

## TERMS OF REFERENCE

### National institutional consultancy to Conducting a Regulatory Review on Lead exposure and health impacts in Viet Nam.

#### Summary

Title	Conducting a Regulatory Review on Lead exposure and health impacts in Viet Nam.
Objective	To review, assess and provide recommendations for regulations related to lead in order to reduce lead exposure, protect public health, especially maternal and child health, and align with international best practices and standards.
Location	Ha Noi, Viet Nam
Budget	All-costs inclusive
Duration	03 months
Start Date	Tentatively starting from end July 2025

#### Background

In Viet Nam, it is estimated that more than 3.2 million children aged 0-19 have blood lead levels at or above 5 µg/dL, the level that requires interventions. Lead could come from various sources, including contaminated groundwater, improper recycling of lead-acid batteries and waste disposal, pesticides, toys and other children's products, paints, cosmetics, traditional medicines, and also food and food contact materials. Pregnant women and children are identified as particularly vulnerable groups<sup>1</sup>. A survey conducted by MOH (National Institute of Occupational and Environmental Health), in a commune near a lead-zinc mine, found that average blood lead levels for children were  $15.42 \pm 6.45$  µg/dL (95% CI: 14.50 -16.33 µg/dL). The percentage of children with lead levels >10 µg/dL (value considered to be lead poisoning for children according to the Ministry of Health of Vietnam) was 79.49% of the total number of children<sup>2</sup>.

It is estimated that annually about 49,131 kilograms of mercury is emitted in Viet Nam annually and 59% of this is emitted in the atmosphere. Children's health is at greatest risk as a result of this high levels of emissions into the environment<sup>3</sup>. The mean concentrations of heavy metals (Chromium, Cadmium, Lead, and Arsenic) detected in water, seafood, and vegetable samples in the northern coastal area of Vietnam exceeded the national permitted standards and World Health Organization (WHO) recommendation values by at least 2-fold, 2.5-fold, and 5-fold for surface water, vegetables, and well water, respectively. The concentrations of all 4 heavy metals detected in seafood samples were higher than the standards<sup>4</sup>. Other reports revealed that concentrations of heavy metals such as Arsenic, Iron, and Manganese in

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<sup>1</sup> Pure Earth and UNICEF report – The Toxic Truth: Children's Exposure To Lead Pollution Undermines A Generation Of Future Potential

<sup>2</sup> <https://www.hindawi.com/journals/bmri/2018/5156812/>

<sup>3</sup> Minamata Convention Initial Assessment in Vietnam (Vietnam MIA Project), FINAL REPORT, Hanoi, June 2017

<sup>4</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC7223865/>

ground water from the Red River and Mekong River Deltas exceed WHO drinking water guideline levels<sup>5</sup>. Although the Government of Viet Nam has made significant efforts and issued various standards to control lead exposure in order to limit its health impacts on the general population especially mothers and children, but there are still challenges in practice. These standards include for example: **TCVN 6238-3:2011 (ISO 8124-3:2010)**, which sets limits on the migration of certain toxic elements in children's toys, including lead, mercury, cadmium, chromium, arsenic, and antimony; **QCVN 8-2:2011/BYT**, which regulates permissible levels of heavy metal contamination in food, including lead, cadmium, mercury, and arsenic. For instance, the allowable lead content is: Powdered and liquid milk: not exceeding 0.02 mg/kg, White rice: not exceeding 0.4 mg/kg, Tea, coffee, cocoa, and cocoa products: not exceeding 1.0 mg/kg, Table salt: not exceeding 0.5 mg/kg; **QCVN 08:2020/BCT**, which limits the lead content in paints to a maximum of 600 ppm (0.06%) for all paints manufactured, imported, and circulated in Viet Nam. Despite these efforts, there remain significant limitations in terms of legal documents, as well as practical guidance for the implementation and enforcement of these regulations. To systematize existing standards and regulations, align with international standards, and provide appropriate policy recommendations, UNICEF seeks to engage a **national consulting institution/agency** to support the implementation of a "Regulatory Review on Lead exposure and health impacts in Viet Nam." The selected consultancy will work directly with UNICEF and relevant government agencies such as the Ministry of Health and other ministries to ensure the effective implementation of this initiative.

## Objectives

1. Evaluate existing legal and regulatory frameworks related to lead exposure and control in Viet Nam, benchmarking them against international standards and best practices.
2. Identify key gaps and challenges in current regulations, enforcement mechanisms, and institutional coordination that hinder effective prevention and management of lead related risks.
3. Propose policy recommendations and regulatory solutions to strengthen national protections, enhance enforcement capacity, and align with global commitments to reduce lead exposure, especially among pregnant women and children.

## Scope of work

The regulatory review process involves 5 key steps:

### 1) Define the Scope

The review applies comprehensive approach: Adopt a holistic approach by addressing all sectors where lead exposure is relevant, ensuring a broader and more inclusive analysis. It is, then, important to determine the jurisdiction of the regulatory authority in the country. For example: Environmental Agency: Air, Water, Soil Pollution, Industrial Emissions and Hazardous Waste. Occupational Health and Safety Authority: Workplace lead exposure limits in industries like mining, battery manufacturing, smelting and waste recycling. Public Health Ministries and Agencies: Public health policies on blood lead surveillance and public health action. Ministry of Science and Technology: Consumer Protection and Standards Bodies: Regulate and standardized lead in consumer products. Food and Drug Authorities:

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<sup>5</sup> [https://journals.ekb.eg/article\\_237617.html](https://journals.ekb.eg/article_237617.html)

lead contamination in food, water, pharmaceuticals, and cosmetics. Housing and Urban Development Ministries: lead in paints, urban pollution controls Trade and Customs Agencies: Import and export of lead-contained products. Local Government Authorities: Local enforcement.

## **2) Identify and Engage with Key Stakeholders**

Effective regulatory reviews require coordination across multiple government agencies and engagement with a broad range of stakeholders to ensure comprehensive and enforceable lead regulations.

### **Key Actions:**

- **Map Stakeholders:** Identify the relevant stakeholders for discussion, including Legal Experts: Legal and regulatory specialists with expertise in environmental and public health law who can provide insight into how current regulations are applied. Regulatory Authorities: Agencies responsible for developing, implementing, and enforcing lead-related regulations (e.g., environmental, public health, occupational health, consumer protection agencies and local governments authorities). Testing and Inspection Bodies: Organizations conducting product or emissions testing and monitoring compliance with regulatory limits. Civil Society, NGOs: Organizations advocating for environmental health and involved in efforts to prevent lead exposure such as testing of lead in products. Local offices of International Organizations: Entities such as UNEP and WHO, that establish global standards, provide technical guidance, and support international collaboration on lead exposure prevention and control.
- **Objectives of engagement:** Verify the interpretation of existing permissible, as well as compliance and enforcement mechanisms. Collect data on enforcement mechanisms, such as the frequency of inspections and effectiveness of penalties. Identify any challenges or gaps in regulatory compliance and enforcement. Obtain examples of best practices from stakeholders with experience implementing similar regulations in other jurisdictions. Assess current cooperation mechanisms, such as a regular consultation framework or a data-sharing protocol.

## **3) Collect and Review Existing Laws**

This step including two key activities including 1) Identify relevant international regulations, including standards, and compare them with national legislation. 2) Highlight gaps between existing laws and global best practices.

## **4) Conduct a Regulatory Gap and Enforcement Assessment**

To conduct a Regulatory Gap and Enforcement Assessment, begin with a review of legal documents and engage relevant regulatory stakeholders (e.g., environmental, health, trade, and local authorities and whether authorities have a clear mandate and monitoring efforts are well coordinated). Assess laws and enforcement mechanisms for each lead exposure source air, water, soil, food, consumer products, waste, and workplaces to identify legal gaps, inconsistencies, and enforcement challenges. Examine issues such as unclear definitions, missing standards, weak implementation timelines, inadequate compliance systems, and insufficient penalties. Special attention should be given to protecting vulnerable populations like mother and children, poor communities... Use the accompanying risk based regulatory (RBR) maturity assessment tool to evaluate institutional capacity, legal frameworks, and enforcement effectiveness systematically.

## **5) Develop a regulatory review report which includes actionable recommendations**

Based on the findings, governments can create a clear and actionable plan to address gaps and strengthen lead regulations. Effective recommendations which include action to monitor and address informal markets should integrate compliance and enforcement principles to ensure long-term

regulatory success.

This includes organization of a Stakeholder validation workshop to review and provide comments for to the draft legal review report. It is expected that relevant participants from provinces and institutions will have to travel to attend this workshop to ensure adequate representation from different regions and locations.

#### **Deliverables and Timeframes**

**The selected institution/agency (hereinunder shorted as The Contractor) is expected to complete the following deliverables:**

<b>Deliverables</b>	<b>Descriptions</b>	<b>Estimated no. of working days</b>
Deliverable 1	An inception proposal and workplan.	03
Deliverable 2	Stakeholder mapping and engagement planning.	05
Deliverable 3	International and national regulatory document collection and desk review.	10
Deliverable 4	Structured gap and enforcement assessment.	15
Deliverable 5	Key informant interviews and consultations.	15
Deliverable 6	Draft Regulatory review report which includes actionable recommendations.	10
Deliverable 7	Stakeholder validation workshop	02
Deliverable 8	Final legal review report with recommendations	05
<b>Total</b>		<b>65</b>

#### **Management Responsibilities**

The Child Survival and Development and Environment Programme (CSDE) ensures that all tasks conform to UNICEF's standards, norms, and ethics. The overall management will lie with the Chief of CSDE while the day-to-day management responses will be undertaken by the MCH Specialist, and Health Officer. Additionally, technical support and advice will be provided by experts from UNICEF Regional Offices. Relevant Departments of the Ministry of Health (e.g. the Administration of Disease Prevention, National Institute of Occupational Health and Environment, Food Safety Authority) and relevant ministry will be involved and provide necessary assistance to the Contractor in the planning and execution of the Terms of Reference. This includes reviewing tender documents and reference letters. An informal technical working group composed of members from the government and UNICEF will be established to review and assess the quality of the work and documents developed by the Contractor.

The Contractor is responsible for planning, implementing, and finalizing all tasks as outlined in the

Terms of Reference. Hence, the Contractor is expected to provide details on how to manage the project scope, progress, and updates during the implementation. Furthermore, the Contractor should propose the communication procedure between parties, including periodic meetings with UNICEF and relevant government counterparts of Ministry of Health and other Ministries to review progress and gather feedback and/or comments on the deliverables and relevant review reports. All distributed documents including presentations and legal review reports must be approved by UNICEF.

### **Required Qualifications and Experience**

Interested institutions/agencies are expected to have the following qualifications and experience.

#### **1. Institutional Profile**

- Legally registered institution/agency with experience in regulatory and policy analysis, environmental health, or public health law.
- Proven track records of conducting legal and institutional reviews, particularly in the areas of chemicals, pollution, environmental health, or occupational health.
- Strong capacity in stakeholder engagement and coordination with government entities, especially in Viet Nam or Southeast Asia.

#### **2. Technical Expertise**

- Environmental Law and Policy Expertise: Demonstrated experience in reviewing and analyzing national and international legal frameworks related to environmental health, chemical safety, or hazardous waste.
- Public Health and Occupational Safety: Knowledge of health-related regulations, especially on exposure to hazardous substances in environmental, workplace, or consumer contexts.
- Regulatory Compliance and Enforcement: Understanding of institutional mandates, inspection systems, enforcement processes, and penalty mechanisms.
- Risk-Based Regulatory (RBR) Frameworks: Familiarity with tools and approaches to assess regulatory maturity and enforcement effectiveness.

#### **3. Team Composition and Expertise**

- Team Lead with advanced degree (master's or higher) in law, public health, environmental health and policy, or a related field, with at least 15 years of relevant experience.
- Legal/Regulatory Expert (master's or higher) with deep knowledge of Vietnamese legal systems, environmental and health legislation, and legal drafting/review, with at least 10 years of relevant experience.
- Environmental Health Specialist (master's or higher) with knowledge of lead exposure, toxicology, and regulatory standards for environmental media and consumer products, with at least 10 years of relevant experience.
- Stakeholder Engagement/Facilitation Officer experienced in organizing consultations, workshops, and inter-agency coordination, with at least 05 years of relevant experience.

#### **4. Experience in Viet Nam or Similar Contexts**

- Demonstrated experience working with government agencies and development partners in Viet Nam or similar regulatory and institutional settings.
- Knowledge of Viet Nam's legal framework, government structure, and relevant ministries (MAE, MOH, MOIT, etc.) is strongly preferred.
- Proficiency in both English and Vietnamese among team members is highly desirable.

### **Payment Schedules**

Payment will be made in instalments based on submission of the tasks by the expected timelines. Tasks/Deliverables must be approved by UNICEF.

- First instalment: 30% of the contract value will be paid upon completion of the deliverables 1 - 3.
- Second instalment: 40% of the contract value will be paid upon completion of the deliverables 4 - 7.
- Final instalment: 30% of the contract value will be paid upon submission and acceptance of the deliverable 8.

### Evaluation Criteria

**The ratio of technical to price criteria will be 70:30.** Proposals will go through a technical evaluation according to the following criteria and their relative scorings:

Technical criteria	Specific criteria	Maximum Score
<b>Overall Response</b>	Completeness of Response	5
	The overall ability of the proposal to meet the requirements of the Terms of Reference	10
<b>Maximum score for the overall response</b>		<b>15</b>
<b>The Organization and Key Personnel</b>	Reputation of the organization and employees (competence/ trustworthiness, and history of dispute and arbitration).	4
	Overall capability of the organization that can influence the implementation	2
	Quality assurance procedures and warranty policies	2
	The organization's experience in collaborating with the United Nations/non-governmental organizations/governmental agencies, particularly in the fields of health and law.	2
	Experience in conduct regulatory review or environmental health survey.	2
	<b>Key Personnel:</b>	8
	Proposed a team composition that includes a sufficient number of experts and specialists	

	Delineating roles and responsibilities for each team member.	
	Ensured gender balance	
<b>Maximum Score for the Organization and Key Personnel</b>		<b>20</b>
<b>Proposed Methodology and Approach</b>	The Project must include a detailed plan with clear descriptions of specific activities, timelines for implementation, and monitoring procedures that align with the Terms of Reference.	20
	Project management, procedures for coordination and monitoring, along with change management, quality assurance, security, and related documentation must all be strictly implemented.	15
<b>Maximum Score for Proposed Methodology and Approach</b>		<b>35</b>
<b>TOTAL</b>		<b>70</b>

Only proposals that achieve a minimum score of **50 out of 70 points** in the technical evaluation will be considered for the next step i.e. a financial evaluation.

#### **Financial Evaluation:**

- Max points **(30)** will be awarded to the lowest price proposal, and the other proposals will receive points in inverse proportion of the lowest price proposal.
- The proposal that achieves the highest score after combining the technical and financial scores demonstrates the best cost efficiency and will be recommended for awarding of the contract.
- The financial proposal should itemize costs for each task outlined in the project description.
- UNICEF applies EU-UN cost norms for local consultancy.

All quoted prices must be in Vietnamese Dong (VND) and exclusive of taxes as UNICEF is tax-exempted.

Financial and technical proposals must be submitted separately.

Each Proposal must be signed and sealed by an authorized representative of the Proposing Entity.

**Women-owned companies are encouraged to bid. Preference will be given to equally technically qualified women-owned companies.**