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**PILOT PHASE OF THE OECD PARALLEL PROCESS FOR THE NOTIFICATION OF NEW
CHEMICALS**

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This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

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, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. 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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Under the auspices of the OECD New Chemicals Task Force, a two year pilot project is testing a parallel notification process aimed at simplifying and streamlining access to multiple markets for new chemicals, while ensuring high standards of health and environmental protection. Countries are working cooperatively to increase mutual understanding and acceptance of hazard assessments of new substances.

The Parallel Process refers to a company notifying to multiple jurisdictions and authorizing participating governments to sharing information when conducting their reviews. Within the Parallel Process, there are 3 possible ways in which countries can participate: as lead, as secondary or as observer. The lead country would develop the hazard assessment considering the comments received by all participants and the final hazard assessment would be issued to the notifier. Secondary countries are those for whom a formal notification will be received but not until the final hazard assessment is complete. The lead country would be responsible for reviewing the information submitted, developing the hazard assessment and sharing the hazard assessment with the secondary countries for review. Observer status allows the country to receive information and monitor how assessments are conducted and provide informal input on the hazard assessment, without affecting the timing or content of the process. Jurisdictions participating in the Parallel Process shall utilize current evaluation processes to conduct their notification reviews. In addition, throughout this process, jurisdictions retain the sovereign right to make their own risk-based decisions.

The Parallel Process consists of three phases: I) Pre-notification Phase; II) Notification Phase; and III) Assessment Phase. These phases are described in Annex 1.

ANNEX 1

I. Pre-notification Phase

1. The company identifies a candidate substance for the Pilot and decides where it would like to notify for purposes of the Pilot (i.e., identifies the target jurisdictions).
2. The company determines, via current processes, whether or not notification(s) will be needed, in each such jurisdiction.
3. From among the target jurisdictions, the company identifies which to include in the Pilot Phase for the Parallel Process as lead or secondary country. Notifications to any jurisdiction(s) not included in the Parallel Process will be handled separately.
4. The company contacts the potential lead authority and requests their agreement to participate and to be the lead authority.
5. The company contacts the other selected authorities and requests agreement to participate as secondary countries. If any authority declines to participate, the company revises its plans accordingly.
6. The company may identify countries where it would be beneficial to engage as observers.
7. A Modus Operandi (MO) is signed by all participating parties. The MO documents a general agreement by the participants by setting operational procedures and boundaries for sharing information on new industrial chemicals. A copy of the MO will be held by each participating country, and a copy from each country will be provided to the notifier. In addition, an Agreement to Participate (ATP) letter will be signed by each participating country for each new chemical to be assessed under the Parallel Process. A copy of the ATP letter will be held by each participating country and the notifier. At any time during the process, a party may wish to withdraw from participation. Obligations specified in the ATP will still be in effect.
8. In preparation for a Pre-Notification Consultation (PNC), the company gathers a draft Predetermined Set of Information (PSI) for the substance, which is structured around the OECD Minimum Pre-marketing set of Data (MPD) endpoints and will be determined during the PNC on a case-by-case basis. Contents of the PSI should address, as appropriate, physical/chemical properties, environmental fate parameters (including biodegradation and bioaccumulation), ecotoxicity and health effects information relevant to the notified substance, and any additional information in the company's possession. The PSI may be revised accordingly as a consequence of the PNC discussions.
9. The draft PSI package could include (to be determined on a case-by-case basis):
 - basic information on the characterization and intended uses of the substance, any test results on the notified substance that are in the company's possession and test reports for the experimental data generated; and/or
 - a list of any proposed testing that will be completed in time for inclusion in the notification and a description of the test methods (PSI); and/or
 - any read-across data (e.g. experimental data generated for closely related structure(s) of the notified substance) that will address elements of the PSI not covered by direct testing (plus a rationale supporting the suitability of the read-across data to meet the need); and/or

- any QSAR or modeling outputs and a list of any QSAR or modeling outputs that will be completed in time for inclusion in the notification, and that will address elements of the PSI not covered by direct testing (plus a rationale supporting the suitability of the outputs to meet the need); and/or
- a rationale for why any other information elements need not be addressed and identification of non-OECD protocols.

10. The company provides the draft PSI package to the lead authority and to each of the other participating authorities prior to the PNC in order to enable a preliminary review of the notification package.

11. The lead country will chair the PNC meeting(s), or teleconference(s). The intent of the first PNC meeting will be to discuss the PSI with all parties. The company would review the draft PSI package and explain the rationale for its content. The decision on the acceptability of any proposed testing, including approaches used to address the PSI and how these approaches satisfy the needs of participating jurisdictions, may require several meetings before final acceptance by all participants. The participants would work to promptly complete this process, within a timeframe agreed at the start of the PNC process.

12. Subsequent meetings may take place prior to agreement on the PSI depending on the substance, type of data (i.e., experimental, surrogate and/or predicted) submitted by the company, test methods used to generate the data and level of detail of documentation (i.e., test reports, robust study summaries etc.). These meetings may be government only and/or government-industry.

13. Draft final decisions on the PSI including approaches used to address the PSI will be documented and discussed with all participants during the final PNC. Final decisions on the PSI which are based on legal needs and professional judgments, are documented by the lead country and can include:

- Identifying mutually accepted needs
- Derogations
- Areas of disagreement

The final decision is communicated to the notifier by the lead country.

II. Notification Phase

14. The company submits the notification package to the lead country, including any specific notification form as required and payment of any required fees.

15. The lead country assesses the notified substance as per its legally required assessment time clock, following their national regulatory assessment procedures.

III. Assessment Phase

16. Based on the review of the notification package, the lead country prepares a draft hazard assessment for the notified substance.

- If a notifier submitted a proposed hazard assessment with its notification package, the lead country will send a draft hazard assessment to the notifier and the secondary countries simultaneously (Option A, proceed to paragraphs 17 & 18).
- If the notifier does not submit a hazard assessment with its notification package the lead country can choose to send its draft hazard assessment to the notifier and the secondary countries simultaneously or to send its draft hazard assessment to the secondary countries only (Option B, proceed to paragraphs 19 & 20).

Option A:

17. The secondary countries will promptly review and provide comments to all participants including the notifier and may accept the draft hazard assessment. If questions arise during the review period, the lead country will attempt to respond and may engage the company, if further clarification is required. It must be noted that the lead country has not “stopped the clock” for their review period and will need to meet their regulatory commitments. If the secondary countries’ review results do not come on time for the lead country to meet its regulatory commitment, the lead country will proceed to make its regulatory decision.

18. The lead authority will develop the final collective draft hazard assessment considering comments received from the secondary countries and the notifier, if appropriate. This will be issued to the notifier for additional comments prior to finalization (proceed to paragraph 20).

Option B:

19. The secondary countries will promptly review and provide comments, where applicable and may accept the draft hazard assessment. If questions arise during the review period, the lead country will attempt to respond and may engage the company, if further clarification is required. It must be noted that the lead country has not “stopped the clock” for their review period and will need to meet their regulatory commitments. If the secondary countries’ review results do not come on time for the lead country to meet its regulatory commitment, the lead country will proceed to make its regulatory decision (proceed to paragraph 20).

20. The lead authority will develop the final collective draft hazard assessment considering comments received from the secondary countries. This will be issued to the notifier for comments, and subsequently, finalized by the lead country.

21. After receipt of the final hazard assessment, the notifier supplies national notification forms and the completed collective hazard assessment to the secondary countries, with any fees as required by those countries. The notification submission to a secondary country will trigger the start of the assessment clock for that jurisdiction.

22. If any country also prepares a risk assessment for the notified substance as part of their national regulatory assessment process it can be circulated to participating jurisdictions when completed. Risk assessment prepared and submitted by the notifiers can also be circulated to all participants. The other participating authorities may consider this in their risk assessments.

23. Final regulatory conclusions as determined by the lead and secondary countries are communicated to the notifier as per countries’ administrative procedures.

ANNEX 2: PARALLEL PROCESS FLOW

