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Nanoethics for the Plastocene: the value sensitive design of nanofiber materials

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ABSTRACT

This paper focuses on how to respond appropriately to the problem of the (non-)biodegradability of nanofibers and how the integration of ethics could help. First, the paper describes the experience of a bioengineering research team at the Technical University of Liberec in developing a technology for producing filtration materials during the COVID-19 pandemic and the project that was implemented to provide support for ethical decision-making in the field of research and development of nanotechnologies. The paper then looks into the limitations of the EU's new Medical Device Regulation (2017/745) for the development and design of nanomaterials by focusing on the issue of the (non-)biodegradability of nanofibers. The main argument is that to advance sustainable nanotechnology practices it is essential to incorporate ethical frameworks VSD, which includes a more-than-human ethics, is proposed as suitable for addressing these issues.

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Nanoethics; nanofiber materials; (non-)biodegradability; more-than-human values; value sensitive design

Introduction

During the pandemic, nanofibers attracted considerable attention and popularity as a material for producing masks and other protective devices. Although some attention was at the time devoted to the possible harmful environmental impact of nanotextiles, the main concerns related to the potential health risks for users. Much less attention was paid to the biodegradability of the material. However, some evidence and some similarities with the problem of the non-biodegradability of plastics suggest that the critical question about nanomaterials is their (non-)biodegradability (Howard et al. 2021).

In this article, we focus on the activities of a bioengineering research team at the Technical University of Liberec (TUL), led by David Lukáš, whose efforts are primarily dedicated to developing nanomaterials for medical purposes. This paper argues that

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integrating ethics into the lifecycle of nanomaterials addresses critical sustainability challenges overlooked by current regulations.

The pandemic led the researchers to uncover the unexpected potential of the technology they had been developing. That potential resides in the material's excellent filtration properties. During the pandemic emergency, a team of bioengineers involved in developing and producing facial nanomasks were confronted with the issue of the environmental risks associated with the long-term storage and degradability of nanofibrous materials. This issue was also assessed as a value and an ethical challenge in a project titled 'Support for Ethical Decision-Making in the Field of the Research and Development of Nanotechnologies' (NanoEt), which was created in response to the experience of this bioengineering team. Nevertheless, the concern for environmental risks was temporarily pushed aside. During the emergency, the main priority was the immediate protection of human bodies from the harmful viral agency.

According to the bioengineering research team, the new EU Medical Devices Regulation (2017/745), which is relevant for the work that the bioengineering team at TUL does in 'normal times', does not adequately address the issue of the (non-)biodegradability of nanomaterials.

The paper suggests that incorporating value sensitive design (VSD) can bridge these regulatory gaps, leading to more robust and sustainable nanotechnology development. This argument not only sets the stage for the detailed analysis to follow but also underscores the study's contributions to advancing ethical standards in technology design.

The central question of this paper is how an integrated approach that includes ethical considerations can effectively address the challenges posed by the biodegradability of nanofibers within the broader context of environmental sustainability and global health. First, we describe the team's experience during the COVID-19 pandemic emergency. Second, the paper introduces lessons learned from the project NanoEt. The third section critically reflects on the Medical Devices Regulation. Fourth, informed by the approach of value sensitive design (Friedman and Hendry 2019), the paper details how ethical considerations can be gradually integrated into the development of nanofibers so as to enrich research on the risks associated with new nanomaterials. By focusing on the issue of the biodegradability of nanofibers, the paper discusses research ethics in the current 'Synthetic Age' and the need for an experimental VSD to shed light on pending uncertainties while being explicitly sensitive to more-than-human values.

In this way, the paper highlights the issue of the (non-)biodegradability of nanofibrous materials and the pitfalls associated with prioritizing human welfare over environmental wellbeing and emphasizing the 'One Health' approach (WHO 2017) in the design and regulation of nanomaterials. The paper also contributes to the discussion of how VSD can be employed to accommodate societal and environmental values.

The trajectories of nanomaterials in times of emergency

When the COVID-19 pandemic hit in early 2020, within a few weeks of the first lockdown in Czechia an initiative was launched at TUL, with a team of bioengineers as a key player, that involved implementing the production of protective respiratory devices, and this stimulated the production of nanofiber filters on an industrial scale.

When the pandemic started, a prototype nanofiber device was being developed at TUL. Although the technology was not initially intended for producing filtration materials, the nanotextiles produced had excellent filtration properties. Through Liberec Regional Hospital, the team approached the State Institute for Drug Control (Ministry of Health) with a request for an exemption from standard approval for using a new product on the market. The team tested the material at qualified institutions, such as the Occupational Safety Research Institute and the National Institute for Chemical, Nuclear and Biological Protection. The process of obtaining certification of the material was expected to be smooth given the ongoing emergency. However, the application was denied by the State Institute for Drug Control. The university did not challenge the decision. This resulted in a paradoxical situation where the prototype of the nanofiber filter developed for use in face masks did not receive the certification necessary for it to be marketed because of its novel design, but the Ministry of Health allowed the use of nano masks as protective devices despite the lack of a clear definition of what a nano mask is. In the emergency, the nanofibrous filtration material, tested but uncertified, was then distributed by the Regional Crisis Staff to hospitals, social facilities, and other institutions.

The pandemic forced the widespread use of face masks. This accelerated the pace of both research and development and the production of face masks worldwide. Most masks are made using membrane nanofibrous materials produced with electrospinning technologies, and given their submicron pores, low weight, and high filtration efficiency these materials are commercially successful and widely available on the market (Naragund and Panda 2022). However, the polymers contained in the masks, such as Polyethylene, Polypropylene, Polyamide, and Polyvinylidene fluoride, do not decompose easily. Many of the masks made from these materials then degrade in landfills and can pollute the oceans and enter living organisms.

In this light, members of the research team acknowledged the need to address the environmental risks associated with the long-term storage of nanofiber materials. They felt responsible for the consequences of the global production of nanofiber materials that their team had significantly contributed as the co-creators of the methods used to produce them. However, the potential health risks of using nanotextiles as respiratory protection gained much more attention. There were concerns on the part of institutions, including the Ministry of Health and TUL, about the potential health risks of using the product and about protecting people's health. In addition to that, there were no recommendations on how to handle the technology used in this emergency in an ethically responsible manner or how risks should be assessed and managed. Therefore, an intuitive assessment conducted by the team of the ethical challenges involved in producing the filter material prioritized more visible issues, namely, protecting the product's users from contracting a viral disease.

Lessons learned from the NanoEt project

The experience gained during the pandemic prompted the bioengineering team to reflect on the role of academic researchers in contemporary society and the ethical implications of science. In addition to the technical aspects, they considered the moral challenges posed to researchers by the technologies they develop and the degree of responsibility they bear for the technologies' use.

The project NanoEt was set up with funding from the Technology Agency of the Czech Republic, the aim of which was to create a support system to strengthen the skills needed for ethical decision-making in the research and development of nanotechnologies. In addition to meeting the planned outputs, the broader aim was to ensure that societal considerations are not excluded from bioengineering research in the future. This need arose from the experiences of bioengineers during the pandemic.

As part of the process of producing the filter material, the project team defined the following value and ethical challenges as part of the project proposal:

(1) The ambiguous approval process for placing protective equipment on the market during a state of emergency.
(2) The environmental risks associated with the long-term storage of nanofiber materials.
(3) Prioritizing the distribution of protective equipment during a deadly state of emergency and TUL's commitment to providing protective equipment to the Liberec Region.

The project started in November 2020 and ended in October 2022. The team consisted of a mix of experts in nanotechnology, philosophy and applied ethics, anthropology, law, computer science, and applied mathematics. The project's main outputs included: qualitative research; an expert system for ethical decision support in nanotechnology research and development; a legal analysis of the administrative proceedings on an exemption from the use of a new product on the market conducted by the Ministry of Health of the Czech Republic.

The project's first phase was devoted to qualitative research conducted through semi-structured interviews and observations. This resulted in a case study that summarized the experiences that researchers and volunteers had using the original technology (AC Electrospinning) to create the nanofiber filters. Two basic clusters of ethical dilemmas (Mehlich 2017) were identified: (1) 'internal accountability,' e.g. adherence to the ethical standards of the scientific profession, and (2) 'external accountability,' which primarily refers to the issue of the social and environmental impacts of research and development. However, the resulting case study ultimately prioritized other topics over the environmental impacts of research and development. Inspired by the Turnerian understanding of liminality (1977), communitas, and antistructure and by Stenner's concept of liminal spaces (Stenner and Kaposi 2020), the results of the research uncovered 'the potential of the anti-structural character of the initiative and the temporary suspension of hierarchically established university structures' (Jetmarová and Trčka 2022, 217).

As well as explaining the potential anti-structural character of the initiative, the case study also described the multilateral mode of the production of nanofiber filters used by a team of volunteers representing experts from across faculties, academic positions, and disciplinary specializations at TUL, the university, the Liberec Region, the region's crisis staff, and entrepreneurs and companies. This multilateral mode of production corresponded with the recognition that managing disruptive technologies is often a non-hierarchical, multi-actor process (Malakar, Lacey, and Bertsch 2022) – and a multi-actor process involves prioritizing the competing values of different actors.

The second main output of the project – the expert system (ES) – showed the potential for engaging different actors and how their values, imaginations, fears, and moral intuitions can be discussed and considered. The ES was partially inspired by the MIT Moral Machines software project that was designed to study moral intuitions (Awad et al. 2018) and by projects developed in response to the crisis around COVID-19 to facilitate the evaluation of relevant sources of information for research.[1] As well as offering interactive ways of solving real and fictitious ethical dilemmas, the ES makes it possible to evaluate these dilemmas immediately. Alongside this function, the system is supported through its communication component of online participation (e.g. individual commenting on questions by respondents).

The project concluded with a summary research report that contained the third major output: a legal analysis. This analysis addressed the challenges of the approval process required for placing protective equipment on the market in times of emergency. As described in the previous section, TUL's application for an exemption from using a prototype for the nanofiber filters intended for face masks on the market was denied by the State Institute for Drug Control (the Ministry of Health). However, the legal analysis showed that TUL could have pursued an active defense to change the State Institute for Drug Control's opinion or to reverse its decision. For example, there was nothing to prevent TUL from modifying its application to correct for the defects identified in the Ministry of Health's communication and then resubmitting its application, which TUL did not do.

Even if the environmental risks associated with the long-term storage of nanofiber materials had already been described as a value and an ethical challenge in the project proposal and environmental risks had been identified in the qualitative research, the pursuit of three primary objectives led the project team to focus primarily on the ambiguous approval process for placing protective equipment on the market and for the distribution of protective equipment. The resulting recommendations were mainly directed towards making it possible to obtain certification for such products. The ES was the only output that allowed at least partial consideration of environmental aspects.

The following section discusses the question of the extent to which the new regulations governing the work of bioengineers in 'normal times' are sufficient to address the issue of the biodegradability of nanomaterials.

The limits of the regulation of nanomaterials in the EU's new Medical Devices Regulation

Compared to the pandemic emergency, in 'normal times' there are more explicit norms and regulations for the work of bioengineers. In the EU these are mainly described in the EU's new Medical Devices Regulation (MDR 2017).[2] This regulation has introduced stricter requirements for marketing new medical devices (MDDs) in the EU and conducting clinical trials. According to the new MDR, a clinical trial's primary objective is to demonstrate whether the clinical data on a given medical device sufficiently and unequivocally shows compliance with the 'General Safety and Performance Requirements.'

Regarding the application of the MDR to clinical trials, the bioengineering team believes, based on experience, that they already took into account the requirements set out in the regulations. The MDR's stricter procedures, therefore, do not pose any

significant problem for work in 'normal times.' However, the bioengineering team believes that the ambiguous definition of nanomaterials is a problematic aspect of the new MDR, and this ambiguity is linked to the environmental risks associated with the long-term storage of nanofiber materials.

Paragraph 15 of the MDR calls for a uniform definition of nanomaterials based on an earlier recommendation of the European Commission. A uniform definition of nanomaterials is extremely difficult to make. First of all, a uniform definition would make no distinction between biodegradable and non-biodegradable materials for medical devices containing nanofibers. Moreover, in relation to nanofibrous materials used as scaffolds for tissue engineering and medical devices for healing skin wounds, the definitions contained in Commission Recommendation 2011/696/EU (European Commission 2011) and in the newer Commission Recommendation 2022/C 229/01 (European Commission 2022) are ambiguous. Thus, nanofibers are both defined as nanomaterials and excluded from this definition in the same recommendation. Paragraph 11 of the latter recommendation states that the definition of a nanomaterial should not cover large solid products or components, even when they have an internal structure or a surface structure at the nanoscale, such as '[…] complex nanocomponents, including nanoporous and nanocomposite materials.' Paragraph 11 excludes nanofibrous layers and nanofibrous yarns from the definition of a nanomaterial. However, nanofibrous layers and nanofibrous yarns can undergo dissolution, degradation, and disintegration in interaction with nano-objects as they undergo solvation and are attacked by enzymes when they come into contact with tissue (Doratia et al. 2018). At this stage of their dynamic development in an organism, nanofibrous materials are transformed into objects 'consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates' (European Commission 2022, paragraph 9). This meets the definition of a nanomaterial.

One of the goals of the MDR is to establish uniform regulatory standards; however, the terminology relating to nanofibers remains ambiguous. The MDR considers mainly the initial state of the nanomaterial and does not sufficiently address the problem of degradability, where the properties of the material change. Many of the benefits and risks associated with introducing innovative technologies may become apparent only after the technology has been introduced into use. This is also the case of the environmental risks associated with the long-term storage of nanofiber materials. While the bioengineering team's nanofibrous materials have undergone a clinical evaluation that meets the new MDR requirements, the uncertainties associated with the degradability of nanofibrous materials mean that further experiments are required – for example, experiments to simulate aging. Therefore, it is appropriate to reflect on other possible ways to respond to the uncertainties and dynamics of innovation.

In the case of the MDR as it pertains to the clinical investigation and sale of medical devices for human use, the fundamental value to be considered is human welfare (health) and the potential health risks associated with using nanotechnologies in medicine. The environmental risks associated with the long-term storage of nanofiber materials remain secondary. Therefore, even this regulation does not effectively solve the problem that emerged during the pandemic emergency.

Moreover, it would be impossible for current or any regulations to suggest and design procedures that could cover all kinds of potential risks and uncertainties. Therefore,

according to some suggestions, nanotechnology researchers should apply self-regulation and self-imposed standards in the initial stages of risk management (Marchant, Sylvester, and Abbott 2008) and seek to reduce risks by employing processes that take into account not only technical issues but also social aspects. By understanding potential risks, researchers can subsequently contribute to modifying the standards for regulating safe research and development.

Thanks to self-regulation in the initial stages of risk management, the bioengineering team was able to identify the nanofibers' biodegradability as an issue. Although the TUL bioengineering team was not constrained in its development of nanofibrous materials by institutional rules or MDR regulations, nor did it have a grant project that focused on the issue of nanofiber biodegradability, they nonetheless started to investigate this type of risk. Their results could serve as one basis for modifying standards for regulating the safe research and development of nanofibers.[3]

However, this method of self-regulation is neither a systematic approach nor a continuous and iterative evaluation process that is applied throughout the technology development cycle to respond continuously to new issues. Even if the technology is developed within legal boundaries and with the use of self-regulation, this does not necessarily mean that social and ethical considerations will be taken into account (Arnason 2017). The challenge, then, is to create a design method that incorporates a systematic and value sensitive approach.

Nanoethics for the Plastocene

> The replacement of natural processes with synthetic ones is the hallmark of what might be called a Plastocene epoch. […] In the Plastocene, the world is thoroughly reconstructed, from the ground up, by molecular biologists and engineers, marking the beginning of the planet's first Synthetic Age. The remaking of the planet during this Synthetic Age […] will reach deeply into the earth's metabolism. […] In a just world, this shape [the remaking of ourselves and the earth] would be decided by careful and informed popular choice. […] These are not decisions that can be left in the hands of a select few. (Preston 2018, 13–16)

This section focuses on selected methods of ethical reflection that could help create a systematic approach to applying a continuous and iterative process of evaluation throughout the technology development cycle and that could enrich research addressing the risks associated with the (non-)biodegradability of nanofibers. Furthermore, we argue that beyond just the issue of the (non-)biodegradability of nanofibers, the current 'Synthetic Age' needs an experimental design that is capable of illuminating pending uncertainties while being explicitly sensitive to more-than-human values. VSD seems suitable for addressing these issues.

The systematic attention that the engineers devoted to the social and ethical aspects of their technology occurred in response to the engineers' experiences during the pandemic. However, the approach they used was problematic in that the social and ethical aspects were considered separately and not as part of the ongoing research (see, e.g. Rabinow and Bennett 2012). VSD counters this problem by integrating ethics directly into the design of a technology, starting with the phase of analyzing risks, societal implications, and values through to their operationalization in the design, implementation, maintenance, and use of the technology (Timmermans, Zhao, and van den Hoven 2011).

Going beyond the instrumental conception of technology and evaluating the use of a particular technology for good or evil purposes, VSD reflects the inherent morality of technical artifacts and seeks to account for a wide range of values, stakeholders, technologies, populations, contexts, and circumstances, as well as the technology's indirect and longer-term impacts (Friedman and Hendry 2019). In recent years, VSD has become a tool used in nanotechnology. For example, in the proposal by Timmermans, Zhao, and van den Hoven (2011), VSD is presented as a suitable framework for engaging stakeholders to address nanopharmaceutical development responsibly. Similarly, Jacobs and de Vries use VSD to address the safety and sustainability of nanotechnology (2015). However, an earlier implementation of VSD methods focused primarily on human actors and their values. Along with other authors (Borthwick, Tomitsch, and Gaughwin 2022;; Fell et al. 2022; Sapraz and Han 2021 Umbrello 2021), we argue that VSD needs to be addressed by combining it with other approaches that are sensitive to more-than-human values.

One of the central questions in the early stages of the nanotechnology debate was whether the technology posed entirely new ethical challenges (Ferrari 2010). In this debate, our view is that it is not of crucial importance whether nanotechnology gives rise to any new ethical problem, the issue is rather that nanotechnology can influence the framing of older ethical issues in new ways (Bacchini 2013). Addressing the specific issue of nanomaterial biodegradability can help illustrate the latest problems facing environmental ethics today and help frame the challenges associated with the Synthetic Age.

Even if risk management does take place in the early stage of technology development, it can be challenging to identify and predict potential risks. Technology assessment, therefore, has to be a continuous and iterative process of evaluation that occurs throughout the technology development cycle to respond to new challenges continuously (Malakar, Lacey, and Bertsch 2022). The problem of the (non-)biodegradability of nanofibrous materials confirms this need because during degradation the properties of the material change. The evaluation by the State Institute for Drug Control during the pandemic was only a one-time event, as was the granting of permission to provide a new filtering nanomaterial to the Liberec Region's emergency staff. The MDR evaluation is also a one-time evaluation. In contrast, the application of VSD yielded a tripartite methodology that could be deployed iteratively and in an integrative way through *technical*, *empirical*, and *conceptual investigations*.

The bioengineering team at TUL has so far focused mainly on *technical investigations* and their self-regulation also focused on these issues. In the case of nanofibers, there is a potential risk of their persisting in the environment and accumulating in living organisms over the long term. While some nanomaterials 'discovered' at the end of the twentieth century, such as carbon nanotubes and fullerenes, are naturally occurring in nature, their increasing presence in the environment as a result of their increased use in industry and transportation makes them risky. The degree of harmfulness depends on the actual dose, exposure time, and intake of nanomaterials. As recent studies show (e.g. Ganda et al. 2022), the shape and size of the nanoparticles affect not only how they are taken into a cell but also what degradation pathway they subsequently undergo. These issues require further research. The critical challenge is creating accurate hypotheses about the course of degradation of nanofibrous materials, designing experiments regarding

their simulated aging, and comparing results with the theoretical prediction. The bioengineering team assumes that non-biodegradable nanofibrous materials will lose their flexibility (become embrittled) as they age. As a result, these materials will break when they are mechanically excited – by bending them, for example. This technical investigation thus shows that some moral concerns associated with uncertainties and potential risks can only be clarified by further nanoscience research designed in such a way that it can shed light on the uncertainties about what is not known about nanofibers. In this respect, what matters then is what moral and ethical values are inscribed in the research agenda and what the resulting technological parameters of the technology are.

Moreover, integrating ethical considerations into the design of experiments and the daily research practice of bioengineers could help address the imbalance between the speed of rapid technological advances and the slower pace of development of legal regulations. During the pandemic, there were no recommendations on how risks should be assessed or managed. In 'normal times,' the MDR does not sufficiently address the problem of degradability, where the properties of the material change and can form and turn into non-biodegradable particles. However, we agree with Shumpert (2014) and Balmer et al. (2016) that general ethical and social considerations need to be tailored to the characteristics of specific technologies and thereby made meaningful to a particular research and technology community. Moreover, the structures of engineering education very often do not include social considerations (Madhavan 2024). Thus, there is a need to ensure that social science and the humanities become part of the curricula for nanotechnology professionals and that social science and ethical expertise are integrated into multidisciplinary research and development teams.

The bioengineering research team at TUL established bachelor's and master's degree programs in bioengineering in 2019, which include lectures and seminars on bioengineering ethics. In addition, the content of these courses is included in the final bachelor's and master's examinations. Among the forms of technology assessment that have inspired the educational activities of bioengineers lately is VSD. For example, in 2024, students prepared a project in which they applied VSD to the topic of their bachelor's thesis, which is consistent with other findings suggesting that the discussion of potential social and ethical issues needs to relate more to students' actual research projects than to abstract dilemmas (e.g. Sweeney 2006). Moreover, ethical questions are now also topics addressed in the internal seminars for researchers at which team members present their work in progress. For example, the topic of animal testing was recently discussed. The editorial system component, which is an online interactive library of theories, standards, and practical examples, also covers this topic in the ES. A seminar on VSD will be organized at the end of the academic year 2024/2025.

This type of cooperation is linked to the desire to bring accountability to science and technology, but it has its pitfalls. For example, as Calvert points out,

> a danger is that responsibility becomes conceived of as something extra and in addition to the science itself ('We'll teach 'em the science – you teach 'em the rest'), which takes the focus away from science and technology as objects of social scientific inquiry. (Calvert 2024, 81)

Therefore, rather than dealing with social and ethical 'implications,' social and ethical sensitivity should be inscribed in the research agenda and the structures of

bioengineering education. The *empirical* and *conceptual investigations* of the VSD approach contribute to this social and ethical sensitivity.

Empirical investigations in the frame of the VSD approach focus primarily on stakeholders and questions such as 'How do stakeholders apprehend individual values in the sociotechnical context? How do stakeholders prioritize competing values or otherwise envision resolution of value tensions?' (Friedman and Hendry 2019, 33). These investigations primarily employ various quantitative and qualitative methods used in social science research. In the case of the NanoEt project, the ES showed the potential for engaging different actors and their values. Specifically, this is a communication component for data generation through web-based questionnaires. It allows an expert user to formulate ethical dilemmas and simple questionnaires and it enables other users to fill them in and compare their results with other respondents, comment on individual questions, and interact with researchers. Responses are stored in a database for statistical evaluation or AI processing. The weakness of this output is that it needs to stand up to comparison with already available software (e.g. Qualtrics), as each questionnaire has to be customized. The advantage of having a communication component as part of the questionnaire is that it does not just become a tool for public opinion polling but also allows for the active participation of participants.

However, the biodegradability of nanofibers also concerns non-human species and the biosphere. The application of human-centered approaches to environmental problems can lead to outcomes that consider the immediate benefits to people without addressing the long-term impact on ecosystems (Borthwick, Tomitsch, and Gaughwin 2022). In this way, environmental sustainability can be interpreted as referring to maintaining ecosystems. This then raises the question: how should non-human actors be taken into account in considerations of stakeholder values in technology development?

Clues to answering this question can be provided by engaging in *conceptual investigations* that 'comprise analytic, theoretical, or philosophically informed explorations of the central issues and constructs under investigation' (Friedman and Hendry 2019, 32). Contrary to criticism of VSD (e.g. see a summary of several criticisms in Davis and Nathan 2014) that deems it a weakness in that it does not prescribe a single normative framework and, therefore, cannot provide methodological guidance for distinguishing fundamental moral values from the mere preferences of those involved in the design process, we argue that the openness of the conceptual investigations of VSD is an advantage of this approach because '[it] conveys the idea of values potentially in opposition but allows for solutions that balance each value in relation to the others, such that the adjudication of the tension holds each value intact' (Friedman and Hendry 2019, 45).

While environmental ethics is a diverse field of theories and practices (reverence for life ethic, weak anthropocentrism, an ecosystemic holism, a deep ecology), it is marked by the shared ethical intuition that 'nature deserves moral consideration for its own sake based on the fact that the biotic community is the product of millions of years of natural forces that have generated a system that is life supporting, complex, and often diverse' (Preston 2006, 223). The inherent value of individual plants, species, and communities of organisms implies that all organisms are unique and reclaim their good in their way (Fell et al. 2022, 8). As in life-centered design (Borthwick, Tomitsch, and Gaughwin 2022), assessing the long-term impact of design proposals should involve

the perspectives of all living things because humans and other species are strongly interdependent, and it should plan for intergenerational concerns because the decisions we make now will have an impact for generations to come.

Thanks to self-regulation in the initial stages of risk management, the bioengineer team was able to identify the nanofibers' (non-)biodegradability as an issue. On the other hand, the investigations outlined in this article show that the team of bioengineers still faces some challenges: addressing the imbalance between rapid technological advances and the slower pace of development of legal regulations, analyzing values and their operationalization in design to tackle ethical issues, and considering different values in the socio-technical context. The uncertainties about nanofibers mean that assessing their (non-)biodegradability must be a continuous and iterative process. Moreover, the evaluation process needs to include a biocentric perspective to consider environmental interdependency and all the priorities of those affected by developing nanomaterials. In addition to considering unexpected effects and non-human actors, a biocentric perspective expands considerations to take in ecological systems and aims for a holistic view of the impact of science and technology on the biosphere. By trying to understand potential risks from a biocentric perspective, VSD and research on the uncertainties of nanomaterials can contribute to modifying the standards that regulate research and development so that it is safe not only for humans, as in the case of the MDR, but also for communities of organisms and ecosystems.

Conclusion

This article explored various methods for integrating ethical considerations into materials design, emphasizing how such integration can enhance research on the risks related to new nanomaterials. The discussion underscored the need for an iterative assessment process throughout the technology development cycle, enabling timely responsiveness to emerging challenges. One key insight is the importance of multidisciplinary university curricula that bridge technical and social disciplines, addressing a critical educational gap.

The paper reviewed the VSD approach, demonstrating through technical investigations of the bioengineering team at TUL that some moral concerns, particularly those associated with uncertainties and potential risks, can only be clarified through research explicitly designed to address the degradability of nanofibers. Empirical investigations focused on how well the diverse imaginations, fears, and moral intuitions of stakeholders are incorporated into research design, highlighting the broader implications of the (non-)biodegradability of nanofibers, which extend beyond human concerns to affect non-human species and the biosphere.

Regarding EU MDR regulations, it becomes clear that while these regulations provide a framework for medical devices, they fall short in addressing the unique challenges posed by nanomaterials, particularly regarding environmental impacts and biodegradability. The paper advocates for revisiting these regulations to better integrate environmental considerations.

We argue that the current 'Synthetic Age' needs an experimental design, such as VSD, that would be capable of illuminating pending uncertainties while being explicitly sensitive to more-than-human values.

This approach supports a more holistic view that includes intergenerational justice and considers non-human forms of life, aiming for an ethical framework that guides the responsible development of nanotechnologies. By integrating a biocentric perspective, research on nanomaterials can help to modify existing standards, ensuring that research and development practices do not harm humans or more than human ecologies, thus aligning technological progress with sustainability goals.

Notes

1. Namely, the CORD-19 dataset (https://www.semanticscholar.org/cord19) and its associated information retrieval and evaluation software AI-powered literature review (https://www.kaggle.com/covid-19-contributions) or, for example, SciSight (https://scisight.apps.allenai.org/).
2. The MDR classifies medical devices into different classes based on their potential risks. Nanomaterials are primarily affected by this regulation in relation to their biocompatibility and toxicity. This primarily concerns the reduction of the risks associated with the size of particles that may be released into a patient's body. All devices containing a nanomaterial with an invasive propensity, such as skin wound covers, belong to the highest risk class III. A link for the full text of this regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A32017R0745.
3. See, e.g. Madheswaran et al. (2024) on composite nanofibrous yarns; another paper focusing primarily on the biodegradability of nanofibers will probably be published in 2025.

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