Wednesday 20 January 2021

Bjorn Hansen
Executive Director
European Chemicals Agency
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Dear Mr. Hansen,

We, the undersigned organisations, are writing to seeking clarifications on both the applicable legal framework and risk management measures in place, for nano/biocidal-treated articles in the context of the current COVID-19 pandemic. Please note that we intend to publish this letter and your responses.

As a result of laboratory tests supposedly showing antiviral activity against a range of viruses, the use of biocides/nanoparticles to combat SARS-CoV-2 transmission (particularly silver) is rapidly growing.

Today on the EU market you can find products such as: face masks treated with silver, zinc oxide, or copper nanoparticles, "anticovid" paper containing nanostructured zinc-silver or nanosilver-containing surface disinfectants. Treated fabrics, clothing, furniture, appliances, packaging, restroom accessories, and shower enclosures are being used in medical facilities, laboratories, schools, childcare facilities, hotels, and other public spaces.

According to market research, the demand is growing for antimicrobial and antiviral nanocoatings as (new) products come to the market; the global nano-colloidal silver market is expected to rise at a significant rate between 2020-2025 due to "pandemic protection accelerating investment in nanotechnology".

In that respect, it should be noted that there is currently no sufficient evidence that the presence of antimicrobial agents in products such as face masks or other clothing protective apparel adds value to routine cleaning and/or disinfection.

As evaluated by ANSES recently, these additional routes of exposures (such as wearing facemasks treated with silver) may give rise to toxicological effects in the medium term and human health impacts cannot be ruled out. Further evidence also shows that indiscriminate use of biocides in numerous products may contribute to the increasing release to environment and development of antimicrobial resistance (AMR).

This situation raises serious concerns and requires regulatory oversight to keep pace with "innovations" and ensure safety and effectiveness. In light of the above, we are seeking clarifications on the following issues:

1) While articles treated with a biocide placed on the EU market do not need authorisation, individual active biocidal substances must be approved (or reviewed) under the BPR before being used in the EU.
   - What mechanisms ensure that only approved active substances are used in articles available on the EU market?
   - What measures are/will be taken regarding nano-treated masks sold on the EU market for example?

2) How is the efficacy of biocidal treatment(s) in such products assessed? What measures are in place to ensure that biocide treatments are fit for purpose?

3) When trying to decide if a face mask with antimicrobial or antiviral treatment is a biocidal product or a treated article, we find different opinions:
   - The European Commission provides a decision tree (p.14) on the distinction between primary and secondary function. Assuming the primary function of a mask is mechanical filtering of air, this would suggest that masks are a treated article, however, this is not clear.
   - The Swedish Chemicals Agency states that "*when such treatment is to protect the user against infestation* [infection]*, there are strong reasons to assume that the biocidal function is the main function of the*

product. If so, the article will be considered as a biocidal product". This implies that the mask is a biocidal product, as the function of the treatment and the mechanical function is protection of the user.

- ECHA's explanation suggests that a treated mask is a treated article. Could you clarify if the biocidal function of the treatment of articles claimed as "protecting against viruses and bacteria" should be regarded as a primary or a secondary function, and for what reason?

4) Under the BPR, when a treated article placed on the market refers to the biocidal properties of the active substances contained therein, the label should include a statement that the treated article incorporates biocidal products, the names of the active substances, and if present, the names of each biocidal (nano-)substance followed by the word 'nano' in brackets. The recently published BEF-1 Report on treated articles , however, reveals that in 2019 the quality of information provided on these labels was inadequate in 36% of cases, and that basic information, such as the name of the biocidal active substance used for treatment of the product, was often missing.
    - As this report only covered treated articles in 2019, and considering the significant rise of biocide/nanomaterial treated articles in 2020, is ECHA considering an extra compliance check in the near future?
    - Is a list of all "antimicrobials" used in newly marketed products treated with biocides available (which chemicals and in which (nano?-)forms)?

5) The anti-pathogen properties of certain nanoparticles may also make them toxic to human cells and organ systems. Potential exposure largely depends on whether nanoparticles can migrate into the human body and/or the environment. Risks may be higher if products are older or worn down by abrasion, weathering, or disposal. The most relevant and concerning exposure routes are inhalation, dermal, and ocular. Can you clarify what are the obligations of manufacturers to study and report on biocides/nanoparticles migration (or confirm a lack thereof) throughout the product lifespan?

6) Products treated with biocides can accelerate the development of resistance in bacteria. The BPR requires that each biocidal product

placed on the market must have no unacceptable effects on target organisms, in particular resistance or cross-resistance. Which approach(es) and/or method(s) for assessing this resistance/cross-resistance are approved by ECHA and the competent authorities?

7) Finally, French regulatory agency ANSES recently recommended accelerating the evaluation of active substances at European level in order to ensure that treated items contain only active substances that have been approved as suitable for the product. Which specific measures are taken by ECHA and competent authorities to do so?

At a time of increased public health awareness, it is important to provide clarity on these critical issues and safeguard human health and environment. We look forward to your responses, and would be happy to discuss with you further.

Yours sincerely,

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On behalf of:

AVICENN (Association de Veille et d'Information Civique sur les Enjeux des Nanosciences et des Nanotechnologies)
Agir pour l'Environnement (France)
BUND/Friends of the Earth Germany
Center for International Environmental Law (CIEL)
ClientEarth
Ecologistas en Acción
European Environmental Bureau (EEB)
Health Care Without Harm (HCWH) Europe
Health and Environment Alliance (HEAL)
Health and Environment Justice Support (HEJSupport)
Pesticide Action Network Germany (PAN Germany)
Women Engage for a Common Future (WECF)
ZERO – Association for the Sustainability of the Earth System