

Ask the 3Expert

What are the key legislative changes to Vietnam's final decree on management of household insecticides and disinfectants? How does it impact manufacturers and importers doing business in Vietnam?

Alert Summary

On 18 July 2016, the Vietnamese government published Decree 91/2016/ND-CP on Management of Chemicals and Preparations Intended as Household Insecticides and Disinfectants in the electronic government portal. The Decree includes requirements such as labeling, packaging, product registration, storage and transport of these products. Domestic companies or subsidiaries who manufacture these products must ensure that the manufacturing plants are certified to manufacture the products by 1 July 2017. The rest of the Decree, including new labeling requirements, takes effect on 1 July 2018.

3E Analysis

Under the Decree, no household insecticide or disinfectant products may contain active ingredients that are: classified as Ia or Ib under the World Health Organization's Recommended Classification of Pesticides by Hazard; classified as Category I or II under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or on the list of prohibited active ingredients for use in these products, as issued by the Ministry of Health (MOH).

Product Registration

All insecticide and disinfectant products must be registered to the Ministry of Health and receive a registration number. Specifically, registration must be completed for any products whose active ingredients are: manufactured in Vietnam for the first time (except those manufactured for export only); imported to Vietnam for the first time but have been permitted for use in other countries;

already on the market but whose formulations or contents have changed; already on the market but whose license is only for a limited time and must be renewed; and for those which are under a license that is still valid but certain conditions upon which the license are based have been changed.

The following entities may register the products: the products' owner(s) (manufacturers, importers, suppliers, government co-ops, etc); certified Vietnamese agent(s) of the products' owners; or the Vietnamese representative of the products' owners.

Each registration must include the following documents: business license of the party registering (or documentation showing that the registrant is an agent of the party registering); certificate of free sale; testing results for both the content and composition of the product; relevant technical documents regarding the product and/or active ingredient; sample label (either in Vietnamese only or a Vietnamese supplemental label if the label is in a foreign language); copies of documentation and testing results submitted to other jurisdictions for products already registered or notified in other countries; and any available data obtained from reputable international entities for products containing active ingredients that are introduced to the Vietnamese market for the first time.

Significantly, the final Decree appears to narrow the scope of which products are required to be registered. The draft included registration for products that contain new chemicals and active ingredients, whereas the focus in the final regulation centers on the final products.

Labeling

Out of all of the requirements, the labeling obligations are most significantly changed from both the existing regulatory framework and the draft decree. The government streamlined the labeling requirements for these products into a single set of requirements in the Decree. When it becomes effective, the Decree

will repeal Article 12, Section 12 of Decree 89/2006/ND-CP on Labeling of Goods, which gave rise to the current labeling scheme.

A major departure from the draft Decree is that new labels will have to have to comply with GHS but the Decree provides little information on how to comply with GHS except requiring the industry to follow guidance from the Ministry of Industry and Technology. Moreover, the labels of insecticides and disinfectants must include the following features: name of the product, composition and content of active ingredient(s), function of the product and direction for usage, instructions for storage, warning statements regarding harmful effect to human health and the environment, first aid instructions when in direction contact with the product (via skin, eye, digestion, respiratory), the name and address of the manufacturer, the name and address of the processor or packager (if any), the name and address of the entity registering the product, batch number, the manufacturing date (in either format: day, month, year or month, year), expiry date, and the registration number.

The name of the product (or logo or pictures making up the name of the product) on the label must match that of the name being registered and should be as large as the largest text on the label. The font of any portion of the label must be 0.9 mm or greater. The label must be securely attached or printed on the product packaging. The labels must avoid any coloring schemes that are similar to coloring schemes indicating the toxicity of the active ingredient.

For chemical mixtures with active ingredients which are used to manufacture or formulate insecticide and disinfectant products, the labels must include the following: name of the product, composition and content of the active ingredient, instruction for storage, warning statements regarding harmful effect(s) to human health and the environment, name of the manufacture of the product, batch number, manufacturing date (in either format: day, month, year or month, year), and expiry date.

For chemicals and products whose toxicity may be classified as I, II or III under the WHO Recommended Classification of Pesticides by Hazard, the label must contain certain pictograms. For products classified as Ia and Ib, the pictogram is a black skull and cross bone being placed inside the white diamond with black borders, similar to the pictogram used in UN's Recommendations on the Transport of Dangerous Goods. For products that are classified as category II, the pictogram is a black cross on a white diamond with a black border. For products that are classified as category III, the pictogram is a white diamond with black borders and a black dotted line running horizontally through the pictogram.

The Decree requires users, suppliers, and product owners to dispose of the products and packaging materials in accordance with manufacturers' instructions and relevant national laws on environmental protection. Therefore, the product should include instruction on disposal of the products and their packaging either on the labels or through other means, even though such a requirement is not explicitly stated.

Imports

Imported products should follow all customs rules and regulations. Imported products and/or ingredients used to manufacture the products must be accompanied by the relevant registration numbers and documents certifying the completed registration. Imported products for testing or trial purposes must include documentation of the organization conducting the test and/or trial.

Revocation

The regulation will also repeal portions of the following regulations: Article 12, Section 12 of Decree 89/2006/ND-CP on Labeling of Goods; Article 8, Section 2 and 3 of Decree 108/2008/ND-CP detailing and guiding the implementation of a number of articles of the Chemical Law; Article 8, Section 1 of Decree 26/2011/ND-CP amending and supplementing a number of articles of the

Government's Decree No. 108/2008/ND-CP; Article 18, Section 3 of Decree No. 104/2009/ND-CP of November 09, 2009, providing for the list of dangerous goods and the transport of dangerous goods by road motor vehicles. These articles and sections are related to the regulatory framework for each respective type of product.

Business Impact

Products with labels based on the existing framework are permitted for use until 1 July 2018. However, all products must comply with the new labeling requirements after that date.

The Decree signaled that the government is implementing GHS labeling for consumer products. So far, only chemical and pesticide products are required to follow GHS.

Companies who manufacture or import these types of products should consult the Decree to ensure compliance. Companies are also advised to continue monitoring the development of future amendments to this Decree. The Ministry of Health and/or the Ministry of Industry and Technology may also issue further guidance on how to comply with this new Decree.