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Towards a sustainability-oriented development of biointelligent products

Surya Mächtlen[a,c], Yannick Baumgarten[a,*], Alexandra Müller[b], Jörg Woidasky[c], Robert Miehe[a]

[a]*Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Nobelstrasse 12, 70569 Stuttgart, Germany*
[b] *Wageningen University & Research, Droevendaalsesteeg 4, 6708 PB Wageningen, The Nethderlands*
[c]*Pforzheim University of Applied Sciences, School of Engineering, Tiefenbronner Str. 65, 75175 Pforzheim, Germany*

* Corresponding author. Tel.: +49-711-970-1957. E-mail address: yannick.baumgarten@ipa.fraunhofer.de

Abstract

A sustainable and safe satisfaction of needs can be expected to be achieved through so-called biointelligent systems, resulting from the convergence of life, engineering, and computer sciences. In the context of product design, two fundamental challenges emerge. First, the integration of living elements represents a component that has been largely absent from traditional development processes. Second, a variety of additional challenges arise to ensure contributions to sustainability, resulting from its multidisciplinary nature, e.g. miscommunication, various methodological approaches or conflicts of objectives. Therefore, a product development process that integrates biology, technology and informatics while considering sustainability aspects from the outset is becoming necessary. Given that existing sustainable product development concepts like Design for Sustainability or Ecodesign primarily refer to conventional product development methods, addressing sustainability in the development of biointelligent products poses a novel challenge. This work aims to propose a "Design for Biointelligence" framework by elaborating conceptual thoughts on a sustainability-oriented guideline for the development of biointelligent products. As a result, we state that a biointelligent product integrates biological and technical parts, transmits information through interaction between these parts and promotes sustainability. Through a case study of a biointelligent sensor system, potential challenges associated with developing biointelligent products were identified and conceptual thoughts on a guideline were elaborated.

Keywords: Product Development, Biointelligence, biological transformation, sustainable and safe product design

1. Introduction

With progressive global warming, ongoing population growth and increasing resource consumption, sustainability is becoming a core management topic [1–5]. Sustainable development balances present needs with those of future generations by integrating economic growth, social equity, and environmental protection. Conversely, unsustainable practices prioritize short-term gains, leading to irreversible harm such as climate change and environmental degradation [5, 6]. The United Nations emphatically states that the "survival of our societies and […] shared planet depends on a […] sustainable world" [6]. The European Union (EU) is developing strategies to achieve climate neutrality by 2050 through the European Green Deal [7]. According to Miehe et al. [8] a sustainable and resource-saving satisfaction of needs is achievable through a biological transformation of manufacturing and energy systems [3, 9, 10]. The third mode of this transformation – "biointeraction" – describes the interaction of information technology, biotechnology, and production technology, resulting in so-called "biointelligent systems". Intelligent biosensors are an example as they form interfaces between biology, engineering and information technology [2, 11, 12]. To embed and anchor sustainability in the concept of biointelligence, Miehe et al. [3] expand on their original definition by concretizing biointelligence through the introduction of an explicit understanding, mainly focusing on the technological aspects at the micro level and an implicit

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understanding. The latter refers to a new framework that follows the premise of doing “no harm to people and the environment” [3] and is intended to manage the complexity of sustainability by questioning traditional approaches.

For the concept of biointelligent manufacturing, comparable initiatives and concepts can be found globally: The Israel Innovation Authority [13] emphasizes the fusion of engineering, software, and biotechnology, referred to as "bioconvergence", especially in the health sector. This term is also embraced by companies such as BICO [14]. The US-based BioMADE platform [15], targets innovation, education and collaboration in bio-industrial manufacturing to generate novel sustainable materials. The Advanced Regenerative Manufacturing Institute [16] promotes a bioeconomy in manufacturing, healthcare and education.

Biointelligence and its related concepts offer opportunities for sustainable value creation in the industry and open up new fields of innovation [9]. For the design of biointelligent products, it is necessary to map biology, technology, and computer science in an integrative development process [3]. Considering sustainability aspects as early as possible in the process by taking a holistic view of the product life cycle helps enhance positive environmental effects and reduce negative impacts [17]. An early example of the need to expand the scope of life cycle accounting in the context of manufacturing systems is shown by Full et al. [18, 19]. Current sustainable development concepts primarily refer to conventional product development approaches, making the consideration of possible sustainability effects of biointelligent products largely new [3]. Furthermore, sustainability contributes to the complexity of design processes [20]. This work focuses on the question if the development of biointelligent products requires a guideline that combines development methods of engineering, biology, informatics, and sustainability. Supporting research questions are:

- What is a biointelligent product?
- What are the challenges that arise from the development of biointelligent products with regard to sustainability?
- What product development methods exist in the field of sustainable product development, and how can their relevant parts be integrated into a sustainability-oriented guideline for biointelligent product design?

The work was conducted within the project "BioProS" (number 101070120), funded by the EU within the Horizon Europe program [21, 22]. The project's objective is to develop a biointelligent sensor to measure viral activities in the production of advanced therapeutics [23]. This provides a practical use case for the evaluation of the guideline that will be published in a subsequent article.

The research commenced with a literature analysis on sustainability and the development of sustainable products. Results from the literature analysis were consolidated for use in later workshops. These workshops involved 25 academic and industrial experts from different areas, such as biology (n=13), engineering (n=6), information science (n=2), and sustainability (n=4). Seven workshops, two with Fraunhofer IPA internal experts and five with BioProS project partners were conducted. Workshops loosely followed the concept presented by Unterauer [24], aiming to collectively define requirements for a product development guideline, emphasizing “what” the current challenges in the development of biointelligent products are and “how” solutions for the guideline may look like. Further literature research followed each expert workshop to deepen the knowledge of the topics shared during these workshops.

2. State of the art of sustainable product development

Not only are requirements for products themselves changing rapidly, but the increasing complexity of products makes product development more difficult [25, 26]. A product development process describes how a series of small and precisely defined steps with clear interfaces, lead from ideas to a finished product [27]. This enables model-based planning of a later physical product, which allows for forward-looking, decisive considerations of the product properties. The development and construction process maps the product characteristics through models and data. Design serves as a bridge between humans and nature, considering functionality, cultural values, and sustainability [28].

Sustainable design aims to balance human well-being with environmental concerns, challenging traditional design methods to adapt to increasing complexity and sustainability requirements [29, 30]. Notably, 80 % of a product's environmental impact is determined at early design stages, highlighting the pivotal role of designers in sustainable growth by creating environmentally friendly products [7, 17, 31]. As of today, sustainability is an integral part of design knowledge, making designs “more efficient, effective, reliable […] [as well as] energy efficient, reusable, and recyclable with fewer wastes and harmless environmental impacts” [28]. A wide range of tools regarding sustainable product design and development, as well as integrated frameworks for life cycle engineering have been developed [32, 33]. Since the 2000s, increasingly radical approaches such as Design for Sustainability (DfS) have been practised [28, 34]. Today, Design for X (DfX) covers a range of strategies like Design for Circularity, where the X is replaced by a directional term, here, a concept for the Circular Economy, a rather holistic approach [35–37]. However, DfX approaches only focus on aspects to be included in already existing product development processes, such as checklists or environmental design criteria as from Vezzoli [38], without forming an integrated approach. Popular product development approaches such as the V-model (VDI 2206) or stage-gate do not inherently consider sustainability [39–41]. This leaves developers without a clear action plan on how to implement these approaches in their product development. However, ongoing research such as the "Design for Circularity Industry" project, aims to approach this issue by incorporating design rules depending on product characteristics into a product development process in the context of the circular economy and the energy transition [42].

Concerning sustainability in the biotechnology sector, the Safe-and-Sustainable-by-Design (SSbD) framework is increasingly relevant, Following its successful implementation in nanotechnology and chemical industries [43–45]. The essence of SSbD is to proactively identify risks and challenges in the early design stages, adopting a responsible research and innovation approach keeping the 17 Sustainable Development Goals of the United Nations in mind [46–50]. This involves asking critical safety and sustainability questions, covering the entire value chain of bioprocesses. Similarly, Herrmann et al. emphasize the importance of taking a systematic and life cycle approach in regard to the biological transformation [51]. In addition, Miehe et al. presented the idea of a holistic framework called "design for biointelligence" which is illustrated in Fig. 1. The scope of design intervention starts with specific products and extends to socio-technical systems.

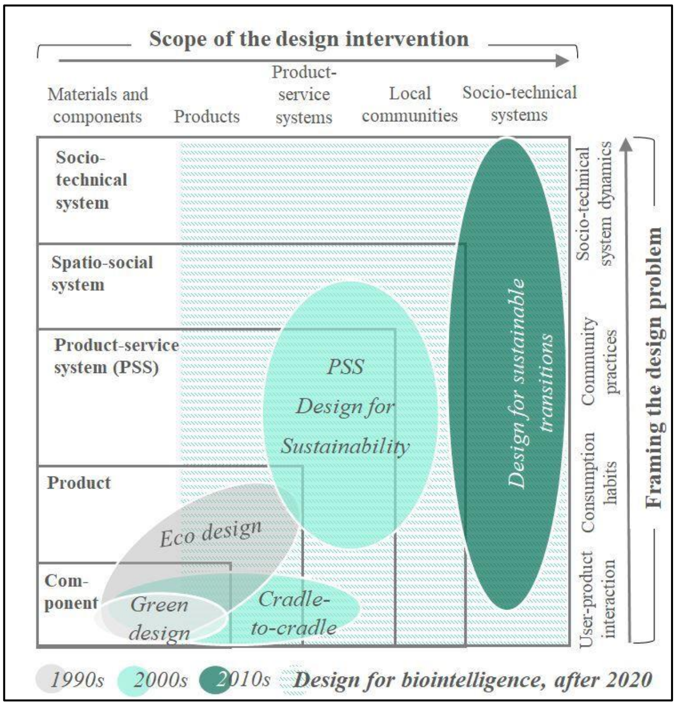

Fig. 1 The design for biointelligence framework [3, 34]

3. Results

3.1. The challenges of biointelligent products' development

According to the Collins English Dictionary, "a product is something that is produced and sold […] often as a result of a manufacturing process." [52]. Products can be tangible or intangible, such as services. The focus in the course of this work lies on tangible products. Moreover, a definition of the term "biointelligent product" must be provided to form a sound scientific basis for a development guideline: A product can be considered biointelligent if it integrates biological and technical components that interact with each other in a way that information is transmitted [3, 53]. In this way, the system can incorporate analytical and responsive self-optimization capabilities that enable intelligence in the narrow sense to be expressed. Furthermore, it should contribute to sustainable development. The development of biointelligent products covers all activities from ideation to a ready-to-market product. In the workshops, the following challenges arising from the development of biointelligent products were identified:

Sustainability (a) is an integral part of biointelligent products (see implicit biointelligence in the introduction) and a complex topic, as decisions in the development process may leverage impacts later, often being neither properly identifiable nor quantifiable by designers. Thus, sustainability requires sufficient resources (time, money, workforce) to control this effect during development, and responsibilities must be clear.

Biology requires a high degree of flexibility (b): Predictions on the behaviour of biological components are hard to make, and often experimental efforts may be inefficient due to complexity. Even today, there is still little understanding of how biological components (e.g. microorganisms) function and what changes in external (e.g. temperature, pH value, process times etc.) or internal parameters (nutrients) induce which impacts (e.g. on the state of cell, metabolic pathways etc.). This is also the reason why only little information may be obtained from biological components on high granularity (e.g. on cell or molecule level), hindering monitoring and control of the development and production processes.

Lack of standardization (c) in biotechnology is an additional aspect: At the molecular and cellular level, biology is very complex, which complicates standardization. An example may be the coupling of molecules or cells with proteins on surfaces that can have different requirements in each application, even within the same class of proteins. Additional substances may be required, affecting the quality and homogeneity of adhesion. Standardisation plays a role at various levels. On one hand, microfluidic systems, laboratory equipment, and processing machines are not standardized, making both material transfer between devices and results transfer complicated. Standard vessels such as plates, tubes etc. may be standardized, but in production lines, they often require different vessels or specific, non-standardized connections (e. g. tubes). On the other hand, data transfer between devices also lacks standardization.

Ethics and safety (d) must be considered now more than ever, to prevent unintended consequences of new technologies or biological materials. Well-intentioned policies could inadvertently support harmful practices and may result in moral hazards [54]. Biointelligence further raises ethical challenges such as responsibility gaps, justice dilemmas, property rights, weaponization, and instrumentalization [28, 54–56]. Additional ethical and safety aspects identified in BioProS workshops include the uncertainty in predicting the behaviour of biomaterials (see second challenge *(b)*), unknown effects in recycling 3D printed materials, variations in laboratory safety, and gender equality as well as guaranteed use by instructions. On the other hand, *regulations (e)* impose restrictions, especially in the medical field. Country-specific regulations, for instance regarding safety, ethical issues and gender equality, complicate cooperation. Furthermore, product development should not be restricted by regulations.

The *multidisciplinary (f)* of biointelligent product development requires proper coordination and intense cooperation. The *integrative alignment of all disciplines of biointelligence* (engineering, life, and computer sciences) in the development process is crucial. Moreover, each project partner may work with different product development methods and standards, leading to misunderstandings and incompatibilities.

The increase of biointelligent products to be developed will soon rise to an extent that requires a streamlined framework for orientation and efficiency. *Project management (g)* must coordinate the different working approaches and needs of all disciplines, establish an appropriate *understanding* of the other disciplines among all designers, and promote considerate *communication (h)* between the disciplines to overcome the individual languages of each discipline. For this, it is necessary but challenging to make use of passed-on *knowledge and experience* of previous developments.

3.2. Conceptual thoughts on a sustainability-oriented guideline for the development of biointelligent products

The guideline should emphasize an understanding of sustainable product development and address the target groups including project management, and project partners with a focus on sustainability. This involves making the development procedure easily comprehensible and identifying relevant data for sustainability assessment, supporting awareness, and fostering an understanding of sustainability. The aim is to ensure that sustainability is considered right from the project start as a standard within the entire project. The four key parts (I-IV) and guide components (III.A-III.D) are shown in Fig. 2, as well as the in chapter 3.1 identified challenges *(a-h)*. Furthermore, Fig. 2 references methods and shows a possible integration of the guide components into the stage-gate model [38, 57–59]. In addition to content-related requirements, formal requirements were identified in the workshops: The guideline must be digitizable, accessible online, easily retrievable, and printable. It should be written in English and in a generally understandable way. This can be achieved by dividing information into small portions, and making extensive use of illustrations, infographics, factsheets, and checklists instead of explanatory texts. Maintenance of the guideline is also relevant – in particular, links and regulations must be kept up to date, and new information on legislation must be added.

4. Discussion

The challenges presented, are primarily based on the knowledge and experience of the workshop participants and thus may not be considered fully conclusive and comprehensive. Additional literature research to objectify the findings showed that the authors Panagiotopoulou and Stavropoulos [60] obtained similar challenges arising from biointelligent product development. Furthermore, "bio-intelligence" represents a term that has been recently (in 2018) introduced to manufacturing sciences. Hence, different understandings of this term have been established to date, making an interdisciplinary dialogue and work on a common interpretation of the term necessary to ensure comprehensive implementation of the concept in practice. A standardised guideline may help reach this goal. Although many of the challenges described are not new to their original discipline or are caused by their multi-disciplinary nature, it is the combination of factors that makes biointelligent product development a challenging and increasingly complex undertaking. Especially, the missing predictability of biological systems and lack of standardization in biotechnology, coupled with the increasing use of artificial intelligence (AI), raise concerns about safety and ethics. It is important to note that the guideline is not intended to solve these challenges, but to warn the potential user to consider them in their development process. Since, in the implicit understanding of biointelligence, products strive for sustainable optima, sustainability aspects must be regarded from the very beginning of the product development process and considered along the whole product life cycle as well as across all disciplines involved. As there is no product development process that holistically integrates biology, engineering, computer science and sustainability in one development, we conclude that a guideline or new framework is required. However, the conceptual considerations presented represent only an initial approach and do not claim to fully realize such an integrative framework but rather focus on aspects of sustainability. Future work should therefore concentrate on multidisciplinary and timely integration.

While the conceptual thoughts presented focus on the development of biointelligent products, it is important to consider their transferability to the development of biointelligent processes as well. The SSbD approach, for instance, focuses on a comprehensive workflow, encompassing all steps from feed-stock selection to the management of side and waste streams. Sustainable feed-stocks and novel bioprocesses for waste-derived streams, raise new safety and sustainability questions [61, 62]. Additionally, the biointelligence sector, with its increasing integration of automation and AI tools, adds a new dimension to production systems. In this context, our conceptual thoughts on a guideline serve as a starting point for addressing associated challenges, enriching frameworks as the SSbD concept. Moreover, both the approach presented in this paper and the SSbD approach emphasize the question of "when" potential sustainability challenges, risk assessments and stakeholder involvement are to be integrated into the development process.

The SSbD highlights further critical aspects that extend beyond the technical realms, encompassing ethical, socio-economic, and knowledge transfer challenges and therefore underscores the importance of proactive stakeholder engagement. This includes, but is not limited to, representatives from regulatory bodies, policymaking, industry, research, ethics, social science, media, medicine, local communities, and agriculture [63–65]. Questions such as “Who is responsible for specific steps?” and “Who needs to be engaged to identify sustainable and safe practices in certain value chain stages?” are essential for ensuring comprehensive oversight and accountability in the biotech industry [66]. To facilitate open dialogues, new concepts of engagement are being developed, such “innovation communities” that serve as platforms for stakeholders' collaboration to collectively address the complex challenges presented by technological advancements [67, 68]. Given the challenges identified in this work, it seems advisable to include these aspects in the development of biointelligent products. Moreover, this aligns well with the widening of the scope of process and product development to include socio-economic aspects as stated in the “design for biointelligence” framework by Miehe et al. (Fig 1.) [3].

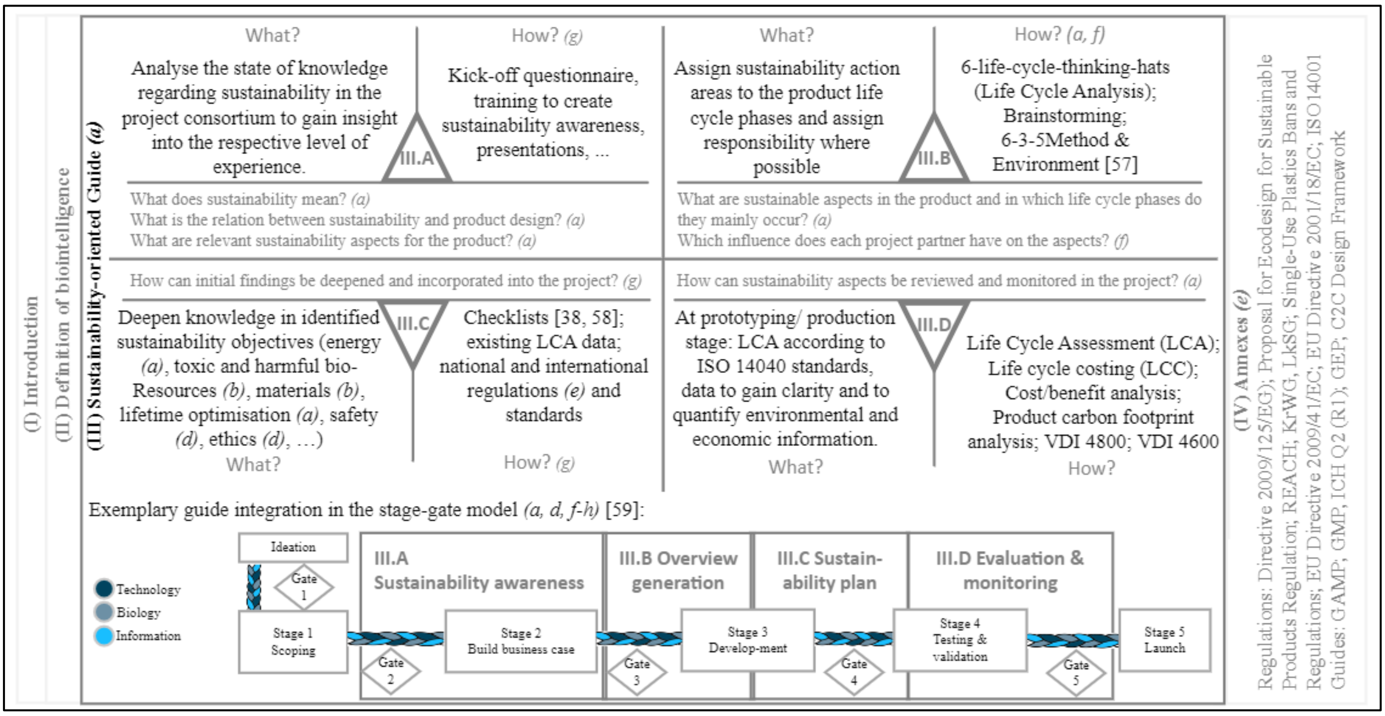

Fig. 2 Conceptual thoughts on a possible sustainability-oriented guideline, including guide integration in the stage-gate-model, own illustration.

5. Summary

Amid challenges like global warming and resource depletion, biointelligence holds promise for industries thriving for sustainable innovation. This article delves into the challenges associated with the development of biointelligent products and presents conceptual thoughts on a guideline for sustainability-oriented development in this field. The conclusion drawn is that while many challenges are not entirely new, the combination of factors makes biointelligent product development a challenging and an increasingly complex undertaking. Therefore, the integrative alignment of diverse disciplines within biointelligence in a single development process is crucial. Especially, ethical and safety issues were identified that may arise from biointelligence concerning the disciplines of biology (gene modification) and information technology (e.g. AI and data security). This was also eminent in the SSbD framework, which represents a similar guideline from the process development perspective. The two approaches do take on different viewpoints, and often share the same basic ideas, but are also complimentary to each other. Based on these considerations, the development of a framework for "design for biointelligence" seems to be the next logical step.

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