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COVID-19: Key Issues if You Are Starting to Manufacture or Import Personal Protective Equipment (PPE)

Many businesses are considering adapting production capability away from their usual products and activities (particularly where there may be spare capacity and/ or production lines), specifically geared toward helping deal with the effects of the coronavirus disease 2019 (COVID-19) pandemic.

In particular, reported shortages of equipment such as face visors, gowns, aprons, gloves and masks, are leading some to investigate the production or import of such equipment. For example, there have been press reports of high fashion producers, such as Barbour and Louis Vuitton, supplying gowns to hospitals; a group of manufacturers in Liverpool making visors; and, in the US, Under Armour producing face masks.

We have previously published a guidance note on continuing regulatory requirements in relation to the production and import of one particular type of PPE - hand sanitisers (despite the removal of some "red tape"). In particular, the Health and Safety Executive (HSE) in the UK had already announced a relaxation of the usual biocidal product rules for hand sanitisers that use propan-2-ol as their active ingredient, but relaxations depended on formulation, and labelling requirements still apply (we have since published an updated article in Speciality Chemicals magazine, also dealing with the position for hand sanitisers containing ethanol).

However, there are various other regulatory requirements that apply in relation to the production of barrier/clothing types of PPE. Given the current need for such equipment to be made available quickly, particularly in health care settings, some requirements have been temporarily relaxed, but the extent of the relaxation will depend on various matters, including the specifications of the equipment, who it is intended for and whether it is for the duration of the COVID-19 crisis only. Therefore, any businesses that are looking to diversify production or start to import PPE, should ensure that they understand what requirements will still need to be followed.

Deregulation/Removal of "Red Tape"

PPE are products that are designed and manufactured to be worn or held by a person to be protected against risks, whether at work, or at home. Laws apply within the EU (and the UK) to any such equipment. Any PPE must comply with the requirements in EU Regulation 2016/425, including essential health and safety requirements, and there are provisions in relation to conformity assessment procedures and testing, CE marking and information/ instructions.

The relaxations of the usual requirements in the UK in relation to PPE required in connection with COVID-19, include in particular that:

- if PPE is made to the relevant standard (e.g. with visors, if they're produced in accordance with BS EN 166:2002); **and**
- it is for supply to the NHS/ healthcare workers via the UK government,

then it will not need to undergo CE assessment via a notified body. However, it will still need to be assessed by a Cross-Government Decision Making Committee (there is a web form to register interest for this assessment). The government has published guidance on the applicable technical specifications for the various type of PPE that may be needed.

However, if produced otherwise than for supply through the government, even where PPE meets the required specifications, it **would still need to be assessed by a notified body**, albeit a 'fast track process' has been introduced in connection with the COVID-19 crisis. If the notified body determines that the product meets the essential safety requirements, then a business may start to supply it; but other requirements in relation to labelling and safety information, will still apply. There is guidance available for businesses on how the different procedures for conformity assessment in these circumstances will apply.

Other Requirements

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

- Requirements that apply to medical devices, including requirements for CE marking and labelling. For example, surgical face masks, intended to protect a patient, would be a Class I medical device, according to guidance from the Medicines and Healthcare Products Regulatory Agency (MHRA) on the regulatory status of equipment being used to help prevent coronavirus, as would examination gloves. The borderline between what is a medical device and what is PPE can sometimes be difficult to determine.

- Requirements to provide safety data sheets for products that fall under Control of Substances Hazardous to Health (COSHH) Regulations 2002.
- Health and safety obligations and assessments in connection with new equipment and/ or methods of production, and in connection with the storage and use of any potentially dangerous substances or chemicals, which the business would not usually have on site.
- Other labelling requirements, e.g. requirements to label fibre composition under EU Regulation 1007/2011 on textile names and related labelling and marking of textile products.
- Depending on the extent to which relaxations will apply, requirements for declarations of conformity, conformity assessment procedures, retention of technical documentation and CE marking, in accordance with the usual requirements for PPE.
- Claims that can be made about the efficacy of the particular product. These would need to be backed up by robust and independent data, and can affect how the product is classified (e.g. as a medical device, as opposed to PPE).

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

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