FCBA
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Update on the ongoing activities of CEN/TC 38 Focus on the revision of efficacy criteria standards and related work on interpretation documents

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WEI IEO Spring meeting – March 2017 – Brussels

EUROPEAN LANDSCAPE OF BIOCIDES EFFICACY ASSESSMENT

Asking for efficacy assessment of biocides (PT8 – PT18)

EC Regulation on Biocidal Products (BPR)
Member states

ECHA TNsG
(Technical Notes for Guidance)
ECHA Doc 2017

Providing test methods and efficacy criteria

Standardisation bodies (CEN/TC38, national committees)
Test laboratories/institutes

Efficacy test standards/methods
Efficacy criteria standards

5.5.8 PT8 Wood preservatives

- This document deals with **the evaluation methodology of efficacy tests for wood preservatives biocidal products** that are applicable in the frame of the **EU Biocidal Products Regulations (BPR)** for the **authorisation of biocidal products** (BPR Annex VI).

- **The document is not intended to replace standards, standardized methods or other methods used as reference** for developing the required data. It is considered as scientific guidance and the reader is advised to refer to the standards themselves or appropriate literature in case details should require further clarification.

- The aim of this document is to provide **a common base for the assessment of the efficacy** for the biocidal product authorization for **PT8 products** for the applicants and the Competent Authorities (CAs).

- Although alternative test methods could be taken into account, this document is mainly based on the **EN 599-1 standard for preventive uses** and on the **EN 14128 standard for curative uses**.

PREVENTIVE EFFICACY OF BIOCIDAL PT8

Efficacy test methods/standards

LAB TESTS

Beetles (Hylotrupes, Anobium, Lyctus), subterranean termites, decay fungi (brown/white), soft rot, blue stain, marine borers

+ artificial ageing EN 73 / EN 84

FIELD TESTS

subterranean termites, decay fungi (brown/white), soft rot, blue stain, marine borers

Efficacy criteria

EN 599-1 (2009) + A1 (2013)

Takes into account target:

- Mode of application (surface/deep)
- Use class
- Biological agent

Need for revision currently discussed (CEN/TC38/WG22)

CURATIVE EFFICACY OF BIOCIDAL PT8

Efficacy test methods/standards

LAB TESTS

Beetles (*Hylotrupes, Anobium, Lyctus, Hesperophanes, Xestobium*)

Dry rot *Serpula lacrymans*

NO FIELD TESTS

Efficacy criteria

EN 14128 (2004)

Takes into account target:

- Mode of action
- Biological agent

Standard currently under revision

(CEN/TC38/WG22)

CURATIVE EFFICACY OF BIOCIDAL PT8

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- Test methods should be **appropriated to demonstrate the efficacy claimed on the label for the product**
- To test wood preservatives**, the CEN standards** are highly recommended.
- Two main categories of treatment are described:
  Preventive treatments, which are covered by **EN 599-1**
  Curative treatments, which are covered by **EN 14128**
- **It is highly recommended to perform the studies according to these standards.**
- If the standards are not applicable or suitable, the applicant **may adapt the methodology or use another method** (including his own method).
- When a standard is modified or when a non CEN standard is used, **a robust justification and description have to be provided.**

In cases no CEN standard exist, how to support/justify the choice of a different kind of assessment, how to define/validate efficacy criteria ?

What will be (is) accepted by the authorities ?

BPR versus CEN/TC 38

HOW BPR CAN DRIVE THE REVISION OF TC38 STANDARDS ?

Examples of FAQs on evaluation under BPR in relation to CEN/TC 38 standards

PREVENTIVE EFFICACY TESTS

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- The species presented below are the species being representative of wood attacking organisms.
- For specific claims, efficacy data against each named target pest will be required.

Table 21: Examples of target organisms for wood preservatives

(N.B. these examples are not intended to be exhaustive with respect to target organisms or prescriptive with respect to data to be generated).

Target organisms				
Common English term	**Code F forproduct**	**Target organisms according to EN 1001**	**Classification**	**Scientific name**
Fungi			**Fungi**	
Wood rotting fungi				
Wood rotting basidiomycetes	G.10	Brown rot fungi	Basidiomycetes	e.g. *Gloeophyllum trabeum*
	G.11	White rot fungi	Basidiomycetes	e.g. *Coriolus versicolor*
Soft rot fungi	G.12	Soft rot fungi	Ascomycetes, Deuteromycetes	e.g. *Chaetomium globosum*
Wood discolouring fungi	G.21.1	Sapstain fungi (bluestain mainly)	Ascomycetes, Deuteromycetes	e.g. *Ophiostoma piliferum (Ceratocystis pilifera)*
	G.21.2	Bluestain in service	Ascomycetes, Deuteromytcetes	e.g. *Aureobasidium pullulans*
	G.22	Mould fungi	Ascomycetes, Deuteromycetes,	e.g. *Aspergilus niger*
Insects			**Insecta**	
Beetles	G.30	Wood boring beetles	Coleoptera	
	G.31	House longhorn beetle		e.g. *Hylotrupes bajulus.*
	G.32	Common furniture beetle		e.g. *Anobium punctatum*
	G.33	Powder post beetles		e.g. *Lyctus brunneus*
	G.40	Fresh wood insect	Coleoptera	e.g. *Scolytus spp*
Termites	G.50	Termites (genus claimed)	Isoptera	
	G.51	Subterranean termites (genus claimed)		e.g. *Reticulitermes spp*, e.g. *Coptotermes spp*
	G.52	Drywood termites (genus claimed)		e.g. *Cryptotermes spp*
	G.53	Tree termites (genus claimed)		e.g. *Nasutitermes spp*
Wood destroying marine organisms	G.60	Marine borers (genus claimed)		
	G.61	Mussels	*Teneridae, Pholadidae*	e.g. *Toredo sp, Martesia sp*
	G.62	Crustaceans	*Isopoda, Amphipoda*	e.g. *Limnoria spp, Chelura spp*

PREVENTIVE EFFICACY TESTS / TERMITES

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- For specific claims, efficacy data **against each named target pest** will be required.

Termites	G.50	Termites (genus claimed)	
	G.51	Subterranean termites (genus claimed)	e.g. *Reticulitermes spp*, e.g. *Coptotermes spp*
	G.52	Drywood termites (genus claimed)	e.g. *Cryptotermes spp*
	G.53	Tree termites (genus claimed)	e.g. *Nasutitermes spp*

OK, reference test methods exist
Lab → EN 118, EN 117
Field → EN 252 (UC 4)

NO reference test methods !

How to support a claim for curative efficacy against drywood termites, tree nesting termites, subterranean termites (as no EN standard exists)?

Termite species with different biology, ecology … → Methodological adaptations are necessary (from EN 117, EN 1390)

+ Need to define efficacy criteria (amend/improve EN 599-1)

PREVENTIVE EFFICACY / CRITERIA → EN 599-1

SOME QUESTIONS THAT NEED AN ANSWER …

- How to use the results of tests performed on *H. bajulus* to derive a vrb / claim efficacy against other wood boring insects ?
- Anti-termite claim: why is it based on efficacy tests done on beetles ?
- How to support efficacy claims specifically for tropical areas ? (is there a need to test additionally tropical fungal species ?)
- Annex A → pretty unclear for many people + the annex is “only” an informative one → is retesting mandatory if changes in formulations occur ?
- Bridging studies → in case the formulation/active ingredient changes (old/new formulation → should it be retested or is documentation enough?)

CURATIVE EFFICACY / CRITERIA → EN 14128

WOOD BORING « BEETLES » – ECHA Document 2017

- Data required to support label claims for curative efficacy may include some tests generated using existing EN standards for the relevant beetle species or other **alternative supporting data**.

EN 14128 (2003) Durability of wood and wood-based products — Performance criteria for curative wood preservatives as determined by biological tests

- Minimum testing requirements for PT8 products claiming curative activity against **wood boring insects** (and products applied to prevent growth of dry rot fungus through masonry)

Hylotrupes bajulus (house longhorn beetle)

Anobium punctatum (common furniture beetle)

Lyctus brunneus (powderpost beetle)

Xestobium rufovillosum (deathwatch beetle)

Trichoferus holosericeus (syn. *Hesperophanes cinnereus*)

→ EN standard tests exist for curative efficacy against *Hylotrupes bajulus* (ENV 1390) and *Anobium punctatum* (EN 48/EN 370)

How to support a curative efficacy claim against the other insect species and species not listed in EN 14128?

→ Adapted methods, reference to practical field demonstration ?

→ What are the efficay criteria ?

→ Is it needed/relevant ?

CURATIVE EFFICACY / TERMITES

TERMITES – ECHA Document 2017

- The control of termites enters into the scope of the **PT8** and the **PT18** depending of the use of the product.

- **If the product is applied on wood, then this product is covered by the requirement of the PT8**.

BUT: Termites are not in the scope of the standard EN 14128

Drywood termites (*Cryptotermes, Kalotermes*)

Subterranean termites (*Reticulitermes, Coptotermes, Heterotermes*)

Tree termites (*Nasutitermes*)

How to support a curative efficacy claim against termites ?

→ no existing standards (only for PT 18)

→ no efficacy criteria

CURATIVE EFFICACY

SOME OTHER QUESTIONS TO BE ANSWERED …

- How to demonstrate a curative efficacy of a product when application by injection is stated as possible in the application claim ?

  → is it necessary ? use lab method ? refer to long-term experience ?

- How to support a claim for a given mode of action ? And how to not support a mode of action driven by EN 14128 ?

Ex: if curative efficacy against *Anobium* is tested according to EN 370 → EN 14128 indicates that EN 370 is the test to be done for deferred effect → applicants cannot support any other claim than « deferred effect » ? (which is absolutely not demonstrated by EN 370)

→ should the mode of action be in the scope of the standard ?

- How to support a claim on hardwoods when the product was tested on a softwood species ? Why different wood species are used in different standards for the same biological agent (ex: Anobium → oak in EN 49-1, Scots pine or beech in EN 48 and EN 370)

  → consider that wood is only a matrix and that the species used makes no difference ?

Actions undertaken in 2016 – 2017 by CEN TC/38 WG 22

CEN/TC 38 / WG 22 "Performance, assessment and specification" (Convenor Mrs Elena CONTI)

- **October 2016** - Organisation of a workshop in in CATAS, Italy

- **November 2016** - Opening of a new Work Item "Interpretation document for standards related to efficacy requirements and specifications of wood preservatives".

This document is intended to give guidance on the interpretation of the European standards where specifications of wood preservative products are defined. It is believed that users (manufacturers, specifiers, authorities…) will benefit from the availability of a comprehensive document, in which strictly technical matters are presented in a more accessible form.

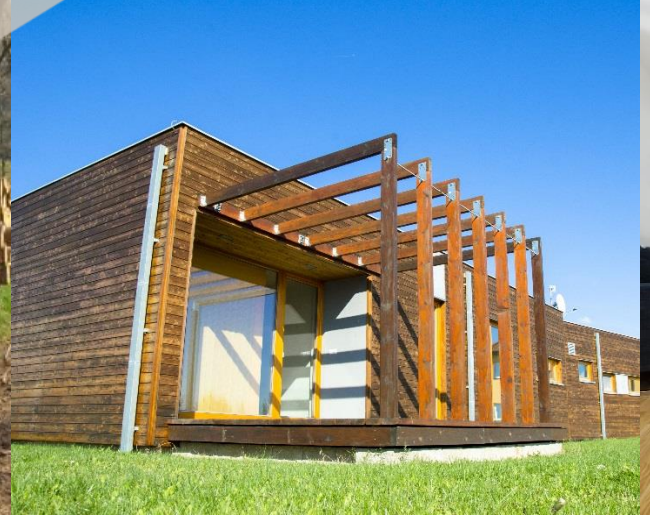
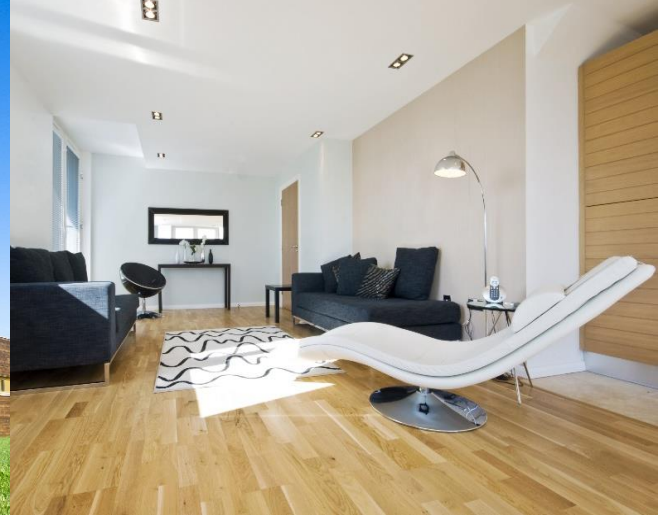
The initial idea and scope of this document was to provide the historical and technical background of the CEN standards referenced in EN 599-1 and EN 14128, for the assessment of the efficacy of wood preservatives.

- **February 2017** – WG 22 meeting in BAM, Berlin

EN 14128 was discussed (ongoing revision)

The WG decided to bring the ECHA Guidance to a wider audience with the aim of disseminating the information and to trigger discussion among the experts of IRG WP (next conference will take place in June 2017).



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Thank you for your attention

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