International Association for Soaps, Detergents and Maintenance Products

COVID-19 OUTBREAK AND THE EU RESPONSE

Industry statement

17 March 2020

Over the last few years, outbreaks of pathogenic viruses have become a regular occurrence; H1N1, SARS, MERS and now SARS-COV-2 which leads to the coronavirus disease COVID-19. Due to the impact of these outbreaks on public health and the economic disruption they cause, there is a strong need for populations to exercise superior hygiene practices as a key preventative measure against the spread of the pathogens. It is therefore critically important to ensure that consumers and professionals can identify and access disinfectant products that are both safe and efficacious. As these products are highly regulated and subject to pre-marketing authorisation, there is strong need to ensure that the regulatory system effectively fosters timely access to disinfectants with efficacy against an emergent pathogen such as SARS-COV-2.

A.I.S.E. wishes to stress its unequivocal support for public health and access to safe and efficacious disinfectants for professionals and the general public. A.I.S.E. deplores the tragic situation and wishes to support the fight against the virus. The industry is actively contributing to urgent and weekly queries from the European Commission (DG GROW, DG SANTE) relating to the state of the market for product-type 1 (disinfectants for human hygiene purposes), and product-type 2 (general disinfectants). A.I.S.E. membership has noticed a steep increase in the demand for disinfectants in the EU. Major challenges have however been identified relating to the sourcing of primary packaging for these products, and the availability of some active substances and coformulants for mixture formulations. Disruptions due to limited production capacities, and a lack of personnel at factory-level, have also been reported in some cases. This problematic situation is equally valid for product-type 4 (disinfectants for food and feed areas).

In order to appropriately address this public health crisis and its urgency for solutions, A.I.S.E. recommends that Article 55 of the Biocidal Products Regulation ((BPR, Regulation (EU) 528/2012)[1] be invoked. Art. 55 allows for a temporary derogation from the BPR requirements, stating:

"By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means".

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=EN, Art. 55.1. EU BPR

A.I.S.E. aisbl • Boulevard du Souverain 165 • 1160 Brussels • Belgium
Phone: +32 2 679 62 60 • Fax: +32 2 679 62 66 • Email: aise.main@aise.eu • VAT: BE 0538 183 615
www.aise.eu

A.I.S.E. calls upon the Commission to take a leadership role in the coordination and information sharing among the EU member states authorities, and at global level. We urge the European Commission to remind all EU competent authorities about the possibility to trigger this temporary derogation on the basis of exceptional circumstances.

Indeed, it seems that for some competent authorities no procedures currently exist on how and when to manage a derogation from the requirements. Given the pandemic nature of the crisis, a constant dialogue and alignment between all parties will prove extremely beneficial. A.I.S.E. is at the disposal of EU and national authorities to address existing bottlenecks and barriers to facilitate the placing on the market of disinfectants with proven virucidal efficacy.

A.I.S.E. also has concerns regarding the recent export limitations set up in some EU member states (EU MS), as these also contribute to a shortage of disinfectants. The Commission should encourage EU MS to refrain from this practice, as plants located in a country often serve surrounding countries as well.

The association advocates for pragmatic, flexible and expedited regulatory pathways that will ensure continued access for professionals and consumers to essential disinfectant products during exceptional periods of time, when outbreaks such as the SARS-COV-2 virus hit.

In line with the WHO and ECDC recommendations on maintaining good hygiene practices and adopting preventative measures to reduce the further spread of pathogens like SARS-COV-2, it is essential for the general public and professionals to have continued access to disinfectants, hand sanitizers and other hygiene products that are safe to use and have a proven virucidal efficacy.

Regulatory divergence and trade barriers must not, in any way, delay or prevent access to these products. To this end we call on authorities to:

- Apply regulatory flexibility, under the "Do and Tell" principles, when minor changes to registrations are required to enable increase or continuity of supply of disinfectants, that would otherwise require pre-authorization prior to implementation.
- Make use of legal instruments such as Article 55 of the EU BPR to accelerate regulatory approval of biocidal products that meet safety requirements and suitable virucidal efficacy standards such as EN 14476, ASTM E2406. Provisions should be made for products already authorised by other EEA member states to be recognised and have their approval expedited, on the proviso that a label or leaflet with user instructions is provided in the local language.
- Enable provision of appropriate and adequate information to the public regarding products that may be effective against emerging pathogens such as SARS-COV-2, following the recommendations of the World Health Organisation[2] and other scientific principles (eg. Spaulding classification model) on type of products for disinfection.

[2] https://www.who.int/news-room/q-a-detail/q-a-on-infection-prevention-and-control-for-health-care-workers-caring-for-patients-with-suspected-or-confirmed-2019-ncov (see: *What are the disinfectants recommended for environmental cleaning in healthcare facilities or homes housing patients with suspected or confirmed 2019-nCoV infection?)*