

NEW BPOM REGULATION ON IMPORTING DRUGS AND FOOD

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The Head of the National Drug and Food Control Agency (*Badan Pengawas Obat dan Makanan* – “**BPOM**”) recently issued Regulation No. 27 of 2013 on The Supervision of Drugs and Food Imports into Indonesian Territory which came into effect on 28 May 2013. This Regulation repeals and replaces the previous regulations on Imports of Processed Foods, Cosmetics and Drugs.

Additional Requirements

Under the Regulation, in addition to a distribution permit (*izin edar*) and any applicable requirements under the prevailing import law, importers of drugs and food require approval from the Head of BPOM, ie an Import Certificate (*Surat Keterangan Impor* – “**SKI**”) which is valid for one import. This requirement also applies to imports in free trade areas and free ports.

The imported products must meet the following storage time requirements:

1. At least 1/3 of the storage life for drugs, traditional medicines, quasi drugs, health supplements, and cosmetics;
2. At least 9 months before the expiry date for biological products; and
3. At least 2/3 of the storage life for processed food.

Registration Procedure

1. The Regulation introduces an online procedure for applying for an SKI from the Head of BPOM. Applicants must first register on the BPOM official website to acquire a user ID and password by submitting an online registration form with the required supporting documents.

In general the SKI application is submitted online accompanied by electronic documents (pdf file) of the required supporting documents, namely (a) the Distribution License

Approval; (b) the Analysis certificate; (c) the Invoice; (d) the Packing list; (e) the Bill of Lading, or Air Way Bill; and (f) the Non-tax State Revenue (*Penerimaan Negara Bukan Pajak*) payment receipt.

For an SKI for vaccines, the application must also be enclosed with (a) the Batch/lot release certificate issued by the authorized institution from the exporting country; and (b) the Summary batch/lot protocol issued by the producer. Vaccines will be further evaluated and tested by the BPOM, for which the applicant will bear the costs.

For SKI for traditional medicines, quasi drugs, cosmetics and health supplements, the product name stated in the invoice has to be the same as that stated on the Distribution License. SKI applications for cosmetics may be exempt from this obligation, if the producer submits an affidavit.

SKI applications for processed food must also satisfy certain requirements provided in the Regulations, namely:

an Approved label at the registration stage;

2. an Affidavit from the producer, if the exporter and the producer are different parties, or the import documents and the distribution license does not state the same processed food name;
3. a Recommendation letter from the Minister of Agriculture for animal-based processed foods; and
4. any other Certificates/statements required under the applicable laws (if any).

The SKI will be issued within one working day of the SKI application requirements being fulfilled. SKIs are issued in electronic form (paperless) and can be printed out by the applicant company if necessary, or manually in the event of force majeure or at POM Centers (

Balai Besar/Balai POM) that have not yet been equipped with the Indonesia National Single Window system.