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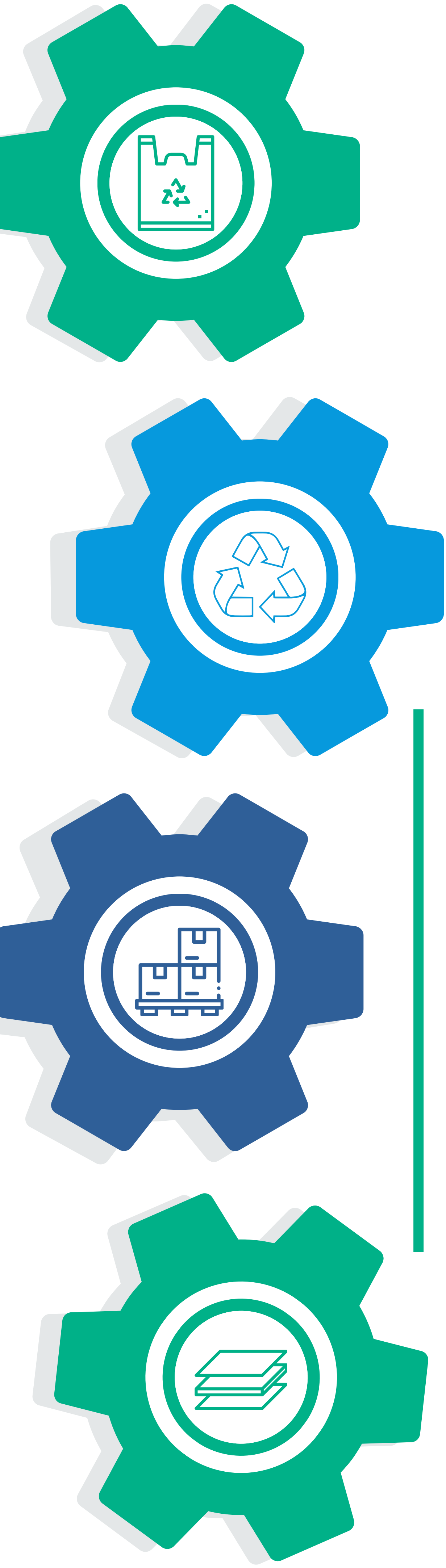


PRIORITIZING ECODESIGN PRINCIPLES: A SYSTEMATIC APPROACH TO ECODESIGN

AT THE ALLIANCE TO ZERO

Enabling Net Zero Pharma Products

Contents

1 Introduction

Did you know that up to 80% of a product's environmental impact is determined during its development[1]?

At the Alliance to Zero, we tackle this challenge through Ecodesign, an approach that integrates environmental considerations into product development, balancing ecological and economic needs[2].

In practice, this means adhering to a set of "Dos and Don'ts" throughout the design process,

allowing us to create products that are not only safe for patients but also sustainable for the planet.

The suitability of Ecodesign principles varies depending on the product, its application, resources available, and timelines.

While strategies like "Design for Reuse" or "Closed-loop Recycling" require significant system changes, others can be applied quickly to existing products for immediate sustainability improvements.

At the Alliance to Zero, we are committed to **long-term, transformative change** while simultaneously embracing **fast and effective** immediate improvements.

As a collaborative effort across all our member companies[3], eleven potential incremental Ecodesign principles for an automated disposable injector device were identified.

To ensure these Ecodesign principles are systematically prioritized and implemented, we have evaluated the various Ecodesign principles based on their **ease of implementation** and their **impact on the Product Carbon Footprint (PCF)**[4].

As can be seen in Figure 1 below, "Replacement With Bioplastics", "Open-loop Recycled Content", and "Increase Recyclability", and "Packing Density Optimization" have been identified as our **priority principles**, meaning that they are relatively easier to implement while having a high impact on the PCF of an automated disposable injector device.

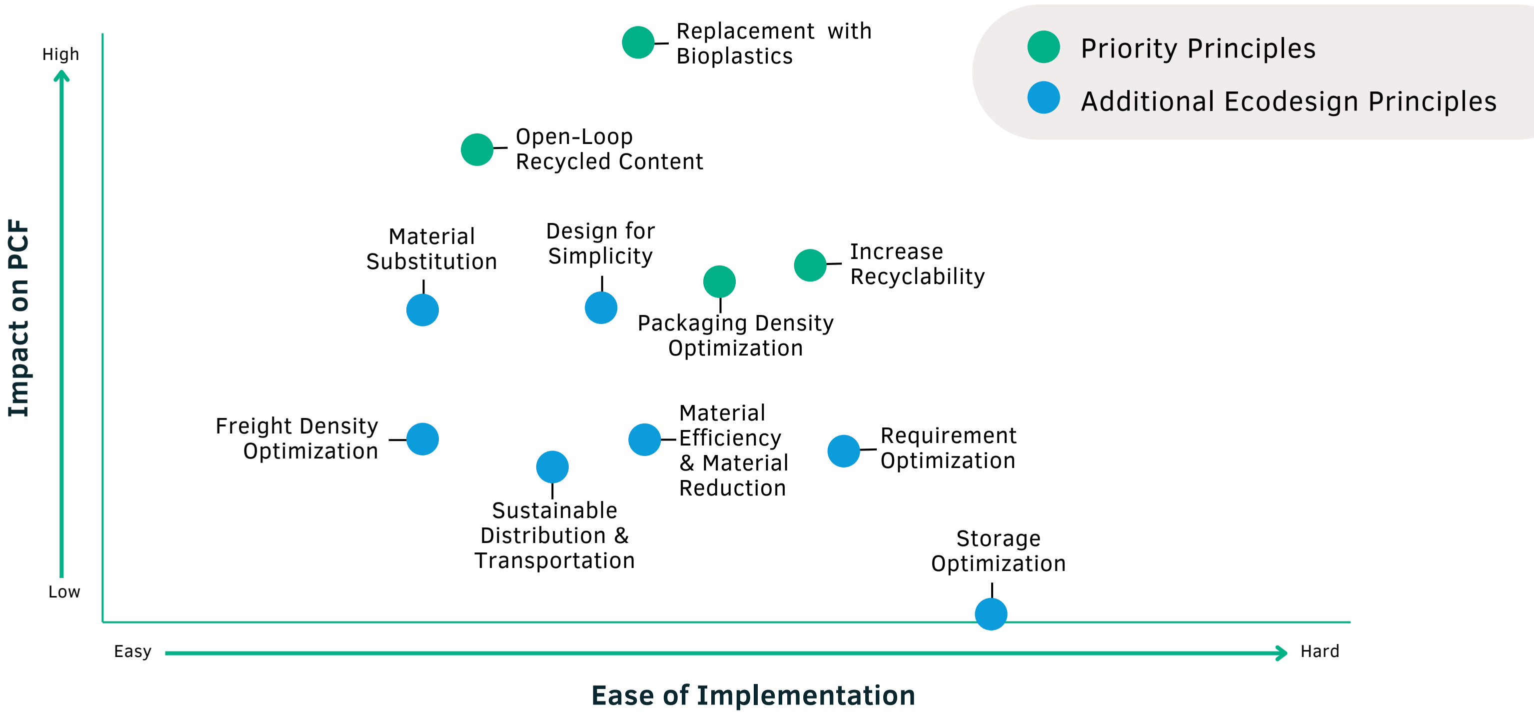


Figure 1: Ecodesign priority principles according to ease of implementation and impact on the PCF.

2 Priority Ecodesign Principles

The following **four Ecodesign principles** were identified as the top priority based on their high impact on the PCF of an automated disposable injector device, and their relative ease of implementation.

2.1 Replacement with Bioplastics

According to the definition by European Bioplastics, which is adopted by most countries, bioplastics encompass a broad range of materials that are either bio-based, biodegradable, or both.[5]

	Non-Biodegradable	Biodegradable
Bio-based	Bioplastic	Bioplastic
Fossil-based	Conventional plastic	Bioplastic

Table 1: Different types of bioplastics. Source: European Bioplastics[6]

Bio-based implies that the plastic is derived at least partially from **biological matter**. Depending on the source, bio-based feedstocks are classified into **different generations**, from 1st to 4th generation.

Biodegradable plastics represent a relatively small subset of bioplastics that **decompose into carbon dioxide, water, and biomass** through the natural action of microorganisms (European Commission, 2024). **Biodegradability is generally unsuitable for medical devices** due to the presence of drug residues, frequent attachment to needles, and potential contamination. Components in direct contact with patients or medications can be classified as medical waste, requiring incineration by many European public health agencies and national governments[7].

Many of the technical plastics can be produced as bio-based polymers using a mass balance approach without changing their chemical composition and thus without changing any properties. This makes a switch much easier as biocompatibility testing does not have to be repeated. From an ecological perspective, the production of bio-based plastics conserves fossil resources compared to traditional plastics. Additionally, under favorable conditions, bio-based plastics can offer a lower carbon footprint.

To avoid negative environmental impacts and reduce waste, feedstock should not be sourced from first generation crops but waste biomass or by-products from other processes e.g. tall oil, bio-methanol from composting, waste cooking oils. Conducting a life cycle assessment (LCA) on a case-by-case basis is essential to verify whether a particular bio-based plastic is more sustainable than its fossil-based counterpart.

2.2 Open-loop Recycled Content

According to the European Waste Framework Directive, recycling is:

> **"any recovery operation by which waste materials are reprocessed into products, materials or substances, whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and reprocessing into materials that are to be used as fuels or for backfilling operations".** [8]

Plastic recycling can be categorized into two main types: **mechanical** and **chemical**. While all forms of recycled plastics help reduce waste, not all offer significant CO_2 savings due to very high energy consumption.

Mechanical Recycling

Mechanical recycling reprocesses plastic without altering its chemical structure, typically through shredding, washing and sorting. It is most effective for pre-sorted, uncontaminated rigid plastics and is the most environmentally friendly and economical recycling method.

However, due to strict pharmaceutical regulations, mechanically recycled materials cannot be used for the primary packaging which is in direct contact with the drug. Recycled content is accepted for components which come into contact with the patient as long as the material fulfills biocompatibility requirements.

Currently only selected inner component parts of the injection device are using recycled material.

Chemical Recycling

Chemical recycling breaks down plastic into its chemical building blocks through thermochemical, depolymerization, and solvent-based technologies. Outputs range from pyrolysis oil to monomers.

While chemical recycling is more versatile and arguably easier to implement in the Pharma industry, particularly pyrolysis is very energy intensive and therefore less CO_2-efficient than mechanical recycling.

However, emissions related to chemical recycling could decrease in the future due to improved efficiency and renewable energy adoption.

2.3 Increase Recyclability

Recyclability refers to how efficiently a material can be **processed and reused** after its initial use, primarily determined by the material's composition.

For instance, paper and cardboard can be recycled up to seven times[9], while plastics are classified by the Resin Identification Code (RIC) from 1 to 7, with lower numbers typically indicating more recyclable plastics. [10]

Addressing common recyclability challenges can help preserve the material's initial recycling potential:

1 Avoid composites

Composite materials, such as laminates, reinforced materials (e.g., fiberglass), coated materials (e.g., ETFE, PFAS), or compounds (e.g., PC&ABS) are difficult or impossible to recycle.

2 Promote material harmonization

Using fewer types and colours of materials reduces contamination of recycling streams, improving recycling quality. This also included labels made from materials different from the item they are attached to. Material harmonization also simplifies waste handling, increasing cost efficiency.

3 Ensure easy separation

When multiple materials are necessary, they should be easily separable. For instance, this can be achieved by differing densities (e.g., PET bottles with HDPE caps) or employing magnetic metals. Adhesives and welding should be avoided, and components such as electronics or contaminated parts must be designed for easy detachment.

4 Avoid hazardous substances

It is critical to minimize the use of hazardous additives to mitigate risks to the environment and human health.

5 Limit dark colors and markings

Single-colored, light or translucent components facilitate easier recycling, whereas dark markings and large-scale printing can degrade the quality of recycled materials.

6 Ensure material identification

Materials should be clearly marked, utilizing the Resin Identification Code (RIC) when applicable and special attention must be given to the identification of hazardous substances.

Notably, **recyclability** and **recycling rate** are related, yet distinct, concepts. Recyclability refers to a material's inherent capacity to be recycled, while the recycling rate measures the extent to which this potential is realized, varying based on regional infrastructure and practices. **Recyclability remains constant, whereas the recycling rate is context dependent**.

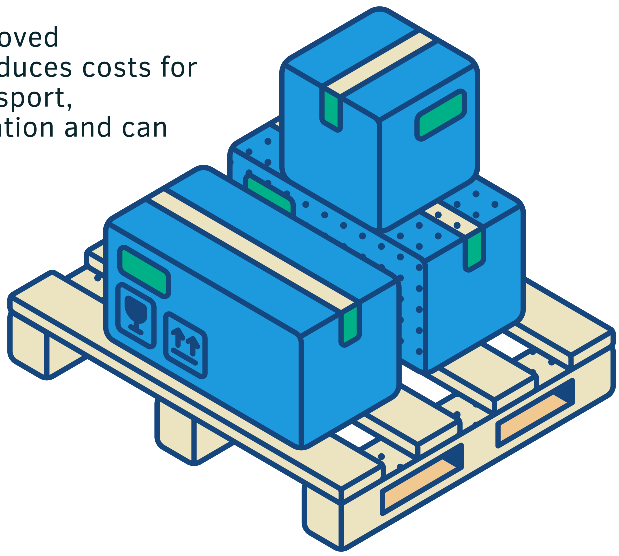
2.4 Packing Density Optimization

Considering the technical requirements, the number of products packed in the secondary and tertiary packaging should be optimized to the maximum.

Reducing packaging materials and space per transported item lowers carbon emissions, both by directly reducing material use and enhancing process efficiency in areas such as sterilization, transportation, warehousing and cooling.

As an added benefit, improved packaging density also reduces costs for packaging materials, transport, warehousing, and sterilization and can improve handling.

For syringes, which are part of the injection devices, blister-free packaging, a collaborative effort by Alliance to Zero members, offers a unique opportunity to optimize packaging density.



3 Additional Ecodesign Principles

In addition to the four priority Ecodesign principles outlined above, additional Ecodesign strategies suitable for an automated disposable injector device are identified below.

However, due to their higher complexity in implementation and/or their relatively smaller impact on the overall PCF, these strategies will be prioritized **only after the principles above have been fully integrated**.

3.1 Design for Simplicity

Designing the injection device with the necessary precision while keeping it as simple as possible is recommended. For instance, internal components may not require aesthetic features like smooth finishes, and the inclusion of electronics should be carefully assessed, particularly in single-use devices. When electronics are necessary, minimizing PCB size, using a single layer to reduce copper consumption, and avoiding hazardous materials such as mercury and cadmium in batteries are beneficial. Rechargeable batteries could reduce waste, and ensuring electronic components can be easily separated for repair and end-of-life treatment is advantageous.

In general, simplifying designs leads to fewer components, reduced resource consumption and easier disassembly and recycling, contributing to more efficient manufacturing and sustainable disposal. Moreover, simplicity can enhance user-friendliness and support correct usage and disposal.

3.2 Requirement Optimization

At the beginning of a development project, customer requirements are translated into a set of technical requirements, including detailed acceptance criteria and other product-specific functionalities. It shall always be questioned whether the customer requirements are well thought through or whether an attempt should be made to re-discuss and make them leaner.

For instance, by increasing the tolerance for cosmetic defects, both costs and emissions[2] can be reduced. Furthermore, safety precautions should always be questioned, especially when internal technical requirements are stricter than customer requirements.

3.3 Material Substitution

When technically and economically feasible, switches to lower-emission materials are recommended. Certain materials can offer clear environmental benefits while being able to fulfill the same function. For example, polypropylene (PP) has a significantly lower carbon footprint (CO_2e) than polyoxymethylene (POM), as its emissions across its lifecycle, from extraction to disposal, are lower.

Additionally, PP's lighter weight reduces transport emissions. Further reasons for material substitution for environmental reasons include considerations such as ozone depletion, acidification, resource depletion, and recyclability. For instance, PP is much easier to recycle than PS. Additionally, substituting materials to reduce overall material consumption or variety can also offer clear sustainability advantages.

3.4 Material Efficiency & Material Reduction

Materials should be durable enough for their intended use, while using as little material as possible to achieve this. Replicating past designs, though convenient, can overlook more efficient alternatives. Therefore, optimizing designs to reduce material usage should always be considered.

For example, replacing paper booklets with QR codes saves paper and using techniques like strength optimization can optimize design while minimizing material thickness. Reducing part count and combining components can streamline designs, while filling simulations help optimize manufacturing and minimize waste.

3.5 Sustainable Distribution & Transportation

The environmental impact of transportation modes is influenced not only by the type of vehicle used but also by the specific transport context. While electric and hydrogen-fueled vehicles are the most sustainable options for short distances, railway and waterborne transport are more appropriate for longer hauls, with air transport being avoided whenever possible. In general, the ‘local for local’ principle can be used in strategic planning for products to be manufactured where they will be distributed. Recognizing that the overall carbon footprint is influenced by a number of factors[11], emphasizes the need for precise data and analytics to optimize logistics and minimize environmental impact.

Freight Transport Emissions in Germany (g CO_2eq per tonne-kilometer)

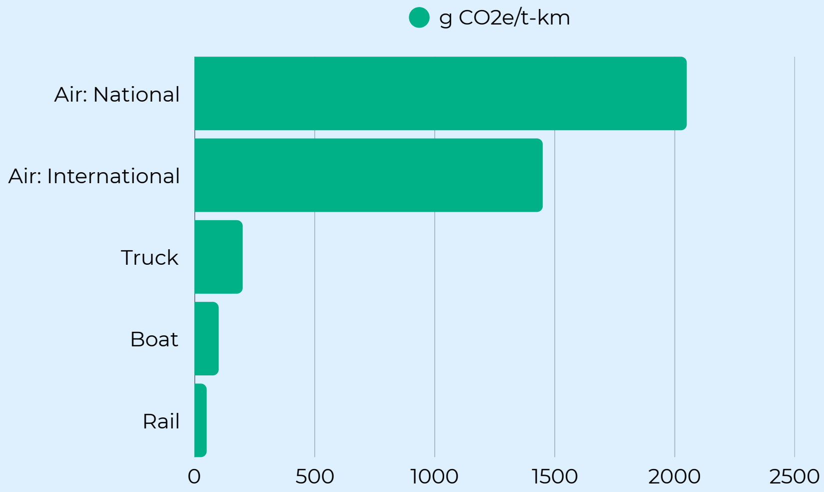


Figure 2: The impact of different modes of freight transport in Germany. Data sourced from the Umweltbundesamt.[11] The figure takes into account the tank-to-wheel usage emissions, well-to-tank energy emissions, vehicle provisions, infrastructure provisions and additional climate impacts of air traffic. Rail travel emissions are based on the average electricity mix in Germany.

Indirectly, employing lighter-weight packaging and increasing packaging density enhances efficiency during transport. Reusable transport materials, such as EPAL or HDPE pallets, can have a lower environmental impact than single-use alternatives, making their consideration not only sensible from an environmental but also an economic perspective. When evaluating pallet usage, it is essential to take reverse logistics into account.

3.6 Freight Density Optimization

Similar to increasing packaging density, carbon emissions can be reduced by maximizing the amount shipped per square meter of a transport vehicle. This necessitates the optimization of both tertiary packaging and vehicle configurations. Important considerations include ensuring that packaging is designed for efficient stacking and minimizing void spaces. Furthermore, data-driven load optimization strategies can contribute to improving logistics efficiency. Overall, a comprehensive approach to freight density not only supports sustainability goals but also enhances operational efficiency and cost-effectiveness.

3.7 Storage Optimization

Incoming goods are delivered from the suppliers and stored until they are used in manufacturing. The delivery should be just in time so that storage is as short as possible. This way, energy and space can be saved. It should also be near the machines, so the internal transport is as short as possible.

4 Conclusion

These Ecodesign principles were ranked for an automated disposable injector device. Every product is different, and the prioritization of the Ecodesign principles will be different depending on location and context. Furthermore, this paper only focuses on incremental changes of existing applications, not system changes such as designing for reuse or remanufacture which would have a very high impact and should be considered for new product developments.

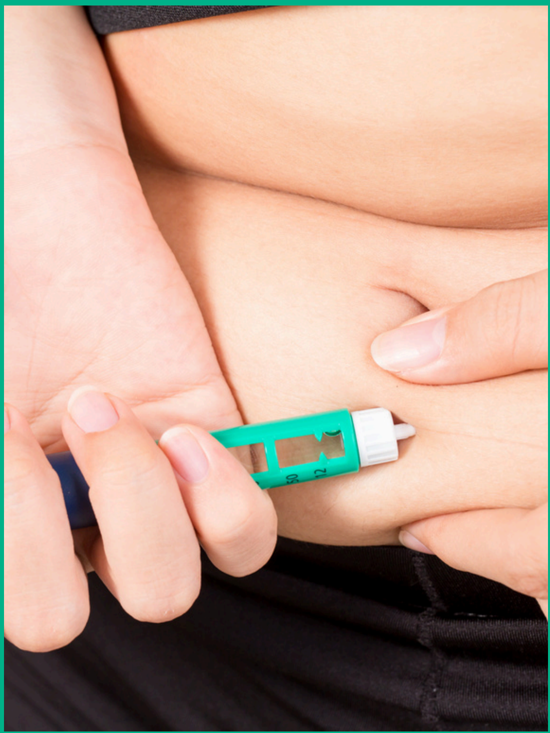
There will always be an optimal combination of a few Ecodesign principles. It is important to weigh up different options in the development process and decide which changes take priority – what will have the highest impact on a large-scale or when considering the full lifecycle of a product. As with all development, this is a work-in-progress, continually adapting and improving future iterations.

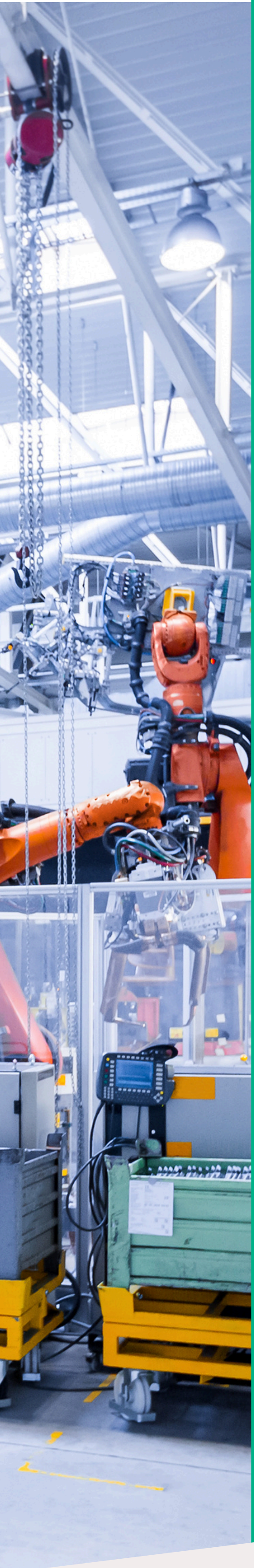
The Alliance to Zero have a paper which concentrates solely on the Ecodesign principles for machinery coming soon.

We believe the key to more sustainable design is in collaboration and education. Each stage of the value chain cannot just exist in isolation, and a key part of Ecodesign is creating holistic solutions that benefit multiple stakeholders; internally, externally and industry-wide.

The work undertaken by the Alliance to Zero has shown that **collaboration between suppliers can reduce the carbon footprint substantially**, from internal transport between component manufacturers to creating reusable trays for production to secure blister-free packaging solutions.

For more information, connect with the Alliance to Zero **here**.





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