VCI POSITION ON THE IMPLEMENTATION OF

Derogation for Biocidal Active Substances with ED-properties

Since 7 June 2018, biocides have been assessed for potential endocrine disrupting (ED) properties following the EFSA/ECHA Guidance on the Identification of Endocrine Disruptors. The BPR provides in Article 5(1) that active substances that may be harmful to humans due to endocrine disrupting properties (human ED) will not be approved. Nevertheless, Article 5(2) provides for derogations: They enable the approval of those active substances if at least one of the following conditions is met:

- The risk to humans, animals or the environment from exposure to the active substance is negligible under realistic worst-case conditions of use.
- It is shown by evidence that the active substance is essential.
- Non-approval would have disproportionate negative impact on society compared to the risk.

It has been observed that there are delays and uncertainties in the evaluation of active substances that have been identified as endocrine disruptors or where classification may not be possible. As a result, the Biocidal Products Committee (BPC) at ECHA is increasingly unable to agree on an opinion for approval or non-approval, resulting in a "no conclusion". This makes it difficult to decide whether the conditions for derogation are met or not. The problem results from the fact that so far binding guidelines have only been established for the hazard-based classification of an active substance as an endocrine disruptor, while there are no corresponding guidelines for the exposure-specific risk assessment of biocidal products or biocidal active substances based on the ED properties.

From the VCI's point of view, however, it should be possible by means of a quantitative assessment including corresponding risk mitigation measures to perform a suitable risk assessment for the respective PT-specific uses.

More and more substances are being identified as having endocrine properties. The evaluation of a possible derogation will thus have to take place more and more frequently. The VCI therefore sees an urgent need for a guidance document that describes the evaluation of derogation criteria for active substances with endocrine disrupting properties, thus enabling a harmonised procedure, providing planning certainty and advancing the completion of assessments. Should no agreement be possible regarding the derivation of a threshold value for an active substance with endocrine disrupting properties, the VCI considers a stepwise qualitative assessment approach, which takes into account the assessment of the risk under realistic conditions for the application of the product in question, to be absolutely necessary in order to enable a regulated procedure.

VCI sees also a need for clarification with regard to the assessment of negligible risk in relation to substance properties where no threshold values exist but may lead to exclusion or substitution criteria. Furthermore, there is no legally binding definition under which condition an active substance is "shown to be essential" or its non-approval would have "disproportionate negative impact". Here, too, binding definitions would be necessary.

In the following, however, we focus on the exemption allowed by Article 5(2) for endocrine disruptors in low-risk applications due to low exposure.

The VCI considers the termination of ongoing and future active substance procedures on the basis of a scientific justification to be an essential task of the authorities under the BPR. It is absolutely necessary for the implementation of the Regulation. We ask the Commission and the Member States to support a harmonised and practicable approach. As a central element for this purpose, we consider a guidance document describing the evaluation of derogation within the framework of Art 5(2) of BPR and addressing the derivation of specific endpoints, safety factors and risk mitigation measures.

Usable instruments for risk assessment

In risk assessment, the hazard posed by a substance is considered in conjunction with the exposure. In most cases, substance-specific limit values are used in the assessment, below which it is assumed that there is no risk.
For endocrine-disrupting properties, no limit values exist so far, so that no reference to an existing substance-specific value is possible.
In our view, however, the following approaches can be taken into account in the assessment:

- Where are endpoints or criteria already considered? Which kind of threshold values are already accepted in similar topics?
  - For carcinogenic substances, a threshold value for labelling has been established.
  - For co-formulants with endocrine properties, these are not considered as Substance of Concern (SoC) in the assessment below a total concentration of 0.1%.
  - For co-formulants with PBT properties, these are not taken into account in the assessment if the total concentration is below 0.1% w/w.
  - The EU Commission's draft delegated act amending the CLP Regulation provides for generic concentration limits of 0.1% w/w (category 1) or 1% w/w (category 2) for the classification of mixtures as endocrine disrupting, staggered by category.

- We consider it possible to set further limit values at application level and to take them into account in the risk assessment. A reference to possible emissions, to leaching or to other acceptable concentrations in the final product or the treated articles is considered as suitable.
  - ➔ Is it possible to set a limit value of 0.1%, analogous to the examples above and use it for the content of the active substance with endocrine disrupting properties in the final product?

- How do other jurisdictions proceed with the assessment?
  - Example: The USA takes a leading role in the development of methods for the detection of endocrine disrupting properties and therefore has many years of experience in the regulatory handling of corresponding substances. A two-step approach is used to scientifically investigate the quantitative relationship between substance and endocrine effect, which is followed by a comparison between risk and exposure, thus establishing a scientific basis for regulatory decisions.
  - Example: For the evaluation of the use of phthalates in certain medical devices, there is a guideline of the EU Commission which is used to derive scientifically limit values for certain phthalates with CMR or ED properties.

- Are there differences in exposure?
  - Example: A substance can have serious effects on infants and young children (development stage), but these effects are not relevant after a certain age (adult stage).
    - ➔ Is it possible to derive individual threshold values for the implementation of individual risk measures?
  - Example: Bioavailability can play a major role: A substance that is quickly eliminated in the organism and quickly degraded in the environment has no accumulation potential and can only influence the endocrine system in the short term.
    - ➔ What possibilities are there to consider the aspects of toxicokinetic and degradability in the risk assessment? What is the likelihood of exposure?

- When is a risk "negligible"? When is a risk acceptable?
  - With appropriate risk mitigation measures, the risk that may be associated with the use of a substance can significantly be reduced. In very few cases, however, the complete exclusion of a risk will be possible, e.g. by preventing any exposure (“excluding contact”).
    - ➔ How can the risk during application be mitigated to an "acceptable level" by realistic means?

A use and product type related risk assessment should consider the specific appropriate and applied risk mitigation measures to minimise the exposure of humans, animals and the environment towards substances with endocrine disrupting properties.

References

(only available in German)

[1] BfR, Fragen und Antworten zu endokrinen Disruptoren, 17. März 2022

Link: https://www.bfr.bund.de/de/fragen_und_antworten_zu_endokrinen_disruptoren-50513.html: *„Wie wird das gesundheitliche Risiko von Verbraucherinnen und Verbrauchern gegenüber endokrinen Disruptoren eingeschätzt?*

Das gesundheitliche Risiko, d. h. die Wahrscheinlichkeit von unerwünschten Auswirkungen durch endokrine Disruptoren auf das Hormonsystem, ist sowohl von den endokrin-schädigenden Eigenschaften einer Substanz, deren Wirkstärke, Wirksamkeit und Effektivität als auch der Höhe der Aufnahme dieser Stoffe abhängig. Entscheidend für die Einschätzung des gesundheitlichen Risikos ist die Exposition (Dosis), also das Ausmaß, in dem ein Mensch mit einer endokrin-schädigenden Substanz in Kontakt kommt. Für jede Substanz wird das gesundheitliche Risiko individuell bewertet.“

VCI-Positionspapier Grenzwerte für endokrine Disruptoren

Link: https://www.vci.de/themen/chemikaliensicherheit/endokrine-wirkung/vci-position-zur-diskussion-ueber-grenzwerte-fur-endokrine-disruptoren-hormonaktive-substanzen.jsp

Contact: Dr. Evelyn Roßkamp
Referentin, Abteilung Wissenschaft, Technik und Umwelt
Bereich Produktsicherheit
T +49 (69) 2556-1962| **E** rosskamp@vci.de

German Chemical Industry Association
Mainzer Landstrasse 55
60329 Frankfurt, Germany

www.vci.de | www.ihre-chemie.de | www.chemiehoch3.de
LinkedIn | Twitter | YouTube | Facebook
Data protection rules | Compliance-Guideline | Transparenz

- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

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 more than 530,000 staff.