VCI POSITION

Protection of Data under the BPR

Data protection is important

Within the approval of active substances and the authorisation of biocidal products, there are extensive data requirements that applicants need to fulfil. These data form the basis for the evaluation.
Generating Data for those BPR dossiers involves much work and cost for applicants. In particular, the elaborate and expensive animal studies required for the gathering of toxicological data often account for the largest share of the costs of active substance dossiers. Thus, the data generated for an active substance dossier by the applicant are of high economic value. The summaries and evaluations of data – including risk assessments and literature research – which are contained in the dossiers as part of the data requirements have an important value, too. They are the result of intellectual work.
The value of data was also recognised by the legislator who describes in Article 95 BPR the access to active substance dossiers, in order to prevent the use of data without sharing the costs ("free-riding").

Data sharing and cost assumption

Under both the BPR and REACH, there are data sharing obligations existing with a view to avoiding unnecessary animal testing. Carrying out animal tests is only permitted if relevant data do not yet exist. Therefore, applicants must first check whether such information is already available. Access to existing data is (usually) made possible by contributing to the costs. This can be done, for example, through cooperation in a consortium or with a Letter of Access (LoA).
Data sharing is regulated separately in the BPR and REACH, respectively, and is not considered covering both legal areas. In practice, for this reason there are numerous examples where both REACH and BPR consortia exist for one substance.

Current situation: Data protection is expiring

According to Article 95(5) BPR, the data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007 will end on 31 December 2025. In the VCI's understanding this is in conflict with the protection periods laid down in Article 60 BPR which relate to the decision on active substance approval or biocidal product authorisation, respectively, due to the significant delays in the completion of the Review Programme. These delays can also lead to a different evaluation status for the same active substance in different product-types, i.e. the active substance is already approved for one product-type while it is still being evaluated for others.

Article 60 – Data protection periods

Data submitted for the purposes of Directive 98/8/EC or of this Regulation [BPR] *shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.*

The protection period for submitted data ends after the prescribed amounts of time, from the first day of the month following the date of adoption of a decision by the Commission:

Active substance approval	Protection period (Article 60(1))
Approval of an existing active substance	10 years
Approval of a new active substance	15 years
Renewal or review of the approval of an active substance	5 years
Authorisation of a biocidal product	Protection period (Article 60(2))
Authorisation of a biocidal product containing only existing active substances	10 years
Authorisation of a biocidal product containing a new active substance	15 years
Renewal or amendment of the authorisation of a biocidal product	5 years

Article 95(5)

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007 […] shall end on 31 December 2025.

In the VCI's understanding, the provisions of Article 95(5) are based on the assumption that the Review Programme would be completed within the period planned at the time of the first publication of the BPR[1] and would end on 14 May 2014. The last dossiers for the existing active substances in the programme (dossiers considered complete at that time) were submitted on 31 October 2008. In this case, the submitted data would have been protected until 31 December 2025, taking into account the evaluation timeframe, for about 12 years.
The protection period for new data submitted for the renewal of active substance approvals or product authorisations then lasts for five years, starting from the relevant decision.

Legal certainty: Clarification of practical implementation issues

For potential users of data as well as for data holders and applicants, the practical aspects at the end of data protection are of great interest. Clarity about the concrete consequences is important for all stakeholders.
At present, many questions remain open:

- **Who has the possibility to use the data?**
  In principle, the end of data protection allows third parties to use the data submitted in the context of an active substance approval. However, it is unclear by whom or for what purpose the data can be used in practice.

[1] BPR published in the EU Official Journal (L 167/1) on 27.06.2012: Article 89(1): The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 14 May 2014.

- Can a company as an active substance manufacturer use it to be newly included in the Article 95 list?
- Can a new applicant use the data for a AS/PT-combination whose evaluation under the Review Programme is not yet completed? Can the data be used for a new AS/PT-combination?
- Can the applicant refer to these data for an authorisation of a biocidal product, which would make a Letter of Access (LoA) obsolete?
- Can the data be used for other purposes?
  - Can the data also be used, for example, for registration, authorisation or restriction under REACH or in plant protection?
  - Is the data used by public authorities in the context of classification?
  - Can the data be used for regulatory purposes outside the EU, for example, for REACH or biocides procedures in the UK or Korea?

- **How can the data be used?**
  It is unclear in what form data will become available once the protection periods end. The following different ways of using data after expiry of the protection period are conceivable:
  - Options would be the publication of the data as such or of the dossier submitted for approval, or the provision of relevant information, e.g. by ECHA, upon request by interested companies.
    Will the data as such be made available to interested parties by ECHA?
  - Another possibility would be for the Agency to allow making reference to the data without making the studies themselves available to the user. Is it planned that ECHA will allow making reference to data whose protection periods have expired to interested parties? Will ECHA grant access rights for use in other legal areas?

  The work, cost and effort that new applicants have to invest in their own applications, i.e. whether their own summaries and evaluations are necessary or whether a blanket reference to an already submitted dossier is sufficient, depend on the possibilities of using the data.
- **Is the data holder informed about the use of the data?**
  Depending on the answer to the question of how the data will be used, data holders may not directly be informed about any interest in their data. Because of the economic relevance, it is interesting whether the data holders are informed about the intention of the Agency to allow the use by third parties.
- **Is the time of submission of data taken into account?**
  Additional data is regularly demanded in the approval of existing active substances. Companies which support existing active substances as participants in the Review Programme usually comply with this demand, so that the evaluation can be finalised and the active substance approval is granted. They carry out the required tests and generate new data. An important example is the additional provision of data to meet the data requirements for the determination of endocrine-disrupting properties. These criteria were

only laid down in 2017 and need to be applied since June 2018.[2] Concrete data requirements were not described before the amendment of the BPR annexes[3] when, however, the dossiers for all existing active substances had already been submitted. A legally secure regime for additionally demanded data is of great interest to the industry, against the backdrop of the immense costs particularly for animal tests.

End of data protection: Potential consequences for companies, public authorities and society

The end of data protection and thus the possibility of using data without contributing to the costs has serious impacts, particularly on the companies involved. But the approach to data required for approval/authorisation can also influence the availability of biocidal products:

- **Use of data without cost contribution**
  The costs of data to be submitted for active substance approval and biocidal product authorisation are considerable. With the possibility of using data for which the protection periods have expired, such costs will no longer have to be incurred by new applicants. This could lead to more biocidal products being made available on the market and creating more competition.
- **Increased workload for evaluating authorities**
  A rising number of market players would increase the number of applications and, consequently, the workload for evaluating authorities.
- **Factual expropriation of data holders**
  Applicants, who are currently generating or have just recently generated data for existing active substances, have an economic interest in their potential competitors being unable to use right away such new data without incurring any cost. This is taken into account in Article 95 BPR by which “free-riding” was meant to be prevented. Free availability of new data contradicts the existing situation where data owners’ rights are protected at least for a given period of time and sharing is regulated either by joining a consortium, a Letter of Access for either the active substance dossier, or a biocidal product. For those companies who have generated data or are still doing so due to additional data requirements from authorities, the absence of protection periods would factually mean an unacceptable expropriation.
- **Less willingness to invest in new data**
  Without all applicants contributing to the costs of generating data and without the possibility to exclusively market a certain active substance for a given period of time, the benefit of new data generation is put into question for economic reasons. The willingness to invest in new data can be adversely affected permanently.
- **Risk to the availability of active substances**
  The availability of approved active substances is a prerequisite for the evaluation and

[2] Commission Delegated Regulation (EU) 2017/2100, Link: https://eur-lex.europa.eu/eli/reg_del/2017/2100/oj

[3] Commission Delegated Regulation (EU) 2021/525, Link: https://eur-lex.europa.eu/eli/reg_del/2021/525/oj

authorisation of biocides which have – as disinfectants, protective agents or pesticides – important functions in ensuring a high standard of hygiene and significantly contribute to extending the lifespan of products. The data on which evaluation is based are fundamental for a high protection level. Without generating new data, the approval of existing active substances would be at stake. This would result in a lack of important biocides, with major consequences for society.

Proposal for a solution

The VCI asks the legislator and the competent authorities for information on how data can be used after the end of the protection period and, in this respect, for a proposal how a balance can be maintained between the interests of data holders and the interests of users of unprotected data**. A fair and workable approach is the basis for supporting existing active substances in the Review Programme.** Only in this way the existing active substances can continue to be approved. Connected with this, the corresponding biocidal products can be evaluated, authorised, and placed on the market under the conditions described in the BPR.
From the VCI's perspective, it is urgently necessary to establish sufficient protection periods for newly generated data, soon. This is relevant not only for new active substances but also for newly requested studies (for example, on endocrine disrupting properties of existing active substances). At the time of dossier submission, such studies were neither necessary nor were there any relevant guidelines existing.
Giving due consideration to a meaningful distinction between genuine old data for which data protection rightly expires and new data for existing active substances, we would propose the following course of action:

- For data already **submitted in the originally submitted dossier** of an existing active substance – the protection periods under BPR Article 95(5) will end on 31 December 2025.
- For data that had to be additionally submitted by the participants in the Review Programme due to new rules, the definition of ED criteria, revised guidelines etc and, therefore, had to be **newly generated at a later moment in time – a 12-year protection period applies** from the date of active substance approval. This also applies to studies that the applicant carried out voluntarily to support a specific claim or to gain new knowledge.
- In consequence of the above, reference to evaluation, risk assessment and summary without LoA granted by the data holder is possible only for those relevant points for which data protection has already ended.
- Furthermore, **additional demands for data on new endpoints should be reduced** to a minimum. This could speed up the completion of the Review Programme. Also, the subsequent consideration of new data in renewals would result in such new data being covered by the relevant protection periods according to Article 60(2) 3.

In view of the deviation from the originally planned timeline and against the backdrop of the possibility given in the BPR to subject active substances and products, even after completion of an evaluation, to yet another examination in cases where there are good reasons to do so, we find the above-proposed course of action both justified and feasible within the legal framework.

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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 interests of around 1,900 companies from the chemical-pharmaceutical industry and related sectors vis-à-vis politicians, public authorities, other industries, science and media. In 2021, the VCI member companies realized sales of ca. 220 billion euros and employed over 530,000 staff.