e-Consultation: Compliance with the Annex H of the standard EN 599-1: +A1: 2013 for PT08.

15th April 2021

On 1st September ES initiated an e-consultation with the aim to find a harmonized approach to comply with Annex H of the guideline EN 599-1: +A1: 2013 for PT08, in particular regarding the concept "10 years' successful use" of the product indicated in the mentioned Annex. The Annex H of the mentioned guideline establishes the validity of test results from former standards after their revision. According to this Annex H, the **results** from **former standards** can be admitted it the "successful use" for the last 10 years can be proven; where successful means that the product has been applied in the practice elements, and during the service life of the components no failure due to insufficient efficacy of the wood preservative in question became obvious.

RESULTS FROM FORMER STANDARDS	+	SUCCESSFUL USE FOR 10 YEARS PROVEN[i]

1st. Would you admit a declaration of an insurance company declaring that to their knowledge for the last 10 years there has been no claims for accidents associated to a certain PT08 product?

GENERAL CONCLUSION: All member states agree that the declaration of an insurance company is not adequate.

2nd. Would you consider that declarations from several clients (final product users i.e. timber user) stating that during 10 years the efficacy of the PT08 has been adequate?

Different views were expressed during the discussion but the conclusion is that the information on declarations from several clients could be useful as supporting documentation, but is not enough to consider the successful use as proven in accordance with outdated standards. It was indicated that, in any case this declaration should be provided by trained professionals/ professionals. The choice of the clients should be justified to demonstrate that their declaration can be valid.

GENERAL CONCLUSION: The declaration from clients is admissible as part of the documentation in support of a 10 years' successful use, together with the other requirements indicated below **and always with the results from former standards**, and provided that it fulfills the minimum quality criteria. See third Q&A.

3rd. Is there any mean of evidence that you would consider sufficient to waive the efficacy studies according to the current standards?

Member states indicated the minimum supporting documentation needed to consider the 10 years' successful use as proven, and the minimum quality criteria that this data

should fulfil. In any case, Member states will decide on a case by case basis if for a particular case all the documentation listed below would be needed, or if it would be enough with part of these documents.

Documentation	Minimum quality criteria
Clients declaration	• The declaration is provided by professional or trained professionals • These professionals or trained professionals have used the product for at least 10 years • These professionals or trained professional can actively monitor the product's performance • Non- professional's declarations are not admitted. Non-professional use may be covered by data obtained from professional users if the composition is similar enough • The applicant has justified soundly the choice of clients • The applicant's internal procedures guarantee that they perform a regular follow up on their clients • The distinct uses are covered • The worst case use is covered • The entire efficacy spectrum is covered • Non critical failure is included when asking final product users for their opinion on product performance
Comparison between current and outdated standards	• Are the changes "significant" in terms of efficacy?
Peer reviewed literature and monitoring data	• The data representative of the product under evaluation should be relevant in terms of active substance, application rate, target organisms, wood category and use class, etc. • The information provided data show growth in (an) untreated control(s)/wood product(s) • For wood preservation area a sufficient degradation of the wood in the control samples should be requested. It should be ensure that no failure has been observed in all the areas where the product has been authorised. This demonstration should be validated for all the uses authorised of the product and not for the worst-case use; or at least, for the target for which the standard is outdated. • The **composition of the product should be exactly the same; or deviations of composition should allow a read-across in line with Annex A of EN 599** (see also Appendix 12 of the current Efficacy Guidance). Data should be ineligible if they were obtained with a product for which either the composition is not fully reported or if the composition would require new biological testing based on the rules of Annex A of EN 599. • The monitoring data provided should include results from different locations in order to confirm the case.

The Member State will **evaluate on a case by case basis the adequacy of the documentation** supporting 10 years' successful use provided, and will conclude:
"*Considering the assays provided according to the former standards and the supporting documentation provided consisting in XXX, is the "successful use" for the last 10 years considered as proven/ not considered as proven*".

[i] the applicant must always submit acceptable results according to former standards