



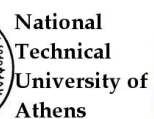
## Task 01/A1

# COMPARATIVE STUDY ON THE NORMATIVE FOR APPLYING OF NANOMATERIALS ON STONE PRODUCTS IN SPAIN



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## 1. INTRODUCTION

The use of nanomaterials is representing a revolution in improving the performance of products made from natural stone. The mechanical characteristics of stone materials have increased their properties thanks to the use of coatings and surface treatments based on the application of nanoparticles and nanocomposites. But at the same rate as the quality of the material has increased with the application of these nanocomposites, the safety of workers is being greatly compromised. Nanomaterials are an invisible threat to workers' health.

Despite the advantages they offer, many workers are not aware that they are working with them, and their harmful effects are not yet clear. Numerous studies establish that there are proven health risks linked to various manufactured nanomaterials, which, given their size, can interact at the cellular level.

This report is included in the task "O1-A1. Comparative study on the normative for applying of nanomaterials on stone products", corresponding to Intellectual Output 1 " Guideline of risks, health and environmental prevention measures in safe production and use of nanomaterials in Stone Sector" of the NanoSafe project.

A comparative study report has been prepared on the current regulations concerning the application of nanomaterials in stone products in the partner countries and in the European Union, including technical, occupational health and safety and environmental protection requirements.

This document provides the target group with an updated version of all published regulations. It has also enabled the consortium to develop the training environment on safety in the application of nanotechnology in accordance with the regulations on safety at work.



All the partners took part in this activity in a collaborative effort to make available to society, in a more accessible and simplified form, all the regulatory measures established in terms of health and safety and risk prevention by the competent authorities.

This report and all the information about the project are available in the following url:

- NanoSafe project web: <https://www.nanosafeproject.eu/>

## 2. SPANISH NORMATIVE FOR APPLYING OF NANOMATERIALS ON STONE PRODUCTS

Nanomaterials related Spanish standards:

	
<p><a href="#">UNE-CEN ISO/TS 21083-2:2019 (RATIFICADA) Método de ensayo para medir la eficacia de los medios de filtración de aire contra los nanomateriales esféricos. Parte 2: Rango de tamaño de partícula de 3 nm a 30 nm (ISO/TS 21083-2:2019) (Ratificada por la Asociación Española de Normalización en mayo de 2019.)</a></p>	<p><a href="#">UNE-CEN ISO/TS 21083-2:2019 (ENDORSED) Test method to measure the efficiency of air filtration media against spherical nanomaterials - Part 2: Size range from 3 nm to 30 nm (ISO/TS 21083-2:2019) (Endorsed by Asociación Española de Normalización in May of 2019.)</a></p>
<p><a href="#">UNE-EN ISO 21083-1:2020 Método de ensayo para medir la eficacia de los medios de filtración de aire contra los nanomateriales esféricos. Parte 1: Intervalo de tamaño de partículas de 20 nm a 500 nm. (ISO 21083-1:2018).</a></p>	<p><a href="#">UNE-EN ISO 21083-1:2020 Test method to measure the efficiency of air filtration media against spherical nanomaterials - Part 1: Size range from 20 nm to 500 nm (ISO 21083-1:2018)</a></p>
<p><a href="#">UNE-CEN ISO/TS 12025:2015 (Ratificada) Nanomateriales. Cuantificación de la liberación de nano-objetos a partir de polvos por la generación de aerosoles (ISO/TS 12025:2012) (Ratificada por AENOR en noviembre de 2015.)</a></p>	<p><a href="#">UNE-CEN ISO/TS 12025:2015 (Endorsed) Nanomaterials - Quantification of nano-object release from powders by generation of aerosols (ISO/TS 12025:2012) (Endorsed by AENOR in November of 2015.)</a></p>
<p><a href="#">UNE-EN 62607-3-1:2014 (Ratificada) Nanofabricación. Características de control clave. Parte 3-1: Nanomateriales luminiscentes. Eficiencia cuántica (Ratificada por AENOR en diciembre de 2014.)</a></p>	<p><a href="#">UNE-EN 62607-3-1:2014 (Endorsed) Nanomanufacturing - Key control characteristics - Part 3-1: Luminescent nanomaterials - Quantum efficiency (Endorsed by AENOR in December of 2014.)</a></p>
<p><a href="#">UNE-EN ISO 29701:2010 (Ratificada) Nanotecnologías. Ensayo de endotoxinas en muestras de nanomateriales para sistemas in vitro. Ensayo del lisado de amebocitos del Limulus (LAL). (ISO 29701:2010) (Ratificada por AENOR en octubre de 2010.)</a></p>	<p><a href="#">UNE-EN ISO 29701:2010 (Endorsed) Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems - Limulus amoebocyte lysate (LAL) test (ISO 29701:2010) (Endorsed by AENOR in October of 2010.)</a></p>



TASK 01/A1. COMPARATIVE STUDY ON THE NORMATIVE FOR APPLYING OF NANOMATERIALS ON STONE PRODUCTS.

<a href="#"><u>REGLAMENTO (UE) 2018/1881 DE LA COMISIÓN de 3 de diciembre de 2018 por el que se modifica el Reglamento (CE) n.o 1907/2006 del Parlamento Europeo y del Consejo, relativo al registro, la evaluación, la autorización y la restricción de las sustancias y mezclas químicas (REACH) en cuanto a sus anexos I, III, VI, VII, VIII, IX, X, XI y XII para tener en cuenta las nanoformas de sustancias</u></a>	<a href="#"><u>COMMISSION REGULATION (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, VIII, IX, X, XI and XII thereto to take into account nanoforms of substances</u></a>
<a href="#"><u>Reglamento UE Nº 582/2012 Biocidas</u></a>	<a href="#"><u>EU Regulation No. 582/2012 Biocides</u></a>
<a href="#"><u>Ley 31/1995, de 8 de noviembre, de prevención de Riesgos Laborales</u></a>	<a href="#"><u>Law 31/1995, of November 8, 1995, on Occupational Risk Prevention</u></a>
<a href="#"><u>Real Decreto 374/2001, de 6 de abril, sobre la protección de la salud y seguridad de los trabajadores contra los riesgos relacionados con los agentes químicos durante el trabajo.</u></a>	<a href="#"><u>Royal Decree 374/2001, of April 6, 2001, on the protection of the health and safety of workers against risks related to chemical agents at work.</u></a>
<a href="#"><u>Real Decreto 665/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes cancerígenos durante el trabajo</u></a>	<a href="#"><u>Royal Decree 665/1997, of May 12, 1997, on the protection of workers against risks related to exposure to carcinogens at work.</u></a>
<a href="#"><u>Real Decreto 349/2003, de 21 de marzo, por el que se modifica el Real Decreto 665/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes cancerígenos durante el trabajo, y por el que se amplía su ámbito de aplicación a los agentes mutágenos.</u></a>	<a href="#"><u>Royal Decree 349/2003, of March 21, 2003, amending Royal Decree 665/1997, of May 12, 1997, on the protection of workers against risks related to exposure to carcinogenic agents at work, and extending its scope of application to mutagenic agents.</u></a>
<a href="#"><u>Real Decreto 681/2003, de 12 de junio, sobre la protección de la salud y la seguridad de los trabajadores expuestos a los riesgos derivados de atmósferas explosivas en el lugar de trabajo.</u></a>	<a href="#"><u>Royal Decree 681/2003, of June 12, 2003, on the protection of the health and safety of workers exposed to the risks derived from explosive atmospheres in the workplace.</u></a>
<a href="#"><u>Real Decreto 1215/1997, de 18 de julio, por el que se establecen las disposiciones mínimas de seguridad y salud para la utilización por los trabajadores de los equipos de trabajo.</u></a>	<a href="#"><u>Royal Decree 1215/1997, of July 18, 1997, establishing the minimum health and safety provisions for the use of work equipment by workers.</u></a>
<a href="#"><u>Real Decreto 773/1997, de 30 de mayo, sobre disposiciones mínimas de seguridad y salud relativas a la utilización por los trabajadores de equipos de protección individual.</u></a>	<a href="#"><u>Royal Decree 773/1997, of May 30, 1997, on minimum health and safety provisions regarding the use of personal protective equipment by workers.</u></a>
<a href="#"><u>RECOMENDACIÓN DE LA COMISIÓN de 18 de octubre de 2011 relativa a la definición de nanomaterial</u></a>	<a href="#"><u>COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial</u></a>



<p><a href="#"><u>Corrección de errores de la Recomendación 2011/696/UE de la Comisión, de 18 de octubre de 2011, relativa a la definición de nanomaterial</u></a></p>	<p><a href="#"><u>Corrigendum to Commission Recommendation 2011/696/EU of 18 October 2011 concerning the definition of nanomaterial</u></a></p>
<p><a href="#"><u>COMUNICACIÓN DE LA COMISIÓN AL PARLAMENTO EUROPEO, AL CONSEJO Y AL COMITÉ ECONÓMICO Y SOCIAL EUROPEO Segunda revisión de la normativa sobre los nanomateriales</u></a></p>	<p><a href="#"><u>COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Second review of the nanomaterials legislation</u></a></p>

### 3. CONCLUSION

From 2001 to 2008, occupational exposure of workers to nanomaterials grew at an average annual rate of 25%, which shows the need for more legislation and social awareness of the theme.

There are no regulations in Spain concerning nanomaterials in the stone sector. Given that the stone sector, in addition to the stone itself, can be associated with the use of chemical products, we must broaden our search for regulations. If we speak of nanomaterials in general terms, or of occupational safety in all areas, we can find regulations such as those mentioned above and other less relevant ones specific to sectors such as food, pharmaceuticals, cosmetics, etc.