands in relation to the total amount of phosphate applied in agriculture. This is a simplification, because it would be more precise to distinguish P applied in agriculture from artificial fertilizer from P from other sources, such as manure. However, this distinction is hard to make for the influent on the national scale. Another issue is the fact that P in influent is partly also due to the import of P from outside the Netherlands. In a study conducted by Smit et al. (2015), a detailed material flow analysis was done for P in the Netherlands. They show that there was a total import of 110.5 ± 4 M kg P in 2011. They also calculated that 13.1 ± 0.8 M kg of P goes to the communal WWTPs and an additional 5 ± 0.2 to Industrial WWTPs. CBS data show a total of 13.9 and 13.4 M kg of P in WWTP influent for 2011 and 2015, respectively (CBS, 2018). Although the data is several years old, we chose to use the data reported by Smit et al. (2015) to calculate the recyclability of P.
A qualitative correction is applied to this indicator of recyclability based on the quality of the resource recovered. In this case, the phosphate in the form of struvite is assumed to have a similar quality as phosphate from virgin sources, giving a quality factor of 1. However, if any unacceptable level of contamination is expected, specifically in comparison with virgin sources of phosphor for the production of manufactured fertilizer, this quality factor should be adjusted accordingly.
This leads to the following calculation of recyclability:

$$Rec = \frac{13.1 + 5 \;\; Mkg\ P\ in\ influent}{110.5 \;\; Mkg\ P\ imported} * 1 = 0.16$$

Overview circularity

Indicator	**Score**
Recovery efficiency	0.09-0.47
Contribution	0.01-0.1
Recyclability	0.16

The three indicators for the circularity of struvite as a phosphate mineral for manufactured fertilizer are 0.09-0.47 for recovery efficiency (dependent on taking auxiliary materials into account), 0.01-0.1 for market contribution and 0.16 for recyclability.
It should be noted that these indicators for circularity are novel and its application to the phosphate mineral cycle posed some challenges. The phosphate cycle is not contained in the Netherlands now that the indicators are a mix of national losses of phosphate and method-specific recovery efficiencies and there is a national, or even global, demand for manufactured fertilizer. These could be very different if a local system was observed. For example, when considering the difference in potential recyclability in a greenhouse system compared with the total for different agricultural systems in the Netherlands.
However, given these limitations, the outcome indicates a qualitative and quantifiable contribution to increasing circularity, e.g. phosphate is a CRM and the recovery efficiency or market contribution would default

to 0 if no phosphate is recovered. The recyclability is specific for the potential for recovery through a WWTP.

Environmental Impact – Energy and Land use

Cumulative energy demand (CED) and land use are applied as indicators for environmental impact. The outcome of this assessment will show how much of a reduction of environmental impact, e.g. less energy demand or CO_2 emission, is obtained when producing struvite compared with a baseline scenario. In practice, applying this module mainly consists of the Tier 2 method and Tier 0 for indicating whether land use needs to be quantified as well, see Chapter 4.

Definition of scope and baseline scenario:

1. What material flows and resulting products are assessed?
2. What is the reference product that is replaced by the new application of the non-virgin material?
3. What are the system boundaries?

In this case study, phosphate in struvite is recovered from domestic waste water, with and without the WASSTRIP process. The struvite is then used for the production of artificial fertilizer. There are materials required for the precipitation of struvite (MgCl) and for adjusting the pH (NaOH) and for the reactor vessel (RVS).
The reference product is phosphate from primary sources, in this case diammonium phosphate from mining.
The SSL and baseline scenario take into account a waste water treatment plant servicing 100,000 inhabitant equivalents annually. The material flows that are different in the WWTP are considered from the influent up to the struvite grain. These are the cradle-to-gate life stages, the gate-to-grave stage is assumed to be the same for the two scenarios. This means that the avoided use of some materials and a reduction in the energy required in the case of including a struvite recovery step in a WWTP are included in the baseline scenario (see Figure 10-1). These are the use of iron sulphate for phosphate removal, extra polyelectrolyte for dewatering and less energy consumed for the aeration and dewatering process steps. Where the SSL scenario considers the energy demand to produce struvite, the baseline scenario considers the energy demand to produce ammonium phosphate from phosphorus rock. The functional unit is the cumulative energy demand per kg of P.

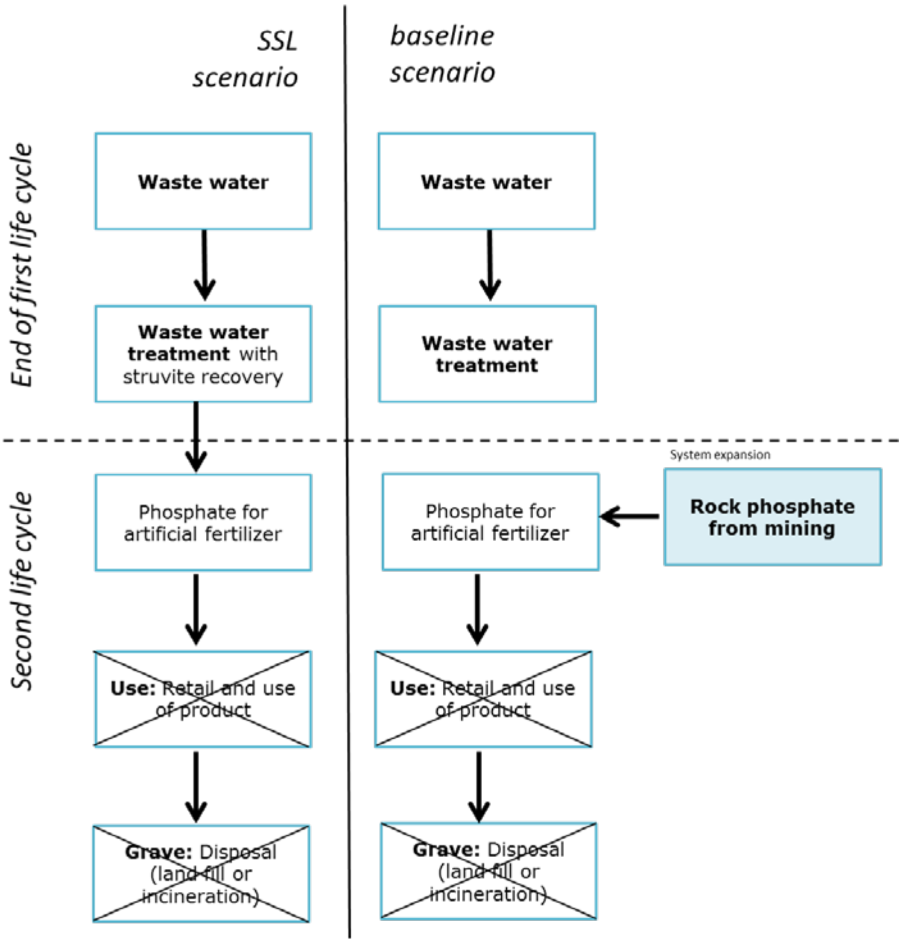


Figure 10-1. Schematic overview of the SSL and baseline scenario for the production of artificial fertilizer.

Tier 2:

1. Determine scope: is the functionality of the new product different from the product it replaces? Is there a difference in function, quality or durability?
2. Make a list of materials and energy required for each scenario.
3. Search for generic CED or CO_2 emission values and land use estimations for the materials and energy used.
4. Sum the CEDs, CO_2 eq. and land use per functional unit and compare different scenarios.

1. It is assumed that there is no difference in the functionality of phosphate from struvite compared to phosphate from rock phosphate mining. Therefore a cradle-to-gate perspective is used as the scope. This means that the use and end-of-life stages are not taken into account.
2. In the SSL scenario, the production of material struvite is considered with the use of auxiliary materials: magnesium chloride (MgCl), sodium hydroxide (NaOH) and stainless steel (RVS). Furthermore, the added energy use for running the struvite reactor and sludge processing are included. In the baseline scenario with wastewater treatment without struvite recovery, additional iron sulphate is used for precipitation of

phosphate and extra polyelectrolyte is required for dewatering. Furthermore, added energy is required for dewatering and aeration processes.

3. The cumulative energy demand (CED) for struvite needs to be derived based on the relevant materials and processes. These are largely based on the cumulative energy budgets reported in a study conducted by STOWA (STOWA, 2016) for each of the steps in the production of struvite. The CED of transport to the artificial fertilizer production plant is assumed to be equal to that of the baseline scenario and is not explicitly taken into account here. The reported CED for diammonium phosphate is 23.1 MJ/kg (RVO, 2018), which equals 98.5 MJ/kg of P. The various CED values are given in Table 10-2.
4. The CEDs presented in Table 10-2 are added up. All CED values were already converted to represent the production of 1 kg of phosphorus (P).

Table 10-2, Energy demand of different materials and process steps of a WWTP with struvite reactor or struvite reactor with added recovery step from sludge (WASSTRIP).

MJ/kg P	**Struvite reactor**	**Baseline scenario**	**Struvite reactor + WASSTRIP**	**Baseline WASSTRIP**
Struvite reactor (RVS)	0.3		0.3	
Magnesium	36.5		25.2	
Sodium hydroxide	4.3		6.0	
Iron Sulphate		42.5		17.4
Polyelectrolyte		22.8		18.4
Diammonium phosphate		98.5		98.5
Subtotal-materials	**41.1**	**163.8**	**31.5**	**134.3**
Sludge processing	3.6		2.9	
Struvite production	17.7		20.5	
Aeration and dewatering		15.4		8.5
Subtotal – process energy	21.3	15.4	23.4	8.5
Total	**62.4**	**179.2**	**54.9**	**142.5**

This assessment is based on readily available data from RVO and STOWA. A rough estimate of struvite transport energy demand was made. All of the used data can be improved by using location-specific data for the origin of rock phosphate, the origin of struvite and the location of the WWTP and artificial fertilizer production plant. This would be part of a further assessment in Tier 3.

The outcome of the assessment is that the application of phosphate from mining requires more energy than that recovered from a WWTP. Even if the avoided material use in the WWTP are not taken into account, the energy demand is still about half that of P coming from a virgin source. Note that an important assumption made here is that an atom of P in di-ammonium phosphate is equal to an atom of P in struvite. In fact, this is not necessarily true from the perspective of an artificial fertilizer, which means that the overall environmental impact could be a bit lower or higher. Furthermore, the investigation of the optimal use of P present in waste water is much more complicated, with many more recovery options, e.g. from sludge after incineration, etc.

Several LCA studies have compared several scenarios. Their scope and quality varies, making a direct comparison difficult and outside the scope of this assessment (Sena and Hicks, 2018). The results from the study conducted by STOWA clearly indicate a reduction of environmental impact due to phosphate recovery, including the prevented use of virgin phosphate from mining (STOWA, 2016). A more detailed analysis can be conducted as part of Tier 3.

ZZS

Tier 0:
Are there ZZS present in the material flow?

The ZZS module is considered relevant because ZZS can be present in the waste stream (domestic waste water) from which struvite is recovered. Assessment of some ZZS in struvite was performed in an earlier study (STOWA, 2016) to comply with the regulatory framework for fertilizers (Meststoffenwet, 2016). The results from that study showed no concern related to ZZS for struvite use as fertilizer. Therefore, the ZZS module was not further applied.

Pharmaceutical residues
Tier 0, relevance of the module

Tier 0:
Does the material contain human excreta or wash water?

The waste stream used for struvite recovery in this case is likely to contain human pharmaceutical residues, considering the source is sewage water (combination of toilet water, bathroom and kitchen water, rainwater, sometimes hospital waste water, etc.). For this reason, the pharmaceutical residue module is selected.
Theoretically, veterinary pharmaceuticals could end up in domestic sewage water as well, e.g. by wash-off of dog faeces in streets (combined sewage systems) or by cat litter discharged through toilets. The load of pharmaceuticals of veterinary origin is considered to have marginal importance in this waste stream, compared with human pharmaceuticals. Therefore, only human pharmaceuticals are considered in Tier 1.

Tier 1 Screening

In Tier 1, it should be determined what human pharmaceuticals can be expected. This is followed by measurements of the concentrations in the input or output material flow and an assessment with trigger values (when available).

Tier 1:

a. Identification of relevant VPs and HPs for further analysis and collecting information on their presence in a specific (waste) material flow.
b. Retrieve data on concentrations of relevant VPs and HPs in the applied input and / or output material flows.
c. Comparing concentrations with trigger values and concluding on no concern (concentrations < trigger values) or further risk assessment (Tier 2).

a. The most relevant pharmaceutical residues for the waste stream from which struvite is recovered need to be identified. Currently, there is no standardized list available of indicator pharmaceuticals present in the waste stream of domestic waste water or, specifically, the sub stream from which struvite is recovered (sludge fraction). According to the SSL systematic approach, when no standardized list of indicator compounds is available, a list should be made following the principles specified in Tier 2 of the Pharmaceutical residues module. See Tier 2 for identification of relevant pharmaceutical residues in the struvite case.
b. Data on concentrations of the specified indicator pharmaceutical residues in the waste stream or resulting product is required. In the struvite case, relevant pharmaceutical residues were selected using Tier 2 and data on concentrations of most of the relevant pharmaceutical residues in the waste water are available in the Watson database (www.emissieregistratie.nl). However, accumulation of some residues during the production process in the struvite crystal cannot be excluded and is likely to depend on additional washing steps during production (Ye *et al.*, 2017). There are some measurements of pharmaceutical residues in struvite itself available (summarized in van der Grinten and Spijker (2018)). However, these measurements are not yet made with the prescribed list of indicator compounds or the potentially accumulating compounds and, moreover, consist of one singular measurement per recovery technique. Therefore, in the struvite case, a next step is being taken currently (in Tier 2) to complement the original dataset with additional data, specifically on potentially accumulating compounds in the crystal and on a recovery technique, which includes a washing step.
c. Data on concentrations are compared with reference values. These reference values are needed to determine whether there is no concern for risks or whether a further risk assessment is needed. In the struvite case, it has been proposed, as a first trigger value, to use detection limits of the measured compounds (van der Grinten and Spijker, 2018). Some of the measurements in the first available dataset are above the detection limit. For these compounds, no other trigger value is yet available in Tier 1c. If these data are confirmed by the current measuring campaign (which should generate data by the end of 2018), further assessment in Tier 3 is needed for these compounds.

Tier 2, Indicator compounds

Tier 2 (Section 1):

a. Retrieving existing data on contributing streams.
b. Retrieving existing information on emission profiles.
c. Retrieving existing information on degradation during the recycling process or in the environment.
d. Generating information on HPR and VPRs in ingoing and outgoing streams and materials.
e. Selection of indicator compounds

a. For struvite, monitoring data on concentrations of HPRs in the WWTP influent (the relevant waste stream in the case of struvite) are available from the Watson database (van der Grinten and Spijker, 2018). Additionally, for the selection of indicator compounds, their physical chemical properties (e.g. water solubility, log Kow, affinity to sludge and soil, biotransformation and environmental toxicity) are taken into account because struvite is formed in the sludge fraction of domestic waste water. Therefore, compounds with the highest affinity for sludge are also prioritized in the struvite case. Top 10 lists of maximum concentration per compound, of average concentration per compound and of the number of occasions that a compound is detected were made and combined to generate a list of 19 potentially relevant compounds for the struvite case.
b. Emission profiles also determine the relevancy of pharmaceutical residues. Ideally, the level of pharmaceutical residues expected in the ingoing stream (emission) is estimated from data on the use and metabolism in the whole population. However, for practical reasons in the struvite case, the selection of data made in the diaper study (Spijker *et al.*, 2016; Lijzen *et al.*, 2019), which was based on use of pharmaceuticals in the population 0-4 years-old and >70 years-old, was taken as a starting point. In the struvite case, we assume that this selection is also applicable to the whole population.
c. The criteria degradation and ecotoxicity in the environment and analytical measurability were taken into account. From lab studies there are indications that specific compounds (e.g. tetracyclines) can end up in the struvite crystal (Ye *et al.*, 2017). Therefore, a representative of these compounds is prioritized for the indicator list in the struvite case.
d. From the data retrieved in the above steps (a, b and c), it has been concluded that insufficient information is available on the concentrations of pharmaceutical residues in input and output material flows for further assessment of concern. Tier 2d requires a degradation test in which the ingoing material is spiked with the selected relevant pharmaceutical residues in order to assess the fate of pharmaceutical residues under process conditions. However, an exemption is given for cases in which the spiking of ingoing material is impossible. In the struvite case, this exemption is used because, technically, it is not possible to spike a full scale WWTP, with a continuous flow system, in which struvite is recovered. Instead, the relevant pharmaceutical residues in the outgoing stream (the struvite itself) are being measured currently. The results are expected by the end of 2018.

e. In the selection of relevant pharmaceutical residues in the struvite case, antibiotics are a specific concern because of their presence in the ingoing stream. Antibiotics found in the highest concentrations in influent in a recent Dutch field study (Schmitt *et al.*, 2017) have also been prioritized in the struvite case (van der Grinten and Spijker, 2018) and are being measured currently.

The selection of relevant compounds in Tier 2 was finalized and the measurement data on these compounds in the struvite itself are being collected at the moment. These data will feed into the next section of Tier 2 for comparison with trigger values and quality criteria when the data become available. This should result in a conclusion on concern, or invoke derivation of quality standards or effect measurements as part of Tier 3.

Pesticides
Tier 0

Tier 0:
Does the material originate from agriculture, horticulture, herbal cultivation or forestry?

Contributions to the domestic waste stream originating from agriculture, horticulture, herbal cultivation or forestry are not likely or are liable to be very small. This module is considered not relevant to the struvite case.

Pathogens
Tier 0

Tier 0:
Does the material contain human excreta or wash water?

The starting material in the struvite case is potentially contaminated with human pathogenic microorganisms because the struvite is recovered from waste water.

Tier 1

Tier 1:
Does the process involve a full risk reducing step?

A potential risk-reducing step is present in the production of struvite (drying), but there is no clear sterilization step with high pressure or high temperature. Full risk reduction cannot be proven, so we continue on to Tier 2.

Tier 2

Tier 2:
Is an additional risk reduction step required and feasible?

To establish this, criteria are needed, but are not available for the application of struvite as fertilizer. From the few data available, a reduction of indicator pathogens (spore-forming microorganisms (SSRC)) in the production process of struvite has been observed. However, because of very few data and the lack of criteria, it is not clear whether this is sufficient. In the current measuring campaign, reduction of microbiological activity in an additional washing step will also be determined, but these data are not yet available. The pathogen module of SSL states that Tier 3 is needed when the level of risk reduction is unknown.

Tier 3

Tier 3:
Is a challenge test possible to check the overall risk reducing effect of the process?

A challenge test is not available for the struvite case.
In the struvite case, we argue that the matrix of application (soil) is probably not pathogen-free (there is a background concentration). Also, the processing of struvite into fertilizer contains more risk-reducing steps. Although we have no specific data, we conclude that there is probably no reason for concern. SSL, however, advises that a challenge test be conducted to confirm this. A challenge test for struvite production is not feasible because it involves an entire WWTP.

Antimicrobial resistance (AMR)
Tier 0

Tier 0:
Does the material contain animal manure or animal/human wastewater or fecal matter?

Yes, the starting material is potentially relevant for antimicrobial resistance because struvite is recovered from domestic waste water, containing faecal matter, so we go on to Tier 1.

Tier 1

Tier 1:
The module for pathogens and pharmaceutical residues is applied.

SSL refers to Tiers 1-3 of the modules Pharmaceutical residues and Pathogens. For the struvite case, there is not enough data to exclude AMR risks.
Therefore, antibiotics are prioritized in Tier 2e of the Pharmaceutical residues module as being relevant pharmaceutical residues in the struvite case. Antibiotics found in the highest concentrations in influent in a recent Dutch field study (Schmitt *et al.*, 2017) are currently being measured in the struvite.
We have found some indicative reference values for antibiotic compounds (Schmitt *et al.*, 2017), which could be used as trigger values when measurement data become available.

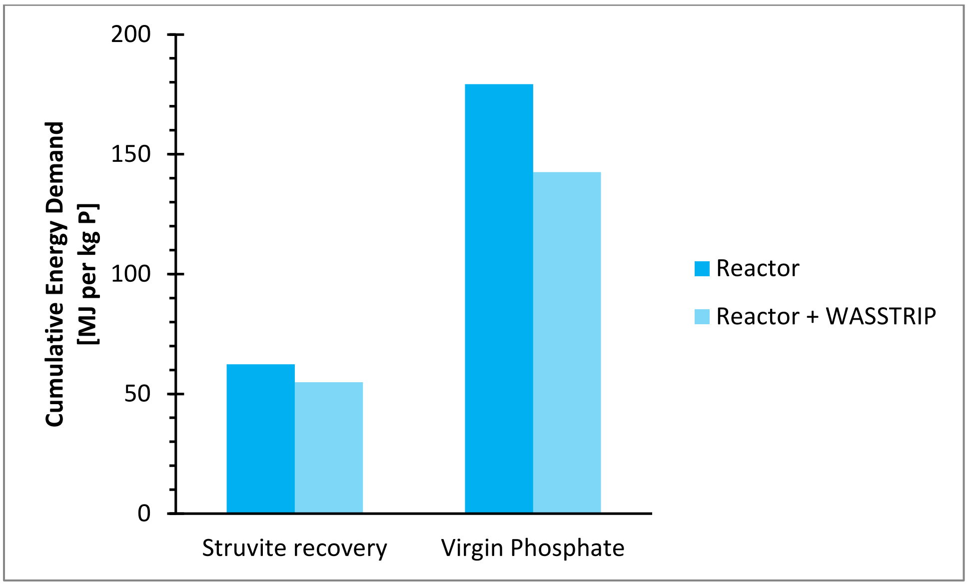


Figure 10-2. Cumulative Energy Demand (CED) derived for production of 1 kg of P from struvite or from virgin phosphate rock, as calculated using the Environmental Impact module.

10.1.3 *Integrated results*

The material safety and sustainability sheet is given in Figure 10-3. For the struvite case, the circularity module indicates an increase of circularity compared with the use of phosphate from mining for the production of fertilizer. Sustainability in terms of energy demand shows a decrease in impact or even an absolute reduction in total impact of a WWTP. This absolute reduction is caused by the reduction in energy demand in other technical steps in the water treatment (e.g. dewatering).

In terms of risks, there is uncertainty. More data is needed to decrease uncertainty, particularly for pharmaceuticals. New data could confirm a negligible risk, or indicate any degree of risk for pharmaceuticals, although high risks are not likely.

Even if the outcome for risks is elevated and risk-reducing measures are needed, the positive scores for circularity and sustainability show that there is room (in terms of, say, energy, see Figure 10-2) for added measures to diminish the risks indicated by the contaminant modules, e.g. by adding extra risk-lowering production steps in the recovery process and still close the loop with benefits to the environment.

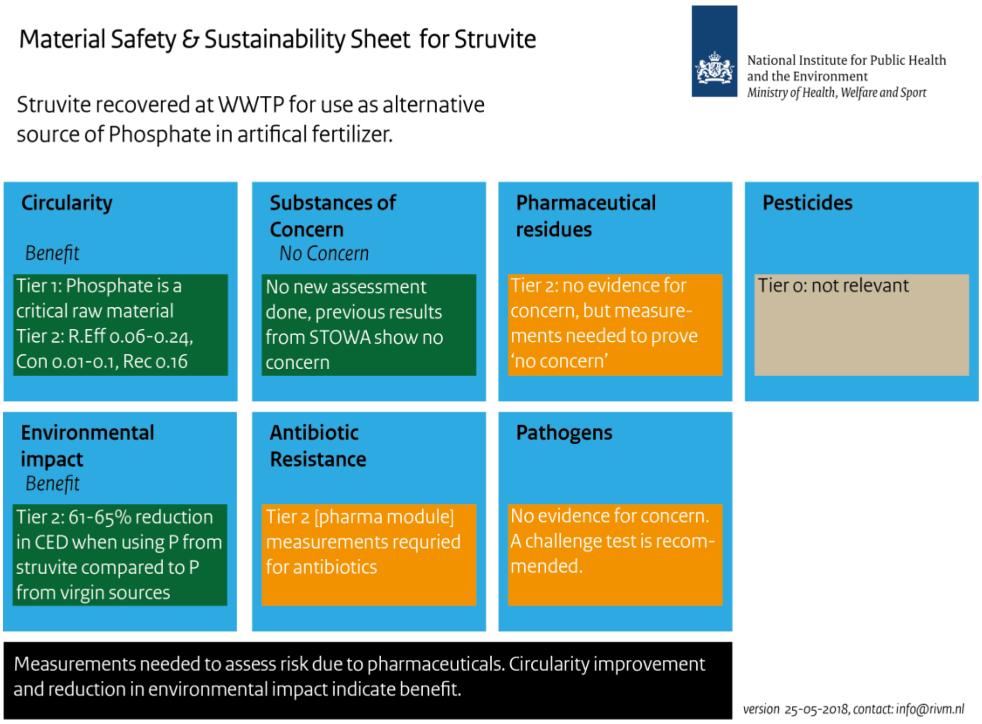


Figure 10-3, Material Safety and Sustainability sheet for struvite from waste water based on assessment with the SSL framework.

10.2 Extruded Polystyrene with HBCDD (see erratum)

10.2.1 *Background*

Extruded PolyStyrene (EPS) foam boards have been widely used for building insulation in Europe since the 1960s. As the service life of these boards ranges from 30 to 100 years, the construction industry expects a significant increase of EPS foam waste from demolition. These large quantities represented quite a challenge for the recycling industry.
Another issue is the presence of the flame retardant Hexabromocyclododecane (HBCDD) in many existing EPS foam boards, since EPS is highly flammable. Because of its persistence in the environment, HBCDD has been listed as a substance of very high concern (SVHC) under the EU REACH Regulation, and as a persistent organic pollutant (POP) under the UNEP Stockholm Convention. Today, all EPS producers in Europe have replaced HBCDD with other, new polymeric flame retardants. However, because of the long-life of EPS insulation foam, the waste management of EPS waste containing HBCDD will remain a challenge for the coming 50 - 100 years.
Up to now, considerable amounts of EPS at end of life are being land-filled or incinerated with energy recovery (CONSULTIC, 2011). Only recently, a promising method for recycling EPS that contains HBCDD was developed that is based on a special dissolution technique (solvolysis) (M.P.M. Janssen, 2016). This technique is applied in a new process for the recycling of EPS insulation foam waste called the 'polystyrene loop process' (PS loop) and will be applied on an industrial scale in a pilot plant in Terneuzen, NL (Tange *et al.*, 2016).
Here, recycling of EPS using the PS loop process, including the solvolysis technique, will be assessed using the SSL framework.

10.2.2 *Environmental impacts and benefits*

The outcome of this assessment will show how much of a reduction of environmental impact, e.g. reduction in energy demand or CO_2 footprint, is reached when recycling EPS, compared with incineration with energy recovery. In practice, applying this module mainly consist of the Tier 2 method and Tier 0 for indicating whether land use needs to be quantified as well, see Chapter 4.

Definition of scope and baseline scenario:

1. What material flows and resulting products are assessed?
2. What is the reference product that is replaced by the new application of the non-virgin material?
3. What are the system boundaries?

In this case study, EPS that contains HBCDD is chemically recycled using the PS loop process with recovery of polystyrene for production of new EPS and the recovery of bromine (Tange *et al.*, 2016; TUVRheinland and BASF, 2018).
The reference product is EPS that contains another polymeric flame retardant based on virgin material sources.
The system boundaries of the SSL and baseline scenarios are largely based on the LCA study performed by TUV Rheinland (2018). In brief, Europe is chosen as the geographic scale. Data on the PS loop process were collected in 2016 from the lab scale application of the CreaSolv process and pilot scale application of the bromine recovery process in Terneuzen. These data were then extrapolated to full scale. This has indicated some uncertainty in the data, due to a relatively low technology readiness level (TRL) varying between 3 and 4.

Tier 0

In Tier 0, the applicability of also including land use in the assessment, in addition to cumulative energy demand, is addressed.

Tier 0:
Should energy demand and/or land use be assessed?

Land use is relevant when a product or material in one of the considered scenarios comes from agriculture or forestry. This is not the case for the materials as a part of EPS recycling or production.

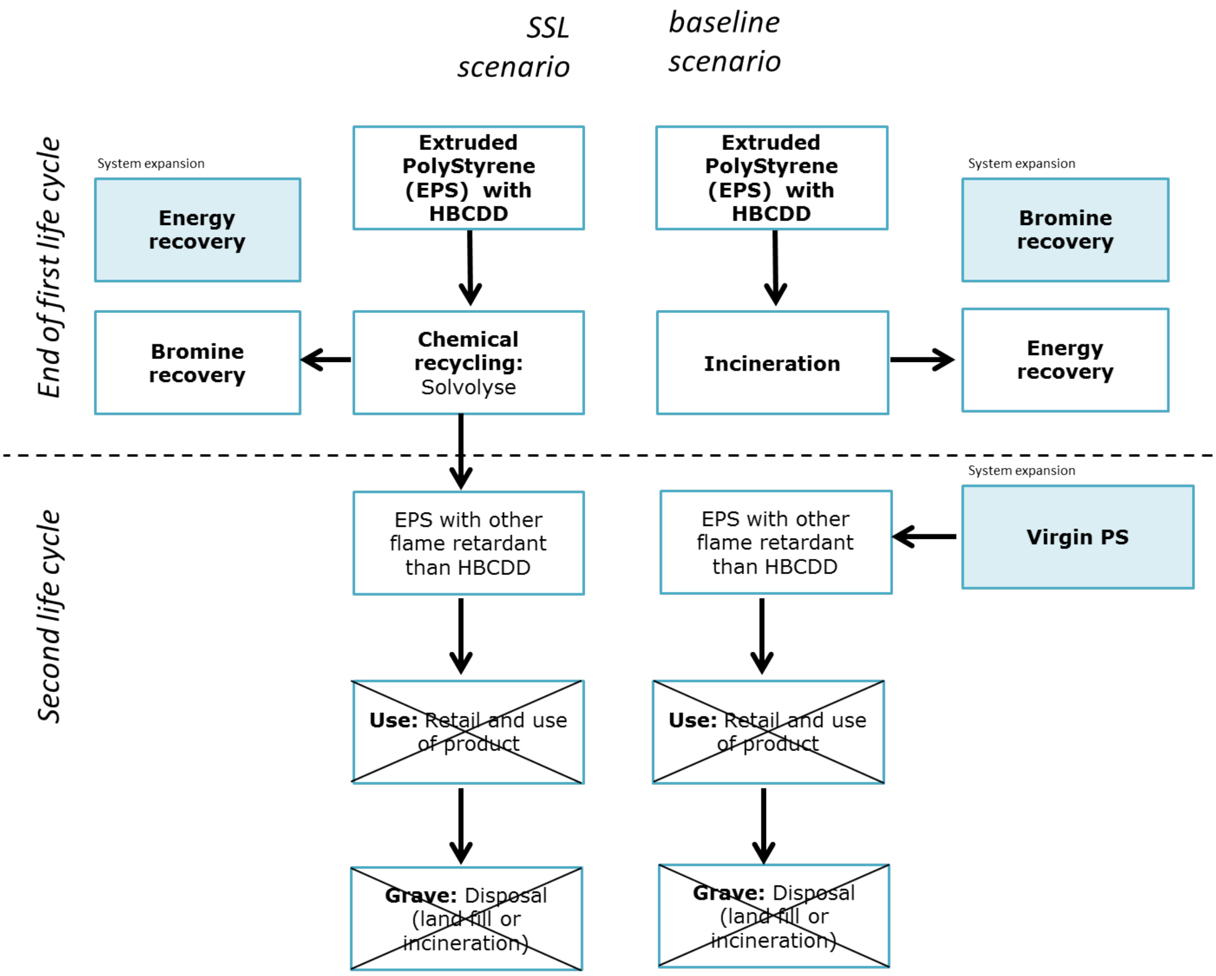


Figure 10-4. Schematic overview of the SSL scenario for recycling of EPS and the baseline scenario.

Tier 2

In Tier 2, Benefits in terms of Cumulative Energy Demand and, when required, Land use are assessed. This is done based on 4 steps depicted below.

Tier 2:
1. Determine scope: is the functionality of the new product different from the product it replaces? Is there a difference in function, quality or durability?
2. Make a list of materials and energy required for each scenario.
3. Search for generic CED or CO_2 emission values and land use estimations for the materials and energy used.
4. Sum the CEDs, CO_2 eq. and land use per functional unit and compare different scenarios.

1. It is assumed that there is no difference in the functionality of EPS produced in the SSL or baseline scenario. Therefore, a cradle-to-gate perspective can be used as the scope. This means that the scope ranges from the dismantling of EPS from existing applications up to the production of EPS in the second life cycle, see Figure 10-4.

2. For the SSL scenario, energy is used for dismantling and shredding EPS boards, transport and processing EPS using the PS loops process, which results in the recovery of EPS and Bromine. In the baseline scenario, energy is recovered from the incineration of EPS and virgin PS is required for the production of new EPS for use in the second life cycle. In both the SSL and baseline scenario, another flame retardant is applied.
3. Data were used from an existing LCA study in which CED values for both scenarios were reported per ton of EPS present in building material (TUVRheinland and BASF, 2018). Based on the reported recovery efficiency of 0.85, the CED for 1 kg of recovered polystyrene (PS) was calculated to be 65 MJ or 4.0 kg CO_2-eq. per kg of PS for the SSL scenario. For the baseline scenario (incineration), this was 96 MJ or 7.6 kg CO_2-eq. per kg of PS. The same order of magnitude CED or CO_2 footprint was found from an alternative source, reporting for the production of virgin EPS foam slabs: 107 MJ or 4.6 kg CO_2-eq. per kg (RVO, 2018). The benefit of energy recovery (electricity and steam) after incineration of EPS in the baseline scenario was approximately 30 MJ or 1.6 kg CO_2-eq. per kg of PS (TUVRheinland and BASF, 2018).
4. As an existing LCA study was used as the basis for this comparison, this required only converting the data to the required functional unit: per kg of recovered PS. The resulting data is reported in Table 10-3. In addition to the scope used in the TUV Rheinland study, the total CED and footprint is also reported when energy recovery is excluded based on the assumption that the recycling step extends the life of the PS and will become available for energy recovery after the second life cycle.

Table 10-3. Overview of the cumulative energy demand and CO_2 footprint for the SSL scenario and baseline scenario aimed at assessing the benefit of EPS recycling.

	SSL scen.		**Baseline scen. 1**		**Source**
For 1 kg PS	MJ	Kg CO_2 eq.	MJ	Kg CO_2 eq.	
Total (including Energy recovery)	65	4.0	96	7.6	(TUVRheinland and BASF, 2018)
Total (excluding energy recovery)	35	2.4	96	7.6	(TUVRheinland and BASF, 2018)

Conclusion

The SSL scenario has a lower CED and CO_2 footprint than the baseline scenario. The difference is even greater when the energy recovery due to electricity and steam is not taken into account. This result shows that there is a relevant benefit with respect to reduced environmental impact in terms of energy demand and CO2 footprint.

10.2.3 ZZS module

In waste streams containing EPS, several different substances occur. In this assessment for ZZS, only HBCDD is taken into account.

Tier 0

Tier 0:
Are there ZZS present in the material flow?

EPS use in the building sector contains HBCDD in percentages of 0.8 to 2.5% (UNEP, 2011). Occasionally, HBCDD has been used in EPS for consumer products, such as beanbags and for packaging material. This clearly answers the question in Tier 0 that, indeed, ZZS (HBCDD) are expected in this material flow. Continue on to Tier 1.

Tier 1

Tier 1:
1. Are POPs present above the concentration limit as included in Annex IV of the POP regulation?
2. Are individual ZZS present above 0.1% in the waste stream?
3. Could exposure of man and the environment be considered as more critical for the intended application compared to the material in its original application?

- *Are POPs present above the concentration limit?*
  Yes, HBCDD is regulated as a Persistent Organic Pollutant following several regulations, such as REACH and the Stockholm Convention, for its application in products, currently restricted to levels below 100 mg/kg in materials, mixtures or objects. The disposal of waste containing POPs follows the Basel Convention.

Because the first question is answered with a 'yes', the other two questions become irrelevant. The POPS present should be removed or the material should be disposed of adequately following existing regulations for POPs. Legally, methods applied for the waste treatment of POP waste should follow and comply with the guidelines of the Basel Convention. Continue on to the first part of Tier 2, related to removal of ZZS.

Tier 2

The first part of Tier 2 (Block 1), to which Tier 1 refers, is related to the question of whether removal of ZZS from the material is achievable? This is assessed by answering the following three questions.

Tier 2, Block 1:
1. Are there any measures to remove ZZS from the material flow?
2. Are these measures technically feasible?
3. Is removal of ZZS economically feasible?

1. *Are there any measures to remove ZZS from the material flow?*
   Yes, there is a solvolysis method for HBCDD, which results in recovery of Polymer and the retrieval of bromine. This was recently recognized by the Basel Convention as an acceptable method for the treatment of EPS that contains HBCDD above 1,000 mg/kg. For this method, the HBCDD concentration in recovered polymer should be below the set 100 mg/kg following the EU POP regulation.
   Other legally accepted methods are incineration and landfilling, which are the common options in conformity with the Basel

Convention for disposal of hazardous waste. However, in the Netherlands, limitations for landfilling prohibit the last option.

2. *Are these measures technically feasible?*
   There are data on the application of these techniques as applied on lab scale and a pilot plant from the scientific literature that show the resulting EPS has HBCDD levels below the set 100 mg/kg (Tange *et al.*, 2016). This has not yet been tested in a larger scale treatment plant, which is planned. The answer to question 2 in Block 1 is therefore 'yes', with some uncertainty related to the upscaling of the method.
3. *Is the removal of ZZS economically feasible?*
   The supply of secondary EPS that contains HBCDD is expected to grow the coming decade. EPS and bromine are recovered, which should cover some of the costs. The bromine is recovered from the extracted HBCDD at the bromine recovery plant. Currently, a pilot plant is planned in Terneuzen. No further analysis of feasibility is conducted here, but should be provided by the stakeholders in order to answer this question with greater certainty.

It is expected that the reduction of HBCDD in polystyrene is enough to fall below the current limit of 100 mg/kg for HBCDD in new products, following Annex A of the EU POP regulation. The overall outcome of this part of Tier 2 would be that removal is achievable, which in turn removes the concern related to the ZZS present.

10.2.4 *Other modules*

The modules related to pharmaceutical residues, pathogens, antimicrobial resistance and plant protection products result in no concern in Tier 0. The circularity module is relevant to conduct. In Tier 0, this results in the indication that an increase in circularity is expected. However, no further assessment of Tiers 1 and 2 was conducted.

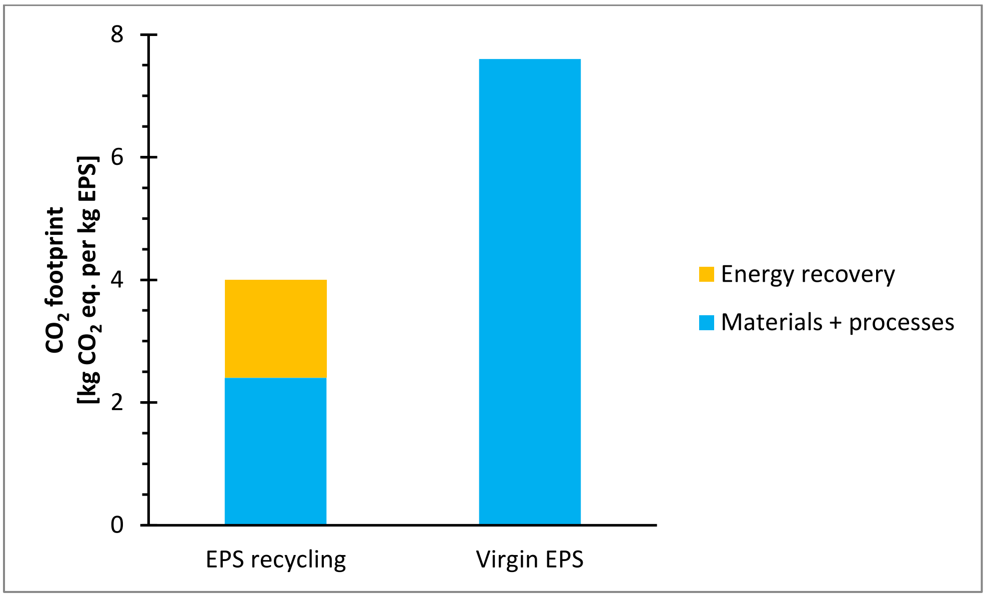


Figure 10-5. CO_2 footprint for the production of 1 kg of EPS from recycling EPS or the production of virgin EPS as calculated using the Environmental Impact module.

10.2.5 *Integrated results*

The results from the ZZS module show that, for HBCDD, the resulting secondary EPS is safe for use, with HBCDD values expected to fall below the safety limit of 100 mg per kg of PS (Figure 10-6). Additionally, there is a clear indication of reduced environmental impact, based on a smaller CED and CO_2 footprint for recycled EPS compared with virgin EPS (Figure 10-5). This is furthermore supported by the full LCA study conducted by TUV Rheinland for the comparison of the recycling method with the business-as-usual incineration method.

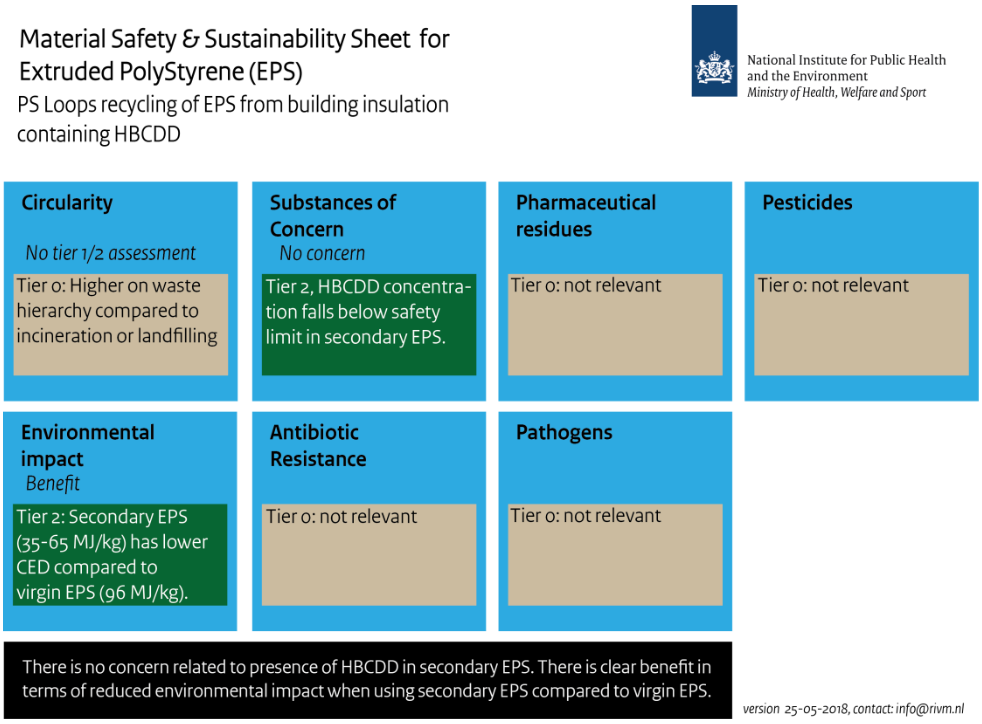


Figure 10-6. Material Safety and Sustainability sheet for recycling EPS with HBCDD based on assessment with the SSL framework.

10.3 Granulated rubber

10.3.1 *Background*

In recent years, many synthetic turf pitches have been installed for sports purposes in the Netherlands. In the majority of these pitches, rubber granulate has been used as infill material, which is mainly produced from end-of-life tyres (ELT). In the Netherlands, large amounts of rubber waste are produced from scrap rubber tyres. In 2017, 8.7 million tyres were collected (0.3 million of which came from abroad); equal to approximately 70,000 tonnes per year). Of these collected tyres, 34% are reused as a tyre, 61% are recycled into a different product, such as rubber granulate (material recycling), and 5% are used for the regeneration of energy (RecyBEM, 2018). Within the material recycling process, tyres are shredded first and, if necessary, the size is further reduced using a cutting mill. During this process, metal pieces are removed using a magnet and textile fibres are filtered off by suction. In this way, rubber granulates of various grain sizes or rubber powders are produced. These particles can be used to develop ‘new’ products, such as infill material for synthetic turf or moulded

articles such as shock absorption tiles. Such applications of ELT reduce the amount of rubber tyre waste that otherwise would need to be disposed of, e.g. by incineration.
In this section, the application of end-of-life tyres as rubber infill on synthetic turf pitches will be assessed as a test case for the different topics currently addressed in the Safe and Sustainable Loops framework. The purpose of the framework is to demonstrate the environmental benefits and to address the human and environmental safety issues of a product as an integral part of the development of a novel material application and business model.
The chemicals contained in ELT granulate (such as zinc, cobalt, copper and polycyclic aromatic hydrocarbons) raise a concern for human health and the environment when the granulates are applied as infill in synthetic turf pitches. Initiated almost 20 years ago, the public debate about the safety for humans and the environment of using rubber granulate is still ongoing. Several risk assessment studies have been conducted to estimate the risks of human exposure and the environmental risk of substances leaching into soil, groundwater, surface water and sediment, e.g. Oomen and de Groot (2016); (Verschoor *et al.*, 2018). These studies were triggered by the fact that rubber granulate was used in open applications, knowing that it contained several priority substances or other substances of concern. As a result of the open application, the direct exposure of workers, athletes and playing children and the potential leaching of substances into rainwater and the distribution of granules to the environment is possible. This case study is included in this report to retrospectively demonstrate the usefulness of the framework to indicate ELT infill as a material with potential safety issues and its ability to effectively trigger and specify research that is needed that would have allowed a prior-informed decision on whether or not the ELT infill application is considered a Sustainable and Safe Loop.

10.3.2 Modules

Circularity

In applying rubber granulate as infill, it is implicit that primary material use is reduced by substitution with secondary material use (scrap tyres into granulates) and thus it is a contribution to the circular economy. Here we quantify the material loop of circularity, based on indicators for recovery efficiency, contribution and recyclability, mainly to assess the contribution towards the circular economy. Ultimately, an improvement in material circularity should lead to a reduction in environmental impact, assessed in the next section.

In the material circularity module, only the application of rubber granulate as infill material in synthetic turf is considered. This module can be applied to obtain an absolute indication of the degree of circularity in the rubber granulate material loop, indicated by a score between 0 and 1, 0 meaning not circular and 1 meaning fully circular. Although possible, no additional scenarios – such as the use of natural grass or the application of other types of infill, such as other types of plastics or natural infill materials such as cork – are assessed here. The comparison of material circularity to such scenarios could be part of further research.

Circularity - Tier 0

This tier is aimed at estimating whether this module is applicable.

Tier 0:
Will the intended application of the residual material or waste stream be higher, equal or lower on the LAP-3 waste hierarchy compared to the current application?

The alternative treatment for old tyres is either incineration (i.e. energy recovery in cement kilns) or moulding into other products (e.g. tiles or wheels). Landfilling is prohibited in the Netherlands based on the EU-wide landfilling prohibition for scrap tyres. Hence, the application of ELT granulates on synthetic turf pitches is an application that is higher or equal on the LAP-3 waste hierarchy compared to incineration or other recycling options, respectively. Therefore, we should continue with tier 1. There are also chemical recycling options, such as pyrolysis into carbon black, process gas and aromatic oils. The carbon black could be reused in the manufacture of new tyres, though the current state of play is that it is mostly sold to the pigment industry as it is not yet suitable for tyre manufacture. Yet another recycling option is chemical recovery through the devulcanization of rubber, but currently this is still in a R&D phase.

Tier 1

In Tier 1, circularity is not quantified, but further assessment is not deemed strictly necessary based on answering yes to the questions in the text box below.

Tier 1:
1. Does the material under consideration contain any of the EU critical raw materials?
2. Supply check: Is there a concern for source material supply due to a significant increase in demand for this material?

1. Rubber granulate is not identified as a critical raw material (CRM) by the EU.
2. It is estimated that 30-40% of the total supply of ELT rubber material in the Netherlands is needed to fulfil the demand for infill materials on the national market. Although this is a significant percentage of total supply, there is currently no concern in relation to residual material supply.

For further assessment of the material circularity, a Tier 2 should be conducted because rubber granulate is not a CRM.

Tier 2

In Tier 2, circularity is quantified based on recovery efficiency, contribution and the recyclability of material flows.

Tier 2:
1. Recovery efficiency: The resource fraction recovered from the total material flow, corrected for auxiliary material use.
2. Contribution: Contribution of the recovered resource fraction towards total resource use in an application or material cycle.
3. Recyclability: The resource fraction available for recovery or reuse after the use phase of the intended application.

1. *Recovery efficiency*
   The recovery efficiency is based on the fraction of ELT used to make rubber granulate. It was found that a recycling efficiency of 80% was used in a study by RecyBEM and ARN (RecyBEM and ARN, 2011). No auxiliary materials are considered as this is a purely mechanical process. This leads to a recovery efficiency score of 0.8.
2. *Contribution*
   In potential all synthetic turf fields can be accommodated using the available rubber granulate from ELT without the addition of alternative infill materials. We do not have the exact numbers of the tonnage of annual rubber granule recovery versus application as infill. In practice, the estimate is that, in previous years, about 90% of synthetic turf used ELT granulate as infill. We estimate the contribution to be 0.9. This may change based on changes in preference for other infill materials.
3. *Recyclability*
   ELT granulates used as infill are commonly not recycled a second time for use as infill for a new synthetic turf field after the old field is decommissioned (Pleizier, 2017). A rough estimate is that about 90%[23] of the rubber granulate can be recovered from an artificial turf field for recycling. However, applications for this tertiary material still need to be found. It is unclear whether this has to do with the quality of the material recovered from synthetic turf and/or the market saturation for ELT rubber granulate and the economic feasibility of cleaning used granulates for reuse as tertiary material. The worst-case scenario is that the recovered granulate will be incinerated in cement kilns and escape from the material loop. This results in a quality indicator (Qr) of 0. This then also yields an overall recyclability of 0 (=0.9*0). This shows that, indeed, finding an application would increase the quality indicator by a maximum of 1 if it can be used as infill again. So the potential recyclability could be 0.9 (=0.9*1).

Overview circularity assessment

Indicator	**Score**
Recovery efficiency	0.8
Contribution	0.9
Recyclability	0

The indicators mentioned in the overview table show the implication of using a three-dimensional assessment of circularity. A material loop is not closed if any of these indicators is 0. When based solely on recyclability, the overall contribution to circularity would be 0. However, by including two other factors related to the actual contribution to an application and the efficiency of the recovery process, the full scope of a material loop is considered. For ELT granulate, this provides a more nuanced result. Ultimately, the recyclability can still be increased when ELT material is used in high quality and valuable applications, such as in new tyres, resulting in a quality indicator of 1. In further research, it is

[23] Based on loss of about 400 kg/year Weijer, A., J. Knol and U. Hofstra (2017). Verspreiding van infill en indicatieve massabalans, Sweco Nederland B.V. & SGS Intron B.V. from a field containing 100 tons of rubber granulate and a life span of between 10 and 15 years.

advised to compare different scenarios, e.g. comparing the circularity of using alternative infill materials such as TPE, EPDM and cork in order to better understand the value of these indicators. This is clearly a subject for further investigation. Further Tier 3 assessment is not conducted.

Environmental Impact – Energy and Land use

Cumulative energy demand (CED) and land use are applied as indicators for environmental impact. The outcome of this assessment will show how much the environmental impact has been reduced, e.g. less energy demand or CO_2 emission is achieved when using ELT granulate as infill in artificial turf fields compared with a baseline scenario. In practice, applying this module mainly consist of the Tier 2 method and Tier 0 for indicating whether land use needs to be quantified as well, see Chapter 4.

Definition of scope and baseline scenario:

1. What material flows and resulting products are assessed?
2. What is the reference product that is replaced by the new application of the non-virgin material?
3. What are the system boundaries?

In this case study, ELT material is recycled into rubber granulate. This ELT granulate is then used as infill in synthetic turf pitches as the novel application.
The reference product is another rubber or plastic infill material of virgin source. Currently, TPE- or EPDM-based products are often applied as alternative materials. In this case, we used PolyEthylene (PE). Although this is not the most obvious choice, the required data was readily available and, in theory, a suitable PE infill product is available (Pleizier, 2017).
The baseline scenario that is related to this alternative infill includes the alternative end-of-life stage of ELT granules (e.g. incineration) and the application of virgin PE (baseline 1) or recycled PE (baseline 2) material infill in synthetic turf, see Figure 10-7.
The SSL and baseline scenarios are related to the situation on the national scale in the Netherlands. Data are based on annual material flows. As the main difference between the three scenarios lies in the origin of the infill material, the life cycle stages included in the assessment are from cradle to gate. Furthermore, it is assumed that the energy recovery of the ELT granulate at the end-of-life (grave) stage of the second life cycle as turf infill material is possible, see Figure 10-7. For this reason, the benefits of energy recovery in the baseline scenario are not taken into account.

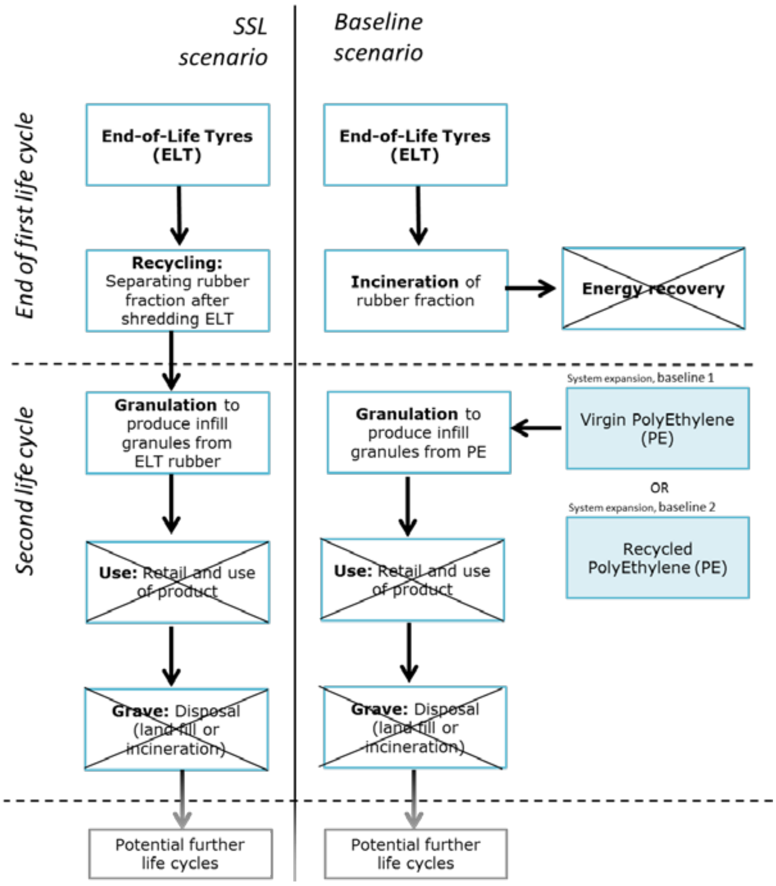


Figure 10-7. Schematic overview of the SSL and baseline scenarios for the production of infill for synthetic turf pitches. Two baseline scenarios are assessed: 1.) using virgin PE, 2.) using recycled PE.

Note: the baseline scenario is partly hypothetical, as there are several options of other materials that can be used as infill instead of PE granules, e.g. EPDM, cork and TPE. And there are also end-of-life options other than energy recovery due to the incineration of ELT granulate.

Tier 0

In Tier 0, the applicability of including land use in the assessment in addition to cumulative energy demand is addressed.

Tier 0:
Should energy demand and/or land use be assessed?

Land use is relevant when a product or material in one of the considered scenarios comes from agriculture or forestry. This is not the case for the current components of ELT rubber and PE or auxiliary materials. Therefore, only a CED analysis should be performed. Analysing land use is not required. This type of quantitative analysis is considered to be Tier 2. In light of the harmonized tiered setup of the SSL framework, a Tier 1 would be expected, which is currently not available for the environmental impact module.

Tier 2

In Tier 2, Benefits in terms of Cumulative Energy Demand and, when required, Land use are assessed. This is done based on the four steps depicted below.

Tier 2:
1. Determine scope: is the functionality of the new product different from the product it replaces? Is there a difference in function, quality or durability?
2. Make a list of materials and energy required for each scenario.
3. Search for generic CED or CO_2 emission values and land use estimations for the materials and energy used.
4. Sum the CEDs, CO_2 eq. and land use per functional unit and compare different scenarios.

1. Determine the scope. It is assumed that there is no difference in the functionality of infill made from ELT granulate or from PE. Therefore a cradle-to-gate perspective can be used as the scope. This means that the use and disposal life stage are not taken into account.
2. In the SSL scenario, rubber granulate for infill is produced from ELT. This is done by shredding ELT and separating the rubber fraction from the additional recovery of metals, textile and some waste materials. This rubber fraction is recycled into granulate for infill. In the baseline scenario, the rubber fraction is incinerated, with energy recovery, and either virgin or recycled PE is used as infill. Because it is assumed that energy recovery is also possible in a similar way after the use phase of ELT granulate, this step is not taken into account in the baseline scenario. A schematic overview of the SSL scenario and two baseline scenarios for the production of infill is given in Figure 10-7. Note also that the recovery of metals and textile is not included, as this is assumed to be the same for the SSL and baseline scenarios.
3. The functional unit applied is 1 kg of infill being produced. The result is reported in Mega Joule (CED) and CO_2 equivalents (CO_2 footprint). CED values and the CO_2 footprint were obtained from the RVO and Idemat CED databases (Idemat, 2018; RVO, 2018). Direct energy demand estimations were not available for all processes. This was the case for the process of ‘shredding and separating ELT’. Instead a generic value for the process of recycling, polymer material is applied. The outcome can be improved for this step, but we assume that the value will be in the same order of magnitude. Furthermore, the granulation process resulting in the specific size range required for infill materials can be neglected, since this process is equal for the SSL and baseline scenarios.
4. The summation of the different processes and materials, including the system expansion, are given in Table 10-3. The results show an order of magnitude, lower CED and CO_2 footprint for the SSL scenario compared with the first baseline scenario using virgin PE granulate. This difference is a lot smaller and likely falls within the uncertainty of the values (same order of

magnitude) when comparing the SSL scenario to the second baseline scenario using recycled PE.

Table 10-4. Overview of the cumulative energy demand and CO_2 footprint for the SSL scenario and two baseline scenarios aimed at assessing the benefit of ELT granulate application in artificial turf.

	SSL scen.		**Baseline scen. 1**		**Baseline scen. 2**		**Source**
Production of 1 kg	MJ	CO_2 eq.	MJ	CO_2 eq.	MJ	CO_2 eq.	
ELT granulate	5.9	0.4					r-mix. polym. (Idemat, 2018)
Virgin PE			77.3	2.0			HDPE (RVO, 2018)
Recycled PE					10.6	0.6	r-HDPE (RVO, 2018)

	SSL scen.		Base. scen. 1		Base. scen. 2	
Total	5.9	0.4	77.3	2.0	10.6	0.6

Conclusion

Assessing the CED and carbon footprint using the approach described in the environmental impact module (Chapter 4) results in a benefit when using recycled materials. It is likely that this will also hold for other, more common rubber-based infill materials, such as EPDM (CED 45.6 MJ/kg). It is unknown how this will be for cork, as land use would also need to be included in the assessment of that material. Additionally, for the purpose of procurement of an infill material, another approach is likely better suited for decision support. The aim here was to support decisions regarding the use of the ELT rubber fraction as infill. However, it is expected that the CED and carbon footprint method can be applied for procurement purposes, e.g. (Kok and Zijp, 2017). In that sense, the data presented here suggests a 10 times higher carbon footprint when switching from an ELT rubber infill to a virgin alternative.

ZZS

Specifically regarding ZZS and other substances of concern, the safety of ELT granulate has already been assessed in great detail in other studies (Oomen and de Groot, 2017; Postma and Oost, 2018; Verschoor *et al.*, 2018). This is an exercise of applying the approach detailed in Chapter 5, the ZZS module, to the ELT granulate case. Footnotes are used to help put the results of using the ZZS module in perspective with respect to the existing studies and to provide some extra context with regard to the safety assessment of substances.

Tier 0

Tier 0:
Are there ZZS present in the material flow?

Based on measured data, it is clear that several ZZS are present in ELT granulate (Oomen and de Groot, 2017). An overview of the ZZS that were identified in rubber granulate is given in Table B-1 in Appendix B. Therefore, a potential concern regarding the group of ZZS compounds in

ELT granulate is identified. The result of Tier 0 of the ZZS module is: 'Go to Tier 1' in order to assess whether the ZZS pose a risk to humans or the environment.
In Tier 1, three questions are answered in order to make an initial assessment based on the likelihood of exposure to ZZS coming from ELT granulate:

Tier 1:
1. Are POPs present above the concentration limit as included in Annex IV of the POP regulation?
2. Are individual ZZS present above 0.1% in the waste stream?
3. Could exposure of humans and the environment be considered as more critical for the intended application compared with the material in its original application?

If the answer to one or more of these questions is 'yes', a Tier 2 assessment should be performed. The basis for answering these questions is information on ZZS content and information on the intended future form of application. An overview of the concentrations of ZZS that were identified in ELT granulate, as provided in the recent RIVM report (Oomen and de Groot, 2017)[24,25], is given in Table B-1 in Appendix B.

1. No POPs are present above the concentration limit as included in Annex IV of the POP regulation (PCBs were measured with maximum levels of 0.2 mg/kg. The concentration limit in the POP regulation is 50 mg/kg).
2. None of the ZZS[25] are present in a concentration above 0.1% (1,000 mg/kg).
3. Exposure of humans and the environment can be considered more critical for ELT granulate compared with rubber tyres (the original application) because ELT granulate has a higher surface-volume ratio and because human contact is considered to occur more directly and more frequently. Both of these factors are known to lead to a higher exposure to ZZS, compared with the difference in the route of exposure for rubber tyres. This is less clear when considering exposure of the environment because the unintended generation of tyre wear particles from tyres in the Netherlands is similar (approximately 800 ton/year, Verschoor et al 2016) to the mass of ELT granulate estimated to be lost to the environment from synthetic turf fields (approx. 800 ton/year[26], (Weijer *et al.*, 2017)). Albeit the emission from turf fields is more locally concentrated than the more diffuse emission of tyre wear particles along roads.

Therefore, a more detailed risk analysis of the ZZS should be conducted[27], based on the principles that a novel exposure route for human contact has been introduced to the ZZS present in ELT granulate. The output of Tier 1 of the ZZS module thus advises to 'Go to

[24] Note: For this example, only the ZZS as measured in the RIVM report (RIVM, 2017b) have been considered. No additional sources have been analysed.
[25] Note: It should be noted that only ZZS substances are considered in this module. Other potentially harmful substances, such as zinc, are not considered by this module.
[26] Assuming loss per field of about 400 kg/year of rubber granulate at 2,000 fields in the Netherlands.
[27] In fact, this detailed risk assessment has been conducted (for instance, Oomen, A. and G. de Groot (2017). Verschoor, A. J., C. W. M. Bodar and R. A. Baumann (2018).

Tier 2' because of the higher expected exposure compared with the application in the previous life cycle.

Tier 2

Because Tier 1 resulted in a remaining uncertainty about the actual risks caused by ZZS in the material flow, two options (i.e. removal of ZZS from the material and the continued presence of the ZZS in the material) are further investigated in this tier.
Within Tier 2, a more in-depth analysis is conducted based on all available data.

Tier 2, Block 1:
Is removal of ZZS achievable?

To our knowledge, there are no techniques available (yet) that can remove ZZS from ELT granulate. This is considered to be difficult due to the many different ZZS present in the material. Some methods have been described that result in the regeneration of feedstock materials, such as carbon black and oil, by pyrolysis (Pourriahi, 2017) and polymers by devulcanization (Saiwari, 2013), but these do not aim to remove ZZS. Therefore, we continue with Block 2 of Tier 2 for an additional evaluation of risks.

Tier 2, block 2:
Is the continued presence of ZZS in the material acceptable?
This question is divided into three parts.

1. Does the material flow meet relevant human and environmental limit values?
2. Are ZZS fixed in the matrix throughout the life cycle?
3. Can the material in the intended application be recovered after use?

1. *Does the material meet relevant limit values? (Block 2.1)*
   For several ZZS in ELT granulate, limit values are available. There is one REACH restriction which is directly applicable to carcinogenic PAHs ELT granulates supplied as mixtures to the general public (entry 28-30 of REACH Annex XVII). Maximum concentrations of PAHs in ELT granulate were all below these limit values or no limit values were present (see Table B-1 in Appendix B). However, it has been noted in recent studies conducted by RIVM and ECHA that these limit values are too high for the safe application as infill on soccer fields (ECHA, 2016; ECHA, 2017; Oomen and de Groot, 2017). In light of this finding, we compare the ZZS concentrations to limit values for other applications, e.g. considering consumer articles and toys or building materials and soil. These limit values are not directly applicable to ELT granulate as infill because rubber infill is not considered to be a toy or consumer product. These limit values are much lower than those in the REACH restriction and are not met for some ZZS in ELT granulate (see Table B-1 in Appendix B). The exceedances do not reflect actual risks, but are a trigger for answering the next questions (Blocks 2.2 and 2.3). Options for the safe use of material for which the potential concern of ZZS cannot be excluded can be found when the exposure of humans and the environment to this material is limited, and

when this material remains distinguishable and recoverable in order to keep track of the ZZS at the end of the material life cycle, for which a new assessment can take place, providing potentially new insights in applicable safety limits or removal techniques.

2. *Are ZZS fixed in the material? (Block 2.2)*
   Within this block, it is assessed whether the ZZS could migrate or leach from the material during its life cycle. There are no migration or leaching limits which are directly applicable to rubber granules. However, it is shown that conditions during the life cycle result in the weathering of the ELT granulate. This indicates a potential concern for the leaching of ZZS out of the granulate. Moreover, it is shown that other non-ZZS substances, such as cobalt and zinc, leach from ELT granulate (Verschoor *et al.*, 2018). For cobalt, this leads to the exceedance of quality criteria for soil and sediments. This indicates a potentially relevant exposure of the environment to hazardous substances other than ZZS.
3. *Can the material in the intended application be recovered after use? (Block 2.3)*
   For the application of ELT granulate as infill, it is clear that there is loss of granulate to the environment. This is estimated to be about 280-460 kg/year per field (Weijer *et al.*, 2017). This means that, although for application as infill, a large fraction remains in the turf and potentially can be recovered, a fraction is lost which poses some concern. Once spread into surrounding soils and ditches, ELT granulate cannot be easily recovered. See monitoring studies in Tier 3.

Overview of Tier 2 output

For the ZZS in ELT granulate, a more thorough assessment of the application of ELT granulate was conducted by answering a specified set of questions. This shows that, for ELT granulate, there is no legally required designation or labelling and that, by comparison, the limit values of comparable products are not always met (Q1), that ZZS can leach out, resulting in the exposure of humans and the environment to these ZZS (Q2), and that there are material losses in the application as infill and there is no recovery system with any guarantees for collection (Q3). As a consequence, it is unlikely that the further spreading and exposure to ZZS in rubber granulate can be prevented or controlled. Therefore, the Tier 2 safety assessment of ZZS in rubber granulate indicates that removal of ZZS is not feasible and there remains some concern related to the continued presence of ZZS in rubber granulate. This means that refined risk assessments are needed for those substances which were triggered in Blocks 2.1 and 2.2.

In theory, given the currently applicable regulatory limit values, the assessment in Tier 2 indicates uncertainty in relation to missing limit values for several ZZS. However, it is also known that presently an update of the existing limit values of PAHs in the restriction of rubber granulate will be conducted for the specific application as infill material in synthetic turf (NL REACH Annex XV Restriction proposal, submitted 20 July 2018). This might have an effect on the assessment in Tier 2, as it is expected that limit values for PAHs will be lower in the future.

Furthermore, ECHA has also received a request from the European Commission to examine the need for regulatory measures to control the risks of other hazardous substances present in rubber granulate. This initiative could result in additional limit values for ZZS and other substances contained in ELT infill.
Overall, the outcome of Tier 2 contains considerable uncertainty related to missing limit values and concerns about exposure and losses to the environment. This uncertainty might be taken away in the future, but for now remains open for decision-makers to interpret.

In terms of the applicability of the method suggested above, this case illustrates the complexity of such an assessment for material that contains a lot of different substances. In this case, considerable expertise is required to conduct the assessment in Tier 2. This case also shows that the focus on ZZS only is no guarantee for safe use, bearing in mind that zinc and mineral oils in rubber infill cause contamination of field border soil and ditch sediments (Verschoor *et al.*, 2018). It is recommended to extend the analysis to all substances for which environmental quality criteria exist.

For the other ZZS for which no limit values are available, the outcome of Tier 2 is inconclusive or, in other words, uncertain. The only option for the safe use of a material for which the potential concern of ZZS cannot be excluded is the limited exposure of humans and the environment to this material and, when further use of this material is warranted, e.g. by being able to discern its presence and potentially remove the contamination at the end of the material life cycle. In this case, several such studies have been performed as part of extensive research on the safety of ELT granulate. This is part of Tier 3 aimed at filling data gaps.

Tier 3

In the case of rubber infill, several studies have been conducted in the Netherlands which can be characterized as Tier 3 studies. For example, studies have been conducted into the ageing of rubber infill in relation to the leaching of zinc, the adsorption of zinc into the typical sublayers beneath the synthetic turf, the monitoring of substances in drainage water, field borders, ditches, groundwater, technical sublayers, and bioassays with drainage water, soil and sediments (Hofstra, 2008; Hofstra, 2009; Zwerus, 2012; Hofstra, 2013; de Groot *et al.*, 2017; Pochron *et al.*, 2017; Verschoor *et al.*, 2018).

Around synthetic turf fields with ELT rubber granulate in the Netherlands, significantly higher cadmium, cobalt and PAH concentrations were measured. Non-ZZS substances like zinc and mineral oil were of particular concern. Concentrations of cobalt exceeded environmental quality standards in soil and in the technical layers beneath the synthetic turf (Verschoor *et al.*, 2018). In bioassays with drainage water, significantly higher pyrene concentrations were observed. Bioassays showed a negative response when exposed to drainage water. On some sites, the sediment of surrounding ditches was contaminated, which led to adverse effects on *Hyalella* and *Chironymus* (Postma and Oost, 2018).

A human health impact study showed that the risk for humans is virtually negligible (Oomen and de Groot, 2017). The results indicate that the rubber granulate can only be used safely when accompanied by (site-specific) mitigation measures that prevent the distribution of granules and prevent the distribution of leached zinc, cobalt and mineral oil to the aquatic systems.

Other modules

The pharmaceutical residues, pesticides, pathogens and antimicrobial resistance modules were not selected as part of the SSL Tier 0 analysis.

10.3.3 *Integrated results*

The Material safety and sustainability sheet is given in Figure 10-8. The ZZS module clearly indicates the presence of ZZS such as cadmium, cobalt and PAHs in ELT granulate. Tier 3 studies showed virtually negligible risks for human exposure, but an unacceptable risk for soil and aquatic ecosystems. Mitigation measures should be considered. It is not clear whether effective mitigation is possible. Since ZZS leach from the material and granules are spread in the environment, a continued exposure to these substances is likely, even after replacement of the ELT infill by a cleaner material. This shows that concerns regarding these substances remain.

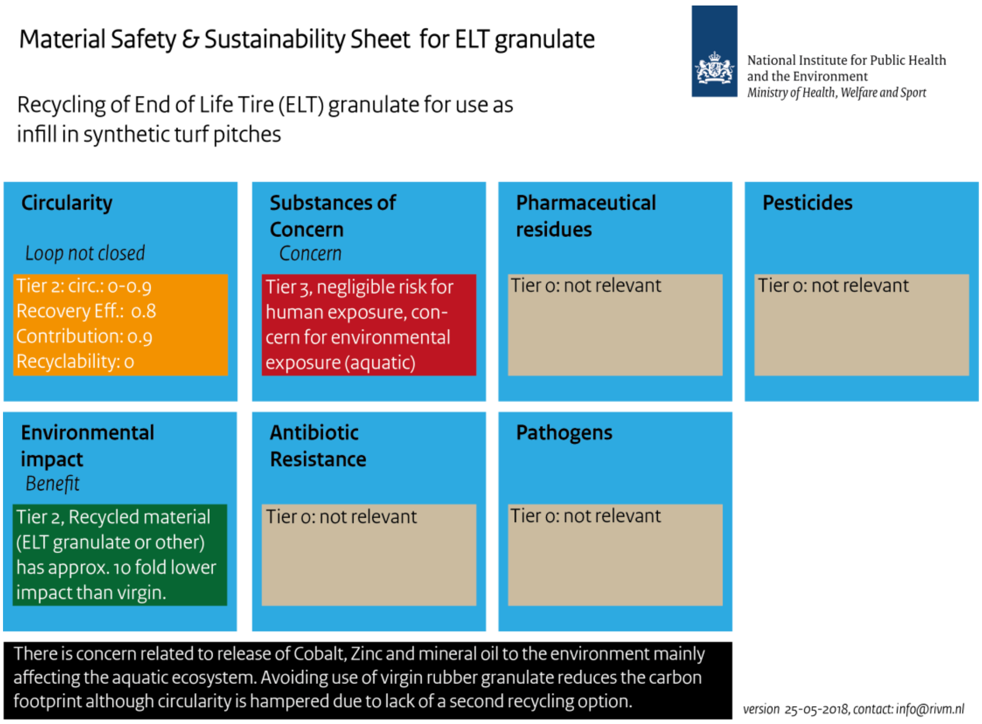


Figure 10-8. Material safety and sustainability sheet for ELT granulate applied as infill in artificial turf based on an assessment with the SSL framework.

The ELT case shows that zinc and mineral oil are the major contaminants of environmental importance. However, these substances are not ZZS and hence are not captured by the SSL framework. It is recommended to accommodate these types of substances with Environmental Quality Standards (EQS) to overcome this gap. This can be done by adding another module or by harmonizing all modules related to substances (ZZS, pesticides, pharmaceuticals, etc.) and find a practical way of

including other potentially hazardous substances, specifically those with available EQS.
On the short term, there seems to be a benefit in the contribution towards achieving the circular economy for the application of ELT rubbers as infill material, although the loop is not closed due to the absence of a second recycling step at the synthetic turf's end of life. The benefit in terms of the carbon footprint and cumulative energy demand remains unclear because baseline scenario 2 (recycled PE granulate) has a similar footprint compared to ELT granulate (Figure 10-9). When ELT replaces virgin rubber granulates, there is a much clearer benefit, showing an approximately 10-fold lower impact for ELT granulate.

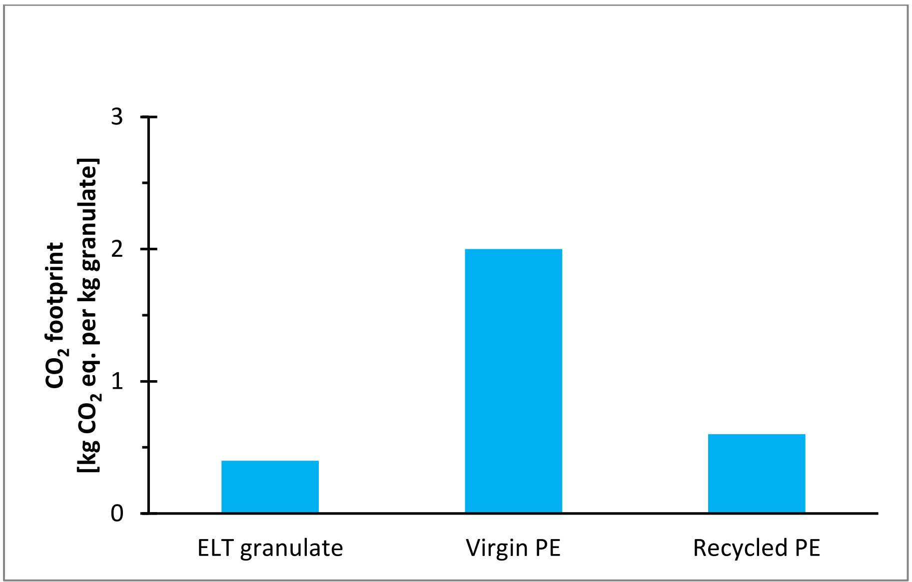


Figure 10-9. CO_2 footprint for the production of 1 kg of granulate from End-of-Life Tyres (ELT), virgin PolyEthylene or recycled PolyEthylene using the Environmental Impact module.

The results from this SSL assessment of ELT rubber recycling shows that it can be used to inform further decision-making on the application of waste streams. The outcome shows three areas of potential improvement for ELT granulate use as infill in artificial turf. First, release to the environment needs to be contained. Second, without a useful recycling option at the end of life of an artificial turf pitch, this application does not result in a closed material loop. Third, there might be much better alternative types of infill materials available. However, this aspect falls outside the scope of the current assessment and would require the SSL framework to be applied to alternatives such as EPDM, TPE or cork. Also for these alternatives, material circularity can be improved by finding ways to recycle the materials used as infill in artificial turf.

11 Discussion and conclusion

11.1 Safe and Sustainable material loops

The recycling of materials is an important strategy as a part of the transition towards a circular economy in which material loops are closed. Increasing the recycling of materials from the standard recycling options that are available now comes with some serious challenges. This includes controlling the risks posed by hazardous substances present in the current products, materials and waste streams (Wassenaar *et al.*, 2017; Bodar *et al.*, 2018; Gezondheidsraad, 2018; Hofstra, 2018). Other human and environmental health concerns relevant to recycling are the presence of pathogens or the development of antimicrobial resistance (Schmitt *et al.*, 2017; van der Grinten and Spijker, 2018). In a circular economy, society benefits from the sustainability related advantages of recycling. These sustainability benefits are related to an increase in resource efficiency and a reduction of environmental impact. At the same time, the identified safety concerns should be addressed and controlled in order to fully profit from increased recycling and to close material loops. To do this, an approach is needed to integrate the assessment of risks and benefits.

Such an approach should be available to stakeholders in the recycling supply chain so that they can maximize the sustainability benefits of recycling options/processes, while controlling potential risks due to hazardous substances or other agents. This means that the methodology to perform such an integral assessment should be science-based, yet pragmatic and practically applicable.

The Safe and Sustainable Loops framework presented here is designed to fulfil this need. It facilitates stakeholders in addressing the safety and sustainability of recycling options in order to close material loops. Several RIVM studies have addressed the safety concerns of recycled materials in the past (Janssen *et al.*, 2015; Spijker *et al.*, 2015; Oomen and de Groot, 2017; Bodar *et al.*, 2018; van der Grinten and Spijker, 2018). Without the specific safety assessment of recycled materials, the uncertainty concerning future risks due to the presence of substances of concern or other agents would remain. This could potentially result in negative impacts to human health and the environment, eventually blocking such recycling options. The goal of the SSL framework is to provide a transparent and systematic methodology that fits the needs of stakeholders in the recycling sector, both government and industry. This should eventually lead to assessments requiring less effort and should provide the tools for increasing material recycling rates.

The basis of the SSL framework consists of a selection of modules, each addressing a separate safety or sustainability theme. The implemented modules are on Circularity, Environmental Impact, Substances of Very High Concern (Dutch abbr.: ZZS), Pharmaceutical Residues, Pesticides, Pathogens and Antimicrobial Resistance. These all consist of a systematic method to provide relevant information to stakeholders and to optimize the safety and sustainability of recycling.

The SSL framework should address the current complexity of sustainability and risk assessments, because this complexity currently hampers recycling when there is concern about a chemical or microbiological contamination. This is the main reason for a tiered assessment. Each module in the SSL framework is designed to keep matters simple, where possible, and only add complexity when needed. To facilitate decision-making on recycling options and the use of secondary materials, it is necessary to balance the need for sufficient knowledge about sustainability benefits and potential safety concerns with the effort and cost of collecting information on the source and composition of the material. Most importantly, this is done through a tiered approach, taking the assessor by the hand via a carefully designed decision tree. In Tier 0, the relevant modules are selected. For these modules, in Tier 1, a simple assessment is done, based on generic quality criteria or trigger values. In Tier 2, a quantitative, more detailed analysis is conducted. If the assessment outcomes for Tier 2 are still unclear or specific data are missing, Tier 3 should be used to provide these, but this also requires much more specific expertise and information to conduct. To evaluate the usefulness and applicability, the SSL framework is applied to three case studies.

11.2 Lessons from case studies: Polystyrene foam, Rubber granulate and Struvite

Assessment of the recycling of polystyrene foam boards, i.e. those used as isolation material in buildings, shows that the environmental benefits can be worthwhile even when the removal of a Substance of Very High Concern (HBCDD) is needed to effectively control risks. Based on the existing limit values in the EU, the assessment using the ZZS module indicated that the presence of HBCDD in Polystyrene foam was unacceptable from a human and environmental health perspective, meaning that the foam boards containing HBCDD would have to be disposed of if the risks could not be controlled. This was recognized by the industry and, for this reason, a specific process was developed that removes HBCDD and recovers bromine in order to control the risk that HBCDD poses to human health and the environment. The combination of the assessment using the environmental impact module and the ZZS module eventually showed that the additional steps in the recycling process resulted in reducing the original concern and still achieved a positive balance in terms of reduced CO_2 footprint compared with virgin polystyrene foam.

For the use of rubber granulate from End of Life Tyres (ELT) as infill in artificial turf pitches, there is a lack of further recycling options in order to close the rubber granulate material loop as indicated by the circularity assessment. Although the material loop is not closed by using ELT rubber as infill, there is a benefit in terms of reduced environmental impact compared with the use of a virgin alternative infill. This outcome provides a clear argument for increasing the sustainability benefits of ELT rubber recycling as infill by adding further recycling options, i.e. by developing options for reuse after the end of the life cycle as infill in artificial turf pitches.
For ELT rubber granulate as infill, there was no evidence for concern related to ZZS for human health and the environment. However,

concern was identified for the adverse effects on the environment due to the leaching of other hazardous substances such as zinc and cobalt (Verschoor *et al.*, 2018). This concern could be taken away with potential risk management options that would reduce leaching to the environment, e.g. with adaptations to the drainage system. Although the ZZS module is not designed for use with substances other than ZZS, it contains all the key factors in order to assess the safety of other hazardous substances. For this reason, it is recommended that the applicability of the module is extended to a broader set of substances in the next update.

The outcome on the sustainability benefits need to be integrated with the outcome of the safety assessment. Both outcomes indicate room for improvement with regard to benefits and control of risks to the environment. There is some uncertainty to take into account. First, due to the chosen scope of the assessment. When, for example, ELT rubber granulate is not compared to virgin rubber but to another recycled granulate as the baseline, the relative benefit is reduced considerably as shown in Figure 10-9. Therefore, changing the scope or extent of the analysis can greatly affect the outcome. This should always be clearly reported when applying the SSL framework. Also, other factors not assessed here will greatly affect the implementation of recycling options. In this case, the use of ELT rubber granulate as infill has caused social unrest in the aftermath of media attention to this topic (ZEMBLA, 2016). This can negatively influence the social acceptance of this recycling option. These issues should also be taken into account in an integrated assessment in which new management options are considered. The SSL framework could be adapted in the future by including a module for socio-economic aspects, thereby broadening the themes addressed as a part of the sustainability benefit assessment.

For the recovery of struvite from waste water, the safety assessment is inconclusive due to data missing on the content of pharmaceutical residues. This information is needed in order to rule out any risk of pharmaceutical residues in struvite. The assessment of the sustainability benefits resulted in a net positive outcome for both circularity, due to phosphate being a critical raw material, and the environmental impact being reduced in comparison with virgin phosphate from mining. This provides an argument for further efforts to be made in assessing and controlling potential risks. At the moment, the waste water treatment sector is building up its knowledge of quality control, which initially takes greater effort, but which should pay off later once analysis and quality control is standardized.

These case studies highlight several strengths of the SSL framework and its modules, such as the integral approach taken to assess safety and sustainability, thus simplifying these assessments and only increasing the detail and complexity of an assessment when needed. Several opportunities for improvement also come with this that currently lie outside the scope of these modules, such as further development to allow application by stakeholders. Although we have provided several options to deal with a lack of data or criteria, this report is not yet a ready-made manual to support application of this approach. There is a clear relationship between the simplicity of assessment methods and the data needed for such an assessment. It is recommended that the modules be updated based on further application in new cases, together with external stakeholders, in order to increase the robustness and practical applicability. These issues are further discussed below and are relevant for the further application of the SSL framework.

11.3 Availability of information in the supply chain

The application of the SSL framework shows that an integral assessment is highly dependent on the availability of three key types of information: the composition of waste streams with regard to hazardous substances or microbiological agents, the waste process conditions and the information needed to calculate the sustainability and circularity benefits. The lessons learned from the case studies indicate that the SSL framework is viable and can support decision-making on alternative waste processing alternatives. Nevertheless, the limited availability of data can seriously hamper the assessment, e.g. due to missing data on the presence of pathogens or SVHC in a waste stream. A routine application of the lower, most simple tiers in the modules usually requires information on the composition of residual material and on the outgoing processed materials or products. For the circularity and environmental impact module, data is required on the quantities of material that are required to run a processing plant and information on energy demand, and on the supply and demand of recycled materials. For the safety modules, the presence and concentrations of chemicals of concern and the types of pathogens are required, as well as the relevant processing steps that might affect the concentrations in the final products. To improve the practical utility of the method, the recycling supply chain should increase the availability of these three types of information.

Available data sources on the composition of materials are given in this report. In practice, it is often still difficult to acquire specific information on the presence and concentrations of contaminants. It is the shared responsibility of the supplier and the material recycler to know the properties of their materials. For this reason, every module lists existing data sources that can be used. For instance, there are inventories of ZZS commonly found in waste (Hofstra, 2018; RIVM, 2018). In the pharmaceutical residues module, an entire section is devoted to how to derive a list of indicator compounds based on several selection criteria. Once waste operators and recyclers develop standardized analytical methods for the input or output material in waste processing, it will become much easier to control the quality of the materials. This requires sharing knowledge on the composition of common waste streams in the supply chain, thereby improving the ability of the sector to apply the lower, easier-to-apply tiers of the SSL framework.

In this stage of development of the SSL framework, it took quite some effort to collect information on the actual waste processing technology and processing steps. This is required to understand the potential for risk mitigation (e.g. a heat treatment to sterilize waste streams, where needed) or the performance of clean-up technologies where ZZS need to be removed. This is also needed to quantify the energy demand and CO_2 footprint of the various processes in order to make a correct comparison of the overall CO_2 footprint of alternative recycling options.

Although the sustainability and circularity modules of the SSL framework are much easier to apply than full-blown LCA studies, they still require some input of essential data. To maximize the benefits of recycling, the life cycle of alternative methods or technologies should be analysed. The various processing steps and the associated energy demands need to be known, yet details on novel technology is often not available to regulators due to confidentiality.

Information exchange in the supply chain on the three topics mentioned is therefore essential to improve the practical application of the SSL framework. Even if such information is confidential, it could be used by the stakeholders in the sector or shared with consultants or regulators, as is done in in other contexts, such as in regulations for the building sector (i.e. using www.milieudatabase.nl), for the implementation of the Manure Act or for the evaluation of chemicals under REACH. Industry is often responsible for the safety of their products, for the exchange of data and for communication in the supply chain. Existing chemicals legislation, such as REACH, is currently improving the exchange of compositional information in the supply chain, e.g. on SVHC in products (ECHA, 2018). The revised waste framework directive 2008/98/EU introduces an extended producer responsibility whereby producers of products bear responsibility for the management of the waste stage of a product’s life cycle, including collection, sorting and treatment operations. As a part of these new responsibilities, additional attention should be paid to the exchange of essential data in the recycling supply chain.

11.4 Criteria for the safety assessment

The criteria for assessment, such as environmental or human health quality standards, are relevant for any safety assessment and are referred to in the safety modules (e.g. on ZZS, pesticides, pharmaceuticals and pathogens). When criteria are not available, it hampers the assessment of risks of aforementioned compounds and hazards in different compartments and materials, even if data on their composition is available. More trigger values for further assessment with respect to groups of compounds or situations and more quality standards for specific compounds are needed.

The use of trigger values in the first level of the assessment (Tier 1) helps to easily exclude situations in which the risks of recycled materials or emissions are assumed to be negligible. A trigger value for a compound or situation is the level below which no risk is expected and above which further assessment is needed. When substances of concern or pathogens are expected to influence the use of recycled materials, measured concentrations can be compared with criteria such as trigger values or quality standards. When no criteria are available or when criteria were developed within a different policy framework, an easy safety assessment of materials and their application is hampered.
In the pharmaceutical residues module in Chapter 6, for instance, three different approaches are introduced to derive trigger values or quality criteria:

1. the use of generic trigger values for a specific compartment, below which no effects are expected. For surface water, for example, a lower percentile of the Potential No Effect

Concentrations (PNEC) for a range of pharmaceuticals of 0.01 µg/L is available that can be used as a trigger value (except for hormone-like compounds). This level is proposed in the case of diapers. For sludge/manure and soil, such a level is also available;
2. the use of an indicative Acceptable Daily Intake for humans (ADI) based on the lowest dose (a fraction of 1/10,000) in combination with a worst-case exposure scenario;
3. the use of a detection limit of an analytical method as a quality standard, as proposed in the case of struvite (a detection limit has no direct relation to potential effects, but is a practical way of implementing a conservative trigger value).

In the pesticides module, two types of criteria are used: (i) a concentration of 0.1 µg/L in groundwater at 1 m depth is used as a trigger value (Chapter 7), and (ii) criteria are defined for the application of residual substances with fertilizers on soil (Leerdam et al., 2015).

These approaches for deriving criteria fit perfectly in the first tier of the SSL Framework. Another example of a trigger value is the practical limit 0.1% m/m used for ZZS in products (most critical generic level for the classification of mixtures according to CLP legislation (1272/2008/EC) (see Chapter 5). Another example is for Food Contact Materials (FCM), for which a substance-specific migration limit (SML) of 50 µg/kg of food is applied (Regulation (EC) No 1935/2004) based on a standard exposure scenario. Below these values, recycled materials can be used safely, with exceptions for specific substances, such as persistent organic pollutants (POPs).
Because substance-specific quality standards are often lacking, a detailed and substance-specific safety assessment is time-consuming and relatively inefficient. It is most urgent to improve Tier 1 screening assessments in order to facilitate the responsible care of the waste treatment and recycling sectors.

It is recommended to improve the scientific underpinning and the number of generic trigger values. For specific groups of compounds, such as hormones or pharmaceuticals, increased differentiation between groups of compounds and types of application is probably needed, e.g. based on the total composition of a material or based on leaching or migration from materials.

The use of effect measurements is recommended for impacts that are caused by groups of compounds (e.g. endocrine disruption) that are analytically difficult to detect and for groups of compounds that have the same type of effect. For certain types of compounds, generic trigger values do not apply. For instance, Endocrine-Disrupting Chemicals (EDC), such as the hormone ethinylestradiol, pose a concern even at very low concentrations. For such cases, effect measurements and limit values for a reference compound can be useful. Especially in higher tiers of assessment, effect measurements can be applied, for example the use of bio-assays for the assessment of waste water. Once more experience is gained, these type of tests could be applied in Tier 1 methods.

The criteria for safety assessment are essential to draw conclusions on the safety of recycled materials and on emissions to the environment. Available criteria are presented in this report. For a quick and easy assessment, more generic trigger values for groups of compounds or situations have been proposed, but more experience is needed to test their practical applicability and to improve their use in Tier 1 screening assessments.

11.5 Integral assessment of sustainability benefits and safety concerns

Integrating safety and sustainability assessments helps to justify investments in risk management options based on the sustainability benefits of a recycling option. Revealing the scope for investing in risk management or risk mitigation is an important outcome of applying the SSL framework. An assessment could, for instance, indicate that recycling would lead to substantial savings in natural resources, although there are safety concerns to tackle. In such a case, the expected 'sustainability surplus' of recycling (compared to incineration, landfill or other less beneficial recycling options) helps to legitimize additional regulation and investment for installing risk management options, with the aim of bringing safety concerns in the recycling process to acceptable levels.

Such an integral assessment of safety and benefits requires a fundamentally new approach to assessing recycling options. This requires a combination of different scientific disciplines, primarily those focused on Life Cycle Assessment (LCA) and Risk Assessment (RA) (Cowell *et al.*, 2002). This is not an easy task. Even within the risk assessment community, there are differences in approach, including approaches used for industrial chemicals, pharmaceutical residues, plant protection products (pesticides), pathogens and antimicrobial resistance. Although the principal risk assessment approach is the same, it is not easy to come to one generic risk assessment language. In this version of the SSL framework, this complexity is worked out by defining a specific scope for each module and harmonizing the modules to adhere to the same tiered approach. This means that the scope of each module differs and that certain themes are not yet worked out in order to cover the whole width of themes that may play a role in the safety and sustainability domain. For this reason, it is recommended to consider the SSL framework as a dynamic catalogue of important themes relevant to assessing materials and their applications. It is important not to forget other safety themes or sustainability themes that are currently not part of the SSL framework, see Table 11-1 for an overview. For instance, concern due to chemical substances can be much broader, e.g. not limited to the three categories (ZZS, pharmaceuticals and pesticides) currently addressed. In addition, the sustainability benefits can be extended to include social and economic elements. The challenge with any addition or update of the SSL framework and its modules is to keep it viable in terms of complexity and applicability in practice.

The Environmental impact module manages the complexity, for instance, by working with a limited number of indicators for environmental impact: energy and land use. These were found to be good proxies for estimating climate impact, as well as other of potential impacts (e.g. Eutrophication and Ozone depletion) (Huijbregts *et al.*, 2010; Steinmann *et al.*, 2016; Steinmann *et al.*, 2017). In addition, the scope of the recycling system (the object of study) is made as narrow as possible for comparison with the baseline scenario. This means that the use and subsequent 'grave' phase of a material (when recycling is no longer possible) can often be neglected, since these phases are frequently similar in both scenarios. Ultimately, the goal is to indicate the sustainability benefits of the novel recycling scenario for the environmental impact in terms of Cumulative Energy Demand or CO_2 footprint.

The sustainability benefits are also estimated using the novel approach for assessing the degree of material circularity. The circularity module addresses the fact that resource efficiency has several pillars, which are relevant to address separately: 1) the efficiency of the materials recovery process, 2) the contribution of the recycled materials to the materials market (market share) and 3) future recyclability (second loop recycling). Furthermore, it was found that correcting for the use of the additional materials needed for the recycling process can considerably reduce the resource efficiency.

The integral assessment of safety and sustainability was made possible with the SSL framework by adding two modules for assessing the material circularity and reducing the environmental impact of the recycling options. Combining the assessment of benefits with risk assessment is not common practice yet; although Life Cycle thinking is currently being addressed in waste management and the broader risk assessment community. It is recommended to further test the applicability and, where necessary, to extend the scope of the assessment. This can be done, for instance, by updating the safety and benefit assessment for application to lifespan extension strategies (R3-R7, in Figure 1-1) or to smart product or process design strategies (R0-R2) because, as a rule of thumb, these are more circular strategies than recycling (R8).

Table 11-1. Overview of implemented themes and other themes (potentially) relevant for addressing the integral assessment of material processing options in a circular economy.

		Theme	Implemented	Description of scope of assessment
Sustainable development (includes safety)	Sustainability benefits	Circularity	X	Material processing into the same (high) or lower quality.
		Environmental Impact	X	Comparison of the material processing scenario to a baseline scenario.
		Social		Benefit to society in terms of resilience or other indicators of social development could be included.
		Economics		Different scales of monetary benefit could be included, with specific attention given to feasibility, e.g. long-term resilience and full-scale rollout of circular strategies.
	Chemical risks	ZZS	X	The presence of substances that fulfil the SVHC criteria in materials and products that play a role in material processing.
		Pharmaceutical Residues	X	The presence of pharmaceuticals in materials and products that play a role in material processing.
		Pesticides	X	The presence of plant protection products in materials and products that play a role in material processing.
		Other substances		Substances that do not fall within one of the mentioned categories could be included because these can still pose a concern, e.g. the metals and PAHs not classified as ZZS.
		Emerging contaminants		Novel emerging contaminants, such as nanomaterials, could be included in the assessment due to the unique properties not taken into account for existing substances, e.g. properties such as particle size for nanomaterials.
	Biological risks	Pathogens	X	The presence of pathogenic microorganisms in materials and products that play a role in material processing.
		Antimicrobial Resistance	X	The effects of antibiotic residues and micro-organisms as factors inducing antimicrobial resistance.
		Others		Other causes of concern related to biological factors that might be relevant to include, for example, due to presence of Genetic Modification.
	Physical Risks	Radiation		Effects of low-level radiation from materials could be relevant when more of these materials are recycled.
		Explosions		External security can be relevant for the surroundings of recycling companies and the safety of the processed materials.
		Others		Other concerns might be relevant due to material properties, for example concerns related to microplastics.

11.6 Conclusion and recommendations

This study shows that a systematic methodology for the integral assessment of recycling options is a viable path to follow as indicated by the case studies. Applying the SSL framework facilitates decision-making on the use of recycled materials and balances the required information with the effort and cost of collecting such information on the source and composition of the material. Assessing the sustainability benefits shows that, even when the material and energy use of risk management options are incorporated, the remaining sustainability benefits can still be worthwhile.
The approaches to safety assessment are now part of a systematic methodology incorporated in the different modules of the SSL framework.

At the same time, there are several challenges to tackle in order to improve the practical applicability of the framework. These can be roughly addressed using a three-pronged approach:

1. Further method development for the themes currently implemented in the SSL framework. This relates to the different recommendations for the update of each module (Chapters 3 to 9).
2. Extend the applicability domain of the SSL framework in terms of themes as well as the circularity strategies addressed (lifespan-extending or smart design). As the SSL framework is a dynamic catalogue of the most important themes to be addressed; some guidance to look further than the included themes is advised. This can eventually result in including more modules in the SSL framework or by identifying triggers, similar to the Antimicrobial Resistance module, when a separate method is relevant or for a safety and sustainability assessment.
3. Optimize the interaction between stakeholders. This is relevant for application of the SSL framework. The challenge with any addition or update of the SSL framework and its modules is to keep it viable in terms of complexity and applicability in practice. For this reason, it is essential that the relevant stakeholders are included in the process of improving and extending the SSL framework.

Ultimately, after testing the SSL framework in practice, it could be adopted by policymakers, regulators and industry to provide what they need for assessing safety and sustainability. This can be on a national scale, where currently the 3rd national waste management plan is in place (Ministerie van Infrastructuur en Waterstaat, 2017). Additionally, on a European scale, the waste framework directive and circular economy packages also require approaches to deal with waste in a sustainable way. Last but not least, it is industry that should be able to easily apply policies and that is seen as one of the most important contributors to the transition towards a circular economy. The SSL framework needs to be made fit for implementation in their research and development process in order to support the safe and sustainable design of (secondary) materials and products.

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Appendix A – Annex I and II of the ZZS module

Annex I: Limit values as listed in Annex IV of the POP regulation [May 2018]

Substance	CAS-no.	EG No.	Limit values	
Endosulfan	115-29-7 959-98-8 33213-65-9	204-079-4	50 mg/kg	0.005%
Hexachlorobutadiene	87-68-3	201-765-5	100 mg/kg	0.01%
Polychlorinated naphthalene			10 mg/kg	0.001%
Alkanes, C10-C13, chlorine (chlorinated paraffins with a short chain) (SCCPs)	85535-84-8	287-476-5	10000 mg/kg	1%
Tetrabromodiphenyl ether C12H6Br4O			Som van de concentraties: 1000 mg/kg	0.1%
Pentabromodiphenyl ether C12H5Br5O				
Hexabromodiphenyl ether C12H4Br6O				
Heptabromodiphenyl ether C12H3Br7O				
Perfluoroctanesulfonic acid and its derivates (PFOS) C8F17SO2X (X = OH, metal salt (O-M+), halide, amide and other derivatives, including polymers)			50 mg/kg	0.005%
Polychloro dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD's/PCDF's)			15 µg/kg	0.0000015%
DDT (1,1,1-trichloor-2,2-bis(4-chloorfenyl) ethaan)	50-29-3	200-024-3	50 mg/kg	0.005%
Chlordane	57-74-9	200-349-0	50 mg/kg	0.005%
Hexachlorocyclohexanes, including lindane:	58-89-9	210-168-9	50 mg/kg	0.005%
	319-84-6	200-401-2		
	319-85-7	206-270-8		
	608-73-1	206-271-3		
Dieldrin	60-57-1	200-484-5	50 mg/kg	0.005%
Endrin	72-20-8	200-775-7	50 mg/kg	0.005%
Heptachlor	76-44-8	200-962-3	50 mg/kg	0.005%
Hexachlorobenzene	118-74-1	200-273-9	50 mg/kg	0.005%
Chlordecone	143-50-0	205-601-3	50 mg/kg	0.005%
Aldrin	309-00-2	206-215-8	50 mg/kg	0.005%
Pentachlorobenzene	608-93-5	210-172-5	50 mg/kg	0.005%
Polychlorinated biphenyls (PCBs)	1336-36-3 en andere	215-648-1	50 mg/kg	0.005%
Mirex	2385-85-5	219-196-6	50 mg/kg	0.005%
Toxaphene	8001-35-2	232-283-3	50 mg/kg	0.005%
Hexabromobiphenyl	36355-01-8	252-994-2	50 mg/kg	0.005%

Annex II: More stringent substance specific limit values as listed in Annex IV of the CLP Regulation [May 2018]

Substance	CAS-no.	EC no.	Limit value	
Dimethylcarbamoyl chloride	79-44-7	201-208-6	Carc. 1B	0.001 %
1,2-dimethylhydrazine	540-73-8		Carc. 1B	0.01 %
Hexamethylphosphoric triamide; Hexamethylphosphoramide	680-31-9	211-653-8	Carc. 1B	0.01 %
Indium phosphide	22398-80-7	244-959-5	Carc 1B	0.01 %
Dimethyl sulphate	77-78-1	201-058-1	Carc 1B	0.01 %
1,3-propanesultone; 1,2-oxathiolane 2,2-dioxide	1120-71-4	214-317-9	Carc 1B	0.01 %
Cobalt dichloride	7646-79-9	231-589-4	Carc 1B	0.01 %
Cobalt sulfate	10124-43-3	233-334-2	Carc 1B	0.01 %
Cobalt di(acetate)	71-48-7	200-755-8	Carc 1B	0.01 %
Cobalt dinitrate	10141-05-6	233-402-1	Carc 1B	0.01 %
Cobalt carbonate	513-79-1	208-169-4	Carc 1B	0.01 %
Cadmium fluoride	7790-79-6	232-222-0	Carc 1B	0.01 %
Cadmium chloride	10108-64-2	233-296-7	Carc 1B	0.01 %
Cadmium sulphate	10124-36-4	233-331-6	Carc 1B	0.01 %
Lead powder; [particle diameter < 1 mm]	7439-92-1	231-100-4	Repr. 1A	0.03%
Benzo[a]pyrene; benzo[def]chrysene	50-32-8	200-028-5	Carc. 1B	0.01 %
Dibenz[a,h]anthracene	53-70-3	200-181-8	Carc. 1B	0.01 %
1,4-dichlorobut-2-ene	764-41-0	212-121-8	Carc. 1B	0.01 %
Bis(chloromethyl) ether; oxybis(chloromethane)	542-88-1	208-832-8	Carc. 1A	0.001 %
Chlorophacinone	3691-35-8	223-003-0	Repr. 1B	0.003%
Warfarin	81-81-2 5543-57-7 5543-58-8	201-377-6 226-907-3 226-908-9	Repr. 1A	0.003%
Coumatetralyl	5836-29-3	227-424-0	Repr. 1B	0.003%
Difenacoum	56073-07-5	259-978-4	Repr. 1B	0.003%
Brodifacoum	56073-10-0	259-980-5	Repr. 1A	0.003%
Flocoumafen	90035-08-8	421-960-0	Repr. 1B	0.003%
Bromadiolone	28772-56-7	249-205-9	Repr. 1B	0.003%
Difethialone	104653-34-1		Repr. 1B	0.003%
2-naphthylamine	91-59-8	202-080-4	Carc. 1A	0.01 %
Benzidine; 1,1'-biphenyl-4,4'-diamine; 4,4'-diaminobiphenyl; biphenyl-4,4'-ylenediamine	92-87-5	202-199-1	Carc. 1A	0.01 %
Dimethylnitrosoamine; N-nitrosodimethylamine	62-75-9	200-549-8	Carc. 1B	0.001 %
1-methyl-3-nitro-1-nitrosoguanidine	70-25-7	200-730-1	Carc. 1B	0.01 %
Nitrosodipropylamine	621-64-7	210-698-0	Carc. 1B	0.001 %
2-methylaziridine; propyleneimine	75-55-8	200-878-7	Carc. 1B	0.01 %

Appendix B – supporting information to the case studies.

Table B-1: Different types of information requirements in the tiers of the Safe loops framework. ZZS were identified in field samples of rubber granulate (Oomen and de Groot, 2017) and (Bocca et al., 2009). The limit values of REACH Annex XVII (entry 28-30) are *__directly applicable__* *to rubber granulate, the other limit values are potentially relevant but* *__not directly applicable__* *to rubber granulate. Bold values are limit values that are exceeded when compared to concentrations in rubber granulate.*

__Tier 0__	**__Tier 1__**	**__Tier 2__** Limit values				
Substances present in ELT	Concentration in ELT granulate	REACH Annex XVII		Toys safety directive	Building materials	Soil Quality[7]
	(max, mg/kg)	entry 28-30 (mg/kg)	other entries (mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)
phenanthrene	12.3					20
anthracene	11.9					**10**
fluoranthene	20.3					35
pyrene	37					
benzo(ghi)perylene	29.2					40
benzo(c)fluorene	0.7					
cyclopenta(cd)pyrene	2.5					
benzo(a)anthracene	15.3	1000*	0.5[3], 1[1,2]			40
benzo(b+j)fluoranthene	15.7	1000*	0.5[3], 1[1,2]			
benzo(k)fluoranthene	7.3	1000*	0.5[3], 1[1,2]			40
benzo(a)pyrene	10.7	100	0.5[3], 1[1,2]			**10**
benzo(e)pyrene	7.8	1000*	0.5[3], 1[1,2]			
chrysene	7.6	1000*	0.5[3], 1[1,2]			10
dibenzo(a,h)anthracene	8.1	100	0.5[3], 1[1,2]			
sumPAH[6]					50	6.8
di-2-ethylhexylphthalate	62	3000	1000			**8.3**
di-isobutylphthalate isomers	175	250000				**1.3**
dicyclohexylphthalate	0.2	3000				
4-tert-octylphenol	22.4					
bisphenol A	2.5	3000	200[4]	0.1 mg/L[5]		
PCBs	0.2				0.5	**0.04**
cadmium	1.9	p.m.	p.m.	p.m.	4.3	**1.2**
cobalt	234	p.m.	p.m.	p.m.	**130**	**35**

Tier 0	**Tier 1**	**Tier 2** Limit values				
Substances present in ELT	Concentration in ELT granulate	REACH Annex XVII		Toys safety directive	Building materials	Soil Quality[7]
	(max, mg/kg)	entry 28-30 (mg/kg)	other entries (mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)
mercury	0.16	p.m.	p.m.	p.m.	4.8	0.83
lead	46	p.m.	p.m.	p.m.	308	210
nickel	5.8	p.m.	p.m.	p.m.	100	39

**This concentration limit for mixtures applies for the sum of the PAHs with a Carc. 1A/B harmonized classification (with the exception of benzo[a]pyrene and dibenzo[a,h]anthracene).*
[1] Article (consumer product) (entry 50);
[2] Extender oils for rubber processing in tyre production (entry 50); also subject to a limit value of 10 mg/kg for the sum of the 8 PAHs in REACH Annex XVII entry 50;
[3] Toys (entry 50);
[4] Thermal paper;
[5] Migration limit in accordance with the methods in EN 71-10:2005 and EN 71-11:2005;
[6] Sum total of naphthalene, phenanthrene, anthracene, fluoranthene, chrysene, benzo(a)anthracene, benzo(a)pyrene, benzo(k)fluoranthene, indeno(1,2,3,cd)pyrene, benzo(ghi)perylene;
[7] Soil which fulfils the requirements for this class can be used for homes with a garden, locations where children play, and green spaces that have environmental significance. The limit values in the Regulation are safe for the environment and for humans in the event of lifelong exposure, the MPR-human (Maximum Permissible Risk level for humans) for threshold substances and the 'Negligible Risk' ($1*10^6$ per life) for non-threshold substances.

Erratum RIVM report 2018-0173

Creating Safe and Sustainable Material Loops in a Circular Economy. Proposal for a tiered modular framework to assess options for material recycling

Bilthoven: 5 april 2019
Subject: Erratum for report 2018-0173

In the RIVM report 2018-173, titled, *Creating Safe and Sustainable Material Loops in a Circular Economy, Proposal for a tiered modular framework to assess options for material recycling,* an error occurred.

In section 10.2 of this report, Extruded PolyStyrene foam should be Expanded PolyStyrene foam (EPS foam) instead. The complete corrected section is now available below.

10 Case Studies

10.2 Expanded Polystyrene with HBCDD

10.2.1 Background

Expanded PolyStyrene (EPS) foam boards have been widely used for building insulation in Europe since the 1960s. As the service life of these boards ranges from 30 to 100 years, the construction industry expects a significant increase of EPS foam waste from demolition. These large quantities represented quite a challenge for the recycling industry. Another issue is the presence of the flame retardant Hexabromocyclododecane (HBCDD) in many existing EPS foam boards, since EPS is highly flammable. Because of its persistence in the environment, HBCDD has been listed as a substance of very high concern (SVHC) under the EU REACH Regulation, and as a persistent organic pollutant (POP) under the UNEP Stockholm Convention. Today, all EPS producers in Europe have replaced HBCDD with other, new polymeric flame retardants. However, because of the long-life of EPS insulation foam, the waste management of EPS waste containing HBCDD will remain a challenge for the coming 50 - 100 years.

Up to now, considerable amounts of EPS at end of life are being land-filled or incinerated with energy recovery (CONSULTIC, 2011). Only recently, a promising method for recycling EPS that contains HBCDD was developed that is based on a special dissolution technique (solvolysis) (M.P.M. Janssen, 2016). This technique is applied in a new process for the recycling of EPS insulation foam waste called the 'polystyrene loop process' (PS loop) and will be applied on an industrial scale in a pilot plant in Terneuzen, NL (Tange *et al.*, 2016).

Here, recycling of EPS using the PS loop process, including the solvolysis technique, will be assessed using the SSL framework.

10.2.2 Environmental impacts and benefits

The outcome of this assessment will show how much of a reduction of environmental impact, e.g. reduction in energy demand or CO_2 footprint, is reached when recycling EPS, compared with incineration with energy recovery. In practice, applying this module mainly consist of the Tier 2 method and Tier 0 for indicating whether land use needs to be quantified as well, see Chapter 4.

Definition of scope and baseline scenario:
1. What material flows and resulting products are assessed?
2. What is the reference product that is replaced by the new application of the non-virgin material?
3. What are the system boundaries?

In this case study, EPS that contains HBCDD is chemically recycled using the PS loop process with recovery of polystyrene for production of new EPS and the recovery of bromine (Tange *et al.*, 2016; TUVRheinland and BASF, 2018).

The reference product is EPS that contains another polymeric flame retardant based on virgin material sources.

The system boundaries of the SSL and baseline scenarios are largely based on the LCA study performed by TUV Rheinland (2018). In brief, Europe is chosen as the geographic scale. Data on the PS loop process were collected in 2016 from the lab scale application of the CreaSolv process and pilot scale application of the bromine recovery process in Terneuzen. These data were then extrapolated to full scale. This has indicated some uncertainty in the data, due to a relatively low technology readiness level (TRL) varying between 3 and 4.

10.2.2.1.1. Tier 0

In Tier 0, the applicability of also including land use in the assessment, in addition to cumulative energy demand, is addressed.

Tier 0:
Should energy demand and/or land use be assessed?

Land use is relevant when a product or material in one of the considered scenarios comes from agriculture or forestry. This is not the case for the materials as a part of EPS recycling or production.

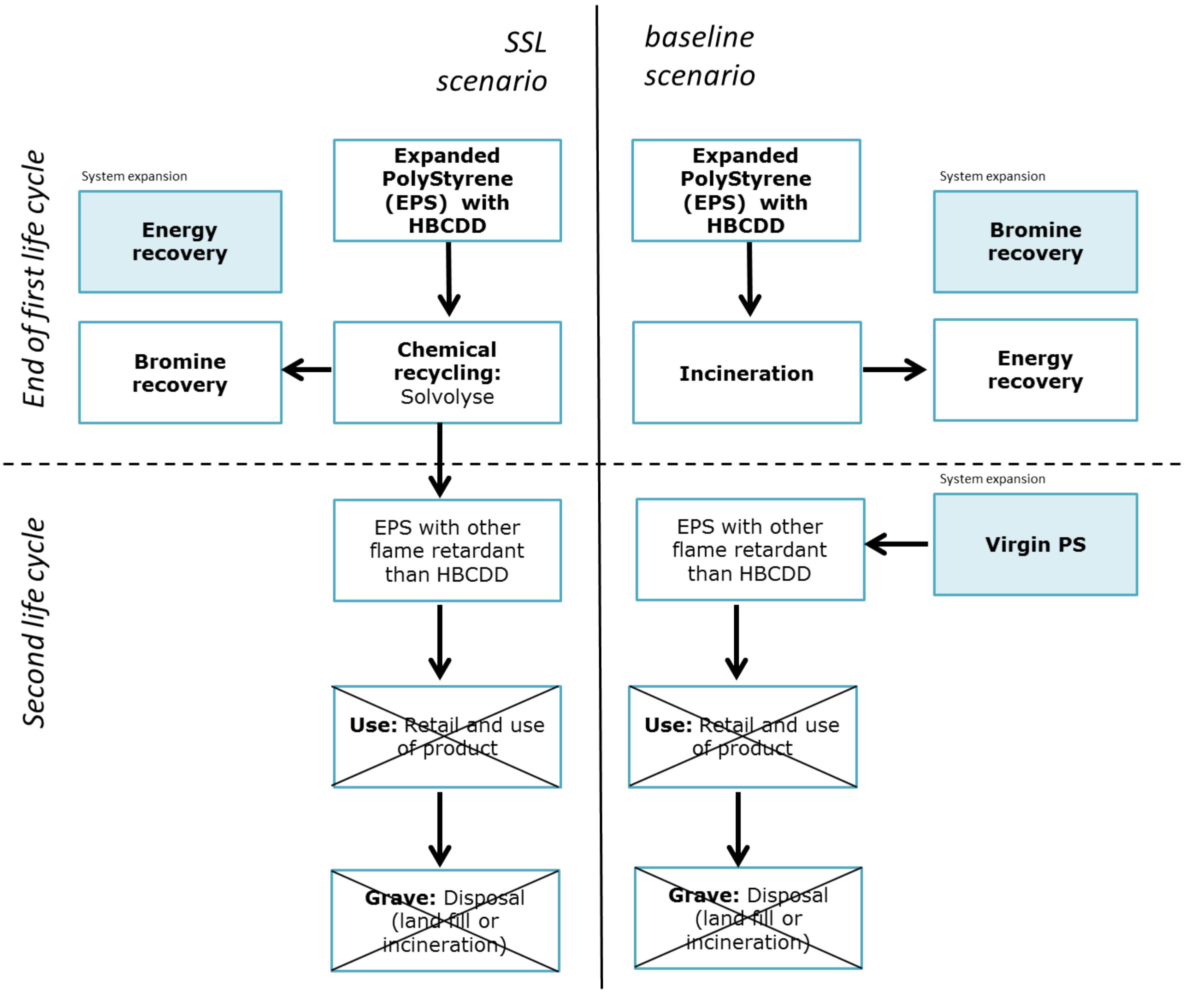

Figure 10-1. Schematic overview of the SSL scenario for recycling of EPS and the baseline scenario.

11.6.1.1.1 Tier 2

In Tier 2, Benefits in terms of Cumulative Energy Demand and, when required, Land use are assessed. This is done based on 4 steps depicted below.

Tier 2:
1. Determine scope: is the functionality of the new product different from the product it replaces? Is there a difference in function, quality or durability?
2. Make a list of materials and energy required for each scenario.
3. Search for generic CED or CO_2 emission values and land use estimations for the materials and energy used.
4. Sum the CEDs, CO_2 eq. and land use per functional unit and compare different scenarios.

1. It is assumed that there is no difference in the functionality of EPS produced in the SSL or baseline scenario. Therefore, a cradle-to-gate perspective can be used as the scope. This means that the scope ranges from the dismantling of EPS from existing applications up to the production of EPS in the second life cycle, see Figure 10-4.
2. For the SSL scenario, energy is used for dismantling and shredding EPS boards, transport and processing EPS using the PS loops process, which results in the recovery of EPS and Bromine. In the baseline scenario, energy is recovered from the incineration of EPS and virgin PS is required for the production of new EPS for use in the second life cycle. In both the SSL and baseline scenario, another flame retardant is applied.
3. Data were used from an existing LCA study in which CED values for both scenarios were reported per ton of EPS present in building material (TUVRheinland and BASF, 2018). Based on the reported recovery efficiency of 0.85, the CED for 1 kg of recovered polystyrene (PS) was calculated to be 65 MJ or 4.0 kg CO_2-eq. per kg of PS for the SSL scenario. For the baseline scenario (incineration), this was 96 MJ or 7.6 kg CO_2-eq. per kg of PS. The same order of magnitude CED or CO_2 footprint was found from an alternative source, reporting for the production of virgin EPS foam slabs: 107 MJ or 4.6 kg CO_2-eq. per kg (RVO, 2018). The benefit of energy recovery (electricity and steam) after incineration of EPS in the baseline scenario was approximately 30 MJ or 1.6 kg CO_2-eq. per kg of PS (TUVRheinland and BASF, 2018).
4. As an existing LCA study was used as the basis for this comparison, this required only converting the data to the required functional unit: per kg of recovered PS. The resulting data is reported in Table 10-3. In addition to the scope used in the TUV Rheinland study, the total CED and footprint is also reported when energy recovery is excluded based on the assumption that the recycling step extends the life of the PS and will become available for energy recovery after the second life cycle.

Table 10-1. Overview of the cumulative energy demand and CO_2 footprint for the SSL scenario and baseline scenario aimed at assessing the benefit of EPS recycling.

	SSL scen.		**Baseline scen. 1**		**Source**
For 1 kg PS	MJ	Kg CO_2 eq.	MJ	Kg CO_2 eq.	
Total (including Energy recovery)	65	4.0	96	7.6	(TUVRheinland and BASF, 2018)
Total (excluding energy recovery)	35	2.4	96	7.6	(TUVRheinland and BASF, 2018)

10.2.2.1.3 Conclusion

The SSL scenario has a lower CED and CO_2 footprint than the baseline scenario. The difference is even greater when the energy recovery due to electricity and steam is not taken into account. This result shows that there is a relevant benefit with respect to reduced environmental impact in terms of energy demand and CO2 footprint.

10.2.3. ZZS module

In waste streams containing EPS, several different substances occur. In this assessment for ZZS, only HBCDD is taken into account.

10.2.3.1.1 Tier 0

Tier 0:
Are there ZZS present in the material flow?

EPS use in the building sector contains HBCDD in percentages of 0.8 to 2.5% (UNEP, 2011). Occasionally, HBCDD has been used in EPS for consumer products, such as beanbags and for packaging material. This clearly answers the question in Tier 0 that, indeed, ZZS (HBCDD) are expected in this material flow. Continue on to Tier 1.

10.2.3.1.2 Tier 1

Tier 1:
1. Are POPs present above the concentration limit as included in Annex IV of the POP regulation?
2. Are individual ZZS present above 0.1% in the waste stream?
3. Could exposure of man and the environment be considered as more critical for the intended application compared to the material in its original application?

- *Are POPs present above the concentration limit?*
  Yes, HBCDD is regulated as a Persistent Organic Pollutant following several regulations, such as REACH and the Stockholm Convention, for its application in products, currently restricted to levels below 100 mg/kg in materials, mixtures or objects. The disposal of waste containing POPs follows the Basel Convention.

Because the first question is answered with a ‘yes’, the other two questions become irrelevant. The POPS present should be removed or the material should be disposed of adequately following existing regulations for POPs. Legally, methods applied for the waste treatment of POP waste should follow and comply with the guidelines of the Basel Convention. Continue on to the first part of Tier 2, related to removal of ZZS.

10.2.3.1.3 Tier 2

The first part of Tier 2 (Block 1), to which Tier 1 refers, is related to the question of whether removal of ZZS from the material is achievable? This is assessed by answering the following three questions.

Tier 2, Block 1:
1. Are there any measures to remove ZZS from the material flow?
2. Are these measures technically feasible?
3. Is removal of ZZS economically feasible?

1. *Are there any measures to remove ZZS from the material flow?*
   Yes, there is a solvolysis method for HBCDD, which results in recovery of Polymer and the retrieval of bromine. This was recently recognized by the Basel Convention as an acceptable method for the treatment of EPS that contains HBCDD above 1,000 mg/kg. For this method, the HBCDD concentration in recovered polymer should be below the set 100 mg/kg following the EU POP regulation.
   Other legally accepted methods are incineration and landfilling, which are the common options in conformity with the Basel Convention for disposal of hazardous waste. However, in the Netherlands, limitations for landfilling prohibit the last option.

2. *Are these measures technically feasible?*
   There are data on the application of these techniques as applied on lab scale and a pilot plant from the scientific literature that show the resulting EPS has HBCDD levels below the set 100 mg/kg (Tange *et al.*, 2016). This has not yet been tested in a larger scale treatment plant, which is planned. The answer to question 2 in Block 1 is therefore ‘yes’, with some uncertainty related to the upscaling of the method.

3. *Is the removal of ZZS economically feasible?*
   The supply of secondary EPS that contains HBCDD is expected to grow the coming decade. EPS and bromine are recovered, which should cover some of the costs. The bromine is recovered from the extracted HBCDD at the bromine recovery plant. Currently, a pilot plant is planned in Terneuzen. No further analysis of feasibility is conducted here, but should be provided by the stakeholders in order to answer this question with greater certainty.

It is expected that the reduction of HBCDD in polystyrene is enough to fall below the current limit of 100 mg/kg for HBCDD in new products, following Annex A of the EU POP regulation. The overall outcome of this part of Tier 2 would be that removal is achievable, which in turn removes the concern related to the ZZS present.

10.2.4. *Other modules*

The modules related to pharmaceutical residues, pathogens, antimicrobial resistance and plant protection products result in no concern in Tier 0. The circularity module is relevant to conduct. In Tier 0, this results in the indication that an increase in circularity is expected. However, no further assessment of Tiers 1 and 2 was conducted.

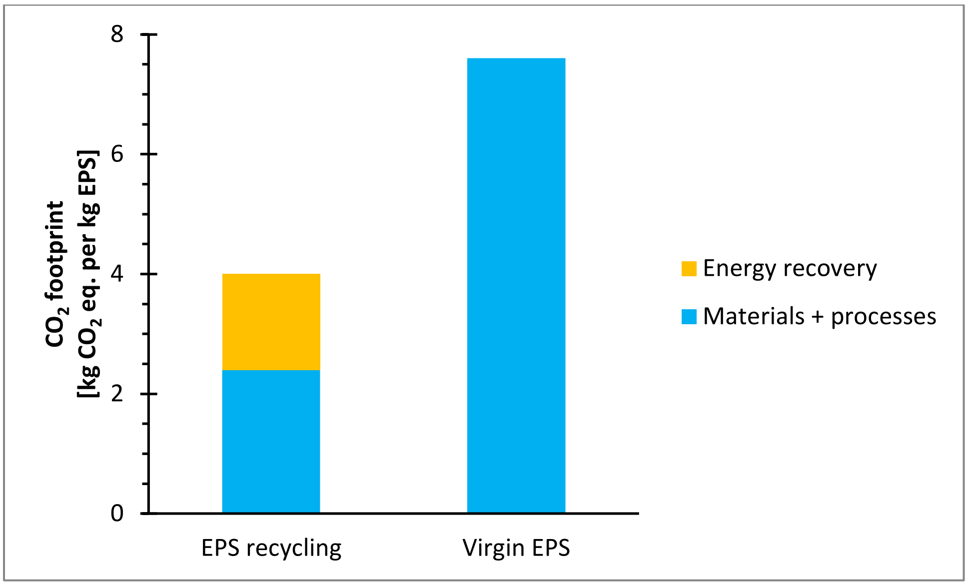

Figure 10-2. CO_2 footprint for the production of 1 kg of EPS from recycling EPS or the production of virgin EPS as calculated using the Environmental Impact module.

10.2.5. *Integrated results*

The results from the ZZS module show that, for HBCDD, the resulting secondary EPS is safe for use, with HBCDD values expected to fall below the safety limit of 100 mg per kg of PS (Figure 10-6). Additionally, there is a clear indication of reduced environmental impact, based on a smaller CED and CO_2 footprint for recycled EPS compared with virgin EPS (Figure 10-5). This is furthermore supported by the full LCA study conducted by TUV Rheinland for the comparison of the recycling method with the business-as-usual incineration method.

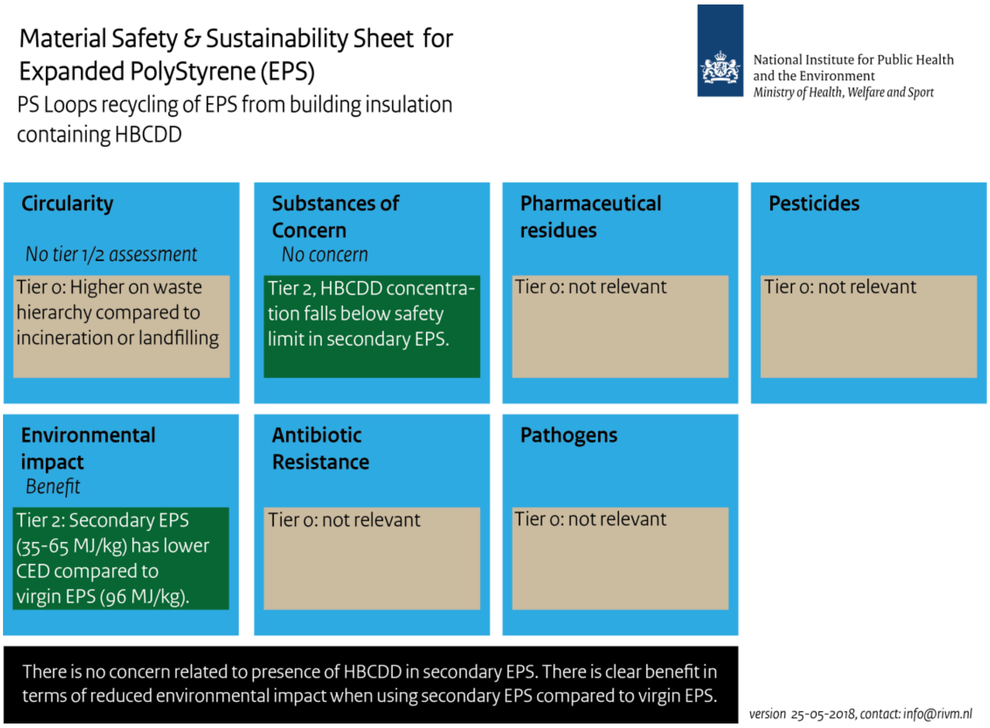

Figure 10-3. Material Safety and Sustainability sheet for recycling EPS with HBCDD based on assessment with the SSL framework.

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