Working document on Risk Assessment of PPPs in the Central Zone – Ecotox
-
Implications for biocontrol and at zonal level

BPWG - Brussels, 10-11 June 2024

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Working document on Risk Assessment of PPPs in the Central Zone – Ecotox

IBMA acknowledged the final endorsement of the working document (WD) and its implementation from 1 January 2024.

<u>IBMA discussion at Central Zone Steering Committee meeting, 6 June 2024:</u>

- IBMA discussed the potential critical impact of the working document on biocontrol. IBMA is ready to share in detail its comments to explain the specificities of biocontrol, and why they do not fit on the working document.
- IBMA agreed to provide comment in the next two months on the document, providing input on the implication of the document for biocontrol in the Central Zone.

Case study – Natural Substance

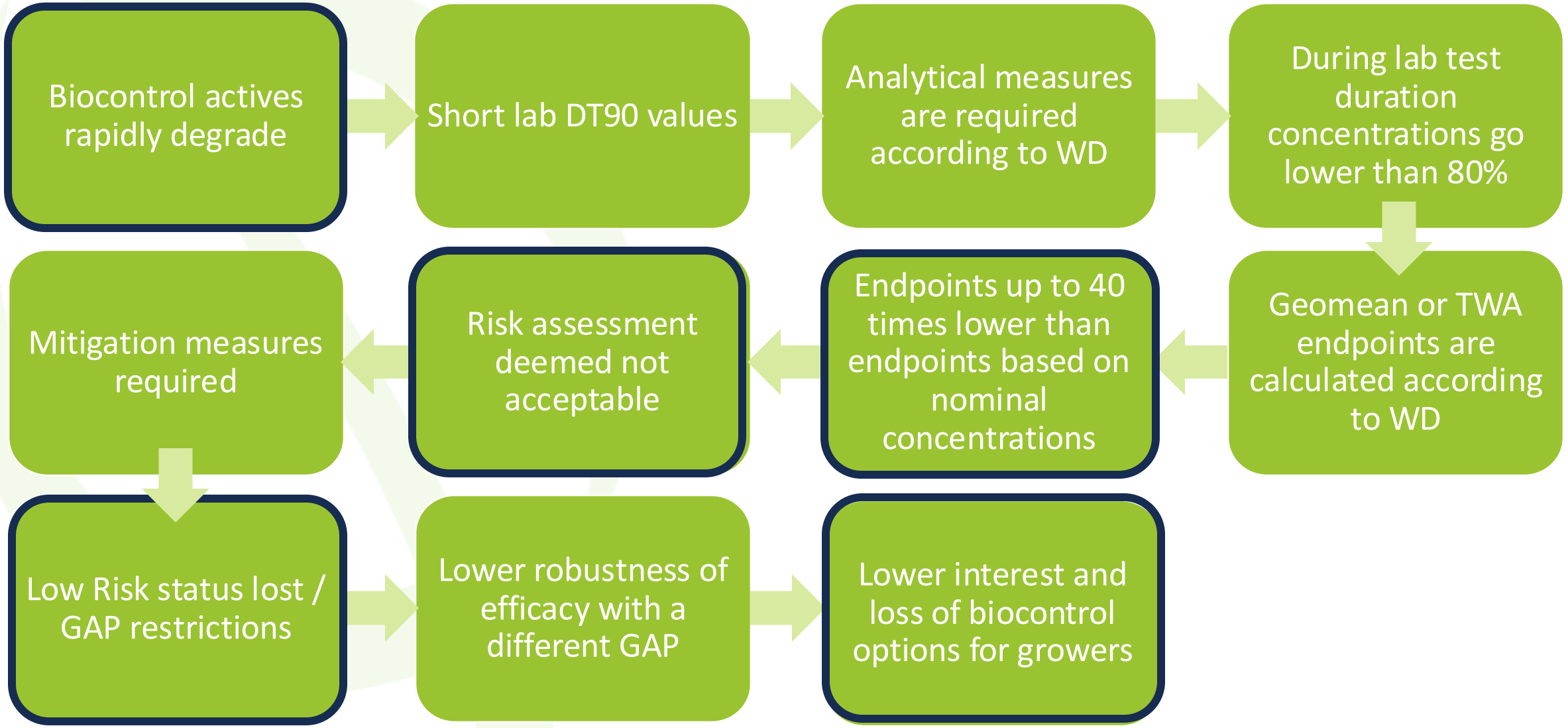
Technical and scientific aspects – Case study: Natural Substance

- Biocontrol will be penalised during evaluation: existing data requirements tailored for classical PPPs (conservative criteria).
- The proposed risk assessment scheme applied are designed for conventional chemical AS. They are not fit-for-purpose for naturally occurring substances.
- Lack on technical guidance on study conduct for these products when containing multicomponent substances or/and fast degrading/dissipating substances. No technical guidance on analytical determination during studies or dealing with substances with a background level in the testing mediums. No consideration on the exposure side of natural occurrence and presence in the NTO diet (natural products)
- Endpoints will be reduced to unrealistic values discriminating readily biodegradable substances → Example for Soil NTO studies (WD point 3.6.5*) in the following slide.
- If laboratory studies cannot be performed according to the current guidances (conservative approaches), authorities request high tier studies directly for risk assessments → increased costs, delays, uncertainties
- Disproportionality between costs and benefits (economical, ecological and sustainable sense)
- Lack on harmonised approaches to evaluate studies with analytical follow-up (evaluation relying on evaluator´s opinion)

** A detailed example can be presented (refer to background slides)*

Technical and scientific aspects - Case study: Natural Substance

Example for Soil NTO studies (Working Document point 3.6.5):



Facts:

If the tier1 (laboratory) DT90 of an active substance, however defined, is smaller than the study duration,
CZSC proposes to follow-up the exposure concentrations analytically.
In this case, if the exposure concentration(s) fall(s) below 80% of nominal, endpoints should be determined using the (geometric) mean or time-weighed-average .

Applicant‘s summary:

This opinion is unsuitable in several technical, scientifical and regulatory respects, i.e.:

Technical aspects:

- Lack on technical guidance on study conduct (test design).
- Lack on guidance to adapt study designs for difficult substances (e.g., fast degrading/ dissipating).
- No guidance on number, frequence and replicated analytical determinations during the study.
- No guidance how to deal with multicomponent substances.
- Background concentrations in artificial substrate especially for natural products.

Scientific and regulatory aspects:

- Lack on harmonized approaches to fulfil a uniform evaluation standard
- Discrimination against readily biodegradable/ natural substances
- Enhancing difficulties to analyse multicomponent-active substances
- Artificially worsening of risk assessment (conservative anyway), with need of higher tier studies even for harmless substances in case concentrations cannot be maintained throughout the test
- Disproportionality between costs and benefits (economical, ecological and sustainable sense)

Details on Technical Aspects:

General:
A clear guidance needs to be provided how to design a study considering the CZ‘s requirements.
No harmonized approaches available. Any study can potentially be biased based on the opinion of the evaluator.

Test design for continuous or semi-continuous renewal of substrate containing the analyte of interest:

Continuous renewal („flow-through“)

- Technically not feasible for soil

Semi-continuous renewal:

- Not possible without disturbance of animals/ loss of animals, artificial stress
- Non-feasibility to distribute the spiked analyte homogeneously into the soil after (multiple) additions

Static:

- Only possibility, however, no chance to include freshly contaminated soil
- Additional application (e.g., every two days) may cause artificial effects which are not present in common cases
- If a carrier (organic) solvent is used, effects even in the solvent-control may occur, reducing statistical power and endanger matching validity criteria as set out in the OECD Guidance Documents.

How can excessive volatilization be prevented when testing volatile substances?

Details on Analytical Aspects

- It remains unclear how many samples have to be taken to adequately assess fate of an analyte throughout the study
  - a.) study start and study end in all test item concentrations
  - b.) study start, 1 intermediate, study end in all test item concentration
  - c.) study start, 2 (3, 4) intermediates, study end in all test item concentration
  - c.) […]

- It remains unclear how many test concentrations needs to be analytically assessed
  - a.) lowest and highest concentration (as per EFSA Guidance), extrapolation to all other test rates
  - b.) all test item concentrations
  - c.) lowest and highest concentration, including concentrations around the expected NOEC/EC10

- It remains unclear how many replicated analyses should take place per sampling to follow up the fate.
- Evaluation of DT50 (or fTWA) remains unclear (according to FOCUS Guidance)?
- TWA is the only possibility to calculate mean exposure levels if samplings are not spaced equally.
  - TWA is highly depending on the distance between samplings and recovery to be found > biased
- It remains unclear how to deal with multicomponent-substances (e.g. plant extracts) where components show different behaviour in soil? What about the lead-substance concept?
- Especially for natural substances, which are found in constituents of artificial soils… background contamination can play a critical role to match analytical validity criteria

Without special guidance on study design, study conduct, […] all studies considering analytical follow-up are biased and reliability lies in the hand of the evaluator in absence of a harmonized evaluation standard.

Scientific and regulatory aspects:

Lack on harmonized approaches to fulfil a uniform evaluation standard

- Evaluation perhaps highly biased, depending on evaluator‘s opinion.
- Absence of evidence of maintained concentrations will lead to invalidation of a study, which was assigned valid before 01 January 2024 in the CZ, as matching all validity criteria in force on conduct/ submission

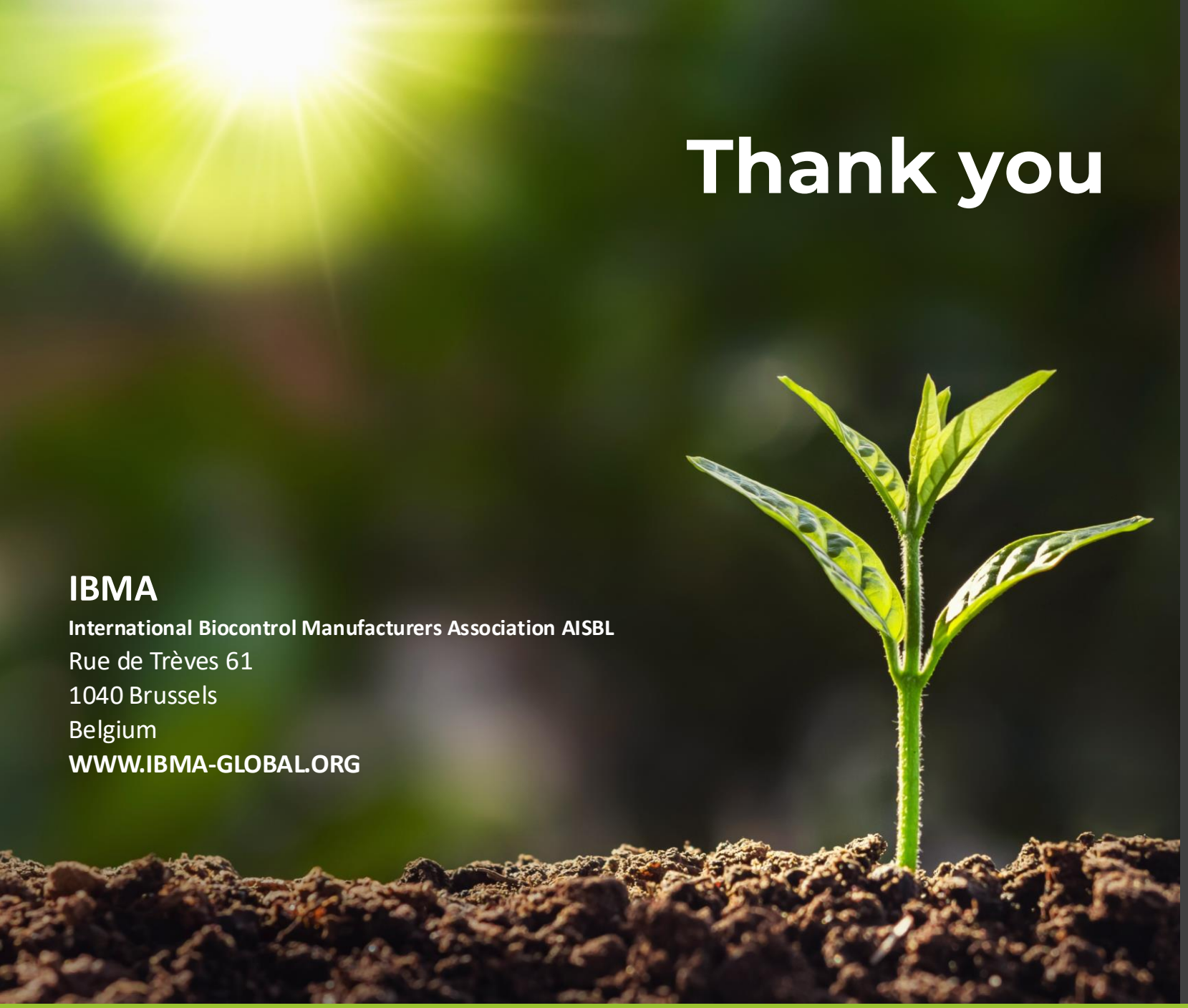
Discrimination against readily biodegradable substances with high efficacy, designed (or due its nature) to degrade/ dissipate quickly in non-target compartments (do not accumulate) would be discriminated due to their actual favourable properties.

Meaning: Artificial lowering NOEC and/or EC10 in mortality/ reproductive outcome

- Enhancing difficulties to analyse multicomponent-active substances (e.g. plant extracts)
- Artificially worsening of risk assessment (conservative anyway), with need of higher tier studies even for harmless substances in case concentrations cannot be maintained throughout the test)
- Disproportionality between costs and benefits (economical and sustainable sensibility)
- Absence of guidance how to achieve constant exposure concentrations (see also technical aspects)

Considering sustainability, economic and ecological aspects, the absence of guidance and the absence of a harmonized approach for evaluation, the opinion by CZHW does not contribute to any reliable and traceable evaluation of the risk to soil-dwelling organisms at all.

Thank you



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