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GUIDANCE

Guidance on the Biocidal Products Regulation

Volume II Efficacy - Assessment and Evaluation (Parts B+C)

DRAFT Version 2.0 (Appendix 12 only)
xxxxxx 2017

LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C)

Reference: ECHA-17-G-03-EN
Cat. Number: ED-04-17-144-EN-N
ISBN: 978-92-9495-756-6
DoI: 10.2823/175784
Publ.date: February 2017
Language: EN

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DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	February 2017
Version 2.0	Update to add a new Appendix for PT8 The text has been revised as follows: • To add a new Appendix 12 • To revise section 5.5.8.3 to remove footnote 28 • To re-number Appendices after the new Appendix to 13-24 and revise all cross references to these Appendices.	Xxxx 2017

PREFACE

The Guidance on the Biocidal Products Regulation (BPR) is to be applied to applications for active substance approval and product authorisation as submitted from 1 September 2013, the date of application (DoA) of the Biocidal Product Regulation (the BPR).

This document describes the BPR obligations and how to fulfil them.

The scientific guidance provides technical scientific advice on how to fulfil the information requirements set by the BPR (Part A), how to perform the risk assessment and the exposure assessment for the evaluation of the human health and environmental aspects and how to asses and evaluate the efficacy to establish the benefit arising from the use of biocidal products and that it is sufficiently effective (Parts B & C).

In addition to the BPR guidance, the Biocidal Products Directive (BPD) guidance and other related documents are still considered applicable for new submissions under the BPR in the areas where the BPR guidance is under preparation. Furthermore these documents are still valid in relation to the applications for active substance approval or applications for product authorisation under the BPD that may still be under evaluation. Also the Commission has addressed some of the obligations in further detail in the Biocides competent authorities meetings documents which applicants are advised to consult. Please see ECHA Biocides Guidance website for links to these documents: [https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation].

Applicability of Guidance

Guidance on applicability of new guidance or guidance related documents for active substance approval is given in the published document "*Applicability time of new guidance and guidance-related documents in active substance approval*" available on the BPC Webpage[1] [https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee] and for applicability of guidance for product authorisation, please see the CA-document CA-july2012-doc6.2d (final), available on the ECHA Guidance page [https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf].

[1] Link available under Working Procedures (right column) [https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee]

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NOTES to the reader:

In this document text cited from the Biocidal Products Regulation (EU) No 528/2012 is indicated in green boxes.

This symbol highlights text to be noted.

Section 5.4.5 PT5 Drinking water disinfectants: A preliminary draft text for PT 5 is included in this section: the section is currently under review within the ECHA "Disinfectants Project". (see section for full details of note).

Section 5.6 and sub-sections for PT10, PT11, PT12, PT15, PT16, PT17, PT19 (non-arthropods) and PT20: please refer to the General sections 1-3 of this guidance and the TNsG.

1 List of Abbreviations

Abbreviation	Explanation
AFNOR	Association française de normalisation; French national organisation for standardisation http://www.afnor.org/
AOAC	Association of Official Analytical Chemists http://www.aoac.org/
AS	Active substance
ASTM	American Society for Testing and Materials http://www.astm.org/
ATCC	American Type Culture Collection http://www.lgcstandards-atcc.org/
BP	Biocidal product
BPD	Biocidal Products Directive 98/8/EC
BPF	Biocidal product family
BPR	Biocidal Products Regulation (EU) No 528/2012
BS	British standard
CA/CAs eCA	Competent Authority/Competent Authorities • Evaluating CA (eCA) is the Competent Authority that evaluates the application for an active substance approval or an application for a Union authorisation. • Receiving CA is the Competent Authority that receives an application for a National Authorisation.
CAR	Competent Authority Report, (also known as the assessment report).
CEN	Comité Européen de Normalisation; European Committee for Standardisation http://www.cen.eu/
CFU	Colony forming units
CIP	Cleaning-in-Place
CT	Concentration x Time
CV	Critical value
DIN	Deutsches Institut fuer Normung; German national organisation for standardisation http://www.din.de/
DVG	Deutsche Veterinaermedizinische Gesellschaft; German Veterinary Medical Society http://www.dvg.net/
EN	European Standard
EPPO	European and Mediterranean Plant Protection Organization www.eppo.org
ESL	Estimated service life

Abbreviation	Explanation
EU	European Union + Norway, Iceland and Lichtenstein Please note the BPR applies to the European Economic Area (EEA) and thus all references to the EU in the text should be understood as EEA (EU + Norway, Iceland and Lichtenstein)
GLP	Good laboratory practice
ISO	International Organization for Standardisation http://www.iso.org/
KD	Knock down
KD_{50}	Knock down for 50% of the group of tested animals
KT_{50}	Knock down time for 50% of the group of tested animals
LD_{50}	Lethal dose for 50% of the group of tested animals
MAD	Mutual acceptance of data
OECD	Organisation for Economic Co-operation and Development http://www.oecd.org/
prEN	Draft European Standard
PAR	Provisional assessment report
PEG	Partner expert group
PT	Product-type
SPC	Summary of Product Characteristics
TC	Technical Committee
TM	Technical Meeting
TNsG	Technical Notes for Guidance
TVC	Total viable count
UC	Use Class
US-EPA	United States Environmental Protection Agency http://www.epa.gov/
VAH	Verbund fuer Angewandte Hygiene; Association for Applied Hygiene http://www.vah-online.de/
VOC	Volatile organic compound

Glossary of Terms

Standard term	Explanation
Activity against enveloped viruses (see also Virucidal activity and Limited spectrum virucidal activity)	A claim for hygienic hand and skin disinfectants with activity against enveloped viruses only.
Algaecide	A product or active substance used to control (inhibit the growth) or kill algae.

Standard term	Explanation
Algaecidal activity	The capability of a product or active substance to produce a reduction in the number of viable algae cells under defined conditions.
Antimicrobial product	A product which prevents the growth of/reduces the number of/mitigates the growth of micro-organisms
Bactericide	A product or active substance which irreversibly inactivates vegetative bacteria under defined conditions
Bactericidal activity	The capability of a product or active substance to produce a reduction in the number of viable bacterial cells of relevant test-organisms under defined conditions
Bacteriostatic activity	Capability of a product or active substance to inhibit the growth of bacteria under defined conditions
Biocidal product/ Biocide	BPR Article 3(1)(a): *— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,* *— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.* *A treated article that has a primary biocidal function shall be considered a biocidal product.*
Biofilm	An accumulation of microbial cells immobilised on a substratum and embedded in an organic polymer matrix of microbial origin
Biostatic product	A product which inhibits the growth of micro-organisms under defined conditions
Curative effect on biofilm	The biocide is added after the biofilm is formed and acts on biofilm stability, facilitating the biocide interaction with cells – it may or may not act as detergent and detach the biofilm from the surface
Disinfectant within PT 2, 3, 4 and 5	A disinfectant is a product that reduces the number of micro-organisms in or on an inanimate matrix- achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose
Disinfection within PT 2, 3, 4 and 5	disinfection is the reduction of the number of micro-organisms in or on an inanimate matrix- achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose
Skin disinfection within PT1	Skin disinfection is the reduction of the number of micro-organisms on skin, achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose
Efficacy	The ability of a product or active substance to produce an effect as described in the label claims made for it, when used under actual use conditions.

Standard term	Explanation
Flow condition (for biofilm)	Biofilm is formed on supports of different nature placed along a tube or a chamber where the medium (inoculated and/or fresh) is circulated in a closed (reservoir-pump-tubing) or open (reservoir-pump-tubing-outlet) system
Fungicide	A product or active substance which irreversibly inactivates fungi (vegetative mycelia, budding yeasts and/or their spores) under defined conditions
Fungicidal Activity	The capability of a product or active substance to produce a reduction in the number of viable vegetative yeast cells and mould spores of relevant test organisms under defined conditions
Fungistatic activity	The capability of a product or active substance to inhibit the growth of fungi under defined conditions
Hygienic hand disinfectants	A hygienic hand disinfectant is a hygienic handrub disinfectant or a hygienic hand wash disinfectant
Hygienic handrub disinfectant	product used for post-contamination treatment that involves rubbing hands, without the addition of water, which is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora
Hygienic handwash disinfectant	product used for post-contamination treatment that involves washing hands with water, which is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora
Limited spectrum virucidal activity (see also Virucidal activity and Activity against enveloped viruses)	Limited spectrum virucidal activity is a claim for hygienic hand and skin disinfectants using Adenovirus and Murine Norovirus as test organisms, thus including activity against the test viruses and all enveloped viruses (see Appendix 5).
Log reduction / $\log_{10}$ reduction / lg reduction	Reduction presented in a logarithmic scale. Example 1: when a disinfection reduces 10^8 bacteria to 10^2 bacteria, this is a lg reduction of 6. Example 2: when a disinfection reduces 5.10^7 fungal spores to 8.10^3 fungal spores this is a lg reduction of 3.79.
Microbes/micro-organisms	bacteria (including vegetative cells bacterial spores and mycobacteria) fungi (including yeasts, moulds and fungal spores) algae, viruses (including bacteriophages), protozoa (including cysts and other permanent states), etc.
Mycobactericide	A product or active substance which irreversibly inactivates mycobacteria under defined conditions
Mycobactericidal activity	The capability of a product or active substance to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions
Neutraliser	A chemical agent or formulation which suppresses the residual activity of an disinfectant within a test but does not inhibit or inactivate micro-organisms
Performance standard	Regulatory or scientific standard for biocides that is either quantitative or qualitative (that may also be specified in the test method) by which a decision is taken on the acceptability of a claim.
Preventive effect on biofilm	The biocide is present before the biofilm is formed and may act both on cell viability and/or on cell adhesion/biofilm maturation

Standard term	Explanation
Product type (PT)	Product types (PT) are defined in BPR annex V
Sporicide	A product or active substance which inactivates dormant bacterial spores under defined conditions
Sporicidal activity	The capability of a product or active substance to produce a reduction in the number of viable bacterial spores of relevant test organisms under defined conditions
Sporistatic activity	The capability of a product to inhibit the germination of dormant bacterial spores under defined conditions
Static condition (for biofilm)	Biofilm is formed on supports such as microplates without agitation after an incubation time that depends on the micro-organism considered
Surgical hand disinfectants	A surgical hand disinfectant is a surgical handrub disinfectant or a surgical hand wash disinfectant
Surgical handrub disinfectant	Product used for preoperative treatment that involves rubbing hands, without the addition of water, which is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound
Surgical handwash disinfectant	Product used for preoperative treatment that involves washing hands with water, which is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound
Treated article	A treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products
Tuberculocide	A product or active substance which irreversibly inactivates *Mycobacterium tuberculosis* under defined conditions
Tuberculocidal activity	The capability of a product or active substance to irreversibly inactivate Mycobacterium tuberculosis, demonstrated by the capability to produce a reduction in the number of viable cells of the test organism *Mycobacterium terrae* under defined conditions
Virucide	A product or active substance which irreversibly inactivates viruses under defined conditions
Virucidal activity (see also Limited spectrum virucidal activity + Activity against enveloped viruses)	The capability of a product or active substance to produce a reduction in the number of infectious virus particles of relevant test organisms under defined conditions "Full spectrum" virucidal activity is a claim for biocidal products using relevant test organisms and thus showing activity against the enveloped and non-enveloped viruses.
Yeasticide	A product or active substance which irreversibly inactivates yeast under defined conditions
Yeasticidal activity	The capability of a product or active substance to produce a reduction in the number of viable vegetative yeast cells of relevant test organisms under defined conditions

1

2

3

1 1. General Introduction

2 2. Claims
3

4 3. General considerations for the development and
5 reporting of efficacy data

6 4. Active substance approval

7 5. Product authorisation

8 Appendix 1. Claims Matrices

9 Appendix 2. Standards and testing methods for efficacy-
10 testing of disinfectant biocidal products (PT 1-5)

11 Appendix 3. Table of Reference Test Organisms (PT 1-5)

12 Appendix 4. Overview of standards, test conditions and
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14 Appendix 5. Examples of viruses sorted according to
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16 infection

17 Appendix 6. Selection of recommended tests for solid
18 materials (excluding wood-preservatives)[2]

19 Appendix 7. Selection of recommended tests for liquid
20 materials[3]

21 Appendix 8. Commonly Used Methods to Measure the
22 Effects of Preservative/Curative Action in Liquid
23 Matrices[4]

[2] These tests are not necessarily appropriate for all claims and materials. Tests have to be chosen depending on the claim made, the materials used and the conditions of use foreseen for the treated material/article.

[3] These tests are not necessarily appropriate for all claims and materials. Tests have to be chosen depending on the claim made, the materials used and the conditions of use foreseen for the treated material/article.

[4] Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated

Appendix 9. Commonly Used Methods to Measure the Effects of Protecting Material[5]

Appendix 10. Commonly Used Methods to Measure Antimicrobial Activity[6]

Appendix 11. Information on the principle target organisms for PT 8 as outlined in the document (5.5.8)

material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.

[5] Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.

[6] Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.

Appendix 12. Annex A of EN 599-1 and EN 14128

Introduction

Additional explanations regarding the Annex A of the standard EN599-1:2009+A1 :2013, mainly on cases where no new biological testing is necessary, are presented here, following the sections of the Annex.

At the time when EN599 and its Annex A were developed, the provisions for changes to the formulation were intended to be considered as providing guidance to help those dealing with the issues without having detailed knowledge of wood preservation. It should be noted that Annex A is not a normative Annex in EN 599-1 but only Informative and intended to act as guidance.

Note: in this appendix, a ready for use formulation refers to the product as marketed. It includes concentrated products (which can be diluted before application) and also products which do not need an additional dilution step before application. The efficacy will be demonstrated at the concentration used.

The composition of the products as marketed and used in its original form is the basis to assess the variations that can occur in a biocidal product family (BPF)

The introduction to Annex A lists the modifications which can occur during the development of a product for the first or subsequent authorisations (e.g. minor change, major change).

Variations can occur within a BPF which fall outside some of the guidelines given in Annex A, that will require additional efficacy testing even if the products are considered within the same BPF. Nor should Annex A be considered as being only applicable to a BPF.

This appendix has been written to give guidance on whether existing test results could still be considered valid where formulation changes had been made. This is a helpful and pragmatic approach regardless of whether a BPF is being considered or a first or subsequent authorisation.

Sections of the Annex – additional explanation

Paragraph A.2 No requirements for new biological testing

Section A.2.1

This section lists all the allowed variations (given in sub-sections A.2.2, A.2.3 and A.2.4) for which no new biological testing is required. It should be clarified if only one variation is allowed between the two products or if several variations are allowed.

→ Any or all of the variations are allowed.

Section A.2.2 In the case of organic solvent based products (ready for use)

- **Sub-section A.2.2 a**

  Changes involving substitution of any co-formulant by one which is chemically equivalent, from another supplier

  → "Substitution" means replacement of a chemically equivalent co-formulant performing the same function in the product formulation.

  "Chemically equivalent" means that chemicals have the same CAS number and the same physical properties (e.g. pH, molecular weight distribution (for polymers), HNL number (for surfactants). It is **a chemical from another supplier**.

Information on function of co-formulant should be provided:

Co-formulants are any ingredient (other than an active ingredient) in a formulated wood preservative product

Typical chemical functions for non-active ingredients of wood preservative can be, for example, surfactant, emulsifier, corrosion inhibitor, binder, pH stabiliser, mordant, dye, pigment, 'penetration marker' water repellent and co-solvent.

- **Sub-section A.2.2 b**

Products to be applied by penetrating treatment processes, for changes in the aromatic content or chemical nature of hydrocarbon solvent carriers, providing that not less than 90% (v/v) of the carrier distils below 250°C.

→ The reason for such a change is that a product could have been tested (e.g. in an EN113 test) using the organic solvent, xylene. The xylene evaporates during drying of the treated blocks leaving the active substance in the dry wood blocks, so the solvent does not affect the efficacy of the product. The blocks are exposed to the test fungus and the Biological Reference Value (BRV) and the Critical Value (CV) for the product will be determined. This point in Annex A allows an organic solvent based product containing the active substance to be formulated (using an aromatic substance such as 'Caromax 18', 'white spirit', 'Stoddard solvent' or 'odourless kerosene' to dissolve the active substance) without retesting the product. The principle is that the organic solvent evaporates after treatment, leaving the product solids at or above the CV, and the type and composition of the organic solvent carrier does not affect the efficacy of the product. Thus an efficacy test of a product (e.g. EN 113, EN 47) with a xylene solvent / carrier can be used to confirm the efficacy of an organic solvent based product, applied by a penetrating process, with a different solvent carrier, providing that not less than 90% (v/v) of the carrier distils below 250°C.

- **Sub-section A.2.2 c**

Product to be applied by superficial processes, for a change in the aromatic content of hydrocarbon solvent carriers of no greater than 10% (v/v of the total aromatic hydrocarbon solvent content)

→ See point A.2.2 point b

Example:

A formulation tested (e.g. EN113) with 20% m/m aromatic hydrocarbon solvent / carrier, can be read across to a biocidal product containing no less than 18% and no more than 22% total aromatic hydrocarbon solvent (=± 10% of 20%).

- **Sub-section A.2.2 d + e**
  - **Changes involving the addition or deletion of a soluble dyestuff:**
  - **Changes in pigments to an equal or lower pigment content of the product:**

→ "Soluble dyestuffs" ('dyes' in the BPR) are coloured, non-biocidal **soluble** substances which do not impede the flow of liquid through the wood structure; this is so that they do not reduce penetration of the active substances in a wood preservative and do not affect the efficacy of an active substance or biocidal product. Dyes may be included in a wood preservative as a penetration marker to differentiate between treated and untreated timber and / or to colour the preserved wood.

Dyes do not reduce the penetration of the wood preservative into the wood and do not reduce the efficacy of an active substance or wood preservative product.

"Pigments" are coloured, non-biocidal, **insoluble**, materials, dispersed in a suitable medium. Some pigments have been found to reduce the penetration of the active substances in a wood preservative.

Some pigments, resins, and wax-based water repellents were found in the 1990's to reduce wood preservative penetration, so these are specifically considered in Annex A of EN599.

Due to the **potential** impact of pigments on penetration it was decided to allow changes only up to the former content of pigment in the formulation when the 'no additional testing rule' shall apply.

It can be accepted to test a formulation without pigment.

In cases where additional pigments are used in the product, it has to be demonstrated that the conditions of A.2.5 are fulfilled.

- **Sub-Section A.2.2 f**

Product containing 10% (m/m) or less of solids containing resins and/or water repellents[7], relative changes in content of these constituent(s) of no more than ± 20% (m/m) and products containing more than 10% (m/m) solids, relative changes of no more than ± 10% (m/m)

→ With reference to wood preservative formulations, a solid is the proportion of non-volatile material contained in a formulation after the volatile solvent (which serves as a carrier or vehicle for the solid content) has vaporized or evaporated.

A "resin" is a non-volatile organic polymer and can be solid, semi-solid or liquid form.

An ingredient can be considered to make up the 'solid' portion of the preservative if it is non-volatile. However, in this section the solid content being referred to is specifically resins plus water repellents.

Example of a calculation of the allowed variations in case of a product containing resin and water repellent:

> For a product containing 5% resin + 7% water repellent (non-volatile portion) then the allowed variation is (5+7) * 10 / 100 = ± 1.2%

- **Sub-Section A.2.2 h**

Adding and/or Replacing a co-formulant providing the additive constitutes less than 2% of the total formulation and providing the physical properties are not affected (A.2.5)

→"Replacing" means changing one co-formulant for another. Partial replacement is permissible.

"Adding" refers to both the addition of a new co-formulant and to the increasing of an existing co-formulant.

The 2% relates to each individual substance. This value was chosen on the basis that it represents safe levels of change within a formulation that experts were confident would not affect the efficacy of a formulation, provided that stability was unaffected (hence the requirement that the provisions in A.2.5 shall be met).

[7] Water repellents are co-formulants in a formulation impart additional resistance to the absorption of water by the treated wood product. Typically water repellents are, but not limited to, of waxes or silicon base

An example of formulation modification to illustrate this section could be the exchanged/amended of propylene glycol with ethylene glycol by a change in the + - 2%.

Section A.2.3 In the case of water-soluble preservatives

- **Sub-section A.2.3 a:** see A.2.2 a.
- **Sub-section A.2.3 b:** see A.2.2 d.
- **Sub-section A.2.3 c**

For products in their ready for use form containing 10% (m/m) or less of solids containing resins and/or water repellents, relative changes in content of these constituent(s) of no more than ± 20% (m/m) and for products containing more than 10% (m/m) solids, relative changes of no more than ± 10% (m/m)of these constituents

See also Sub-section A.2.2 f for the definitions of "solid" and "resin".

- **Sub-section A.2.3 d:**

Refers to no additional testing for inorganic active ingredients not resulting in a change in the ratio, total content or nature of the active chemical elements.

- **Sub-section A.2.3 e:** see A.2.2 e.
- **Section A.2.3 g:** see A.2.2 h.

Section A.2.4 In the case of emulsion products

→ Differentiation between water soluble preservative (2.3) and emulsion products (2.4) Often products are part suspension and part emulsion.

At the time of the development of EN 599, emulsion concentrates were a relatively new technology. This explains why all the comparisons were made in relation to water-borne preservatives. With the knowledge and widespread experiences nowadays this separation is not justified anymore. It is recommended that section A2.3 is used for all water-based preservative formulation types (i.e. solution / emulsion / suspension or combinations of these) while ensuring the physical form of the active substance in the formulation is unchanged (i.e. solution / emulsion / suspension).

See section A.2.3.

Section A.2.5.

- **For the sub-sections A.2.2 h, A.2.3 g, A.2.4 b and c, it should be confirmed that:**
  - **the penetration into the wood is not adversely affected;**
  - **the stability of the product is not adversely affected;**
  - **by chemical analysis, that the above changes do not alter the content of the active ingredients after storage at 40 °C.**

→ You cannot generally predict the penetration of a wood preservative product from its composition. The combination of product composition and application process governs the wood preservative penetration.

Laboratory scale or pilot plant trials using standard timber species and standard process cycles would be appropriate to demonstrate that the penetration into the wood is not adversely affected.

Paragraph A.3 Requirement for minimum new biological testing

Practical case: Is it possible to combine section A.3 and A.2?

Example:

- **Product A is a fungicidal and insecticidal product. Data on the efficacy of this product is available;**
- **Product B is insecticidal only and the composition is very close to the product A except the fungicide active substance deleted and one compound added to the formulation A (at 1.5% w/w).**

When it is taken into account that efficacy data demonstrate that the fungicidal active substance has no impact on the insecticidal active substance and that the point A.2.3 and A.2.5 are fulfilled. Is the double read across be acceptable?

- A2 and A3 are for different situations;
- A2 specifies conditions where there is no requirement for new biological testing;
- A3 specifies conditions for minimum new biological testing (though in the case of changes to fungicide and insecticide levels it also describes instances where no additional testing will be required).

In the example the data provide sufficient demonstration of the effectiveness of Product B against insects.

The 'double read across' is acceptable. The results from the insect efficacy studies for Product A can be read across to Product B according to Annex A of EN599. The insect studies on Product A are acceptable to read across to Product B because the addition of the compound to Product A is less than 2% w/w. Assuming that the description of the function of the compound in the 'Identity' section is acceptable under Annex A, because it will not adversely affect penetration, Product B does not require retesting under Annex A and Product B can be considered to be effective against insects under BPR.

Under Annex A, the fungicidal active substances could be omitted from Product B without retesting the efficacy of Product B against insects if data exist which confirm that the removal of the fungicide does not affect the insecticidal efficacy (section A.3.2.2). Product B (without fungicide) can only be claimed to be effective against insects, and the insect studies for Product A can be used to confirm the effectiveness of Product B against insects.