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GUIDANCE ON DEFINITIONS OF KEY TERMS FOR NEW CHEMICAL NOTIFICATION

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or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2 rue André-Pascal
75775 Paris Cedex 16
France**

**Fax: (33-1) 44 30 61 80
E-mail: ehscont@oecd.org**

FOREWORD

This document provides a set of definitions of key terms that apply to groups of chemicals that could be subject to reduced notification requirements and to exemptions and exclusions.

Taking into account the need to facilitate work sharing between governments on new chemical notifications, a draft set of definitions was published in 2005 [ENV/JM/MONO(2005)7]. These definitions were prepared to initiate discussion on the standardisation of such definitions and the manner in which they could be incorporated into new and existing chemical assessment and management schemes, including notification exemption and exclusion requirements.

The working definitions were submitted to a two-year period evaluation, during which comments from governments and the general public were solicited on the phrasing and possible applicability of such definitions. The terms were also tested by those participating in the pilot phase of the parallel process for the notification of new chemicals [see ENV/JM/MONO(2006)12]. Based on the comments received, some of the definitions have been changed and the final version follows.

Governments are now encouraged to use the definitions as appropriate within their national authorities, and to promote their use with non-member countries that are either developing new chemicals notification schemes or modifying existing ones.

The next phase of work in OECD will involve the preparation of proposals for a mutual understanding of the implementation of these definitions.

GUIDANCE ON DEFINITIONS OF KEY TERMS

Articles

Article means a manufactured object formed to a specific shape or design relevant to its function. An article undergoes no change of chemical composition or form during its use, other than that which is incidental to its use, that which is an intrinsic part of its use, or that which has no commercial purpose separate from that of the article.

Intermediates

Intermediate is a substance produced and consumed in the course of the manufacture of another substance.

Consumed means the substance has chemically reacted to form a different chemical substance, although some of the substance may remain as an impurity in the final product.

Non-isolated intermediate is an intermediate that is not intentionally removed (other than sampling or disposal), from the equipment in which it is produced. The equipment includes the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, any equipment through which the chemical substance passes during a continuous flow or batch process, and vessels in which the substance is transiently held.

Site-limited Intermediate is an intermediate that is manufactured and consumed at the site of manufacture.

Transported Intermediate is an intermediate that is manufactured at one site and transported to a second site where it is consumed.

Imported Intermediate is an intermediate that is imported and transported directly to the site where it is consumed.

Site is defined as an individual location, which includes one or more different legal entities, to which there is controlled access.

Hydrates

Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water".

Substances occurring in nature

Substances occurring in nature are substances that are unprocessed, processed only by manual, gravitational, or mechanical means, or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means, without chemical change in the substance.

Polymers

Polymer means a substance consisting of:

- 1) Molecules characterized by the sequence of one or more types of monomers units;
- 2) A simple weight majority of molecules containing at least three monomer units that are covalently bound to at least one other monomer unit or reactant;
- 3) Less than a simple weight majority of molecules of the same molecular weight; and
- 4) Molecules distributed over a range of molecular weights wherein differences in the molecular weights are primarily attributable to differences in the number of monomer units.

Incidental reaction products

Incidental reaction products are substances produced when a substance undergoes a chemical reaction that is consequent to the use to which the substance is put or that results from storage or from environmental factors.

Impurity

An **impurity** is an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it was not intentionally added, nor does it enhance the commercial value of that substance.

Mixtures

Mixture means a mixture or a solution composed of two or more substances in which they do not react.

Research and Development

Research and development substance means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objective of which is:

- 1) to create or improve a product or process; or
- 2) to determine the technical viability or performance characteristics of a product or process; or
- 3) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials other than marketing, in order to modify the technical specifications in response to the performance requirements of potential customers.