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NEW CHEMICAL ASSESSMENT COMPARISONS AND IMPLICATIONS FOR WORK SHARING

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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.

This document summarizes the main conclusions from the comparison studies from the Rome Workshop *Aligning National Systems for New Chemical Notification and Assessment* and from the Washington Work Group Meeting on *Comparison of New Chemicals Assessments*. It focuses on areas of similarities and differences in the overall risk assessment process used by the various jurisdictions. Furthermore, it identifies areas for cooperation and information sharing (e.g., hazard assessments) and presents obstacles for certain aspects of the risk assessment (e.g., exposure assessments), including legislative barriers which affect the scope of the assessments. This document provides a solid basis for the Task Force on New Chemicals Notification and Assessment to elaborate detailed proposals for international work sharing in the area of new chemicals [See document ENV/JM(2004)29]. The Task Force at its September 2004 meeting reviewed this document and approved its submission to the Joint Meeting for declassification.

EXECUTIVE SUMMARY

1. This document describes the results of chemical risk assessment comparison activities under the OECD Work Programme on New Chemicals and summarizes the main conclusions from the comparison studies from the Rome Workshop (17-19 April 2002) and Washington Work Group Meeting (1-3 March 2004). It focuses on areas of similarities and differences in the overall risk assessment process used by the various jurisdictions. Furthermore, it identifies areas for cooperation and information sharing (e.g., hazard assessments) and presents obstacles for certain aspects of the risk assessment (e.g., exposure assessments), including legislative barriers which affect the scope of the assessments. This document *provides a solid basis for the Task Force on New Industrial Chemicals Notification and Assessment to elaborate detailed proposals for international work sharing in the area of new chemicals.*

2. The first assessment comparison study culminated in the Workshop in Rome and involved examining chemicals of lesser concern. The preliminary work leading up to the Workshop was organized in three Steering Groups pertaining to the following participating chemical companies: DuPont Canada, The Lubrizol Corporation, and Ciba Specialty Chemicals. There were nine chemicals, including one polymer examined in the review process. Country participation included: Australia, Austria, Canada, Japan, Switzerland, the United Kingdom and the United States.

3. At the Rome Workshop, participants discussed similarities and differences of assessment reports from the various jurisdictions, focussing on various aspects of a risk assessment, including hazard, exposure and risk. Similarities included: the assessment of physical chemical and fate data; differences included the use of predicted data by some countries, legislative data requirements and the conduct of quantitative versus qualitative risk assessments. One significant recommendation to governments was to conduct comparisons on chemicals of higher hazard in order to build on the knowledge gained from the initial comparisons.

4. The second assessment comparison study took place during 2003-04 and involved comparing assessments on three higher hazard chemicals provided by The Lubrizol Corporation, Eastman Kodak Company and Ciba Specialty Chemicals. The same countries participated in the second round as in the first round, with the exception of Austria. Following the assessment report exchanges, numerous chemical-specific teleconferences and the generation of comparison reports and summaries by participating countries, the assessment comparisons were presented at the Washington Meeting, chaired by Canada.

5. From the comparison work presented in Washington, areas of cooperation and information sharing were identified by participating member countries, as well as by industry. Recommendations for information sharing on various aspects of the risk assessment were proposed in the following areas: 1) environmental fate assessments, 2) exposure assessments, and 3) assessment policies (e.g., PBT criteria).

6. The most obvious area of cooperation was the hazard component of a risk assessment, since hazard assessment methodologies between countries were comparable. It was agreed by participants, that ideally, when evaluating the same set of hazard data presented by industry, member countries should be able to concur on several factors of the hazard assessment.

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1.0 OVERVIEW

1.1 Background

1. Over the past decade, governments and industry have engaged in discussions on ways to promote international cooperation on new chemicals assessments. The duplication of efforts and differences in national notification and assessment schemes, were the motivating factors for the emergence of the concept of Mutual Acceptance of Notifications, which was introduced by the OECD Business and Industry Advisory Committee (BIAC) in the early 1990's. BIAC challenged OECD member countries to progress toward this vision and implement a system by the year 2005.

2. In response to the above challenge, a Workshop was held in Vienna in April, 1999 between industry and government participants, to discuss the concept of work sharing. At this Workshop, participants shared views and ideas on ways to enhance work sharing on new chemical notifications and assessments and consequently, how to maximize the use of other countries' assessment work.

3. In June, 1999, the Joint Meeting created a Task Force on New Industrial Chemicals Notification and Assessment, which included Work Element I (WE 1), to oversee work sharing on new chemicals notifications and assessments. Since 2001, the WE I Work Group has been engaged in assessment comparison studies between a number of OECD jurisdictions. The first round of assessment comparisons was reported in a Workshop in Rome in April, 2002 and the second and final round of assessment comparison work culminated in a meeting in Washington in March, 2004.

1.2 Work Element I

4. Between 2001-04, a number of jurisdictions and companies have collaborated on two assessment comparison studies under WE I. The first comparison round involved the exchange of assessments on a number of lesser concern substances (Table 1).

Table 1: Company/Country Involvement for Round 1 Comparisons

Chemicals	Company	Countries
C	DuPont Canada	Australia, Canada, US
D	DuPont Canada	Canada, US
F	The Lubrizol Corporation	Canada, US
H	The Lubrizol Corporation	Canada, Japan, UK and US
I	The Lubrizol Corporation	Canada, US
J	The Lubrizol Corporation	Australia, Canada, US
K	Ciba Specialty Chemicals	Australia, Austria, US
L	Ciba Specialty Chemicals	Canada, Switzerland, UK and US
M	Ciba Specialty Chemicals	Australia, Canada, Switzerland, UK and US

5. Comparison results were presented in April, 2002, in Rome, at the *OECD Workshop on Aligning National Systems for New Chemical Notification and Assessments*. Representatives from Australia, Austria, Canada, Japan, Switzerland, the UK and the US presented their analyses comparing their assessments with those of other jurisdictions. The comparison work included details on report presentation, data provided by companies to jurisdictions, and assessment usability (i.e. whether reports

would suffice as source documents for assessment of hazard, exposure and/or risk). At the Workshop, similarities noted between jurisdictions included report formats for hazard assessment data and physical chemical data. Differences between jurisdictions included legislative requirements and approaches to risk assessment. One of the recommendations that resulted from the Rome Workshop was that governments conduct a second round of assessment comparisons on higher hazard chemicals in order to build on the knowledge gained from the initial comparisons. Further details on the Rome comparisons are presented in Section 2 of this document.

6. In the second assessment comparison study, Governments and BIAC were called upon to identify new candidate chemicals. The criteria for selection of new candidate substances included substances which were: 1) newly notified 2) notified to multiple jurisdictions and 3) representative of higher hazard/risk. Australia, Canada and the UK agreed to provide a list of candidates through internal database searches; BIAC indicated that a number of companies were considering proposing candidates and others were invited to submit lists of candidates. Following discussions on the applicability of substances with respect to the criteria mentioned above, the WE I working group selected three substances (designated A, B and D) for inclusion in the comparison study (Table 2). All three substances were noteworthy from an environmental or from a human health perspective, as well as from an exposure perspective.

Table 2: Company/Country Involvement for Round 2 Comparisons

Chemicals	Company	Countries
A	The Lubrizol Corporation	Australia, Canada, Japan, Switzerland, UK, US
B	Eastman Kodak Company	Australia, Canada, UK, US
D	Ciba Specialty Chemicals	Australia, Canada, Switzerland, US

7. The two assessment comparison studies described above have served to build trust and increase understanding on how new chemical assessments are conducted in each jurisdiction. However it also identified areas where assessment methodologies diverged between jurisdictions.

8. This document summarizes the main conclusions from the assessment comparison studies from the Rome and Washington meetings, focusing on areas of similarities and differences in the overall risk assessment process used by the various jurisdictions, as well as legislative barriers which affect the scope of the assessments.

2.0 Rome Comparisons

9. Prior to exchanging assessment reports and initiating the assessment comparison studies, there was a need to identity and establish procedures for sharing new chemicals assessments with participating OECD countries and ensure confidential business information (CBI) contained within the assessment reports was not being compromised.

10. Firstly, based on discussions between government and industry representatives, it was agreed that only countries that had assessed a chemical would exchange information for that particular chemical and participate in chemical-specific teleconferences.

11. Participating governments were required to seek approval from companies to share assessment-related information with other jurisdictions. In addition, in order to participate in the work sharing exercise, all countries signed a specific agreement entitled “Agreement for Sharing of Notified Chemical Information between OECD Countries for the Purpose of Understanding New Chemical Notification Procedures”, which included provisions for sharing CBI.

12. The procedures for undertaking the assessment comparisons were discussed with each company. These procedures required countries to remove third party CBI (belonging to and supplied by one company, and used by one government in a review of another company's notification) prior to sharing with other governments. The WE I Work Group agreed that documentation that was being exchanged would include assessment reports, any reports generated in-house (including predictions, modelling outputs) and a copy of the notification form, which would serve as a checklist of test data available to that particular country. Notifying companies also were required to submit a master list of tests that had been conducted for each substance.

13. The comparison reporting format used to present results in preparation for the Rome Workshop and Washington Meeting, involved a summary of information gleaned from country by country spreadsheets, which included details on report presentation, report content, assessment usability, and overall conclusions with respect to the utility of other countries assessment reports. For the second round of assessment comparisons, in addition to the comparison reports, each country agreed to develop a comparison summary for each chemical that was reviewed. The comparison sheets and individual summaries have served as the basis for the Rome and Washington comparisons described in detail in Sections 2 and 3.

14. The first round of assessment comparisons culminated in the *OECD Workshop on Aligning National Systems for New Chemical Notification and Assessments* held in Rome in April, 2002. The theme for this comparison work was "Learning from Experience with Multilaterals in Sharing and Comparing Assessments". The objectives were to identify similarities and differences in regulatory systems, risk assessment approaches and outcomes, as well as to describe actions needed to make meaningful progress where key differences were identified. This WE I session was held over a 2 day period; the first day dealt with an overview of notification and assessment schemes, and the second day included discussions and break-out groups addressing differences and similarities between the various jurisdictions.

15. Australia hosted the first day, where each of the 7 jurisdictions presented overviews of their new chemical notification and assessment schemes. The information was summarized in a matrix "Comparing Assessment Approaches Across Countries". The matrix contained information from the various jurisdictions on assessment approaches, including hazard and exposure assessments, risk characterization and PBT (persistence, bioaccumulation and toxicity) aspects of risk assessments.

16. The second day involved discussions based on assessment comparisons conducted for nine substances. These assessment comparisons included an analysis of the different data requirements, report presentation and content, hazard, exposure and risk assessments between various jurisdictions, which are described below.

2.1 Data Requirements

17. Differences in legislative data requirements were noted. The data requirements were similar between Australia, Austria, Canada, Switzerland and the U.K., and were based on the OECD Minimum Pre-marketing set of Data (MPD). In Japan, additional data requirements were dependent on the outcome of biodegradation tests. In the US, pre-manufacture data requirements included providing information on identity, use and volume and any existing available data. Following an initial risk assessment, the provision of additional data may be required. In place of upfront data requirements, the US bases their hazard assessments on Quantitative Structure-Activity Relationships (QSAR) predictions, as well as data on analogue substances.

2.2 Report Presentation

18. Differences were noted in the format of assessment reports and the level of detail between the different jurisdictions. For instance, some countries produce one assessment report per chemical (e.g., Australia), while others generate a number of specialized reports for each chemical (e.g., US). Reports generated by most jurisdictions contained separate sections for identity, hazard, exposure and risk determinations, both for the environment, occupational and human health. Those jurisdictions not familiar with the US assessment process found the generation of multiple reports by the US more difficult to follow.

2.3 Report Content

19. For most of the chemicals, the data on identity and use, physical-chemical, fate and transport were similar. This was largely due to the similar data requirements for the notification of new substances by the various regulatory authorities. The toxicity data provided to the different countries were largely similar; however, there were some differences in the amount of data received or reviewed by the different countries. For instance, in some reports summaries of test data were reported but it was not clear if full studies had been received (e.g., Austria and Switzerland). In some US reports, experimental data were absent as a result of legislative requirements and predicted or estimated data were used instead. There were also some differences in the amount and type of data received by various jurisdictions, for example with Chemical J, a genotoxicity study was submitted to Canada but not to Australia.

2.4 Hazard Assessment

20. Where similar test data were provided, comparable conclusions were reached in terms of the hazard of the chemical. There were some variations in the level of detail used to report the data. For instance, in some countries only a summary of the results was provided (Austria, Switzerland) while in others (Australia, Canada) a more substantial discussion of the hazard data was provided. Overall, no significant hazard was identified for any of the chemicals, despite the variable amount of information received or generated. For one of the substances (Chemical M) Switzerland requested an additional chronic ecotoxicity study to address concerns raised for benthic toxicity.

2.5 Exposure Assessment

21. Significant differences were noted both in the level of detail reported and approaches taken by the various jurisdictions when conducting exposure assessments. Some countries conducted extensive environmental fate and exposure assessments while others carried out cursory exposure assessments or did not undertake an exposure assessment (Japan). For human exposure, some countries assessed both general population and worker exposure while others focused on one sub-population, or did not conduct an exposure assessment. In instances where environmental exposure was conducted, different environmental release scenarios were used by different countries. The level of detail also varied between countries: brief qualitative descriptions (Austria and Switzerland), detailed qualitative description (Australia), detailed qualitative and quantitative descriptions (Canada, US). Similar variations in the level of detail were also observed in conducting human exposure. Occupational health exposure was considered only in the Australian and US reports. The Japanese report did not include an exposure assessment.

2.6 Risk Assessment

22. Differences in levels of exposure assessment lead to significant differences in details and approaches used in conducting and reporting risk. Some countries conducted extensive quantitative risk assessments (Canada, Switzerland-eco, US) while in the case of others, risk assessment was qualitative (Australia), or not conducted (Austria-human, Japan). Risk assessment for the occupational setting was conducted only in the Australian and US reports.

23. Although the regulatory outcomes across governments were similar in that no regulatory actions were taken for 8 of the 9 substances, this was likely due to the small sample size and selected substances that did not display significant environmental or human health hazards. Regulatory action was taken on the one remaining chemical (Chemical C) by Canada based on global warming potential concerns, and by the US based on occupational concerns. In the US, potential global warming concerns were referred to the EPA's Air Office, which is working on these issues. Overall, it was evident that there were differences between the different new chemicals notification schemes in terms of their strategy, mandate and authority in conducting risk assessments and in implementing risk management.

2.7 Observations and Recommendations

24. Participants noted that there were some differences in the criteria for hazard classification but it was suggested that the Globally Harmonized System for Classification and Labelling of Chemicals may increase consistency with respect to hazard classification once it has been implemented.

25. Obstacles to sharing assessment information were also identified and included: CBI; differences in report format and content; differences in approaches in conducting hazard, exposure and risk assessment; and constraints in the national legislations for regulating new chemicals. Because of these differences, it was suggested that sharing of information may have to be limited to some parts or elements of the assessment reports, e.g., the hazard assessment.

26. One of the more significant recommendations made by Workshop participants was to build upon the knowledge gained from these initial comparisons, by conducting additional assessment comparisons on chemicals with higher degrees of hazard. Additional recommendations from the Rome Workshop are provided in Appendix 1.

3.0 Washington Comparisons

27. In response to the Rome Workshop recommendations, a second round of retrospective assessment comparisons was undertaken. In order to initiate this second round, government and Industry representatives were asked to identify new chemical candidates which met the following criteria: 1) recently notified 2) notified to multiple jurisdictions, and 3) represented higher hazard/risk.

28. A total of 18 substances from four different companies were initially screened in as potential candidates. Following discussions on the applicability of substances with respect to the criteria mentioned above, the WE I Work Group selected three substances (A, B and D) for the assessment comparison study. All three substances were of interest either from an eco- and/or human health perspective, as well as from an exposure perspective. These comparisons are presented below.

3.1 Overview of Assessment Approaches

29. In terms of overall assessment approaches, Australia, Canada, the UK and the US, have risk-based systems which are initiated with a hazard assessment, followed by a qualitative or quantitative exposure assessment. In Japan, the assessment approach is typically hazard-based, while in Switzerland, the human health component of the assessment is hazard-based and the environmental component is risk-based.

30. Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) addresses public health and occupational effects, and the Department of Environment and Heritage addresses environmental effects. Industry is responsible for generating the test data, and the federal government is responsible for conducting the risk assessment. Recommendations for control action can be made to industry, other federal agencies or State/Territory government agencies. In many cases, enforcement of recommendations falls within the scope of State/Territory government legislation.

31. Under the Canadian Environmental Protection Act (CEPA), Health Canada is responsible for assessing human health and Environment Canada is responsible for assessing environmental effects. Occupational Health and Safety (OHS) is not regulated under CEPA as it is the responsibility of the provinces and territories. Industry is responsible for generating the test data, and the federal government is responsible for conducting the risk assessment, as well as imposing control measures.

32. In Japan, under the Chemical Substances Control Law (CSCL), only human health is addressed and exposure and risk are not characterized[1]. The three ministries which conduct the assessment are: the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE). OHS is not regulated under the CSCL. Industry is responsible for generating the test data and the government is responsible for conducting the hazard assessment and also implementing control measures.

33. In the case of Switzerland, an environmental impact report is required by the notifier. The Swiss Agency for the Environment, Forests and Landscape (SAEFL) is responsible for reviewing the environmental assessment, while the Federal Office of Public Health (FOPH) is responsible for conducting the human health assessment[2]. OHS is currently not assessed in Switzerland.

34. In the UK, the Notification of New Substances Regulations (NONS) addresses risk to the environment, human health, including OHS. The Health and Safety Executive (HSE) assesses the human health and OHS components and the UK Environment Agency (EA) assesses the environmental component of the risk assessment. Industry is responsible for generating the test data and the government is responsible for conducting the risk assessment.

35. The Toxic Substances Control Act (TSCA) in the US addresses all three components of the risk assessment. There are no legislative data generation requirements for new chemicals; typically, the government develops estimates for hazard and fate in order to conduct the risk assessment. The government is also responsible for the identification of control measures and can require development of hazard and fate studies, if necessary.

3.2 Data Requirements

36. For the most part, Australia, Canada, Switzerland and the UK have test data requirements based on the OECD MPD. Data requirements include providing information on the identity, use and exposure of the substance, including its physical-chemical properties, toxicological studies and ecotoxicological studies. In addition, in Switzerland, an initial hazard/risk assessment (environmental impact report) is required by the Notifier when submitting a notification.

37. In the US, TSCA does not require testing prior to the submission of a PMN. Some of the required information includes identity, uses, volumes, and any test data already in possession of the Notifier. Additional test data may be requested if a concern has been identified in the initial assessment.

38. In Japan, a biodegradability test of a new substance is required. If the new substance is biodegradable, no further tests are required and the substance is not regulated. In the case of low biodegradability, bioconcentration testing is required to determine whether a screening test or longer-term toxicity test is required. Degradation products have to be assessed in Japan for ecotoxicity, toxicity to human health, as well as bioaccumulation potential.

[1] It is noted that as of April 1st, 2004, assessment of ecotoxicity will be introduced in Japan's regulations.

[2] Human health hazard, exposure and risk assessments are currently not conducted in detail, but should be introduced with a new legislation in 2005.

3.3 Use of Surrogate and Modelled Data

39. For these specific assessment comparisons, Australia, Japan and Switzerland were the only jurisdictions that did not generate surrogate or modelled data for physical chemical properties, fate and exposure, toxicity and ecotoxicity parameters. There was one exception (Substance B) in which fugacity modelling was used by Australia to estimate partitioning of the substance in various environmental media.

40. In Canada, the assessment reports included modelling for physical chemical properties (ECOSAR, EPIWIN, Pallas, ClogP), fate/exposure estimates (ChemCAN), transformation products (OASIS Catabol) toxicity (TOPKAT) and ecotoxicity (OASIS Forecast, ECOSAR). In-house searches of historical notification data for surrogate substances were also conducted for toxicity and ecotoxicity.

41. In the UK, the assessment reports included some modelling for physical chemical parameters (HYDROWIN) and fate/exposure estimates (SimpleTreat, EASE).

42. The US included extensive modelling for physical chemical and exposure parameters (EPIWIN, E-FAST and Chemsteer), toxicity and ecotoxicity (ECOSAR), and where possible, in-house searches of databases were conducted for surrogate substances.

3.4 Hazard Assessment

43. Hazard assessments were conducted by all countries, however the types of assessments conducted (qualitative vs. quantitative) and the type of data incorporated (predicted vs. measured) varied between jurisdictions. In general, Australia, Japan, Switzerland and the UK did not have ecotoxicity modelling in their assessments. In contrast, Canada and the US used extensive modelling. Canada uses predicted data as part of a weight of evidence approach in the assessments, in conjunction with measured and surrogate data. The US relied on predicted values to conduct the effects assessments since ecotoxicity data are not routinely submitted with the PMN.

44. In addition to the assessment of the aquatic compartment, Canada, Switzerland and the UK incorporated a multicompartment approach, including assessing toxicity to the sediment, soil and terrestrial compartments. Australia and the US focussed their effects assessments on the aquatic compartment.

3.4.1 Effects Assessment on Notified Substances

45. For Substances A and B, similar data packages were received by the various jurisdictions, although Japan and the US lacked some toxicity and genotoxicity studies. For these substances, the US did not have the 28-day repeated oral dose toxicity studies, which were available to the other jurisdictions. For Substance D, there were some discrepancies noted in the physical-chemical data and ecotoxicity data provided to the various countries. For instance, BCF/BAF data, 21-day daphnia toxicity and algal inhibition test data were not available to Canada and the US, but were available to Australia and Switzerland. Furthermore, Canada and the US had two repeated dose and three genotoxicity studies that were not available to Australia and Switzerland. The US had a 14-day repeated dose study in dogs which was not available in the other three jurisdictions (Australia, Canada and Switzerland).

46. In general, Australia, Canada, Switzerland and the UK had full test reports for all substances. The level of detail in reporting ecotoxicity data varied across jurisdictions. For Substances A and B, the UK assessment reports included ecotoxicity data, while the Summary Notification Interchange Format (SNIF) report provided further details on the individual ecotoxicity tests. The SNIF report is intended to be read in conjunction with the UK risk assessment report and not as a stand-alone document. The level of detail in reporting the human health data was comparable between Australia, Canada, UK and US, in contrast to the Japanese and Swiss reports which were not as comprehensive.

47. For Substance D, Canada and Australia presented data in a tabular format. Furthermore, the Australian assessment report included more details on the ecotoxicity tests, including test conditions, number of specimens, and physical effects of the substance on aquatic organisms. Switzerland provided a short summary of effects, and Japan provided a summary of the ecotoxicity data in the form of an evaluation data sheet.

48. Based on test data, Australia, Canada and Switzerland concluded that Substance A was of high concern for aquatic species and the US concluded high chronic toxicity based on predicted data. In contrast, Japan and the UK indicated the substance was not of concern. The different ecotoxicity conclusions were based on reporting of measured concentrations (Australia, Canada, and Switzerland) vs. nominal concentrations (Japan[3] and UK). Australia, Canada, Switzerland and the UK reached similar conclusions that the substance did not represent a significant hazard to human health. In the US, a Consent Order was issued to address the concern of thyroid effects identified during the review, by requiring a 28-day dermal study. The hazard assessment in the US report for other endpoints was essentially similar to the other jurisdictions. Similarly, in the Japanese report, concerns were also raised for liver and thyroid effects.

49. For Substance B, Australia and Canada concluded that the substance was of high acute and chronic concern to aquatic organisms based on test data, while the US concluded high concern based on predicted values. In the UK report, concern for the environment was indicated by the labelling/classification statements "Dangerous for the environment" and "Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment." The risk assessment conclusion in the UK report demonstrated that the substance was of concern for the environment and further information was required. The UK assessment report included fish and algae toxicity data which differed from the data provided to Australia and Canada. The differences in the reported test data were likely based on the use of nominal test concentrations rather than measured test concentrations.

50. For Substance B, all four jurisdictions reached similar hazard conclusions for human health. The only exception being that the UK reclassified the acute oral study in rats based on results from the 28-day repeated oral dose study. All four jurisdictions received the same test data, with the exception of the US, which did not have the 28-day repeated oral toxicity study.

51. For Substance D, surrogate data were provided in lieu of data on the notified substance; all jurisdictions deemed this information to be acceptable. Australia and Canada concluded that the notified substance was of low concern for ecotoxicity, based on the test data submitted, while the US concluded the substance was of low concern based on predicted values. Australia was the only jurisdiction to report the test concentrations at which physical effects had occurred. Switzerland did not classify the hazard of the substance, however, an overall conclusion was made that "no environmental danger for aquatic organisms is to be expected". With respect to the human health hazard of Substance D, all four jurisdictions concluded low toxicity.

52. For all three substances, Canada and the US incorporated modelling data from ECOSAR to predict ecotoxicity. These toxicity predictions were in the same order of magnitude.

3.4.2 Degradation Products and Impurities

53. Canada and Japan were the only jurisdictions that assessed the hazard of the degradation products. Canada concluded Substance A would not be persistent under certain environmental conditions and consequently, the hazard of the degradation product was assessed. Similarly, for Substance A, Japan concluded the substance would degrade and as a result, the hazard of the degradation product was

[3] Under Japan's amended CSCL, ecotoxicity will be evaluated based on measured concentrations.

addressed in the assessment. For Substance D, Canada assessed the toxicity of the degradation product which represented a worst-case scenario relative to the notified substance. In Japan's case, the degradation product is assessed under the CSCL and test data are required on the degradation product when appropriate.

54. Switzerland was the only jurisdiction to assess the environmental hazard of the impurity for Substance A, which was present at a very low concentration. The toxicity data were based on information available from a Screening Information Data Set (SIDS) Summary and from an internal database.

3.4.3 Determination of No-Effect Levels

55. Although a similar methodology was used by jurisdictions to determine Predicted No Effect Concentrations (PNECs) and No-Observed-Effect-Levels (NOELs) for the different substances, the selection of the critical study, point of departure and magnitude of the safety factor varied across jurisdictions. Furthermore, aquatic PNECs were calculated by most jurisdictions, with the exception of Japan, however, some jurisdictions (Canada, Switzerland and the UK), also calculated PNECs for the soil and sediment compartments. In cases where identical data packages were received, the same critical study was used for the PNEC and NOEL determinations.

Aquatic PNECs

56. In general, aquatic PNECs were calculated by all jurisdictions, except by Australia (Substance A) and the US (Substance D). In the case of the US, a qualitative assessment of effects was conducted because of low expected environmental hazard (i.e., no effects at saturation). However, in Australia's case, at the time of the assessment, quantitative ecological risk assessments were not being conducted. In Japan, a PNEC was not calculated for Substance A, since risk is not addressed in the initial assessment under the CSCL. In contrast to the other jurisdictions, the US used predicted data to generate PNECs for Substances A and B.

Substance A

57. For Substance A, Canada calculated the PNEC using the measured 21-day Daphnia EL50 (reproduction) toxicity value with a safety factor of 100 to account for the lack of a chronic base set and to extrapolate to a chronic PNEC. Switzerland identified the same critical study but used the NOEC (reproduction) value and a safety factor of 100. In addition, Switzerland calculated a PNEC for the impurity, since the impurity had a higher water solubility and toxicity compared to the notified substance. A safety factor of 1000 was applied to the 48 hour Daphnia EC50 value for the impurity. The UK used the nominal 48 hour Daphnia EC50 (reproduction) value and a safety factor of 1000 to derive the PNEC, in contrast to the measured concentrations used by Canada and Switzerland.

58. The US used predicted chronic data from ECOSAR to generate PNECs using a safety factor of 10 to extrapolate to a chronic PNEC.

Substance B

59. Australia and Canada used the same critical study but different points of departure to derive the PNECs. In Canada, the PNEC was based on the Daphnid 21d MATC value, while in Australia the LOEC value was used. Furthermore, Canada used a safety factor of 10 to account for inter/intraspecies variability, while Australia did not apply a safety factor. Australia indicated that if this were a current assessment, the Daphnia NOEC value and a safety factor of 10 would be used to generate the PNEC. The UK used the 96h fish LC50 value and a safety factor of 100 to generate the PNEC. The US used predicted chronic data from ECOSAR to calculate a PNEC, using a safety factor of 10.

Substance D

60. For Substance D, a number of different approaches were taken to calculate the aquatic PNEC. Australia and Switzerland calculated PNECs for the notified substance, while Canada and the US did not determine a PNEC, based on low expected environmental hazard. However, Canada assessed the toxicity of the degradation product as a worst-case scenario. A PNEC was calculated for the degradation product, based on the predicted Daphnid 21d ChV and dividing by a safety factor of 10. Australia, similar to Canada and the US, also concluded low environmental toxicity for the notified substance, but calculated PNECs for toxicological and physical effects using the fish 96h LC50 value and dividing by a safety factor of 100. In Switzerland, the PNEC was derived using 1/100 of the water solubility for a surrogate substance, which represented a worst-case scenario.

Soil, Sediment, Aquatic Wildlife

61. For each substance, Canada determined PNECs for the sediment compartment, using the equilibrium partitioning relationship outlined in the European Commission's Technical Guidance Document (TDG) (EC 2001). This was derived using the aquatic PNEC and the adsorption coefficient (log Koc), by adjusting the toxicity value relative to the organic carbon content of natural suspended sediments, and using a default value for the bulk density of suspended matter.

62. For Substance A, Switzerland used the aquatic PNEC for the assessment of the soil pore water for the notified substance and for the impurity.

63. For Substances A and B, the UK used aquatic toxicity data to extrapolate to soil and sediment PNECs using the equilibrium partitioning method employed by Canada. For Substance B, the sediment PNEC derived by the UK was approximately 50 times lower than the sediment PNEC derived by Canada. The soil compartment was included in the UK risk assessment based on sludge application to agricultural land.

64. For Substance D, Australia used a trigger level estimate to derive a soil PNEC and Switzerland used the aquatic PNEC for the assessment of the soil pore water.

65. Given the inherent properties of the substances i.e., potential for bioaccumulation and persistence, Canada calculated wildlife PNECs for all three substances, while the UK calculated a wildlife PNEC for Substance B. The PNECs were derived using chronic data available from the repeated oral dose study (rat) provided for these substances. In Canada, separate PNECs were derived for mink and river otter which represented the sentinel species. For Substance B, a safety factor of 10 was used by the UK, while Canada did not use a safety factor because the No-Observed-Adverse-Effect-Level (NOAEL) was used. For Substances A and D, Canada used a safety factor of 10 to account for inter/intraspecies variation.

Environmental Hazard Assessment Comparisons

Differences:

- Level of reporting detail and type of data received
- Use of predicted data vs. measured data
- Hazard conclusions differed based on use of nominal vs. measured concentrations
- Selection of critical study, point of departure, uncertainty factors and calculation of PNECs
- Use of multicompartment approach vs. single compartment approach
- Assessment of impurities and degradation products
- Varied application of multicompartment approach (e.g., inclusion of wildlife PNECs)

Similarities:

- Similar hazard conclusions reached using experimental or predicted data (Chemical B)
- Similar methodology used to calculate PNECs

Human Health Hazard Assessment Comparisons

Differences:

- Level of reporting detail and type of data received
- Only Japan and US identified thyroid concerns from 28 day study (Chemical A)
- Use of models/analogues in predicting toxicity
- Classification differences of an acute study (Chemical B)
- Assessment of degradation products
- Calculation of Tolerable Daily Intake (TDI)

Similarities:

- Hazard conclusions were similar for most endpoints

3.5 Fate Assessment

66. Although all countries discussed fate at varying levels of detail, a quantitative discussion on partitioning into the various compartments was not always provided. From a multimedia fate perspective, Canada, Switzerland and the UK considered the mode of entry (i.e., release to the aquatic environment) when conducting their fate assessments.

67. For all three substances, Canada included Mackay's Level III fugacity model predictions for the notified substance and/or transformation product to identify compartmentalization based on aquatic releases. The UK included compartmentalization estimates for the fate of the notified substances in the wastewater treatment plant (WWTP), using the SimpleTreat model.

68. The Australian report contained some detail on the partitioning of Substance A based on its physical chemical properties. The sediment compartment was identified as the main compartment for partitioning.

For substance B, Mackay's Level I fugacity model was used to predict the fate of the notified substance, which indicated significant partitioning to the soil and sediment compartments.

69. Switzerland and the US did not include fugacity modelling or compartmentalization estimates in their reports. In Switzerland, the notifier provided some information on the environmental fate of the substances and Switzerland assessed the fate based on end use applications. In the US, partitioning was discussed using predicted and measured physical chemical properties.

70. The environmental fate of Substance A was not addressed in the Japanese report, since exposure is not assessed under the CSCL in the initial assessment.

3.6 Exposure Assessment

71. Exposure assessment approaches varied between jurisdictions as a result of differences in use patterns and volumes, as well as exposure assumptions and release scenarios employed in the risk assessments.

3.6.1 Use Patterns and Volumes

72. The notified volumes varied substantially between jurisdictions; however, in general the same uses were notified for all substances. Furthermore, the level of detail pertaining to use patterns reported in the assessments varied across jurisdictions. Canada and the US were the only jurisdictions to investigate and assess other potential uses. However, in Australia and Switzerland, any change in the notified use pattern or significant change in import or production volume requires re-notification of the substance.

73. The intended function of Substance D was the same for all the countries, however, the end use in the Canadian and Swiss reports differed from that reported in the Australian and US assessments.

3.6.2 Human Exposure

74. The assessment methodology employed in conducting human exposure assessments varied between countries. Furthermore, human exposure was not addressed in the Japanese report, however, the five remaining jurisdictions considered exposure to the general public. Australia, UK and the US conducted occupational exposure assessments. Direct and indirect[4] exposures were considered in the Canadian, UK and US reports. Most countries also considered exposure to the notified substance as well as the notified substance in finished products. The level of detail for reporting these exposure assessments also varied substantially between jurisdictions.

75. For Substance A, the Australian and Canadian reports indicated some potential for exposure of the substance in the finished product to the general public. In addition, the Australian and US reports indicated a potential for occupational exposure to the notified substance during blending and packaging operations. Furthermore, occupational concerns were identified based on a potential for exposure to the substance in the finished products. For Substance A, the UK concluded no significant occupational or general public exposure, while Japan and Switzerland did not conduct human exposure assessments.

76. For Substances B and D, where a human exposure assessment was conducted, no significant exposure of the notified substance to the general public was identified by any jurisdiction. For Substance D, the Australian report indicated some potential for occupational exposure during formulation and use of the substance.

[4] Indirect exposure implies exposure via the environment (e.g., through drinking water).

3.6.3 Determination of a Predicted Environmental Concentration

77. The predicted environmental concentrations (PECs) determined by the jurisdictions varied due to different variables used in estimating releases and different receiving environments (e.g. dilution factors, flow rates of receiving waters). Furthermore, when similar scenarios were considered, there were differences in percentage process losses and number of production days used. Waste treatment removal rates were generally considered by all jurisdictions when calculating PECs.

Aquatic PECs

78. For Substances A and D, Australia and the US conducted qualitative assessments of the substances due to either low environmental hazard or no expected release to water. Japan did not calculate environmental releases, since exposure and risk are not typically examined in the initial assessment under the CSCL.

79. Australia, Canada, the UK and the US examined releases from blending and formulating processes. In addition to these releases, Switzerland and the UK examined releases from end use applications. Switzerland based its release assumptions from information available in an OECD Emission Scenario Document. The UK employed the European Union System for the Evaluation of Substances (EUSES) program to calculate regional and local PECs for the aquatic compartment.

Soil, Sediment, Aquatic Wildlife

80. Switzerland calculated soil PECs for Substance A and the impurity, based on releases to soil and water from the notified use. The assumptions made in the exposure assessment were based on emissions from rainwater run-off and soil infiltration. Soil PECs were calculated according to the European Commission's Technical Guidance Document (TDG) (EC 2001), and were based on average soil concentrations after 10 years. The EUSES program was used to calculate regional and local PECs for soil and soil pore water.

81. Similar to Switzerland, the UK calculated local and regional soil and soil pore water PECs. The soil compartment was considered in the assessment to account for application of sewage sludge onto agricultural lands. However, in Switzerland the land application scenario was not considered due to prohibition of this practise.

82. Canada calculated PECs for the sediment compartment for all three substances, based on multimedia fate predictions which indicated partitioning of the substances to sediment. The PECs were calculated using the equilibrium partitioning equation outlined in the EC's TDG (EC 2001). The UK also included local sediment PECs for Substance B using the same method employed by Canada.

83. Canada calculated PECs for the wildlife compartment for all three substances. The PECs were based on the calculation of the total daily intake (TDI) of the notified substance by mink and river otters and using the wildlife exposure model from the US EPA's Exposure Factors Handbook (US EPA 1993). These equations account for uptake of the notified substance in fish via water (using the highest aquatic PEC) and via the diet (using a BAF). For Substance B, the UK calculated wildlife PECs for worm-eating and fish-eating birds and mammals using a different approach which resulted in different PEC estimates in wildlife.

Environmental Exposure Assessment Comparisons

Differences

- Exposure assessments varied due to different release scenarios and receiving environments

Similarities

- Waste treatment was always considered, where appropriate
- Consideration of mode of entry as basis for multicompartment modelling (Canada, Switzerland, UK)

Human Health Exposure Assessment Comparisons

Differences

- Different assumptions used when calculating direct and indirect exposures

Similarities

- Similar uses were assessed
- Identification of similar routes of exposure
- In most cases, occupational exposure and exposure to the general population were low

3.7 Risk Characterization, Control Measures, and Post-Assessment Follow-up

84. A PEC/PNEC approach was applied when quantitative assessments were conducted by the various jurisdictions. In the absence of quantitative assessments, qualitative conclusions on risk were made. In addition, Switzerland considered the environmental risk from impurities (Substance A) and both Canada and Switzerland considered the environmental risk from degradation products (Substances A and D).

85. For Substance A, all jurisdictions identified no risk to the aquatic environment. A quantitative PEC/PNEC approach was used by Canada, Switzerland and the UK when calculating risk. Switzerland was the only jurisdiction to identify a risk to the soil compartment. Different release scenarios and PNEC values resulted in the difference in the risk conclusions. As a consequence of the risk identified in soil, Switzerland requested further data on soil degradation and effects on soil organisms. The environmental risk assessment in Switzerland is on-going for Substance A.

86. In the US, a significant risk for workers was identified, based on the concern of thyroid effects concluded from the predictive hazard assessment. As a consequence, a Consent Order was issued, requiring a 28-day dermal study in rats.

87. In Japan, a risk assessment was not conducted for the environment or human health in the initial assessment (i.e. prior to manufacture or import). Under the CSCL, risk is assessed for a "Designated Substance" having the potential to cause human health effects (after the manufacture or import). Substance A was classified as "To be Designated" on the basis of low biodegradability, low bioaccumulation and suspected chronic toxicity for human health.

88. For Substance B, the UK was the only jurisdiction that identified a risk to the sediment and soil compartments for local and regional exposures. Risk outcomes differed as a result of: i) the use of different PNECs and ii) risk ratios increased by a factor of 10 when extrapolating from the aquatic column to sediment to account for the bioaccumulative nature of the substance.

89. For Substance D, Australia, Canada and Switzerland concluded no risk to the environment, based on a quantitative PEC/PNEC approach. The US did not conduct a quantitative risk assessment, based on the assumption that the substance would not be released to water, resulting in no exposure. It was noted that the substance may be a candidate for a high production volume (HPV) chemical in the future, and would be subject to basic hazard and environmental fate testing.

Environmental Risk Characterization Comparisons

Differences:

- Risk quotients calculated for impurities and degradation products
- Differences in approaches to calculating risk for soil and sediment compartments

Similarities:

- PEC/PNEC approach used for quantitative risk assessments

- When a quantitative exposure approach was conducted, risk was quantified; qualitative conclusion on risk where appropriate
- Similar risk assessment outcomes in most cases

Human Health Risk Characterization Comparisons

Differences:

- Differences when jurisdictions conducted qualitative vs. quantitative risk assessments

- The US issued a Consent Order for Chemical A

Similarities:

- Similar risk assessment outcomes in most cases

3.8 Persistence and Bioaccumulation

90. In certain jurisdictions (Canada, Japan, the US and EU), there is a set of defined policy criteria for persistence and bioaccumulation, while other jurisdictions (UK) have internal screening criteria to make final determinations. Australia and Switzerland do not have formal criteria in their legislations. Although countries may not have domestic policies, they are all signatories to the Stockholm Convention on Persistent Organic Pollutants (POPs). The Stockholm Convention sets out obligations for countries covering the production, use, import, export, release and disposal of POPs.

91. In Canada, the Persistence and Bioaccumulation Regulations published in the Canada Gazette (2000) define the criteria for persistence and bioaccumulation in various compartments. In Japan, the criteria for

persistence and bioaccumulation are published on the METI website (2003). In the US, the "Category for Persistent, Bioaccumulative, and Toxic Chemical Substances" published in the US Federal Register (1999) defines a rating system for these substances.

92. In most cases, all countries commented on the persistence and bioaccumulation potentials for the substances. In addition, Canada and Japan assessed the persistence and bioaccumulation potentials of the transformation products for Substance A. Conclusions varied as a result of the use of different endpoints to assess bioaccumulation (e.g. BCF vs. log Kow) and persistence, as well as the availability of different studies and types of data (predicted vs. measured) across jurisdictions.

93. For Substance A, all countries (except the US), concluded the substance was persistent, based on measured biodegradation data. Canada concluded the substance was bioaccumulative based on predicted log Kow data (Canada). Australia, Japan and the US concluded the substance had a low bioaccumulation potential based on low water solubility (Australia), measured BCF data (Japan) and predicted BCF data (US). In addition, Canada and Japan concluded a low bioaccumulation potential for the degradation product of Substance A, based on predicted log Kow and BCF data (Canada) and measured BCF data (Japan).

94. For Substance B, all countries concluded the substance was persistent. The US concluded persistence based on predicted data, while the other jurisdictions concluded on the basis of ready biodegradation data provided by the notifier. In the US report, a rating system was not included, since the PBT policy criteria were not in place at the time of the assessment. Canada and the UK concluded the substance was persistent and bioaccumulative. The UK indicated that it met the screening criteria for vPvB (very persistent and bioaccumulative) according to the European Commission's Chemicals Policy. In contrast, Australia concluded a low bioaccumulation potential based on low bioavailability.

95. For Substance D, Australia, Canada, Switzerland and the US concluded the substance was persistent, based on surrogate ready biodegradation data. Australia, Switzerland and the US, concluded the substance was not bioaccumulative, based on surrogate BAF data (Australia), surrogate BCF data (Switzerland) and estimated BCF data (US). Canada concluded the substance was not bioaccumulative based on predicted log Kow data.

Persistence and Bioaccumulation

Differences:

- Lack of defined policy criteria in some jurisdictions
- Assessment of persistence and bioaccumulation potentials for transformation products in addition to notified substances
- Conclusions differed depending on the availability of studies, type of data (predicted vs. measured) and endpoints (i.e. log Kow vs. BCF) used to predict persistence and bioaccumulation

Similarities:

- All jurisdictions commented on the persistence and bioaccumulation potentials of the substances

4.0 Areas of Cooperation and Information Sharing

96. In the previous sections, the comparison studies from the Rome Workshop and the Washington Meeting were presented. The results of these comparisons represented a consensus reached by participants on assessment differences and similarities between the various jurisdictions. Furthermore, it was evident to participants at the Washington Meeting that areas of cooperation and information sharing are feasible with some components of a risk assessment. These areas of cooperation would be beneficial to both regulators and industry and ultimately, of benefit to the general public.

97. In particular, the participants agreed that countries could cooperate and share hazard assessment information both from a human health and environmental perspective. Although the area of hazard assessment presented much of the opportunity for cooperation and sharing, aspects of environmental fate assessment and environmental exposure assessment were also identified as areas in which countries could exchange assessment information. The group also recognized that there were administrative areas which, if harmonized, could increase consistency in assessment outcomes (e.g., PBT criteria).

98. The following sections outline in greater detail the proposed areas of cooperation and information sharing.

4.1 Hazard Assessment

99. During the discussions, the most obvious area of cooperation and information sharing was the hazard component of the risk assessment. Theoretically, identical hazard outcomes should result if all countries perform their hazard assessments using the same set of data and identical assessment approaches. In practice however, as observed in the Rome and Washington comparisons, different hazard outcomes between countries can result even with the same set of data. The differences in outcomes are a function of varied hazard assessment methodologies employed by each country. Specifically, hazard assessment approaches and outcomes are affected by:

1. The absence or inclusion of SAR data
2. The selection of the critical study (e.g., is the most sensitive species being selected as the critical study?)
3. Selection of the most critical endpoint or value from the dose-response curve (e.g., NOAEL vs. LOAEL)
4. The type and magnitude of safety factors (e.g., 10 vs.100)
5. Use of measured vs. nominal concentrations

100. Ultimately, even slight differences in any of the above factors between countries will influence the value of the PNEC or critical value (e.g., TDI, NOAEL, or potential for genotoxicity).

101. At the Washington Meeting, the hazard component of the risk assessment was the most obvious area for cooperation.

Hazard Assessment Recommendation

Undertake evaluation of:

i) the use of SAR data
ii) the selection of the critical study
iii) the selection of the most critical endpoint or value
iv) the type and magnitude of safety factors
v) use of measured vs. nominal concentrations

4.2 Environmental Fate Assessment

102. During the comparison of assessments it was noted that all countries addressed fate assessment, with varying levels of detail, and discussed aspects influencing the fate of a substance in the environment. Accordingly, the WE I Work Group acknowledged that the sharing and acceptance of fate assessments can be achieved provided that guidance on format and content of an environmental fate assessment is made available to participating countries. It was also recommended that guidance include fate assessment models that can be used to describe the fate of a substance when released to the environment. The main advantage of a common fate assessment is that all participating countries would identify the same environmental compartments into which the substance is expected to partition. This approach can also benefit countries less familiar with multimedia fate modelling. Industry would benefit from having common elements included in a country's environmental fate assessment as well as a common format.

Fate Assessment Recommendations

a) Harmonize format and content of fate assessments

b) Achieve consensus on appropriate fate models

c) Standardize use of fate models in assessments

4.3 Exposure Assessment

103. Unlike hazard and fate assessments, it was agreed that exposure assessments could not be readily shared. This is due primarily to country-specific differences with respect to the manner in which a substance is released to the environment and differences in the receiving environment (e.g., the aquatic environment in Canada would not be the same as that in Australia or Europe). Ultimately, this means that a PEC derived in one country will often not be acceptable for use in another country. Similarly, concerns for human exposure could differ among the different jurisdictions. However, the WE I Work Group recognized that emission scenarios was one area of exposure assessment in which steps could be taken towards information sharing and cooperation. Among the participating countries, the OECD Emission Scenario Documents (ESDs) or the US EPA industrial and consumer release scenarios are used to estimate the quantity of a substance released. Participants agreed that these release scenarios could be shared and, similar to a hazard review, the ESDs or US EPA scenarios can be examined and potentially adopted by all countries for estimating releases. While it may not be possible to completely standardize the ESD or US EPA release scenarios for all countries (e.g., annual import or manufacturing quantity, number of production days), the same release scenario and similar default release parameters that are specific to a

process could be employed, regardless of location, to ensure consistency when estimating releases. The rationale for using the default release parameters would also be shared among participating countries. This idea may be further developed by the OECD Environmental Exposure Assessment Task Force (EEATF), currently examining ESDs for common use internationally.

104. The advantage to industry and government of sharing and agreeing on a common release scenario is the minimization of variables that lead to different PECs or different conclusions with regard to predicted exposure of workers or the general public. This would reduce the uncertainty in PEC calculations, allow exposure assessments to be more transparent and provide consistency in exposure assessments conducted across various jurisdictions. In addition, a review of emission scenarios may in some cases lead to adoption by participating countries.

Exposure Assessment Recommendations

a) Ensure participating countries are taking full advantage and contributing to the Emission Scenario Documents (ESDs) being developed by the OECD Environmental Exposure Assessment Task Force (EEATF)

b) US to make available release scenario documents with participating countries

c) Ensure participating countries take advantage of and contribute to developments by the OECD EEATF with respect to default release parameters

4.4 Impact of Legislation on Scope of Assessments

105. Another area that was discussed in the context of cooperation and information sharing was different legislations and how these impact assessments produced by each jurisdiction. For instance, Australia, the UK and the US currently undertake environmental, human health and occupational assessments. Switzerland, with the introduction of new Regulations in 2005 will also be assessing these three areas. It was noted that under their current new chemical legislations, Canada, Switzerland and Japan do not conduct occupational health assessments, however, for some of these countries these are addressed under separate legislations.

106. As part of the scope of data requirements for new chemicals, it was agreed by participants that ideal data coverage for conducting hazard assessments for new chemicals included both the use of experimental data and the use of SAR analysis. SAR information can serve as supporting documentation and as weight of evidence in risk assessments. In addition, the harmonization of data requirements would provide each jurisdiction with the benefit of a more robust dataset on which to base their risk assessments. There was interest in Canada and the US sharing their knowledge and expertise on SARs with member countries. Correspondingly, other jurisdictions were encouraged to develop the internal capacity to evaluate and use SAR data as part of their assessment process.

107. As discussed in the comparison sections above, a number of jurisdictions do not have domestic PBT policies in place or guidance criteria to address persistence and bioaccumulation. Participants agreed that the US EPA tiered approach to PBT classification warranted further review by the various jurisdictions, in addition to their obligations under the Stockholm Convention.

108. The mechanism for inclusion of a substance onto a public inventory was also considered. Some jurisdictions (Canada, US) have open, public inventories whereby a substance is added to the inventory upon completion of the risk assessment when no concerns have been identified. Other jurisdictions (Australia, Switzerland) have secondary notifications in place which require re-notification if circumstances in the initial notification change (e.g., use, volume changes). Participants agreed that this can be considered as an area for potential cooperation, however, the inventory criteria for inclusion of a substance need to be further examined by the various jurisdictions.

109. It was also noted that all jurisdictions had similar authorities to reject unacceptable data and request additional information as necessary to address data gaps in their risk assessments. Jurisdictions also had various administrative mechanisms in place to pause or suspend a notification, in cases where information was missing or technical issues required resolution.

110. Jurisdictions were not subject to limitations with respect to seeking advice from external sources, as long as this did not result in the disclosure of CBI. These discussions lead to a proposal to develop an inventory of government expertise. Initially, jurisdictions could circulate contact information of program scientists which would include names, areas of expertise, phone numbers and e-mail addresses. In the longer term, other avenues of information technology can be considered such as electronic discussion groups.

Impact of Legislation on Scope of Assessments Recommendations

a) Canada, US and the OECD Expert Group on QSARs share their knowledge and expertise on SARs with participating member countries

b) Participating countries examine US EPA approach to tiered PBT classification criteria

c) Develop a government inventory of new chemical assessment expertise within OECD Member countries

5.0 Work Element I Conclusions

111. The assessment comparison results presented in this document reveal areas where further work can be conducted in order to achieve mutual acceptance of hazard assessments and ultimately, risk assessments. The recommendations made in the areas of hazard, fate, exposure assessments and legislative scope can be grouped into two categories: i) Harmonization and ii) Information/Work Sharing.

112. Hazard assessment methodologies can be evaluated to address the differences across OECD jurisdictions, more specifically:

i) the use of SAR data
ii) the selection of the critical study
iii) selection of the critical endpoint or value
iv) magnitude of safety factors and
v) the use of measured vs. nominal concentrations

113. Furthermore, harmonizing the format and content of the fate and exposure assessments and standardizing the type of models that are used by jurisdictions would be beneficial in order to arrive at common risk assessments. In the area of exposure assessments, harmonization can be achieved by working

toward adopting emission scenarios in order to ensure consistency between jurisdictions when estimating releases.

114. From a work sharing perspective, information related to hazard assessments, environmental fate and exposure assessments could be shared between OECD jurisdictions. Sharing information and knowledge in these areas when assessing new substances would allow for jurisdictions to quantify the hazard, describe the fate of the substance, identify the same environmental compartments for partitioning, as well as establish a similar exposure profile based on use, in order to arrive at common fate and exposure assessments. In addition, sharing knowledge and expertise on the use of SAR information, as well as classification of substances with respect to persistence, bioaccumulation and toxicity parameters also warrants further examination.

115. Maximizing opportunities for developing common understanding of assessment methodologies and information sharing in the area of new chemical assessments will result in greater confidence in individual hazard, exposure and risk assessment outcomes. The proposed areas for cooperation and information sharing described in this document will serve to contribute to tangible benefits for both governments and industry, with a view to increase work efficiencies among member countries without compromising human and environmental health protection and ultimately progressing toward the mutual acceptance of notifications.

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Appendix 1

Recommendations from the Rome Workshop

To Task Force:

All Members

- Establish an agreed procedure between governments on the Task Force and industry for dealing with exchange of industry information including CBI, based on that used in the initial multilaterals; once agreed, bring to the Joint Meeting for OECD-wide endorsement.

- Proceed with the development of a standardised assessment report format under WE III, using the Australian template under development as a starting point.

- Extend the SAR validation starting with one to two data elements and consider referring this work to the OECD special session on QSARs.

Produce a consolidated matrix of the government comparisons for this work element for incorporation in the November 2002 Joint Meeting document to highlight the substantial progress and valuable conclusions reached in Work Element I.

- Explore each government's rationale in choosing quantitative vs. qualitative exposure and risk assessment.

Regulatory Authorities on the Task Force

- Conduct prospective comparisons on chemicals and comparisons of chemicals of anticipated higher hazard to build on the knowledge gained from the initial comparisons.

- Explore the pros and cons of applying SAR to decision-making to understand why it does not have widespread use and ask authorities to explain their positions on SAR.

- Develop and share documents describing their risk assessment decision-making process.

To the Joint Meeting:

- The workshop recommends, for consideration during the discussion at the November 2002 Special Session on QSARs, that OECD explore ways to increase the understanding of SARs and how and why they are used in OECD Member countries.

- As many Member countries are considering amending their legislation, and others may do so in the near future, when amending such legislation, countries should build in, to the extent possible, flexibility to accommodate international agreements on the regulation of industrial chemicals (i.e. international sharing activities).

To Industry:

- Supplement notifications with additional data to assist the authority in regulatory assessment and decision-making, e.g., additional physico-chemical data could facilitate the application of predictive models.

- Facilitate data sharing by authorizing the exchange of CBI information, e.g. proceeding with Work Element IV.

- Use concurrent notifications to different regulatory authorities to aid in the development of Work Elements I, III and IV.

Appendix 2
OECD WE I Meeting (Washington, D.C)
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