INTRODUCTION

Although nanoparticles (NP) and nanomaterials (NM) are terms with a definition that is clearly accepted by the ECHA (European Chemical Agency) [1] – “chemical substances or materials with a diameter between 1-100 nm” – their use still causes a lot of confusion in the industrial community as well as in the decision-making bodies in the field of public health.

Of these, NP, and in particular metal oxide NP, are used in a variety of commercial and industrial applications that result in direct human contact (such as TiO2 NP in paints, food and cosmetic dyes), or indirect contact through the release of NP-containing materials into the environment [2].

Due to their excessive surface area, NP may have different physicochemical properties, and thus require setting up maximum permissible limits and appropriate protective measures for workers exposed to these materials or substances. However, the NP-using industry has developed exponentially each year over the past 10 to 20 years, far exceeding scientific research on health effects, especially the health of those who manipulate these substances in the industrial environment [3].

Although the use of NP is an attribute of the 21st century, there are many examples from the pre-modern era: "The Lycurgus Cup" from 4th century Rome, "Damascus" sword blades from the 13th-18th centuries, etc. [4].

The classification of NP is based on their morphology, the material from which they can be composed, and the type of application in which they can be used (Table 1) [5]:

<table>
<thead>
<tr>
<th>Morphologies</th>
<th>Type of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nanotubes</td>
<td>carbon</td>
</tr>
<tr>
<td>Nanowires</td>
<td>metals, semiconductors, oxides, sulphides, nitrides</td>
</tr>
<tr>
<td>Nanocrystals</td>
<td>insulators, semiconductors, metals, magnetic materials</td>
</tr>
<tr>
<td>Other</td>
<td>ceramic oxides, metals</td>
</tr>
</tbody>
</table>

Table 1. Classification of NP: categories and applications

Persons exposed to "natural" or "engineered" nanoparticles – either in production processes or during the transport of these materials, and especially when using nanoparticles/nanomaterials – are susceptible to their toxic action by inhalation, ingestion or skin contact. The study aimed to analyse the legislation and concerns of international nanoscience agencies as compared to the provisions of the relevant legislation in Romania, in order to describe the current status quo of health policies in the field of occupational exposures to nanoparticles. European institutions are turning to modern and varied solutions to raise awareness of the risk that nanoparticle represent for public health, and to stimulate scientific research in the field; they also encourage Member States to pursue a similar policy. Romanian legislation has not yet taken on the European Union’s recommendations regarding health protection for occupational exposure to nanoparticles.

Keywords: nanoparticles, nanomaterials, occupational exposure, public health

The use of NP causes a potential health and environmental hazard. Their small size allows them to enter the body through several barriers and to penetrate into the bloodstream and the lymphatic system, from where they can reach organs and tissues and interact strictly with the biological structures, thus affecting their normal functions in different ways. These NP are considered cytotoxic because the interaction between their surface and the biological system induces oxidative stress, inflammation and destruction of proteins, cell membranes, and ultimately, the destruction of DNA.

Thus, NP have a detrimental effect on the consumers, but also a major impact on the environment and the health of the workers involved in the production process. The following are among the many occupational activities with exposure to NP: the construction industry (materials that improve wear resistance and insulation materials), medical care (drug delivery systems), the automotive and aerospace industries (fuel additives), and the chemical industry (catalysts).

Occupational exposure is a major concern, as inhaled or ingested NP, or their simple contact with the skin, can lead to various pathologies:
- ingestion of NP - Crohn's disease, colon cancer.
- inhalation of NP - Alzheimer's disease, Parkinson's disease, asthma, bronchitis, emphysema, lung cancer, etc.
- skin contact - Kaposi's sarcoma [6-10].

AIM

Our study aimed to analyse the legislation and concerns of international nanoscience agencies as compared to the provisions of the relevant legislation in Romania, in order to describe the current status quo of health policies in the field of occupational exposures to NP.
METHODS
We conducted a cross-sectional study by analysing the legal documents extracted from the Official Journal of the European Union (EU) using the search engine on the official website of the journal [11], as well as documents from the Romanian legislation using the LexNavigator software [12]. In addition, we used information collected from official EU websites and Romanian institutions in the field of health and safety at work.

RESULTS AND DISCUSSION
The ECHA’s preoccupations in the field of NP are conducted using two components called REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) and CLP (Classification, Labelling and Packaging).

The REACH is an EU regulation adopted to improve the protection of human health and the environment against the risks that chemicals may pose, improving the competitiveness of the EU’s chemical industry [13]. It also promotes alternative methods for assessing the hazards of substances, so as to reduce the number of animal tests. In principle, REACH applies to all chemicals, not only to those used in industrial processes, but also those used in everyday life, for example in cleaning products, paints and items such as clothing, furniture and electrical appliances. Its central information system – REACH-IT – allows industry, competent authorities of Member States and the ECHA to transmit, process and manage data and files in a safe manner. Each of these three parties has access to specific functions in REACH-IT, which they can use to fulfil their tasks according to the REACH and CLP regulations. In addition, REACH-IT provides them with a secure communication channel, which they can use to coordinate the processing and evaluation of data and files.

The CLP is an EU regulation from 2008, aligning the EU’s system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS). This facilitates global trade as well as the harmonised communication of the hazard information on chemicals, while promoting regulatory efficiency [14].

Table 2 summarises EU concerns regarding NP.

Table 2. EU NP initiatives

<table>
<thead>
<tr>
<th>No.</th>
<th>Type of initiative</th>
<th>Year</th>
<th>Description</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>CLP [14]</td>
<td>2008</td>
<td>In order to determine which properties of substances and mixtures should lead to a risk classification, so that the dangers of substances and mixtures are properly identified and communicated.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Resolution P6_TA(2009) 0328 [15]</td>
<td>2009</td>
<td>EP resolution of 24 April 2009 on the regulatory aspects of NM</td>
<td>It is probably the most important EU document stating that NM may pose new significant risks due to their very small size, such as increased reactivity and mobility, which could lead to higher toxicity in the human body. It also recognizes that the term “nano” appears to have a positive marketing effect, despite the negative health effects. At the same time, it is highlighted that funding for research into the environmental, health and safety aspects of NM in FP7 is far too low, and NM should be included in a safe, pluriform and evolving legislative body based on the precautionary principle. It is also recognized that, over their whole life cycle, NM represent major challenges for health and safety at work, given that many workers in the production chain are exposed to these materials without knowing whether safety procedures applied and the protection measures taken are appropriate and effective; it also notes that an increase in the number and diversity of workers exposed to the effects of NM is foreseen in the future. Furthermore, this EP resolution calls for the urgent development of appropriate testing protocols and metrology standards for the assessment – in a multidisciplinary approach – of the dangers associated with NM and the exposure of workers, consumers and the environment to NM throughout their lifecycle, including in the event of accidents. Finally, the EP resolution calls on the Member States to stimulate research and to launch a public debate at EU level on nanotechnologies and NM, as well as the regulatory aspects of NM.</td>
</tr>
</tbody>
</table>
Regarding the Romanian legislation, although the word "nanoparticles" appears in only 3 normative acts from 2006 to 2018, these acts refer strictly to research activities. The situation is similar for the 8 normative acts that include the term "nanomaterial".

### CONCLUSIONS

Currently the European Union shows intense preoccupation with NP and their effects on health. European institutions are turning to modern and varied solutions in order to raise awareness of the risk that NP
represent for public health, as well as to stimulate scientific research in the field, and they encourage Member States to pursue a similar policy.

However, Romanian legislation has not yet taken on the European Union’s recommendations regarding health protection for occupational exposure to NP.

Occupational exposure to NP is not yet a public health issue in Romania, despite the scientific evidence and recommendations of the European institutions.

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References


Author contribution statement

VS contributed to study conception and design, participated in drafting the manuscript and revising it critically for important intellectual content. GH and AM contributed to study design and participated in critically revising the manuscript for important intellectual content. HM designed the study, prepared the material and critically revised the manuscript. All authors read and gave approval of the final manuscript.

List of abbreviations

BPR Biocidal Product Regulation
CLP Classification, Labelling and Packaging
ECHA European Chemical Agency
EU European Union
EUON European Union Observatory for Nanomaterials
EP European Parliament
GHS Globally Harmonised System
NM Nanomaterials
NMEG Nanomaterials expert group
NP Nanoparticles
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals