VCI POSITION ON THE

Swedish Proposal on Treated Articles

In the document CA-Sept21-Doc.4.1, *Swedish Proposal on the Regulation of Treated Articles under the BPR*, the Swedish competent authority KEMI presented in September 2021 options for a much tighter regulation of treated articles under the BPR[1] and concretised this proposal in November 2021 in a supplementary document, CA Dec21 Doc.4.1, *SE Proposal - Next Step to Regulate Treated Articles*.

The VCI has critically analysed these proposals. The association concludes that a careful study of the legal basis must first take place and the need for stricter regulation must be clearly demonstrated before any discussion of implementation issues begins.
This position addresses and evaluates the Swedish proposal from the industry's viewpoint.

Summary of the first Swedish proposal

From the Swedish authority's point of view, there is a regulatory gap especially for treated articles imported into the EU, as there is no control which treated articles are made available on the EU market. For the Swedish authority this means that action is therefore required.

- Sweden proposes listing acceptable uses in the active substance approval. Treated articles in categories not specified in the decision would then not be permitted on the market. Importers would also be bound by this.
- Risk mitigation measures should not be limited to labelling but should consider all options.
- In current practice, Sweden has the following points of criticism:
  - When evaluating a dossier, only the included uses are assessed, but a large part of the possible uses is not. A ban of certain uses only occurs if they are deemed unsafe in the evaluation. Sweden concludes that uses not included in the dossier thus may be unknown and might be unsafe.
  - In the active substance approval, the assessment is often shifted to the biocidal product authorisation level. This may lead to inconsistencies due to the different views of the several Member States.
  - If there is need for regulation in the evaluation of an active substance concerning the making available of corresponding treated articles, the only instruments applied so far at the active substance level have been a non-authorisation or specific labelling requirements.

[1] BPR: Biozidal Products Regulation (EU) N° 528/2021 concerning the making available on the market and use of biocidal products

- Sweden sees the following advantages in its proposal:
  - Prevention: Previously unknown risks could be identified and thus avoided with better control of treated articles.
  - Harmonization would be improved.
  - The use of biocidal products would be reduced to a *"sustainable level"* and to necessary uses.
- Missing uses can, according to the Swedish authorities, be added subsequently at the request of companies according to EU BPR Article 7.

In November 2021, additional points and implementation issues were taken up in the supplementary document CA-Dec21-Doc.4.1.

- In order to avoid further delays in the implementation of the BPR the above proposals should at first only be applied if there are no delays associated with it. They should in general only be taken into account in the renewal and at an earlier stage only if the deadlines can still be met.
- The existing guidelines and CA documents should be consolidated in just one document. If necessary, points relevant to approval should be topic of a second document.
- It is noted that in applications already submitted under the BPD[2], the depth of information is greater than in applications submitted after 1st September 2013 under the BPR.

VCI Evaluation of the proposal

The VCI can partly understand the approaches to increase the consideration of treated articles in legal requirements and agrees with certain aspects.

- Industry supports the idea of combining the existing guidance documents dealing with treated articles in one document. This would facilitate the comprehension for all parties involved and increase a harmonised implementation.
- Sweden's proposal to make broader use of the range of risk mitigation measures in the active substance approval and to consider further options besides labelling requirements and general restrictions is a good approach. In our view, personal protective equipment and quantitative risk assessment should also be discussed in greater depth as additional options and should in particular be considered in the approval of active substances with sensitising properties.

Nevertheless, the industry has serious concerns about the legal basis for the proposed approach to consider all uses in the active substance evaluation and approval. Furthermore, the implementation would also cause an enormous effort for evaluating authorities and industry, thus lead to further delays for active substance approvals in the review programme and

[2] BPD: Directive 98/8/EG concerning the placing of biocidal products on the market

massively hinder innovation. For existing and established uses of biocidal products for the production of treated articles, it would also create great legal uncertainty.

The various points of criticism are outlined in the following:

- Contrary to Sweden, industry and other stakeholders are of the opinion that the proposal to declare every use in a treated article already in the active substance dossier goes plainly beyond the requirements set in the legal text and is contradictory to the BPR. According to Article 6 (1) b) of the BPR, information on one representative biocidal product is sufficient for the evaluation of the active substance. >The VCI therefore does not see any legal basis for the requirement to specify more than one use in the active substance dossier.
- Whether a product is necessary is not a question to be addressed under the BPR. Solely in case of approval of active substances falling under the exclusion criteria, in emergency authorisation and in exemptions in the interest of defence the product has to be considered as necessary or essential.[3]
- The burden of assessing applications and dossiers is already high. This is particularly evident in the delays in the review programme.[4] The active substance dossier would become extremely complicated. The evaluation effort would be multiplied: In most cases, one active substance is used in several biocidal products formulated by different applicants, one biocidal product is used to produce several different treated articles.[5] The evaluation of all possible uses in treated articles would further increase the burden for both evaluation authorities and applicants and further delay the completion of the review programme.
- In addition, many practical questions arise from the proposal:
  - How should permitted uses be described in the active substance approval?
  - Should the evaluation of the uses in the biocidal product dossier be dropped?
  - The inclusion of additional (end) uses in a dossier causes additional costs due to necessary supporting tests and risk assessments. Who is responsible for this? Who is the data owner? Who bears these costs - the applicant of the active substance dossier, the manufacturer of a corresponding biocidal product or the user/manufacturer of the respective treated article to be additionally considered in the dossier?

  Especially if the participant in the active substance process does not have any economic interest in certain applications, clarity is needed on these questions. This is particularly important in the case of the production of treated articles outside the EU: in this case, manufacturers are not bound to the use of active substances from approved suppliers according to Article 95 of the BPR, so that a participant in the European active substance procedure has no benefit at all.

[3] BPR Article 5(2), BPR Article 55(1), BPR Article 2(8)

[4] Delegated Regulation (EU) No 1062/2014

[5] Example PT 6: Several biocidal products manufacturers use the same active substances or combinations thereof. These in-can preservatives are used to preserve a large variety of different mixtures.

- If a missing application is not supported by the initial applicant through an additional application for approval (as proposed by Sweden), for example the manufacturer of the relevant treated article would have to apply for it. It is unclear whether this would require the submission of a complete application for active substance approval (possibly supported by a letter of access from the initial applicant if the treated article manufacturer's own data is not sufficiently available).
- The applicant is usually not aware of all uses of the active substance.[6] In order to ensure that all market participants have the possibility to continuing placing their products on the market, every possible application in treated articles would have to be identified, e.g. via public consultations. To avoid trade barriers, such information would even have to be requested globally.
- According to the current legal situation, submitted dossiers only very rarely contain information on all possible uses in treated articles. An addition would mean enormous effort in the entire supply chain. There is also a great risk that smaller applications in particular would be left out and corresponding products would no longer be allowed to be manufactured and placed on the market. There would be hardly any legal certainty for both applicants and users.
- The use of a new active substance to produce a new treated article – i.e. a totally new treated article or the replacement of an active substance in a product already being available on the market as treated article - is not possible without enormous time delay. In our understanding a supplement would have to be applied for and an amendment of the active substance approval has to be made in advance. This combination of effort and time delay is a brake on innovation.
- The use of more than one active substance in a biocidal product and thus also in a treated article further complicates the situation. It is unclear how these cases could be represented in the active substance dossier(s).

Against the background of the complexity and the multitude of open questions, an implementation of the proposal would only make sense if stricter regulation was absolutely necessary. In our view, however, this is not the case. We cannot understand Sweden's concerns that unsafe uses would be allowed in the EU due to a lack of evaluation in the active substance dossier.

- On the one hand, the biocidal product authorisation includes a broad evaluation of uses. For this reason, at this level there is the possibility to exclude unsafe uses in principle. On the other hand, the EU chemicals legislation in general and BPR, article 47 in particular offer the possibility to change the authorisation and thus to exclude hazardous uses.

[6] BPR Annex V Main Group 2 (preservatives) largely comprises products with end uses in treated articles. However, for PT 6 (preservatives during storage or "in-can preservatives") alone, the most diverse application possibilities are given in various types of products. The current guidance documents only cover a few main applications in seven sub-groups. Nevertheless, there are many essential uses.

- For the exclusive control of imported treated articles, we consider the proposal inappropriate due to the enormous effort and the negative impact on innovation.
- Different instruments under the chemicals legislation regime already cover substances and articles with certain properties or certain ingredients.
  - Since January 2021, companies have to report articles containing SVHC in concentrations higher than 0.1% to the SCIP database when placing them on the EU market.
  - According to the CLP Regulation, mixtures classified as dangerous for human health have to be notified to ECHA since 1 January 2020.

  A treated article meeting these conditions is also subject to these obligations, regardless of whether the cause is the biocidal active substance or another substance.

Conclusions

The rules for treated articles are a major aspect in the implementation of the BPR.

In VCI's view, Sweden's proposal takes up important aspects – as a compilation in just one document. Nonetheless, on the whole, it is neither necessary to improve the regulation of treated articles or the approval of active substances, nor is it within the legal framework. On the contrary, the VCI considers the proposal to include all uses in the approval of the active substance to be detrimental. The breadth of new information requirements and the restriction of use options would further complicate the implementation of the BPR and increase the hurdle for innovation. This also undermines the idea of the Green Deal, which aims to support environmentally friendly innovations and improve the sustainability and longevity of products.

For many small and medium-sized enterprises, an additional hurdle would rise that could not be overcome for financial reasons. For a better picture of the consequences of the proposal, it is essential that practical issues are also taken into account in possible further discussions of the Swedish proposal.

A pragmatic attitude is necessary so that treated articles can also be produced in the EU in the future and compliance with the obligations can be checked by the European monitoring authorities.

It is explicitly emphasised that the VCI, like the Swedish KEMI, aims to prevent the EU wide availability of treated articles that pose an undue risk to the environment or to human health. Nevertheless, the BPR is not the suitable instrument to regulate each and every product. However, the VCI believes that the existing legal framework is suitable to achieve this goal. Besides the BPR, which focuses on the making available and use of safe biocidal products, there are other regulations that close the regulatory gaps left by the BPR. Overarching REACH and CLP regulations apply to all chemical substances and mixtures, and downstream product regulations also cover treated articles that fall within their respective scopes.

For these regulations to have an effect, however, they must be implemented and compliance with the obligations must be enforced. The VCI is therefore particularly in favour of intensifying EU wide as well as national enforcement measures in order to detect and penalise non-compliance regarding the existing legislation.

Demand for information on necessity and legal basis

Before implementation issues of the Swedish proposal are discussed in more detail, it is crucial from the VCI's point of view to carefully evaluate the need for additional provisions as well as the legal basis.

The VCI therefore requests information on how many treated articles legally made available on the market under the current EU chemicals legislation and whose active substances have been assessed following the "one safe use" principle in the BPR are causing severe problems with regard to environmental, occupational or consumer protection.

Furthermore, the VCI has considerable doubts that under the BPR a complete evaluation of treated articles is foreseen by the legislator at all. The VCI would therefore like to ask the European Commission to scrutinise the legal basis for a more detailed regulation of treated articles.

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered in the “public list on the registration of associations and their representatives” of German Parliament (Deutscher Bundestag).

The VCI represents the politico-economic interests of over 1,700 German chemical and pharmaceutical companies and German subsidiaries of foreign businesses in contacts with politicians, public authorities, other industries, science and media. In 2020, the industry realised sales of nearly 190 billion euros and employed around 464,400 staff.