VCI Position on

Innovation in In-can Preservation: Opportunities and Limitations

Content

Introduction and Challenges

As explained in the VCI information on the preservation of chemical products[1] conservation is mandatory for many different intermediate and end products. An important reason for this is the development of the past decades, which has led to water-based formulations in many areas of application. The use of solvents has been significantly reduced or even completely avoided in numerous products such as coatings, paints or adhesives for end users as well as for industrial applications.

The reduction of solvents and the increased use of water-based formulations are significantly contributing to the improvement of occupational health and safety, consumer protection and environmental protection. According to the current state of the art, however, such water-based products can only meet the desired quality and functional requirements by means of adequate preservation, which is subject to the Biocidal Products Regulation (BPR)[2]. Physical or mechanical alternatives to this have been so far practicable or economically feasible, only for a few specific individual cases.

[1] VCI-Information on preservation of chemical products (18 December 2018)

[2] Regulation (EU) No 528/2012 (BPR)

IN-CAN PRESERVATION CONTRIBUTES TO SUSTAINABILITY

- All consumers must have access to safe and impeccable products.
- The growth of germs, which can, for example, cause mould infestation and lead to diseases, must be prevented.
- Products must be stable during the entire storage, transport and use phase in order to avoid waste and to preserve resources.
- In manufacturing processes and in the use phase, attention should be paid to minimising energy consumption.[3]

The BPR evaluates both active substances and biocidal products (preservatives) for in-can preservation. The approval of an active substance and the authorisation of a biocidal product are only granted if strict safety and environmental standards are met and it can be assumed that their use does not have any unacceptable effect on humans, animals or the environment. If in doubt, the biocidal product will not be authorised or its use is restricted to certain applications. The purely hazard-based classification of an active substance is often the decisive factor in use restrictions. In addition, the effectiveness of both active substances and biocidal products must be demonstrated in the authorisation procedure.

The availability of suitable active substances and biocidal products for preservation plays an important role with regard to the quality and safety of the various end products. Nevertheless, the worrying trend is that there is an increasing restriction in the currently available active substances. In order to enable further preservation, on the one hand, more planning certainty is required for the approval of active substances. On the other hand, innovations would be useful in order to constantly improve occupational health and safety, consumer and environmental protection and to compensate for the loss of available active substances and biocidal products. They are also required by the legislator.[4]

Particularly with regard to the European substitution programme[5] increased research activities and the development and the approval of new active substances should be better supported.

---

[3] Thermal treatment therefore is not expedient and beside that not feasible for mixtures with temperature-sensitive components. Extensive hygiene measures in chemical production are often energy-intensive.

[4] CA-Sept18-Doc7.4-rev1: “Towards the substitution of active substances of high concern in biocidal products and innovation in areas where a need for alternatives is identified”

[5] The substitution programme aims to support the replacement of critical substances by new, less harmful substances. ECHA - *Strategy to promote substitution to safer chemicals through innovation*

However, VCI worries that the number of available active substances - also due to the reference of the BPR to substance classification according to the CLP Regulation - will continue to fall, although safe use can be proven in the application. VCI recognises as well the danger that, in addition to the challenges related to research and development, regulatory approval hurdles will prevent the development of new active substances and their products in the EU in the future - with serious consequences for industry and consumers:

- Certain products, as hand dishwashing detergents, craft adhesives and artists' paints would either no longer be sufficiently durable or not available.
- A large number of products, such as water-based interior paints, coatings and detergents, would no longer be available to consumers despite safe use.
- In the case of industrial use of products there are concerns that further processing will be relocated to non-EU countries. Examples are processes in the textile and leather processing industry. The industrial location with jobs and tax revenues would be at risk.
- Further development of active substances, biocidal products and their applications would only take place outside the EU. The low incentive to bring innovations to the EU market would result in the EU being outpaced on the state of the art.
- Lower shelf life of finished and intermediate products would impair the free movement of goods within the EU, as transport would be limited. Surfactants, polymer dispersions as well as colour and pigment pastes, which are used in many production processes, could only be supplied over shorter distances and could not be stored for enough time. Printing inks for different applications such as napkins or magazines could no longer be transported over larger distances, either.

This VCI position shows the existing limits and hurdles for innovation and makes concrete proposals to improve the innovation environment.

What are existing starting points for innovations in preservation?

The basis for a targeted discussion is a coherent understanding of the term "innovation". When preserving products, in principle innovation can take place at the active substance as well as at the biocidal product level. In the following, the theoretically possible starting points for innovations at both levels will be analysed in more detail.

- **Innovation at the active substance level**
  Targeted research on active substances that act against a large number of organisms - and thus unspecifically and with unknown mechanisms of action - is always a major challenge. In addition to compatibility with the respective applications, high efficacy (in the sense of a low dosage) with low toxicity is desired. Due to the requirement profile, however, it is very likely that an active substance or biocidal product can have undesirable toxic and ecotoxic properties beside its intended high efficacy against the target organism. The chances of identifying an

active substance that does not have any undesirable properties but nevertheless shows high efficacy are therefore very low, even at considerable expense.

- **Synthesis of totally new active ingredients in the biocides industry**
  In the past two decades, no previously completely unknown new biocidal active substances have been developed and approved. The efforts and costs for the development are extremely high, while there are major uncertainties regarding the approval of the active substance and its market success.
- **Active substances through adaptation from other legislations**
  There is a number of examples of active substances that have been used for a long time in plant protection and for which active substance approvals or applications for approvals under biocides law are now existing. Due to differences in target organisms, however, only in a few cases active substances developed for plant protection also can be used for preservation. Among the currently approved active substances there is only one single example of an active substance for product type 6 (PT 6) originating from plant protection.[6] The use of active substances from other legislation is typically not possible or not reasonable.
- **Derivatives of already known active substances**
  There are examples of active substances based on a common chemical structure. Derivatives of known active ingredients may also be suitable as biocidal active ingredients. Research on derivatives usually requires less efforts in synthesis and testing than research on completely new substances. However, intrinsic properties of substance classes, such as sensitizing properties of isothiazolinones, usually cannot be completely overcome by derivatization.

- **Innovation at biocidal product level**
  - **Further development of technical options**
    With the use of releasers[7], progress in preservation was achieved by a technical means. Example: Compared to the addition of formaldehyde, the use of a formaldehyde releaser has the advantage that there is a low temporary concentration of formaldehyde in the product and the release takes place over a longer period of time.[8] Comparable effects were achieved in film protection (PT 7) by encapsulation of active substances.

---

[6] Regulatory requirements in plant protection have increased, too. Therefore, in this decade only 22 new active substances have been approved. In the medium term, it is unlikely that the biocides industry will benefit from any usable innovations in this area.

[7] Agent that releases the active substance, e.g. formaldehyde releaser

[8] However, due to the classification of formaldehyde (CMR), this substance class may only be of limited or no use in the future due to the BPR evaluation.

- **Combination of active substances**
  The combination of active substances in a biocidal product can close gaps in efficacy against certain target organisms and optimise the amount of active substances used. However, this presupposes that appropriate active substances are available.

Improvement of innovation environment needed: Barriers to innovation and authorisation need to be lowered

In order to protect products against microbial infestation, a variety of different active ingredients will be necessary in future. On the one hand this is due to the large number of different end products to be preserved, on the other hand it is also due to the different target organisms that may occur in the respective products and application situations.

Improving the general conditions for the availability of active substances

Suitable biocidal products can only be formulated with a sufficient spectrum of active substances. Innovation at product level is therefore only possible if the necessary active ingredients are available.

Innovation in the sense of developing totally new active substances specifically for use in preservatives, is - as described above - extremely challenging, very unlikely and difficult to plan. For the use of potentially obtainable new active substances (e.g. adaptations from other legal areas or derivatives of known active substances), VCI believes that the hurdles for the approval of active substances, the authorisation of biocidal products and the production of treated articles must be removed as far as possible. The improvement of the regulatory environment for the evaluation of existing active substances would also increase the above-mentioned availability of active substances and thus mitigate the consequences of the innovation problems described above - also at product level.

In order to promote existing innovation potential, regulatory hurdles must be eliminated, for which the following points are of utmost importance:

- **Provide planning certainty for the approval of active substances**

  A stable regulatory environment provides reliable framework conditions. In particular, the continuous development and tightening of evaluation rules must not influence ongoing approvals and licensing procedures. The focus has to be on the implementation of existing regulations.

Experience shows that the implementation of the BPR so far has been a "living process". Many questions could not be answered in time before the application date of the BPR in 2013 but have been– and are still being – discussed in parallel with the evaluation of active substances and biocidal products. Guidelines are continuously developed, so that the applicant often does not have legal certainty.

In addition, a new harmonised classification of active substances according to CLP[9] often differs severely from the previous classification. Both aspects can substantially influence the result of the evaluation of active substances and biocidal products, so that an active substance may either not be approved as applied for or not approved at all. For downstream users, this means that the decision whether the application of a new active substance in the respective end products does make sense can only be taken after the active substance approval.[10]

- **Reduce the time required for active substance approval and biocidal product authorisation**

  A faster marketing of new active substances would be possible for example by pragmatic implementation of article 55 (2) of the BPR.

Data requirements in applications for active substance approvals are very extensive and must be met prior to submission of the dossier. Thus, once a suitable chemical substance has been identified, an application for approval as an active substance can usually only be submitted after about four to five years. Experience has shown that the evaluation by the competent authorities and the granting of the active substance approval are carried out after a further two to four years. The application for authorisation of a corresponding biocidal product is usually subsequently evaluated[11], which takes another two to three years. This means that the actual marketing of a biocidal product/preservative with a new active substance can only take place about 7 to 13 years after identification of a new substance. The marketing of conserved products containing a new active substance is then once again associated with a considerable time delay, since use in the respective end products is based on product development processes that are often time-consuming and cost intensive.

[9] CPL Regulation (EC) No 1272/2008

[10] Research and development may start already earlier in accordance with BPR, article 56. At this stage, however, there is no regulatory planning reliability.

[11] A provisional authorisation according to BPR, article 55 (2), may take place in parallel to the approval process and can reduce the time to introduce a product on the market. This possibility is limited to completely new active substances.

- **Adapt data requirements**

  Reduced or staggered data requirements according to the intended use volume and application profile ("tonnage approach") can lower the economic risk.

Compared to the very high costs the market for preservatives and active substances therein is rather small, as the quantities used in the respective products are generally as low as possible. As a rule, the concentration of the active substance is significantly below 0.1 % in the preserved product. In particular products for very special applications are only sold in small quantities. The potential turnover is usually very unfavourable in relation to the costs incurred. For economic reasons, other - more lucrative - areas are often preferred for investments in research and development.

The applicant for an active substance or biocidal product authorisation bears the full economic risk. The costs for the complete dossier and all fees must be paid in advance. In contrast to other investments, planning reliability is very low.

- **Reduce bureaucracy and fees**
  Economic reasons also play a role. In order to promote the submission of applications, the fees for the approval of active substances and the authorisation of biocidal products should be reduced as far as possible.

In addition to the costs for research and development to identify suitable chemical structures, the generation of data required for active substance applications and biocidal product applications as well as for the preparation of the dossier takes a lot of effort and is expensive. Additionally, significant fees have to be paid to the ECHA (see Fees Regulation[12]) and to the evaluating Member State (see national fee regulations, e.g. Germany: ChemKostVO[13]).[14] The total costs resulting for an application for approval of an active substance for use in preservatives average around € 5,000,000[15].

The approval of an active substance is usually limited to a maximum of 10 years. Subsequently, a renewal can be applied for, which again involves costs and fees. In

[12] Regulation (EU) No 564/2013

[13] German fee regulation, ChemKostVO

[14] Fee calculation for the approval of an active substance for PT 6 when Germany is the evaluating competent authority:

ECHA-fee for the approval of one AS for one PT (e.g. PT 6):	120 000 €
German fee for the evaluation of an application for AS approval:	189 800 €
Sum:	309 800 €

[15] Total regulatory costs for AS approval, toxicological studies included

addition, there are the fees and costs associated with the authorisation of the biocidal product required before application.

- **Consider the benefits of the products**

  Appropriate preservation has many benefits for society and the environment.[1] It has a positive impact on occupational health and safety and consumer protection. It also contributes to environmental protection by avoiding waste.

The purely hazard-based classification of an active ingredient is often decisive for restrictions of the application. However, the consequences of a lack of active ingredients and biocidal products have not yet been taken into account in the evaluation.

Opportunities for innovation only if hurdles are removed

The availability of suitable active substances and biocidal products is the prerequisite for appropriate preservation, which is important for the quality and safety of the various end products. The formulation of suitable biocidal products is only possible with a sufficient spectrum of active substances. Innovation in the sense of developing completely new active substances, specifically for use in preservatives, is extremely challenging and unlikely. Reducing the regulatory hurdles in the approval would help to promote the existing opportunities for possible innovations and also enable the preservation of the various end products and intermediates in the future.

Explanation of the terms used

BPR definitions, with some relation to in-can preservation

- "**biocidal product** means any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action […]"

  → This means a preservative (in-can preservative) contains one or more active substances and is intended to act against harmful organisms - e.g. fungi and bacteria - which are harmful to the shelf life of a product.
- "**active substance** means a substance or a micro-organism that has an action on or against harmful organisms"
- "**treated article** means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products"

Contact: Dr. Evelyn Roßkamp, Dept. Science, Technical and Environmental Affairs – Product Safety
Phone: +49 (69) 2556-1962
E-Mail: rosskamp@vci.de

Internet: www.vci.de · *Twitter:* http://twitter.com/chemieverband · *Facebook:* http://facebook.com/chemieverbandVCI

German Chemical Industry Association
Mainzer Landstrasse 55, 60329 Frankfurt, Germany

- 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 around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. The VCI stands for over 90 percent of the chemical industry in Germany. In 2018 the German chemical industry realised sales of ca. 204 billion euros and employed 462,000 staff.