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Machinery Regulation and Remanufacturing: A Link Between Machinery Safety and Sustainability

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Abstract: On 14 June 2023, the European Parliament adopted Regulation (EU) 2023/1230 on machinery, which entered into force on 19 July 2023 (with some exceptions as per art. 54, according to a corrigendum issued to address a clerical error as regards the application dates in the original version) and shall apply from 20 January 2027, replacing the Machinery Directive 2006/42/EC. The main innovations/differences introduced by the Machinery Regulation (MR) compared to the Machinery Directive (MD) are critically analysed here, with a focus on sustainability issues. Some of these issues are covered by several international standards (such as BS 8887, ISO 10987 or DIN 91472), which also define the criteria and requirements for the remanufacturing process, although some technical gaps remain. Using the example of agricultural machinery, this paper proposes a methodology for determining the areas of acceptability for remanufactured products: these are expressed in terms of structural performance (e.g., the number of cycles ahead to failure expressed as the mutual of damage $1 - D = 0.625$) and the functional and safety requirements of the original machine. In this way, the issue of "substantial modification of machinery" is explored in terms of the safety obligations that the remanufactured machinery must fulfil. The paper is therefore a contribution to circular design by providing general criteria for the extension of the service life of machinery while at the same time considering safety issues.

Keywords: remanufacturing; machinery regulation; safety; sustainability; structural performance; machine design; second-life product

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1. Introduction

On 14 June 2023, the European Parliament and the Council formally adopted and published the new Regulation (EU) 2023/1230 on machinery (the Machinery Regulation, MR), which will be applicable starting 20 January 2027. The new MR repeals the Machinery Directive (MD) 2006/42/EC and transforms it into a regulation. While directives (such as the MD) require Member States to achieve a specific objective (for both the MD and MR, these objectives primarily refer to safety and health), they leave it to the national legislature to decide how to achieve it. A regulation, on the other hand, is directly applicable in the same way across all Member States upon its entry into force, eliminating any modifications or different interpretations by Member States, thereby removing ambiguities in its transposition, increasing legal certainty, and eliminating trade barriers for machinery between Member States.

Despite this, the MR, like the MD before it, contains a series of references to harmonized technical standards to provide a more practical guide for designers in creating a "safe" machine. These technical standards (generally not mandatory) offer designers a highly useful guideline for solving the various design issues ("how") posed by meeting the various requirements ("what"), which are described in general (but not vague) terms. The MR is an evolution of the MD and clarifies several concepts that were implicit in the MD or required proper interpretation, reflecting developments in the field over the past two decades. One of these concepts is that of "substantial modification", which in this work is analysed from a remanufacturing perspective, interpreted and understood from a mechanical design standpoint.

The regulation, as will be further elaborated in the following sections, addresses the topic of machine modification and defines a modification as substantial if it affects the machine's safety level. In such cases, the regulation mandates the addition of devices or protective measures to restore the machine's safety levels. When this definition is applied in the context of remanufacturing, safety levels must be evaluated through an accurate assessment of the condition of the components, allowing their structural performance to be compared with that of an equivalent new component. Imagine that a new "device" (substantial modification) is added to a machine, or that the same machine is fitted with a previously used "device": by applying the criteria in this paper, it would be possible to determine when the used device should be considered as a substantially modified.

It should be noted that the scope of the MR (like that of the MD) does not cover all possible machinery; a list of specific exclusions is provided to define its applicability. Nonetheless, its scope is very broad (it also includes "interchangeable equipment", "safety components", and "partly completed machinery"), and, in this work, it is focused on agricultural machinery, excluding tractors, which follow a homologation process according to Regulation (EU) 167/2013 for their commercialization. Agricultural machinery, on the other hand, according to the MR (and currently the MD), follows the methodologies of the so-called New Approach directives, which began in the mid-1980s.

The paper is structured as follows: after an introduction about remanufacturing—from both process and product design perspective—and the Machinery Regulation, it delves into the concept of substantial modification along with the interpretation provided by the sector's regulations concerning the "as-new" condition; in Section 2, the methodological framework for evaluating the usability conditions of a remanufactured component is proposed and organized, based on the required structural performance; in Section 3, a conceptual application of the methodology is applied and presented in a case study in the field of agricultural machinery; in Section 4, conclusions and further developments are discussed.

1.1. Remanufacturing

Sustainable development plays a primary role in national and European Union (EU) policies. The EU has approved the Climate Law, aiming to reduce greenhouse gas emissions by at least 55% by 2030 and achieve climate neutrality by 2050. As outlined in the "European Green Deal: Circular and Climate-Neutral Manufacturing" and the "2030 Agenda for Sustainable Development", the economic and environmental sustainability of manufacturing (both European and national) must be achieved through technological enhancement and the transition of the manufacturing/production sector towards genuinely circular models, characterized by environmental neutrality and minimized dependence on natural resources [1]. In this context, remanufacturing plays a crucial role as a strategy for minimizing the environmental impact of the production cycle of goods and contributing to the gradual shift from linear to circular production. Gunasekara et al., in their attempt to develop a comprehensive business model for automotive part remanufacture, underscored the significant sustainability contributions of remanufacturing. Across their studies, the authors report that remanufacturing can achieve energy savings of up to 60% and reduce greenhouse gas emissions by approximately 70% compared to traditional manufacturing processes. These savings underscore remanufacturing's alignment with circular economy principles by extending product life cycles, reducing reliance on virgin materials, and preventing significant amounts of waste from reaching landfills. The authors also address the economic sustainability of remanufacturing, highlighting cost advantages for both producers and consumers. Remanufactured products are often priced at 40–80% of the cost of new ones, making them economically viable while maintaining quality standards equivalent to new items [2,3]. Xia and Zhang analysed the impact of authorized remanufacturing on environmental sustainability and the manufacturing/remanufacturing supply chain. Authorized remanufacturing facilitates collaboration between original equipment manufacturers (OEMs) and third-party remanufacturers, ensuring a reduction of environmental impacts by up to 80% compared to new products while also saving 50–70% on raw materials, energy, and costs [4].

To confirm and enhance these beneficial effects, a more robust regulatory and directive framework is essential. An industrial regulatory system that is both cross-cutting and sector-specific, with unified guidelines, can increase business opportunities, ensure the quality and safety of remanufactured products, and, in turn, foster consumer confidence. Without standardization, remanufacturing (and, more generally, the second-life use of structural components) will not be able to fully exploit its theoretical potential, which, according to European Remanufacturing Network (ERN) forecasts, is expected to triple by 2030, reaching an overall value of EUR 100 billion in Europe while remaining confined solely to the aftermarket and used parts sectors [5].

1.1.1. Definitions

There are numerous definitions of remanufacturing. Essentially, these definitions describe a process in which a product, having reached the end of its life cycle, is recovered and reintroduced into an industrial process aimed at restoring its functionality, performance, and reliability to a level equal to or even greater than that of an equivalent new product, and then reintroduced to the market with a warranty that is at least equivalent to that of the original product. This is achievable because, unlike other practices such as reconditioning, repair, and reuse, remanufacturing requires the complete disassembly of a product and the verification of each of its components before it is reassembled.

The following are definitions of remanufacturing provided by the main industry standards:

- British Standard 8887-220:2010 [6]: a series of steps necessary to transform a used product (with at least one life cycle) into one that can be considered new, having at least the same performance and warranty as the equivalent new product.
- DIN 91472, June 2023 [7]: the highest quality value-retention process at the component level. It also defines some characteristics of a remanufactured product:
- The product of a reconditioning process is considered new;
- A reconditioned product has at least the same functionality and performance as the original product;
- A reconditioned product always comes with a standard market warranty;
- A reconditioned product can be composed of restored components from different used parts, as well as new components;
- Through hardware and software updates, a reconditioned product can reach a technical level that exceeds the applicable technical standard in place when the reconditioned product was first marketed;
- ISO 10987: Part 2–2017 [8]: a process that must restore a core, understood as a product at the end of its life, to a condition that is as good as new or better, in terms of both quality and performance.

1.1.2. The Process: Phases and Requirements

For these definitions to materialize, it is necessary for a product, once it has reached the end of its life cycle and has been recovered, to undergo a series of operations. The exact type and sequence of phases will naturally depend on the type of object being processed. However, particularly with regard to mechanical systems, a remanufacturing process can be generalized according to the following phases, as shown in Figure 1 [9]:

1. Identification and Sorting: The recovered cores are registered to determine their product identity. The used parts are evaluated and classified based on their product identity, overall quality level, or the effort required for reconditioning.
2. Disassembly: This involves breaking down a complex product into all its individual parts, enabling all subsequent operations. In some cases, from this phase onward, components lose their traceability, and the origin of the core is no longer maintained. The components are treated uniformly and are randomly reintroduced into the final reassembled product.
3. Washing and Cleaning: The disassembled components are cleaned of (foreign) substances accumulated during their use.
4. Inspection: Components that continue through the process are analysed using visual inspections or non-destructive testing to assess their condition. This phase is crucial as it determines the health status of the parts and whether they will proceed in the process.
5. Restoration: This phase involves components that require the restoration of specific properties and specifications. The main operations include general repairs, surface grinding and finishing, restoration of geometries, and removal of surface cracks. These operations mainly involve material removal, which results in some alteration of the original specifications, which should, where possible, be balanced by the other components.
6. Reassembly: This phase replicates the original assembly process. The individual recovered and restored components, now available on the shelf, are integrated with new parts and pass through the entire assembly line as a new product, ensuring compliance with the same requirements.
7. Functional Testing: The finished and assembled product undergoes functional testing to ensure that the reassembled components operate correctly and that the performance of the assembly matches that of a new product.

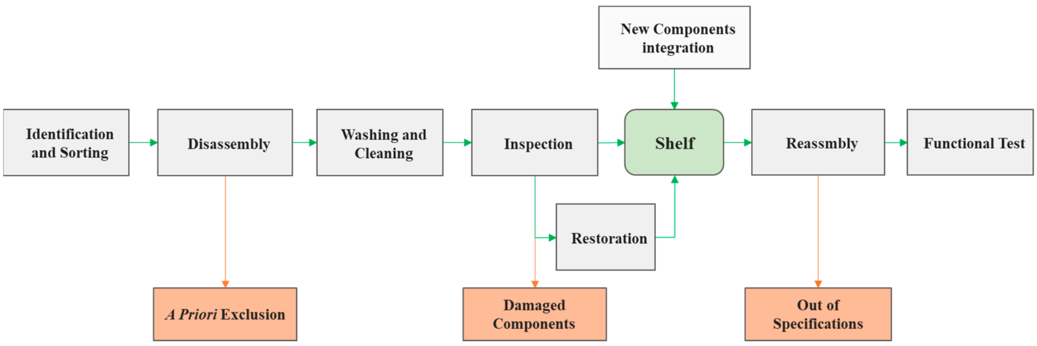

Figure 1. The remanufacturing process of a mechanical product.

Recent studies highlight the importance of optimizing remanufacturing processes for improved efficiency and sustainability. Wang et al. propose mathematical and heuristic models to optimize scheduling across key stages, such as disassembly, reprocessing, and reassembly, reducing processing time and delays, particularly in complex systems [10]. They also emphasize energy-efficient strategies, like the "Turn Off and On" approach, which lowers energy consumption by up to 6.68% during machine inactivity. This approach is particularly relevant to energy-intensive stages such as disassembly and reprocessing. By integrating these strategies into hybrid algorithms, their work demonstrates how remanufacturing can achieve both environmental and economic benefits, reinforcing its value for scalable and sustainable operations [11].

The findings from these studies underline the necessity of adopting advanced models and strategies to enhance the efficiency of remanufacturing processes. As the demand for remanufacturing grows, integrating such innovative approaches into the process framework will be essential for achieving scalable and sustainable operations.

1.1.3. The Remanufactured Product: Classification, Characteristics, and Design

At the end of the remanufacturing process, the result is a product that, in general, has been assembled according to the assembly specifications of its new equivalent. When analysing the remanufactured product at the component level, in the broadest possible sense, it is an assembly composed of three categories of elements, whose definitions are presented in Table 1 [12].

Table 1. Categories of components in a remanufactured product.

Component	Description
New/Replaced	Single component, identified at the industrial level by a unique part number, which has had no prior life cycle
Restored	Single component, identified by a unique part number and recovered from a non-new assembly, which has thus undergone at least one operational cycle and been subjected to any treatment aimed at restoring damage
Used/Reused	Single component, identified by a unique part number and recovered from a non-new assembly, which has thus undergone at least one operational cycle. It is not subjected to any operation that alters its condition before being reintroduced into the assembly

For an assembly to be defined as "remanufactured", it must be composed of at least one non-new component, whether used or restored. This work focuses on the third category of components in the table, for which accumulated damage, due to technological, economic, or simply process-related reasons, may not be traceable. It should be noted that, in the context of remanufacturing, when a device replaces a new one and this device contains a component with accumulated damage in a structural part, this replacement represents, potentially, a substantial modification, as it reduces the material's residual resistance capacity. In such cases, it is necessary to ensure that the machine's safety level is not compromised by the reused component.

In this context, the Machinery Regulation represents the most suitable legislative tool for this purpose: through specific harmonized standards, guidelines could be provided to ensure that remanufactured machine components have the same safety levels as new ones, thus allowing their use in one or more subsequent life cycles.

To fuel such a circular and sustainable industrial mechanism, products must be designed, analysed, and processed with circularity in mind. The criteria necessary for a product to be successfully remanufactured and introduced to the market are described by William Hauser and Robert Lund, based on twenty-five years of research in the remanufacturing industry [13]:

- Existence of technology to restore the product: the technology must be capable of extracting a component without damaging it [14];
- Availability of interchangeable standard parts;
- The cost of the core is low relative to the savings achieved on the product's cost due to the reuse of the end-of-life product;
- The product's technology is stable for more than one life cycle.

These concepts are visually represented by Hollins' "Remanufacturing Engineering Potential" model, shown in Figure 2, which illustrates a range within which parameters align to make remanufacturing feasible. The model demonstrates that the potential for remanufacturing depends on three key parameters:

- The intrinsic value of the core and its individual components.
- The rate of product evolution.
- The ability of the item to be recovered and processed.

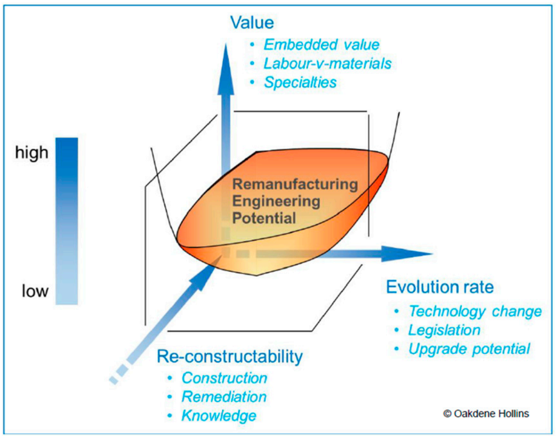

Figure 2. Remanufacturing feasibility space as a function of product attributes.

According to Nick Morley, who proposed this model in 2006, design (understood as the choice of design) significantly influences aspects of the product's evolution rate and its reconstruction potential [15]. It is intuitive to recognize that the intrinsic value of a product and its components depends, among other factors, on how they were designed and then manufactured. Thus, even for the product's value concept, design dependency becomes essential.

Certain product properties can positively or negatively affect remanufacturability, and the importance of Design for Remanufacturing (DfRem) is endorsed by industry representatives, such as the Automotive Parts Remanufacturing Association (APRA) [16]. Since certain product characteristics influence their suitability for remanufacturing, some types of products are particularly suited to this practice. In summary, typical products considered remanufacturable to date are those that:

- Have a slow rate of technological evolution.
- Are durable enough to withstand multiple life cycles.
- Have a relatively long lifespan and retain residual value over time.

Recoverability, the possibility of non-destructive disassembly, parts standardization and technological availability, which relate more to joining and connection methods and the restoring of a component, are fundamental aspects of the DfRem practice [17,18]. In addition to these, what is highlighted in this article is the structural integrity and durability of the products that are to be processed, with all the uncertainties related to this particular aspect. Structural assessment is a fundamental aspect of the product and must be integrated into the objectives of design for remanufacturing, as various references in the literature have noted. Wu et al. (2015) explored the use of Remaining Useful Life (RUL) assessment to estimate the residual structural strength of components in large construction machines. Through crack growth analysis, using Linear Elastic Fracture Mechanics (LEFM) models and Finite Element (FE) simulations, the results support decisions on the feasibility of reintegrating components for a second life. This approach presupposes that a crack initiation has been monitored, allowing the residual life to be established through an FE model and compared to the operational life of the component [19]. Bhandari and Jung (2022) studied the structural stability of grinding machinery for remanufacturing. Using FE simulations to evaluate resistance in technological recovery applications, the researchers found that chrome plating significantly improves durability and abrasion resistance. This type of restoration, analysed and intended for reintegration in remanufacturing, allows structural performance like the original, making it suitable for components with high structural stability and reliability requirements [20]. Regarding restoration to original conditions, Xue et al. (2019) demonstrated that combining laser cladding with Six Sigma analysis can significantly improve the quality of regenerated components, ensuring that they meet original specifications for strength and durability. Their study analysed how design variables influence the strength of a shaft after applying a regenerative coating layer. This approach allows for optimizing coating parameters to ensure that the regenerated component can withstand operational stresses effectively, enhancing durability and ensuring performance comparable to a new component [21]. In the case just described, structural evaluation was combined with technological restoration operations for the components. However, a different approach is discussed by Zhou et al. (2014), who, based on the concept that remanufacturing requires that parts maintain a good recoverability state at the end of their life cycle, propose a proactive method for regenerating mechanical components, taking their structural characteristics into account. The authors introduce the concept of "proactive remanufacturing" as an approach that predicts and anticipates the optimal time for regenerating a component, optimizing the overall durability and performance of the product. This methodology uses a remanufacturability index, the Proactive Remanufacturing Factor f_{AR}, which considers various structural parameters to avoid premature or delayed regeneration, both of which are economically disadvantageous. The f_{AR} is calculated as a comprehensive index measuring a component's overall "remanufacturability", assessing the component's suitability for optimal regeneration from both economic and technological perspectives. The f_{AR} is calculated by analyzing a component's design characteristics, considering their influence on its ability to be effectively recovered at the end of its life cycle [22]. The method proposed by the authors highlights and confirms an important concept: the remanufacturability of a product depends on its design characteristics, and more specifically, its structural characteristics. However, this factor remains valid only in contexts where the structural property can be restored through a technological intervention. In other cases, especially those involving direct reintegration of mechanical components for a second life, this factor may not be sufficient to determine the suitability of the component for reuse, particularly if the final product's overall performance must reach like-new levels.

Following this general, interdisciplinary, and by no means exhaustive review of product aspects integrated into design for remanufacturing, it is essential to emphasize a concept related to the goals of this practice from a machinery construction perspective.

Based on bibliographic research and case study analysis considerations, it is evident that the success of remanufacturing is closely linked to a product's ability to endure over time. As confirmed by the ERN, the need for a durable and reliable product is the most common requirement among industries involved in the analysis, followed by ease of disassembly and the use of durable and valuable materials [23]. This capability, given that technological interventions are not always possible, strongly depends on the sizing and material selection made during the initial design phase. Furthermore, analysing failure mechanisms is a fundamental step to identify critical issues that compromise an object's operational lifespan, making it essential for design optimization.

What appears to be missing within the current scientific, industrial, and regulatory landscape on this topic is the ability to assign to a component/product, which has reached a certain point in its first useful life, a classification or designation for second use based on its operating conditions, design technique, and reliability and safety requirements. DfRem should be interpreted not only as a discipline aimed at integrating process requirements into the component/product during the initial design phase (and so equipping a product with features that enhance its remanufacturability) but also as a technical practice capable of determining the suitability, in terms of health/damage status, of an existing component that has already undergone operational use, and with that the end of life (EOL) destinations of single parts of an assembly. This is particularly critical in cases where such an assessment cannot be determined through observation and the suitability of a machinery can be assessed with criteria applicable both to existing components and to future product developments, and it must not compromise its safety, which remains the foremost priority for manufacturers and those guiding industrial processes, as well as for meeting the safety certification requirements imposed by regulations.

1.2. European Regulatory and Directive Framework

As previously mentioned, this work connects two particularly sensitive aspects concerning industrial production, specifically machinery: environmental sustainability and safety. These topics, both addressed from the perspective of mechanical construction and design, are primarily discussed here with a regulatory approach and referencing standards and directives to highlight gaps or points of intersection on which to develop the proposals presented in this article.

1.2.1. The Substantial Modification in the MD and MR

The principle of "substantial modification of machinery" is implicitly present in the current MD. In fact, according to the guide for the application of the MD [24], the MD also applies to machines based on used machinery that have been transformed or rebuilt so substantially as to be considered new machines. Furthermore, any modifications made to a new machine, even before it is put into service, if substantial (e.g., a modification of the machine's function and/or performance) and not foreseen or agreed upon with the manufacturer, will result in the invalidation of the original CE marking. The entity that made these modifications must therefore carry out a new risk assessment in accordance with the MD regarding the changes made. In this case, the party making the modifications is considered as the manufacturer and is required to fulfil all the obligations set forth by the MD [25].

It is therefore clear that introducing a "substantial modification" to a machine results in such a change that the machine is considered as if it were a new machine and thus subject to a new conformity assessment under the MD. Consequently, it is particularly important to define when a modification should be considered substantial. Having that in mind, the new MR clarifies and explicitly defines the concept of "substantial modification" and what it entails in relation to risk assessment and the resulting obligations.

The definition of "substantial modification" is provided in point 16 of Article 3 of the MR as follows: "A modification of a machine or related product, by physical or digital means, after such machine or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which impacts the safety of the machine or related product by creating a new hazard or increasing an existing risk, and that requires:

(a) the addition of guards or protective devices to the machine or related product, an operation that necessitates modification of the existing safety control system, or
(b) the adoption of supplementary protective measures to ensure the stability or mechanical strength of such machine or related product."

Therefore, according to Article 18 of the MR, a natural or legal person who makes a substantial modification to a machine or a related product is considered a manufacturer and is subject to the obligations of the manufacturer for that machine or related product. The objective is to ensure that the machine or related product affected by the substantial modification complies, in all cases, with the applicable essential safety requirements [26].

1.2.2. Protective Measures Against Mechanical Risks

The second conceptual element emphasized in this article concerns a specific Essential Health and Safety Requirement (EHSR), outlined in Annex III (Essential health and safety requirements for the design and construction of machines or related products—Protective Measures Against Mechanical Risks—Risk of Failure During Operation) which states:

> "Machine components or related products, as well as their connecting parts, must withstand the stresses they will be subjected to during use. The materials used must exhibit sufficient resistance characteristics suited to the intended environment specified by the manufacturer, particularly regarding fatigue, aging, corrosion, and abrasion".

This point in the Regulation establishes and clarifies a fundamental principle: the risk of failure of a structural component is associated with a potential safety hazard. Therefore, the design of a machine must ensure that the required structural performance for the specific application is met for the second-life application.

1.2.3. Functionality, Performance, and Warranty of the Remanufactured Product: The "As-New" Condition

The premise of this study is that, from an engineering perspective, a remanufactured product/component, or more generally one in its second life, to be considered equivalent to a new product, must guarantee, for at least a second (or generally n-th) life cycle, performance that is:

- For the same application: at least equal to the equivalent new component in terms of efficiency and reliability for at least the same duration as the first service life (the service life estimated during the design phase, not the actual service life, which will depend on real conditions).
- For "downgraded" applications: at least equal, again in terms of efficiency and reliability, to a new product/component for the new application for which it is intended.

Based on these considerations, Table 2 presents the interpretations and guidelines provided by the main technical standards (some of which have already been mentioned) in the field of remanufacturing at the international level, concerning the interpretation and guidelines for the "as-new" condition.

Table 2. "As new" definition in the main Remanufacturing Standards.

Standard	"As New" Definition	Criteria
BS 8887-220:2010 [6]	The Remanufacturing process must transform a used product into an "as-new" product, with performance and warranty at least equivalent to a new one, including and detailing the various process phases to be followed (including inspection) and the component treatment options to restore its "as-new" condition: - Functional remediation; - Cosmetic remediation; - Replacement.	The proposed criterion for verifying the performance of the component/product is through an inspection and functional testing during the process.
DIN SPEC 91472:2023-06 [7]	- The product of a remanufacturing process is a new product; - A remanufactured product has at least the same functionality and performance of the original product; - A remanufactured product is always provided with a standard market warranty; - A remanufactured product can be composed of restored components of several used parts, as well as new components; - By means of hardware upgrades and software updates, a remanufactured product can be brought to a technical level that exceeds the technical standard applicable when the remanufactured product was placed on the market.	The criterion for a product to be defined as remanufactured and therefore "as new" with at least the same quality and performance as the original, is that the product has undergone all the phases of the process described in the standard itself.

Table 2. *Cont.*

Standard	"As New" Definition	Criteria
ISO 10987:2–2017 [8]	The ISO standard related to the remanufacturing of earth-moving machinery uses the expressions "like new" or "better than new". A reconditioned product is one that, after undergoing the process, is restored to a "like-new" or "better-than-new" condition in terms of both quality and performance. These conditions may include design improvements for reconditioning that are compatible with the original design. Reconditioning must be carried out only by the original equipment manufacturer (OEM) or its affiliates or by a formally authorized entity. The remanufacturer must ensure that all safety improvement programs have been completed.	No criteria are defined to establish the performance and quality level of an item. However, although the standard refers to "like-new" conditions, it states that the remanufactured product must be marketed as "remanufactured".

Given that this article addresses the issue of structural safety with reference to the Machinery Regulation, which is a European regulation, it was a deliberate choice to focus solely on European (or ISO) technical standards. These standards were selected for their potential integration into the Machinery Regulation to address and support the practice of remanufacturing.

1.2.4. Criticalities, Research Gap, and Research Question

The critical issue observed and highlighted in this study is that, although the regulations and standards on remanufacturing agree that a product undergoing such a process should and can be considered as new, there are fewer guidelines on the criteria to be adopted for verifying this condition: once again, the "what" is specified but not the "how". Moreover, there is no indication of the performance criteria being referenced, and one might question whether structural performance can always be verified through inspection or non-destructive testing. In relation to the structural performance of the components within an assembly, it is also fair to ask whether ensuring the quality and performance of the product/component can be achieved merely by demonstrating and assuring compliance with the process.

The introduction of the Machinery Regulation within the context of remanufacturing is suggested as an interpretative and analytical tool to ensure the compatibility of remanufactured products with the intrinsic requirement of the "remanufactured product" definition: "like new". This requirement, in fact, must also be met in terms of the structural performance of a product, which is intrinsically linked to the safety of machinery as outlined in EHSR 1.1.3 of the MR.

The gap that this article aims to address focuses on two key aspects:

- The current regulatory framework: The lack of explicit guidance in existing regulations concerning the structural integrity and safety compliance of remanufactured components.
- Structural performance assessment in the literature: In existing studies, the structural performance of mechanical components is evaluated primarily through observation, non-destructive testing, and load history. However, in most real-world remanufacturing applications, these elements are not known or cannot be reliably traced.

This paper argues that the assessment of damage, in preparation for remanufacturing, must be conducted based on the design model with which the component was originally engineered. This approach ensures compliance with EHSR 1.1.3 of the MR and guarantees that the component, when integrated into the assembly, does not compromise the overall safety level of the machinery.

In the absence of predefined technical requirements and acceptance criteria for components, the "as-new" condition of the remanufacturing process seems to be taken as an assumption: how, then, can the safety level of a remanufactured product be scientifically established and assessed without precisely knowing the condition of its components?

Although the current regulatory framework, as formulated, may be well suited for verifying and satisfying requirements related to a product's functionality, it is deemed insufficient for addressing its structural requirements, as these are often not verifiable through non-destructive means. Given that the structural performance of a machine component (and, more generally, of a structural element) is intrinsically linked to safety, the following sections will propose an approach based on constructing acceptability domains for a mechanical element intended for remanufacturing. This approach will be based on the type of structural performance required and the criteria used during its design.

2. Materials and Methods: Definition of Acceptability Domains for Structural Components and Machinery

The fundamental principles and calculation methodologies of design are encompassed within a comprehensive regulatory framework. For this study, reference was made to the Eurocodes, specifically to the standard EN 1990:2023 [27] and EN 1993 series [28,29], which describe the principles and requirements for safety, functionality, and durability of steel structures. Both are based on the concept of the limit state, used in conjunction with the partial factor method (or semi-probabilistic method). EN 1990 also provides guidelines for structural reliability aspects related to safety, functionality, and durability. According to the Eurocodes, a structure must be designed to have adequate levels of durability, reliability, and safety. The use of Eurocodes in this context is not intended as a mandatory standard but rather as a representative guideline that demonstrates how structural criteria can be systematically defined and applied. The authors acknowledge that this choice can be expanded and tailored to specific applications.

The first necessary step in formulating a methodological framework for the evaluation and acceptability of mechanical components used in a second life is to differentiate the performance of a product into functional and structural categories. The former includes all the performance factors related to the purpose for which a generic product is designed, such as power, torque, energy efficiency, and so on. In almost all cases, these performance factors can be verified, directly or indirectly, at the end of the assembly line through specific non-destructive functional tests that determine whether the functional performance is equivalent to that when the same object was initially produced. Structural performance, on the other hand, pertains to all performance aspects related to failure prevention, which ensures that the structure and all its components can perform the intended function without failure for at least a certain period and with a certain level of reliability. Structural performance is intrinsically linked to the safety of structures since the failure to meet structural requirements can result in hazardous conditions. For this class of performance, non-destructive testing techniques are limited in their ability to accurately determine the integrity of a used component at the time of its reuse in a remanufactured product. This technological limitation necessitates an evaluation criterion for residual capacity that considers the design model with which a given component was originally designed and, if possible, determines the load history it experienced during its previous service life.

For this reason, the proposed approach includes, as its second main element, the categorization of the structural performance of a generic structural component or machine element, along with the respective verification criteria, as reported in Table 3.

Table 3. Structural performance and respective verification criteria.

Performance			Criteria	Standard
Static Strength	In the absence of damage		$\sigma_{ED} \cdot \gamma_P \leq \frac{f_y}{\gamma_M}$	EN 1993 1-1 [28]
	In the presence of damage	SIF criterion Energetic criterion	$K_I \leq K_{ICR}$ $\left\lvert \frac{dU}{da} \right\rvert \geq \frac{dW}{da}$	
Fatigue Strength	Fracture Mechanics	Paris Low	$\frac{da}{dN} = C(\Delta K)^m$ à $a \leq a_{cr}$	EN 1993 1-9 [29]
	High-Cycle fatigue (Stress Life)		$\Delta\sigma_{E,2} \cdot \gamma_{Ff} \leq \frac{\Delta\sigma_L}{\gamma_{Mf}}$	
	Cumulative Damage Fatigue	Palmgren–Miner Damage Model	$D_d = \sum_i \frac{n_{Ei}}{N_{Ei}} \leq 1$ $\Delta\sigma_{E,2} \cdot \gamma_{Ff} \leq \sqrt[m]{D_d} \cdot \frac{\Delta\sigma_C}{\gamma_{Mf}}$	
Surface Fatigue Resistance (Surface Shear Resistance)			$p_{max} = \frac{2F}{\pi b l} \leq S_c$	
Creep			$\varepsilon_{tot\ creep} \leq \varepsilon_{lim}$	ISO-899-1-2017 [30]
Instability			$N_{Ed} \leq N_{b,Rd} = \frac{\chi \cdot A \cdot f_y}{\gamma_{M1}}$	EN 1993 1-1 [28]
Structural Reliability			$p_f \leq p_{fmax}$	EN 1990 [27]

The acceptability of a machine component that has already undergone one life cycle, with respect to its potential reintegration into an assembly that will be defined as "remanufactured", depends on its ability to meet both functional and structural requirements. Since requirements such as residual strength, service life (understood as the number of cycles before failure), and the reliability of an assembly depend on those of its individual parts, it follows that the "as new" definition must be satisfied by each individual part. Based on the categorization of component types in Table 1 for a remanufactured assembly, Table 4 presents the possible structural conditions for the three categories of components.

Table 4. Performance verification.

Component	Performance Verification
New/Replaced	Performance satisfied by definition.
Restored	It has accumulated damage (detectable or non-detectable) during operation. The accumulation of damage inevitably reduces structural performance, which, in this case, is fully restored (at least theoretically) through a technological intervention (repair, load reversal, grinding, etc.).
Used/Reused	May have accumulated damage (detectable or non-detectable) during operation. Any accumulated damage will reduce structural performance.

The potential accumulation of damage in a mechanical component, and consequently its residual structural performance, depends on the way it was designed and falls into two main categories:

- Infinite Life Design. This category includes products or individual parts designed to last indefinitely under nominal operating conditions. These products are usually subjected to loads well below their maximum capacities to ensure long life and safety. For all such products, if the verification/design rule provided by the standard is valid for the initial use, and if all the parameters and variables of the criterion remain unchanged over time (e.g., if the geometries and dimensions have not changed, there is no surface corrosion, and the chemical properties of the material have not changed), from an engineering standpoint, there is no reason to believe that the criterion would not be verified again in its second life with the same result. The semi-probabilistic approach used by the standards, which relies on safety factors to account for uncertainties related to design variables, can still be valid for the verification of the second life cycle. If the result is positive, it ensures, by definition, infinite life under the given operating conditions. From the perspective of the probability density distributions of load and strength, there is no reason to assume that the nominal values of load and strength would change over time.

- Finite Life Design. This category includes products designed for operating conditions where damage accumulation is unavoidable or for which a specific number of load cycles or a defined period of use is expected before showing signs of deterioration or failure. A significant portion of mechanical applications inevitably lead to the degradation of residual properties (strength, number of cycles, reliability, etc.) of machine components. For this type of application, the scientific literature's models and standards (where available) help estimate the time-dependent decrease in residual properties, and the verifications (or design) will necessarily be valid within a certain finite time interval.

Since, under certain operating conditions, for $t \geq t_0$, the initial structural properties (in t_0) will necessarily decrease over time, to assert that a second-life component can have the same performance as a new one, it is advisable to establish thresholds that define Acceptability Domains for Remanufacturing, or more generally, for reuse. Expressing this concept qualitatively, conditions such as those presented in Table 5 can be utilized. Although in a qualitative manner, formalizing the issue of the suitability of structural components for reuse in this way allows for the consideration of all possible options that may occur at the industrial level concerning the origin or destination of a remanufactured item.

Table 5. Acceptability domain definitions.

Condition of Structural Properties	Acceptability Criterion
$\sigma_{lim}(t_0) \geq \sigma_{lim}(t)$	$Acceptability\ Threshold \leq \frac{\sigma_{lim}(t)}{\sigma_{lim}(t_0)} \leq 1$
$N(t_0) \geq N(t)$	$Acceptability\ Threshold \leq \frac{N(t)}{N(t_0)} \leq 1$
$R(t_0) \geq R(t)$	$Acceptability\ Threshold \leq \frac{R(t)}{R(t_0)} \leq 1$

In these scenarios, the numerator represents the residual capacity (e.g., residual strength), which can vary as greater or less than the value estimated during the design phase when the component has operated outside the intended operating conditions. The distinction between "greater" and "less" relates to the loading history experienced by the component during its operation: a more severe loading history results in a "lesser" residual property, while a less severe loading history results in a "greater" residual property compared to the estimated value. The denominator, on the other hand, represents the residual capacity evaluated at the time of commissioning and takes on values that fall within the cases presented in Table 6. Such an approach, although demanding in terms of validation for identifying appropriate acceptability thresholds or their combinations, provides a high level of flexibility and specificity when evaluating individual cases based on specific applications.

Table 6. Possible case values.

	Value
Numerator	Equal to the theoretical value expected if the component has operated within the intended operating conditions Different (either greater or less than) from the value estimated during the design phase if it has operated outside the intended operating conditions
Denominator	Equal to the theoretical value estimated during the design phase for the operating conditions foreseen in the original application → like new, original Equal to the theoretical value estimated during the design phase for the operating conditions foreseen for a different application → like new, "downgraded"

3. Discussion and Considerations on the Agricultural Sector

A particularly representative sector for remanufacturing practices is that of heavy-duty industrial, agricultural, and earth-moving machinery (Heavy Duty Off-Road). In recent decades, this sector has experienced significant growth in the implementation of techniques and processes aimed at recovering components that have reached the end of their life cycle, reconditioning them, and reintroducing them to the market through aftermarket channels and warranty services. This industrial methodology allows manufacturers to offer a more economical and high-margin alternative on the market, with a reduced environmental impact, ensuring component availability even in periods and geopolitical conditions that are not particularly favourable. Remanufacturing applied to agricultural machinery is an increasingly understood and accepted option that is well suited to relatively simple and robust structures made predominantly of metallic materials, which are characterized by a high rate of recoverability, recyclability, and remanufacturability.

Since a specific feature of the agricultural sector is the operation of machinery beyond what would normally be considered its service life, it becomes necessary to manage, from the perspective of the MR, elements reintroduced for a second life or those constituting a substantial modification, which have an impact in terms of performance and safety requirements. This also occurs because, aside from the significant cost considerations, agricultural operators, being familiar with the productive and functional capabilities of their machinery, tend to prefer it over a new one, even if the latter is much more productive and advanced.

An example of an application case from this sector is the mechanical transmission for tractors, combine harvesters, and, in general, agricultural harvesting machinery, produced by CNH Industrial Spa and remanufactured by FPT Industrial Spa. Figure 3 shows the data over time on the introduction to the market of machinery equipped with this transmission and of the transmission itself as a spare part separately introduced to the market. This graph allows us to observe, based on a real industrial case, the lifespan of this type of product and the market trend towards using remanufactured products.

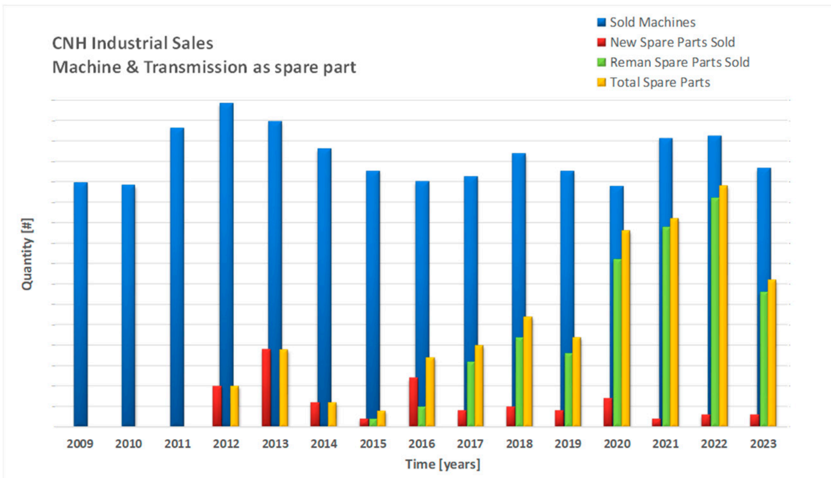

Figure 3. Sales trend of the machinery and its corresponding transmission.

Quality data show that the first replacement of the transmission, from the time the vehicle is produced, occurs on average after about nine years, with average machine working hours of 6000.00 h and a maximum that can reach the 18,000.00 h. Excluding an initial peak in spare parts demand, likely related to defects in the early production runs of the machinery, the sales trend (both for machinery and transmission spare parts) seems to confirm this figure, as the trend between machinery sales and spare part sales shows a shift of approximately ten years. As can be observed, the demand for replacement transmissions, which were initially available only as new parts, has been almost entirely replaced by demand for remanufactured transmissions since 2015, the year when remanufacturing was implemented by CNH EMEA.

The mechanical transmission in question, with a total weight of approximately 700.0 kg, performs the following functions:

(1) Transferring power, torque, and rotational motion from the engine to the traction system (axles and wheels).
(2) Transferring power, torque, and rotational motion from the engine to the hydraulic pump for the load handling system.
(3) Bearing function of the machine: it is an integral part of the machine's frame.
(4) Providing sufficient inertia to stop moving parts within the time limits imposed as a safety requirement of the machine.

Focusing on the product details, Table 7 provides a list of the main categories of components that make up the transmission, along with relevant information related to their entry into the remanufacturing process and their structural requirements. A preliminary analysis of the structural requirements and the ability of the assembly's elements to meet these requirements is crucial.

Table 7. Main categories of transmission components.

Category	Entry into the Process	Rejection Rate	Structural Requirements
Bearings Blocking Elements Sealing Elements	Excluded a priori	100% 100% 100%	Operating under High Level of Surface Stress → Highly Worn
Gears Shafts Hydraulic Systems	Recovered	37.0% 53.4% 50.0%	Fatigue Design → Finite Life
Housing and Covers	Recovered	20.0%	Fatigue Design → Infinite Life

The categories of components that do not enter the remanufacturing process, consisting mostly of highly critical elements and those subject to high wear (polymeric material elements, small parts, etc.), represent no more than 10% of the total mass of the transmission. For the remaining 90%, the mass surpasses the disassembly phase and proceeds into the process. It is clearly during the inspection phase, where the state of damage and specification compliance are verified, that the remaining components will either be discarded or reintroduced into the final product depending on the detected damage.

Main components of the transmission, such as shafts and gears, are by definition subjected to cyclic fatigue loads, making damage accumulation inevitable. Therefore, together with the inspection, these elements should be treated according to the relationship between residual and initial performance, as outlined in Table 5.

To further evaluate the accumulated damage and structural performance of the components that enter the remanufacturing process, a detailed analysis can be conducted based on operational data. The mechanical transmission under study is characterized by the following data:

- An average first life cycle of 9 years before being recovered for remanufacturing;
- The machinery operates for an average of 6000 working hours, with a peak of more than 18,000 working hours;
- Average rotational speed of approximately 600 revolutions per minute (rpm) for the transmission components.

Under the assumption that the maximum working hours represent the maximum capability for the transmission components that operate under fatigue conditions, it is possible to calculate first of all the maximum number of cycles ahead to failure at the starting service time $N(t_0)$ and the average number of cycles ahead to failure at the average return time $N(t)$ for the transmission rotating elements during their first life cycle. They can be estimated as follows:

$$N(t_0) = \textit{Rotational Speed}\ (\text{rpm}) \cdot \textit{Max Working Time}\ (\text{min}) = 600\ \text{rpm} \cdot 18,000\ \text{h} \cdot 60 = 5.76 \cdot 10^8 \text{cycles}$$

$$\begin{aligned} N(t) = N(t_0) - \textit{Rotational Speed}\ (\text{rpm}) \cdot \textit{Avg Working Time}\ (\text{min}) = N(t_0) - n(t) \\ = 5.76 \cdot 10^8 - 600\ \text{rpm} \cdot 6000\ \text{h} \cdot 60 = 5.76 \cdot 10^8 - 2.16 \cdot 10^8 = 3.6 \cdot 10^8 \text{cycles} \end{aligned}$$

where $n(t)$ represents the effective average number of cycles performed by a generic rotating element of the transmission. The gears and shafts, which are subjected to cyclic fatigue loads, inevitably experience damage accumulation over this life cycle. Using the Palmgren–Miner rule for cumulative fatigue damage, this can be assessed:

$$D = \frac{n(t)}{N(t_0)} = \frac{2.16 \cdot 10^8}{5.76 \cdot 10^8} = 0.375$$

First of all, it is possible to verify if this cumulative damage is still acceptable according to the Palmgren–Miner Damage Criteria reported in Table 3. For the remanufacturing purpose, the components must meet the acceptability thresholds, qualitatively outlined in Table 5, ensuring their structural performance remains within safe operational limits, in this case:

$$\textit{Acceptability Threshold} \leq \frac{N(t)}{N(t_0)} = 1 - D = \frac{3.6 \cdot 10^8}{5.76 \cdot 10^8} = 0.625$$

For components that show damage exceeding the threshold, so for lower values, restorative operations such as surface treatment, grinding, or material deposition may be required, when available, to restore structural integrity. In other cases, replacing the component with a new one or designating it for a less severe application should be considered.

Conversely, the situation is different for covering elements (e.g., casings, covers, housing), which are typically oversized relative to operating requirements and are subjected to loads with low variability. These elements can be considered capable of maintaining their initial structural performance for an indefinite lifespan. Furthermore, the analysis confirms that the structural integrity and reliability of the transmission are consistent with "as-new" conditions, providing a robust foundation for second-life applications.

Taking into account the previous functions of the transmission and assuming it is used in a combine harvester, which falls within the scope of the MR, by way of example (but not limited to), the EHSRs listed in Annex III of the MR that could be indirectly affected by the remanufacturing process of the transmission are [10]:

- 1.1.3 Materials and products, where the first paragraph states that "materials used to construct machinery or related products, or products used or created during its use, shall not endanger the health and safety of persons". Therefore, attention must be paid to the health and safety risks for operators or other exposed individuals, including during maintenance, due to contact with such materials or, for example, due to hazardous substances that could be released from these materials when overheated, disturbed, or subject to wear.
- 1.3.2 Risk of break-up during operation, with reference to the first three paragraphs. Specifically, the first paragraph states that "the various parts of machinery or related products and their linkages shall be able to withstand the stresses to which they are subject when used". In this regard, it is necessary that all machine elements, including the transmission in question, are constructed to withstand breakage during operation by using suitable materials and by designing and manufacturing the components and assemblies to endure the stresses they will be subjected to during activity. In certain cases, harmonized standards provide specifications regarding the materials, design, construction, and testing of specific critical machine elements. In other cases, these requirements can be met by adhering to established engineering practices and principles.

The second paragraph states that "the durability of the materials used shall be adequate for the nature of the working environment foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion". In this case, the remanufacturing process of the mechanical transmission must also consider the conditions under which the machine's manufacturer expects it to be used during its various phases of existence. Some operating conditions may compromise the strength of certain materials and assemblies, such as an extremely hot or cold environment, corrosive atmospheres, or the presence of moisture. For example, in such situations, excessive rotational speed can pose a risk of breakage, which must therefore be avoided. To this end, it is necessary to refer to the machine's manual to determine the usage conditions for which it was designed and the associated limits. Where fatigue is a significant factor, it is essential to consider the expected lifespan of the machine and the nature of the functions it is intended to perform, thus determining in advance the number of operational cycles to which the remanufactured transmission will be subjected during its lifespan.

Lastly, the third paragraph requires that the manufacturer indicates in the instruction for use "the type and frequency of inspections and maintenance required for safety reasons. They shall, where appropriate, indicate the parts subject to wear and the criteria for replacement". Accordingly, it is necessary to verify that the information provided in the machine's instruction for use is still compatible with the characteristics of the remanufactured transmission and with the specified inspection and maintenance intervals, where provided.

- 3.3.3 Travelling function, with reference to the first paragraph, which states that "without prejudice to road traffic regulations, self-propelled machinery and its trailers shall meet the requirements for slowing down, stopping, braking, and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for". Therefore, the remanufactured transmission must not alter the original travel functions of the machine in order to maintain the machine's compliance with this EHSR.

4. Conclusions and Future Developments

Remanufacturing is confirmed as a key strategy for achieving the sustainability and climate neutrality goals set by the European Union. Sustainability is an intrinsic concept of remanufacturing. The recovery and reuse of a mechanical component in its second life, and its reintroduction into the market, result in reduced amounts of newly processed materials and lower energy consumption, along with the associated reductions in environmental impact. However, significant challenges remain in defining, especially at the regulatory level, clear technical criteria for assessing the structural capacity and related safety levels of structural components with at least one service life, particularly when it comes to ensuring their strength and reliability over time. Safety remains a priority and crucial aspect to be guaranteed when machinery is put into service, which is why the integration of remanufacturing practices with the requirements of the MR could form the basis for a solid regulatory framework that ensures remanufactured products not only comply with sustainability standards but also maintain safety levels equivalent to those of new products, thereby expanding the applicability potential of second-life components. This work, starting from this principle, aims to emphasize that the sustainability of the process must not, especially in the practice of remanufacturing, compromise the structural integrity and reliability of an assembly. In other words, the recovery of a machine component, with its associated environmental benefits, must be carried out provided that the structural capacity of both the individual component and the entire assembly is equally ensured. This paper highlights the need to develop methodologies for analysing structural requirements based on design models, verification of technical standards, and essential safety requirements, and, where possible, knowledge of an item's load history. Approaching the issue of remanufacturing and, more generally, the second-life reuse of mechanical components, damage accumulation requires criteria based on threshold definitions that establish acceptability domains, ensuring that remanufactured products fully meet functional and structural safety requirements, preventing the risk of failure or accidents.

Identification and Discussion of Research Results

This research identifies and evaluates the cumulative damage and structural integrity of key components in a transmission for agricultural applications, using a combination of operational data and theoretical models. Through the analysis of operational conditions, it was determined that the transmission components, including shafts and gears, are subjected to cyclic fatigue loads. Using the Palmgren–Miner rule for cumulative fatigue damage, the study calculated an average damage value of D = 0.375 after a first life cycle of an average of 6000 working hours, corresponding to approximately 216 million cycles. This result corresponds to a number of cycles ahead-to-failure ratio of 0.625, which expresses the potential of restoring these components to "as-new" conditions, ensuring compliance with structural performance requirements.

The study identifies the key categories of components that either enter or are excluded from the remanufacturing process, as summarized in Table 7:

- Gears: Recovered with a rejection rate of 37% and evaluated under fatigue life constraints.
- Shafts: Recovered with a rejection rate of 53.4%, requiring careful assessment of accumulated damage.
- Housing and Covers: Retain an infinite fatigue life due to their oversized design and low variability in load conditions.

The research emphasizes the importance of verifying that remanufactured components comply with the EHSR outlined in the MR. Specific requirements, such as 1.1.3 (Materials and products) and 1.3.2 (Risk of break-up during operation), were identified as critical benchmarks.

This research highlights that remanufacturing, when performed with a focus on structural integrity, can ensure that components meet the "as-new" condition, balancing sustainability goals with safety requirements. The cumulative damage assessment provides a quantitative basis for evaluating component suitability, while the analysis of essential safety requirements establishes a clear connection between remanufacturing practices and regulatory compliance. These findings emphasize the potential of remanufacturing in reducing environmental impact, extending the life cycle of mechanical components, and aligning with the EU's sustainability and climate neutrality goals. However, this study also identifies challenges, such as the need for standardized methods to define acceptability thresholds and integrate these into a robust certification system to ensure safety and reliability.

Looking ahead, the identification of precise and specific threshold values for individual applications and the standardization of a certification system that places safety at the centre of the remanufacturing process could further strengthen the confidence of companies, end consumers, and legislators in remanufacturing.

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Nomenclature

EU	European Union
MR	Machinery Regulation
MD	Machinery Directive
EHSR	Essential Health and Safety Requirements
DfRem	Design for Remanufacturing
OEMs	Original Equipment Manufacturers
ERN	Europear Remanufacturing Network
EOL	End of Life
RUL	Remaining Useful Life
LEFM	Linear Elastic Fracture Mechanics
FE	Finite Element
BS	British Standard
DIN	Deutsche Industrie Norm
ISO	International Standard Organization

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