August 2024

Guidance for Stakeholders: participating in the ECHA combined Public Consultation on ZnPT substitution and essentiality

This document provides **a practical guidance** for stakeholders on how to participate in the ongoing ECHA public consultation as regards the **derogation to the exclusion criteria** and the **viability of alternatives to Zinc Pyrithione "ZnPT" as a product type (PT) 6, 7, 9 and 21** for the following specific uses:

- **industrial, professional and individual use** (DIY);
- **PT 6: preservatives for products during storage;**
- **PT 7: film or coatings preservatives for surfaces of materials or objects;**
- **PT 9: preservatives for fibres, leather, rubber, and polymerized materials;**
- **PT 21: antifouling products and coatings.**

Please note that this will be the only official opportunity to provide your feedback in this process.

Introduction

ZnPT is undergoing the approval process at EU level following the dossier submission by co-Applicants Arxada & Janssen PMP to eCA Sweden (KEMI) for several product types (incl. PT-6, PT-7, PT-9 & PT-21). Due to its CLP classification, it is eligible to be re-approved under the derogation criteria of the Biocidal Products Regulation, but this needs a positive opinion from the Biocidal Product Committee chaired by the European Chemicals Agency (ECHA).

For these purposes, ECHA has launched a 60-day consultation period to gather feedback from interested parties.

The consultation will collect information on:

- **Availability of substitutes or alternatives to ZnPT in its PT-6, PT-7, PT-9 and PT-21 uses;**
- **Socio-economic impacts of the non-approval of ZnPT on industry and society.** To justify the derogation, it must be shown that at least one of the following applies:
    - the **risk to humans, animals or the environment** from exposure to ZnPT **is negligible**;
    - ZnPT is essential to **prevent or control a serious danger to human health**, animal health or the environment; or
    - **non approval would have a disproportionate negative impact on society** when compared to the risks posed by ZnPT.

Why is your participation crucial?

Currently, **there are no sufficiently efficient alternatives to ZnPT for many products applications**. Alternatives often lack the technical efficacy and economic efficiency of ZnPT. Non-approval of ZnPT could lead to:

- Significant sales losses for small and medium-sized enterprises (SMEs);
- Increased prices for products treated with ZnPT;
- Increased costs from production to end-users due to the reliance on less effective biocides, including:
    - reduced cost-efficiency of alternatives compared to ZnPT,
    - the need for higher concentrations of alternatives to match ZnPT's effectiveness,
    - more frequent applications necessary to maintain desired results.

- Potential absence of viable solutions to prevent material degradation or discoloration.

How to participate?

Your input is vital to inform national authorities about the lack of efficient alternatives and the socio-economic impact of potentially losing ZnPT. The evaluation of ZnPT and its continued use will heavily rely on the information collected during this consultation.

If you are concerned with multiple product types, please submit a separate and complete contribution for each one.

Simplified participation steps:

1. **Share your insights on available substitutes and the socio-economic impacts of ZnPT's non-approval.**
2. **Participate in the consultation within the designated 60-day period.**

Your contribution can significantly influence the decision-making process, ensuring that the authorities have a comprehensive understanding of the essentiality of ZnPT and the implications of its potential ban.

Sections I and II (submitter and organisation information)

ECHA has launched its combined public consultations on 05 August, and will last until 04 October. This 60-day consultation period allows stakeholders to provide input on ZnPT. **The information submitted can be marked confidential** if justified and must be submitted using a secure web form available through this link.

- Section I: Personal information – **this information will not be disclosed**
  - name of the contact person
  - email of the contact person
  - nationality of the contact person
- Section II: Organisation – **you can request this information not to be disclosed** (check the box)
  - Type of submission: as an individual or on behalf of an organisation (drop down menu to select the type among downstream user, manufacturer, importer)
  - Name of the company/organisation/authority
  - Country where the company is established

Section III (Comments)

This section is for detailed feedback on ZnPT, including technical, economic, and risk-related information. **Clear, specific, and personalized contributions are essential for a comprehensive evaluation.**

Stakeholders are encouraged to be as detailed and comprehensive as possible in their explanations, **especially when discussing the limited and inefficient alternatives to ZnPT**. This includes providing both technical and economic arguments to illustrate the limitations of these alternatives.

Sub-section A on availability of alternatives

1. **Alternative identity and properties:** highlight that no suitable alternatives exist for all your uses (industrial, professional, DIY). Explain why less suitable alternatives fall short. If you need help in identifying and naming substances, you may find useful the Guidance on substance identification.
2. **Technical feasibility**: Demonstrate that ZnPT is the best option for its intended purposes. Describe any obstacles or difficulties in replacing ZnPT for the specified use(s) and treated articles.

3. **Economic feasibility:** Estimate the costs (direct and indirect) of switching to weaker alternatives. Direct costs are those which automatically result from switching from ZnPT to the potential substitute. Indirect costs are more challenging to quantify but could include, for example, the increased carbon emissions from applying other substances more frequently to protect end-products, impacts of failure/shorter lifespan of the treated articles, including waste. Additionally, consider any costs related to the unique aspects of your industry and/or production methods.

4. **Hazard and risks of the alternative**: Describe any increased risks to health and the environment from using less suitable alternatives. These may also be related to other aspects affecting the overall hazard/risk reduction capacity of the transfer to the alternative, such as changes in energy or raw material consumption.

5. **Availability:** Discuss if alternatives are available in **sufficient quantity and without delay**. Explain the impact on production needs and treated articles.

6. **Other comments:** Add any relevant information that does not fit in other fields, such as general economic or regulatory trends that highlight the importance of ZnPT.

7. **Conclusion on suitability and availability of the alternative:** Provide a short conclusion on the overall absence of alternatives to ZnPT and/or the unsuitability of the alternatives mentioned above. You may want to summarize the main technical, economic and risk-related arguments that led to that conclusion.

8. **References**: Provide a well-referenced list of sources to support your comments. Strong scientific and technical foundations enhance the impact of your input.

Sub-section B on derogation to the exclusion criteria

Indicate which derogation of Article 5(2)(a), (b) and/or (c) of the BPR you believe are met (you can select all that apply).

1. **Risk from human, animal and environmental exposure to ZnPT**

Please confirm from your own experience that the risk to humans, animals or the environment from ZnPT exposure in biocidal products, under realistic worst-case conditions of use, is negligible. This is especially relevant when the product is used in closed systems or under other conditions designed to minimize contact with humans and release into the environment.

Provide detailed information on safety measures and stewardship programs you have in place to manage risks effectively. Emphasize the safety margin that excludes toxicity (including reproductive toxicity) and environmental effects.

2. **ZnPT is essential to prevent or control serious danger to health or the environment**

If, from knowledge on the usage of the substance, you can confirm that ZnPT helps prevent a serious danger to human health, animal health or the environment, you are welcomed to share you experience here. An example of this can be the environmental and climate change damages that may result if ZnPT was not renewed linking it to the overall impact that this would additionally have on preservatives product as a whole.

3. **Not approving the active substance would have a disproportionate negative impact on society**

This point is especially important in line with the contributions shared within the public consultation on the lack of alternatives (under Sub-section A).

You may want to consider the following aspects:

- **Direct economic impact** –quantify, if possible, the cost of losing ZnPT on your business/area of work;

- **Other economic impacts** – for instance, in form of supply chain disruptions, higher prices, cease of production and business activities, potentially shorter guarantees, costs associated with failure/shorter lifespan of the treated articles. etc;
- **Societal impacts** – for instance, negative repercussions on employment rates;
- **Impact on environment** – for instance, due to increased pest/insect propagation; shorter lifespan/replacement frequency of articles, potentially increased article waste.
- **Impact on other political objectives,** such as climate neutrality, circular economy and economic autonomy – due to increased necessity to rely on non-EEA products;
- **Any other relevant impact from your experience**, etc.

Please ensure that the information you provide is well-referenced throughout the document. The stronger the scientific/technical basis of the comments, the greater the impact in the decision-making process and the higher the chances for ZnPT to get approved.

Section IV (uploading attachments and confidentiality)

In **Section IV** the interested party is allowed to **upload any documents supporting the information provided in Section III.** You are encouraged to provide:

- Documents and/or studies that detail the methodology, sources of data provided, its quality and reliability, the assumptions and uncertainties in the analysis and their impact on the conclusions of the assessment.
- Information on research and development activities.

You can also use the attachment section to upload a much more detailed explanation of all the comments submitted above in the **form of a written statement**.

If you claim some of the information shared is confidential, you will be asked to provide a **justification for confidentiality** for each of the comments or attachments submitted. Said justification should contain:

(i) Demonstration of Commercial Interest;

(ii) Demonstration of Potential Harm; and

(iii) Limitation to Validity of Claim – i.e., the period of time for which the claim will be valid.

Conclusion

The availability of suitable and sufficient alternative substances and substantiated data on the derogation to the exclusion criteria are key considerations for ECHA when deciding on the approval of an active substance.

This is why you are kindly encouraged to participate in this Consultation Period. To keep ZnPT on the market and maintain a sufficient toolbox for preservative products, it is critical to make the socio-economic impacts of non-approval and the scarcity of suitable alternatives explicit to ECHA at this stage of the process. The impact on the decision-making process will be aligned with the level of detail and comprehensiveness in your contribution.