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Philippines Draft Policy on Polymer Exemption application

The Draft Policy on Polymers and Polymer of Low Concern (PLC) Exemption from the Pre-Manufacture and Pre-Importation Notification (PMPIN) process has been issued on DENR-EMB website for more than half a year. The new policy is not yet finalized, and the Polymer Exemption application is still suspended by DENR-EMB. Then the applicant must choose SQI or PMPIN for the polymers.

Compared with the old policy, the Draft Policy mainly has the following changes.

1. Add Polymer Exemption conditions- low concern polymer

The low concern polymer shall fall into one of the categories:

- a. Polymers that have:
- Number Average Molecular Weight (NAMW) equal to or greater than 10,000 Da,
- Less than 5% of oligomers with MW lower than 1000 Da and less than 2% of oligomers with MW lower than 500 Da, and
- An Functional Group Equivalent Weight (FGEW) for cationic polymers of greater than 5000 Da.
- b. Polymers that have:
 - NAMW equal to or greater than 1000Da and less than 10,000 Da,
- Less than 25% of oligomers with MW lower than 1000 Da and less than
 10% of oligomers with MW lower than 500 Da, and
 - -No reactive functional groups in excess of the levels of 2% by weight.

2. Add one data requirement:

Test data/report to prove that the polymer falls in the criteria of low concern polymer (GPC, IR Spectroscopy and others).

3. Prolong processing time:

The DENR-EMB shall review the Polymer Exemption application within forty (40) working days from receipt of the application.

4. Limit supplement time

In case of incomplete submission of the requirement, a letter for additional information shall be issued to the applicant. Failure to submit the additional information within 60 days upon receipt of letter shall consider their application "null and void".

In addition, the Draft Policy also gives some terms definition and transitional period. **Definition:**

Applicant – Philippine companies/industries that are registered to import and/or to manufacture new polymer.

Cationic Polymer – a polymer containing a net positively-charged atom/s or associated group/s of atoms covalently linked to its polymer molecule. Examples are the ammonium, phosphonium and sulfonium cations.

Functional Group Equivalent Weight (FGEW) – as the ratio of the Number Average Molecular Weight (NAMW) to the number of functional groups in the polymer. It is the weight of a polymer that contains one formula weight of the functional group. NAMW as thearithmetic mean average of the molecular weights of all molecules in a



aggregation and branching.

polymer, not taking into account unreacted monomers and other reactants but must include oligomers. statistical average molecular weight ofall the polymer chains. **Gel Permeation Chromatography (GPC)** – is an analytical technique that separates dissolved macromolecules by size based on their elution from columns filled with a porous gel. It can measure absolute molecular weight, molecular size and intrinsic viscosity, and generate information on macromolecular structure, conformation,

Infrared (IR) Spectroscopy – is the analysis of infrared light interacting with a molecule.IR Spectroscopy measures the vibrations of atoms, and based on this it is possible to determine the functional groups.

Molecular Weight (MW) – is the mass of a molecule of an element or compound. **Monomer** – molecule that has reactive functional groups or double/triple bonds capable to forming a polymer. A chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

New Monomer – monomers not listed in the PICCS.

Reactant – a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition

Oligomer - a compound intermediate between a monomer and a polymer, normally having a specified number of units between about five and a hundred.

Polymer – (1) means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

- (2) is a substance composed of more than 50% of molecules containing a sequence of at least three monomer units covalently bound to at least one other monomer unit or other reactant;
- (3) has molecules distributed over a range of MW; and
- (4) has no single MW molecule reaching 50% (w/w) of total molecules.

Polymer of Low Concern (PLC) – (a) must meet the definition of polymers;

- (b)cationic polymercan be exempted if the FGEW is >5000 Daltons; and
- (c)must not be unstable, degradable, decompose, or depolymerize.

Transition

All polymers previously granted Exemption are no longer subject to this policy. All new polymers that meet the criteria are given one year to comply. Polymers that do not meet the PLC criteria should comply with the PMPIN procedures.

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