# # Section 0: Overview

This Supplementary Information (SI) file provides additional details on our methodology, along with step-by-step implementation in R. Source data, including extracted datasets and R code scripts are available at <https://github.com/aelsai/Dietary-Pesticide-Exposure-in-Ethiopia.git>.

Overall, this file is structured into two main sections. The first section offers additional details and justifications for key methodological components (e.g., handling of non-detects and missing data imputation, multilevel meta-analysis, and how these methods align with our study objectives). The second section covers R implementation and preliminary results not included in the main text. Accordingly, this file is organized into five main outlines: SI Method (background and literature search), dataset preparation and exploration, missing data handling (non-detects, standard deviation, sample size), multilevel meta-analysis, and probabilistic risk assessment.

# Section 1: Introduction

## Literature Search and Dataset Preparation

The studies included in this analysis were part of a much more comprehensive literature database compiled to support a national-scale, multi-pathway, multi-pesticide exposure and cumulative risk assessment in Ethiopia (see the Supplementary file for the unregistered systematic review protocol).

Briefly, a systematic search was conducted across 13 international and local databases and repositories using validated search terms to identify studies reporting pesticide levels in multiple environmental media (e.g., air, water, soil, food) in Ethiopia. Search terms were categorized into pesticide-related terms (e.g., agrochemical, insecticide, fungicide, herbicide), occurrence- or exposure-related terms (e.g., pollution, exposure, monitoring, residue, contamination, air, soil, water, food), and geographic location (Ethiopia). As per the suggestion of Lagisz *et al.* (2025), the evaluation of these terms using a Scopus search against 25 benchmark articles retrieved a priori revealed 100% sensitivity. The final search retrieved a total of 1,539 records, from which 45 studies specifically addressing pesticide residues in food were included here. The overall process is summarized using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram, as shown in SI Figure 1.

In addition to the main eligibility criteria presented in our protocol, we assessed whether primary, non-duplicate food residue data were presented. As such, 5 studies were removed because sufficient quantitative data were not presented. From the remaining 40 studies, we extracted study characteristics (first author, title, DOI, publication year), sample characteristics (food source type, analytical instrument, sample size, sample year), and pesticide data (name, summary statistics). We also extracted and summarized all screened pesticides, regardless of detection status, along with reported limits of detection and quantification (LOD/LOQ). Whenever available, raw residue concentrations were prioritized (i.e., unique sample/location measurements) over summary statistics (see Source Data).

## Addressing Data Challenges in Pesticide Residue Meta-Analysis

In data-limited Global South contexts like Ethiopia, where pesticide use is rampant but monitoring is weak (Asefa et al., 2024; Mengistu et al., 2025), synthesizing sparse residue data via meta-analysis is crucial for quantifying dietary risks. However, conventional methods struggle with hierarchical clustering (e.g., dependencies across studies, regions, or food groups), left-censoring (non-detects below detection limits), missing values, variabilities (e.g., in consumption or residues), and uncertainties (e.g., measurement errors) (Helsel, 2006; Nakagawa & Freckleton, 2008; US EPA, 2014). Our dataset, compiled from 40 studies with 18,298 samples across 87 pesticides and 18 food groups, exemplifies these issues: ~41% of effect sizes were NDs, with 64% missing standard deviations (SDs), 12.5% missing sample sizes (SS), and 6.5% missing detection limits (DLs). To overcome these, our novel MMA-MC-PRA framework incorporates advanced imputation techniques, enabling robust national-scale residue estimates and probabilistic risk distributions that test hypotheses on residue variations, moderators (e.g., food origin, location), and population risks.

Pesticide residue datasets in under-monitored, data-limited settings like Ethiopia are often plagued by non-detects (NDs)—values below the analytical detection limit—and missing data in key statistical parameters such as standard deviations (SDs), sample sizes (SS), and detection limits (DLs). In our compiled database of 18,298 samples from 40 studies, we observed a high proportion of left-censored data (41% NDs), with 64% missing SDs, 12.5% missing SS, and 6.5% missing DLs. These challenges, if unaddressed, can severely bias meta-analytical effect sizes and risk estimates.

## Handling Left-Censoring (Non-Detects)

Left-censoring is prevalent in environmental datasets, where NDs (below DLs) may represent true absences or undetectable positives, potentially inflating zeros (zero-inflation) (Helsel, 2012). In our case, with 41% NDs, naïve substitutions (e.g., zero or ½ DL) recommended by regulators (EFSA, 2010; US EPA, 2000) introduce bias, underestimating means and variances, especially in heterogeneous data with high censoring (>30%) (Helsel, 2006). This distorts risk assessments in data-sparse regions like Ethiopia, where inconsistencies in detection (e.g., 29-100% frequencies) are common (Tang et al., 2025; Ingenbleek et al., 2020). We evaluated advanced methods—zero-inflated lognormal (ZILN), maximum likelihood estimation (MLE), regression on order statistics (ROS), and KM imputation—and selected KM for its non-parametric nature, which avoids distribution assumptions and preserves the empirical cumulative distribution of detected values (Antweiler & Taylor, 2008; Shoari & Dubé, 2018). KM outperformed others by preventing underestimation of central tendencies (SI Figure 5), making it ideal for our MMA models handling hierarchies and MC-PRA propagating uncertainties, thus ensuring accurate, replicable risk estimates without excluding valuable ND data.

Conventional substitution methods (e.g., replacing NDs with 0, ½ DL, or DL), though common in regulatory practice (EFSA, 2010; US EPA, 2000), are known to introduce significant bias when censoring exceeds 30%, as they systematically underestimate means and variances, particularly in heterogeneous data (Helsel, 2006; Shoari & Dubé, 2018). Given the potential for zero-inflation and the absence of explicit detection rates in our studies, distinguishing true zeros from undetectable positives was not feasible—necessitating a method that avoids distributional assumptions and preserves empirical variability.

Non-detects (NDs), or left-censored measurements below the detection limit (DL), are prevalent in environmental datasets. This censoring arises because analytical methods cannot distinguish concentrations between zero and the DL, potentially inflating apparent zeros (zero-inflation) if NDs represent true absences rather than undetectable positives (Helsel, 2012). In our dataset, zero-inflation is plausible due to the high ND proportion, but we lack explicit detection rates to confirm this, complicating differentiation from true zeros (WHO/FAO, 2009). Excluding NDs or using naïve substitutions (e.g., zero, DL, or ½ DL) is common in regulatory guidance (EFSA, 2010; US EPA, 2000) but introduces significant bias—underestimating means and variances—especially with >30% censoring (Helsel, 2006). Such methods fail to account for data heterogeneity (e.g., by food group, origin, or lab), leading to inaccurate risk estimates (EFSA, 2010). Advanced methods are preferred for robust imputation, preserving the original distribution and reducing bias in meta-analyses (Shoari and Dubé, 2018).

We evaluated four advanced techniques, selected based on their suitability for left-censored environmental data with potential zero-inflation:

* **Zero-Inflated Lognormal (ZILN) Model**: Assumes a mixture of true zeros and lognormally distributed positives (Sang et al., 2024). For NDs, we heuristically assigned 50% as true zeros (randomly) and imputed the rest via truncated lognormal draws from parameters fitted to detected values (Canales et al., 2018; Gómez-Carracedo et al., 2014). This addresses zero-inflation but risks bias if true zeros are overestimated, as we lack evidence that residues are absent (WHO/FAO, 2009).
* **Maximum Likelihood Estimation (MLE)**: Fits a censored lognormal distribution to all data, then imputes NDs by random draws from the truncated distribution below each DL, reintroducing variability (Lee et al., 2024). Parametric and efficient for moderate censoring but sensitive to distribution assumptions.
* **Regression on Order Statistics (ROS)**: Semi-parametric; ranks detected values and regresses on normal quantiles under lognormal assumption to estimate NDs (Helsel, 2012). Robust for heterogeneous data but may underestimate in high censoring.
* **Kaplan-Meier (KM) Imputation**: Non-parametric; uses the empirical cumulative distribution function (survival function) from detected and censored values to impute NDs by drawing from the distribution below each DL (Antweiler and Taylor, 2008). Ideal for unknown distributions and high censoring, as it avoids parametric assumptions and handles heterogeneity well.

Comparative performance (SI Figure 5) showed KM provided the most robust estimates, closely preserving the original detected distribution's central tendencies and variability. Other methods (ZILN, MLE, ROS) underestimated means by skewing imputed NDs toward lower values, likely due to over-penalizing zero-inflation or parametric mismatches. KM was selected to minimize bias in downstream meta-analyses, consistent with recommendations for environmental datasets with >40% censoring (Shoari and Dubé, 2018; Helsel, 2012). Missing DLs (6.5% of data) were substituted with the median available DL (1 µg/kg) to enable imputation, as this reflects typical analytical sensitivity without introducing extremes (EFSA, 2010).

## Handling Missing Data with MICE

Missing SDs and SS reduce power and bias estimates in meta-analyses, particularly for variance-dependent models (Parker et al., 2016; Gurevitch et al., 2018). Complete-case deletion exacerbates this in our large, clustered dataset, assuming missingness at random (MAR) tied to observed means (Nakagawa & Freckleton, 2008). We used MICE with predictive mean matching (m=100 imputations) for its flexibility in imputing mixed variables iteratively, outperforming single imputation and yielding less biased grand means (van Buuren & Groothuis-Oudshoorn, 2011; Azur et al., 2011; Pridham et al., 2022). Validated via convergence diagnostics (SI Figure 6), we selected one optimal dataset (lowest absolute percentage error) over Rubin's pooling due to computational constraints in our complex MMA-MC-PRA (e.g., 251 stratified models, 10,000 simulations). This choice balances feasibility with accuracy, supporting hypothesis testing on moderators and equitable, probabilistic risk assessments for Global South policy.

***Non-Detects (left-censorship)***

The presence of non-detects, i.e., measurements below the analytical methods detection limit (also known as censored data) are common in environmental monitoring dataset, and this is also true for our residue dataset (41%). Another challenge is the difficulty to discern NDs from true zeros, i.e., whether NDs truly represent absence of pesticide residues or inability to measure the already presenting concentration above zero. The probability of zero expansion or zero-inflation in our dataset is high given the high proportion of NDs, however, properly handling the issue is difficult since we don't have explicit detection rates or information to rigorously estimate the detection rate. When a laboratory test did not detect a chemical, the chemical concentration in the sample could have any value between zero and the LOD.

In handling left-censored data, regulatory bodies recommend a traditional simple substitution methods for NDs (e.g., replacing with 1/2 DL or zero). However, studies have showed that the method is known to introduce significant bias in datasets with greater than 30% missing values. In this regard, most regulatory bodies suggest replacing NDs with zero, the detection limit (DL), or half the DL instead simply removing them (EFSA, 2010; US EPA, 2000a). However, this has been a center of debate for a long time (Helsel, 2006), and it has now been shown that such simple substitution introduce a significant, leading to inaccurate risk estimations especially when the proportion of ND is high. Results showed that the number of samples had a relatively limited impact on the accuracy and precision of estimates, but the degree of censoring had a large effect. When analysing a complex set of data, it was also shown that it is essential to identify possible sources of heterogeneity in a dataset, such as country of sample collection/origin, food group, laboratory, etc. Statistical analyses should either be conducted separately from these factors, or, to explicitly account for this heterogeneity, fixed/random effect ML models could be used (EFSA, 2010).

Given the substantial proportion of left-censored data (NDs), several advanced imputation methods were considered and compared: Zero-Inflated Lognormal (ZILN), Maximum Likelihood Estimation (MLE) with random draws, Regression on Order Statistics (ROS), and Kaplan–Meier (KM) imputation (Canales *et al.*, 2018; Gómez-Carracedo *et al.*, 2014; Lee *et al.*, 2024). In brief, ZILN method account for the possibility of true zero concentrations (complete absence) alongside concentrations below the DL. For NDs, a heuristic approach was used where 50% were randomly assigned as "true zeros" and the remaining were imputed through truncated lognormal random draws, based on the estimated parameters from the censored lognormal fit. We introduced ZILN, a method which assumes a mix of true zeros and lognormal values (Sang *et al.*, 2024), depending on the suspected likelihood of zero-expansion in our data (SI Figure 3), but it is important to note that unless there is reason to assume that a food does not contain a residue (which there is none in our case), it should be assumed that NDs may contain the actual pesticide (WHO/FAO, 2009). MLE method involved fitting a censored lognormal distribution to the data and then imputing NDs by drawing random values from the fitted distribution, truncated at the respective detection limits, reintroducing variability into the imputed non-detects. ROS method provides a semi-parametric fit under a lognormal assumption and is robust even with moderate censoring, estimating concentrations for NDs based on the observed values and their ranks. KM method is a non-parametric method that does not assume any underlying distribution and it uses the empirical cumulative distribution function derived from both detected and non-detected values to impute missing concentrations, where NDs were imputed by drawing from the estimated survival function below the respective DLs. A comparative analysis revealed that the KM imputation most closely preserved the original distribution of the detected concentrations, thus selected for subsequent analyses, while others underestimated central values by pulling imputed NDs towards lower concentrations.

## Handling Missing Data

It has been widely noted that meta-analyses in many disciplines commonly encounter missing and incompletely reported data in original publications, especially for variance measures (Parker *et al.*, 2016)(Gurevitch *et al.*, 2018). The most common approach to dealing with missing data is to delete cases containing missing observations. However, this approach reduces statistical power and increases estimation bias (Nakagawa and Freckleton, 2008). Various previous studies have suggested that multiple imputations can yield grand mean estimates that are less biased than those obtained from complete-case analyses (Azur *et al.*, 2011; Ian *et al.*, 2011; Kambach *et al.*, 2020). We derived missing residue means from geometric means (n = 8) and medians (n = 18), and SDs using modified Hozo method (n = 10) (SI Section 3).

For the remaining SD and sample size, we used multiple imputation using multivariate imputation by chained equations (MICE) (Buuren and Groothuis-Oudshoorn, 2011). MICE is popular due to its flexibility, and it has been shown to outperform classical data imputation methods (Pridham *et al.*, 2022). Our imputation model was run based on the assumption missingness is at random and highly depend on observed mean using predictive mean matching over 50 imputations and 20 iterations (SI Section 3.5). Convergence diagnostics confirmed the plausibility and robustness of imputed values (SI Figure 6). The final complete dataset was selected based on minimal absolute percentage error from observed values.

Typically Rubin’s rules are applied to combine the results from the multiple imputed datasets after analysis, however, given our large dataset, complexity of implemented MMA models, and computation limitations, we selected only one complete dataset with minimal absolute percentage error from observed values (SI Section 3.5).

## Multilevel Meta-analysis

Multilevel meta-analysis offers a powerful statistical technique for synthesizing such complex datasets, along with a better understanding of sources of variability, leading to more reliable and informative conclusions for environmental management and policy (Nakagawa *et al.*, 2023). Detailed background and practical applications of MMA are provided elsewhere (Assink and Wibbelink, 2016; Harrer *et al.*, 2021; Nakagawa *et al.*, 2023; Van den Noortgate *et al.*, 2013).

## Probabilistic Risk assessment

Traditional deterministic risk assessments often use single “point estimates” (e.g., average or worst-case values) and this could lead to an overly conservative, and potentially unrealistic, overall risk estimate. In contrast, PRA combined with Monte Carlo simulations is recommended in regulatory settings because it provides a scientifically robust, comprehensive and realistic risk estimates, generating range of outcomes that reflects true population variability and uncertainty. More details on PRA can be here (Flinders *et al.*, 2025; Khalid, 2023; US EPA, 2000b, 2014). Traditional deterministic risk assessments often rely on single-point estimates for exposure parameters, which inherently fail to capture the full extent of variability and uncertainty present within a population. In contrast, probabilistic models, such as those employing Monte Carlo simulations coupled with Latin Hypercube Sampling (LHS), provide a more realistic and comprehensive estimation of chemical intake and associated health risks. This approach explicitly accounts for the natural variations in food consumption patterns, pesticide residue concentrations, and individual body weights across a diverse population.

In dietary intake assessments, the concentration data used will depend on the nature of the specific intake assessment. The concentration of an ingredient or chemical constituent in food can be obtained from

**Pesticide Registration and Control Regulation, *Legal basis for assessing consumer exposure through food*.** *Schedule II – Article 1.1.4***.** *(The Ministry ... shall evaluate ...) the exposure of consumers and animals through their diet following the intended uses and under locally relevant conditions of use, and:*

*a. The pesticide shall not be registered if its intended use will lead to residue levels at harvest, slaughter or after storage or processing, as appropriate, which exceed the nationally established maximum residue limit (MRL) or a provisional MRL. b. In the absence of a nationally established MRL or provisional MRL, Codex Alimentarius MRLs shall apply, if established for the commodity and pesticide under review. c. Taking into account all registered uses of the pesticide, the intended use shall not be authorized if the estimated total dietary exposure exceeds the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD).*

As Ethiopia is a member of CODEX Alimentarius, the CODEX MRLs (CXLs) are used as a basis for risk assessment. Where CODEX MRLs do not cover the use of a plant protection product in Ethiopia, no national MRL will be set as appropriate national Ethiopian legislation is currently not in place. For the chronic consumer risk assessment the WHO-GEMS IESTI model version revision 14 is used using the GEMS food consumer cluster diets from August 2006. The model has been slightly adapted to Ethiopian circumstances by marking irrelevant commodities in red and by adding teff as a commodity. The model ***IEDI\_calculation\_Ethiopia.xltm*** enables the calculation of the International Estimated Daily Intake (IEDI) based on estimated Supervised Trial Median Residue (STMR, STMR-P) or the Maximum Residue Level (MRL) for relevant commodities. It summarizes the total intake in mg/person/day and calculates the total intake as percentage of the Acceptable Daily Intake (ADI) for 13 world food clusters. Food cluster A is considered appropriate for Ethiopia. A scientifi c evaluation system for the registration of pesticides in Ethiopia

# Novelty and Impact

The novelty of our methodological framework is justified by: (i) comparing four methods and selecting the best-performing approach to minimize bias in left-censored data (i.e., Zero-Inflated Lognormal, MLE, Regression on Order Statistics, KM); (ii) incorporating RVE into MMA models to quantify heterogeneity while also adjusting for small-sample biases; (iii) utilizing 20,932 unique dietary records from 7,527 households to derive nationally representative food consumption rates; and (iv) being the first study of its kind in Africa, and among the few in the Global South, to provide comprehensive and representative dietary pesticide risk estimates.

First, our analytical methodological innovations are novel. We present one of the first known implementations in a low-income country setting of a full pipeline combining three-level multilevel meta-analysis with population-wide probabilistic risk assessment via Monte Carlo–based Latin Hypercube Sampling. This allows us to accurately capture hierarchical variance (sampling, within-study, and between-study) and generate distributions of dietary exposure and health risk—not mere point estimates. Furthermore, we rigorously compared and adopted a Kaplan–Meier nonparametric estimator for handling heavily left-censored residue data; this is rare in environmental meta-analyses and outperforms standard approaches (e.g., ZILN, MLE, ROS) in preserving distributional integrity. Simultaneously, we used MICE with predictive mean matching to impute missing sample sizes and variances, minimizing bias and maximizing data retention.

Second, the study addresses a long-standing geographic data void—Ethiopia and much of sub-Saharan Africa lack national dietary pesticide risk assessments. We synthesized over 2,200 unique residue measurements from 40 local studies covering 18 food subgroups, filling a critical information gap. Our analysis revealed persistent exposure to legacy organochlorine pesticides (e.g., DDT, endosulfan), especially in high-risk foods like khat and honey—highlighting ongoing public health exposures despite global bans.

Third, the impact pathways are substantial. By identifying priority pesticide–food combinations and quantifying non-cancer (HQ) and cancer risk burdens, we provide actionable evidence to inform Ethiopian regulators in policymaking—such as revising MRLs, targeting monitoring, or phasing out high-risk chemicals. Moreover, our methodology offers a replicable template for LMICs and other data-scarce regions, showcasing how advanced statistical frameworks (e.g., KM, MICE, MMA, PRA) can enable robust exposure analysis even with fragmented datasets. This has implications for global food safety frameworks and the evolution of risk analysis in environmental health.

In summary, our integration of cutting-edge missing data handling, hierarchical meta-analysis, and probabilistic risk modeling within a poorly-studied LMIC context contributes uniquely to exposure science. It advances methodological rigor, fills continental data gaps, and delivers a policy-ready assessment with wider applicability to other global-South settings—thereby amplifying both the novelty and impact of dietary pesticide exposure research.

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