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COVID-19: Key Issues If You Are Starting to Manufacture or Import Hand Sanitiser

Many companies are looking at modifying their production lines/utilising spare capacity to manufacture hand sanitiser, which is in short supply due to the coronavirus disease 2019 (COVID-19) pandemic. Others may be looking into importing this product into the UK for the first time. For companies already manufacturing or importing similar products, this may not pose any particular challenges. However, many companies, for example distilleries, breweries and food manufacturers, may not be familiar with the rules and regulations that apply when placing this sort of product on the market.

Although there has been removal of some "red tape" by the government, to facilitate the production of sanitiser, there are some regulatory requirements that will still need to be followed.

Deregulation/Removal of "Red Tape"

Hand sanitisers are usually classified as a biocidal product, so are regulated under the EU Biocidal Products Regulation (528/2012) (BPR). BPR requires companies that wish to place biocidal products on the UK or EU market to obtain an authorisation from the HSE or European Chemical Agency, before they place that product on the market.

The good news is that the Health and Safety Executive (HSE) in the UK has already announced a relaxation of the usual biocidal product rules for biocidal hand sanitiser products that use propanol as their active ingredient. Under the exemption, biocidal hand sanitiser products containing Propan-2-ol will not need a biocidal product authorisation, provided that they use the relevant World Health Organisation (WHO) "specified formulation II". The HSE makes it clear, however, that this is not a complete de-regulation, and that "While this action will enable manufacturers to place hand sanitiser products on the UK market quickly, we still expect them to meet their responsibilities to adhere to the correct standards, which protect the people and the environment from potentially harmful chemical effects."

The exemption will not apply to sanitisers made to alternative formulations and it should be remembered that any alternative formulation/primary purpose could mean that hand gels and sanitisers are potentially considered as a cosmetic or a medicinal product, both of which are subject to detailed regulation under other EU legislation. However, it is more likely that a basic alcohol-based hand sanitiser, whose sole purpose is to kill viruses and bacteria on hands, would be regulated as a biocide.

Note that the BPR does still apply in the UK during the Brexit transition period, and will be transposed into UK law at the end of that period.

HMRC has also made temporary changes to the use and supply of denatured alcohol and duty-free spirits, to further help businesses who produce hand sanitiser and gel.

Other Requirements

Despite the relaxations outlined above, companies will still need to be aware of, and comply with where applicable:

- The EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (1272/2008) – particularly in relation to labelling and warnings for any sanitiser products manufactured in, or imported into, the EU.
- Claims that can be made about the efficacy of the product – as these need to be backed up by robust data, and can affect how the product is classified (for example, specific claims about preventing the COVID-19 virus may lead the product to be classed as a medicinal product).
- Potentially the EU REACH Regulation (1907/2006) – although this is of more limited applicability to biocides.

If you need any further guidance on the regulatory regime applicable to hand sanitisers in the UK and the EU, please contact us.

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