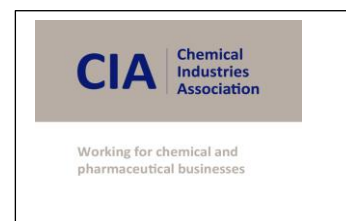


Manufacture of Hand Sanitiser and the Biocidal Products Regulations (BPR):

CIA Guidance and interpretation - Manufacture and supply of hand sanitiser products during the Coronavirus outbreak (COVID-19)



1. Background

Availability of hand sanitiser is clearly one of the fundamental contributors to combatting the coronavirus and COVID-19 infection. Several CIA member companies have the capacity to commit some of their manufacturing capability to manufacturing sanitiser, and have asked for information about the regulator's position under the Biocidal Products Regulation (BPR). CIA raised the issue with HSE on behalf of members and asked for clarification; in response to enquiries HSE's Chemicals Regulation Division published comprehensive guidance on this on 27 March 2020, now available on HSE's website:

<https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm>

The guidance covers hand sanitiser manufacture using the active ingredients Propan-2-ol (Isopropanol); Propan-1-ol; or Ethanol. It is extremely helpful, and HSE's approach remains to be as pragmatic as possible within the legal framework of BPR to help reduce supply chain pressures due to the increased demand, and to offer short-term derogations where necessary to facilitate increased manufacture. Nevertheless, CIA policy leads and member companies identified several further questions and practical queries and requested clarification from HSE.

This note sets out the issues raised and the clarification given by HSE which we hope will be helpful to member companies. As such it represents CIA's interpretation, and manufacturers requiring further information should check with the original guidance or with HSE via the Biocides Enquiries helpdesk referenced in the guidance.

2. Structure of the guidance

HSE's guidance sets out the policy for allowing derogations from product authorisation requirements under PBR (according to which active ingredient is being used for manufacture), links to the World Health Organisation (WHO) formulations for hand sanitiser, and the compliance rules with BPR Article 95 on supply chain for biocidal product ingredients.

3. Short summary for manufacturers

While CIA cannot recommend one method of sanitiser manufacture over any other, potential manufacturers of hand sanitiser may wish to note the following key points of interpretation which CIA has checked with HSE:

(i) Because WHO formulations are available for hand sanitiser using Propan-2-ol and for Ethanol, and because suppliers listed in the European Chemical Agency's (ECHA) database of active ingredients are already compliant with BPR Article 95, HSE's present guidance is likely to be more straightforward for potential manufacturers using these combinations. This is not to say that Propan-1-ol and non-Article 95 suppliers cannot be used (as the guidance makes quite clear), but simply that additional assurances and information may be required.

(ii) Manufacturers using

- Ethanol;
- **and** following the WHO formulation;
- **and** using an Article 95 supplier

do **not** have to contact HSE and can begin manufacture. This is because Ethanol is not yet approved under BPR, the regulations do not apply to the authorisations of products yet, so there is nothing to derogate from.

(iii) Manufacturers using

- Propan-2-ol (Isopropanol);
- **and** following the WHO formulation;
- **and** using an Article 95 supplier

are not required to obtain a product authorisation; they do however need to contact HSE (details of how are given in the guidance) with their intention to place a product on the market, and HSE can issue confirmation that their product will be included by a derogation that is already in place. Manufacturers must not supply the product until they receive the confirmation from HSE.

(iv) Following exactly the WHO propan-2-ol recipe should result in a much quicker (and free) route to getting isopropanol-based hand sanitisers onto the market. Deviations from the WHO recipe and other formulations will require specific application for derogation which includes providing hazard, risk and efficacy assessments for those formulations - more complex and longer than notifying under the derogation for the WHO propan-2-ol formulation that is already in place.

(v) HSE's guidance indicates there are 44 companies (including 4 in the UK) recognised under Article 95 for supplying Propan-2-ol; and 98 companies (including 7 in the UK) recognised under Article 95 for supplying Ethanol. The guidance also provides links to the WHO formulations.

(vi) HSE's guidance states that they expect product manufacturers to take all reasonable steps to source ingredients in such a way that they are compliant with Article 95 obligations; and that HSE inspectors will take a sensible and proportionate approach if they become aware of hand sanitisers that are not strictly in line with normal BPR Article 95 supply chain requirements, recognising the urgent wider need for safe and effective products. This should not stop companies notifying HSE that they wish to be included by the propan-2-ol derogation that is in place; however, evidence of the chemistry of the propan-2-ol will be required to ensure integrity of the product if using supply outside BPR Article 95.

(vii) Manufacturers should also be aware that application to HM Revenue & Customs (HMRC) may also be required, to facilitate the use of alcohol without payment of excise duty. HMRC has introduced a number of relaxations on their rules on approvals for use of alcohols (including ethanol and bioethanol). Further guidance on these aspects is outside the scope of this CIA guidance note, but further information on various potential scenarios and what businesses need to do is available online through the following link:

<https://www.gov.uk/guidance/producing-hand-sanitiser-and-gel-for-coronavirus-covid-19>

4. Other issues and queries raised with HSE

- (i) Is manufacture for 'own use' on site only covered? **Yes** – for manufacture using ethanol, which has not yet been approved and so is still under transitional arrangements. BPR Article 95 requirement is still a key duty; other aspects of BPR also apply including advertising and marketing. Labelling requirements still apply and manufacturers should ensure that the product is properly labelled and avoid making any unproven claims.
- (ii) Do the same authorisations and derogations apply for manufacture of surface (as opposed to hand) sanitisers? **No** – the guidance only applies to hand sanitiser manufacture; **however** for surface disinfectants using Propan-1-ol or -2-ol to which BPR applies, manufacturers should still contact HSE as the WHO formulation does not apply to surface disinfectants. Manufacturers need to demonstrate they are facing significant

challenges to their normal supply chains for derogations to be introduced. For manufacture with Ethanol to which BPR does not currently apply there is no need to contact HSE;

(iii) Does the guidance apply to hand sanitisers that don't contain alcohol? (for example, other active ingredients such as hydrogen peroxide). **No**, the guidance only relates to alcohol-based hand sanitisers (with or without other co-formulants). **However manufacturers should note that Public Health England has advised that sanitisers should have 60% or higher alcohol content to be effective against COVID-19;**

(iv) How long do derogations last? Legally, derogations under BPR last a maximum 180 days.