

*These guidelines were developed as the outcome of the “Fundamental Study for Developing LCA Guidelines for Biomanufacturing”, commissioned by the New Energy and Industrial Technology Development Organization (NEDO).

TENTATIVE TRANSLATION

LCA Guidelines for Biomanufacturing (Principal Guide) ver. 1.0

April 2026

Japan Bioindustry Association

Preface

Biomanufacturing — the technology for production of materials by harnessing the capabilities of microorganisms, plants and animals — is regarded as an important alternative for realizing a decarbonized society. However, “made by biomanufacturing” does not automatically mean a lower environmental burden. Depending on the choices of feedstocks, process design and energy usage, bioprocesses are not necessarily environmentally superior to conventional fossil-resource-based processes. It is therefore essential to quantify environmental impacts as well as to evaluate and improve them based on scientific evidence.

Life Cycle Assessment (LCA) is a fundamental methodology underpinning this type of evaluations. It supports a wide range of decision-making, from the process design and improvement in the research and development phase to the obtainment of certifications and the marketing communication of environmental value in the commercialization phase. In particular, obtaining international certifications and disclosing environmental information based on accurate LCA are becoming increasingly important for securing and enhancing competitiveness in the global market. Amidst the calls for the transition away from petrochemicals, LCA is of further importance in that it enables quantitative comparisons with conventional processes.

At the same time, in the biomanufacturing field, there exist fluctuations in the implementation levels of LCA and in the interpretations of its results due to the fact that many of the technologies are still in the development phase and that it has some unique challenges such as difficulties in obtaining and handling data. Consequently, there are cases where discussions among stakeholders break down, and it has been indicated that there is also a risk that evaluations based on insufficient assumptions may lead to misleading or inaccurate environmental claims. This is an issue that cannot be overlooked in an increasingly competitive international environment. Furthermore, bioprocesses require long development timelines from the strain development through lab, bench, pilot and on to the commercial scale. Under the conventional approach where the accurate LCA is conducted only at the commercialization stage and improvements are made based on results thereof, reworking can cause significant losses of time and cost. On the other hand, when aiming for obtainment of certification and the like, the LCA based on accurate data is indispensable. It is therefore crucial to apply LCA from the early stages of development to identify environmental bottlenecks, while progressively increasing the level of quality in line with the purpose of the assessment.

These guidelines have been compiled by the “Study Group on LCA Guidelines for Biomanufacturing” organized by the New Energy and Industrial Technology Development Organization (NEDO) and the Japan Bioindustry Association (JBA), based on discussions among experts. In addition to accurate LCA for fully developed processes, the guidelines present a framework for conducting LCA and interpreting its results at levels appropriate to different development stages. At the core of this framework is the introduction of Bio-LRLs (Biomanufacturing LCA Readiness Levels), an indicator that systematically classifies the accuracy of impact assessment results in a stepwise manner. This is the novel concept that is to clarify the position of LCA results based on data collection methods as well as to enable the applications and the formation of a common understanding according to different purposes.

The guidelines Version 1.0 set out the basic concepts in the principal guide and present practical methodologies for implementing LCA in real-world settings in the practical guide. Through future applications in practice and feedback from users, the content is expected to be further refined and developed into a framework capable of addressing more advanced and diverse applications. We expect these guidelines to function as a common language for LCA in the biomanufacturing field and to provide a foundation for constructive discussions, thereby contributing to the development of a sustainable and competitive industry and, ultimately, to enhancing the international competitiveness of Japan’s biomanufacturing sector.

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Project Professor, LCA Center for Future Strategy,
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March 2026

Expert Panel on LCA Guidelines for Biomanufacturing

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*Affiliation and title as of March 2026

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LCA Guidelines for Biomanufacturing (Practical Guide)

Calculation Tool (Excel)

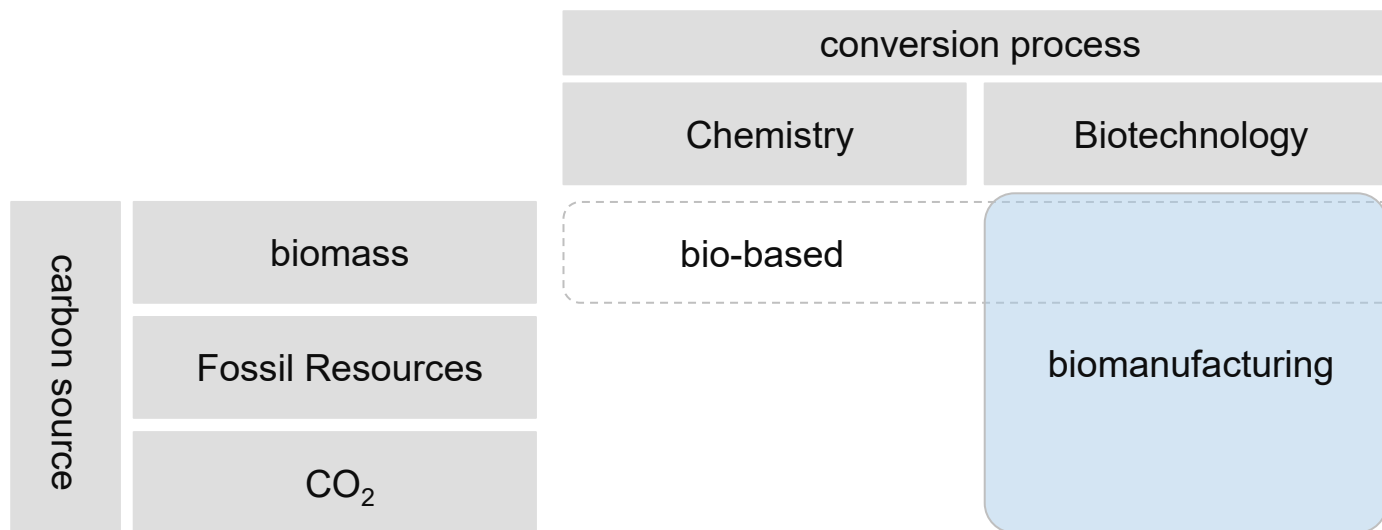
Part 1: Introduction

- (1) Background
- (2) About the Guidelines

(1) Background

What is Biomanufacturing?

- Biomanufacturing is defined as “the production of substances using cells from microorganisms, plants, animals and the like through the application of genetic engineering, a technology utilized in various industrial sectors such as chemical materials, fuels, pharmaceuticals, animal fibers and foodstuffs”^[1].
- While biomass is often used as a raw material, it is not limited to this; fossil resources (such as waste plastics and waste fibers) and CO₂ can also be considered as raw materials. When bioconversion is performed using biological functions, including these materials, it falls under the category of biomanufacturing (see figure below).
- In these guidelines, “biomanufacturing” is broadly defined as the production of substances using cells from microorganisms, animals, plants or like materials, regardless of whether genetic engineering is utilized.



(Source)

[1] Ministry of Economy, Trade and Industry, “バイオものづくり革命の実現(Realizing the Biomanufacturing Revolution)” (April 19, 2023)

(1) Background

What is Life Cycle Thinking and Life Cycle Assessment (LCA)?

■ Life Cycle Thinking and Life Cycle Assessment (LCA)

- "Life Cycle Thinking" refers to an approach which takes into account the impacts across the entire product lifecycle — including raw material extraction, energy supply, product manufacturing, distribution, use, and disposal. ^[1]
- Life Cycle Thinking enables organizations and entire value chains to reduce resource consumption and emissions while improving social and economic performance, thereby integrating the environmental, social, and economic dimensions. ^[2]
- "Life Cycle Assessment (LCA)" is a method for quantitatively evaluating environmental impacts based on this Life Cycle Thinking, and it is widely used for setting reduction targets for the environmental burden and managing progress. ^[1, 2]

(Source)

[1] Japan Society for Life Cycle Assessment, "LCAを知る・使う(*Understanding and Using LCA*)", <https://www.ilcaj.org/introduce/index.html>

[2] Life Cycle Initiative, "What is Life Cycle Thinking?", <https://www.lifecycleinitiative.org/activities/what-is-life-cycle-thinking/>

(1) Background

The Significance of LCA in Biomanufacturing

■ Biomanufacturing and Environmental Impact

- Efforts are underway to produce bio-manufactured equivalent of conventional products (such as those derived from fossil resources). Since biomanufacturing often uses biomass—which has undergone atmospheric CO₂ uptake—as a raw material and employs processes at ambient temperature and pressure, it is widely perceived as “environmentally friendly.” However, quantitative verification through LCA is necessary. It is also important to note that environmental impacts include not only the climate change but also such perspectives as those on water consumption and eutrophication.
- Biomanufacturing also enables the creation of products with new value through bioconversion. Even in such cases, it is important to work on understanding and reducing environmental impacts in order to realize more sustainable production processes. Furthermore, depending on the functionality of the product, it may be possible to reduce the total environmental impact—including not only the production stage but also the use stage and end-of-life stage—compared to conventional systems.

■ Utilizing LCA for Process Development and Improvement

- By identifying process steps with high environmental burdens (hotspots), technical challenges can be established. Furthermore, evaluating multiple scenarios can inform process design.
- LCA is also a tool for continuous improvement, and it is important to use LCA to continuously review processes even after they have been established.

[Case Study]

- Production of methyl ketone using agricultural residue (wheat straw) as a raw material
 - Identified that potassium hydroxide, added in trace amounts as a pH control agent, contributes significantly as a hotspot in the fermentation stage
 - Pushpendra, Schonhoff, A., Fuchsl, S. C., Röder, H., & Zapp, P. (2025). Prospective Life Cycle Assessment and upscaling of an emerging biorefinery process: A case study on methyl ketone. *Journal of Cleaner Production*, 498, 145208. <https://doi.org/10.1016/j.jclepro.2025.145208>

[Case Study]

- Fermentation production of aromatic compounds (p-hydroxybenzoic acid (pHBA))
 - A case study conducting a Life Cycle Impact Assessment and cost evaluation across 17 scenarios with varying fermentation conditions
 - Krömer, J. O., Ferreira, R. G., Petrides, D., & Kohlheb, N. (2020). Economic Process Evaluation and Environmental Life-Cycle Assessment of Bio-Aromatics production. *Frontiers in Bioengineering and Biotechnology*, 8, 403. <https://doi.org/10.3389/fbioe.2020.00403>

(1) Background

The Significance of LCA in Biomanufacturing (Continued)

■ Utilizing LCA in marketing

- Generally, while production costs for bio-manufactured products are higher than those for conventional products (such as those derived from fossil resources), it is expected that these products will be evaluated in the market—including their value—by highlighting their quantitative environmental burden reduction effects.
- In some cases, requirements for obtaining various certifications or for establishing eligibility under public policies (regulations and incentives) mandate that a product's environmental impact be assessed and that the assessment results meet specific standards. While detailed calculation methods must follow the rules of each system, LCA serves as the foundation for quantifying environmental impacts.

[Case Study]

■ Solar Foods' Environmental Claims for Single Cell Protein

- Claims that water resource consumption, land use, and GHG emissions are lower in comparison to beef and plant-based proteins
 - Solar Foods, "Impact", <https://solarfoods.com/impact/>
 - Järviö, N., Maljanen, N.-L., Kobayashi, Y., Ryyänen, T., & Tuomisto, H. L. (2021). An attributional life cycle assessment of microbial protein production: A case study on using hydrogen-oxidizing bacteria. *Science of The Total Environment*, 776, 145764. <https://doi.org/10.1016/j.scitotenv.2021.145764>

(1) Background

Challenges of LCA in Biomanufacturing

- **LCA is to be conducted on the processes intended for the commercial production stage while still at the R&D stage.**
 - Many initiatives in biomanufacturing are in the R&D stage and conducting an LCA for a future process presents the following challenges.
 - It is difficult to foresee the full scope of commercial production processes in the early stages of R&D (particularly downstream processes such as separation and purification).
 - It is difficult to estimate data related to operations after scale-up (e.g., energy required for aeration, agitation, and cooling).
- **There are also other challenges specific to biomanufacturing regarding data handling**
 - In particular, there are inputs and outputs with unknown compositions, such as in the cultivation process, making it difficult to achieve a material balance.
 - The emission factors for raw materials used may not be available in databases.
 - Although the development of processes using waste materials and CO₂ as raw materials is underway, their treatment in LCA often poses challenges.



It has been pointed out that there are variations among the levels of accuracy in LCA impact assessment results and among the interpretations of results thereof depending on the implementers, leading to situations where discussions among stakeholders break down, and that the assessments based on insufficient assumptions carry the risk of leading to erroneous environmental claims.

Part 1: Introduction

- (1) Background
- (2) About the Guidelines

(2) About the Guidelines

Objectives of the Guidelines

1. These guidelines present a framework and indicators to align stakeholders' perspectives regarding the level of accuracy required for Life Cycle Impact Assessments in biomanufacturing. Additionally, it provides guidelines on the recommended level of accuracy for key LCA goals.
 - Version 1.0 introduces the concept of **Bio-LRLs (Biomanufacturing LCA Readiness Levels)**, which represents the level of accuracy of Life Cycle Impact Assessment results based on data collection methods.
2. These guidelines provide guidance on LCA implementation methods that can be utilized in biomanufacturing initiatives at various stages, from development through commercialization.
 - Data collection methods are categorized based on their impact on the level of accuracy of results, and details are explained in the “Practical Guide”.
 - Version 1.0 of these guidelines is primarily intended for researchers in the biotechnology field and explains methods for conducting simplified LCAs on processes currently under development.
 - As supplementary material to the guidelines, we also provide a calculation spreadsheet (Excel) that can be used when conducting an LCA.

[Positioning of These Guidelines]

- These guidelines outline the fundamentals for conducting LCA in biomanufacturing, drawing on ISO 14040:2006 and ISO 14044:2006, which establish the framework for LCA.
- Version 1.0 does not establish calculation rules for LCA in biomanufacturing; rather, it is intended to serve as a guide for researchers and others in the bio-sector who are not necessarily LCA experts when conducting LCA.
- While these guidelines enable the implementation of basic LCA for biomanufacturing, if compliance with various certification schemes, systems, or other guidelines (such as Together for Sustainability) is sought, it is necessary to meet the specific requirements stipulated by each.

Part 2: Level of Accuracy of the Life Cycle Impact Assessment Results

(1) Data Collection Methods

(2) Introduction of Bio-LRLs (Biomanufacturing LCA Readiness Levels)

(1) Data Collection Methods

Conducting LCA Using Databases

- In recent years, when conducting LCA, Life Cycle Impact Assessments are often performed by multiplying **activity data** (inputs and outputs of materials and energy) by the **emission factors** (environmental burden per unit of activity; in the case of GHG emissions, these are also referred to as emission factors) listed in databases and other sources.
- To collect activity data and emission factors for biomanufacturing during commercial production, several methods are available, each with different collection costs and varying data quality; the choice of method affects the level of accuracy in the Life Cycle Impact Assessment results.
 - **Activity data**: While high-quality data are available for collection during the commercial production stage, during the development stage, however, it is necessary to estimate post-scale-up data based on test data.
 - **Emission factors**: In the commercial production stage, if raw material sources are established, high-quality intensity factors reflecting information from suppliers may be available; otherwise, database data (such as market averages) must be used. Additionally, raw materials frequently used in bioprocessing are often not listed in databases, in which case proxy data must be used.

$$\text{Environmental impact} = \sum \left(\text{Activity data} \times \text{Emission factor} \right)$$

e.g., GHG emissions per 1 kg of product (kg-CO₂ eq./kg-product)

e.g., Amount of glucose required to produce 1 kg of product (kg-glucose/kg-product)

e.g., GHG emissions when producing 1 kg of glucose (kg-CO₂ eq./kg-glucose)

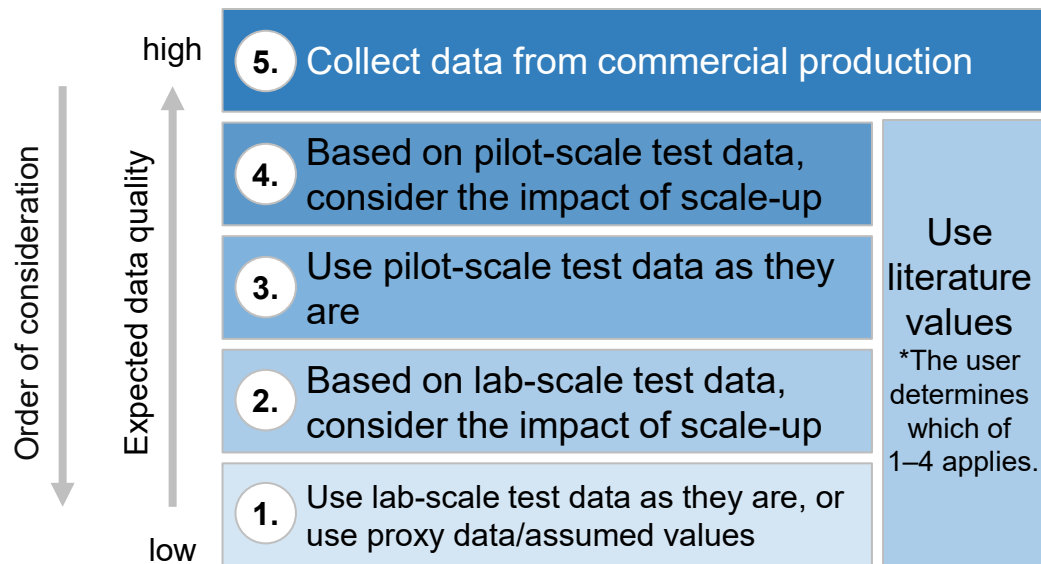
- There are various data collection methods with differing collection costs and data quality.
- The choice of data collection method affects the level of accuracy in the Life Cycle Impact Assessment results.

(1) Data Collection Methods

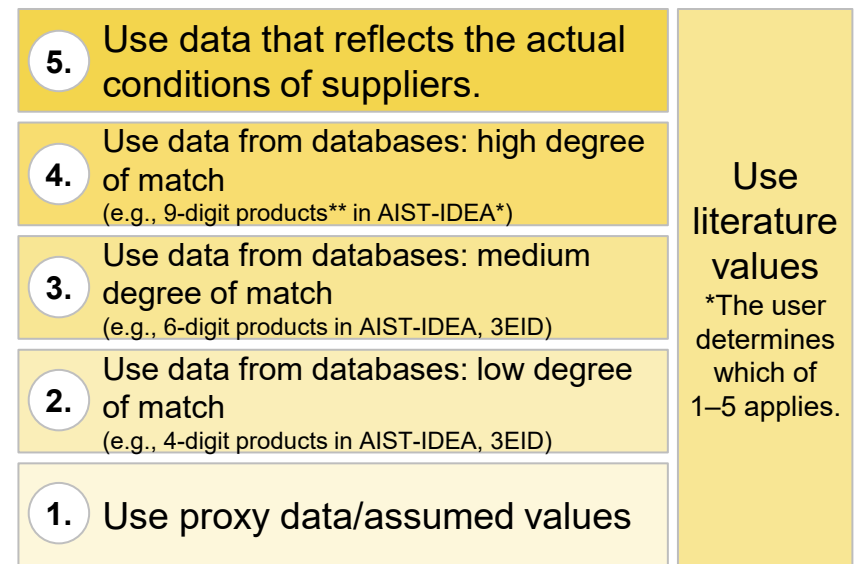
Methods for Activity Data Collection and Emission Factor Data Collection

- Based on the discussion leading up to this point, these guidelines classify data collection methods for activity data and emission factors into the following five categories-by taking data quality into account, on the premise that the evaluation targets the processes at the commercial production stage.
- For details, refer to the “**Practical Guide**”.

Methods for collecting Activity data



Methods for collecting Emission factor



* In these guidelines, AIST-IDEA is abbreviated as IDEA. ** For the number of digits in IDEA, refer to "Practical Guide (ver. 1.0), p. 47."

Notes

- When using "i) proxy data/assumed values," it is recommended to verify their validity through sensitivity analysis. (See "Part 3 (2) v Interpretation")
- Since the data quality based on input-output analysis varies by item, the user must determine whether it corresponds to category 2 or 3.
- Emission factor data are illustrated with the Japanese database (AIST-IDEA and 3EID), but European databases (such as ecoinvent) can also be applied.

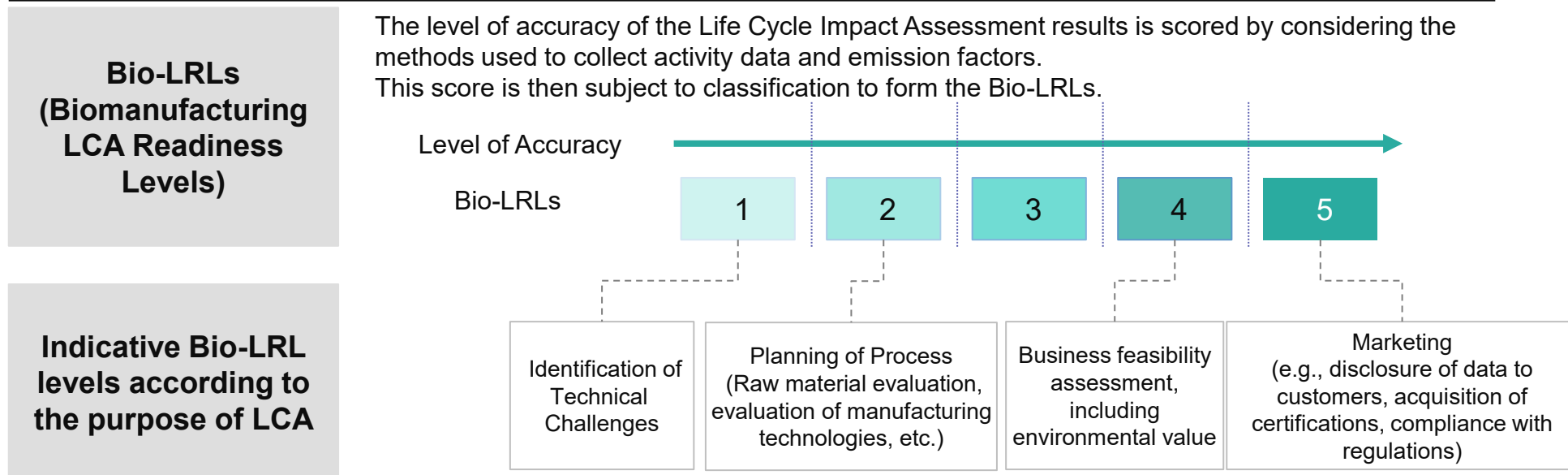
Part 2: Level of Accuracy of the Life Cycle Impact Assessment Results

- (1) Data Collection Methods
- (2) Introduction of Bio-LRLs (Biomanufacturing LCA Readiness Levels)

Introduction of "Bio-LRLs," an Indicator of the Level of Accuracy of Life Cycle Impact Assessment Results

- Since the methods used to collect activity data and emission factors affect the level of accuracy in Life Cycle Impact Assessment results, these guidelines propose **Bio-LRLs (Biomanufacturing LCA Readiness Levels)** as an indicator.
- The level of accuracy in Life Cycle Impact Assessment results is quantified as scores based on the data collection methods for activity data and emission factors, and then Bio-LRLs is established as the compartmentalization of said scores .
- Furthermore, by providing recommended Bio-LRLs benchmarks for key LCA goals, we hope this will help align the perspectives of stakeholders involved in LCA for biomanufacturing. (Details will be added in Guidelines ver. 2.0 and later)

Definition and Possible Application Concept of Bio-LRLs (Biomanufacturing LCA Readiness Levels)



*Guideline ver. 1.0 provides only a general overview.

Methods for evaluating the level of accuracy and their relationship to goals are scheduled to be added in Guidelines ver. 2.0 or later.

Part 3: Fundamentals of LCA for Biomanufacturing

- (1) Process of LCA (Overview)
- (2) Methods for Conducting LCA in Biomanufacturing

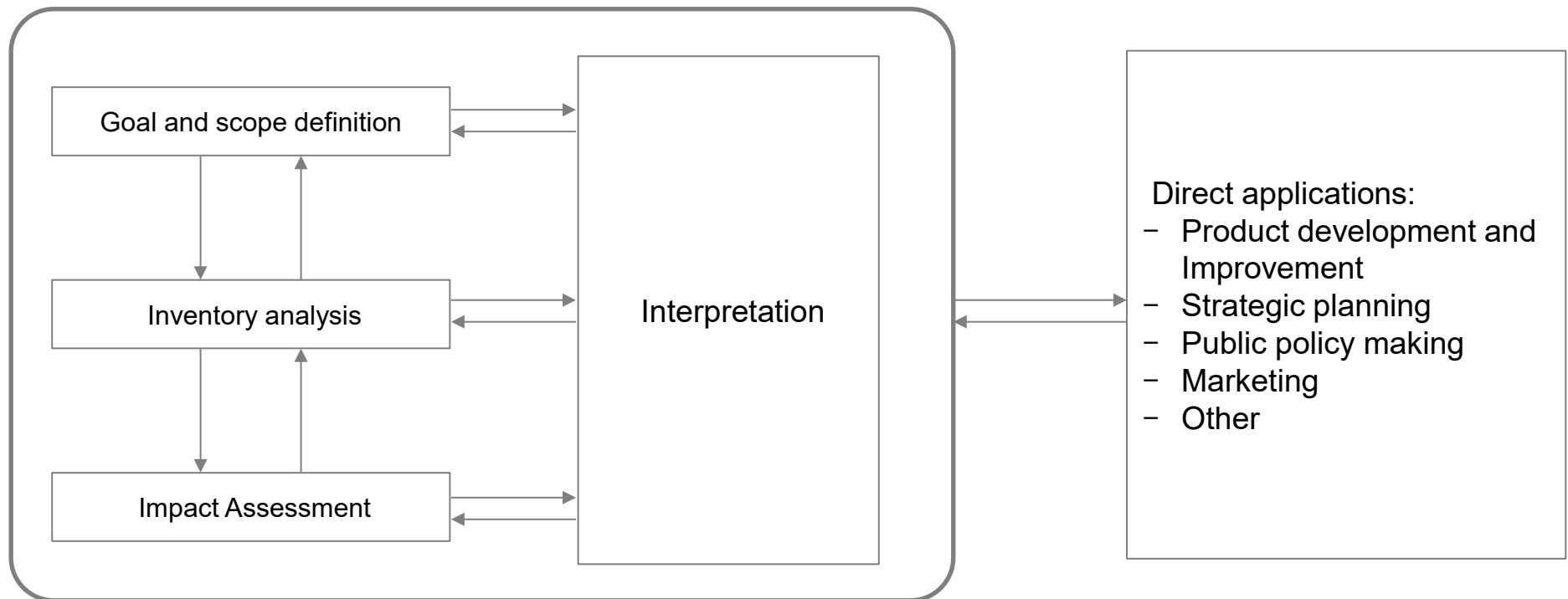
(1) Process of LCA (Overview)

Stages of LCA

■ Elements of a Standardized LCA

- LCA has been standardized in ISO 14040:2006 and ISO 14044:2006, and it consists of the following four stages.
- LCA is an “iterative” process, and each step is repeated until the goal is achieved.

Four Stages of an LCA [1]



(Reference)

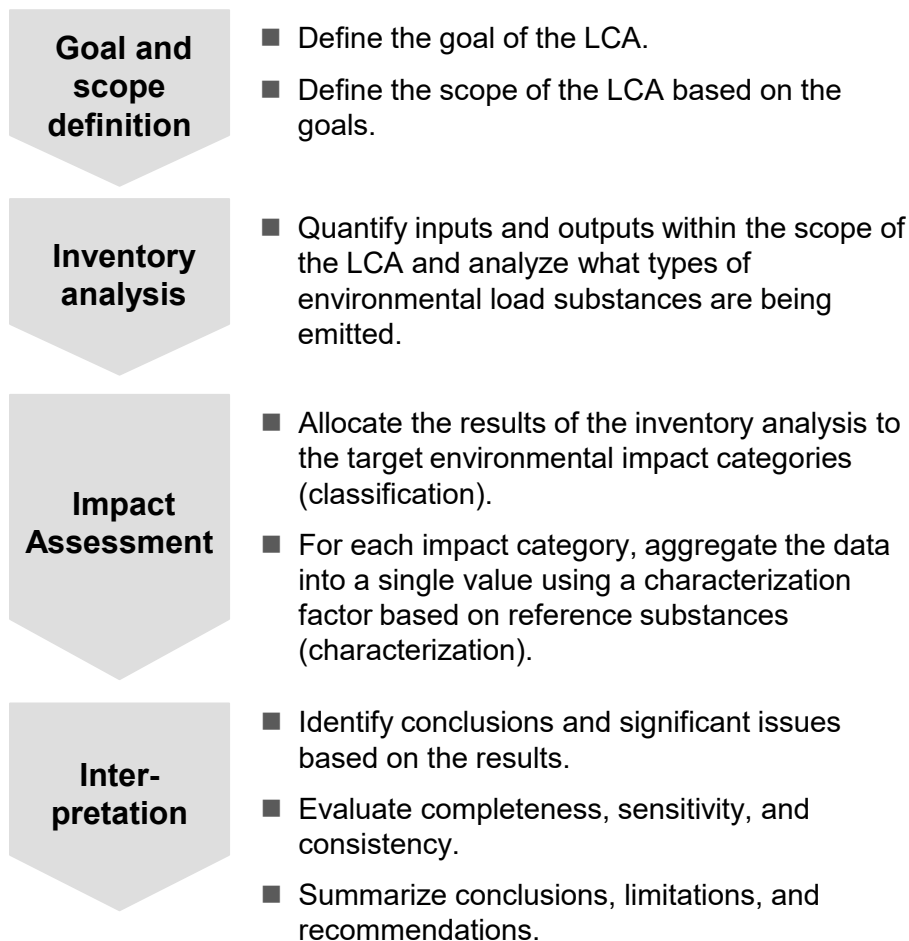
[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

(1) Process of LCA (Overview)

LCA Process (Overview)

- The LCA stages based on the ISO 14040 series is shown below. In practice, Life Cycle Impact Assessment is often performed by multiplying activity data by emission factors obtained from databases or other sources.

LCA Phases Based on the ISO 14040 Series



In practice, it is common to perform Inventory analysis and Impact Assessment by multiplying activity data by emission factors obtained from databases or other sources.

$$\text{Environmental impact} = \sum \left(\text{Activity data} \times \text{Emission factor} \right)$$

e.g., GHG emissions per 1 kg of product (kg-CO₂ eq./kg-product) e.g., Amount of glucose required to produce 1 kg of product (kg-glucose/kg-product) e.g., GHG emissions when producing 1 kg of glucose (kg-CO₂ eq./kg-glucose)

⇒ In the following section “(2) Methods for Conducting LCA in Biomanufacturing”, the phases were categorized as below.

- i) Goal and scope definition
- ii) Collection of activity data
- iii) Collection of emission factors
- iv) Life Cycle Impact Assessment
- v) Interpretation

Part 3: Fundamentals of LCA for Biomanufacturing

- (1) Process of LCA (Overview)
- (2) Methods for Conducting LCA in Biomanufacturing

(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

■ Defining Goals

- ISO 14040:2006 and ISO 14044:2006 require that the following four items be described when defining the goals of an LCA.
- Note that detailed requirements are established when making comparative assertions intended to be disclosed to the public.
- See p.26 for notes regarding comparative assertions (detailed explanations are scheduled to be added in ver. 2.0 and later).

LCA goals and example settings

Items ^[1, 2]	Example
Intended application	<ul style="list-style-type: none"> • Marketing • Investment decision • Process Development and Improvement
Reasons for carrying out the study	<ul style="list-style-type: none"> • To quantify environmental impacts • To reduce greenhouse gas emissions
Intended audience (To whom the results of the study are intended to be communicated)	<ul style="list-style-type: none"> • Internal stakeholders • Suppliers (vendors) /Customers • Consumers
Whether the results are intended to be used in comparative assertions intended to be disclosed to the public	<ul style="list-style-type: none"> • Yes • No

(Reference)

[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

[2] ISO, "ISO 14044:2006", <https://www.iso.org/standard/38498.html>

(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

■ Defining the Scope of the Study

- ISO 14040:2006 and ISO 14044:2006 require that the following 12 items be clarified when defining the scope of the study. This guideline explains the particularly important items among these: “functional units,” “system boundaries,” and “allocation procedures.”

Items within the scope of the LCA survey^{[1], [2]}

- Product system to be studied
 - Functions of the product system
 - **Functional unit**
 - **System boundary**
 - **Allocation Procedures**
 - Impact categories selected*, and methodology of impact assessment, and subsequent interpretation to be used
 - Data requirements
 - Assumptions
 - Limitations
 - Initial Data Quality Requirements
 - (If any) Types of critical reviews
 - Types and format of the report required for the study
- } **Explained in this guideline
(For allocation procedures, see “ii) Collection of activity data
(pp. 30–31)”**

*Although these Guidelines, Version 1.0, were developed primarily with climate change (greenhouse gas emissions) in target, the impact category is not limited to climate change (see p. 38)

(Reference)

[1] ISO, “ISO 14040:2006”, <https://www.iso.org/standard/37456.html>

[2] ISO, “ISO 14044:2006”, <https://www.iso.org/standard/38498.html>

(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

■ Defining the Scope of the Study (Continued)

Defining Functional Units

- In LCA, it is necessary to define specific functions for the assessment subject based on the goal. This quantified unit representing the performance of a product system is called a “functional unit.” When making comparisons in LCA, functional units must be made equivalent. It is important to note that a single product system may possess multiple functions.
- The amount of resources required to fulfill a functional unit is called a “reference flow.”

Examples of settings for functions, functional units, and reference flow rates

Function	Do laundry	Quantifying functions
Functional unit	Launder 5 kg of clothes	
Reference flow	75 mL of detergent (Amount required to wash 5 kg of clothes)	Quantifying the amount of resources required to meet a functional unit

(Reference)

- ISO, “ISO 14040:2006”, <https://www.iso.org/standard/37456.html>
- ISO, “ISO 14044:2006”, <https://www.iso.org/standard/38498.html>

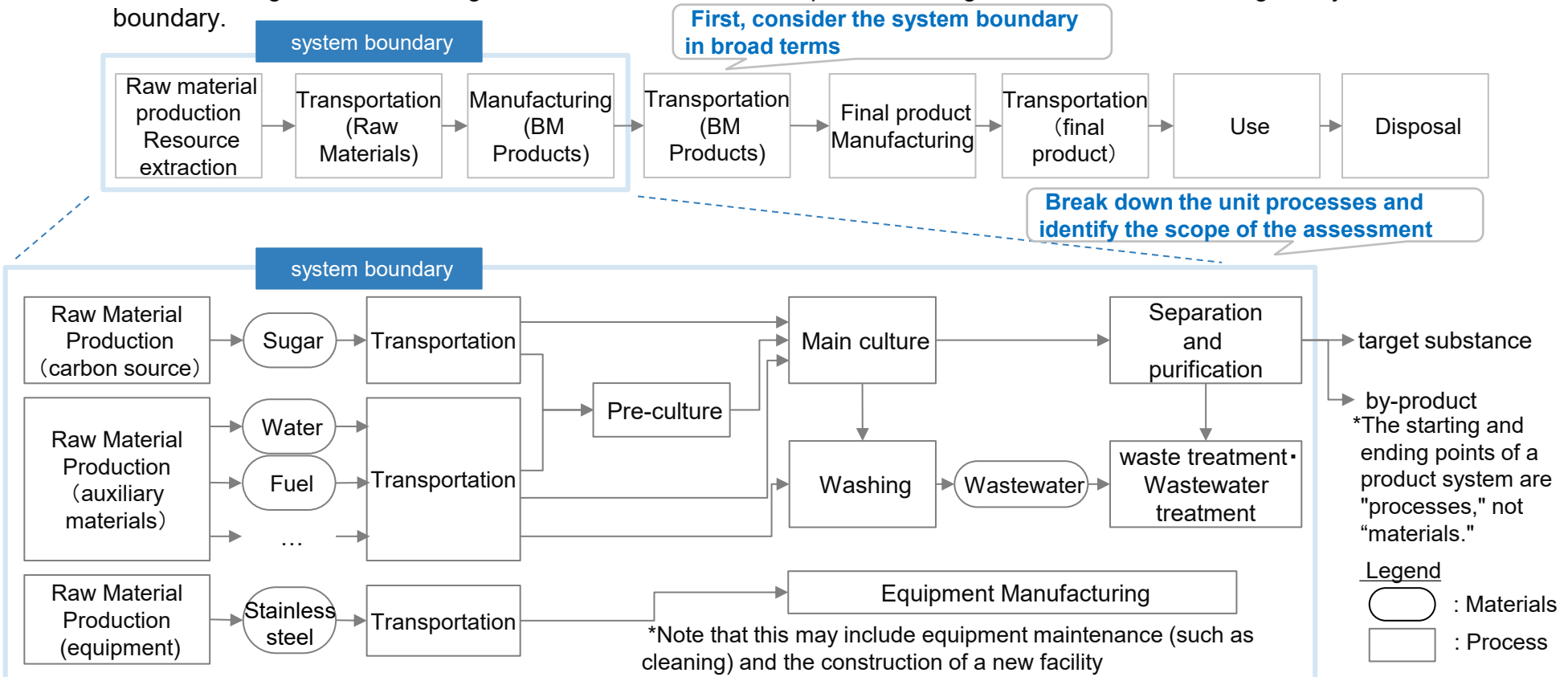
(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

Defining the Scope of the Study (Continued)

Defining the System Boundary

- Each stage that constitutes a product's life cycle is referred to as a "unit process," and the collection of unit processes subject to LCA assessment is collectively referred to as a "product system." The boundary between the product system and processes not included in the assessment is called the "system boundary."
- When defining the system boundary, it is necessary to consider which unit processes to include in the product system based on the goal. The following illustrates this consideration process, along with methods for drawing the system boundary.



(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

Common Examples of Goals and Scope in LCA for Biomanufacturing

goal	functional unit and reference flow	Comparison	system boundary							
			Raw material production Resource extraction	Transport (Raw Materials)	Manufacturing (BM Products)	Transportation (BM Product)	final product Manufacturing	Transportation (final product)	Use	Disposal
Identification of Technical Challenges (Identification of Factors with High Environmental Burden)	One culture, one year of operation, production of 1 kg of BM product, etc.	None	Cradle to gate			(Consideration of raw material production, cultivation, and purification)				
Comparison and evaluation of raw materials	Equivalent raw materials: Procurement of 1 kg of raw material	Raw Materials	Cradle to gate			Gate to gate (Analysis of the cultivation process to purification)				
	Non-equivalent raw materials: Manufacturing 1 kg of BM product		Cradle to gate							
Comparison of Manufacturing Technologies Evaluation (cultivation methods, etc.)	Production of 1 kg of BM product	Manufacturing Technology	Cradle to gate							
Comparison of product environmental impacts	Enzyme Example 1: Per 1 U of activity	BM Products (In-house)	Cradle to gate							
	Enzyme Example 2: Production of 1 kg of final product	BM Products (In-house)	Cradle to gate							
	Example of laundry detergent: Per laundry	Final product (In-house)	Cradle to grave							
Disclosure of data to customers	Production of 1 kg of BM product	None	Cradle to gate							
Comparison and marketing against competing products (e.g., fossil-based products)	When functions are equivalent: Manufacturing 1 kg of BM product	BM Products/ final product (In-house or comparison with other companies)	Cradle to gate							
	When functions differ: Per laundry (example)		Cradle to grave							

*BM: biomanufacturing

*Caution is required when making comparative assertions

(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

■ Points to Note Regarding Comparisons

- When making disclosed claims regarding superiority or equivalence relative to competing products (comparative assertions), the scope of the study must be defined so that the subjects under evaluation are equivalent. In addition, strict requirements apply, such as the need for a panel composed of interested parties to conduct a critical review of the LCA. ^[1]
- On the other hand, comparisons with the company's own products or technologies (performance tracking) do not constitute comparative assertions, so claims regarding superiority or equivalence may be made.

Examples Requiring Caution in Comparison

Comparison with the Company's Own Products	Comparable if calculated under the same calculation conditions (Note that if the company's product is not the mainstream product in the market, the comparison results—specifically the environmental impact reduction effects—do not represent the market as a whole.)
Comparison with Market Averages	When using values from databases or other sources as market averages, it is necessary to confirm that the calculation conditions were the same.
Comparison with Competing Products	After calculating under the same calculation conditions, a panel composed of interested parties must conduct a critical review of the LCA. (For details, refer to ISO 14044:2006)

(Reference)

[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

(2) Methods for Conducting LCA in Biomanufacturing

i) Goal and Scope Definition

■ Level of Accuracy to be Achieved

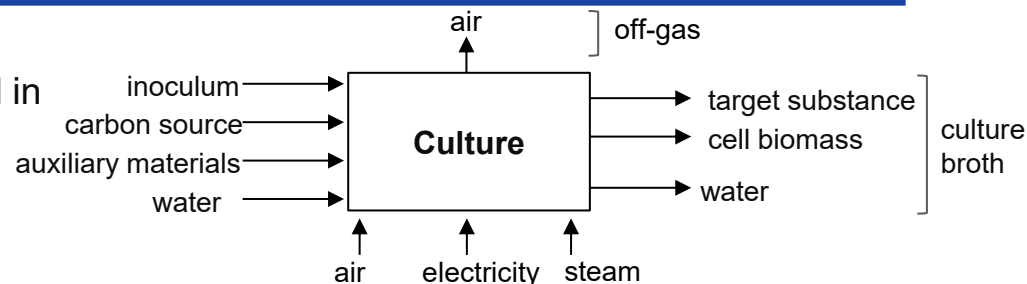
- As explained in “Part 2: Level of Accuracy for Life Cycle Impact Assessment Results,” the level of accuracy in Life Cycle Impact Assessment results is influenced by the data collection methods used to collect activity data and emission factor data.
- It is important to consider the level of accuracy required based on the goal of the LCA.
(Guidelines ver. 2.0 and later are scheduled to provide guidelines on the relationship between goals and Bio-LRLs)

(2) Methods for Conducting LCA in Biomanufacturing

ii) Collection of Activity Data

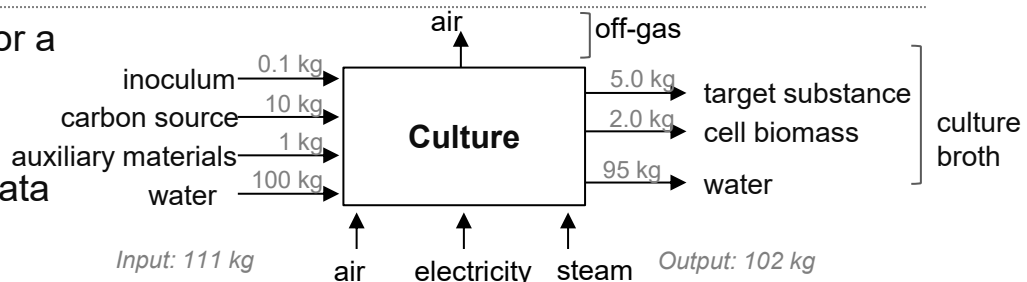
Step 1 Organize Inputs and Outputs

- Identify the inputs and outputs included in the system boundary (unit processes).



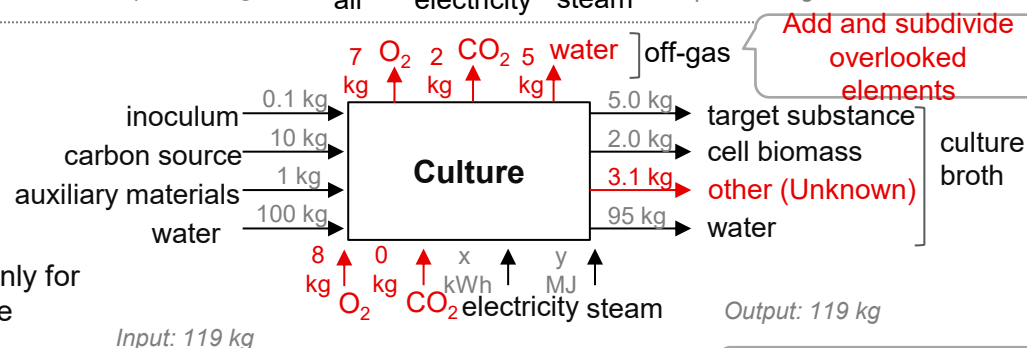
Step 2 Collection of Activity Data

- Collect the data of inputs and outputs for a one-year period or per batch.
- For lab data or other like data, they must be converted into the estimated data after scale-up (see "Practical Guide").



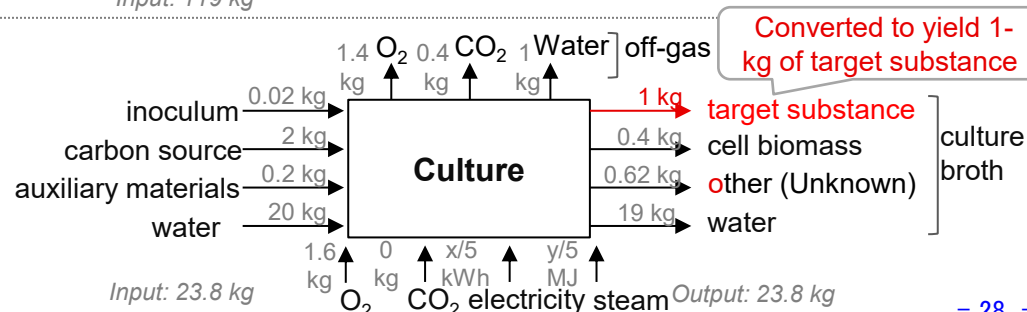
Step 3 Verification of Material Balance

- Verify the material balances and check for any overlooked elements.
 - For unknown quantities, assign assumed values and assess their significance in Step 5 (Interpretation).
- * Material balance checks must be performed not only for each individual unit process but also for the entire process within the system boundary.



Step 4 Conversion to Functional Units

- Convert activity data to functional units (reference flow).
- In the example on the right, convert the values so that they are expressed as "per 1 kg of target substance produced."



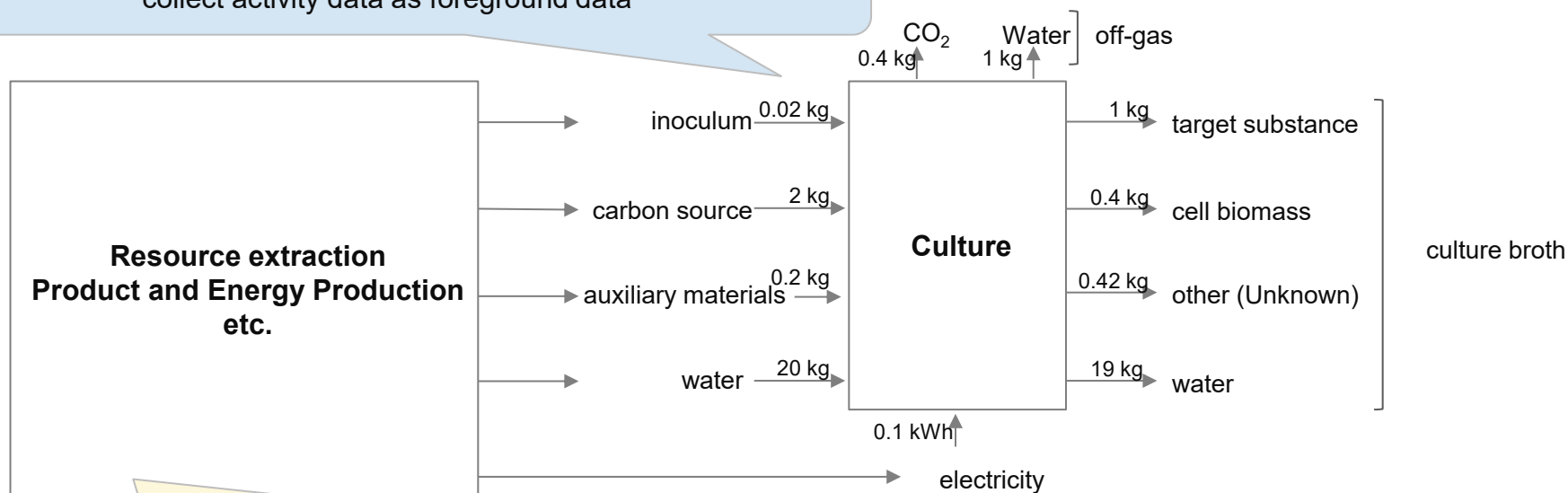
(2) Methods for Conducting LCA in Biomanufacturing

ii) Collection of Activity Data

■ Foreground Data and Background Data

- For inputs and outputs of processes within the scope of the LCA implementer's technical review (such as culture medium usage and electricity consumption), it is desirable to collect activity data for the target processes to the extent possible by measurement or by other similar means. Such processes and data are referred to as foreground processes and foreground data, respectively.
- On the other hand, for processes outside the scope of the LCA implementer's technical review — such as resource extraction or waste treatment — of which processes direct data collection is hardly feasible, market average values or similar data may be utilized (see "iii) Collection of emission factors"). These are referred to as background processes and background data.

Regarding the subjects of technical review, such as the cultivation process, collect activity data as foreground data



Since LCA implementers cannot determine how much amounts of environmental load substances are being emitted through electricity generation and the like processes, emission factors are used as background data

(2) Methods for Conducting LCA in Biomanufacturing

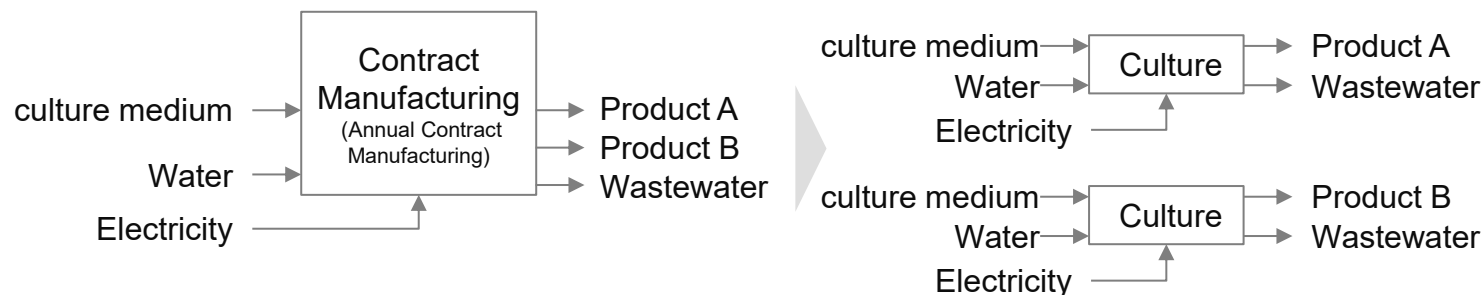
ii) Collection of Activity Data

Allocation Procedure

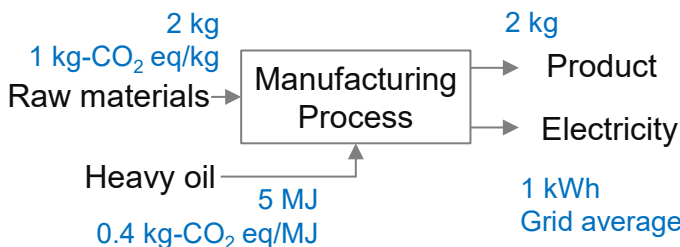
- When two or more products are produced from a single process, there must be an allocation of the inputs and outputs of that process to each product.
- ISO 14044:2006 stipulates that the allocation procedure must be based on the following order of priority^[1]

(a) Avoid allocation

If a unit process can be subdivided, divide the process



When conducting a system expansion



GHG emissions from the product = GHG emissions from raw materials

+ GHG emissions from heavy oil

– GHG emissions from electricity

$$= 2 \times 1 + 10 \times 0.4 - 1 \times 0.5 \quad \text{Expansion of the system boundary}$$

$$= 3.5 \text{ kg-CO}_2 \text{ eq/kg-B}$$

[Notes on System Expansion]

- In the case of grid power primarily generated by thermal power, the credit associated with expanding the system boundary may become significant, potentially resulting in a negative environmental impact for the target system. The feasibility of system expansion and potential alternatives must be carefully evaluated.

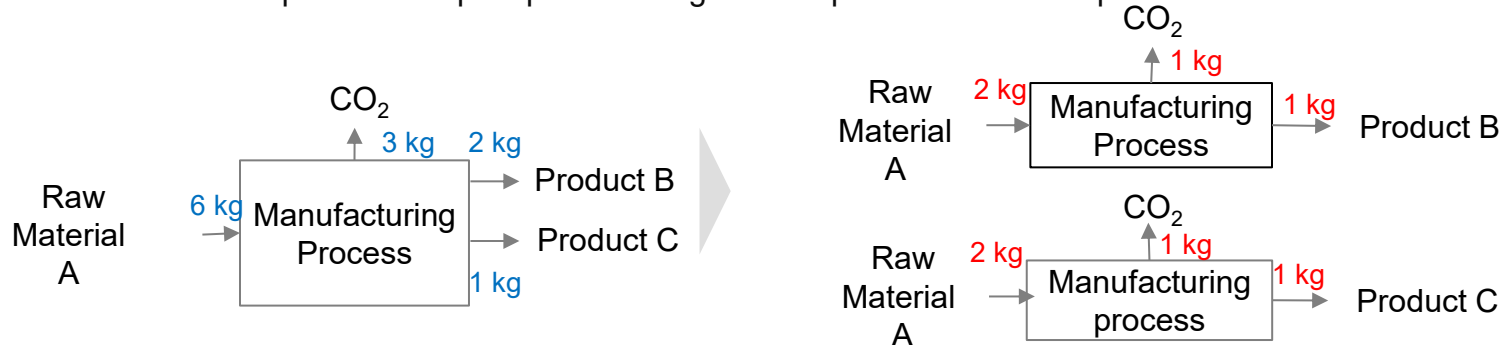
(2) Methods for Conducting LCA in Biomanufacturing

ii) Collection of Activity Data

Allocation Procedure (continued)

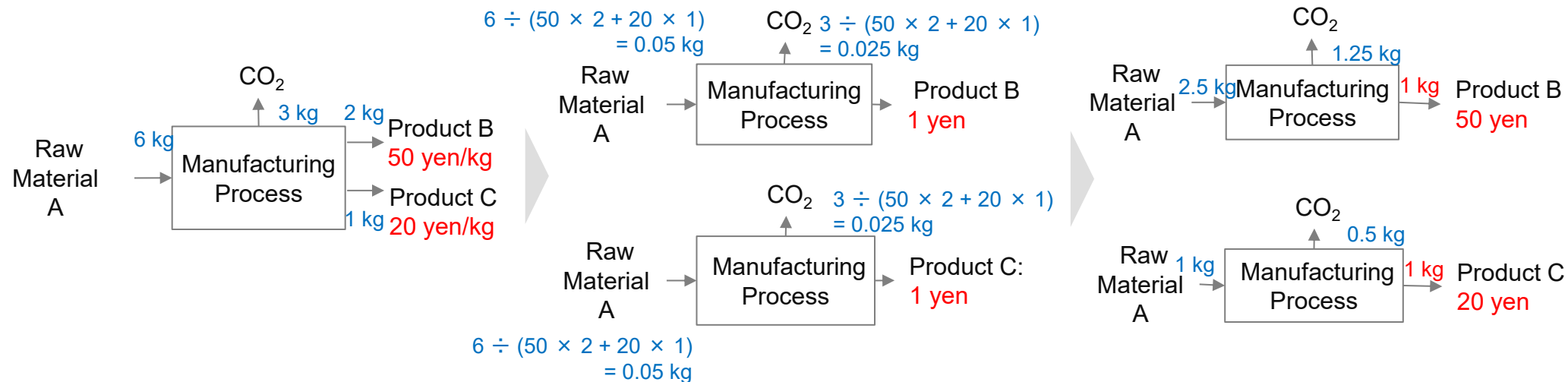
(b) Allocation based on physical parameters (e.g., mass, energy content)

Features: Inputs and outputs per unit weight of the product become equal



(c) Allocation based on other relationships (e.g., economic value)

Features: Inputs and outputs per unit price of the product become equal



(2) Methods for Conducting LCA in Biomanufacturing

ii) Collection of Activity Data

■ cut-off

- "Cut-off" refers to the practice of omitting inputs and outputs that are considered to make a minor contribution to the overall environmental impact, taking into account the workload involved in data collection. The standards used to determine whether to apply a cut-off are referred to as "cut-off standards."^[1]
- Cut-off inputs and outputs are included within the system boundary but are excluded from the calculation^[2] . Therefore, since it is not desirable to subject inputs and outputs to cut-off unless their environmental impact is determined to be sufficiently small, cut-off must be performed with caution.
- When cut-off is applied, it is desirable to explicitly identify the cut-off inputs and outputs and analyze their impact in "v) Interpretation."

■ Consideration of the Construction of a New Facility

- For the facilities newly constructed for biomanufacturing (such as culture equipment), the construction thereof could also be included in the assessment. In such cases, it is desirable to set activity data by considering factors such as the depreciation period, useful life, and actual period of use.

(Reference)

[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

[2] Ministry of Economy, Trade and Industry (METI) and Ministry of the Environment (MOE), "CFP Guidelines", https://www.meti.go.jp/shingikai/energy_environment/carbon_footprint/pdf/20230526_3.pdf

(2) Methods for Conducting LCA in Biomanufacturing

iii) Collection of Emission Factors

- An emission factor represents the environmental burden per unit of activity data. It utilizes databases and other sources as background data for processes—such as resource extraction and waste treatment—that fall outside the scope of the LCA practitioner’s technical analysis.
- For conducting an accurate LCA, the collection and selection of appropriate emission factors (background data) are critical. This guideline divides the methods for data collection into five stages, and explains them by process in the “Guideline (Practical Guide).” If data is insufficient, assumed values should be used, and their significance must be verified in “v) Interpretation.”

Examples of methods for collecting emission factors and points requiring caution

In the case where emission factors will be provided from suppliers

- When emission factors can be obtained from the company’s contractors—such as for raw material production, energy production, or wastewater treatment—it is desirable for the LCA practitioner to assess the appropriateness of such emission factors before using them.
 - It is also desirable to obtain the calculation conditions for the data (system boundaries, data collection methods, etc.) and to assess their appropriateness for use.
 - When requesting emission factors from suppliers, please be mindful of the Act on the Proper Conduct of Transactions with Small and Medium-Sized Contractors (the Proper Transactions Act), etc. (See Ministry of Economy, Trade and Industry, Ministry of the Environment, “CFPガイドライン(CFP Guidelines),” p. 50)^[1]

In the case of using one or more databases

- Since the information listed in databases varies, and calculation conditions and accuracy differ, selecting the appropriate database is important.

In the case of using literature values from academic papers or other literature

- It is advisable to investigate the calculation conditions of the relevant data and determine its appropriateness for use.

(Reference)

[1] Ministry of Economy, Trade and Industry (METI) and Ministry of the Environment (MOE), “CFPガイドライン(CFP Guidelines),”

https://www.meti.go.jp/shingikai/energy_environment/carbon_footprint/pdf/20230526_3.pdf

(2) Methods for Conducting LCA in Biomanufacturing

iii) Collection of Emission Factors

■ Database of Emission Factors

- Databases of life cycle emission factors can be broadly categorized into the following two types based on how they are created. The appropriate type must be selected according to the goal of the LCA.
- Since each database differs in its creation method (system boundary, allocation, etc.), the concurrent use of multiple databases is not recommended^[1], however, depending on the availability of data, it may be necessary to use multiple databases.
- When using multiple databases, it is important to note that the Life Cycle Impact Assessment methods may differ. (Examples: The greenhouse gases included in GHG emissions calculations may differ; global warming potentials (GWPs) may differ; even within the same acidification impact category, Life Cycle Impact Assessment methods may differ, etc.)

(Note) IDEA states: “We do not recommend mixing the use of IDEA with databases from other companies. This is because methods for data creation, allocation, cut-off standards, and life cycle impact assessment techniques differ between databases. If you are compelled to use multiple databases from different developers, please exercise caution regarding the results and conclusions derived from such mixed use.”

(Reference) [1] National Institute of Advanced Industrial Science and Technology (AIST), Safety Science Research Division, IDEA Lab, “AIST-IDEA Ver. 3.5 標準版 マニュアル 第 1 部 (Standard Edition Manual), Part 1”

	Examples	Advantages ^[2]	Disadvantages ^[2]
<p>Based on the process-based approach database</p> <p>Environmental impact is calculated by collecting and aggregating the inputs and outputs of the process.</p>	<p>AIST-IDEA JLCA Database Ecoinvent Agri Footprint, etc.</p>	<p>■ Inputs and outputs for the relevant process are collected and aggregated, enabling highly accurate and detailed analysis.</p>	<p>■ There are items not listed in the database.</p>
<p>Based on input-output tables database</p> <p>Environmental impact is calculated based on the flow of production activities (in monetary terms) between product sectors using input-output tables.</p>	<p>3EID Eora Global MRIO ...</p>	<p>■ Because it is based on interindustry input-output tables, with all commodity sectors being listed, coverage of the target fields is highly comprehensive.</p>	<p>■ Average emissions per unit production value are listed, making it difficult to analyze individual items.</p> <p>■ The range of environmental load substances covered is limited.</p>

(Reference)

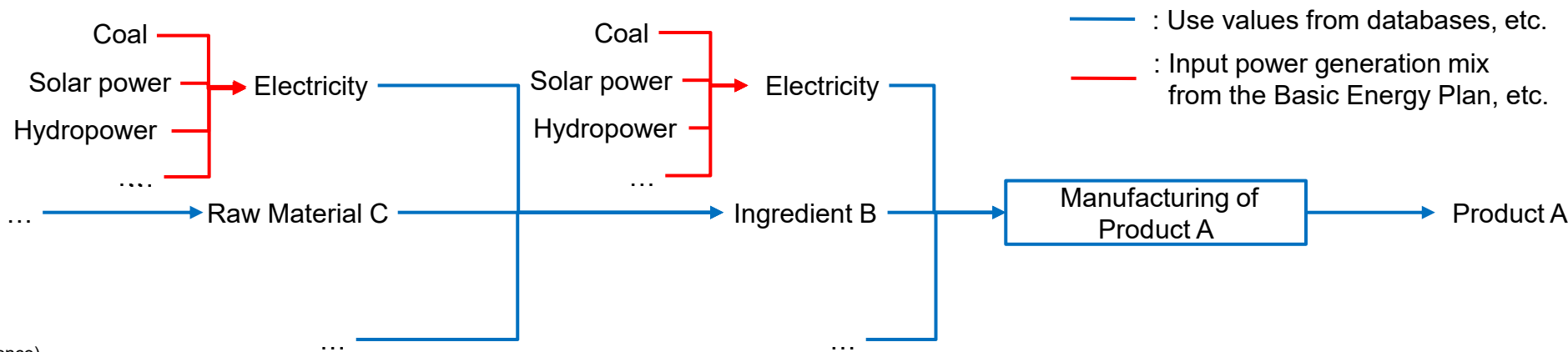
[2] Ministry of the Environment, “サプライチェーンを通じた組織の温室効果ガス排出等の算定のための排出原単位について Ver.3.5 (Emission Factors for Calculating an Organization’s Greenhouse Gas Emissions, etc., Through the Supply Chain Ver. 3.5),” https://www.env.go.jp/earth/ondanka/supply_chain/gvc/files/tools/unit_outline_V3-5.pdf

(2) Methods for Conducting LCA in Biomanufacturing

iii) Collection of Emission Factors

■ (Reference) Future Emission Factors

- Currently, various future emission factors are being published by the government and industry operators. While this information can be utilized when estimating future emission factors, it must be used with a full understanding of the associated uncertainties.
 - Government target based on the “Outlook for Energy Supply and Demand in FY2030”: **0.25 kg-CO₂ eq/kWh** ^[1]
 - Target for FY **2030** set by the Electric Power Industry Council for a Low-Carbon Society: Approximately **0.37 kg-CO₂ eq/kWh** (at the point of use) ^[2]
- Research on the development of future emission factors is underway, and there are examples in the “ecoinvent” database where future scenarios from **integrated assessment models**—which estimate climate change countermeasures, the economy, and population dynamics—have been incorporated.^[3]
- For the creation of simplified future emission factors, a method that reflects future energy trends—as shown in the figure below—is also effective. This involves using **LCA** software such as **MiLCA**, **SimaPro**, or **OpenLCA** based on emission factors derived from the process-based approach. However, it is necessary to be mindful of uncertainties, such as the failure to reflect future technological innovations.



(Reference)

[1] Agency for Natural Resources and Energy, “2030年度におけるエネルギー需給の見通し(Outlook for Energy Supply and Demand in FY2030),”

https://www.enecho.meti.go.jp/category/others/basic_plan/pdf/20211022_03.pdf

Ministry of the Environment, “2030年度排出削減目標に関する対策・施策の一覧(List of Measures and Policies Regarding the FY2030 Reduction Target),” <https://www.env.go.jp/content/000290553.pdf>

[2] Electric Power Industry Council for a Low-Carbon Society, “電気事業における地球温暖化対策の取組み(Initiatives for Global Warming Countermeasures in the Electric Power Industry),” https://e-lcs.jp/assets/2021FU_torikumi1.pdf

[3] Sacchi, R., et al., “Prospective Environmental Impact Assessment (premise): A streamlined approach to producing databases for prospective life cycle assessment using integrated assessment models,” *Renewable and Sustainable Energy Reviews*, vol. 160, p. 112311, May 2022, <https://doi.org/10.1016/j.rser.2022.112311>

(2) Methods for Conducting LCA in Biomanufacturing

iii) Life Cycle Impact Assessment

- Life Cycle Impact Assessment is performed by multiplying activity data by emission factors and summing the results.

$$\begin{array}{ccc}
 \text{Environmental impact} & = & \sum \left(\text{Activity data} \times \text{Emission factor} \right) \\
 \text{e.g., GHG emissions per 1 kg of product (kg-CO}_2 \text{ eq./kg-product)} & & \text{e.g., Amount of glucose required to produce 1 kg of product (kg-glucose/kg-product)} \times \text{e.g., GHG emissions when producing 1 kg of glucose (kg-CO}_2 \text{ eq./kg-glucose)}
 \end{array}$$

- Although the calculation method above is commonly used because it is simple, it does not allow for analysis of which environmental load substances are dominant (e.g., it is not possible to determine whether the primary cause of GHG emissions is CO₂, CH₄, or N₂O, etc.). To confirm this, an inventory analysis must be conducted (see p. 37).

Inventory Analysis and Life Cycle Impact Assessment

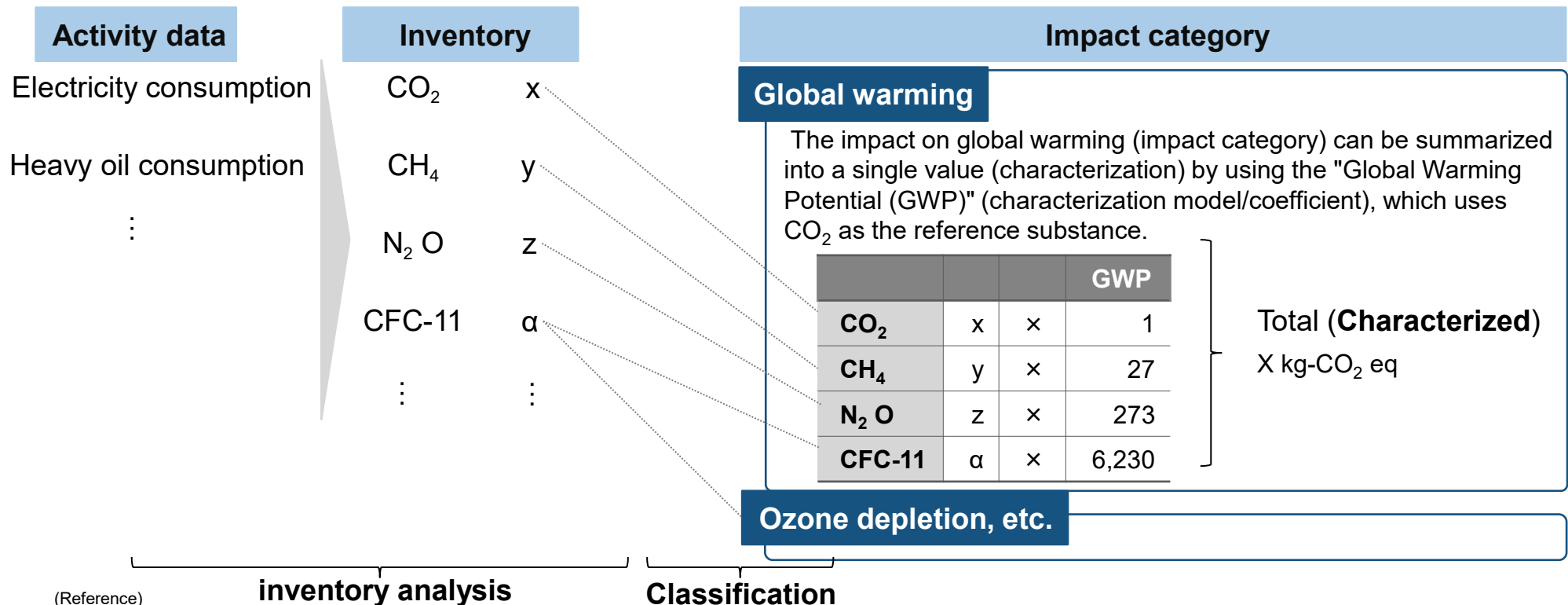
- In recent years, with the development of emission factor databases, the above calculation method has become commonly used; however, this method cannot analyze which environmental load substances have the dominant influence (e.g., it cannot analyze whether the primary cause of GHG emissions is CO₂, CH₄, or N₂O, etc.).
- To determine which environmental load substances have the greatest impact, it is necessary to conduct an inventory analysis (see p. 37).
- Although the above calculation method (activity data × emission factor) has not undergone inventory analysis and therefore cannot be said to comply with ISO 14040:2006 and ISO 14044:2006, the approach and methodology used in the calculations are based on the ISO standards and do not deviate from them.

(2) Methods for Conducting LCA in Biomanufacturing

(Reference) Inventory Analysis and Life Cycle Impact Assessment in the ISO 14040 Series

- In the ISO 14040 series, inventory analysis and Life Cycle Impact Assessment are conducted according to the following process.^[1]
 - Analyze which environmental load substances are being emitted (inventory analysis)
 - Allocate the results of the inventory analysis to the impact categories under investigation (classification)
 - For each impact category, aggregate the results into a single value using characterization factors based on reference substances (characterization)
- Databases contain pre-characterized emission factors, allowing for a simplified LCA without the need for inventory analysis, classification, or characterization.

Procedure of Life Cycle Impact Assessment



(Reference)

[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

(2) Methods for Conducting LCA in Biomanufacturing

(Reference) Environmental Impacts Assessable via LCA and LIME2

- LCA can quantitatively assess not only the impact on climate change (GHG emissions) but also various other environmental impacts.
- Various characterization factors have been developed to date, and the Japanese damage-based Life Cycle Impact Assessment method "LIME2" recommends the following characterization factors.

Characterization factors recommended by LIME2 and their characteristics^[1]

Impact category	Recommended characterization factor by LIME2	Unit for assessment result	Content assessed by characterization method
Ozone layer destruction	ODP	CFC-11eq. kg	Ozone layer destruction capacity
Global warming	GWP	CO ₂ eq. kg	Infrared radiation power
Acidification	DAP	SO ₂ eq. kg	Quantity of protons with consideration for deposition
Urban area air pollution	UAF	SO ₂ eq. kg	Reflection of weather conditions in each region in Japan
Photochemical oxidants	OEFC	C ₂ H ₄ eq. kg	Reflection of weather conditions in each region in Japan
Toxic chemicals	HTP cancer	C ₆ H ₆ air eq. kg	Hazard ratio of carcinogenic substance
	HTP chronic disease	C ₆ H ₆ air eq. kg	Hazard ratio of chronic illness
Biological toxicity	AETP	C ₆ H ₆ water eq. kg	Toxicity to aquatic creatures
	TETP	C ₆ H ₆ soil eq. kg	Toxicity to terrestrial creatures
Eutrophication	EPMG	PO ₄ ³⁻ eq. kg	Consumption of dissolved oxygen
Indoor air contamination	TVOC	kg	Predicted intake and daily human limit value
Land use	LOF	1/m ² /yr	Area and period of land possession
	LTF	1/m ²	Area of rearranged land
Consumption of resources (mineral resources, fossil fuels, biological resources)	Consumption energy	MJ	Heat value
	1/R	1/kg	Reciprocal of recoverable reserves
Waste	WPF	m ³ /kg	Ratio of volume to area of disposal site
Noise	NPF	J/no. of vehicles. km	Energy of sound source

(Reference)

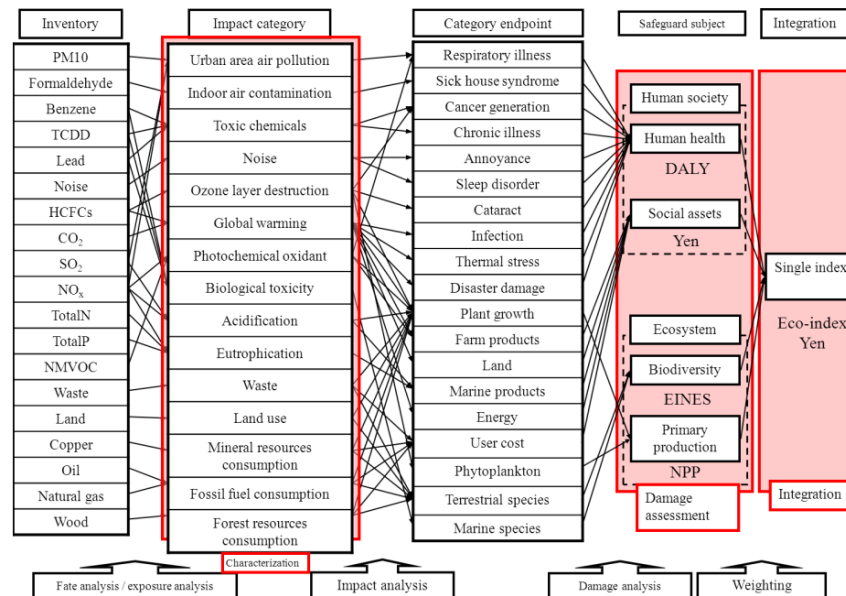
[1] LCA Japan Forum, "LIME2Life-cycle Impact assessment Method based on Endpoint modeling (summary)", https://lca-forum.org/english/pdf/No12_Summary.pdf

(2) Methods for Conducting LCA in Biomanufacturing

(Reference) Weighting

- While LCA allows for the quantitative assessment of various environmental impacts, it is associated with difficulty in identifying which impact categories are significant. Therefore, environmental impacts are sometimes “weighted” and converted into a single numerical value. (Weighting is an optional element of LCA.)
- While this makes interpretation easier because the results are expressed as a single numerical value, it is important to note that weighting requires subjective value judgments, and results may vary depending on the weighting method used. Furthermore, weighting is restricted in comparative assertions intended for disclosure to the public^[1].
- The Japanese damage-based Life Cycle Impact Assessment method "LIME2" identifies four protection targets: "human health," "social assets," "biodiversity," and "primary production." By performing weighting on these items, the results are converted into a single indicator (Eco-index Yen).

Conceptual Diagram of LIME and Scope of Assessment^[2]



(Reference)

[1] ISO, "ISO 14044:2006", <https://www.iso.org/standard/38498.html>

[2] LCA Japan Forum, "LIME2Life-cycle Impact assessment Method based on Endpoint modeling (summary)", https://lca-forum.org/english/pdf/No12_Summary.pdf

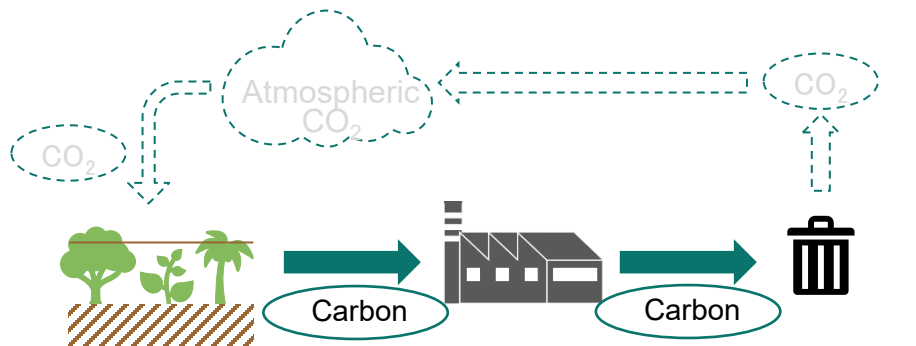
(2) Methods for Conducting LCA in Biomanufacturing

(Reference) Concept of Biogenic Carbon

- There are two approaches to biogenic carbon: the “0/0 approach,” which treats the CO₂ absorbed during biomass production and the CO₂ emitted during disposal (incineration) as zero, and the “-1/+1 approach,” which considers both.
- Note that ISO 14067:2018 stipulates the use of the “-1/+1 approach”^[1].

0/0 approach

- CO₂ uptake (removal) during biomass production is not taken into account
- CO₂ emissions from incineration are considered zero.



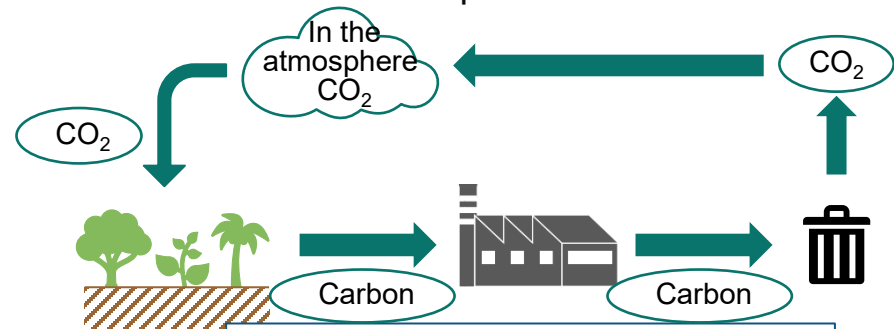
Absorption and removal through photosynthesis

Manufacturing

Disposal (Incineration)

-1/+1 approach

- Take into account the uptake (removal) of CO₂ during biomass production
- The same amount of CO₂ is emitted during incineration as is taken up



Absorption and removal through photosynthesis

Manufacturing

Disposal (Incineration)

Emissions from cradle to grave remain unchanged regardless of the method used

(Reference)
[1] ISO, "ISO 14067:2018," <https://www.iso.org/standard/71206.html>

(2) Methods for Conducting LCA in Biomanufacturing

v) Interpretation

- ISO 14044:2006 specifies how to conduct an interpretation.^[1]
 - Identify significant issues based on the results of the inventory analysis and Life Cycle Impact Assessment
 - Evaluate completeness, sensitivity, and consistency
 - Summarize conclusions, limitations, and recommendations
- Of the above, the points that are particularly important for LCA in biomanufacturing are listed below.

Points to verify

Mitigation Measures

i) Goal and scope definition	<ul style="list-style-type: none"> ✓ Are the evaluation targets and scope appropriate for drawing conclusions? 	<ul style="list-style-type: none"> ✓ Modify the system boundaries as necessary 	
ii) Collection of activity data	iii) Collection of emission factors	<ul style="list-style-type: none"> ✓ Are there any omissions in the process or any inappropriate data? ✓ Is there any data with uncertainty? ✓ Is the contribution of proxy data or assumed values to the Life Cycle Impact Assessment results minimal? 	<ul style="list-style-type: none"> ✓ Verify the material balance ✓ Verify the appropriateness of the activity data used ✓ Conduct a sensitivity analysis (see p. 42)
iv) Life Cycle Impact Assessment		<ul style="list-style-type: none"> ✓ What are the key life cycle stages and unit processes? ✓ Is it acceptable to disregard impact categories other than climate change? 	<ul style="list-style-type: none"> ✓ Identify the life cycle stages and inputs and outputs that account for a large proportion of the total ✓ Identify which impact categories are significant (land use, water resource consumption, eutrophication, etc.)

Summarize the conclusions and limitations derived from the LCA

If necessary, make recommendations to decision-makers who would review the LCA results

(Reference)

[1] ISO, "ISO 14040:2006", <https://www.iso.org/standard/37456.html>

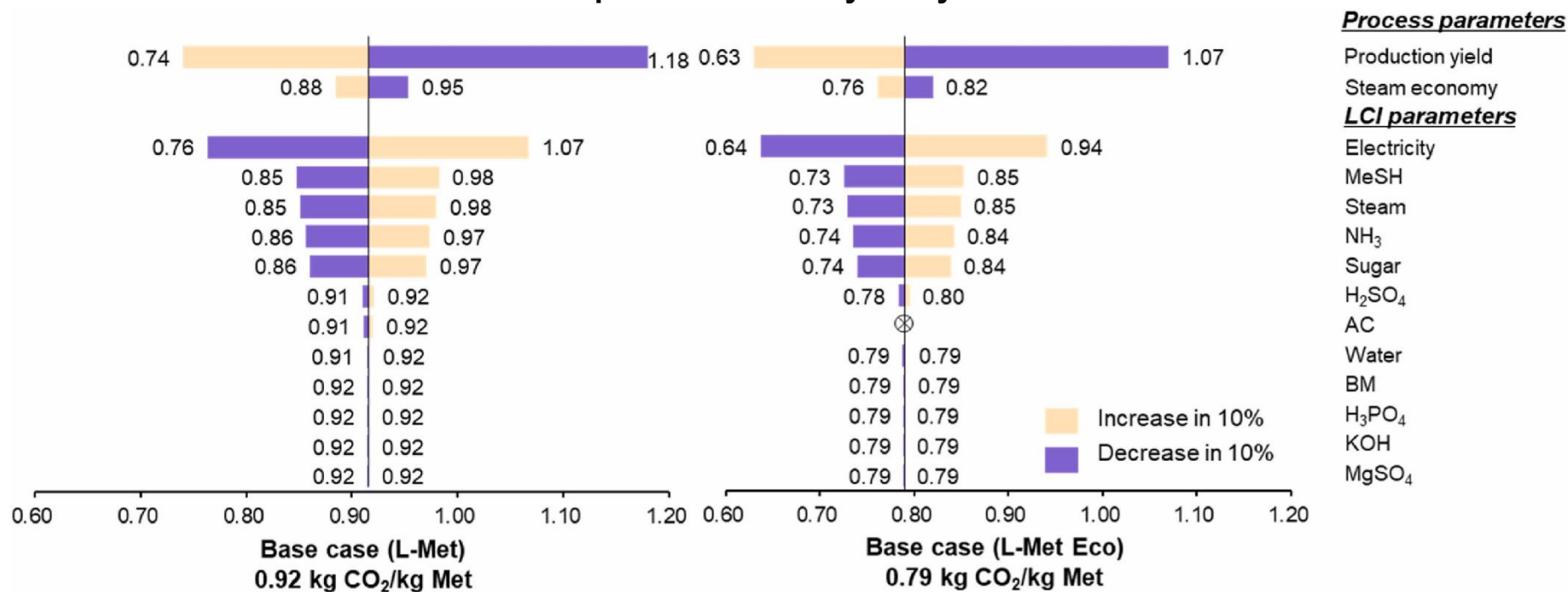
(2) Methods for Conducting LCA in Biomanufacturing

v) Interpretation

■ Example of How to Conduct a Sensitivity Analysis

- Conduct a sensitivity analysis on the activity data collected in “ii) Collection of activity data” and the emission factors collected in “iii) Collection of emission factors.” As an example, verify how the Life Cycle Impact Assessment results vary when each value (activity data and emission factors) is increased or decreased by 10%.
 - A chart that ranks these values in order of sensitivity is called a “tornado chart” (see figure below).
- It becomes thereby clear which parameters have the greater impact on the overall results and, accordingly, it becomes clear which data need to be improved in terms of accuracy.

Examples of Sensitivity Analysis [1]



(Reference)

[1] Kim, H., Saremi, B., Park, S., Jung, M., Yun, Y., Son, J., Lee, J., Kim, J.-W., & Won, W. (2024). Comparative life cycle assessment for the sustainable production of fermentation-based L-methionine. *Journal of Cleaner Production*, 462, 142700. <https://doi.org/10.1016/j.jclepro.2024.142700>

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LCA Guidelines for Biomanufacturing (Principal Guide)

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