

## **Bottleneck in the crisis - derogations for disinfectants in Germany**

Due to the spread of coronavirus SARS-CoV-2 in Germany, the demand for disinfectants for hands and surfaces increased rapidly and it became obvious that the amount of products available on the German market under the regular legal framework (Biocidal Product Regulation (EU) Nr. 528/2012 (BPR)) was insufficient to meet this high demand.

To address the necessity of disinfectants in critical areas, such as hospitals and dialysis facilities, the Federal Office for Chemicals (BfC) - established at the German Federal Institute for Occupational Safety and Health (BAuA) – was asked to take measures. Therefore, the BfC granted general derogation decisions pursuant to Article 55 (1) of the BPR, to permit the placing on the market and use of certain disinfectants, limited to a period of 180 days, which would not be actually marketable under the BPR.

In order to make larger quantities of these products available, the general decision was not aimed at individual companies, but included a wider range of addressees. Furthermore, to ensure that only effective and safe products reach the market, the formulations covered by the derogations were precisely defined. The first general decision issued in the beginning of March 2020 on hand disinfectants by the BfC contained very specific requirements: only pharmacies and companies in the pharmaceutical industry were allowed to manufacture or import the products, as it was assumed that they had the necessary technical skills and experience. These first measures were however not sufficient to meet the increased demand and to remedy the shortage of the necessary basic chemicals, such as isopropanol and ethanol. The general decision was therefore adjusted in April, firstly by broadening the target group to include other actors such as the chemical industry and legal entities under public law. Secondly, companies that do not belong to this group but produce or import the required basic chemicals in the relevant specifications, such as breweries and distilleries, may be used as suppliers of raw materials to producers of hand disinfectants. In addition, some further formulations have been added to the general decision derogation.

The BfC also issued a further general derogation decision for surface disinfectants for professional users, and addressed in a third derogation decision the preventive antimicrobial treatment of fuel systems of decommissioned aircrafts which had to stay on ground due to the pandemic. All general decision were developed at the BfC in consultation with relevant national authorities and published in very close coordination with the Federal Ministry of Health and the Federal Ministry for the Environment.

The publication of these general decisions led to a large number of inquiries to the REACH-CLP-Biozid Helpdesk set up at the BfC. For example, questions were asked as to whether and which substances are permitted under the derogation decisions, who is allowed to use them, whether they are effective and who can import them. In the beginning, these inquiries came mainly from pharmacies and companies of the chemical industry. Because of the extension of the general decision to include, for example, the permission for distilleries to produce the active ingredient ethanol, other companies and some private individuals also contacted the helpdesk. Based on these high numbers of enquiries, additional information, such as frequently asked questions (FAQs) were developed and published. Over 50 FAQs on surface and hand disinfectants are now available. At the beginning of May, a guide to classification and labelling including sample labels was also published. This was necessary because the enquiries had shown that some of the disinfectants placed on the market according to the general decisions had been labelled in a very "creative" way and that in particular health-endangering properties had been played down.

Regarding the numbers of enquiries, whereas in January and February around 70 enquiries were made per month on the BPR, in March and April they amounted to around 530 each month - an increase of 660 percent.

Currently, it seems that with the publication of the general decisions the situation has eased to some extent. There are indications that the measures are taking effect and that the market can meet the current demand. However, it is uncertain how the situation will develop. A further extension of the derogation decisions, which are limited to 180 days, is under examination. Whether an adjustment of the measures taken and an extension will be necessary, will be decided by the BfC in close consultation with the responsible ministries. If the situation eases, a return to the standard procedure is envisaged.

Information in German and English is available on:

[https://www.reach-clp-biozid-helpdesk.de/DE/Home/Covid19/Covid19\\_node.html](https://www.reach-clp-biozid-helpdesk.de/DE/Home/Covid19/Covid19_node.html)

[https://www.reach-clp-biozid-helpdesk.de/EN/Home/Covid19/Covid19\\_node.html](https://www.reach-clp-biozid-helpdesk.de/EN/Home/Covid19/Covid19_node.html)

Author: Suzanne Wiandt, head of unit REACH-CLP-Biozid Helpdesk