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PROGRAM ON ESCAPING THE MIDDLE – INCOME TRAP: CHAINS FOR CHANGE

ADOPTING RELEVANT PRACTICES IN REGULATING FOOD AND HOUSEHOLD HAZARDOUS SUBSTANCES

Recommendations for the Food and Drug Administration (FDA)

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INTRODUCTION

On June 10 2025, the Joint committee on Trade and Industry and Health of the House of Representatives called the Philippine Food and Drug Administration (FDA) to provide a briefing to the members of the joint committee regarding their processing of applications for Certificates of Product Registration (CPR) of food, medical devices, pharmaceutical, and other products. The private sector has raised, among other concerns, unattended CPR applications as well as backlogs and redecking of CPRs (House of Representatives website).[1] This underscores the importance of addressing the various concerns of stakeholders about the agency and the urgent need to address bottlenecks.

The FDA, which is under the Department of Health (DOH), plays a critical role in safeguarding public health through its regulation of food, drugs, cosmetics, medical devices, and household hazardous substances (HHS). However, the FDA is constrained, among others, by institutional inefficiencies and bureaucratic delays. These not only undermine health governance but also contribute to broader structural barriers facing Philippine businesses, particularly small and medium enterprises (SMEs), in their efforts to scale up, innovate, and compete globally. Larger firms are also affected, particularly in their plans to introduce innovative, sustainable, and price-competitive products due to slow and costly registration processes (Pinlac 2022; FDA 2023).

This policy brief is part of the wider research initiative on escaping the middle-income trap, which underscores how enabling regulatory environments are essential for inclusive and sustained development. Of particular concern in this policy brief are non-drug products namely food and household hazardous substances including cleaning materials (e.g., cleaning agents, air fresheners, insecticides) and other domestic goods.

HHS products require FDA approval before they can be sold, but distinct regulatory issues hamper their entry into the domestic market. The FDA applies a uniform pre-market registration process regardless of risks.

1 CPR redecking pertains to reassignment or reordering of applications, often resulting in longer delays.

This contrasts with Thailand where HHS regulation and handling are tiered based on actual hazard levels and managed primarily through post-market surveillance and labeling rules (3E 2022). The National Environment Agency (NEA) of Singapore, for its part, has clear rules on the management of hazardous substances and clear guidance for applicants (NEA n.d.).

For food products, the regulatory challenge lies in the tedious process that entails the submission of various documents to the FDA and other agencies. In contrast, Singapore and Thailand have clearer rules. They also use the Codex Alimentarius as a set of scientific standards to reduce regulatory redundancy and enhance trade facilitation (Ratanakorn 2016; SFA n.d.; The Nation 2020).

The *Escaping the Middle-Income Trap: Chains-for-Change (EMIT C4C)* Program of the University of the Philippines Center for Integrative and Development Studies has interviewed several Philippine firms regarding their competitiveness and inclusiveness as part of its research agenda. The interviews were held from April to May 2025 through online and in-person discussions. One of the common concerns of companies regardless of their size is the difficulty of securing FDA approval for low-risk and non-medicine items. This led EMIT C4C to investigate the relevant policies concerning the FDA. This policy brief is crafted for key decision makers of the executive branch of government particularly the DOH and the FDA. Considering the recommendations in this policy brief will improve the overall competitiveness of Philippine firms without compromising public health.

THE FDA

The FDA was reorganized under Republic Act No. 9711 in 2009 to strengthen its regulatory mandate. Despite this, the agency is encumbered by slow processing times, limited staff, limited scientific and technical capacity, lack of fiscal autonomy, and weak enforcement mechanisms (Pharma Boardroom n.d.). These constraints diminish the FDA's ability to fulfill its mandate. It also limits the introduction of timely, innovative, and safe products in the market. For medium- and big-sized firms, these constraints make them lose technological opportunities and product development partners who were hoping for a timely launch of novel products in the country.

REGULATORY PROBLEMS WITH HOUSEHOLD HAZARDOUS SUBSTANCES

The FDA is heavily preoccupied with pre-market approvals, often at the expense of post-market surveillance. Its CPR requirement extends even to low-risk items in the HHS regardless of toxicity or public health risk. This blanket regulation is governed by FDA Circular No. 2013-009 and creates unnecessary regulatory friction, especially for low-risk products such as general use cleaners. At present, there is an extended transitory period where Household/Urban Hazardous Products (HUHS) without a CPR from FDA may still be distributed, provided that HUHS establishments have obtained appropriate License to Operate. The transitory period is extended until December 31, 2025 (FDA 2025).

While the transitory period provides a respite, the regulation of imposing a CPR regardless of risks adds burdens to SMEs that sell or consume these products. SMEs have also long complained about the costly and lengthy registration process. According to the Pampanga Chamber of Commerce and Industry, small businesses encounter pressing issues during FDA application and renewal processes. These include extensive regulatory requirements, high cost of laboratory testing, lack of regulatory personnel, and technical difficulties with the online portal (PamCham 2025).

In interviews, large manufacturers have similarly expressed concern over delays and unpredictability of product registration. These firms often operate across ASEAN and global markets and face challenges when Philippine regulations lag behind regional harmonization. As a result, many innovative products, including reformulated eco-friendly cleaners or new product variants, are delayed or abandoned altogether due to regulatory bottlenecks.

In contrast, Singapore regulates those products primarily through labeling and post-market surveillance while Thailand utilizes a four-tier classification system (3E 2022). Type 1 or low risk products require only notification, not full registration. These include items like general-use cleaners or household chemicals with low toxicity. Importers or manufacturers must still comply with labeling and safety standards but approval is simplified. Type 2 or moderate risk products and substances in this tier pose a moderate risk and require registration and

control over production, importation, exportation, and possession. There are specific reporting obligations and some form of regulatory monitoring. Type 3 or high-risk substances pose a high risk to health or the environment. They require strict registration, licensing, and approval from the Thailand FDA before being distributed. Detailed product safety information must be submitted and regulatory inspections are more stringent. Type 4 or prohibited/severely restricted substances are considered too dangerous for public use and are either prohibited or subject to very strict government control, often reserved only for specific industrial or research purposes.

REGULATORY CHALLENGES WITH FOOD PRODUCTS

According to Llanto and Manalili (2018), food establishments in the Philippines are mandated to comply with numerous regulatory requirements and must secure different permits and clearances from varying agencies. Importers of processed foods must obtain a license to operate from the FDA, secure a certificate of accreditation from the Bureau of Animal Industry of the Department of Agriculture (for meat and meat product importers), and a certificate of accreditation from the Bureau of Plant Industry if importing fresh fruits and vegetables. Food exporters are also expected to comply with various requirements before they can export to other countries.

Singapore and Thailand offer models for streamlining food regulation without compromising public health. Both align their standards with Codex Alimentarius and the ASEAN Food Safety Policy to facilitate cross-border trade and ensure scientific consistency in evaluation processes (Singapore Food Agency N.D.; The Nation n.d.).

CONTINUING AND FULLY IMPLEMENTING REFORMS

The FDA has previously taken steps that align partially with the recommendations proposed in this policy brief. For instance, under FDA Circular No. 2020-025 implementing Administrative Order No. 2019-019, the agency began classifying HHS products and licensing establishments based on defined categories (NDV Law 2020). However, while categorization exists, it was not a fully developed risk-tiered system that streamlines regulation proportionately to product risk. On the food regulation side, efforts have also been made to align with international standards. The FDA has adopted certain Codex Alimentarius provisions. For example, FDA Circular No. 2010-008 on food contaminants and guidelines on food labeling is informed by Codex norms. The FDA also categorizes food products based on risk - low risk food, medium risk food, and high-risk food where the higher the risk level, the higher the level of regulation. Despite these efforts, the process remains cumbersome so this policy brief echoes earlier recommendations from stakeholders to improve the FDA's operational capacity and effectiveness and to enhance the capacity of the Food Safety Regulation Coordinating Board, which is in charge of establishing and coordinating the policies on food safety. Those interviewed for this policy brief also recommend having a one-stop processing venue for various certifications including those coming from other agencies like the Department of Agriculture (Llanto and Manalili 2018).

CONCLUSIONS AND RECOMMENDATIONS

The DOH holds a critical leadership role in improving FDA's regulation of household hazardous substances and food products. The DOH can initiate reforms through executive and administrative channels to improve the FDA and reduce regulatory burdens on both SMEs and large firms. The FDA needs to be strengthened with resources including technical staff and experts to address its backlogs. The Philippine government, in general, should also consider the creation of a one-stop shop mechanism for all food regulations.

This brief has reviewed key practices of Singapore and Thailand to illustrate the possibility of implementing risk-based regulation for HHS and standards-based alignment for food. Their experience demonstrates how agile and science-based regulatory systems can protect public health while enabling economic competitiveness. Adopting similar reforms could accelerate product roll-outs by months and improve SME participation in value chains. These are fundamental conditions for the Philippines to escape the middle-income trap. In summary, we propose for the DOH to undertake the following:

Recommendations for regulating household hazardous substances

- Amend FDA Circular No. 2013-009 to adopt a risk-based classification system;
- Require only notification for low-risk HHS and focus on post-market surveillance; and
- Reduce compliance costs for SMEs handling low-risk HHS.

Recommendations for regulating household hazardous substances

- Issue an administrative order utilizing Codex Alimentarius to standardize regulation;
- Clarify CPR procedures with public checklists and timelines; and
- Coordinate with the Department of Agriculture (DA) to reduce the number of requirements and fast track reviews and approvals.

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