Possibilities for measures to increase availability of disinfectant products in Member States

The purpose of this note is to provide Member States with information on measures that could be used (or have been used by some Member States already) to permit the making available and/or use of disinfectant products to support efforts to reduce the spread of SARC-CoV-2 virus [1].

In addition, Union authorisations are valid throughout the Union. Currently the Commission has granted three Union authorisations containing the biocidal active substance propan-2-ol [2].

Lastly, the European Centre for Disease Prevention and Control (ECDC)[3] plans to issue soon recommendations on the environmental persistence of the SARS-CoV-2 virus and options for cleaning in healthcare and non-healthcare settings. Discussion with ECHA and the Commission are ongoing.

Products containing active substances approved under the BPR.

1. **Permit disinfectant products authorised in another Member State also on your market**

A number of products authorised under the Biocidal Products Regulation have virucidal claims and through mutual recognition are available in various Member States. All authorisations are recorded in R4BP and ECHA will publish soon a list of these products on its website. https://echa.europa.eu/covid-19

If one or more of these products does not have currently an authorisation in a given Member State, the competent authority of that Member State can grant a permit for the product in accordance with Article 55(1).

2. **Permit pharmacies or other companies to produce hand rub disinfectants**

Several Member States have used Article 55(1) to permit pharmacies or companies active in other sectors (such as cosmetics, pharmaceuticals, chemicals) which were already active in the production of disinfectants to place on the market hand rub disinfectants respecting the compositions recommended by the WHO as effective against Covid 19[4]. Companies wishing to start production and placing on the market disinfectants are advised to contact the competent authorities in the Member States concerned for further details [5].

[1] The disease is referred to as Coronavirus disease 2019 (COVID-19), and the causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
[2] 'Contec IPA Product Family', 'CVAS Disinfectant product based on propan-2-ol' and 'PAL IPA Product Family'; details are available on CIRCABC: https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942.
[3] https://www.ecdc.europa.eu/en
[4] France: Decrees adopted on 13 and 20 March:
https://www.legifrance.gouv.fr/eli/arrete/2020/3/20/TREP2008113A/jo/texte
Germany: General Decree adopted on 13 March
Sweden: Decree adopted on 20 March
[5] Their contact details are available at: https://echa.europa.eu/contacts-of-the-member-state-competent-authorities

3. **Permit disinfectant products authorised on your market which contain biocidal active substances with a different technical specification, a different source or manufacturing site/process than a product authorised**

Biocidal products have to comply with certain criteria linked to the specifications of the approved active substance(s) contained therein (the 'specifications'). The most effective way to address the needs to have more biocidal products on the market with different 'specifications' is that Member States use Article 55(1) of the BPR to permit the placing on the market of biocidal products under derogation from Article 19 and in particular derogation from the technical equivalence requirement in Art. 19(1)(c). ECHA proposes to support industry and the Member States by providing guidance on the minimal requirements for the active substance in order to ensure that it can be safely used in the biocidal products. ECHA intends to have such guidance available in the course of this week.

An alternative for biocidal products under regular authorisations of the BPR is that supplying companies which want to have products authorised with new sources of active substances submit a request for technical equivalence of the new source to ECHA. ECHA proposes to provide within a few working days a preliminary conclusion on the basis of limited information that would be confirmed later (if necessary) in a second step using additional information. In addition, ECHA proposes to provide a service to companies to check whether their source of isopropanol or 1-propanol is already recognised as technically equivalent.

Notification of measures taken under Article 55(1) to the Commission and the other Member States

Measures taken by Member States under Article 55(1) have to be notified to the Commission and the other Member States. This is particularly relevant to quickly inform other Member States who can then consider taking similar measures.

The Commission makes the notifications publicly available[6] so that other Member States and companies can check on this site whether their products have received permits in Member States where so far they had no product authorisation.

4. **Accept that industry implements minor changes related to authorised biocidal products and notifies afterwards**

The European Soap and Detergents Industry Association (AISE) has approached the Commission to suggest that Member States should flexibly accept changes as regards authorised biocidal products in accordance with the 'Do and Tell' principle already foreseen in the Regulation on minor changes (i.e. companies make the changes and then inform the authorities without having to wait for agreement).

[6] The notification forms of Member States are published here: https://circabc.europa.eu/w/browse/47c6e2b3-27a1-4137-83e4-9605a64e2de7. Also an overview table is published of notifications: https://circabc.europa.eu/w/browse/92bd0162-f4b3-49a7-9351-76cf1037287a, the latest version of the table is indicated as "Overview March".

The following examples were given: an authorisation holder that will use the same active substance manufactured on another site[7], change of supply source of other ingredients (co-forumlants) in products, or change of the packaging size (due to supply constraints for certain containers) etc..

5. **Products containing existing active substances still under review**

Products containing existing active substances still under examination in the review programme, are subject to the transitional provisions set out in Article 89 of the BPR. Member States can consider any necessary actions under their national provisions during this transitional period[8] to address the need of disinfectant products on their markets.

15 and 79 biocidal active substances are still under review for product-types 1 and 2, respectively (see Table 1 in the Annex for the list of approved active substances and those substances under review). Member States can permit disinfectant products containing the non-approved active substances in accordance with their national system.. The Belgian, Dutch and Spanish authorities provided an overview of disinfectant products made available on their market under national legislation. Table 2 in the Annex contains an overview of the active substances contained in these disinfectant products.

The Swiss authorities published in early March a list of all authorised products authorised in Switzerland that can be effective to combat SARS-CoV-2:

https://www.anmeldestelle.admin.ch/chem/de/home/themen/pflicht-hersteller/zulassung-biozidprodukte/uebergangszulassung/zulassung-zn/zulassungsverfahren-zn-desinfektionsmittel/liste-der-vom-bag-zugelassenen-desinfektionsmittel-zur-bekaempfung-von-influenza-und-coronaviren.html

[7] According to Commission Implementing Regulation (EU) No 354/2013 a change in manufacturing location or process is an administrative change requiring prior notification before implementation.
[8] This is particularly relevant for Member States that have an authorisation system in place during the transitional period set out in Article 89 of the BPR.

Annex .

Table 1. Biocidal active substances approved or under review for product-types 1 and 2

PT1_PT2_AS_Approved_Under review_versic

Table 2. Biocidal active substances contained in biocidal products available with virucidal claim on the territory of Belgium, Spain and The Netherlands under transitional measures of the Biocidal Products Regulation

	Belgium	Spain	The Netherlands
1	Active chlorine released from sodium hypochlorite	Active chlorine released from sodium hypochlorite	
2		Acetic acid	
3		Active chlorine released from sodium hypochlorite	
4		ADBAC	
5	ADBAC/BKC(C12-16)	ADBAC/BKC(C12-16)	ADBAC/BKC(C12-16)
6	Ampholyt 20		
7		Biphenyl-2-ol	
8	Chlorine dioxide		
9	Chlorhexidine gluconate		
10			Citric acid
11	DDAC	DDAC	DDAC
12			
13	EINECS 220-239-6		
14	EINECS 247-500-7		
15	Ethanol	Ethanol	Ethanol
16			
17	Glutaral		
18			Formaldehyde
19		Glutaraldehyde	
20			Hydrogen chloride
21	Hydrogen peroxide	Hydrogen peroxide	Hydrogen peroxide
22	Lactic acid	Lactic acid	Lactic acid
23			MMPP
23		N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	
24		Pentapotassium bis(peroxymonosulphate) bis(sulphate)	Pentapotassium bis(peroxymonosulphate) bis(sulphate)
25	Peracetic acid (PAA)	Peracetic acid (PAA)	Peracetic acid (PAA)
26		2-phenoxyethanol	
27			2-phenylphenol
28	Propan-1-ol	Propan-1-ol	Propan-1-ol
29	Propan-2-ol	Propan-2-ol	Propan-2-ol
30		Salicylic acid	Salicylic acid
31		Silver	
32			Sodium benzoate
33			Sodiumchlorite
34			Sodium dichloroisocyanurate

35			Sodium hypochlorite
36		Sodiumdichloroisocyanurate dihydrate	
37			Tartaric acid
38			Triacetin/triglyceride