Summary: Conclusions of the 2\textsuperscript{nd} EU Leaching Workshop on Wood Preservatives

The 2\textsuperscript{nd} EU Leaching Workshop took place in Varese, Italy on 12 June 2013. The aim of the leaching workshop was to

- compile experiences gained during product authorisation
- identify different assessment approaches between MS
- discuss open points and problematic issues
- decide on open points for harmonisation for future work.

\textit{Note: This document was prepared as an “interim document” until all points raised at the workshop are closed and the conclusions of the workshop are published. Thus only those points and related conclusions are stated in the following, which have been endorsed in the meanwhile at TM III 2013/WG-I-2014. Open points currently still under discussion are indicated but no conclusion is provided.}

1. Request of leaching studies

\textbf{a. Is a leaching test - regardless from its performance - necessary for product authorisation in any case to fulfil the formal requirements of the Biocides Regulation (EU) No. 528/2012, i.e. is a leaching test a core data? Is the decision on a tiered testing approach made during the 1st EU Leaching Workshop still valid (see also 1 b)?}

\textbf{Conclusions:}

No leaching test is required if no risk is identified for the active substance (AS) and substances of concern (SoC) for Time 1 and Time 2 by assuming:

- 50\% leaching during Time 1 and
- 100\% leaching during Time 2.

Assumptions of leaching lower than 100\% for Time 2 or 50\% for Time 1 need to be supported with a leaching test. The outcome of the current on-going discussions on SoC needs to be taken into account.

\textbf{b. Which leaching test guidelines for wood preservatives are currently available (laboratory testing, field testing)? Are there any recommendations for selecting a specific test guideline in a certain case?}

\textbf{Conclusions:}

Laboratory tests are acceptable, which can be used in particular for bridging and read across. However, semi field tests are preferred to assess the long-term leaching behaviour (a list of state of the art laboratory and semi field tests is provided in the Annex to this document).
2. Evaluation of leaching studies and data processing

a. How to perform leaching rate calculations? The procedure is not consistent throughout MS. Is a tiered approach feasible?

Conclusions:
In order to perform the leaching rate calculation the following stepwise approach can be used. In the proposed approach, the calculated leaching rate gets closer to the worst-case with higher steps. The decision whether to proceed from step 1 to step 2 and from step 2 to step 3 will depend, among others factors on the goodness of the fit and the amount of data available. However, the decision on the calculation should be done case by case, depending on the test results:

**Step 1:** Calculate leaching rate by fitting the experimental FLUX (Δt) = f(t) curve using a polynomial regression of second order.

**Step 2:** Calculate leaching rate based on a first order decay curve fitting the cumulative quantities leached [Qc(t)] versus time plot.

**Step 3:** Calculate mean leaching rate using the cumulative quantity leached during the first test period for Time 1 (after about 30 normalized days) and during the whole test for time 2.

**Step 4:** Calculate leaching rate using 100 % leaching for Time 2 and 50% leaching for Time 1.

b. Should an assessment factor be used if laboratory studies are evaluated?

Conclusions:
The following assessment factors (AF), to be used in the exposure assessment, on leaching rates derived from laboratory leaching tests with wood in vertical orientation have been agreed:

For scenarios with wood in vertical orientation (e.g. fence):
3 x 1 minute dipping regime: no AF to be applied
2 x 60 minutes dipping regime: no AF to be applied

For scenarios with wood in horizontal orientation (e.g. deck or bridge):
3 x 1 minute dipping regime: an AF of 5 is to be applied (case by case this factor can be lowered to a value of 2)
2 x 60 minutes dipping regime: no AF to be applied

For semi-field or field tests, in general no AF needs to be applied. However, if a study shows major deficiencies (e.g. in design) but is still considered acceptable, case by case an AF can be applied.

3. Top coat as risk mitigation measure (RMM) and request for studies

a. Should an assessment factor (AF) be applied on the leaching rates for topcoat for Time 1 and Time 2?

Conclusions:
The aim of the AF provided in the following is to cover the uncertainties in the stability of the applied topcoat over the time but not the variability of topcoats that can be applied.
For the assessment of Time 1, no AF needs to be applied on the leaching rate. For the assessment of Time 2, an AF of 2 needs to be applied if the service life is lower or equal to 5 years and an AF of 5 needs to be applied if the service life is longer than 5 years. AF are default values and can be lowered if information is available that justifies the lowering.

The proposed AF for studies with topcoat should be re-assessed when further results of leaching studies using topcoat for additional existing and new AS are available.

N.B.: If studies for the same product with and without topcoat are available, use the leaching rates from the study without top coat for Time 2, if the calculated leaching rates from the study with topcoat using the above AF exceed those from the study without topcoat.

Assume 100% leaching for Time 2 if the calculated leaching rates for Time 2 of the study with topcoat using the above AF exceed 100% leaching.

b. Top coat as RMM for amateur use: Is it practical to allow amateur users application of BP which are restricted by using a top coat or should BP be restricted to professional users when a top coat is necessary as RMM?

Conclusions:
Topcoat as risk mitigation measure should not be restricted to professional users, but is also applicable for amateur use.
The application rate of the topcoat (xy L/m²) should be indicated in the environmental exposure assessment and on the topcoat label.

4. How to deal with environmental risks identified during product authorisation?

a. Currently, no agreed approach for dealing with cumulative risks is available. Such cumulative risks are often identified for wood preservatives having more than one active substance or having active substances from other product types or having further substances of concern. How to deal with these risks?

Conclusions:
Cumulative risk assessment: For assessing the part “mixture toxicity” within the cumulative risk assessment, the PEC/PNEC values for AS and SoC in a product should be summed up (tier 1; see also TNsG on product authorisation, chapter 5).
Further tiers should follow the guidance currently under preparation for mixture toxicity. An aggregated environmental exposure assessment should follow the future guidance document which will be prepared in BIP 6.7 part E2.

b. Most of AS are included in Annex I of the BPD despite a risk that was identified for the environment at the initial assessment period (Time 1, 30 days). How to deal with that during product authorisation?

OPEN POINT currently under discussion (linked to the definition of protection goals for PT 8).
Conclusions:

The procedure stipulated in OECD ESD for wood preservatives (2003) in chapter 6.3 (in revised ESD integrated in chapter 4.3) is followed:

The initial concentration immediately after the last application (e.g. at the end of the application day = Time 0) is calculated and no degradation processes are considered (worst-case: refer also to paragraph 41 in the revised OECD ESD for PT 8).

This initial concentration is assessed and an environmental risk assessment is performed. If necessary, RMMs are defined (e.g. soil must be covered during application or no application near water bodies).

Application is assessed for brush and spray application, respectively, if both applications are requested by the applicant. For spray application two receiving soil compartments have to be considered in the environmental exposure and risk assessment (adjacent soil and distant soil).

In case of an identified risk following in-situ application (Time 0), covering the soil during the application is considered as an acceptable RMM. This should be stated in the CAR/PAR and on the label of the product.

5. Further open points

a. Should the new revised OECD ESD for PT 8 applied for product authorisation in general? And from when (timeline to be decided)?

Conclusions:

It was concluded that the revised OECD ESD for PT 8 can be used for the environmental exposure assessment for products in PT 8 starting from now.

N.B.: For the service life of the in-situ spray scenario, 5 years should be considered for Time 2 which is in line with the other in-situ treatment scenarios. For the service life for other application see report of the first leaching Workshop (Arona, 2005)

b. How should the environmental exposure assessment of temporary wood preservatives against blue stain fungi (anti-sapstain treatment) be performed as long as scenarios for this specific use pattern are lacking?

Conclusions:

The following tiered approach for assessing the exposure from anti-sapstain treatment for service life, i.e. after the life cycle stages “application” and “storage of treated wood” was agreed on:

**Tier 1**: Assess exposure from storage as worst case situation for service life (i.e. evaluate the respective storage scenario of the OECD ESD for PT 8, e.g. after spray application or dipping) → if risk is identified go to Tier 2

**Tier 2**: Qualitative approach → Assessment of the further life cycle of the treated wood: What are the subsequent uses of the wood treated with anti-sapstain products? Is an environmental exposure during these subsequent uses possible and how is the wood exposed to weathering? Is the wood containing anti-sapstain products further treated (e.g. by planning) prior to final use? What are the consequences of further treatment with
regard to environmental emissions? → if a distinct environmental exposure of anti-sapstain products cannot be excluded go to Tier 3

**Tier 3:** As appropriate → choose an applicable scenario from the OECD ESD for PT 8 representing the subsequent service life of the treated wood or develop a new scenario (e.g. as it was done with the palette scenario for AS sorbic acid)

It should be noted that anti-sapstain treatment is a minor use pattern, therefore no a large number of product applications are expected.
Annex

**Laboratory leaching tests:**

Use Class 3:
- CEN/TS 15119-1

Use Classes 4 and 5:
- OECD Guidelines for testing of chemicals, Test No. 313 “Estimation of Emissions from Preservative-Treated Wood to the Environment: Laboratory Method for Wooden Commodities that are not Covered and are in Contact with Fresh Water or Seawater” (2007) [http://www.oecd-ilibrary.org/docserver/download/9731301e.pdf?expires=1374231526&id=id&accname=guest&checksum=2440A5C8F3C76B9B3B0435363929774A](http://www.oecd-ilibrary.org/docserver/download/9731301e.pdf?expires=1374231526&id=id&accname=guest&checksum=2440A5C8F3C76B9B3B0435363929774A)
- CEN/TS 15119-2

**Field leaching tests:**