Division of Environmental Health | UCT

Chemical Risk Assessment for Low- and Middle-Income Countries:
What are the steps, key issues and solutions?

Factsheet

March 2024

Executive summary

Conducting a specific chemical risk assessment for industrial chemicals, and pesticides, including those used for public health, is costly and time-consuming. Therefore, it should be considered the last option when making a regulatory decision after a hazard assessment and after reviewing mutually acceptable risk data from other countries. In this factsheet, we highlight the steps and decisions that should be taken before conducting a detailed risk assessment, and then outline key issues to be aware of when conducting such an assessment in low- and middle-income countries (LMICs). This factsheet is designed to aid regulators and decision-makers in LMICs with the most cost-effective and time-efficient methods for assessing the hazards and risks of chemicals. The emphasis is on reducing health and environmental risks as quickly and economically as possible, particularly to protect vulnerable populations (e.g. women, children, the elderly, immunocompromised persons, and persons with disabilities).

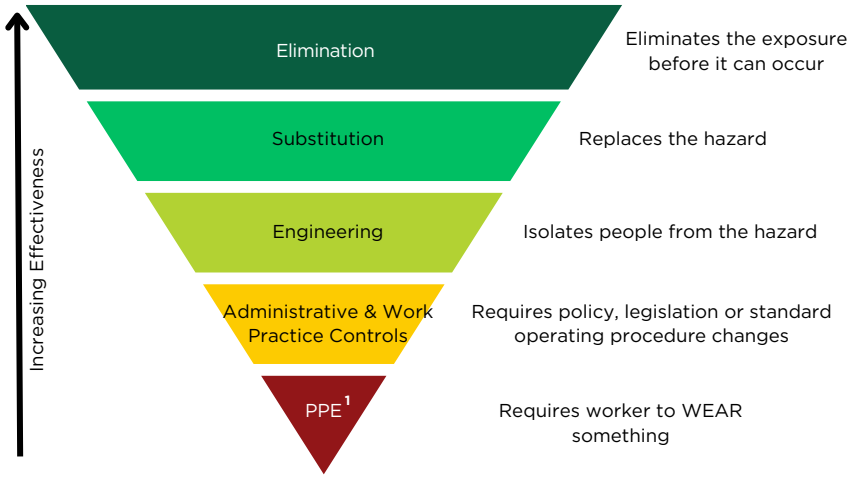
Decision-Making: Chemical Hazard and Risk Reduction

The ultimate goal of chemical risk management and control is to ensure that humans are not exposed to harmful chemicals that can cause short-term (acute) or long-term (chronic) health effects. This includes contamination of the environment (e.g. air, soil, water). Thus, using hazard and risk assessments (the focus of this factsheet) linked to legislation is vital for decision-making to reduce risks.

The **Hierarchy of Control** helps regulators see what measures are required to reduce exposure at the source depending on the decision made (see Fig 1).

Hazard assessments are for assessing how hazardous a chemical may be. Regulators can use decisions from hazard assessments to implement an immediate ban, withdrawal of registration or non-registration to eliminate the hazard (see Fig 1).

Figure 1: The Hierarchy of Control for Chemical Risks



Source: adapted from: https://www.osha.gov/chemical-hazards/controlling-exposure

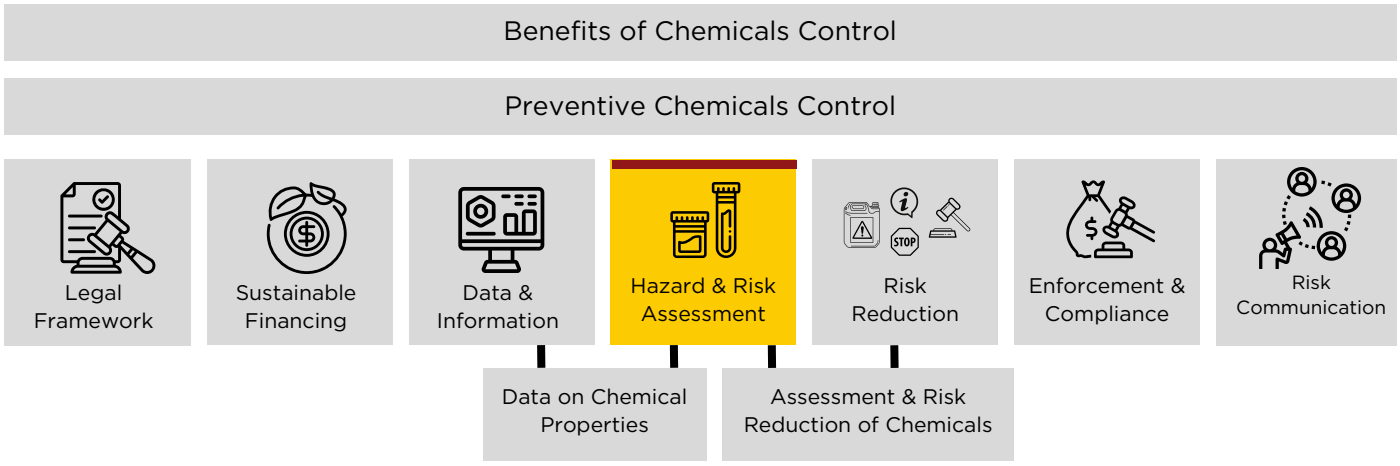
[1] PPE: Personal Protective Equipment

Should a country decide to allow a harmful/hazardous chemical to be used or added to products, it is then important that exposures are prevented. Although not the focus of this factsheet, when assessing the hazards and risks of a chemical or mixtures of chemicals, regulators should consider what the challenges may be in a country to reduce exposures. Preventing, reducing or managing risks at the source using the **Hierarchy of Control** is crucial (see Fig 1).

Reducing Negative Health and Environmental Impacts

An effective and sustainable chemical and waste management (control) system has several key elements to reduce the negative impacts of chemicals and waste. **Figure 2** shows the stages required for a sound and sustainable management system. The first element is a sound legal framework that ensures chemical and waste management is grounded in legislation. Hazard and risk assessment builds on legislation, sustainable financing of chemical and waste management, and the collection of up-to-date health and environmental data and information. Hazard and risk assessment include data on the properties of different chemicals (and soon mixtures of chemicals in products). These data need to be used in the process and decision-making of how to reduce the risks from these chemicals.

Figure 2: Elements of an Effective Chemicals and Waste Control System



Source: adapted from an illustration by Maja Modén

The two main approaches to regulating chemicals are a ***hazard-based approach*** versus a ***risk-based approach***. These approaches to chemicals and waste management must be grounded in national legislation. That is, legislation needs to indicate if chemicals are regulated through a hazard-based approach versus a risk-based approach or if a spectrum of both is used. Countries differ in terms of their approach and what is stipulated in their legislation. For example, the European Union (EU) uses a hazard-based approach, meaning they first screen out the most hazardous chemicals based on their hazards. However, those not eliminated based on hazard will be assessed based on risk assessments. Whereas the United States of America (USA) relies on a risk-based approach where they do not ban chemicals based on hazard but rather on risk assessments.

It is important to understand how these approaches are used and the benefits of first screening chemicals based on hazards. There are two commonly used hazard classification systems - the *Globally Harmonized System of the Classification and Labelling of Chemicals* (GHS: includes acute and chronic hazards) and *The WHO Recommended Classification of Pesticide by Hazard and guidelines to classification, 2019 edition* (WHO - World Health Organization; only for acute hazards). There is a global momentum to use the GHS which is more comprehensive and covers pesticides and chemicals.

A **hazard** is the inherent property or toxicity of a chemical. On the other hand, a **risk** is the function of the probability of negative health and environmental impacts, with varying severity, following an exposure to the hazard of a chemical. That is **Risk = Hazard x Exposure** (see Fig 3). **Exposure** is when a person comes into contact with a chemical, and it enters the body or remains on the skin through one of four routes (inhalation, ingestion, skin contact/absorption or through the eyes), and includes potential, accidental or possible, contact/exposure.

Figure 3: Difference Between Hazard and Risk

Source: https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/2608/Annex%205.%20HHP%20Factsheet%201.pdf

The extent to which a risk can be seen as "acceptable" for human and environmental exposures needs to be defined in legislation. For example, how much pesticide residue can remain in food (i.e., maximum residue limits)? Is it acceptable to register and allow the sale of chemicals classified as carcinogenic, mutagenic or toxic for reproduction (CMRs)? By including the GHS in a country's legislation chemicals can be identified with, for example, CMR properties. However, a provision will need to be made in legislation that CMR's are unacceptable for use and formulation. Acceptable risks for environmental exposures should be in relation to PBT and vPvB assessment; that is, substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), and are of very high concern because of their persistence, their ability to accumulate in living organisms, and their toxicity.

To effectively reduce the risks from chemicals in LMICs, a three-step assessment process is recommended, noting that it is possible to stop at step one or step two as not all three steps are required for decision-making. However, it is important to note that some countries will have elements of both a hazard-based and risk-based approach. Governments need to ensure these steps and the process is enshrined in legislation.

Step 1	**Step 2**	**Step 3**
Assess the hazard of the chemical or class of chemicals.	Use **risk assessment data produced by other countries.**	When deemed necessary, **conduct in-country risk assessments.**

As illustrated above, **Step 1** focuses on hazard assessments gathered from other regulatory jurisdictions for regulators to reach conclusions on the hazards of the chemical (based on systems such as the GHS and the WHO pesticide hazard classification). If it is not possible to suggest management measures based on the hazard only, **Step 2** is initiated. Here, risk assessments from other regulatory jurisdictions are gathered for regulators to conclude on the risk of the chemical for their country. If hazard and/or risk assessments are missing for the chemical or a local assessment is deemed necessary, the required data and assessments are generated in **Step 3**.

1 Step 1: Using Existing Hazard Assessment Data

Hazard assessment is the identification of the nature (type) of adverse effects that a chemical substance or a mixture of chemical substances has the inherent capacity to cause in an organism, system or population.

The GHS helps regulators enhance the protection of human health and the environment during the handling, transport and use of chemicals. The GHS guides on how to classify, for example, both the acute (short-term) and chronic (long-term) hazards, along with physical and environmental hazards.

Hazard assessment data produced by other countries or organisations can be accessed from these sources:

- *Organisation for Economic Cooperation and Development (OECD) eChemPortal.* https://www.echemportal.org/echemportal/
- *European Chemicals Agency Information on Chemicals.* https://echa.europa.eu/information-on-chemicals
- *The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification,* 2019 edition. https://www.who.int/publications/i/item/9789240005662

2 Step 2: Using Existing Risk Assessment and Exposure Data

At the global level, chemical risk assessment is one of the fundamental steps in informing risk management decisions for policymakers and government. Chemicals are used in almost every process worldwide, whether for domestic or industrial purposes, and it is up to the government to regulate the usage of these substances to avoid adverse health effects. Information from chemical risk assessments provides technical support to regulators and governments when a substance constitutes a potential health or environmental risk. However, not every chemical requires a risk assessment.

After a country has conducted a hazard assessment and decided to regulate the use of the chemical as it is not carcinogenic, mutagenic or toxic to reproduction (GHS Class 1A and 1B chemicals), the next step is to assess exposure risks.

Many chemicals, or chemicals with similar molecules, have already been put through a costly and time-consuming risk assessment. LMICs would benefit from having the use of mutually acceptable data (i.e., OECD Mutual Acceptance of Data (MAD) system) stipulated in their legislation. Some of the challenges experienced by LMIC regulators in using mutually acceptable data are:

- The risk assessment might not address the unique risks of a specific country.
- In the case of pesticides, exposure scenarios may not be the same in LMICs and high-income countries (HICs) due to differences in agricultural and handling practices.
- Ensuring that human exposure level recommendations and adverse effect studies are unbiased (e.g. are not generated by industry, resulting in a conflict of interest).
- Country-generated scientific studies and research on represented species or local peculiarities is already available.
- Local residue data and local food consumption patterns exist.

Exposure data can be found at:

- *Chemical Exposure Health Data*. https://www.osha.gov/opengov/health-samples
- *OECD Product Release and Exposure Data Warehouse.* https://www.oecd.org/chemicalsafety/risk-assessment/product-release-and-exposure-data-warehouse.htm

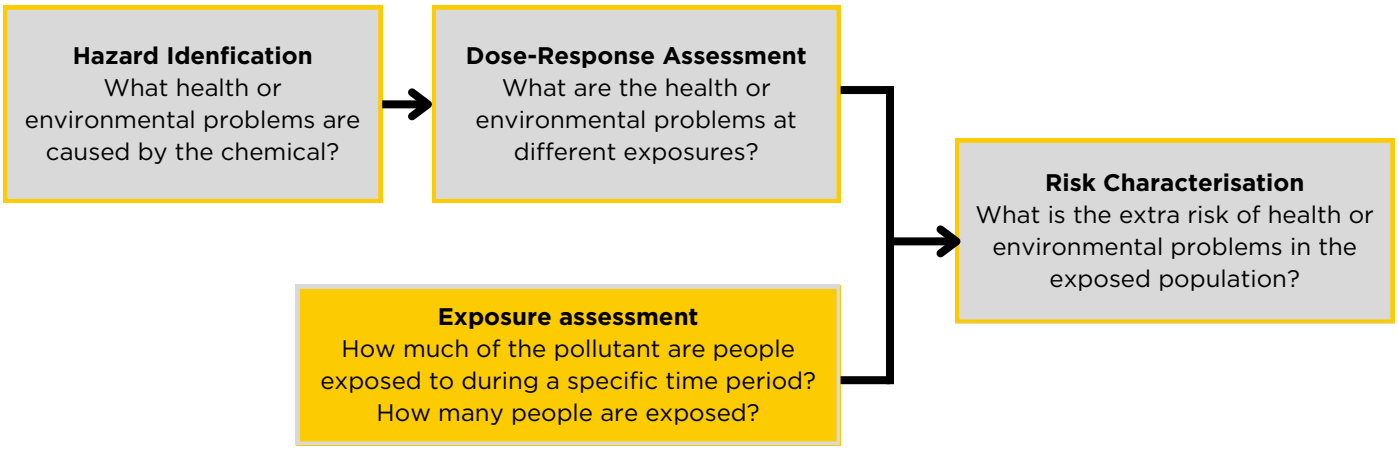
3 Step 3: Deciding to Conduct a Local Risk Assessment

Before deciding to conduct a detailed country-based chemical risk assessment, the following should be considered as reasons to conduct this assessment:

- No existing data –globally is available on the chemical or class of chemicals in question.
- Data for the particular use context is not available.
- Disaggregated gender data is not available.
- Laboratories and required technical staff/researchers are available in the country.

LMIC governments should ensure in their legislation that the **burden of proof** as to whether there is a risk related to a particular chemical or group of chemicals **rests with the industry**. Governments in LMICs may not have the time, resources, and, sometimes, the expertise required to conduct risk assessments (see Fig 4). Therefore, risk assessment data for a chemical must be provided by the industry - this includes funding the research and conducting the research. However, the review of these data submitted with a registration application must be conducted by **independent toxicologists**. This is to prevent **conflicts of interest**.

Figure 4: The Four Components in Chemicals Risk Assessment



Source: adapted from https://www.epa.gov/risk/conducting-human-health-risk-assessment

The WHO provides a roadmap for human health risk assessment for chemicals (see Box 1) and the OECD for environmental exposure risks (https://www.oecd.org/chemicalsafety/risk-ssessment/environmental-risk-assessment-toolkit.html).

Box 1: WHO Human Health Risk Assessment Toolkit for Chemical Hazards

The WHO Toolkit is a manual on how to identify and characterise chemical hazards, assess exposures to these chemicals and determine whether these exposures are dangerous to public health. To assist with performance of a risk assessment, this Toolkit:

- provides roadmaps for conducting chemical risk assessments;
- identifies information that must be gathered to complete an assessment;
- provides references, including internet URLs, for international resources from which an assessor can obtain information and methods essential to a risk assessment.

Source: https://www.who.int/publications/i/item/9789240035720

Table 1 highlights some of the major issues LMICs face when conducting chemical risk assessments. Given that these issues exist in many LMICs and challenge many LMIC regulators, the first step is to assess why a risk assessment is needed and why a hazard assessment or using existing risk assessment data is not sufficient.

Table 1: Challenges with Conducting Risk Assessments (RAs) in LMICs

Challenge	Details	How to address?
Lack of Ability to Manage Hazards	Staff and decision-makers not trained to identify, monitor and forecast hazards; especially increased chemical hazards for communities at risk and vulnerable populations.	Increase training of regulators and decision-makers on how to understand and apply hazard assessments. Set up monitoring and forecasting systems.
Lack of Funds	Conducting local RA is costly.	Require industry to fund the research. However, the data generated by industry need to be assessed by independent toxicologists.
One Chemical Focus	RA approaches currently only review the risks of exposure to one chemical at a time. In reality, workers and consumers are exposed to multiple chemicals at any given time.	Governments should ensure that legislation refers to a mixture of risk assessments which request assessments for **aggregate** (one substance exposure from multiple sources/routes) and **combined** (multiple chemical exposures from single or multiple route) **exposures**. (For example, assess the risk for the combination of all chemicals in a product - paint, personal care products, pesticides).
Lack of Toxicologists	Governments conducting or assessing RAs, need to have access to toxicologists and eco-toxicologists who can assess the data without any conflicts of interest.	Government funding should be made available to provide bursaries for local students to study postgraduate degrees in toxicology and ecotoxicology.
Lack of Analysis Labs	Once data are collected, the samples require analysis with specific lab equipment.	LMICs should limit requests for labs as they are expensive to set up and maintain. Rather, require industry to conduct laboratory analysis when using existing RA data is not viable.
Lack of Trained Research Staff	The data for RAs have to be collected by trained researchers.	Governments to dedicate funding for postgraduate training of academics and researchers who can conduct the required health and environmental research.

Concluding Points:

If the industry does not provide data for a product (including mixture assessments), then the product should not be licensed for sale. The EU is working on implementing the "**no data - no market**" principle, which LMICs should consider.

Remember - hazard assessment first, then use existing risk assessment data and only request local risk assessment data when the first two steps are not available or adequate.

Resources

- **Main Document**: Swedish Chemical Agency. (2020). *Guidance on National Chemicals Control. Hazard and Risk Assessment of Chemicals, an Introduction*. Stockholm: Swedish Chemical Agency. https://www.kemi.se/download/18.32f4eb311753c0a67fe1cf6/1604653630900/Guidance-Hazard-and-risk-assessment-an-introduction.pdf

- ILO-WHO International Chemical Safety Cards (ICSCs). The International Chemical Safety Cards (ICSCs) are data sheets intended to provide hazard, risk and safety and health information on chemicals in the workplace. https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm#:~:text=The%20International%20Chemical%20Safety%20Cards,of%20chemicals%20in%20the%20workplace.

- United Nations. (2023). GHS Purple Book - *The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*. Tenth Revised Edition. New York and Geneva: United Nations. https://unece.org/transport/documents/2023/07/standards/ghs-rev10

- UNITAR Online Courses on Key Aspects of Chemicals and Waste Management. https://cwcourses.unitar.org/

- OECD Guidelines for the Testing of Chemicals. https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en

- Pesticide Action Network UK. (2021). *Hazard vs Risk-Based Approaches to Protecting Health and Environment From Pesticides*, Brighton: Pesticide Action Network UK. https://www.pan-uk.org/site/wp-content/uploads/Hazard-versus-risk-based-approaches-to-protecting-health-and-environment-from-pesticides.pdf

- UCT Pesticide Discussion Forum. (2021). *Conducting Risk Assessments in Africa: Issues and Challenges*, Cape Town: UCT Pesticide Discussion Forum. https://health.uct.ac.za/sites/default/files/media/documents/29.07.2021_digest_conducting_risk_assessments_in_africa_issues_and_challenges_0.pdf

Produced by: Division of Environmental Health, School of Public Health, University of Cape Town, South Africa.

Contact: environmentalhealth@uct.ac.za

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School of Public Health
Departement Openbare Gesondheid
Isikolo Sempilo Yoluntu
UNIVERSITY OF CAPE TOWN

Sweden
Sverige