a **science group** company

15th May 2020

Dear [redacted]

In reference to your letter dated 18th February 2020 (Ref: Ares(2020)1036324 – 18/02/2020), Agria SA, as an Applicant for Zineb as an Active Substance under the Biocidal Products Regulation (BPR), acknowledge receipt of your communication and request you consider the following response in relation to the potential for Zineb to have endocrine disrupting (ED) properties and therefore, potentially not satisfying the conditions of Article 4(1) of the BPR.

The assessment report for the use of Zineb as a Biocide in marine paints as an anti-fouling agent (under PT 21) dated July 2013 relied upon just a single Zineb specific study (a repeat dose 90 day study in rats) that has relevance to an assessment of the potential for ED properties. All other Zineb specific toxicology data was acute toxicity, ADME or genotoxicity data; none of which are relevant for identifying effects for potential endocrine disruption. In addition to the Zineb specific data, the Approval was based upon data generated on other EBDC (ethylene bisdithiocarbamate) fungicides (e.g. Mancozeb, Maneb etc.) and the known toxicological profile of the key toxophore, ETU (ethylene thiourea), which is a common metabolite to the EBDC group of fungicidally active molecules. An extensive and robust evaluation of Zineb from both a mammalian toxicity and ecotoxicological perspective was conducted by the UK Competent Authority[1] which references the relevant ETU and other EBDC data, which is, in turn, referenced in the Submission for Approval of Zineb under the BPR.

Agria SA therefore propose to the European Commission that the outcome for Mancozeb is awaited and appropriate action taken accordingly. This is of relevance to the Commission's proposal to review Zineb, as there is minimal Zineb specific data to be considered and with an ongoing regulatory evaluation for Renewal of Approval for Mancozeb within the context of the Regulation (EC) No. 1107/2009[2], including a specific ED Evaluation to ECHA and EFSA Guidance[3], re-submitting the same dataset will unnecessarily consume expertise. Agria SA are an Applicant for the Renewal of Approval of Mancozeb within the context of Regulation (EC) No. 1107/2009 and are actively engaged with the Mancozeb Task Force (MTF) in developing the necessary database to support the Renewal. As such, Agria SA is explicitly aware of the developing regulatory situation regarding the common metabolite, ETU, and the regulatory consequences for Active Substances of which it is a metabolite, e.g. Zineb.

Agria SA wishes to take this opportunity to reassure the Commission that it is fully committed to ensuring that Zineb can be demonstrated to be safe under its approved conditions of use.

[1] Zineb: Use as a Booster Biocide in Antifouling Products. Advisory Committee on Pesticides (ACP), UK Health and Safety Executive (HSE), March 2004.
[2] Regulation (EC) No. 1107/2009 of the European Parliament and of the Council Concerning the Placement of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, 21 October 2009.
[3] Guidance for the Identification of Endocrine Disruptors in the Context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN.

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To this extent, Agria SA proposes to commission the following OECD Conceptual Framework Level 2 assays:

1. Estrogen Receptor Transactivation Assay (OECD 455)
2. Androgen Receptor Transactivation Assay (OECD 458)
3. Steroidogenesis Assay (OECD 456)

Agria SA recognise that these studies will only deliver data regarding the potential for ED activity, but coupled with other relevant data for an assessment of potential adversity mediated via an ED mode of action (MoA), it is considered that a robust data package demonstrating a lack of ED potential will exist for Zineb. Whilst the regulatory decision-making process regarding Mancozeb continues, it is considered premature to take decisions regarding the necessity to develop a package of vertebrate data specifically utilising Zineb, rather than relying upon the current read across to Mancozeb and other EBDC fungicides. However, the Applicant reiterates that it is fully committed to generating a database of studies necessary to demonstrate the safety of Zineb to ensure that adequate data is provided to the Competent Authority at the time of Zineb's Renewal of Approval (current Approval until 2025).

As an example of a potential approach, Agria SA are aware of data that demonstrate the production of ETU via metabolic and or degradative processes is substantially different between Mancozeb and Zineb and it is the Applicant's understanding that there are scientifically robust approaches that would allow demonstration of different exposures to ETU (the toxophore in this case) between the two Active Substances that would show acceptable risk, despite the hazard profiles, *per se*, essentially being the same. There is strong merit in considering the risk profile for Zineb rather than basing a regulatory decision regarding Renewal (or maintenance) of Approval on hazard alone and a substantially different level of exposure to ETU could have an important impact on the overall risk paradigm for Zineb.

Further to the above, Agria SA consider the use of Zineb as an anti-fouling agent within PT 21 products, results in exposure levels that are incredibly low. A report prepared by NIVA, commissioned by the Norwegian Climate and Pollution Agency (Klif), demonstrated, following sampling and analysis of marina waters, that Zineb was not present above the level of detection and that ETU was present at extremely low concentrations – i.e. between 1 and 16 ng/L[4]. This is in notable contrast to the potential exposure to Mancozeb and ETU as an Active Substance within plant protection products (PPP's), where the predicted environmental concentrations in surface water (PECsw) of ETU range from 2.86 – 13.05 μg/L[5]. This demonstrates an approximate 1000-fold difference in the environmental concentrations of ETU following Zineb's use as an anti-fouling paint and Mancozeb's use as a plant protection product.

In addition to committing to the development of a robust Zineb specific database meeting the requirements for regulatory decision making, Agria SA would like to draw the Commission's attention to the socio-economic benefits of Zineb in PT 21 Products (please see letters

[4] Screening of Selected Alkylphenolic Compounds, Biocides, Rodenticides and Current Use Pesticides. NIVA, (Report Ref. TA 2899), 2012.
[5] Mancozeb - Renewal Assessment Report Prepared According to the Commission Regulation (EU) No. 1107/2009. Rapporteur Member State, UK. 2019 (Version: February 2019).

provided in Appendix 1) and the lack of alternative Active Substances for such uses. The provision of effective and reliable Active Substances for these Products is essential to the marine industry, which is why Agria SA is committed to delivering the necessary data to Competent Authorities to ensure Zineb's ongoing Approval.

Agria SA consider it can be demonstrated that the existing hazard data relied upon for the Approval of Zineb continues to be robust (with additional data to supplement the current package as described above), and that the differences in use and exposure can provide the necessary regulatory assurance for the ongoing Approval of Zineb within the context of the BPR and therefore it's continued use in Products of the PT 21 family. Agria SA request that the Commission actively engage with us to ensure that we can work constructively and collaboratively to ensure that Zineb, critical for inclusion in anti-fouling paints, continues to be available to the marine industry. To such an end, Agria SA request active communication with the Commission and appointed eCA to successfully achieve this objective.

Yours sincerely,

[redacted]

[redacted]

Appendix 1: Letters of Support Received for the Use of Zineb in PT 21 Products

JOTUN
Jotun Protects Property

TO WHOM IT MAY CONCERN

Your ref.:	Our ref.:	Direct phone:	Fax:	Date:
		+47 45 85 41 04		11 May 2020

Importance of zineb in antifouling paints

Jotun A/S is one of the world's largest producers of antifouling paints. Dicopper oxide is the main active substance in our products, but an additional active substance (a co-biocide) is needed for acceptable performance on ships in challenging trades. The number of available co-biocides have decreased dramatically over the last 20 years.

Today, you get 14 results when you search for PT21 active substances on ECHA's website:
Four are copper compounds.
Two (dichlofluanid, tolylfluanid) are no longer produced.
One (cybutryne) was not approved.
One (free radicals generated in situ…) is on the experimental stage.
One (zinc pyrithione) is still under BPR review.
Two (medetomidine, tralopyril) work well against animal fouling like barnacles, but not against algae.

And only three (copper pyrithione, DCOIT, zineb) are approved, available on the market, and suitable as co-biocides in dicopper oxide-containing antifouling paints.

It is therefore very important for us that the approval of zineb is extended.

Yours sincerely

Kjersti Fjelde

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Hempel A/S
Lundtoftegårdsvej 91
DK-2800 Kgs. Lyngby
Denmark

HEMPEL

Date: 12 May 2020

Dear Sir / Madam,

RE: Zineb use in antifouling coatings

Antifouling coatings serve a crucial role in preventing excessive biofouling of ships and yachts helping to protect the vessel from erosion/corrosion of the structure, reduce drag and minimise fuel consumption and ensuring safe handling of the vessel. Active ingredients are essential to the mode of action of these products to ensure a broad spectrum of control against over 4000 potential fouling species.

In the commercial sector effective antifouling paints contribute significantly to the reduction of fuel consumption and commensurate reduction of greenhouse gases and other air pollutants (e.g. carbon dioxide, nitrogen oxides and sulphur oxides). It has been estimated that fuel consumption of a heavily fouled ship may be over 50 % greater than that of a clean hull. Currently the emission of carbon dioxide from marine shipping is estimated at 3 % (over 1 billion tonnes) of the total CO_2 emission[2] and a potential loss of effective coatings and the corresponding increase of 50% in fuel consumption would raise this to 4.5 %. The EU has incorporated reduction of CO_2 emission in its environmental policy, wherein a target of a 50 % reduction of CO_2 emissions by 2050 compared to the 2005 emissions has been set[1]. The use of efficient antifouling products will be crucial for the EU to meet their targets according to the revised Emissions Trading Systems (ETS) Directive (Directive (EU) 2018/410[2]).

Antifouling coatings also play a critical role in minimising the introduction and establishment of non-indigenous populations of marine species into EU waters. They directly support the EU biodiversity strategy and that of the International Maritime Organisation (IMO) to minimise such introductions and preserve marine biodiversity.

Introduction of non-indigenous species has been shown to have a significant biological impact. Non-indigenous species are known to be carried by commercial vessels over large distances and leisure craft contribute to their local distribution[3].

Meeting these challenges requires the use of multiple active ingredients which have different efficacies against different groups of taxa, for example an individual active ingredient which is effective against hard fouling (such as barnacles) maybe ineffective against soft fouling species (such as algal species). Combining active substances allows the development of antifouling coatings which provide control against all fouling species.

Since the introduction of the Biocidal Products Directive (98/8/EC) and it subsequent replacement by the Biocidal Products Regulation (Regulation (EU) 528/2012) only ten antifouling active substances (Product Type 21) remain of the original 51 submitted for review. In that same period only two "new" active substances were approved for use in antifouling products. Of these twelve active substances three have been removed from the market following review, with a further substance expected to be banned in the next two years. Each one of the active substances lost was critical to the control of algal and soft fouling species. Of the remaining actives, including the two new active substances, 5 of these are specific to animal control.

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[1] CEPE (2019): Sustainable use of biocidal antifouling products.

[2] https://ec.europa.eu/clima/policies/transport/shipping_en

[3] Ullman *et al* (2019). Alien species spreading via biofouling on recreational vessels in the Mediterranean Sea. J Appl Ecol. 56:2620-2629

Whilst this is testament to the objectives of the BPD and BPR to ensure a high level of protection to both humans and the environment, the concerns raised regarding the overly conservative approach regarding risk assessment have largely been ignored. Concern surrounding the further unnecessary loss of approved active substances in the second review period is high. The impact that such a loss will have on coating suppliers capability to develop effective products is significant.

Zinc ethylene bis(dithiocarbamate) (Zineb: CAS 12122-67-7) is one of the remaining three active substances effective against soft fouling. It is the second most used biocide for this purpose and is therefore a crucial active substance. Replacement of Zineb with the remaining two biocides, should it be lost from the market, would be practically impossible due to compatibility issues in the paint formulations that currently rely upon zineb.

Ensuring that there is an effective 'tool box' of active substances available for the formulation of antifouling coatings for supply to the European market is crucial if the coatings industry is to support the ambitions of the EU for the shipping industry to reduce green-house gas emissions and maintain the protection of marine biodiversity.

The continued use of Zineb is crucial in enabling the industry to produce effective antifouling coatings and we respectfully request that the critical socio-economic benefits that this active substance provides is recognised and that realistic risk assessments are carried out in any re-evaluation of zineb that takes place in the future. Any unnecessary restriction of Zineb could have dramatic unintended consequences for environmental protection elsewhere.

Yours sincerely

Gareth Prowse, PhD,

Sustainable Marine Solutions Manager
Hempel A/S

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