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GUIDELINES ON THE EFFICACY DATA
REQUIREMENTS FOR APPROVAL OF
NON-AGRICULTURAL PESTICIDE PRODUCTS

WOOD PRESERVATIVES

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DEFINITION OF TERMS

Active ingredient	The component of a product which fits it for use as a pesticide.
Application	An application seeking approval to sell, supply, store, use or advertise a pesticide product in Great Britain.
Approval	An approval given jointly by Ministers under Regulation 5 of The Control of Pesticides Regulations 1986 (As Amended) (COPR).
Committees	The Advisory Committee on Pesticides (ACP), established under SI 1985 No 1517, and the Interdepartmental Secretariat (IDS).
Evaluation	A written assessment of study reports or other data examined in the course of an appraisal by the Registration Authority.
Ministers	This refers to the Ministerial representatives of the following: Department of Environment, Food and Rural Affairs (DEFRA), Department of Transport, Local Government and the Regions (DTLR), Department of Health, the Scottish Executive and the National Assembly for Wales.
Pesticide	As defined in The Food and Environment Protection Act 1985 (FEPA) (part III., section 16. (15) + (16)) and COPR (section 3. (1)).
Quality Assurance	Those procedures and controls, including inspections and audits, designed to monitor studies to assure the quality of the data.
Raw Data	All original records and documentation, including verified copies thereof, which are the results of original observations and activities in a study.
Registration Authority	The Health and Safety Executive (HSE), Biocides and Pesticides Assessment Unit (BPAU).

FOREWORD

1. As part of the commitment to FEPA and COPR, the Registration Authority (HSE) is obliged to assess the effectiveness (efficacy) of non-agricultural pesticide products submitted for approval.

Efficacy will be considered as part of the approval of non-agricultural pesticides on the basis of a flexible, cost effective framework that requires a sufficient amount of data necessary to:

- i) Establish that a product is efficacious in relation to its conditions of approved use and that label claims are justified, and;
- ii) satisfy the requirements of Ministers who give approval on the basis of recommendations from the Advisory Committee on Pesticides (ACP) and the IDS.

In order to meet this obligation a structured approach towards the efficacy evaluation of products has been adopted whereby efficacy will be addressed principally at a number of key stages (see Section 2).

2. This document gives **guidance** on the nature and extent of the efficacy data required to gain a commercial approval for the sale, supply, use, storage and advertisement of a pesticide containing active ingredient(s) intended for use as a wood preservative or to support continuing approval of current products containing existing active ingredients at review.

3. It embodies the efficacy policy for non-agricultural pesticides endorsed by the ACP in January 1993, the basic framework of which is outlined in the 'Consolidated Data Requirements for Non-Agricultural Pesticide Products and Their Active Substances' which was made available to approval holders in July 1993. It outlines and formalises, but does **not** represent a change to, the methods which have been used in evaluations presented to, and endorsed by, the Committees in this time.

4. The document is prepared both for applicants who are routinely involved in efficacy testing strategies and those who may not be so familiar with such strategies. It is hoped that the presentation style adopted in the document will be amenable to all current and potential approval holders of non-agricultural pesticides and other interested parties.

5. It is intended to be of use not only to companies, and staff within companies, involved in conducting efficacy tests and establishing efficacy strategies but also to companies' registration departments involved in preparing dossiers of efficacy data in support of product applications.

1 INTRODUCTION

This document gives guidance on the nature and extent of the efficacy data required to obtain a commercial approval of non-agricultural pesticide products containing active ingredient(s) intended for use as a wood preservative and also for continuing approval of current products of existing active ingredients following review.

The guidelines are designed to be as flexible as possible and do not specify rigid protocols to which tests must be conducted. However it is intended that the guidelines should be compatible with other testing requirements within the industry e.g. either through the British Wood Preserving and Damp-proofing Association (BWPDA) or through compliance with some elements of the European Union Construction Products Directive.

Applicants are encouraged to submit data generated to a sound scientific standard using either their own testing strategies or commissioned studies conducted to national or international efficacy standards.

EACH STUDY PRESENTED WILL BE EVALUATED ON ITS OWN MERITS.

The assessment will be made solely in relation to the claims made on the product label for the effectiveness of the product. However these claims will need to be sufficiently detailed to enable an assessment to be made taking into account the organisms to be controlled, the method(s) of application and the use patterns of the product.

The efficacy data submitted in support of the product application containing the active ingredient(s) will be assessed to determine whether the pesticide can effectively be classed as a 'wood preservative'. **The full product Service life will not be considered, nor will any information be used as a basis for a product guarantee scheme.**

The assessment will consider the potential performance of the product containing the active ingredient(s) of interest against known hazards (both insect and/or fungal). The assessment aims to make a judgment of the likelihood that the product has a reasonable probability of being effective in its intended service environment based on an evaluation of the supporting data submitted. It will therefore be necessary for the applicant to define clearly the function, target organisms and use patterns intended for each product application.

2 WHEN EFFICACY DATA ARE REQUIRED

To support the approval of non-agricultural pesticide products, efficacy data to support each and every product application will not normally be required. A structured approach has been adopted towards the efficacy assessment of product applications and data are required to be submitted at a number of key stages as outlined below.

a) In support of new active ingredients (and their products) / and extensions of use of existing active ingredients (and their products).

- i) e.g. to support applications for products containing a new active ingredient yet to be assessed prior to first approval in the UK.
- ii) e.g. to support applications for products containing an active ingredient previously used in agricultural pesticides (e.g. a MAFF insecticide active ingredient now intended for use in non-agricultural pesticides as a wood preservative).
- iii) e.g. to support applications for products containing an active ingredient previously used in another sphere of non-agricultural pesticide use (e.g. an active ingredient currently used in public hygiene insecticide products now intended for use as a wood preservative insecticide).
- iv) e.g. to support applications for products containing an existing active ingredient but incorporating either novel formulation types or novel* application / delivery methods.
- v) e.g. to support applications for products containing an existing active ingredient targeted against novel* organisms.

b) To support existing active ingredients (and their products) at review.**

c) To satisfy either post approval data requirements or post review data requirements set by the ACP arising from evaluation at submission times (a) or (b).

** 'Novel' in this instance is considered to be a case where no precedent exists for formulation type, application method or target organism(s).*

*** It should be noted that a review will consider all available existing data (both positive and negative) relevant to a particular active ingredient and its products. It is recognised that the nature of these data may not always conform to current testing practices and the data requirements outlined within this document. As all data are assessed on their own merits, such issues will be considered by the Registration Authority and the Committees at the review stage.*

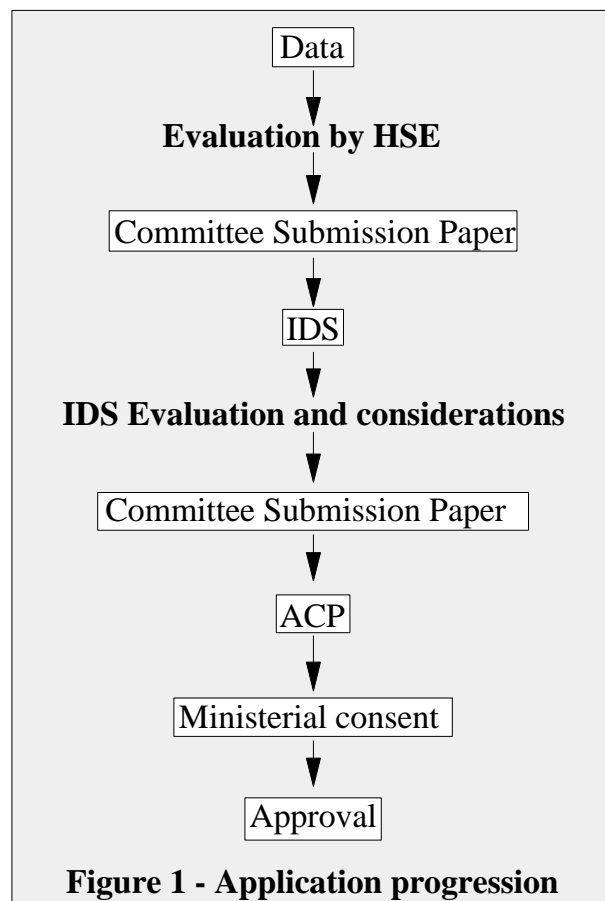
3 FRAMEWORK OF THE ASSESSMENT PROCESS FOR COMMERCIAL APPROVAL

The five Government Department signatories to COPR 1986 are advised by the ACP after interdepartmental scrutiny of pesticides issues by the IDS.

Data submitted by the applicant in support of new active ingredients (and their products), extensions of use of existing active ingredients (and their products) or existing active ingredients (and their products) at review are evaluated by the HSE on behalf of the Committees and a presentation (tabled in the form of a committee submission paper) is made initially to the IDS. This presentation critically evaluates all aspects of the data submitted with the application (including chemistry data, toxicity, risk to human health, risk to the environment and efficacy data). In relation to that application it will include recommendations and possible further data requirements necessary to fill gaps or deficiencies in the data set. The IDS will consider the scientific data in relation to the application. Such considerations will be presented to the ACP alongside the committee submission paper. The ACP will then consider the application taking into account broader issues concerning pesticides.

The ACP's recommendations are forwarded to the five Government Departments for Ministerial agreement and, where appropriate, the product's Notice and Schedule are forwarded to Ministers for signing; granting commercial approval.

The IDS/ACP process is summarised in Figure 1. At any of the Committee stages or before Ministerial agreement the Registration Authority may be requested to further evaluate certain pieces of data or approach the applicant for additional data before the application can be progressed to the next stage of the process.



It must be stressed that the appropriateness of the data submitted to the Registration Authority has a major effect on the presentation of the application to the IDS and ACP and ultimately whether or not commercial approval is granted.

4 DRAFT LABEL INFORMATION / LABEL CLAIMS

4.1 INTENDED LABEL CLAIMS

It will be necessary for the applicant to define clearly the target organisms/use patterns/function intended for each product application.

Hence for an evaluation to be undertaken, HSE will require a draft label or statements concerning the label claims which are proposed for the product application.

4.2 FUNCTION/TARGET ORGANISMS

It will not be necessary to include the entire range of natural hazards to which the preservative may be exposed in practice, instead the possible target organisms to be included in general testing strategies are confined to several broad groups as indicated below.

(i) **Fungi**

Wood rotting basidiomycetes
Soft rot microfungi
Moulds and sapstaining fungi (green timber)
Blue stain fungi (in service)

(ii) **Insects**

Common furniture beetle
House longhorn beetle
Death watch beetle
Powder post beetle

(iii) **Marine Borers**

Teredo spp.
Limnoria spp.

The possible target organisms against which activity can be claimed are summarised in Appendix 1 with further descriptions and information on the organisms detailed in Appendix 2.

4.3 USE PATTERNS

The use patterns for wood preservative products are seen as falling into 2 broad categories. The applicant must indicate for which categories the product application is intended.

(i) **Timber Pre-treatment (Industrial and non-industrial Pre-treatment)**

Includes all processes carried out on timber prior to its installation where some degree of future protection is intended. For products used in the pre-treatment of timber it will be necessary to identify the end-use of the preserved timber as

this provides some indication of the likely biological challenges to which the timber will be subjected and against which the product will provide protection. These end-uses should be related to the Hazard Classes 1-5 outlined in EN 335-1 (see Appendix 3).

Section 5.4.1 outlines those tests appropriate for pre-treatment (preventive) efficacy. Most of the tests are carried out in the laboratory and relate to the organisms for which biocidal effectiveness is claimed. Field tests, although desirable in cases where the product is intended for use in the more severe service environments (e.g. in ground contact) are not always considered mandatory to fulfil the minimum performance criteria, as this could lead to a compulsory delay of more than 5 years before a new product could be introduced to the market.

However field data will be compulsory for a product claiming use in the **marine** environment.

(ii) **In situ/remedial treatment**

Covers all aspects of eradicant and preservative treatment carried out while the wood remains in its service position. The testing of these treatment systems will be more varied because of the wide range of likely treatment methods and more complex since both *eradicant* and *preventive* action may need to be considered. Some of the biological tests outlined in Section 5.4.1 for preventive efficacy will also be relevant for the active ingredients in remedial preservatives.

There may be additional eradicant test methods relevant to the remedial preservatives but these would normally be for formulated products.

4.4 SERVICE ENVIRONMENTS

The service environments which treated timber is likely to encounter have been divided into 5 main groupings or classes according to the severity of exposure and wetting and type of biological hazard. These classes are consistent with those defined in EN 335-1 and are described in Appendix 3 of this guidance document.

4.5 METHODS OF APPLICATION

Where the test method allows for the product under test to be applied by more than one method then the application method most similar to the process intended for the test product for which approval is being sought should be selected.

The various methods available can be broadly split into 3 groups.

4.5.1 Penetrating Processes

Such processes include the currently practised technologies of double vacuum, vacuum-pressure and diffusion treatments.

4.5.2 Surface Applications

Such processes include brush and spray techniques and short term immersion (dipping) processes (where wood has only a few minutes contact time with the preservative).

4.5.3 Other Application Methods

For application methods other than those processes described above then either specifically relevant data will need to be provided or some justification for non-inclusion of data (i.e. details on penetrability/retention etc.) will need to be submitted to the Registration Authority for consideration.

5 DATA REQUIREMENTS

5.1 DATA SOURCES

Data from any source will be considered, provided they are valid and relevant to the application. These data could represent nationally/internationally accepted standards if these are available for this type of product. Sources of data may include:-

(i) Well conducted studies carried out or commissioned by the applicant which are either laboratory tests of biological effectiveness, or field trials of products carried out under simulated service conditions. Such field trials must have been running for a period sufficient to demonstrate effectiveness (3 to 5 years will be a minimum in most cases). Unpublished work from persons or organisations other than the applicant will only be accepted if accompanied by the appropriate authorisation. For example, statements that the work was conducted on behalf of the applicant or the right to access these data has been granted to the applicant.

(ii) Evidence relevant to the product from published work in reputable journals. Scientific/technical papers in refereed journals are usually acceptable. It is recognised that published data provided in support of an application may often lack important detail. The applicant should explain whether the formulation(s) referred to in a published paper are equivalent to those for which approval is sought. If this is not the case then the applicant should present a reasoned case based on data as to why and how the proposed formulations will behave similarly to that/those described in the published paper. Further advice on the preparation of reasoned cases is given in the Pesticides Newsletter No. 38, March 1998.

(iii) Data from outside the UK are also acceptable provided it can be shown that the methods used, climatic conditions and pests studied are relevant to the application.

(iv) Lack of complaints, customer testimonials and anecdotal evidence will not be acceptable.

5.2 ACTIVE INGREDIENT AND FORMULATION DATA

To support applications for products the applicant should provide evidence of the innate efficacy of the candidate active ingredient(s). This may be done in 'screening' type laboratory tests using the active ingredient(s) in a carrier solvent or simple formulation (e.g. miniblock test screens or an equivalent might be considered appropriate). In addition the applicant must provide efficacy data on representative formulations or 'frame formulations' relevant to the product applications containing the active ingredient(s). These data must reflect in-use concentrations and application methods equivalent to the applications for which approval is sought (a list of typical formulation types [not exhaustive] is given in Appendix 4).

Since field tests involve long term exposure to practical conditions, they can be regarded as in-service tests, and as such, any field data generated in support of an application should be conducted on products or representative products that resemble closely the fully formulated commercial product. It should be pointed out that evidence of performance based on service or field trial testing will be more convincing, owing to the difficulties of representing the conditions of service through laboratory testing. In addition it is also recognised that data

arising from field trial testing requires many years to carry out and is more likely to be available for established active ingredients (and their products) than for products containing newer active ingredients where laboratory test data only may be available.

It is important that the applicant gives careful consideration to the types of product intended to be registered for approval and is encouraged to discuss any problems with the Registration Authority at an early stage.

Full details of the formulations used in the studies should be reported where possible.

The active ingredient(s) employed in the various test formulations should be well defined and relevant to the product applications. Where more than one source of the active ingredient is available the source of the active ingredient(s) used in each of the studies should be reported.

Ideally studies should be conducted on formulations containing only the active ingredient(s) for which approval is sought. If other active ingredients are present the full spectrum of their activity must be defined or it will be difficult to interpret the results of the test with respect to the active ingredient(s) in question.

5.3 READ-ACROSS OF EFFICACY DATA WITHIN DIFFERENT FORMULATION TYPES

It **will not** be necessary always to provide data on each and every individual product because wherever possible extrapolation for similar formulations within defined formulation types will be considered provided such read-across is deemed appropriate. Justification of read-across may be provided through either the provision of a reasoned case or through bridging arguments. This is also the case when submitting a data package to support an application where the formulation type used in the study and the product for which approval is sought are not the same. A reasoned case based on data would be required to justify why data from the study are relevant to that product application. In the majority of cases data extrapolation will not be permitted between different formulation groups in the absence of supporting data.

e.g. efficacy testing of a solvent based formulation will not support an application for a water based formulation.

Appendix 4 provides a list of possible wood preservative formulation types and these are presented in the groups where read-across may be considered.

5.4 BIOLOGICAL TEST REQUIREMENTS

Applicants should note that many standard protocols are available covering the various biological tests indicated below. These tests cover preservative products applied in liquid form and are mainly intended for pre-treatment (preventive) use of timber. A list of current EN standards available for efficacy testing of wood preservative products is presented in Appendix 5 of this document.

It should be noted that it is not mandatory to conduct efficacy tests to these standards and that the Regulatory Authority will consider alternative testing strategies and non-standard test data provided they are relevant.

For products intended for application as solids, pastes or encapsulated forms and those products intended for remedial (in-situ) use, modification of the relevant protocols / testing strategies may be required or some other direct evidence may be given of their potential efficacy against the claimed biological organisms (e.g. for pastes such evidence could be in the form of penetrability and retention characteristics).

Data should be presented in respect of test formulations relevant to the product for which approval is being sought and should use the most relevant application process (penetrative treatments, surface treatments or both, where applicable), against the target organisms specified on the label.

The biological organisms relevant as challenges in each service environment (defined by Hazard Class) are outlined below.

It should be noted that although the testing requirements refer, in the main, to laboratory tests, it is acknowledged that if appropriate field data are available then these should be submitted in support of product applications.

5.4.1 Preventive Efficacy Tests

5.4.1.1 Hazard Class 1: Insect risk only (no risk of fungal attack)

Data required are suitable laboratory data performed using test blocks, treated either by impregnation with the test formulation (penetrative treatment) or surface treatment to investigate the protective effectiveness against the various challenge insects. Data should be presented on test blocks subjected to pre-conditioning by an evaporative ageing process (e.g. EN 73 or an equivalent test method would be considered appropriate).

Insect Test Species:

Test data submitted will depend on whether a general or species specific efficacy claim is to be made; tests should be carried out against one or more of the following specific insects: *Hylotrupes bajulus*, *Anobium punctatum*, and/or *Lyctus brunneus*. It is recognised that a number of testing strategies might be possible but generally the following guidance will apply.

a) For general claims against ‘wood boring beetles’

Although it is acknowledged that the majority of submissions are likely to be for treatments against *A. punctatum*, suitable laboratory data to demonstrate the efficacy against *H. bajulus* as an indicator species will normally be adequate to cover a general insect claim.

However, if existing data are available (e.g. laboratory screening tests) and these data have shown the insecticide to be more or less equally effective against the 3 different wood borers then suitable efficacy data (on test blocks subjected to an evaporative ageing procedure such as EN 73) against any of the 3 indicator species can be provided.

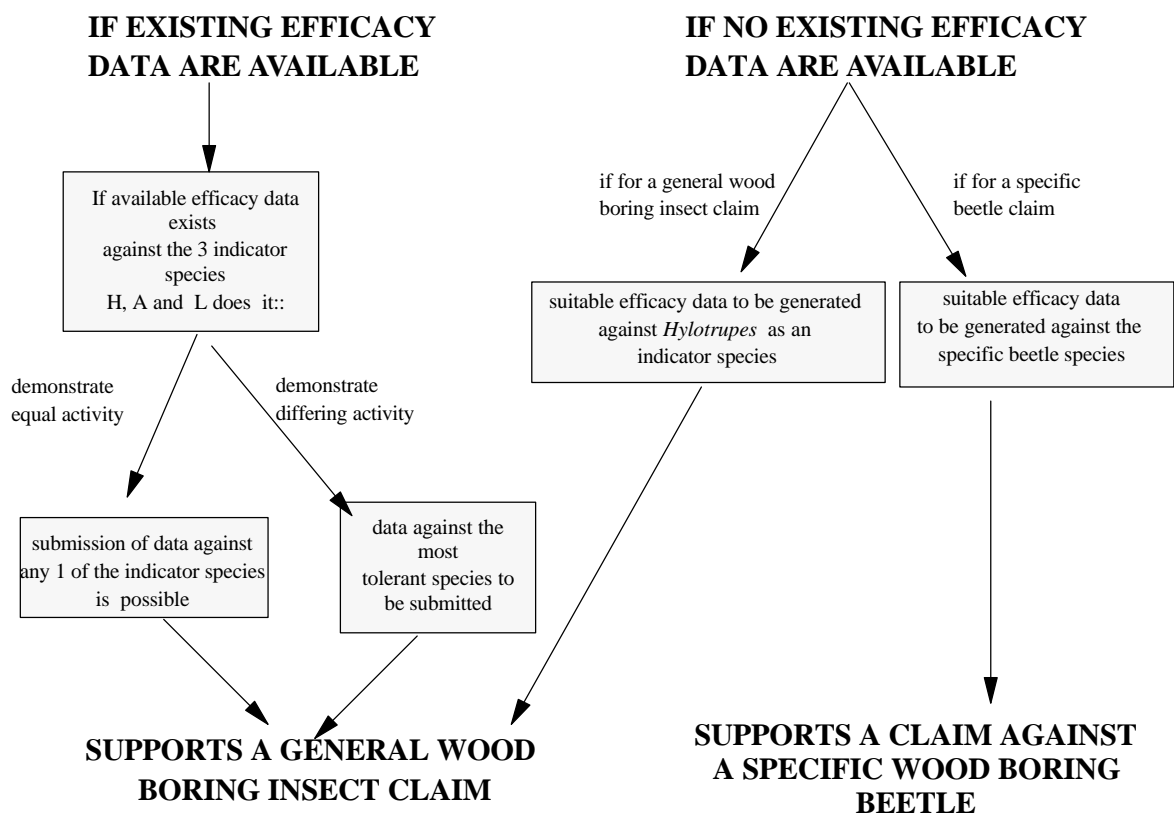
Similarly, if existing data are available and these data have shown the insecticide to have different activities against the 3 different wood borers, then suitable efficacy data against the most tolerant insect should be provided.

In most cases it will normally be sufficient to supply evidence of efficacy against only *H. bajulus* to cover a general claim against ‘wood boring beetles’.

b) For claims against a specific named beetle species

If claims against individual beetle species are detailed on a product label then suitable efficacy data against those named target pests should be presented.

These various scenarios are summarised in Figure 2.



key H: *Hylotrupes bajulus*
 A: *Anobium punctatum*
 L: *Lyctus brunneus*

Figure 2. Data required to support claims for activity against wood boring beetles (arising from a number of possible testing strategies)

c) For claims against termites

Data on efficacy against termites will only be required when the product is to be marketed for use as a termiticidal product or where local requirements demand such activity. Applications for such claims will be considered on a case-by-case basis by the Registration Authority.

For a product to claim activity against termites, suitable efficacy data demonstrating preventive activity against an indicator species such as *Reticulitermes santonensis* will be required.

5.4.1.2 Hazard Class 2

Fungal tests

Wood rotting fungi

For products intended for use as fungicides in Hazard class 2, efficacy against basidiomycete **brown rot fungi** should be demonstrated. Examples of the types of data required could include suitable laboratory data generated using treated test blocks to determine the toxic values against the fungi. Wherever possible the data should be relevant to label claims for penetrative and surface treatments. However in the absence of a recognised standard test for surface treatments against basidiomycetes, data on penetrative treatments will be acceptable.

The data requirements for wood rotting fungi are summarised in Table 1.

Table 1: Data requirements for wood rotting fungi in Hazard class 2

Service environment	Minimum laboratory tests	Evaporative ageing (EN 73 or equivalent)	Leaching (EN 84 or equivalent)
Above Ground (Risk of wetting)	Brown rot	YES	NO

Wood disfiguring fungi

For claims against **blue stain in service** suitable laboratory test data on the protective effectiveness of the product preferably following natural weathering (or alternatively, aged via evaporative ageing to EN 73 or an equivalent ageing procedure) should be provided. The application process whether by surface or penetrative treatment should be in line with label claims.

Insect tests (if relevant to label claims)

Products intended for use as insecticides in these situations will need to demonstrate efficacy against wood boring beetles as outlined in Hazard Class 1.

5.4.1.3 Hazard Class 3***Fungal tests****Wood rotting fungi*

For products intended for use as fungicides in Hazard Class 3 efficacy against **brown rot fungi** will need to be demonstrated. In some situations additional efficacy testing against **white rot fungi** may also be required.

The data requirements for wood rotting fungi are summarised in Table 2.

Table 2: Data requirements for wood rotting fungi in Hazard class 3

Service environment	Minimum laboratory tests	Evaporative ageing (EN 73 or equivalent)	Leaching (EN 84 or equivalent)	Field tests
Above Ground (not covered)	Brown rot (White rot)	YES	YES	L-joint type test (optional)

Suitable laboratory tests as for Hazard Class 2 but additionally either:

- (i) For claims against wood rotting basidiomycetes, efficacy should be demonstrated following pre-conditioning of the treated test blocks by a suitable leaching procedure (e.g. to EN 84 or an equivalent procedure);
- or;
- (ii) if the applicant considers that a leaching procedure is not appropriate (e.g. for overpainted timbers) then the option to provide an above ground field test (painted L-joint type tests or similar) is available, in addition to the test requirements outlined in Hazard Class 2.

Wood disfiguring fungi

For claims against **blue stain in service** then a suitable laboratory tests determining the protective effectiveness of the product preferably following natural weathering (or alternatively, aged via evaporative ageing to EN 73 and leaching to EN 84 separately or an equivalent ageing procedure) should be provided. The application process whether by surface or penetrative treatment should be in line with label claims.

Insect tests (if relevant to label claims)

Products claiming insecticidal activity will be subject to the same requirements as outlined in Hazard Class 1 with the addition that efficacy is demonstrated following pre-conditioning of the treated test blocks by a suitable leaching procedure (e.g. to EN 84 or an equivalent procedure).

5.4.1.4 Hazard Class 4***Fungal tests****Wood rotting fungi*

For products intended for use as fungicides in Hazard Class 4 efficacy against **brown and white rot fungi and soft rot microfungi**.

The data requirements for wood rotting fungi are summarised in Table 3.

Table 3. Data requirements for wood rotting fungi: Hazard class 4

Service environment	Minimum laboratory tests	Evaporative ageing (EN 73 or equivalent)	Leaching (EN 84 or equivalent)	Field tests
In Ground contact or fresh water	*Brown rot *White rot **Soft rot	YES	YES	***Stake test (optional)

* As for hazard class 3 but all laboratory data must derive from treated test blocks impregnated (i.e. a penetrative treatment) with the test formulation to determine the toxic values against both brown and white rot basidiomycetes separately.

** Data from a suitable laboratory test to determine the toxic effectiveness against soft rot microfungi and other soil inhabiting microfungi should be presented.

*** Field data: Field data are preferred to demonstrate the relative protective effectiveness of treated wood stakes in ground contact to support use of a product in this situation. Ideally the tests should run for a minimum period of 5 years.

Wood disfiguring fungi

For claims against **blue stain in service** suitable laboratory tests determining the protective effectiveness of the product preferably following natural weathering (or alternatively, aged via evaporative ageing to EN 73 and leaching to EN 84 separately or an equivalent ageing procedure) should be provided. The application process whether by surface or penetrative treatment should be in line with label claims.

Insect tests (If relevant to label claims)

The requirements are as for Hazard Class 1, with the addition that efficacy is demonstrated following pre-conditioning of the treated test blocks by a suitable procedure (e.g. to EN 73 and EN 84 separately or an equivalent ageing procedure).

5.4.1.5 Hazard Class 5***Fungal tests***

For products intended for use in Hazard class 5 the data requirements are summarised in Table 4.

Table 4. Data requirements for wood rotting fungi: Hazard class 5

Service environment	*Minimum laboratory tests	Evaporative ageing (EN 73 or equivalent)	Leaching (EN 84 or equivalent)	Field tests
In salt water	Brown rot White rot Soft rot	YES	YES	**Marine test (5 year) compulsory

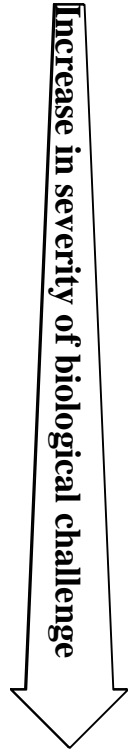
* As detailed for Hazard Class 4

It is acknowledged that there is not a recognised standard laboratory test for assessment of timber intended for use in salt (marine) water.

** Field trial data: Any relevant marine field trial data carried out for a minimum of 5 years (e.g. EN 275 or an equivalent would be considered a suitable test).

The preventive efficacy data required in each of the hazard classes are summarised in Table 5.

TABLE 5. BASIC PREVENTIVE EFFICACY TEST REQUIREMENTS NEEDED TO SUPPORT WOOD PRESERVATIVE FORMULATIONS



Hazard Class	Service Environment	Minimum Laboratory Tests *	Field Tests#
1	Above ground (dry).	Wood boring insects only (no fungal risk).	
2	Above ground (risk of wetting, protected from the weather).	Wood rotting basidiomycetes - brown rot.	
3	Above ground (exposed to wetting, but not in ground contact).	Wood rotting basidiomycetes - brown rot and in some cases white rot.	L-joint test (5 year) <u>optional</u>
4	Timbers in contact with the ground or fresh water.	Wood rotting basidiomycetes - white rot and brown rot. Soft rot microfungi.	Stake test (5 year) <u>optional</u>
5	Timbers in the marine environment.	Wood rotting basidiomycetes - white rot and brown rot. Soft rot microfungi. Marine borers.	Marine test (5 year) compulsory

* Appropriate ageing procedures will also be required. Tests against additional risks (including wood boring insects) may apply.

If applicants hold field data for timber used in Hazard classes 1 to 4 situations then this may be submitted in support of product applications.

5.4.2 Eradicant Efficacy Tests

For those remedial wood preservative products claiming eradicant activity, suitable efficacy data will need to be provided.

5.4.2.1 Insecticides

Applicants may submit data to existing EN standards for the relevant beetle species or other alternative supporting data to substantiate their product claims.

A number of EN standard tests exist for remedial (curative) treatments for insecticides against the 3 wood boring insects *H. bajulus*, *A. punctatum* and *L. brunneus*. Test data submitted will depend on the individual beetle species for which activity is to be claimed (see Section 5.5.1.1).

5.4.2.2 Fungicides

Any claims for eradicator activity against wood rotting basidiomycete fungi should be supported by suitable efficacy data or some other direct evidence. No standard test protocols presently exist for remedial (curative) treatments for wood rotting basidiomycetes.

6 DETAILS TO BE INCLUDED IN A TEST REPORT/ STANDARD OF TEST REPORTING

A basic checklist for details to be included in the submitted study

Test reports submitted to the Registration Authority typically should include the following details:-

- | | |
|---|---|
| 1. The name and number of any standard protocol used (if applicable) | Z |
| 2. The nature and full details of the formulation(s) used (where relevant) | Z |
| 3. The density of the material tested | Z |
| 4. The solvent or diluent used | Z |
| 5. The application method for each test | Z |
| 6. The concentrations (% m/m) of the active ingredient(s) present in the material tested | Z |
| 7. The species of wood used in the test | Z |
| 8. The average density of the test specimens used | Z |
| 9. The dimensions of the test specimens | Z |
| 10. The names (and where relevant, the strains) of the organism(s) used | Z |
| 11. The retentions of the active ingredient(s) if applicable to test used (expressed in kg m ⁻³ or g m ⁻² as appropriate) | Z |
| 12. Details of any pre- and post- conditioning of test specimens | Z |
| 13. Scoring or other assessment system used in the test and degree of deterioration (where applicable) | Z |
| 14. Dates and time(s) for exposure periods | Z |
| 15. Presentation of all results data including tabulation or graphical presentation of the summarised results | Z |
| 16. Any deviations from standard protocols (<u>if</u> standard protocols are used) | Z |
| 17. Test reference including Author(s), title, test house, year of publication/report and a statement on whether these results have been published (if so a full journal reference should be included where possible) | Z |

N.B. The checklist is not exhaustive and the items necessary will vary between test types that are reported in the efficacy data submission for a product.

6.1 PRESENTATION OF RESULTS FROM EFFICACY STUDIES

For a critical scientific assessment of the data package to be undertaken, each study should be reported in sufficient detail and should include details of the test protocol, the in-use concentrations, numbers of replicates, controls, diluents, and application rates and assessment criteria used in the particular test protocol. These should be relevant wherever possible to the product for which approval is sought and the label claims.

The results may be presented in the form of tables, figures or graphs as appropriate, but where either of the latter two are presented, the data which have been used to construct the figure or graph should also be provided where possible. If detailed statistical analyses are to be presented (e.g. analyses of variance etc.) these will not be accepted without the raw data on which these statistical analyses were performed. However simple statistics such as mean or range, and regression analyses for graphical presentations may be presented.

The applicant's interpretation of these results should also be presented although the evaluation and conclusions drawn from these data by the Registration Authority will be established before examining the applicants statements.

Although efficacy data are not subject to the requirements of Good Laboratory Practice (GLP), the Registration Authority are aware that in the production of efficacy data applicants are likely to adopt standard Quality Assurance procedures (e.g. with respect to study personnel, methods, procedures, documentation, archive storage and retrieval of raw data). Applicants are encouraged to continue this approach to ensure that if the Registration Authority require further information (e.g. raw data) it will be readily available.

7 CONCLUDING COMMENTS

These guidelines are designed to be flexible and are intended to give **advice** regarding the nature and type of efficacy data required to support the approval of non-agricultural pesticide products containing active ingredients intended for use as wood preservatives. They do not set out a protocol to be followed exactly nor do they specify rigid protocols to which tests must be conducted in the process of generating efficacy data. They cannot give details on every possible evaluation scenario but outline the nature of the data required and the policy framework within which the data will be evaluated. It is recognised that the wide diversity of products and their intended uses necessitates flexibility in the structure, layout and presentation of data.

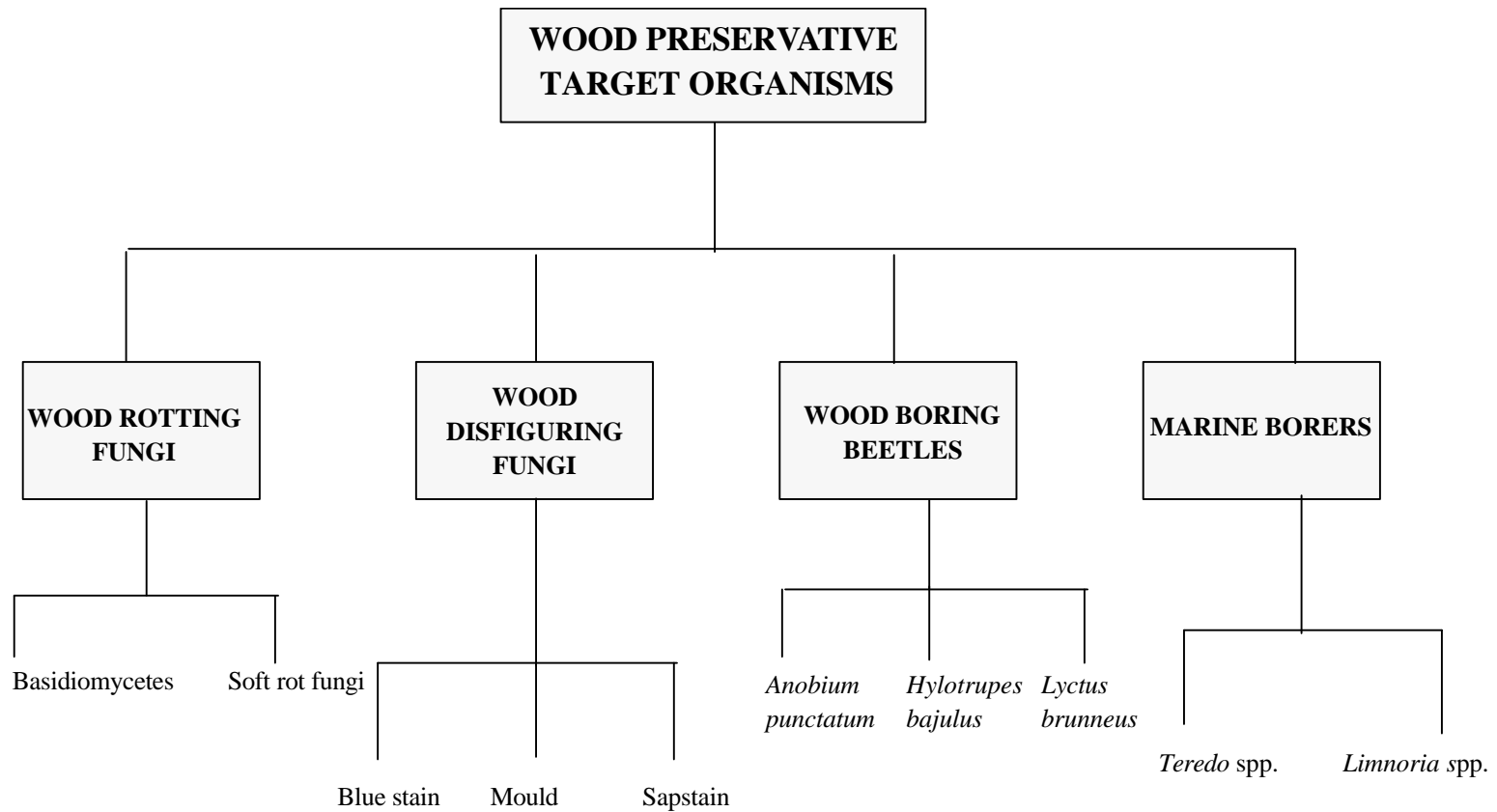
Applicants wishing to submit such products for approval, approval holders supporting active ingredients at review or addressing post approval data requirements, or interested parties requiring any further guidance on efficacy requirements are encouraged to contact Biocides and Pesticides Assessment Unit (BPAU) at their earliest convenience.

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Magdalen House
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APPENDIX 1

POSSIBLE WOOD PRESERVATIVE EFFICACY CLAIMS: A BREAKDOWN OF THE INFORMATION WHICH MAY BE REQUIRED REGARDING CLAIMED TARGET ORGANISMS



APPENDIX 2

INFORMATION ON THE PRINCIPLE TARGET ORGANISMS OUTLINED IN THE DOCUMENT

1) Fungi

Wood rotting fungi

A wood moisture content of more than 20 % (m/m) is necessary for the development of these fungi.

Wood rotting basidiomycete fungi

Fungi responsible for brown rot and white rot, but not soft rot.

Soft rot fungi

Fungi responsible for a type of rot characterised by surface softening of the wood although they also cause rot at depth. These fungi need a higher wood moisture content than basidiomycetes. They are of special significance for wood in ground contact or in water.

Wood disfiguring Fungi

Fungi causing mould and blue stain in service.

These fungi are only of practical concern in relation to aesthetic appearance, though they can increase wood permeability and degrade decorative coatings.

Blue stain fungi

Fungi causing blue to black permanent discolouration of variable intensity and depth mainly in the sapwood of certain woods. This does not result in appreciable alteration of the mechanical properties but can increase the permeability. They are highly significant where the surface appearance is important.

Mould fungi

Fungi being evident as spots of various colours on the surface of wet wood and they can occur when only the wood surface moisture content is above 20 % (m/m) (for instance, as a result of high relative humidity or of condensation of water vapour). They do not significantly alter the mechanical properties of the wood. They are only of special significance for wood in service if disfigurement is undesirable or unacceptable.

These fungi are not necessarily specific to wood and can occur on any material with a high moisture content.

Sapstain fungi

Sapstain fungi are of economic importance in causing blue-black and brown disfigurement of freshly felled logs or sawn timber. They only infect timber as long as it is green and are controlled by rapid drying. When handling practices cannot ensure rapid surface drying, chemical treatments are sometimes used. The minimum moisture level for growth is approximately 27 % m/m. Sapstaining fungi tend to be resistant to low temperatures and consequently may survive in severely cold and frosty conditions. Attack by sapstaining fungi may reduce the ability of the timber to resist shock and consequently may constitute a risk where the timber in question requires particular toughness. Common sapstaining species include *Ceratostomella pilifera* with other species of staining fungi being *Aureobasidium pullulans* spp., *Alternaria* spp., *Ceratocystis* spp. and *Phialophora* spp.

2) Insects

Wood boring beetles (Coleoptera)

Insects which lay their eggs in wood pores or cracks and which have larvae that attack the wood. They are present throughout Europe but the risk of attack varies greatly from high to insignificant. The most important are *Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*.

Hylotrupes bajulus (House longhorn beetle)

Attacks the sapwood only of many softwood species and its vitality and longevity depend principally on the ambient temperature and the wood moisture content. Where present, it can be of serious structural significance.

Anobium punctatum (Common furniture beetle)

Insect responsible for attack of the sapwood of certain softwood and hardwood species. The damage can extend to the heartwood in some wood species. Occasionally regarded as of structural significance. Its presence is particularly noted in coastal climates and where damp conditions prevail.

Lyctus brunneus (Powder post beetle)

Insect which attacks sapwood of certain starch-containing hardwoods. Of significance throughout Europe in both European and imported hardwood timbers.

Termites (Isoptera)

The most destructive wood destroying pests in warm climates, about 1800 different species occur in all the warm climates of the world. Termites exist throughout the tropics but extend into Southern Europe. Their life style is quite different from the wood boring beetles. Two distinct groups of termites attack wood:- subterranean termites and dry wood termites.

The subterranean termites build their nests in contact with the ground and are responsible for the characteristic termite mounds. Only a few of the many species of subterranean termites

cause significant damage to buildings (these include the *Reticulitermes* sp. found in Southern Europe). They forage over a distance for their food and build tunnels between their nests and the source of timber. Control of subterranean termites can therefore consist of excluding them from buildings by such means as toxic barriers and soil poisoning or by direct treatment of the timber.

Dry wood termites (Kalotermitidae), in contrast, live independent of the ground excavating clean galleries within the timber structure. The colonies are much smaller but once established in a building can be difficult to eradicate. Prevention by exclusion of flying insects and conventional wood preservation are considered to be the most effective measures.

3) Marine borers

This term is applied to marine invertebrates such as *Limnoria* spp. and *Teredo* spp. which need a certain salinity of water and which hollow out extensive tunnels and cavities in wood. These organisms can cause serious damage to fixed or floating structures.

APPENDIX 3

END USE HAZARD CLASSES (as defined in EN 335-1)

Hazard class 1

Wood or wood-based product under cover, fully protected from the weather and not exposed to wetting. (e.g. domestic roof timbers).

Hazard class 2

Timbers not in ground contact, protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting. (e.g. general building timbers).

Hazard class 3

Timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting (e.g. fencing rails, joinery, cladding).

Hazard class 4

Timbers in contact with the ground or fresh water and permanently exposed to wetting (e.g. fence posts, poles, silage walls, river jetties).

Hazard class 5

Timbers in the marine environment exposed to salt water (e.g. marine piling, harbour jetties).

APPENDIX 4

TYPICAL FRAME FORMULATIONS CONSIDERED IN PRECEDENT SETTING OF PRODUCTS

These formulation types are placed into similar groups where read-across within the group may be considered. Read-across will only be considered when the application rates, areas of use etc. are equivalent.

This list is not an exhaustive one into which all product applications must be categorised. Applicants may submit novel formulation types not covered in this list or they may, in some cases, wish to submit a reasoned case in support of their product application if the product cannot readily be categorised into one of these groups.

Water-based concentrate. Water-based ready for use.	Water borne in-use systems which are not emulsion based systems.
Solvent-based concentrate. Solvent-based ready for use.	Organic solvent based in-use systems.
creosote products.	
Liquid emulsion products.	Diluted emulsion in-use formulations in water.
Paste formulations.	Solid/semi-solid preparations either water based or solvent based typically intended to be applied via trowel or caulking gun.
Solid/ plug compounds. Powder formulations.	Particle-based preparations which may be applied as water based solutions or solid 'diffusible' plug compounds to be inserted into timber.

APPENDIX 5

CURRENT LIST OF EN STANDARDS FOR EFFICACY TESTING OF WOOD PRESERVATIVE PRODUCTS

Standard	Date	Title
Physico-chemical testing		
EN 73	1988	Accelerated ageing of treated wood prior to biological testing. Part 1 - Evaporative ageing.
EN 84	1989	Accelerated ageing of treated wood prior to biological testing. Part 2 - Leaching Procedure.

Laboratory testing against fungi		
EN 113	1997	Method of test for determining the protective effectiveness against wood rotting <i>Basidiomycetes</i> - Determination of toxic values.
EN 152-1	1988	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain in service - Brushing procedure.
EN 152-2	1988	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain in service - Application other than by brushing.
DD ENV 839	1994	Determination of the preventive efficacy against wood destroying <i>Basidiomycete</i> fungi.
ENV 12038	1996	Durability of wood and wood-based products - Wood-based panels - Method of test for determining the resistance against wood destroying <i>Basidiomycetes</i> .
ENV 807	1993	Determination of the toxic effectiveness against soft rotting micro-fungi and other soil inhabiting micro-organisms.
ENV 12404	1997	Assessment of the effectiveness of a masonry preservative to prevent growth into wood of Dry Rot (<i>Serpula lacrymans</i>).

Laboratory testing against insects		
EN 117	1989	Determination of toxic values against <i>Reticulitermes santonensis</i> de Feytaud (laboratory method).
EN 118	1990	Determination of preventive action against <i>Reticulitermes santonensis</i> de Feytaud (laboratory method).
EN 20-1	1992	Determination of the protective effectiveness against <i>Lyctus brunneus</i> (Stephens) - Application by surface treatment (Laboratory method).
EN 20-2	1993	Determination of the protective effectiveness against <i>Lyctus brunneus</i> (Stephens) - Application by impregnation (laboratory method).
EN 21	1988	Determination of the toxic values against <i>Anobium punctatum</i> (De Geer) by larval transfer (Laboratory method).
EN 22	1975	Determination of eradicant action against <i>Hylotrupes bajulus</i> (Linnaeus) larvae (laboratory method).
EN 46	1988	Determination of the preventive action against recently hatched larvae of <i>Hylotrupes bajulus</i> (Linnaeus) (Laboratory method).
EN 47	1988	Determination of the toxic values against larvae of <i>Hylotrupes bajulus</i> (Linnaeus) (Laboratory method).
EN 48	1988	Determination of eradicant action against larvae of <i>Anobium punctatum</i> (De Geer) (Laboratory method).
EN 49-1	1992	Determination of the protective effectiveness against <i>Anobium punctatum</i> (De Geer) by egg laying and larval survival - Application by surface treatment (Laboratory method).
EN 49-2	1992	Determination of the protective effectiveness against <i>Anobium punctatum</i> (De Geer) by egg laying and larval survival - Application by impregnation (laboratory method).
EN 273	1992	Determination of the curative action against <i>Lyctus brunneus</i> (Stephens) (Laboratory method).
EN 370	1993	Determination of eradicant efficacy in preventing emergence of <i>Anobium punctatum</i> (De Geer).
DD 1390	1995	Determination of the eradicant action against <i>Hylotrupes bajulus</i> (Linnaeus) larvae - Laboratory method.

Field Efficacy Testing		
EN 330	1993	Field test method for determining the relative protective effectiveness of a wood preservative for use under a coating and exposed out-of-ground contact.
ENV 12037	1996	Field test method for determining the relative protective effectiveness of a wood preservative exposed out of ground contact: horizontal lap-joint method.
EN 252	1989	Field test for determining the relative protective effectiveness of a wood preservative in ground contact.
EN 275	1992	Determination of the protective effectiveness against marine borers.

Other standards relevant to efficacy testing		
EN 335-1	1992	Hazard Classes of wood and wood-based products against biological attack - Part 1: Classification of Hazard Classes.
EN 335-2	1992	Hazard Classes of wood and wood-based products against biological attack - Part 2: Guide to the application of Hazard Classes to solid wood.
EN 335-3	1995	Durability of wood and wood-based products. Guide to the application of hazard classes to wood-based panels.
EN 599-1	1997	Durability of wood and wood-based products - Performance of preventive wood preservatives as determined by biological tests - Part 1: Specification according to Hazard Class.