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| **Specification of Requirements regarding evaluation of efficacy studies of wood protection products under the Biocidal Products Regulation** |  |

# Introduction

The Danish Environmental Protection Agency (DEPA/Miljøstyrelsen) is the Danish Competent Authority under the Biocidal Product Regulation (Regulation (EU) No 528/2012 as amended by Commission Delegated Regulation (EU) 2021/807 of 10 March 2021) (hereinafter referred to as BPR) when it comes to evaluation of biocidal products in Denmark, as well as certain active substances at the EU-level.

As a part of the evaluation, the efficacy of the biocidal product must be assessed. DEPA has drawn upon external experts regarding the efficacy of wood protection products (product type 8 under the BPR) the last few years. This contract is up for renewal for 2022-2023, with the possibility for an extension for an additional two years.

# Background

# The contract will be a framework agreement that contain product evaluations for national and Union applications where Denmark is evaluating Member State, as well as mutual recognitions of evaluations that have been conducted by other member states. It is also expected that some assistance regarding the renewals of the active substances IPBC and Tebuconazol relevant for PT 8, including follow-up questions regarding the evaluation of reference products for the active substances, will be a part of the contract.

#  The evaluations involves the implementation of efficacy assessments of wood preservatives according to the current guidance in "Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), version 3" from April 2018.

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# Denmark receives applications for EU approvals, national approvals and mutual recognition of wood preservatives covered by Regulation 528/2012 of 1 September 2013, Product Type 8. All types of applications may regard a single product or a product family, consisting of several products.

# Another part of the evaluation that may be necessary is a comparative assessment report for products including active substances that fulfil the exclusion criteria in article 5 of the BPR, or candidates for substitution as described in article 10. In these evaluations the efficacy experts will be expected to review the claims and documentations made by the applicant.

# Delivery – minimum requirements

# The supplier undertakes to perform the efficiency assessments that the client specifically requests. The contracting authority is not required to submit applications to the supplier. Since the number of evaluations contained by the contract is dependent on the number of applications received by DEPA the value of the contract cannot be fixed and cannot be guaranteed.

The Supplier undertakes to provide a completeness check of the application upon request. The individual efficacy assessment should be provided within a period as specified by DEPA after a written request and relevant documentation has been provided by DEPA.

Below the maximum allowed timeline is set for each request type. A deviation from the below deadlines may be agreed between the parties.

The maximum timelines for representative requests.

* Completeness check of the applications is 14 days.
* Efficacy assessments when Denmark is evaluating Member of the application is 45 days for applications under the simplified procedure, or for minor changes.
* Efficacy assessments when Denmark is evaluating Member of the application is 60 days for national applications or union applications.
* Commenting on evaluation of a Union authorisation performed by another member state is 7 days.
* Commenting on evaluations performed by other member states in mutual recognition in sequence or is 30 days,
* Commenting on evaluations performed by other member states in mutual recognition in parallel is 20 days,
* When a commenting process is initiated by a member state (Denmark or another country), the standard operating procedure is to be follow. The timelines for the individual task could be as low as 1-7 days.

The efficacy assessment must be delivered to DEPA in English by a secure method that will be specified by the Danish EPA, eg. Secure email, cloud solution or another other solution.

When Denmark is evaluating Member State:

The form should be in a previously agreed template that should cover the claims made by the applicant, as well as the assessment made by the supplier. See Annex 1 A for suggestions.

For mutual recognitions:

An evaluation as such is not necessary, but comments on the evaluation performed by the evaluating member state should be provided in a commenting table.

As a part of the delivery, the supplier should be prepared to answer follow up questions from DEPA regarding elaboration or documentation of the basis of the assessment. If the basis for the assessment changes, eg. upon submission of new documentation from the applicant, this will be considered as a request for a new assessment, unless otherwise agreed.

The supplier must ensure the quality of the project's deliveries. Quality assurance must be in accordance with industry standard standards for quality assurance. The supplier must ensure that employees who perform assessments for the contracting authority have not been involved in the work on the efficiency studies to be assessed.

The contracting authority makes quality assurance within two weeks after the assessments or comments has been received. As a response to any comments in the quality assurance, the supplier will have one week to make necessary changes or elaborations in the assessment. In some cases a shorter commenting and revision periods is needed in order to comply with the biocidal product regulation, the contracting authority will specify this in the communication with the supplier.

In the eventuality where another member state disagrees with the efficacy assessment made by DEPA, the supplier will be expected to support the DEPA with written arguments in bilateral and EU-level discussions. This will also be the case when the supplier disagrees with the assessment made by another member state.

The contract also includes options on consultations regarding the development of guidance regarding product type 8, as well as written discussions in the technical working groups on principal issues regarding efficacy in wood protection products.

# Price and budget

The contract is a framework agreement where all services under the agreement can be considered as options. The tender price shall be given as a binding average hourly rate of the included employees . The tender shall only state the calculated average hourly rate.

The framework agreement as a total maximum budget of DKK 200,000 exclusive of VAT.

**Payment Terms**

Payment is made by invoice from the supplier with specification of assessed evaluations and hours taken if relevant, after the assessment is finished and not more often than quarterly. The invoice must also state item number as agreed.

Annex IA Example of template for assessment

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| --- | --- | --- | --- |
| **Company, MST ref. no., product** |  | **Label claim from company** | **Assessment** |
|  | Active substance(s)  |  |  |
|  | Formulation type  |  |  |
|  | User category (Industrial, professional, private) |  |  |
|  | Wood category (Softwood/hardwood) or masonry |  |  |
|  | Application aim and use classes (preventive/curative and UC1-5 |  |  |
|  | Method of application and application rate |  |  |
|  | Target organisms |  |  |
|  | Code for product (A.xx, B.xx, C.xx, D.xx, E.xx, F.xx and G.xx) |  |  |
|  | Use of topcoat  |  |  |
|  | Tests performed  |  |  |
| **Evaluation of the test reports provided to support applicants claim:**Include evaluation for each claim/test **Conclusions and any additional requirements (to be copied into the product assessment report):**The provided test reports allow to support the following efficacy claim:**Notes:** |

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| Application type | Application type | Maximum hours spent (hours) |
| Union authorisation(new or renewal) | Product |  |
| Product family |  |
| National application(new or renewal) | Product |  |
| Product family |  |
| Mutual recognition | Product |  |
| Product family |  |
| Simplified procedure | Product |  |
| Product family |  |
| Changes in existing applications | Major changes in a product approved under a EU authorisation |  |
| Major changes in a product family approved under a EU authorisation |  |
| Major changes pr. product, national application or mutual recognition, where Denmark is rapporteur member state |  |
| Major changes pr. Product family, national application or mutual recognition, where Denmark is rapporteur member state |  |
| Major changes pr. product, national application or mutual recognition, where Denmark is concerned member state |  |
| Major changes pr. Product family, national application or mutual recognition, where Denmark is concerned member state |  |
|   | Derogation |  |

Annex I B – suggestions for the most common application types