For: Economic Zone Locator Enterprises
Economic Zone Administrators and Managers

From: Director General LILIA B. DE LIMA

Subject: Chemical Importation Advisory - Requirements for importation of goods considered as household urban hazardous substance (HUHS)

Date: 26 June 2015

We have been receiving reports from locator enterprises that imported goods, considered as household urban hazardous substance (HUHS), are being put on-hold at the port pending presentation of appropriate Food and Drug Administration (FDA) permits to port officials. We wish to inform that as a result of the issuance last 10 April 2015, of the Customs Memorandum Order (CMO) 9-2015 (Annex 1) with the subject “On the strict enforcement of rules concerning regulated imports”, importation requirements for goods considered as HUHS are now being stringently implemented at all ports.

How to ensure compliance to FDA regulation on importation of HUHS?

1. Check the Material Safety Data Sheet of the chemical or materials to be imported and compare with the list of HUHS (Annex 2). [Reference: Section II. Scope and Coverage FDA MC 2013-045]


Use the filter in the first column entitled “Category” of the excel file and select “Household Urban Hazardous Substance” to view the complete list. Screenshots of the BoC website link and the MS Excel file of regulated materials are provided in Annex 3.

2. Lodge the PEZA electronic import permit (e-IP) application and allow the supplier to ship the chemical or materials only after:
   a. Goods are cleared by the PEZA Zone Office as unregulated; OR,
   b. Regulated goods are accompanied by appropriate permits and PEZA Zone Office has given clearance to lodge e-IP application.

What are the requirements for importation of materials considered as HUHS?

3. Importers are required to secure the FDA License to Operate (LTO) and Certificate of Product Notification (PN), these shall be presented to the port of entry for every shipment of HUHS. [Reference for LTO: FDA MC 2014-003; Reference for PN: FDA MC 2013-045]
What if the HUHS are already at the port and the appropriate permits have yet to be secured?

4. The Center for Cosmetics Regulation and Research (CCRR) of the FDA has advised PEZA that a Bureau of Customs (BoC) Clearance may be issued by the CCRR to importers if the HUHS is intended solely for the company’s own consumption and will not be for commercial or wholesale distribution.

5. The BoC Clearance may be issued by the CCRR in lieu of the LTO and PN per shipment to establishments that import HUHS products subject to submission of the following requirements to the FDA:
   a. Letter of intent / cover letter addressed to Secretary of Health and Acting FDA Director General Janette P. Loreto – Garin, MD, MBA-H.
   b. Notarized affidavit of undertaking stating that the imported product/s does not contain any banned ingredient/s and is intended solely for own consumption and not for marketing nor for commercial or wholesale distribution,
   c. Copy of bill of lading, invoice and packing list.
   d. Proof of payment of Php 510.00.

Kindly submit documents during office hours from Monday – Friday at the FDA office in Alabang, Room 106, Annex Bldg., Filinvest Corporate City. Application shall be processed by the FDA within five (5) working days. Once application is lodged, the FDA will issue a Document Tracking Number and applicants will be able to check the status of their application through the FDA website. [Reference: FDA MC 2015-006]

Can we apply for a BoC Clearance from the FDA annually instead of a per shipment basis?

6. PEZA is working with the FDA to streamline the requirements for registered enterprises especially those who frequently import HUHS. The FDA be issuing guidelines to enable this. To ensure that said guidelines will be responsive to the needs of the stakeholders, we will need your support to back up your claims.

Thus, please write a letter to PEZA requesting for an expanded BoC Clearance for the release of HUHS with the following information:
   a. Material Safety Data Sheet of the HUHS;
   b. Frequency and volume of importation per month of HUHS; and,
   c. Brief description of how the HUHS is used in the PEZA-registered activity with a declaration that the HUHS does not contain any banned ingredient/s and is intended solely for own consumption and not for marketing nor for commercial or wholesale distribution.

You may visit the PEZA Zone Office or email esg@peza.gov.ph for assistance.

For information and compliance. [1519-2015-00150]
Annex 1
Customs Memorandum Order 9-2015

Customs Memorandum Order
No. 9-2015

10 April 2015

Subject: On the Strict Enforcement of Rules Concerning Regulated Imports

A. Background

A.1. The Bureau of Customs has published a final, complete list of all regulated imports. The list can be downloaded from:


A.2. Details on how the list is organized can be found in the User’s Guide to the Bureau of Customs Regulated Imports List, which can be viewed at:


and downloaded from:


A copy of the User’s Guide is also attached as Appendix A.

A.3. Strict enforcement of the requirements in the list shall begin on 11 May 2015 (not on 20 April 2015 as previously announced).


B.1. All importers of any product in the Regulated Imports List must provide the required import permits when filing import entries with the Bureau of Customs.

B.2. All Bureau of Customs assessment and operations staff processing consumption, warehousing, and transshipment entries containing any product in the Regulated Imports List, including those destined for PEZA zones and freeports, must verify whether the required import permits were issued and submitted to the Bureau of Customs, prior to their final assessment. In the case of transshipments, the permits must
be obtained, and a copy provided to the Bureau of Customs, prior to transshipment from the port of discharge.

B.3. No Bureau of Customs official shall require the submission of import permits for any product which is not on the Regulated Imports list. To do so is a Grave Offence, and will be dealt with as described in Section B.7.

B.4. Bureau of Customs staff are reminded to take particular care in processing imports of food and drink, drugs and pharmaceutical products, and chemicals, taking note of the following:

B.4.a. All food and drinks, whether for human or animal consumption, are regulated imports, and must have a permit from one of the following agencies:
   B.4.a.i. Bureau of Animal Industry
   B.4.a.ii. Bureau of Fisheries and Aquatic Resources
   B.4.a.iii. Bureau of Plant Industry
   B.4.a.iv. Food and Drug Administration

In addition, alcoholic drinks must have a permit from the Bureau of Internal Revenue.

The specific rules for each product are shown in the list.

B.4.b. All drugs and pharmaceutical products, whether for human or animal consumption, are regulated imports, and must have permit from one of the following agencies:
   B.4.b.i. Bureau of Animal Industry
   B.4.b.ii. Bureau of Fisheries and Aquatic Resources
   B.4.b.iii. Bureau of Plant Industry
   B.4.b.iv. Food and Drug Administration

The specific rules for each product are shown in the list.

B.4.c. Many chemicals are regulated imports, in some cases by more than one agency. This list contains all known regulated chemicals. If a particular chemical is not on the Regulated Imports list, it does not automatically mean that it is not regulated. For chemicals which are not on the Regulated Imports list, Customs staff, importers, and brokers should determine whether that chemical is found in the Philippine Inventory of Chemicals and Chemical Substances (PICCS):

B.4.c.i. If a particular chemical is not in the Regulated Imports list but is in the Philippine Inventory of Chemicals and Chemical Substances, then that chemical is not a regulated import.
B.4.c.ii. If a particular chemical is not in the Regulated Imports List, and also not in the Philippine Inventory of Chemicals and Chemical Substances, then that chemical is a regulated import and must secure a permit from the Environment Management Bureau.

B.4.c.iii. The Philippine Inventory of Chemicals and Chemical Substances (PICCS) is contained in the file PICCS 2012.pdf, a link to which is shown in the User's Guide to the Bureau of Customs Regulated Imports List.

B.5. If any Bureau of Customs staff believes that a product which is not in the Regulated Imports List should be regulated, he or she shall:

B.5.a. Inform the Office of the Commissioner, by e-mail to inquiry.test@email.com, including the following information:

B.5.a.i. Description of imported product which is not in the Regulated Imports List

B.5.a.ii. Specific legal basis for requiring an import permit (cite the law or executive issuance, including the specific section which applies to the product)

B.5.a.iii. Regulating Agency from which a permit should be acquired

B.5.b. Wait for the inclusion of the product in future versions of the Regulated Imports List before requiring import permits for it.

B.6. Importers and brokers are strongly urged to acquire the necessary import permits for products in the Regulated Imports List prior to the scheduled arrival of their imports in the Philippines. Failure to present the necessary import permits within the time frames for filing of entry (30 days after date of last discharge of the last package) or claiming of importation (15 days after filing of entry) shall not be grounds for extension of the periods after which a shipment shall be deemed abandoned, nor be accepted as a justification for lifting of abandonment.

B.7. Non-compliance by any Customs official with Section B.3 of this CMO will be an incidence of Grave Offence as used in CMO 25-2010, Title IV, Section 1, and shall be punishable upon first offense by Dismissal.
B.8. Non-compliance by any Customs official with any section of this CMO, except for Section B.3, will be an incidence of Simple Neglect of Duty as used in CMO 25-1010, Title IV, Section 2, and shall be punishable upon second offense by Dismissal.

JOHN P. SEVILLA
Commissioner
Annex 2: Products considered as household urban and hazardous substance (HUHS)

A. Paints (household/car paints), lacquers, varnish;
B. Paint solvent, lacquer thinner, mineral spirits, turpentine;
C. Adhesives and sealants;
D. Polishes and waxes;
E. Bleaches;
F. Cleaning agents;
G. Disinfectants;
H. Detergents;
I. Dishwashing liquid and pastes;
J. Dyes, softeners, conditioners, fresheners, ironing agents for fabrics;
K. Educational set and miscellaneous chemistry set (paste, pencils, pens and markers, water colors, glues, fluid/rubber erasers, crayons, oil pastels, chalk, moulding clays, inks);
L. Paper (colored and/or scented);
M. Air fresheners (deodorizer, scented candles, gels, oil spray, dehumidifier);
N. Lubricants, brake fluid and rust inhibitors.

[Reference: Section II. Scope and Coverage FDA MC 2013-045]

Annex 3: Screenshots
BoC website link and MS Excel file of regulated materials

BoC website link to list of regulated imports (select regulated imports by Category)


Downloaded MS Excel file of list of regulated imports by category


References:

FDA Memorandum Circular 2013-045 "Guidelines on notification of selected household urban hazardous substances (HUHS) Products" – for list of HUHS

FDA Memorandum Circular 2014-003 "Filing and receiving of registration, licensing, and other applications using the integrated form" – use as guide for LTO application

FDA Memorandum Circular 2015-006 "Release of imported household/urban hazardous substances (HUHS) finished products from the Bureau of Customs (BoC) intended solely for own consumption"