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The Impact of External Factors on Technological Advancement: The Case of Nanosilver

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Abstract:

Purpose: *The aim of the paper is to identify the role and influence of the external factors on the development of technology based on the example of nanosilver particles. On the basis of selected EU regulations and recommendations we have indicated their consequences for the further application of the analysed technology.*
Design/Methodology/Approach: *Based on the literature review in the field of barriers to technology transfer, the role of Responsible Research and Innovation as a systemic tool for monitoring the development of technologies, in particular potentially environmentally and biologically toxic, was indicated. Then, a review of European regulations and recommendations in the years 1998-2024 was carried out and the impact of these regulations on the development of silver nanoparticle technology was indicated.*
Findings: *The research carried out in the article has shown that despite the wide use of nanomaterials in many industrial sectors due to their unique size- and shape-dependent properties, extensive applications of nanomaterials lead to anxieties due to their potential environmental and human health hazard. The public is exposed to nanosilver particles due to their wide utilisation in medical applications, cosmetics, food packaging, fruit treatments, and textile finishing. Hence, successive regulations and recommendations carried out at the EU level contain increasing restrictions on the industrial use of this nanotechnology and increase technological, legal and organizational barriers to its transfer.*
Practical implications: *The restrictions indicated in the article may affect the result in significant technological challenges for manufacturers in the process of technology development and transfer: prohibition of substance selling, the necessity of product reformulation, and significant investment in research, testing and certification.*
Originality/Value: *The research carried out in the article contributes to the existing literature in several ways. First, the study indicate the role of Responsible Research and Innovation in the process of technology development and its applications. Second - it emphasises the role of external barriers to technology transfer, especially in the form of regulatory barriers. Third, it describes the impact of subsequent regulations on nanosilver technology and their impact on the further development of this technology.*

Keywords: *Responsible Research and Innovation, commercialisation, nanosilver.*
JEL: *K32, L67, O33.*
Paper type: *Research article.*

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1. Introduction

Innovation and the development of new technologies are the engine of progress in almost every area of life. The mechanisms and barriers to commercialization are a relatively well-known problem, from the scientific, organizational and implementation side. Nevertheless, despite a number of studies and developed methodologies, the pace and direction of technology development in many areas are influenced by unpredictable factors, often from the external environment.

One of the solutions is the Responsible Research and Innovation proposed by the European Commission (2012), which is aimed at, among other things, increasing the participation of stakeholders (European Commission, 2013) in the development of research projects (especially in the field of technology development) and counteracting the potentially adverse effects of implemented technologies.

There are many historical examples of the implementation of technologies that have been withdrawn from life due to their threats (e.g., biological or environmental). These examples include technologies such as asbestos, benzene and PCBs. In recent years, research on nanotechnology and the possibility of commercialising the results of this research have been very popular. One of the first commercialized nanotechnologies were Nano-silver compounds. Despite economically successful implementation examples, research conducted in recent years on the toxicity of these compounds, has led to a gradual tightening of regulations on the use of these nanoparticles.

Therefore, the aim of the article is to indicate the external conditions forcing technological changes and changing the possibilities of technology transfer. The starting point in the study will be to indicate, based on the analysis of changes in regulations and guidelines on technology, the need to implement new actions or recommended changes in technology. An example of a technology for which research will be carried out is silver in the form of nanoparticles.

2. Barriers to Technology Transfer

Scientific research and technology development and their transfer to business has been the subject of research interest for many years. A well-recognized problem is in particular barriers to technology transfer (Jung, 1980), the typology of which is relatively diverse. For example, Jung (1980) focused his attention mainly on personal and organizational barriers, while later typologies distinguished broader divisions.

A broad review of barriers to technology transfer was developed by Khan (2017), the classification distinguishes barriers in 17 different areas: lack of top management support, lack of awareness, lack of human resources, lack of communication, cultural barriers, insufficient guidelines for implementing new technology, investment cost, excessive government intervention and regulation, inadequate information and technological systems, limited forecasting and planning, lack of infrastructure, resistance to change, lack of R&D and individual capability, lack of clear demand, lack of trust among partners, organisational risk, country risk.

Despite a very broad typology, based on a review of several dozen leading literature items, it is noteworthy that, in our opinion, a very important barrier to technology transfer is missing in the previous typology – environmental risk. Currently, very extensive research is being carried out in the field of many technologies, the purpose of which is to detect potential risks of negative impact on the natural environment, as well as on the life and health of living organisms.

3. Responsible Research and Innovation (RRI)

The postulate proposed by the European Commission is the implementation of the principles of Responsible Research and Innovation (RRI), which are intended to contribute to a full evaluation of the effects of the actions taken in the field of development and implementation of a given technology, along with an understanding of their positive and negative effects.

An important role in this regard must be played by key stakeholders in the research work carried out in the field of technology development and implementation, in the form of at least four different groups (Matyjas, 2015), investors, research and innovation organizations, residents (EU countries) and legislative and regulatory bodies.

The latter group of stakeholders in particular has a particularly important role to play, their role, often negatively assessed by scientists and business due to excessive overregulation, is crucial from the point of view of forcing changes in potentially environmentally or health-threatening technologies. It should be borne in mind that already at the time of presenting the basic assumptions of RRI (Von Schomberg, 2013), there were a number of examples of companies that were struggling with serious problems due to underestimating the risks associated with RRI. These examples are divided into four basic groups: pushing technology, disregard for basic ethical principles, political influence, and lack of preventive measures/technological foresight.

The concept of Responsible Research and Innovation is the subject of great research interest, for example, recent research in this area has concerned, among others, RRI in the additive manufacturing industry (Ruckstuhl, 2020), Navigating the perils of artificial intelligence with the Focus on responsible research and innovation (Polyportis, 2024), or driving entrepreneurial alertness across heterogeneous innovation ecosystems through digital applications (Fellnhofer, 2022).

The definitely growing interest in the issue of RRI may indicate growing problems related to legal and regulatory barriers to technology transfer and the lack of sufficient attention to specific environmental and biological risks at the time of making a decision to commercialize the technology.

4. Technological Applications of Silver Nanoparticles

For centuries, silver has been used to treat burns, chronic wounds, leprosy, venereal disease, etc. After the introduction of penicillin in 1940, the utilisation of silver as an antibacterial agent decreased. Silver regained interest in the 1960s after the introduction of silver sulfadiazine, and the increased popularity of silver has been observed since the 2000s.

The area of silver use covers electronic industry applications (microchips, semiconductors, conductive layers, batteries, etc.), medical applications (wound dressing, antimicrobial agents, medical equipment, etc.), automotive industry (batteries, electric cars), solar energy production, chemical processes and catalysis, food and agricultural sector as well as leather and textile industry.

Based on the aquatic toxicity of metal silver products, the European Chemical Agency (ECHA) classified them as massive (Ag particles size ≥ 1 mm), powder (1 mm ≤ Ag particles size ≥ 100 nm), and nano (100 nm ≤ Ag particles size ≥ 1 nm) (ECHA, 2024). However, silver compounds are mainly used as nanoparticles (AgNPs).

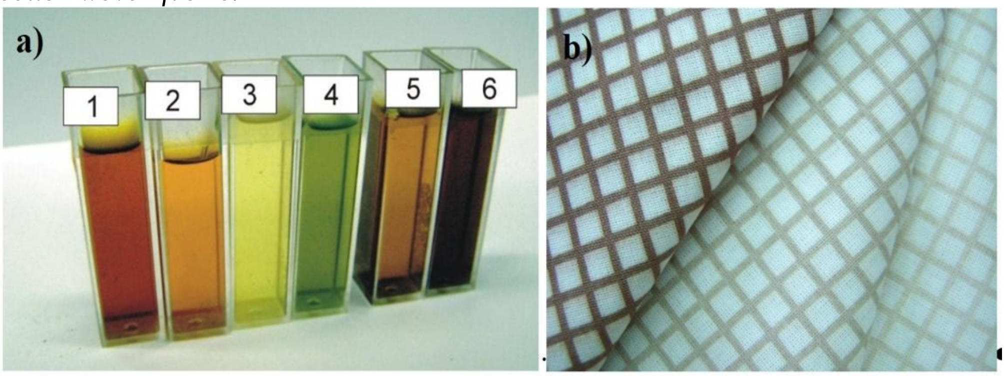
Synthesis of AgNPs:
AgNPs can be synthesised from bulk materials using physical methods and molecular compounds using chemical, physical and biological processes, where chemical processes are mainly used. Physical methods of AgNPs formation involve various processes such as grinding, crushing, milling, laser ablation, thermal evaporation, etc. Particle sizes range from 10 nm to 100 nm with more uniform particle distribution and high purity. The main problems with such a method are the utilisation of complex equipment, high energy consumption, and lack of a stabilisation agent that prevents the aggregation of particles (Nguyen, 2023).

Chemical methods of AgNPs synthesis are based on silver ions reduction with the presence of a stabilising agent preventing massive agglomeration of silver particles. Reaction can be facilitated by light, ultrasound, gamma radiation, heat, and so on. Several chemical substances can be used as reducing agents, such as sodium citrate, formaldehyde, Tollens reagents, ascorbate, borohydride, polyols or hydrazine hydrate. Silver ions are submitted from silver precursors (silver salts) such as silver nitrate, silver acetate, or silver citrate. Surfactants are mainly used as stabilising agents (Bacciarelli-Ulacha, 2014, 2022; Czaplicki, 2018; Matyjas-Zgondek, 2008; Nguyen, 2023; Zang, 2007).

Antimicrobial activity of AgNPs:
Silver is an antimicrobial active substance in various products and articles used as micro-, sub-micro-, and nanoparticles (AgNPs). Silver exhibits a broad spectrum of antimicrobial action against bacteria, fungi, yeast, and viruses. The mechanism of silver antibacterial action is poorly understood. Tree mechanisms have been proposed: interference with bacterial electron transport, binding to the bacterial DNA (Atiyeh, 2007) or interaction with protein thiol groups, interaction with the cell wall membrane, and preventing dehydro-oxygenation process (Yuranova, 2003).

The antifungal action of silver involves disrupting water balance by blocking water binding (Keuk-Jun, 2008). Several factors, such as size, shape, surface area charge, and release of silver ions, influence the antimicrobial action of silver nanoparticles. Several factors, such as size, shape, surface area charge, and release of silver ions, influence the antibacterial action of AgNPs. The smaller the particle size and the higher the surface area of AgNPs, the more accelerated interaction with bacterial cell membranes. Antimicrobial action is proportional to its concentration in the environment.

Figure 1. *Nanosilver containing articles: a) printing inks, b) nanosilver finished cotton woven fabric.*



Source: *Own elaboration.*

5. Selected EU Tegulations for AgNPs

The definition of "nanomaterials" was introduced and adopted into EU regulations by Commission Recommendation (CELEX 2011) in 2011. In 2020, the definition was reviewed and updated to involve different shapes of nanomaterials with CELEX 2020. According to CELEX 2020, "*'nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1* *nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.*"

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, 2006) is the main EU regulation concerning the protection of human health and the environment from risks posed by chemical agents. Initially, the REACH (2006) Regulation did not specify any records concerning nanomaterials. In 2018, the Commission amended REACH (2018) Regulation with suitable Annexes to regard substances in nanoform. Further changes (REACH, 2020) included the introduction of new provisions on safety data sheets for nanomaterial requirements.

REACH (2018) requires registrations of substances that are manufactured or imported in quantities of 1 tonne or more / registrant; however, in some cases, other obligations may apply (such as obligations concerning restrictions, substance usage, communications, safety data sheets provision). Human health and environmental impact of nanomaterials must be assessed according to REACH (2018; 2020).

An EU ECHA was established based on REACH (2006) Regulation. The agency implements the safety of nanomaterials within REACH regulations. ECHA recommendations are often updated and extended according to new outcomes . Moreover, ECHA offers advice on technical and scientific issues in the case of REACH as well as CLP - Classification, Labelling and Packing regulations (Rauscher, 2017).

Depending on the application, the utilisation of AgNPs as an antimicrobial agent in the EU area is subjected to several regulatory frameworks, for example, Biocidal Products Regulation (BPR, 2012) in the case of antibacterial treatment, Cosmetic Products Regulations (CPR 1223/2009 EU) when AgNPs are used in cosmetics.

According to BPR (2012) biocidal substance is "*any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action*".

Moreover, the authorisation of biocidal-contained nanomaterials requires additional assessment of the risk to human and animal health and the environment. Substances classified as carcinogen category 1A or 1B, mutagen category 1A or 1B, and toxic for reproduction category 1A or 1B shall not be approved as biocidal substances. Carcinogen, mutagen, and reproduction categories A are known largely based on human evidence, and B are presumed based on animal action (carcinogen and reproduction) or results on human cells (mutagen), respectively.

Table 1. *Selected EU regulations and recommendations in the case of nano-silver*

Regulation or recommendation	**Publication year**	**Nanoparticle hazard**	**Suggested regulatory action or conclusion**
Directive 98/8/EC[1]	1998	not established	nanosilver is treated like bulk silver (Schneider, 2017)
REACH, 2006	2006	not established	not established
CELEX, 2011	2011	not applicable	usage of the formal definition of nanomaterials in EU legislation
BPR, 2012	2012	nanosilver is authorised according to the guidelines for bulk silver	assessment of risk to human health, animal health and the environment
SEC, 2018	2018	Aquatic Acute 1 Aquatic Chronic 1	no reason to classify nanosilver more stringently than silver nitrate
ECHA, 2022	2022	Reproduction 2[2] STOT RE 2[3] Aquatic Acute 1 Aquatic Chronic 1	silver classification: massive (particle diameter ≥ 1 mm), powder (1 mm ≤ particle diameter ≥ 100 nm), and nano (100 nm ≤ particle diameter ≥ 1 nm) ionic silver is either equally or more toxic than nanoforms of silver
ECHA, 2024	2024	Reproduction 1B[4] STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	inconclusive carcinogenic and mutagenic hazard[5]

[1]*Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market*

[2]*means potential hazard*

[3]*Specific Target Organ Toxicity - Repeated Exposure 2 - potentially toxic to target organs after repeated exposure*

[4]*classification in registration*

[5]*for some form of nanosilver*

Source: *Own elaboration.*

Although nanotechnology shows great potential in the improvement of human life, its introduction to widespread usage leads to serious human health and environmental concerns. Therefore, since nanosilver was introduced, it has been necessary to conduct continuous research on the safety of nanoparticles in the case of human health and the environment and the development of appropriate EU regulations (Table 1).

6. Discussion and Conclusions

Nanomaterials, such as nanosilver particles, have been extensively used in various applications because of their unique size- and shape-dependent properties. Extensive applications of nanomaterials lead to anxieties due to their potential environmental and human health hazard.

The public is exposed to nanosilver particles due to their wide utilisation in medical applications, cosmetics, food packaging, fruit treatments, and textile finishing. For example, 50% of AgNPs are leached out from textiles during the long-term usage of nanosilver-finished textiles (Bacciarelli-Ulacha, 2022). Discharged particles end up in waste, which precipitates into groundwater and may pose a risk to humans, and aquatic life.

Based on current research, AgNPs are classified as very toxic to aquatic life after short-term and long-lasting exposure. Discrepancies in the reproductive toxicity classification of nanosilver require the conduction of the extended one-generation reproductive toxicity study (EOGRTS) with developmental neurotoxicity (DT). If reproductive classification 1B was confirmed, it would result in the exclusion of nanosilver from the list of biocidal substances, according to BPR (2012). Also, special protection of sensitive populations (pregnant women and young people) at work and updating exposure limits would be necessary.

Such restrictions result in significant technological challenges for manufacturers: prohibition of substance selling, the necessity of product reformulation, and significant investment in research, testing and certification.

The situation presented for the analysed nanotechnology does not necessarily have to be repeated in the case of other compounds (for example graphene – Matyjas, 2018), but it requires further studies and research beyond the scope of the current article.

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