REACH provisions for polymers and monomers

Identification of polymer substances

Polymers are substances whose structure results mainly from the repetition of low molar mass units (monomers). Plastics are examples of polymers. Manufacturers and importers have to identify whether a substance falls under the definition of a polymer in accordance with REACH article 3(5). In this article, a polymer is defined as a substance meeting the following two criteria:

- a) over 50 percent of the weight for that substance consists of polymer molecules. A "polymer molecule" is a molecule that contains a sequence
- of at least 3 monomer units*, which are covalently bound to at least one other monomer unit or other reactant;
- b) the amount of molecules presenting the same molecular weight must be less than 50 weight percent of the substance.
- The preferred method to identify whether a substance falls under the definition of a polymer is Gel Permeation Chromatography (GPC).
- * A "monomer unit" means the reacted form of a monomer substance in a polymer.

Whenever a substance does not fall under this definition or whenever it is not scientifically possible to establish whether the substance falls under this definition, the substance should be considered as a standard substance with the relevant obligations.

Tasks and obligations for the manufacture or import of polymer substances

Polymer substances are for the time being exempted from registration and evaluation to preserve workability and to focus resources on substances of more concern.

However, polymers may still be subject to authorisation and restriction and general rules on information down the supply chain and classification/labelling shall apply.

Moreover, manufacturers and importers of polymers must submit a registration to the European Agency of Chemicals for the monomer substance(s) or any other substance(s), that have not already

been registered by an actor up the supply chain, if both the following conditions are met:

- a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomer units and chemically bound substance(s);
- b) the total quantity of such monomer substance(s) or other substance(s), i.e. the quantity of these substances ending up in the final polymer substance as unbound or chemically bound to the polymer, makes up 1 tonne or more per year.

Tasks and obligations for the formulation or import of polymer preparations

Substances are commonly added to polymer for the purpose of adjusting or improving the appearance and/or the physicochemical properties of polymeric material. Examples of polymer additives include pigments, lubricants, thickeners, antistatic agents, compatibilisers, antifogging agents, nucleating agents, flame retardants, etc.

In accordance with the REACH definition of a substance, any additive necessary to preserve the stability of a polymer substance is regarded as a constituent of that polymer. Consequently, the manufacturer or the

importer of a polymer containing an unbound stabiliser does not need to register it.

A polymer containing any unbound additive other than polymer stabilisers must however be treated as a preparation composed of the mixture of polymer substance and the additive substance. There is the general obligation to register the additive substance manufactured or imported on its own or in the polymer preparation in quantities of at least 1 tonne per year.

Tasks and obligations for the manufacture or import of monomers

Manufacturers or importers of monomers have to register their monomers in accordance with the normal registration obligation laid down in article 6 of REACH. Although monomers are by definition intermediates, these substances cannot be registered in accordance with the provisions which normally apply to on-site isolated or transported intermediates. If a natural or legal person manufactures or imports a substance to be used as a monomer and as non–monomeric intermediate, he needs to submit one "standard" registration dossier. The part of the tonnage manufactured or imported for a use as non-monomeric intermediate and handled under

strictly controlled conditions, will not need to be taken into account for the information requirement of the registration dossier.

Monomers are by definition intermediates. These substances cannot be subject to authorisation under REACH for the use as monomers in polymerisation reactions.

The manufacturer or importer of a monomer substance has otherwise the same obligations under REACH as for any standard substance: general rules on evaluation, restriction, information down the supply chain and classification and labelling shall therefore apply.



