Particles Platform

Latest recommendations

Searching science-based practical solutions for the regulatory uncertainties and challenges related to particles

Introduction

The Particles Platform (PP) is an informal alliance of EU industry associations established in 2022. It is dedicated to developing practical, science-based solutions to regulatory uncertainties and challenges related to particles. The PP held well-attended workshops in December 2022 and October 2025. Following the October 2025 workshop, the PP recommended establishing an ECHA Expert Group, comprising experts from ECHA and other relevant stakeholders. A proposed scope for this group was presented at the CARACAL meeting on 28 January 2026.

Following discussions with the European Commission, the proposed scope was narrowed to areas that fall within EU and ECHA competence and can be advanced through EU processes, such as ECHA guidance.

Proposed areas of uncertainty

Lung overload

Lung overload occurs when excessive amounts of inhaled particles accumulate in the lungs beyond the capacity of alveolar macrophages to clear them, potentially leading to effects such as inflammation. It is comparable to the concept of the maximum tolerated dose (MTD) in the Classification, Labelling and Packaging Regulation (CLP), and it is generally accepted that rats are more susceptible to this phenomenon than humans. Current ECHA CLP guidance on the classification of substances for specific target organ toxicity – repeated exposure (STOT-RE) states that the relevance of lung overload observed in animals to humans is unclear and remains subject to scientific debate. Greater clarity would help distinguish effects caused by overload from effects caused by other mechanisms when interpreting inhalation studies. A macrophage research project is also underway to help understand the deposition of particles in the alveoli and the cleaning process linked to lung overload and is near completion.

Applicable concentrations

Improved guidance on scientifically applicable concentration ranges for inhalation studies would reduce uncertainty. This topic is closely linked to lung overload and to the interpretation of guidance values under the STOT-RE classification criteria. The applicable physiochemical parameters are also important in this work.

Low toxicity

Most particle-related regulatory issues concern poorly soluble low-toxicity (PSLT) particles. Although substantial research has assessed criteria for poor solubility, uncertainty remains about how to define “low toxicity”. The STOT-RE criteria refer to significant health effects, which implies that the severity of effects should be considered. For particles, it is particularly important to differentiate normal physiological defence responses from significant adverse effects.

Species differences between rats and humans

It is widely accepted that rats are more sensitive to inhaled particles than humans and other species, due to differences in airway anatomy, lung physiology and cellular responses. Human alveolar macrophages are more numerous, enabling humans to clear more particles from the lungs than rats. This creates uncertainty when using rat studies for human hazard assessment.

Epidemiology

Numerous epidemiological studies of workers in factories handling particulate materials have shown no statistically significant differences compared with the general population. However, concerns often remain about limitations in exposure measurement and potential confounding factors, such as individual lifestyle. This area is also linked to the greater sensitivity of rats compared with humans for particle-related effects. Many industry operators monitor worker health and commission studies in this area. It is important that this valuable information is better integrated into weight-of-evidence assessments.

Alignment between chemicals and occupational safety and health (OSH) regulations

ECHA is currently undertaking a scoping study to set an occupational exposure limit (OEL) for PSLTs. This exercise will include a scientific evaluation of current workplace exposure limits and will collect scientific information on PSLTs, including information on the definition of PSLT and the identification of representative substances. Other considerations include approaches to OELs, exposure, health effects, toxicology, epidemiology and mode(s) of action.

No health-based OEL will be derived in the scoping project, although this may follow the project through the normal prioritisation process with ECHA's Committee for Risk Assessment (RAC). The project will also examine the grouping of PSLTs for hazard identification and help clarify the definition of PSLT. Currently, a large range of different terms is used, from particles not otherwise classified (PNOC) to nuisance dust.

Strong alignment between the OSH OEL approach and chemicals legislation is essential, particularly with respect to scientific interpretation, grouping and definitions.

Recommended next step

The recommended next step is to establish an ECHA Expert Group involving ECHA, the European Commission, Member States, academia, industry and other stakeholders. The group would address scientific and regulatory challenges related to particles, including lung overload, applicable concentrations, low toxicity, species differences between rats and humans, epidemiology, and alignment between the ECHA scoping study for an OEL for PSLTs and chemicals legislation.