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Subject: Reply to letter from HCWH Europe

Dear Dr Napierska,

Thank you for your letter to Mr Hansen of 20 January 2021, to which he asked me to reply. You wrote to seek clarifications concerning the applicable legal framework and risk management practices for treated articles in the context of the COVID-19 pandemic.

In this letter, we will be addressing each of the issues you raised. As they relate to the regulatory framework and its implementation, we have also consulted with DG SANTE in the European Commission on this response.

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?

The companies making available the treated articles are responsible for ensuring their compliance with the legal requirements. The Member States through their control and enforcement activities, supported by ECHA, check the legal compliance of biocidal products and treated articles.

What measures are / will be taken regarding nano-treated masks sold on the EU market for example?

The Member States are responsible for assessing and enforcing the legal compliance of the products and treated articles available in their territory. ECHA is not informed of related measures that may be decided by Member States.

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?

Face masks claiming a biocidal function should contain only either approved active substances or substances covered by the Biocides Review Programme. During the review of an active substance, both the efficacy of the active substance and of a representative biocidal product are assessed. The active substance needs to have the ability to provide a sufficient effect on one or several target organisms groups, for the use considered.

To be authorised, the biocidal products should be safe and efficacious. The efficacy is evaluated in relation to the label claims made for the product, for all relevant target organism groups.

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?

There is no general answer to this question as this requires first to clarify the applicable regulatory framework and then for products within the scope of the Biocidal Products Regulation a case by case assessment of the specific product with the consideration of its biocidal claims.

Masks that are considered medical masks fall within the scope of the EU legal framework on medical devices - Directive 93/42/EEC (Medical Devices Directive), to be replaced by Regulation (EU) 2017/745 (Medical Devices Regulation) as of 26 May 2021. For further information please see the Guidance on regulatory requirements for medical face masks[1]. The Biocidal Products Regulation (BPR) is not applicable to medical face masks.

Face masks treated with a biocide ('treated face masks') that are not medical devices have to comply with the BPR and they qualify as treated articles. However, a treated face mask is considered a biocidal product if it has a primary **biocidal** function. According to the European Commission a facemask with the claim "protecting against viruses and bacteria" as referred to in your question, should be regarded as having a primary biocidal function and is, therefore, a biocidal product.

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?

The BPR Forum Subgroup (BPRS) included in the recommendations of their first Biocides Enforcement Project (BEF-1) Report the possibility to conduct a follow-up project on treated articles. For the time being, no decision has been taken by the BPRS on such a follow-up project.

[1] https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance-reg-req-med-face-masks.pdf.

Is a list of all "antimicrobials" used in newly marketed products treated with biocides available (which chemicals and in which (nano?-)forms)?

On ECHA's website, there is a list of the active substances allowed for use in treated articles: https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles. ECHA's public database provides additional details on the active substances: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances.

It should be noted that only two active substances in nanoform are currently allowed for disinfectants (main group 1 as defined in Annex V of the BPR) or preservatives (main group 2) in the EU, as a consequence of their current examination in the review programme of existing active substances: silver as a nanomaterial (for PT2, 5 and 9) and silver adsorbed on silicon dioxide as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale (for PT9). A non-approval decision should be adopted in the near future for silver as a nanomaterial following the withdrawal of the corresponding participant from the review programme[2].

Using other nanomaterials as active substances in biocidal products or in treated articles is currently not allowed in the EU.

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?

The Article 19 of the Biocidal Products Regulation (BPR - Regulation (EU) No 528/2012) defines the conditions for granting an authorisation for biocidal products, including products manufactured with nanomaterials. This article establishes that a biocidal product shall be authorised if the following conditions are met: it contains only approved active substances; it is sufficiently effective; and it has no unacceptable effects on human health, animals and environment. The evaluation of whether the biocidal product fulfils these conditions shall take into account realistic worst-case conditions of use and the consequences of use and disposal of the products. According to Annex III of the BPR, which contains the information requirements for biocidal products, information on human exposure associated with the use of the product and information on hazard properties via oral, dermal and inhalation route should be provided in the application. This information is used to establish whether the biocidal product has no unacceptable effects on human health. The risk assessment of a biocidal product shall take into account "how any 'treated articles' treated with or containing the product may be used and disposed" (Annex VI of the BPR, Common principles for the evaluation of the dossiers for biocidal products). Where nanomaterials are used in that product, the risk to human health, animal health and the environment must be assessed separately (Article 19(1)(f) of the BPR), and when test methods are applied to nanomaterials, an explanation shall be provided by the applicant of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/ adjustments that have been made in order to respond to the specific characteristics of these materials (paragraphs 5 of Annex II and III of the BPR).

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

[2] https://echa.europa.eu/documents/10162/5604808/list_of_notifications_en.pdf/0ad3b68a-1e01-304e-722d-f4a8457842c3

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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?

During the assessment of an active substance, information on the occurrence of resistance, or possible occurrence of the development of resistance, and appropriate management strategies need to be reported. The Efficacy Working Group of the Biocidal Products Committee is currently working on developing guidance for resistance assessment of antibacterial biocidal products.

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?

We agree with the recommendation by ANSES to accelerate the evaluation of existing active substances to ensure that treated articles contain only active substances that have been evaluated and approved at European level as suitable for the product. The evaluations are done by the Member State competent authorities (MSCA) and we acknowledge the efforts being undertaken by all parties to achieve the necessary acceleration.

ECHA, the European Commission and the Member States have agreed in February 2020 on the Active Substance Action Plan: a number of actions to accelerate the pace of the review programme of existing active substances[3].

The Active Substance Action Plan was developed by ECHA as a follow-up of a survey conducted in 2018 on the status of the Review Programme dossiers and a Workshop with MSCAs, the European Commission and stakeholders in 2019 on how to improve the active substance approval process.

ECHA and MSCAs started the implementation of the Active Substance Action Plan in 2020 and an update on its progress is provided regularly to the Biocides Competent Authorities meeting.

For more information, the Active Substance Action Plan is available at:
https://circabc.europa.eu/w/browse/9b8a5c0c-9d25-4373-b89f-8ddfeeabe2e8

Yours sincerely,

[e-signed][4]

Peter van der Zandt
Director of Risk Management

[3] CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf
[4] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision approval process.