

BLOOD AND BLOOD DERIVED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES

PRODUCT CATEGORY CLASSIFICATION: UN CPC 35270

PCR 2016:07

VERSION 2.0

VALID UNTIL: 2026-03-14



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1 INTRODUCTION

This document constitutes Product Category Rules (PCR) developed in the framework of the International EPD® System: a programme for type III environmental declarations¹ according to ISO 14025:2006, ISO 14040:2006, ISO 14044:2006, and product-specific standards such as EN 15804 and ISO 21930 for construction products. Environmental Product Declarations (EPD) are voluntary documents for a company or organisation to present transparent, consistent and verifiable information about the environmental performance of their products (goods or services).

The rules for the overall administration and operation of the programme are the General Programme Instructions (GPI), publicly available at www.environdec.com. A PCR complements the GPI and the normative standards by providing specific rules, requirements and guidelines for developing an EPD for one or more specific product categories (see Figure 1). A PCR should enable different practitioners using the PCR to generate consistent results when assessing products of the same product category.

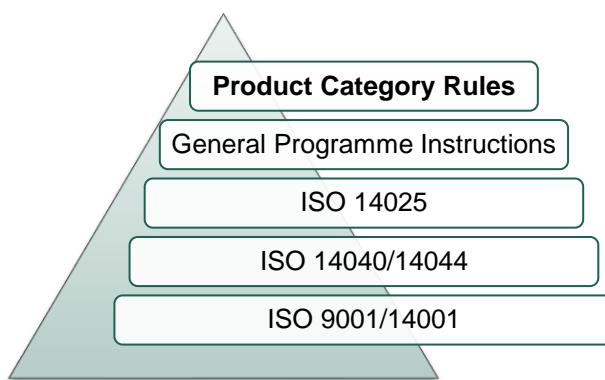


Figure 1 The hierarchy between PCRs, standards and other documents. EN 15804 and ISO 21930 are normative standards for construction products only.

Within the present PCR, the following terminology is adopted:

- The term “shall” is used to indicate what is obligatory, i.e. a requirement.
- The term “should” is used to indicate a recommendation, rather than a requirement. Any deviation from a “should” requirement shall be justified in the PCR development process.
- The terms “may” or “can” is used to indicate an option that is permissible.

For definitions of further terms used in the document, see the normative standards.

A PCR is valid for a pre-determined period of time to ensure that it is updated at regular intervals. The latest version of the PCR is available at www.environdec.com. Stakeholder feedback on PCRs is very much encouraged. Any comments on this PCR may be sent directly to the PCR Moderator and/or the Secretariat during its development or during its period of validity.

Any references to this document shall include the PCR registration number, name and version.

The programme operator maintains the copyright of the document to ensure that it is possible to publish, update, and make it available to all organisations to develop and register EPDs. Stakeholders participating in PCR development should be acknowledged in the final document and on the website.

¹ Type III environmental declarations in the International EPD® System are referred to as EPDs, Environmental Product Declarations.

2 GENERAL INFORMATION

2.1 ADMINISTRATIVE INFORMATION

Name:	Blood and blood derived products for therapeutic or prophylactic uses
Registration number and version:	2016:07 version 2.0
Programme:	 The International EPD® System
Programme operator:	EPD International AB, Box 210 60, SE-100 31 Stockholm, Sweden. Website: www.environdec.com E-mail: info@.environdec.com
PCR Moderator:	Elena Neri, INDACO2 SRL, elena.neri@indaco2.it
PCR Committee:	INDACO2 SRL, KEDRION SPA
Date of publication and last revision:	2022-03-14 (Version 2.0) See section 8 for version history
Valid until:	2026-03-14
Schedule for renewal:	A PCR is valid for a pre-determined time period to ensure that it is updated at regular intervals. When the PCR is about to expire, the PCR Moderator shall initiate a discussion with the Secretariat how to proceed with updating the PCR and renewing its validity. A PCR may be also be updated without prolonging its period of validity, provided significant and well-justified proposals for changes or amendments are presented. See www.environdec.com for the latest version of the PCR. When there has been an update of the PCR, the new version should be used to develop EPDs. The old version may however be used for 90 days after the publication date of the new version, as long as the old version has not expired.
Standards conformance:	<ul style="list-style-type: none">General Programme Instructions of the International EPD® System, version 4.0, based on ISO 14025 and ISO 14040/14044
PCR language(s):	At the time of publication, this PCR was available in English. If the PCR is available in several languages, these are available at www.environdec.com . In case of translated versions, the English version takes precedence in case of any discrepancies.

2.2 SCOPE OF PCR

2.2.1 PRODUCT CATEGORY DEFINITION AND DESCRIPTION

This document provides Product Category Rules (PCR) for the assessment of the environmental performance of blood and blood derived products for therapeutic or prophylactic uses and the declaration of this performance by an EPD. The product category corresponds to UN CPC 35270 Other pharmaceutical products.

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Blood and blood derived products constitute the raw material that is withdrawn from individuals, both human and animal, to provide therapeutic products used to treat different kind of disorders and maintain the flow of life of other diseased individuals. Blood can be injected as it is (after rigorous checks) or fractionated in different components (e.g. plasma and plasma derived) and used depending on the disease type (e.g. anemia, bleeding disorders as haemophilia and blood clots, blood cancer such as leukemia, lymphoma and myeloma). Albumin, globulins, gamma globulins, immunoglobulin, coagulation factors, of human or animal origin, prepared for therapeutic or prophylactic uses, are included in the scope of the PCR.

The present PCR deals with blood as raw material to produce plasma and plasma derived products for therapeutic and prophylactic uses.

The classification in the UN CPC system is Subclass 35270:

- Division: [35](#) - Other chemical products; man-made fibres
 - Group: [352](#) - Pharmaceutical products
 - Class: [3527](#) - Other pharmaceutical products
 - **Subclass: 35270 - Other pharmaceutical products (this PCR)**

More information is available at: <https://unstats.un.org/unsd/classifications/Family/Detail/1074>

2.2.2 GEOGRAPHICAL SCOPE

This PCR may be used globally.

2.2.3 EPD VALIDITY

An EPD based on this PCR shall be valid for a 5-year period starting from the date of the verification report ("approval date"), or until the EPD has been de-registered from the International EPD® System.

An EPD shall be updated and re-verified during its validity if changes in technology or other circumstances have led to:

- an increase of 10% or more of any of the declared indicators of environmental impact,
- errors in the declared information, or
- significant changes to the declared product information, content declaration, or additional environmental, social or economic information.

If such changes have occurred, but the EPD is not updated, the EPD owner shall contact the Secretariat to de-register the EPD.

3 PCR REVIEW AND BACKGROUND INFORMATION

This PCR was developed in accordance with the PCR development process described in the GPI of the International EPD® System, including open consultation and review.

3.1 OPEN CONSULTATION

3.1.1 VERSION 1.0

This PCR was available for open consultation from 2016-07-08 until 2016-09-15, during which any stakeholder was able to provide comments by posting on the PCR forum on www.environdec.com or by contacting the PCR moderator.

A total of 202 stakeholders were invited via e-mail or other means to take part in the open consultation and were encouraged to forward the invitation to other relevant stakeholders.

3.1.2 VERSION 2.0

This PCR was available for open consultation from 2021-07-02 until 2021-09-01, during which any stakeholder was able to provide comments by contacting the PCR Moderator and/or the Secretariat.

Stakeholders were invited via e-mail or other means to take part in the open consultation and were encouraged to forward the invitation to other relevant stakeholders. The following stakeholders provided comments during the open consultation and agreed to be listed as contributors in the PCR and at www.environdec.com.

- Gaia Esposito, University of Siena

3.2 PCR REVIEW

3.2.1 VERSION 1.0

PCR review panel:	<p>The Technical Committee of the International EPD® System. A full list of members available on www.environdec.com. The review panel may be contacted via info@.environdec.com.</p> <p>Members of the Technical Committee were requested to state any potential conflict of interest with the PCR moderator or PCR committee and were excused from the review.</p>
Chair of the PCR review:	Lars-Gunnar Lindfors
Review dates:	2016-11-01 until 2016-12-07

3.2.2 VERSION 2.0

PCR review panel:	<p>The Technical Committee of the International EPD® System. A full list of members is available at www.environdec.com. The review panel may be contacted via info@.environdec.com.</p> <p>Members of the Technical Committee were requested to state any potential conflict of interest with the PCR Committee, and if there were conflicts of interest they were excused from the review.</p>
Chair of the PCR review:	Maurizio Fieschi
Review dates:	2021-10-22 until 2021-12-10

3.3 EXISTING PCRS FOR THE PRODUCT CATEGORY

As part of the development of this PCR, existing PCRs and other internationally standardized methods that could potentially act as PCRs were considered to avoid unnecessary overlaps in scope and to ensure harmonisation with established methods of relevance for the product category. The existence of such documents was checked among the following EPD programmes and international standardisation bodies:

- International EPD® System. www.environdec.com.
- JEMAI EcoLeaf www.ecoleaf-jemai.jp
- JEMAI CFP Program www.cfp-japan.jp/english
- Product Environmental Footprint (PEF) www.ec.europa.eu/environment/eussd/smgp

No PCRs exist for CPC 35270.

3.4 REASONING FOR DEVELOPMENT OF PCR

This PCR was developed to enable publication of EPDs for this product category based on ISO 14025, ISO 14040/14044. The PCR enables different practitioners to generate consistent results when assessing the environmental impact of products of the same product category, and thereby it supports comparability of products within a product category.

This PCR is an update of the PCR 2016:07 v.1.1.

3.5 UNDERLYING STUDIES USED FOR PCR DEVELOPMENT

The methodological choices made during the development of this PCR (declared/functional unit, system boundary, allocation methods, impact categories, data quality rules, etc.) were primarily based on the following underlying studies:

- Project reports of "Life Cycle Assessment of the Emoclot (Factor VIII)", "Life Cycle Assessment of the Albumin" and "Life Cycle Assessment of the Ig-Vena" by Kedron SpA (Indaco2 srl, 2019), elaborated by Indaco2 srl, were the fundamental reference studies for the development of the PCR, as support for the choice of e.g. system boundaries, allocation methods and impact categories.
- EPD for EMOCLOT 500IU/10ml (2018 - S-P-00888).
- EPD for Albumin 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL (2019 - S-P-01595).
- EPD for Ig Vena 50g/l 100ml, 50ml and 200ml (2019 - S-P-01596).

From a general literature research, there are a few environmental sustainability analyses for this type of products. Downstream environmental effects, due to metabolites and pharmaceutical compound residues addressed to human use, have been largely examined (Buser et al., 1999; Heberer, 2002; Igos et al., 2012; Köhler et al., 2012; Löffler et al., 2005), mainly regarding toxicological impacts on aquatic organisms (Cunningham et al., 2006; Fent et al., 2006) and the accumulation in freshwater sediments (Bruce et al., 2010; Kümmerer, 2010; Kunkel and Radke, 2011; Radke et al., 2010; Rand-Weaver et al., 2013). Studies on upstream environmental effects of these compounds are also rare (Jiménez-González et al., 2013; Jiménez-González and Overcash, 2014; Wernet et al., 2010). This lack is probably due to the limited data on industrial production processes, often classified as confidential. The abovementioned studies suggest that electricity and fossil fuel consumption, disposable materials and packaging constitute the hotspots of the production chain. Transport and product distribution have a small relevance in terms of environmental impacts.

4 GOAL AND SCOPE, LIFE CYCLE INVENTORY AND LIFE CYCLE IMPACT ASSESSMENT

The goal of this section is to provide specific rules, requirements and guidelines for developing an EPD for the product category as defined in Section 2.2.1.

4.1 FUNCTIONAL UNIT

The functional unit is a single dose of product, ready to be administered to one recipient (human or animal). It should also include the kit necessary to inject the dose (e.g. syringe, pipe, needle, solvent, leaflet) and the primary and secondary packaging (e.g. vial, plastic bag, cardboard box). The single dose concentration shall be declared. The reference flow is defined as one dose of product at the administration.

If the product is produced and sold in different concentration options, the choice of a single dose concentration should refer the most commonly produced (and sold).

Any deviation should be declared and justified.

The functional unit shall be stated in the EPD. The environmental impact shall be given per functional unit. A description of the function of the product should be included in the EPD.

4.2 TECHNICAL SPECIFICATION, LIFESPAN AND REFERENCE SERVICE LIFE (RSL)

Not applicable for this product category.

4.3 SYSTEM BOUNDARY

The scope of this PCR and EPDs based on it is “cradle to grave”.

All environmentally relevant processes from “cradle to grave” should be included, so that at minimum 99% of the total energy use, mass of product content, and environmental impact is accounted for (see Section 4.5).

For intermediate products or other products for which further processing and/or the end use is unknown, the system boundary may be limited to “cradle to gate”. In this case, it shall be specified and justified in the EPD.

4.3.1 LIFE-CYCLE STAGES

For the purpose of different data quality rules and for the presentation of results, the life cycle of the product is divided into three life cycle stages:

- Upstream processes (from cradle-to-gate)
- Core processes (from gate-to-gate)
- Downstream processes (from gate-to-grave)

In the EPD, the environmental performance associated with each of the three life-cycle stages above shall be reported separately and in aggregated form. The processes included in the scope of the PCR and belonging to each life cycle stage are described in Sections 4.3.1.1–4.3.1.3.

4.3.1.1. Upstream processes

The following unit processes are part of the product system and shall be classified as upstream processes:

- extraction and processing of raw materials,
- production of input components,
- production of auxiliary materials, such as detergent for cleaning etc.

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- production of semi-products used in the core process, if applicable (e.g. primary separation of different blood component as plasma, platelets)
- relevant services, such as transport of raw materials and components along the upstream supply chain to a distribution point (e.g. a stockroom or warehouse),
- recycling processes of secondary materials from other product life cycles,
- production of distribution and consumer packaging
- generation of electricity and production of fuels, steam and other energy carriers used in upstream processes.

Upstream processes not listed may also be included. All elementary flows at resource extraction shall be included, except for the flows that fall under the general cut-off rule in Section 4.5.

4.3.1.2. Core processes

All relevant unit processes along the supply chain shall be included, for example:

- transportation of materials and components to the manufacturing of the product under study,
- manufacturing of the product under study,
- storage
- maintenance of equipment (< 5yrs) e.g. ordinary replacement of parts of machineries, silicon pipes
- end-of-life treatment of manufacturing waste, even if carried out by third parties, including transportation, and
- generation of electricity and production of fuels, steam and other energy carriers used in core processes

Core processes not listed may also be included. Manufacturing of a minimum of 99% of the total weight of the declared product including packaging shall be included.

The following processes shall not be included:

- manufacturing of production equipment, buildings and other capital goods,
- business travel of personnel,
- travel to and from work by personnel, and
- research and development activities.

4.3.1.3. Downstream processes

All relevant unit processes shall be included, for example:

- transportation of the product to retailer/distribution platform/consumer,
- product use, e.g. use of electricity or water, use activities causing direct emissions, maintenance activities,
- end-of-life treatment of product packaging, including transportation, and
- generation of electricity and production of fuels, steam and other energy carriers used in downstream processes.

4.3.2 OTHER BOUNDARY SETTING

4.3.2.1. Boundary towards nature

Boundaries to nature are defined as where the flows of material and energy resources leaves nature and enters the technical system (i.e. the product system). Emissions cross the system boundary to nature when they are emitted to air, soil or water.

4.3.2.2. Boundary towards other technical systems

Boundaries towards other technical systems define the flow of materials and components to/from the product system under study and from/to other product systems. If there is an inflow of recycled material to the product system in the production/manufacturing stage,

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the transport from the scrapyard/collection site to the recycling plant, the recycling process, and the transportation from the recycling plant to the site where the material is being used shall be included. If there is an outflow of material or component to recycling, the transportation of the material to the scrapyard/collection site shall be included. The material or component going to recycling is then an outflow from the product system.

See Section **Error! Reference source not found.4.1** for further guidance.

4.3.2.3. Temporal boundary

The temporal boundary defines the time period for which the life cycle inventory data is recorded, e.g. for how long emissions from waste deposits are accounted. As default, the time period over which inputs to and outputs from the product system is accounted for shall be 100 years from the year that the LCA model best represents, considering the representativeness of the inventory data. This year shall, as far as possible, represent the year of the publication of the EPD.

4.3.2.4. Geographical boundary

The geographical boundary defines the geographical coverage of the LCA. This shall reflect the physical reality of the product under study, accounting for the representativeness of technology, input materials and input energy.

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4.4 SYSTEM DIAGRAM

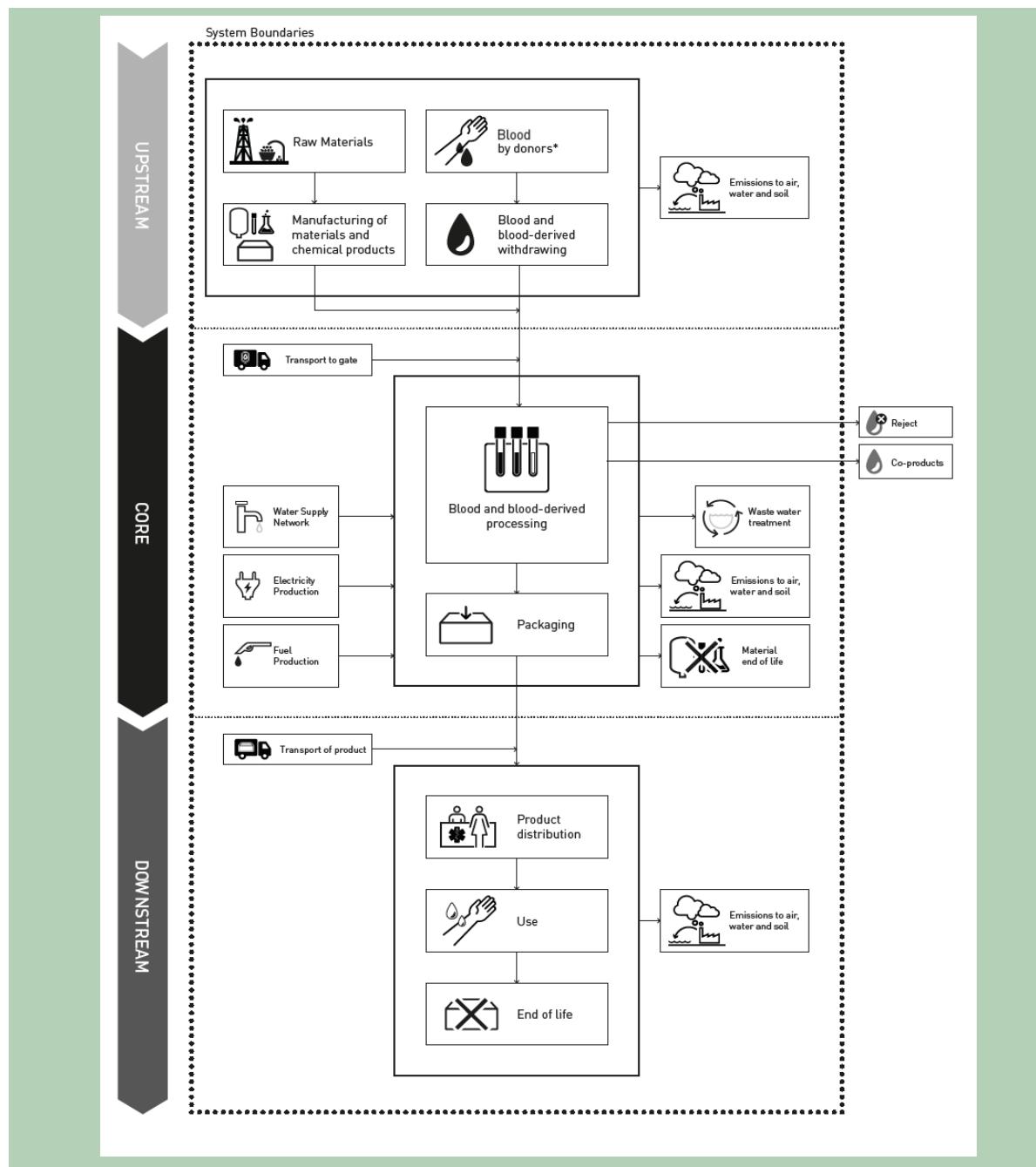


Figure 2 System diagram illustrating the processes that are included in the product system, divided into upstream, core and downstream processes. If any omission of life-cycle stages and processes are made, the system diagram should indicate it.

4.5 CUT-OFF RULES

A cut-off rule of 1% shall be applied. In other words, the included inventory data (not including inventory data of processes that are explicitly outside the system boundary as described in Section 4.3) shall together give rise to at least 99% of the results of any of the environmental impact categories. Also, 99% of the mass of the product content and 99% of the energy use of the product life cycle shall be accounted for. The cut-off of inventory data should, however, be avoided, and all available inventory data shall be used.

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The cut-off of inventory data, based on the above cut-off rule, should be an output of a sensitivity analysis, alone or in combination with expert judgment based on experience of similar product systems. Further, the cut-off shall be possible to verify in the verification process, hence the exclusion of inventory data based on the cut-off rule shall be documented in the LCA report, and the EPD developer shall provide the information the verifier considers necessary to verify the cut-off.

4.6 ALLOCATION RULES

Allocation can be divided into allocation of co-products, i.e. allocation of unit processes that generate several products, and allocation of waste, i.e. allocation of unit processes that generate materials that are, for example, landfilled recovered, recycled or reused, and which require further processing to cease being waste and become products (see criteria for end-of-waste state in Section 4.6.2).

The principles for allocation of co-products and allocation of waste are described separately in the following subsections.

4.6.1 CO-PRODUCT ALLOCATION

The following hierarchy of allocation methods shall be followed for co-product allocation:

1. Allocation shall be avoided, if possible, by dividing the process to be allocated into sub-processes and collecting the inventory data for each sub-process.
2. If allocation cannot be avoided, the inventory data should be partitioned between the different co-products in a way that reflects the underlying physical relationships between them, i.e. allocation should reflect the way in which the inventory data changes if the quantities of delivered co-products change.

In particular, since data often refer to a whole production plant (e.g. electricity, natural gas, gasoline, glycol, refrigerant gases, wastewater, sludge treatment) and are not monitored per specific production department or production chain (e.g. a number of co-products processed in a single production plant), an allocation procedure by mass should be performed. This assumption shall be opportunely justified and demonstrated in the LCA report.

3. If a physical relationship between the inventory data and the delivery of co-products cannot be established, the inventory data should be allocated between the co-products in a way that reflects other relationships between them. For example, inventory data might be allocated between co-products in proportion to their economic values. If economic allocation is used, a sensitivity analysis exploring the influence of the choice of the economic value shall be included in the LCA report.

4.6.2 ALLOCATION OF WASTE TREATMENT PROCESSES

Allocation of waste shall follow the polluter pays principle and its interpretation in EN 15804: "processes of waste processing shall be assigned to the product system that generates the waste until the end-of-waste state is reached." The end-of-waste state is reached when all the following criteria for the end-of-waste state are fulfilled (adapted from EN 15804):

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

The above outlined principle means that the generator of the waste shall carry the full environmental impact until the point in the product life cycle in which the end-of-waste criteria are fulfilled. Waste may have a negative economic market value, and then the end-of-waste stage is typically reached after (part of) the waste processing and further refinement, at the point at which the waste no longer has a negative market value. This allocation method is (in most cases) in line with a waste generator's juridical and financial responsibilities. See the GPI for further information and examples.

4.7 DATA QUALITY REQUIREMENTS AND SELECTION OF DATA

Life cycle inventory data are classified into specific data and generic data, where the latter can be selected generic data or proxy data. The data categories are defined as follows:

- specific data (also referred to as "primary data" or "site-specific data"):

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- data gathered from the actual manufacturing plant where product-specific processes are carried out;
- actual data from other parts of the life cycle traced to the product under study, for example site-specific data on the production of materials or generation of electricity provided by contracted suppliers, and transportation data on distances, means of transportation, load factor, fuel consumption, etc., of contracted transportation providers; and
- LCI data from databases on transportation and energyware that is combined with actual transportation and energy parameters as listed above.
- generic data (sometimes referred to as "secondary data"), divided into:
 - selected generic data: data (e.g. commercial databases and free databases) that fulfil prescribed data quality requirements for precision, completeness, and representativeness (see below Section 4.7.1),
 - proxy data: data (e.g. commercial databases and free databases) that do not fulfil all of the data quality requirements of "selected generic data".

Specific data shall be used for the core processes. Specific data shall be used for upstream and downstream processes, when available, otherwise generic data may be used. Generic data should be used in cases in which they are representative for the purpose of the EPD, e.g. for bulk and raw materials on a spot market, if there is a lack of specific data on the final product or if a product consists of many components.

4.7.1 RULES FOR USING GENERIC DATA

For generic data to be classified as "selected generic data", the following requirements apply:

- datasets shall be based on attributional LCA modelling (e.g., not be based on marginal data and not include credits from system expansion),
- the reference year shall be as current as possible and should be representative for the validity period of the EPD,
- the 1% cut-off rule (as described in Section 4.5) shall be met on the level of the product system,
- datasets shall represent average values for a specific reference year; however, how data are generated could vary, e.g. over time, and then they should have the form of a representative annual average value for a specified reference period (such deviations shall be justified and declared in the EPD), and
- the representativeness of the data shall be assessed to be better than $\pm 5\%$, in terms of the environmental impact calculated on the basis of the data, of data that is fully representative for the given temporal, technological and geographical context.

If selected generic data that meets the above data quality requirements are not available, proxy data may be used. The environmental impacts associated with proxy data shall not exceed 10% of the overall environmental impact of the product system.

The EPD may include a data quality declaration to demonstrate the share of specific data, selected generic data and proxy data contributing to the results of the environmental impact indicators.

4.7.2 EXAMPLES OF DATABASES FOR GENERIC DATA

No specific databases are recommended for generic data.

4.7.3 DATA QUALITY REQUIREMENTS AND OTHER MODELLING GUIDANCE PER LIFE-CYCLE STAGE

Below are further data quality requirement per life-cycle stage. Exceptions to the requirements may be accepted, if justified in the EPD; such exceptions are subject to the approval by the verifier on a case-to-case basis.

4.7.3.1. Upstream processes

- Data referring to processes and activities upstream in a supply chain over which an organisation has direct management control shall be specific and collected on site.
- Data referring to contractors that supply main parts, packaging, or main auxiliaries should be requested from the contractor as specific data, as well as infrastructure, where relevant.

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- Data on transport of main parts and components along the supply chain to a distribution point (e.g. a stockroom or warehouse) where the final delivery to the manufacturer can take place, should be specific and based on the actual transportation mode, distance from the supplier, and vehicle load.
- In case specific data is lacking, selected generic data may be used. If this is also lacking, proxy data may be used (see Section 4.7).
- For upstream processes modelled with specific data, generation of electricity used shall be accounted for in this priority:
 1. Specific electricity mix as generated, or purchased from an electricity supplier, demonstrated by a Guarantee of Origin or similar as provided by the electricity supplier.
 2. Residual electricity mix of the electricity supplier on the market.
 3. Residual electricity mix on the market.
 4. Electricity consumption mix on the market.

The residual electricity mix is the mix when all contract-specific electricity that has been sold to other customers has been subtracted from the total consumption mix.

“The market” in the above hierarchy may correspond a national electricity market, if this can be justified.

The mix of electricity used in upstream processes shall be documented in the EPD, where relevant.

- According to cut-off rules, in the case of blood derived products (e.g. blood fractionated in its different components, such as plasma and plasma derived products), the processes of blood withdrawing from donors (e.g. in hospitals or blood donation centres), energy and material use for blood withdrawing, transport of blood to control and storage centres, separation and storage before the processing, may be excluded from system boundaries. The production of any substance/material (e.g. solvent solutions, needle, pipe, leaflet) necessary to the usability of the product shall be included in the upstream phase, if produced by an external supplier company.

If blood is just pre-treated (e.g. leukocyte removal) and used for transfusion, processes from blood withdrawing to packaging in plastic bags shall be included in the upstream phase.

For both the cases above, the upstream shall also include the production of (primary and secondary) materials for packaging and disposable equipment (e.g. disposable gloves and coveralls).

- Packaging: specific data shall be used for the consumer packaging production if it is under the direct control of the organization or if the environmental impact related to the consumer packaging production is more than 10% of the total product environmental indicators. In other cases, generic data may be used. When consumer packaging shows the organization's logo, the LCA report should report the exerted/non-exerted direct control on the production of consumer packaging by the organization.

4.7.3.2. Core processes

- Transport from the final delivery point of raw materials, chemicals, main parts, and components (see above regarding upstream processes) to the manufacturing plant/place of service provision should be based on the actual transportation mode, distance from the supplier, and vehicle load, if available.
- Goods: Specific data shall be used for the assembly of the product and for the manufacture of main parts as well as for on-site generation of steam, heat, electricity, etc., where relevant.
- Services: Specific data shall be used for the consumption of materials, water, chemicals, steam, heat, electricity, fuels etc., necessary for execution of the service
- Electricity and refrigerating agents consumption (including direct emissions for refrigerating agents, if applicable) for refrigerating systems
- For electricity used in the core processes, generation of electricity used shall be accounted for in this priority:
 1. Specific electricity mix as generated, or purchased from an electricity supplier, demonstrated by a Guarantee of Origin or similar as provided by the electricity supplier.
 2. Residual electricity mix of the electricity supplier on the market.
 3. Residual electricity mix on the market.

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4. Electricity consumption mix on the market. This option shall not be used for electricity used in processes over which the manufacturer (EPD owner) has direct control².

The residual electricity mix is the mix when all contract-specific electricity that has been sold to other customers has been subtracted from the total consumption mix.

“The market” in the above hierarchy may correspond a national electricity market, if this can be justified.

The mix of electricity used in the core processes shall be documented in the EPD, where relevant.

- Waste treatment processes of manufacturing waste should be based on specific data, if available.
- The end of life of materials used during the production process (excluding the materials that constitutes the final product kit) shall be considered in the core process. These include the packaging of materials or components (e.g. pipes, filters, caps, vials), all the disposable materials contaminated by organic matter, disposable gloves and coveralls. Transport of waste to the waste plant shall be also considered. If the distance to the waste collection plant should be unknown, 50km as average distance can be used.

The core phase shall refer to gate-to-gate processes, including control, registration, transformation/production and storage.

It shall include water (and the supply network) and fuel consumption (and production).

Materials and energy necessary to produce co-product shall be excluded from the system boundaries. Rejected or unsuitable products (if not exceed 1%) are negligible and therefore may be excluded.

4.7.3.3. Downstream processes

The use phase consists in the transfusion of blood or administration of blood-derived products to recipient individuals. The environmental impacts related to the use phase (i.e. the effects on environment after the product administration) can be considered if direct measurement are available and if relevant. Otherwise, they can be neglected. The effects on human health after the administration are out of the scope of this PCR.

The following requirements apply to the downstream process:

- Data for the use stage are usually based on scenarios, but specific data should be used when available and relevant.
- Data on the emissions from the use stage should be based on documented tests, verified studies in conjunction with average or typical product use, or recommendations concerning suitable product use. Whenever applicable, test methods shall be internationally recognised.
- The use of electricity in the region/country where the product is used (as specified in the geographical scope of the EPD) shall be accounted for in the following priority:
 1. Residual electricity mix on the market.
 2. Electricity consumption mix on the market.

The residual electricity mix is the mix when all contract-specific electricity that has been sold to other customers has been subtracted from the total production mix.

“The market” in the above hierarchy may correspond a national electricity market, if this can be justified.

The mix of electricity used in the downstream processes shall be documented in the EPD, where relevant.

- The transport of the product to the customer shall be described in the EPD, where relevant, and be accounted for in this priority:
 1. Actual transportation modes and distances to specific a customer or market, representing the geographical scope of the EPD.
 2. A weighted average of transportation modes and distances, based on transportation to several customers or markets, representing the geographical scope of the EPD.

² For electricity markets without trade of Guarantees of Origin (or similar), the residual mix will, however, be identical to the consumption mix.

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3. Calculated as fixed distance, if no specific data are available, by railway (1 000 km distance) as average distribution scenario.
- Transport of final products from points of sale (pharmacy or hospital) to the final user (home) may not be included.
- Transport of waste to the waste plant should be also considered. If specific data regarding the distance to waste collection plant are not available, 50km as average distance may be used.
- Scenarios for the end-of-life stage shall be technically and economically practicable and compliant with current regulations in the relevant geographical region based on the geographical scope of the EPD. Key assumptions regarding the end-of-life stage scenario shall be documented in the LCA report.

4.7.4 DATA QUALITY DECLARATION

EPDs may include a declaration of the quality of data used in the LCA calculations.

4.8 ENVIRONMENTAL PERFORMANCE INDICATORS

The EPD shall declare the default environmental performance indicators and their methods as described at the website (www.environdec.com/indicators), which includes both inventory indicators and indicators of potential environmental impact. The source and version of the impact assessment methods and characterisations factors used shall be reported in the EPD. Alternative regional impact assessment methods and characterisation factors may be calculated and displayed in addition to the default list. If so, the EPD shall contain an explanation of the difference between the different sets of indicators, as they may appear to the reader to display duplicate information.

If the default list of environmental performance indicators and methods at the website is updated, the previous version of the list is valid in parallel to the new version during a transition period of 90 days, as described at the website.

Apart from the required inventory indicators, other inventory data may also be declared in the EPD, if relevant and useful for EPD users. Such data shall not be declared in the main body of the EPD, but in an annex.

4.9 INCLUDING MULTIPLE PRODUCTS IN THE SAME EPD

4.9.1 PRODUCTS FROM THE SAME COMPANY

Similar products from a single or several manufacturing sites covered by the same PCR and manufactured by the same company with the same major steps in the core processes may be included in the same EPD if none of the declared environmental performance indicators differ by more than 10% between any of the included products. The results for the environmental performance indicators of one representative product shall be declared according to Section 5.4.5. The choice of representative product shall be justified in the EPD, using, where applicable, statistical parameters.

4.9.2 SECTOR EPDS

The International EPD® System allows for an industry association to develop an EPD in the form of a Sector EPD. A Sector EPD declares the average product of multiple companies in a clearly defined sector in a clearly defined geographical area. Products covered in a sector EPD shall follow the same PCR and the same declared/functional unit shall be applied.

Any communication of the results from a Sector EPD should contain the information that the results are based on averages obtained from the sector as defined in the EPD. The communication shall not claim that the sector EPD results are representative for a certain manufacturer or its product.

The following information shall also be included a Sector EPD:

- a list of the contributing manufacturers that the Sector EPD covers,
- a description of how the selection of the sites/products has been done and how the average has been determined, and
- a statement that the document covers average values for an entire or partial product category (specifying the percentage of representativeness) and, hence, the declared product is an average that is not available for purchase on the market.

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5 CONTENT AND FORMAT OF EPD

EPDs based on this PCR shall contain the information described in this section. Flexibility is allowed in the formatting and layout provided that the EPD still includes the prescribed information. A generic template for EPDs is available at www.environdec.com.

The EPD content shall:

- be in line with the requirements and guidelines in ISO 14020 (Environmental labels and declarations – General principles),
- be verifiable, accurate, relevant and not misleading, and
- not include rating, judgements or direct comparison with other products³.

An EPD should be made with a reasonable number of pages for the intended audience and use.

The content of EPDs published in machine-readable format shall correspond with the content of the underlying EPD.

5.1 EPD LANGUAGES

EPDs should be published in English but may also be published in additional languages. If the EPD is not available in English, it shall contain an executive summary in English including the main content of the EPD. This summary is part of the EPD and, thus, also subject to the verification process.

5.2 UNITS AND QUANTITIES

The following requirements apply for units and quantities:

- The International System of Units (SI units) shall be used where available, e.g., kilograms (kg), Joules (J) and metres (m). Reasonable multiples of SI units may be decided in the PCR to improve readability, e.g., grams (g) or megajoules (MJ). The following exceptions apply:
 - Resources used for energy input (primary energy) should be expressed as kilowatt-hours (kWh) or megajoules (MJ), including renewable energy sources, e.g., hydropower, wind power and geothermal power.
 - Water use should be expressed in cubic metres (m³)
 - Temperature should be expressed in degrees Celsius (°C),
 - Time should be expressed in the units most practical, e.g., seconds, minutes, hours, days or years.
 - Results of the environmental performance indicators shall be expressed in the units prescribed by the impact assessment methods, e.g. kg CO₂ equivalents.
- Three significant figures⁴ should be adopted for all results. The number of significant digits shall be appropriate and consistent.
- Scientific notation may be used, e.g. 1.2E+2 for 120, or 1.2E-2 for 0.012.
- The thousand separator and decimal mark in the EPD shall follow one of the following styles (a number with six significant figures shown for illustration):
 - SI style (French version): 1 234,56
 - SI style (English version): 1 234.56

In case of potential confusion or intended use of the EPD in markets where different symbols are used, the EPD shall state what symbols are used for thousand separator and decimal mark.

- Dates and times presented in the EPD should follow the format in ISO 8601. For years, the prescribed format is YYYY-MM-DD, e.g., 2017-03-26 for March 26th, 2017.

³ Therefore, results of normalization are not allowed to be reported in the EPD.

⁴ Significant figures are those digits that carry meaning contributing to its precision. For example with two significant digits, the result of 123.45 shall be displayed as 120, and 0.12345 shall be displayed as 0.12. In scientific notation, these two examples would be displayed as 1.2*10² and 1.2*10⁻².

- The result tables shall:
 - Only contain values or the letters "ND" (Not Declared). It is not possible to specify ND for mandatory indicators. ND shall only be used for voluntary parameters that are not quantified because no data is available.⁵
 - Contain no blank cells, hyphens, less than or greater than signs or letters (except "ND").
 - Use the value "0" only for parameters that have been calculated to be zero.
 - Footnotes shall be used to explain any limitation to the result value.

5.3 USE OF IMAGES IN EPD

Images used in the EPD, especially pictures featured on the cover page, may in themselves be interpreted as an environmental claim. Images such as trees, mountains, wildlife that are not related to the declared product shall therefore be used with caution and in compliance with national legislation and best available practices in the markets in which the EPD is intended to be used.

5.4 EPD REPORTING FORMAT

The reporting format of the EPD shall include the following sections:

- Cover page (see Section 5.4.1)
- Programme information (see Section 5.4.2)
- Product information (see Section 5.4.3)
- Content declaration (see Section □)
- Environmental performance (see Section 5.4.5)
- Additional environmental information (see Section 5.4.6)
- Additional social and economic information (see Section 5.4.7)
- References (see Section 5.4.9)

The following sections shall be included, if relevant:

- Differences versus previous versions (see Section 5.4.8)
- Executive summary in English (see Section 5.4.10)

5.4.1 COVER PAGE

The cover page shall include:

- Product name and image
- Name and logotype of EPD owner
- The text "Environmental Product Declaration" and/or "EPD"
- Programme: The International EPD® System, www.environdec.com
- Programme operator: EPD International AB
- Logotype of the International EPD® System
- EPD registration number as issued by the programme operator⁶
- Date of publication (issue): 20XX-YY-ZZ

⁵ This requirement does not intend to give guidance on what indicators are mandated ("shall") or voluntary.

⁶ The EPD shall not include a "registration number" if such is provided by the certification body, as this may be confused with the registration number issued by the programme operator.

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- Date of revision and version of the document: 20XX-YY-ZZ, V. W.W, when applicable
- Date of validity: 20XX-YY-ZZ
- A note that “*An EPD should provide current information and may be updated if conditions change. The stated validity is therefore subject to the continued registration and publication at www.environdec.com.*”
- A statement of conformity with ISO 14025.
- For EPDs covering multiple products: a statement that the EPD covers multiple products and a list of all products covered by the EPD.
- For Sector EPDs: a statement that the EPD is a Sector EPD.

Where applicable, the cover page shall also include the following information:

- Information about dual registration of EPD in another programme, such as registration number and logotype.
- A statement of conformity with other standards and methodological guides.

5.4.2 PROGRAMME INFORMATION

The programme information section of the EPD shall include:

- Address of programme operator: *EPD International AB, Box 210 60, SE-100 31 Stockholm, Sweden, E-mail: info@environdec.com*
- The following statement on the requirements for comparability of EPDs, adapted from ISO 14025: “*EPDs within the same product category but from different programmes may not be comparable. For two EPDs to be comparable, they must be based on the same PCR (including the same version number) or be based on fully aligned PCRs or versions of PCRs; cover products with identical functions, technical performances and use (e.g. identical declared/functional units); have equivalent system boundaries and descriptions of data; apply equivalent data quality requirements, methods of data collection, and allocation methods; apply identical cut-off rules and impact assessment methods (including the same version of characterisation factors); have equivalent content declarations; and be valid at the time of comparison.*”
- A statement that the EPD owner has the sole ownership, liability and responsibility of the EPD
- Information about verification⁷ and the PCR in a table with the following format and contents:

Product category rules (PCR): <name, registration number, version and UN CPC code(s)>
PCR review was conducted by: <name and organisation of the review chair, and information on how to contact the chair through the programme operator>
Independent third-party verification of the declaration and data, according to ISO 14025:2006:
<input type="checkbox"/> EPD process certification <input type="checkbox"/> EPD verification <input type="checkbox"/> Pre-verified tool
<i>In case of certification bodies:</i> Accredited by: <name of the accreditation body and accreditation number, if applicable>.
<i>In case of individual verifiers:</i> <Name, and organisation of the individual verifier. The signature may also be included> Approved by: The International EPD® System
The procedure for follow-up during EPD validity, as defined in the GPI, involves third-party verifier:
<input type="checkbox"/> Yes <input type="checkbox"/> No

⁷ If the EPD has been verified by an approved individual verifier who has received contractual assistance from a certification body that is not accredited, this certification body shall not be included in this table.

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5.4.3 PRODUCT INFORMATION

The product information section of the EPD shall include:

- address and contact information to EPD owner,
- description of the organisation. This may include information on products- or management system-related certifications (e.g. ISO 14024 Type I environmental labels, ISO 9001- and 14001-certificates and EMAS-registrations) and other relevant work the organisation wants to communicate (e.g. SA 8000, supply-chain management and social responsibility),
- name and location of production site,
- product identification by name, and an unambiguous identification of the product by standards, concessions or other means,
- identification of the product according to the UN CPC scheme system. Other relevant codes for product classification may also be included, e.g.
 - Common Procurement Vocabulary (CPV),
 - United Nations Standard Products and Services Code® (UNSPSC),
 - Classification of Products by Activity (NACE/CPA),
 - Australian and New Zealand Standard Industrial Classification (ANZSIC), or
 - Global Trade Item Number (GTIN).
- a description of the product,
- a description of the technical purpose of the product, including its application/intended use,
- a description of the background system, including the main technological aspects,
- for EPDs covering multiple products: a description of the selection of products/sites, a list of contributing manufacturers (if Sector EPD), etc. (see Section 4.9),
- geographical scope of the EPD, i.e., for which geographical location(s) of use and end-of-life the product's performance has been calculated,
- functional unit,
- reference service life (RSL) and/or technical/actual lifespan, if relevant,
- declaration of the year(s) covered by the data used for the LCA calculation and other relevant reference years,
- reference to the main database(s) for generic data and LCA software used, if relevant,
- system diagram of the processes included in the LCA, divided into the life cycle stages,
- description if the EPD system boundary is "cradle-to-gate", "cradle-to-gate with options" or "cradle-to-grave",
- information on which life-cycle stages are not considered (if any), with a justification of the omission, and
- references to any relevant websites for more information or explanatory materials.

This section may also include:

- name and contact information of organisation carrying out the underlying LCA study,
- any additional information about the underlying LCA-based information, such as cut-off rules, data quality, allocation methods, and other methodological choices and assumptions,
- a description of the material properties of the product with a declaration of relevant physical or chemical product properties, such as density, etc., and
- if end-of-life treatment is not included, the EPD shall contain a statement that it shall not be used for communicating environmental information to consumers/end users of the product.

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5.4.4 CONTENT DECLARATION

The content declaration section shall declare the weight of one unit of product, as purchased, and contain information about the content of the product in the form of a list of materials and chemical substances including information on their environmental and hazardous properties. The gross weight of each material/substance shall be declared, including a minimum of 99% of the materials/substances in one unit of product.

The constituent materials of the product that shall be declared are:

- the content of the product and its concentration (including solvents or other materials necessary to administer the product, if applicable)
- auxiliary materials necessary to inject the product (e.g. butterfly valve, pipe, syringe)
- all packaging constituents

All components shall be expressed per unit quantity.

The content declaration does not apply to proprietary materials and substances covered by exclusive legal rights including patent and trademarks. In general, an indication that a product is “free” of a specific hazardous material or substance should be done with caution and only when relevant, following the rules in ISO 14021 on self-declared environmental claims.

Information on the hazardous properties of materials and chemical substances should follow the requirements given in the latest revision of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS),⁸ issued by the United Nations or national or regional applications of the GHS. As an example, the following regulations should be used for EPDs intended to be used in the European Union:

- Regulation (EC) No 1907/2006 of the European parliament and of the council of 18 December 2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH); and
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures.

5.4.4.1. Information about recycled materials

Not relevant for this product category.

5.4.5 ENVIRONMENTAL PERFORMANCE

5.4.5.1. Environmental impacts

The EPD shall declare the environmental impact indicators, per functional unit, per life-cycle stage and in aggregated form, using the default impact categories, impact assessments methods and characterisation factors available at www.environdec.com/indicators. The source and version of the impact assessment methods and characterisation factors used shall be reported in the EPD.

Alternative regional life cycle impact assessment methods and characterisation factors may be calculated and displayed in addition to the default list. If so, the EPD shall contain an explanation of the difference between the different sets of indicators, as they may appear to the reader to display duplicate information.

Taking into consideration the scope of the EPD, regional aspects or requirements, and the maturity of the methods, the following additional (optional) potential environmental impacts may be included in the LCA report and in the EPD:

- Emissions that contribute to stratospheric ozone depletion, “Ozone Depletion Potential” ODP (expressed as kg CFC-11 eq., method for the indicator calculation: CML-IA baseline , 2016).
- Emissions of P containing nutrients to freshwater, “Freshwater Eutrophication Potential” FAETP (expressed as kg P eq., method for the indicator calculation: ReCiPe v.1.11, Goedkoop et al., 2009).

⁸ The GHS document is available at www.unece.org.

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5.4.5.2. Use of resources

The EPD shall declare the indicators for resource use listed at <http://www.environdec.com/indicators> per functional unit, per life-cycle stage and in aggregated form.

5.4.5.3. Waste production and output flows

Waste generated along the whole life cycle production chains shall be treated following the technical specifications described in the GPI. The EPD shall declare the indicators for waste production and output flows as listed at www.environdec.com/indicators per functional unit, per life-cycle stage and in aggregated form.

5.4.6 ADDITIONAL ENVIRONMENTAL INFORMATION

An EPD may declare additional environmentally relevant information not derived from the LCA-based calculations, such as:

- the release of dangerous substances into indoor air, soil, and water during the use stage,
- instructions for proper use of the product,
- instructions for proper maintenance and service of the product, e.g. to minimise energy or water consumption or to improve the durability of the product,
- information on key parts of the product that determine its durability,
- information regarding disposal of the product, or inherent materials, and any other information considered necessary to minimise the product's end-of-life impacts, and
- a more detailed description of an organisation's overall environmental work, in addition to the information listed under Section 5.4.3, such as:
 - the existence of any type of organised environmental activity, and
 - information on where interested parties may find more details about the organisation's environmental work.

Any additional environmental information declared shall be substantiated and verifiable, and be derived using appropriate methods and be specific, accurate, not misleading, and relevant to the specific product. Quantitative information is preferred over qualitative information.

5.4.7 ADDITIONAL SOCIAL AND ECONOMIC INFORMATION

The EPD may also include other relevant social and economic information as additional and voluntary information. This may be product information or a description of an organisation's overall work on social or economic sustainability, such as activities related to supply chain management or social responsibility.

Any additional social and economic information declared shall be substantiated and verifiable, and be derived using appropriate methods and be specific, accurate, not misleading, and relevant to the specific product. Quantitative information is preferred over qualitative information.

5.4.8 DIFFERENCES VERSUS PREVIOUS VERSIONS

For EPDs that have been updated, the following information shall be included:

- a description of the differences versus previously published versions, and
- a revision date on the cover page.

5.4.9 REFERENCES

A reference section shall be included, including a list of all sources referred to in the EPD, including the GPI (including version number), and PCR (registration number, name, and version) used to develop the EPD.

Other references shall be reported in the EPD:

- Underlying LCA studies

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- Other documents that verify and complement the EPD®

5.4.10 EXECUTIVE SUMMARY IN ENGLISH

The executive summary, if included (see Section 5.1), shall contain relevant summarised information related to the programme, product, environmental performance, information related to pre-certified EPDs, and information related to sector EPDs. Besides this, further information may be added such as additional environmental, social or economic information, references as well as differences versus previous EPD versions.

6 LIST OF ABBREVIATIONS

ANZSIC	Australian and New Zealand Standard Industrial Classification
CPC	Central product classification
CPV	Common procurement vocabulary
EPD	Environmental product declaration
GPI	General Programme Instructions
GTIN	Global trade item number
ISO	International Organization for Standardization
LCA	Life cycle assessment
LCI	Life cycle inventory
NACE/CPA	Classification of products by activity
ND	Not declared
PCR	Product category rules
REACH	Restriction of chemicals
RSL	Reference service life
SI	The International System of Units
UN	United Nations
UNSPSC	United Nations standard products and services code

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ISO (2000) ISO 14020:2000, Environmental labels and declarations – General principles.

ISO (2004) ISO 8601:2004 Data elements and interchange formats – Information interchange – Representation of dates and times.

ISO (2010) ISO 14025:2010, Environmental labels and declarations – Type III environmental declarations – Principles and procedures.

ISO (2013) ISO/TS 14067:2013, Greenhouse gases – Carbon footprint of products – Requirements and guidelines for quantification and communication.

ISO (2014) ISO 14046:2014, Environmental management – Water footprint – Principles, requirements and guidelines.

ISO (2015a) ISO 14001:2015, Environmental management systems – Requirements with guidance for use.

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ISO (2016b) ISO 14021:2016, Environmental labels and declarations - Self-declared environmental claim (Type II environmental labelling).

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ISO (2018) ISO 14024:2018, Environmental labels and declaration – Type I environmental labelling – Principles and procedures.

ISO (2020) - Environmental management — Life cycle assessment — Principles and framework — Amendment 1, ISO 14040:2006/AMD 1:2020

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BLOOD AND BLOOD DERIVED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES

PRODUCT CATEGORY CLASSIFICATION: UN CPC 35270

8 VERSION HISTORY OF PCR

VERSION 1.0, 2016-12-14

Original version of this PCR.

VERSION 1.1, 2019-01-30

Updated in accordance with GPI 3.0 and new PCR basic module.

VERSION 2.0 2022-03-14

Updated in accordance with GPI 4.0 and new PCR template.

BLOOD AND BLOOD DERIVED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES

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