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THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

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

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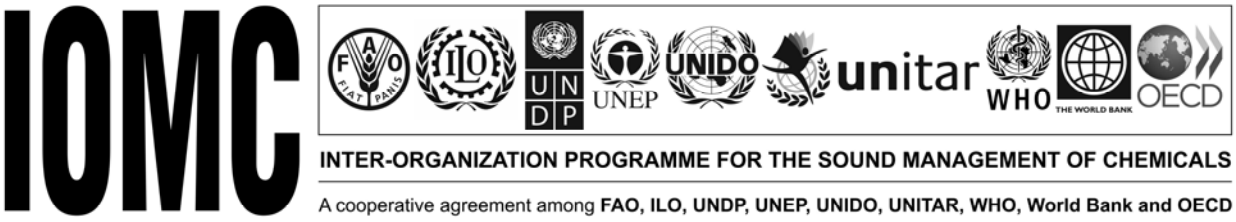
OECD Environment, Health and Safety Publications

Series on New Chemicals

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



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Paris 2012

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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 provides detailed guidance for both notifiers and jurisdictions participating in the Parallel Process, and will be revised, as needed, to incorporate improvements identified by participants. A companion document, which summarises the key features in this document is published elsewhere [*see* ENV/JM/MONO(2012)27]

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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I. Introduction

1. The vision of Mutual Acceptance of new substance Notifications (MAN) includes acceptance of hazard assessments by participating jurisdictions as the first step.

2. Under the Parallel Process (PP), a notifier submits a notification for a new substance into multiple jurisdictions using a Predetermined Set of Information (PSI), and authorises the participating jurisdictions to share information when conducting their reviews. A jurisdiction is requested by the notifier to serve as lead jurisdiction, and if it agrees to serve in this capacity, it conducts the hazard assessment or reviews/accepts 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.

3. This guidance document will be revised, as needed, to incorporate improvements identified by notifiers and jurisdictions.

II. Acronyms

ATP	Agreement to Participate letter
CBI	Confidential Business Information
MAN	Mutual Acceptance of new substance Notifications
MLDA	Multi-lateral Limited Disclosure Agreement
MOU	Memorandum of Understanding
MPD	OECD Minimum Pre-marketing set of Data
PNC	Pre-Notification Consultation
PP	Parallel Process
PSI	Predetermined Set of Information
SIAR	SIDS Initial Assessment Report
SIDS	Screening Information Data Set
SOP	Standard Operating Procedures

III. Glossary

Joint notification. A PP notification involving two or more notifiers working cooperatively to have a new chemical assessed.

Jurisdiction. The agency granted authority by a government or group of governments to oversee the regulation of new chemicals within a particular geographic region.

Lead jurisdiction. The jurisdiction that will write the hazard assessment and organise and distribute correspondence during the PNC stage and chair any teleconferences.

Notification. A document submitted in order to introduce a new chemical into a jurisdiction.

Notifier. The company/organisation/individual that submits a new chemical notification in the lead and secondary jurisdictions.

Observer jurisdiction. A jurisdiction that will not be receiving a notification for the new chemical under the PP but has accepted an invitation from the notifier to monitor and make suggestions in the review process. An observer jurisdiction may have already assessed the chemical and, if so, are encouraged to provide a copy of their assessment report as part of the process. Observer jurisdictions are welcome to provide comments at any stage of the PP but are not obliged to do so. Conversely neither the notifier nor the other participating jurisdictions are required to respond to comments from observer jurisdictions.

Participating jurisdictions. The lead, secondary and observer jurisdictions.

Primary notifier. The company/organisation/individual that is the primary contact in a joint notification.

Secondary jurisdiction. A jurisdiction, other than the lead jurisdiction, to which the notifier is intending to submit a notification for the subject chemical and which has been invited by the notifier to participate in the PP. The role of the secondary jurisdiction is to participate in the PNC, including providing input on the proposed PSI, and provide comments on the draft hazard assessment prepared by the lead jurisdiction.

Secondary notifier. Any company/organisation/individual involved in joint notification that is not the primary notifier.

IV. Communication Protocol

4. Once the notifier has obtained signed ATP letters from the participating jurisdictions, further communications between the notifier and participating jurisdictions are through the lead jurisdiction unless other arrangements have been made. Communications should also be shared with all of the participating jurisdictions so that everyone is aware of what is happening with the PP application at any time.

Forms of communication

5. It is preferable that all documents be submitted by the notifier to the lead and secondary jurisdictions in electronic format. If this is not possible, then hard copies (of all non-electronic documents) are sent by the notifier to the lead and secondary jurisdictions. It is recommended that copies also be sent to any observer jurisdictions.

6. Where possible, teleconferences should be organised in such a way as to allow as many participants to attend during Monday to Friday 9 – 5 working hours. The lead jurisdiction organises all teleconferences 14 days or more in advance where possible. However, the lead jurisdiction may ask the notifier to organise any teleconferences that include the notifier as a participant. An agenda should be developed by the lead jurisdiction and distributed prior to the teleconference. If there are any specific issues that need to be discussed a brief report on these should also be distributed prior to the teleconference. The lead jurisdiction should also produce a summary of the outcomes and actions arising from the meeting.

7. If a teleconference is organised involving a subset of all the participating parties (e.g., a notifier would like to discuss a particular matter that only affects a small number of the participating jurisdictions), the lead jurisdiction should still attend when possible. If the lead jurisdiction cannot attend, then a brief summary of the teleconference is to be provided by the notifier to the lead jurisdiction and to the jurisdiction(s) that participated in the teleconference.

8. Language and geographic distribution may be barriers to communication and all participating jurisdictions and notifiers should consider these barriers. If communication is in a language in which the lead or a secondary jurisdiction is non-native, native language jurisdictions and the notifier should assist non-native language jurisdictions in order to smooth the process of the notification. For example the notifier should prepare summaries of the test reports in the native language of the lead or secondary jurisdictions when requested by the jurisdictions. If a teleconference is organised in a language which is not native in the lead or a secondary jurisdiction, native language jurisdictions and the notifier should assist by drafting a summary of the teleconference. Non-native language jurisdictions may also choose to submit their questions in written form in advance and/or request a written response to their questions.

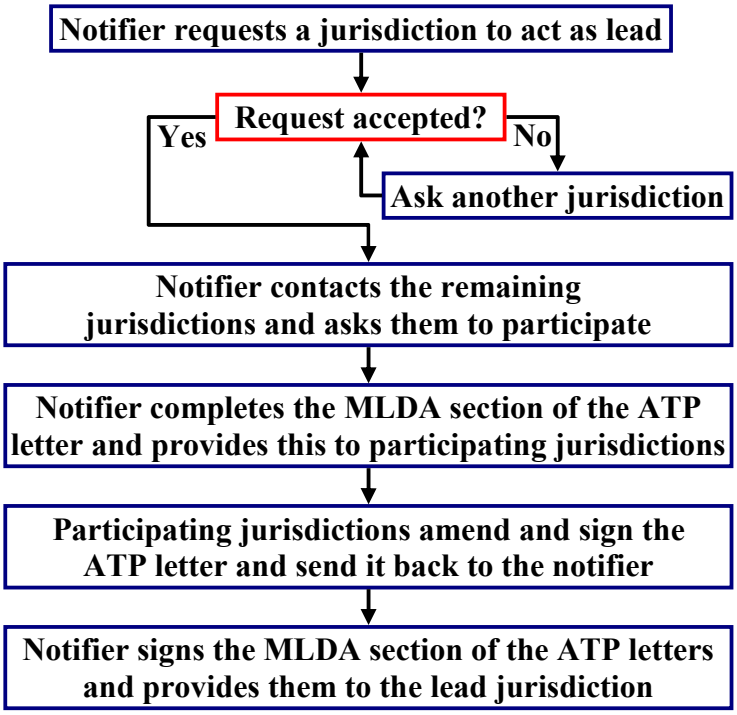
Confidentiality

9. Confidential third party information: In certain circumstances, a notifier may not have access to all information required for a complete PSI on a chemical being notified. This may be because a third party holds this information, considers the information to be confidential information, and is not willing to release it to the notifier. If the third party holding this information agrees, then the information can be sent directly by the third party to the participating jurisdictions who are obliged to keep it confidential from the notifier. When the third party provides the information to the participating jurisdictions, the third party must include a cover letter specifying what information is to be kept confidential. If no information is specified confidential, the participating jurisdictions should treat all the information provided as confidential and not disclose any of it without receiving written permission. If the third party provides the information to only one jurisdiction then that jurisdiction should ensure that it has permission from the third party to provide the information to the other participating jurisdictions, before doing so. Please note that there may be some jurisdictions that cannot accept the use of third party information under their legislation. However, these jurisdictions could still be observers in PP notifications where such information is used.

10. The hazard assessment report must not be made available to anyone (jurisdiction, company, organisation or individual etc) who has not signed an ATP letter for that particular chemical notification. The only exception would be if the notifier or third party that provided the information in the report gives written approval for a jurisdiction to do so.

11. No Confidential Business Information (CBI) of the notifier for the notified substance will be disclosed to the public without the consent of the notifier for the notified substance except in conformity with the laws of the participating jurisdictions. The notifier shall make his or her claim for confidentiality when the notification dossier is submitted to these jurisdictions. Any information exchanged between participating jurisdictions during the PP cannot be disclosed to the public except in accordance with the laws of those jurisdictions, due consideration being given to the notifier's claim for confidentiality, if any. It is the notifier's responsibility to be aware of such laws within the participating jurisdictions and how they may affect any requests for confidentiality.

V. Determining Participating Jurisdictions



12. The notifier identifies the jurisdictions to which the notifier intends to submit a notification. Normally, there should be at least one secondary jurisdiction involved in the PP notification. However, at the discretion of the lead jurisdiction, PP notifications may be allowed where there are just the lead and observer jurisdictions, although this is anticipated to be an exceptional situation.

13. Notifier requests a jurisdiction to act as lead.

a) The lead jurisdiction is the jurisdiction to which the notifier will submit the notification first (after completing the PNC process).

b) If a jurisdiction declines to participate as the lead, the notifier should request a different jurisdiction to act as lead.

c) The lead jurisdiction asks the OECD Clearing House on New Chemicals secretariat to generate a reference number for the PP notification and update the tracking sheet on the OECD Clearing House on New Chemicals protected Website.

d) The lead jurisdiction ensures that the OECD Clearing House Secretariat is kept updated on the progress of the PP so that the tracking sheet is up to date.

14. The notifier contacts the other jurisdictions where it wishes to notify a chemical and requests their agreement to participate as secondary jurisdictions.

15. The notifier may choose to invite jurisdictions to participate as observers.

a) Observer jurisdictions can join or leave the PP at any time after being invited by the notifier and are not obliged to contribute.

b) The notifier may accept suggestions for observer jurisdictions from other participating jurisdictions.

16. A Memorandum of Understanding (MOU) is signed by all participating jurisdictions involved in a PP notification. The MOU is a general agreement by the jurisdictions that establishes operational procedures and boundaries for sharing information (includes test reports) on new industrial chemicals. The MOU needs to be signed only once by a jurisdiction regardless of how many PP notifications in which that jurisdiction participates. A copy of the signed MOU from each jurisdiction is included on the OECD Clearing House on New Chemicals website.

17. Agreement to Participate (ATP) letters must be signed by each participating jurisdiction (including observer jurisdiction) and the notifier every time there is a new PP notification. The steps involved in signing the ATP letters are detailed below.

a) The notifier must complete the Multi-lateral Limited Disclosure Agreement (MLDA) part of the ATP letter (page 2 onwards) but not sign the ATP letter at this stage.

b) The ATP letter is then sent by the notifier to all of the participating jurisdictions. The lead jurisdiction must then advise the participating jurisdictions and the notifier of the file number that the lead jurisdiction will be assigning to this notification.

c) Participating jurisdictions must then complete and sign the cover letter (first page of the ATP), add the lead jurisdiction's file number and then send the ATP letter back to the notifier.

d) The notifier must then sign the MLDA and provide copies of all the signed ATP letters to the lead jurisdiction.

e) At any time during the process, a party may withdraw from participation; however, confidential information obligations remain in effect. The lead jurisdiction must not distribute the Predetermined Set of Information (PSI) or any confidential information to another jurisdiction until it has received an ATP letter for the particular notified chemical in question from that jurisdiction.

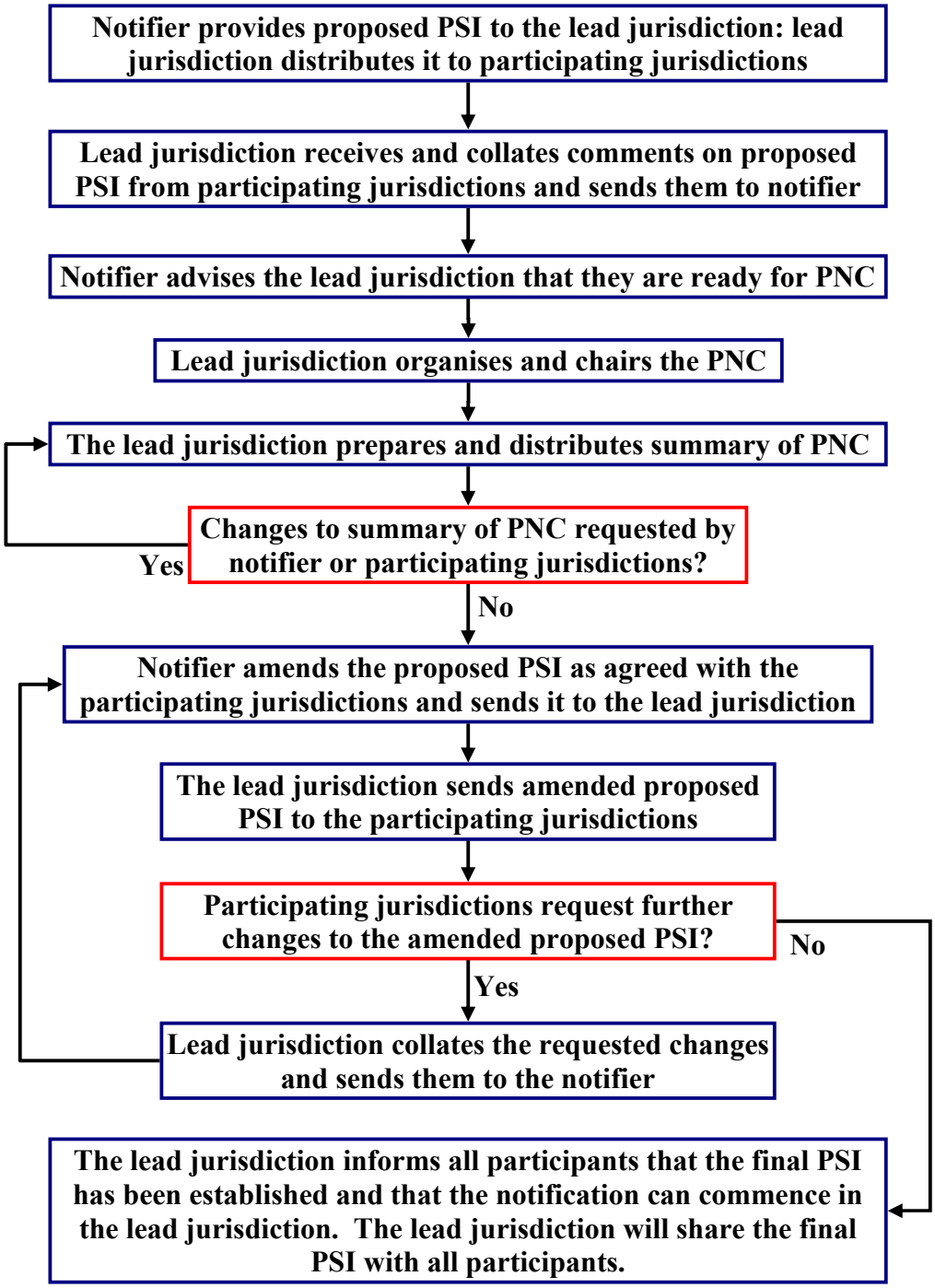
18. If there is joint notification (i.e., notification involving two or more companies working cooperatively), then it is the responsibility of the joint notifiers to identify a 'primary notifier' who will be responsible for communicating with the lead jurisdiction.

a) The joint notifiers are required to submit the PSI/notification packages to the lead jurisdiction.

b) Once the lead jurisdiction has finished and distributed the final report containing the hazard assessment, the joint notifiers would be able to notify a chemical in a secondary jurisdiction only if joint notification is allowed under that jurisdiction's legislation. However, this should have been determined already during the effort to identify participating jurisdictions or during the PNC phase.

c) Where one or more of the joint notifiers does not have access to all of the information in the notification package, then the same arrangements for confidentiality as mentioned above for third party information will apply.

VI. Pre-Notification Consultation Phase



Information requirements

19. 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.

a) Therefore, the notifier should propose a PSI for a chemical on a case by case basis. However, the proposed PSI should be guided by a consideration of the information outlined in the OECD Minimum Pre-Marketing Set of Data (MPD), contain information (including any surrogate data) believed by the notifier to be relevant, and be consistent with the legal requirements of the lead and secondary jurisdictions.

b) The results from all physical/chemical, degradation/bioaccumulation and toxicological (including ecotoxicological) tests on the notified chemical in the possession or control of the notifier must be provided. If the toxicological tests were conducted using protocols that are not consistent with OECD test guidelines, this must be noted. Please note that there may be some jurisdictions or circumstances where tests conducted using protocols that are not consistent with OECD test guidelines will not be deemed sufficient. However, the general expectation should be that all scientifically valid information would be considered as part of the assessment of the notified chemical.

c) If tests are intended to be conducted by the notifier on the notified chemical but are not yet completed (i.e., either under way or planned), this must be stated in the proposed PSI. The notifier must include a description of the testing methods/protocols for any tests that are still to be conducted. Participating jurisdictions must advise the notifier of circumstances when certain results from planned testing may require the development of further information.

d) Read-across data (i.e. experimental data generated for a closely related analogue of the notified chemical) that could address elements of the PSI not covered by direct testing may be provided. Read-across data must be supported by a scientific rationale describing why data for the analogue chemical are relevant for assessing the notified chemical. Please note that there may be some jurisdictions or circumstances where read-across data will not be deemed sufficient.

e) QSAR or modelling outputs and a list of any modelling outputs that will be completed in time for inclusion in the notification that will address elements not covered by direct testing may be included in the proposed PSI. A scientific rationale describing why QSAR data are relevant for assessing the notified chemical must be provided. Please note that not all jurisdictions will accept QSAR or modelling outputs for all endpoints. However, the general expectation should be that all scientifically valid information, including valid modelling outputs, would be considered as part of the assessment of the notified chemical.

f) Animal welfare issues should be considered and tests using animal subjects must be avoided, where possible within the legal authority of the participating jurisdictions.

g) If parts of the proposed PSI are based on confidential third party information that will be submitted separately by a third party, then this must be stated in the proposed PSI along with the name of the third party.

h) Notifiers are encouraged to provide in the proposed PSI information about the potential public, occupational and environmental exposures from the use of a chemical, to allow jurisdictions to determine appropriate notification categories, which may be dependent on exposure criteria.

i) If the notifier is planning on using a waiver/variation for any data requirements then it is recommended that the participating jurisdictions are advised of this when the notifier submits their proposed PSI. This allows the participating jurisdictions to provide the notifier with advice on whether the waiver/variation will be accepted within their jurisdiction as early as possible, giving the notifier more time to make alternative arrangements to provide the data if the

waiver/variation is not accepted, or allowing the notifier to revisit the decision to invite the particular jurisdiction(s) to participate in the PP.

Submitting and reviewing the proposed PSI

20. The notifier provides the proposed PSI to the lead jurisdiction. The lead jurisdiction will send the proposed PSI to all of the secondary and observer jurisdictions. When distributing the proposed PSI, the lead jurisdiction advises the other participating jurisdictions of the time-frame in which responses/comments need to be received by the lead jurisdiction; generally, this should be two weeks but may be longer.

21. Once the lead jurisdiction receives comments from the other participating jurisdictions on the proposed PSI, or the time-frame has elapsed, the lead jurisdiction will collate the comments received and send them to the notifier.

a) It may be necessary to have a "government only" teleconference prior to sending the collated comments to the notifier, if the lead or participating jurisdictions deem it necessary. In such circumstances, it is the lead jurisdiction's responsibility to organise and chair the teleconference, prepare the agenda, and distribute the agenda in advance. The lead jurisdiction summarises the teleconference and incorporates any conclusions from the teleconference into the original comments. These revised comments will then be sent to the participating jurisdictions for checking prior to being sent to the notifier.

b) Observer jurisdictions are encouraged to comment on the information that is provided by the notifier in the proposed PSI. However, the notifier can finalise the PSI with the lead and secondary jurisdictions.

c) Within three weeks of receiving comments on the proposed PSI from the lead jurisdiction, the notifier responds to advise the lead jurisdiction when they will be ready to conduct the Pre-Notification Consultation (PNC) meeting. The PNC should be conducted as soon as possible after the notifier has received the initial comments from the lead jurisdiction. The notifier is not required to provide at the PNC meeting any of the information that may have been requested in the comments on the proposed PSI. However, the notifier should be able to articulate strategies to provide the information, or lay out a rationale why the requested information is not needed. The notifier will discuss these ideas with the participating jurisdictions at the PNC, with the objective of reaching consensus.

22. Once a notifier has received the comments on the proposed PSI and advised the lead jurisdiction that they are ready, the lead jurisdiction organises the PNC.

a) The aim of the PNC is to reach agreement on establishing the PSI and discuss options for providing that information. The notifier provides a briefing about the PP notification during the PNC.

b) The lead jurisdiction chairs the PNC, which is arranged with at least two weeks notice to allow all participants to get organised.

c) The lead jurisdiction prepares an agenda for the PNC and distributes the agenda prior to the meeting.

d) If jurisdictions would prefer to submit written comments, the comments must be sent to the notifier and participating jurisdictions prior to the PNC so that they can be discussed at the PNC if necessary.

e) The time-frame for the notifier to respond to changes to the proposed PSI requested by the lead and secondary jurisdictions is discussed during the PNC as well as the need for any follow up teleconferences or other logistical arrangements.

f) Discussion on the timing for submission of the notification to the lead and secondary jurisdictions also takes place during the PNC.

23. After a PNC, the lead jurisdiction summarises the meeting and circulates this summary to the notifier and the participating jurisdictions.

a) If any of the participating jurisdictions or the notifier wish to offer amendments to the summary of the PNC after the lead jurisdiction first distributes it, they would contact the lead jurisdiction, who would amend the summary where appropriate and redistribute it.

b) The summary focuses on any changes to the proposed PSI requested by the participating jurisdictions.

c) The summary of the PNC also includes a list of the participating jurisdictions and the time-frame for the notifier to respond to the comments from the participating jurisdictions.

24. Once the notifier receives a summary of the PNC from the lead jurisdiction the notifier addresses the requested changes and resubmits an amended proposed PSI or a suitable addendum to the lead jurisdiction.

a) The notifier responds within the time-frame agreed upon during the PNC. If this is not possible, the notifier informs the lead jurisdiction to negotiate a new schedule and inform the other participating jurisdictions.

25. The lead jurisdiction then distributes the amended proposed PSI or a suitable addendum to the other participating jurisdictions.

a) When distributing the notifier's response, the lead jurisdiction proposes a schedule for the secondary jurisdictions to respond. The response time-frame takes into account the amount of information to be reviewed by the secondary jurisdictions.

b) The secondary jurisdictions then review the changes that the notifier made and, if further changes are still needed, then this request is sent to the lead jurisdiction.

26. If further changes are requested to the amended proposed PSI, then the lead jurisdiction communicates this to the notifier and proposes a time-frame for the response. The process of finalising the PSI could happen over multiple steps.

a) Each of the steps would roughly follow the process outlined above, i.e. the lead jurisdiction distributes the notifier's amended proposed PSI to the participating jurisdictions and receives comments from them, and these comments are then sent to the notifier for a response, etc.

b) If any of the participating jurisdictions or the notifier deems that a teleconference would be useful in helping to finalise the PSI, then the lead jurisdiction would organise a teleconference. Note that e-mail based communications are preferred over a teleconference due to potential time and native language differences in the participating jurisdictions.

27. In circumstances where there is an issue related to the PSI that affects only one jurisdiction (not the lead jurisdiction), the notifier may wish to communicate with this jurisdiction directly. The notifier sends such a request to the lead jurisdiction and the jurisdiction in question. If the request is accepted, the lead jurisdiction will still be sent a copy of all correspondence.

28. Once agreement is reached on the PSI, then the lead jurisdiction will communicate this to the participating jurisdictions and the notifier. A copy of the final PSI must be sent to all of the participating jurisdictions and the notifier by the lead jurisdiction. The notifier can then submit their notification package to the lead jurisdiction.

When agreement on the PSI cannot be reached

29. If it is not possible for the notifier and a particular jurisdiction to agree on the contents of the PSI, then it is up to the notifier to decide whether to continue to include the jurisdiction in the PP. If the notifier does not wish for a jurisdiction to proceed as a secondary jurisdiction, the notifier should inform the lead jurisdiction and the secondary jurisdiction. If the notifier no longer wants the lead jurisdiction to be the lead, then the notifier should inform all the participating jurisdictions and invite one of the secondary jurisdictions to be the lead jurisdiction.

a) In such circumstances, the affected jurisdiction could become an observer jurisdiction for the remainder of the PP (subject to invitation by the notifier), or could choose to withdraw from the PP completely.

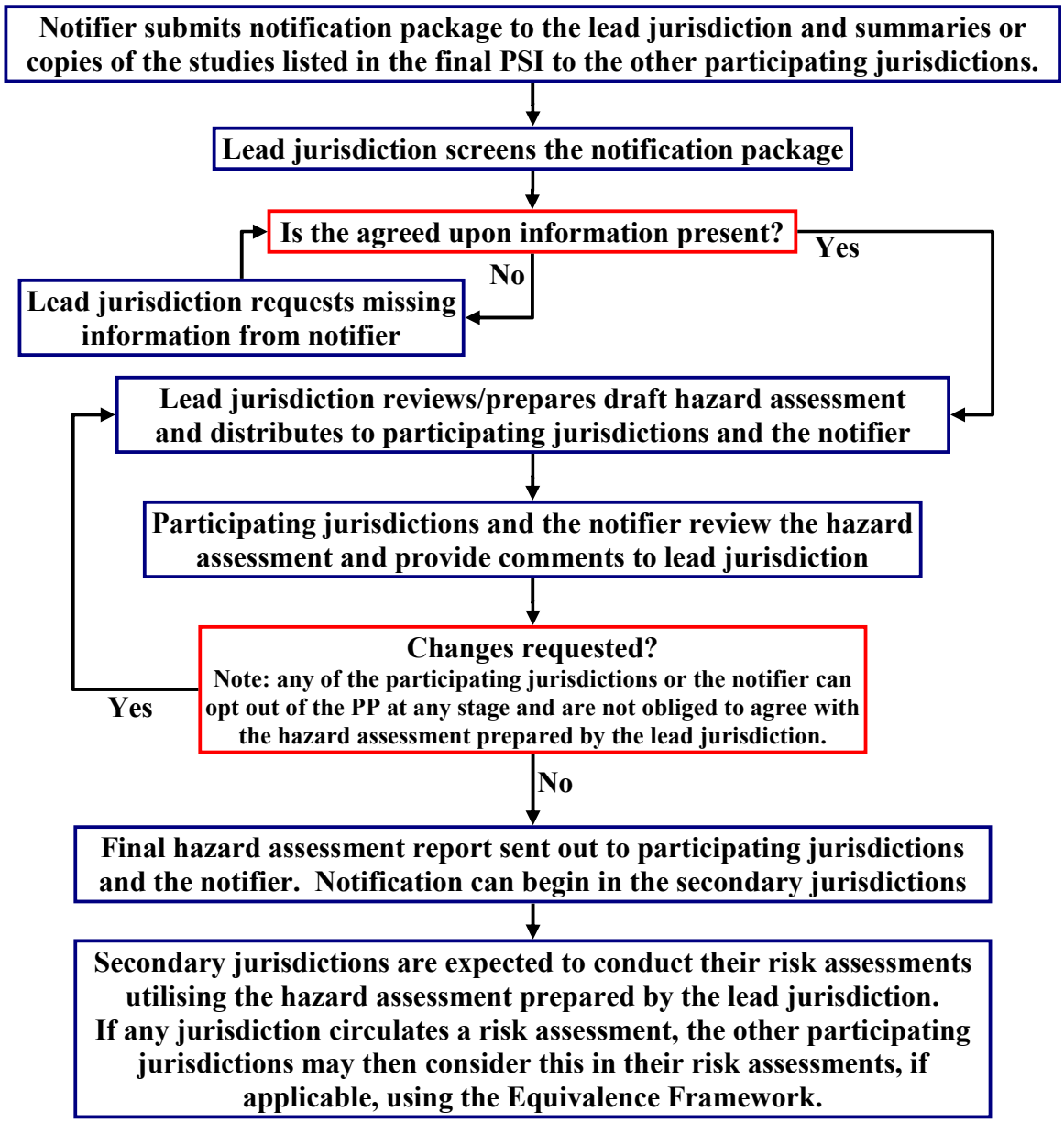
b) The notifier and a secondary jurisdiction that requests information that is not required by the lead jurisdiction may ask the lead jurisdiction to start the assessment of the notified chemical, while they continue to work on finalising agreement on the information required for notification into that secondary jurisdiction.

30. There may be circumstances where the PP notification needs to be terminated by the participating jurisdictions. Prior to terminating a PP notification, the lead and all of the secondary jurisdictions should be in agreement. If one or more of the secondary jurisdictions wish to continue then that secondary jurisdiction could become the lead jurisdiction with the notification continuing with the other jurisdictions as observers. Prior to terminating a PP notification, the participating jurisdictions should work with the notifier to investigate possible opportunities to continue. The following situations are examples where a PP application could be terminated.

a) The notifier is unable or unwilling to provide the information deemed necessary by the lead and secondary jurisdictions for notification in the appropriate categories.

b) The notifier is unable to provide the necessary information within a reasonable time-frame. What is considered a reasonable time-frame will depend on the type and volume of information requested and will be decided on a case by case basis.

VII. Notification and Assessment Phase



31. When the notifier submits the notification package to the lead jurisdiction, the notification package must include:

a) The information described in the final PSI, as agreed during the PNC process, including any explanations supporting the adequacy of the information provided for the notification process.

b) Information on the exposure of the notified chemical as required by the lead jurisdiction.

c) Specific notification forms as required for the particular notification category in the lead jurisdiction (these need to be sent only to the lead jurisdiction).

d) If the lead jurisdiction does not receive all of the required forms, fees (if applicable) and information to start notification proceedings, then the assessment of the notification and preparation of the hazard assessment cannot begin, unless special arrangements have been made.

32. When the notifier submits the notification package to the lead jurisdiction, the notifier will also submit summaries or full copies of the studies listed in the final PSI to the other participating jurisdictions; decisions as to whether summaries are adequate or full copies are needed by each participating jurisdiction for purposes of the PP will be made by each participating jurisdiction during the PNC phase. The notifier will be expected to submit full copies of studies if requested to do so by a participating jurisdiction at any time during the notification and assessment phase for that jurisdiction. Electronic summaries/copies should be sufficient for the participating jurisdictions at this stage unless a jurisdiction specifically requests otherwise during the PNC phase. Studies submitted during the PP may need to be resubmitted to a secondary jurisdiction when a notification is submitted to that jurisdiction, if required by the laws and regulations of that jurisdiction; such jurisdictional requirements will be communicated during the PNC phase so that the notifier is informed about jurisdictional requirements.

33. The lead jurisdiction then assesses the notified chemical as per its legally required assessment time-frame and regulatory assessment procedures in that jurisdiction. For an example time-frame see Appendix 1.

a) The lead jurisdiction should take into account the additional time required to send the hazard assessment to the other participating jurisdictions and receive their feedback when assessing the notified chemical within any legislated time-frame.

b) If the lead jurisdiction does not have a legislated time-frame for conducting the assessment, then as part of the PNC process the lead jurisdiction should provide an estimate to the participating jurisdictions and the notifier of how long the assessment will take, once they have all the required information. The lead jurisdiction should also provide an update if the time-frame changes from the original estimate at any stage.

c) The details of the assessment process will vary depending on the assessment category/type and the jurisdiction that is acting as lead. However, listed below are some general steps that will be the same for all assessments:

d) The lead jurisdiction screens the notification package and determines if all the elements of the agreed upon PSI are included. If necessary the lead jurisdiction can stop the assessment clock while waiting for this information.

e) Based on the notification package, the lead jurisdiction prepares a draft hazard assessment for the notified chemical. The format of the draft hazard assessment report is determined by the lead jurisdiction. The lead jurisdiction might choose the format it generally uses for hazard assessments or the lead jurisdiction may choose the adapted SIAR format, which can be found on the OECD Clearing House on New Chemicals Website.

f) Once a draft of the hazard assessment has been completed by the lead jurisdiction it should be sent to the participating jurisdictions and the notifier. The participating jurisdictions and the notifier review the draft hazard assessment and provide comments either at a teleconference organised by the lead jurisdiction or in writing.

g) Observer jurisdictions are encouraged to make comments on the draft hazard assessment. However, accommodation of comments from observer jurisdictions in the final hazard assessment is at the discretion of the lead jurisdiction.

h) If there are aspects of the draft hazard assessment about which the participating jurisdictions and/or the notifier cannot reach agreement within a reasonable time, then these issues should be recorded by the lead jurisdiction. A copy of these issues should be sent to the participating jurisdictions and the notifier by the lead jurisdiction. Please note that any of the participating jurisdictions or the notifier can opt out of the PP at any stage and are not obliged to agree with the hazard assessment prepared by the lead jurisdiction.

i) Once agreement upon the hazard assessment has been reached by the participating jurisdictions and the notifier, the lead jurisdiction should send the final version of the hazard assessment report to them.

34. After the final hazard assessment has been distributed to all of the participating jurisdictions by the lead jurisdiction, the notifier may submit a notification package to the secondary jurisdictions at any time.

a) The notification submission to a secondary jurisdiction will trigger the start of the assessment clock for that jurisdiction provided no further information is required.

b) The notifier is not obliged to notify in secondary jurisdictions immediately and may choose to wait before submitting the notification. However, if there is an excessive delay in notifying the chemical in the secondary jurisdiction or if additional information becomes available in the intervening period then the secondary jurisdiction may revisit the hazard assessment.

c) Please note that in some cases, the secondary jurisdiction might require further information according to the domestic law.

35. If any jurisdiction prepares a risk assessment for the notified chemical as part of their national regulatory assessment process it should be, where possible, circulated to the other participating jurisdictions when completed. The other participating jurisdictions may then consider this in their risk assessments.

36. Final regulatory conclusions as determined by the secondary jurisdictions are communicated to the notifier as per the jurisdictions' administrative procedures.

VIII. Appendix 1

Parallel Process – Time-lines

The PP time-lines for the Notification and Assessment Phase will vary depending on the jurisdiction that is acting as the lead. The lead jurisdiction must include in their time-line suitable allowance for the other participating jurisdictions to comment on the hazard assessment and time for themselves to respond to those comments if required.

The following time-line is an EXAMPLE only and lead jurisdictions should devise a time-line that best suits their needs.

Although the time-line below is based on August 2011 Australian (NICNAS) processes it may change at any time and should not be assumed to be an accurate representation of the time-lines if Australia is the lead jurisdiction in the future.

Day	**Target activity**
Day 1	Acceptable notification package received.
Day 8	Letter to notifier regarding any outstanding issues.
Day 55	**Send draft hazard assessment report to participating jurisdictions and the notifier.**
Day 70	Receive comments from participating jurisdictions and the notifier (the final hazard assessment should be agreed on by everyone within a 10 day period)
Day 90*	Send out the day 90 report in SIAR adapted format.

* Statutory timeline for the completion of the hazard assessment.