VERBAND DER CHEMISCHEN INDUSTRIE e.V.
WIR GESTALTEN ZUKUNFT.

VCI comments on

Draft amendments to state ordinance of the federal state of Schleswig-Holstein - MedIpVO and HygieneVO

In order to provide information and to avoid barriers to trade, the European Commission publishes certain national rules and gives interested parties the opportunity to submit comments and to draw attention to critical points in those rules. Thus, the following documents were published for comments on 2 December 2019:

- Ordinance of the Ministry of Social Affairs, Health, Youth, Family and Senior Citizens of Schleswig-Holstein: State Ordinance on the prevention of communicable diseases (HygieneVO), notification number 2019/600/D[i]
- Ordinance of the Ministry of Social Affairs, Health, Youth, Family and Senior Citizens of Schleswig-Holstein: State Order on infection prevention in medical facilities (Medical Infection Prevention Order - MedIpVO), notification number 2019/601/D[ii]

From the point of view of the VCI, the proposed changes will result in double regulation of the products concerned. They contradict the EU-wide harmonised regulation of biocidal products through the Biocidal Product Regulation (BPR)[iii] and would create new barriers to trade. The VCI therefore is very critical of both drafts. The points of criticism are explained below.

Proof of Efficacy

The efficacy of disinfectants used to prevent infection and to avoid the transmission of diseases is undoubtedly of great importance for the protection of humans (patients and staff alike).

Regulations of the State of Schleswig-Holstein - MedIpVO and HygieneV

Both documents, which are to amend the federal state regulations in Schleswig-Holstein, require the proof of efficacy of disinfectants for the areas concerned newly described. In both of the documents there is stated under point 1 the need for efficacy against certain target organisms. "*All disinfectants used must be suitable and proven effective in preventing infection in medical facilities. The efficacy for the required range of action must be at least bactericidal, levurocidal and limited virucidal, if necessary additionally fungicidal, tuberculocidal, mycobactericidal and effective against bacterial spores. It must be proven by at least two independent expert opinions and the associated test reports. The efficacy is considered confirmed if the tests have been carried out by test laboratories independent of the manufacturer and the test reports are confirmed by independent experts in a scientifically substantiated assessment. The testing laboratories must have the necessary competence, which can be proven e.g. by accreditation according to DIN ISO EN 17025:2018-03 of March 2018. The respective test method must be validated, e.g. by interlaboratory comparisons, in order to be able to take into account the statistical variability, which includes a number of at least two required test repetitions. Tests which have been carried out in accordance with technical specifications of another Member State of the European Union or Turkey or another Contracting State to the Agreement on the European Economic Area shall be recognised as equivalent if the technical specifications achieve the level of protection required in accordance with the second sentence above on an equally permanent basis*"[iv]

Biocidal Product Regulation (BPR)

The BPR regulates, among other issues, the placing on the market and use of biocidal products through a two-tiered authorisation procedure. Disinfectants in hospitals and healthcare institutions are explicitly included. The conditions for granting an authorisation are laid down in Article 19 of the BPR, the first of the criteria to be met is efficacy (BPR, Article 19 (1) b) i: *"The biocidal product is sufficiently effective."*). Beside other aspects the effects on humans, animals and the environment are also evaluated. The basis for this evaluation is a detailed biocidal product dossier. The information requirements are legally defined in Annex III of the BPR. In ECHA guidelines, the requirements for the proof of efficacy are further specified, whereby reference is made to established test standards and OECD test methods.[v] Besides, the evaluation of efficacy is also described in guidelines following harmonised and transparent criteria.[vi]

Conclusion

The BPR, which as European Union law is directly applicable in each Member State, ensures that the respective biocidal products, such as disinfectants, are effective for the authorised use. Both data requirements and evaluation criteria, which are applied by the evaluation authorities of the Member States, are described in guidelines. In Germany, the Federal Institute for Occupational Safety and Health (BAuA) is as competent authority responsible for evaluating the efficacy of disinfectants. In the case of Union authorisation and mutual recognition procedures, the competent authorities of more than one Member State and ECHA are also involved in the granting of an authorisation.
A confirmation of the efficacy already evaluated by the authorities through independent experts is not necessary.

Consequences of federal regulations as the changes submitted for comment

As described in the previous section, from the VCI point of view, an additional provision for the proof of efficacy for disinfectants does not contribute to increase the level of protection, neither in the scope of the HygieneVO nor the MedIpVO. It would result in negative economic consequences:

- **Contradiction to harmonisation of EU regulations**
  One of the objectives of the BPR is to harmonise the rules on the making available on the market and use of biocidal products. This objective is clearly supported, especially with the possibility of a Union authorisation. The Union authorisation is granted by an implementing regulation of the EU Commission and is directly applicable in all EU member states. Additional requirements, as described in the notifications for the amendment of the regulations of Schleswig-Holstein, would contradict this Union authorisation.
- **Trade barriers in the internal market**
  The harmonisation of the rules on biocidal products in the BPR is intended to improve the functioning of the internal market. National or regional additional regulations as well as supplementary requirements in individual federal states would oppose the harmonisation of the internal market and create new barriers to trade. The free movement of goods would be hindered not only in the EU but also within one Member State.

- **Burden on small and medium-sized enterprises in particular**
  The preparation of further test reports is closely connected with effort and costs. As the authorisation procedure under the BPR already includes an independent assessment by the national competent authorities, this additional burden is not justified. Especially for small and medium-sized enterprises, the increased effort and extra costs must be viewed critically.

VCI proposal

In the VCI perspective, the requirements for the proof of efficacy for disinfectants described in the federal state regulations MedIpVO and HygieneVO must not exceed the authorisation procedure according to the BPR. As biocidal products, the products in question are also subject to this BPR authorisation procedure, which includes the evaluation of efficacy assessment and the competent authorities' conclusions if they may be made available and used on the market in the EU. Reference should be made to the BPR instead of additional expert reports to confirm efficacy. The BPR authorisation ensures that the authorised disinfectants are effective in the authorised uses.
In this context, the VCI would like to point out that the implementation of the BPR and the finalisation of the review programme for existing active substances[vii] is of great importance for the improvement of the level of protection and plays an important role in the harmonisation of the internal market.

Text References

[i] Amendment of the state ordinance in Schleswig-Holstein - HygieneVO, notification number 2019/600/D
https://ec.europa.eu/growth/tools-databases/tris/de/search/?trisaction=search.detail&year=2019&num=600

[ii] Amendment of the state ordinance in Schleswig-Holstein - MedIpVO, notification number 2019/601/D
https://ec.europa.eu/growth/tools-databases/tris/de/search/?trisaction=search.detail&year=2019&num=601

[iii] Biozidprodukte-Verordnung (EU) Nr. 528/2012
https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32012R0528

[iv] Original German, translated by deepl

[v] Guidance on the Biocidal Products Regulation, Volume II (Part A): Efficacy - Information Requirements
https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_ii_part_a_en.pdf/

[vi] Guidance on the Biocidal Products Regulation, Volume II (Part B+C): Efficacy – Assessment and Evaluation
https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf

[vii] Review-Programm für alte Wirkstoffe, Verordnung (EU) Nr. 1062/2014
https://eur-lex.europa.eu/legal-content/DE/TXT/?qid=1417691098051&uri=CELEX:32014R1062

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