# A sustainable alternative to pre-filled syringes and multi-dose glass vial


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# AGENDA

1

Unither Pharmaceuticals and Blow Fill Seal (BFS)

- Unither Pharmaceuticals
- An introduction to Blow Fill Seal technology
- Application to Euroject®

2

Euroject ® Life Cycle Assessment (LCA)

- Methodological approach
- Assessment scope and functional unit
- Environmental performance of Euroject ® injector

3

Comparison between Euroject® and current vaccine delivery solutions through comparative LCA

- Comparison of the different injectors


# Unither Pharmaceuticals
## Blow Fill Seal and Euroject®

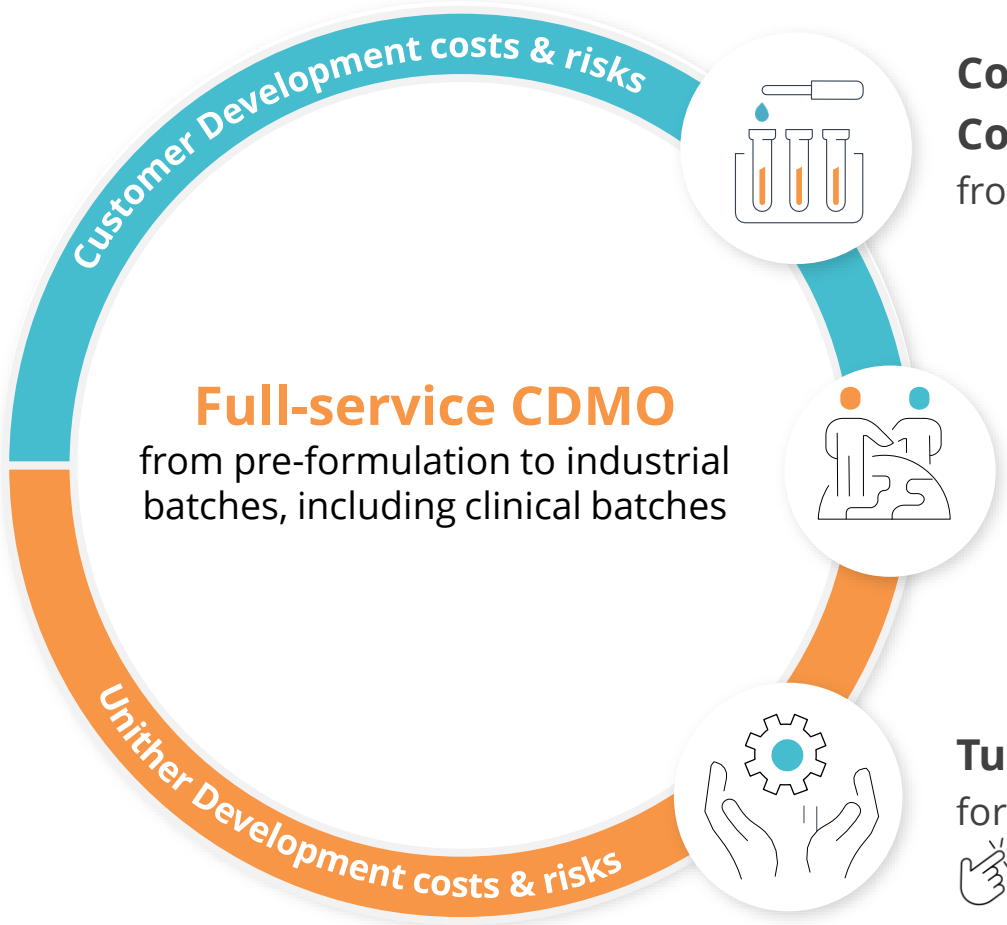
UNITHER PHARMACEUTICALS

Unither Pharmaceuticals is a global subcontractor specializing in the development and manufacturing of health products.

With more than 30 years of experience, our CDMO has become the **world leader in Blow-Fill-Seal technology**, with an industrial presence on four continents and products sold in more than 100 countries.

# Business model

02- Types of collaboration




**Contract Development**
**Contract Manufacturing**
from pre-clinical to commercial

**Co-Development**
with our customers

**Turnkey Products & Dossiers**
for out-licensing

OUR PRODUCT LIST

# Global organization
## Our Plants

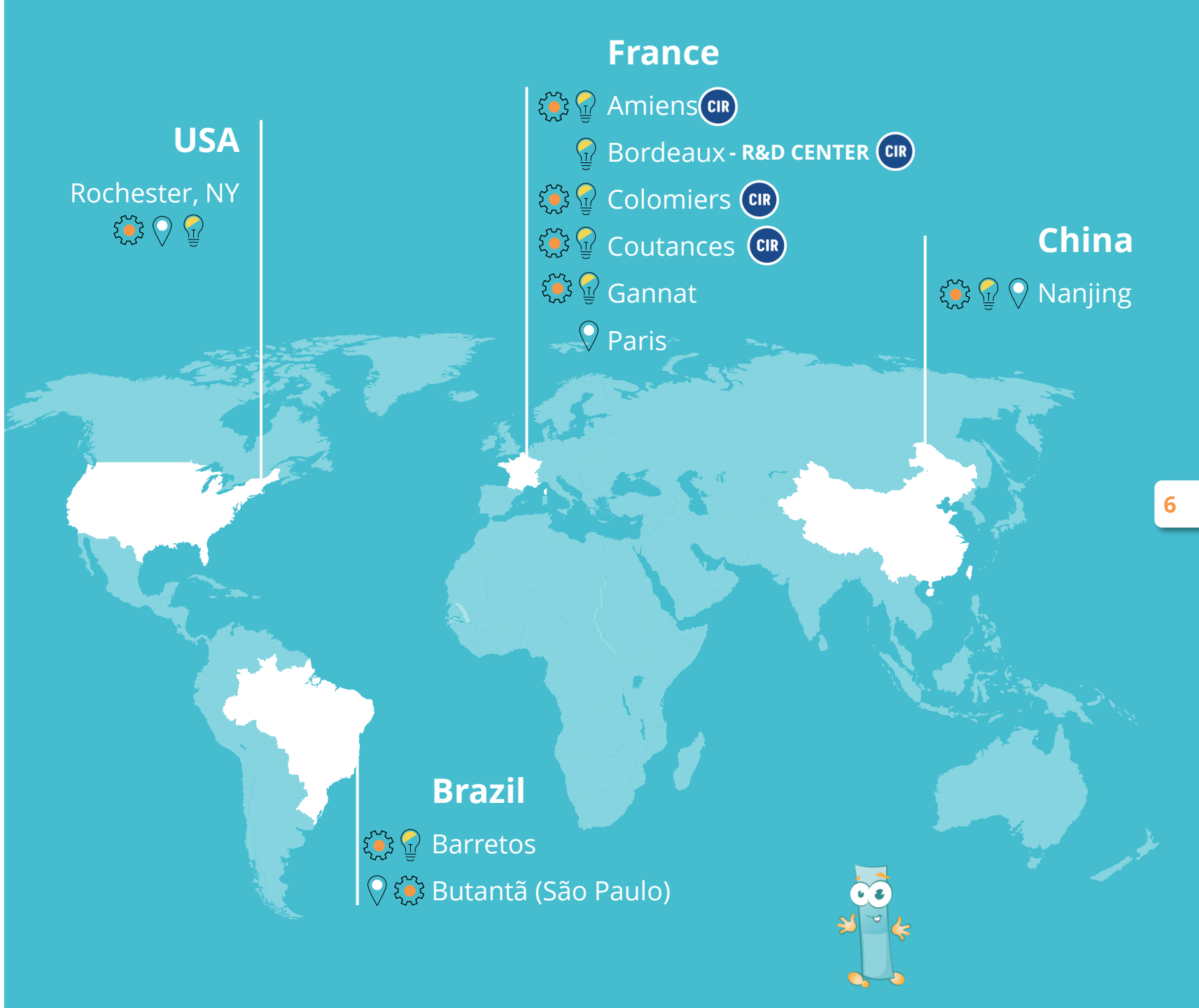
Production

Commercial Office

Innovation & Development

*CIR: crédit d'impôt recherche*
Research tax credit

Global reach
#100 countries
Industrial Footprint on 4 continents
Products sold in more than 100 countries (France, USA, Brazil, China)



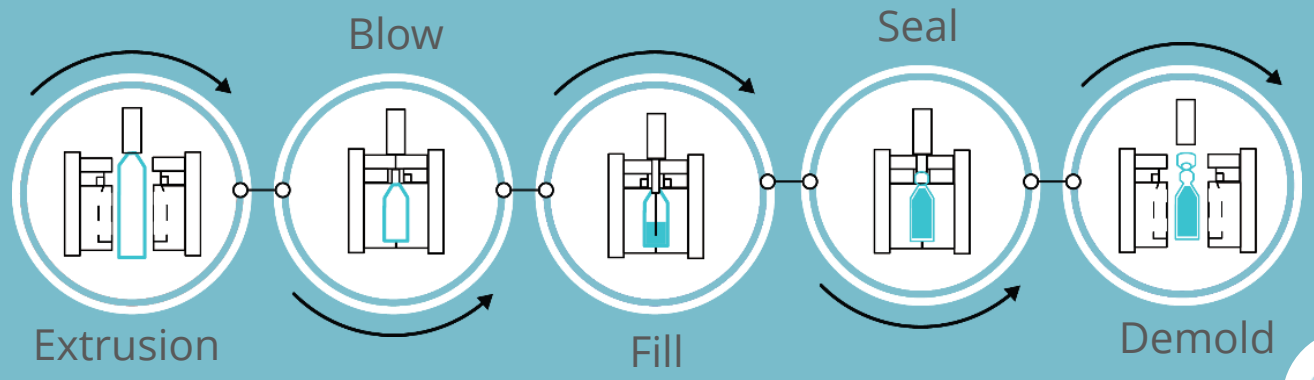
# BLOW FILL SEAL TECHNOLOGY



LDPE pellets

Blow-Fill-Seal vials

BFS machine



# BLOW FILL SEAL TECHNOLOGY

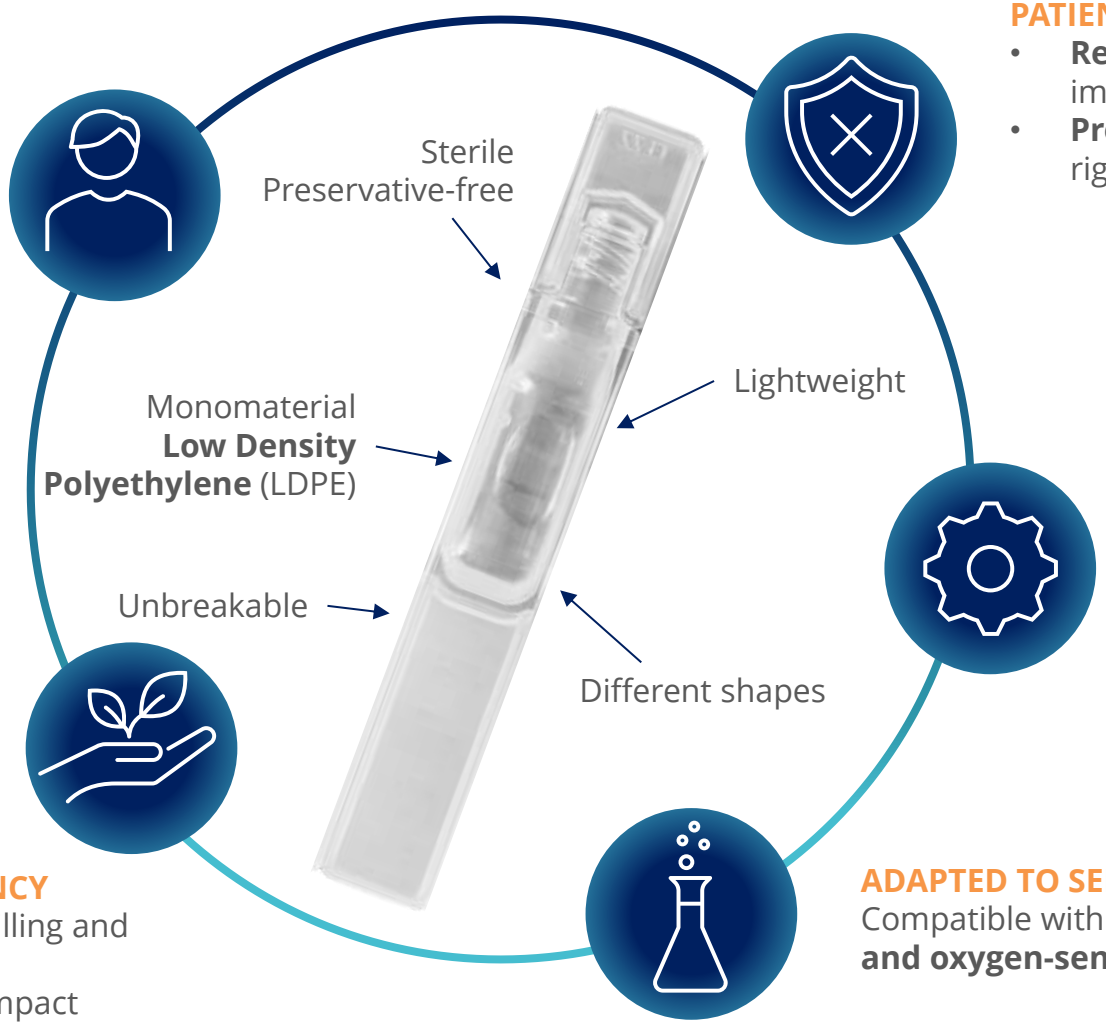
# REASONS TO CHOOSE BFS



## PRODUCT INTEGRITY & SAFETY

- **Sterility** – Closed, aseptic process with no human intervention
- **No cross-contamination –** Monodose, no preservative, no backflow

ISO 13485 | Class A | ISO 5




## PATIENT-CENTRIC DESIGN

- **Ready-to-use** – Simplifies the use and improves patient compliance
- **Precise dosing** – Each unit delivers the right dose, every time

## COST & SUSTAINABILITY

- **Lower total cost** of ownership – Especially for large volumes
- **Eco-friendly** formats – Less waste, recyclable materials

## OPERATIONAL & SUPPLY CHAIN EFFICIENCY

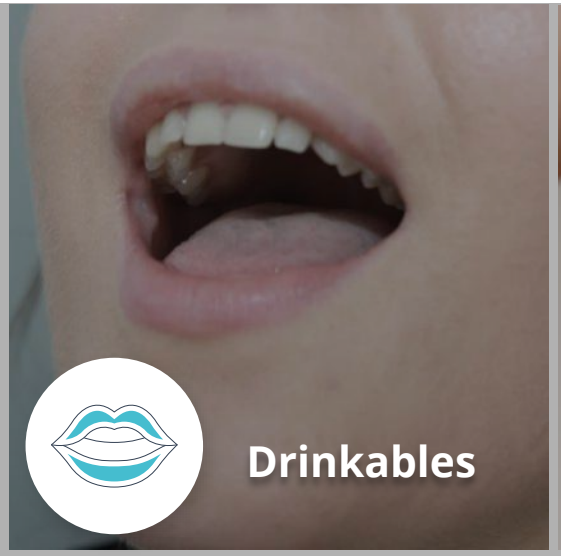
- **High-speed production** – Integrated filling and sealing in one step
- **Optimized logistics** – Lightweight, compact
- Controlled excursion time

## ADAPTED TO SENSITIVE PRODUCTS

Compatible with **pH, light, temperature, and oxygen-sensitive** or **potent** products.

# FIELDS OF APPLICATION



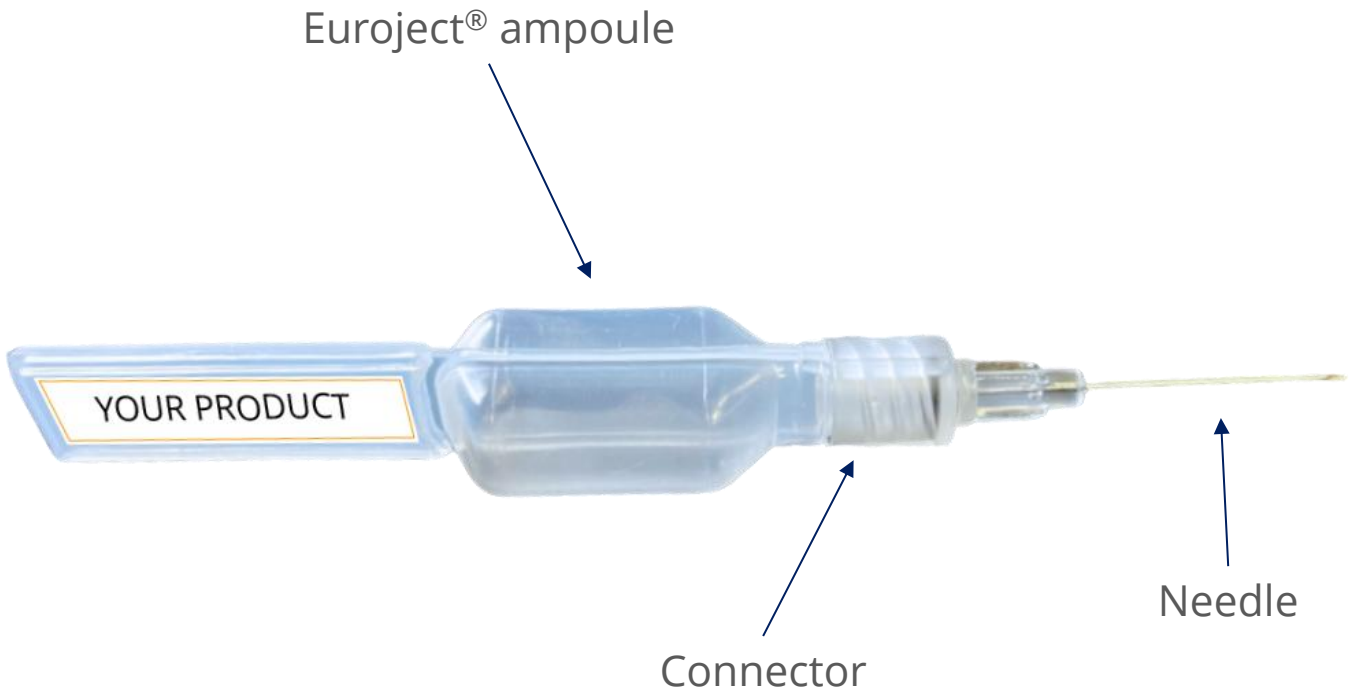






# BLOW FILL SEAL TECHNOLOGY - EUROJECT®

**Euroject®:** an innovative BFS-based device for single dose injection of therapeutics.

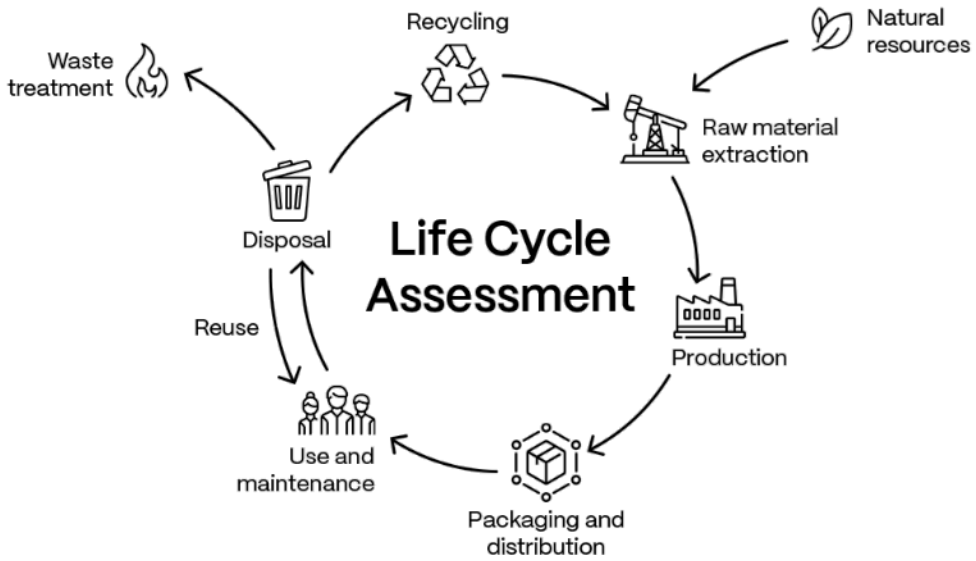



- Easy to use
- Low cost per dose
- Low risk of cross contamination
- Resilient supply chain
- Lightweight and compact
- High production and scalability
- No product wastage
- Sustainable ?

# Euroject®

## Life Cycle Assessment (LCA)

# EUROJECT® – LIFE CYCLE ASSESSEMENT




*Source: Swiss Federal Office for the Environment (BAFU) (2022)*

- Life cycle assessment (LCA) is a holistic decision support tool that calculates the potential environmental impacts of different products and systems.
- This study aligns with principles, framework, methodology and practices for LCA established by ISO 14040 and ISO 14044.
- This LCA shows results using Product Environmental Footprint 3.1 methodology and its 16 environmental indicators.

| Impact category | Indicator | Unit |
|---|---|---|
| **Climate change** | Global Warming Potential 100 years. Baseline model of the IPCC 2021. | kg CO2-eq |
| **Acidification terrestrial and freshwater** | Accumulated Exceedance (AE) characterizing the change in critical load exceedance of the sensitive area in terrestrial and main freshwater ecosystems, to which acidifying substances deposit. | mol H+ eq |
| **Ecotoxicity, freshwater** | An estimate of the potentially affected fraction of species (PAF) integrated over time and volume per unit mass of a chemical emitted (PAF m3 year/kg). | CTUe |
| **Particulate matter** | Disease incidence due to kg of PM2.5 emitted. | disease incidence |
| **Eutrophication, freshwater** | Expression of the degree to which the emitted nutrients reaches the freshwater end compartment (phosphorus considered as limiting factor in freshwater). | kg P eq |
| **Eutrophication, marine** | Expression of the degree to which the emitted nutrients reaches the marine end compartment (nitrogen considered as limiting factor in marine water). | kg N eq |
| **Eutrophication, terrestrial** | The change in critical load exceedance of the sensitive area, to which eutrophying substances deposit. | mol N eq |
| **Human toxicity, non-cancer** | Estimated increase in morbidity in the total human population per unit mass of a chemical emitted | CTUh |
| **Human toxicity, cancer** | Comparative Toxic Unit for human (CTUh) expressing the estimated increase in morbidity in the total human population per unit mass of a chemical emitted (cases per kilogram) | CTUh |
| **Ionising radiation - human health** | Quantification of the impact of ionizing radiation on the population, in comparison to Uranium 235 | kBq U-235 eq |
| **Land Use** | Soil quality index. | Pt |
| **Ozone depletion** | Ozone Depletion Potential (ODP) calculating the destructive effects on the stratospheric ozone layer over a time horizon of 100 years. | kg CFC11 eq |
| **Resource use, fossils** | The amount of extracted fossil fuel extracted, based on the lower heating value. | MJ |
| **Resource use, minerals and metals** | The primary extraction of a mineral resource | kg Sb eq |
| **Water use** | Relative Available WAter REmaining (AWARE) per area in a watershed, after the demand of humans and aquatic ecosystems has been met | m3 water eq. deprived |
| **Photochemical ozone formation** | Expression of the potential contribution to photochemical ozone formation. | kg NMVOC eq |

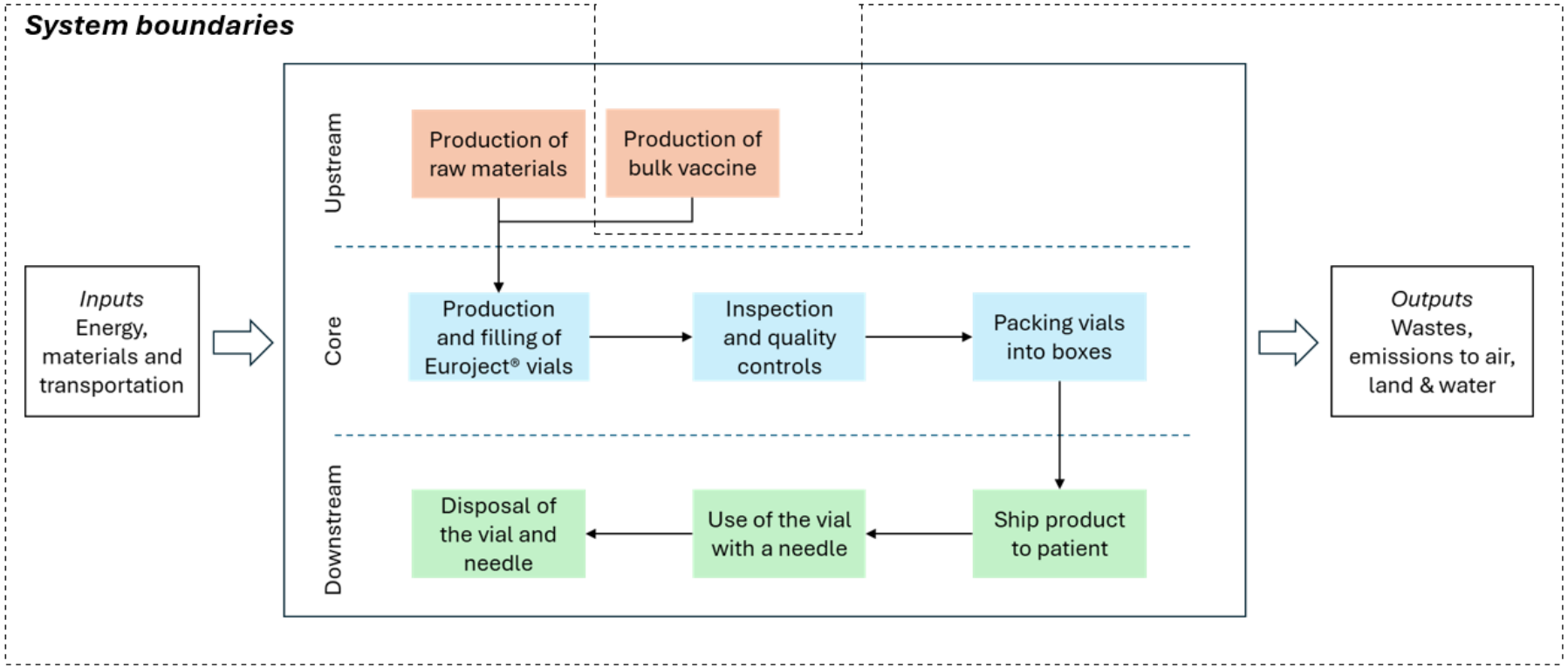
# EUROJECT® – LCA – DEFINITION OF THE STUDY



The functional unit defined for the LCA is :

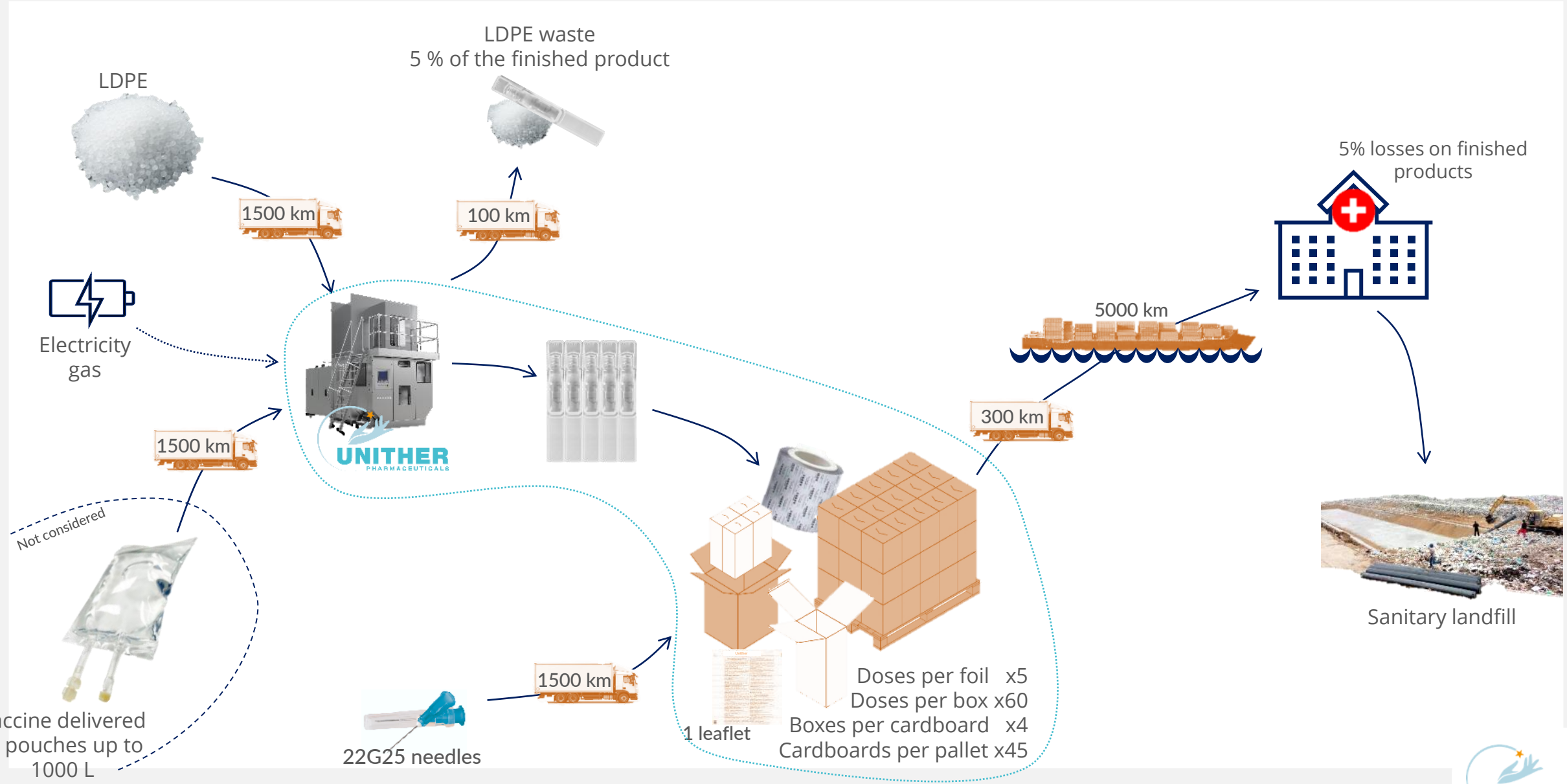
*"Delivering a single 0.5 mL dose of vaccine by injection, produced in Western Europe and injected in Africa."*

The boundaries of the system studied are :



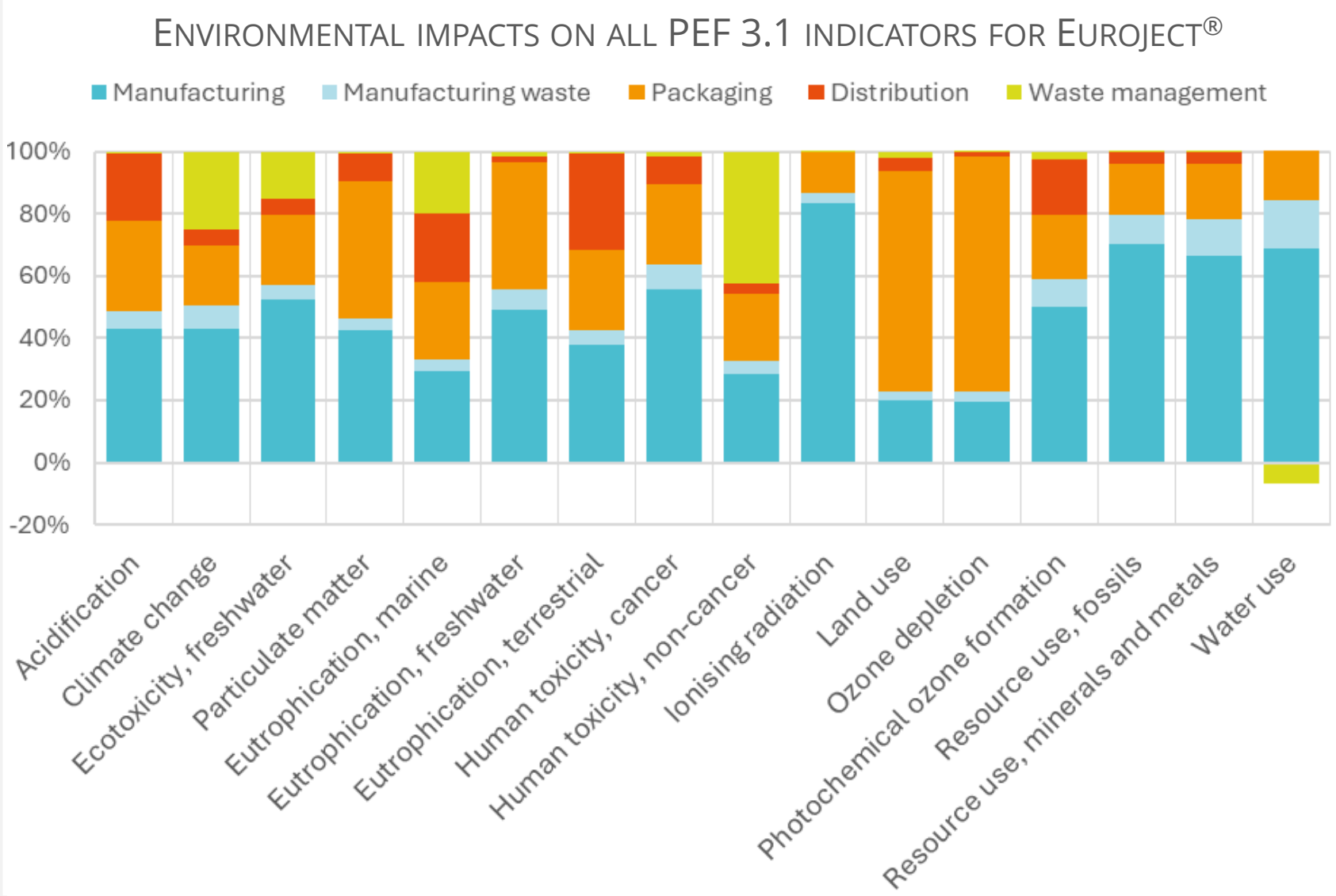
# EUROJECT® – LCA – HYPOTHESIS





# EUROJECT® – LCA – ALL IMPACTS



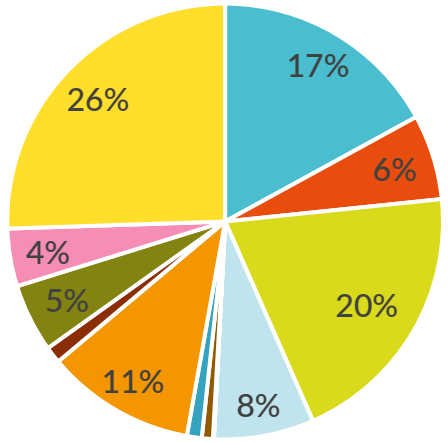


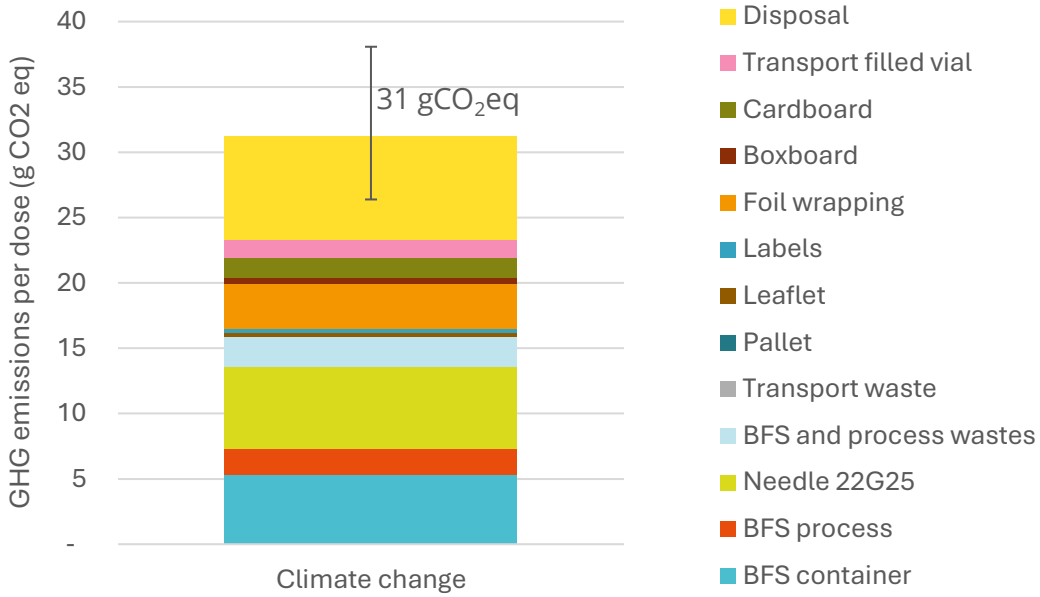

- Globally, the main provider of impact is the manufacturing step.
- Packaging step holds a significant part of the impact on several indicators.
- Vaccine production is not included.

# EUROJECT® – LCA – FOCUS ON CLIMATE CHANGE



## ENVIRONMENTAL IMPACT ON CLIMATE CHANGE FOR EUROJECT®




- **31 $gCO_2eq$** are emitted to produce each dose.
- The production of the **LDPE** and its disposal are responsible of **43% of the total impact.**

- **The needle** has an important share of the impact, due to the use of metal. Smaller needles can reduce the emissions, when medically relevant.
- The **foil wrapping** is also an important contributor. This multi-layer foil contains aluminium, a high impact material.

- **Transportation has a low impact**. This is due to the fact that the doses are small, therefore the transportation is dense.

# Comparative LCA

## Euroject® vs other injectors

# EUROJECT® AND CURRENT VACCINE DELIVERY SOLUTIONS



For this study, Euroject® is compared to 4 other delivery solutions :

- Single dose glass vials
- Multi dose glass vials (10 doses)
- Prefilled syringe (PFS), staked type
- Prefilled syringe (PFS), luer type

Glass vial with stopper and aluminium cap

Injection needle and syringe + cap

Preparation needle and cap

Preparation syringe

Prefilled syringe, staked type

Prefilled syringe, luer type with injection needle

The data required to model these four injectors comes from a study called *Life Cycle Assessment of the Prefilled ApiJect Injector*, published in June 2024 by Matthew Eckelman and Robert Litan.

# EUROJECT® AND CURRENT VACCINE DELIVERY SOLUTIONS



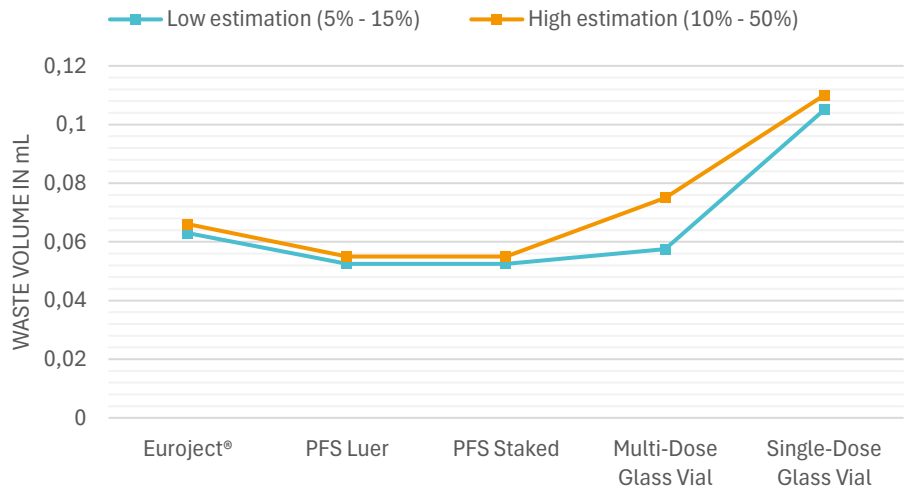
The reference flows, representing the number of systems required to fulfil the functional unit, are:

- one Euroject® dose and needle;
- one pre-filled syringe (Luer or staked) with needle;
- one single-dose glass vial with needles;
- The glass multi-dose vial studied has a capacity of 10 mL with needles. The inventory takes this into account to relate the impact to a single use.



## STUDY OF THE TOTAL WASTE OF VACCINE PER DELIVERY SOLUTION

| | Euroject® | PFS Luer | PFS Staked | Multi-Dose Glass Vial | Single-Dose Glass Vial |
|---|---|---|---|---|---|
| **Overfill (mL)** | 0,06 | 0,05 | 0,05 | 0,05 | 0,1 |
| **Low waste scenario** | 5% | 5% | 5% | 15% | 5% |
| **High waste scenario** | 10% | 10% | 10% | 50% | 10% |
| **Low scenario (mL)** | 0,063 | 0,053 | 0,053 | 0,058 | 0,105 |
| **High scenario (mL)** | 0,066 | 0,055 | 0,055 | 0,075 | 0,110 |

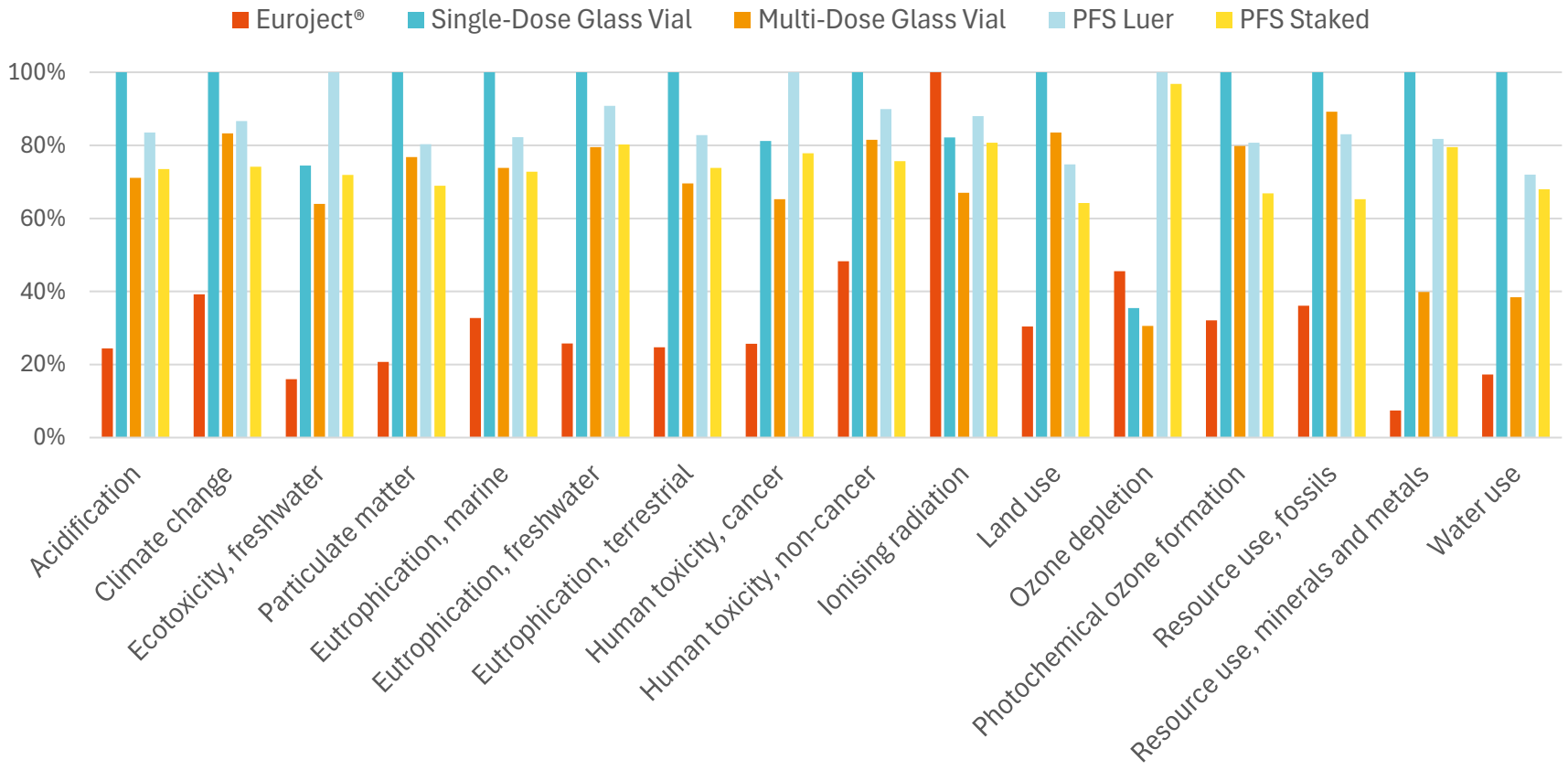



Vaccine has a potentially very high environmental impact. Therefore, reducing wastage can be the most effective action mitigate impacts.

# EUROJECT® AND CURRENT VACCINE DELIVERY SOLUTIONS



## COMPARISON OF THE IMPACTS OF THE 5 INJECTORS ON ALL PEF 3.1 INDICATORS

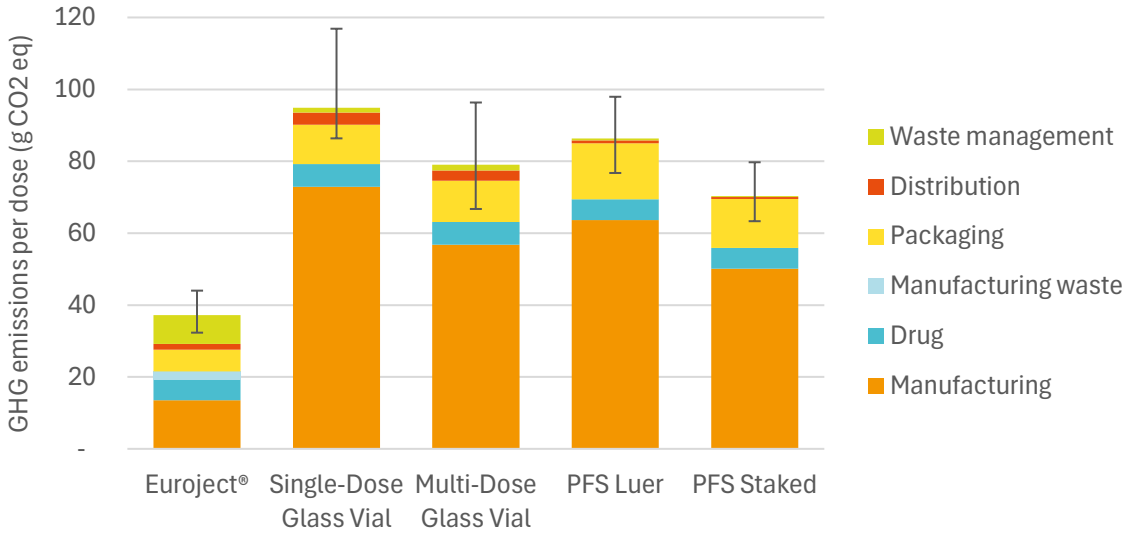



Euroject® :

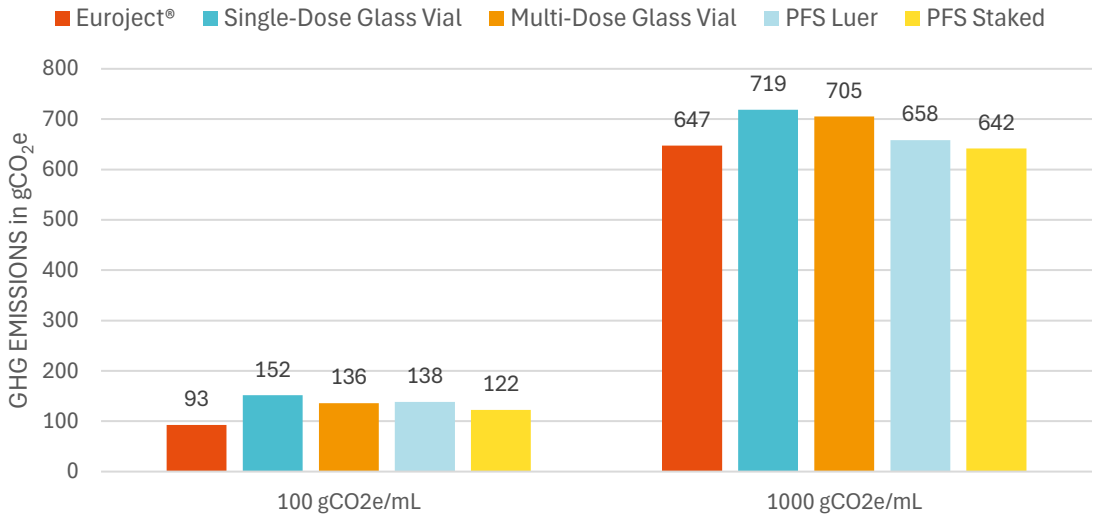
- Is globally the most efficient injector to reduce environmental impacts
- Is 2 times better than the second best, PFS staked, on climate change.
- Is he most impacting injector on ionising radiation, due to the highly nuclear electric mix in France.
- Has a bigger impact on ozone depletion than glass vials.

# EUROJECT® AND CURRENT VACCINE DELIVERY SOLUTIONS

## COMPARISON OF THE IMPACTS OF THE 5 INJECTORS ON CLIMATE CHANGE




## 2 SCENARIOS ON VACCINE RELATED EMISSIONS




Euroject® is :

- Globally the most efficient injector to reduce environmental impacts on climate change.
- 2 times better than the second best, PFS staked.
- The manufacturing of the injectors are the most important steps.

- Vaccine emission factor has a preeminent impact on the result.
- With an emission factor under 990 gCO2e/mL, Euroject® is the best device to fulfil the functional unit on climate change.

# TO CONCLUDE


This LCA determined that considering its efficient delivery volume and lower impacts from the packaging:

- Euroject® injector has great chances to be less impacting on climate change than the other injectors studied.
- On all other indicators, except Ozone Depletion and Ionising Radiation, Euroject® carries a lower environmental burden.
- Except the vaccine related impacts, the manufacturing of the injectors are the most important steps.

# Thank you for your attention!

**Where to meet us next?**
PFS & Injectable Drug Devices East Coast | Boston, USA (April 27-29)


## Your points of contact:

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