ANNEX 2

Ministry of Environment and Food of Denmark
Environmental Protection Agency

Pesticides and Biocides
Ref. CHAWA
November 20 2017

Specification of Requirements regarding evaluation of efficacy studies of wood protection products under the Biocial Products Regulation

Introduction

The Danish EPA (DEPA/Miljøstyrelsen) is the Danish Competent Authority under the Biocidal Product Regulation (Regulation (EU) No 528/2012) 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 2018-2019, 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 assistance regarding the renewals of the active substances IPBC and Tebuconazole, including evaluation of reference products, 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in "Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C)" from February 2017, as well as superseded versions ("Transitional Guidance on Efficacy Assessment for PT 8" from March 2015 and "Technical Notes for guidance in support of Annex VI of Directive 98/8 / EC of the European Parliament and Council concerning the placing of biocidal products on the market" (short title TNsG on product Evaluation. 2008)[1].
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 Provider will be expected to review the claims and documentations made by the applicant.

Delivery

The Provider undertakes to perform the efficiency assessments that the Contracting Authority specifically requests. The Contracting Authority is not required to submit all applications to the Provider. Since the number of evaluations contained by the contract is dependent on the number of applications received by DEPA the value of the contract won't be fixed and can't be guaranteed.

The Provider undertakes to provide a completeness check of the application upon request. The individual efficacy assessment should be provided within a period of maximum 1 month after a written request and relevant documentation has been provided by DEPA. A deviation from the above deadline may be agreed between the parties. A shorter timeframe might be necessary for commenting on evaluation of a Union authorisation performed by another member state, since the commenting period in total may be as short as 28 days.

The efficacy assessment should be delivered to DEPA in English by email.

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 Provider. See Annex 2A (below) 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 Provider 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

[1] https://echa.europa.eu/da/guidance-documents/guidance-on-biocides-legislation

changes, e.g. upon submission of new documentation from the applicant, this will be considered as a request for a new assessment, unless otherwise agreed.

The Provider must ensure the quality of the project's deliveries. Quality assurance must be in accordance with industry standard standards for quality assurance. The Provider 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 of the delivered material within two weeks after the assessment has been received. As a response to any comments in the quality assurance, the Provider will have one week to make necessary changes or elaborations in the assessment.

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

The contract is a framework agreement where all services under the agreement can be considered as options. Price shall be given as an hourly rate, combined with an estimate for the number of hours expected to evaluate the most common application types (see Annex 2B for suggestions).. The tender should contain how other ad hoc consultations and contributions should be priced within the frame of the contract.

Payment Terms

Payment is made by electronic invoice from the Provider in accordance with the contract, 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 2A Example of template for assessment

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:

Annex 2B – suggestions for the most common application types

Application type	Application type	Timeframe (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	