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Press Release

Highlighting the toxicity of certain nanomaterials, ANSES is calling for a stronger regulatory framework

Confronted with the wide range of nanomaterials in everyday life and the many questions surrounding them, ANSES today published a review of the available literature on health and environmental issues relating to manufactured nanomaterials. This will help clarify scientific understanding and demonstrate the toxic effects of some nanomaterials on living organisms and the environment. It also emphasises the complexity of understanding the various situations to which humans and the environment are exposed, and the limitations of existing risk assessment methodologies. Due to this complexity, it is difficult to assess the specific risks associated with nanomaterials. Given the time it would require, the Agency recommends the immediate implementation of tools to improve risk management through a stronger regulatory framework at European level.

Some "older" nanomaterials have been around for almost a century and certain nanoparticles can also be produced naturally. It was not however until the late 1990s that technological developments emerged that led to a wide diversification of industrial applications. Nanomaterials are now found in many everyday products: cosmetics, textiles, food, paints, medical applications, etc. This technological deployment has been accompanied by studies on their potential health impact, yet many doubts remain as to their effects on health and the environment. This uncertainty has led to questions about the degree to which these risks are controlled, and the appropriate regulatory framework.

Issues and update of current knowledge

ANSES has consequently set a high priority on the investigation of nanomaterials and has initiated a great deal of expert appraisal work on this subject. At the same time, the Agency has also been coordinating the Nanogenotox joint action, whose scientific objective was to provide the European Commission and Member States with a rigorous and reliable method for detecting the genotoxic potential of manufactured nanomaterials.

In 2012, ANSES set up a permanent group of experts whose mission is to continuously update knowledge of the health and environmental issues related to exposure to nanomaterials, and also a dialogue committee on "Nanomaterials and health" whose members include interested stakeholders.

Finally, the Agency issued an internal request in order to update current knowledge of the effects of nanomaterials on health, and of the corresponding regulatory and societal context at both the national and international levels. The results of this work were published today.

This summary of knowledge shows that despite the advances in scientific knowledge, major uncertainties remain about the effects of nanomaterials on health and the environment. It

identifies a wide variety of hazard characteristics and notes the great complexity involved in understanding exposure situations for humans and the environment, thus making it difficult to conduct specific risk assessments. Given the time such assessments would take, the Agency recommends implementing, without delay, tools to improve risk management through a stronger regulatory framework at European level.

Effects of certain nanomaterials on living organisms

Drawing on a review of all available data and scientific publications around the world, the report documents the effects identified on living organisms. Based on *in vitro* and *in vivo* animal tests, it first demonstrates the ability of nanomaterials to cross physiological barriers, and highlights the toxicity of certain nanomaterials, noting that there are currently no data directly concerning humans, due to the lack of epidemiological studies.

Given these factors and faced with the complexity of the subject, the Agency has made several recommendations with a view to stimulating research: to reduce the numerous scientific uncertainties in our knowledge, and to developing regulations and standards that provide better protection for humans and the environment.

ANSES's recommendations

Regarding research, the Agency recommends implementing multidisciplinary projects to develop knowledge of the characteristics and hazards of nanomaterials, throughout the product life cycle. This mainly involves promoting the development of appropriate safety tests for assessing the health risks of products containing nanomaterials intended to be placed on the market.

In addition, ANSES is calling immediately for a strengthened regulatory framework for manufactured nanomaterials at the European level, in order to better characterise each substance and its uses, taking into account the entire product life cycle.
ANSES believes that the array of available scientific data on the toxicity of certain nanomaterials is sufficient to consider regulating them according to the European CLP (classification, labelling and packaging of substances and mixtures) and REACh (chemicals) Regulations. In this context, ANSES recently published recommendations on adapting the REACh Regulation to take into account the specific characteristics of nanomaterials[1].
This regulatory framework would enhance the traceability of nanomaterials intended to be used in consumer products, from production through to distribution, mainly with a view to improving characterisation of population exposure, and better targeting the risk assessments to be conducted. These risk assessments could lead to restrictions on their use or even to their prohibition, in the framework of the REACh Regulation.

[1] ANSES Opinion on the modification of the REACh annexes with a view to taking nanomaterials into consideration