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**ENVIRONMENT DIRECTORATE  
JOINT MEETING OF THE CHEMICALS COMMITTEE AND  
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

**SUMMARY OF THE STANDARD OPERATING PROCEDURES (SOP) FOR THE OECD CLEARING  
HOUSE ON NEW CHEMICALS PARALLEL PROCESS**

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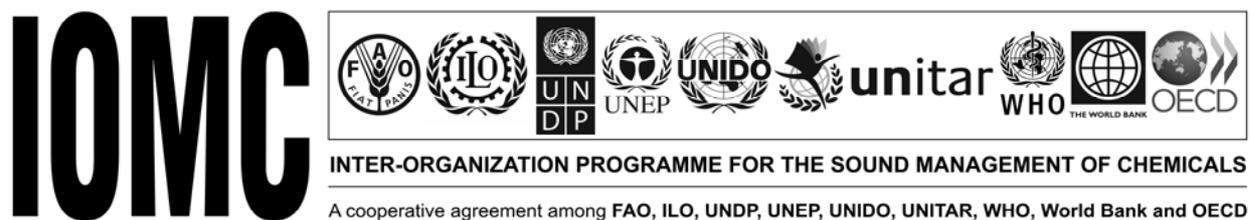
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**OECD Environment, Health and Safety Publications**

**Series on New Chemicals**

**Summary of the Standard Operating Procedures (SOP)  
for the OECD Clearing House on New Chemicals Parallel  
Process**



Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

Paris 2012

**Other OECD publications on New Chemicals:**

*Standard Operating Procedures (SOP) for the OECD Clearing House on New Chemicals Parallel Process [ENV/JM/MONO(2012)26] (2012)*

*Data Analysis of the Identification of Correlations Between Polymer Characteristics and Potential for Health or Ecotoxicological Concern [ENV/JM/MONO(2009)1] (2009)*

*Guidance on Definitions of Key Terms for New Chemical Notification [ENV/JM/MONO(2007)13] (2007)*

*Pilot Phase of the OECD Parallel Process for the Notification of New Chemicals [ENV/JM/MONO(2006)12] (2006)*

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*This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations*

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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## FOREWORD

As a first step towards the mutual acceptance of new chemical notifications, the OECD Clearing House on New Chemicals has developed a multilateral notification arrangement which involves acceptance of hazard assessments by participating jurisdictions. This process, termed the 'Parallel Process', enables companies to declare to all affected countries at the time of first notification that it wants them to cooperate, share information and build on the efforts of the country where it will first initiate manufacture or import of the chemical. The hazard assessment is developed by the 'lead' jurisdiction and can then be utilized by other participating jurisdictions when the chemical is subsequently notified in the other participating jurisdictions.

The Parallel Process was initiated in 2005, with a pilot phase to test how the process would work in practice. During this pilot phase, benefits to both industry and governments were realized, and improvements to the process were identified. One such improvement was enhancing the guidance document in order to streamline the process, to make it consistent, and to make the operation of the process transparent to all interested parties.

This document is a *summary* of a complete guidance document, published elsewhere [*see* ENV/JM/MONO(2012)26] for both notifiers and jurisdictions participating in the Parallel Process.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

## **I. Introduction**

1. This document is a summary of the publication “Standard Operating Procedures (SOP) for the Parallel Process (PP)” [ENV/JM/MONO(2012)26]. It is intended to give a brief overview only and the complete PP SOP should also be consulted by notifiers and jurisdictions contemplating participating in the PP.

2. The vision of Mutual Acceptance of new substance Notifications (MAN) includes acceptance of hazard assessments by participating jurisdictions as the first step. Under the PP, a company notifies to multiple jurisdictions using a Predetermined Set of Information (PSI), and authorises participating jurisdictions to share information when conducting their reviews. A jurisdiction chosen by the notifier agrees to serve as the lead jurisdiction and to conduct the hazard assessment or review/accept a hazard assessment provided by the notifier. Input is provided from the other participating jurisdictions. The final hazard assessment can then be used in the risk assessment of a chemical in other participating jurisdictions.

## **II. Overview of the PP**

### ***Determining the participating jurisdictions***

3. The notifier identifies the jurisdictions (agencies granted authority by a government or group of governments to oversee the regulation of chemicals within a particular geographic region) to which they intend to submit a notification. The notifier then makes a request for a jurisdiction to act as lead and contacts the other jurisdictions where it wishes to notify a chemical and requests their agreement to participate as secondary or observer jurisdictions.

4. Agreement to Participate (ATP) letters must be signed by each participating jurisdiction and the notifier every time there is a new PP notification. The notifier must complete the Multi-lateral Limited Disclosure Agreement (MLDA) in the ATP letter and send it to all of the participating jurisdictions. Participating jurisdictions must then amend and sign the cover letter (first page of the ATP) and then send the ATP letter back to the notifier. The notifier must then sign the MLDA and provide copies of all the signed ATP letters to the lead jurisdiction.

### ***Pre-Notification Consultation phase***

5. The required information for a notification will depend on the type of chemical, the quantity being introduced, and also the way that it will be introduced and used within the jurisdictions. Therefore, the notifier should propose the PSI for a chemical on a case by case basis; however, there are general requirements described in the complete PP SOP.

6. The notifier provides the proposed PSI to the lead jurisdiction who oversees and coordinates communications with the other participating jurisdictions and organises the Pre-Notification Consultation (PNC) meeting. Once the lead and secondary jurisdictions and the notifier agree on the contents of the PSI it can be finalised.

### ***Notification and Assessment Phase***

7. The notifier submits the notification package to the lead jurisdiction and summaries or full copies of the studies listed in the final PSI to the other participating jurisdictions. The lead jurisdiction will then carry out the hazard assessment as per its legally required assessment time-frame and the regulatory assessment procedures in that jurisdiction.

8. The hazard assessment is shared with all participating jurisdictions and the notifier. The notifier may wish to stagger notification to the secondary jurisdictions.

III. Flowchart of the PP

