Joint position of FCIO and VCI on

Delays in the authorisation of biocidal products

Background

The Biocidal Products Regulation EU 528/2012 (BPR) describes the authorisation procedure for biocidal products. The objective is “authorisation” as prerequisite for the making available and use of biocides.

However, there are increasing delays in the authorisation of biocidal products. This has major consequences, especially for small and medium-sized enterprises, and causes much uncertainty:

- **Market Freeze:**
  An already granted authorisation is the prerequisite for the marketing of same products and for mutual recognition in sequence. Without authorisation, no new trade names can be marketed, and no existing products can be newly placed on the market in other Member States.
- **Market distortion:**
  Authorised and non-authorised biocidal products of the same product-types are sometimes legally available on the market in parallel for more than 10 years. This market distortion is a particular burden on companies which produce "niche products" for special requirements. In certain circumstances, the consequences for such companies can be as severe as going out of business.
- **Obstacle to innovation:**
  Improved formulations as well as innovative products cannot be made available on the market.
- **Legal uncertainty:**
  The legal basis is unclear for products for which no authorisation is granted three years after approval of the active substance.

In this position paper, FCIO and VCI explain the consequences of the delays in authorisation procedures for industry and society. Proposals are made on how policy-makers and authorities can counteract this development and keep the described problem from intensifying.

Industry welcomes that the EU Commission, ECHA and public authorities, too, are already looking into delays in authorisation.[1] From the associations’ viewpoint, an exchange on solution approaches and a discussion of the different proposals would help speed up authorisation procedures and improve the implementation of the BPR.

[1] CA-Sept20-Doc.4.7 Monitoring Report Authorisations of Biocidal Products

Marketability of biocidal products

Biocidal products with existing active substances can benefit from the transitional measures.

Under the transitional measures, biocidal products with so called existing active substances – i.e. active substances that were on the market as active substances of biocidal products already in the year 2000 and are named in the review programme – can be made available on the market without authorisation for a transitional period of a maximum of three years after the approval of the last active substance to be approved, according to the BPR. The following prerequisites apply for this:

- In most Member States, the transitional measures only apply if the biocidal product is on the market in that country at the time of active substance approval and has been notified, registered or even authorised accordingly.
- A dossier/application for biocidal product authorisation must have been submitted by the date of the active substance approval.
- The application must be processed, evaluated and the procedure completed by the competent authority within the time limits specified in the BPR.
- During this transitional period, the biocidal product placed on the market is nevertheless subject to existing national rules in the respective Member State which in some cases differ considerably. Depending on the Member State, the rules consist of authorisation or registration procedures – while in some cases there are no national requirements at all.

Not all biocidal products with existing active substances benefit from the transitional measures.

Biocidal products for which no application for authorisation was submitted under the transitional measures, e.g. because the formulation was developed later, can only be made available on the market after authorisation has been granted. This is also the case where a national application for authorisation was submitted for a biocidal product under the transitional measures, but the applicant later applies additionally for authorisation in another Member State. In this situation, marketing is only possible after the national authorisation has been granted by way of mutual recognition.

Biocidal products with new active substances require authorisation.

As a rule, biocidal products with a new active substance can only be made available on the market after the active substance has gone through the multi-year approval procedure, the subsequent initial authorisation of the biocidal product and the granting of the authorisation.

The authorisation procedure and deadlines

The deadline for the authorisation of biocidal products, which fall under the transitional measures, is stipulated in Article 89(3) BPR which reads: *"Following a decision to approve a particular active substance for a specific product-type, Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval."*

The BPR lays down timelines for the individual procedural steps, resulting in the following periods for the authorisation procedure:

- National authorisation: 425 days; the period can be extended up to 695 days if additional demands are made.
- Union authorisation: 605 days; the period can be extended up to 875 days if additional demands are made.
- Mutual recognition in sequence: 180 days.

In practice, however, it becomes apparent that these timelines cannot be met in many cases. Currently, the time required for marketing authorisation is usually significantly over three years.

Purposes of the BPR

From our perspective, it is important to refer to the purpose defined in the biocides legislation also in connection with the authorisation of biocidal products. We see clear discrepancies between the current situation and the BPR goals described in Article 1(1). In the following, we would address these points:

- **Purpose: Functioning of the internal market through harmonisation of the rules on the making available on the market and the use of biocidal products**

  Current situation:

  - The delays cause market distortions and a longer application of "old" national provisions.
  - Delays in mutual recognition impair the competitiveness of companies. In some cases, a market expansion is not possible or cannot be planned reliably in advance for a given date.
  - The relocation of a production site cannot take place if the authorisation cannot be changed.
  - No new product names, for example for "private label" customers, can be placed on the market.

- **Purpose: Ensuring a high level of protection of both human and animal health and the environment … underpinned by the precautionary principle. … Particular attention shall be paid to the protection of vulnerable groups.**

Current situation:

- In some instances, after more than 10 years since the granting of the first product authorisations for a certain product-type, there are still biocidal products of the same product-type on the market which have not yet gone through the authorisation procedure and are thus at least in some countries completely unregulated.
- Biocidal products are essential for the protection of humans, animals and the environment. To ensure the protection level, it is essential that the products needed today are available. New products might also be required to meet future challenges and problems. Innovation is indispensable to improve products and to respond to new demands. In the current framework conditions, it cannot be ensured that the necessary number of products will be available on the market.
- It might be necessary to modify formulations to safeguard a high level of protection. Improving formulations might be rendered impossible by very high costs and the large amount of time needed for changes to existing or new authorisations.

In principle, we consider the BPR and the authorisation procedure for biocidal products described therein to be well suited for achieving the given goals.

Reasons for delays

In order to improve the BPR implementation, we believe it is important to address the causes for delays in authorisation. Beside analysing the delays, the EU Commission and Member States are already working on identifying the underlying reasons, from which concrete improvements to speed up the procedures will then be derived.

Industry attributes the delays to several causes:

- **(Further) development and application of guidance documents**
  For many questions – e. g. on the authorisation of biocidal product families, proof of efficacy, technical equivalence, approval of *in situ* active substances and corresponding authorisations – guidance documents first had to be developed. Many guidance documents are being revised several times and continuously or are not yet completed.
- **Additional demands for data/information**
  - Competent authorities take the stance that the latest version of the guidelines is to apply invariably. Therefore, sometimes the exposure and risk models need to be adapted once again in the evaluation phase.
  - The latest state of legislation is taken into consideration, e. g. harmonised classification according to CLP. Changes to the existing classification of active substances and also of co-formulants in biocidal products can have serious consequences for authorisation.

- During the authorisation phase, active substance evaluations of other product-types are updated. This leads to changed endpoints that are not included in relevant PT-specific active substance dossiers. In practice, this causes uncertainties and, depending on the data situation, leads to re-evaluations.
- Quite often, a very high level of detail is required, i. e. every use of every variant of a biocidal product is considered in terms of efficacy and risk assessment.
- Open questions that have been shifted from the active substance approval procedure ("BPC Opinion") to product authorisation need to be clarified in the context of each individual product authorisation procedure.

- **Evaluation of co-formulants in biocidal products**
  Many biocidal products are highly complex mixtures with sometimes large numbers of co-formulants. These co-formulants are absolutely necessary for certain technical properties of such specific products. Where each individual co-formulant is assessed in the authorisation procedure, e. g. with regard to potential endocrine properties, the evaluation effort of the competent authority is immense.
- **Acceptance of evaluations**
  Evaluations by one Member State are often intensively reviewed by other countries in mutual recognition procedures, which practically equals a reassessment and often leads to additional demands for data/information. This causes delays, especially in mutual recognition in sequence.

The situation is worsening for the following reasons, causing heavy strains on the evaluating competent authorities:

- Brexit and the assessment of potential endocrine disrupting properties increase the workload for the authorities.
- In some cases, renewals of the active substance approval are coming up while biocidal product authorisations have not yet been granted.
- The approval of an active substance entails a larger number of applications for biocidal product authorisations. Due to the limitation of the family concept, it must be expected that the number of applications for authorisation of individual biocidal products and product families will further rise.

In order to accelerate authorisation in line with the BPR purposes, the causes of delay need to be remedied and more legal certainty should be brought about.

Proposals for solutions

In our view, the Biocidal Products Regulation – by means of active substance approval and authorisation of biocidal products – contains important instruments for achieving the protection goals described in Article 1 BPR and for the harmonisation of the internal market. However, the concrete implementation of the regulation is of central importance for this.

In order to speed up the assessment processes and to bring about more legal certainty for applicants, we would propose the following approach to solutions and put them up for discussion:

- Fast first evaluation of all active substances and first authorisation of all biocidal products
  - Co-formulants are regulated in REACH. In the authorisation of biocidal products, the emphasis should not be on the assessment of co-formulants. The question whether they might have properties as "endocrine disruptors" should be clarified exclusively under REACH and only then be taken into account in the authorisation procedure. It should also be taken into consideration in what concentrations these substances are present in the product.
  - Only the endpoints laid down in the active substance dossier for the specific product-type should be used in the assessment.
  - A harmonised level of scientific and technical knowledge and the acceptance of EU (or OECD) guidelines must be the basis of the assessment by national competent authorities.
- Reliable determination of the scope of requirements when submitting applications and "fine-tuning" in downstream harmonised processes
  - The use of new, agreed guidance documents should be linked to the date of application in a binding manner. Additional requirements from progressing assessment practice and from new guidance documents or guidance updated during an ongoing assessment should only be considered in the renewal process. This establishes a clear and recognisable profile of requirements for the authorisation applied for, both for authorities and applicants. Thus, this ensures reliability and legal certainty for all parties involved in the procedure and is in line with the time limit for authorisation described in the BPR.
  - The taking into account of a new classification in the assessment of the biocidal product during an ongoing authorisation procedure should be aligned with the requirements of the CLP Regulation and ATP. RAC opinions on the classification proposal cannot be taken into consideration at this stage, because they merely serve as a basis for further discussion (CLP Regulation Article 37(4)). A binding determination of the classification is only made when the ATP enters into force and must be implemented within 18 months.
- Optimisation of processes involving competent authorities from multiple Member States
    - Mutual recognition in sequence can be accelerated by means of a defined commenting period for other Member States at the initial authorisation.
  - After that, the mutual recognition authorisation should be prompt without further dossier assessment.

- Bring about legal certainty for the assessment period
  - For cases where the evaluation cannot be completed in three years, binding procedures must be developed to safeguard the marketability of existing products.

In order to speed up the assessment processes, we also consider thought-provoking impulses helpful, as they are practiced in other countries/jurisdictions:

- Following the Australian model, authorisation could be granted automatically if there are no direct, clearly understandable reasons to the contrary (e. g. "imminent danger"). Products which are in the authorisation process should still be marketable.
- The assessment should focus on essential information, following the example of the USA. This could be achieved by giving up the depth of detail and an improved acceptance of existing, older information (according to old guidelines). There would be fewer or no additional requirements after the completeness check.
- “Inert lists” – also like in the USA – could ease the assessment effort for ingredients already tested within the product-type.

Contact: Dr. Evelyn Roßkamp, Science, Technical Affairs and Environment / Product Safety
Phone: +49 (69) 2556-1962
E-Mail: rosskamp@vci.de
Internet: www.vci.de · Twitter · LinkedIn

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

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The VCI represents the politico-economic interests of over 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. In 2020 the German chemical industry realised sales of over 186 billion euros and employed around 464,000 staff.

Ansprechpartner: Dr. Dominique Schröder
Telefon: +43 05 90 900 3373
E-Mail: schroeder@fcio.at
Internet: www.fcio.at · Twitter

Fachverband der chemischen Industrie Österreichs / Wirtschaftskammer Österreich
Wiedner Hauptstraße 63 | A-1045 Vienna, Austria

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