Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices

GHG Protocol Product Life Cycle Accounting and Reporting Standard

November 2012

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This guidance has been reviewed by WRI for conformance with the GHG Protocol Product Life Cycle Standard

http://www.sdu.nhs.uk/pharma-md

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For and on behalf of
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CONTENTS

FOREWORD

The pharmaceutical and medical device sectors are central to healthcare combating greenhouse gas emissions and reducing our impact on the environment. In 2010 an estimated 22% of NHS England's greenhouse gas emissions were attributable to pharmaceuticals and 8% to medical devices.

I am therefore delighted to see the NHS, the pharmaceutical and medical device industries, international health experts, and greenhouse gas accounting specialists working together to produce these international guidelines. This guidance will form the cornerstone of our joint action to reduce environmental impact and provide a fantastic example to other sectors of how to tackle climate change and develop sustainably in partnership. It is the first international greenhouse gas life cycle assessment guidance for the pharmaceutical and medical device sectors, and only the second of its kind for any sector.

Measuring greenhouse gas emissions in a consistent manner across national boundaries will help us all understand where the emission "hot-spots" are, and consequently where we initially need to focus our attention to achieve the greatest possible impact.

This guidance marks an important first step. It will be a globally relevant, living document that is freely available, and continually revised and updated. It is international in its scope, encourages transparent and accurate reporting, and helps to create a common language and methodology that will form the basis for further development.

What is being proposed is in the interest of all of us, to gain a better understanding of what is good for business, good for health, and good for our common future.
I would like to thank all those involved from the different countries and different sectors in breaking new ground.

Sir Neil McKay CB
NHS CEO of NHS Midlands and East and Lead CEO for Sustainable Development, NHS England.

"NICE is committed to exploring methods for building sustainability into NICE guidance and to promoting sustainable growth in the life sciences industries. We warmly welcome this guidance. It represents an important extension of the scope and methods of carbon accounting. It's also a very practical support to industry efforts to reduce the carbon footprint of the drugs and medical devices that are so important to NHS patients."

Sir Andrew Dillon CBE
CEO of the UK National Institute for Health and Clinical Excellence

ACKNOWLEDGEMENTS

This guidance has been developed in conjunction with a steering group comprising representatives from a range of organisations involved in the production and administration of pharmaceutical products and medical devices, as well as representatives of Government, health care providers and other stakeholders. Acknowledgement is given to the invaluable input of the following individuals and organisations:

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API - Active Pharmaceutical Ingredient.

Allocation - The partitioning of emissions and removals from a common process between the studied product's life cycle and the life cycle of the co-product(s).

Assurance - The level of confidence that the inventory results and report are complete, accurate, consistent, transparent, relevant and without material misstatements.

Attributable processes - Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle.

Biogenic - Produced by living organisms or biological processes, but not fossilised or from fossil sources.

Carbon footprint - The sum of greenhouse gas emissions released in relation to a product or service, expressed as carbon dioxide equivalents (CO_2e).

Co-product - A product exiting the common process that has value as an input into another product's life cycle.

Cradle-to-gate inventory - A partial life cycle of an intermediate product, from material acquisition through to when the product leaves the reporting company's gate (eg, immediately following the product's production).

Cradle-to-grave inventory - Removals and emissions of a studied product from material acquisition through to end-of-life.

Emission factor - Greenhouse gas emissions per unit of activity data.

End-of-life stage - A life cycle stage that begins when the used product is discarded by the consumer and ends when the product is returned to nature (eg, incinerated) or allocated to another product's life cycle.

Functional unit - The quantified performance of the studied product.

Gate-to-gate inventory - The emissions and removals attributable to a studied product while it is under the ownership or control of the reporting company.

Global warming potential - A factor used to calculate the cumulative radiative forcing impact of multiple specific greenhouse gases in a comparable way.

Greenhouse gas (GHG) - Gas released to the atmosphere that absorbs and emits infrared radiation, contributing to the greenhouse effect. Sources of GHGs include combustion, emissions from chemical processes, waste degradation, etc.

Inventory report - The full reporting requirements, plus any optional information, reported publicly in conformance with the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard.

Inventory results - The GHG impact of the studied product per unit of analysis.

Land-use change - Occurs when the demand for a specific land use results in a change in carbon stocks on that land, due to either a conversion from one land-use category to another or a conversion within a land-use category.

Life cycle - Consecutive and interlinked stages of a product system, from raw material acquisition or generation of natural resources to end-of-life.

Life cycle assessment - A method of assessing the environmental impacts of a product through the product's life cycle stages.

Medical device - A product intended to be used for medical diagnosis, cure, treatment or disease prevention, but which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

Non-attributable processes - Processes and services, materials and energy flows that are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle.

Pharmaceutical product - A substance used for medicinal purposes, for the purpose of medical diagnosis, cure, treatment or disease prevention.

Primary data - Data from specific processes in the studied product's life cycle.

Process activity data - Physical measures of a process that result in GHG emissions or removals.

Product - Any good or service.

Product GHG inventory - Compilation and evaluation of the inputs, outputs and the potential GHG impacts of a product system throughout its life cycle.

Product Rule - A document containing additional specifications needed to enable comparisons or declarations about a product or product category.

Product Standard – The title used throughout this guidance document to refer to the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard.

Reference flow - The amount of studied product needed to fulfil the function defined in the unit of analysis.

Removal - The sequestration or absorption of GHG emissions from the atmosphere, which most typically occurs when CO_2 is absorbed by biogenic materials during photosynthesis.

Scope 1 - all direct GHG emissions from a company.

Scope 2 - Indirect company GHG emissions from the consumption of purchased electricity, heat or steam.

Scope 3 - All indirect emissions that occur in the value chain of a company (excluding Scope 2), including both upstream and downstream emissions.

Secondary data - Process data that are not from specific processes in the studied product's life cycle.

Sector - An industry group that is based on similar production processes, products, or behaviour in financial markets.

Sector Guidance - A document or tool that provides guidance for performing a product GHG inventory within a given sector.

Unit of analysis - The basis on which the inventory results are calculated; the unit of analysis is defined as the functional unit for final products and the reference flow for intermediate products and processes.

COLOUR BOXES

Boxes are used throughout the document to highlight important information. Colour coding has been has been included to differentiate between information based on the following colour schemes.

Orange boxes highlight important general text throughout the document.

White boxes with blue borders include examples.

Blue boxes show attributable processes to be included in a GHG inventory.

Green boxes show non-attributable processes to be included in an inventory.

Red boxes show attributable and non-attributable processes to be excluded.

1 INTRODUCTION

1.1 THE PURPOSE OF THIS GUIDANCE DOCUMENT

The objective of this guidance is to enable consistent quantification of the GHG inventory of pharmaceutical products and medical devices. It is relevant for all pharmaceutical products and medical devices, as defined below, and is applicable to products manufactured and administered in any geography.

The document is freely available and is intended to be updated as knowledge in this area increases. The document was released at the end of 2012 and to find out more or provide feedback visit the following link: http://www.sdu.nhs.uk/pharma-md.

A **pharmaceutical product** is a substance used for medicinal purposes, for the purpose of medical diagnosis, cure, treatment or disease prevention.

The life cycle of a pharmaceutical product includes extraction of material/resources; production of an active pharmaceutical ingredient (API); combination of the API with other materials (including delivery mechanisms and packaging); to form a final product; distribution and delivery of the product to a patient; packaging and product end-of-life management.

Examples can include tablets and dry powder, creams and ointments, patches, administering devices, etc.

A **medical device** is a product intended to be used for medical diagnosis, cure, treatment or disease prevention, but which does not achieve its principal intended action in, or on, the human body by pharmacological, immunological or metabolic means.

The life cycle of a medical device may include R&D; extraction of material/resources; materials production; pre-processing; assembly; sterilisation and packing; distribution to point of use; use (including energy and materials consumption, and sterilisation of multi-use items); and packaging and product end-of-life management.

Examples can include instruments that may be active, passive, implantable, etc. and can be used in such applications as the prevention, diagnosis or treatment of disease.

The sector-specific guidance within this document builds upon the requirements of the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard [1] (Product Standard), and it is intended for use alongside this standard.

(1) GHG Protocol Product Life Cycle Accounting and Reporting Standard, http://www.ghgprotocol.org/standards/product-standard

The guidance provides:

- details of the life cycle stages and processes that should be included when undertaking a GHG inventory assessment of pharmaceutical products and medical devices;
- details of the life cycle stages and processes that may be justifiably excluded from an assessment (based on existing evidence of insignificance, or expert consensus of minor significance);
- specific guidance on challenging aspects of the inventory calculation process, such as multiple processing stages in organic API synthesis, and the use phase of multi-use medical devices;
- requirements, recommendations and guidance for users on primary/secondary data needs, sources and data quality appraisal; and
- specific additional requirements and recommendations with regard to reporting and assurance.

1.1.1 *Product Comparisons Are Not Supported*

This document does not provide guidance for assessments that aim to externally report comparative assertions between products, or claims of favourable environmental performance of one product over another.

The guidance is intended to provide additional support for assessments that are undertaken for:

- internal product appraisals (including internal product comparisons) - for example, to support hotspot analysis or eco-design initiatives;
- performance tracking of a product's GHG inventory and GHG emissions reductions over time; and
- public reporting of information on the estimated life cycle GHG emissions associated with specific products, or product groups (when accompanied by a data quality appraisal and assurance statement).

This level of guidance was deemed appropriate by the authors and Steering Group as a first step towards consistent product GHG inventory accounting for pharmaceutical products and medical devices. Additional prescriptiveness on the accounting methodology and data sources is needed for product labelling, performance claims, or quantitative procurement/prescription decisions.

Such external product comparisons are discussed further in the Product Standard (*Chapter 1.5*, *Chapter 5.3.2* and *Appendix A*), and the Product Standard requires additional Product Rules to be developed to support product comparisons. Product Rules are outside the scope of this sector guidance. This guidance document is, however, considered a useful first step towards their potential development – serving to identify where they might be most relevant, and to determine the likely availability of information to support their development.

1.1.2 *Limitations on Scope*

This sector guidance only addresses the accounting of GHG emissions.

The resulting limitation is that potential trade-offs between environmental impacts can be missed across the product life cycle. The results of a GHG footprint exercise should not, therefore, be used in isolation to communicate the overall environmental performance of a product. Non-GHG environmental impacts occurring during the life cycle of a product should also be considered when making decisions to reduce GHG emissions based on the results of a GHG footprint assessment. Examples of potentially significant non-GHG impacts for pharmaceutical products and medical devices include resource depletion and wider pollution of air/water/land based ecosystems.

Other potential impacts across the product life cycle which are not covered by this sector guidance include social impacts, ethical considerations, patient performance etc. Specifically, this sector guidance does not include the ethical considerations of using products derived from animals and humans.

1.2 How the Document is Structured

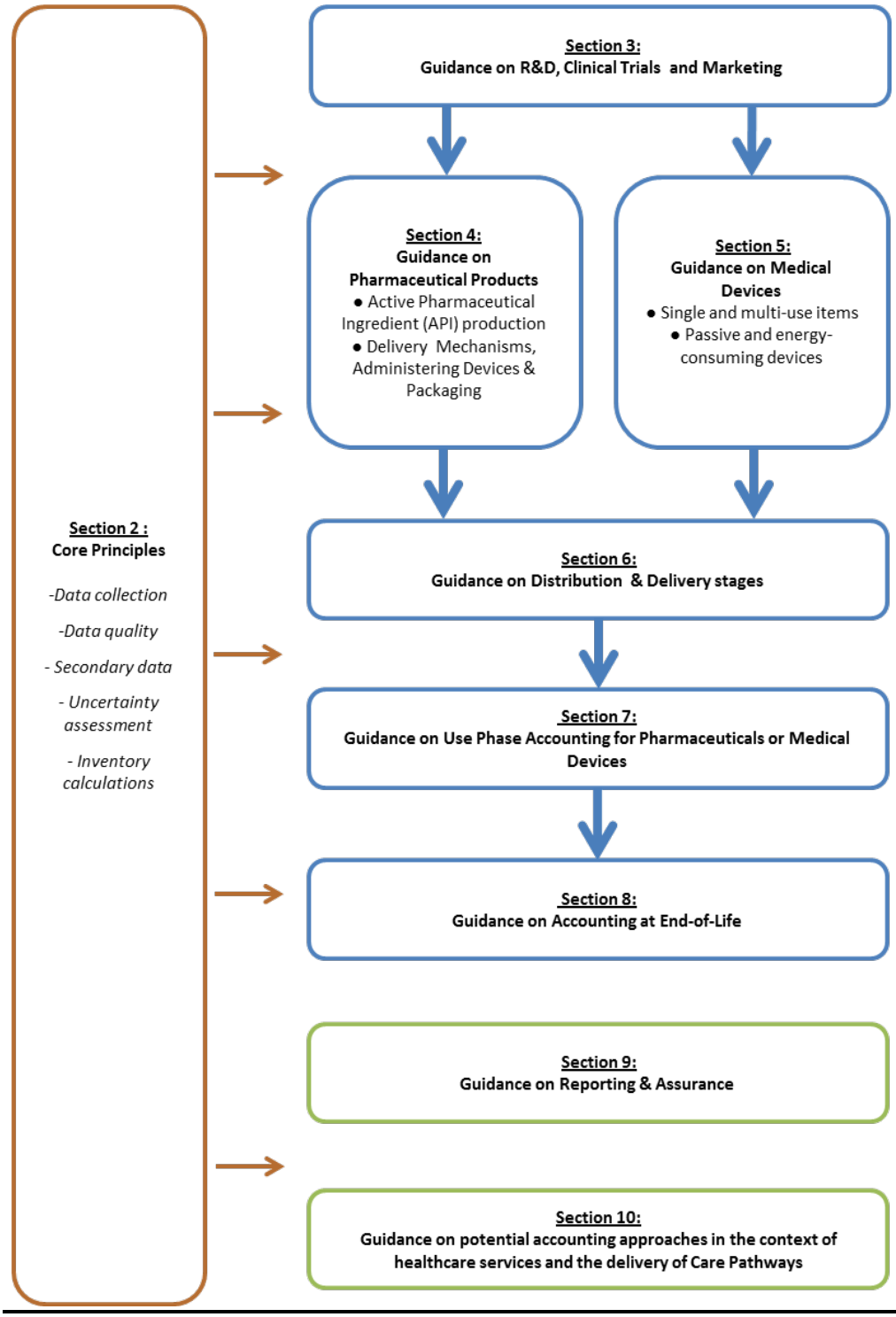
The life cycle of pharmaceutical products and medical devices includes various stages, including research and development (R&D), production of intermediates and final product, marketing, distribution and delivery, use and end-of-life. Some stages are specific to particular types of pharmaceutical or medical device; and some are common to all product systems to some extent.

To address this variability as well as the wide range of potential production and use pathways across the pharmaceutical and medical devices sector, the guidance has been developed using a modular approach. Specific guidance modules address different life cycle stages and processes and can be combined in order to build a full life cycle profile for any type of pharmaceutical products or medical devices.

Figure 1.1 provides an overview of the structure of this document. Refer to each chapter for specific elements of guidance.

The document is a supplement to the Product Standard. It thus assumes that the reader is familiar with the principles and content of the Product Standard. The majority of guidance provided complements, and builds on, the requirements of the Product Standard – providing additional guidance where considered helpful to the reader. In some sections, notably the reporting section (*Section 9)*, the requirements of the Product Standard are reproduced, as they are broadly applicable in the context of pharmaceutical products and medical devices and require only minor clarification. Hence, the structure of *Section 9* differs slightly from the remainder of this guidance, which is focused only on specific aspects for pharmaceutical products and medical devices.

Figure 1.1 Structure of Guidance Document



1.3 *How To Use The Document*

The guidance document is designed to complement the Product Standard and steps outlined within the standard should be followed when undertaking a GHG inventory.

Section 2 to *8* provide information on defining the scope, developing a process map, collecting primary data, sourcing secondary data, defining reference flows, allocation issues and calculating inventory results.

When developing a process map, guidance is provided for likely attributable and non-attributable processes that should be included or excluded.

What is an Attributable Process?

"Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle."

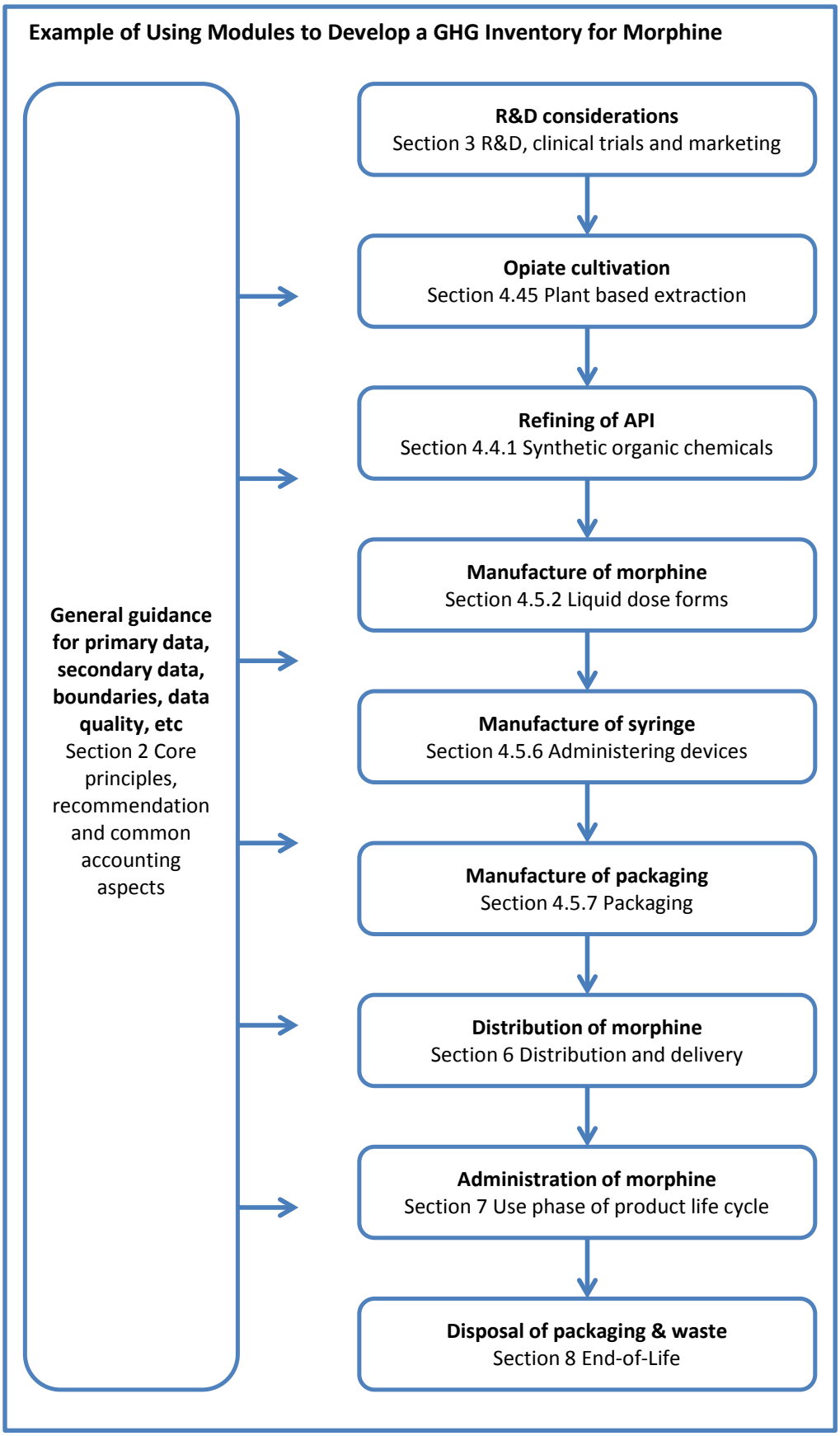
Examples of attributable processes may include the manufacture of chemical feedstocks and solvents, energy used during processing and disposal of waste.

What is a Non-Attributable Process?

"Processes and services, materials and energy flows that are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle."

Examples of non-attributable processes may include chemicals used during cleaning, sterilisation GHG emissions, and protective gear used by operators.

As shown in *Figure 1.1*, the document uses a modular approach to developing the GHG inventory of a product. Specific recommendations can be combined for each relevant life cycle stage to build up an overall inventory of a product. An example of combining modules within the document to build up an inventory is included below.



Each module within the guidance document has a reference flow to define how the GHG inventory results from that module should be considered. These reference

flows can be combined to build up an overall functional unit for the product assessed. Guidance on combining reference flows to achieve a product functional unit is discussed in *Section 4.3* and *Section 5.3* for pharmaceutical products and medical devices respectively.

1.4 WHO SHOULD USE THE GUIDANCE DOCUMENT?

This sector guidance is intended for use by pharmaceutical and medical device producers, and others acting in the value chain, to calculate consistent cradle-to-gate and cradle-to-grave product GHG footprints.

It is designed for companies and organisations of all sizes and in all countries.

1.4.1 *Target Audience and Uses*

The document is intended primarily for use by practitioners carrying out GHG assessments of pharmaceutical products and medical devices. Many sections are therefore orientated towards a technical and informed audience. Typical users are envisaged to be practitioners working for, or on behalf of, a company supplying pharmaceutical/medical device products or components, with some understanding of GHG footprinting or life cycle assessment methods. However, there are elements of guidance that consider a wider audience and application, as outlined in *Table 1.1*.

Table 1.1 Audience, Applications and Benefits of this Guidance

Potential User	Guidance Provided
GHG footprint or LCA practitioner (internal/expert)	Specific guidance on boundary setting, unit of analysis, data requirements, calculation aspects, reporting and assurance. Details of the life cycle stages and processes that are required to be included when undertaking a carbon footprint or GHG assessment of pharmaceutical products and medical devices.
Producers within the sector or value chain that may have limited prior knowledge of GHG footprinting	As above, plus detailed descriptions of data needs and the data collection process (*Section 2*). Note: It is recommended that the Product Standard is consulted in order to gain a more general overview of the GHG assessment process and to clarify the core approach and requirements.
Healthcare services / regulators /policy makers	As previously stated, the guidance is primarily intended for a technical audience. However, it is noted that the document may be useful for wider stakeholders to understand the scope and scale of the assessment process, and the importance of aspects such as data quality and transparency. Thus, it might serve as a useful educational tool and to indicate future data and information needs.
Procurement teams	The guidance is not yet intended to support quantitative procurement decisions (see *Section 1.1.1*). However, as well as raising awareness, the document serves as a first step towards the potential development of Product Rules – potentially informing discussions on where they might be most usefully progressed.

1.4.2 *Why Use It?*

The use of this guidance benefits organisations seeking a better understanding of the GHG impacts of products they design, manufacture, sell, purchase, or use. It is intended that information on pharmaceutical product and medical device GHG inventories can be used to support informed discussions internally, with customers and suppliers regarding life cycle hotspots and potential interventions. The development of a common language and approach to GHG inventory assessment that can be used across the sector by producers and users alike is also considered to be of potential benefit to all parties.

Taking a thorough approach to quantifying GHG emissions across the life cycle of products puts businesses and others in the value chain in a stronger position to introduce improvements in areas such as product design, materials choice, supplier screening, energy efficiency and waste minimisation. This will support efforts to:

- **reduce greenhouse gases emissions** - with associated reputational benefits and ability to differentiate;
- **identify potential cost savings** - directly affecting the bottom line;
- **identify points of risk in the value chain** - and help to minimise them early;
- **inform customers** - stakeholders require robust and well-founded information to ensure confidence in current and future performance;
- **prepare** for any future questions from stakeholders, or for any strengthening of the relevant regulations; and
- **engage internal staff** - thereby involving them in the organisation's sustainability initiatives.

1.5 HOW WAS IT DEVELOPED?

It is known that, globally, pharmaceutical products and medical devices contribute a large proportion of healthcare GHG emissions. In 2009, the NHS Sustainable Development Unit (SDU) carried out their first top-down footprinting exercise for NHS England, which estimated that a significant proportion of NHS England's CO_2e emissions were attributable to pharmaceuticals and medical devices (see *Section 1.7*).

The SDU organised two summits (in 2010 and 2011), attended by healthcare and pharmaceuticals experts, aiming to facilitate collaboration towards achieving low carbon pharmaceuticals and health care. During the 2011 summit, the need for guidance to aid in the carbon footprinting of pharmaceutical products and medical devices was agreed by the attendees.

The development of this guidance was commissioned and funded by the NHS Sustainable Development Unit (SDU) and a collaboration of leading international pharmaceutical and medical devices companies. The document has been written by Environmental Resources Management Ltd, with steer from the contributing partners and a committee of international health and carbon footprinting experts,

including representatives from: Baxter Healthcare; GlaxoSmithKline; Johnson & Johnson; Novo Nordisk; Pfizer; AstraZeneca; UK Department of Health (DH); National Institute for Health Clinical Excellence (NIHCE); Medicines and Healthcare Products Regulatory Agency (MHRA); British Generic Manufacturers Association (BGMA); Association of British Pharmaceutical Industries (ABPI); Association of British Healthcare Industries (ABHI); Hull and East Yorkshire NHS Trust; SustainPharma; UNDP Europe; and Western Health Australia.

The World Resource Institute (WRI) has also advised on the document, and reviewed for consistency and alignment with the Product Standard.

A detailed overview of the governance and consultation processes undertaken is provided in *Annex A*.

1.6 THE SCOPE OF THIS GUIDANCE IN THE CONTEXT OF WIDER GHG ACCOUNTING METHODS AND STANDARDS

The practice of calculating a GHG inventory of corporate activities is relatively well established, with over 3,000 organisations worldwide disclosing their GHG emissions through the Carbon Disclosure Project (CDP (1)), for example. Increasingly, best practice has been for organisations to consider impacts beyond their own operations – extending the scope of GHG accounting to consider the climate change impacts of the goods and services they purchase from suppliers and/or sell to customers. GHG accounting standards provide a means for this.

The GHG Protocol has developed the following standards for GHG accounting and reporting.

- ***GHG Protocol Corporate Accounting and Reporting Standard (2004)***: A standardised methodology for companies to quantify and report their corporate GHG emissions. Also referred to as the Corporate Standard.

- ***GHG Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard (2011)***: A standardised methodology for companies to quantify and report their corporate value chain (scope 3) GHG emissions, to be used in conjunction with the Corporate Standard. Also referred to as the Scope 3 Standard.

- ***GHG Protocol Product Life Cycle Accounting and Reporting Standard (2011)***: A standardised methodology providing requirements and guidance for companies and other organisations to quantify and report an inventory of GHG emissions and removals associated with a specific product.

The GHG Protocol Scope 3 Standard and Product Standard, developed simultaneously, both take a value chain or life cycle approach to GHG accounting. The Scope 3 Standard builds on the GHG Protocol Corporate Standard and accounts for value chain emissions at the corporate level, while the Product Standard accounts for life cycle emissions at the individual product level.

(1) Further detail about the Carbon Disclosure Project can be found at https://www.cdproject.net/

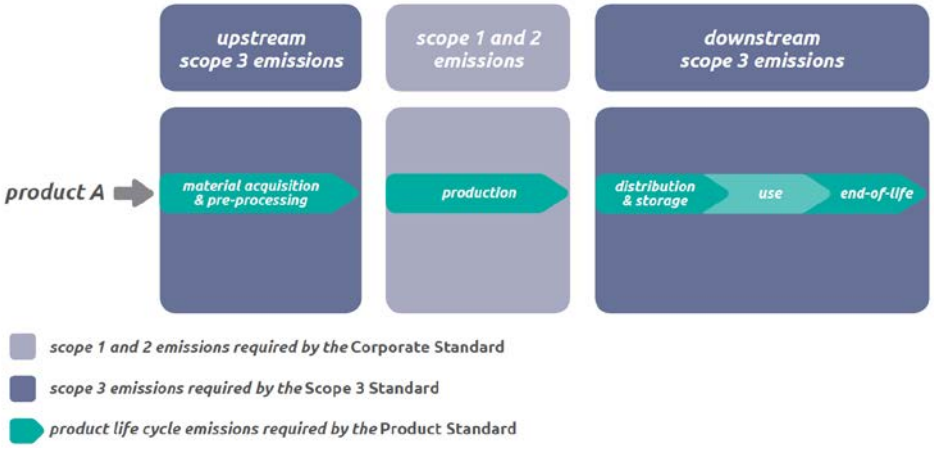
Different Standards for Different Purposes

The reporting company's business goals should drive the use of a particular GHG Protocol accounting standard. The Scope 3 Standard enables a company to identify the greatest GHG reduction opportunities across the entire corporate value chain, while the Product Standard enables a company to target individual products with the greatest potential for reductions. The Scope 3 Standard helps a company identify GHG reduction opportunities, track performance, and engage suppliers at a corporate level; while the Product Standard helps a company meet the same objectives at a product level.

In many instances, common data are used to develop scope 3 inventories and product inventories, including data collected from suppliers and other companies in the value chain. Since there can be overlap in data collection, companies may find added business value and efficiencies in developing scope 3 and product inventories in parallel.

The Product Standard (*Section 1*) contains further information in this respect. *Figure 1.2* illustrates the relationship between the Corporate Standard, Product Standard, and Scope 3 Standard.

Figure 1.2 ***The Relationship between the Corporate, Scope 3 and Product Standards for a Company Manufacturing Product A***



Source: extracted from the Product Standard

1.6.1 *Other Relevant Methods and Standards*

Other methods, standards and product guidance are also relevant in the context of the sector guidance, and further commentary on these is provided in *Annex B - Related and Other Standards*. These include:

- the PAS 2050 – Specification for the Assessment of the Life Cycle Greenhouse Gas Emissions of Goods and Services;
- ISO14067 – Carbon Footprint of Products. Requirements and Guidelines for Quantification and Communication (in draft); and

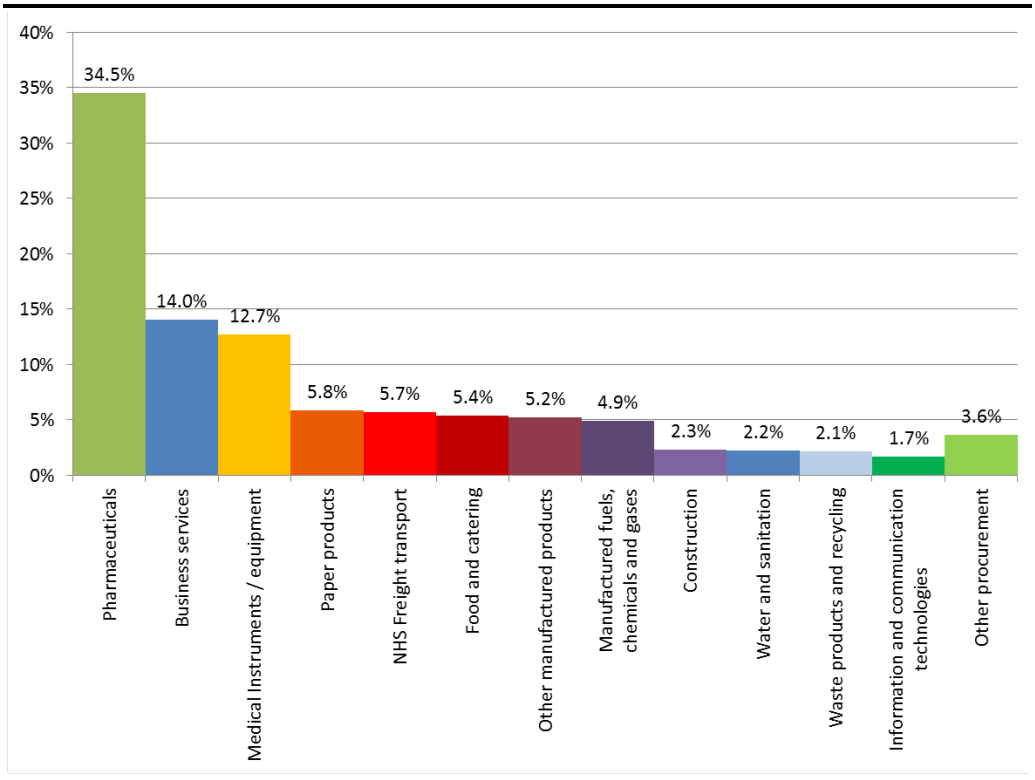
- existing product category rules (PCRs) relevant for pharmaceutical products or medical devices.

1.7 *GHG ACCOUNTING IN THE PHARMACEUTICAL AND MEDICAL DEVICES SECTOR*

Pharmaceutical and medical device companies are increasingly making efforts to understand the environmental footprint of their businesses and products. A large proportion of pharmaceutical and medical device companies within the Global 500 (1) have reported the emissions associated with their business operations through submission to the Carbon Disclosure Project (2). Scope 3 emissions have been found to contribute as much as two thirds of the total emissions reported, and demonstrate the importance of taking a life cycle approach.

Similarly, in England, the NHS has calculated that only 19% of its 20 million tonne carbon footprint in 2010 (3) was associated with its use of energy, 16% from travel-related activities, and the remainder arising from activities beyond its operational fence (4). In particular, procurement is estimated to contribute 65% of the carbon footprint of NHS England. Within 'procurement', the carbon footprint of pharmaceuticals and medical devices was found to be a significant component of the overall healthcare system footprint.

Figure 1.3 Breakdown of the NHS England Procurement Carbon Footprint 2010



Source: http://www.sdu.nhs.uk/documents/publications/NHS_Carbon_Footprint_Published_2012.pdf

(1) The Global 500 are the largest companies by market capitalisation included in the FTSE Global Equity Index Series.
(2) Further detail about the Carbon Disclosure Project can be found at https://www.cdproject.net/en-US/Pages/HomePage.aspx
(3) This assessment was undertaken using economic input output analysis and available on the NHS SDU website - http://www.sdu.nhs.uk/publications-resources/26/NHS-Carbon-Footprint-/
(4) NHS (2012), NHS England GHG Footprint

The scope of this sector guidance is to address product life cycle emissions, as required by the Product Standard, by providing additional guidance on the application of that Standard to pharmaceutical products and medical devices, as described in *Section 1.1*.

Within this context the need for additional and more consistent information on the life cycle GHG emissions associated with pharmaceutical products and medical devices has been noted.

2 CORE PRINCIPLES, RECOMMENDATIONS AND COMMON ACCOUNTING ASPECTS

2.1 STANDARD TERMINOLOGIES

The Product Standard and this sector guidance use precise language to indicate which provisions are requirements, which are recommendations, and which are permissible or allowable options that companies may choose to follow.

The term '*shall*' is used to indicate what is required for a GHG inventory to conform to the Product Standard and this sector guidance. The term '*should*' is used to indicate a recommendation, but not a requirement. The term '*may*' is used to indicate an option that is permissible or allowable.

Companies using this sector guidance shall abide by the requirements of the Product Standard, and these requirements are upheld within this guidance document.

2.2 CORE ACCOUNTING PRINCIPLES

Five accounting principles are set out in the Product Standard, intended to underpin all aspects of GHG accounting and reporting for products. These shall be used to help to ensure that the product GHG inventory constitutes a true and fair representation.

Refer to *Chapter 4* of the Product Standard for an outline of the five accounting principles.

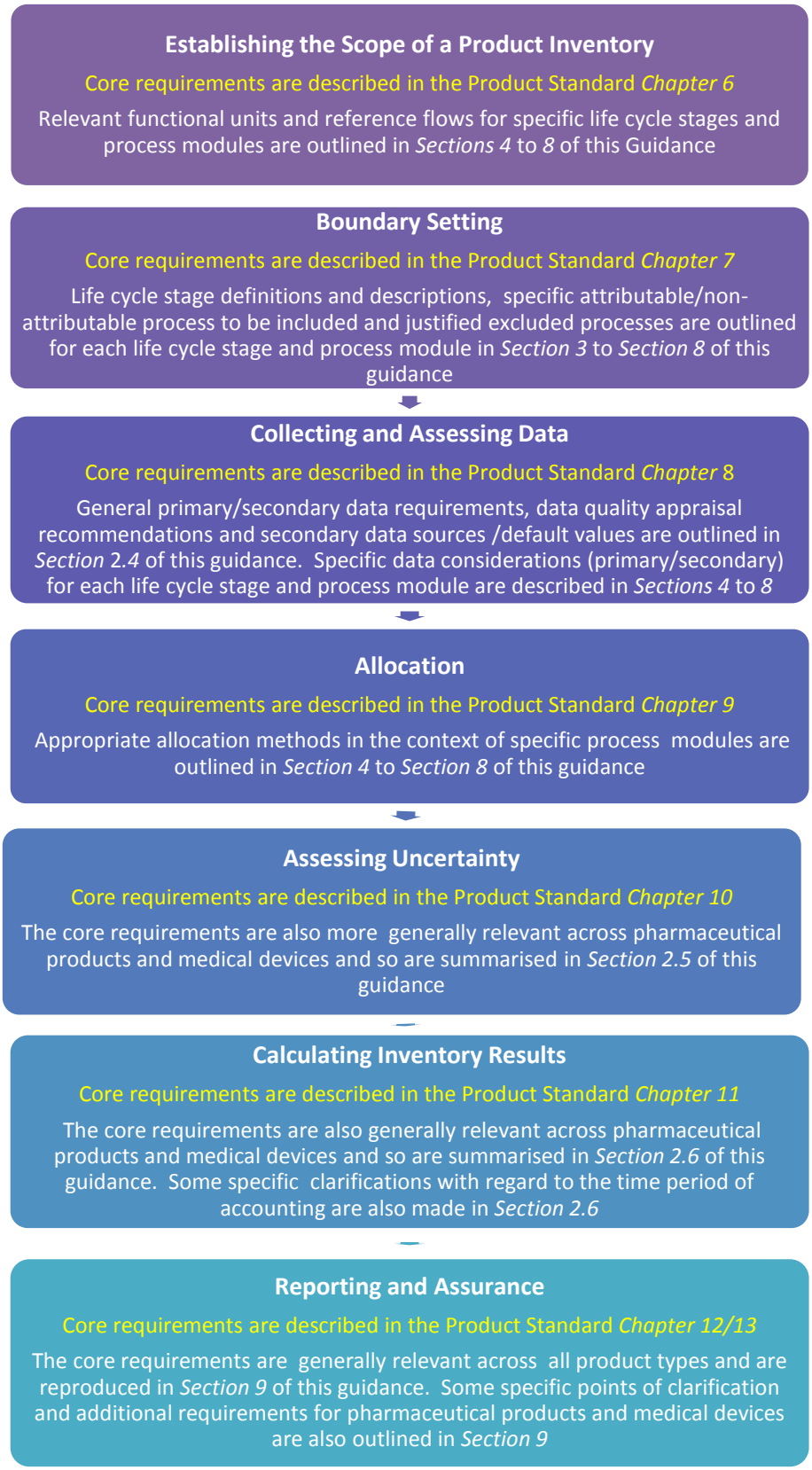
2.3 OVERVIEW OF KEY STEPS

An overview of key steps in product inventory accounting and reporting, in accordance with the Product Standard, is shown in *Figure 2.1*.

Refer to *Chapter 3.2* (*Table 3.1*) of the Product Standard for a list of requirements against each of these steps.

Figure 2.1 shows the overlap in structure between this sector guidance and the Product Standard, and highlights the specific points of guidance provided by this document.

Figure 2.1 ***Overview of Assessment Steps and Key Aspects of this Guidance that Build on the Product Standard***



2.4 COLLECTING DATA AND ASSESSING DATA QUALITY

2.4.1 *Data Types*

The data needed to carry out a product GHG inventory calculation in accordance with the Product Standard fall into the following categories (for further explanation of these data types refer to *Chapter 8* of Product Standard):

1) Direct emissions data: refer to the direct emission of greenhouse gases from a process (eg continuously measured GHG emissions from a chemical process).

2) Activity data: can be further split into Process Activity data and Financial Activity data, as below:

- **Process Activity data:** referring to quantities of physical inputs and outputs (materials, energy, gaseous emissions, solid/liquid wastes, co-products, etc.) for a process – typically described for a unit of production for a specified year of production (eg litres of water per kg of tablets produced in 2011). This also includes details of any transportation of incoming materials, wastes or distribution of the final product (distances travelled, vehicles used, etc.).
    - Two types of Process Activity data are referred to in *Section 4 and 5:*
        - Raw material data include those chemicals and materials included directly in the product and are typically described through a bill of materials; and
        - Process data that include additional inputs/outputs such as energy, solvents, direct emissions and waste.
- **Financial Activity data:** are monetary measures of a process or flows that result in GHG emissions. These data can then be combined with a financial emission factor (eg environmentally extended input-output [EEIO] emission factors).

Both direct emissions data and activity data can be either:

- **Primary data** – defined in the Product Standard as data from specific processes in the studied products life cycle. This is first-hand information, specific to the activity in question (eg kWh consumed by a process at an individual site, or an average across sites), collected internally or from the value chain. Primary data can be measured, calculated or modelled, as long as the result is specific to a process in the product's life cycle.
- **Secondary data** – data not from specific processes in the studied product's life cycle and may take the form of average, or typical, information about an activity (eg energy requirements and refrigerant losses for chilled storage) from a published study or other source.

3) Emission factors: values that convert activity data quantities into GHG emissions – based on the GHG emissions associated with producing & processing, materials/ fuels/energy, operating transport carriers, treating waste, etc. These are usually expressed in units of 'kg CO_2e' (eg kg CO_2e per litre of diesel, per km of transport or per kg of inert waste to landfill). Emission factors are most often from secondary sources and there is no requirement for them to be from primary sources.

2.4.2 *Choosing Primary Data or Secondary Data*

Section 8.2 of the Product Standard states that "*Companies shall collect primary data for all processes under their control*". A company owns or controls a process if the former is under its operational or financial control[1].

Where a process is not under the control of the company calculating the GHG inventory (eg production of purchased commodity raw materials), the Product Standard points to the benefits of collecting primary data from the value chain where data are available and of sufficient quality.

Where primary data collected are of insufficient quality, then secondary data may be used. This is because primary data are generally more representative of the process under investigation, and increase the accuracy of the GHG inventory calculated. Secondary data are usually less accurate, as they will relate to processes only similar to the one that actually takes place, or to an industry average for that process.

Collecting primary data from significant activities in the value chain is seen as an important consideration, placing a recommendation on business to request data from outside their organisation.

There are examples in this guidance where the use of secondary data is suggested, for example when including commodity products such as excipients for solid dose form (see *Section 4.5.1*).

Wherever there is a choice between the use of primary data or secondary data it is important that data quality is considered (as outlined in *Section 2.4.3*, *Section 2.4.5* and *Section 2.4.7)* and companies should seek to use the highest quality data available. This means that, where the quality of primary data is poor, good quality secondary data may be preferred.

2.4.3 *Data Quality Principles*

The Product Standard requires that "*During the data collection process, companies shall assess the data quality of activity data, emission factors, and/ or direct emissions data by using the data quality indicators".*

The accuracy or 'quality' of the result of a product GHG inventory is ultimately dependent on the quality of the data used to calculate it. It is critical to consider the quality of the primary and secondary data used, and demonstrate that they appropriately represent the product assessed.

The Product Standard defines five data quality indicators to use in assessing data quality. They are:

[1] *Box 8.1* in the Product Standard provides a full description of the coverage of this requirement.

- **Technological representativeness:** the degree to which the data reflect the actual technology (-ies) used in the process.
- **Geographical representativeness:** the degree to which the data reflect actual geographic locations of the processes within the inventory boundary (eg, country or site).
- **Temporal representativeness:** the degree to which the data reflect the actual time (eg, year) or age of the process.
- **Completeness:** the degree to which the data are statistically representative of the process sites.
- **Reliability**: the degree to which the sources, data collection methods, and verification procedures used to obtain the data are dependable.

Assessing data quality is not an exact science. There are many ways in which data quality assessments can be performed, and different scoring approaches could be used in each case. The important thing is that due consideration is given to the quality of the data, and that this is done in a transparent way. Semi-quantitative and qualitative methods for assessing data quality are outlined in *Section 2.4.5* for Primary data and *Section 2.4.7* for Secondary data.

The data quality assessment, along with any accompanying assumptions shall be reported with the product GHG inventory calculations (see *Section 9*).

Significant processes and data points should be identified by assessing their contribution to the total GHG Inventory. All processes that contribute more than a selected cut-off level percentage of the total GHG inventory (eg 10% of the total GHG inventory) should be deemed significant processes. For each of these processes, details of the data sources and data quality scores or descriptions for both primary and secondary data should be provided.

Collecting data and assessing its quality is an iterative process for improving the overall data quality of the product inventory. If data sources are identified as low quality for a significant process, companies should aim to re-collect data for these processes. Significant processes should be identified as part of the assessment of the GHG inventory. Focusing on improving the data quality of significant processes will improve the quality of the GHG inventory calculation overall as well as the conclusions that can be drawn.

2.4.4 *Collecting Primary Data*

Within Your Organisation

Identifying clear requirements and communicating these in a relevant way to data owners within the company is a key to successfully collecting data.

The following steps are adapted from the GHG Protocol Supplier Engagement Guidance [(1)], but are also applicable to collecting data within your own organisation.

- Identify internal departments responsible for data collection and departments/sites that will hold the data.
- Develop a method for managing data, including the data collection process and quality assessment.
- Provide a training or information session to all those involved in the data collection process, explaining the wider context.
- Make requests as simple as possible and questions as relevant as possible – taking into account the recipient's role.
- Assess data quality and follow up with internal departments to resolve data questions and identify ways of improving data collection in future.

Outside Your Organisation

Engaging suppliers in the GHG inventory process will help you collect specific primary data for your value chain, giving greater insight into emissions sources. It can also encourage future co-operation in terms of finding practicable opportunities to reduce the life cycle GHG emissions of the product.

The following steps are proposed in the GHG Protocol *Supplier Engagement Guidance*.

- Internal planning prior to engaging suppliers:
  - Identify relevant internal departments.
  - Select suppliers and identify supplier information.
  - Engage procurement staff to ensure that correct suppliers have been identified.
  - Develop a method for managing the supplier data, including the data collection process and quality assessment.
- Working with suppliers to collect GHG data:
  - Contact suppliers and discuss their processes prior to developing and sending any survey forms / data collection templates.
  - Provide a training or information session if required.
  - Check in periodically with suppliers regarding their progress.
  - Determine the consequences for suppliers that choose not to respond.
  - Assess data quality and follow up with suppliers to resolve data questions.

Often the best way to collect data from a supplier is through the preparation of a supplier survey form or data collection template, specifying recommended data, together with all necessary information to assess the data quality. The most successful data collection templates are tailored to a specific product or process, but

(1) GHG Protocol Supplier Engagement Guidance - http://www.ghgprotocol.org/standards/product-standard

if tailoring is not possible (eg due to lack of information), a generic template will still be a valuable tool. An example data collection template is provided in *Annex C.*

Once data have been received from the supplier, it is important to assess the accuracy and quality of the information provided. A data quality assessment process is described in *Section 2.4.5.* Initial checks can also highlight any errors and whether the data are suitable for use. Typical checks are outlined in *Box 2.1*.

Box 2.1 Supplier Primary Data Checks

- Compare the data provided to secondary data from published data sources. Is the degree of variation justifiable?
- Check the units and make sure that they are in line with expectation (eg the variance above could be due to unit errors).
- There is always wastage in a process. If there is none, this should be questioned. It may be that waste is reused in the process, but a sense check is useful.
- Each process step should mass balance with inputs equalling outputs. If not, is there something missing, or is there a justified explanation?
- Is there any potential double counting of emissions? For example, if carbon dioxide emissions are reported for a process, is this associated with fuel combustion? If so, this may also be included in the fuel emission factor you later apply.

Sampling

In some cases, a product will be produced at a large number of sites. Data collection for each site in such an instance could be prohibitively time consuming, and a sampling approach is recommended. *Annex D* provides some guidance on sampling options.

2.4.5 *Assessing Primary Data Quality*

Different methods for assessing the quality of primary data are applicable in different contexts:

1. ***Semi-quantitative assessment*** - a semi-quantitative approach is recommended in support of external disclosures, to aid consistency and transparency. A semi-quantitative approach may also add value to internal assessments, potentially allowing greater comparability and consistency over time.
2. ***Qualitative assessment*** - for internal assessments (eg to identify hotspots in the value chain), formal assessment/recording may not be needed, but it is important to ensure that differences in data quality are not unduly influencing findings and conclusions.

Semi-Quantitative Assessment

The benefit of a semi-quantitative approach for data quality appraisal is that scores can be generated and summed in order to generate an overall estimate of the quality of data supporting a product GHG inventory. Whilst this is only an estimate, it

provides a clear and simple indication of the potential representativeness of the results of the assessment. A minimum score can also be set where applicable.

Both the International Reference Life Cycle Data System (ILCD) Handbook (Annex A) [(1)] and the European Commission's harmonised methodology for the calculation of the environmental footprint of products [(2)] describe a semi-quantitative approach for data quality appraisal that may be used.

Qualitative Assessment

A qualitative assessment should take into account the five data quality indicators outlined in *Section 2.4.3*, assessing them as *Very good, Good, Fair* or *Poor*, along with relevant commentary. An example scoring procedure is shown in *Table 2.1*.

Table 2.1 Example Qualitative Data Quality Appraisal

Score	Technology	Time	Geography	Completeness	Reliability
Very good	Data generated using the same technology	Data age less than 3 years	Data from the same area	Data from all relevant process sites over an adequate time period to even out normal fluctuations	Verified data based on measurements
Good	Data generated using similar but different technology	Data age between 3 and 6 years	Data from the similar area	Data from more than 50% of sites for an adequate time period	Verified data partly based on assumptions or non-verified data based on measurements
Fair	Data generated using a different technology	Data age between 6 and 10 years	Data from different areas	Data from less than 50% of sites for an adequate time period to even out normal fluctuations or more than 50 % of sites but for a shorter time period	Non-verified data partly based on assumptions or a qualified estimate (eg by sector expert).
Poor	Data where technology is unknown	Data age greater than 10 years	Data from an area that is unknown	Data from less than 50% of sites for a shorter time period or representativeness is unknown	Non-qualified estimate

Source: adapted from the Product Standard

(1) http://lct.jrc.ec.europa.eu/pdf-directory/ILCD-Handbook-General-guide-for-LCA-DETAIL-online-12March2010.pdf
(2) http://ec.europa.eu/environment/eussd/product_footprint.htm

2.4.6 *Secondary Data Sources*

A list of life cycle inventory databases is provided on the GHG protocol website [(1)]. These can be used to source specific inventory data (eg secondary activity data or direct emissions data) or to calculate emission factors (see *Section 2.4.1*).

In general, the following hierarchy for secondary data sourcing is recommended:

1. Emission factors generated from average industry data and contained in life cycle inventory databases, industry association reports, government reports and that are compliant with ISO Life Cycle Assessment standards [(2)] and have been critically reviewed ;
2. Where unavailable, other existing peer-reviewed life cycle data from published life cycle studies or from proprietary packages should be used; and
3. Where an emission factor for a specific material input or process is unavailable, substitute data may be used - for example, substituting materials with similar manufacturing processes.

If you are using aggregated secondary data/emission factors, care needs to be taken that that they are fit for purpose. As an example, is the system boundary of the subject product consistent with the boundary requirements in the Product Standard and this guidance? If not, the emission factor may need to be amended before use. Some recommended checks are outlined in *Box 2.2*. *Box 8.5* in *Chapter 8* of the Product Standard also provides a list of questions to assist with selecting a life cycle inventory database.

(1) http://www.ghgprotocol.org/Third-Party-Databases. Note - the list includes both databases which charge a licence fee and databases which are free to use.
(2) ISO14040:2006, Life Cycle Assessment: Principles and Framework and ISO14044:2006, Life Cycle Assessment: Requirements and Guidelines

Box 2.2 Emission Factor Checks

Do the numbers look reasonable?
- Compare to other similar processes if possible.

Does the emission factor reflect cradle-to-gate emissions (up to the point of final production), or cradle-to-grave emissions (across the full life cycle)?
- Use and end-of-life emissions may need to be removed to avoid double counting. If transportation is not included, it will need to be added. Both production and eventual release of refrigerant gases needs to be considered.

Does the emission factor need to be location-specific?
- If the emission factor is a large consumer of grid electricity, consideration of the country of manufacture will be required. Grid electricity emissions differ significantly between some countries.

Are there any potential inconsistencies with the Product Standard and this guidance?
- Is biogenic carbon uptake, and subsequent release, accounted for appropriately?
- If there is potential for land use change that has not been accounted for in the emission factor, this will need to be added.
- If the product processes are likely to generate co-products (eg agricultural processes), appropriate allocation methods should have been used. Supporting evidence should be provided to demonstrate this.
- Non-attributional processes, such as capital burdens are often included in secondary databases. As such, emissions might be overestimated in comparison with the Product Standard boundaries. These emission factors can be used, but the inconsistency should be noted.

2.4.7 *Assessing Secondary Data Quality*

Secondary data (whether used for activity data or as an emission factor) should also be assessed using scores for key criteria, as described in *Section 2.4.3*. The objective of a data quality assessment in this case is to ensure that the secondary data used are the most appropriate, and that any areas of uncertainty are identified. The secondary data should be assessed against the specific process for which the data are being used. An assessment of data quality is, in particular, recommended for processes deemed significant to the GHG inventory.

As for the scoring for primary data quality, details of a semi-quantitative scoring system and a qualitative scoring system are provided in the ILCD Handbook [(1)] and in the draft EC method for environmental footprint of products [(2)]. A semi-quantitative approach is recommended in support of external disclosures, as this will aid in assuring that data are assessed in a consistent and transparent manner. For internal assessments (eg to identify hotspots in the value chain), formal assessment/ recording may not be needed, but it is important ensure that differences in data quality do not unduly influence findings and conclusions.

A qualitative assessment is recommended for internal appraisals. This should take into account the five data quality indicators outlined in *Section 2.4.3*, assessing them as *Very good, Good, Fair* or *Poor*, along with relevant commentary. An example scoring procedure is shown in *Table 2.1*, as earlier presented.

(1) http://lct.jrc.ec.europa.eu/pdf-directory/ILCD-Handbook-General-guide-for-LCA-DETAIL-online-12March2010.pdf
(2) http://ec.europa.eu/environment/eussd/product_footprint.htm

2.5 *CONSIDERING UNCERTAINTY*

There will be uncertainty and variability in the GHG inventory calculated for any product. Inevitably, there will be inaccuracies, due to limitations in the accuracy of measurements and errors, in standard emission factors used, data collected, knowledge gaps filled by assumptions and global warming potentials used.

It is important to understand the uncertainties associated with results from a GHG inventory and the sources of those uncertainties. The Product Standard requires that *"Companies shall report a qualitative statement on sources of inventory uncertainty and methodological choices."*

The Product Standard (*Chapter 10*) describes three types of uncertainty within a GHG inventory:

- **Parameter Uncertainty:** Uncertainty arising from accuracy of direct emissions data, activity data, emission factors or global warming potentials. Uncertainty can typically be represented by a range or probability distribution. Further quantitative analysis may then be undertaken using methods such as Monte Carlo Analysis (this may be done in common LCA modelling packages such as *SimaPro* or *GaBi*) or Taylor Series expansion.
- **Scenario uncertainty:** Uncertainty arising from methodological choices such as allocation methods, product use assumptions or end of life assumptions. Analysis of this may be undertaken by changing the assumptions made and comparing the results. This may also commonly be called sensitivity analysis.
- **Model Uncertainty:** Uncertainty arising from limitations in the ability of modelling approaches to reflect the real world.

All three types of uncertainty should be considered in the assessment, but organisations are only required to report a qualitative statement on sources of uncertainty (see *Section 9* of this guidance).

Wherever possible, companies should also report quantitative uncertainty results in the inventory report. Knowledge of this uncertainty will allow for a better assessment of the results when making decisions on hotspot prioritisation, material choices, process choices, etc. Further details of how to undertake quantitative assessments of uncertainty are provided in the supplementary guidance document to the Product Standard Quantitative Inventory Uncertainty (1).

2.6 *CALCULATING PRODUCT GHG INVENTORY RESULTS*

Refer to *Chapter 11* of the Product Standard for full guidance on calculating a Product GHG Inventory value. There are no specific additional requirements for

(1) http://www.ghgprotocol.org

pharmaceutical products or medical devices. A number of key points to note are as follows:

The 100-year global warming potential (GWP) factors for GHG emissions should be used when calculating inventory results for pharmaceutical products, based on the IPCC fourth assessment report (2007), or the most recent released version of these factors. A table of the most recent GWP values is available on the GHG Protocol website [(1)].

- For each module, results should be reported as a mass of carbon dioxide equivalent per reference flow (eg kg CO_2e / kg of product). Modules can be combined to develop a full life cycle profile, as discussed in *Section 4* and *Section 5*.
- When calculating inventory results for modules, some results are recommended to be reported separately and aggregated as part of the inventory results, such as any biogenic-derived CO_2 removals/emissions calculated in the assessment; and any GHG emissions from direct land use change.

2.6.1 *Time Period Considerations*

The time period that the assessment covers shall be clearly defined and reported. The assessment time period is described in the Product Standard as: "The period of time when attributable processes occur during the studied product's life cycle, from when materials are extracted from nature until they are returned to nature at the end-of-life (eg incinerated) or leave the studied product's life cycle (eg recycled)."

The time period defined for assessments undertaken in accordance with this sector guidance should be 100 years from the point of creation of the product. *Box 7.2* of the Product Standard provides further guidance on GHG removals within the specified time period.

(1) http://www.ghgprotocol.org

Research and development, marketing and clinical trials are non-attributable processes and should be excluded because of:

- the complexity of product development;
- the difficulty in consistently and accurately quantifying GHG emissions associated with these activities; and
- the difficulty of attributing emissions to a specific quantity of product in a specific year.

The EFPIA (1) report that for every substance that makes it to market, 10,000 start the process. A typical development timeline is reported as taking 10 years, with product life to patent expiration a further 10 years. Additionally the research and development pipeline for pharmaceutical products will result in other avenues of research and spin-off products resulting in a difficult allocation problem. Alongside the issue of generics, where a number of manufacturers produce products who may not have been associated with the original product research and development, these complexities make it inappropriate to appraise and attribute the R&D GHG emissions to a specific product for a specific year. Clinical trials and marketing activities incur similar complexities.

The GHG emissions associated with R&D, marketing and clinical trial activities are best appraised by Pharmaceutical and Medical Device companies through the Corporate Value Chain (Scope 3) Accounting and Reporting Standard.

R &D, marketing and clinical trials associated with the development of pharmaceutical products and medical devices are considered by the Product Standard to be non-attributable processes alongside capital goods (e.g., machinery, vehicles), overhead operations (e.g., facility lighting, air conditioning) and other corporate activities and services (e.g., administrative functions). Companies are therefore recommended to exclude these non-attributable processes from their product assessments.

(1) Source: European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical Industry in figures - 2010 Edition

4 PHARMACEUTICAL PRODUCTS

A pharmaceutical product is a substance used for medicinal purposes, intended for use in medical diagnosis, cure, treatment or disease prevention. The European Union defines medicinal products based on the description in the box below.

Article 1 of Directive 2001/83/EC [1] as amended defines a 'medicinal product' as:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

4.1 TYPES OF PHARMACEUTICAL PRODUCT AND PRODUCTION PROCESSES CONSIDERED IN THIS GUIDANCE

Any pharmaceutical product included within the scope of the definition above is considered within this guidance document.

The production of pharmaceutical products can be broadly split into two major stages: API manufacture, and conversion with a suitable delivery mechanism for administration to patients. Each is covered in separate 'modules' of guidance, broken down according to the following.

- Active pharmaceutical ingredient (API) manufacture including;
    - **synthetic organic chemical** batch-processes that start from commercially available commodity and speciality chemicals;
    - fermentation by use of microorganisms or **cell cultures**;
    - **egg-based cultivation** for vaccine incubation;
    - production of **conjugate vaccines**;
    - **plant-based extraction** of chemicals for processing; and
    - extraction of materials from **animal and human-derived** sources.
- Delivery mechanisms including;
    - **solid dose forms** such as tablets or a dry powder for use in a further delivery mechanism;

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF

- **liquid dose forms** and suspensions for ingestion or use in other delivery mechanisms;
- **creams and ointments** for transferring APIs onto the skin;
- **patches** for API administration in doses through the skin;
- **gases** for inhalation;
- **administering devices** such as metered dose inhalers (MDI), dry powder inhalers, auto-injectors and nebulisers; and
- **packaging** such as vials, ampules and bags and packaging to protect and store the products before use.

There are additional categories of pharmaceutical products that represent a smaller proportion of the industry (eg radio-pharmaceuticals). These categories of products may not be currently covered in this guidance document however; the Product Standard and the principles and general approaches described in this document will be applicable.

The guidance is provided in a modular format to allow for a product life cycle GHG inventory to be built by including different APIs and delivery mechanisms. The following steps should be taken into account in doing so;

1. Develop an overall process map of the product to be assessed.

2. Identify which 'modules' (production processes and steps) in this Section are relevant.

3. Use the module guidance in this Section to calculate inventory results and report based on the unit of analysis.

4. Sum modules to build up inventory results based on the developed process map (including for transport and storage steps along the way, and accounting for any wastage).

5. Account for other life cycle stages (eg distribution, use and disposal in *Section 6, Section 7 and Section 8*).

6. Calculate a product GHG inventory in accordance with *Chapter 11* of the Product Standard.

7. Assess uncertainty and data quality according to guidance in *Section 2*.

8. Consider assurance and reporting needs according to guidance in *Section 9*.

Any further guidance for specific product systems in addition to these modules and the Product Standard will require the use of Product Rules, whether existing or requiring development.

4.2 STRUCTURE OF MODULE GUIDANCE

The following headings are outlined for each module in the pharmaceutical production pathway.

Description

A general overview is provided to describe the module, including practical examples.

Boundary Setting

For each module, boxes are used to define:

- Attributable processes to be included;
- Non-attributable processes to be included; and
- Attributable and non-attributable processes to be excluded.

Both attributable and non-attributable processes may be included in the inventory.

What is an Attributable Process?

"Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle."

Examples of attributable processes may include manufacture of chemical feedstocks and solvents, energy used during processing and disposal of waste.

What is a Non-Attributable Process?

"Processes and services, materials and energy flows that are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle."

Examples of non-attributable processes may include chemicals used during cleaning, sterilisation GHG emissions and in protective gear used by operators.

A general principle to note is one of significance – focusing efforts on those aspects of greatest environmental importance. This is addressed in each specific module by identifying relevant inclusions and exclusions, but also by making note of the following materiality principles set out below.

Material Cut-Off Rules

To reduce the amount of data required, it is possible to exclude immaterial inputs from the assessment. Immaterial inputs are defined as any materials that contribute less than 1% to the unpackaged weight of the product.

There are some limits to this 'cut-off rule', however:

- The total inputs excluded should not be greater than 5%.
- Inputs that are known to have a high GHG impact or are the primary purpose for manufacturing the product should always be included in the bill of materials.
- All APIs used should be included in the assessment regardless of its significance to the mass of the final product (because of their high GHG impact).

A screening assessment should be undertaken to identify any materials of high significance and determine the applicable materials to consider under the cut-off rules. Screening assessments and materiality tests provide valuable insight into the GHG emissions of a product and will allow prioritisation of data collection and efficient use of time and resource.

Unit of Analysis

The reference flow for the module is defined.

Primary Data and Allocation

Guidance on primary data requirements and collection is provided. Any relevant allocation issues are also discussed.

Secondary Data

Where secondary data are required, they are discussed in this section, and guidance on appropriate sources is provided.

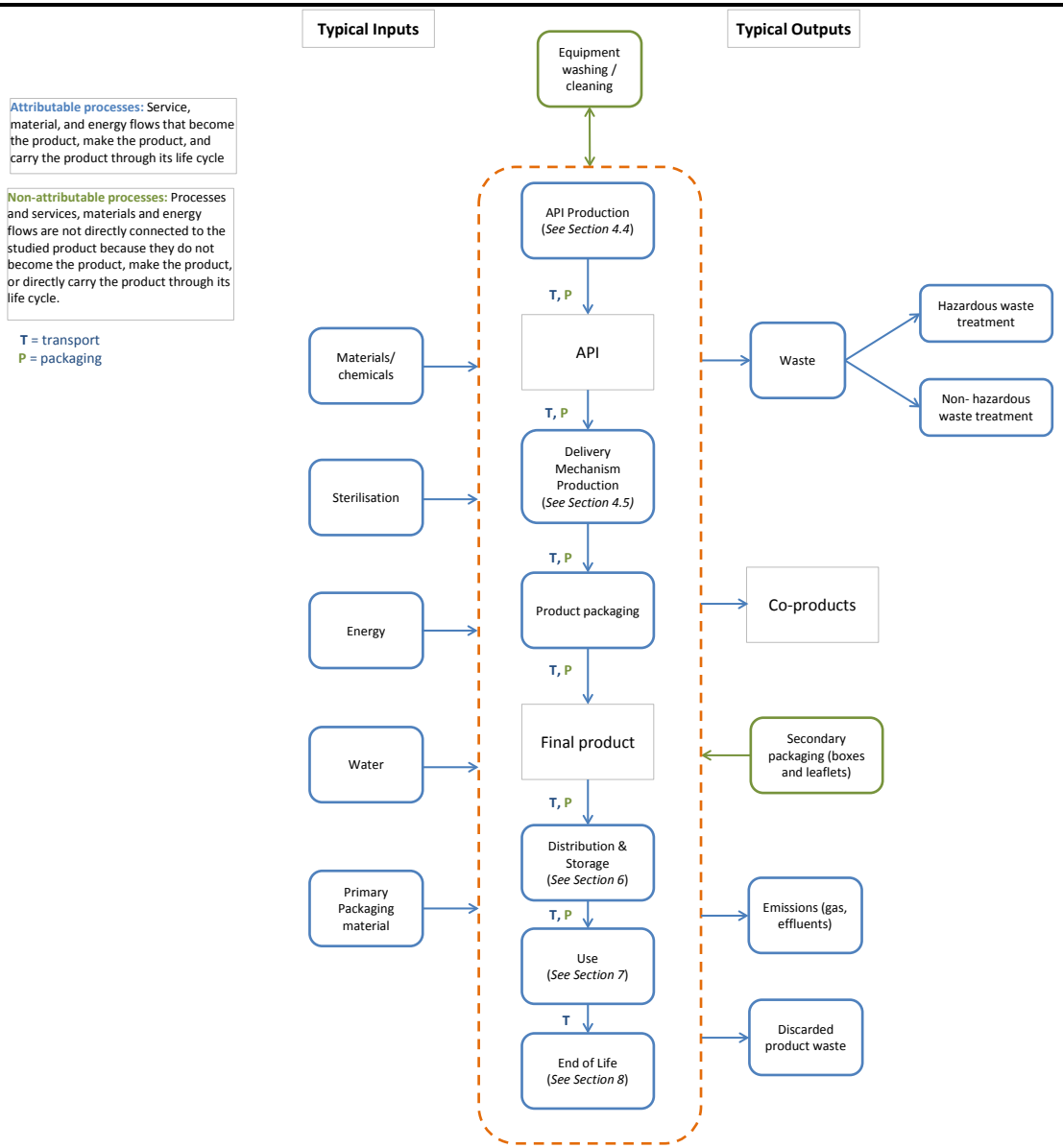
4.3 COMMON PHARMACEUTICAL GUIDANCE

Boundary Setting

The modular guidance in *Section 4* should be used when determining the cradle to gate impacts of pharmaceutical products. These modules should be combined with guidance in *Sections 5, 6 , 7 and 8* to build up the cradle to grave impact of the pharmaceutical product.

Figure 4.1 shows a general life cycle diagram of a pharmaceutical product.

Figure 4.1 Sample Process Map for Pharmaceutical Products



Unit of Analysis

Each module used to build up the product life cycle (eg the morphine life cycle example in *Section 1.3*) will have a recommended reference flow[1]. To complete the overall life cycle of a product these reference flows should be combined into a functional unit for the product.

What is a Functional Unit?

Reporting an API on a mass basis may be useful when considered individually. However, when a product's whole life cycle is assessed, there are further considerations that need to be accounted for. The reference for reporting should describe the function of the product when in use. Information to help define the product functional unit may be available in the leaflets and instructions for the product.

The following questions may be useful when defining the functional unit.

- **What is the product?**
  (the functional unit should describe what the product is)
- **How much of the product is considered?**
  (the quantity of product included in the assessment)
- **How is the product used and what does it do?**
  (the quality of use and function provided by the product)
- **How long is the product used for?**
  (the length of time the product is considered to be used and the product lifetime)
- **Where is the product used?**
  (the geographic location considered for product use)

[1] For example, for solid APIs, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass basis however the concentration of the API should also be reported.

Example Pharmaceutical Functional Unit

Consider a cradle-to-grave assessment of paracetamol. A simple reference flow may refer to the GHG inventory of one paracetamol tablet. This describes a product poorly, providing little information about dosage or how/where the product is used. Should an internal assessment investigate variation between use in different facilities, geographies, with different quantities of API, etc then further definition would be needed.

Including information to describe these additional considerations, a functional unit might be '*the purchase and ingestion of one paracetamol tablet, with 500mg API, by a customer at home in a specific geographic location*.

Guidance in *Section 9* should be referred to when reporting functional units. Functional units for care pathways are discussed in *Section 10*. Additional functional unit guidance is provided for medical devices in *Section 5.3*.

Some pharmaceutical products may require medical devices for administration and use. These are considered in this guidance as combination products and the supplementary information in *Section 5* should be considered.

Primary Data and Allocation

Primary data are required for processes under direct control of the company conducting the assessment, and are preferred in most instances. For further explanation of primary data recommendations and collection options, refer to *Section 2* of this guidance and *Chapter 8* of the Product Standard. The quality of data collected should be reported based on guidance provided in *Section 2* and *Section 9*.

Primary data are described below in terms of raw materials data and process manufacturing data. Raw materials data refer to the materials and chemicals included and consumed through the manufacture of the product, and can typically be described as the bill of materials data. Process data refer to all other inputs and outputs that occur during the manufacturing process. These may include processing chemicals (eg solvents), energy consumed through the process, emissions and waste arisings and discarded product. It is important to account for production efficiency (eg rework) when quantifying the inputs and outputs for a manufacturing process.

Raw Materials Data

Raw material and chemical inputs of all manufactured APIs are likely to be significant to the assessment. Therefore, accurate recording of input feedstocks is key to a robust assessment. Potential methods of collecting primary material data are explained below.

Collecting Materials Data

Data for material and chemical feedstock inputs should be collected for the operations identified as inclusions in the process map. Material and chemical data can be collected from a number of sources and methods including

- Operating and batch **manufacturing instructions** (process guides) for API manufacture typically contain detailed information for the material inputs and outputs required from the process and are a useful source of information.
- **Bill of materials** data can be used to identify raw material inputs, quantities and wastage rates for the API.
- **Financial systems** used for procurement and supply monitoring can provide useful information about materials purchased, supplier locations and quantities consumed.
- **Mass balances** from processes and chemical equations should always be undertaken to ensure losses in the process as well as waste are accounted for.

When documenting chemical inputs, the source and concentration should be clearly reported including commentary on where in the intermediate process chain the chemical lies.

Process Data

Depending upon the level of data that are available to describe the direct operations, a number of possible data collection methods exist for process data, including (in order of preferred approach):

1. direct measurement from process;
2. allocating site level data; and
3. theoretical calculations.

These approaches to process data collection are described in the following boxes.

1. Direct Measurements

Collecting process data based on direct measurements is the preferred approach. Examples of methods to collect data through direct measurements include

- Sub-metering of machinery used in operations
- Using flow meters or measurements to record mass or volume of consumable inputs

This approach is possible if operations identified in the process map are isolated and no co-product allocation is required.

2. Allocation of Process Data from Site

An individual operation or whole site may produce multiple products where it is not possible to identify the energy, consumables and emissions that are required for each individual product or co-product. Allocation of the process GHG emissions is then recommended. In practice, it is likely that multiple API products from the same process will have similar market value and, therefore, allocation based upon mass of the products should be used.

Single API Manufacture
Where a single API is produced data should be collected describing inputs for the site, sub-site or process over a period of one year and divided by yearly production.

Multiple API Manufacture with Similar Market Value
Where multiple APIs or co-products are produced from the same process and data cannot be disaggregated, the total process inputs for a period of one year should be collected. Should all APIs and co-products from the process have similar value in the marketplace then the total mass of all products and co-products for the period of data collection should be used to allocate GHG emissions per product / co-product.

Multiple API Manufacture with Different Market Value
Where multiple APIs or co-products are produced from the same process and they have notably different market values, allocation should be undertaken on an economic basis(where co-products have nominal value, allocating on a mass of output basis is not an accurate method for apportioning process GHG emissions). Yearly process data should be collected and all products and co-products identified. The total value of all products and co-products sold should be calculated and yearly process data divided by this value.

3. Theoretical Calculations

Operating instructions (process guides) for API manufacture describe detailed information regarding consumables, solvent use and heating/energy requirements for direct operations. For energy consumption the theoretical requirements can be calculated based upon thermodynamic equations for each process stage. Where multiple stages exist and cannot be separated, the theoretical energy demand from thermodynamic reactions can be aggregated.

Calculating energy consumption based upon theoretical methods excludes practical efficiency losses through conversion of energy in machinery or losses to the environment. These process losses should be considered and a representative scaling factor should be applied to the theoretical calculations. Should theoretical calculations be used, the scaling factor applied should be reported. Scaling factors should attempt to account for energy consumption in buildings associated with processes such as heating, ventilation and air conditioning (HVAC). A scaling factor can be based on expert judgement of process efficiency.

Secondary Data Sources

Guidance on general secondary data requirements and sources is provided in *Section 2* and specific guidance is provided in the sub-sections below. Further secondary data sources, in addition to those described in this document can be found on the GHG protocol website (1).

4.4 MODULE GUIDANCE: PRODUCTION OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)

4.4.1 *Synthetic Organic Chemicals*

Description

Organic synthesis covers the construction of organic compounds through reactions involving solvents. Chemical feedstocks from various sources typically undergo transformations and are then purified to make APIs. A survey indicating the types of chemical transformations which are used in the synthetic manufacture of APIs has been published and includes alkylation, acylation, deprotection and functional group interconversion (2).

Examples of APIs manufactured through organic synthesis may include:

- Acetaminophen (eg paracetamol);
- Aspirin (eg acetylsalicylic acid);
- Sildenafil citrate;
- Various nutritional supplements.

(1) http://www.ghgprotocol.org/Third-Party-Databases

(2) 'Analysis of the reactions used for the preparation of drug candidate molecules', Carey J, et al, 2006

Boundary Setting

Manufacturing an API via chemical synthesis can require many intermediate chemical transformations (>25 in some cases). Any of these intermediate stages can be outsourced, and the API manufacturer may purchase intermediate products at any stage along this process. For example, half of the chemical transformations for an API manufacturer may be outsourced. As a result the whole organic synthesis chain may not be under the direct control of the API manufacturer.

A sample process map showing some example intermediate chemical transformations is described in *Figure 4.2.* A similar process map should be developed when undertaking inventory calculations for API production. It should clearly identify all core processes in the product chain, as well as all processes under the direct control of the company undertaking the assessment.

Typical processes to consider in the organic synthesis of APIs are outlined below.

Include these attributable processes:

- Material and chemical inputs
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal
- Solvent manufacture, use and disposal
- Catalyst manufacture, use and disposal
- Solvent recovery and incineration
- Process emissions from synthesis

Include these non-attributable processes:

- Chemicals used for cleaning
- Sterilisation
- Refrigerant leakage associated with product manufacturing

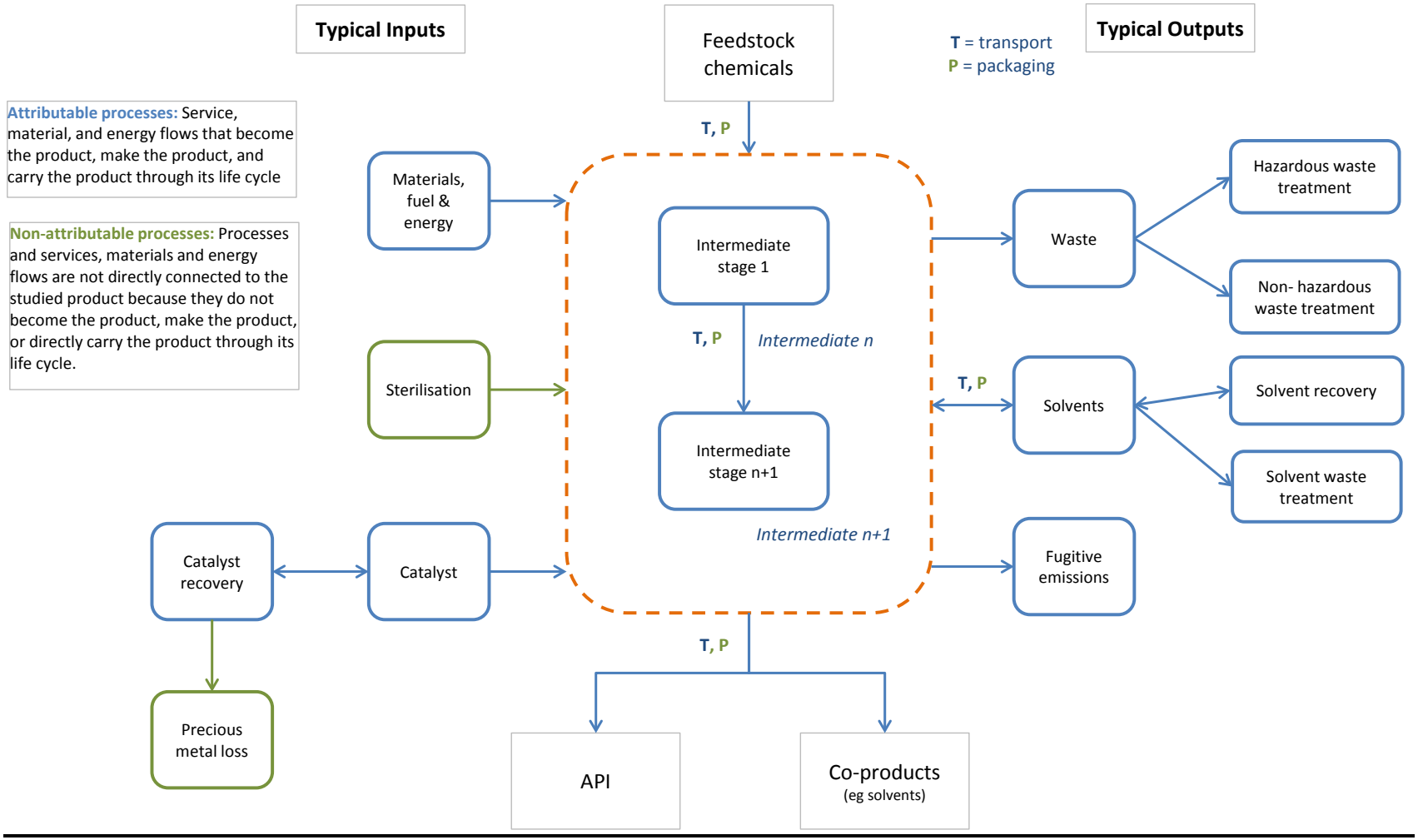
Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

Unit of Analysis

For APIs manufactured in solid form, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Figure 4.2 ***Sample Process Map for Synthetic Organic Chemical APIs***



Primary Data and Allocation

Primary data are required for processes under direct control of the company conducting the assessment, as identified in the developed process map. For further explanation of primary data recommendations and collection options, refer to *Section 2* and *Section 4.3* of this guidance and *Chapter 8* of the Product Standard. The quality of data collected should be reported based on guidance provided in *Section 2*.

Salbutamol Sulphate Example

The GHG inventory of salbutamol sulphate, an Active Pharmaceutical Ingredient (API) in asthma inhalers, was investigated. Synthesis of salbutamol sulphate requires five separate process stages and over 30 raw materials. These stages add functional groups to an advanced intermediate chemical, which is eventually hydrogenated and purified into a salt.

Raw Material Primary Data Collection

The bill of materials (BOM) was used to identify the quantities of purchased raw materials as opposed to intermediates and waste products. This was then scaled up for the number of batches produced during that year. Consumables were excluded as these are normally not contained within the BOM, and their impact is normally negligible.

Manufacturing Primary Data Collection

A number of specific data sources were obtained from a Technical & Operations director on-site. These included building energy, fugitive emissions, and production volumes. A contact on-site provided more detailed data relating to the API (eg building-level or site-level monitoring of energy consumption & emissions). Where building-specific data were not available, corporate environmental data was a good source for water and waste data. This was subsequently divided by the total production volumes for all the site's outputs (APIs & intermediates) and scaled for the API.

Secondary Data Source Selection

Site energy and fugitive emission data were characterised using Defra GHG reporting emission factors for electricity, natural gas and process carbon dioxide.
For purchased raw materials related to salbutamol sulphate, emission factors were generated from published life cycle inventories using the following hierarchy:

- an exact match;
- similar chemistry;
- combining its constituent chemicals for synthesis, and finally;
- chemical source (organic/ inorganic)

A palladium catalyst was used during a hydrogenation step, which was sent back once spent and regenerated. To calculate the amount of palladium used within the process, the metal loss rate was requested from the supplier. This would not include the energy and solvents required during the regeneration process, but gave an estimate of its possible impact.

Transport

For all purchased raw materials, an assumption of 2,000km by articulated lorry was used. This was agreed as reasonable during a call with the on-site contact as most of the chemicals are sourced from mainland Europe. The transport of waste allocated to the API was sourced from a waste management schedule sent to the Scottish Environment Protection Agency. This document provided the transportation mode as well as facility addresses so that a distance could be calculated and appropriate emission factors selected.

Secondary Data Sources

For processes identified in the process map that are outside the direct control of the company, primary data collection is still preferred. However, suitable secondary data

sources can be used to represent these inputs and modules, when the quality of secondary data is better than the quality of the primary data.

General secondary data sources can be found on the GHG protocol website [1]. Specific sources relevant for organic synthesis are considered here.

Chemical Feedstocks

Typically a chemical is purchased as a feedstock to begin the organic synthesis process. A company may only directly undertake some of the intermediate processes to manufacture the API, but the initial base feedstock used should always be determined regardless of the stage at which the company begins processing. For simple chemicals, effort should be made to collect primary data as far up the value chain as possible.

To approximate purchased chemicals from secondary data sources, the following hierarchy should be used:

- an exact match;
- similar chemistry;
- combination of constituent chemicals for synthesis (eg using stoichiometric calculations with acrylic acid and ethanol data to approximate ethyl acrylate); and
- chemical source category (eg organic versus inorganic chemicals).

Potential sources for chemical feedstock secondary data include:

- Ecoinvent;
- US LCI;
- ILCD; and
- International Journal of LCA.

Should the relevant chemicals data not be available through these sources, or other life cycle inventory databases, a software tool called Finechem has been developed by ETH Zurich [2] and may be used to estimate GHG emissions from chemical manufacture. To effectively use the Finechem software tool, knowledge of chemistry and chemical structures is beneficial.

(1) http://www.ghgprotocol.org/Third-Party-Databases
(2) http://www.sust-chem.ethz.ch/tools/finechem

Finechem – Approximating Petrochemical Based Feedstocks

Finechem is a freely distributed software tool that approximates emission factors of petrochemical based feedstocks from their molecular structure. When primary and secondary data are not available, Finechem can be used to approximate the GHGs of relevant feedstocks without needing to approximate the manufacturing process. This model should only be used for base feedstocks and not for any chemical transformations used to manufacture the API. Using Finechem approximations is considered a lower data quality than using life cycle inventory datasets and this should be reflected in data quality reporting (see *Section 2)*.

Comparative example:
Using the Finechem method the emission factor for Para-hydroxyacetophenone is 5.0 kg CO_2e / kg. An approximation from public LCI datasets based upon a phenol and acetic anhydride and resulted in a calculated emission factor of approximately 7.0 kg CO_2e / kg.

Intermediate Chemical Transformations (Intermediate Products)

Manufacture of an API may contain many intermediate chemical transformations, and a company can take on any number of these intermediate processes throughout API manufacture. A company may purchase a partially manufactured API from a contractor and not be able to collect primary data for the upstream intermediate processes. To approximate these intermediate processes outside the company's direct control, the following approach can be taken.

Accounting for Intermediate Chemical Transformations

If primary data for intermediate processes outside the control of the company are not available, the intermediate processes should be approximated using one of two methods. Method 1 is the preferred approach. Using either method should be considered as having a low data quality score and this should be reflected in data quality appraisal (see *Section 2*).

Method 1: Theoretical Approximation
The initial chemical feedstock should first be identified followed by the chemical processes that the API undergoes during manufacture. These data should be readily available through either the company R&D activities or through the detailed operating instructions. Theoretical calculations based on thermodynamics and chemical equations can be undertaken to calculate each intermediate process stage. The intermediate process stages can be combined with the chemical feedstock to develop an emission factor for the intermediate product entering the company's direct operations.

Method 2: Chemical Transformation Scaling Method
Should the intermediate process stages not be known, or it is not possible to calculate the theoretical process GHG emissions, a scaling system can be applied. The initial chemical feedstock should still be identified and approximated. Once the number of intermediate chemical transformations is identified, a scaling factor can be applied per chemical transformation to produce an estimate for the API. This should be given a lower data quality score and reported based on guidance in *Section 2*.

A study of a number of synthetic APIs collated by the ABPI indicated that the median emission factor for synthetic APIs was 1,500 kg CO_2e / kg API, with a range of 100-10,000+ kg CO_2e / kg API.

In all cases, the initial feedstock chemical and the intermediate processes undertaken outside of the company's direct operations should be identified and reported in the process map.

Solvent Manufacture and Disposal

The use of solvents can be significant in the process of organic synthesis. Their manufacture and importantly disposal needs consideration.

Manufacture
Many solvents are considered as commodity materials and, therefore, consistent use of emission factors for solvent manufacture when calculating different APIs should be considered. The Ecoinvent dataset contains approximately 50 solvents that are

described in detail in Ecoinvent documentation [1]. A further document lists emission factors for these solvents based on Ecoinvent data [2].

These emission factors represent average processing for a specific geography and time period. Consideration should be given to amending these datasets to be more specific to the solvents used.

Disposal

There are a number of processing pathways that used solvents can follow, including:

- recovery/recycling/ use as non-pharmaceutical grade solvent (eg in paint thinners); and
- disposal via incineration (with/without energy recovery).

Primary data are preferred and should be collected wherever possible. If primary data are not available, the disposal process can be modelled based on secondary data sources from average data sets. One useful example is the Ecosolvent tool developed by ETH Zurich [3]. Ecosolvent is an LCA tool that allows for various waste solvent treatment methods to be assessed for user-defined waste solvent mixtures. This model can be applied for distillation, incineration and waste water treatment technologies to approximate an emission factor for waste solvents, and pre-treatment impacts can be accounted for in the process.

Co-products from solvent disposal (eg energy recovery, solvent recycling or sale of waste solvent for further use) should be considered based on guidance for co-product allocation in *Section 4.3*. Where energy is recovered from solvent incineration, this should be accounted for either within the direct operations of the company's energy consumption, or considered as a co-product where sold off-site.

4.4.2 *Cell Culture*

Description

API manufacture through the cell culture process (or biopharmaceutical process) involves the generation of APIs from cell lines. This category includes development of cell lines, a fermentation stage to allow for cell proliferation in small or large scale, followed by the extraction of monoclonal antibodies, enzymes, anticancer agents, vaccines or other drug substances. Additional processes to manufacture the API may include various gross and fine separations steps, filtration and centrifugation to extract the relevant product.

(1) Ecoinvent data v2.0 Life-Cycle Inventories of Petrochemical Solvents and Highly Pure Chemicals
http://www.ecoinvent.org/fileadmin/documents/en/080314_ecoinvent-event/Wernet_chemicals_080314.pdf
(2) Roundtable on Sustainable Biofuels GHG Calculation Methodology, Version 2.0, 2011
(3) Ecosolvent tool, http://www.sust-chem.ethz.ch/tools/ecosolvent

Boundary Setting

Cell culture can be carried out in small or large scale processes. Typically, cell lines are cultivated internally through R&D operations. These cell lines are then transferred to vessels containing growth medium. These vessels are agitated continuously at temperatures that depend on optimum growth conditions of the cell type until the viable cell count is achieved. The resulting material goes through filtration and purification steps, and the API is extracted for use. Fermentation typically occurs as a batch process. However, continuous fermentation is a current area of development.

A sample process map showing some example intermediate processes is illustrated in *Figure 4.3.* A similar process map should be developed when undertaking inventory calculations for API production via cell culture. It should clearly identify all core processes in the product chain, as well as all processes under the direct control of the company undertaking the assessment.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Storage of cell lines
- Growth media
- Fermentation heat and energy
- Extraction & filtration energy
- Disposal of growth media
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal

Include these non-attributable processes:

- Chemicals used for cleaning
- Vessels for fermentation (excluding batch)
- Sterilisation of vessels
- Manufacture and disposal of filtration material
- Refrigerant leakage associated with product manufacturing

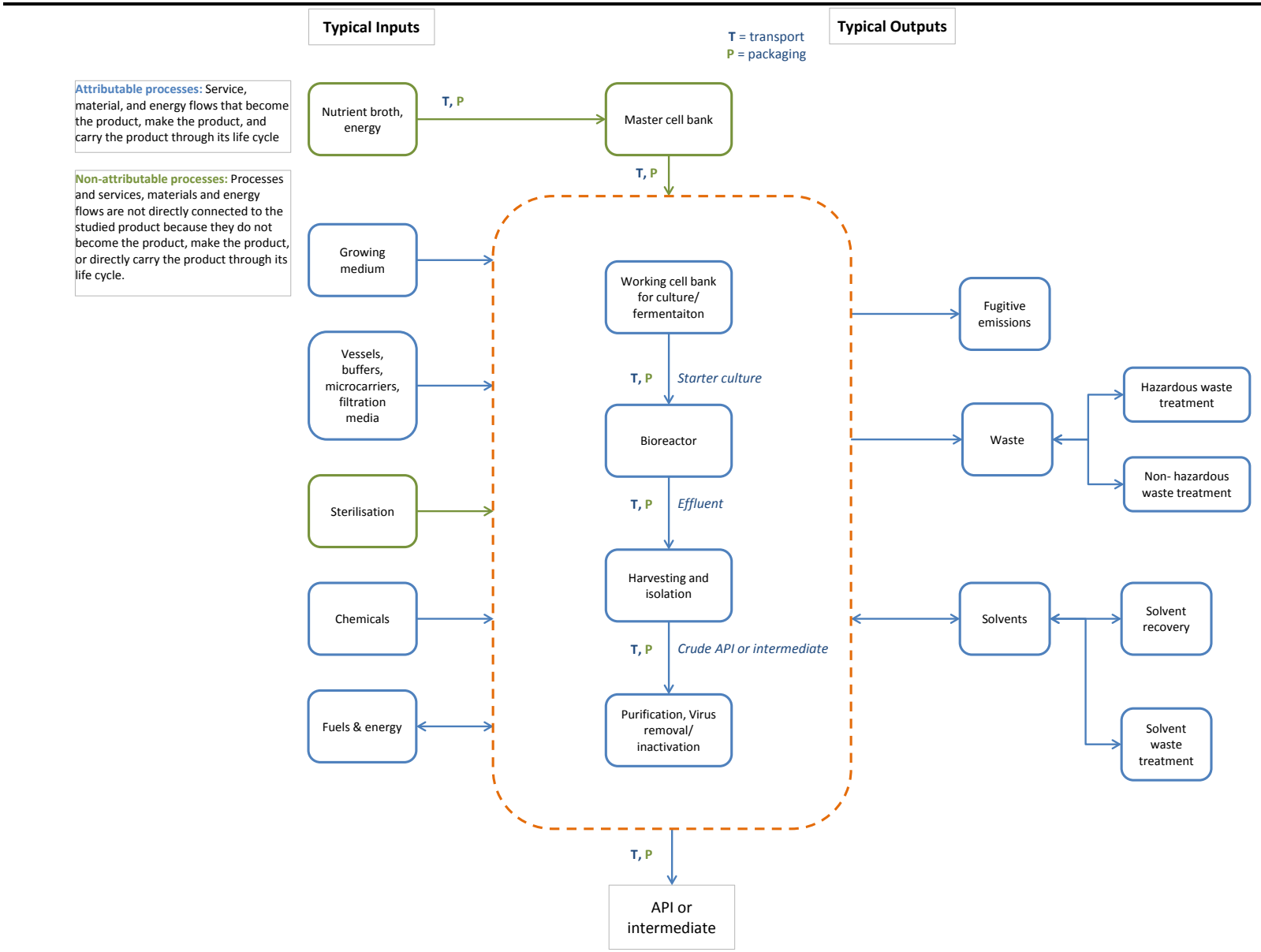
Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Batch vessels for fermentation
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

Unit of Analysis

For solid APIs manufactured from the cell culture process, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Figure 4.3 Sample Process Map for Cell Culture API



Primary Data and Allocation

Primary data are required for processes under direct control of the company conducting the assessment, and are preferred in most instances. For further explanation of primary data requirements and collection options, refer to *Section 2* and *Section 4.3* of this guidance and *Chapter 8* of the Product Standard. The quality of data collected should be accurately reported based on guidance provided in *Section 2*.

An explanation of different methods for collecting process data are outlined in the box in *Section 4.3*. This approach is particularly relevant for chilled storage of cell lines and filtration (eg energy consumption by the centrifuge) where site-wide data may be available and allocation is recommended.

Collecting Fermentation Primary Data

Fermentation
Primary data for the materials and energy used in fermentation should be collected. Warming and agitation are often required during the fermentation process. Energy should be collected and reported based upon guidance provided for direct measurements or theoretical calculations in *Section 4.4.1*.

Emissions from the fermentation process are particularly relevant and should be accounted for when collecting primary data. Fossil and biogenic GHG release should be reported separately, based on the composition of the growth media and content of biogenic carbon. If measuring emissions release from fermentation is not possible, determining emissions from theoretical calculations and proportioning these based upon the biogenic content of the growth media is an acceptable approach.

Disposal of waste growth media should be accounted for based upon measured quantities of waste growth media.

Sterilisation
Energy and chemicals consumed through sterilisation of fermentation vessels is likely to contribute significantly to the results for cell culture API manufacture. Data should be collected and allocated per reference flow for energy, water and chemicals consumed through vessel sterilisation.

Growth Media

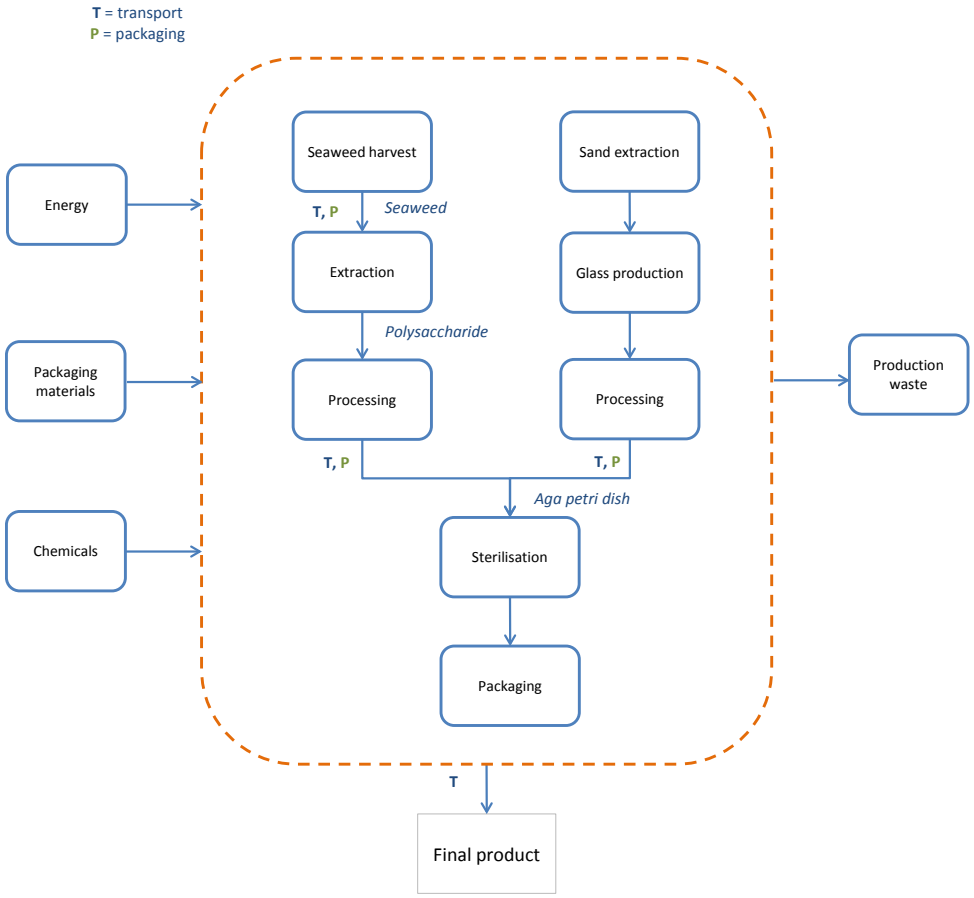
The growth media used is an attributable process. The type of material and source should be reported. Biogenic carbon in the growth media will need to be addressed as required by the Product Standard. Should the growth media be manufactured by the company, manufacturing data should be collected for this process including material inputs, energy, emissions and waste. Measurements should be taken in order to understand the quantity of growth media required to produce the desired yields, and these data are to be combined with the growth media primary data or secondary data emission factor.

An example process diagram for the manufacture of the growing medium is given below.

Disposal of the waste growth media can be equally significant and should be considered in the assessment. A number of disposal pathways may exist, and should be considered based on guidance given in *Section 8*.

Growth Medium Example

Raw material, in this case seaweed, is first acquired and the chemicals of interest are extracted in order to manufacture the growth medium. In this example, petri dishes are used as the growing environment.



Secondary Data Sources

For processes identified in the process map that are outside the direct control of the company, primary data collection is still preferred. However, suitable secondary data sources can be used to represent these inputs and modules, when the quality of secondary data is better than the quality of the primary data.

General secondary data sources can be found on the GHG protocol website (1).

4.4.3 *Egg-Based Cultivation*

Description

API manufactured through the egg-based cultivation process uses eggs (typically chicken eggs) as growing vessels for cell cultivation. Cell lines developed through R&D activities are injected into eggs specially grown for cultivation and incubated until the cells have sufficiently grown. The cells are extracted and undergo further processing whilst the egg is discarded. An example of an API manufactured through the egg-based cultivation process includes influenza vaccines.

Boundary Setting

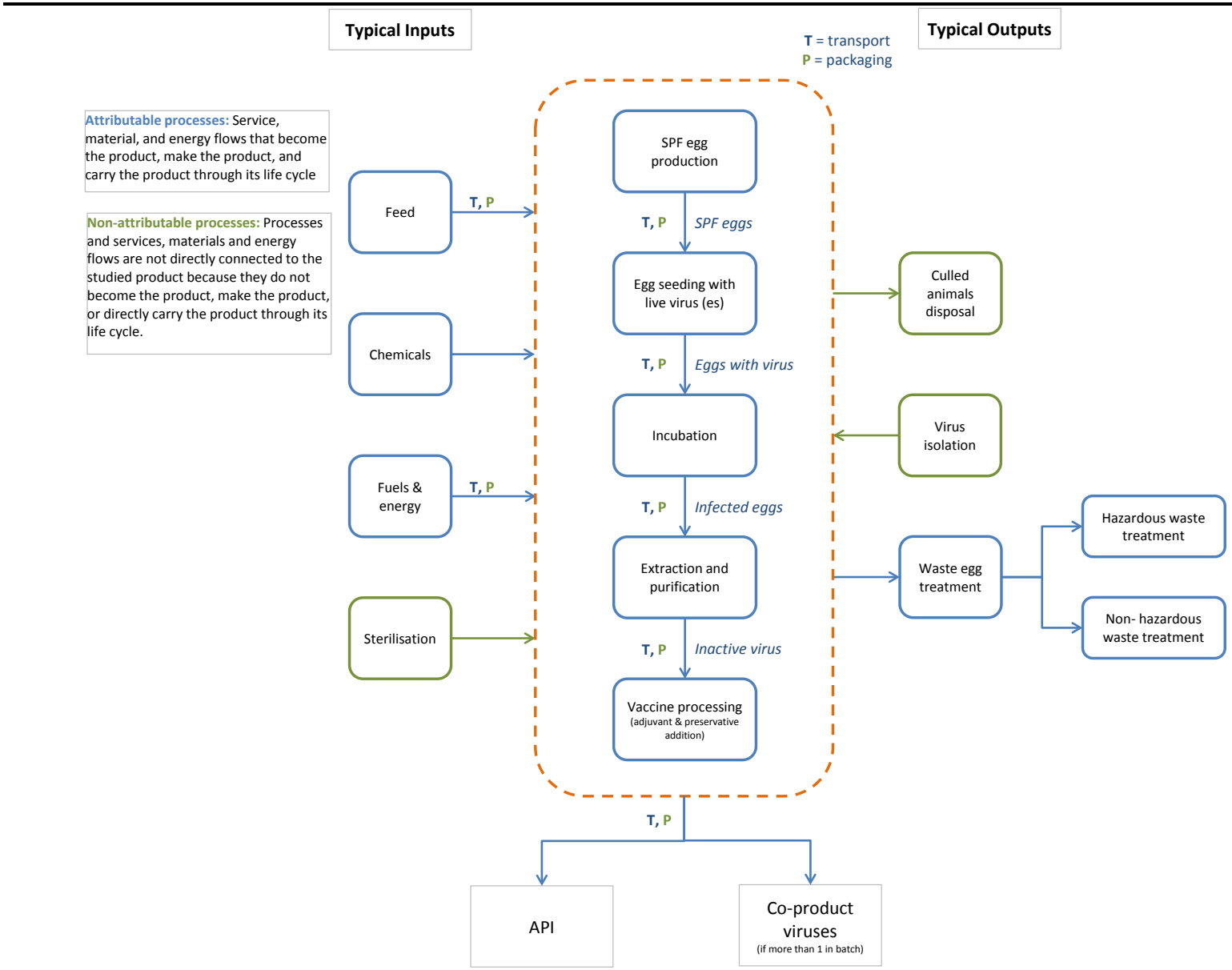
The process requires chicken eggs to be produced in a sterile environment, and then transferred for use as an incubation vessel. The GHG emissions associated with producing the eggs are regarded as being within the scope of the API manufacture. Storage of the cell lines before injecting into eggs is also considered. Once the cells have been injected into the eggs, these are incubated. The incubation step requires heat and energy. Once grown, the cells are extracted for further processing. Additional refining may involve processes similar to that described in organic synthesis in *Section 4.4.1*.

Multiple vaccines can be grown in one egg vessel. Allocation is recommended and is discussed further in this section. The waste egg can be cooked to remove any residual vaccine, and disposed via appropriate pathways.

A sample process map showing some example intermediate processes is depicted in *Figure 4.4.* A similar process map should be developed when undertaking inventory calculations for API production. It should clearly identify all core processes in the product chain and all processes under the direct control of the company undertaking the assessment.

(1) http://www.ghgprotocol.org/Third-Party-Databases

Figure 4.4 Sample Process Map for Egg-Based Cultivation (Vaccine) API



Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:	Include these non-attributable processes:
• Chicken rearing & egg production • Injection and incubation • Extraction • Further synthesis processes • Material and chemical transport • Energy/fuel generation and consumption • Cooking and appropriate disposal of waste egg • Storage after extraction	• Chemicals used for cleaning • Sterilisation • Culled animal disposal • Isolation of viruses • Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

Unit of Analysis

For solid APIs manufactured from the egg vaccine process, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Primary Data and Allocation

Primary data are required for all processes under direct control of the company. Some processes, such as egg production, may be outsourced to contractors. In this case, primary data are preferred, but secondary data for egg production may be used (see later in this section).

Additional injection, incubation, extraction and cooking/disposal stages also require that primary data be collected. This should be undertaken based upon guidance given in *Section 4.4.1* for direct measurements. Wherever possible, energy, process inputs, emissions and waste should be reported through measurements. If this is not possible, site data should be reported and appropriately allocated.

Disposal of egg material occurs in the form of damaged eggs during production, and used eggs after vaccines have been cultivated. Damaged eggs should be taken into consideration when determining the egg production GHG emissions. Egg disposal

from the incubation process should be accounted for based on the recommendations below.

Incubation Primary Data

Once eggs are received, a section of shell is usually removed and the cell line is injected into the egg for incubation. Incubation requires a sterile environment, heat and energy. Data should be collected through direct measurements, site wide data or theoretical calculations on a per egg basis for:

- heat and energy required for incubation; and
- energy, chemicals and water required for sterilisation of equipment

The vaccine yields per egg are important for determining the quantity of egg required per mass of vaccine produced. Where multiple vaccines are grown in a single egg, allocation is recommended (see box).

Egg Disposal Data

Once the vaccine is cultivated, the egg is discarded. The egg can be cooked before disposal to ensure residual cells are destroyed. Should cooking be carried out, primary data should be collected for energy related to the cooking process (per egg). It is likely that the disposal process is not under the direct control of the company. However, the disposal pathway should still be identified so that secondary data may be used.

Requirements for the disposal of waste egg can vary depending on the region of operation. In some regions, the waste egg is considered hazardous whilst in others, the waste is classified as non-hazardous.

Take the following steps to account for egg disposal.

- Identify the classification given to the waste egg (hazardous / non-hazardous).
- Identify the actual disposal pathway of the egg (incineration, landfill, anaerobic digestion, etc) – either actual or estimate.
- Apply secondary emission factors as described in Section 8.
- If disposal is under the direct control of the company, collect energy consumption and emissions data from the process.

It is possible to grow different vaccines in a single egg at the same time and, therefore, allocation of the production processes is recommended as discussed below.

Egg Vaccine Allocation

Should multiple vaccines be incubated in a single egg, allocation is recommended. Allocation should follow the approach outlined in *Section 4.6.1*.

Where the vaccines have similar market value, allocation should be undertaken on a mass basis. Where vaccines have significantly different market value, economic allocation is advised.

Secondary Data Sources

Production of eggs for vaccine growth and disposal of waste eggs is likely to lie outside the direct control of the company manufacturing the API. Secondary data should be used for these processes where primary data are not available.

For the process stages under the direct control of the company (eg incubation), secondary data for energy generation and combustion, chemical manufacture and other process inputs can be used based on secondary data described in *Section 2.4.6*.

Egg Production Secondary Data

Should the rearing of chickens be outside the direct control of the company, secondary data may be used.

Various sources exist for the impacts associated with egg production. One example is the Defra study that identifies the GHG emissions per egg produced (*Defra, Determining the environmental burdens and resource use in the production of agricultural and horticultural commodities).* Further information is available in the associated report and model. As a guide, however, a GHG value of 5.5 tonnes CO_2 per 20,000 eggs is provided.

Consideration should be given to the geography, time period and technology of the egg production, and secondary datasets should be amended where possible to reflect this.

Secondary values should be reported as both mass per egg and on a 'per egg' basis for use in incubation. Both are recommended due to the varied mass of eggs and the need to document the quantity of egg being disposed.

It is expected that egg production specifically for vaccine cultivation requires environmental control measures beyond those normally encountered for egg production for food. Consideration should be given as to whether an uplift factor is to be applied to GHG emissions from eggs produced for food.

4.4.4 *Conjugate Vaccines*

Description

Conjugate vaccines are created by linking antigens or toxoids with a microbe that can be recognised and accepted by the receiver. By conjugating the antigens with a carrier protein the risk of bacterial disease is minimised. Examples of vaccine manufacture via the conjugation process include various meningococcal conjugate vaccines.

Boundary Setting

Conjugate vaccines include the production of proteins, and cultivation of antigens and toxoids to be combined to produce the conjugate. The protein and antigens are made reactive through derivativization and combined to produce the vaccine. Purification and filtration is then undertaken to produce the final product.

Other methods of manufacturing vaccines exist and the guidance provided for other modules (eg cell culture, egg-based cultivation and synthetic organic chemicals) should be consulted where relevant to the vaccine production processes being appraised.

A sample process map showing some example intermediate processes for conjugate vaccines is depicted in *Figure 4.5.* A similar process map should be developed when undertaking inventory calculations for any API production. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Key attributable and non-attributable processes that should be included in the assessment are outlined in the boxes overleaf.

Unit of Analysis

For solid APIs manufactured as conjugate vaccines, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Primary Data and Allocation

Data requirements for conjugate vaccine creation should follow the life cycle stages presented above. Primary data collection processes described in *Section 4.3* can be employed to build up the GHG inventory of the conjugate vaccine product. Data collected should consider the use of chemicals and energy for each process. Particular consideration should be given to the use of solvents and membranes for the filtration and purification of vaccines.

Secondary Data Sources

For processes identified in the process map that are outside the direct control of the company, primary data collection is still preferred. However, suitable secondary data

sources can be used to represent these inputs and modules, when the quality of secondary data is better than the quality of the primary data.

General secondary data sources can be found on the GHG protocol website [1].

Include these attributable processes:

- Creation of proteins
- Creation of antigens or toxoids
- Chemicals and energy for derivativization
- Conjugation
- Chemicals and energy for filtration and purification
- Further synthesis processes
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal
- Storage

Include these non-attributable processes:

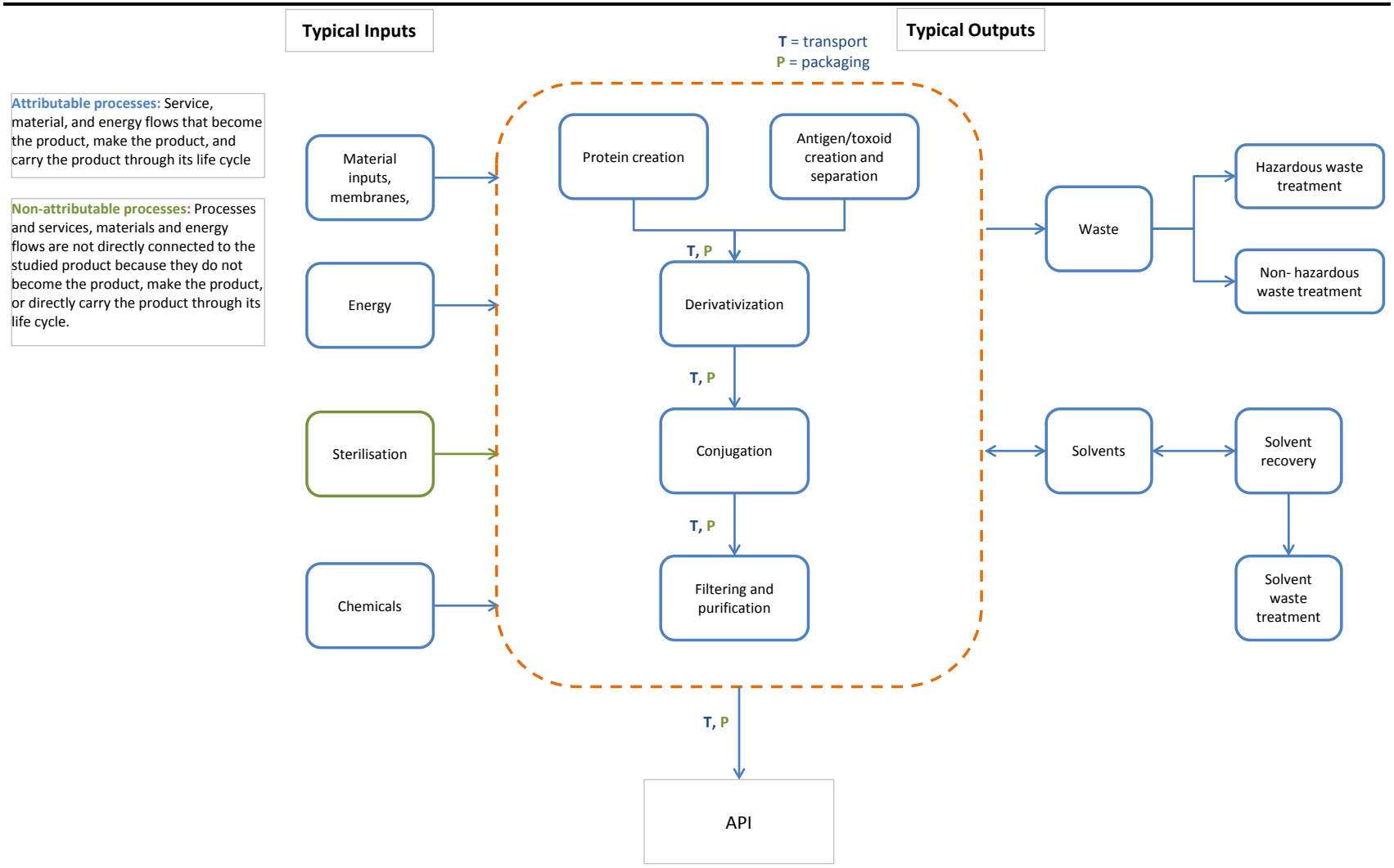
- Chemicals used for cleaning
- Sterilisation
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

(1) http://www.ghgprotocol.org/Third-Party-Databases

Figure 4.5 Sample Process Map for Conjugate Vaccines



4.4.5 *Plant-Based Extraction*

Description

The manufacture of APIs through plant-based extraction involves the cultivation and extraction of substances from plant-based sources for further processing. Typically, plants are cultivated and then crushed to extract the amino acids and sugars. Chemical extraction is then undertaken and further refined to produce the API.

Examples of APIs manufactured through plant-based extraction include:

- alkaloids from poppies;
- taxols from yew needles; and
- digoxin from foxglove.

Boundary Setting

A sample process map showing some example processes for plant based extraction is illustrated in *Figure 4.6.* A similar process map should be developed when undertaking inventory calculations for any API production. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Cultivation of plants
- Fertilisers and pesticides
- Mechanical processing (eg extraction)
- Chemical extraction
- Artificial cultivation impacts (eg greenhouses)
- Harvesting and drying energy
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal

Include these non-attributable processes:

- Chemicals used for cleaning
- Sterilisation
- Disposal of waste material from cultivation
- Land use change
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

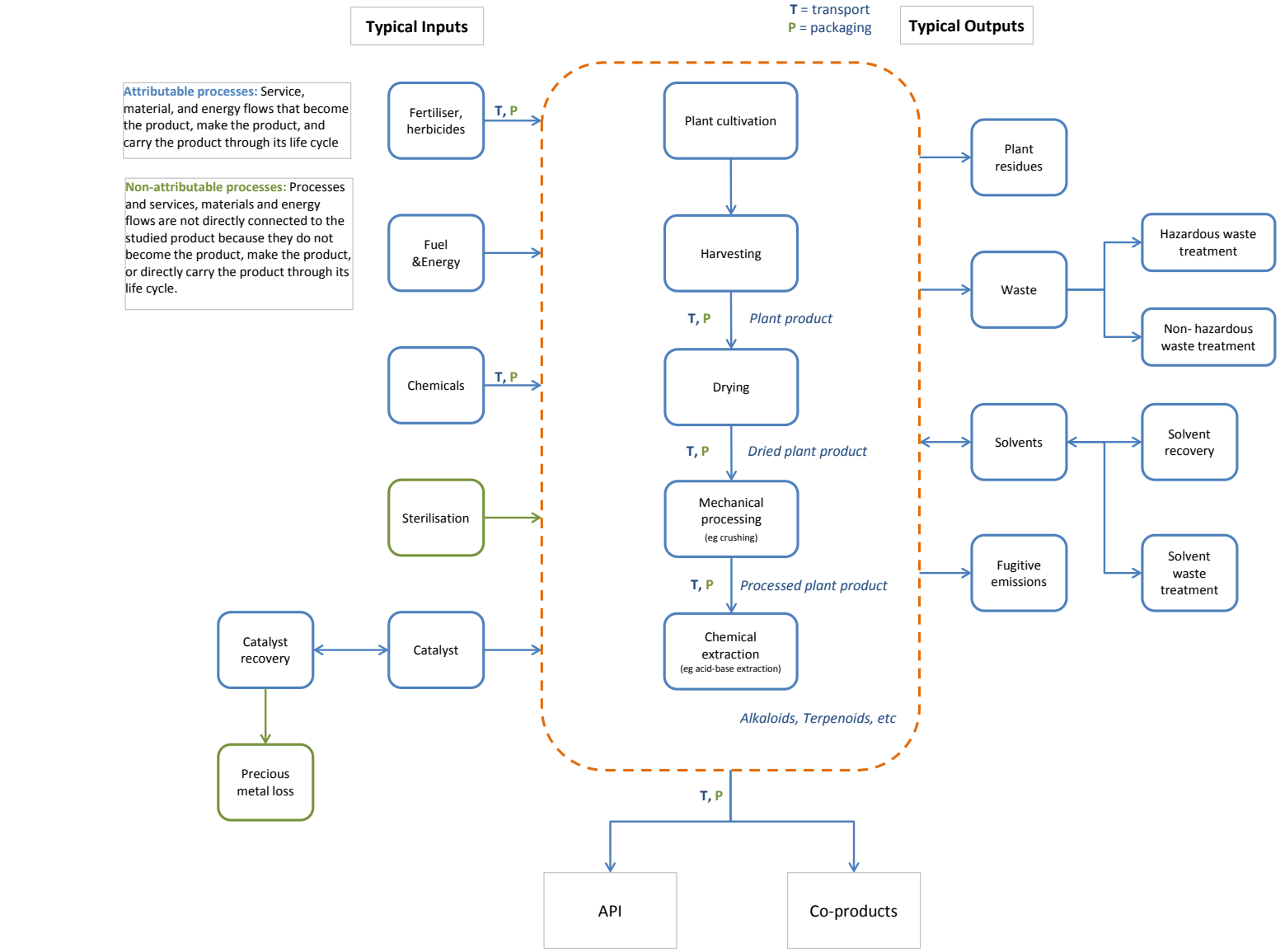
- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

Special consideration should be given to the method of plant cultivation and extraction processes. The cultivation of plants should be included in the assessment. However, should plants be grown naturally and require no anthropogenic input during growth, this process stage can be excluded as their growth is considered to occur without interference. If any materials or energy are required to aid plant growth, these should be considered. Collecting yew needles instead of farming yew trees commercially can be considered as natural plant growth.

The impacts associated with land use change shall also be considered where relevant and calculated, as described in Appendix B of the Product Standard.

Further refining after chemical extraction may reflect the organic synthesis pathway outlined in *Figure 4.2 (Section 4.4.1)*, and specific guidance for these processes can be drawn from *Section 4.4.1*. Enzymatic processes can often be used downstream for the manufacture of APIs through plant-based extraction techniques and further guidance on inclusion of these processes can be found in *Section 4.4.2*.

Figure 4.6 Sample Process Map for API Manufactured from Plant-Based Extraction



Unit of Analysis

For solid APIs manufactured from the plant-based extraction process, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Primary Data and Allocation

Primary data are required for processes under direct control of the company conducting the assessment, and are preferred in most instances. For further explanation of primary data recommendations and collection options, refer to *Section 2* of this guidance and *Chapter 8* of the Product Standard. The quality of data collected should be accurately reported based on guidance provided in *Section 2*.

Should the company own or operate farms to cultivate plants for chemical extraction primary data are recommended describing cultivation. Additionally, should the extraction processes be under direct control of the company, primary data are required.

Data recommendations for plant cultivation and chemical extraction are discussed in the boxes below.

Collecting Plant Cultivation Data

Where primary cultivation data are required, useful guidance is provided in the *PAS2050-1 Horticulture Supplementary Requirements* with regard to data needs and allocation procedures. This document should be referred to and data for the following processes included where relevant.

- Seed or young plant production
- Storage of young plant material
- Crop growing
- Storage of crops
- Transport
- Waste management
- Land use change impacts

Typical data recommended to capture the cultivation stages include

- Crop yield over time
- Vehicle fuel consumption during cultivation
- Fertiliser, pesticide and herbicide consumption
- Energy consumption for irrigation

Sampling of Agricultural Processes

Where there are multiple growers in the value chain, it may be possible to undertake sampling to limit the extent of data collection needed. Sampling should be considered if the number of agricultural suppliers is greater than 10.

Guidance for sampling should follow the description and examples provided in *PAS2050:2012 Assessment of life cycle greenhouse gas emissions for horticultural products, Section 7.3*.

When processing plants, a number of co-products may arise. The process of allocating cultivation GHG emissions to the co-products is discussed in below.

Plant Co-Product Allocation

A number of useful products and co-products can be sourced from plant-based material. Typically, when extracting chemicals for refining into APIs, co-products are generated. The most common co-product is the waste plant material, which may be sold as a feed or a fuel for energy generation.

The following hierarchy is advised when allocating to co-products:

- Expand the product system to avoid the need for allocation if possible.
- If co-products have similar characteristics, functionality or market value, then allocation should be undertaken on a mass basis.
- If co-products do not have similar characteristics, functionality or market value, then allocation should be undertaken on an economic basis.

In practice, the different co-products from cultivation are likely to differ significantly in market value and, therefore, economic-based allocation will be the preferred method. Further guidance for co-product allocation can be found in the *PAS 2050 Horticulture Supplementary Requirements*.

A special case exists where residual plant material from extraction may be combusted for heat and energy generation instead of being sold onwards. Should the heat and energy be used internally, emissions arising from the combustion process should be included, and the use of plant material will be reflected in the reduction of external energy consumed. Should heat and energy be generated on-site and exported, the system should be expanded by including the avoided energy consumption through use of the plant material (see *Chapter 9* of the Product Standard).

Accounting for Land Use Change

Release of sequestered carbon through previous land use change should be included where applicable, based upon recommendations provided in Appendix B of the Product Standard.

Should land use change have occurred during the previous 20 years of use, this should then be accounted for. Land use change impacts should be reported separately, as specified in the Product Standard.

Collecting Chemical Extraction Data

After plant cultivation, the chemical is extracted from the plant for further refining. Solvents are frequently used for extraction (such as for alkaloid extraction from poppies).

Typical data relevant to extraction of chemicals may include:

- Solvent consumption
- Solvent recovery and disposal
- Energy consumption
- Emissions and waste processing

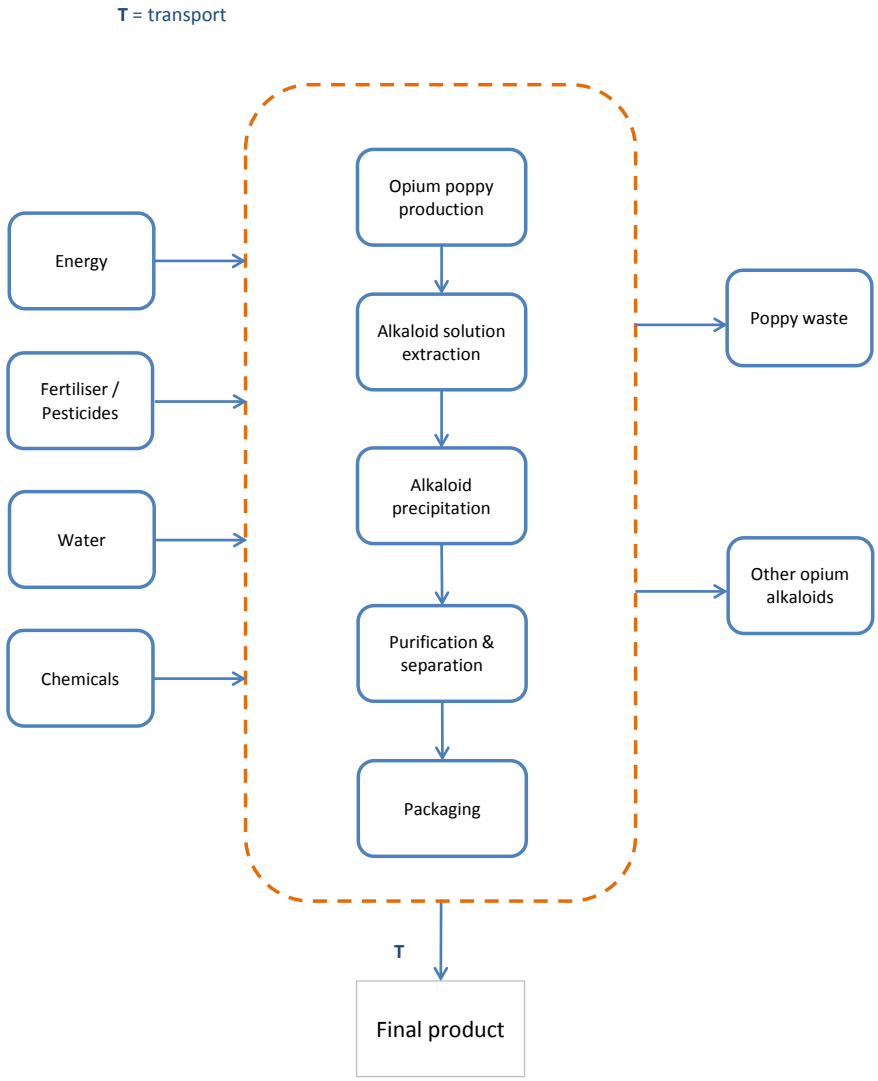
If measuring process inputs is not possible, calculating process inputs including solvent use, energy consumption and emissions may be possible from API operating instructions. Regardless of the method for collecting primary data, the actual yield rate from extraction is key to correctly allocating the process GHG emissions.

After chemical extraction, the API manufacture may follow a similar process as described in organic synthesis in *Section 4.4.1*.

An example of collecting data for API manufacture through plant-based extraction is outlined in the box overleaf.

Morphine Production Example

Poppies are grown and the head of the plant is removed to extract opium. Opium then passes through further extraction and purification stages before being packaged and used by the consumer.



Secondary Data Sources

For processes identified in the process map that are outside the direct control of the company, primary data collection is still preferred. However, suitable secondary data sources can be used to represent these inputs and modules, when the quality of secondary data is better than the quality of the primary data.

General secondary data sources can be found on the GHG protocol website (1). Should secondary data be required for plant cultivation, a number of potential sources are available depending on the plant type.

(1) http://www.ghgprotocol.org/Third-Party-Databases

Plant Cultivation Secondary Data

Potential sources of secondary data for cultivation of plants may include

- PAS2050 Horticultural Products Supplementary Requirements (www.bsigroup.com/pas2050)
- NNFCC UK's National Centre for Biorenewable Energy, Fuels and Materials (http://www.nnfcc.co.uk/)
- Food and Agriculture Organisation of the United Nations (http://faostat.fao.org/site/567/default.aspx#ancor)

4.4.6 *Animal and Human Derived*

Description

Animal-derived APIs refer to the extraction of ingredients from animal sources, whether they are farmed or reared naturally. Ingredients may be extracted from a living animal or alternatively it may be required to slaughter the animal. Co-products can arise from the rearing of animals.

Human-derived APIs refer to the sourcing of human plasma for further processing into vaccines. Albumin is typically extracted from blood through a centrifugation step and a subsequent separation process to use the proteins for vaccine cultivation. Separation can be carried out using various methods, such as ethanol fractionation.

Examples of APIs manufactured through these processes include:

- Blood clotting factors from human plasma;
- Heparin from pig intestines.

Boundary Setting

For animal derived APIs the rearing of animals for API manufacture should be included in the inventory calculations. If animals are reared and slaughtered to extract the required materials, co-products (eg meat) can be produced from the animal. Allocation should be considered under these circumstances based on guidance in *Section 4.3* and the Product Standard *Chapter 9*.

For human derived APIs, plasma is typically sourced from blood donations and albumin is separated through a centrifugation step, and an ensuing fractionation or purifying process. The albumin is used as a basis for vaccine cultivation, and further processing can be carried out to produce an API. Further processing may follow a similar path as described in the guidance for organic synthesis.

A sample process map showing some example intermediate processes is depicted in *Figure 4.7.* A similar process map should be developed when undertaking inventory calculations for any API production. It should clearly identify all core processes in the

product chain as well as all processes under the direct control of the company undertaking the assessment.

Key attributable and non-attributable processes that should be included in the assessment are outlined in the boxes below. For human derived APIs, impacts associated with donating blood for plasma extraction are considered as being outside the scope of the assessment.

Include these attributable processes:

- Rearing of animals
- Extraction of material from animals
- Energy and waste for human albumin plasma separation
- Chemicals and energy from fractionation and purification
- Further synthesis processes
- Material and chemical transport
- Energy/fuel generation and consumption
- Waste disposal
- Storage

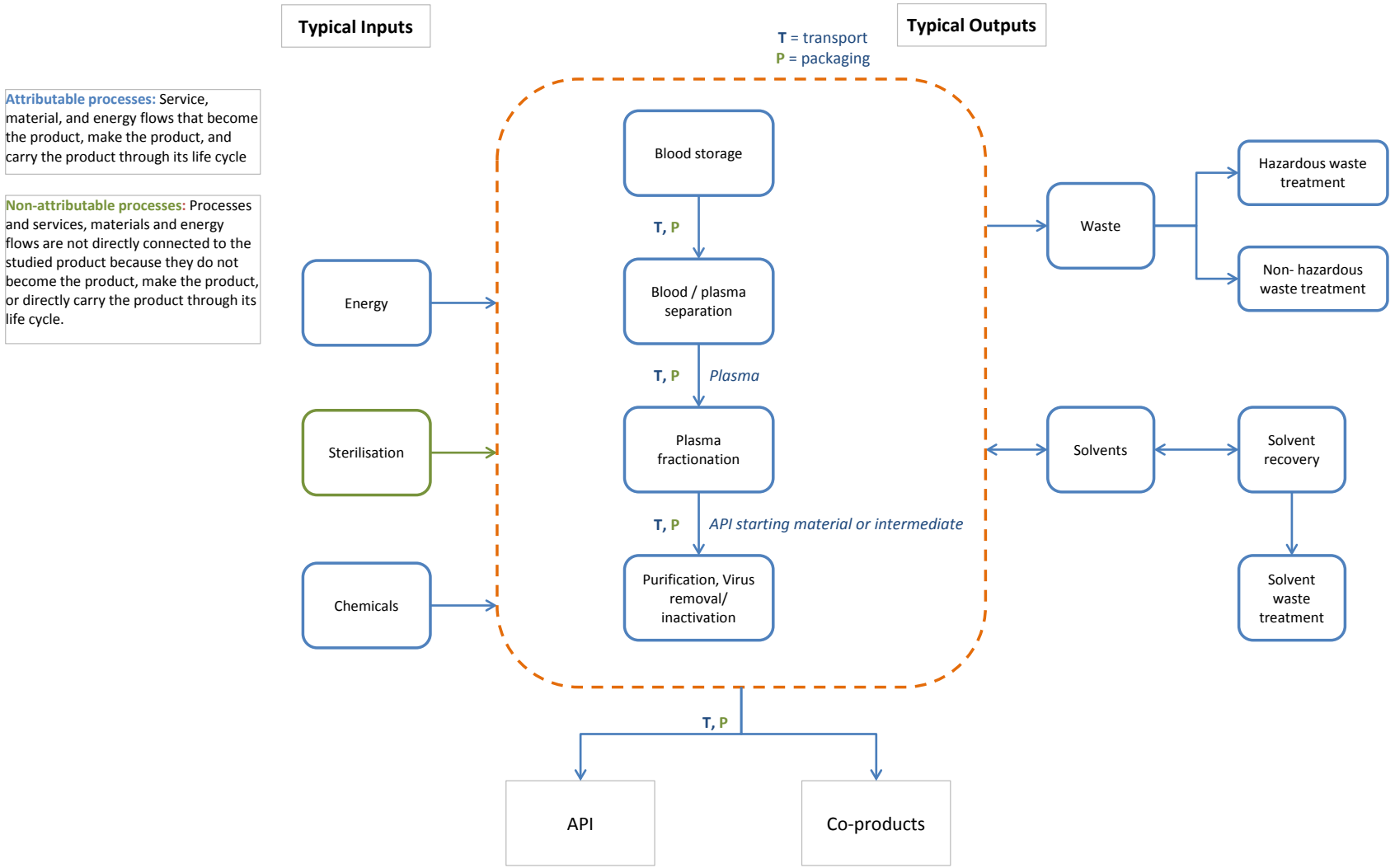
Include these non-attributable processes:

- Chemicals used for cleaning
- Sterilisation
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Extraction of blood through donations
- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

Figure 4.7 Sample Process Map for Human Derived API



Unit of Analysis

For solid APIs manufactured from the animal or human derived process, the output reference flow should be reported on a mass basis, ie per kilogramme of API. For APIs delivered in liquid form, the reference flow should still be provided on a mass of API basis however the concentration of the API should also be reported.

Primary Data and Allocation

For human derived APIs, extraction of blood from donations is excluded from the boundaries for plasma-derived products. Once the blood is sourced, the GHG emissions associated with storage, separation, purification and fractionation should be included as described in the process map for the product in question. For these operations under the direct control of the company, primary data shall be collected, based on methods detailed below for direct measurement, site data or theoretical calculations (also see *Section 4.3*).

Primary Data for Human Plasma

Once blood is sourced through donations, the GHG emissions associated with albumin separation should be included. Data should be sourced for all separation, fractionation and purification processes identified, and data quality should be considered and reported. For example:

- Energy consumption from separation by centrifugation;
- Energy consumption from fractionation and purification;
- Chemicals used throughout separation including ethanol in fractionation;
- Disposal of wastes and chemicals from the process through proper disposal pathways.

The rearing of animals for API extraction should be considered when calculating GHG inventory results.

Rearing of Animals

Where APIs are sourced from animals, the rearing of animal should be considered. Data that may be relevant to the rearing of animals can include:

- Animal feed;
- GHG emissions from animals (eg methane);
- Farming emissions through fertilisers/pesticides and energy use;
- Energy and waste from animal slaughtering.

Where animals are sourced from multiple farms, sampling practices should be considered to limit the extent of data collection needed. Similar sampling considerations as for plant products are considered and sampling should be used where there are greater than 10 farms. Guidance for sampling should be adapted to follow the description and examples provided in *PAS2050:2012 Assessment of life cycle greenhouse gas emissions for horticultural products, Section 7.3*.

Many of the processes required to extract APIs from animal or human sources can yield co-products. Additional guidance is provided on allocating GHG emissions.

Allocation of Products from Animal or Human Derived Processes

The separation of blood for plasma or the rearing of animals can yield other valuable co-products. Should co-products exist, allocation of the separation GHG emissions is recommended. Using the same approach as described in *Section 4.4.1*, if the co-products have a similar market value, allocation based upon mass can be used. Should the co-products differ significantly in market value, or are sold for a nominal value, economic allocation is preferred.

Should there be no co-products, or if the co-products cannot be identified, the GHG emissions of separation can then be allocated entirely to the albumin, provided this is reported.

Secondary Data Sources

For processes identified in the process map that are outside the direct control of the company, primary data collection is still preferred. However, suitable secondary data sources can be used to represent these inputs and modules, when the quality of secondary data is better than the quality of the primary data.

General secondary data sources can be found on the GHG protocol website (1).

4.5 MODULE GUIDANCE: PROCESSING INTO DELIVERY MECHANISMS

4.5.1 Solid Dose Forms

Description

Solid dose forms (eg tablets and powders) are one method of delivering the API. The API is habitually mixed with excipients (eg fillers and binders) to produce the powder. Tablets are then moulded and coated for use. Powder can also be used in other forms (eg capsule, inhalers, etc), and may thus be combined with other delivery mechanisms.

Boundary Setting

When manufacturing solid dose forms (eg powders or tablets), the API is typically combined with a binder whose purpose is to hold the API, and with a filler in order to produce the required product size for human handling. Powders can then be used or combined with another delivery mechanism such as in capsules, dry inhalers, etc. Manufacture of tablets requires further moulding and coating to produce the final product. Solid dose forms are then generally packaged in formats such as large and small bottles, blister packs, foil packs, etc before being distributed.

(1) http://www.ghgprotocol.org/Third-Party-Databases

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Material inputs (fillers, binders, additives, etc)
- Packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

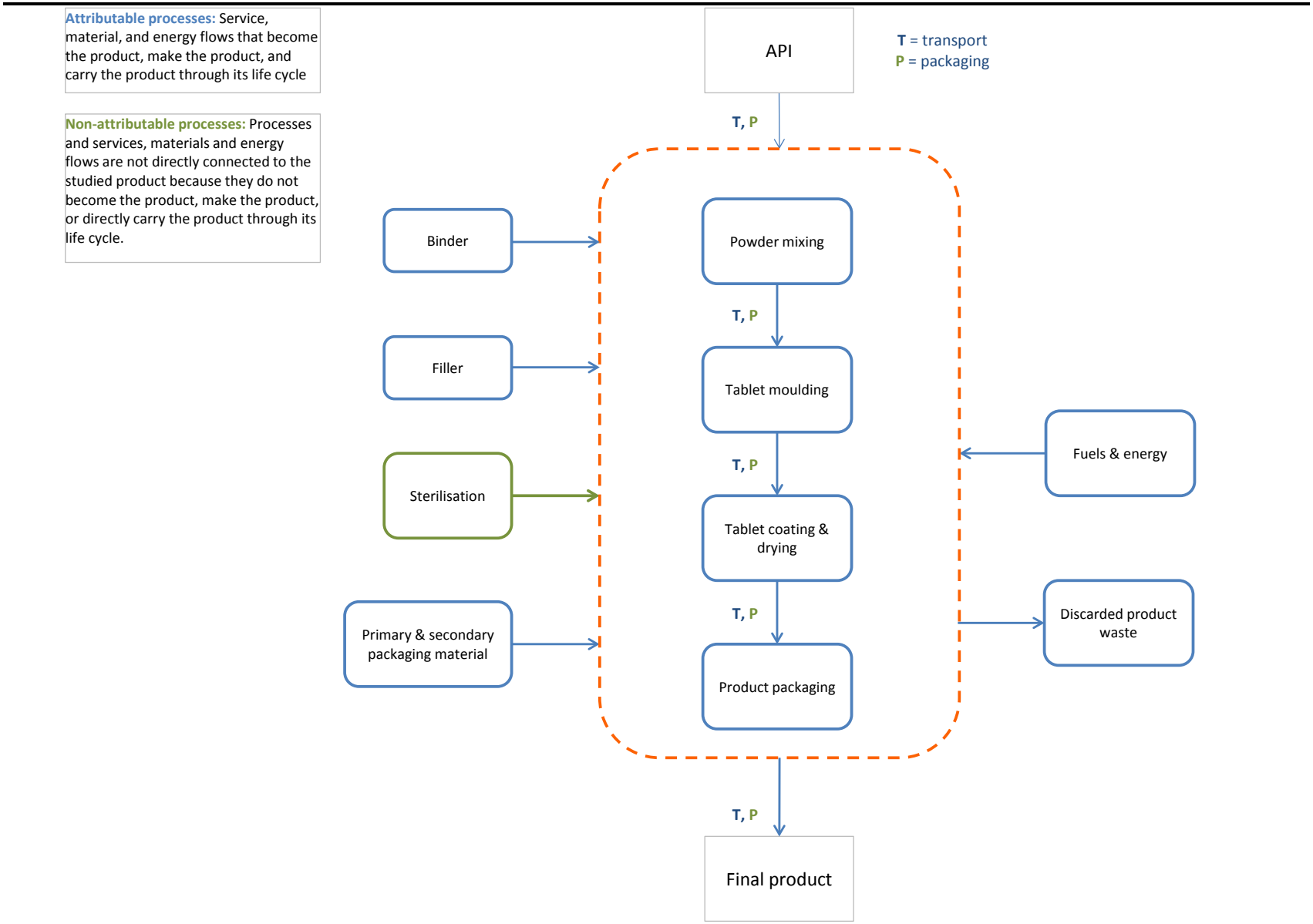
- Secondary packaging
- Instructions for use (Leaflets with packaging)
- Process cleaning chemicals and energy
- Land use change impacts associated with filler materials
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

A sample process map showing some example intermediate processes is given in *Figure 4.8.* A similar process map should be developed when undertaking inventory calculations for the delivery mechanism in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Figure 4.8 Sample Process Map for Solid Dose Forms (eg Tablets)



Unit of Analysis

The output reference flow should be reported both on a per mass and per tablet basis where applicable. The quantity and percentage of active ingredient should also be reported.

Primary Data and Allocation

Key primary data required for manufacture of solid dose forms (eg tablets and powders) include material inputs, process energy and packaging. These are discussed in the following boxes.

Primary Data for Excipients (eg Fillers, Binders, Additives and Coatings)

In most instances, it is expected that the additional materials used in tablet and powder form will be sourced externally as commodity materials. Guidance on secondary data is provided in the boxes below. However, should the manufacture of these materials be under the direct control of the company, or where primary data collection is possible, additional guidance is provided here.

Should primary data collection be possible, data should be collected for material production processes, and should include raw material inputs, energy and fuel consumption, emissions and generated waste. Data collection should follow the guidelines set out in *Section 4.6.1,* where direct measurements are taken, site-wide data are allocated or theoretical calculations made. Data quality should be considered and reported in all cases.

Biogenic content
Additional materials used in tablet manufacture may be from biogenic sources. For example, many types of filler are based on plant material (eg mono crystalline cellulose, lactose, corn starch, sugars, whey, yeast, etc). The Product Standard requires the assessment of biogenic carbon, and this should be reported separately.

When including agricultural products as an input material for filler manufacture, consider the guidance provided under Plant-Based Extraction in *Section 4.4.5*, including whether land use change impacts are relevant.

The following box describes when material inputs can be considered insignificant to the assessment and thus excluded for practicality purposes.

Determining Insignificance of Excipients

Many minor materials may be included as additives for tablets and powders (eg flavour enhancers). When collecting data for material inputs to the powder or tablet, it is possible to exclude immaterial inputs from the assessment. Immaterial inputs are defined as any inputs that contribute less than 1% to the unpackaged weight of the product. The total inputs excluded should not be greater than 5%.

Inputs that are known to have a high GHG impact, or are the primary purpose for manufacturing the product, should always be included in the bill of materials. For example, the API used should be included in the assessment regardless of its significance to the mass of the final product.

Primary Data for Tablet Manufacture

Tablet and powder manufacture can go through a number of processes to manufacture the final product for use. Possible process stages include mixing, moulding and coating.

Where the processes are under the direct control of the company, primary data shall be collected through the guidance provided in *Section 2*. Data should be collected for these inputs including (but not limited to):

- Material inputs (through measurements or the bill of materials);
- Energy used in mixing, moulding, coating and other relevant processes;
- Packaging;
- Waste and emissions generated;
- Sterilisation energy and associated chemicals.

Allocation for tablet manufacture
Where multiple tablets types are processed through the same production lines and sub-metering is not available (eg spray drying), allocation of process data is recommended. Allocation on the basis of product mass is the preferred approach to apportion process GHG emissions to different products.

Secondary Data Sources

Although tablet and powder manufacture are likely to be under the direct control of the company undertaking the assessment, many fillers and material inputs are commodity products, and secondary data for their production may be used. The box overleaf provides some example sources.

Secondary Data for Excipients (eg Fillers, Binders, Additives and Coatings)

A wide variety of excipients can be used depending on the application. Secondary data sources may be used where primary data are not available. The age, geography and technology representativeness of the secondary data should be considered and amended to be product specific where appropriate.

Possible sources of secondary data for material inputs include:

- US NREL LCI (http://www.nrel.gov/lci/)
- ELCD (http://lca.jrc.ec.europa.eu/lcainfohub/datasetArea.vm)
- Ecoinvent (http://www.ecoinvent.org/)

The quality of chemicals and excipients should be considered when using secondary data sources and a scaling factor should be considered for industrial grade emission factors when pharmaceutical grade chemical quality is required.

Should excipient secondary data be required but not available, guidance for chemical feedstock approximation may be applicable, as discussed in *Section 4.4.1*. Of particular relevance is the Finechem tool for approximating petrochemical based materials.

4.5.2 *Liquid Dose Forms*

Description

This category of delivery mechanism refers to the use of API through sterile liquid form or suspensions for dispensing in syringes, bags, ampules, etc. An example of this category includes dextromethorphan in cough syrup.

Boundary Setting

The API is mixed into a liquid in a sterile environment by combining it with inert liquids and sugars (eg saline, dextrose, sucrose, etc). The liquid is then packaged in a range of different products, including vials, bottles, ampules, bags, etc.

Administering devices are sometimes required (eg syringes) and further guidance for their inclusion is provided in *Section 4.5.6* and for medical devices in *Section 5*.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:	Include these non-attributable processes:
• Material inputs • Sterile liquids (saline, etc) • Primary packaging materials • Material and chemical transport • Energy/fuel generation and consumption • Waste disposal	• Secondary packaging • Sterilisation • Leaflets with packaging • Process cleaning chemicals and energy • Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

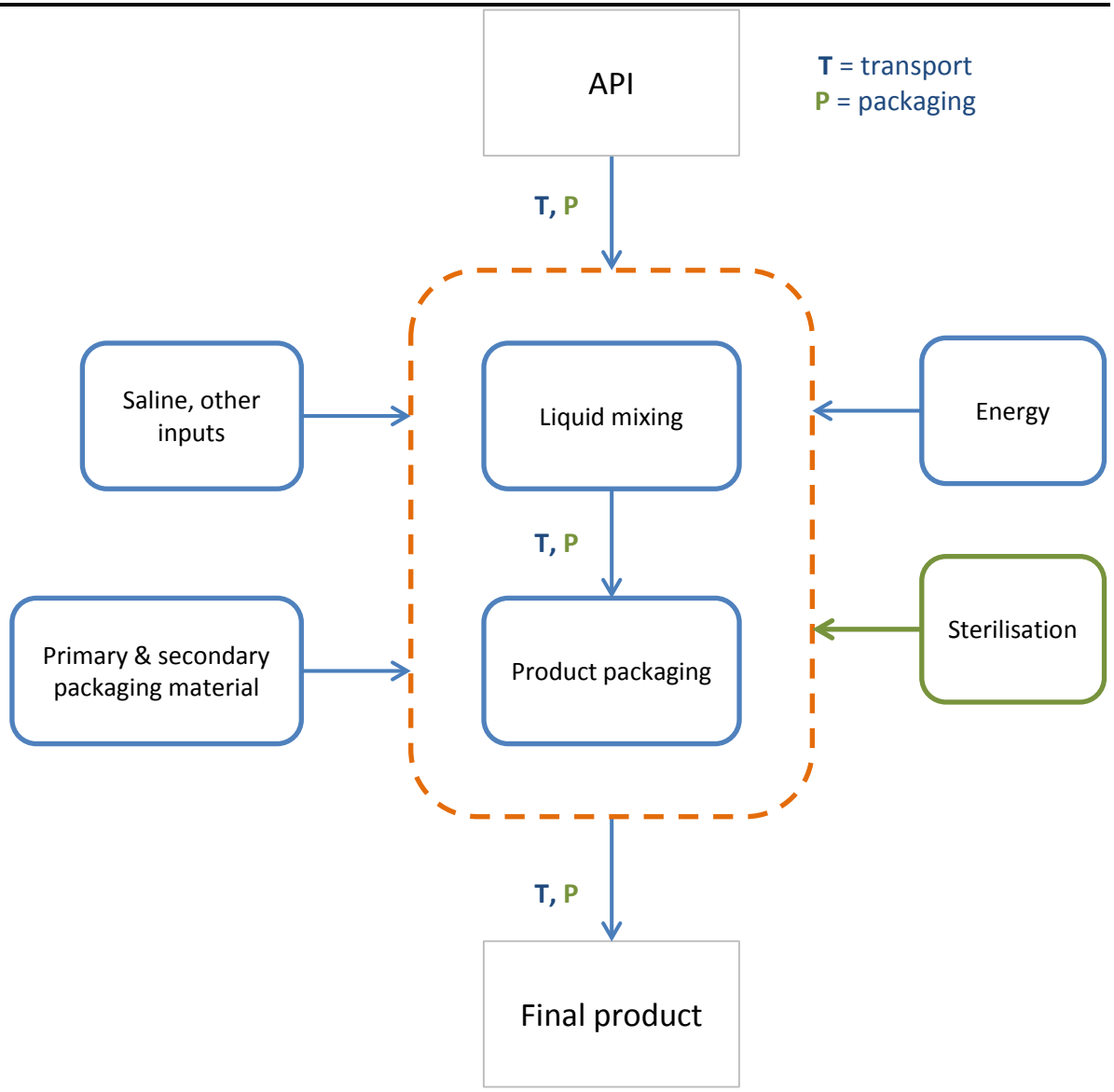
- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

A sample process map showing some example intermediate processes is shown in *Figure 4.9.* A similar process map should be developed when undertaking inventory calculations for the delivery mechanism in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Figure 4.9 ***Sample Process Map for Liquid Dose Forms***

Attributable processes: Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle

Non-attributable processes: Processes and services, materials and energy flows are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle.



Unit of Analysis

Reporting should be based on a volume of unpackaged liquid. The quantity of API should also be reported in the reference flow.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company and include those processes described above. Of particular importance are the GHG emissions related to mixing the API into liquid form, the excipients used and maintaining the sterile environment.

Packaging formats should be included, and can vary depending on use of the liquid API. Further guidance for packaging is included in *Section 4.5.7*.

Secondary Data Sources

Should liquid API manufacture lie outside the direct operations of the company, secondary data may be used. Consideration should be given to the age, technology and geography representativeness of the secondary data, and data should be amended where appropriate.

Secondary Data for Liquid Excipients

A wide variety of excipients can be used depending on the application. Examples of liquid excipients may include saline, purified water, gelatin, ethanol, etc.

Data quality should be considered when applying secondary data sources, and this should be assessed as per the guidance given in *Section 2*.

Possible sources of secondary data for material inputs include:

- US NREL LCI (http://www.nrel.gov/lci/)
- ELCD (http://lca.jrc.ec.europa.eu/lcainfohub/datasetArea.vm)
- Ecoinvent (http://www.ecoinvent.org/)

Should excipient secondary data be required but not available, guidance for chemical feedstock approximation may be applicable as discussed in *Section 4.4.1*.

4.5.3 *Creams and Ointments*

Description

This category of delivery mechanism refers to the use of API as topical medications in the form of creams, ointments, lotions, etc. The main differences between these forms are in their viscosity and water-to-oil ratio. Administering devices may be required to apply the topical medications, and can include spoons, gauze or cotton balls.

Examples of creams and ointments covered in this category include:

- Clotrimazole in anti-fungal creams;
- Methyl salicylate in pain relief creams.

Boundary Setting

The API is mixed into a cream or ointment in a sterile environment by combining with inert materials to act as carriers/fillers (eg petroleum jelly). The cream is then packaged into a range of different products. Administering devices are sometimes required and further guidance for their inclusion is provided in *Section 4.5.6* and for medical devices in *Section 5*.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Material inputs (fillers, binders, additives, etc)
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Refrigerant leakage associated with product manufacturing
- Process cleaning chemicals and energy

Exclude these attributable and non-attributable processes:

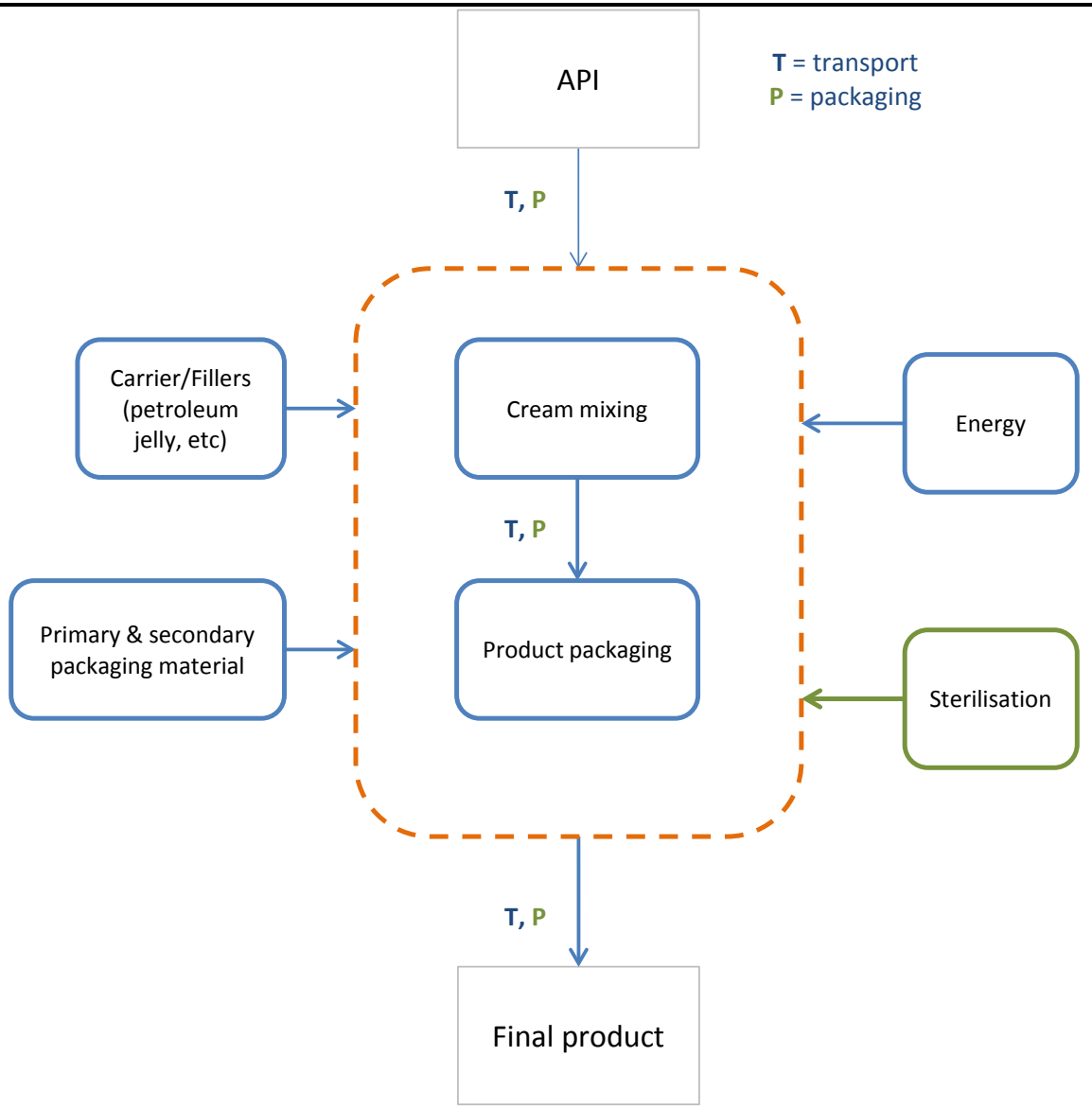
- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

A sample process map showing some example intermediate processes is given in *Figure 4.10.* A similar process map should be developed when undertaking inventory calculations for the delivery mechanism in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Figure 4.10 ***Sample Process Map for Cream Products***

Attributable processes: Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle

Non-attributable processes: Processes and services, materials and energy flows are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle.



Unit of Analysis

Reporting should be based on a mass of unpackaged cream. The quantity of API should also be reported in the reference flow.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company, and include the processes described above. Of particular note are the GHG emissions related to mixing the API into the topical form, and the excipients (eg fillers, stabilisers, etc) used.

Administering devices should be included, and can vary depending upon use of the API. Further guidance is included in *Section 4.5.6*.

Secondary Data Sources

Should API manufacture lie outside the direct operations of the company, secondary data may be used. Consideration should be given to the age, technology and geography representativeness of the secondary data, and data should be amended where appropriate.

Secondary Data for Excipients

A wide variety of excipients can be used depending on the application. Examples of excipients may include stabilisers, purified water, oils, petroleum jelly, etc.

Data quality should be considered when applying secondary data sources, and this should be assessed as per the guidance given in *Section 2*.

Possible sources of secondary data for material inputs include:

- US NREL LCI (http://www.nrel.gov/lci/)
- ELCD (http://lca.jrc.ec.europa.eu/lcainfohub/datasetArea.vm)
- Ecoinvent (http://www.ecoinvent.org/)

Should excipient secondary data be required but not available, guidance for chemical feedstock approximation may be applicable as discussed in *Section 4.4.1*.

4.5.4 *Patches*

Description

This category of delivery mechanism refers to the use of API in conjunction with a patch applied to the skin for dermal or transdermal API delivery. Patches may be considered in either pharmaceutical or medical devices, depending on the classification given within a company. Guidance is provided in this Section. Common guidance in *Section 5* may also be applicable.

Examples of this category include:

- Nicotine patches;
- Hormone replacement therapy patches;
- Contraceptive patches.

Boundary Setting

A patch can typically include a protection liner (removed in use), outer protection layer, membrane, adhesive and API. All of these should be considered in the assessment.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Additional substances, alcohols, etc
- Patch and adhesive manufacture
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

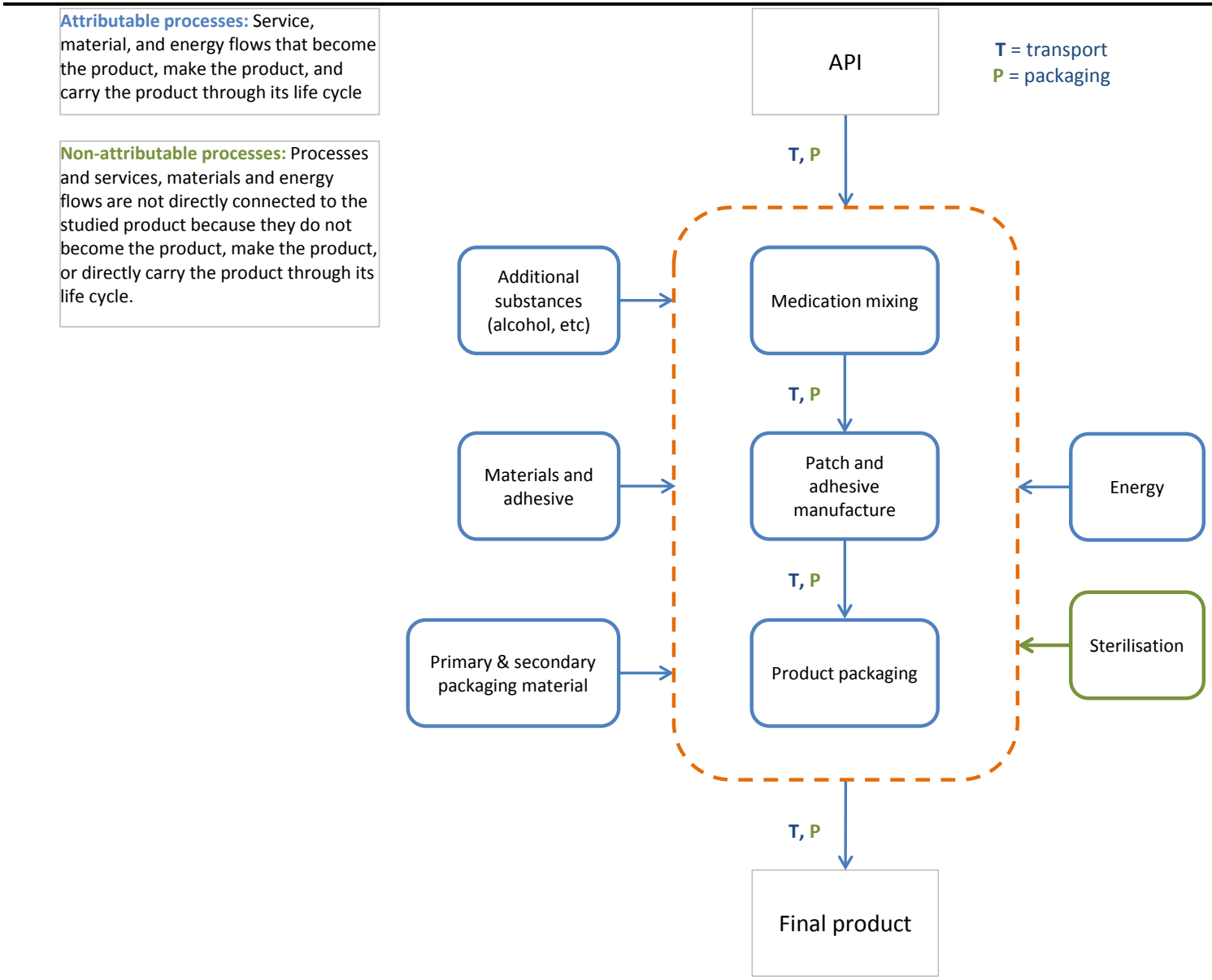
- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

A sample process map showing some example intermediate processes is illustrated in *Figure 4.11.* A similar process map should be developed when undertaking inventory calculations for the delivery mechanism in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Figure 4.11 Sample Process Map for Patch Products



Unit of Analysis

Reporting should be based on a mass of unpackaged patch, and on a per patch basis. The quantity of API should also be reported in the reference flow.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company, and include those processes described above. All components of the patch should be considered in the assessment. Materiality rules can be applied, as discussed in *Section 4.3.* However, the API should be considered in all assessments regardless of mass materiality.

Secondary Data Sources

Should patch manufacture lie outside the direct operations of the company, secondary data may be used. Consideration should be given to the age, technology and geography representativeness of the secondary data, and data should be amended where appropriate. Data quality should be assessed, based on guidance in *Section 2*.

Further guidance on secondary data for patch manufacture can be found in the common pharmaceutical guidance in *Section 4.3*, and the medical devices guidance in *Section 5*.

4.5.5 ***Gases***

Description

This category of delivery mechanism refers to the use of gas to deliver medication. Examples of this category include anaesthetic gases and aerosols.

Boundary Setting

API delivered through a gaseous pathway can be via the gas itself, or through dispersion of solid or liquid particles. Should liquid or solid forms be used, the guidance above should be considered.

Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:	Include these non-attributable processes:
• API manufacture • Aerosol propellant production • Propellant release • Material and chemical transport • Energy/fuel generation and consumption • Waste disposal	• Secondary packaging • Leaflets with packaging • Process cleaning chemicals and energy • Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)
- Disposal of input packaging (eg IBCs, drums, pallets, etc)

A sample process map showing some example intermediate processes is depicted in *Figure 4.12.* A similar process map should be developed when undertaking inventory calculations for the delivery mechanism in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Unit of Analysis

Reporting should be based on a volume of gas delivered. The quantity of API should also be reported in the reference flow.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company, and include those processes described above. The gas used to deliver the API is likely to be material and should be included in the assessment.

Secondary Data Sources

Should gas manufacture lie outside the direct operations of the company, secondary data may be used. Consideration should be given to the age, technology and geography representativeness of the secondary data, and data should be amended where appropriate. Data quality should be reported based on guidance in *Section 2*.

Published journals may hold additional secondary data sources that can be applied for gas API delivery. One example is a study undertaken to calculate the GHG emissions from five anaesthetic drugs [(1)]. Further guidance on secondary data for gas manufacture can be found in the common pharmaceutical guidance in *Section 4.3*, and guidance on inclusion of propellants can be found in *Section 4.5.6*.

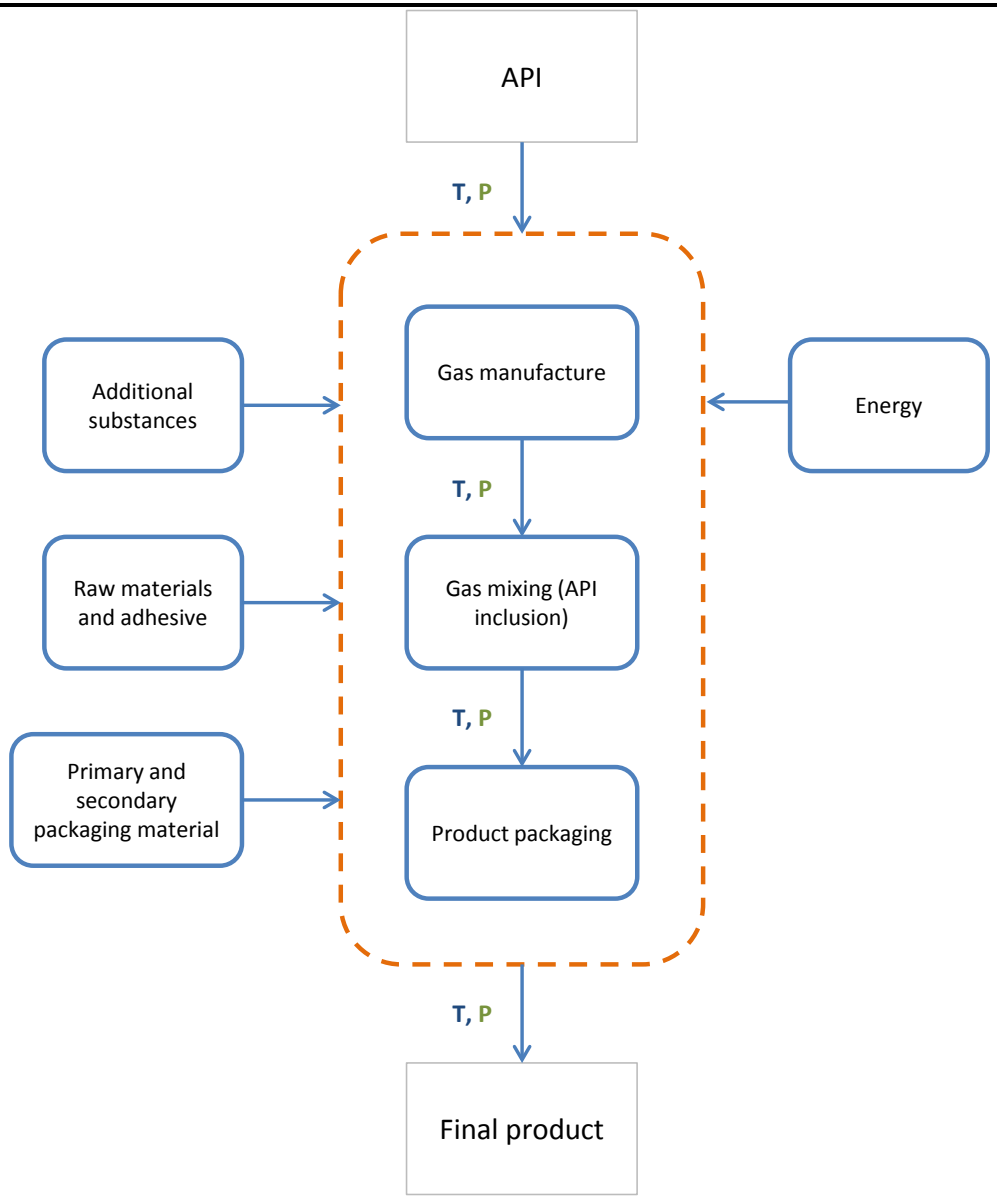
(1) Life Cycle Greenhouse Gas Emissions of Anesthetic Drugs, Sherman J, et al, Anesthesia & Analgesia, May 2012

Figure 4.12 Sample Process Map for Gases

Attributable processes: Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle

Non-attributable processes: Processes and services, materials and energy flows are not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle.

T = transport
P = packaging



4.5.6 *Administering Devices*

Description

Delivery of an API often requires the use of additional equipment for administration/application. This can be for any type of API delivery mechanism including, but not limited to, solid doses, liquid doses and creams.

Examples of administering devices include:

- Metered dose inhalers (MDI);
- Dry powder inhalers;
- Spoons;
- Pens;
- Bags for liquids;
- Syringes.

Boundary Setting

The delivery mechanism can be in a variety of forms including solid doses, liquid doses and creams. These should be included where appropriate, based on guidance given in *Section 4.3*. Guidance for the manufacture of administering devices required in conjunction with the delivery mechanisms is considered here.

Care should be taken so as not to account for an administering device more than once in the product life cycle, for example where a syringe can be included as an administering device and as part of the product final packaging. Key attributable and non-attributable processes that should be included in the assessment are outlined below.

Include these attributable processes:

- Delivery mechanism manufacture
- Administering device manufacture
- Assembly energy
- Canister and propellant (if applicable)
- Electronics in device
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Release of propellant
- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Packaging of material & chemical inputs
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

A sample process map showing some example intermediate processes is shown in *Figure 4.13.* A similar process map should be developed when undertaking inventory calculations for the administering device in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Unit of Analysis

Reporting should be based on one manufactured device, and per dosage of delivery mechanism; eg per inhaler and per dosage of dry powder.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company, and include those processes described above. Manufacture of the active component of the delivery mechanism shall be included, based on guidance in *Section 4.5*.

Many similarities exist between administering devices and medical devices when undertaking GHG assessments. Guidance provided in *Section 5* may also be useful for administering devices.

Consideration should be given to whether the administering device is intended for single or multiple uses, based on guidance in *Section 5.*

The use of some administering devices requires gas canisters and propellant. Where applicable, these should be included in the assessment based on guidance given in the box below.

Primary Data for Administering Device Manufacture

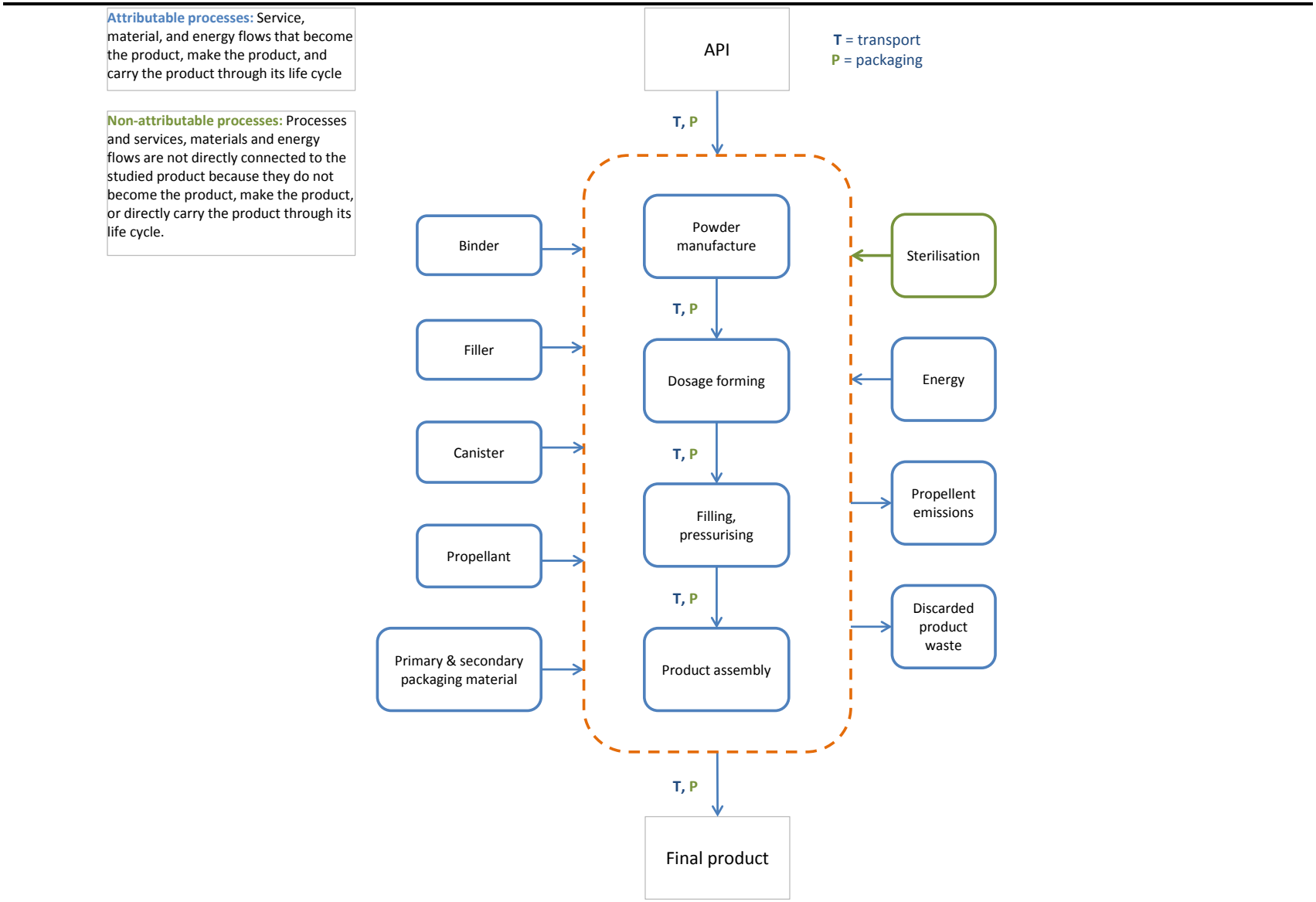
Data for manufacture of the administering device should be collected where operations are under the direct control of the company. Data collection should follow the guidance outlined in *Section 2*. Guidance for medical devices in *Section 5* may also be applicable. Data should be collected for the following processes:

- component manufacture (eg plastic casing, actuators, etc);
- canister manufacture (if applicable);
- gas sourcing (if applicable);
- canister filling and pressurising (if applicable);
- device assembly.

Propellant

The manufacture and release of gas should be included. Guidance is provided for the use of secondary data for gas manufacture in *Section 4.5.5*. The release of propellant should be included in the assessment and can be calculated based on the mass of propellant used and other theoretical calculations. The release of propellant in the use of the product should be multiplied by an appropriate Global Warming Potential and reported separately.

Figure 4.13 Sample Process Map for Administering Devices (Inhaler)

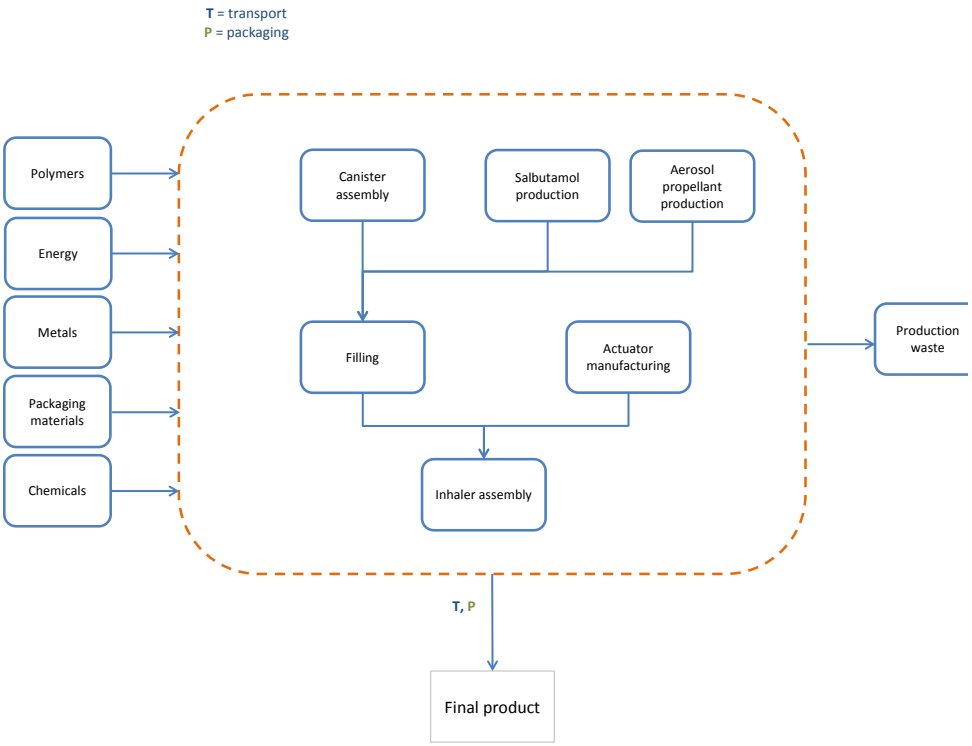


Packaging of the administering device should also be included in the assessment, including secondary packaging and additional materials (eg leaflets), as described in *Section 4.5.7*.

An example of a process map for an inhaler is shown below.

Inhaler Example

A metered dose inhaler is manufactured using different material components. The API is included and combined with a canister and propellant to administer the appropriate dosage.



Secondary Data Sources

Secondary Data for Administering Device Manufacture

If the administering device is manufactured outside the company's operations, secondary data may be used.

Data should be collected, documenting the weight and material of each component in the device or packaging, and noting any recycled content. This collected bill of materials can be combined with secondary data sources for raw materials and average material processing to build a model of the device/packaging.

Data sources available for raw materials and processing impacts are as identified in *Section 2* and *Section 5*.

4.5.7 ***Packaging***

Description

Packaging of the pharmaceutical product can include a number of possible types. The product may require storage in a sealed container before use. This is often referred to as primary packaging. Examples of these primary packaging types include:

- Vials;
- Ampules;
- Cartridges;
- Pre-filled syringes.

Additional packaging can also be used when providing the product to the user, to group multiple products together and can also contain printed materials, such as leaflets. This is often referred to as secondary packaging. Examples of these secondary packaging types include:

- Cardboard boxes;
- Blister packs;
- Plastic bottles;
- Instructions (eg leaflets).

Packaging may also be used when transporting or distributing products for the purposes of minimising damage. This is often referred to as tertiary packaging.

Examples of these tertiary packaging types include:

- Intermediate Bulk Containers (IBCs);
- Steel drums;
- Pallets.

Boundary Setting

Generally, the use of raw materials will be the most significant contributor to packaging-related impacts. However, packaging manufacture, assembly, filling and wastage should also be considered. Sterilisation and filling/sealing energy requirements should, in particular, be carefully considered, eg for sealing glass ampules once these are filled.

Key attributable and non-attributable processes that should be included in the assessment are outlined overleaf.

Include these attributable processes:	Include these non-attributable processes:
• Raw materials • Sealing of packaging (eg for ampules) • Filling of packaging with product • Assembly energy • Material and chemical transport • Energy/fuel generation and consumption • Waste materials disposal	• Secondary packaging • Leaflets with packaging • Sterilisation of packaging • Process cleaning chemicals and energy • Refrigerant leakage associated with product manufacturing
Exclude these attributable and non-attributable processes:	
• Infrastructure associated with packaging manufacture	

A sample process map showing some example intermediate processes is given in *Figure 4.13.* A similar process map should be developed when undertaking inventory calculations for the packaging type in question. It should clearly identify all core processes in the product chain as well as all processes under the direct control of the company undertaking the assessment.

Unit of Analysis

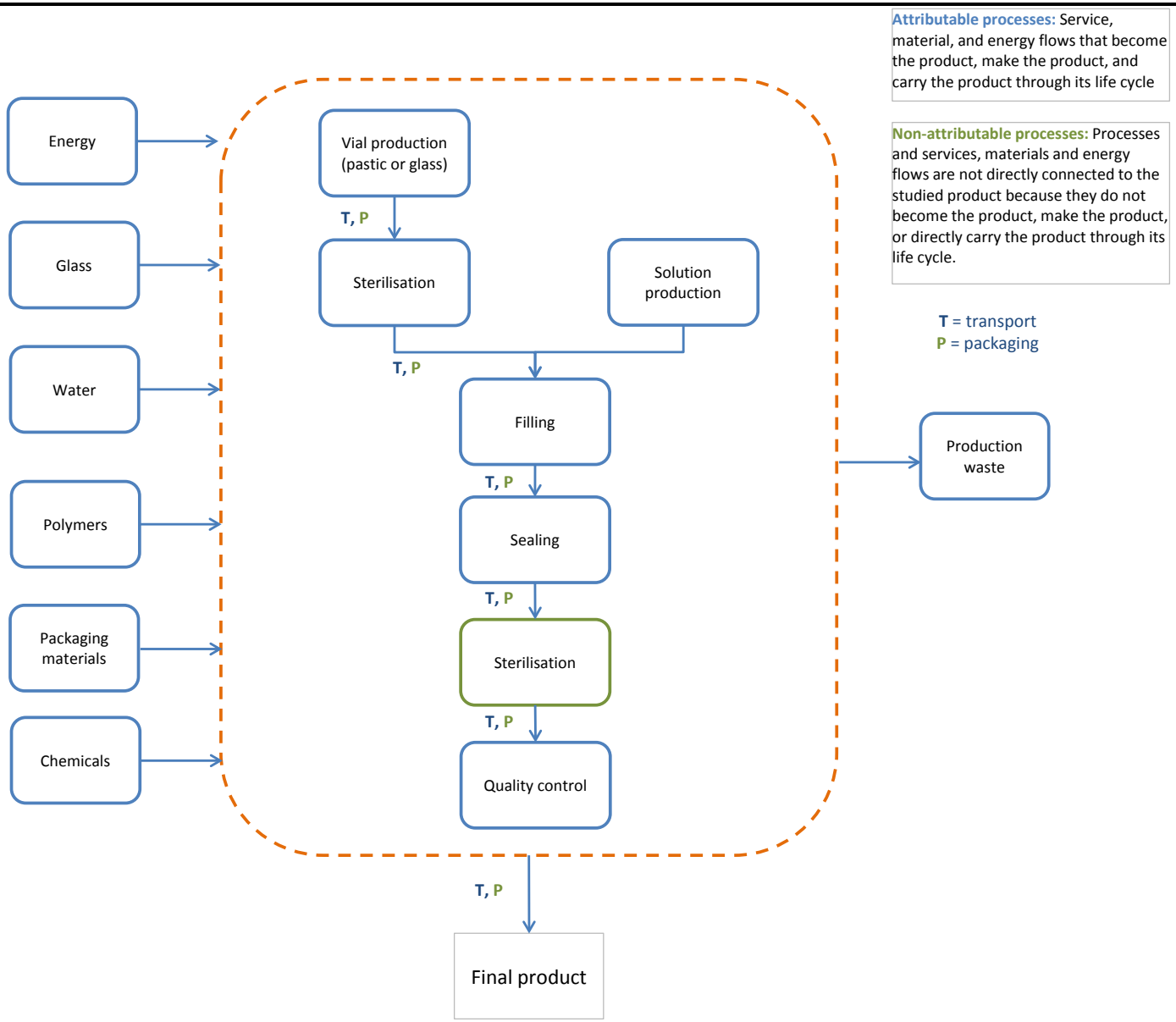
Reporting should be based on one packaging product, mass of packaging or per dosage of delivery mechanism; eg per vial, mass of vial or per dosage of dry powder in an ampule.

Primary Data and Allocation

Data shall be collected for all operations under the direct control of the company, and include those processes described above.

Packaging is likely to have a significant contribution for some products due to the mass of material relative to the pharmaceutical product, and particularly in relation to the API. A level of primary data is therefore recommended, even if packaging manufacture is not under the direct control of the company.

Figure 4.14 Sample Process Map for Packaging (Vial)



Primary Data for Packaging

Packaging may be in a variety of different formats, comprising small or large bottles, blister packs, foil packs, etc. Bottles may be purchased as preforms, and blown on-site for use. In such instances, the process map should identify which parts of the process are under the direct control of the company.

If packaging is manufactured off-site, some primary data are still recommended including:

- Type/weight of materials used in primary/secondary packaging;
- Weight and material type of constituent components (eg leaflets);
- Source location of packaging;
- Recycled content of all packaging.

Recycled content of packaging
The packaging recycled content should be reported for all packaging used. GHG emissions associated with recycled material should be included, based on guidance provided in *Chapter 9* of the Product Standard.

Guidance for primary data inclusion in *Section 2* and *Section 4.3* is applicable for other stages including assembly, sterilisation and filling. Wastage of material during packaging manufacture can be significant (eg during cardboard assembly) and this should be considered when determining material consumption.

Secondary Data Sources

Relevant secondary data sources for packaging are described in the box overleaf, or can be found on the GHG Protocol website (1).

(1) http://www.ghgprotocol.org/Third-Party-Databases

Secondary Data for Packaging

Packaging Materials
A variety of materials can be utilised for packaging, including paper, cardboard, glass, aluminium and various plastics.

When using secondary data sources, the age, geography and technology should be considered, and datasets are to be amended where appropriate.

Many materials used for packaging can have recycled content. The recycled content of packaging materials should be considered, based on guidance in *Section 2* and *Section 9* of the Product Standard.

Possible sources of secondary data for packaging materials include:

- Inventory of Carbon and Energy (publically available) (http://opus.bath.ac.uk/12382/)
- Plastics Europe (http://www.plasticseurope.org/plastics-sustainability/eco-profiles.aspx)
- European Aluminium Industry (http://www.alueurope.eu/en/environment-health-safety/lca/)
- Ecoinvent (http://www.ecoinvent.org/)

Manufacture of Packaging
Energy recommendations for packaging assembly can be approximated based on secondary data sources on a mass basis of packaging, and should be included when assessing packaging impacts. Possible sources for these data include:

- Ecoinvent (http://www.ecoinvent.org/)
- International Journal of LCA (http://www.springerlink.com/content/0948-3349)

Additionally there are various software packages that exist specifically for packaging appraisals and may be useful for detail analysis of packaging.

5 MEDICAL DEVICES

5.1 TYPES OF MEDICAL DEVICE CONSIDERED IN THIS GUIDANCE

The definition of a medical device is provided in EU Directive 93/42/EEC (as amended) and includes both Active Implantable Medical Devices (90/385/ECC, as amended) and In-Vitro Diagnostic Medical Devices (98/79/ECC, as amended) [(1)]. The definition of a medical device is presented in the box below.

Medical Devices Definition

"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- *investigation, replacement or modification of the anatomy or of a physiological process;*
- *control of conception;*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"

This sector includes an extremely wide range of products, from bandages to x-ray equipment. No central product classification system exists that covers the whole category (for example, there is a UNCPC group for medical and surgical equipment, but one covering the full scope of medical devices does not exist).

This guidance is applicable to all medical devices included within the scope of the definition within the Medical Devices Directive. However, it has been necessary to limit the scope of guidance provided to a high-level 'sign-posting' approach, for a number of key reasons:

- The wide range of products and applications provided for is such that very few generalisations can be made, and specific case-by-case guidance would be required that is beyond the scope of this document.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF

- The Product Standard provides good general provisions for the assessment of core products and materials, such as simple plastic components – eg tubing and rubber gloves; or metal components – eg surgical instruments. There is no need, or scope, to repeat this general guidance here. It does however remain important to note particular aspects of these devices to consider, such as sterilisation of reusable items.

5.2 STRUCTURE OF MEDICAL DEVICES GUIDANCE

The 'sign-posting' approach taken for medical devices guidance is outlined in *Figure 5.1*. It is a simplified approach that takes a series of principal criteria, such as whether the device is energy-using, or reusable, or comprised of multiple components. The approach then outlines key points to consider during an assessment of this type of product.

The following headings are outlined for each module in the production of medical devices, and closely follow the structure outlined for pharmaceutical products.

Description
A general overview is provided to describe the product category, including practical examples.

Boundary Setting
Boundaries are defined for the following product categories:

- Passive, Single Use Devices with Multiple Components/Materials;
- Passive, Single Use Devices with Few or Single Components/Materials;
- Passive, Reusable Devices;
- Implantable Devices; and
- Energy Consuming Devices.

Definitions, examples and inclusions/exclusions are provided for each category.

Furthermore, for each product type, boxes are used to define:

- attributable processes to be included;
- non-attributable processes to be included; and
- attributable and non-attributable processes to be excluded.

Focusing data collection and analytical efforts on those aspects of the product life cycle of greatest environmental significance is an important general principle that underpins GHG assessment methodologies. This is addressed in each specific module by identifying relevant inclusions and exclusions, but also through consideration of materiality principles as discussed in *Section 4.2.*

What is an Attributable Process?

"Service, material, and energy flows that become the product, make the product, and carry the product through its life cycle."

Examples of attributable processes may include the manufacture of plastic and metal components, electronic sub-assemblies and energy used during assembly.

What is a Non-Attributable Process?

"Processes and services, materials and energy flows not directly connected to the studied product because they do not become the product, make the product, or directly carry the product through its life cycle."

Examples of non-attributable processes may include chemicals used during cleaning, sterilisation GHG emissions, and protective gear used by operators.

Unit of Analysis

The reference flow for medical devices is defined.

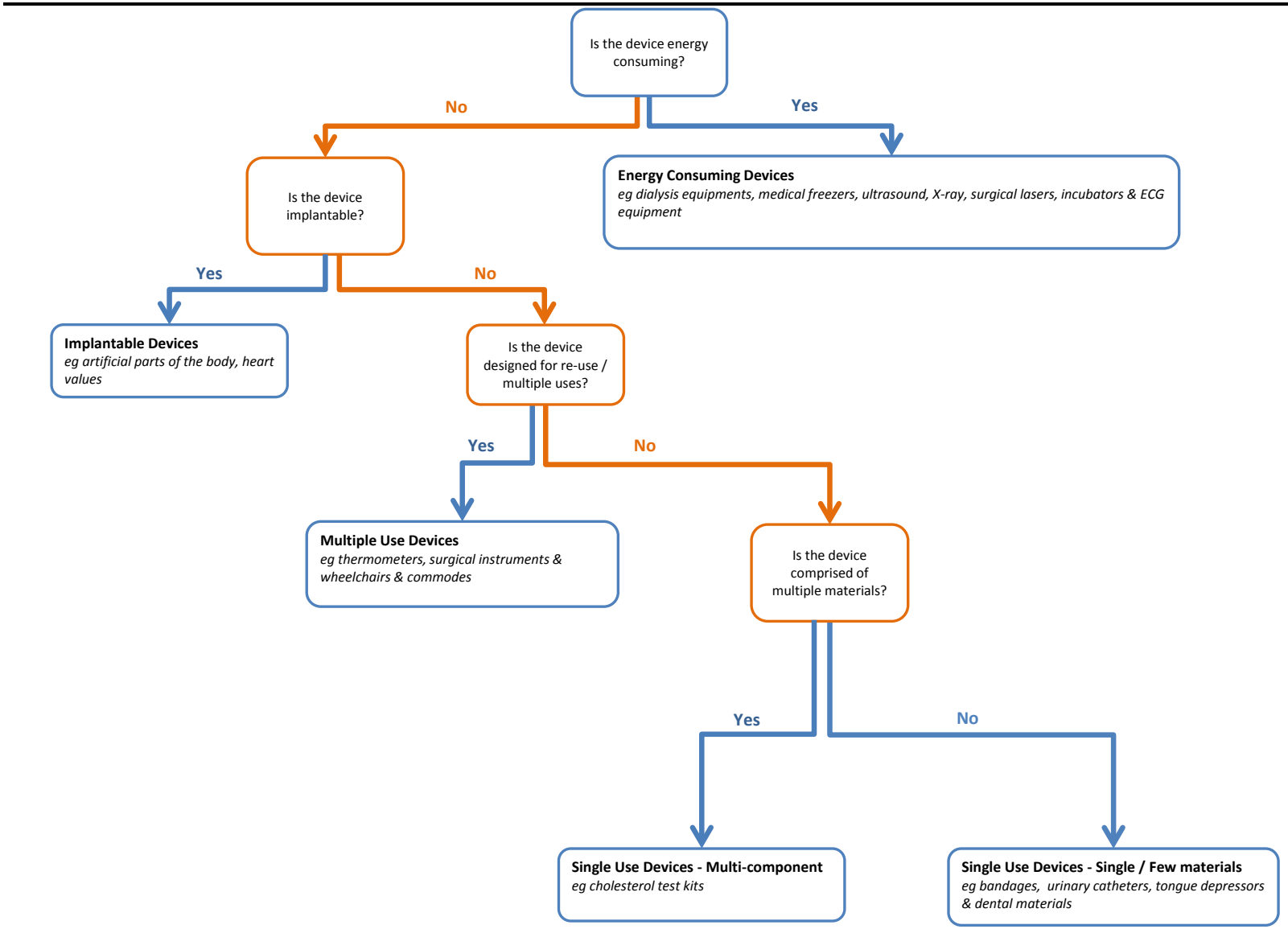
Primary Data and Allocation

Guidance on primary data requirements and recommendations and collection is provided. Any relevant allocation issues are also discussed.

Secondary Data

Where secondary data are required, they are discussed in this section and guidance on appropriate sources is provided.

Figure 5.1 Decision tree for Assessing Medical Devices



5.3 COMMON MEDICAL DEVICE GUIDANCE

5.3.1 *Description*

This guidance covers all products as defined in *Section 5.1*. Boundaries have been described for the following categories, and examples of each product category are included in the sections below.

5.3.2 *Boundary Setting*

The following guidance applies to all medical device products. Attributable and non-attributable processes, along with justifiable exclusions, are described in the boxes in this sub-section. General inclusions and exclusions are described in the box below.

Include these attributable processes:

- Production, processing and transport of raw materials, including batteries and packaging materials
- Manufacture, sterilisation, packing, storage and distribution of the medical device product
- Production and distribution of energy, water and materials consumed by the medical device during operation
- Production of spare parts/materials, and energy required for refurbishment and repair of devices
- Waste management activities at end-of-life, including transportation

Include these non-attributable processes:

- Production and distribution of energy/water/chemicals for sterilisation of reusable devices
- Production and distribution of consumables required for the operation of a medical device for its intended purpose
- Sterilisation and cleaning chemicals
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Transport of staff involved in delivery, maintenance, refurbishment and repair
- Transport of patients to receive treatment
- General hospital/clinic/home infrastructure to support use of the medical device
- Software to run medical devices
- Ancillary products and equipment, eg protective clothing, etc. – with the exception of energy used for sterilisation (before distribution or during use)

A screening exercise should always be undertaken to determine the significance of processes that form part of the product boundary. Guidance for undertaking a screening exercise is provided for a multiple component device type below. The processes described in the box above can be excluded, unless they are deemed significant during the screening exercise.

Consideration should be given to products that include both medical devices and pharmaceutical products, denoted as 'combination products'.

Combination Products

Where medical devices and pharmaceutical products can only be considered to be in their complete and final form when combined within one product – the assessment should include both the pharmaceutical and medical device components (in accordance with the relevant sections of this guidance). On reporting the product GHG inventory, the contribution from each component should be clearly reported.

Each module used to build up the product life cycle (eg the morphine life cycle example in *Section 1.3*) will have a recommended reference flow. To complete the overall life cycle of a product these reference flows should be combined into a functional unit for the product.

What is a Functional Unit?

Reporting a GHG inventory for a medical device on a per product or per use basis may be useful when considered individually. However, when a product's whole life cycle is assessed, there are further considerations that need to be accounted for. The reference for reporting should describe the function of the product when in use. Information to help define the product functional unit may be available in the leaflets and instructions for the product.

The following questions may be useful when defining the functional unit.

- **What is the product?**
  (the functional unit should describe what the product is)
- **How much of the product is considered?**
  (the quantity of the product included)
- **How is the product used and what does it do?**
  (the quality of use and function provided by the product)
- **How long is the product used for?**
  (the length of time the product is used and the product lifetime)
- **Where is the product used?**
  (the geographic location considered for product use)

Example Medical Device Functional Unit

Consider a cradle-to-grave assessment of a magnetic resonance imaging (MRI) machine. A simple reference flow for this product may refer to the GHG inventory of one device. This describes a product but provides little additional information that may be required when undertaking internal appraisals to understand variations in products. For example, variation between use in different facilities, geographies, with different quality of imaging, etc.

Including information to describe these additional considerations, a functional unit might be '*the use of an MRI machine in-centre, three times a day for a period of five years in a specific geographic location*.

When reporting functional units, refer to the guidance in *Section 9* and consider the level of additional detail required with respect to the product being assessed. Functional units for care pathways are discussed in *Section 10*. Further functional unit guidance can be found for pharmaceutical products in *Section 4.3*.

Examples of specific points of guidance for the different types of medical device product are outlined below. Product types are defined according to their likely impact profile, ie the relative contribution of different life cycle stages. Guidance is provided to reflect likely data needs and key points in each case; for example, with regard to functional units and use phase profiles.

Passive, Single Use Devices with Multiple Components/Materials

This medical device type refers to complex products comprising many components and materials. This description includes products that do not require external resources during use, and that are therefore described as being passive devices. For products that are both complex components, and consume energy during use, the guidance provided below for energy-consuming devices should also be considered.

Example Products

Cholesterol test kits; pregnancy test kits; sets (tubing and devices to allow intravenous administration to the patient); incontinence aids; single use orthopaedic instruments.

Primary data for operations under the direct control of the company shall be included (eg materials consumption/wastage, energy and ancillaries for assembly, packaging, storage, etc) as per the guidance given in *Section 2*. Estimated GHG emissions for distribution and end-of-life disposal should also be considered with reference to *Section 6* and *Section 8*.

Key attributable and non-attributable processes that should be included in the assessment are outlined below, in addition to those in the general medical device boundaries.

Include these attributable processes:

- Significant component manufacture (determined during screening exercise)
- Assembly energy
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Production and disposal of consumables (eg gloves and protective clothing, filters, cartridges, etc)

In some instances, for multi-component devices, no one material is clearly the major contributor, and the impacts associated with product assembly tend to be small. When this is the case, a screening approach can be used to identify those components or materials that are significant to the product's GHG inventory and so would benefit from the collection of primary data.

Bill of Material (BOM) Component Screening

The bill of materials of a product is useful when determining which components are significant to the assessment and warrant collection of primary data. The significance of a component is based on its associated GHG impact, and can be determined at a high level by combining BOM data with generic emission factors.

For significant material/component contributors to the footprint, it is recommended that specific primary data are collected. Cradle-to-gate emissions for this material/component should be calculated using the core guidance in the Product Standard, or by referring to other relevant sector guidance or Product Rules (listed at http://www.ghgprotocol.org/ or under http://www.environdec.com/en/Product-Category-Rules/).

The following steps can be employed when undertaking a screening analysis:

- Assess measured weights of components in bill of materials
- Combine with generic GHG emission factors (consider sources discussed in *Section 2* and http://www.ghgprotocol.org/Third-Party-Databases)
- Determine the significance of each component (% contribution)
- Define significant components (eg >10% contribution) whereby primary data should be collected
- Apply appropriate cut-off rule to insignificant components (ie exclude from the GHG inventory)
- Document cut-off approach in reporting

An estimate of material/component wastage can also be included in the BOM approach, should this potentially be significant, or differ for different materials/components. The % wastage in the final product manufacture should be determined from production data, and used to 'uplift' the weight of that material/component in the BOM.

This BOM screening approach can be used to appraise where more specific data is required. If it is to be used in a final footprint estimate, data quality reporting should reflect the generic nature of the data employed.

Passive, Single Use Devices with Few or Single Components/Materials

This type of medical device refers to simple products made of single or few components and materials. This description includes products that do not require external resources during use, and that are thus described as being passive. For products that are both simple in composition and consume energy during use, the guidance provided below for energy-consuming devices should also be taken into account.

Example Products

Bandages; cotton wool; gauze; lint; plasters, other dressings; gloves; syringes and injection aids; needles; catheters; cannulae; feeding tubes/gastrostomy tubes; empty IV bags and containers; dialysis consumables (sets, tubing and caps); fluids for irrigation (sodium chloride/sterile water/glucose); protective masks having neither mechanical parts nor replaceable filters; splints and other fracture appliances; tongue depressors; peak flow meters (single use parts); specimen collection tubes; urine test strips

Key attributable and non-attributable processes that should be included in the assessment are outlined below, in addition to those detailed in the general medical device boundaries.

Include these attributable processes:

- Component manufacture
- Assembly energy
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Transport of staff and patients
- General hospital/clinic/home infrastructure

Primary data for operations under the direct control of the company shall be included (eg materials consumption/wastage, energy and ancillaries for assembly, packing, storage, etc) as per the guidance outlined in *Section 2*. Estimated GHG emissions for distribution and end-of-life disposal should also be taken into account with reference to *Section 6* and *Section 8*.

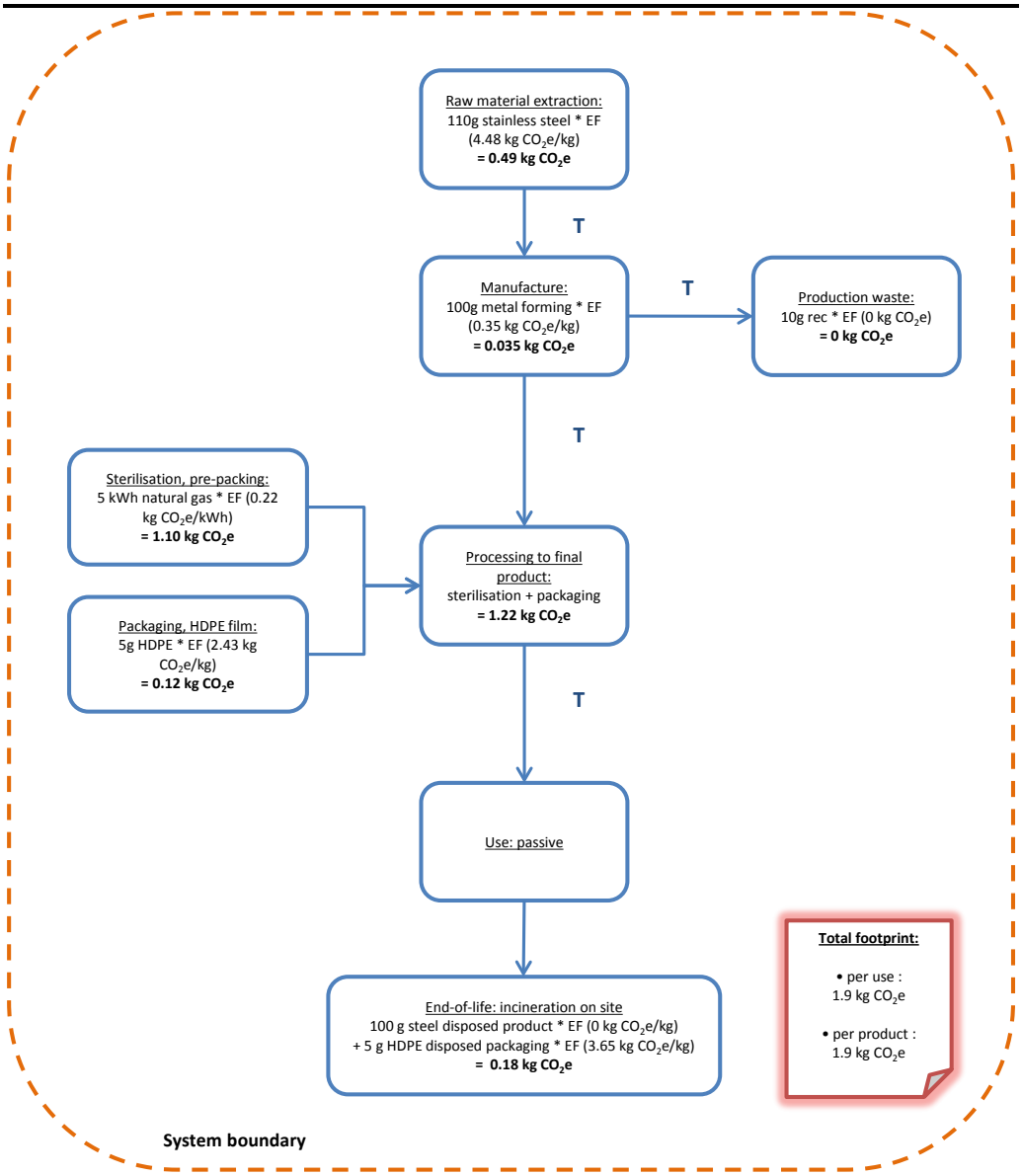
Much of the guidance provided in the *complex passive device* section above can be applied to single component products. However, there should be more focus on collecting robust and accurate data surrounding material production for devices with few components – as each of these components is likely to be significant to the product's GHG inventory. Should component manufacture lie outside the boundaries of the company, primary data collection for the few components is still preferable wherever possible.

High level estimates of GHG emissions from products with few components can be undertaken, using generic GHG emission factors for core materials and production processes (eg plastic moulding and extrusion processes), and based on guidance in the previous section for product screening.

These assessments are recommended for internal purposes only, due to the variability of material impacts and processing variations. For a more representative assessment, it is recommended that specific data representing the material value chain are collected.

An example, where the life cycle GHG accounting approach is applied to a general medical device, is provided in *Figure 5.2*.

Figure 5.2 Passive, Single Use GHG Inventory Example (Surgical Instrument)



Passive, Reusable Devices

This category refers to products designed for multiple uses, but not requiring external resources during use, and therefore described as being passive. For products that are both simple in composition and consume energy during use, the guidance provided below for energy-consuming devices should also be taken into consideration.

Example Products

Surgical instruments; ophthalmic instruments; orthopaedic appliances; therapeutic respiration apparatus (non-energy consuming); breathing appliances and gas masks (excluding protective masks having neither mechanical parts nor replaceable filters); sets (tubing and devices to allow intravenous administration to the patient); commodes; sphygmomanometers (manual); thermometers (manual); adjustable beds; lifting poles; patients hoists and slings; pressure relief equipment; bathing equipment; prescription footwear; walking aids; standing frames; wheelchairs; massage apparatus; psychological aptitude-testing apparatus; appliances which are worn or carried (non-energy consuming); peak flow meters (multi-use parts)

Key attributable and non-attributable processes that should be included in the assessment are outlined below, in addition to those included in the general medical device boundaries.

Include these attributable processes:

- Significant component manufacture (determined from screening)
- Assembly energy
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Transport of product between uses
- Waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Sterilisation energy and other reuse GHG emissions
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Transport of staff and patients
- General hospital/clinic/home infrastructure
- Software to run medical devices

Guidance on accounting procedures for the manufacture of reusable devices may closely resemble the guidance provided for the two passive, single use device types in the previous sub-sections, and relevant guidance should be used where applicable.

If transportation between cleaning, sterilisation, redistribution and reuse is undertaken then this should be accounted for in the assessment.

The difference with this device type is that the product is designed for multiple uses. Therefore, the GHG emissions associated with the manufacture of the device may be

allocated across all uses of the product. Emissions associated with the device use phase, eg sterilisation, refurbishment, repair, etc should also be accounted for in the study. Sterilisation of equipment for reusable devices is likely to be significant, and guidance is provided in the box below.

Accounting for Sterilisation

Sterilisation is likely to be a significant contributor in the life cycle of relevant multiple use devices. Additionally, significant variations in emissions are likely, according to the assumptions made regarding energy consumption, load rate (ie energy per unit of product), and potential transport to centralised sterilisation facilities.

Primary data should be considered for device sterilisation during use where possible. Where operations are not under the direct control of the company, secondary data may be used. However, the use of secondary data shall be clearly stated.

A number of publicly available studies exist that describe sterilisation processes. One useful article describes an approach to account for sterilisation (*Eckleman et al (2012) Comparative Life Cycle Assessment of Disposable and Reusable Laryngeal Mask Airways)*.

Due to the likely significance of the sterilisation phase, primary data recommendations are outlined below:

- Primary data shall be collected for typical loading recommendations of sterilisation machines for the product in question, including estimates of the number of product uses.
- Energy and water consumption of the sterilisation machines per load shall be collected.
- If a screening assessment determines that heat-seal packaging and cleaning detergents are immaterial, these can be excluded.
- Estimates of transportation and consumables (eg packaging) should be included where relevant.
- Full disclosure of assumptions relating to sterilisation should be provided.

Where products do not require full sterilisation between uses, consumption of energy/water/chemicals for cleaning following each use need only be included if considered significant. Significance should be determined using theoretical calculations. Should this stage be excluded, any assumptions regarding this justification should be provided to users in the inventory report.

The production of spare parts/materials, and the energy required for refurbishment and repair of devices should be included wherever relevant. Guidance for inclusion of product refurbishment is provided in *Section 7.1.2*.

Due to the complex nature of reusable products, further guidance is provided to assist in determining the reference unit for the device.

Unit of Analysis and Reporting Guidance

The functional unit should be carefully considered when appraising reusable and single use devices (ie the 'per use' comparison). In particular, the lifespan and frequency/number of uses of the reusable item should be determined, so that emissions from the production and other life cycle stages prior to use of the device, can be allocated to one 'use'.

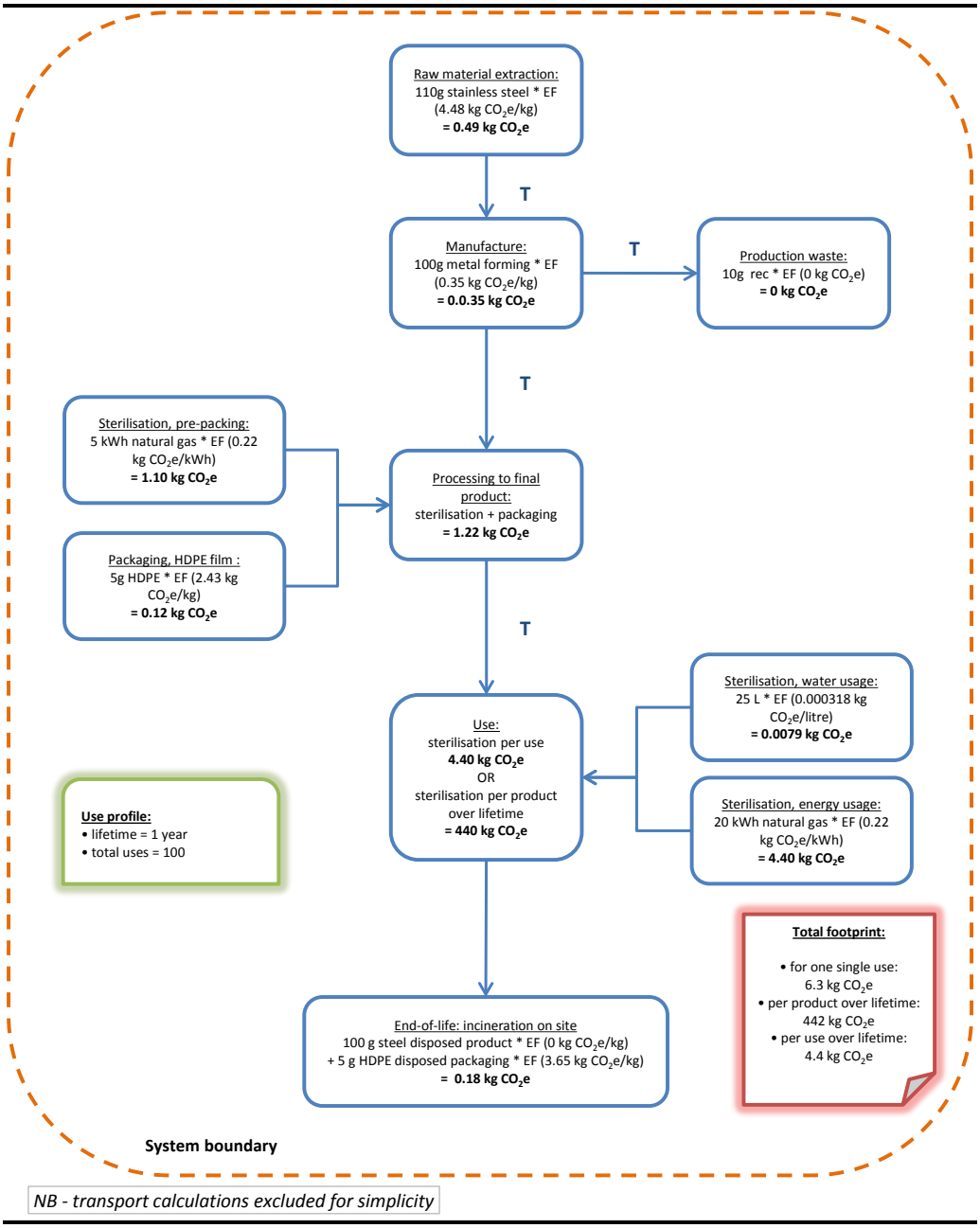
When reporting emissions for reusable devices, both emissions 'per use' and emissions for the total product lifespan should be disclosed. The assumed lifespan and frequency of use should also be reported and taken into account when assessing data quality.

Where actual data exists, this should be used to determine the number of uses and lifetime of a product. Where these data are not available, the assumed use profile from product design can be used instead and noted in reporting.

An example that shows the application of the life cycle GHG accounting approach to a general medical device is provided in *Figure 5.3*. This can be used in conjunction with *Figure 5.2* to understand the difference between single and reusable devices.

For the example of a reusable product below, the number of uses over the lifetime is estimated, and used to share the GHG emissions of manufacture over the lifetime of the device. The device boundaries also include cleaning and sterilising between each use, while a single use device, for instance, would have additional waste and disposal emissions.

Figure 5.3 Passive, Reusable GHG Inventory Example (Surgical Instrument)



Implantable Devices

This category refers to products that are intended to be implanted in the patient. The description includes products not requiring external resource during use, and that are thus denoted as being passive. For products that are both implantable and consume energy during use, the guidance provided below for energy-consuming devices should also be considered.

Much of the guidance provided for passive, single use devices above is applicable for implantable devices, and should be followed where relevant.

Example Products

Artificial parts of the body; heart valves; other appliances required to be implanted in the body

Key attributable and non-attributable processes that should be included in the assessment are outlined below, in addition to those outlined in the general medical device boundaries.

Include these attributable processes:

- Significant component manufacture (determined from screening)
- Assembly energy
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Surgical emissions from implanting or removing devices
- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Transport of staff and patients
- General hospital/clinic/home infrastructure
- Software to run medical devices

The surgical process for implanting or removing devices is an excludable process. However, surgical emissions form part of the wider care pathway, and these processes may be included as part of a care pathway inventory, as discussed in *Section 10*.

Disposal of implantable devices should be considered, based on the guidance provided for various disposal pathways (eg recycling, landfill, incineration) in *Section 8*.

Energy Consuming Devices

This category refers to active products that consume energy and other resources during use. Much of the guidance provided for passive, single use devices above is applicable for the manufacture of energy-using devices, and should be considered where relevant.

Example Products

ECG; CT computers; MRI (Magnetic Resonance Imaging)/MRT (Magnetic Resonance Tomography); diagnostic ultrasound; scanners; sterilisers/autoclaves; anaesthesia equipment; medical and surgical lighting; surgical lasers; therapeutic ultrasound; PET (Positron Emission Tomography)/SPECT (Single-Photon Emission Computed Tomography); patient warming systems; intensive care equipment; linear accelerators; massage apparatus; psychological aptitude-testing apparatus; ozone therapy; oxygen therapy; aerosol therapy; atomisers

Key attributable and non-attributable processes that should be included in the assessment are outlined below, in addition to those detailed in the general medical device boundaries.

Include these attributable processes:

- Significant component manufacture (determined from screening)
- Assembly energy
- Energy consumed during use and other use phase GHG emissions
- Primary packaging materials
- Material and chemical transport
- Energy/fuel generation and consumption
- Process waste disposal

Include these non-attributable processes:

- Secondary packaging
- Leaflets with packaging
- Process cleaning chemicals and energy
- Process cleaning chemicals and energy
- Refrigerant leakage associated with product manufacturing

Exclude these attributable and non-attributable processes:

- Disposal of input packaging (eg IBCs, drums, pallets, etc)
- Transport of staff and patients
- General hospital/clinic/home infrastructure
- Software to run medical devices

Primary data for operations under the direct control of the company shall be included (eg materials consumption/wastage, energy and ancillaries for assembly, packing, storage, etc) as per the guidance provided in *Section 2*. Estimated GHG emissions for distribution and end-of-life disposal should also be considered with reference to *Section 6* and *Section 8*.

Energy-using devices will mostly be multiple component products, and screening should be used to focus data collection on the most significant aspects for the GHG inventory, and enable a pragmatic assessment. Bill of materials data are often the most useful source of information for undertaking a screening assessment.

Screening for Energy Using Devices

A screening stage is needed to determine the likely significance of production (cradle-to-gate) and use phase emissions. Screening is described in more detail in *Chapter 8.3.3* of the Product Standard and for components in the multiple component device section above. Ensure that all of the relevant attributable and non-attributable processes listed above are included in this screening exercise.

Having determined the relative significance of the production stage and of specific materials and components, the same guidance, as described for *passive/multi-component* products, is relevant for the production of the device and should therefore be followed.

Due to the complex nature of energy using products, further guidance is provided to assist in determining the reference unit for the device.

Unit of Analysis and Reporting Guidance

The functional unit needs to be carefully defined for energy-using products, to provide a meaningful inventory within the context of its use.

Typically, the functional unit can be defined in terms of use per 'treatment', annual use or total use per lifetime. This unit should be grounded in a precise description of the function provided by the product system, focusing on the quantitative and qualitative aspects of the function (what, how much, how well and for how long).

The quantitative definition often refers to the technical standards for the specification and measurement of the function. The qualitative definition is a description of the way in which the function is provided, or a presentation of other qualities of the product to ensure a representative analysis.

Both emissions per functional unit and emissions for the total product lifespan should be reported. The assumed use profile should also be reported.

It is estimated that 80-90% of the GHG inventory of energy-consuming medical devices can arise in the use phase, and this is likely to be the case specifically for long lifespan equipment, and products with high frequency of use. For short lifespan equipment, and low frequency use products, it is likely, however, that production emissions are significant across the life cycle. Guidance is provided below to assess the use profile of energy-using devices.

Defining the Use Phase

Use phase profiles (energy consumption per treatment/per year/over lifetime, frequency of use and lifespan) are key to the calculation of consistent GHG inventory for energy-consuming devices.

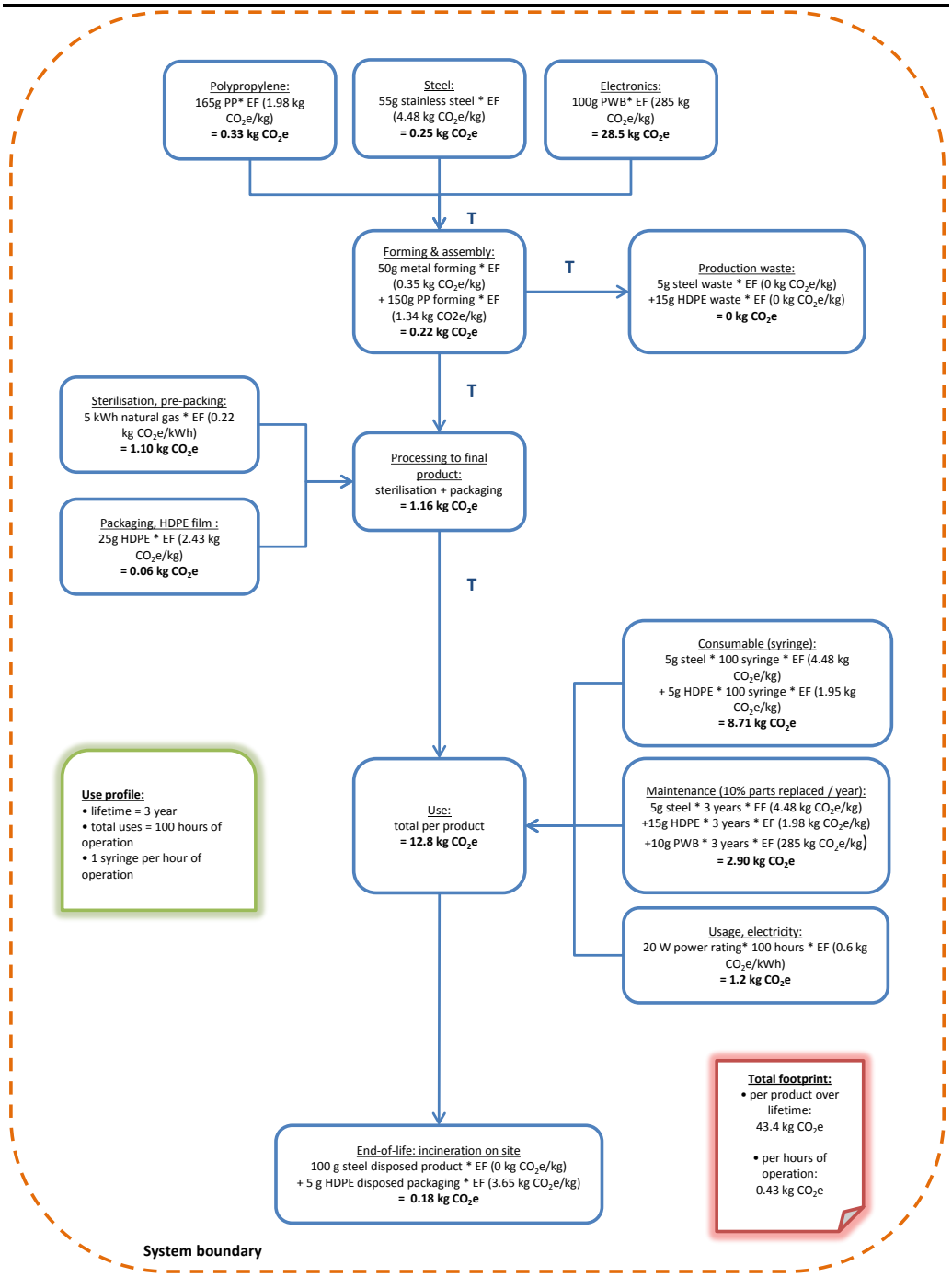
Use phase emissions should be scaled by the frequency of use of the device over its lifetime and these emissions should be added to production/distribution/disposal emissions (in accordance with the chosen functional unit). All energy consumed by the device in its lifetime should be accounted for, including energy consumed while the product is in non-active use.

GHG emissions from other materials consumed in the use phase (eg water, refrigerants, maintenance or refurbishment recommendations) should also be calculated and added to the GHG inventory by determining consumption per functional unit and using generic GHG emission factors. A list of databases containing generic GHG emission factors for such materials and processes can be found at http://www.ghgprotocol.org/Third-Party-Databases.

Energy using products may require portable or fixed stationary sources (eg batteries or grid electricity). Energy requirements should be considered based on guidance in the box above. For the use of fixed energy sources, GHG emission factors should be applied for specific geographies. For products that consume energy through batteries, the manufacture and disposal of these batteries should be taken into account during the assessment.

An example of applying the energy-consuming device guidance is given below for an infusion pump.

Figure 5.4 Energy Consuming GHG Inventory Example (Infusion Pump)



NB - transport calculations excluded for simplicity

5.3.3 *Unit of Analysis*

The unit of analysis for medical devices are complex, due to the function they fulfil and their potential to be reused. When determining the functional unit for medical devices, consideration should be given to the purpose of the device and the product lifetime.

Both emissions per functional unit and emissions for the total product lifespan should be reported. The assumed use profile should also be reported for transparency.

Reusable Devices Functional Unit

The functional unit should be carefully considered when appraising reusable and single use devices (ie considering the 'per use' scenario). In particular, the lifespan and frequency/number of uses of the reusable item should be determined, so that emissions from the production and other life cycle stages prior to use of the device can be allocated to one 'use'.

When reporting emissions for reusable devices, both emissions 'per use' and emissions for the total product lifespan should be reported. The assumed lifespan and frequency of use should also be reported and considered when assessing data quality.

Energy Using Devices Functional Unit

The functional unit needs to be carefully defined for energy-using products, and can be defined in terms of use per 'treatment', annual use or total use per lifetime. This unit should be grounded in a precise description of the function provided by the product system, focusing on the quantitative and qualitative aspects of the function (what, how much, how well and for how long).

The quantitative definition often refers to the technical standards for the specification and measurement of the function. The qualitative definition is a description of the way in which the function is provided or a presentation of other qualities of the product to ensure a representative analysis.

5.3.4 *Primary Data and Allocation*

Primary data are required for processes under the direct control of the company conducting the assessment, as identified in the developed process map, and are preferred in most instances. For further explanation of primary data recommendations and collection options, refer to *Section 2* of this guidance, and to *Chapter 8* of the Product Standard. The quality of data collected should be accurately reported, based on guidance provided in *Section 2*.

Primary data are similar to those discussed for pharmaceutical products in *Section 4.3*, and are additionally described below in terms of raw materials data, process manufacturing data and use data. Raw materials data refer to the materials included and consumed through the manufacture of the product, and can typically be described as the bill of materials data. Process data refer to all additional ancillary inputs required during the manufacturing process. This may include processing chemicals, energy consumed through the process, emissions and waste arisings. Use data may refer to the collection of primary data for energy-consuming devices or devices that have multiple uses, and include electricity consumption and sterilisation impacts. Primary data for additional life cycle stages are covered elsewhere in this document.

Raw Materials Data

Raw material inputs of medical devices are likely to be significant to the assessment (for passive devices), and accurate recording of raw materials is therefore key to a robust assessment. Potential methods of collecting primary material data are explained below.

Collecting Materials Data

Data for material and chemical feedstock inputs should be collected for the operations identified as inclusions in the device's process map.

Materials and data can be collected from a number of sources and methods including:

- **Bill of materials** data are the most useful in the first instance, when determining materials data for medical devices, and can be used to identify raw material inputs, quantities and wastage rates of the product.
- **Financial systems** used for procurement and supply monitoring can provide useful information about materials purchased, supplier locations and quantities consumed.
- **Mass balances** for processes should always be undertaken to ensure losses in the process as well as waste are accounted for.

The following box describes the types of information that may be required when collecting primary data.

Type of Materials Data to Collect

Raw materials or components used may be encountered in many forms. However, the data required to include these primary data are largely similar. Bill of materials data offer a significant reference point to enable an understanding of the material requirements for a product. Additional information can be identified when developing a process map for the device.

Typical primary data recommended for the raw materials include:

- Type and weight of individual raw materials
- Wastage rates of materials
- Weight and material type of constituent components
- Source location of raw materials
- Recycled content

The recycled content of raw materials should be reported for all components used. Emissions associated with recycled material should be included based on guidance provided in *Chapter 9* of the Product Standard.

Process Data

In addition to primary data for raw material inputs, manufacturing data describing direct operations should be collected. These data will be based on the process map and may include (amongst others):

- fuel and energy inputs;
- direct emissions from fuel combustion and chemical processes;
- relevant consumables; and
- waste generated.

Depending on the level of data that are available to describe the direct operations, a number of possible data collection methods exist including:

- direct measurements from process (es); and
- allocating site level data.

These approaches to process data collection are described in the boxes below.

Direct Measurements

Collecting process data based on direct measurements is the preferred approach.

Examples of methods to collect data through direct measurements include:

- Sub-metering of machinery used in operations
- Using flow meters or measurements to record mass or volume of consumable inputs

This approach is possible if operations identified in the process map are isolated, and no co-product allocation is required.

Allocation of Process Data from Site

An individual operation or the whole site may produce multiple products whereby it is not possible to identify the energy, consumables and emissions required for each individual product or co-product. Allocation of the process GHG emissions is then recommended. In practice, it is likely that multiple products from the same assembly process will have similar market value, and, therefore, allocation based on mass, or on a per product basis should be used.

Single Device Manufacture
Where a single device is produced, data should be collected describing inputs for the site, sub-site or process over a period of one year and subsequently dividing by yearly production.

Multiple Device Manufacture with Similar Market Value
Where multiple devices or co-products are produced from the same process and data cannot be disaggregated, the total process inputs for a period of one year should be collected. Should all devices and co-products from the process have similar value in the marketplace, the total mass of all products and co-products for the period of data collection should then be used to allocate GHG emissions per product / co-product.

Multiple Device Manufacture with Different Market Value
Where multiple devices or co-products are produced from the same process and they have notably different market values, allocation should be undertaken on an economic basis. Co-products may have nominal value and allocating on a mass of output basis is not an accurate method for apportioning process GHG emissions. Yearly process data should be collected, and all products and co-products identified. The total value of all products and co-products sold should be calculated and yearly process data divided by this value.

Use Data

Where products have an active use phase (eg consume energy or resources) or are multiple use products, the GHG emissions from the product use phase should be considered.

Guidance for sterilisation impacts associated with multiple device use is discussed in detail in the previous sections referring to Passive, Reusable Devices.

The use phase of a product should be determined based on guidance in the Energy-Consuming Devices section above, and in the box below.

Collecting Energy Consumption Use Data

Collecting use data based on direct measurements is the preferred approach. If the product cannot be measured whilst in use, the following steps can be employed to identify the GHG emissions of the use phase.

- Identify each mode of use of the device (eg, on, active, standby, off, etc)
- Measure energy consumption of the device in each mode
- Determine an appropriate use profile for the device based on the identified modes (eg % on, % standby, % off)
- Determine the useful lifetime of the device

Once these data are known, the overall use phase impact related to energy consumption can be calculated and proportioned out to the relevant functional unit.

5.3.5 ***Secondary Data Sources***

Guidance for secondary data requirements and sources is provided in *Section 2*, and specific guidance is given in the boxes below. Further secondary data sources, in addition to those described in this document can be found on the GHG Protocol website (1).

Guidance for collecting secondary data for administering devices is outlined below.

Secondary Data for Medical Device Manufacture

If the medical device (or any component) is manufactured outside the company's operations, secondary data are recommended.

Data documenting the weight and material of each component in the device or packaging should still be collected, noting any recycled content. This collected bill of materials can be combined with secondary data sources for raw materials and average material processing to build a model of the device/packaging.

Data sources available for raw materials and processing impacts closely resemble sources identified in *Section 2* and *Section 4*.

Additional guidance for sourcing secondary data for raw materials is described below.

(1) http://www.ghgprotocol.org/Third-Party-Databases

Secondary Data for Raw Materials

A variety of materials may be required for medical devices including plastics, steel, aluminium and various other materials.

When using secondary data sources, the age, geography and technology should be considered, and datasets are to be amended where appropriate.

Many materials used in medical devices can have recycled content. The recycled content of materials should be considered based on guidance in *Chapter 2* and *Chapter 9* of the Product Standard.

Possible sources of secondary data include:

- Inventory of Carbon and Energy (publically available) (http://opus.bath.ac.uk/12382/)
- Plastics Europe (http://www.plasticseurope.org/plastics-sustainability/eco-profiles.aspx)
- World Steel Association
- (http://www.worldsteel.org/steel-by-topic/life-cycle-assessment.html)
- European Aluminium Industry (http://www.alueurope.eu/en/environment-health-safety/lca/)
- Ecoinvent (http://www.ecoinvent.org/)

For energy-consuming products, guidance for determining the use phase is described in the primary data section above. Secondary data are recommended for energy generation, and is discussed below.

Secondary Data for Energy in Use

Energy generation will usually lie outside the direct control of the company, whether off-site generation of heat, or production of grid electricity. For energy generation under the direct control of the company, this should be accounted for under primary data considerations.

Possible sources of secondary data for energy generation, including country specific electricity grid mixes include:

- International Energy Agency (for the most recent generation mix) (http://www.iea.org/stats/prodresult.asp?PRODUCT=Electricity/Heat)
- Defra GHG Conversion Factors (http://www.defra.gov.uk/publications/files/pb13625-emission-factor-methodology-paper-110905.pdf)
- US EPA Emission Factors & eGRID data (http://www.epa.gov/climateleadership/documents/emission-factors.pdf) (http://www.epa.gov/cleanenergy/energy-resources/egrid/index.html)
- Ecoinvent (http://www.ecoinvent.org)

Description

This stage covers all transportation and storage steps (prior to use) from point of production to point of issue (to hospital/doctor/nurse for use/patient if home delivered). After the product is manufactured, it is generally stored in an on-site warehouse, or moved to a regional distribution centre. From there onwards, it may have multiple transport steps before arriving at the point of issue. The urgency of the product's delivery and its shelf life will have a large influence over the modes of transport used.

Two distinct types of distribution and storage are used: ambient and chilled/frozen. Ambient storage is used for products that are not as sensitive to fluctuations in temperature and that are less perishable than chilled and frozen products.

Boundary Setting

A number of possible delivery pathways exist. Some potential distribution choices are described in *Figure 6.1*.

Typical processes to consider through distribution and delivery of the product are described below.

Include these attributable processes:

- Fuel extraction, production and consumption for all transportation modes
- Refrigerant loss in distribution and storage, where applicable
- Energy consumption during storage from heating, cooling, lighting, etc

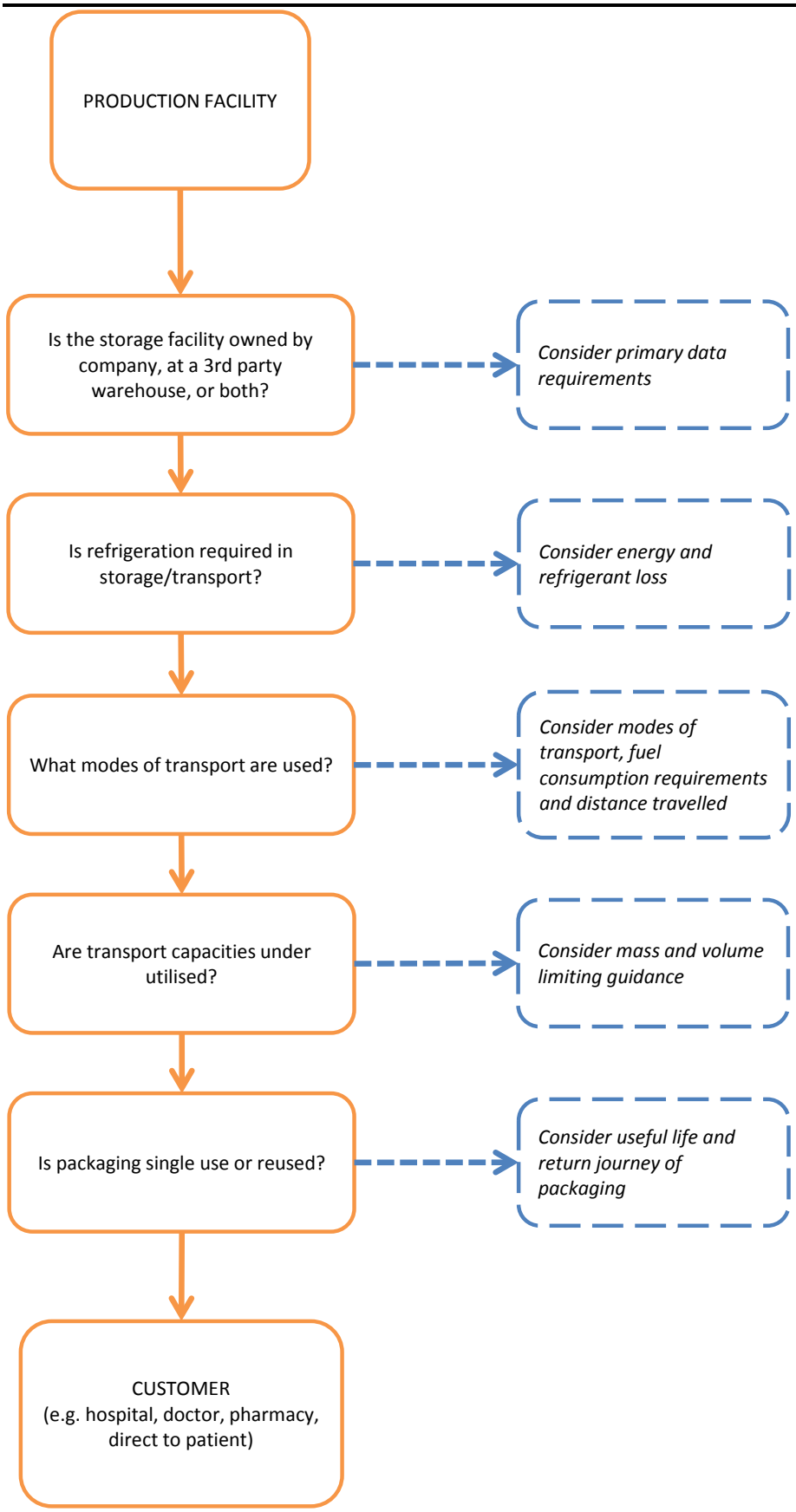
Include these non-attributable processes:

- Packaging used during transit and that may be used to speed delivery, protect or insulate product, including its disposal (eg pallets, plastic wrap and polystyrene insulation boxes)

Exclude these attributable and non-attributable processes:

- Capital goods such as the production of the vehicle or infrastructure used to transport the products
- Capital goods related to storage of the products at any stage during distribution
- Patient transport to receive final delivery or administration of products (covered elsewhere in this document)
- Security requirements for product transportation

Figure 6.1 Sample Process Map for Distribution and Delivery



Unit of Analysis

Emissions for this life cycle stage should be reported per unit or mass of delivered product to facilitate appraisal of the life cycle.

Additional guidance on aggregating modules to develop a functional unit for the product appraised is considered in *Section 4.3* and *Section 5.3.*

Primary Data and Allocation

Collection of primary data is required if the transportation stage is under the direct control of the company conducting the assessment. In the first instance, the fuel consumption per weight or volume capacity of the vehicle should be allocated to the product based on the weight transported. If these data are not available, the average fuel consumption of the delivery vehicle, the distance travelled and the weight of transported goods can be used. All data should be scored for quality according to the guidance set out in *Section 2*.

Screening Assessment for Distribution

The significance of the distribution and delivery life cycle stage to the assessment should be understood prior to collecting primary distribution data. Should distribution be immaterial to the results, secondary data may be used for the assessment.

Determining the materiality of the distribution phase can be calculated by estimating the travel distances, frequency of transport, transport mode and average loading of the product using secondary data sources.

Distribution paths for pharmaceutical products or medical devices may have under-utilised loads due to security requirements, contamination risk or insurance liability. Under-utilised loads can lead to transportation being volume-limited (as opposed to mass-limited), owing to the vehicle's capacity or dimensions. For example, if bulky packaging is required for protection, the load may be volume-limited as the vehicle could, in theory, carry more weight, but effectively does not through lack of available space. The limiting factor for transport capacity should be taken into consideration along with guidance in *Box 9.1* of the Product Standard, and in the box below.

Data and Steps to Calculate Transportation Impacts

The level of data quality can vary depending on the level of detail used to determine the impact of product distribution.

Where transport distances are known, the following data should be collected for each individual transport stage:

- Vehicle type
- Vehicle capacity (volume or mass)
- Volume or weight of load carried

To calculate the amount of fuel consumed, a hierarchy of data should be followed so as to obtain the required level of accuracy. The above data should be combined with the data described below (in order of highest to lowest data quality):

- Fuel consumed by vehicle over the specified transport distance
- Calculated distance (postcode > city> region> country) and secondary data for average fuel consumption
- Estimated distance and secondary data for average fuel consumption

Refrigerated or Frozen Transport

Where chilled transportation is used to deliver a product, this should be taken into consideration. If the GHG emissions for the transportation stage are based on fuel consumed by the vehicle, the fuel GHG emissions may account for additional energy needed for refrigeration. Where other approaches have been employed, an uplift factor to account for energy used through refrigeration should be considered and applied.

Any known release of refrigerants through distribution should be accounted for and if not known these should either be estimated or justification provided why they are excluded.

Additional Transport Considerations

There are other considerations when distributing high value or sensitive products such as pharmaceutical products and medical devices. These may include:

- Transport of intermediates before final production and the splitting of batches into several shipments to minimise loss
- The requirement for temperature controlled environments

This guidance should also be applied for transportation pathways relating to the repair, return or refurbishment of products. The box below provides guidance for determining the average distribution pathway.

Calculating Global or Regionally Specific Distribution

As products can be sent to many locations globally, determining a representative average of transportation requires consideration. The reporting recommendations should be taken into account when determining the representative transportation impacts.

- Identify the reporting recommendations (eg whether figures are required on a global, regional or local basis).
- Collect sufficient data as described in the box above to develop a representative distribution average.

When determining a representative average, sampling of distribution paths may be used based on volume of product transported to each location within the region to be assessed. This may take the form of a percentage cut-off value to practically account for distribution. Any cut-off value used when determining distribution impacts should be reported.

Storage of the product during distribution should be included based on guidance outlined in the box below and in *Section 2*.

Primary Data Recommendations for Storage

Storage facilities should be accounted for when distributing the product to the consumer. Site energy data and refrigerant loss rates can be used to determine GHG emissions from the storage facilities. These data can then be allocated to the products based on the quantity of product held in the storage facility and the specific length of time over which the relevant product is held in storage. GHG emissions associated with refrigeration of the stored product should be included in the assessment where applicable.

Transportation packaging should be included in the assessment. Common guidance is provided for packaging inclusion in *Section 2* and *Section 4.5.7*, and should be considered along with guidance provided in the box below.

Primary data Recommendations for Transport Packaging

The following data should be collected for the packaging of the product:

- Type of material(s) used
- Weight of packaging (empty)
- Volume of packaging (if utilisation in transport is likely to be a consideration)
- Number of units packaged per container (eg tray, box, pallet)

Disposable and Reusable Packaging

Distribution packaging may be in both reusable and disposable form. Where packaging is reusable, the GHG emissions associated with its manufacture can be shared across the number of uses of the packaging. Transportation to reuse the packaging should be accounted for.

The GHG emissions associated with disposal of transportation packaging should be included in all assessments.

Secondary Data

Where primary data are not available (or of poor quality based on the data quality indicators), or the transportation stages are not under the direct control of the organisation, secondary data can be used as an alternative. Secondary data for transportation and packaging are discussed in *Section 4.5.7,* along with additional guidance given below.

Secondary Data Sources for Transportation

Many GHG emission factors for different transportation modes exist and are applicable to distribution impacts. Consideration should be given to the mode of transport and utilisation, and adjustments made where possible to make these factors relevant to the product studied.

Two examples of useful publicly available transportation factors include (check for the most recent updates):

- Defra GHG Conversion Factors (http://www.defra.gov.uk/publications/files/pb13625-emission-factor-methodology-paper-110905.pdf)
- US EPA Emission Factors (http://www.epa.gov/climateleadership/documents/emission-factors.pdf)

Secondary Data Sources for Storage

Where storage facilities lie outside the boundaries of the company conducting the study, the GHG impact of these facilities can be accounted for using secondary data. The location of the storage facilities should be considered (including relevant use of regional electricity grid factors). Estimates of energy consumed by warehouses and other buildings are publicly available. These can be used in conjunction with approximations of product storage space and periods to estimate storage facility impact.

An example of such a reference for warehouse energy consumption is

- US EIA Commercial Buildings Energy Consumption Survey 1999 (http://www.eia.gov/emeu/cbecs/pba99/warehouse/warehouseconstable.html)

Secondary Data Sources for Packaging

A variety of materials can be utilised for packaging, including paper, cardboard, glass, aluminium and various plastics. Further guidance for packaging data is provided in *Section 2* and *Section 4.5.7.*

Many materials used for packaging can have recycled content. The recycled content of packaging materials should be considered based on guidance provided in *Section 2* and *Section 9* of the Product Standard.

Possible sources of secondary data include (amongst others):

- Inventory of Carbon and Energy (publicly available) (http://opus.bath.ac.uk/12382/)
- Ecoinvent (http://www.ecoinvent.org/)

7.1.1 *Description*

This section considers the use, administration or consumption of pharmaceutical products and medical devices. Products are considered to be used at the following locations:

- local/regional/national hospital;
- local/regional/national clinic;
- local GP surgery; or
- patient home.

This guidance refers specifically to the GHG emissions arising from a product's use phase, as opposed to determining a care pathway through use of a product. *Section 10* discusses how the use phase may be included in order to assess full care pathways.

7.1.2 *Boundary Setting*

The first step is to define the use profile and develop a process map identifying attributable and non-attributable processes to be included for the specific product.

The way a product is used will vary significantly between users. As a result, companies often find it difficult to define attributable processes. The options available include either:

- determining an average use scenario, where data on user habits are available; or
- specifying a number of use profiles based on typical scenarios - in this instance, appraising a range of use profiles will provide insight into the GHG implications of alternate use processes.

The specified use instructions, care pathways and functionality of a pharmaceutical product or medical device can help to define the use profile and attributable processes, and to develop a process map. The process map developed should clearly identify all core processes in the use stage as well as all processes under the direct control of the company undertaking the assessment.

Attributable and non-attributable processes that should be included are described in the box below. Additionally attributable and non-attributable exclusions are considered.

Include these attributable processes:

- Production, distribution, consumption and disposal of single use items, eg syringe used to contain or administer (used to carry the pharmaceutical product into the patient or to directly apply it to the patient) the pharmaceutical product or to utilise the medical device
- Energy use of equipment relating to the administration of pharmaceutical products or use of medical devices
- Energy required to warm or cool the product or carrier substance or liquids
- Use and disposal of packaging
- Material and chemical input transport

Include these non-attributable processes:

- Non-commuting travel by the patient or the clinician to receive/collect/administer the pharmaceutical product or to utilise the medical device
- Production, distribution and consumption of the carrier substances or liquids required to dilute, dissolve, hydrate, administer the pharmaceutical product or to utilise the medical device
- Sterilisation and cleaning inputs

Exclude these attributable and non-attributable processes:

- All ancillary products and equipment, eg protective clothing etc
- The production, distribution, cleaning and disposal of multi-use equipment used to contain or administer the pharmaceutical product or to utilise the medical device
- The consumption of food or drink by the patient
- Health consequences for the patient
- Employee commuting
- Buildings – capital goods, lighting, heating
- Other medicines, excluding required carrier substances or liquids, administered in tandem with the product of concern
- Disposal of waste medicine
- Human metabolism

Companies should assume a use profile that most accurately represents the use of their product, using specific data from customer surveys, when available; or data based on industry average values for the average product use.

Attributable processes in use will vary between users and geographical locations. While companies can apply average values, they may find that focusing on a specific user provides greater insight into the GHG impacts of the product's use stage. The geographic location selected should be determined based on the reporting recommendations, eg if reporting requires a global average, or necessitates the identification of specific regions.

Pharmaceutical Products

Guidance for determining the use phase of pharmaceutical products should be considered in conjunction with the modules presented in *Section* 4. In addition to the inclusions and exclusions above, pharmaceutical products should consider the packaging and any administering devices.

Medical Devices

The use phase of medical devices is further discussed in the guidance provided in *Section 5*. Categories of medical devices considered include:

- Passive, Single Use Devices with Multiple Components/Materials;
- Passive, Single Use Devices with Few or Single Components/Materials;
- Passive, Multiple Use Devices;
- Implantable Devices; and
- Energy Consuming Devices.

Passive devices have a use profile that aligns with the general use guidance above, with no additional use phase GHG emissions to be considered.

Multiple use devices require additional use phase GHG emissions related to preparing the device for subsequent uses through sterilisation and utilisation of ancillary materials. Sterilisation of devices may be of significance to the whole life GHG emissions and specific guidance for its inclusion is discussed in *Section* 5.

Implantable devices have similar overlap with passive devices, and the surgical emissions related to implanting or removing the devices are judged as an exclusion in the guidance.

Energy consumption of a medical device may contribute significantly to the overall GHG emissions of a device, and the energy use profile of a product should be included. Guidance is provided in *Section* 5 to include these GHG emissions.

Once a medical device has reached the end of its useful lifetime, in some instances the product can be refurbished for further use. In some ways this can be seen as

similar to a maintenance process where materials and energy are required to continue operation of the device. Guidance for the refurbishment of medical devices is provided in the box below.

Refurbishment of Medical Devices

Refurbishment (as opposed to reprocessing) of medical devices should be considered as a route to extending the lifetime of the product and that additional GHG emissions (eg material and energy use, transportation and waste generated) are needed to continue operation. Refurbishment, conceptually, is therefore little different to maintenance, however care needs to be taken to ensure the requirements of the relevant medical device legislation is met and that patient safety is not compromised. Refurbishment should normally only be undertaken by the manufacturer of the device, or by an organization authorized by the manufacturer to undertake refurbishment.

For any medical devices that undergo refurbishment (single use or multi use) the refurbishment should be included as a separate life cycle stage between the different use stages of the product.

The functional unit of the product should be carefully considered so as to capture multiple lives where additional use is achieved through refurbishment.

Additionally, when determining the total lifetime of a product, including refurbishment, the initial manufacturing GHG emissions should be attributed across the entire useful lifetime of the product.

It is recommended that manufacturers appraise the product systems in terms of intended use of the product; however, it is also possible to appraise the actual use of the product within care pathways and to reflect real world circumstances and variation. Considerations when appraising actual product use can include the wastage of medicines or devices through damage, returns, product recall, replacement, etc.

7.1.3 *Unit of Analysis*

For pharmaceutical products, the reference flow should be based upon the quantity of product delivered to the patient. Reporting can be given on a mass basis or a volume basis, depending on the most relevant unit of measurement. The reference flow should include all administering devices and packaging required to deliver the product to the patient.

For medical devices, the reference flow should be based upon one ‘use’ of the device and is also to be reported per total life of the device. Defining the ‘use’ of the device is discussed in *Section* 5.

Further information on defining the functional unit of pharmaceutical products and medical devices, including examples, can be found in *Section 4.3 and 5.3*.

7.1.4 *Primary Data and Allocation*

Collection of primary data is recommended if the administering of the pharmaceutical product or the use of medical devices is under the direct control of the company conducting the assessment.

The following information may be required when collecting data to determine the use profile of a product or device:

- Quantities of single use items consumed.
- Energy consumption of equipment.
- Mode of transport, distances and fuel consumption of vehicles under the direct control of the company conducting the assessment.
- Quantities of carrier and dilution products consumed.
- Release of gases and refrigerants.

The inclusion of single use products or administering devices in addition to the pharmaceutical product or medical device should be included based on the guidance provided below.

Including Additional Materials

Guidance for including additional materials for the use profile is similar to that described for administration devices in *Section 4.5.6*.

All relevant materials required for administration or use of the product should be included. Where primary data can be collected, these should describe the following:

- Type and weight of individual raw materials
- Wastage rates of materials
- Weight and material type of constituent components
- Source location of raw materials
- Recycled content

Where these materials are outside the direct control of the company, secondary data may be used based on guidance provided in *Sections 2, 4* and *5.*

Energy use for medical devices or any other additional devices required for pharmaceutical product delivery is discussed below.

Accounting for Energy Use

Guidance for inclusion of energy consumption data is provided in *Section 5.3.2*.

Collecting use data based on direct measurements is the preferred approach. If the product cannot be measured whilst in use, the following steps can be used to identify the GHG emissions of the use phase.

- Identify each mode of use of the device (eg, on, active, standby, off, etc)
- Measure energy consumption of the device in each mode
- Determine an appropriate use profile for the device based on the identified modes (eg % on, % standby, % off)
- Determine the useful lifetime of the device

Travel by the patient to receive medication or to utilise medical devices should be considered as being part of the assessment.

Patient Travel

Travel by the patient to receive the pharmaceutical product or to use the medical device is considered as being within the boundary. Average patient transport should be included based on definitions in the use profile of the product.

Consideration should be given to the following data:

- Frequency of travel (as defined in the use profile)
- Representative location of patient and administering/use facility (eg hospital, clinic, etc)
- Average distance travelled by patient
- Mode of transport typically used

All assumptions made regarding patient travel should be reported.

Home Use
Use of pharmaceutical products or medical devices may be undertaken at the patient's home and, therefore, no patient travel is required. In some instances, a healthcare professional will be required to visit the patient at home, and this specific staff transport should be included.

7.1.5 *Secondary Data Sources*

Where primary data are not available or the use stages are not under the direct control of the company undertaking the assessment, secondary data can be used as

an alternative. All data (primary and secondary) should be scored according to the guidance set out in *Section* 2.

Examples of secondary data that may be required include:

- Quantities of materials consumed based on standard administering protocols or published user studies
- Energy consumption of equipment
- Mode of transport and distances travelled
- GHG emissions from the production, distribution, consumption and disposal of single use items
    - a syringe is an example of a single use product
    - sources of data include published carbon footprints or life cycle assessments of syringes
    - in the absence of published studies or data from suppliers, an estimate can be made using the mass and material composition of the syringe
- Energy use of equipment used to administer or store to pharmaceutical product
    - a pump is an example of a product that may be used to administer a pharmaceutical product
    - energy consumption can be estimated by multiplying the specified power rating of pump equipment by the specified time required to administer the product
- Travel by the patient or clinician to receive/collect/administer the pharmaceutical product
    - average distances by mode of transport are recommended
    - travel surveys conducted by health authorities are a likely source of information

Secondary data sources relevant to determining the use profile of the products is described below, and in *Sections 2, 4* and *5*.

Sourcing Secondary Data

Energy

Energy generation will usually lie outside the direct control of the company, whether off-site generation of heat or production of grid electricity. For energy generation under the direct control of the company, this should be accounted for under primary data considerations.

Possible sources of secondary data for energy generation, including country specific electricity grid mixes include:

- International Energy Agency (for the most recent generation mix) (http://www.iea.org/stats/prodresult.asp?PRODUCT=Electricity/Heat)
- Defra GHG Conversion Factors (http://www.defra.gov.uk/publications/files/pb13625-emission-factor-methodology-paper-110905.pdf)
- US EPA Emission Factors & eGRID data (http://www.epa.gov/climateleadership/documents/emission-factors.pdf) (http://www.epa.gov/cleanenergy/energy-resources/egrid/index.html)
- Ecoinvent (http://www.ecoinvent.org)

Transport

Many GHG emission factors for different transportation modes exist and are applicable to travel impacts. Consideration should be given to the mode of transport that products are carried on, or that patients are likely to use.

Two examples of useful publicly available transportation factors include (check for the most recent updates):

- Defra GHG Conversion Factors (http://www.defra.gov.uk/publications/files/pb13625-emission-factor-methodology-paper-110905.pdf)
- US EPA Emission Factors (http://www.epa.gov/climateleadership/documents/emission-factors.pdf)

8 END-OF-LIFE

8.1 GENERAL GUIDANCE

Description

The end-of-life stage begins when the used product is discarded, and ends when the product is returned to nature as waste or enters another product's life cycle (eg in a reprocessing step). A number of key considerations for pharmaceutical and medical device end-of-life accounting are outlined in this section.

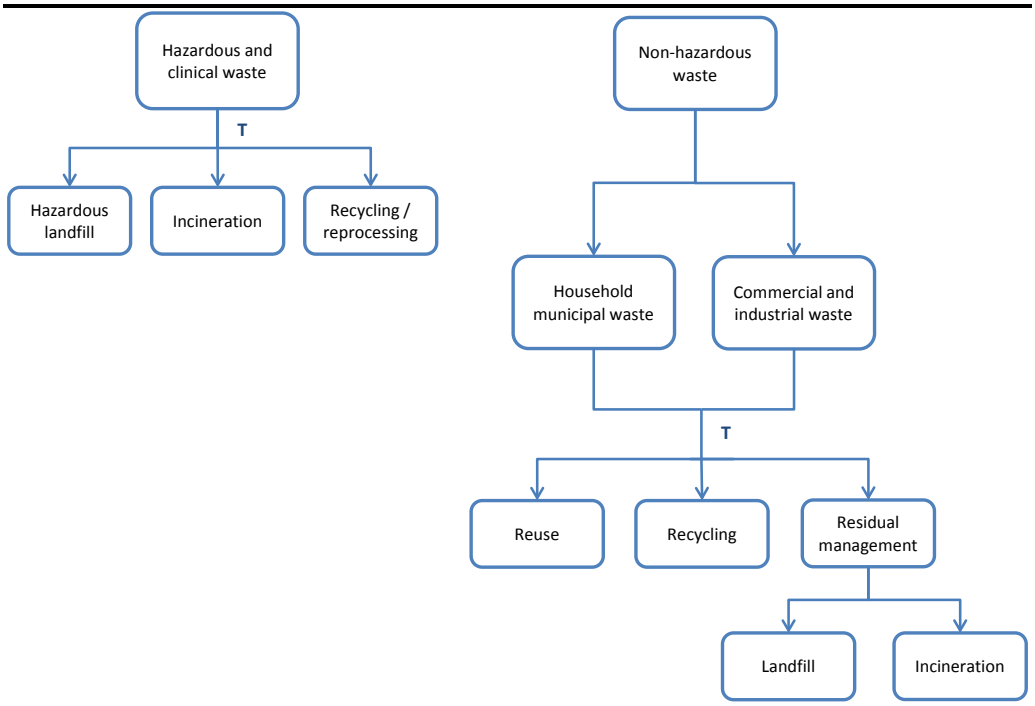
Waste is also created at other stages in a product life cycle, such as when manufacturing an API, creating a medical device or administering a product. The guidance in this section is also relevant for the management of wastes generated at other stages across the life cycle. The GHG emissions result from the management of wastes should be attributed to the life cycle stages that gave rise to the waste.

Waste from pharmaceutical products and medical devices systems falls into two general categories: hazardous and non-hazardous. Waste classification is an important factor, as it has a large influence on potential management options - for example, if it can be refurbished, where clinically safe.

Waste classification will vary dependent on the composition of the waste stream and local permitting regulations. Consider the geography in which waste arises and any specific requirements in a local context. Waste permits are a good source of information on waste composition, tonnages and onwards management.

Figure 8.1 broadly outlines the predominant types of waste arising across the life cycle of pharmaceutical products and medical devices along with key management routes. These are discussed further in the following sections.

Figure 8.1 Types and Fate of Waste Material



Boundary Setting

Typical processes to be considered at end-of-life are described below.

Include these attributable processes:

- Transport of waste product and packaging from the point of delivery to its point of final treatment - this should include intermediate transport stages, such as return of medicines or take-back of medical devices, etc
- Energy and materials for waste handling and treatment processes
- Direct GHG emissions from the degradation or destruction of materials at end-of-life (combustion or biodegradation)

Include these non-attributable processes:

- Energy and materials for any pre-treatment required for the safe handling and management of waste/recyclable/ reused equipment
- Production of spare parts/materials, and energy required for the refurbishment and repair of reused devices

Exclude these attributable and non-attributable processes:

- Capital goods such as the production of the vehicle or infrastructure used to transport, store or treat waste materials or reused/recycled products.
- Consequential effects of pharmaceutical release into the environment
- Infrastructure/containers used to contain waste

GHG accounting at end-of-life should reflect the use scenario defined. For manufacturers of pharmaceutical products and medical devices it is recommended to assume that any disposal procedures specified in the instructions (eg to put sharps in a special bin for separate collection, to return unused medicines to the producer) are followed by the user.

It is acknowledged that there are instances of improper management of unused medicines, such as disposal to a municipal sewer system. However, this is best considered as part of an assessment of a care pathway. There is also the potential for pharmaceuticals to pass through the body and to be excreted into the environment via municipal sewer systems. This can result in wider environmental consequences, and the need for additional wastewater treatment requirements. Human metabolism and wastes are generally excluded from product GHG appraisals. If considered material and included, it is recommended that the GHG emissions are reported separately.

Unit of Analysis

Emissions at end-of-life should be calculated and reported according to a relevant functional unit and should be consistent with the scope of the product inventory. For example, if an appropriate functional unit is defined 'per use' of a reusable or energy-consuming medical device, emissions at end-of-life should also reflect this unit (see *Section* 5 and *Section* 7).

For a cradle-to-gate study, it may be appropriate to estimate and report indicative end-of-life emissions per unit or kilogramme of delivered product (including packaging used for transportation).

Primary Data

There are no primary data requirements for the end-of-life stage of a product GHG inventory. However, companies should endeavour to reflect the geographic context in which waste arises, and the potential that this has to influence management options.

Where companies directly operate, or coordinate take-back schemes for unused pharmaceuticals or end-of-life/reused medical devices, they should collect specific process data on the operation of that scheme; including rates of take-back, logistics, refurbishment requirements, etc.

Secondary Data

Where primary data are not available or the end-of-life stages are not under the direct control of the organisation, secondary data can be used as an alternative.

8.2 SPECIFIC GUIDANCE: NON-HAZARDOUS WASTE

Non-hazardous waste will encompass packaging and most of the product waste arising at a patient's home [(1)], as well as some waste streams arising at hospitals, clinics, surgeries, etc or across other stages in a product life cycle.

Non-hazardous waste can have multiple fates, and secondary data are recommended to approximate a relevant proportion of each component that is reused/recycled/landfilled/incinerated/other – ie an 'end-of-life profile'. Consideration should be given to both the location and context of the point of waste arising in determining an appropriate end-of-life profile. For instance, reported statistics for municipal and industrial waste treatment methods for each EU member state can be found through the European Commission website [(2)].

Other similar national datasets should be used for other geographies.

For an inventory that considers an 'average' product, rather than a specific country of use, consideration should be given to the weighted end-of-life profile across at least 80% of the product market.

8.3 SPECIFIC GUIDANCE: HAZARDOUS AND CLINICAL WASTE

Hazardous waste commonly arises at the point of manufacture where large volumes of solvents, contaminated consumables and by-products are produced; and during the administration or use of the product in a clinical setting.

Hazardous and clinical waste is generally disposed of via incineration or hazardous waste landfills, although specific regulations will vary between countries and in some specific instances, methods of recycling specific hazardous waste types may be identified. The proportion of hazardous waste recycled, disposed to landfill or incinerated should be determined in order to establish an appropriate end-of-life profile. These proportions should be geography-specific wherever possible; for example, drawing from national regulations/policies/targets, or national average statistics where available.

For an inventory that considers an 'average' product, rather than a specific country of use, consideration should be given to the weighted end-of-life profile across at least 80% of the product market.

Having determined a relevant end-of-life profile, specific calculation recommendations and potential data sources for different management routes are outlined in the boxes below.

(1) There may be take-back schemes for specific hazardous waste streams such as sharps/ syringes, which will be treated as clinical waste by the pharmacy, hospital or clinic.
(2) http://epp.eurostat.ec.europa.eu/portal/page/portal/waste/data/main_tables

Reuse and Recycling

Where part of the product, such as packaging or electrical equipment is reused or sent for recycling, further guidance on accounting is provided within *Chapter 9, Section 9.3.6* of the Product Standard. The guidance in this chapter is applicable to materials arising across pharmaceutical products and medical devices and so is not reproduced here. Refer directly to the Product Standard.

Incineration

Without Energy Recovery

Emissions associated with incinerating wastes where energy recovery does not occur should be calculated based on the carbon content of the material (for example, a range of carbon content values for typical waste materials can be found Table B1.7 of http://randd.defra.gov.uk/Document.aspx?Document=WR0602_4745_FRA.pdf) and the assumption that all carbon is oxidized to carbon dioxide (use the relative mass of CO_2/C, and multiply by 44/12 (= 3.67)). Note that carbon/CO_2 from fossil and biogenic sources should be quantified and reported separately.

With Energy Recovery

Emissions associated with incinerating wastes where energy recovery occurs should be included in the GHG inventory as described above. The amount of energy recovered and exported for useful purpose (eg sold to the national grid or used for district heating) should be quantified and reported, together with any key assumptions. The avoided emissions from producing an equivalent quantity of electricity or heat by conventional means should be calculated using a system expansion approach, as specified in *Chapter 9* of the Product Standard. These emissions should be subtracted from the product GHG inventory.

Landfill

Inert Wastes

Emissions associated with non-biodegradable wastes to landfill can usually be assumed to be zero, as no GHG will be released from this material, and processing GHG emissions at a landfill site will be minor.

Biodegradable Wastes

Where landfill is not an important part of the product system, emissions can be estimated using the material-specific factors in Annex 9 of the Defra/DECC reporting guidelines (http://www.defra.gov.uk/environment/economy/business-efficiency/reporting/). These factors are inconsistent with the GHG Protocol boundaries in that they do not include biogenic carbon dioxide emissions. This will lead to an underestimate of emissions, and so should be noted as a limitation.

Where considered potentially significant, an estimate of 50% of the carbon contained within the material could be assumed to be released as carbon dioxide, and these emissions should be added to the product GHG inventory (reported separately). These emission factors are also based on an infinite time period and so assume that all the carbon within the waste material degrades. This is a conservative assumption and is reasonable in this context – but should be noted within any inventory reporting.

Where landfill is an important part of the product system, a more detailed estimate should be sought. The discussions and default data in the following sources provide a good overview of approaches to do so:

- Doka, G. (2009) Life Cycle Inventories of Waste Treatment Services. Final report ecoinvent v2.1, No. 13. Dübendorf: Swiss Centre for Life Cycle Inventories
- Defra (2006) Carbon Balances and Energy Impacts of the Management of UK waste Streams, WR0602, London

9 COMMUNICATION, REPORTING AND ASSURANCE

9.1 COMMUNICATION SUPPORTED

In line with the Product Standard, this guidance is intended for use by pharmaceutical and medical device producers, as well as by other actors in the value chain, to calculate cradle-to-gate and cradle-to-grave product GHG inventories.

This guidance is intended for reporting GHG inventory information so that it can be used to support informed discussions internally to:

- identify hotspots in the product life cycle;
- identify potential opportunities to reduce the GHG emissions;
- track the performance of a product over time; and
- undertake product and process comparisons for internal use only.

Reporting of the GHG inventory may also be undertaken for the provision of information to inform discussions, with customers and with suppliers to:

- identify hotspots in the product life cycle; and
- identify potential opportunities to reduce the GHG emissions.

It should be noted that this guidance is not intended to support comparative assertions between products, or claims of favourable environmental performance of one product over another. Such external product comparisons are discussed further in the Product Standard (*Chapter 1.5*, *Chapter 5.3.2* and *Appendix A*), and the Standard requires additional Product Rules to be developed to support product comparisons. Product Rules are outside the scope of this sector guidance.

When supplying information to customers and suppliers, companies should be particularly aware of recommendations set out in this guidance for data quality (*Section 2.4.3*), and adhere to the following recommendations around reporting (*Section 9.2*) and assurance (*Section 9.3*).

9.2 REPORTING RECOMMENDATIONS

Full reporting requirements and further general guidance for reporting a GHG inventory using the Product Standard are provided in *Chapter 13* of the Product Standard, and are reproduced below. Where there are specific or additional recommendations relating to this guidance document, supporting text (shown in *italics*) has been included.

Reporting companies shall publicly report the following information to be in conformance with the Product Standard.

General Information and Scope

- Contact information
- Studied product name and description
- The unit of analysis and reference flow
- Type of inventory: cradle-to-grave or cradle-to-gate
- Additional GHGs included in the inventory
- *A declaration of conformance with this sector guidance document*
- Inventory date and version
- For subsequent inventories, a link to previous inventory reports and description of any methodological changes
- A disclaimer stating the limitations of various potential uses of the report
  Reports should state that the GHG inventory is intended for use either in:
  - *identifying hotspots in the product life cycle*
  - *identifying potential opportunities to reduce GHG emissions; or*
  - *tracking the performance of a product over time*

  This may be for use internally with a company or for sharing with direct customers to aid in the above aims. If the report is to be made more widely available to the general public, it should be clearly stated that this is not the intended audience and what the intended aims of the report are.

Boundary Setting

- Life cycle-stage definitions and descriptions
- A process map including all attributable processes in the inventory
- Non-attributable processes included in the inventory
- Excluded attributable processes and justification for their exclusion
- Justification of a cradle-to-gate boundary, where applicable
- The time period
- *The geographic scope – eg single product system and market, or average regional/global market – and the approach used to define the average market*
- The method used to calculate land use change impacts, when applicable *and as specified in this sector guidance*

Allocation

- Disclosure and justification of the methods used to avoid or perform allocation due to co-products or recycling, *as specified in this sector guidance*
- When using the closed loop approximation method for recycling or reuse, any displaced emissions and removals to be disclosed separately from the end-of-life stage

Data Collection and Quality

- For significant processes, a descriptive statement on the data sources, data quality, and any efforts taken to improve data quality
- *Significant processes and data points should be identified by assessing their contribution to the total GHG Inventory. All processes that contribute more than a selected cut-off level percentage of the total GHG inventory (eg 1-5% of the total GHG inventory) should be deemed significant processes. For each*

of these processes, details of the data sources and data quality scores or descriptions for both primary and secondary data should be provided.

Uncertainty

- A qualitative statement on inventory uncertainty and methodological choices. Methodological choices include:
    - Use and end-of-life profile
    - Allocation methods, including allocation due to recycling
    - Source of emission factors used
    - Calculation models

Quantitative assessment is not required but when available; companies should report quantitative uncertainty results in the inventory report. Knowledge of this uncertainty will allow a better assessment of the results when making decisions on hotspot prioritisation, intervention opportunities and tracking performance.

Inventory Results

- The source and date of the emission factors used
- Total inventory results in units of CO_2e per unit of analysis, which includes all emissions and removals included in the boundary from biogenic sources, non-biogenic sources, and land use change impacts
- Percentage of total inventory results by life cycle stage
- Biogenic and non-biogenic emissions and removals separately, where applicable
- Land use impacts separately, when applicable
- Cradle-to-gate and gate-to-gate inventory results reported separately (or a clear statement that confidentiality is a limitation to providing this information)
- The amount of carbon contained in the product or its components that is not released to the atmosphere during waste treatment, when applicable
- For cradle-to-gate inventories, the amount of carbon contained in the intermediate product

Assurance (*see further details in Section 9.3*)

The assurance statement includes:

- Whether the assurance was performed by a first or third party
- Level of assurance achieved (limited or reasonable) and assurance opinion or the critical review findings
- A summary of the assurance process
- The relevant competencies of the assurance providers
- How any potential conflicts of interests were avoided for first party assurance

Note – When reporting product GHG inventories it is a requirement that a link to the above documentation can be found, this includes the assurance statement.

9.3 ASSURANCE AND VERIFICATION

The Product Standard requires that the product GHG inventory is assured by a first or third party. Full details of this process are set out in *Chapter 12* of the Product Standard. A summary of requirements is provided in this section.

Assurance can be undertaken by a first party (the company reporting the GHG inventory) or a third party (a party other than the reporting company):

- **First party:** Person(s) from within the reporting company but independent of the GHG determination process conducts internal assurance.
- **Third Party:** Person(s) from an organisations independent (different business entity from reporting company) of the product GHG inventory determination process conducts third party assurance.

The Product Standard requires that assurance providers are independent of, and have no conflict of interest with, the product GHG inventory process.

Inherently, assurance provided by a third party should offer a higher degree of objectivity and independence. *Third party assurance is considered good practice and is recommended for any external reporting.*

Where first party assurance is used, companies are required to state how potential conflicts of interest were avoided during the assurance process. The selected assurer should also be able to demonstrate that they are competent to undertake the assurance, in order to ensure credibility to support the reporting company's findings.

Assurance Process

Assurance of the product inventory results can be achieved via two methods: verification and critical review as discussed in *Chapter 12.2* of the Product Standard.

Verification: is an independent assessment of the reliability of the product GHG inventory. It may be undertaken by a first or third party, and may take place in several ways (eg on-site checking and review). Verification should be conducted before the public release of the inventory report by the reporting company. This allows for material misstatements to be corrected prior to the release.

Critical Review: is a process intended to ensure consistency between the product inventory, and the principles and requirements of the Product Standard and this guidance. The critical review process ensures that methods used to carry out the product inventory are technically valid and consistent with the Product Standard and this guidance. A critical review may be performed by an internal or external expert, or a review panel of interested parties. For solely internal projects, internal critical review by an employee independent of the assessment is advised. Where suppliers and customers have provided input to the study and there is an intention to share results with them, it is advisable to include representatives from these groups on a review panel.

Assuring product GHG inventories through critical review and verification will provide increased confidence in the results of assessments.

A statement confirming conformance with the Product Standard assurance methodology is a requirement for reporting (see *Section 9.2*).

9.3.1 *Recipients of GHG Product Inventories*

Recipients of GHG Product inventories are encouraged to utilise the guidance to ensure correct interpretation of the information provided. *Section 9.2* details the expectations with regard to reporting, the provision of supporting information and type of assurance. Awareness of the unit of analysis, system boundaries, use scenarios, data quality and level of assurance require specific attention to appreciate what is being reported and how it is to be interpreted.

The calculation of product GHG inventories by organisations demonstrates a commitment to understanding and managing GHG emissions. The assessments are not appropriate for external product comparisons; therefore procurement requirements directed at the product GHG emissions inventory should not be specified. Procurement requirements should encourage product inventory development, public reporting, management of GHG emissions and demonstration of inventory reductions through the use of this sector guidance and conformance with the Product Standard.

10 CARE PATHWAYS

It is anticipated that health managers and health providers will increasingly wish to understand the greenhouse gas emissions of alternate models of care and care pathways. This guidance is primarily directed at providing a consistent basis for appraising individual products in the health practitioner's tool box. The consistent appraisal and reporting of the GHG inventories associated with individual pharmaceutical products and medical devices will facilitate the appraisal and design of care pathways.

In the absence of specific guidance for care pathways it is considered useful to provide some initial thoughts on how care pathways can be appraised.

10.1.1 *Description*

A care pathway describes the planned activities and interventions that need to occur for a patient with a particular condition as they move through the care system. It is evidence-based and multidisciplinary by nature and can involve the provision of assessment, treatment and monitoring clinics as well as the provision and use of pharmaceutical products and medical devices. Care pathways can be considered a service in the context of the Product Standard and this guidance.

10.1.2 *Unit of Analysis*

The unit of analysis is a particularly important consideration when attempting to define care pathways. A well-defined functional unit for a care pathway will consist of three general parameters:

- the magnitude of the care pathway (eg an average adult patient requiring a certain service);
- the duration or service life of that function or service (eg one year); and
- the expected level of quality or outcome (eg effective management of condition with no unforeseen clinical or technological complications).

For care pathways, the patient profile and consideration of the variability of patient experience will need consideration when selecting an appropriate unit of analysis and undertaking the assessment.

Example of a Unit of Analysis
An adult patient receiving in-centre maintenance haemodialysis provided by South London Healthcare NHS Trust for one year.

10.1.3 *Boundary Setting*

The next key step before sourcing emissions data and calculating the GHG emissions as described in the Product Standard is to define the care pathway and develop a process diagram identifying attributable and non-attributable processes to be

included. To assess a care pathway it is necessary to specify the profile of an average patient's experience and to quantify the resources that are required to be expended by both the healthcare providers and the patient.

When developing a system boundary for a service such as a care pathway it may not always be clear how to define where the life cycle starts or ends, particularly where boundaries with other service life cycles, eg general practice, shared buildings are blurred. Processes that are directly required to deliver the care pathway should be identified.

A process map for a care pathway should be developed identifying all activities that are associated with the care pathway. It should clearly identify all core processes and all processes under direct control of the organisation undertaking the assessment.

Pharmaceutical and medical device companies who wish to appraise their products in the context of a care pathway should assume a user profile that most accurately represents the use of their product in the care pathway. See *Section 7* for further guidance in this respect. The specification and sharing of care pathway user profiles for pharmaceutical products by health authorities will aid consistent appraisals.

The following boundary clarifications are recommended by this sector guidance for the assessment of care pathways:

Inclusions:

- Production, distribution, consumption and cleaning or disposal of consumables (eg laundry, paper towels)
- Energy use of equipment and buildings that can be directly attributed to care pathway
- Travel of the patient or clinicians to receive or deliver care
- Production, distribution, consumption and disposal of medical devices
- Production, distribution, consumption and disposal of pharmaceutical products
- Laboratory testing of patient samples required by the care pathway;
- Testing (eg micro-biological testing) of medical devices, buildings and services as required by the care pathway
- Energy and material consumption for administrative activities that are associated with the care pathway
- Employee commuting
- Production and maintenance of buildings and vehicles required for the delivery of the care pathway if initially appraised through screening to be material

Exclusions:

- Activities and materials not directly associated with the delivery of the care pathway
- Patient consumption of food and drink
- Activities and materials deemed immaterial through screening

To simplify the process maps and the assessment, specific inclusions and exclusions should be made on the basis of materiality and through application of screening as described in *Chapter 6* and *Chapter 8.3.3* of the Product Standard. The clear specification and consideration of the lifetimes of multi-use items and infrastructure will be essential in the screening and subsequent detailed assessment.

10.1.4 *Data*

Collection of primary data is required if the provision and management of the care pathway is under the direct control of the organisation conducting the assessment.

Care pathways, due to the potential for variability in patient profile and the response of the care pathway, combined with high levels of human activity introduce a complexity into assessments and the interpretation of results. The consumption of resources is likely to vary from patient to patient, and as a result data requirements will be guided by the functional unit and the patient profile it defines.

The following information may be required when appraising a care pathway:

- Inventory of purchases associated with delivery of a care pathway
- Number and profile of patients treated
- Quantities of pharmaceutical products consumed
- Types and quantities of medical devices used
- Energy and water consumption of equipment and buildings
- vehicles, distances and fuel consumption associated with the care pathway and under the direct control of the organisation conducting the assessment
- Employee travel surveys
- Patient travel surveys
- Release of gases and refrigerants
- Quantities and types of wastes generated (including unused medicines), by the users and providers of the care pathway, and their management(including improper disposal)

Section 7 and *Section 8* provide a useful reference for data recommendations and secondary data sources when appraising a care pathway as the use and end of life phases for pharmaceutical products and medical devices form a significant component of most care pathways.

Providers of pharmaceutical products and medical devices when appraising and reporting a product's GHG emissions using this guidance and the Product Standard should therefore consider the use of their data in the appraisal of care pathways. Providers of care pathways should likewise appreciate the need to share information to increase the utility of pharmaceutical product and medical device assessments for the assessment of care pathways.

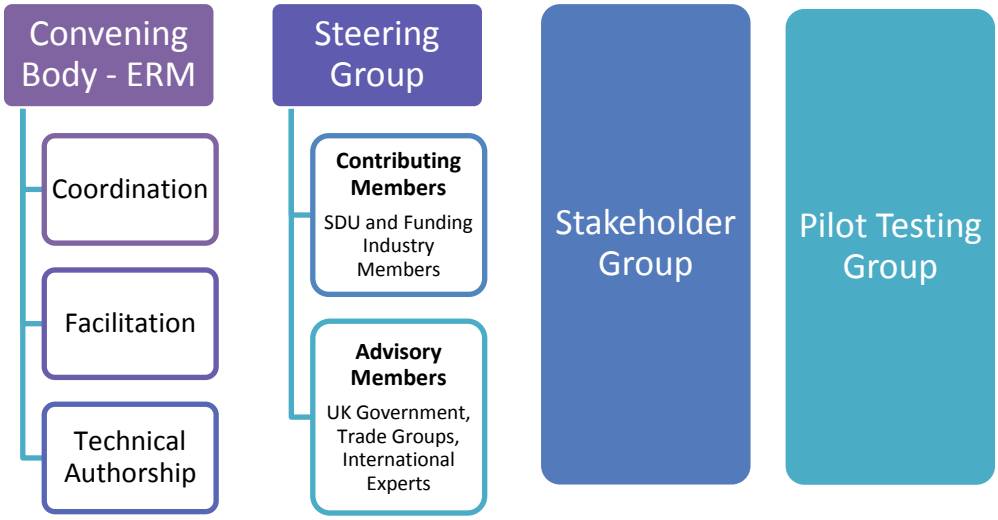
Annex A

Guidance Development: Governance and Consultation Processes

A1 GOVERNANCE STRUCTURE AND PROCEDURES FOR THE DEVELOPMENT OF THIS SECTOR GUIDANCE

The governance process to oversee and develop this Sector Guidance consists of four groups:

1. Convening Body and Technical Author (ERM)
2. Steering Group (Contributing and Advisory membership)
3. Stakeholder Group
4. Pilot Testing Group



A1.1 ROLE OF CONVENING BODY AND TECHNICAL AUTHOR

The technical author's role has been to convene and facilitate the Sector Guidance development process. The technical author organisation has provided secretarial support to the process, responsible for convening meetings, for chairing the steering group, for preparing the agenda for meetings, and for writing the minutes of meetings.

The technical author has also been responsible for the production of each draft of the Sector Guidance document, and for collating and responding to comments. In doing so, the technical author has had an overarching role to provide consistency in the method and approach.

A1.1.1 *Responsibilities*

- Facilitation and coordination of meetings of the Steering Group and stakeholder and pilot testing groups, as required.
- Review of relevant existing standards and methods, consolidation of issues and challenges and development of consensus around the content of the Guidance.

- Development of chapters and draft text as appropriate.
- Development of inputs to inform, explain and/or justify provisions to the Steering Group, and Stakeholder Group and support decision making processes.
- Receipt and response to feedback on draft chapters following consultation and review periods.
- Management of pilot testing, as required.
- Production of final chapters, taking into account feedback received.
- Support to the adoption of the Guidance.

A1.2 THE COMPOSITION AND ROLE OF THE STEERING GROUP

The Steering Group has provided strategic guidance and built consensus during the development of the Sector Guidance.

The Steering Group is comprised of:

- *Contributing Members* - the NHS sustainable development unit (SDU) and the pharmaceutical/medical device companies who are between them be funding the project: Baxter; GlaxoSmithKline; Johnson and Johnson; Novo Nordisk; Pfizer; and AstraZeneca.
- *Advisory Members* - including representatives from UK government and regulatory bodies, trade groups, International bodies and experts with relevant experience: UK Department of Health (DH); National Institute for Heath and Clinical Excellence (NICE); Medicines and Healthcare Products Regulatory Agency (MHRA); British Generic Manufacturers Association (BGMA); Association of British Pharmaceutical Industries (ABPI); Association of British Healthcare Industries (ABHI); Hull and East Yorks NHS Trust; Sustain Pharma; UNDP Europe; and Western Health Australia.

Steering Group meetings are attended by both Contributing Members and Advisory Members (either in person or remotely).

A1.2.1 Decision Making Processes

The Sector Guidance development has occurred through an open, transparent, inclusive, multi-stakeholder process. Decisions have been facilitated by building consensus and the document is subject to review by stakeholders. ERM as the Convening Body have made every effort to reach consensus within the Steering Group on each aspect of the Guidance. On the occasion that the wider Steering Group are unable to reach a consensus, the majority vote by Contributing Members was the authority with regard to final decisions.

A1.2.2 The Steering Group's Responsibilities

- Provision of advice and guidance on strategy, objectives and scope of the Sector Guidance documents.

- Provision of guidance on the structure of the document (including content, level of detail, etc.) based on agreed objectives.
- Provision of technical support, data and materials to support the drafting process.
- Resolution of disagreements on technical issues.
- Review of document drafts for technical accuracy, consistency and completeness.
- Recruitment of pilot testers.
- Support to the broad adoption and use of the Sector Guidance.

A1.3 STAKEHOLDER GROUP

The role of the Stakeholder Group is to provide feedback on the draft Sector Guidance.

The group consists of any interested stakeholders from government, industry, NGOs and academia. Interested parties were sought by the Steering Group and participants were asked to provide feedback on the draft Guidance during the public consultation period.

Incorporation of comments from the Stakeholder Group was at the discretion of the Steering Group.

Stakeholders who contributed to the content of the Sector Guidance document are acknowledged and recognised as "General Contributors & Reviewers" and listed by name/affiliation in the final publication.

A1.3.1 Consultation Process

The Sector Guidance consultation period ran from June 11th 2012 until July 13th 2012. The NHS SDU and World Resources Institute (WRI) publically hosted the consultation on their website and a range of stakeholders have also been directly contacted directed by the Steering Group, such as the Centre for Sustainable Healthcare, WHO, UNICEF, UNDP, Consumers International and the British Standards Institute. ERM, WRI, the NHS SDU and Steering Group members also circulated information about the consultation to their mailing lists.

A comment template was developed in order to facilitate the consolidation of technical comments. The NHS SDU also sought consultation input from stakeholders who may not consider themselves able to comment on the technical aspects of the guidance. This was in order to take the opportunity to ensure that the Guidance is as relevant as possible to healthcare experts, addresses the issues that they consider important, and allows the information generated to be used in a way that is useful to them. In order to do so, a series of more general questions were developed for non-technical comment/feedback.

As part of the consultation process, four webinar events were held – to explain the background, scope and purpose of the document, to field any questions and to

gather initial feedback. To allow international stakeholders to attend, these were webinars and held at times to accommodate different time zones: 7am and 3pm BST on June 26th, and 9am and 5pm BST on June 27th. ERM hosted and lead the webinars, following a format based on previous consultation webinars hosted by the WRI. Further details regarding the webinars are found on the SDU website (www.sdu.nhs.uk).

Following the consultation process, stakeholder comments were consolidated and a summary of resulting actions produced. In the instance that disagreements arose, a summary of issues and decision points was compiled and circulated to the Steering Group for agreement. A teleconference was held with the Steering Group shortly after the consultation process to review stakeholder comments, actions and agree Guidance amendments.

A1.4 PILOT TESTING GROUP

After the final draft of the Sector Guidance was prepared, a select group of companies had the opportunity to test the document within their organisations to ensure that the Guidance can be practically implemented, and provide any feedback for their improvement.

ERM provided technical support and guidance to pilot testers in implementing the draft final Guidance document.

Feedback from the pilot testing was incorporated into the final version of the Sector Guidance.

Pilot testers are recognized as “Pilot Testers” in the final publication.

A1.5 OVERVIEW OF GUIDANCE DEVELOPMENT PROCESS

A summary of the overall Sector Guidance development process is shown in *Figure A1.1.*

Figure A1.1 Outline of Sector Guidance Development Process

Annex B

Related and Other Standards

B1 OTHER RELEVANT PRODUCT GHG FOOTPRINTING METHODS, STANDARDS AND GUIDANCE DOCUMENTS

This Sector Guidance document was developed to build on the requirements of the Greenhouse Gas Protocol (GHGP) Product Standard and is intended for use alongside the Product Standard. As such, the structure of the document, and the specifics of its requirements have been designed to meet this purpose. However, there are a range of other methods, standards and product guidance related to product GHG footprinting that are also relevant for pharmaceutical and medical device products.

The intention for this Sector Guidance to sit alongside the GHGP Product Standard does not preclude its use to support footprinting activities for companies using, or wishing to use, other product footprinting approaches. The detail provided in the Guidance is generally applicable across all product footprinting methods. There are some specific areas of potential difference across methods that users should be aware of, however. Further commentary on these is provided in *Table B1.1* for the following key existing documents:

- PAS 2050 – Specification for the Assessment of the Life Cycle Greenhouse Gas Emissions of Goods and Services;
- ISO 14067 – Carbon Footprint of Products. Requirements and Guidelines for Quantification and Communication (in draft); and
- existing product category rules (PCRs) relevant for pharmaceutical of medical device products.

Note – two other documents also have specific relevance, but are either not publically available or are currently in draft and may be subject to significant change and so have not been commented on in this draft. These are the LEEM/ADEME guidelines for GHG footprinting pharmaceutical products; and the European Commission's harmonised methodology for the calculation of the environmental footprint of products [(1)].

(1) http://ec.europa.eu/environment/eussd/product_footprint.htm

Table B1.1 Overlaps and Points of Difference with other Methods, Standards and Guidance

PAS 2050:2011 http://www.bsigroup.com/upload/Standards%20&%20Publications/Energy/PAS2050.pdf	
The primary objective of PAS 2050:2011 is to provide a common basis for the quantification of GHG emissions to inform emission reduction programmes. The output from a PAS 2050:2011 product GHG footprint is particularly suited to business-to-business communication. PAS 2050:2011 and the GHGP Product Standard are broadly aligned in terms of approach and requirements. Key differences that might have implication for footprint calculations are set out below.	
Key Points of Difference with GHGP Product Standard	***Potential Impact on Approach and/or Results***
• PAS 2050:2011 requires that primary data be collected to account for 10% of the cradle-to-gate GHG emissions associated with the product. This must include primary data for processes under the control of the party calculating the GHG footprint, plus data from upstream activities up to 10% of the total GHG emissions. • GHGP requires that primary data be collected only for processes under the control of the party calculating the GHG footprint.	• The primary data requirement for PAS 2050:2011 GHG footprints potentially entails a greater degree of primary data collection that includes the participation of suppliers. However, if the processes under the control of the party calculating the GHG footprint account for at least 10% of the total GHG emissions associated with the product being assessed, data collection will be the same as for the GHGP Product Standard.
• PAS 2050:2011 does not allow the use of multipliers and/or correction factors to account for the additional radiative force of aircraft transport. • GHGP allows the use of multipliers and/or correction factors to account for the additional radiative force of aircraft transport. When used, the type of multiplier and sourced should be disclosed.	• No significant impact on approach. • The application of a multiplier for aircraft transport will increase the product GHG footprint results where air transport is used. However, as it is required that information relating to the multiplier is disclosed, the effect of using a multiplier will be transparent.
• PAS 2050:2011 allows the inclusion of avoided emissions from the export of energy generated on-site to a larger system (eg to the national electricity grid). • GHGP does not include avoided emissions. However, avoided emissions can be recorded and reported separately.	• No significant impact on approach. • Resulting footprints may differ, but avoided emissions should be separately reported and so should be transparent.
• PAS 2050:2011 does not state requirements for communication and disclosure of the product GHG footprint. • GHGP sets out specific reporting requirements for public disclosure.	• No significant impact to the approach taken for calculating the product GHG footprint. • The reporting requirement for the GHGP reflects the difference in the primary objectives of the two methods.
• PAS 2050:2011 requires the inclusion of GHG emissions and removals within a 100 year time period from the formation of the product. • GHGP requires the inclusion of GHG emissions and removals over a time period that represents the expected lifetime of the product, including degradation of waste.	• A 100-year time period is specified in this Sector Guidance and so there should be no effect on the resulting footprint. • Any credits for storage of biogenic carbon must be separately reported and so should be transparent.
• PAS 2050:2011 requires the inclusion of GHG emissions as a result of land use change. • GHGP requires the inclusion of GHG emissions as a result of land use change but these should be reported separately.	• The method for estimating GHG emissions arising from land use change are aligned.

ISO 14067

http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=59521

The purpose of ISO 14067 is to provide an International Standard detailing the principles and framework requirements for the quantification of greenhouse gas emissions of products. This is in contrast to PAS 2050:2011, which does not claim to be either a national or an international standard. ISO 14067 is currently in draft format and is therefore subject to change prior to publication. In the event that ISO 14067 is sufficiently aligned to the GHGP, it may be the case that PAS 2050:2011 will be subsequently withdrawn.

Key differences between the current draft ISO 14067 and the GHGP are set out below.

Key Points of Difference with GHGP Product Standard	***Impact on Approach and/or Results***
• ISO 14067 requires the inclusion of GHG emissions and removals over a time period that represents the expected lifetime of the product, including degradation of waste. Removals and emissions within 10 years are treated as one release; removals and emissions over 10 years are treated relative to the year of formation of the product. • GHGP requires the inclusion of GHG emissions and removals over a time period that represents the expected lifetime of the product, including degradation of waste, but does not allow the use of weighting factors or delayed emissions. This Guidance states a time period of 100 years.	• The approach taken to estimate the impact of carbon storage differs and will likely lead to different results. However, data collection requirements will be the same.
• ISO 14067 requires the use of multipliers and/or correction factors to account for the additional radiative force of aircraft transport. • GHGP allows the use of multipliers and/or correction factors to account for the additional radiative force of aircraft transport. When used, the type of multiplier and sourced should be disclosed.	• The use of a multiplier for aircraft requires sourcing an alternative emission factor to represent the GHG impact from air travel. • The Defra GHG reporting factors state a multiplier of 1.9 and so this will likely lead to different results for systems that include air travel.
• ISO 14067 does not require communication or public disclosure of the GHG footprint. In the event that the GHG footprint is to be communicated, ISO 14067 sets out specific requirements dependent on the type of communication. • GHGP sets out specific reporting requirements for public disclosure, where relevant.	• These requirements relate to communication only and there is no impact on the approach for the calculation of the product GHG footprint.
• ISO 14067 requires the inclusion of GHG emissions as a result of land use change. • GHGP requires the inclusion of GHG emissions as a result of land use change but these should be reported separately.	• The approach for estimating GHG emissions arising from land use change are aligned.
• ISO 14067 requires the product GHG footprint to be accompanied by a report – the type and format will be dependent on the intended scope of the product assessment. • GHGP sets out specific reporting requirements for public disclosure, where relevant.	• No significant difference in approach to calculation or reporting.

Product Category Rules

- PCR Basic Module for CPC Division 35 Other chemical products; man made fibers - http://www.environdec.com/en/Product-Category-Rules/Detail/?Pcr=7066
- PCR for the assessment of the life cycle environmental performance of UN CPC 35270 "Other Pharmaceutical products - Vaccines for human or veterinary medicine, whether or not put up as medicaments" - http://www.environdec.com/en/Product-Category-Rules/Detail/?Pcr=7848
- PCR Basic Module for CPC Division 48 Medical appliances, precision and optical instruments, watches and clocks - http://www.environdec.com/en/Product-Category-Rules/Detail/?Pcr=7069
- PCR) for the assessment of the environmental performance of UN CPC 48140 product group "Medical, surgical or laboratory sterilizers" - http://www.environdec.com/en/Product-Category-Rules/Detail/?Pcr=5870

- JEMAI (Japan Environmental Management Association for Industry) has taken over the Japanese CFP scheme. Approved PCR for electronic thermometer (flow chart only in English) - http://www.cms-cfp-japan.jp/english/pcr/pdf/PA-AP-01_ElecThermo_Flow.pdf

Product Category Rules (PCRs) are specific requirements and/or guidance documents that relate to a particular product category. These are based on the understanding that some groups of products have similar materials and processes and therefore the same set of general rules should be applied. The rules set out requirements and guidance for data collection, calculation approach and communication, based on sector wide agreement of what is representative. As such, they are similar in purpose to this Sector Guidance Document.

PCRs are used as guidance for the environmental assessment of products and for the preparation of Environmental Product Declarations. PCRs often cover a wide range of product types and are intended to be applicable for different objectives. Consequently, they are broader in scope and contain less technical information than the product GHG footprinting standards and methods described above. However, PAS 2050:2011, the GHGP and ISO 14067 all state that PCRs should be referred to when calculating a product GHG footprint, if available for the product being assessed.

The existing PCRs relevant for pharmaceutical and medical devices products (listed above) contain general guidance/requirements relating to the environmental assessment of products but do not provide information in the same level of detail as found in this Sector Guidance document. Instead, the listed PCRs contain general requirements relating to the following:

- Defining the product, including requirements to specify the manufacturing company, define the functional unit and define the material and chemical composition of the product. *These are consistent with, but provide less detail than the provisions of this Sector Guidance.*
- Rules for life cycle assessment (LCA), including a high level overview of the system boundary, activities to include in the assessment, broad allocation rules and data quality. *These are consistent with, but provide less detail than the provisions of this Sector Guidance.*
- Reporting requirements in communicating product related information. *These differ from the requirements set out in this Sector Guidance, but refer only to reporting/communication.*

Annex C

Example Data Collection Template

C1 EXAMPLE DATA COLLECTION TEMPLATE

Site Data - Note use one sheet per manufacturing site	**Site Name**			**Data Collection Period**	**1st Jan 2010 - 31st Dec 2010**	
Energy		**Units (per annum)**	**Site Total**	**Allocation**		**Comment**
Energy from Natural Gas		kWh		Product 1 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
				Product 2 %		
				Product 3 %		
				Product 4 %		
Energy from Fuel Oil		kWh		Product 1 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
				Product 2 %		
				Product 3 %		
				Product 4 %		
Energy from Electricity for Operations		kWh		Product 1 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
				Product 2 %		
				Product 3 %		
				Product 4 %		
Energy from Coal		kWh		Product 1 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
				Product 2 %		
				Product 3 %		
				Product 4 %		
Energy from other sources e.g Imported Steam, Hot water, LPG etc		kWh		Source 1		Enter type of energy source
				Source 2		Enter type of energy source
Electricity **generated on site from renewables**		kWh				Renewables e.g. Wind, Solar, Geothermal, Biomass, Biogas etc.
Energy consumption allocation by activity				HVAC %		
				Chillers %		
				Air Compressors %		
				Lighting %		
				Process %		
				Others %		If known please confirm % of site energy consumed by equipment category
Energy saving projects completed in the previous calendar year		kWh		HVAC / AC reduction		Please provide description of projects undertaken.
				High efficiency motors		Add or delete rows as necessary
				Lighting upgrades		Example projects listed
				VSD's on CW pumps		Variable speed drive on cooling water pumps
Long term energy trend - Please provide energy consumption from 2001 - present		attachment				
Water		**Units (per annum)**	**Site Total**	**Allocation**		**Comments**
Water Consumption (mains)		m^3		Product 1 %		
				Product 2 %		
				Product 3 %		
				Product 4 %		
Water Consumption (other sources)		m^3		Product 1 %		
				Product 2 %		
				Product 3 %		
				Product 4 %		
Waste water volume to sewer		m^3		Product 1 %		
				Product 2 %		
				Product 3 %		
				Product 4 %		

Other Utilities			Units (per annum)	Site total	Comments		
Nitrogen			kg		Only inlcude if imported onto site. E.g. If N2 is generated on site this will be captured in the energy number. If imported onto site please allocate a % to 'pharma comp' products.		
Other Gases			kg				
Refrigerant gases recharge	Type		kg		Please allocate a % to 'pharma comp' products		
Other			kg				

Hazardous Waste - Solvents Disposal	Receiving site location	Distance in (km)	Units (per annum)	Site total	Allocation		Comments
Solvent Waste treated with energy recovery on site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
Solvent Waste treated with no energy recovery on site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
Solvent recovery on site for reuse			kg				Please provide detail of solvent recovery operations
Solvent Waste **reuse, recovery, recycled** off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
Solvent Waste treated with energy recovery off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)
Solvent Waste treated with no energy recovery off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		Allocation: This is used to apportion the correct amount of usege to a product. This is achieved by either direct measurement or estimation. To estimate it is acceptable to use activity (i.e processing time, or mass output)

Hazardous Waste - Other Disposal	Location	Distance in (km)	Units (per annum)	Site total	Allocation		Comments
Haz Waste treated with energy recovery on site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		
Haz Waste treated with no energy recovery on site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		
Haz Waste **reuse, recovery, recycled** off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		
Haz Waste treated with energy recovery off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		
Haz Waste treated with no energy recovery off site			kg		Product 1 % Product 2 % Product 3 % Product 4 %		
Haz Waste to landfill			kg		Product 1 %		

					Product 2 %		
					Product 3 %		
					Product 4 %		
Non-Hazardous Waste Disposed	**Location**	**Distance in (km)**	**Units (per annum)**	**Site total**	**Allocation**		**Comments**
Site waste treated with energy recovery on site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		
Site Waste **reuse, recovery, recycled** on site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		
Site Waste **reuse, recovery, recycled** off site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		
Site Waste treated with energy recovery off site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		
Site Waste treated with no energy recovery off site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		
Site Waste landfill off site			kg		Product 1 %		
					Product 2 %		
					Product 3 %		
					Product 4 %		

Product 1 Name	Stage 1	Data Collection Period		1st Jan 2010 - 31st Dec 2010		
Production Volume Data				**Units**	**Total**	**Comments**
Batches per annum				No.	10	
Kg per annum				kg	3000	
Raw Material Name	**Supplier Location**	**Distance to site (km)**	**Mode of transport**	**Units**	**Total**	**Comments**
Solvent 1	UK	6000	Road and Ship			
Solvent 2	Uk	6000	Road and Ship			
Solvent 3	UK	6000	Road and Ship			
Solvent 3 recovered	On site	0	N/A			
Reagent 1	France	5500	Road and Air			
Reagent 2	Germany	5000	Road and Air			
Reagent 3	India	400	Rail and Road			
Packaging Materials	**Supplier Location**	**Distance to site (km)**	**Mode of transport**	**Units**	**Total**	**Comments**
Product Shipment	**Destination**	**Distance to site (km)**	**Mode of transport**	**Units**	**Total**	**Comments**

Annex D

Example Sampling Approaches

In some cases, a product will be produced at a large number of sites. In this case, data collection for each site could be prohibitively time consuming, and a sampling approach is required.

There are three key sampling approaches that are recommended, dependent on the number of sites/data sources and the potential for variability:

1. **Complete sampling** – in some cases it may be practical, or advisable, to sample all sites. These cases arise where there are a small number of sites, or when production at different sites is likely to be highly variable.
2. **Random sampling** – in the case where there are a large number of sites and these are likely to be very similar in nature, random sampling is appropriate to develop an average dataset. In the absence of any information of variability, a sample size that is the square root of the population size is a common rule of thumb.
3. **Stratified sampling** – in situations where there are a large number of sites and there is likely to be variation in the type of site, or production process, a random sample may miss an important aspect of this variation. In these cases a stratified approach to sampling is favoured. For this method, initial scoping is required in order to identify relevant sub-groups within the population and a random sample should be taken from within each sub-group. A simple example is shown in the box below. However, this can be a difficult area and in complex situations it is recommended that a statistician is consulted.

Stratified sampling example

A pharmaceutical manufacturer produces an API derived from poppy seeds from Tasmania. The poppy seeds are sourced from 100-200 poppy farms annually. The mix of farms supplying the company varies year on year. For the time period of the assessment, the poppy seeds were sourced from a total of 180 farms. Collecting data from each farm would be prohibitively time consuming, and a sampling approach is required. Due to the variation between the farms and their operations, and the impact this has on their GHG emissions, a stratified sampling approach is being adopted.

The farms can be categorized into six homogeneous sub-groups that reflect their size. These can then be further categorized into sub-groups according to the farming method (intensive/ extensive). Fertiliser application was demonstrated to be the main contributor to GHG emissions for poppy cultivation and fertiliser application was found to be dependent on the farm size and the type of farming method employed (large, intensive farming found to be more efficient per hectare). As a result, these two parameters are used for sampling sub-groups.

In order to determine the number of sites to sample from each sub-group, the pharmaceutical manufacturer determined the proportion of API derived from poppies supplied by farms in the different groups. For example, in this data collection period, farms <25 hectares using an extensive farming system accounted for 21% of the supply of Tasmanian poppy seeds for this particular product. The number of farms sampled was therefore calculated as the square root of 180 farms multiplied by 21%, i.e. 3 farms from this sub-group. This process was repeated across all sub-groups, to determine the profile, and minimum number of, farms from which data should be collected.

Farm size (hectares)	Type of farming	% of supply	Minimum number of sites to sample
< 25	Intensive	5%	1
	Extensive	21%	3
25-50	Intensive	33%	5
	Extensive	1%	1
50-75	Intensive	17%	3
	Extensive	14%	2
75-100	Intensive	2%	1
	Extensive	4%	1
> 100	Intensive	1%	1
	Extensive	2%	1

Further information and details about how to provide feedback on the document can be found at: www.sdu.nhs.uk/pharma-md

NHS Sustainable Development Unit

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