Life Cycle Assessment Guidance

Contact Lenses and Lens Care Products

Developed in partnership with

Anthesis

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Disclaimer

This guidance aims to provide EUROMCONTACT members and wider stakeholders with a methodology to conduct life cycle assessments that are consistent, reliable, and comparable.

Though this guidance is based on the Product Environmental Footprint Category Rules (PEFCR) template defined in the Joint Research Centre Technical Report Suggestions for updating the Product Environmental Footprint Method [2], this document is not an official PEFCR.

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1 Introduction

This document contains guidance to conduct a Product Environmental Footprint (PEF) for contact lenses and lens care products. The PEF method is a standard framework developed by the European Commission for Life Cycle Assessment (LCA).

The PEF method provides detailed and comprehensive technical rules on how to conduct PEF studies that are more reproducible, consistent, robust, verifiable and comparable. Results of PEF studies are the basis for the provision of Environmental Footprint (EF) information, and they may be used in a diverse number of potential fields of applications, including in-house management and participation in voluntary or mandatory programmes.

Product Environmental Footprint Category Rules (PEFCR) provide guidance across a particular product category or industry, to allow PEF-compliant studies to be conducted.

This guidance is based on the PEFCR template, but is not fully compliant with the PEFCR framework, nor is this an official PEFCR. The development of this guidance has not followed the formal process of developing a PEFCR.

Terminology: shall, should and may

This guidance uses precise terminology to indicate the requirements, the recommendations and options that could be chosen when a PEF study is conducted.

- The term “shall” is used to indicate what is required for a PEF study to be in conformance with this guidance.
- The term “should” is used to indicate a recommendation rather than a requirement. Any deviation from a “should” requirement has to be justified when developing the PEF study and made transparent.
- The term “may” is used to indicate an option that is permissible. Whenever options are available, the PEF study shall include adequate argumentation to justify the chosen option.

A list of acronyms and definitions are provided in Appendix A.

2 General Information

2.1 Consultations and stakeholders

This guidance was commissioned by EuromContact and conducted by Anthesis Group, an independent sustainability consultancy.

EuromContact is the European association representing manufacturers of contact lenses and lens care products. EuromContact members include: Alcon, Avizor, Bausch & Lomb, CooperVision, Johnson & Johnson Vision Care, Mark'ennovy, Menicon, Spectaris, Assottica, NAC, AEO, Optics Swiss Suppliers Association, ACLM, and NÄE.

This guidance should be used to inform the future development of Product Category Rules (PCR).

2.2 Review statement

This guidance does not claim conformance to any PCR standard.

A critical review of this guidance conducted by a third party has not been conducted.

2.3 Geographic validity

This guidance is valid for products sold or consumed on the global market.

Each PEF study shall identify its geographical validity listing all the countries where the object of the PEF study is consumed or sold with the relative market share.

2.4 Language

This guidance is written in English. The original in English version supersedes translated versions in case of conflicts.

2.5 Conformance to other documents

This guidance does not claim conformance to the requirements of any standard. However, this guidance has been prepared using the principles of the following documents:

1) Product Environmental Footprint (PEF) method

3 Scope

3.1 Product classification

The product category for this guidance is contact lenses and lens care products.

The full life cycle, cradle-to-grave, of contact lenses and lens care products sold on the global market is within the scope of the guidance.

Three sub-categories are included in this guidance as defined by Table 1. Sub-categories were defined based on the intended function of the studied products.

Table 1: Product sub-categories and descriptions.

No.	Sub-Category	Typical Products	Intended Function
1	Soft Contact Lenses	Daily Disposable Lenses, Bi-weekly Disposable Lenses, Monthly Disposable Lenses.	Vision correction with a lens that moulds to the cornea.
2	Hard Contact Lenses	Rigid Gas Permeable Lenses.	Vision correction with a lens that holds its shape.
3	Contact Lens Solution	Multipurpose Solutions, Hydrogen Peroxide-Based Solutions, Saline Solutions, Disinfecting Solutions.	Solution to clean, disinfect, and store contact lenses.

Table 2 lists categories and codes from the Classification of Products by Activity (CPA) that are covered by this PEFCR.

Table 2: CPA codes covered by the guidance.

CPA Code	Coverage
32.50.41 Contact lenses; spectacle lenses of any material	Partly covered
21.20.2 Other pharmaceutical preparations	Partly covered

This guidance covers contact lenses for corrective vision and contact lens solution only. Other spectacle lenses, contact lens or lens care products e.g. glasses, smart contact lenses, eye drops, etc. are not covered by this guidance, as these different product types vary in function.

3.2 Representative product

When developing this guidance insufficient data was available to develop a representative product whilst preserving the confidentiality of members data.

Additional work is required to develop a virtual product for each sub-category.

3.3 Functional unit and reference flow

The functional unit (FU) for each sub-category is defined in Table 3.

Table 3: Functional unit of sub-categories.

Sub-category	Functional Unit
Soft Contact Lenses	“Vision correction in one eye for one day with a lens that moulds to the cornea."
Hard Contact Lenses	“Vision correction in one eye for one day with a lens that holds its shape.”
Contact Lens Solution	“Contact lens cleaning for one lens for one day”

Table 4 defines the key aspects used to define the FU.

Table 4: Key aspects of the functional unit.

Key Aspect	Description
What?	To provide a contact lens or lens care product to meet the consumers need, as defined per sub-category in Table 1.
How much?	Amount of product required for one eye for one day.
How well?	According to the specifications of the producer.
How long?	One day.

Contact lens prescription is not relevant as a product differentiator as the consumer will be required to use the prescription issued by their optician. When making comparative assertions the same prescription should be considered.

3.4 System Boundary

The scope of this guidance is cradle-to-grave. A system boundary diagram for the soft contact lenses and hard contact lenses sub-categories is presented in Figure 1. A system boundary diagram for the contact lens solution sub-category is presented in Figure 2.

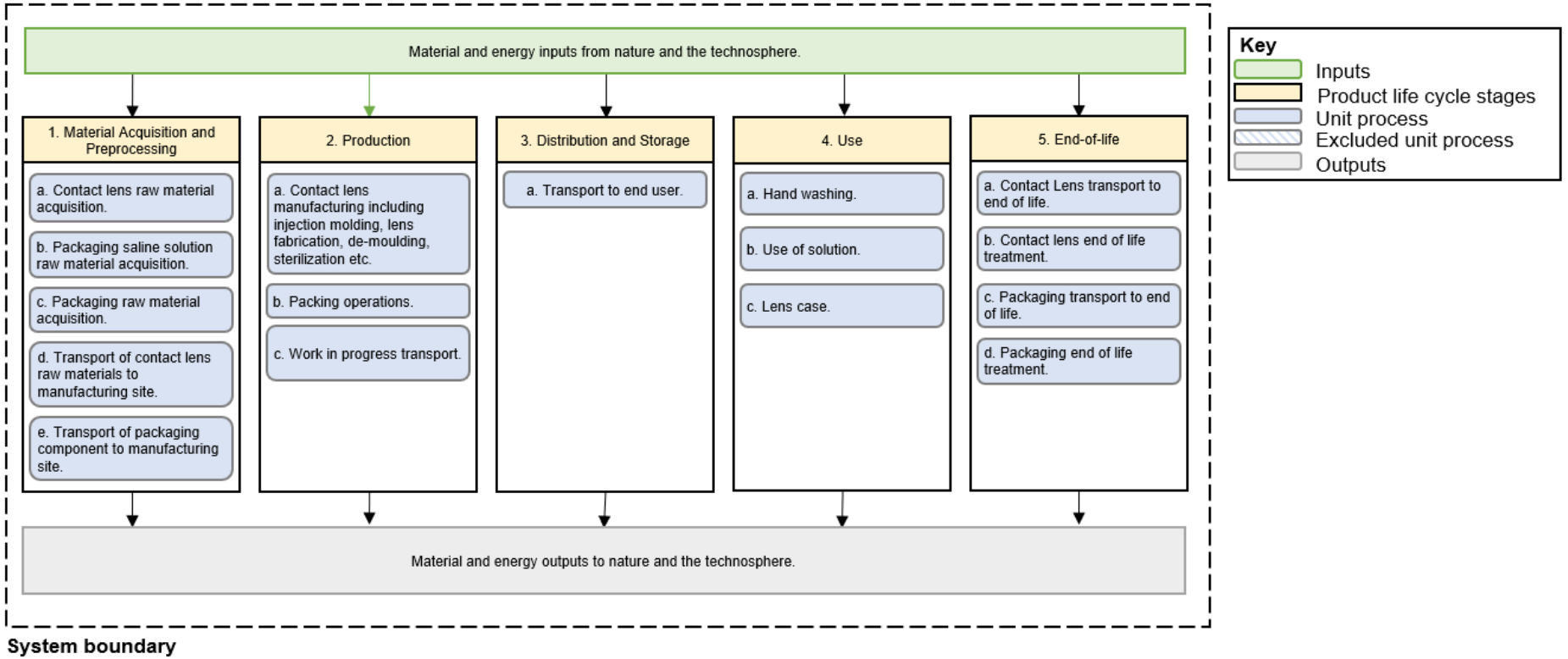

Figure 1: System boundary diagram for the soft contact lenses and hard contact lenses sub-categories.

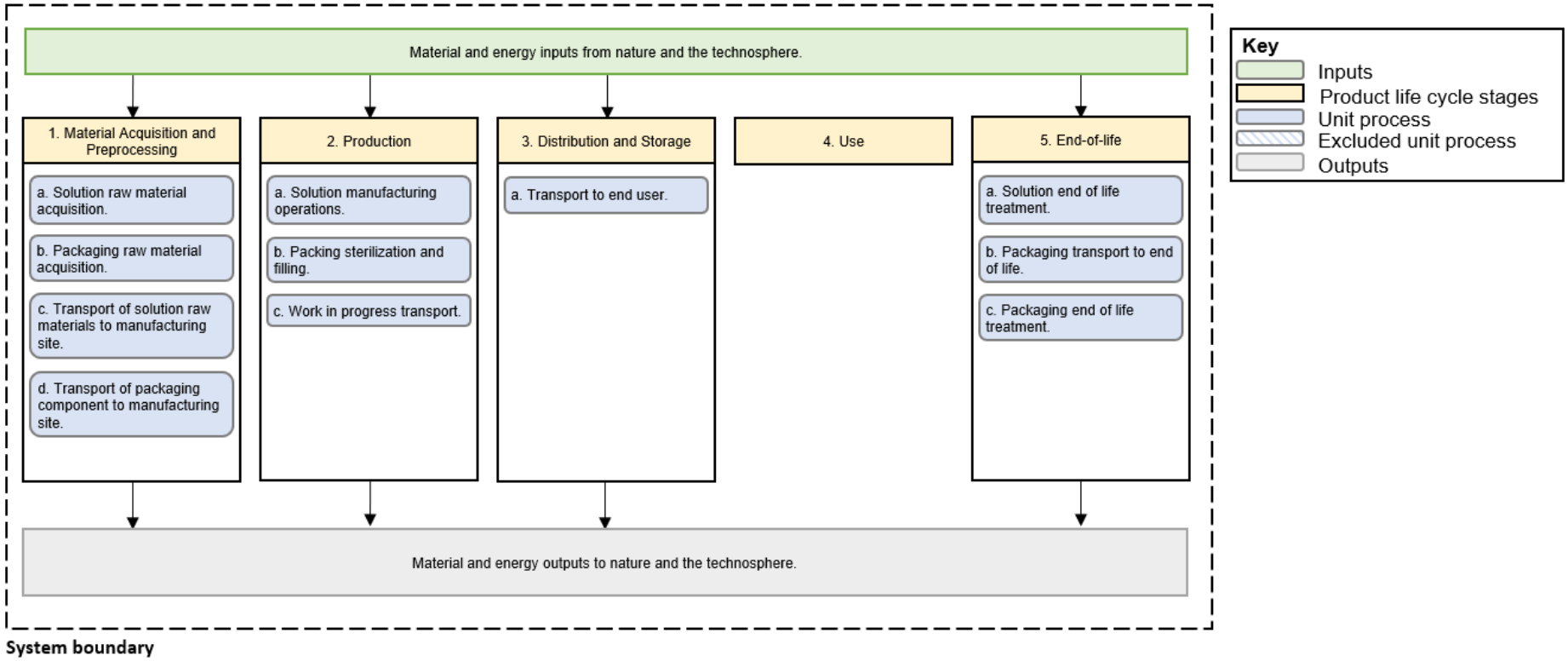

Figure 2: System boundary diagram for the contact lens solution sub-category.

Table 5 defines the life cycle stages and processes that shall be included in the system boundary for the soft contact lenses and hard contact lenses sub-categories.

Table 5: A description of the life cycle stages for the soft contact lenses and hard contact lenses sub-categories.

Life cycle stage	Description of the processes included
Material Acquisition and Preprocessing	Sourcing and preprocessing of materials that are used in the production of the studied products e.g. polypropylene, polymethyl methacrylate, hydroxyethyl methacrylate, silicone acrylate, sodium chloride, disodium edetate, etc. Sourcing and preprocessing of materials that are used in the packaging of the studied products e.g. blister pack, film, cardboard, etc. The three levels of packaging are considered, namely, primary, secondary and tertiary. Primary, secondary, and tertiary packaging are defined in Table 12. Includes transport of all raw materials to the manufacturing site.
Production	Includes the resources and energy required to produce and package the studied product. Includes all relevant production processes including lathe-cutting, cast moulding, spin casting, and other. Should production be disaggregated between multiple manufacturing sites, this stage includes the transport of intermediate products between manufacturing sites.
Distribution and Storage	Transport of the studied product to the end consumer, including any storage at distribution centres or retail.
Use	Includes washing of hands with soap and water before handling contact lenses. In the case of reusable lenses, this phase includes contact lens solution and a contact lens storage case.
End-of-life	Disposal of the studied product and packaging to municipal solid waste treatment or wastewater treatment as applicable.

100 Table 6 defines the life cycle stages and processes that shall be included in the system boundary
101 for the contact lens solution sub-category.

102 *Table 6: A description of the life cycle stages for contact lens solution sub-category.*

Life cycle stage	Description of the processes included
Material Acquisition and Preprocessing	Sourcing and manufacturing of ingredients that are used in the manufacturing of the studied products (sodium chloride, disodium edetate, sodium phosphate buffer and others). Sourcing and manufacturing of materials that are used in the packaging of the studied products (bottle, cardboard and others). The three levels of packaging are considered, namely, primary, secondary and tertiary. Primary, secondary, and tertiary packaging are defined in Table 12. Includes transport of all raw materials to the manufacturing plant.
Production	Includes the material and energy required to produce and packaging the studied product. Includes all relevant production processes including sterilisation, mixing, and other. Should production be disaggregated between multiple manufacturing sites, this stage includes the transport of intermediate products between manufacturing sites.
Distribution and Storage	Transport of the studied product to the end consumer, including any storage at distribution centres or retail.
Use	No use phase activity included in scope.
End-of-life	Disposal of the studied product and packaging to municipal solid waste treatment or wastewater treatment as applicable.

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3.5 List of EF impact categories

All studies carried out in compliance with this guidance shall use EF reference package 3.1 and shall include all impact categories listed in Table 7.

Table 7: List of the impact categories to be used.

Impact category	Impact indicator	Unit	Characterization model
Climate change	Radiative forcing as Global Warming Potential (GWP100)	kg $CO_{2\ eq}$	Baseline model of 100 years of the IPCC (based on IPCC 2013)
- Climate change - biogenic			
- Climate change - land use and land use change			
Ozone depletion	Ozone Depletion Potential (ODP)	kg CFC-11 $_{eq}$	Steady-state ODPs as in (WMO 2014 + integrations)
Human toxicity, cancer	Comparative Toxic Unit for humans (CTU_h)	CTUh	USEtox model 2.1 (Fantke et al., 2017)
Human toxicity, non-cancer	Comparative Toxic Unit for humans (CTU_h)	CTUh	USEtox model 2.1 (Fantke et al., 2017)
Particulate matter	Impact on human health	disease incidence	PM method recommended by UNEP (UNEP 2016)
Ionising radiation, human health	Human exposure efficiency relative to U^{235}	kBq U^{235} $_{eq}$	Human health effect model as developed by Dreicer et al. 1995 (Frischknecht et al. 2000)
Photochemical ozone formation, human health	Tropospheric ozone concentration increase	kg NMVOC $_{eq}$	LOTOS-EUROS model (Van Zelm et al. 2008) as implemented in ReCiPe 2008
Acidification	Accumulated Exceedance (AE)	mol H^+ $_{eq}$	Accumulated Exceedance (Seppälä et al. 2006, Posch et al. 2008)
Eutrophication, terrestrial	Accumulated Exceedance (AE)	mol N $_{eq}$	Accumulated Exceedance (Seppälä et al. 2006, Posch et al. 2008)
Eutrophication, freshwater	Fraction of nutrients reaching freshwater end compartment (P)	kg P $_{eq}$	EUTREND model (Struijs et al. 2009) as implemented in ReCiPe
Eutrophication, marine	Fraction of nutrients reaching marine end compartment (N)	kg N $_{eq}$	EUTREND model (Struijs et al. 2009) as implemented in ReCiPe
Ecotoxicity, freshwater	Comparative Toxic Unit for ecosystems (CTU_e)	CTU_e	USEtox model 2.1 (Fanke et al. 2017)

Impact category	Impact indicator	Unit	Characterization model
Land use	- Soil quality index - Biotic production - Erosion resistance - Mechanical filtration - Groundwater replenishment	- Dimensionless (pt) - kg biotic production - kg soil - m^3 water - m^3 groundwater	Soil quality index based on LANCA (Beck et al. 2010 and Bos et al. 2016)
Water use	User deprivation potential (deprivation-weighted water consumption)	m^3 world $_{eq}$	Available WAter REmaining (AWARE) as recommended by UNEP, 2016
Resource use, minerals and metals	Abiotic resource depletion (ADP ultimate reserves)	kg Sb $_{eq}$	CML 2002 (Guinée et al. 2002) and van Oers et al. 2002
Resource use, fossils	Abiotic resource depletion – fossil fuels (ADP-fossil)	MJ	CML 2002 (Guinée et al. 2002) and van Oers et al. 2002

The full list of normalisation factors and weighting factors are available in Appendix B and the full list of characterization factors is available on the European Platform on LCA [1].

3.6 Additional technical information

No additional technical information currently needs to be reported.

3.7 Additional environmental information

Biodiversity is not considered as relevant for this PEFCR.

3.8 Limitations

Even when a PEF study is carried out in accordance with this guidance, it will have limitations. This section includes the list of limitations a PEF study will have when conducted in line with this guidance.

3.8.1 Critical Review

This guidance draws on the PEFCR template but does not fully adhere to the PEFCR framework and is not an official PEFCR. Its development did not follow the formal process required for creating a PEFCR and has not been critically reviewed by a third party.

3.8.2 Comparisons and Comparative Assertion

The results of studies based on this guidance may be used to support comparative assertions between products within each defined sub-category. This guidance is not designed to support competitive claims between products not part of this guidance.

3.8.3 Database

This guidance does not define the Life Cycle Inventory (LCI) database to be used nor does this guidance dictate specific processes to be employed when modelling. This guidance is limited by the variation in LCI databases available to practitioners and the subjective choices they make when selecting LCI processes.

3.8.4 Data gaps and proxies

The following data gaps on the company-specific data to be collected are most frequently

encountered by companies:

2) Production: In previous LCA studies conducted by member organisations a data gap exists when collecting production energy data. Frequently, process specific or line level energy consumption data was not available and is allocated from the site level via mass allocation.

3.8.5 Allocation method

The end-of-life phase often involves recycling, energy recovery, reuse, or landfilling, each with different environmental impacts. The allocation method determines how burdens and benefits are attributed between the original product system and future systems. End-of-life allocation approaches include cut-off, closed loop approximation and the circular footprint formula. The selection of an end-of-life method is a subjective choice and can significantly alter LCA outcomes.

The end-of-life allocation approach defined in the guidance is cut-off. The cut-off approach for end-of-life allocation, sometimes referred to as the recycled content approach or the 100:0 approach, assigns all environmental burdens and benefits of recycling or reuse to the product system that uses the recycled material.

The operator of the PEF study is encouraged to conduct a sensitivity analysis to understand the implications of other end-of-life approaches. This sensitivity analysis provides confidence that the conclusions of the study do not change should a different allocation approach be selected.

Note that further details on the allocation method are included in Section 5.7.

4 Most Relevant Impact Categories, Life Cycle Stages, Processes and Elementary Flows

The most relevant impact categories, life cycle stages, processes, and elementary flows are determined for each sub-category based on a representative product. However, since no representative product was defined during the development of this guidance, these key aspects have not been identified.

5 Life Cycle Inventory

5.1 List of mandatory company specific data

Company-specific data shall follow the requirements of **Error! Reference source not found.**.

Table 8: Mandatory company specific data

Life cycle stage	Required data which shall be included
Material acquisition and preprocessing	Raw materials used to produce the product and mass of each material required per unit of product. Materials and masses of primary packaging components, per unit of product.
Manufacturing	Manufacturing locations, energy types e.g. electricity, natural gas, etc, quantity of energy used, materials and water use relating to manufacturing processes under operational control of the producer.
Distribution	Mass, distance travelled, and mode of transport for any transportation under operational control of the producer.
Use	Additional inputs required for use of the product, as specified in the instructions for use (IFU).

When a process provides several functions the allocation rules in Section 5.7 should be employed.

5.2 List of processes expected to be run by the company

There are no further processes expected to be run by the company in addition to those listed as mandatory company-specific data.

5.3 Data quality requirements

The data quality shall be calculated and reported. The study may select either the calculation of the Data Quality Requirements in line with the PEF methodology outlined below, or an alternative simplified data quality assessment as outlined in Appendix C.

The calculation of the Data Quality Requirements (DQR) shall be based on the following formula with four criteria:

$$DQR = \frac{TeR+GR+TiR+P}{4} \qquad \textit{Equation 1}$$

where TeR is technological representativeness, GR is geographical representativeness, TiR is time representativeness, and P is precision. The representativeness (technological, geographical and time-related) characterises to what degree the processes and products selected are depicting the system analysed, while the precision indicates the way the data is derived and related level of uncertainty.

Section 5.3.1 includes a table with the criteria to be used for the semi-quantitative assessment of each criterion.

5.3.1 Company specific datasets

The DQR shall be calculated at the level-1 disaggregation, before any aggregation of sub-processes or elementary flows is performed. The DQR of company-specific datasets shall be calculated as following:

1. Select the most relevant activity data and direct elementary flows: most relevant activity data are the ones linked to sub-processes (i.e. secondary datasets) that account for at least 80% of the total environmental impact of the company-specific dataset, listing them from the most contributing to the least contributing one. Most relevant direct elementary flows are defined as those direct elementary flows contributing cumulatively at least with 80% to the total impact of the direct elementary flows.
2. Calculate the DQR criteria TeR, TiR, GR and P for each most relevant activity data and each most relevant direct elementary flow. The values of each criterion shall be assigned based on

4. Table 9.
    a. Each most relevant direct elementary flow consists of the amount and elementary flow naming (e.g. 40 g carbon dioxide). For each most relevant elementary flow, the user of the PEFCR shall evaluate the 4 DQR criteria named TeR_{-EF}, GR_{-EF}, TiR_{-EF} and P_{-EF}. For example, the user of the PEFCR shall evaluate the timing of the flow measured, for which technology the flow was measured and in which geographical area.
    b. For each most relevant activity data, the 4 DQR criteria shall be evaluated (named TeR_{-AD}, GR_{-AD}, TiR_{-AD} and P_{-AD},) by the user of the PEFCR.
    c. Considering that the data for the mandatory processes shall be company- specific, the score of P cannot be higher than 3, while the score for TeR, TiR, and GR cannot be higher than 2 (The DQR score shall be ≤1.5).
5. Calculate the environmental contribution of each most relevant activity data (through linking to the appropriate sub-process) and direct elementary flow to the total sum of the environmental impact of all most-relevant activity data and direct elementary flows, in % (weighted, using all EF impact categories). For example, the newly developed dataset has only two most relevant activity data, contributing in total to 80% of the total environmental impact of the dataset:
    - Activity data 1 carries 30% of the total dataset environmental impact. The contribution of this process to the total of 80% is 37.5% (the latter is the weight to be used).
    - Activity data 2 carries 50% of the total dataset environmental impact. The contribution of this process to the total of 80% is 62.5% (the latter is the weight to be used).
6. Calculate the TeR, TiR, GR and P criteria of the newly developed dataset as the weighted average of each criteria of the most relevant activity data and direct elementary flows. The weight is the relative contribution (in %) of each most relevant activity data and direct elementary flow calculated in step 3.

The user of the PEFCR shall calculate the total DQR of the newly developed dataset using Equation 1, where, $\overline{\overline{\mathrm{TeR}}}, \overline{\mathrm{TiR}}, , \overline{\mathrm{GR}}$ and $\overline{\mathrm{P}}$ are the weighted average calculated as specified in point (4).

$$DQR = \frac{\overline{TiR}+\overline{TeR}+\overline{GeR}+\bar{P}}{4} \qquad \textit{Equation 1}$$

Table 9: How to assess the value of the DQR criteria for datasets with company-specific information.

Rating	P_{-EF} and P_{-AD}	TiR_{-EF} and TiR_{-AD}	TeR_{-EF} and TeR_{-AD}	GR_{-EF} and GR_{-AD}
1	Measured/calculated and externally verified	The data refers to the most recent annual administration period with respect to the EF report publication date	The elementary flows and the activity data exactly the technology of the newly developed dataset	The activity data and elementary flows reflects the exact geography where the process modelled in the newly created dataset takes place
2	Measured/calculated and internally verified, plausibility checked by reviewer	The data refers to maximum 2 annual administration periods with respect to the EF report publication date	The elementary flows and the activity data are a proxy of the technology of the newly developed dataset	The activity data and elementary flows) partly reflects the geography where the process modelled in the newly created dataset takes place
3	Measured/calculated/literature and plausibility not checked by reviewer OR qualified estimate based on calculations plausibility checked by reviewer	The data refers to maximum three annual administration periods with respect to the EF report publication date	Not applicable	Not applicable
4-5	Not applicable	Not applicable	Not applicable	Not applicable

P_{-EF}: Precision for elementary flows; P_{-AD}: Precision for activity data; TiR_{-EF}: Time Representativeness for elementary flows; TiR_{-AD}: Time representativeness for activity data; TeR_{-EF}: Technology representativeness for elementary flows; TeR_{-AD}: Technology representativeness for activity data; GR_{-EF}: Geographical representativeness for elementary flows; GR_{-AD}: Geographical representativeness for activity data.

5.4 Data Needs Matrix

All processes required to model the product and outside the list of mandatory company-specific data (listed in Section 5.1) shall be evaluated using the Data Needs Matrix (DNM), see Table 7. The user of the PEFCR shall apply the DNM to evaluate which data are needed and shall be used within the modelling of its PEF, depending on the level of influence the user of the PEFCR (company) has on the specific process. The following three cases are found in the DNM and are explained below:

1. **Situation 1**: the process is run by the company applying the PEFCR;
2. **Situation 2**: the process is not run by the company applying the PEFCR but the company has access to (company-)specific information;
3. **Situation 3**: the process is not run by the company applying the PEFCR and this company does not have access to (company-)specific information.

Table 10: Data Needs Matrix[1].

		Most relevant process	Other process
Situation 1: process run by the company using the PEFCR	Option 1	Provide company-specific data (as requested in the PEFCR) and create a company-specific dataset, in aggregated form (DQR≤1.5).2 Calculate the DQR values (for each criterion + total).	
	Option 2		Use default secondary dataset in PEFCR, in aggregated form (DQR≤3.0). Use the default DQR values.
Situation 2: process not run by the company using the PEFCR but with access to company-specific information	Option 1	Provide company-specific data (as requested in the PEFCR) and create a company-specific dataset, in aggregated form (DQR≤1.5). Calculate the DQR values (for each criterion + total).	
	Option 2	Use company-specific activity data for transport (distance), and substitute the sub-processes used for electricity mix and transport with supply-chain specific EF compliant datasets (DQR≤3.0). Re-evaluate the DQR criteria within the product specific context.	
	Option 3		Use company-specific activity data for transport (distance), and substitute the sub-processes used for electricity mix and transport with supply-chain specific EF compliant datasets (DQR≤4.0) Use the default DQR values.
Situation 3: process not run by the company using the PEFCR and without access to company-specific	Option 1	Use default secondary data set in aggregated form (DQR≤3.0). Re-evaluate the DQR criteria within the product specific context.	
	Option 2		Use default secondary data set in aggregated form (DQR≤4.0). Use the default DQR values.

[1] The options described in the DNM are not listed in order of preference

[2] Company-specific datasets shall be made available to the EC.

5.4.1 Processes in situation 1

For each process in situation 1 there are two possible options:

- The process is in the list of most relevant processes as specified in the PEFCR or is not in the list of most relevant process, but still the company wants to provide company- specific data (option 1);
- The process is not in the list of most relevant processes and the company prefers to use a secondary dataset (option 2).

Situation 1/Option 1

For all processes run by the company and where the user of the PEFCR applies company- specific data. The DQR of the newly developed dataset shall be evaluated as described in Section 5.3.1.

Situation 1/Option 2

For the non-most relevant processes only, if the user of the PEFCR decides to model the process without collecting company-specific data, then the user shall use the secondary dataset listed in the PEFCR together with its default DQR values listed here.

If the default dataset to be used for the process is not listed in the PEFCR, the user of the PEFCR shall take the DQR values from the metadata of the original dataset.

5.4.2 Processes in situation 2

When a process is not run by the user of the PEFCR, but there is access to company-specific data, then there are three possible options:

- The user of the PEFCR has access to extensive supplier-specific information and wants to create a new EF compliant dataset (option 1);
- The company has some supplier-specific information and want to make some minimum changes (option 2);
- The process is not in the list of most relevant processes and the company wants to make some minimum changes (option 3).

Situation 2/Option 1

For all processes not run by the company and where the user of the PEFCR applies company-specific data, the DQR of the newly developed dataset shall be evaluated as described in Section 5.3.1.

Situation 2/Option 2

The user of the PEFCR shall use company-specific activity data for transport and shall substitute the sub-processes used for electricity mix and transport with supply-chain specific PEF compliant datasets, starting from the default secondary dataset provided in the PEFCR.

Please note that the PEFCR lists all dataset names together with the UUID of their aggregated dataset. For this situation, the disaggregated version of the dataset is required.

The user of the PEFCR shall make the DQR context-specific by re-evaluating TeR and TiR using Table 16. The criteria GeR shall be lowered by 30% and the criteria P shall keep the original value.

Situation 2/Option 3

The user of the PEFCR shall apply company-specific activity data for transport and shall substitute the sub-processes used for electricity mix and transport with supply-chain specific PEF compliant datasets, starting from the default secondary dataset provided in the PEFCR.

Please note that the PEFCR lists all dataset names together with the UUID of their aggregated dataset. For this situation, the disaggregated version of the dataset is required.

In this case, the user of the PEFCR shall use the default DQR values. If the default dataset to be used for the process is not listed in the PEFCR, the user of the PEFCR shall take the DQR values from the original dataset.

Table 11: How to assess the value of the DQR criteria when secondary datasets are used

	TiR	TeR	GR
1	The EF report publication date happens within the time validity of the dataset	The technology used in the EF study is exactly the same as the one in scope of the dataset	The process modelled in the EF study takes place in the country the dataset is valid for
2	The EF report publication date happens not later than 2 years beyond the time validity of the dataset	The technologies used in the EF study is included in the mix of technologies in scope of the dataset	The process modelled in the EF study takes place in the geographical region (e.g. Europe) the dataset is valid for
3	The EF report publication date happens not later than 4 years beyond the time validity of the dataset	The technologies used in the EF study are only partly included in the scope of the dataset	The process modelled in the EF study takes place in one of the geographical regions the dataset is valid for
4	The EF report publication date happens not later than 6 years beyond the time validity of the dataset	The technologies used in the EF study are similar to those included in the scope of the dataset	The process modelled in the EF study takes place in a country that is not included in the geographical region(s) the dataset is valid for, but sufficient similarities are estimated based on expert judgement.
5	The EF report publication date happens later than 6 years after the time validity of the dataset	The technologies used in the EF study are different from those included in the scope of the dataset	The process modelled in the EF study takes place in a different country than the one the dataset is valid for

5.4.3 Processes in situation 3

If a process is not run by the company using the PEFCR and the company does not have access to company-specific data, there are two possible options:

- It is in the list of most relevant processes (situation 3, option 1);
- It is not in the list of most relevant processes (situation 3, option 2).

Situation 3/Option 1

In this case, the user of the PEFCR shall make the DQR values of the dataset used context- specific by re-evaluating TeR, TiR and GR, using the table(s) provided. The criteria P shall keep the original value.

Situation 3/Option 2

For the non-most relevant processes, the user of the PEFCR shall apply the corresponding secondary dataset listed in the PEFCR together with its DQR values.

If the default dataset to be used for the process is not listed in the PEFCR, the user of the PEFCR shall take the DQR values from the original dataset.

5.5 Which datasets to use?

For studies that are compliant with the European Commission's Environmental Footprint (EF) method, the EF database shall be used. For other studies, LCA databases (e.g. ecoinvent database, GaBi or sector specific databases) may be applied as secondary data sources.

LCA software (e.g. GaBi, SimaPro or OpenLCA) may be used to conduct the calculations. Primary data collection is often done with spreadsheets and spreadsheets may be used in this case.

5.6 How to calculate the average DQR of the study

To calculate the average DQR of the PEF study, the user of the PEFCR shall calculate separately the TeR, TiR, GR and P for the PEF study as the weighted average of all most relevant processes, based on their relative environmental contribution to the total single overall score. The calculation rules explained in Section 4.6.5.8 of the PEF method shall be used.

5.7 Allocation rules

When a process/activity provides several functions (e.g., multiple products or services), it is 'multifunctional'. In such case, allocation shall be handled to attribute environmental impacts to several functions (outputs) provided by a certain process/activity. This can also include the allocation of environmental impacts between subsequent life cycles of products/materials in a circular economy (e.g., in case of reuse of parts or recycle of materials). Allocation subdivides inputs and emissions, and thus also the related environmental impacts, between different functions.

There are several options that can be applied, and the preference of the options according to the PEF recommendations is the following.

1. Allocation should be avoided by using process subdivision or system expansion, if possible.
    a. Subdivision means that the multifunctional process is disaggregated to collect data on a more detailed level to attribute inputs and emissions to a specific function (this is often not possible in a rigorous way).
    b. System expansion broadens the system boundaries and considers several functions simultaneously, thus affecting the definition of functional unit(s) of the system.
2. The allocation should be based on relevant underlying physical relationship.
    a. This can for example be based on the mass or energy content of the products.
    b. A direct substitution of a similar function is also possible if there is a direct substitution effect and it is possible to subtract an LCI of the substituted product (e.g., by-product electricity is sold to a grid, substituting average electricity mix in the country).
3. The allocation can also be based on some other relationship, e.g., economic market value.

Allocation procedures might be flow-specific, for example, some flows might be allocated by mass and others by economic value. In this case, the used allocation shall be clearly described in the documentation.

5.8 Electricity modelling

The following electricity mix shall be used in hierarchical order:

a) Supplier-specific electricity product shall be used if, for a country, there is a 100% tracking system in place, or if:
    i. available, and
    ii. the set of minimum criteria to ensure the contractual instruments are reliable is met.
b) The supplier-specific total electricity mix shall be used if:

i. available, and
ii. the set of minimum criteria to ensure the contractual instruments are reliable is met.

c) The ‘country-specific residual grid mix, consumption mix’ shall be used. Country-specific means the country in which the life cycle stage or activity occurs. This may be an EU or non-EU country. The residual grid mix prevents double counting with the use of supplier-specific electricity mixes in a) and b).
d) As a last option, the average EU residual grid mix, consumption mix (EU+EFTA), or region representative residual grid mix, consumption mix, shall be used.

Note: for the use stage, the consumption grid mix shall be used.

The environmental integrity of the use of supplier-specific electricity mix depends on ensuring that contractual instruments (for tracking) are **reliably and uniquely convey claims to consumers.** Without this, the PEF lacks the accuracy and consistency necessary to drive product/corporate electricity procurement decisions and accurate consumer (buyer of electricity) claims. Therefore, a set of minimum criteria that relate to the integrity of the contractual instruments as reliable conveyers of environmental footprint information has been identified. They represent the minimum features necessary to use supplier-specific mix within PEF studies. Evidence such as Renewable Energy Guarantees of Origin or Power Purchase agreements shall be included in the PEF study as required data where a supplier-specific electricity mix is used.

Set of minimum criteria to ensure contractual instruments from suppliers

A supplier-specific electricity product/ mix may only be used if the user of the PEF method ensures that the contractual instrument meets the criteria specified below. If contractual instruments do not meet the criteria, then country-specific residual electricity consumption-mix shall be used in the modelling.

The list of criteria below is based on the criteria of the GHG Protocol Scope 2 Guidance – An amendment to the GHG Protocol Corporate Standard – Mary Sotos – World Resource Institute. A contractual instrument used for electricity modelling shall:

Criterion 1 – Convey attributes

- Convey the energy type mix associated with the unit of electricity produced.
- The energy type mix shall be calculated based on delivered electricity, incorporating certificates sourced and retired (obtained or acquired or withdrawn) on behalf of its customers. Electricity from facilities for which the attributes have been sold off (via contracts or certificates) shall be characterized as having the environmental attributes of the country residual consumption mix where the facility is located.

Criterion 2 – Be a unique claim

- Be the only instruments that carry the environmental attribute claim associated with that quantity of electricity generated.

- Be tracked and redeemed, retired, or cancelled by or on behalf of the company (e.g. by an audit of contracts, third party certification, or may be handled automatically through other disclosure registries, systems, or mechanisms).

Criterion 3 – Be as close as possible to the period to which the contractual instrument is applied

Modelling 'country-specific residual grid mix, consumption mix':

Datasets for residual grid mix, consumption mix, per energy type, per country and per voltage are made available by data providers.

If no suitable dataset is available, the following approach should be used:

Determine the country consumption mix (e.g. X% of MWh produced with hydro energy, Y% of MWh produced with coal power plant) and combine them with LCI datasets per energy type and country/region (e.g. LCI dataset for the production of 1MWh hydro energy in Switzerland):

- Activity data related to non-EU country consumption mix per detailed energy type shall be determined based on:
  - Domestic production mix per production technologies;
  - Import quantity and from which neighbouring countries;
  - Transmission losses;
  - Distribution losses;
  - Type of fuel supply (share of resources used, by import and / or domestic supply).

These data may be found in the publications of the International Energy Agency (IEA (www.iea.org).

- Available LCI datasets per fuel technologies. The LCI datasets available are generally specific to a country or a region in terms of:
  - fuel supply (share of resources used, by import and/ or domestic supply);
  - energy carrier properties (e.g. element and energy contents);
  - technology standards of power plants regarding efficiency, firing technology, flue-gas desulphurisation, NOx removal and de-dusting.

Allocation rules:

Please refer to Section 5.7.

If the consumed electricity comes from more than one electricity mix, each mix source shall be used in terms of its proportion in the total kWh consumed. For example, if a fraction of this total kWh consumed is coming from a specific supplier a supplier-specific electricity mix shall be used for this part. See below for on-site electricity use.

A specific electricity type may be allocated to one specific product in the following conditions:

a) If the production (and related electricity consumption) of a product occurs in a separate site (building), the energy type physical related to this separated site may be used.
b) If the production (and related electricity consumption) of a product occurs in a shared space with specific energy metering or purchase records or electricity bills, the product- specific information (measure, record, bill) may be used.
c) If all the products produced in the specific plant are supplied with a publicly available PEF study, the company wanting to make the claim shall make all PEF studies available. The allocation rule applied shall be described in the PEF study, consistently applied in all PEF studies connected to the site and verified. An example is the 100% allocation of a greener electricity mix to a specific product.

On-site electricity generation:

If on-site electricity production is equal to the site own consumption, two situations apply:

- No contractual instruments have been sold to a third party: the own electricity mix (combined with LCI datasets) shall be modelled.
- Contractual instruments have been sold to a third party: the 'country-specific residual grid mix, consumption mix' (combined with LCI datasets) shall be used.

If electricity is produced in excess of the amount consumed on-site within the defined system boundary and is sold to, for example, the electricity grid, this system may be seen as a multifunctional situation. The system will provide two functions (e.g. product + electricity) and the following rules shall be followed:

If possible, apply subdivision. Subdivision applies both to separate electricity productions or to a common electricity production where you may allocate based on electricity amounts the upstream and direct emissions to your own consumption and to the share you sell out of your company (e.g. if a company has a windmill on its production site and exports 30% of the produced electricity, emissions related to 70% of produced electricity should be accounted in the PEF study).

If not possible, direct substitution shall be used. The country-specific residual consumption electricity mix shall be used as substitution[3].

Subdivision is considered as not possible when upstream impacts or direct emissions are closely related to the product itself.

[3] *For some countries, this option is a best case rather than a worst case.*

5.9 Climate change modelling

The impact category 'climate change' shall be modelled considering three sub-categories:

1. **Climate change – fossil**: This sub-category includes emissions from peat and calcination/carbonation of limestone. The emission flows ending with '(fossil)' (e.g. 'carbon dioxide (fossil)' and 'methane (fossil)') shall be used, if available.

2. **Climate change – biogenic**: This sub-category covers carbon emissions to air (CO_2, CO and CH_4) originating from the oxidation and/or reduction of biomass by means of its transformation or degradation (e.g. combustion, digestion, composting, landfilling) and CO_2 uptake from the atmosphere through photosynthesis during biomass growth – i.e. corresponding to the carbon content of products, biofuels or aboveground plant residues, such as litter and dead wood. Carbon exchanges from native forests[4] shall be modelled under sub-category 3 (incl. connected soil emissions, derived products, residues). The emission flows ending with '(biogenic)' shall be used.

   A simplified modelling approach shall be used when modelling foreground emissions.

   Only the emission 'methane (biogenic)' is modelled, while no further biogenic emissions and uptakes from atmosphere are included. If methane emissions can be both fossil or biogenic, the release of biogenic methane shall be modelled first and then the remaining fossil methane.

3. **Climate change – land use and land use change**: This sub-category accounts for carbon uptakes and emissions (CO_2, CO and CH_4) originating from carbon stock changes caused by land use change and land use. This sub-category includes biogenic carbon exchanges from deforestation, road construction or other soil activities (including soil carbon emissions). For native forests, all related CO_2 emissions are included and modelled under this sub-category (including connected soil emissions, products derived from native forest[5] and residues), while their CO_2 uptake is excluded. The emission flows ending with '(land use change)' shall be used.

   For land use change, all carbon emissions and removals shall be modelled following the modelling guidelines of PAS 2050:2011 (BSI, 2011) and the supplementary document PAS2050-1:2012 (BSI, 2012) for horticultural products. PAS 2050:2011 (BSI, 2011): "Large emissions of GHGs can result as a consequence of land use change. Removals as a direct result of land use change (and not as a result of long- term management practices) do not usually occur, although it is recognized that this could happen in specific circumstances. Examples of direct land use change are the conversion of land used for growing crops to industrial use or conversion from forestland to cropland. All forms of land use change that result in emissions or removals are to be included. Indirect land use change refers to such conversions of land use as a consequence of changes in land use elsewhere. While GHG emissions also arise from indirect land use change, the methods and data requirements for calculating these emissions are not fully developed. Therefore, the assessment of emissions arising from indirect land use change is not included.

   The GHG emissions and removals arising from direct land use change shall be assessed for any input to the life cycle of a product originating from that land and shall be included in the assessment of GHG emissions. The emissions arising from the product shall be

[4] Native forests – represents native or long-term, non-degraded forests. Definition adapted from Table 8 in Annex V C(2010)3751 to Directive 2009/28/EC.

[5] Following the instantaneous oxidation approach in IPCC 2013 (Chapter 2).

assessed on the basis of the default land use change values provided in PAS 2050:2011 Annex C, unless better data are available. For countries and land use changes not included in this annex, the emissions arising from the product shall be assessed using the included GHG emissions and removals occurring as a result of direct land use change in accordance with the relevant sections of the IPCC (2006). The assessment of the impact of land use change shall include all direct land use change occurring not more than 20 years, or a single harvest period, prior to undertaking the assessment (whichever is the longer). The total GHG emissions and removals arising from direct land use change over the period shall be included in the quantification of GHG emissions of products arising from this land on the basis of equal allocation to each year of the period[6].

1. Where it can be demonstrated that the land use change occurred more than 20 years prior to the assessment being carried out, no emissions from land use change should be included in the assessment.
2. Where the timing of land use change cannot be demonstrated to be more than 20 years, or a single harvest period, prior to making the assessment (whichever is the longer), it shall be assumed that the land use change occurred on 1 January of either:
    - the earliest year in which it can be demonstrated that the land use change had occurred; or
    - on 1 January of the year in which the assessment of GHG emissions and removals is being carried out.

The following hierarchy shall apply when determining the GHG emissions and removals arising from land use change occurring not more than 20 years or a single harvest period, prior to making the assessment (whichever is the longest):

1. where the country of production is known and the previous land use is known, the GHG emissions and removals arising from land use change shall be those resulting from the change in land use from the previous land use to the current land use in that country (additional guidelines on the calculations can be found in PAS 2050- 1:2012);
2. where the country of production is known, but the former land use is not known, the GHG emissions arising from land use change shall be the estimate of average emissions from the land use change for that crop in that country (additional guidelines on the calculations can be found in PAS 2050-1:2012);
3. where neither the country of production nor the former land use is known, the GHG emissions arising from land use change shall be the weighted average of the average land use change emissions of that commodity in the countries in which it is grown.

Knowledge of the prior land use can be demonstrated using a number of sources of information, such as satellite imagery and land survey data. Where records are not available, local knowledge of prior land use can be used. Countries in which a crop is grown can be determined from import statistics, and a cut-off threshold of not less than 90% of the weight of imports may be applied. Data sources, location and timing of land use change associated with inputs to products shall be reported."

[6] In case of variability of production over the years, a mass allocation should be applied.

Soil carbon storage shall not be modelled, calculated and reported as additional environmental information.

The sum of the three sub-categories shall be reported.

The sub-category 'Climate change-biogenic' shall not be reported separately.

The sub-category 'Climate change-land use and land transformation' shall not be reported separately.

5.9.1 Bioplastics

When bioplastics are used, careful consideration should be taken to ensure that biogenic carbon is accounted for in line with the guidance in Section 0. Biogenic carbon shall be modelled using the 0/0 approach[7]. Under this convention, all carbon uptake during biomass growth shall neither be counted as a credit at feedstock acquisition nor as a burden at end-of-life, since the organic carbon sequestered in the product is expected to be fully returned to the atmosphere within the 100-year assessment horizon. This simplification avoids misrepresenting temporary carbon storage as a long-term climate benefit. Practitioners shall therefore report greenhouse gas emissions associated only with fossil inputs, energy use, and end-of-life treatments, while biogenic carbon inputs and outputs remain neutral.

The -1/+1 approach to biogenic carbon may be included as an additional sensitivity analysis. However, the -1/+1 approach shall not be used to present cradle-to-gate LCA results as these will be misleading (i.e. carbon sequestration during the production of the product would be considered, but the release of carbon at end-of-life of the product would not be considered).

5.10 Modelling of end-of-life and recycled content

A major deviation from the PEF methodology in this guide is the modelling of the end-of-life and recycled content. Instead of using the Circular Footprint Formula (CFF) developed for the PEF methodology, the cut-off (polluter-pays) principle from EN 15804 shall be used.

As defined by the EN 15804, the polluter-pays principle assigns the processes of waste processing to the product system that generates the waste until the end-of-waste state is reached. All the following criteria must be met to reach end-of-waste state (adopted from EN 15804):

- the recovered material, product or element is commonly used for specific purposes;
- a market or demand, identified, e.g., by a positive economic value, exists for such a recovered material, product or element;
- the recovered material, product or element fulfils the technical requirements for the specific purposes[8] and meets the existing legislation and standards applicable to products; and
- the use of the recovered material, product or element will not lead to overall adverse environmental or human health impacts[9].

The user shall follow the methodology developed by Environdec on the application of the polluter-pays principle. A detailed explanation of this methodology can be found in the General Programme Instructions for the International Environmental Product Declatation (EPD) System created by EPD International (2024).

[7] Note that the 0/0 approach shall be followed for all the bio-based materials e.g. wood, cardboard, paper, etc.

[8] The "Specific purpose" in this context is not restricted to the function of a certain product but can also be applied to material serving as input to the production process of another product or of energy (EN 15804).

[9] The criterion for "overall adverse environmental or human health impacts" shall refers to the limit values for pollutants set by regulations in place at the time of assessment and where necessary shall take into account adverse environmental effects. The presence of any hazardous substances exceeding these limits in the waste or showing one or more properties as listed in existing applicable legislation, e.g. in the European Waste Framework Directive, prevents the waste form reaching the end-of-waste state (EN 15804).

6 Life Cycle Stages

6.1 Raw material acquisition and pre-processing

This lifecycle stage includes the raw materials required to produce the products, the raw materials required to produce the packaging, and the upstream transport from suppliers to the production site(s).

Table 12: Product and packaging definitions

Name	Definition	Example (rigid and soft contact lens subcategories)	Example (contact lens solution subcategory)
Product	The main product being assessed, which performs the desired function	Contact lens	Solution
Primary packaging	Packaging in direct contact with the product, providing containment, protection and sterility	Blister pack, vial, etc.	Bottle, screw cap, inner tamper-proof seal, etc.
Secondary packaging	Consumer facing pack holding one or more units, with branding, labelling, instructions	Folding boxboard carton or sleeve, display tray, instruction leaflets, etc.	
Tertiary packaging	Packaging primarily used for shipping, palletization, and storage; may hold several secondary packs	Cardboard shipping box, pallet, stretch-wrap for pallets	

Typical raw materials used for soft contact lenses are described in Table 13. Please note that this is not an exhaustive list and will not reflect the materials used in every case.

Table 13: Common materials used in soft contact lens production

Function	Material category	Example materials
Structural polymer	Hydrogel base	• 2-Hydroxyethyl methacrylate (HEMA)
	Silicone hydrogel base	• TRIS (tris-trimethylsiloxysilylpropyl methacrylate) • PDMS-MA (polydimethylsiloxane methacrylate)
Hydrophilicity enhancers	Hydrophilic comonomers	• N-Vinylpyrrolidone (NVP) • Methacrylic acid (MAA) • DMA (N,N-dimethylacrylamide)
Crosslinking agents	Di-/multimethacrylates	• EGDMA (ethylene glycol dimethacrylate) • TEGDMA (triethylene glycol dimethacrylate)
Polymerization initiators	Thermal / photoinitiators	• APS/SMBS (ammonium persulfate / sodium metabisulfite) • UV photoinitiators (e.g. PI-184)
Surface/wetting additives	Polymeric wetting agents	• PVP (polyvinylpyrrolidone) • PEG (polyethylene glycol)
UV-blocking ingredients	UV-absorbing monomers/additives	• Benzotriazole derivatives • UV-absorbing acrylate monomers
Tint/pigment agents	Dyes and colorants	• Reactive dyes (e.g. α-chloroacrylamide dyes) • Mineral oxide pigments

Typical raw materials used for rigid contact lenses are described in Table 14. Please note that this is not an exhaustive list and will not reflect the materials used in every case.

Table 14: Common materials used in rigid contact lens production

Function	Material category	Typical monomers/additives
Structural polymer	PMMA (hard lens)	• Methyl methacrylate (MMA)
	Silicone-acrylate	• PDMS-MA • TRIS
	Fluorosilicone-acrylate	• Fluoro-silicone acrylate copolymers
Hydrophilicity enhancers	Hydrophilic comonomers	• NVP • MAA
Crosslinking agents	Di-/multimethacrylates	• EGDMA • TEGDMA
Polymerization initiators	Thermal / photoinitiators	• APS/SMBS • UV photoinitiators (e.g. PI-184)
Surface treatments	Plasma / chemical coatings	• Plasma oxidation • Silicate-based coatings
UV-blocking ingredients	UV-absorbing monomers/additives	• Benzotriazole derivatives • UV-absorbing acrylates
Tint/pigment agents	Dyes and colorants	• Reactive dyes • Mineral oxide pigments

Typical raw materials used for contact lens solution are described in Table 15.

Table 15: Common materials used in contact lens solution production

Function	Material category	Typical ingredients
Buffering agents	pH buffers	• Borate buffer (boric acid/borate salts) • Phosphate buffer (monobasic/dibasic phosphates)
Tonicity agents	Osmotic regulators	• Sodium chloride • Potassium chloride
Preservatives	Antimicrobial compounds	• Polyhexamethylene biguanide (PHMB) • Polyquaternium-1 (PQ-1)
Surfactants / Wetting agents	Non-ionic surfactants	• Poloxamer 407 • Tetronic 1304
Chelating agents	Metal ion binders	• EDTA (disodium edetate) • Citric acid
Viscosity modifiers	Polymers	• Hydroxypropyl methylcellulose (HPMC) • Carboxymethylcellulose (CMC)
Isotonicity enhancers	Sugars / polyols	• Glycerol • Sorbitol
Stabilizers / antioxidants	Anti-oxidants	• Sodium citrate • Ascorbic acid
Comfort agents	Cycloplegics / demulcents	• Hydroxypropyl guar • Dextran

Company-specific data shall be used for the material types and masses of the product components and primary packaging components. However, secondary data may be used for background processes. The source location or region of raw materials should be considered where possible, to account for geographic differences. Global average data may be used where the source region is unknown.

Company-specific data should be used for secondary packaging. If company-specific data is not available for secondary packaging, the most likely secondary packaging option should be estimated. Any assumptions shall be clearly documented.

Company-specific data should be used for tertiary packaging, however if company-specific data is not available for tertiary packaging then the default data in Table 16 shall be used instead.

Table 16: Default data for tertiary packaging

Packaging component to be included	Material	Mass	Transport (sourcing of raw materials)	Number of units held (lenses)	Number of units held (solution)
Pallet	Wood	22 kg allocated across 25 uses; 0.88 kg per use	Use data in Table 17	XX lenses per pallet	XX bottles of solution per pallet
Shrink wrap (for pallet)	LDPE	200 g per pallet	Use data in Table 17	XX lenses per pallet	XX bottles of solution per pallet
Shipping carton (box)	Corrugated board	300 g per box	Use data in Table 17	XX lenses per box	XX bottles of solution per box

The transformation of packaging materials (e.g. injection moulding, blow moulding, metal sheet rolling etc.) shall be considered in this life cycle stage. Where company-specific information is not available, an assumption about the transformation process shall be made and clearly documented. Generic transformation processes can be found in LCA databases. Transformation yields (i.e. the accounting for losses during transformation) shall be considered when applicable. Where company-specific information about yields are not available, generic assumptions (e.g. yields documented in LCA databases) shall be used. These assumptions shall be documented, including any processes where transformation yields have not been included.

6.1.1 Raw material transport

To model the transport from suppliers to production site(s), users shall consider the mass of raw material, transport mode, distance per transport mode, utilisation ratios for truck transport, and empty return modelling for truck transport. Company-specific data may be used for transport if this data is available. If company-specific transport data is not available, default data in Table 17 shall be used instead.

Table 17: Product material and packaging material transport

Component being modelled	Geography of supply	Transport mode	Transport distance	Details	Utilisation*
Packaging material	European: For suppliers located within Europe AND primary manufacturing location within Europe	Truck (lorry)	230km	>32 tonne truck, EURO 4	64%
		Rail	280km	Average freight train	N/A
		Ship	360km	Barge	N/A
		Air	N/A	N/A	N/A
Product raw material	European: For suppliers located within Europe AND primary manufacturing location within Europe	Truck (lorry)	130km	>32 tonne truck, EURO 4	64%
		Rail	240km	Average freight train	N/A
		Ship	270km	Barge	N/A
		Air	N/A	N/A	N/A
Packaging material OR product raw material	International: For suppliers located outside of Europe OR primary manufacturing location outside of Europe	Truck (lorry)	1,000km	>32 tonne truck, EURO 4	64%
		Rail	N/A	N/A	N/A
		Ship (either ship or air to be used, not both)	18,000km	Transoceanic container ship	N/A
		Air (either ship or air to be used, not both)	10,000km	Cargo plane	N/A

**Utilisation rate considers return journey*

Default data follows the PEFCR guidance version 6.3 [3].

6.2 Manufacturing

The manufacturing life cycle stage shall include product manufacturing, beginning when raw materials are received at the production site(s) and ending when the final product is ready for distribution. Internal transport (of the unfinished product between production sites) shall be included. Sterilisation, testing, inspection, packaging, and filling shall also be included.

The waste of products used during the manufacturing shall be included in the manufacturing life cycle stage. Where possible, company-specific loss rates should be used. However, the default loss rate in Table 18 may be used.

Table 18: Manufacturing loss rates

Loss rate
6% of all product.

6.2.1 Product manufacturing

For contact lenses, typical manufacturing stages can be seen in Table 19. Please note that this is not an exhaustive list and different manufacturers may use different approaches. Furthermore, new manufacturing processes may become available in future.

Table 19: Common manufacturing processes for contact lenses

Manufacturing method	Stage	Description
Lathe cutting	Polymerisation	Converting raw inputs into polymer rod.
	Back surface lathe	Slice of rod placed on lathe and shaped to form back surface.
	Front surface lathe	Slice of rod transferred to lathe which forms front surface.
	Edge polishing	This stage may not be performed in all cases.
	Inspection	Anhydrous lens is inspected.
	Lens hydration	Lens is hydrated in saline solution; increases in size; some monomers may be extracted; may include coating.
	Insertion into blister pack or vial	This may be a blister pack, a glass vial with a bung and aluminium seal, or alternative option.
	Autoclaving	Vial or other pack with lens inside are autoclaved.
Cast moulding	Mould creation	A male and female tool are used to make a female and male mould.
	Monomers inserted into mould	Monomers are added to mould and male and female moulds are combined to form the desired shape.
	Polymerisation	This may be thermal or UV polymerisation.

	Inspection	Anhydrous lens is inspected.
	Lens hydration	Lens is hydrated in saline solution; increases in size; some monomers may be extracted; may include coating.
	Insertion into vial or blister pack	This may be a glass vial with a bung and aluminium seal, blister pack, or alternative option.
	Autoclaving	Vial or other pack with lens inside are autoclaved.
Spin casting	Mould creation	A male tool is used to create a female mould.
	Monomers inserted into spinning mould	Monomers are added into the spinning female mould to form desired shape.
	Polymerisation	This may be thermal or UV polymerisation.
	Edge polishing	This stage may not be performed in all cases.
	Inspection	Anhydrous lens is inspected.
	Lens hydration	Lens is hydrated in saline solution; increases in size; some monomers may be extracted; may include coating.
	Insertion into blister pack or vial	This may be a blister pack, a glass vial with a bung and aluminium seal, or alternative option.
	Autoclaving	Vial or other pack with lens inside are autoclaved.
Other	N/A	N/A

For contact lens solution, a typical manufacturing process may include the steps in Table 20.

Table 20: Common manufacturing processes for contact lens solution

Stage	Description
Water purification	Treatment of water to meet desired specifications.
Formulation	Formulation of raw ingredients and water.
Mixing	Mixing of ingredients.
Filtration	Filtration of product in sterile environment.

In addition, the activities in Table 21 shall be included within the manufacturing stage, where applicable.

Table 21: Other activities included in manufacturing stage

Activity	Description
Sterilisation	Activities performed to make the products clean, free from any microorganisms, and safe for consumer use. Includes personal protective equipment (PPE) requires for sterilisation process.
Inspection	Inspection of product to check for defects
Testing	Any testing performed on product to ensure it meets required standards.
Filling	Inserting liquid products into primary packaging.
Packing	Inserting products into primary packaging.

Company-specific information shall be collected for: manufacturing location(s), energy types (e.g. electricity, natural gas, etc), quantity of energy used, and water use relating to manufacturing processes under operational control of the producer. The same data should be obtained where possible for manufacturing processes outside of the operational control of the producer. However, for any manufacturing stages where data cannot be obtained, the best possible estimate shall be made and the assumptions behind these estimates shall be clearly documented.

The use of renewable or grid electricity may be considered.

Company-specific data should be collected for the masses and materials of other auxiliary inputs (any inputs not considered in the raw material acquisition stage) where possible. Estimates may be used where auxiliary inputs are unknown, but these estimates shall be clearly documented and available for users of the LCA results (if no auxiliary inputs are assumed to be relevant, the assumption that no additional auxiliary inputs are included should also be documented).

Secondary data may be used for background processes.

6.2.2 Internal transport

All transportation of the unfinished products (e.g. between different manufacturing sites) shall be included within the manufacturing lifecycle stage. Company-specific data should be collected on the transport distances, mass of material transported (relating back to the functional unit), and transport mode. Where company-specific data on internal transport cannot be obtained, estimates may be used. However, these estimates shall be clearly documented and available for users of the LCA results (if no internal transport is assumed to be relevant, the assumption that internal transport is not included should also be documented).

6.2.3 Sterilisation, packing, and filling

The manufacturing life cycle stage should include activities relating to sterilisation, packing, and filling.

Company-specific data about the energy use, water use, material use, and other auxiliary inputs of the sterilisation stage should be used where possible. Estimates may be used where details about the sterilisation process are unknown, but these estimates shall be clearly documented and available for users of the LCA results (if no sterilisation is assumed to be relevant, the assumption that sterilisation is not included should also be documented). Waste produced during the sterilisation process should be included in this life cycle stage. Waste should also include any PPE required during the sterilisation phase (e.g. single-use sterile gowns, hair nets, etc).

6.3 Distribution

Transport from factory to final client (including consumer transport) shall be modelled within this life cycle stage. The final client is defined as the user of the contact lens or contact lens solution.

In case supply-chain-specific information is available for one or several transport parameters, they should be applied following the Data Needs Matrix.

The distribution stage shall include transport and storage activities, including any energy-use requirements of storage (i.e. keeping the product at a certain temperature). Infrastructure such as the construction of storage facilities, ports, or roads should be excluded from this life cycle stage.

Distribution may be direct to the customer or indirect via a third-party. Two scenarios have been defined below. In some cases, both scenarios may be applicable to a product. In those cases, a weighted average of the two scenarios may be applied, based on the mass of product applicable to each scenario. Any estimates or assumptions made shall be clearly documented.

In both cases, supply-chain-specific data should be used where possible, including mass of raw material, transport mode, distance per transport mode, utilisation ratios for truck transport, and empty return modelling for truck transport. Where supply-chain-specific data is unavailable, the default data in

Table 22 shall be used.

When using the below table select the geographic scenario that applies and include all transport modes within that scenario.

Table 22: All distribution.

Geography – distribution takes place:	Transport mode	Transport distance	Details	Utilisation*
Within one country	Truck (lorry)	200 km	>32 tonne truck, EURO 4	64%
Within one continent	Truck (lorry)	1,900 km	>32 tonne truck, EURO 4	64%
	Ship	1,600 km	Transoceanic container ship	N/A
	Air freight	1,000 km	transport, freight, aircraft, long haul	N/A
International (between continents)	Truck (lorry)	1,000 km	>32 tonne truck, EURO 4	64%
	Ship	9,000 km	Transoceanic container ship	N/A
	Air freight	5,000 km	transport, freight, aircraft, long haul	N/A

**Utilisation rate considers return journey of truck*

Default data follows the PEFCR guidance version 6.3 [3].

6.3.1 Distribution to optician, third-party retailer or other intermediary

This scenario applies when the product is not distributed directly from the manufacturer to the customer, but instead is distributed via an optician, third-party retailer, or other intermediary.

In addition to the distribution to retail or optician, customer transport should be included. The default data Table 23 in shall be used for customer transport in all cases where the customer collects the product from a retailer or optician.

Table 23: Customer transport (from retail to location of use)

Transport mode	Transport distance	Details	Utilisation
Car	5 km	Average passenger car	20%
Van	5 km	Average van, <7.5 tonnes	20%
Other	N/A – assumed to have zero impact	N/A – assumed to have zero impact	N/A – assumed to have zero impact

Default data follows the PEFCR guidance version 6.3 [3].

6.3.2 Distribution direct to customer

This scenario applies when the product is distributed directly from the manufacturer to the customer (including cases where it is temporarily stored at another facility during its journey).

In addition to the distribution to the general location of the customer, such as the distribution centre (DC), the final leg of transport to the customer's location shall be included. Where supply-chain-specific data is unavailable, the default data in Table 24 shall be used.

Table 24: Distribution to final customer

Transport mode	Transport distance	Details	Utilisation
Van	250 km	Average van, <7.5 tonnes	20%

Default data follows the PEFCR guidance version 6.3 [3].

No additional consumer transport is relevant in this scenario.

6.4 Use

The use stage starts at the moment when the end user uses the product, until it enters the end-of-life cycle stage.

Use phase activities are considered for the soft contact lenses and hard contact lenses sub-categories only. The product's instructions for use (IFU) shall be used to determine the applicable use phase activities.

Table 25 defines the use phase activities that may be relevant. Hand washing shall be considered for both daily disposable and reusable contact lenses. Cleaning and storage of contact lenses shall be considered for reusable contact lenses only.

Where the lenses require the use of a case, the manufacturing and end-of-life (EOL) impacts of the case shall be included, allocated based on the lifetime number of uses of the case. For example, if a case was expected to last for 30 uses, 1/30th of the total impacts of the manufacture and EOL impacts of the case would be applied to one use of the lens.

Table 25: Default data to be employed in the use phase.

Process	Unit of Measurement	Default amount per FU
Water Consumption	litres/contact lens use	2
Wastewater	litres/contact lens use	2
Soap	ml/contact lens use	6
Multipurpose Solution	ml/contact lens use	3
Contact lens case	g/contact lens use	0.22

This guidance assumes a 5% loss rate of studied products in line with the assumptions provided in Annex F of the PEF method. [2] It should be assumed that 5% of lenses are lost to wastage (i.e. tears, splits, etc) and it should be assumed that 5% of solution is wasted.

6.5 End-of-life

The end-of-life stage begins when the product in scope (i.e. lens or solution) and its packaging is discarded by the user and ends when the product is returned to nature as a waste product or enters another product's life cycle (i.e. as a recycled input). In general, it includes the waste of the product in scope, such as the lens or solution, and primary packaging.

Other waste (different from the product in scope) generated during the manufacturing, distribution, retail, use stage or after use shall be included in the life cycle of the product and modelled at the life cycle stage where it occurs.

As defined in Section 5.10, the cut-off approach shall be used by default. However, other end-of-life allocation approaches such as the Circular Footprint Formula (CFF) may be applied as an optional additional assessment.

End-of-life should consider the mass of the product, the material types, and the likely end-of-life pathways (i.e. recycling, landfill, incineration) within the relevant geography. Therefore, users of this guidance should understand the recycling, landfill, and incineration rates within the geographies that the products are sold. All assumptions about end-of-life pathways shall be clearly documented.

7 PEF Results

The user of the PEFCR shall calculate the environmental profile of its product in compliance with all requirements included in this PEFCR. The following information shall be included in the PEF report:

- full life cycle inventory, with confidential data redacted as required;
- characterised results in absolute values, for all impact categories (as a table);
- normalised results in absolute values, for all impact categories (as a table);
- weighted result in absolute values, for all impact categories (as a table);
- the aggregated single overall score in absolute values.

8 References

[1] European Commission, “European Platform on LCA | EPLCA,” [Online]. Available: http://eplca.jrc.ec.europa.eu/LCDN/developerEF.xhtml.

[2] L. Zampori and R. Pant, “Suggestions for updating the Product Environmental Footprint Method,” *JRC Technical Reprots,* 2019.

[3] European Comission, “PEFCR Guidance document - Guidance for the 13 development of Product Environmental Footprint Category Rules (PEFCRs), version 6.3,” 2018.

[4] K. Hughes, “The manufacture of contact lenses,” Optician, [Online]. Available: https://www.opticianonline.net/cpd-archive/6066/. [Accessed 9 January 2025].

[5] European Commission, “Normalization Factors (NF) for Environmental Footprint (EF) 3.1,” 2022. [Online]. Available: https://eplca.jrc.ec.europa.eu/permalink/EF3_1/Normalisation_Weighting_Factors_EF_3.1.xlsx.

[6] World resources institute, “GHG Protocol Corporate Accounting and Reporting Standard,” 2011. [Online]. Available: https://ghgprotocol.org/corporate-standard.

Appendix A

A.1 List of acronyms

Table 26: List of acronyms.

Abbreviation	Definition
ADEME	Agence de l'Environnement et de la Maîtrise de l'Energie
AF	Allocation factor
AR	Allocation ratio
B2B	Business to business
B2C	Business to consumer
BoC	Bill of components
BoM	Bill of materials
BP	Bonne practique
BSI	British Standards Institution
CF	Characterization factor
CFCs	Chlorofluorocarbons
CFF	Circular Footprint Formula
CPA	Classification of Products by Activity
DC	Distribution centre
DMI	Dry matter intake
DNM	Data Needs Matrix
DQR	Data Quality Rating
EC	European Commission
EF	Environmental Footprint
EI	Environmental impact
EMAS	Eco-Management and Audit Scheme
EMS	Environmental Management Systems
EoL	End-of-life
EPD	Environmental Product Declaration
FU	Functional unit
GE	Gross energy intake
GHG	Greenhouse gas
GR	Geographical representativeness
GRI	Global Reporting Initiative
GWP	Global warming potential

ILCD	International Reference Life Cycle Data System
ILCD-EL	International Reference Life Cycle Data System – Entry Level
IPCC	Intergovernmental Panel on Climate Change
ISIC	International standard industrial classification
ISO	International Organisation for Standardisation
IUCN	International Union for Conservation of Nature and Natural Resources
JRC	Joint Research Centre
LCA	Life Cycle Assessment
LCDN	Life Cycle Data Network
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
LCT	Life Cycle Thinking
LT	Lifetime
NACE	Nomenclature Générale des Activités Economiques dans les Communautés Européennes
NDA	Non-disclosure Agreement
NGO	Non-governmental Organisation
NMVOC	Non-methane Volatile Compounds
P	Precision
PAS	Publicly Available Specification
PCR	Product Category Rules
PEF	Product Environmental Footprint
PEFCR	Product Environmental Footprint Category Rules
PEF-RP	PEF Study of the Representative Product
RF	Reference Flow
RP	Representative Product
SB	System Boundary
SMRS	Sustainability Measurement & Reporting System
SS	Supporting Study
TeR	Technological Representativeness
TiR	Time Representativeness
TS	Technical Secretariat
UNEP	United Nations Environment Programme
UUID	Universally Unique Identifier
WBCSD	World Business Council for Sustainable Development
WRI	World Resources Institute

A.1 List of definitions

Activity data - This term refers to information which is associated with processes while modelling Life Cycle Inventories (LCI). The aggregated LCI results of the process chains that represent the activities of a process are each multiplied by the corresponding activity data[10] and then combined to derive the environmental footprint associated with that process. Examples of activity data include quantity of kilowatt-hours of electricity used, quantity of fuel used, output of a process (e.g. waste), number of hours equipment is operated, distance travelled, floor area of a building, etc. Synonym of “non-elementary flow”.

Acidification - EF impact category that addresses impacts due to acidifying substances in the environment. Emissions of NO_x, NH_3 and SO_x lead to releases of hydrogen ions (H+) when the gases are mineralised. The protons contribute to the acidification of soils and water when they are released in areas where the buffering capacity is low, resulting in forest decline and lake acidification.

Additional environmental information - Environmental information outside the EF impact categories that is calculated and communicated alongside PEF results.

Additional technical information - Non-environmental information that is calculated and communicated alongside PEF results.

Aggregated dataset - Complete or partial life cycle of a product system that next to the elementary flows (and possibly not relevant amounts of waste flows and radioactive wastes) lists in the input/output list exclusively the product(s) of the process as reference flow(s), but no other goods or services. Aggregated datasets are also called "LCI results” datasets. The aggregated dataset may have been aggregated horizontally and/or vertically.

Allocation - An approach to solving multi-functionality problems. It refers to “partitioning the input or output flows of a process or a product system between the product system under study and one or more other product systems” (ISO 14040:2006).

Application specific - It refers to the generic aspect of the specific application in which a material is used. For example, the average recycling rate of PET in bottles.

Attributional - Refers to process-based modelling intended to provide a static representation of average conditions, excluding market-mediated effects.

Average Data - Refers to a production-weighted average of specific data.

Background processes - Refers to those processes in the product life cycle for which no direct access to information is possible. For example, most of the upstream life-cycle processes and generally all processes further downstream will be considered part of the background processes.

Benchmark - A standard or point of reference against which any comparison may be made. In the context of PEF, the term ‘benchmark’ refers to the average environmental performance of the representative product sold in the EU market.

Bill of materials - A bill of materials or product structure (sometimes bill of material, BOM or associated list) is a list of the raw materials, sub-assemblies, intermediate assemblies, sub-

[10] Based on GHG protocol scope 3 definition from the Corporate Accounting and Reporting Standard [6].

components, parts and the quantities of each needed to manufacture the product in scope of the PEF study. In some sectors it is equivalent to the bill of components.

Business to Business (B2B) - Describes transactions between businesses, such as between a manufacturer and a wholesaler, or between a wholesaler and a retailer.

Business to Consumers (B2C) - Describes transactions between business and consumers, such as between retailers and consumers. According to ISO 14025:2006, a consumer is defined as “an individual member of the general public purchasing or using goods, property or services for private purposes”.

Characterisation - Calculation of the magnitude of the contribution of each classified input/output to their respective EF impact categories, and aggregation of contributions within each category. This requires a linear multiplication of the inventory data with characterisation factors for each substance and EF impact category of concern. For example, with respect to the EF impact category “climate change”, CO_2 is chosen as the reference substance and kg CO_2-equivalents as the reference unit.

Characterisation factor - Factor derived from a characterisation model which is applied to convert an assigned life cycle inventory result to the common unit of the EF impact category indicator (based on ISO 14040:2006).

Classification - Assigning the material/energy inputs and outputs tabulated in the life cycle inventory to EF impact categories according to each substance’s potential to contribute to each of the EF impact categories considered.

Climate change - All inputs or outputs that result in greenhouse gas emissions. The consequences include increased average global temperatures and sudden regional climatic changes. Climate change is an impact affecting the environment on a global scale.

Co-function - Any of two or more functions resulting from the same unit process or product system.

Commissioner of the EF study - Organisation (or group of organisations) that finances the EF study in accordance with the PEF method and the relevant PEFCR, if available (definition adapted from ISO 14071/2014, point 3.4).

Company-specific data - It refers to directly measured or collected data from one or multiple facilities (site-specific data) that are representative for the activities of the company. It is synonymous to “primary data”. To determine the level of representativeness a sampling procedure may be applied.

Company-specific dataset - It refers to a dataset (disaggregated or aggregated) compiled with company-specific data. In most cases the activity data is company-specific while the underlying sub-processes are datasets derived from background databases.

Comparative Assertion - An environmental claim regarding the superiority or equivalence of one product versus a competing product that performs the same function (including the benchmark of the product category) (adapted from ISO 14044:2006).

Comparison - A comparison, not including a comparative assertion, (graphic or otherwise) of two or more products based on the results of a PEF study and supporting PEFCRs.

Co-product - Any of two or more products resulting from the same unit process or product system (ISO 14040:2006).

Cradle to Gate - A partial product supply chain, from the extraction of raw materials (cradle) up to the manufacturer’s “gate”. The distribution, storage, use stage and end-of-life stages of the supply chain are omitted.

Cradle to Grave - A product's life cycle that includes raw material extraction, processing, distribution, storage, use, and disposal or recycling stages. All relevant inputs and outputs are considered for all of the stages of the life cycle.

Critical review - Process intended to ensure consistency between a PEFCR and the principles and requirements of the PEF method.

Data Quality - Characteristics of data that relate to their ability to satisfy stated requirements (ISO 14040:2006). Data quality covers various aspects, such as technological, geographical and time-related representativeness, as well as completeness and precision of the inventory data.

Data Quality Rating (DQR) - Semi-quantitative assessment of the quality criteria of a dataset based on Technological representativeness, Geographical representativeness, Time-related representativeness, and Precision. The data quality shall be considered as the quality of the dataset as documented.

Delayed emissions - Emissions that are released over time, e.g. through long use or final disposal stages, versus a single emission at time t.

Direct elementary flows (also named elementary flows) - All output emissions and input resource use that arise directly in the context of a process. Examples are emissions from a chemical process, or fugitive emissions from a boiler directly onsite.

Direct land use change (dLUC) - The transformation from one land use type into another, which takes place in a unique land area and does not lead to a change in another system.

Directly attributable - Refers to a process, activity or impact occurring within the defined system boundary.

Disaggregation - The process that breaks down an aggregated dataset into smaller unit process datasets (horizontal or vertical). The disaggregation may help making data more specific. The process of disaggregation should never compromise or threat to compromise the quality and consistency of the original aggregated dataset

Downstream - Occurring along a product supply chain after the point of referral.

Ecotoxicity, freshwater - Environmental footprint impact category that addresses the toxic impacts on an ecosystem, which damage individual species and change the structure and function of the ecosystem. Ecotoxicity is a result of a variety of different toxicological mechanisms caused by the release of substances with a direct effect on the health of the ecosystem.

EF communication vehicles - It includes all the possible ways that may be used to communicate the results of the EF study to the stakeholders (e.g. labels, environmental product declarations, green claims, websites, infographics, etc.).

EF compliant dataset - Dataset developed in compliance with the EF requirements provided at http://eplca.jrc.ec.europa.eu/LCDN/developer.xhtml.

Electricity tracking[11] - Electricity tracking is the process of assigning electricity generation attributes to electricity consumption.

[11] https://ec.europa.eu/energy/intelligent/projects/en/projects/e-track-ii

Elementary flows - In the life cycle inventory, elementary flows include “material or energy entering the system being studied that has been drawn from the environment without previous human transformation, or material or energy leaving the system being studied that is released into the environment without subsequent human transformation” (ISO 14040, 3.12). Elementary flows include, for example, resources taken from nature or emissions into air, water, soil that are directly linked to the characterisation factors of the EF impact categories.

Environmental aspect - Element of an organisation’s activities or products or services that interacts or can interact with the environment (ISO 14001:2015).

Environmental Footprint (EF) Impact Assessment - Phase of the PEF analysis aimed at understanding and evaluating the magnitude and significance of the potential environmental impacts for a product system throughout the life cycle of the product (based on ISO 14044:2006). The impact assessment methods provide impact characterisation factors for elementary flows in order to aggregate the impact to obtain a limited number of midpoint indicators.

Environmental Footprint (EF) Impact Assessment method - Protocol for quantitative translation of life cycle inventory data into contributions to an environmental impact of concern.

Environmental Footprint (EF) Impact Category - Class of resource use or environmental impact to which the life cycle inventory data are related.

Environmental Footprint (EF) impact category indicator - Quantifiable representation of an EF impact category (based on ISO 14000:2006).

Environmental impact - Any change to the environment, whether adverse or beneficial, that wholly or partially results from an organisation’s activities, products or services (EMAS regulation).

Environmental mechanism - System of physical, chemical and biological processes for a given EF impact category linking the life cycle inventory results to EF category indicators (based on ISO 14040:2006).

Eutrophication - Nutrients (mainly nitrogen and phosphorus) from sewage outfalls and fertilised farmland accelerate the growth of algae and other vegetation in water. The degradation of organic material consumes oxygen resulting in oxygen deficiency and, in some cases, fish death. Eutrophication translates the quantity of substances emitted into a common measure expressed as the oxygen required for the degradation of dead biomass. Three EF impact categories are used to assess the impacts due to eutrophication: Eutrophication, terrestrial; Eutrophication, freshwater; Eutrophication, marine.

External Communication - Communication to any interested party other than the commissioner or the practitioner of the study.

Extrapolated Data - Refers to data from a given process that is used to represent a similar process for which data is not available, on the assumption that it is reasonably representative.

Flow diagram - Schematic representation of the flows occurring during one or more process stages within the life cycle of the product being assessed.

Foreground elementary flows - Direct elementary flows (emissions and resources) for which access to primary data (or company-specific information) is available.

Foreground Processes - Refer to those processes in the product life cycle for which direct access to information is available. For example, the producer’s site and other processes operated by the producer or its contractors (e.g. goods transport, head-office services, etc.) belong to the foreground processes.

Functional unit - The functional unit defines the qualitative and quantitative aspects of the function(s) and/or service(s) provided by the product being evaluated. The functional unit definition answers the questions “what?”, “how much?”, “how well?”, and “for how long?”.

Gate to Gate - A partial product supply chain that includes only the processes carried out on a product within a specific organisation or site.

Gate to Grave - A partial product supply chain that includes only the distribution, storage, use, and disposal or recycling stages.

Global warming potential - Capacity of a greenhouse gas to influence radiative forcing, expressed in terms of a reference substance (for example, CO2-equivalent units) and specified time horizon (e.g. GWP 20, GWP 100, GWP 500, for 20, 100, and 500 years respectively). It relates to the capacity to influence changes in the global average surface air temperature and subsequent change in various climate parameters and their effects, such as storm frequency and intensity, rainfall intensity and frequency of flooding, etc.

Horizontal averaging - it is the action of aggregating multiple unit process datasets or aggregated process datasets in which each provides the same reference flow in order to create a new process dataset (UN Environment, 2011).

Human toxicity - cancer - EF impact category that accounts for adverse health effects on human beings caused by the intake of toxic substances through inhalation of air, food/water ingestion, penetration through the skin insofar as they are related to cancer.

Human toxicity - non cancer - EF impact category that accounts for the adverse health effects on human beings caused by the intake of toxic substances through inhalation of air, food/water ingestion, penetration through the skin insofar as they are related to noncancer effects that are not caused by particulate matter/respiratory inorganics or ionising radiation.

Independent external expert - Competent person, not employed in a full-time or parttime role by the commissioner of the EF study or the user of the EF method, and not involved in defining the scope or conducting the EF study (adapted from ISO 14071/2014, point 3.2).

Indirect land use change (iLUC) - It occurs when a demand for a certain land use leads to changes, outside the system boundary, i.e. in other land use types. These indirect effects may be mainly assessed by means of economic modelling of the demand for land or by modelling the relocation of activities on a global scale.

Input flows - Product, material or energy flow that enters a unit process. Products and materials include raw materials, intermediate products and co-products (ISO 14040:2006).

Intermediate product - Output form a unit process that is input to other unit processes that require further transformation within the system (ISO 14040:2006). An intermediate product is a product that requires further processing before it is saleable to the final consumer.

Ionising radiation, human health - EF impact category that accounts for the adverse health effects on human health caused by radioactive releases.

Land use - EF impact category related to use (occupation) and conversion (transformation) of land area by activities such as agriculture, forestry, roads, housing, mining, etc. Land occupation considers the effects of the land use, the amount of area involved and the duration of its occupation (changes in quality multiplied by area and duration). Land transformation considers the extent of changes in land properties and the area affected (changes in quality multiplied by the area).

Lead verifier - Verifier taking part in a verification team with additional responsibilities compared to the other verifiers in the team.

Life cycle - Consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal (ISO 14040:2006).

Life cycle approach - Takes into consideration the spectrum of resource flows and environmental interventions associated with a product from a supply-chain perspective, including all stages from raw material acquisition through processing, distribution, use, and end-of-life processes, and all relevant related environmental impacts (instead of focusing on a single issue).

Life cycle Assessment (LCA) - Compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle (ISO 14040:2006).

Life cycle impact assessment (LCIA) - Phase of life cycle assessment that aims at understanding and evaluating the magnitude and significance of the potential environmental impacts for a system throughout the life cycle (ISO 14040:2006). The LCIA methods used provide impact characterisation factors for elementary flows to in order to aggregate the impact to obtain a limited number of midpoint and/or damage indicators.

Life cycle inventory (LCI) - The combined set of exchanges of elementary, waste and product flows in a LCI dataset.

Life cycle inventory (LCI) dataset - A document or file with life cycle information of a specified product or other reference (e.g., site, process), covering descriptive metadata and quantitative life cycle inventory. A LCI dataset could be a unit process dataset, partially aggregated or an aggregated dataset.

Loading rate - Ratio of actual load to the full load or capacity (e.g. mass or volume) that a vehicle carries per trip.

Material-specific - It refers to a generic aspect of a material. For example, the recycling rate of PET.

Multi-functionality - If a process or facility provides more than one function, i.e. it delivers several goods and/or services ("co-products"), then it is “multifunctional”. In these situations, all inputs and emissions linked to the process will be partitioned between the product of interest and the other co-products according to clearly stated procedures.

Non-elementary (or complex) flows - In the life cycle inventory, non-elementary flows include all the inputs (e.g. electricity, materials, transport processes) and outputs (e.g. waste, by-products) in a system that need further modelling efforts to be transformed into elementary flows. Synonym of activity data.

Normalisation - After the characterisation step, normalisation is the step in which the life cycle impact assessment results are multiplied by normalisation factors that represent the overall inventory of a reference unit (e.g. a whole country or an average citizen). Normalised life cycle impact assessment results express the relative shares of the impacts of the analysed system in terms of the total contributions to each impact category per reference unit. When displaying the normalised life cycle impact assessment results of the different impact topics next to each other, it becomes evident which impact categories are affected most and least by the analysed system. Normalised life cycle impact assessment results reflect only the contribution of the analysed system to the total impact potential, not the severity/relevance of the respective total impact. Normalised results are dimensionless, but not additive.

Output flows - Product, material or energy flow that leaves a unit process. Products and materials include raw materials, intermediate products, co-products and releases (ISO 14040:2006).

Ozone depletion - EF impact category that accounts for the degradation of stratospheric ozone due to emissions of ozone-depleting substances, for example long-lived chlorine and bromine containing gases (e.g. CFCs, HCFCs, Halons).

Partially disaggregated dataset - A dataset with a LCI that contains elementary flows and activity data, and that only in combination with its complementing underlying datasets yield a complete aggregated LCI data set.

Partially disaggregated dataset at level-1 - A partially disaggregated dataset at level-1 contains elementary flows and activity data of one level down in the supply chain, while all complementing underlying datasets are in their aggregated form.

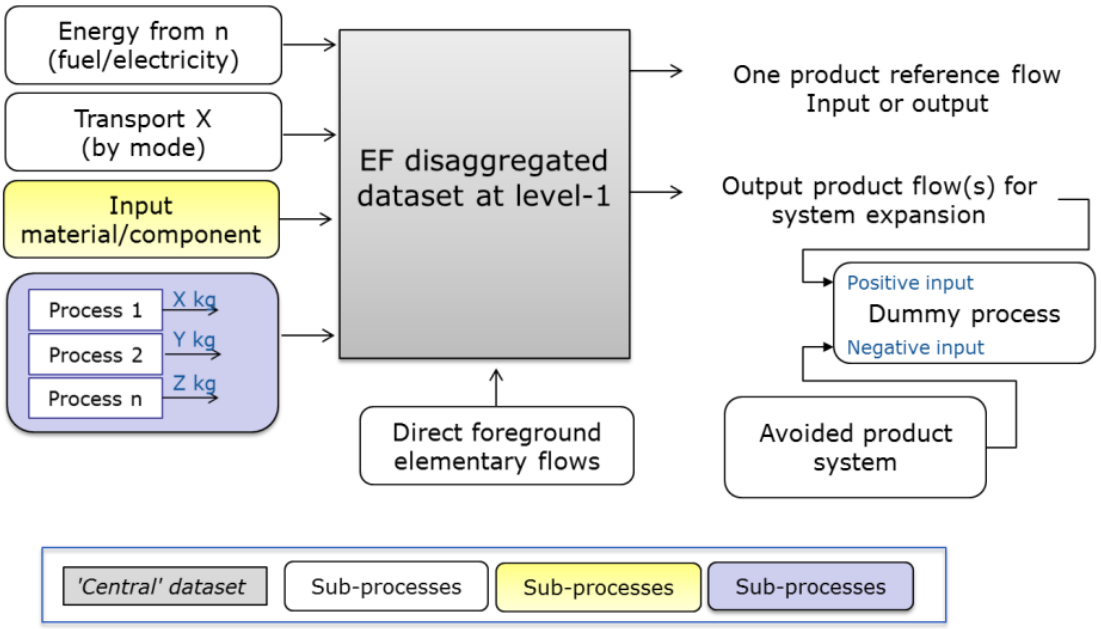

Figure 3: Example of dataset partially disaggregated at Level-1.

Particulate Matter - EF impact category that accounts for the adverse health effects on human health caused by emissions of Particulate Matter (PM) and its precursors (NOx, SOx, NH3).

PEFCR supporting study - PEF study based on a draft PEFCR. It is used to confirm the decisions taken in the draft PEFCR before the final PEFCR is released.

PEF profile - The quantified results of a PEF study. It includes the quantification of the impacts for the various impact categories and the additional environmental information considered necessary to report.

PEF report - Document that summarises the results of the PEF study.

PEF study of the representative product (PEF-RP) - PEF study carried out on the representative product(s) and intended to identify the most relevant life cycle stages, processes, elementary flows, impact categories and any other major requirements needed for the definition of the benchmark for the product category/ sub-categories in scope of the PEFCR.

PEF study - Term used to identify the totality of actions needed to calculate the PEF results. It includes the modelling, the data collection, and the analysis of the results. It excludes the PEF report and the verification of the PEF study and report.

Photochemical ozone formation - EF impact category that accounts for the formation of ozone at the ground level of the troposphere caused by photochemical oxidation of volatile organic compounds (VOCs) and carbon monoxide (CO) in the presence of nitrogen oxides (NOx) and sunlight. High concentrations of ground-level tropospheric ozone damage vegetation, human respiratory tracts and manmade materials through reaction with organic materials.

Population - Any finite or infinite aggregation of individuals, not necessarily animate, subject to a statistical study.

Primary data[12] - This term refers to data from specific processes within the supply chain of the user of the PEF method or user of the PEFCR. Such data may take the form of activity data, or foreground elementary flows (life cycle inventory). Primary data are site-specific, company-specific (if multiple sites for the same product) or supply chain specific. Primary data may be obtained through meter readings, purchase records, utility bills, engineering models, direct monitoring, material/product balances, stoichiometry, or other methods for obtaining data from specific processes in the value chain of the user of the PEF method or user of the PEFCR. In this method, primary data is synonym of "company-specific data" or "supply-chain specific data".

Product - Any goods or services (ISO 14040:2006).

Product category - Group of products (or services) that can fulfil equivalent functions (ISO 14025:2006).

Product Category Rules (PCRs) - Set of specific rules, requirements and guidelines for developing Type III environmental declarations for one or more product categories (ISO 14025:2006).

Product Environmental Footprint Category Rules (PEFCRs) - Product category specific, life cycle based rules that complement general methodological guidance for PEF studies by providing further specification at the level of a specific product category. PEFCRs help to shift the focus of the PEF study towards those aspects and parameters that matter the most, and hence contribute to increased relevance, reproducibility and consistency of the results by reducing costs versus a study based on the comprehensive requirements of the PEF method. Only the PEFCRs listed on the European Commission website (http://ec.europa.eu/environment/eussd/smgp/PEFCR_OEFSR_en.htm) are recognised as in line with this method.

Product flow - Products entering from or leaving to another product system (ISO 14040:2006).

Product system - Collection of unit processes with elementary and product flows, performing one or more defined functions, and which models the life cycle of a product (ISO 14040:2006).

Raw material - Primary or secondary material that is used to produce a product (ISO 14040:2006).

Reference flow - Measure of the outputs from processes in a given product system required to fulfil the function expressed by the functional unit (based on ISO 14040:2006).

Refurbishment - It is the process of restoring components to a functional and/ or satisfactory state to the original specification (providing the same function), using methods such as

[12] Based on GHG protocol scope 3 definition from the Corporate Accounting and Reporting Standard [6].

resurfacing, repainting, etc. Refurbished products may have been tested and verified to function properly.

Releases - Emissions to air and discharges to water and soil (ISO 14040:2006).

Representative product (model) - The RP may be a real or a virtual (non-existing) product. The virtual product should be calculated based on average European market sales-weighted characteristics of all existing technologies/materials covered by the product category or sub-category. Other weighting sets may be used, if justified, for example weighted average based on mass (ton of material) or weighted average based on product units (pieces).

Representative sample - A representative sample with respect to one or more variables is a sample in which the distribution of these variables is exactly the same (or similar) as in the population from which the sample is a subset.

Resource use, fossil - EF impact category that addresses the use of non-renewable fossil natural resources (e.g. natural gas, coal, oil).

Resource use, minerals and metals - EF impact category that addresses the use of non-renewable abiotic natural resources (minerals and metals).

Sample - A sample is a subset containing the characteristics of a larger population. Samples are used in statistical testing when population sizes are too large for the test to include all possible members or observations. A sample should represent the whole population and not reflect bias toward a specific attribute.

Secondary data[13] - It refers to data not from a specific process within the supply-chain of the company performing a PEF study. This refers to data that is not directly collected, measured, or estimated by the company, but sourced from a third party LCI database or other sources. Secondary data includes industry average data (e.g., from published production data, government statistics, and industry associations), literature studies, engineering studies and patents, and may also be based on financial data, and contain proxy data, and other generic data. Primary data that go through a horizontal aggregation step are considered as secondary data.

Sensitivity analysis - Systematic procedures for estimating the effects of the choices made regarding methods and data on the results of a PEF study (based on ISO 14040: 2006). Site-specific data – It refers to directly measured or collected data from one facility (production site). It is synonymous to “primary data”.

Specific Data - Refers to directly measured or collected data representative of activities at a specific facility or set of facilities. Synonymous with “primary data.”

Subdivision - Subdivision refers to disaggregating multifunctional processes or facilities to isolate the input flows directly associated with each process or facility output. The process is investigated to see whether it may be subdivided. Where subdivision is possible, inventory data should be collected only for those unit processes directly attributable to the products/services of concern.

[13] Based on GHG protocol scope 3 definition from the Corporate Accounting and Reporting Standard [6].

Sub-population - Any finite or infinite aggregation of individuals, not necessarily animate, subject to a statistical study that constitutes a homogenous sub-set of the whole population. Synonymous with “stratum”.

Sub-processes - Those processes used to represent the activities of the level 1 processes (=building blocks). Sub-processes may be presented in their (partially) aggregated form (see Figure 3).

Sub-sample - A sample of a sub-population.

Supply chain - It refers to all of the upstream and downstream activities associated with the operations of the user of the PEF method, including the use of sold products by consumers and the end-of-life treatment of sold products after consumer use.

Supply chain specific - It refers to a specific aspect of the specific supply chain of a company. For example the recycled content value of an aluminium may produced by a specific company.

System boundary - Definition of aspects included or excluded from the study. For example, for a “cradle-to-grave” EF analysis, the system boundary includes all activities from the extraction of raw materials through the processing, distribution, storage, use, and disposal or recycling stages.

System boundary diagram - Graphic representation of the system boundary defined for the PEF study.

Temporary carbon storage - happens when a product reduces the GHGs in the atmosphere or creates negative emissions, by removing and storing carbon for a limited amount of time.

Type III environmental declaration - An environmental declaration providing quantified environmental data using predetermined parameters and, where relevant, additional environmental information (ISO 14025:2006). The predetermined parameters are based on the ISO 14040 series of standards, which is made up of ISO 14040 and ISO 14044.

Uncertainty analysis - Procedure to assess the uncertainty in the results of a PEF study due to data variability and choice-related uncertainty.

Unit process - Smallest element considered in the LCI for which input and output data are quantified (based on ISO 14040:2006).

Unit process, black box - Process chain or plant level unit process. This covers horizontally averaged unit processes across different sites. Covers also those multifunctional unit processes, where the different co-products undergo different processing steps within the black box, hence causing allocation problems for this dataset.

Unit process, single operation - Unit operation type unit process that cannot be further subdivided. Covers multi-functional processes of unit operation type.

Upstream - Occurring along the supply chain of purchased goods/ services prior to entering the system boundary.

User of the PEFCR - a stakeholder producing a PEF study based on a PEFCR.

User of the PEF method - a stakeholder producing a PEF study based on the PEF method.

User of the PEF results - a stakeholder using the PEF results for any internal or external purpose.

Verification - Conformity assessment process carried out by an environmental footprint verifier to demonstrate whether the PEF study has been carried out in compliance with the most updated version of the PEF method adopted by the Commission.

Validation - Confirmation by the environmental footprint verifier, that the information and data included in the PEF study, PEF report and the communication vehicles are reliable, credible and correct.

Validation statement - Conclusive document aggregating the conclusions from the verifiers or the verification team regarding the EF study. This document is mandatory and shall carry the electronic or handwritten signature of the verifier or, in case of a verification panel, of the lead verifier.

Verification report - Documentation of the verification process and findings, including detailed comments from the verifier(s), as well as the corresponding responses. This document is mandatory, but it may be confidential. The document shall carry the electronic or handwritten signature of the verifier, or in case of a verification panel, of the lead verifier.

Verification team - Team of verifiers that will perform the verification of the EF study, of the EF report and the EF communication vehicles.

Verifier - Independent external expert performing a verification of the EF study and eventually taking part in a verification team.

Vertical aggregation - Technical- or engineering-based aggregation refers to vertical aggregation of unit processes that are directly linked within a single facility or process rain. Vertical aggregation involves combining unit process datasets (or aggregated process datasets) together linked by a flow (UN Environment, 2011).

Waste - Substances or objects which the holder intends or is required to dispose of (ISO 14040:2006).

Water use - It represents the relative available water remaining per area in a watershed, after the demand of humans and aquatic ecosystems has been met. It assesses the potential of water deprivation, to either humans or ecosystems, building on the assumption that the less water remaining available per area, the more likely another user will be deprived (see also http://www.wulca-waterlca.org/aware.html).

Weighting - Weighting is a step that supports the interpretation and communication of the results of the analysis. PEF results are multiplied by a set of weighting factors, which reflect the perceived relative importance of the impact categories considered. Weighted EF results may be directly compared across impact categories, and also summed across impact categories to obtain a single overall score.

Appendix B

Global normalisation factors are applied within the EF. The normalisation factors as the global impact per person are used in the EF calculations.

Table 27 defines the normalisation and weighting factors used in EF 3.1 [5].

Table 27: Normalisation and weighting factors used in EF 3.1.

Impact categories	Unit	Normalisation factors (unit/person)	Weighting factors (%)
Acidification	mol H+ eq	5.56E+01	6.20%
Climate change	kg CO2 eq	7.55E+03	21.06%
Ecotoxicity, freshwater	CTUe	5.67E+04	1.92%
EF-particulate matter	disease incidences	5.95E-04	8.96%
Eutrophication, freshwater	kg P eq	1.61E+00	2.80%
Eutrophication, marine	kg N eq	1.95E+01	2.96%
Eutrophication, terrestrial	mol N eq	1.77E+02	3.71%
Human toxicity, cancer	CTUh	1.73E-05	2.13%
Human toxicity, non-cancer	CTUh	1.29E-04	1.84%
Ionising radiation	kBq U-235 eq	4.22E+03	5.01%
Land use	pt	8.19E+05	7.94%
Ozone depletion	kg CFC-11 eq	5.23E-02	6.31%
Photochemical ozone formation	kg NMVOC eq	4.09E+01	4.78%
Resource depletion, fossils	MJ	6.50E+04	8.32%
Resource depletion, minerals and metals	kg Sb eq.	6.36E-02	7.55%
Water use	m3 water eq of deprived water	1.15E+04	8.51%

Appendix C

Data quality assessment of generic and specific data defined by the UN Environment Global Guidance on LCA database development as described in Annex E of the EN 15804:A2 standard.

Table 28: Data quality level and criteria of the UN Environment Global Guidance on LCA database development

Quality level	Geographical representativeness	Technical representativeness	Time representativeness
Very good	Data from area under study	Data from processes and products under study. Same state of technology applied as defined in goal and scope (i.e. identical technology)	Less than 3 years difference between the reference year according to the documentation, and the time period for which data are representative
Good	Average data from larger area in which the area under study is included	Data from processes and products under study (with similar technology). Evidence of deviations in state of technology, e.g. different by-product.	Less than 6 years of difference between the reference year according to the documentation, and the time period for which data are representative
Fair	Data from area with similar production conditions	Data from processes and products under study but from different technology. This score is also applied when not technology is specified; e.g. wheat (no further specification)	Less than 10 years of difference between the reference year according to the documentation, and the time period for which data are representative
Poor	Data from area with slightly similar production conditions	Data on related processes or products; organic wheat under study, data for organic rye provided.	Less than 15 years of difference between the reference year according to the documentation, and the time period for which data are representative
Very poor	Data from unknown or distinctly different area (North America instead of Middle East, OECD-Europe instead of Russia)	Data on related processes on but with a different scale or from different technology; organic wheat under study, data for conventional wheat provided.	Age of data unknown or more than 15 years of difference between the reference year according to the documentation, and the time period for which data are representative