

Central Zone requirement for analytical measurements in soil organism ecotoxicology studies: What is the impact?

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Introduction

Under Regulation (EC) No 1107/2009, in addition to the approval and renewal of pesticide active substances at an EU level, Plant Protection Products (PPPs) containing these substances must be authorised in EU Member States before they can be sold and used. These authorisations are often considered via a ‘Zonal’ evaluation process, and each Zone may introduce additional or deviating approaches to standard EU-wide data requirements or risk assessment methods.

In August 2023 the Central Zone published an update to their ‘Working document on Risk Assessment of Plant Protection Products in the Central Zone’¹. A significant addition to this Working document is the requirement for ecotoxicology studies with soil macro-organisms to include analytical verification of exposure throughout a study’s duration, should the tested substance be considered as “unstable” – defined as having a laboratory 90% degradation time (DT₉₀) in soil of less than the duration of the ecotoxicology study. This represents a requirement not historically conducted for such studies and may therefore create a significant need to repeat studies to support future registration of PPPs in Central Zone Member States.

The aim of this presented work is to establish the potential impact of this new Central Zone requirement in terms of what proportion of pesticide active substances may trigger the need for analytical verification in one or more of the soil macro-organism studies which are, in most cases, a standard regulatory data requirement for PPPs.

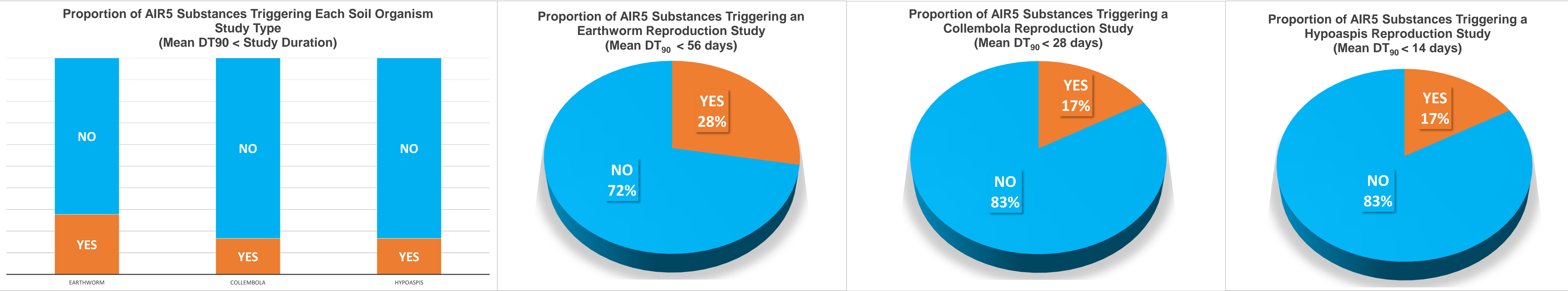
Methodology

A representative set of pesticide active substances was identified using the so-called ‘AIR5’² list for the renewal of approval of these substances (n = 66) in the EU. This provided a suitable sample size from which to identify trends, whilst also including only substances for which existing DT₉₀ values are reported in publicly available documents – EFSA Conclusion Lists of Endpoints (LoEPs). From the AIR5 list, substances were excluded from analysis under the following justified criteria:

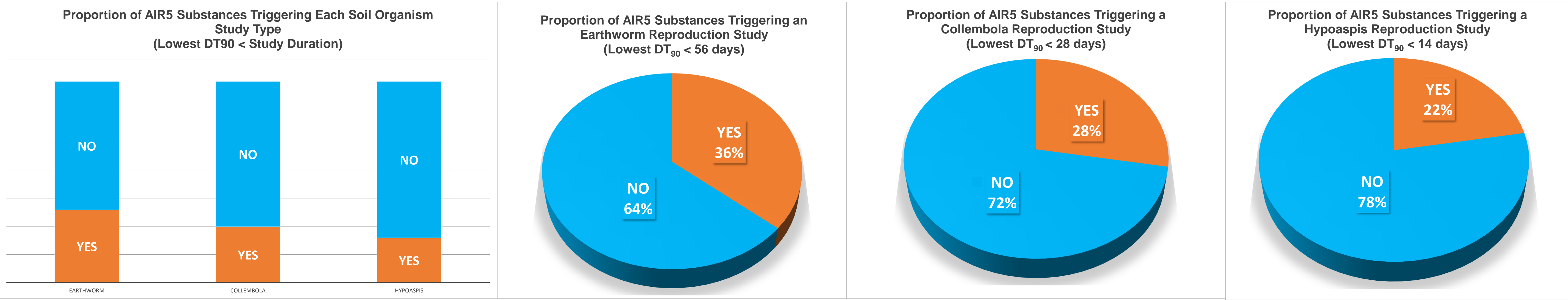
- No renewal of approval notification was submitted, as in such cases there would be no possibility to (re)register plant protection products containing the active substance and so no further data would need to be generated to meet the updated Central Zone requirement for soil organism studies
- No existing laboratory soil DT₉₀ data were available for the substance in existing EFSA Conclusion LoEPs, either because of the nature of the substance (e.g. biopesticides ubiquitous to the environment), the representative use pattern (e.g. precluding exposure of the soil environment), or due to an identified data gap. Without existing soil DT₉₀ data, analysis against the Central Zone requirement is not possible

After application of these criteria there were 36 active substances with renewal notified and laboratory soil DT₉₀ values available. These substances were considered in the analysis as to whether they would be considered as ‘unstable’ – having a soil DT₉₀ less than the in-life duration of the three relevant soil macro-organism ecotoxicology tests according to the current OECD test guideline study designs^{3,4,5}. Due to a current lack of clarity within the Central Zone Working document, analysis was performed considering both a geometric mean laboratory DT₉₀ value and a worst-case (lowest) single soil laboratory DT₉₀ value.

Results: Geometric mean laboratory soil DT₉₀



Results: Lowest single soil laboratory soil DT₉₀



Conclusions and discussion

If considering the geometric mean soil DT₉₀ value from all laboratory-tested soil types, it is indicated that 28% of investigated active substances (10/36 substances) would be defined as sufficiently ‘unstable’ to require at least one soil organism study to include analytical verification of substance concentrations through the study duration. 17% (6/36) would be sufficiently unstable to trigger this requirement for all three soil macro-organism study types.

If considering the lowest single soil laboratory DT₉₀ values, the proportions are increased to 36% (13/36) and 22% (8/36) of substances requiring at least one, and all three studies, respectively.

Given that a single active substance may be included in many different Plant Protection Products (PPPs) registered in a single EU Central Zone Member State, and each PPP will typically be required to provide soil macro-organism studies, this requirement of the Central Zone nonetheless represents a significant total undertaking of new studies, with possible implications on the defined toxicity endpoints used for risk characterisation of a PPP.

References

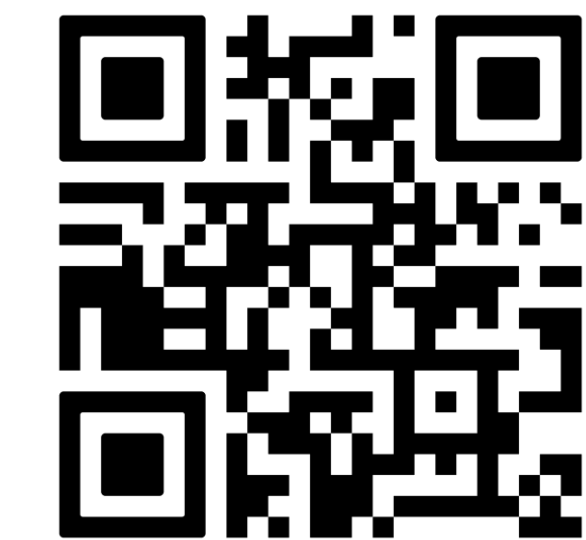
1 Working document on Risk Assessment of Plant Protection Products in the Central Zone – Ecotoxicology; V 2.0 – August 2023

2 The 5th Renewal Programme – Applications for Renewal of Approval Submitted Under Article 14 of Regulation (EU) No 1107/2009 and in Accordance with Regulation (EU) No 844/2012 or Regulation (EU) No 2020/1740; SANTE-2019-13022–rev.13. October 2023

3 OECD (2016), *Test No. 222: Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris, <https://doi.org/10.1787/9789264264496-en>

4 OECD (2016), *Test No. 226: Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil*, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris, <https://doi.org/10.1787/9789264264557-en>

5 OECD (2016), *Test No. 232: Collembolan Reproduction Test in Soil*, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris, <https://doi.org/10.1787/9789264264601-en>



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