Unclassified **ENV/JM/MONO(2007)29**

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

01-Oct-2007

English - Or. English

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

SERIES ON CHEMICAL ACCIDENTS
Number 16

Report of the OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases, 16-18 October 2006, Varese, Italy

JT03232988

OECD Environment, Health and Safety Publications

Series on Chemical Accidents

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Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

Paris, 2007

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FOREWORD

This report presents the main output of the OECD-EC workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases, which took place in Varese, Italy, on 16-18 October 2006. The Workshop was sponsored by Environment Canada – Environmental Emergencies Branch and the European commission Major Accident Hazards Bureau (MAHB).

49 participants from 17 OECD member countries, one non-member country and the European Commission attended the Workshop with the goal of sharing information and experiences on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing and managing chemical accidents. The List of Participants is presented in Annex 3.

The overall objectives of the workshop were to: (i) share experience, on a scientific basis, used by OECD member countries in identifying the hazards posed by chemicals involved in accidental releases, focusing on characteristics, criteria and the establishment of threshold quantities; (ii) examine commonalities and differences of approaches, criteria and methodologies employed by OECD countries and regions; (iii) explore how development in the chemicals assessment area could have an impact on processes used in OECD countries for identifying and selecting hazardous substances for regulation with respect to preventing and managing accidents; and (iv) investigate the possibility of launching collaboration to support more consistent criteria to identification/selection of regulated substances/groups of substances, and to facilitate greater data and information exchange.

The workshop included sessions on: (1) How hazardous substances involved in major accidents are identified and managed in OECD countries? (2) Current processes for selecting 'regulated' chemicals and determining thresholds of effects under accident prevention policies; (3) Examples of divergences in approaches and potential for future implications; (4) Elaboration of a consistent approach to identify chemicals of interest for accident regulation purposes; and (5) The path forward. The Workshop Agenda-Programme is presented in Annex 2.

The first part of this report consists of the Workshop Conclusions, Observations and Recommendations. This is followed by the Discussion Document prepared for the Workshop; it is presented in Annex 1. This document provides a comprehensive overview of the processes used in OECD countries or regions for identifying and selecting dangerous substances regulated under chemical accident prevention programmes.

EXECUTIVE SUMMARY

The OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases took place in Varese, Italy, on 16-18 October 2006. It was sponsored by Environment Canada - Environmental Emergencies Branch and the European Commission - Major Accident Hazards Bureau (MAHB). Forty-nine participants from 17 OECD member countries, one non-member country and the EC attended the workshop.

The overall objective of the workshop was **to share information and experiences** on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing/managing chemical accidents.

The workshop **examined commonalities and differences** in approaches, criteria and methodologies employed; investigated feasibility of developing common criteria and principles in the context of sharing information on results and experiences; encouraged discussion on the selection process for candidate chemicals and categories, and the determination of their threshold quantities; and discussed experiences with the respective approaches.

The workshop pursued collaboration to support more consistent criteria and principles to identification and selection of individual substances or groups of substances (categories/classes), thereby, possibly allaying trade/competitiveness concerns through such greater harmonization in approaches.

The workshop enabled participants to obtain a better common understanding of each others respective approaches and set the foundation for some interesting discussions. The differences between the European and North American systems and the divergence in views and expectations among the participants, was noted. It was acknowledged that each country has its own legislative and administrative constraints to deal with, which essentially prevent harmonization of any such regulations but still enables fruitful international collaboration on the scientific underpinnings for those decisions.

The workshop however was clearly successful in establishing and elaborating on what some of the areas of common ground actually are. Workshop participants agreed to **explore opportunities to facilitate greater data/information exchange** and try to reduce workload through work sharing.

Some of the key observations/conclusions were: a common theme was agreement that **major accidents pose a significant threat** to man, the environment and particularly workers. All OECD countries have a common pragmatic approach which uses expert judgment to define hazardous sites. Since expert judgment is a combination of practical experience with scientific knowledge, it would be most appropriate to increase the number of “expert judgment tools” in order to further facilitate prevention of major accidents and mitigation of the consequences.

Another was that implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) will result in changes which need to be managed. The new European chemicals policy called REACH (Registration, Evaluation and Authorisation of Chemicals) on the other hand aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. There are also

several future challenges related to land-use planning, particularly on how to deal with pre-existing situations of incompatibility between hazardous installations and neighboring residential areas.

Some chemicals, chlorine and ammonium nitrate for example, have large variations in thresholds among OECD countries. The basis for defining threshold quantities should possibly be re-evaluated when new scientific evidence becomes available. For instance, the Immediately Dangerous to Life and Health (IDLH) values which were used to set threshold quantities for chlorine were lowered in the mid 1990's. The main hazards with ammonium nitrate are fire hazards, thermal decomposition and explosion hazards. The discussion on appropriate thresholds through joint scientific reviews is a potential area for future international collaboration.

It was also noted that avoidance strategies sometimes reduce overall risk, which can be considered a positive effect of regulation. On the other hand, avoidance strategies may simply be risk transfer mechanisms that do not affect – or even increase – the overall risk level. Further, despite one's best efforts, operations do not always proceed as planned, so organizations must be ready to turn their mistakes – and those by others – into opportunities to improve accident prevention efforts.

The workshop came up with three main recommendations for further consideration and approval by the OECD Working Group on Chemical Accidents (WGCA) and its parent bodies. They are: (1) to **collaborate on further development of methods to collect and analyse data related to acutely toxic properties**. ACUTEX is supported by most stakeholders but some issues need to be discussed further to achieve a larger consensus. The recommendation proposes using existing communication and research networks under the leadership of the Netherlands to promote mutual exchange and contributions among scientists working on these issues. (2) to **develop a process for identifying advantages, disadvantages and gaps concerning the selection of substances/groups of substances and thresholds for managing potential hazards** associated with the prevention of chemical accidents in relevant legislation of OECD countries. The process would make periodic suggestions/recommendations for the consideration of the WGCA and subsequent prioritization and assignment to others as it deems appropriate. (3) to **improve sharing of knowledge on the risk assessment of chemicals** in the context of accident prevention as part of the current activities under the WGCA. It was agreed to support the Major Accident Reporting System – MARS data base – as the vehicle to consolidate lessons learned from accidents and to make these more accessible to the user community.

Further deliberations on the recommendations from the workshop should lead to the development of a suitable programme of work including if need be, the creation of a group to undertake the work and distribute the task among countries.

Asit Hazra and Michalis Christou, Workshop co-chairs

CONCLUSIONS, OBSERVATIONS AND RECOMMENDATIONS

INTRODUCTION

1. The OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases took place in Varese, Italy, on 16-18 October 2006. It was sponsored by Environment Canada – Environmental Emergencies Branch and the European Commission Major Accident Hazards Bureau (MAHB). Fourty-nine participants from seventeen OECD member countries, one non-member country and the European Commission attended the workshop.

2. The overall objective of the workshop was **to share information and experiences** on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing/managing chemical accidents.

3. The detailed objectives of the workshop were:

a) Share experience, on a scientific basis, used by OECD member countries in identifying the hazards posed by chemicals involved in accidental releases, focusing on characteristics, criteria and the establishment of threshold quantities.

b) Examine commonalities and differences of approaches, criteria and methodologies employed by OECD countries or regions, with a view to launching or pursuing technical exchange on this issue and creating opportunities for increasing greater complementarity and compatibility of those approaches.

c) Investigate the possibility of:

   - developing common criteria and principles for identifying and categorising hazardous substances in the context of ongoing exchange of information on work in this area; and

   - establishing channels of communication to allow countries/stakeholders to continue to share information on results and experiences.

d) Explore how developments in the chemicals assessment area could have an impact on processes used in OECD countries for identifying and selecting hazardous substances for regulation with respect to preventing/managing accidental releases: e.g. the new UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS); the new European chemicals policy called REACH (Registration, Evaluation and Authorisation of Chemicals) – Build awareness of other initiatives related to hazardous substances that could also affect implementation of industrial accident regulations in OECD countries (e.g. Acute Exposure Threshold Levels methodology).

e) Acknowledge the differences in approaches among OECD countries or regions, in terms of threshold quantities assigned to substances and categories of substances for determining regulatory obligations with respect to preventing/managing accidental releases – Encourage discussion on the selection of candidate chemicals and categories, and the determination of their threshold quantities and associated regulatory requirements for different threshold levels – Agree to develop a comparative matrix showing criteria and methodology used by different regulatory systems to identify and select hazardous substances and categories with respect to preventing/ managing risks associated with accidental releases – Describe the advantages and disadvantages of the respective approaches.

f) Investigate the possibility of launching collaboration to support more consistent criteria and principles to identification and selection of individual substances or groups of substances (categories/classes) across OECD membership – Determine interest among member countries for such closer co-operation (the intent being to possibly allay trade/competitiveness concerns through greater harmonisation in approaches) – Consider sharing the burden of possible "re-assessment" of chemicals, resulting from the application of GHS, in the context of accident prevention regulations.

g) Explore possible opportunities to facilitate greater data/information exchange and to reduce workload through work sharing.

4. There were five thematic sessions. The Workshop started with the presentation of a Discussion Document which provides a comprehensive overview of the processes used in OECD countries or regions for identifying and selecting dangerous substances regulated under chemical accident prevention programmes.

CONCLUSIONS AND RECOMMENDATIONS OF THE WORKSHOP

SESSION 1

How Hazardous Substances Involved in Major Accidents are Identified and Managed in OECD Countries?

5. This session consisted of four presentations. The presentations summarised the regulatory regime for major hazards in EU, USA, Canada and Korea.

6. The Joint Research Centre's Major Hazard Bureau provided a **General Overview of Qualifying Criteria for Substances under Seveso II** with the general description of how Annex 1 of the Seveso II Directive works, including a brief historical perspective. The presentation included a discussion of the significant advantages and disadvantages and some of the legal and practical measures introduced to address them.

7. A representative from the US Chemical Safety Board (CSB) provided a **Brief Review of Hazardous Substance Lists Used in the United States.** The paper provided a short description of the lists of hazardous substances used for major hazards at the federal level in the United States.

8. A representative from Environment Canada talked about the **Canadian Methodology for Substance Evaluation.** This presentation addressed the process and approach used to develop Schedule 1 (the list of substances and their threshold quantities) of the Environmental Emergency Regulations under the Canadian Environmental Protection Act (CEPA), 1999. The technical basis for the Risk Evaluation Framework (REF) used in the assessment of candidate chemicals was described along with the results obtained. It involves both the screening of substances proposed for addition to the regulation as well as a re-evaluation of those substances currently covered by the regulation.

9. A representative from the Korea Occupational Safety & Health Agency (KOSHA), talked about the **Korean Risk Assessment Experience.** The presentation described the methodology used by Korea,

under the Safety and Health Act (enacted December 1981, last amendment December 2002) for evaluating hazardous substances involved in major accident hazards.

Key Points, Observations and Conclusions

10. The key points from presentations and the main observations and conclusions from discussions are summarised below.

General Overview of Qualifying Criteria for Substances under Seveso II

11. The main objective of the EC Seveso Directive is to ensure high levels of protection in a consistent and effective manner. The advantages of the EC Seveso approach are: (i) uniform objective criteria: hazard profile provides one common basis for evaluation; (ii) exceptions are allowed but they must be strongly argued for other risk factors (e.g. accident history, process conditions, unique behaviours), and for political and economic factors; and (iii) new findings, 'new' science incorporated without legislation. The potential disadvantages of the EC Seveso approach are: (i) the multi-purpose nature of chemical risk assessments is not suited for process conditions and it is difficult to capture unique properties or behaviour, risk management etc.; (ii) dependence on quantification of a harmful property with test methods is not always achievable – some test methods are still in development – many substances lack data and the formula for extrapolating to mixtures/preparations is very generalised and (iii) there is inconsistency in European member state interpretations for complex situations.

12. The Seveso Directive provides some opportunities for relief: a named list of substances for exceptions; additional qualifying criteria (e.g. process conditions); calibration of threshold quantities; and the exemption of particular industry sectors. In addition, an enforcement strategy and prioritisation, and a forum for reaching common agreement on interpretations (utilising "Questions & Answers" developed by MAHB) are currently in implementation.

13. The development of the annex of the Seveso II Directive from early consideration in the late 1980s was explained. Two studies carried out during that time proposed a structure for the annex with named substances and substance categories, where the named substances should reflect either specific hazards or exemptions necessary because of political/economic necessities. Initially a more systematic approach was foreseen to define the threshold quantities mainly by a logarithmic scale proportional to the risk posed by the substance hazards but this was implemented only partly in annex I of the Seveso II Directive. Instead practical considerations became more relevant, such as the administrative feasibility to control only a certain number of affected sites.

Brief Review of Hazardous Substance Lists Used in the United States

14. The US system for defining hazardous substances and respective thresholds relevant for purposes of major accident prevention and related fields like emergency response or worker protection was described. The US system consists of a variety of lists which refer to specific legal obligations (e.g. those serving as legal basis for the Environmental Protection Agency – EPA).

15. The US Federal Agencies that deal with hazardous substances lists are: the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Department of Transportation, Coast Guard and the Chemical Safety Board. The US State and Local Agencies that deal with hazardous substances lists are: the State Environmental Protection Agencies, the State Emergency Response Commissions, the local Emergency Planning Committees and the Fire Departments. In the United States, federal and state environmental and public safety laws and regulations require the preparation of lists of hazardous substances.

16. Facilities and agencies that store or use any chemical or chemicals on a list must comply with the regulations pertaining to that list. More than 110 chemical lists have been prepared to comply with the above laws. The prevention of accidental releases of toxic substances (EPA) – Clean Air Act 112(r) – applies to releases into the community: (i) 140 chemicals, each with a threshold quantity, are covered; (ii) for processes with more than the threshold quantity (TQ), a hazard assessment must be prepared, and an accident prevention and an emergency response program must be developed; and (iii) the above must be submitted to EPA and local emergency planning agencies. The process safety management of highly hazardous chemicals (OSHA) applies within the workplace: (i) it applies to facilities having more than a TQ of highly hazardous chemicals, toxics, reactives and flammables; and (ii) facilities must develop plans to prevent or minimize the consequences of catastrophic releases of toxic, flammable, or explosive chemicals. The scope of the lists may overlap but there is no common tool for development. The lists are mainly based on accident history knowledge and pragmatic considerations.

Canadian Methodology for Substance Evaluation

17. The Canadian legislation dealing with the management of hazardous substances was created in 1999 when the Canadian Environmental Protection Act (CEPA) was revised, Section 200 of the Act, the regulation-making authority that requires the development and implementation of environmental emergency plans, was described. The CEPA is only broad umbrella legislation that needs further tools to define the facilities which have to follow the requirements; this is achieved by the environmental emergency regulation that identifies the substances covered and their associated threshold quantities. In Canada two efforts were undertaken to develop lists of hazardous substances and related thresholds. One was the “MIACC – list” (Major Industrial Accident Council of Canada), the other the more recent CRAIM (Conseil pour la Réduction des Accidents Industriels Majeurs) list. The lists were developed from accident histories and as well as from the US EPA list and reflect a prioritisation compiled from expert assessment.

18. The threshold quantities are set for flammable substances based on the potential for a Vapour Cloud Explosion (VCE) to cause lethal effects at 100 m and for toxics based on (i) the potential to become airborne, (ii) dispersion potential, (iii) toxicological properties, (iv) chemical reactivity, and, (v) other possible factors. Facilities meeting the qualifying criteria for substance quantity and container size must satisfy a number of requirements including the preparation and implementation of an environmental emergency (E2) plan.

19. Environmental emergency plans cover protection of human health (and safety) and protection of the environment. The current status is: (i) since implementation of the regulation, approximately 3500 facilities are affected; (ii) there is an on-going effort to raise compliance levels; (iii) many facilities are covered for multiple substances; and (iv) about 2300 of the facilities have to meet all requirements, i.e. complete and implement an E2 plan.

Korean Risk Assessment Experience

20. The Korean Industrial Safety and Health Act was amended in January 1995 to include the prevention of major accidents, and has been in force since January 1, 1996. The law stipulates that the owner of hazardous installations shall submit a process safety report to the government. The industrial categories concerned are: oil refineries, petrochemical, organic composite material & synthetic resin, fertilisers, pesticides and explosives. Nuclear and military installations are not covered in the scope of this law. The Industrial Safety and Health Act selected the industrial categories and established the threshold quantities based on relevant information from ILO (International Labour Organisation) Convention No 174, the US PSM (Process Safety Management), the Seveso Directive, etc. The thresholds were then fixed by a comparison of international sources (Seveso II, EPA, etc.) according to specific needs and judged by a pragmatic approach.

Summary of Conclusions of Thematic Session 1

21. In all four presentations the common element referred to major accidents as a threat to man and/or environment and/or workers in particular. To some extent, all systems have a common pragmatic approach which uses expert judgment to achieve the target to define hazardous sites. Since expert judgment may be seen as an applied combination of practical experience with scientific knowledge, it seems most appropriate to increase the number of "expert judgment tools" in order to improve the implementation of the overall target for the prevention of major accidents and mitigation of respective consequences.

SESSION 2

Current Processes for Selecting 'Regulated' Chemicals and Determining Thresholds of Effects under Accident Prevention Policies

22. This session consisted of seven presentations. The presentations described factors affecting the selection of regulated chemicals and their thresholds.

23. A representative from the Université de Sherbrooke, Canada provided a **Comparative Matrix of Dangerous Substances Used in Major Hazard Regulations.** This presentation illustrated the approaches chosen by countries and regions and the criteria used to regulate hazardous substances under respective major accident prevention programs. The comparison was not intended to be comprehensive; however, it provided an example of some notable differences that have been identified. It could serve as a platform to explore areas where collaboration could be developed.

24. A representative from the Joint Research Centre's Major Accident Hazards Bureau (MAHB) provided **Case Studies in Qualifying Seveso Coverage for Substances Dangerous to the Environment and Carcinogens.** This presentation illustrated the complexities of determining qualifying criteria for accident prevention coverage from the Seveso II experience, using particular rich examples from efforts to provide adequate coverage of hazardous installations handling substances dangerous to the environment and carcinogens. These two categories of dangerous substances pose some interesting problems with respect to coverage under Seveso and were the focus of intensive study and debate within two EU Technical Working Groups charged with refining the qualifying criteria for coverage for each category under the 1996 Directive. The outcome of this work eventually was incorporated into the 2003 amendment to the Directive.

25. A representative from the "Institut National de l'environnement industriel et des risques" (INERIS), France presented the **Use of the Classification System of Hazardous Substances and Preparations for the Classification/ Ranking of Installations** in France. This presentation explained how the classification of hazardous substances and preparations, based on the chemicals risk phrases, was used in France to identify which category of the nomenclature of classified installations these hazardous substances and preparations belonged to. The nomenclature allows a ranking of the dangerous industrial facilities and the safety requirements that these installations have to comply with. The link with the Seveso II Directive was detailed.

26. A representative from the US Chemical Safety and Hazard Investigation Board (CSB) provided **Lessons from Accident Investigation and their Influence on Hazardous Substance Lists and their Thresholds.** The CSB is an independent federal agency investigating chemical accidents to protect workers, the public and the environment.

27. A representative from the Joint Research Centre's MAHB presented a **Report on the (January 2006) Vienna Seminar on Chemical Substance Classification Issues in the context of the Seveso Directive**. This paper provided a report on the "Seminar on chemical substance classification issues in the context of the Seveso-II-Directive", held in Vienna in January 2006. This event was organised by the Austrian government (Austria had the EU presidency from January to June 2006) and the MAHB in the context of the 15th Meeting of the Seveso Committee of Competent Authorities (CCA). The presentation also summarised the options and concepts related to the implementation of the new classification scheme in the EU regulation from the Seveso II Directive standpoint.

28. A representative from the Ministry of Housing, Spatial Planning and Environment of the Netherlands gave a presentation on **Standardisation and Implementation Realizing the Required Flexibility.** This paper described some of the challenges faced in the Netherlands in land use planning.

29. A representative from ABS Consulting in the United States presented the **Non-Traditional Approaches in Selecting Substances for Special Accident Prevention Measures.** This paper provided other factors such as process safety management, reactivity and by-products of combustion that could potentially affect the selection of hazardous substances and their thresholds.

Key Points, Observations and Conclusions

30. The key points from these presentations and the main observations and conclusions from the workshop discussions are summarised below.

Comparative Matrix of Dangerous Substances in Major Hazard Regulations

31. Analysis of the matrix brought the following findings. Some regulatory regimes use only named substances as the basis for coverage and others use generic criteria along with a list of named substances. Some regulatory systems deal only with off-site consequences, some only with on-site consequences and others with both on- and off-site consequences. Some accident prevention authorities are also responsible for chemical risk assessments whereas under other regimes (the majority), chemical risk assessment is governed by other legislation. The unit of coverage differs between regulatory regimes, e.g. the total inventory on site, the inventory of a process, the inventory of the largest vessel, etc. Coverage of sites with perceived higher risks versus lower risks are differentiated in various ways under the different regimes.

32. Thresholds for substances named in the various regulatory regimes are generally not the same. Thresholds are set in order to identify facilities covered by regulations on accidental hazards. Thresholds do not necessarily correspond to the lowest amount of the substances that has the potential to cause an accident. It was noted that changes in the list of hazardous substances and their thresholds have a profound impact on the regulated community and the public authorities. Criteria for evaluation of impact on the environment, e.g. acute carcinogenic potential, bioaccumulation and persistence in the environment, may be an area for international collaboration. Most countries regulate essential infrastructures under public safety organisations or agencies. The question was raised about whether this is the appropriate place to regulate public safety and chemical site security? There is a need to determine critical criteria to regulate facilities which may affect essential infrastructures.

33. Each country has its own political infrastructure which stipulates which organisation within the country will develop and implement regulations and this may affect the structure and coverage of those regulations. The comparative matrix should be enlarged to include: (a) a better description of the basis for developing scenarios leading to the selection of chemicals and their thresholds; (b) consideration for chemicals being in commerce; (c) greater precision on the general duty clause, (d) how mixtures are

treated; (e) the impact of worker safety regimes; and, (f) major hazard regimes from counties such as China and India should be included in the matrix (and this may be included in a second phase).

Case Studies in Qualifying Seveso coverage for substances Dangerous to the Environment and Carcinogens

34. Substances dangerous to the environment which have acute toxicity and persistence and single-shot carcinogens are regulated under Seveso. The challenge to identify these substances and set their thresholds was addressed by insuring transparency, consistency and a scientific basis when defining the scope of the regulation. The methodology for determining chemicals on the list should be based on conclusive scientific data, but must also consider pragmatic/political issues. It is important however, that the science narrows down the set of alternatives to scientifically sound solutions, amongst which political/pragmatic criteria may apply.

Use of the Classification System of Hazardous Substances and Preparations for the Classification/ Ranking of Installations in France

35. The Seveso II Directive was implemented in France through national laws and regulations which included a classification system for hazardous industrial facilities. The classification system is a function of the substances (hazard categories) and the activities. There are three thresholds for each category: Declaration, Authorisation (less or equal to lower Seveso tier) and Authorisation with Constraint (equal to upper Seveso tier). Safety reports are required for Authorisation and Authorisation with Constraint Establishments.

Lessons from Accident Investigations and their Influence on Hazardous Substance Lists and their Thresholds

36. Here are some lessons learned from CSB investigations. The process safety management program is an excellent tool, regardless of whether or not the facility meets the threshold levels. However, process safety management programs require commitment to chemical process safety and this must start at the top. There has to be a strong culture of safety. Facilities need to understand the hazards of their process, both the chemistry and the engineering. The price of success is constant diligence. It was noted that community emergency response capabilities vary in effectiveness. There could be benefits in adding the CSB investigation reports and other investigation reports to the Major Accident Reporting System (MARS) Data Base.

Report on the Seminar on Chemical Substance Classification Issues in the Context of the Seveso II Directive on 18 January 2006 in Vienna, Austria

37. The seminar generated the following recommendations: (i) Options for possible amendments of Annex 1 of Seveso II after the Globally Harmonised System for the Classification of Chemicals (GHS) coming into force and effects on the scope of application, mainly the number of sites, should be explored; (ii) There should be consideration for additional conditions to be included in GHS definitions; (iii) Options for improvements to the interpretations of substance classification should be explored; (iv) The number of details in Annex 1 should be increased; (v) An EU-wide Seveso interpretations body should be established to assist with interpretation of Seveso II regulations; and, (vi) Legal "opting out" of the Seveso scope should be available with appropriate justification.

Standardisation and Implementation: Realizing the Required Flexibility

38. Various factors can dramatically influence the quantitative risk assessment (QRA) results in land use planning. Here are some concepts used in the Netherlands to minimize this variance. Standardisation

of only the QRA procedure will still result in scatter. There is a need to specify the parameters used in the QRA. The collection of information is only the start of a standard and, adjustment after implementation can be painful. It is recommended that possible collaboration with relevant disciplines (i.e. toxicology, physics, and chemistry) be investigated and the gathered data should be presented in a format fit for the intended use. Emergency preparedness/response as well as land-use planning require credible acute toxicity guidelines. A methodology to develop acute toxicity guidelines is helpful but insufficient since recommended values may vary substantially. It is better to develop a lasting process to derive/recommend values that is: transparent and timely, with institutional memory (e.g. in a standing committee); robust enough to lend authority, credibility and trust; and, at least on a European scale, preferably global. Land-use planning should be included in the comparative matrix.

Non-Traditional Approaches in Selecting Substances for Accident Prevention

39. Non-traditional approaches for accident prevention should be taken into account in selecting substances for accident prevention. Better coverage criteria should lead to better accident reduction, not just more regulation. There is a need to have a better way of measuring where we are in accident prevention if we are ever going to be able to evaluate the effectiveness of coverage criteria. While establishing coverage criteria, we should consider "separation of purposes", i.e. safety, environment (drives tighter coverage), and security/critical infrastructure (drives broader and tighter coverage). Additional elements which may be taken into account when establishing coverage criteria are: (a) the process amount or largest vessel with capability to generate chemical accidents instead of total entity inventory; (b) a robust, transparent technical basis; (c) subject matter expertise to address coverage issues; and (d) measures/approach for adjusting coverage.

40. We should consider requiring local entity coverage assessment to be submitted. We should consider a multi-tier approach, including general duty for all, accident prevention – "lite" and full programme. We want to encourage prevention and continuous learning on the lower end of the pyramid, i.e. safety legislation is useful at all levels, not only those regulated facilities. It may be desirable to develop harmonised coverage deployment strategies. It might be better to start with a harmonised strategy rather than a single set of criteria.

41. Additionally, the following should be explored: (i) cultural change where the regulated community will not only meet the regulation but reduce risk (some examples of chemical substitution with less hazardous ones were quoted); (ii) where inventories are less than the threshold quantity, in some instances, the general duty clause has been an incentive to apply process safety management and essentially adopt a tier II program; and (iii) non-traditional approaches are a good source for future exchanges, specifically, how they might work, or fit.

Summary of Conclusions and Recommendations of Thematic Session 2

42. The keys to good coverage criteria are: (a) keep the end in mind; (b) match multi-tier coverage to prevention activities; (c) use process amount or largest vessel with capability to generate instead of total entity inventory; (d) employ a robust, transparent technical basis; (e) require local entity coverage assessment to be submitted; (f) provide subject matter expertise to address coverage issues; (g) establish measures/approaches for adjusting coverage; and (h) provide expansive regulated community education on requirements and continuing education provisions. Impact on health and environment e.g. acute carcinogenic potential, bioaccumulation and persistence in the environment, may be an area to further explore.

SESSION 3

Examples of Divergence in Approaches and Potential for Future Implications

43. This session consisted of eight presentations. The presentations were somewhat diverse in the material they covered. The first three presentations looked at two upcoming EU legislative changes, the adoption of the GHS for the Classification of Chemicals and the new REACH (Regulation, Evaluation, Authorisation and Restriction of Chemicals) regulation, and how they could impact future coverage of establishments under the Seveso II Directive. The second two presentations discussed technical difficulties in finding the right coverage criteria for specific substances, chlorine and ammonium nitrate. The final two sessions showed how acute hazard information could be applied effectively in the implementation of accident prevention legislation.

44. The Joint Research Centre's European Chemicals Bureau described **EU Adoption of the Globally Harmonised System and Implications for Seveso II Coverage.** The Seveso II Directive admits establishments for coverage on the basis of categories of hazardous substances present on-site. Adoption of the GHS (Globally Harmonised System for the Classification of Chemicals) in the EU will change provisions for categorising hazardous substances in the EU from the current provisions authorised in the Directive for Classification and Labelling of Dangerous Substances (67/548/EEC) and Preparations (1999/45/EC).

45. A representative from the European Chemicals Bureau also described **Areas where REACH can be Useful to the Seveso Directive,** e.g. higher availability of substance hazard data, development of exposure assessment methodologies including IT tools, inventory of classification of substances, etc.

46. A representative from the "Bundesamt für Umwelt" (BAFU) in Switzerland talked about **Problems and Opportunities arising from a Change to the Classification System for the Definition of Threshold Quantitie**s. Threshold quantities depending on the toxicity, flammability, explosiveness and eco-toxicity criteria are used in Switzerland to determine whether an establishment falls within the scope of the Ordinance on Major Accidents (OMA). Recently, the Swiss classification system for chemicals was adapted based on the EU classification. This presentation illustrated the consequences arising from this amendment for threshold quantities.

47. A representative from the "Institut National de l'environnement industriel et des risques" (INERIS) gave a presentation on **Ammonium nitrate: Changes in the Regulation at the EC and French levels**. This presentation introduced the Seveso classification history for ammonium nitrate and ammonium nitrate-based products including a definition of the hazards and thresholds. In addition, the implementation in France of the Seveso Directive concerning these chemicals was presented.

48. A representative from the Université de Sherbrooke (Canada) presented the topic: **Are the Current Thresholds for Chlorine Adequate to Protect the People and the Environment?** The presentation enumerated the thresholds for chlorine used by countries and regions and described the procedures that were followed to choose these thresholds.

49. A representative from INERIS described the results of the **Acute Exposure Threshold Levels Project (ACUTEX).** The aim of ACUTEX was to develop innovative approaches to define acute exposure levels (AETLs) that could be used to establish acute exposure levels for emergency planning and land-use-planning under the Seveso II Directive.

50. A representative from the Austrian Ministry of the Environment/ Steiermark (STMK) gave a presentation on **Current LUP Practices around Seveso II Establishments and Future Challenges.** This

presentation dealt with risk assessment in the context of Land-Use-Planning in Austria (Article 12 of Directive 96/82/EC).

51. A representative from the Swedish Fire Protection Association described **"Dangerous Good Cards" – Practices for Risk Assessment in Acute Situations.** The 'dangerous cards' are chemical information sheets widely used by the emergency responders in Sweden. They are part of the regular outfits for the rescue teams.

Key Points, Observations and Conclusions

52. The key points from presentations and the main observations and conclusions from discussions are summarised below:

EU Adoption of the Globally Harmonised System and Implication for Seveso II Coverage

53. Implementation of the Globally Harmonised System (GHS) will result in changes which need to be managed. GHS addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. The current EU system and the GHS system are conceptually similar and cover the same structural elements: classification, packaging and hazard communication including labelling and safety data sheets. However, some of the EU criteria for classification will change with the new system. For example, the hazard categories (risk phrases) that exist in the current Classification and Labelling Directive will be transposed into a GHS classification with the new regulation. But there are certain differences in how substances will be classified under the new system, which means that the groups of substances classed together will change. For example, substances in the T+ (very toxic) category of 67/548/EC will not all be grouped together under GHS. Rather, they will be divided into GHS categories 1 and 2 because the current T+ risk phrase includes a wider range of LC/LD 50 values than Category 1, the highest acute toxicity category under GHS, so that it partly extends into Category 2. [1]

54. The GHS provides criteria for harmonised classification and hazard communication for the different target audiences including consumers, workers and emergency responders, and in transport. Therefore, it includes a "building block" approach to enable countries to adopt the system with regard to the various target audiences and thus in different legal areas. The building block approach enables the legislator to choose the hazard classes and hazard categories in order to determine the level of protection for the various target audiences. The building block approach allows the possibility of improving the alignment of substance criteria with the needs of industrial risk management for regulations that use generic criteria (e.g., Seveso) to prevent industrial accidents prevention acute hazards. For example, the new GHS category, Gases Under Pressure, could be combined with Category 1 of the acute toxicity criteria, as a way of eliminating substances from the scope that are not as likely to be involved in an accidental release of toxic substances. Similarly, the GHS criteria also give rise to the idea that the physical state, volatility and dispersion characteristics of the substance could be added as part of the criteria, allowing the possibility of focusing on substances that have the highest likelihood of being involved in an accidental release.

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[1] Also, testing criteria of GHS sometimes do not match exactly the criteria within 67/548/EC and therefore, substances may also be classed into a different hazard category than they would have been classified under 67/548/EC.

Areas where REACH can be Useful to the Seveso Directive

55. A proposal on a new EU regulatory framework for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was adopted 29 October 2003. REACH aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. Under REACH, enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. REACH would furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances. The proposal is now being considered by the European Parliament and the Council of the EU for adoption under the so-called co-decision procedure. (REACH was adopted by the European Parliament in December 2006).

56. The implementation process for REACH represents some uncertainty for coverage under Seveso. In particular, the level of consistency and clarity of the new substance classifications under REACH will determine whether Seveso establishments will be classified in a consistent and clear fashion across the Member States. It is also unknown how new classifications and the greater availability of data will affect Seveso coverage. For example, many substances could be newly introduced into the EU system as acutely hazardous and could increase the scope of Seveso coverage more dramatically than previously foreseen.

57. Moreover, new classifications could be introduced at any time after the effective dates. The pace at which new substances are introduced, and the number of those that have acutely hazardous properties, will determine how much time Seveso authorities and operators will have to react, should new registrations result in additional Seveso coverage for a number of establishments. There are several areas where REACH should be useful to the Seveso Directive: higher availability of substance hazard data, development of exposure assessment methodologies including IT tools and an inventory of classification of substances. There are concerns about by-products of reaction which might not be registered.

Problems and Opportunities Arising from a Change to the Classification System for the Definition of Threshold Quantities

58. Prevention of major accidents in Switzerland is based on a two step approach. In a first step, establishments in which the threshold quantities are exceeded have to submit a summary report. If serious damage to the public or the environment is to be expected, the enforcement authority requires in a second step the owner of the establishment to carry out a risk study. In the evaluation of the summary report and the risk study, expert judgement plays an important role. In 2005, the Swiss chemicals law was amended for compatibility with the one of the EU. Among other things, this adaptation required a re-definition of threshold quantities in the Ordinance on Major Accidents (OMA). A comparison of the threshold quantities for 1 400 widely used substances before and after the amendment shows that threshold quantities were decreased for 160 substances and increased for 130, even though it was tried to avoid any major change in the scope of the OMA. Although the EU and the Swiss classification systems are harmonised, the threshold quantities in the OMA are more conservative than those in the Seveso II Directive because of short distances between the establishments and residential areas. This shows that the classification of chemicals is not the only criterion for the setting of threshold quantities.

59. The current classification systems are generally based on effect levels and developed primarily for application to the workplace and consumers. Dispersion scenarios which are important for accidents are not taken into account. The increase in the number of hazard classes and hazard categories with the GHS, especially for physical hazards, due to new classification criteria will allow more precise categorization of chemicals for their potential danger from the point of view of major accidents. If the criteria included physical state of the chemical such as volatility, the number of establishments covered

would probably be smaller. With GHS, there will likely be many chemicals with either a more or less severe classification than today. Thus, it may not be possible to pass from the old to the new system without some changes in threshold quantities. The implementation of a list of harmonised classifications and labelling for widely used substances is desirable in a harmonised system and provides help for authorities in the labelling process of chemicals. With the implementation of the GHS, threshold quantity calculation is an area that will need to be revisited.

Ammonium Nitrate: Changes in the Regulation at the EC and French Levels

60. It is difficult to define the appropriate threshold quantities for ammonium nitrate taking into consideration the characteristics of the product and the storage method. Ammonium nitrate is currently not classified as an acutely hazardous substance in accordance with the European classification and labelling regime. However, certain mixtures containing ammonium nitrate can have acutely hazardous properties, depending on a number of physical and external factors which are not well-captured by standard evaluation criteria. In particular, the hazardous nature of ammonium nitrate can change due to a slight change in one or more risk factors, which makes standardised testing and standardised classification equally difficult. In the amendment to the Seveso II Directive 2003/105/EC, the classification of ammonium nitrate was modified to accommodate a greater range of variability of circumstances. In particular, the number of ammonium nitrate subcategories was expanded from two to four and a category was added to cover certain mixtures of potassium nitrate that have similar hazardous properties to ammonium nitrate under certain conditions. The main hazards with ammonium nitrate are fire hazards (oxidizer), thermal decomposition and explosion hazards. There is a wide variety in thresholds among countries. The discussion on appropriate thresholds is a potential area for future international collaboration.

Are the Current Thresholds for Chlorine Adequate to Protect the People and the Environment?

61. The basis for defining threshold quantities should be re-evaluated when new scientific evidence becomes available. For instance, the Immediately Dangerous to Life and Health (IDLH) values which were used to set threshold quantities for chlorine were lowered in the mid 1990's. Should not such a change cause us to consider modifying the chlorine threshold? The establishment of thresholds for a particular substance is dependent on what constitutes the basic unit of coverage within the regulation. For many countries, the basic unit of coverage is the establishment or the process. The basic unit of coverage in Canada is the vessel. The size of the threshold quantity is therefore somewhat dependent on the size of the basic unit of coverage. For example, the lower threshold quantities, and greater size of the unit of coverage, predict greater coverage of overall industrial processes under the regulation.

62. The choice of the basic unit of coverage offers different pragmatic solutions for operators to reduce their coverage under the regulation. For example, storage conditions can be designed so that threshold quantities are never reached. The techniques for avoiding coverage may vary depending on whether the establishment, the process or the vessel is the basic unit of coverage. Avoidance strategies sometimes reduce overall risk, which can be considered a positive effect of regulation. On the other hand, avoidance strategies may simply be risk transfer mechanisms that do not affect the overall risk level.

Acute Exposure Threshold Levels (AETLs) **versus** *Acute Exposure Guideline Levels (AEGLs)*

63. Risk managers use acute toxicity threshold values to evaluate the risk to humans resulting from acute exposure to airborne chemicals. Acute exposures are single, non-repetitive exposures for not more than 8 hours. The Acute Exposure Threshold Levels (AETLs) define the limits for airborne concentrations of chemical substances following acute accidental exposure. The EC ACUTEX (AETLs) project proposes a new methodology to derive acute exposure levels for use in implementing Seveso II requirements, such as emergency and land-use planning. The issue was raised of how to compare the European AETLs and

the US AEGLs (Acute Exposure Guideline Levels) values with respect to: (i) Land-Use-Planning *versus* Emergency Planning; (ii) definitions: thresholds, populations of concern (± sub-populations, European diversity in risk assessment), duration (<10 min, 120 min), uncertainty factors, statistical analysis; and (iii) values. The ACUTEX is supported by most stakeholders but some issues need to be discussed further to achieve a larger consensus.

64. When a toxic level is changed, what is the effect on land use planning? Apparently, it is the practice not to change the distance for existing facilities but to take the change into consideration for new facilities. Some participants were uncomfortable with the concept of percentage of lethality used in land-use planning.

Current LUP Practices around Seveso II Establishments and Future Challenges

65. Article 12 on land-use planning of Seveso II, and its 2003 amendment, stipulates that appropriate distances between establishments covered by this Directive and residential areas, buildings and areas of public use, etc. shall be maintained. The practical problems related to land-use planning include: (i) how to prevent or control new developments around existing establishments (in particular housing); (ii) how to assess and compensate land-owners in case of prohibition of use for the dedicated purpose (e.g. housing); and (iii) will the state provide aid for relocation of establishments. Discussing and exchanging information/experience on major topics like risk assessment practices, probability studies, etc. should continue. A part of this objective is the development of a data base including risk data and risk scenarios, to be used for assessing the compatibility between the establishments covered by the Seveso Directive and the areas described in the 2003 amendment.

66. The future challenges related to land-use planning and how to deal with "pre-existing situations" include: (i) managing the economic and social impact on industries and communities; (ii) providing funding for managing change (EU competition rules, structural fund, etc.); (iii) developing standards (technical measures); (iv) sustainability options (change technology, replace hazardous substances with substitute products); (v) undertaking supply chain studies; and (vi) conducting research.

Dangerous Good Cards – Practices for Risk Assessment in Acute Situations

67. Substance criteria are limited in their ability to rank risk associated with different activities and locations. It is only a screening tool and often represents a pragmatic balance between risk level and resources available to manage risk. Therefore, risk management tools for further characterisation are extremely important in ensuring effective implementation of the accident prevention regulations and for achieving its objectives. Examples of ways that risks can further be classified include the establishment of acute exposure threshold values for emergency responders and land-use planners, the use of hazard and risk assessment techniques to further identify the location and severity of potential consequences. In addition, authorities need precise information on hazardous properties of substances, protection measures, mitigation and response strategies to effectively manage hazardous situations and incidents that occur.

Summary of Conclusions and Recommendations of Thematic Session 3

68. The main conclusions and the recommendations from Session 3 are summarised as follows:

- The adoption of GHS will entail important changes to the Classification and Labelling Directives for substances and preparations in OECD countries.

- The implementation of a list of harmonised classifications and labelling for widely used substances is desirable in a harmonised system, and provides help for authorities in the labelling process for chemicals.

- Some chemicals, for example chlorine and ammonium nitrate, have large variations in thresholds among OECD countries. When new scientific information becomes available, joint international scientific collaboration might be an approach in order to develop well founded numbers.

- ACUTEX is supported by most stakeholders, but some issues still need to be further discussed to achieve larger consensus.

- There are several future challenges related to land-use planning and how to deal with pre-existing situations.

SESSION 4

Elaboration of a Consistent Approach to Identify Chemicals of Interest for Accidents Regulation Purposes

69. The impressive list of objectives provided in the agenda was only partially addressed during Session 4. Many of these really apply more to subsequent discussion that took place during consideration of a "Path Forward" in Session 5. The two presentations given were related to the GHS and AETLs. Likewise, the main conclusions and observations from discussions in Session 4 are essentially reflected in the recommendations made in Session 5 on the path forward.

70. A representative from INERIS, France, presented **From Definition to Use of Acute toxicity Threshold Values: Awareness of Uncertainty.** This paper focussed on uncertainties resulting from the acute toxicity threshold values derivation process and uncertainties related to the effect distances calculation. These threshold values are usually used for the toxic risk assessment in order to prepare emergency plans and/or the Land-Use Planning policy around fixed chemical plants. The main problem is to make the risk manager aware of the global uncertainties concerning the effect distances calculations.

71. A representative from Health & Safety Executive (HSE), UK, presented **Seveso Classification and GHS**. This presentation covered the linkage between GHS classification and Seveso application, as well as the development of a technical 'screening filter'.

Key Points, Observations and Conclusions

72. The key points from presentations and the main observations and conclusions from discussions are summarised below:

From Definition to Use of Acute toxicity Threshold

73. Acute toxicity threshold values are used during the risk assessment process to reduce hazard potential, prepare emergency plans and take account of this for land use planning regulations around plants. The author pointed out that it is important to be aware of uncertainties in deriving thresholds and related effects distances. The presentation focussed on thresholds as part of global uncertainty. Thresholds were determined using 1% and 5% lethal concentrations by applying a non-linear log probit statistical model. The quality of the toxicity data is very important for modelling. The uncertainty of the modelling for his two scenarios was evaluated by the 95 % confidence interval. In the first example using sulphur

dioxide, effects distances varied from 510-680 metres. In the second scenario using chlorine, effects distances ranged from 350-960 metres.

74. It is obvious that uncertainty of lethal concentrations can induce important variability for related effects distances, with potentially fatal consequences. The process of getting from toxicity data to establishing lethal effects distances is a sequence of calculating threshold values, choosing an appropriate release scenario and then applying a dispersion model – each step having the potential for introducing uncertainty. This presentation was designed to raise awareness of the uncertainty associated with the threshold derivation process and to indicate a need for further research into global uncertainty and other aspects along the risk assessment continuum.

Seveso Classification and GHS

75. Consultation on implementation of GHS within the EU has begun. The Commission Services report *Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation*, published in August 2006, suggested that for human health effects, substances should be classified for LC50/LD50 in order to maintain the status quo. The HSE has proposed an alternative approach i.e. adopt the same approach for the link to Seveso as that for the link to Directive 67/548/EEC. It is believed that this would result in limited changes in the overall scope. It would mean that more orally toxic substances would be brought into the scope of Seveso but fewer dermally toxic ones. Both are considered to be relatively minor categories of substances from a Seveso point of view. Suggested benefits of such an approach include: some changes in regulatory oversight (from very toxic to toxic) anticipated but would not fall out of the Seveso scope and would provide flexibility for regulators; concentration of regulatory effort and resources on higher risk facilities and consistency of implementation across member states; avoidance of duplicate classification by downstream users (once for Classification, Packaging and Labelling (CPL) purposes and once for LC50/LD50 for Seveso application determination); and, reinforcement of simplicity of GHS and resulting consistency.

76. A project by the Health and Safety Laboratory (HSL) is currently underway to ascertain the possibility of this approach. One of the aims is to provide a view of the effects of a linkage between GHS and Seveso based on current UK Seveso toxic and very toxic substances. These effects could include: (a) the potential for major accidents where facilities move out of scope of the Seveso Directive; (b) the appropriateness of reducing regulatory oversight for those facilities that remain in scope (due to the alignment of the oral, inhalation dust/mist and inhalation gases route); and (c) any increase in regulatory oversight for facilities that remain in scope due to the alignment of the inhalation gases route and its appropriateness with respect to major accident potential and regulatory impact. In the longer term, the aim would be to examine the utility of a filter to screen for major hazard potential based on the physical form of a candidate substance (solid, liquid, mist, vapour or gas) and other properties such as the volatility of a liquid.

77. The impact of GHS on the Seveso Directive was also evaluated by other countries, Germany looked at the impact using a two-tiered approach, high volume >100 tons/year and lower volume. The impact on high volume chemicals appears to have some extent and the lower volume chemicals are still being evaluated. Effects of GHS on North America: Canada has done a screening of the 23 000 domestic substances and 4300 substances were categorized in for further analysis.

78. The research on evaluation of substances is an area where countries could collaborate, in keeping with a key objective of the workshop. Research to reduce uncertainty on acute toxicity thresholds is also an area where international collaboration would be beneficial.

Conclusions and Recommendations of Thematic Session 4

79. The main conclusions and the recommendations from Session 4 are summarised as follows:

- Acute toxicity threshold values are used during the risk assessment process to reduce hazard potential, prepare emergency plans and take account of this for land-use planning regulations around plants. It is essential to be aware of the uncertainty associated with the threshold derivation process and identify the needs for further research in this area.
- Some projects are currently underway to explore the effects of a linkage between GHS and Seveso. The UK project is based on current UK Seveso toxic and very toxic substances. A longer term objective would be to examine the utility of a filter to screen for major hazard potential based on the physical form of a candidate substance (solid, liquid, mist, vapour or gas) and other properties such as the volatility of a liquid.
- Research on evaluation of substances is an area where countries could collaborate.
- A number of countries would be interested in the results of the chemical evaluations.

SESSION 5

The Path Forward

80. There was substantial dialogue on the key issues from the two days of deliberations with the focus being on coming up with a set of **recommendations**. They are summarised below.

Collaborate on further development of methods to collect and analyse data related to acutely toxic properties

81. Accurate risk assessment of the toxic effects in humans following an acute exposure to an individual substance requires both adequate toxicological data, adequate assessment of the actual exposure as well as an advanced methodology to assess the substance specific toxic dose-response relationship (e.g. presented as threshold guidelines). This recommendation recognises that the challenge of obtaining toxicological data and such improved methodology is shared by all OECD countries. There are several efforts underway in both the public and private sectors in these countries aimed at improving the technical basis for policy decisions involving acutely toxic substances. The recommendation proposes using existing communication and research networks to promote mutual exchange and contributions among scientists working on these issues.

82. Some important areas where such activity could be focused include: (i) improving communication on the priorities and focus of chemical risk assessment work to facilitate the development of collaborative work and exchange of information (data, knowledge) on topics of common interest; (ii) including OECD countries in scientific reviews of new and existing methods and tools relevant to assessment of human toxic response following an acute exposure; and (iii) identifying and creating opportunities for OECD partners to work together on research and development of scientific applications related to the assessment of toxic effects following an acute exposure.

Participation in the independent review of ACUTEX case studies

83. Several EU Member States had agreed to participate in an independent review of the technical guidance and “case study” results of the recently completed ACUTEX (**Acute Ex**posure Threshold Levels)

project. As noted by the two presentations on this topic at the workshop, the ACUTEX project developed a new methodology to derive acute exposure levels (Acute Exposure Threshold Levels or AETLs) for use in implementing Seveso II requirements, such as emergency and land-use planning. The AETL methodology was tested on 22 substances ("case studies").

84. An independent review of the methodology and several of the case studies was to be launched late in 2006 with the aim of hosting a meeting to discuss expert opinions of the methodology and case studies in early March 2007 at the Joint Research Center (JRC) in Ispra, Italy. The Netherlands is taking the lead in this effort with support from Germany, France and the JRC.

85. The review represents a potential opportunity to maintain dialogue not only among EU experts but also experts in other OECD countries on an important development in the field of acute toxicology. Therefore, in the spirit of this overall recommendation for improved collaboration and exchange, the OECD urged that the EU allow interested and qualified experts from non-EU OECD countries into the review process.

86. The official meeting was to be announced in early November 2006 with a description of expert requirements and responsibilities. It was recommended that the announcement be distributed to the OECD Working Group on Chemical Accidents so that non-EU organisations could contact the organising team if they were interested in participating.

Participation in an EU Research Project (7th Framework Programme) on ACUTEX

87. Several Member States have indicated interest in continuing the work of the ACUTEX project in follow-up research project within the EU's 7th Framework Programme (FP7) for Research and Technological Development. Several areas of potential interest were identified in the Post-ACUTEX Follow-up Seminar held in May 2006 at the JRC in Ispra, Italy. The independent review of the ACUTEX case-studies is expected to further define specific research and development lines. It is expected that research will further develop some aspects of the AETL methodology and also develop options to increase data collection and availability for study of acutely toxic properties of hazardous substances, to apply the values and to set up a scientific network to develop such values.

88. EU-funded research allows the participation of non-EU country organisations (assuming that their participation can be adequately justified). The OECD urged the planning team (led by the Netherlands) to keep the Working Group on Chemical Accidents informed as project plans develop. It was noted that interested OECD organisations will be particularly well-positioned to participate in such an EU co-funded project if they participate in the independent review of the ACUTEX case studies mentioned above.

Develop a process for identifying advantages, disadvantages and gaps concerning the selection of substances/groups of substances and thresholds for managing potential hazards associated with the prevention of chemical accidents in relevant legislation of OECD countries

89. The process envisaged would engage interested individuals from OECD countries via teleconference a couple a times a year to:

Part 1: *Analyse, document and compare the background of existing and proposed approaches and legislation among member states*

90. This part should explore information on:

- The definition of aims i.e. values to be protected e.g. neighbourhood, workers, environment.

- The considerations made and systems used for the identification of relevant substances and criteria e.g. acute and/or chronic toxic, toxic for man and/or the environment.
- The considerations made and systems used for the definition of thresholds.
- Proposed amendments e.g. proposals for systems based on the GHS.
- Gaps and shortcomings identified within these systems or by comparison of these systems.
- Possibilities for sharing of information and co-operation in amending these systems and legislation.

91. Such additional periodic information would be useful in updating the discussion document and already published information.

92. It probably would be of assistance to OECD countries and non-member countries in drafting or amending "Chemical Accident Legislation" and may help reduce differences in legislation on the long term.

Part 2**:** ***Assess and report to the Working Group on Chemical Accidents (WGCA) on current issues, problems, gaps, shortcomings that are identified***

93. Gaps and shortcomings identified within the systems or by comparison of the systems while drafting part 1 should be further discussed and elaborated upon. This may include the consideration of physical hazards; environmental effects; reactive chemicals; mixtures; and physical state e.g. nano-particles.

94. Every effort will be made to avoid duplication with information that is readily available through other existing publications. Canada and the EC-MAHB propose to refine these initial ideas through dialogue/discussion with interested individuals in OECD countries and present further elaboration for consideration at the 2007 annual meeting of the Chemical Accidents Working Group.

Some initial ideas on the subjects under Part 2

Physical hazards

95. There are still some physical hazards that are not well understood and/or adequately considered in the actual legislation like:

- The effect of aerosols and low temperature on the explosive characteristics of vapour clouds is not currently addressed under regulatory regimes.
- The physical hazard associated with large releases of liquefied natural gas (LNG) and their consideration in the legislation is another area which warrants further discussion. We are better aware of small to medium scale LNG spill behaviour but do not fully understand the behavioural impacts of a large LNG spill. The threshold for LNG in the relevant legislation may have to be re-evaluated for the consideration of these hazards.

Environmental effects

96. The process would identify areas in which the science on environmental effects is relatively well established and allows reliable consideration of these effects in the relevant legislation and would identify other areas that require further research for that purpose. The process would also reflect on how to translate scientific concepts on environmental effects into an easily understandable and useable format for the purpose of assessing and restoring environmental damage from chemical accidents.

97. The relevance of considering acute and long-term environmental effects in chemical-accident legislation needs further investigation.

Mixtures

98. There are significant differences on how countries are treating hazardous substances mixtures. For instance, there are flashpoint differences in the treatment of flammable mixtures as well as more generally how concentrations, carcinogenicity and aquatic toxicity are being dealt with. There is a need to talk about how implementation of GHS may help to reduce these differences.

Physical State e.g. nano-particles

99. There is a need to investigate how the physical state of substances e.g. nano-particles can pose an additional potential risks from a chemical accidents perspective and could be additionally considered in relevant legislation. How to document concerns in this regard needs to be articulated to ensure that they are transmitted to and adequately addressed by the newly formed OECD Working Party on Manufactured Nanomaterials (WPMN).

100. The process would be a collaborative effort. It would, if and when approved by the WGCA, be developed by a group of interested individuals under the joint leadership of Canada and EC (MAHB) for the purposes of making periodic suggestions/recommendations for the consideration of WGCA and subsequent prioritization and assignment to others as it deems appropriate.

Share knowledge on risk assessment of chemicals

101. The workshop participants made a number of recommendations on the theme: Sharing of knowledge.

Sharing of information

102. The objective is to implement mechanisms to make data and information more readily accessible, including: physical hazards; accident reporting; new substances and old substances used in a new way; prioritisation techniques; lessons learned from accident analysis with respect to risk assessment of chemicals or regulatory purposes; and methodologies and tools.

Regulatory Frameworks

103. All regulatory frameworks on major hazards have to some extent a pragmatic approach in common which uses expert judgment to achieve the common policy objective of identifying hazardous sites. Since expert judgment may be seen as an applied combination of practical experience with scientific knowledge it seems most appropriate to document and share the "expert judgment tools" used in OECD member countries to prevent major accidents and mitigate their consequences.

104. Transparency, consistency and a sound scientific basis are necessary when defining the scope of any regulation. Impact on health and also environment e.g. acute carcinogenic potential, bioaccumulation and persistence in the environment, may be an area for future international collaboration.

Land Use Planning

105. To address the variations in the quantitative risk assessment results in land-use planning, we need to investigate possible collaboration with other relevant disciplines like toxicology, physics and chemistry. The gathered data would have to be packaged in an appropriate format for the intended use. There are several future challenges related to land-use planning particularly on how to deal with pre-existing situations.

Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

106. The adoption of GHS is likely to entail important changes to the existing classification and labelling systems for substances and preparations. Some chemicals, chlorine and ammonium nitrate for example, have large variations in thresholds among OECD countries. If and when new scientific information becomes available, joint scientific reviews might be an approach to seriously consider.

Uncertainty

107. Acute toxicity threshold values are often used during the risk assessment process to reduce hazard potential, prepare emergency plans and for land-use planning. The uncertainty associated with the threshold derivation process needs to be recognized along with the identification of further research needs in this area.

Accident Databases

108. Despite one's best efforts, operations do not always proceed as planned, so organizations must be ready to turn their mistakes – and those by others – into opportunities to improve accident prevention efforts. The most cost effective way to do so is: (i) apply best practices in the most effective use of limited resources, (ii) correct deficiencies based on incident history and near-misses, and (iii) apply lessons learned from others (whose own failings paid the price for everyone's education). It was agreed to support the MARS data base as the vehicle to consolidate lessons learned from accidents and to make these more accessible to the user community.

ANNEX 1

OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases

16-18 October 2006, Varese, Italy

DISCUSSION DOCUMENT

5 April 2007

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INTRODUCTION AND OVERVIEW

1. General Purpose of the Workshop

This OECD Workshop is sponsored by Environment Canada's Environmental Emergencies Division (EC-EED) and the European Commission's Major Accident Hazards Bureau (MAHB).

The initial step of hazard identification for accidental releases is carried out through various means in member countries. Examples include the processes inherent in the EC's Seveso II Directive on the control of major accident hazards involving dangerous substances, the US EPA's Risk Management Program (RMP) Rule under the Clean Air Act 112r, Environment Canada's Environmental Emergency (E2) regulations under the Canadian Environmental Protection Act, Korea's Safety and Health Act and Control of Harmful Chemical Substances Act, the Australian regulatory framework and Japan's regulations.

Each member state establishes its own evaluation criteria and set of assumptions to determine which hazardous substances with the potential for adverse consequences from accidental releases should be regulated and at what thresholds. Hence first and foremost, it is necessary to acknowledge this divergence in approaches among OECD countries.

For this reason, the overall objective of the workshop is to share information and experiences on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing/ managing accidental releases.

It is hoped that this OECD workshop will facilitate sharing of information and experiences and thereby promote greater understanding of systems used for selecting substances for coverage under industrial accident prevention regulations. The result is expected to lead to ongoing exchange in this area, sharing of lessons learned to improve programmes in all countries, and where commonalities exist, eventually allow for greater consistency in substance identification and criteria for coverage under accident prevention regulation[2]. Moreover, it is noted that the assessment of acutely hazardous properties plays a key role in determining which substances are selected for coverage under accident prevention regulations. Therefore, identification of areas where the chemical risk assessment process might be improved, notably methods and data for assigning hazardous categories to particular substances, could also be a fruitful area for future collaboration. In addition, these exchanges could also lead to opportunities in some cases where analyses of particular hazardous substances might be shared among several countries, avoiding repeated independent evaluations and allowing greater efficiency and consistency in establishing the acutely hazardous profile of various substances across the member states.

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[2] It is recognized that assessment of the hazardous properties of the chemicals themselves is managed differently within the OECD countries. In some countries (e.g., the United States, Canada) the regulatory authority for accident prevention regulations has a direct role in the evaluation of acutely hazardous properties of substances. Whereas, in other countries, notably Member States of the European Union, the definition of these generic categories of substances and assessment of their hazardous properties is performed elsewhere, that is, under the jurisdiction of another authority.

The timing of this workshop appears to be particularly opportune since most of the OECD countries are currently reviewing their chemical accident prevention programs, including contemplating revisions to the lists of regulated chemicals as a consequence of the UN Globally Harmonised System for Classification and Labelling of Chemicals (GHS) and the Registration, Evaluation and Authorization of Chemicals (REACH).

2. Overview of Workshop Objectives and Expectations

A more detailed elaboration of the workshop objectives is as follows:

- Share experience on the scientific basis used by OECD member countries in evaluating the hazards posed by chemicals involved in accidental releases, focusing on characteristics, criteria and the establishment of threshold quantities;
- Examine commonalities and differences of approaches, criteria and methodologies affecting substance selection in OECD countries or regions, with a view to launching or pursuing technical exchange on areas of common interest and creating opportunities for increasing greater complementarities and compatibility of approaches;
- Investigate the possibility of sharing or developing, as the need arises, common criteria and principles for identifying and categorising hazardous substances in the context of ongoing exchange of information on work in this area and establishing channels of communication to allow countries/stakeholders to continue to share information on results and experiences;
- Explore how developments in the chemicals assessment area could have an impact on processes used in OECD countries for identifying and selecting hazardous substances for regulation with respect to preventing/managing accidental releases: e.g. the new UN Globally Harmonised System for Classification and Labelling of Chemicals (GHS); the new European chemicals policy called REACH (Registration, Evaluation and Authorisation of Chemicals);
- Build awareness of other initiatives related to hazardous substances that could also affect implementation of industrial accident regulations in OECD countries (e.g. Acute Exposure Threshold Levels methodology);
- Acknowledge the divergence in approaches among OECD countries or regions, in terms of threshold quantities assigned to substances and categories of substances for determining regulatory obligations with respect to preventing/managing accidental releases;
- Encourage discussion on the selection of candidate chemicals and categories, and the determination of their threshold quantities and associated regulatory requirements for different threshold levels;
- Agree to develop a comparative matrix showing criteria and methodologies used by different regulatory systems to identify and select hazardous substances and categories with respect to preventing/ managing risks associated with accidental releases;
- Describe the strengths and weaknesses of the respective approaches;
- Investigate the possibility of launching collaboration to support more consistent criteria and principles to identification and selection of individual substances or groups of substances (categories/classes) across OECD membership;

- Determine interest among member countries for such closer co-operation (the intent being to possibly allay trade/competitiveness concerns through greater harmonisation in approaches);

- Consider sharing the burden of activities resulting from the application of GHS in the context of accident prevention regulations;

- Consider developing a programme of work including the creation of a committee to undertake the work and distribute the tasks among countries[3]; and,

- Explore possible opportunities to facilitate greater data/information exchange and to reduce workload through work sharing.

In order to be prepared for the ensuing discussions, it is appropriate to start out with ensuring a common understanding of the practices that are followed in the European Community, in the United States, Canada, Australia and Korea, for identifying and selecting hazardous substances and establishing associated thresholds with respect to preventing/managing accidental releases.

It is recognized that OECD members have specific policies and regulatory regimes that their respective legislatures have established. Such constraints do not allow for the possibility of a common regulatory regime and hence there is no point in debating legislative or regulatory differences within the purview of this OECD workshop. However, this situation should not prevent the delegates from sharing information and experiences on respective approaches and pertinent information on lessons learned and success stories.

The primary focus of the workshop over the next three days will be to understand how hazardous substances and their thresholds in the context of accident prevention are selected within the OECD countries or regions. The scientific basis for identifying less traditional hazards, i.e., impact on the environment of accidental releases such as bioaccumulation, carcinogen potential, etc. will also be explored. It is recognized that decisions for classifying chemicals may be under other regulations than those in place for the prevention of major accidents. Of particular interest is the possible impact of GHS and REACH on the identification of acute hazards.

Case studies of specific substances, such as ammonium nitrate and chlorine, will be presented to highlight opportunities and benefits in the development of a common scientific rationale. National lists of current and future substances will also be shared, helping to focus collaboration in areas where such collaboration might be considered most beneficial and fruitful. In particular, the workshop will also attempt to identify the technical gaps and research needed to support future lists of hazardous substances and their thresholds with respect to preventing/managing accidental releases.

The workshop will also aim to understand the rationale underlying the selection of substances for coverage under accident prevention regulations and their associated thresholds. It is recognized that a marked difference in approaches exists; in particular, the use of defined lists of substances predominates in some countries whereas generic criteria are the primary selection factor in others. Although these approaches have distinct differences, challenges in applying selection criteria are nonetheless similar and regardless of the predominant approach, sharing of lessons learned as well as problems and solutions is expected to be broadly valuable to all countries. Moreover, the approaches are not mutually exclusive and

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[3] However, please note that because of differences between the European and North American systems there are not the same expectations on how collaboration can be established in this area. The workshop discussions should try to clearly establish what the areas of common ground actually are. Moreover, it should be acknowledged that there is diversity in opinion within Europe concerning priorities in this area.

certain elements are shared (e.g., the assignment of thresholds) and, in many cases (for example, the EU), both approaches are applied simultaneously. Therefore, it is expected that sharing of lessons learned and discussions of problems and solutions will be of broad benefit to member states, regardless of which regime is predominant in their country.

In addition, the workshop will explore the scientific underpinnings and potential implications of new initiatives in substance classification, the UN Globally Harmonised System for Classification and Labelling of Chemicals (GHS), and the Registration, Evaluation and Authorization of Chemicals (REACH), on selection of hazardous substances and their thresholds with respect to preventing/managing accidental releases.

Some discussions would also be anticipated on the use of prescriptive hazards-based only criteria *versus* performance-based or other qualitative criteria, e.g., effectiveness of process safety management controls; degree of reactivity including the possible presence of combustible dust; risks associated with nanoparticles; and the potential for fires originating from non-hazardous substances to release hazardous substances as by-products of combustion.

3. Thematic Structure of the Workshop

The Workshop is organized along the following five thematic sessions:

Session 1: Methods by which hazardous substances involved in major accidents are assessed in OECD countries.

Session 2: Current processes for selecting 'regulated' chemicals and determining thresholds of effects under accident prevention policies.

Session 3: Examples of divergence in approaches and potential for future implications.

Session 4: Elaboration of a consistent approach to identify chemicals of interest for accidents regulation purposes.

Session 5: The path forward.

Speakers have been selected to “set the scene” by describing the current framework for identifying and selecting substances for coverage under accident prevention regulations. These presentations are expected to highlight emerging issues related to risk assessment practices for hazardous chemicals in the context of accident hazards control with the aim of focusing discussions and stimulating constructive dialogue among participants.

In each session, the speakers’ presentations will be followed by a general discussion where conclusions and recommendations will be drawn.

The workshop organisers are appreciative of the considerable contributions of government and private sector experts from Europe, North America, Oceania, and Asia involved with chemical accident programs in their respective countries. Participants are encouraged to listen carefully and react to the presentations, sharing their experiences and openly participating in the ensuing discussions.

4. Introduction to the Discussion Document

The Discussion Document (DD) is based on information extracted from laws, regulations, and directives on major hazards from OECD member countries and regions and detailed reports on specific aspects of methodologies used to choose chemicals and set their thresholds. The answers to a questionnaire circulated by the OECD secretariat to member countries on the use of safety reports and equivalent documents on the control of major hazards served as a source of information. A specific questionnaire was also addressed to the Major Accident Hazard Bureau and the US Environmental Protection Agency to clarify points on Seveso II and the EPA Risk Management Program. Finally, information from the open literature was used.

This Discussion Document is charged with achieving the following objectives:

a) Provide an overview of the processes used in OECD countries or regions for identifying and selecting dangerous substances regulated under chemical accident prevention programmes;

b) Describe the themes of the sessions; and,

c) Identify some of the key issues for consideration.

THEMATIC SESSION 1: HOW HAZARDOUS SUBSTANCES INVOLVED IN MAJOR ACCIDENTS ARE IDENTIFIED/MANAGED IN OECD COUNTRIES?

Key objectives to be covered in this session:

a) Share information and experiences on the respective individual approaches to identify and select hazardous substances with respect to preventing/managing accidental releases, including the scientific basis used to evaluate the hazards posed by the accidental release of chemicals, focusing on characteristics, criteria and the establishment of threshold quantities.

b) Review the systems currently used in OECD countries at regional level (e.g. the European Union under the Seveso II Directive, in North America by the United States and Canada, and in Oceania by Korea, Australia and Japan to: (i) identify 'regulated' chemicals under accidents prevention programmes; and (ii) show how economic and regulatory considerations might influence the establishment of threshold quantities and other criteria and mechanisms for defining coverage.

c) Discuss respective approaches to the selection of candidate chemicals and associated regulatory requirements. Compare the hazardous substances/groups of substances lists and threshold quantities to examine commonalities and differences in approaches, criteria and methodologies employed.

Introduction

Over the past several decades, a series of regulations and directives have evolved that are aimed at decreasing the frequency and severity of chemical accidents. Spurred on by the 1974 explosion in Flixborough, England and the 1976 release of 2,3,7,8 –TCCD in Seveso, Italy, the European Union (EU) adopted the Seveso Directives in 1982 (revised in 1996) [1,2]. The 1988 United Nations' Awareness and Preparedness Emergencies at the Local Level (APELL) program explicitly called for the reduction of accident rates and the preparation of response plans [3]. The 1993 directives by the International Labour

Organization (ILO) addressed risk identification, emergency planning, emergency preparedness, and information dissemination [4].

Due to concerns about large-scale chemical accidents, including the Seveso and Flixborough accidents as well as the 1984 methyl isocyanate release in Bhopal, India, the US incorporated the Process Safety Management (PSM) and the Risk Management Program (RMP) Rules into the 1990 Clean Air Act Amendments. The final PSM rule was published in 1992 and the RMP rule became final in 1996. The US efforts built on earlier programs including the 1986 Emergency Planning and Community Right-to-Know Act, the 1986 Accidental Release Information Program, and the 1988 Chemical Safety Audit Program [5-7].

The risk management programs across the world have much in common. For example, the US, EU and Canadian programmes require that large industrial facilities develop risk management plans ("safety reports" in the EU) that incorporate prevention, preparedness, response, and recovery aspects. Covered facilities must assess consequences that could result from fires, explosions and the releases of toxic chemicals. "Hazard zones" representing areas in which an accident could cause injury or death must be delineated. For the release of toxic chemicals, hazard zones may be defined by the length, size (area), or population that might experience exposures exceeding a health-based concentration, that is, the "level of concern" (LOC)[4]. Hazard zones are also defined by an overpressure limit for explosive substances and a radiant energy limit for flammable substances. Off-site and on-site consequences are generally assessed.

Not all facilities handling hazardous substances are required to develop comprehensive risk management plans or safety reports. In general, these plans or reports must be developed only for those establishments or processes that store, transfer, or utilize a quantity of specified chemicals over defined threshold quantities. Thus, these programs apply to only those facilities that have the greatest potential risk, or perhaps viewed more correctly, the programs are designed to exclude facilities that pose relatively lesser risk.

All programmes generally address risks associated with human fatalities and injuries, but over the years legislation has also evolved to include environmental persistence, bioaccumulation, and carcinogenicity as criteria that must be evaluated in some countries or regions [1, 8].

The regulatory approaches in the EU, the US, Canada, Australia, Korea, Switzerland and Japan are described in the following sections.

European Union

Regulatory Framework

On December 9, 1996 Directive 96/82/EC on the control of major accident hazards (so-called "Seveso II Directive") was adopted by the Council of the European (Council Directive 96/61/EC). The Seveso II Directive replaced Directive 82/501/EC ("Seveso I Directive") on the major hazards of certain activities. It has been noted in the background literature that Seveso I was not amended but replaced with a completely new Directive. This dramatic action signalled that important changes were made and new concepts were introduced into the Seveso II Directive [11]. As mentioned in the paper by Wood and Christou, one significant change concerned substance criteria governing coverage of establishments under the Directive.

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[4] A number of levels of concern associated with human health impacts have been produced to address various risk management situations, for example, Acute Exposure Guideline Levels (AEGLs), EmergencyResponse Planning Guidelines (ERPGs), etc.

The “Seveso II Directive” is based on Article 130s of the Treaty (establishing the European Commission) [12]. This article forms part of a Title within the Treaty, which establishes the objectives of the Environmental Policy of the Community and the decision procedures to be followed when adopting measures in order to pursue these objectives. It is important to mention that, according to Article 130t, Member States can maintain or adopt stricter measures than those adopted by the Community in the field of its Environmental Policy.

The aim of the Seveso II Directive is described as two-fold:

- Firstly, the Directive aims at the prevention of major accident hazards involving dangerous substances; and,

- Secondly, as accidents do continue to occur, the Directive aims at the limitation of the consequences of such accidents not only for man (safety and health aspects) but also for the environment (environmental aspects).

It should be noted that management of risks associated with environmental consequences gained more prominence in the Seveso II Directive, in comparison to its predecessor, with the inclusion, for the first time, of substances classified as dangerous to the (aquatic) environment in the scope of the Directive [11].

Scope and definitions

The scope of the Seveso II Directive relates to the presence of dangerous substances in establishments. “Presence of dangerous substances” is defined as the actual or anticipated presence of such substances or the presence of substances which may be generated during the loss of control of an industrial chemical process [11]. Coverage under the Directive is largely governed by Annex I of the Directive (included as Annex 2 of this document) which includes a list of generic categories (Annex I, Part 2) supplemented by a list of around 50 named substances (Annex I, Part 1). The generic categories cover two levels of acute toxicity (toxic and very toxic) which encompass all exposure routes (i.e., oral, dermal, inhalation); two levels of explosivity; three levels of flammability (flammable, highly flammable and extremely flammable); oxidising substances; substances dangerous to the environment; and substances that react with water or when in contact with water liberate toxic gas.

The named substances cover a number of substances that for various reasons (mainly additional technical or economic factors) have been selected for separate treatment notwithstanding their generic classification. Carcinogens, where there is evidence suggesting the possibility of “one-shot” effects (at relatively low doses) are also included in this list.

The generic categories are defined by and large in accordance with the Directives relating to the classification, packaging and labelling of dangerous substances, preparations, and pesticides. (These Directives also establish the procedures for formally classifying individual substances.) Classification and labelling within the EU requires an evaluation of the hazard of substance or mixture in accordance with Directive 67/548/EEC (substances) and 1999/45/EC (preparations)[5] and a communication of that hazard via the label. This evaluation must be made for any substance or preparation manufactured within or imported into the EU and placed on the EU market and results in classification of the substance/preparation as dangerous for one or several end-points concerning physical-chemical properties, health or environmental effects. All marketed substances and preparations must be classified and labelled,

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[5] These pieces of legislation are also sometimes referred to as the « Dangerous Substances » and « Dangerous Preparations » Directives respectively.

irrespective of the quantity placed on the market. As indicated in Article 6 of 67/548/EEC, "the nature of the special risks involved in using the substances must be indicated by one or more of the standard phrases which, in conformity with the references contained in the list in Annex I, are set out in Annex III to this Directive."

There are currently 68 "risk phrases" covering both chronic and acute health effects and also environmental effects. These risk phrases are defined in accordance with protocols defined in 67/548/EEC for testing and evaluating test results. For example, Annex VI of the Directive defines R26 "Very toxic by inhalation" as follows:

Acute toxicity results:

- LC50 inhalation, rat, for aerosols or particulates: $\leq$ 0,25 mg/litre/4h,

- LC50 inhalation, rat, for gases and vapours: $\leq$ 0,5 mg/litre/4h.

In the cases of explosives and flammables, the Seveso Directive further qualifies the generic categories to incorporate addition elements (e.g., storage conditions) that may significantly affect the hazard potential of a particular substance.

With the eventual adoption of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), the thresholds established in 67/548/EEC for classifying hazardous properties will be modified to conform to this new regime. It has already been recognised that, if the Seveso Directive is to maintain consistent coverage of hazardous establishments under the new regime, the linkage with 67/548/EEC will eventually need to be re-defined. Nonetheless, regardless of how the Seveso Directive responds to GHS, it will remain dependent on chemical risk analyses produced in conformance with the EU classification system.[6]

The UNECE Convention on Transboundary Effects of Industrial Accidents

Although the system of coverage under UNECE TEIA will not be detailed here, it should be mentioned. The convention was signed by 26 UN/ECE member countries and the European Community and entered into force on 19 April 2000. Currently, there are 35 Parties to the Convention which include all but 3 EU Member States and also the OECD Member States of Norway and Switzerland. Coverage under the Convention was modelled after the Seveso II Directive, using both generic criteria and a named list of substances, with adaptations to meet the needs of the broader UNECE community but uses actual thresholds (rather than the EU risk phrases) to define generic categories.

Hazardous Substances and Threshold quantities

In defining the scope, the Seveso II Directive follows a so-called two-tier approach which means that for each named substance and for each generic category of substances and preparations, two different qualifying quantities (threshold levels) are mentioned in Annex I, Parts 1 and 2 of the Directive, a lower and an upper value (e.g. for chlorine: 20 and 100 tonnes). It is assumed that the risk of a major accident hazard arising from an establishment, in which dangerous substances are present, increases with the

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[6] Eventually, the new classification procedure, the Registration, Evaluation and Authorisation of Chemicals (REACH) process, will replace the current testing and assessment protocols established by 67/548/EEC. In future, therefore, analyses generated under the new system will be the basis for determining coverage of hazardous establishments under the Seveso II regime. However, unlike GHS, the changes imposed by REACH do not alter the definitions of acutely hazardous properties and therefore, do not automatically cause any alteration in Seveso requirements or coverage.

quantities of substance present at the establishment. Consequently, the Directive imposes more obligations on upper tier than on lower tier establishments [11].

As noted in the paper by Wood and Christou, a study of options for determining threshold quantities was conducted by V.C. Marshall on behalf of the European Commission, as required under Article 9 of the Seveso I Directive. The results of this study undoubtedly formed the basis of the philosophy for determining threshold quantities in the Seveso II Directive. Wood and Christou summarise his basic conclusions in this way:

> Marshall notes that threshold quantities are expected to represent "the mass of substance that must be present for it to acquire the potential for a major-accident hazard".[7] A few lines later, he notes that "There is no single figure which can be used to express the potential of a hazard." He also remarked upon several difficulties in calculating a threshold on this basis, chief among them is the definition of "potential of a hazard" and finding an appropriate methodology and data for physical and chemical properties in order to determine an appropriate threshold. (Seveso experience has also shown that there are even some cases where appropriate methodology and data cannot be found as happened with the named carcinogens of the Seveso II Directive.)[8]

Marshall proposes criteria for establishing threshold quantities for explosive, flammable and acutely toxic hazards. In general, he recommends that threshold quantities should be scaled logarithmically on the basis of blast energy for explosives relative to TNT (to which he assigns a threshold quantity of 50 tonnes). For flammables, he suggests five categories of flammables on the basis of flash point and boiling point, and taking into account pressure and temperature conditions and on the basis of relative flammability (using the traditional measures of flash point and boiling point) for flammables. A comparison with the threshold quantities for the generic categories relating to flammables and explosives in the Directive suggests that Marshall's recommendations were taken into account.

For toxic substances, Marshall proposed allocating quantities in relation to a logarithm of their LD_{50} value, but also taking into account other factors (persistence, potential for long-term effects, severity of effect, etc.). It is less clear how much these recommendations were factored into the determination of threshold quantities for toxic substances. The proposed methodology more clearly applies to individual substances than generic categories. Likewise, it is not clear whether threshold quantities assigned to toxic substances named in Annex I, Part 1 took into account the methodology. In most cases, these substances were specifically named due to a variety of unique technical, economic and political factors surrounding their usage and therefore, it is likely that these same factors may also have had considerable influence on the allocation of threshold quantities and possible much more so than the Marshall methodology.

Maria Smeder described the philosophy for determining threshold quantities used in the Seveso II Directive [14] as follows:

> In the "Seveso II" Directive (Council Directive 96/82/EC), generic criteria are as far as possible used as the basis for the inclusion of substances under the Directive, since the listing of substances of Seveso I [15] has been found inflexible and inappropriate. The assignment of substances into one of the categories in Part 2 of Annex I is based on classification systems addressing the intrinsic properties of substances and established in the Directives 67/548/EEC [16], 88/379/EEC [17] and 78/631/EEC [18].

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[7] Marshall, V.C. 1985. Implementation of the Directive on Major Accident Hazards of Certain Industrial Activities (82/501/EEC). Article 19. Review of Annexes I, II and III. Report prepared for the European Commission.

[8] Christou, M (ed.). 2000. Carcinogens in the context of Council Directive 96/82/EC report by Technical Working Group 8. *op. cit.*

> "However, for some substances it is desirable to establish higher or lower thresholds than they would have according to their category. The reasons for this may be a combination of technical ones (since the classification system addresses the intrinsic properties of substances rather than the potential to cause a major accident), industrial or pragmatic (a reasonable number of establishments to be covered). These substances are listed in Part 1 of Annex I.
>
> "In the Seveso II Directive, differentiation for storage and process of dangerous substances is no longer made. This change is explained by the fact that the application of the Directive is based upon the potential to create a major accident, which is supposed to be identical for the same quantity of dangerous substance wherever it occurs.
>
> "The thresholds are set in order to identify those establishments that should be covered by the Directive. These thresholds do not necessarily correspond to the lowest amount of substance that has the potential to cause a major accident."

United States

EPA Risk Management Program

Regulatory Framework

In the Clean Air Act Amendments (CAA), signed into law in 1990, Congress added subsection (r) to CAA section 112 for the prevention of chemical accidents.

The goal of the chemical accident prevention provisions is to focus on chemicals that pose a significant hazard to the community should an accident occur, to prevent their accidental release and to minimize the consequences of such releases.

Section 112(r) [29] of the CAA has a number of provisions. Under section 112(r) owners and operators of stationary sources who produce, process, handle, or store substances listed under section 112(r) or any other extremely hazardous substances have a general duty to initiate specific activities to prevent and mitigate accidental release. The general duty requirements apply to stationary sources regardless of the quantity of substances managed at the facilities. Activities such as identifying hazards which may result from accidental releases using appropriate hazard assessment techniques; designing, maintaining and operating a safe facility; and minimising the consequences of accidental releases if they occur would be essential activities to be taken as necessary to satisfy the general duty requirements.

Scope and Definitions

Section 112(r) of the CAA required EPA to promulgate an initial list of at least 100 substances ("regulated substances") that are known to cause death, injury, or serious adverse effects to human health or the environment if accidentally released. EPA was required to set threshold quantities for each listed substance. Under CAA section 112(r), the Act required EPA to promulgate reasonable regulations and appropriate guidance to provide for the prevention and detection of accidental releases and for response to such releases. The accident prevention regulations apply to stationary sources that have present more than a threshold quantity of a "regulated substance".

In developing this list, EPA was required to consider, but not be limited to, the list of extremely hazardous substances (EHSs) promulgated under EPCRA (SARA Title III) section 302.

Substances and Threshold Quantities

In 1994, the Environmental protection Agency (EPA) promulgated [29] a list of regulated substances and thresholds required under section 112(r) of the Clean Air Act as amended. The list is composed of two categories: A list of 77 toxic substances and a list of 63 flammable substances. Toxic substances were included on the list based on their toxicity, physical state, vapour pressure, production volume and accident history. Threshold quantities apply to individual processes, not the facility as a whole. Threshold quantities are developed based on ranking methods that consider the toxicity and volatility. EPA assigned identical thresholds to chemicals with similar ranking scores applying the principle of equivalence of harm. The list of substances and threshold quantities is presented in Appendix 2.

Flammable gases and volatile flammable liquids were included on the list based on flash point and boiling point criteria used by the National Fire Protection Association (NFPA) for its highest flammability hazard ranking (flash point below 73°F (22.8°C) and boiling point below 100°F (37.8°C)[9]].

Explosives classified by DOT as Class 1, Division 1.1 and listed as such in 49 CFR 172.101 (the Hazardous Materials Table) are covered by this rule with a threshold quantity of 5,000 pounds.

EPA applies the threshold quantity to the maximum total quantity of a substance in a process. This definition applies to the maximum total quantity, at any one time, in a single vessel, in a group of interconnected vessels or in several vessels that could potentially be involved at one time in an accidental release.

Determination of threshold quantities

The basis of threshold quantities for toxic substances is a simple ranking system; for flammable substances, the basis are historical data indicating that a vapour cloud explosion is unlikely with quantities smaller than 4536 kg [32].

One ranking and five distance-based dispersion-modeling methodologies were considered in developing the US Risk Management Program. The ranking methodology was taken from the Extremely Hazardous Threshold Planning Quantity (EHS TPQ) in the Emergency Planning and Community Right-to-Know Act [32, 29] that considers a chemical's potential to become airborne and disperse and its toxicological properties. Distance is not considered. The distance-based methodologies included those used by the states of Delaware and New Jersey, the federal OSHA Process Safety Management (PSM) guidelines, the Organization Resources Counsellors (ORC) methodology, and an in-house method [32, 33-35]. Similar to Delaware's and OSHA'S PSM guidelines, the in-house method determined the emission quantity necessary to reach a specified concentration 100 m from the release point using a dispersion model and assuming a 10 mph (4.5 m/s) wind speed, atmospheric stability class D, urban conditions, and a 30 min release duration. Threshold quantities ranged from 227 to 9091 kg [33].

Ultimately, EPA selected a relative ranking similar to EHS TPQ with several changes: threshold quantities were set to reflect "a level where the hazard should be considered for planning purposes"; the physical state and volatility of a substance were combined into an overall "ranking factor". The toxic substances were ranked according to the index IDLH/V and assigned threshold quantities as per the following table [30, 31].

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[9] Fire Protection Guide on Hazardous Materials, 1984, 8th edition

Index	Threshold Quantities Kg (lbs)
<0.01	227 (500)
0.01 to <0.05	454 (1,000)
0.05 to <0.1	1,136 (2,500)
0.1 to <0.3	2,273 (5,000)
0.3 to <1	4,545* (10,000)
1 to <10	6,818 (15,000)
≥10	9,091 (20,000)

* Flammable substance thresholds were uniformly set at 4,545 kg (10,000 lbs) using explosion calculation with a 10% efficiency compared to TNT with a 20.68 kPa (3 psi) overpressure on a receptor located at 100 m.

Distance-based methodologies were not considered to be feasible for generic and national application due to the need for an "excess" number of chemical, site, and accident-specific parameters, e.g. wind speed, topography, and distance to receptor or fence line.

The threshold quantities selected are, at the minimum level of 227 kg (500 lbs), representative of drum-size containers, and, at the maximum of 9,091 kg (20,000 lbs) representative of a process tank.

Physical state and volatility were used to derive an index of the chemical's potential to become airborne and disperse. A risk "ranking factor" was defined as IDLH/V, where V is the index of potential to become airborne and disperse and IDLH is Level of Concern (LOC) or factor to measure toxicity. Threshold quantities were assigned to groups of substances according to their relative importance.

The index of potential to become airborne and disperse (V) was derived based on physical state and volatility. For substances that are gases under ambient conditions, V was assumed to have a value of 1, indicating that in an accidental release, the total quantity of chemical involved in the release could become airborne. For liquids, V was calculated by estimating the rate of volatilization from a pool (assumed to be one centimetre in depth) on a flat non-absorbing surface. Liquids were assumed to be at their boiling point, and all liquids were assumed to have the same density as water. A transfer coefficient was estimated by reference to water. Because of these assumptions, the only variables used in the calculation of V were the molecular weight and boiling point of the liquid. Taking into account these assumptions, the equation used to derive V is as follows:

$$V = \frac{1.6 \; x \; MW^{0.67}}{T + 273}$$

Where: MW is the molecular weight, and T is the boiling temperature in degrees Celsius.

Chemical endpoints or "Levels of Concern" are critical parameters for both ranking and distance-based methods. The US Environmental Protection Agency (EPA) selected the Immediately Dangerous to Life and Health (IDLH) air concentration values as the LOC for determining threshold quantities [33]. The IDLH values were originally formulated in the mid-1970s for 387 chemicals by the National Institute for Occupational Safety and Health (NIOSH) for use as respirator selection criteria, based on the effects that might occur from a 30-minute exposure [36]. Later, the US Occupational Safety and Health Administration (OSHA) defined IDLH values in emergency response regulations as "an atmospheric concentration of any toxic, corrosive, or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health effects or would interfere with an individual's ability to escape from a dangerous atmosphere [37]. No specific exposure duration was given. EPA chose the 1990 IDLH values. EPA used IDLH values to set threshold quantities in the ranking procedure for most (53 of 77 or 69%) of listed toxic RMP chemicals [33]. If IDLH values were unavailable, acute toxicity criteria were used: inhalation $LC_{50} \geq 0.5$ mg/l air (for exposures greater than 8h); dermal $LD_{50} \geq 50$ mg/kg; oral $LD_{50} \geq 25$ mg/kg; Threshold Limit Values (TLVs)s (4 of 77 or 5%) [13]. Chronic (long-term) exposure was not considered.

It is important to note that the lists of IDLH were further updated in 1994 [38], 1997 [39], 2001 [40], 2003 [41], 2005 [42] resulting in some significant differences. For instance, the IDLH for chlorine, which was 30 ppm in 1990, was reduced to 10 ppm in 1994. Applying the 1994 IDLH would have an obvious effect on the chlorine ranking and its threshold.

A minimum vapour pressure of 10 mmHg for all toxic liquids (29 of 77 or 38%) was used to select hazardous substances.

In addition, coverage of hazardous installations can be subdivided into different level of obligations using other criteria than the type of substances. For example, the U.S. Risk Management Program (RMP) [5] imposes different obligations depending on the industry sectors, i.e. Programme 1, Programme 2, and Programme 3.

Programme 1	**Programme 2**	**Programme 3**
1. For the five years prior to the submission of an RMP, the process has not had an accidental release: (i) Death; (ii) Injury; or (iii) Consequences on an environmental receptor.	1. Programme 2 eligibility requirements. A covered process is subject to Programme 2 requirements if it does not meet the eligibility requirements of either Programme 1 or Programme 3.	1. The process is in NAICS code 32211, 32411, 32511, 325181, 325188, 325192, 325199, 325211, 325311, or 32532
2. The distance to a toxic or flammable endpoint for a worst-case release assessment is less than the distance to any public receptor.		2. The process is subject to the OSHA process safety management standard, 29 CFR 1910.119.
General requirements		
1. Analyze the worst-case release scenario for the covered process(es); document that the nearest public receptor is beyond the distance to a toxic or flammable endpoint; and submit in the RMP the worst-case release scenario.	1. Develop and implement a management system as provided (PSM)	1. Develop and implement a management system as provided (PSM).
2. Complete the five-year accident history for the process of this part and submit it in the RMP.	2. Conduct a hazard assessment.	2. Conduct a hazard assessment.
3. Ensure that response actions have been coordinated with local emergency planning and response agencies.	3. Implement the Programme 2 prevention steps or implement the Programme 3 prevention steps.	3. Implement the Programme 3 prevention steps.
4. Certify in the RMP the following: "Based on the criteria, the distance to the specified endpoint for the worst-case accidental release scenario for the following process(es) is less than the distance to the nearest public receptor.	4. Develop and implement an emergency response program.	4. Develop and implement an emergency response program.
	5. Submit, as part of the RMP, the data on prevention program elements for Programme 2 processes.	5. Submit, as part of the RMP, the data on prevention program elements for Programme 3 processes.

Legislation is evolving and policy decisions may have an impact on any future approach for regulating hazardous substances. For example in January 2006, the US Office of Management Budget (OMB) released a document titled "Proposed Risk Assessment Bulletin." The document describes a broad set of standards for US federal agencies to follow in their conduct of risk assessments related to health, safety, and the environment [9]. The document is being peer reviewed and finalised. While this document is internal to the United States, it will probably have a significant influence elsewhere on risk assessment to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment. The Workshop participants should take note of this evolution.

OSHA Process Safety Management Rule (OSHA 1910.119)

Regulatory Framework

The major objective of process safety management of highly hazardous chemicals is to prevent unwanted releases of hazardous chemicals especially into locations which could expose employees and others to serious hazards. An effective process safety management program requires a systematic approach to evaluating the whole process. Using this approach the process design, process technology, operational and maintenance activities and procedures, non-routine activities and procedures, emergency preparedness plans and procedures, training programs, and other elements which impact the process are all considered in the evaluation. The various lines of defence that have been incorporated into the design and operation of the process to prevent or mitigate the release of hazardous chemicals need to be evaluated and strengthened to assure their effectiveness at each level. Process safety management is the proactive identification, evaluation and mitigation or prevention of chemical releases that could occur as a result of failures in process, procedures, or equipments.

The process safety management standard targets highly hazardous chemicals that have the potential to cause a catastrophic incident. This standard as a whole is to aid employers in their efforts to prevent or mitigate episodic chemical releases that could lead to a catastrophe in the workplace and possibly to the surrounding community. This OSHA standard is required by the Clean Air Act Amendments, as is the Environmental Protection Agency's Risk Management Plan. Employers, who merge the two sets of requirements into their process safety management program, will better assure full compliance with each as well as enhancing their relationship with the local community.

Scope and Definitions

This rule applies to the following:

A process which involves a chemical at or above the specified threshold quantities listed in Appendix 4 or a process with a flammable liquid or gas on site in one location, in a quantity of 4,545 kg (10000 lbs) or more except for: Hydrocarbon fuels used solely for workplace consumption as a fuel and flammable liquids stored in atmospheric tanks or transferred which are kept below their normal boiling point without benefit of chilling or refrigeration.

Substances and Threshold Quantities

The regulation uses one generic category for flammable substances and a list of named substances with thresholds (Appendix 4).

The generic categories for flammables substance are flammable liquids or gases on site in one location, in a quantity of 4,545 kg (10000 lbs). Flammable substance thresholds were uniformly set at 4,545 kg (10,000 lbs) using an explosion calculation with a 10% efficiency compared to TNT with a 20.68 kPa (3 psi) overpressure on a receptor located at 100 m.

The list of toxic substances represent a compilation of highly hazardous chemicals that can cause a serious chemical accident, by toxicity, or reactivity, and a consequent serious danger to the employees in a workplace. Appendix 4 is based on information drawn from a variety of sources including among others, the Environmental Protection Agency, the Department of Transportation, the World Bank, the National Fire Protection Association, the Health and Safety Commission of the United Kingdom, and the States of Delaware and New Jersey. Every chemical in Appendix 4 is on at least one list compiled by these agencies and organization as warranting a high degree of management control due to its extremely hazardous nature. Most of the chemicals are on several lists. OSHA realized that these lists vary in chemicals as well as in quantities. Based on a review of these sources, OSHA has sought to include those toxics and reactives believed to be the most significant in potentially becoming a catastrophic event. OSHA has also sought to develop a reasonable listing of threshold quantities based on a review of the data available that would sufficiently address potential catastrophic amounts of chemicals.

Toxic substance threshold were determined using the emission quantity necessary to reach a specified concentration at 100 m from the release point using a dispersion model and assuming a 10 mph (4.5 m/s) wind speed, atmospheric stability class D, urban conditions, and a 30-minute release duration.

Canada

Regulatory Framework

Environment Canada's mandate is to preserve and enhance the quality of the natural environment and its vision is to see a Canada where people make responsible decisions about the environment, and where the environment is thereby sustained for the benefit of present and future generations. The mission of its Environmental Emergencies program is to reduce the frequency, severity, and consequences of environmental emergencies.

The events of September 11th 2001 highlighted the need for increased action to prevent and prepare for potential threats to national security. Canadians were becoming more aware of the risks and were demanding that we adopt appropriate emergency management programs that meet international standards and best practices, to address natural and human-caused incidents, including terrorist threats.

Hence, Environment Canada decided to use powers under the Canadian Environmental Protection Act 1999 (CEPA) to ensure that industrial facilities using dangerous substances had emergency plans in place to prevent accidents, and respond quickly and effectively to protect the environment and the health of Canadians in the event of an accident, vandalism or terrorist attack. Part 8 of CEPA - Environmental Aspects Related to Emergencies (Sections 193 to 205) - provide the Minister of the Environment with various powers to address environmental emergencies.

Environment Canada reviewed the relationship between taking action under Section 199 dealing solely with CEPA toxics and that under Section 200, which provides a much broader scope of authority. The department concluded that the most effective and efficient means of achieving departmental objectives was to require environmental emergency (E2) Plans for both CEPA toxics and other hazardous substances by regulation under Section 200.

Section 200 allows the federal government to establish a list of substances that, if they enter the environment as a result of an environmental emergency:

a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

b) constitute or may constitute a danger to the environment on which human life depends; or,

c) constitute or may constitute a danger in Canada to human life or health.

An E2 plan would be required of all facilities that store or use any of these substances at or above the specified threshold quantities.

Consultations held late in 2001 confirmed that there was general support for the proposed regulation. There was also a need to either create or adopt an existing list of substances on which to build the regulation. Due to certain time constraints on the federal government to put a regulation in place, consensus was reached to utilize the list of substances and thresholds already developed by the "Conseil pour la réduction des accidents industriels majeurs" (CRAIM) as the basis for the drafting of the proposed initial regulation. CRAIM is the Montréal regional chapter of the former Major Industrial Accidents Council of Canada (MIACC).

The CEPA National Advisory Committee (NAC), composed of representatives from Canada's provinces and territories, was also engaged through a series of regular briefings. The provinces too were generally supportive of the initiative, the only issue being the need to avoid duplication with any provincial legislated requirements in this area. Environment Canada is fully committed to pursuing administrative agreements or other mechanisms to eliminate or minimize any such duplication.

Hazardous Substances Thresholds

The MIACC Lists

Canada's origins for hazardous substances lists can be traced back to the time of the former MIACC (the Major Industrial Accidents Council of Canada). This organization was formed in 1987 as a voluntary not-for-profit multi-stakeholder forum for government, industry, and non-government organizations to work co-operatively to reduce the frequency and severity of industrial accidents. It was created to address a series of recommendations for accident prevention, preparedness and response made by the federally-appointed Bhopal Aftermath Review Committee in 1986 and ceased operations in late 1999. The development of lists of hazardous substances was initiated in 1991 by MIACC Working Group 1.

The MIACC Lists of Hazardous Substances were developed by members of Working Group 1 who had expertise in the areas of toxicology, health and safety, emergency response, and regulatory compliance/enforcement. These were used as the basis for identifying and ranking sites at which handling of hazardous substances takes place from the perspective of public safety risk.

Three lists were developed as follows:

- MIACC List 1 – Priority Hazardous Substances
- MIACC List 2 – Hazardous Substances
- MIACC List 3 – Environmentally Hazardous Substances.

List 1 was a list of 33 "top priority" substances commonly found in Canada in both fixed facilities and transport situations. These substances represented at the time, the substances that were involved in the highest number of accidents in Canada. If List 1 substances were to be released in quantities larger than the threshold quantities which are typically large, there would be a high probability of causing fatalities off site. The threshold quantities were based on the expert opinion of members of MIACC Working Group 1.

List 2 was a longer list of 212 potentially hazardous substances, which, if released, would cause off-site injuries and possible fatalities. These substances are a combination of MIACC List 1 (at lower thresholds), Extremely Hazardous Substances listed under Section 302 of the Emergency Planning and Community Right-to-know Act (EPCRA or SARA Title III) and hazardous substances listed under the SEVESO I Directive. Hazardous substances from SARA Title III and SEVESO I were retained if they were listed on Environment Canada's Domestic Substances List (DSL). The threshold quantities in List 2 were based on the quantities set out in SARA Title III, SEVESO I and the expert opinion of members of MIACC Working Group 1.

List 3 comprised 68 other hazardous substances which are frequently encountered in Canada but present smaller acute risks than those in Lists 1 and 2, and are less likely to cause or be involved in a major accident. They may however, present environmental or long-term risks.

The Lists gave the name of the substance, the usual physical state, Chemical Abstracts Service (CAS) numbers, product identification number / United Nations number (PIN/UN), transport of dangerous goods (TDG) class and division numbers, and a threshold quantity.

Key factors considered in the compilation of MIACC Lists 1 and 2 were:

- the physical and chemical properties of the substance;
- the physical and chemical properties of the decomposition or combustion products; and,
- historical involvement of the substance in industrial accidents (primarily its inclusion on the Environment Canada Spills List).

Part of the process involved review of existing lists of hazardous substances. These included the following Canadian Lists:

- Transport Canada's Transportation of Dangerous Goods Regulations, Schedule XIII; Environment Canada's Lists of Spilled Chemicals;
- Montréal Urban Community's List of Dangerous Substances;
- The substances listed in the regulation promulgated under the Pest Control Products Act, and,
- The Workplace Hazardous Materials Information System (WHMIS) Lists.

Other lists reviewed included:

The U.S. Environmental Protection Agency's Superfund Amendments and Re-Authorization Act (SARA Title III) Extremely Hazardous Substance List and the Toxic Substances Control Act (TSCA) Inventory;

- The U.S. Occupational Safety and Health (OSHA 1910.119) List;
- The International Labour Office Lists of Recommendations for Process Hazards Management of Substances with Catastrophic Potential;
- The List of Substances from the Netherlands Organization of Applied Scientific Research (TNO) Guide to Hazardous Industrial Activities; and,

– The EC's SEVESO I Directive Annex III.

Criteria for inclusion in the MIACC Lists were developed considering those used in the creation of the above lists along with other Canadian experience. Hazardous substances not currently produced or allowed to be imported into Canada were eliminated from the MIACC Lists.

The CRAIM List of Hazardous Substances

The CRAIM list of hazardous substances was developed using a multi-stakeholder process that reviewed and adopted all the hazardous substances from the Risk Management Program (RMP) developed by the U.S. Environmental Protection Agency (EPA) and a selection of chemicals from the MIACC lists.

The CRAIM List of 178 substances contains 63 inflammables (from RMP), 77 toxics (from RMP), 11 inflammables (from MIACC / Occupational Safety and Health Administration (OSHA) or National Fire Protection Association (NFPA)), 22 toxic (from MIACC / OSHA or NFPA), 4 explosives, and 1 miscellaneous. It was designed to take into account the List of hazardous substances from the EPA Risk Management Program (RMP) while also retaining the most hazardous substances from MIACC List 2.

Knowledge of where specific toxic or hazardous substances and their quantities exist in Canada has been a critical missing element in preparing for emergencies from an environmental, health protection and national security perspective.

The current E2 regulation under Section 200 of CEPA that came into force in November 2003 covers some 174 substances (76 flammables and 98 other hazardous substances) that, if released to the environment as a result of an environmental emergency, act of terrorism or vandalism, may harm human health or environmental quality. They include 16 substances that either are on the List of Toxic Substances (Schedule 1) under CEPA 1999 or are proposed to be added to the List. Hence the regulation addresses both CEPA toxics and other hazardous substances of concern.

Threshold Quantities for Flammable Substances

It is important to have a sound and transparent methodology for assignment of threshold quantities for hazardous substances. The methodology should include an explanation of the basis for establishing the list and account for specific factors in setting the threshold quantities. Moreover, a sound methodology is essential for making changes to the list of substances and their threshold quantities to keep the regulation current. The methodology adopted was the one that EPA used for setting up the RMP (Risk Management Program) lists.

Part 1 of Schedule 1 of the s200 regulation consists of 76 flammable substances. Analysis of the hazards of flammable substances conducted by US EPA indicated that the greatest hazard to the public from these substances is from vapour cloud explosions. Heat radiation from pool fires, vapour cloud fires, or fireball resulting from boiling liquid expanding vapour cloud explosions (BLEVEs) can also be a threat to the public. However, EPA's analysis indicated that for a given quantity of a flammable chemical, vapour cloud explosions pose the greatest threat over the greatest distance. Historical data show that vapour cloud explosions are unlikely for vapour cloud containing quantities less than 4,545 kg (10,000 lbs). The quantity in a vapour cloud resulting from an accidental release of a flammable gas or volatile flammable liquid could vary greatly depending on site-specific and accident-specific conditions, as well as properties of the chemical released.

As indicated above, EPA has a list of 63 flammable gases and volatile flammable liquids under the RMP. Because it would be difficult to set chemical-specific thresholds based on all the factors that might affect a release, EPA chose to set the threshold for all the listed flammable substances at 4,545 kg, based on the potential for vapour cloud explosions. EPA's analysis indicated that the detonation of 4,545 kg of a flammable vapour (e.g., ethylene, propane, propylene, etc.) could have a potentially lethal effect on people at a distance of 100 metres from the site of the detonation. The 4.5 tonne threshold has therefore been selected for Part 1 of Schedule 1 of Environment Canada's environmental emergency regulation.

Other Hazardous Substances Thresholds

Part 2 of Schedule 1 of the s200 regulation consists of 98 other hazardous substances. For the setting of threshold quantities for such substances under the RMP, EPA used the methodology for the development of threshold planning quantities (TPQs) developed for extremely hazardous substances (EHSs) listed under EPCRA (SARA Title III) section 302. This methodology takes into account the potential of toxic substances to become airborne, their dispersion potential and toxicological properties, with adjustment based on chemical reactivity and other factors.

The Immediately Dangerous to Life and Health (IDLH) level developed by the National Institute of Occupational Safety and Health (NIOSH), or an approximation of the IDLH based on animal toxicity data, was used as an index of toxicity. IDLHs presented in the 1990 edition of the NIOSH Pocket Guide to Chemical Hazards were used where available.

The toxic substances were ranked according to the ranking factor IDLH/V (where V is the index of potential to become airborne and disperse) and assigned threshold quantities of 0.22 t (500 lbs), 0.45 t (1,000 lbs), 1.13 t (2,500 lbs), 2.27 t (5,000 lbs), 6.80 t (15,000 lbs) or 9.10 t (20,000 lbs) based on order of magnitude ranges in the ranking factors. The threshold quantities selected are, at the minimum level of 0.22 t (500 lbs), representative of drum-size containers, and, at the maximum of 9.10 t (20,000 lbs). The range of threshold quantities reflect the relative hazards among the listed toxics; the upper limit of 9.10 t (20,000 lbs) represents typical handling quantities, and would still be protective of the public for those substances which would have the higher thresholds.

Substance Selection Using the Risk Evaluation Framework (REF)

For those substances that were not automatically covered by the adoption of the CRAIM list for the s200 regulation, it was necessary to create a screening mechanism to assess whether candidate substances should be added to the s200 list so that environmental emergency plans would be required. This was especially needed for a large number of so-called CEPA toxics that had been identified as requiring risk management strategies based on persistence in the environment, bioaccumulation potential, and inherent toxicity (PBiT) criteria. A Risk Evaluation Framework (REF) was therefore developed in order to satisfy this need. It has been applied recently to evaluate approx. 100 CEPA toxics in order to determine which ones should require environmental emergency plans under s200. Those substances that qualify are being proposed for addition to Schedule 1 of the regulation during the current amendment process. The amended regulation is expected to come into force by Q2 of 2007.

The REF is designed with a pre-screening filter that poses three fundamental questions:

- Is the substance in commerce in Canada?
- Is an emergency plan for it required by another act of Parliament? and,
- Are there realistic emergency pathways associated with the substance?

There is no specific order to enter data for much of the REF, except for in the screening assessment subsection, where it is determined whether or not an assessment should be done, as well as in the human health hazard subsection. Values are entered for vapour pressure prior to entering a value for human inhalation toxicity. This is to ensure that the chemical in question is sufficiently volatile to represent a hazard to humans and the environment. A vapour pressure greater than or equal to 1.333 kPa (10 mm Hg) is considered a possible human inhalation health threat based on the U.S. EPA criteria for their Clean Air Act. Other than that, data can be entered into any subsection, and edited if necessary. The spreadsheet will simply recalculate the values and update the conclusions.

The REF employs a scoring system done in Microsoft Excel that incorporates the CRAIM criteria for human health and safety with environmental criteria. A substance is evaluated in three subsections: environmental hazard, human hazard and physical hazard. Appropriate data from the data collection document are scored according to the criteria tables found in this document. The resulting scores are entered into the REF. An E2 plan may be deemed a requirement based upon the scores of either the environmental health or human health or physical hazard subsections or any combination thereof. A decision for an E2 plan can also be made upon meeting or exceeding any of the single trigger values for most of the criteria used.

All data that were used in the REF spreadsheet are to be included into a chemical assessment report, including the references. When the assessment is completed the summary worksheet will display all of the conclusions that were derived from the REF.

Currently, the REF will generate threshold quantities for substances that may potentially impact humans and/or the environment in regards to aquatic toxicity, carcinogenicity, vapour cloud explosions, inhalation toxicity, and reactivity. The REF is not a static document. It changes as new information arises concerning the science and behaviour of substances and their impact on humans and the environment.

Canadian facilities subject to the regulation are required to submit: a notice containing information on the location and quantities of listed substances if either the substance quantity or capacity of the largest single container exceeds the applicable threshold; a second notice that the required E2 plan has been prepared is required if both these criteria are met as well as a third notice that the E2 plan has been tested and implemented. Deadlines for the three notices are within 90 days, six months, and one year, respectively; of the latter of, the proposed regulation coming into force or after a substance reaches or exceeds the prescribed quantity. Currently, the regulation applies to approximately 3500 facilities of which about 2300 require E2 plans. The balance, that meet only the quantity or container capacity criterion are considered tier-two priorities.

Australia – State of Victoria

Regulatory Framework

The new *Occupational Health and Safety Act 2004* [46] follows on from a major review of the 1985 Act. The new Act clarifies and brings Victoria's workplace safety laws up to date to reflect modern workplaces and arrangements.

Scope and Definitions

Protecting workers and the community

Victoria has strict regulations that promote the safe operation of major hazard facilities. The onus is on facility operators to develop comprehensive Safety Cases that detail the safe operation of their facilities.

What is a major hazard facility?

Any site that stores and uses very large quantities of hazardous chemicals is considered to be a major hazard facility. Examples include refineries, chemical manufacturing sites, gas-processing plants, LPG facilities, and some warehouses and transport depots. The products and services provided by these facilities are important to the quality of life enjoyed by Victorians. There are currently 45 major hazard facilities in Victoria and these facilities have hazards that create risks with potentially far greater consequences for both the site and the surrounding community than at most other industrial sites.

Sites are required by legislation to have highly effective safety management systems in place.

Because a major incident can include fire, explosion or a chemical release, and the consequences can include serious injury or loss of life, Victoria has stringent legislation for the safety of these sites.

Hazardous Substances and Threshold Quantities

Relevant materials

The materials which characterise a workplace as a facility for the purposes of these Regulations are the materials specifically mentioned in Appendix 5 Table 1 and materials that belong to the types, classes and categories mentioned in Table 2.

"Threshold quantity" of one material

a) In relation to each such material, the third column of each Table provides a quantity that is described as the "threshold quantity" of that material.

b) Where a material is mentioned in Table 1, the threshold quantity of the material is that described in Table 1, whether or not the material also belongs to a type, class or category mentioned in Table 2.

c) Where a material is not mentioned in Table 1, and where the material belongs to a type, class or category mentioned in Table 2, the threshold quantity of that material is that of the type, class or category to which it belongs.

d) Where a material is not mentioned in Table 1, and where the material appears to belong to more than one of the types, classes or categories mentioned in Table 2, the threshold quantity of that material is that of the relevant type, class or category which has the lower or lowest threshold quantity.

“Threshold quantity" of more than one material

If there is more than one material, a **threshold quantity** of materials exists where, if a number of materials are present, the result of the following aggregation formula exceeds 1:

$$\frac{qx}{Qx} + \frac{qy}{Qy} + ... + \frac{qn}{Qn}$$

Where:

– x, y, … and n are the materials present or likely to be present;

- qx, qy ..... and qn is the quantity of materials x, y, … and n present or likely to be present, other than:
  1. material that is present or likely to be present in an isolated quantity less than 2% of its individual threshold quantity;
  2. materials that are solely the subject of intermediate temporary storage, while in transit by road or rail;
- Qx, Qy ..... Qn is the individual threshold quantity for each material x, y … and n;
- a material is present or likely to be present in an "isolated quantity", if its location at the facility is such that it cannot, on its own, act as an initiator of a major incident.

Any reference in these Regulations to Schedule 1 materials likely to be present at a facility is a reference to the maximum quantity of the Schedule 1 materials that would meet the capacity of the facility, including:

a) the maximum capacity of process vessels and interconnecting piping systems to contain the materials;

b) the maximum capacity of storage tanks and vessels used for the materials;

c) the maximum storage capacity of other storage areas at the facility that could contain the materials;

d) the maximum capacity of pipelines outside process areas to contain the materials;

e) the maximum quantity of the materials that would, in the event of a failure, escape onto the premises of the facility from a pipeline that is situated off the premises but connected to the facility; and,

f) the maximum quantity of the materials loaded into or onto, or unloaded from, vehicles, trailers, rolling stock and ships that are from time to time present at the facility in the course of the facility's operations.

Korea

The title of the law is **Process Safety Management Law** (PSM). Hazardous installations prescribed in the Law shall be the following business categories or installations handling and storing hazardous materials more than threshold quantities:

- Refineries
- Re-processing of by-products of petroleum refining
- Petrochemical organic chemicals or synthetic resins
- Fertilizers Industries
- Pesticide/ herbicide

- Explosive powder/fireworks products

It is intended to protect employees, residents in community and the environment.

Regulated substances

The following table presents the list of regulated substances. Processes are regulated if they use the daily consumption or more or if they have the maximum inventory or more.

	kg		**kg**
Flammable Gases	5,000[1](200,000)[2]	Hydrogen fluoride[1,2]	1000
Combustible Liquid	5,000[1](200,000)[2]	Hydrogen chloride[1,2]	20,000
Methyl isocyanate	150[1,2]	Hydrogen sulphide[1,2]	1,000
Phosgene	750[1,2]	Ammonium nitrate[1,2]	500,000
Acrylonitrile	20,000[1,2]	Nitro-glycerine[1,2]	10,000
Ammonia	200,000[1,2]	Trinitrotoluene[1,2]	50,000
Chlorine	20,000[1,2]	Hydrogen[1,2]	50,000
Sulphur trioxide	75,000[1,2]	Phosphine[1,2]	50
Carbon disulfide	5,000[1,2]	Silane[1,2]	50
Hydrogen cyanide	1,000[1,2]		

Notes: 1: Daily consumption; 2: Maximum inventory

Switzerland

The Ordinance on Major Accidents (OMA) uses a two-step approach to protect the public and the environment against serious damage resulting from major accidents. In a first step, the owner of an establishment has to determine the hazard potential arising from his establishment with respect to the properties and quantities of substances stored and handled. Owners of establishments, in which the threshold quantities depending on the criteria toxicity, flammability, explosiveness and ecotoxicity are exceeded, have to submit a summary report including the following information:

- a short description of the establishment with the maximum amounts of substances;
- details of the safety measures;
- an estimation of the extent of possible damage to the public or the environment with respect to worst case scenarios.

The enforcement authority checks and evaluates if the worst case scenarios in the summary report are plausible and if serious damage to the public or the environment is not to be expected. If this cannot be assumed, the enforcement authority requires in a second step the owner to carry out a risk study. The risk study must provide a diagram that relates the extent of possible damage to the public or the environment of the essential major accident scenarios to their probabilities of occurrence, taking account of the safety measures. Based on the risk study, the enforcement authority decides whether the risk is acceptable or supplementary safety measures are necessary.

In 2005, the Swiss chemicals law was amended for compatibility with the one of the EU. The adaptation to the EU classification system required a re-definition of threshold quantities in the Ordinance on Major Accidents (OMA). Although the EU and the Swiss classification systems are now harmonised, the threshold quantities in the OMA are more conservative than those in the Seveso II Directive. The differences can be explained by different risk assessment approaches.

Japan

There is no single comprehensive law/registration focusing on chemical accidents in Japan, and Japan has a number of main laws related to chemical accidents including:

- Poisonous and Deleterious Substances Control Law (focuses on the poisonous properties of some chemicals),
- Industrial Safety and Health Law,
- Water Pollution Control Law,
- Air Pollution Control Law,
- Fire Service Law (focusing on combustible nature of some chemicals, etc.),
- High Pressure Gas Safety Law,
- Law on the Prevention of Disasters in Petroleum Industrial Complexes and Other Petroleum Facilities (focusing on the safety of petrochemical complexes),
- Explosives Control Law, and
- Law Concerning the Securing of Safety and the Optimization of Transaction of Liquefied Petroleum Gas.

Q: There is a hierarchy of regulations in the US designed to ensure public safety against major accidents resulting from the release of hazardous substances, e.g. the 1986 Emergency Planning and Community Right-to-Know Act, the 1986 Accidental Release Information Program, and the 1988 Chemical Safety Audit Program. Most of these regulatory instruments have lists of hazardous substances with thresholds. Is there better appreciation now of how these lists were developed? Clarify the purpose of these lists?

Q: The NIOSH IDLH has been significantly modified with time, e.g. chlorine, 30 ppm in 1990 and 10 ppm in 1994. This has significant impact on the chemical ranking and its potential threshold, should such changes in IDLH not warrant a change in threshold values?

Q: Defining thresholds for chemical is not an absolute science. The previous question indicates that it would be appropriate to consider reducing the chlorine threshold. However, there is no accident history of significant consequences at facilities with quantities of chlorine less than the current threshold. How should incident history be factored into the upgrading of thresholds? Is this an area where international collaboration such as sharing of accident reports, alerts would be beneficial?

Q: There is a significant difference between the threshold used for the same substance in Europe and North America. Perhaps, this is due to the way the coverage is applied. Could those differences be explained?

THEMATIC SESSION 2: CURRENT PROCESSES FOR SELECTING 'REGULATED' CHEMICALS AND DETERMINING THRESHOLDS OF EFFECTS UNDER ACCIDENT PREVENTION POLICIES.

Key objectives to be covered in this session:

a) Analyse the role of systems of classification/assessment of chemicals in processes for identification and selection of hazardous substances.

b) Describe experiences with different approaches, including the use of classes of substances vs. lists of individually named substances.

c) Describe experiences in applying environmental effects vs. human effects criteria.

d) Exchange information on how other criteria and measures (not substance-related), such as threshold quantities, exemptions, etc. have affected the definition of scope and their advantages and disadvantages.

e) Discuss other relevant matters and their relative importance, for example: process safety management, reactivity including combustible dust, nanoparticles, and non-specific chemical fires that release hazardous substances as by-products of combustion.

Aim at reaching a common understanding on challenges arising from practical application of different criteria and measures for defining scope in OECD countries

MATRIX

The following paragraphs compare the approaches taken by the EU, the USA, Canada, Australia, Korea, and Japan to regulate hazardous substances. This comparison is not intended to be comprehensive since differences will be further explored at the workshop. However, it provides an example of some notable differences that have been identified, in particular:

- It is well established that some regulatory regimes use only named substances as the basis for coverage and that others use generic criteria along with a list of named substances.

- Some regulatory systems deal only with off-site consequences (e.g., US EPA), some with only on-site consequences (e.g., US PSM), some with both on- and off-site consequences (e.g., EU Seveso, Canada Environmental Emergency Regulation)

- Some accident prevention authorities are also somewhat responsible for chemical risk assessments (e.g., Canada) whereas under other regimes, chemical risk assessment is governed by other legislation (e.g., EU Seveso)

- The unit of coverage differs between regulatory regimes. For example, the Seveso Directive uses the total inventory on site, the US RMP Rule uses the inventory of a process, and Canada uses the inventory of the largest vessel.

- Thresholds for substances named in the various regulatory regimes are generally not the same. However, it is also difficult to make comparisons because of differences between the units of coverage and the fact that some regimes use generic criteria as well as named substances.

– Coverage of sites with perceived higher risks vs. lower risks are differentiated in various ways under the different regulatory regimes. For example, the EU Seveso Directive differentiates between higher and lower risk sites on the basis of threshold quantities. The US RMP Rule uses industrial activity and consequences of a potential accident and accident history. Canada distinguishes between the threshold in a single container and the total inventory on site.

EU uses threshold quantities to differentiate coverage (higher vs. lower coverage) and low tier and US and Canada have one number. However, the US also applies a tiered-system on the basis of either industry category or consequences ("remote facility" concept). The EU uses an aggregation rule and the US and Canada does not. EU uses categories of substances plus named substances, US and Canada use named substances.

	European Union / European Economic Area	**United States (EPA)**	**United States (OSHA)**	**Canada**	**Korea**	**Australia**	**Switzerland**
Directive / Regulation	Seveso II	Risk Management Program	Process Safety Management Rule	Environmental Emergency Regulation	Process Safety Management Law (PSM)	Occupational Health and Safety (Major Hazard Facilities) Regulations 2000	Ordinance on Major Accidents (OMA)
Aim	Man, environment, safety and health protection at work	Man and environment	Safety and health protection at work	Man and environment	Safety and health protection at work	Man, Safety and health protection at work Infrastructures	Man and environment
General duty clause	Yes	Yes	Yes	Yes	Info not available	Yes	Yes
Scope	Establishment:	Process	Process	Largest vessel	Process	Facility	Establishments (chemical and biological hazards), Transportation routes
Differentiated coverage	Upper and lower "tiers" based on threshold[10] quantities	Three "programme" levels based on industrial activity, consequences of a potential accident, and accident history.	One level	First notice: Total inventory exceeds threshold quantity Second notice and emergency plan: Largest vessel inventory exceeds threshold	One level	Two levels: Threshold quantity facility covered; 10% of threshold, inform authorities	Two steps: Based on threshold quantities facilities have to submit a summary report; if serious damage is to be expected, the enforcement authority requires a risk study

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[10] The Seveso Directive represents minimum requirements for EU/EEA Member States. Some Member States have more than two tiers.

	European Union / European Economic Area	**United States (EPA)**	**United States (OSHA)**	**Canada**	**Korea**	**Australia**	**Switzerland**
Authority over the chemical risk assessment process?	No. Chemical risk assessment is conducted under separate regulations and managed as a separate activity by the authorities	Yes.	Yes	Shared with Health Canada	Info not available	Info not available	Yes
Aggregation rule	Yes	No	Yes for flammable	No	Yes for flammable	Yes	No
Basis of Substance Criteria	Generic categories plus a list of named substances	A list of named substances plus a generic category for explosives	Generic categories for flammables plus a list of named toxic substances	A list of named substances	Generic categories for flammables plus a list of named toxic substances	Generic categories plus a list of named substances	Generic categories plus a list of named substances
Types of Acute Hazards Covered	Toxic substances to humans; Toxic to the Environment; Flammables; Explosives; Oxidisers; Water reactives	Toxic substances to humans; Flammables	Toxic to Humans; Flammables	Toxic substances to humans; Flammables; Explosives	Toxic substances to humans; Flammables; Explosives	Toxic substances to humans; Flammables; Explosives	Toxic substances to humans; Toxic to the Environment; Flammables; Explosives; Oxidisers
Populations covered	On-site and Off-site	Off-site only	On-site	Off-site	Info not available	On-site and Off-site	Off-site only
Land Use Planning	On-site and Off-site	Off-site only	On-site	Off-site	Info not available	On-site and Off-site	General duty for the siting of establishments, but no specific regulation

Q: What challenges or successes have OECD Member States experienced in implementing the substance criteria in their accident prevention regulations?

Q: What kinds of criteria are used in addition to substance criteria to identify hazardous installations for coverage under accident prevention regulations? How have these criteria affected actual coverage?

Q: What other kinds of measures are available to compensate for weaknesses in the current approach (e.g., exemptions)?

Q: What are the most common types of coverage problems encountered in the Member States? For example, are their industrial activities that pose classification problems for which the current system does not provide any assistance? Are there specific substances whose properties are difficult to classify? Etc.

THEMATIC SESSION 3: EXAMPLES OF DIVERGENCE IN APPROACHES AND POTENTIAL FOR FUTURE IMPLICATIONS

Key objectives to be covered in this session:

a) Build awareness of other initiatives that are likely to affect implementation of industrial accident policies, e.g., the new UN Globally Harmonised System for Classification and Labelling of Chemicals (GHS), the new European policy REACH (Registration, Evaluation, and Authorisation of Chemicals), the AETL methodologies (Acute Exposure Threshold Levels), the Land-Use-Planning policies (LUP), and research activities.

b) Review potential opportunities to improve current approaches within OECD countries particularly on substances or categories of substances of common concern, and industries and processes of common concern, with the intent of highlighting the opportunities and benefits of developing a common scientific rationale for addressing these areas.

c) Aim at reaching a common understanding of how future developments may further exaggerate or decrease differences in scope.

A number of new, initiatives are expected to influence processes and outcomes for determining hazardous properties of substances in future, as follows:

- The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)", addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. It aims at ensuring that information on physical hazards and toxicity from chemicals is available in order to enhance the protection of human health and the environment during the handling, transport, and use of these chemicals. The GHS also provides a basis for harmonization of rules and regulations on chemicals at national, regional, and worldwide level, an important factor also for trade facilitation. The Plan of Implementation of the World Summit on Sustainable Development (WSSD), adopted in Johannesburg in 2002, encourages countries to implement the GHS as soon as possible with a view to having the system fully operational by 2008.

- REACH (Registration, Evaluation, and Authorization of Chemicals) is another important Directive that is being enacted. REACH lays down provisions which shall apply to the manufacture, import, placing on the market or use of substances on their own, in preparations, or in articles. REACH provides information on substances that will support the operation of worker protection and transport legislation, which operate unchanged.

The use of acute exposure information (e.g., AEGLs, the Acutex project) and other related issues may affect the implementation of industrial accident policies. Some of these initiatives will be presented at the workshop.

Q: What new tools or methods might be needed to improve current approaches to identifying hazardous installations for coverage under accident prevention regulations?

Q: What challenges and opportunities do new initiatives pose in identifying substances for coverage under accident prevention regulations? What are some of the possible impacts that potential changes could have on scope of coverage conceptually (regulatory definitions) and in practice (i.e., due to changes in the hazard profiles of substances)?

Q: What kinds of data and research would be useful in developing such improvements and addressing new challenges?

Q: What kind of technical exchange or collaboration among OECD countries could facilitate this work?

THEMATIC SESSION 4: ELABORATION OF A CONSISTENT APPROACH TO IDENTIFY CHEMICAL OF INTEREST FOR ACCIDENTS REGULATIONS PURPOSES

Key objectives to be covered in this session

a) Investigate future prospects for information exchange among OECD countries so that the results of evaluations of chemicals for accident prevention purposes carried out by one country could be shared and applied by the other member countries.

b) Identify the future needs for "re-assessment" of certain chemicals because of new scientific information or (i.e. chemicals which will change hazard classification category).

c) Explore the possibility of jointly assessing or re-assessing specific substances or categories of substances among member states.

d) Explore the creation of a list of specific substances or groups of substances of common interest.

e) Investigate the benefits and feasibility of standardising terminology and assessment techniques among the various existing systems.

f) Make a list of potential common concerns over the next five years.

g) Explore for the feasibility of sharing the workload of actions generated by the workshop.

The expected outcome of this session includes a list of potential common concerns and future actions that could promote closer collaboration in solving problems in these areas. The results of this discussion will be recorded in the final version of this document.

Q: What are the concerns that OECD member countries have regarding hazardous substances for the next five years? Are there areas where collaboration between countries could be explored?

THEMATIC SESSION 5: THE PATH FORWARD

Key objectives to be covered in this session:

a) Evaluate level of interest among member countries for closer co-operation in the area of control of chemical accident hazards.

b) Consider launching a collaboration to support a more consistent approach to identification and selection of substances or groups of substances (categories/classes) with a view to seeking greater complementarities/compatibility in future.

c) Implement mechanisms for greater information exchange and work-sharing – Envisage future co-operation among OECD countries with respect to assessment of chemicals for accident prevention purposes.

d) Agree to a near future OECD programme of work, including the possible creation of a committee to coordinate future collaborative actions.

Future workload for maintaining or updating the lists of hazardous substance?

Certainly collaboration on research and exchange of data and information among international partners should be encouraged as much as possible within their area of expertise.

If one were to start from scratch and with the knowledge that you now have, would a different approach be taken to developing the lists of hazardous substances and their thresholds for preventing/managing accidental releases?

Q: Are there some areas where international collaboration would be justified due to resource limitations or to reduce the workload through sharing?

Q: Is this really the case or will GHS and REACH cause a significant increase in work for maintaining or upgrading the lists of hazardous substances?

Q: What possible areas of collaboration should be explored?

Q: How could the burden associated with a generic approach be reduced?

Q: Our respective citizens and politicians find it difficult to understand why the lists of hazardous substances and their thresholds are so different between OECD countries and this is hard to reconcile from a sound scientific perspective. Are there ways to resolve this issue?

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Appendix 1
Explanation of terms used

The terms set out below were extracted from the regulations or directives of countries and regions and are included to facilitate understanding.

Establishments:	The whole area under the control of an Operator where dangerous substances are present in one or more installations, including common or related infrastructures or activities. (Seveso II)
Facility:	Facility means any building or other structure on land — a) which is a workplace; and b) at which Schedule 1 materials are present or likely to be present for any purpose (Australia, State of Victoria, Occupational Health and Safety (Major Hazard Facilities) Regulations 2000)
Facility:	Facility means the buildings, containers, or equipment, which contain a process. (OSHA 1910.119)
Highly hazardous chemical:	Hazard shall mean the intrinsic property of a dangerous substance or physical situation, with a potential for creating damage to human health and/or the environment. (Seveso II)
Highly hazardous chemical:	Highly hazardous chemical means a substance possessing toxic, reactive, flammable, or explosive properties and specified by paragraph (a)(1) of this section. (OSHA 11910.119)
Installation:	Installation shall mean a technical unit within an establishment in which dangerous substances are produced, used, handled, or stored. It shall include all the equipment, structures, pipework, machinery, tools, private railway sidings, docks, unloading quays serving the installation, jetties, warehouses, or similar structures, floating or otherwise, necessary for the operation of the installation. (Seveso II)
Local community:	Local community means— a) persons who reside in; and b) persons in management and control of workplaces, or of places where persons gather for recreational, cultural or sporting purposes, located in— the area surrounding the major hazard facility, as indicated on the map forming part of the emergency plan for the major hazard facility in accordance with clause 1.2 of Schedule 3; (Australia, State of Victoria, Occupational Health and Safety (Major Hazard Facilities) Regulations 2000)
Major Accident:	Major incident means an uncontrolled incident, including an emission, loss of containment, escape, fire, explosion or release of energy, that— a) involves Schedule 1 materials; and b) poses a serious and immediate risk to health and safety; (Australia, State of Victoria, Occupational Health and Safety (Major Hazard Facilities) Regulations 2000)

Major accident:	Major accident shall mean an occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by the Directive, and leading to serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substance. (Seveso II)
Major hazard:	Major hazard facility means— a) a facility where Schedule 1 materials are present or likely to be present in a quantity exceeding their threshold quantity; or b) a facility, not being a facility to which paragraph (a) applies, determined by the Authority to be a major hazard facility under regulation 705; (Australia, State of Victoria, Occupational Health and Safety (Major Hazard Facilities) Regulations 2000)
Operator:	Operator shall mean any individual or corporate body who operates or holds an establishment or installation or, if provided for by national legislation, has been given decisive economic power in the technical operation thereof. (Seveso II)
Process:	Process means any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances, or combination of these activities. For the purposes of this definition, any group of vessels that are interconnected, or separate vessels that are located such that a regulated substance could be involved in a potential release, shall be considered a single process. (U.S. RMP)
Process:	Process means any activity involving a highly hazardous chemical including any use, storage, manufacturing, handling, or the on-site movement of such chemicals, or combination of these activities. For purposes of this definition, any group of vessels which are interconnected and separate vessels which are located such that a highly hazardous chemical could be involved in a potential release shall be considered a single process. (OSHA 1910.119)
Presence of dangerous substances:	Presence of dangerous substances is defined as the actual or anticipated presence of such substances or the presence of substances which may be generated during the loss of control of an industrial chemical process. (Seveso II)
Risk:	Risk shall mean the likelihood of a specific effect occurring within a specified period or in specified circumstances. (Seveso II)
Schedule 1 Material:	Threshold quantity, in relation to Schedule 1 materials, means the threshold quantity for those materials determined in accordance with Schedule 1. (Australia, State of Victoria, Occupational Health and Safety (Major Hazard Facilities) Regulations 2000)

Appendix 2

SEVESO II List of Hazardous Chemicals

ANNEX I

APPLICATION OF THE DIRECTIVE

INTRODUCTION

1. This Annex applies to the presence of dangerous substances at any establishment within the meaning of Article 3 of this Directive and determines the application of the relevant Articles thereof.

2. Mixtures and preparations shall be treated in the same way as pure substances provided they remain within concentration limits set according to their properties under the relevant Directives given in Part 2, Note 1, or their latest adaptation to technical progress, unless a percentage composition or other description is specifically given.

3. The qualifying quantities set out below relate to each establishment.

4. The quantities to be considered for the application of the relevant Articles are the maximum quantities which are present or are likely to be present at any one time. Dangerous substances present at an establishment only in quantities equal to or less than 2 % of the relevant qualifying quantity shall be ignored for the purposes of calculating the total quantity present if their location within an establishment is such that it cannot act as an initiator of a major accident elsewhere on the site.

5. The rules given in Part 2, Note 4 governing the addition of dangerous substances, or categories of dangerous substances, shall apply where appropriate.

6. For the purposes of this Directive, a gas is any substance that has an absolute vapour pressure equal to or greater than 101,3 kPa at a temperature of 20 º C.

7. For the purposes of this Directive, a liquid is any substance that is not defined as a gas and that is not in the solid state at a temperature of 20 º C and at a standard pressure of 101,3 kPa.

PART 1

Named substances

Where a substance or group of substances listed in Part 1 also falls within a category of Part 2, the qualifying quantities set out in Part 1 must be used.

Column 1	Column 2	Column 3
Dangerous substances	Qualifying quantity (tonnes) for the application of	
	Articles 6 and 7	Article 9
Ammonium nitrate (see note 1)	5 000	10 000
Ammonium nitrate (see note 2)	1 250	5 000
Ammonium nitrate (see note 3)	350	2 500
Ammonium nitrate (see note 4)	10	50
Potassium nitrate (see note 5)	5 000	10 000
Potassium nitrate (see note 6)	1 250	5 000
Arsenic pentoxide, arsenic (V) acid and/or salts	1	2
Arsenic trioxide, arsenious (III) acid and/or salts		0,1
Bromine	20	100
Chlorine	10	25
Nickel compounds in inhalable powder form (nickel monoxide, nickel dioxide, nickel sulphide, trinickel disulphide, dinickel trioxide)		1
Ethyleneimine	10	20
Fluorine	10	20
Formaldehyde (concentration ≥ 90 %)	5	50
Hydrogen	5	50
Hydrogen chloride	25	250
Hydrogen chloride (liquefied gas)	25	250
Lead alkyls	5	50
Liquefied extremely flammable gases (including LPG) and natural gas	50	200
Acetylene	5	50
Ethylene oxide	5	50
Propylene oxide	5	50
Methanol	500	5 000
4, 4-Methylenebis (2-chloraniline) and/or salts, in powder form		0,01
Methylisocyanate		0,15
Oxygen	200	2 000
Toluene diisocyanate	10	100
Carbonyl dichloride (phosgene	0,3	0,75
Arsenic trihydride (arsine)	0,2	1
Phosphorus trihydride (phosphine)	0,2	1
Sulphur dichloride	15	75
Polychlorodibenzofurans and polychlorodibenzodioxins (including TCDD), calculated in TCDD		0,001
The following CARCINOGENS at concentrations above 5 % by weight: 4-Aminobiphenyl and/or its salts, Benzotrichloride, Benzidine and/or salts, Bis (chloromethyl) ether, Chloromethyl methyl ether, 1,2-Dibromoethane, Diethyl sulphate, Dimethyl sulphate, Dimethylcarbamoyl chloride, 1,2-Dibromo-3-chloropropane, 1,2-Dimethylhydrazine, Dimethylnitrosamine, Hexamethylphosphoric triamide, Hydrazine, 2- Naphthylamine and/or salts, 4-Nitrodiphenyl, and 1,3 Propanesultone	0,5	2
‘Petroleum products: (a) gasolines and naphthas, (b) kerosenes (including jet fuels), (c) gas oils (including diesel fuels, home heating oils and gas oil blending streams)	2 500	25 000

NOTES

1. Ammonium nitrate (5 000/10 000): fertilisers capable of self-sustaining decomposition

This applies to ammonium nitrate-based compound/composite fertilisers (compound/composite fertilisers containing ammonium nitrate with phosphate and/or potash) in which the nitrogen content as a result of ammonium nitrate is

- between 15,75 % (1) and 24,5 % (2) by weight, and either with not more than 0,4 % total combustible/organic materials or which fulfil the requirements of Annex II of Directive 80/876/EEC,
- 15,75 % (3) by weight or less and unrestricted combustible materials,

and which are capable of self-sustaining decomposition according to the UN Trough Test (see United Nations Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria, Part III, subsection 38.2).

2. Ammonium nitrate (1 250/5 000): fertiliser grade

This applies to straight ammonium nitrate-based fertilisers and to ammonium nitrate-based compound/composite fertilisers in which the nitrogen content as a result of ammonium nitrate is

- more than 24,5 % by weight, except for mixtures of ammonium nitrate with dolomite, limestone and/or calcium carbonate with a purity of at least 90 %,
- more than 15,75 % by weight for mixtures of ammonium nitrate and ammonium sulphate,
- more than 28 % (4) by weight for mixtures of ammonium nitrate with dolomite, limestone and/or calcium carbonate with a purity of at least 90 %,

and which fulfil the requirements of Annex II of Directive 80/876/EEC.

3. Ammonium nitrate (350/2500): technical grade

This applies to:

- ammonium nitrate and preparations of ammonium nitrate in which the nitrogen content as a result of the ammonium nitrate is
    - between 24,5 % and 28 % by weight, and which contain not more than 0,4 % combustible substances,
    - more than 28 % by weight, and which contain not more than 0,2 % combustible substances,
- aqueous ammonium nitrate solutions in which the concentration of ammonium nitrate is more than 80 % by weight.

4. Ammonium nitrate (10/50): ‘off-specs’ material and fertilisers not fulfilling the detonation test

This applies to:

- material rejected during the manufacturing process and to ammonium nitrate and preparations of ammonium nitrate, straight ammonium nitrate-based fertilisers and ammonium nitrate-based compound/composite fertilisers referred to in notes 2 and 3, that are being or have been returned from the final user to a manufacturer, temporary storage or reprocessing plant for reworking, recycling or treatment for safe use, because they no longer comply with the specifications of Notes 2 and 3;

- fertilisers referred to in note 1, first indent, and Note 2 which do not fulfil the requirements of Annex II of Directive 80/876/EEC.

5. Potassium nitrate (5 000/10 000): composite potassium-nitrate based fertilisers composed of potassium nitrate in prilled/granular form.

6. Potassium nitrate (1 250/5 000): composite potassium-nitrate based fertilisers composed of potassium nitrate in crystalline form.

7. Polychlorodibenzofurans and polychlorodibenzodioxins

The quantities of polychlorodibenzofurans and polychlorodibenzodioxins are calculated using the following factors:

International Toxic Equivalent Factors (ITEF) for the carcinogens of concern (NATO/CCMS)			
2,3,7,8-TCDD	1	2,3,7,8-TCDF	0,1
1,2,3,7,8-PeDD	0,5	2,3,4,7,8-PeCDF	0,5
		1,2,3,7,8-PeCDF	0,05
1,2,3,4,7,8-HxCDD	0,1		
1,2,3,6,7,8-HxCDD	0,1	1,2,3,4,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDD	0,1	1,2,3,7,8,9-HxCDF	0,1
		1,2,3,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDD	0,01	2,3,4,6,7,8-HxCDF	0,1
OCDD	0,001	1,2,3,4,6,7,8-HpCDF	0,01
		1,2,3,4,7,8,9-HpCDF	0,01
		OCDF	0,001

(T = tetra, P = penta, Hx = hexa, HP = hepta, O = octa)

(1) 15,75 % nitrogen content by weight as a result of ammonium nitrate corresponds to 45 % ammonium nitrate.

(2) 24,5 % nitrogen content by weight as a result of ammonium nitrate corresponds to 70 % ammonium nitrate.

(3) 15,75 % nitrogen content by weight as a result of ammonium nitrate corresponds to 45 % ammonium nitrate.

(4) 28 % nitrogen content by weight as a result of ammonium nitrate corresponds to 80 % ammonium nitrate.

PART 2

Categories of substances and preparations not specifically named in Part 1

Column 1		Column 2	Column 3
	Dangerous substances	Qualifying quantity (tonnes) of dangerous substances as delivered in Articles 3 (4), for the application of	
		Articles 6 and 7	Article 9
1	VERY TOXIC	5	20
2	TOXIC	50	200
3	OXIDIZING	50	200
4	EXPLOSIVE (see note 2) where the substance, preparation or article falls under UN/ADR Division 1.4	50	200
5	EXPLOSIVE (see note 2) where the substance, preparation or article falls under any of: UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3	10	50
6	FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (a)	5 000	50 000
7a	HIGHLY FLAMMABLE (where the substance or preparation falls within the definition in Note 3 (b) (1))	50	200
7b	HIGHLY FLAMMABLE (where the substance or preparation falls within the definition in Note 3 (b) (2))	5 000	50 000
8	EXTREMELY FLAMMABLE (where the substance or preparation falls within the definition in Note 3 (c)	10	50
9	DANGEROUS FOR THE ENVIRONMENT in combination with risk phrases: (i) R50: “Very toxic to aquatic organisms”	200	500
	(ii) R51: “toxic to aquatic organisms”; and, R53: “May cause long term adverse effects in aquatic environment”	500	2 000
10	ANY CLASSIFICATION not covered by those given above in combination with risk phrases: (i) R14: “Reacts violently with water” (including R14/15)	100	500
	(ii) R29: “in contact with water, liberates toxic gases”	50	200

NOTES

1. Substances and preparations are classified according to the following Directives and their current adaptation to technical progress:

   Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1),

   Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations, and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (2).

In the case of substances and preparations which are not classified as dangerous according to either of the above directives, for example waste, but which nevertheless are present, or are likely to be present, in an establishment and which possess or are likely to possess, under the conditions found at the establishment, equivalent properties in terms of major-accident potential, the procedures for provisional classification shall be followed in accordance with the relevant article of the appropriate Directive.

In the case of substances and preparations with properties giving rise to more than one classification, for the purposes of this Directive the lowest qualifying quantities shall apply. However, for the application of the rule in Note 4, the qualifying quantity used shall always be the one corresponding to the classification concerned.

For the purposes of this Directive, the Commission shall establish and keep up to date a list of substances which have been classified into the above categories by a harmonised Decision in accordance with Directive 67/548/EEC.

(1) OJ 196, 16.8.1967, p. l. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
(2) OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).

2. An ‘explosive’ means:

- a substance or preparation which creates the risk of an explosion by shock, friction, fire or other sources of ignition (risk phrase R2),
- a substance or preparation which creates extreme risks of explosion by shock, friction, fire or other sources of ignition (risk phrase R3), or
- a substance, preparation or article covered by Class 1 of the European Agreement concerning the International Carriage of Dangerous Goods by Road (UN/ADR), concluded on 30 September 1957, as amended, as transposed by Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (1).
- Included in this definition are pyrotechnics, which for the purposes of this Directive are defined as substances (or mixtures of substances), designated to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions. Where a
- substance or preparation is classified by both UN/ADR and risk phase R2 or R3, the UN/ADR classification shall take precedence over assignment of risk phrases.

Substances and articles of Class 1 are classified in any of the divisions 1.1 to 1.6 in accordance with the UN/ADR classification scheme. The divisions concerned are:

Division 1.1: ‘Substances and articles which have a mass explosion hazard (a mass explosion is an explosion which affects almost the entire load virtually instantaneously).’

Division 1.2: ‘Substances and articles which have a projection hazard but not a mass explosion hazard.’

Division 1.3: ‘Substances and articles which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

(a) combustion of which gives rise to considerable radiant heat; or
(b) which burn one after another, producing minor blast or projection effects or both.’

Division 1.4: ‘Substances and articles which present only a slight risk in the event of ignition or initiation during carriage. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of virtually the entire contents of the package.’

Division 1.5: ‘Very insensitive substances having a mass explosion hazard which are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions of carriage. As a minimum requirement they shall not explode in the external fire test.’

Division 1.6: ‘Extremely insensitive articles which do not have a mass explosion hazard. The articles contain only extremely insensitive detonating substances and demonstrate a negligible probability of accidental initiation or propagation. The risk is limited to the explosion of a single article.’

Included in this definition are also explosive or pyrotechnic substances or preparations contained in articles. In the case of articles containing explosive or pyrotechnic substances or preparations, if the quantity of the substance or preparation contained is known, that quantity shall be considered for the purposes of this Directive. If the quantity is not known, then, for the purposes of this Directive, the whole article shall be treated as explosive.

3. ‘Flammable’, ‘highly flammable’, and ‘extremely flammable’ in categories 6, 7 and 8 mean:

(a) flammable liquids: substances and preparations having a flash point equal to or greater than 21 ºC and less than or equal to 55 ºC (risk phrase R 10), supporting combustion;

(1) OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2003/
28/EC (OJ L 90, 8.4.2003, p. 45).

(b) highly flammable liquids:

1. — substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy (risk phrase R 17),

   — substances and preparations which have a flash point lower than 55 ºC and which remain liquid under pressure, where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards;

2. substances and preparations having a flash point lower than 21 ºC and which are not extremely flammable (risk phrase R 11, second indent);

(c) extremely flammable gases and liquids:

1. liquid substances and preparations which have a flash point lower than 0 ºC and the boiling point (or, in the case of a boiling range, the initial boiling point) of which at normal pressure is less than or equal to 35 ºC (risk phrase R 12, first indent), and

2. gases which are flammable in contact with air at ambient temperature and pressure (risk phrase R12, second indent), which are in a gaseous or supercritical state, and

3. flammable and highly flammable liquid substances and preparations maintained at a temperature above their boiling point.

4. In the case of an establishment where no individual substance or preparation is present in a quantity above or equal to the relevant qualifying quantities, the following rule shall be applied to determine whether the establishment is covered by the relevant requirements of this Directive.

This Directive shall apply if the sum

$q1/QU1 + q2/QU2 + q3/QU3 + q4/QU4 + q5/QU5 + \ldots$ is greater than or equal to 1,

where qx = the quantity of dangerous substance x (or category of dangerous substances) falling within Parts 1 or 2 of this Annex,

and QUX = the relevant qualifying quantity for substance or category x from column 3 of Parts 1 or 2.

This Directive shall apply, with the exception of Articles 9, 11 and 13, if the sum

$q1/QL1 + q2/QL2 + q3/QL3 + q4/QL4 + q5/QL5 + \ldots$ is greater than or equal to 1,

where qx = the quantity of dangerous substance x (or category of dangerous substances) falling within Parts 1 or 2 of this Annex,

and QLX = the relevant qualifying quantity for substance or category x from column 2 of Parts 1 or 2.

This rule shall be used to assess the overall hazards associated with toxicity, flammability, and eco-toxicity. It must therefore be applied three times:

(a) for the addition of substances and preparations named in Part 1 and classified as toxic or very toxic, together with substances and preparations falling into categories 1 or 2;
(b) for the addition of substances and preparations named in Part 1 and classified as oxidising, explosive, flammable, highly flammable, or extremely flammable, together with substances and preparations falling into categories 3, 4, 5, 6, 7a, 7b or 8;

(c) for the addition of substances and preparations named in Part 1 and classified as dangerous for the environment (R50 (including R50/53) or R51/53), together with substances and preparations falling into categories 9(i) or 9(ii);

The relevant provisions of this Directive apply if any of the sums obtained by (a), (b) or (c) is greater than or equal to 1.

Appendix 3

US EPA Risk Management Program List of hazardous substances

TABLE 1 TO 68.130 - LIST OF REGULATED TOXIC SUBSTANCES AND THRESHOLD QUANTITIES FOR ACCIDENTAL RELEASE PREVENTION [ALPHABETICAL ORDER - 77 SUBSTANCES]

Chemical Name	CAS No.	Threshold Quantity (lbs)	Basis for Listing
Acrolein [2-Propenal]	107-02-8	5,000	b
Acrylonitrile [2-Propenenitrile]	107-13-1	20,000	b
Acrylyl chloride [2-Propenoyl chloride]	814-68-6	5,000	b
Allyl alcohol [2-Propen-1-ol]]	107-18-6	15,000	b
Allylamine [2-Propen-1-amine]	107-11-9	10,000	b
Ammonia (anhydrous)	7664-41-7	10,000	a, b
Ammonia (conc 20% or greater)	7664-41-7	20,000	a, b
Arsenous trichloride	7784-34-1	15,000	b
Arsine	7784-42-1	1,000	b
Boron trichloride [Borane, trichloro-]	10294-34-5	5,000	b
Boron trifluoride [Borane, trifluoro-]	7637-07-2	5,000	b
Boron trifluoride compound with methyl ether (1:1) [Boron, trifluoro[oxybis[metane]]-, T-4-	353-42-4	15,000	b
Bromine	7726-95-6	10,000	a, b
Carbon disulfide	75-15-0	20,000	b
Chlorine	7782-50-5	2,500	a, b
Chlorine dioxide [Chlorine oxide]	10049-04-4	1,000	c
Chloroform [Methane, trichloro-]	67-66-3	20,000	b
Chloromethyl ether [Methane, oxybis[chloro-]	542-88-1	1,000	b
Chloromethyl methyl ether [Methane, chloromethoxy-]	107-30-2	5,000	b
Crotonaldehyde [2-Butenal]	4170-30-3	20,000	b
Crotonaldehyde, (E)- [2-Butenal, (E)-]	123-73-9	20,000	b
Cyanogen chloride	506-77-4	10,000	c
Cyclohexylamine [Cyclohexanamine]	108-91-8	15,000	b
Diborane	19287-45-7	2,500	b
Dimethyldichlorosilane [Silane, dichlorodimethyl-]	75-78-5	5,000	b
1,1-Dimethylhydrazine [Hydrazine, 1,1-dimethyl-]	57-14-7	15,000	b
Epichlorohydrin [Oxirane, (chloromethyl)-]	106-89-8	20,000	b
Ethylenediamine [1,2-Ethanediamine]	107-15-3	20,000	b
Ethyleneimine [Aziridine]	151-56-4	10,000	b
Ethylene oxide [Oxirane]	75-21-8	10,000	a, b
Fluorine	7782-41-4	1,000	b
Formaldehyde (solution)	50-00-0	15,000	b
Furan	110-00-9	5,000	b
Hydrazine	302-01-2	15,000	b
Hydrochloric acid (conc 30% or greater)	7647-01-0	15,000	d
Hydrocyanic acid	74-90-8	2,500	a, b
Hydrogen chloride (anhydrous) [Hydrochloric acid]	7647-01-0	5,000	a
Hydrogen fluoride/Hydrofluoric acid conc 50% or greater) [Hydrofluoric acid]	7664-39-3	1,000	a, b
Hydrogen selenide	7783-07-5	500	b
Hydrogen sulfide	7783-06-4	10,000	a, b
Iron, pentacarbonyl- [Iron carbonyl (Fe(CO)5), (TB-5-11)-]	13463-40-6	2,500	b

Chemical Name	CAS No.	Threshold Quantity (lbs)	Basis for Listing
Isobutyronitrile [Propanenitrile, 2-methyl-]	78-82-0	20,000	b
Isopropyl chloroformate Carbonochloridic acid, 1-methylethyl ester]	108-23-6	15,000	b
Methyl chloride [Methane, chloro-]	74-87-3	10,000	a
Methyl chloroformate [Carbonochloridic acid, methylester]	79-22-1	5,000	b
Methyl hydrazine [Hydrazine, methyl-]	60-34-4	15,000	b
Methyl isocyanate [Methane, isocyanato-]	624-83-9	10,000	a, b
Methyl mercaptan [Methanethiol]	74-93-1	10,000	b
Methyl thiocyanate [Thiocyanic acid, methyl ester]	556-64-9	20,000	b
Methyltrichlorosilane [Silane, trichloromethyl-]	75-79-6	5,000	b
Nickel carbonyl	13463-39-3	1,000	b
Nitric acid (conc 80% or greater)	7697-37-2	15,000	b
Nitric oxide [Nitrogen oxide (NO)]	10102-43-9	10,000	b
Oleum (Fuming Sulfuric acid) [Sulfuric acid, mixture with sulfur trioxide]1	8014-95-7	10,000	e
Peracetic acid [Ethaneperoxoic acid]	79-21-0	10,000	b
Perchloromethylmercaptan [Methanesulfenyl chloride, trichloro-]	594-42-3	10,000	b
Phosgene [Carbonic dichloride]	75-44-5	500	a, b
Phosphine	7803-51-2	5,000	b
Piperidine	110-89-4	15,000	b
Propionitrile [Propanenitrile]	107-12-0	10,000	b
Propyl chloroformate [Carbonochloridic acid, propylester]	109-61-5	15,000	b
Propyleneimine [Aziridine, 2-methyl-]	75-55-8	10,000	b
Propylene oxide [Oxirane, methyl-]	75-56-9	10,000	b
Sulfur dioxide (anhydrous)	7446-09-5	5,000	a, b
Sulfur tetrafluoride [Sulfur fluoride (SF4), (T-4)-]	7783-60-0	2,500	b
Sulfur trioxide	7446-11-9	10,000	a, b
Tetramethyllead [Plumbane, tetramethyl-]	75-74-1	10,000	b
Tetranitromethane [Methane, tetranitro-]	509-14-8	10,000	b
Titanium tetrachloride [Titanium chloride (TiCl4) (T-4)-]	7550-45-0	2,500	b
Toluene 2,4-diisocyanate [Benzene, 2,4-diisocyanato-1-methyl-]1	584-84-9	10,000	a
Toluene 2,6-diisocyanate [Benzene, 1,3-diisocyanato-2-methyl-]1	91-08-7	10,000	a
Toluene diisocyanate (unspecified isomer) [Benzene, 1,3-diisocyanatomethyl-]1	26471-62-5	10,000	a
Toluene diisocyanate (unspecified isomer) [Benzene, 1,3-diisocyanatomethyl-]1	26471-62-5	10,000	a
Trimethylchlorosilane [Silane, chlorotrimethyl-]	**75-77-4**	10,000	b
Vinyl acetate monomer [Acetic acid ethenyl ester]	108-05-4	15,000	b

1 The mixture exemption in 68.115(b)(1) does not apply to the substance.

Note Basis for Listing:
a Mandated for listing by Congress.
b On EHS list, vapor pressure 10 mmHg or greater.
c Toxic gas.
d Toxicity of hydrogen chloride, potential to release hydrogen chloride, and history of accidents.
e Toxicity of sulfur trioxide and sulfuric acid, potential to release sulfur trioxide, and history of accidents.

TABLE 3 TO 68.130 - LIST OF REGULATED FLAMMABLE SUBSTANCES AND THRESHOLD QUANTITIES FOR ACCIDENTAL RELEASE PREVENTION [ALPHABETICAL ORDER - 63 SUBSTANCES]

Chemical Name	CAS No.	Threshold Quantity (lbs)	Basis for Listing
Acetaldehyde	75-07-0	10,000	g
Acetylene [Ethyne]	74-86-2	10,000	f
Bromotrifluorethylene [Ethene, bromotrifluoro-]	598-73-2	10,000	f
1,3-Butadiene	106-99-0	10,000	f
Butane	106-97-8	10,000	f
1-Butene	106-98-9	10,000	f
2-Butene	107-01-7	10,000	f
Butene	25167-67-3	10,000	f
2-Butene-cis	590-18-1	10,000	f
2-Butene-trans [2-Butene, (E)]	624-64-6	10,000	f
Carbon oxysulfide [Carbon oxide sulfide (COS)]	463-58-1	10,000	f
Chlorine monoxide [Chlorine oxide]	7791-21-1	10,000	f
2-Chloropropylene [1-Propene, 2-chloro-]	557-98-2	10,000	g
1-Chloropropylene [1-Propene, 1-chloro-]	590-21-6	10,000	g
Cyanogen [Ethanedinitrile]	460-19-5	10,000	f
Cyclopropane	75-19-4	10,000	f
Dichlorosilane [Silane, dichloro-]	4109-96-0	10,000	f
Difluoroethane [Ethane, 1,1-difluoro-]	75-37-6	10,000	f
Dimethylamine [Methanamine, N-methyl-]	124-40-3	10,000	f
2,2-Dimethylpropane [Propane, 2,2-dimethyl-]	463-82-1	10,000	f
Ethane	74-84-0	10,000	f
Ethyl acetylene [1-Butyne]	107-00-6	10,000	f
Ethylamine [Ethanamine]	75-04-7	10,000	f
Ethyl chloride [Ethane, chloro-]	75-00-3	10,000	f
Ethylene [Ethene]	74-85-1	10,000	f
Ethyl ether [Ethane, 1,1'-oxybis-]	60-29-7	10,000	g
Ethyl mercaptan [Ethanethiol]	75-08-1	10,000	g
Ethyl nitrite [Nitrous acid, ethyl ester]	109-95-5	10,000	f
Hydrogen	1333-74-0	10,000	f
Isobutane [Propane, 2-methyl]	75-28-5	10,000	f
Isopentane [Butane, 2-methyl-]	78-78-4	10,000	g
Isoprene [1,3-Butadiene, 2-methyl-]	78-79-5	10,000	g
Isopropylamine [2-Propanamine]	75-31-0	10,000	g
Isopropyl chloride [Propane, 2-chloro-]	75-29-6	10,000	g
Methane	74-82-8	10,000	f
Methylamine [Methanamine]	74-89-5	10,000	f
3-Methyl-1-butene]	563-45-1	10,000	f
2-Methyl-1-butene	563-46-2	10,000	g
Methyl ether [Methane, oxybis-]	115-10-6	10,000	f

Chemical Name	**CAS No.**	**Threshold Quantity (lbs)**	**Basis for Listing**
Methyl formate [Formic acid, methyl ester]	107-31-3	10,000	g
2-Methylpropene [1-Propene, 2-methyl-]	115-11-7	10,000	f
1,3-Pentadiene	504-60-9	10,000	f
Pentane	109-66-0	10,000	g
1-Pentene	109-67-1	10,000	g
2-Pentene, (E)-	646-04-8	10,000	g
2-Pentene, (E)-	646-04-8	10,000	g
2-Pentene, (Z)-	627-20-3	10,000	g
Propadiene [1,2-Propadiene]	463-49-0	10,000	f
Propane	74-98-6	10,000	f
Propylene [1-Propene]	115-07-1	10,000	f
Propyne [1-Propyne]	74-99-7	10,000	f
Silane	7803-62-5	10,000	f
Tetrafluoroethylene [Ethene, tetrafluoro-]	116-14-3	10,000	f
Tetramethylsilane [Silane, tetramethyl-]	75-76-3	10,000	g
Trichlorosilane [Silane, trichloro-]	10025-78-2	10,000	g
Trifluorochloroethylene [Ethene, chlorotrifluoro-]	79-38-9	10,000	f
Vinyl acetylene [1-Buten-3-yne]	689-97-4	10,000	f
Vinyl chloride [Ethene, chloro-]	75-01-4	10,000	a, f
Vinyl ethyl ether [Ethene, ethoxy-]	109-92-2	10,000	g
Vinyl fluoride [Ethene, fluoro-]	75-02-5	10,000	f
Vinylidene chloride [Ethene, 1,1-dichloro-]	75-35-4	10,000	g
Vinylidene fluoride [Ethene, 1,1-difluoro-]	75-38-7	10,000	f
Vinyl methyl ether [Ethene, methoxy-]	107-25-	10,000	f

Note: Basis for Listing:

a Mandated for listing by Congress.
f Flammable gas.
g Volatile flammable liquid.

Appendix 4

OSHA 1910.119 List of hazardous substances

This Appendix contains a listing of toxic and reactive highly hazardous chemicals which present a potential for a catastrophic event at or above the threshold quantity.

CHEMICAL NAME	CAS No*	TQ**
Acetaldehyde	75-07-0	2500
Acrolein (2-Popenal)	107-02-8	150
Acrylyl Chlorde	814-68-6	250
Allyl Chlorid	107-05-1	1000
Allylamine	107-11-9	1000
Alkylaluminum	Varies	5000
Ammonia, Anhydrous	7664-41-7	10000
Ammonia solutions (greater than 44% ammonia by weight)	7664-41-7	15000
Ammonium Perchlorate	7790-98-9	7500
Ammonium Permanganate	7787-36-2	7500
Arsine (also called Arsenic Hydride)	7784-42-1	100
Bis(Chloromethyl) Ether	542-88-1	100
Boron Trichloride	10294-34-5	2500
Boron Trifluoride	7637-07-2	250
Bromine	7726-95-6	1500
Bromine Chloride	13863-41-7	1500
Bromine Pentafluoride	7789-30-2	2500
Bromine Trifluoride	7787-71-5	15000
3-Bromopropyne (also called Propargyl Bromide)	106-96-7	100
Butyl Hydroperoxide (Tertiary)	75-91-2	5000
Butyl Perbenzoate (Tertiary)	614-45-9	7500
Carbonyl Chloride (see Phosgene)	75-44-5	100
Carbonyl Fluoride	353-50-4	2500
Cellulose Nitrate (concentration greater than 12.6% nitrogen)	9004-70-0	2500
Chlorine	7782-50-5	1500
Chlorine Dioxide	10049-04-4	1000
Chlorine Pentrafluoride	13637-63-3	1000
Chlorine Trifluoride	7790-91-2	1000
Chlorodiethylaluminum (also called Diethylaluminum Chloride)	96-10-6	5000
1-Chloro-2,4-Dinitrobenzene	97-00-7	5000
Chloromethyl Methyl Ether	107-30-2	500
Chloropicrin	76-06-2	500
Chloropicrin and Methyl Bromide mixture	None	1500
Chloropicrin and Methyl Chloride mixture	None	1500
Cumene Hydroperoxide	80-15-9	5000
Cyanogen	460-19-5	2500
Cyanogen Chloride	506-77-4	500
Cyanuric Fluoride	675-14-9	100
Diacetyl Peroxide (concentration greater than 70%)	110-22-5	5000
Diazomethane	334-88-3	500
Dibenzoyl Peroxide	94-36-0	7500

CHEMICAL NAME	CAS No*	TQ**
Diborane	19287-45-7	100
Dibutyl Peroxide (Tertiary)	110-05-4	5000
Dichloro Acetylene	7572-29-4	250
Dichlorosilane	4109-96-0	2500
Diethylzinc	557-20-0	10000
Diisopropyl Peroxydicarbonate	105-64-6	7500
Dilauroyl Peroxide	105-74-8	7500
Dimethyldichlorosilane	75-78-5	1000
Dimethylhydrazine, 1,1-	57-14-7	1000
Dimethylamine, Anhydrous	124-40-3	2500
2,4-Dinitroaniline	97-02-9	5000
Ethyl Methyl Ketone Peroxide (also Methyl Ethyl Ketone Peroxide; concentration greater than 60%)	1338-23-4	5000
Ethyl Nitrite	109-95-5	5000
Ethylamine	75-04-7	7500
Ethylene Fluorohydrin	371-62-0	100
Ethylene Oxide	75-21-8	5000
Ethyleneimine	151-56-4	1000
Fluorine	7782-41-4	1000
Formaldehyde (Formalin)	50-00-0	1000
Furan	110-00-9	500
Hexafluoroacetone	684-16-2	5000
Hydrochloric Acid, Anhydrous	7647-01-0	5000
Hydrofluoric Acid, Anhydrous	7664-39-3	1000
Hydrogen Bromide	10035-10-6	5000
Hydrogen Chloride	7647-01-0	5000
Hydrogen Cyanide, Anhydrous	74-90-8	1000
Hydrogen Fluoride	7664-39-3	1000
Hydrogen Peroxide (52% by weight or greater)	7722-84-1	7500
Hydrogen Selenide	7783-07-5	150
Hydrogen Sulfide	7783-06-4	1500
Hydroxylamine	7803-49-8	2500
Iron, Pentacarbonyl	13463-40-6	250
Isopropylamine	75-31-0	5000
Ketene	463-51-4	100
Methacrylaldehyde	78-85-3	1000
Methacryloyl Chloride	920-46-7	150
Methacryloyloxyethyl Isocyanate	30674-80-7	100
Methyl Acrylonitrile	126-98-7	250
Methylamine, Anhydrous	74-89-5	1000
Methyl Bromide	74-83-9	2500
Methyl Chloride	74-87-3	15000
Methyl Chloroformate	79-22-1	500
Methyl Ethyl Ketone Peroxide (concentration greater than 60%)	1338-23-4	5000
Methyl Fluoroacetate	453-18-9	100
Methyl Fluorosulfate	421-20-5	100
Methyl Hydrazine	60-34-4	100
Methyl Iodide	74-88-4	7500

CHEMICAL NAME	CAS No*	TQ**
Methyl Isocyanate	624-83-9	250
Methyl Mercaptan	74-93-1	5000
Methyl Vinyl Ketone	79-84-4	100
Methyltrichlorosilane	75-79-6	500
Nickel Carbonly (Nickel Tetracarbonyl)	13463-39-3	150
Nitric Acid (94.5% by weight or greater)	7697-37-2	500
Nitric Oxide	10102-43-9	250
Nitroaniline (para Nitroaniline)	100-01-6	5000
Nitromethane	75-52-5	2500
Nitrogen Dioxide	10102-44-0	250
Nitrogen Oxides (NO; NO2; N2O4; N2O3)	10102-44-0	250
Nitrogen Tetroxide (also called Nitrogen Peroxide)	10544-72-6	250
Nitrogen Trifluoride	7783-54-2	5000
Nitrogen Trioxide	10544-73-7	250
Oleum (65% to 80% by weight; also called Fuming Sulfuric Acid)	8014-94-7	1000
Osmium Tetroxide	20816-12-0	100
Oxygen Difluoride (Fluorine Monoxide)	7783-41-7	100
Ozone	10028-15-6	100
Pentaborane	19624-22-7	100
Peracetic Acid (concentration greater 60% Acetic Acid; also called Peroxyacetic Acid)	79-21-0	1000
Perchloric Acid (concentration greater than 60% by weight)	7601-90-3	5000
Perchloromethyl Mercaptan	594-42-3	150
Perchloryl Fluoride	7616-94-6	5000
Peroxyacetic Acid (concentration greater than 60% Acetic Acid; also called Peracetic Acid)	79-21-0	1000
Phosgene (also called Carbonyl Chloride)	75-44-5	100
Phosphine (Hydrogen Phosphide)	7803-51-2	100
Phosphorus Oxychloride (also called Phosphoryl Chloride)	10025-87-3	1000
Phosphorus Trichloride	7719-12-2	1000
Phosphoryl Chloride (also called Phosphorus Oxychloride)	10025-87-3	1000
Propargyl Bromide	106-96-7	100
Propyl Nitrate	627-3-4	2500
Sarin	107-44-8	100
Selenium Hexafluoride	7783-79-1	1000
Stibine (Antimony Hydride)	7803-52-3	500
Sulfur Dioxide (liquid)	7446-09-5	1000
Sulfur Pentafluoride	5714-22-7	250
Sulfur Tetrafluoride	7783-60-0	250
Sulfur Trioxide (also called Sulfuric Anhydride)	7446-11-9	1000
Sulfuric Anhydride (also called Sulfur Trioxide)	7446-11-9	1000
Tellurium Hexafluoride	7783-80-4	250
Tetrafluoroethylene	116-14-3	5000
Tetrafluorohydrazine	10036-47-2	5000
Tetramethyl Lead	75-74-1	1000
Thionyl Chloride	7719-09-7	250
Trichloro (chloromethyl) Silane	1558-25-4	100

CHEMICAL NAME	CAS No*	TQ**
Trichloro (dichlorophenyl) Silane	27137-85-5	2500
Trichlorosilane	10025-78-2	5000
Trifluorochloroethylene	79-38-9	10000
Trimethyoxysilane	2487-90-3	1500

Footnote* Chemical Abstract Service Number
Footnote** Threshold Quantity in Pounds (Amount necessary to be covered by this standard.)

Appendix 5

Environment Canada Environmental Emergencies Regulation List of Substances

PART 1

Column 1			Column 2	Column 3
CAS Registry Number	Name of Substance	UN Number	Concentration	Minimum Quantity (tonnes)
60-29-7	ethyl ether (diethyl ether)	1155	1%	4.50
71-43-2	benzene	1114	1%	10.00
74-82-8	methane	1971 and 1972	1%	4.50
74-84-0	ethane	1035 and 1961	1%	4.50
74-85-1	ethylene	1038 and 1962	1%	4.50
74-86-2	acetylene	1001	1%	4.50
74-89-5	methylamine	1061	1%	4.50
74-98-6	propane	1978	1%	4.50
74-99-7	methylacetylene (propyne)	1060	1%	4.50
75-00-3	ethyl chloride	1037	1%	4.50
75-01-4	vinyl chloride	1086	1%	4.50
75-02-5	vinyl fluoride	1860	1%	4.50
75-04-7	ethylamine	1036 and 2270	1%	4.50
75-07-0	acetaldehyde	1089	1%	4.50
75-08-1	ethyl mercaptan	2363	1%	4.50
75-18-3	dimethyl sulphide	1164	1%	150.00
75-19-4	cyclopropane	1027	1%	4.50
75-28-5	isobutane	1969	1%	4.50
75-29-6	2-chloropropane (isopropyl chloride)	2356	1%	4.50
75-31-0	isopropylamine	1221	1%	4.50
75-35-4	vinylidene chloride	1303	1%	4.50
75-37-6	Difluoroethane (1,1-difluoroethane)	1030	1%	4.50
75-38-7	1,1-difluoroethylene (vinylidene fluoride)	1959	1%	4.50
75-50-3	trimethylamine	1083 and 1297	1%	4.50
75-64-9	tert-butylamine (2-amino-2-methylpropane)	1125	1%	150.00
75-76-3	tetramethylsilane	2749	1%	4.50
78-78-4	isopentane (2-methylbutane)	1265	1%	4.50
78-79-5	isoprene	1218	1%	4.50
79-38-9	trifluorochloroethylene (chlorotrifluoroethylene)	1082	1%	4.50
100-41-4	ethylbenzene	1175	1%	7000.00
106-97-8	butane	1011	1%	4.50
106-98-9	1-butene (alpha-butylene)	1012	1%	4.50
106-99-0	1,3-butadiene	1010	1%	4.50
107-00-6	ethylacetylene	2452	1%	4.50
107-01-7	2-butene	1055	1%	4.50
107-25-5	vinyl methyl ether	1087	1%	4.50
107-31-3	methyl formate	1243	1%	4.50
108-88-3	toluene	1294	1%	2500.00
109-66-0	n-pentane (pentane)	1265	1%	4.50
109-67-1	1-pentene	1108	1%	4.50
109-92-2	vinyl ethyl ether (ethyl vinyl ether)	1302	1%	4.50
109-95-5	ethyl nitrite	1194	1%	4.50
110-82-7	cyclohexane	1145	1%	550.00
115-07-1	propylene	1077	1%	4.50
115-10-6	dimethyl ether (methyl ether)	1033	1%	4.50

Column 1			Column 2	Column 3
CAS Registry Number	Name of Substance	UN Number	Concentration	Minimum Quantity (tonnes)
115-11-7	Isobutylene (2-methylpropene)	1055	1%	4.50
116-14-3	tetrafluoroethylene	1081	1%	4.50
124-40-3	dimethylamine	1032 and 1160	1%	4.50
460-19-5	cyanogen	1026	1%	4.50
463-49-0	propadiene	2200	1%	4.50
463-58-1	carbonyl sulphide (carbon oxysulfide)	2204	1%	4.50
463-82-1	2,2-dimethylpropane	2044	1%	4.50
504-60-9	1,3-pentadiene	NA	1%	4.50
557-98-2	2-chloropropene (2-chloropropylene)	2456	1%	4.50
563-45-1	3-methyl-1-butene	2561	1%	4.50
563-46-2	2-methyl-1-butene	2459	1%	4.50
590-18-1	cis-2-butene (2-butene-cis)	1055	1%	4.50
590-21-6	1-chloropropene (1-chloropropylene)	NA	1%	4.50
598-73-2	bromotrifluoroethylene	2419	1%	4.50
624-64-6	trans-2-butene (2-butene-trans)	1055	1%	4.50
627-20-3	cis-2-pentene (beta-cis-amylene)	NA	1%	4.50
646-04-8	trans-2-pentene (trans-beta-amylene)	NA	1%	4.50
689-97-4	1-buten-3-yne (vinyl acetylene)	NA	1%	4.50
1330-20-7	xylenes	1307	1%	8000.00
1333-74-0	hydrogen	1049	1%	4.50
4109-96-0	dichlorosilane	2189	1%	4.50
7722-84-1	hydrogen peroxide	2015	52%	3.40
7775-09-9	sodium chlorate	1495	10%	10.00
7790-98-9	ammonium perchlorate	1442	1%	3.40
7791-21-1	chlorine monoxide (dichlorine oxide)	NA	1%	4.50
7803-62-5	silane	2203	1%	4.50
8006-14-2	liquefied natural gas	1972	1%	4.50
8030-30-6	naphtha	1268	1%	50.00
10025-78-2	trichlorosilane	1295	1%	4.50
25167-67-3	butylene (butene)	1012	1%	4.50
86290-81-5	gasoline (motor fuel)	1203	1%	150.00

PART 2

Column 1			Column 2	Column 3
CAS Registry Number	Name of Substance	UN Number	Concentration	Minimum Quantity (tonnes)
50-00-0	formaldehyde, solution	1198 and 2209	10%	6.80
57-14-7	1,1-dimethylhydrazine	1163	10%	6.80
60-34-4	methylhydrazine (monomethyl hydrazine)	1244	10%	6.80
67-66-3	chloroform (trichloromethane)	1888	10%	9.10
74-83-9	methyl bromide	1062	10%	2.27
74-87-3	methyl chloride	1063	10%	4.50
74-88-4	methyl iodide	2644	10%	4.50
74-90-8	hydrogen cyanide (hydrocyanic acid)	1051, 1613 and 1614	10%	1.13
74-93-1	methyl mercaptan	1064	10%	4.50
75-15-0	carbon disulphide	1131	10%	9.10
75-21-8	ethylene oxide	1040	10%	4.50

Column 1			Column 2	Column 3
CAS Registry Number	Name of Substance	UN Number	Concentration	Minimum Quantity (tonnes)
75-44-5	phosgene	1076	1%	0.22
75-55-8	propyleneimine	1921	10%	4.50
75-56-9	propylene oxide	1280	10%	4.50
75-74-1	tetramethyl lead	NA	10%	4.50
75-77-4	trimethylchlorosilane (chlorotrimethylsilane)	1298	10%	4.50
75-78-5	dimethyldichlorosilane (dichlorodimethylsilane)	1162	10%	2.27
75-79-6	methyltrichlorosilane	1250	10%	2.27
76-06-2	chloropicrin (trichloronitromethane)	1580	10%	2.27
78-00-2	tetraethyl lead	1649	10%	2.27
78-82-0	isobutyronitrile	2284	10%	9.10
79-21-0	peroxyacetic acid (peracetic acid)	3107	10%	4.50
79-22-1	methyl chloroformate	1238	10%	2.27
91-08-7	toluene-2,6-diisocyanate	2078	10%	4.50
106-89-8	epichlorohydrin	2023	10%	9.10
107-02-8	acrolein	1092	10%	2.27
107-05-1	allyl chloride	1100	10%	9.10
107-06-2	1,2-dichloroethane (ethylene dichloride)	1184	10%	6.80
107-07-3	ethylene chlorohydrin (2-chloroethanol)	1135	10%	4.50
107-11-9	allylamine	2334	10%	4.50
107-12-0	propionitrile	2404	10%	4.50
107-13-1	acrylonitrile	1093	10%	9.10
107-15-3	ethylenediamine	1604	10%	9.10
107-18-6	allyl alcohol	1098	10%	6.80
107-30-2	chloromethyl methyl ether (methyl chloromethyl ether)	1239	10%	2.27
108-05-4	vinyl acetate	1301	10%	6.80
108-23-6	isopropyl chloroformate	2407	10%	6.80
108-91-8	cyclohexylamine	2357	10%	6.80
108-95-2	phenol	1671, 2312 and 2821	10%	9.10
109-61-5	n-propyl chloroformate (propyl chloroformate)	2740	10%	6.80
110-00-9	furan	2389	10%	2.27
110-89-4	piperidine	2401	10%	6.80
123-73-9	trans-crotonaldehyde	1143	10%	9.10
126-98-7	methylacrylonitrile	3079	10%	4.50
151-56-4	ethyleneimine	1185	10%	4.50
302-01-2	hydrazine	2029	10%	6.80
353-42-4	boron trifluoride dimethyl etherate	2965	10%	6.80
463-51-4	ketene	NA	1%	0.22
506-68-3	cyanogen bromide	1889	10%	4.50
506-77-4	cyanogen chloride	1589	10%	4.50
509-14-8	tetranitromethane	1510	10%	4.50
542-88-1	bis(chloromethyl) ether [dichlorodimethyl ether]	2249	1%	0.45
556-64-9	methyl thiocyanate	NA	10%	9.10
584-84-9	toluene-2,4-diisocyanate	2078	10%	4.50
594-42-3	perchloromethyl mercaptan	1670	10%	4.50
624-83-9	methyl isocyanate	2480	10%	4.50
630-08-0	carbon monoxide	1016	10%	6.80
814-68-6	acryloyl chloride (acrylyl chloride)	NA	10%	2.27
4170-30-3	crotonaldehyde	1143	10%	9.10
7439-97-6	mercury	2809	NA	1.00
7446-09-5	sulphur dioxide	1079	10%	2.27

Column 1			Column 2	Column 3
CAS Registry Number	Name of Substance	UN Number	Concentration	Minimum Quantity (tonnes)
7446-11-9	sulphur trioxide	1829	10%	4.50
7550-45-0	titanium tetrachloride	1838	10%	1.13
7616-94-6	perchloryl fluoride (trioxychlorofluoride)	3083	10%	6.80
7637-07-2	boron trifluoride	1008	10%	2.27
7647-01-0	hydrochloric acid	1789	30%	6.80
7647-01-0	hydrogen chloride, anhydrous	2186 and 1050	10%	2.27
7664-39-3	hydrofluoric acid	1790	50%	0.45
7664-39-3	hydrogen fluoride, anhydrous	1052	1%	0.45
7664-41-7	ammonia, anhydrous	1005	10%	4.50
7664-41-7	ammonia solution	2073 and 2672	20%	9.10
7697-37-2	nitric acid	2031 and 2032	80%	6.80
7719-09-7	thionyl chloride	1836	10%	6.80
7719-12-2	phosphorus trichloride	1809	10%	6.80
7723-14-0	phosphorus, white	2447	NA	1.00
7726-95-6	bromine	1744	10%	4.50
7782-41-4	fluorine	1045	1%	0.45
7782-50-5	chlorine	1017	10%	1.13
7783-06-4	hydrogen sulphide	1053	10%	4.50
7783-07-5	hydrogen selenide	2202	1%	0.22
7783-60-0	sulphur tetrafluoride	2418	10%	1.13
7784-34-1	arsenic trichloride (arsenous trichloride)	1560	10%	6.80
7784-42-1	arsine	2188	1%	0.45
7790-94-5	chlorosulphonic acid	1754	10%	2.27
7803-51-2	phosphine	2199	10%	2.27
7803-52-3	stibine	2676	10%	2.27
8014-95-7	sulphuric acid, fuming (oleum)	1831	NA	4.50
10025-87-3	phosphorus oxychloride	1810	10%	2.27
10035-10-6	hydrogen bromide (hydrobromic acid)	1048 and 1788	10%	1.13
10049-04-4	chlorine dioxide	NA	1%	0.45
10102-43-9	nitric oxide (nitrogen monoxide)	1660	10%	4.50
10102-44-0	nitrogen dioxide	1067	10%	1.13
10294-34-5	boron trichloride	1741	10%	2.27
13463-39-3	nickel carbonyl	1259	1%	0.45
13463-40-6	iron pentacarbonyl	1994	10%	1.13
19287-45-7	diborane	1911	10%	1.13
20816-12-0	osmium tetroxide	2471	1%	0.22
26471-62-5	toluene diisocyanate	2078	10%	4.50

NOTE: The percentage concentration in column 2, is the percentage concentration based on the proportion of the weight of the substance to the weight of the mixture.

Appendix 6

Australia State of Victoria

SCHEDULE 1 – TABLE 1

The UN number listed against the named material is given for information only. It does not restrict the meaning of the name, which also applies to materials which fall outside the UN number, for example, because they are too dangerous to transport or are part of mixtures covered by another UN number. However, any materials which are covered by the listed UN numbers must be included in the quantity of the material named.

MATERIAL	UN Nos INCLUDED UNDER NAME	THRESHOLD QUANTITY (tonnes)
ACETONE CYANOHYDRIN	1541	20
ACETYLENE	1001	50
ACROLEIN	1092	200
ACRYLONITRILE	1093	200
ALLYL ALCOHOL	1098	20
ALLYLAMINE	2334	200
AMMONIA, ANHYDROUS, LIQUEFIED or AMMONIA SOLUTIONS, relative density less than 0·880 at 15 Deg. C in water, with more than 50 per cent ammonia	1005	200
AMMONIUM NITRATE FERTILISERS	2067 2068 2069 2070	5000
AMMONIUM NITRATE, with not more than 0·2 per cent combustible substances, including any organic substance calculated as carbon, to the exclusion of any other added substance	1942	2500
ARSENIC PENTOXIDE, Arsenic (V) Acid and other salts	1559	10
ARSENIC TRIOXIDE, Arsenious (III) Acid and other salts	1561	0·1
ARSINE	2188	0·01
BROMINE or BROMINE SOLUTIONS	1744	100
CARBON DISULFIDE	1131	200
CHLORINE	1017	25
DIOXINS	---	0·1
DIPHENYLMETHANE 4.4'-DIISOCYANATE	2489	200
ETHYL NITRATE	---	50
ETHYLENE DIBROMIDE	1605	50
ETHYLENE OXIDE	1040	50
ETHYLENEIMINE	1185	50
FLUORINE	1045	25
FORMALDEHYDE	1198 2209	50
HYDROFLUORIC ACID SOLUTION (greater than 50 per cent)	1790	50
HYDROGEN	1049	50
HYDROGEN CHLORIDE		
- Anhydrous	1050	250

MATERIAL	**UN Nos INCLUDED UNDER NAME**	**THRESHOLD QUANTITY (tonnes)**
- Refrigerated Liquid	2186	250
HYDROGEN CYANIDE	1051 1614	20
HYDROGEN FLUORIDE	1052	50
HYDROGEN SULFIDE	1053	50
LP GASES	1011 1012 1075 1077 1978	200
METHYL BROMIDE	1062	200
METHANE or NATURAL GAS	1971 1972	200
METHYL ISOCYANATE	2480	0·15
OXIDES OF NITROGEN, including nitrous oxide, nitrogen dioxide and nitrogen trioxide	1067 1070 1660 1975 2201 2421	50
OXYGEN	1072 1073	2000
PHOSGENE	1076	0·75
PROPYLENEIMINE	1921	200
PROPYLENE OXIDE	1280	50
SODIUM CHLORATE, solid	1495	200
SULFURIC ANHYDRIDE (Alt. SULFUR TRIOXIDE)	1829	75
SULFUR DICHLORIDE	1828	1
SULFUR DIOXIDE, LIQUEFIED	1079	200
TOLUENE DIISOCYANATE	2078	200

SCHEDULE 1 – TABLE 2

Notes

1. The quantities specified for explosives relate to the weight of explosive exclusive of packing, casings and non-explosive components.
2. If explosives of different Hazard Divisions are present in the same area or storage, all of the explosives shall be classified in accordance with the following table:

Div	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**
1.1A	1.1A	1.1A	1.1A	1.1A	1.1A	
1.1	1.1	1.1	1.1	1.1	1.1	1.1
1.2	1.1	1.2	1.1	1.2	1.1	1.2
1.3	1.1	1.1	1.3	1.3	1.1	1.3
1.4	1.1	1.2	1.3	1.4	1.5	1.6
1.5	1.1	1.1	1.1	1.5	1.5	1.5
1.6	1.1	1.2	1.3	1.6	1.5	1.6

3. **"Toxic Solids and liquids"** do not include—
   (a) materials which are classified as Infectious Substances (Class 6.2) or as Radioactive (Class 7); or
   (b) in relation to "mines" within the meaning of the Occupational Health and Safety (Mines) Regulations 2002, sodium cyanide.

MATERIAL	DESCRIPTION	THRESHOLD QUANTITY (tonnes)
Explosive materials	• Explosive of **Class** 1.1A	10
	• All other Explosives of **Class** 1.1	50
	• Explosive of **Class** 1.2	200
	• Explosive of **Class** 1.3	200
Compressed and liquefied gases	• Compressed or liquefied gases of **Class** 2.1 or Subsidiary Risk 2.1	200
	• Liquefied gases of Subsidiary Risk 5	200
	• Compressed or liquefied gases which meet the criteria for Very Toxic in Table 3	20
	• Compressed or liquefied gases which meet the criteria for Toxic in Table 3	200
Flammable materials	• Liquids which meet the criteria for **Class** 3 **Packing Group** I Materials (except for crude oil in remote locations)	200
	• Crude oil in remote locations which meet the criteria for **Class** 3 **Packing Group** I	2000
	• Liquids which meet the criteria for **Class** 3 **Packing Group** II or III	50000
	• Liquids with flashpoints <61^{0}C kept above their boiling points at ambient conditions	200

MATERIAL	DESCRIPTION	THRESHOLD QUANTITY (tonnes)
	• Materials which meet the criteria for **Class** 4.1 **Packing Group** I	200
	• Spontaneously combustible materials which meet the criteria for **Class** 4.2 **Packing Group** I or II	200
	• Materials which liberate flammable gases or react violently on contact with water which meet the criteria for **Class** 4.3 **Packing Group** I or II	200
	• Materials which belong to **Classes** 3 or 8 **Packing Group** I or II which have **Hazchem codes** of 4WE (materials which react violently with water)	500
Oxidising Materials	• Oxidising material listed in Appendix 5 of the **ADG Code**	50
	• Oxidising materials that meet the criteria for **Class** 5.1 **Packing Group** I or II	200
Peroxides	• Peroxides which are listed in Appendix 5 to the **ADG Code**	50
	• Organic Peroxides which meet the criteria for **Class** 5.2	200
Toxic Solids and liquids	• Materials which meet the criteria for Very Toxic in Table 3	20
	• Materials which meet the criteria for Toxic in Table 3	200

ANNEX 2

OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved In Accidental Releases

16 – 18 October 2006, Varese, Italy

AGENDA

Introduction

The Workshop is sponsored by Environment Canada – Environmental Emergencies Division (EC-EED) and the European Commission Major Accident Hazards Bureau (MAHB), at the Joint Research Centre, Ispra, Italy.

The workshop will take place at: **Palace Grand Hotel Varese**, 11 Via Manara, 21100 Varese, Italy.

Objectives and scope of the Workshop

The overall objective of the workshop is to share information and experiences on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing/managing accidental releases.

The detailed objectives of the workshop are:

a. Share experience, on a scientific basis, used by OECD member countries in identifying the hazards posed by chemicals involved in accidental releases, focusing on characteristics, criteria and the establishment of threshold quantities.

b. Examine commonalities and differences of approaches, criteria and methodologies employed by OECD countries or regions, with a view to launching or pursuing technical exchange on this issue and creating opportunities for increasing greater complementarity and compatibility of those approaches.

c. Investigate the possibility of:
   - developing common criteria and principles for identifying and categorising hazardous substances in the context of ongoing exchange of information on work in this area; and
   - establishing channels of communication to allow countries/stakeholders to continue to share information on results and experiences.

d. Explore how developments in the chemicals assessment area could have an impact on processes used in OECD countries for identifying and selecting hazardous substances for regulation with respect to preventing/managing accidental releases: e.g. the new UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS); the new European chemicals policy called REACH (Registration, Evaluation and Authorisation of Chemicals) – Build awareness of other initiatives related to hazardous substances that could also affect implementation of industrial accident regulations in OECD countries (e.g. Acute Exposure Threshold Levels methodology).

e. Acknowledge the differences in approaches among OECD countries or regions, in terms of threshold quantities assigned to substances and categories of substances for determining regulatory obligations with respect to preventing/managing accidental releases – Encourage discussion on the selection of candidate chemicals and categories, and the determination of their threshold quantities and associated regulatory requirements for different threshold levels – Agree to develop a comparative matrix showing criteria and methodology used by different regulatory systems to identify and select hazardous substances and categories with respect to preventing/ managing risks associated with accidental releases – Describe the advantages and disadvantages of the respective approaches.

f. Investigate the possibility of launching collaboration to support more consistent criteria and principles to identification and selection of individual substances or groups of substances (categories/classes) across OECD membership – Determine interest among member countries for such closer co-operation (the intent being to possibly allay trade/competitiveness concerns through greater harmonisation in approaches) – Consider sharing the burden of possible "re-assessment" of chemicals, resulting from the application of GHS, in the context of accident prevention regulations.

g. Explore possible opportunities to facilitate greater data/information exchange and to reduce workload through work sharing.

Workshop Participants

The workshop will bring together representatives of public authorities, industry and labour, from national and international organisations to share experience and discuss openly issues related to risk assessment practices for hazardous chemicals in the context of accident hazards control. Experts from Europe, North America and Asia involved with the domestic chemical accident programmes are invited to provide an overview of the processes in their country/region for assessing dangerous substances. Experts involved in the implementation of REACH and GHS are also invited to participate in the workshop.

Discussion Document

A Discussion Document prepared by ***Asit Hazra*** and ***John Shrives*** of Environment Canada and ***Jean-Paul Lacoursière*****,** Environment Canada consultant, is aimed at stimulating discussions among participants. It is based on contributions from ***Maureen Wood*** and ***Michalis Christou*** of the EC MAHB as well as ***Kim Jennings*** and ***Jim Belke*** of the US EPA and several other members of the planning committee. The Discussion Document (i) provides an overview of the processes used in OECD countries or regions for identifying and selecting dangerous substances regulated under chemical accidents prevention programmes; (ii) describes the themes of sessions; and (iii) identifies the issues for consideration.

Structure of the Workshop

The Workshop is structured as follows:

- Opening Session: Welcome addresses/Opening speeches
- 'Setting the scene': Introduction of the Discussion Document
- Thematic Sessions: Five sessions consisting of speakers' presentations and discussion among workshop participants
- Closing Session: Workshop conclusions and recommendations – General Discussion

Note: Each presentation should last **15-20 minutes** and **MUST NOT** exceed 20 minutes. The aim of presentations is to initiate discussions among participants.

All participants are expected to actively participate in the discussions to exchange experience and information

Workshop Language

The Workshop language will be English.

Workshop Planning Committee

Asit Hazra (Chair), Environment Canada
John Shrives, Environment Canada
Jean-Paul Lacoursière, Université de Sherbrooke, Canada
Marie-Astrid Kordek, INERIS, France
Jochen Uth, UBA, Germany
Pasquale Avino, ISPESL, Italy
Kim Jennings, EPA, US
Michalis Christou, EC MAHB, JRC, Ispra
Maureen Wood, EC MAHB, JRC, Ispra
Michael Struckl, EC MAHB, JRC, Ispra
Marie-Chantal Huet, OECD Secretariat, Paris

Overall Workshop Co-Chairs

Asit Hazra, Environment Canada
Michalis Christou, EC MAHB, JRC

Overall Workshop Rapporteurs

Jean-Paul Lacoursière, Environment Canada Consultant
Marie-Chantal Huet, OECD Secretariat

Thematic Sessions' Chairs and Rapporteurs

See the heading "Session's Chair & Rapporteur" in the Agenda/Thematic sessions.

Output of the Workshop

The workshop report will be published as an OECD Environment, Health and Safety publication in the series on Chemical Accidents. One potential workshop outcome is a common list of chemicals of interest for regulation purposes within the context of accident prevention. In addition to sharing experience among participants, the workshop could be a first step in work sharing for providing, e.g.:

- A system that ensures consistency and encourages the use of complementary terms and techniques for identifying and prioritising substances in the context of accidental releases; this could allay private sector concerns regarding possible competitive advantage in certain member countries;
- The possibility of establishing a working group within the OECD Chemical Accidents Programme to undertake these substances identification and prioritisation; this could prove

attractive, owing to economies made by having several countries participating in this exercise and sharing the workload and results;

- The development of *ad hoc* training programs in assessment and prioritisation techniques for hazardous chemicals involved in accidental releases; and
- The creation of networks for all stakeholders including the establishment of mechanisms for information dissemination.

OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases

16 – 18 October 2006, Varese, Italy

Beginning at 13H30 on Monday 16 October
Finishing at 15H30 on Wednesday 18 October

DRAFT AGENDA

Monday 16 October 2006, 13:30

REGISTRATION – Distribution of badges

OPENING SESSION
13:40 – 14:15

Workshop Co-Chairs

Asit Hazra, Environment Canada, Canada
Michalis Christou, EC MAHB, JRC, Italy

Workshop Rapporteurs

Jean-Paul Lacoursière, Université de Sherbrooke, Canada
Marie-Chantal Huet, OECD Secretariat, Paris

Gerald Vollmer, Hazard Assessment Unit, Institute for the Protection and Security of the Citizen, EC MAHB, JRC, Ispra, Italy

Driving Principles and current Issues Influencing Seveso Qualifying Criteria
This presentation will outline some of the themes underlying Seveso II qualifying criteria and current trends in the technical and policy arena that may influence coverage in future.

Asit Hazra, Environmental Emergencies Division, Environment Canada

Overview of Workshop Objectives

Marie-Chantal Huet, OECD Secretariat

Workshop Agenda

SETTING THE SCENE
14:15 – 15:00

Asit Hazra, Environment Canada

Presentation of the Discussion Document

BREAK 15:00 – 15:30

THEMATIC SESSION 1
15:30 – 18:00
How hazardous substances involved in major accidents are identified/managed in OECD countries?

Session's Chair & Rapporteur

Chair: ***Pasquale Avino***, ISPESL, Italy
Rapporteur: ***Michael Struckl***, MAHB, JRC

Objectives

1. Share information and experiences on the respective individual approaches to identify and select hazardous substances with respect to preventing/managing accidental releases, including the scientific basis used to evaluate the hazards posed by the accidental release of chemicals, focusing on characteristics, criteria and the establishment of threshold quantities.
2. Review the systems currently used in OECD countries at regional level (e.g. the European Union under the Seveso II Directive, in North America by the United States and Canada, and in Oceania by Korea to: (i) identify 'regulated' chemicals under accidents prevention programmes; and (ii) show how economic and regulatory considerations might influence the establishment of threshold quantities and other criteria and mechanisms for defining coverage.
3. Discuss respective approaches to the selection of candidate chemicals and associated regulatory requirements. Compare the hazardous substances/groups of substances lists and threshold quantities to examine commonalities and differences in approaches, criteria and methodologies employed.

Presentations

Maureen Wood, MAHB, JRC

General Overview of Qualifying Criteria for Substances under Seveso II

This presentation will provide the general description of how Annex 1 of the Seveso II Directive works, with a brief historical perspective highlighting how basic principles of the approach have evolved from the 1980's. While the presentation will include a discussion of the significant advantages of the current approach from the EU perspective, it will also touch on disadvantages that have been anticipated or encountered in practice, and some of the legal and practical measures introduced to address them.

John Bresland, US Chemical Safety Board
Brief Review of Hazardous Substance Lists Used in the United States
The paper will provide a short description of the lists of hazardous substances used for major hazards at the federal level in the United States. This presentation will focus on those hazardous substance lists prepared to comply with laws and regulations pertaining to community notification of hazardous substance storage and notification requirements when there is an accidental release of a hazardous into the community. The presentation will also discuss the criteria used for including a chemical on a list.

John Shrives , Environment Canada
The Canadian Approach to Hazardous Substance List Development
This presentation will address the process and approach used to develop Schedule 2 (the list of substances and their threshold quantities) of the Environmental Emergency Regulations under the Canadian Environmental Protection Act, 1999. The technical basis for the Risk Evaluation Framework (REF) used in the assessment of candidate chemicals will be described along with the results obtained. This program involves the screening both of substances proposed for addition to the regulation as well as a re-evaluation of those substances currently covered by the regulation.

Hyuck-myun Kwon , KOSHA (Korea Occupational Safety & Health Agency)
Korean Risk Assessment Experience
The presentation will describe the methodology used by Korea, under the Safety and Health Act (enacted December 1981, last amendment December 2002) for evaluating hazardous substances involved in major accident hazards. The prevention of major industrial accidents, was introduced in January 1995 by amending the Industrial Safety and Health Act, and it has been enforced on January 1, 1996.

DISCUSSION

End of day 1, 18:00

Tuesday 17 October 2006, 8:30

THEMATIC SESSION 2

8:30 – 12:30

Current processes for selecting 'regulated' chemicals and determining thresholds of effects under accident prevention policies

Session's Chair & Rapporteur

Chair: ***Marie-Astrid Kordek***, INERIS, France
Rapporteur: ***Kim Jennings***, US EPA

Objectives

1. Analyse the role of systems of classification/assessment of chemicals in processes for identification and selection of hazardous substances.

2. Describe experiences with different approaches, including the use of classes of substances vs. lists of individually named substances.
3. Describe experiences in applying environmental effects vs. human effects criteria.

4. Exchange information on how other criteria and measures (not substance-related), such as threshold quantities, exemptions, etc. have affected the definition of scope and their advantages and disadvantages.

5. Discuss other relevant matters and their relative importance, for example: process safety management, reactivity including combustible dust, nanoparticles and non-specific chemical fires that release hazardous substances as by-products of combustion.

Aim at reaching a common understanding on challenges arising from practical application of different criteria and measures for defining scope in OECD countries.

Presentations

Jean-Paul Lacoursière, Université de Sherbrooke, Canada
Comparative Matrix of Dangerous Substances Used in Major Hazard Regulations
This presentation will illustrate with a comparative matrix the approaches chosen by countries and regions for criteria used to regulate hazardous substances under respective major accident prevention programs. This comparison is not intended to be comprehensive since differences will be further explored at the workshop. However, it provides an example of some notable differences that have been identified. It should serve as a platform to explore areas where collaboration could be developed.

Michalis Christou, MAHB, JRC

Case Studies in Qualifying Seveso Coverage for Substances Dangerous to the Environment and Carcinogens

This presentation will illustrate the complexities of determining qualifying criteria for accident prevention coverage from the Seveso II experience, using particular rich examples from efforts to provide adequate coverage of hazardous installations handling substances dangerous for the environment and carcinogens. These two categories of dangerous substances pose some interesting problems with respect to coverage under Seveso and were the focus of intensive study and debate within two EU Technical Working Groups charged with refining the qualifying criteria for coverage for each category under the 1996 Directive. The outcome of this work eventually was incorporated into the 2003 amendment to the Directive.

Agnès Vallée, INERIS, France

Use of the Classification System of Hazardous Substances and Preparations for the Classification/ Ranking of Installations in France

This presentation will explain how the classification of hazardous substances and preparations, based on the chemicals risk phrases, was used in France to identify which category of the nomenclature of classified installations these hazardous substances and preparations belong to. The nomenclature allows a ranking of the dangerous industrial facilities and the safety requirements that these installations have to comply with. The link with the Seveso II Directive will be detailed.

John Bresland, US Chemical Safety and Hazard Investigation Board, United States

Lessons from Accident Investigation and their Influence on Hazardous Substance Lists and their Thresholds

The US CBS is an independent federal agency investigating chemical accidents to protect workers, the public and the environment. This presentation will cover lessons from accident investigation and their influence on hazardous substance lists and their thresholds.

Michael Struckl, MAHB, JRC

Report on the (January 2006) Vienna Seminar on Chemical Substance Classification Issues in the context of the Seveso Directive

This paper will present a report on the "Seminar on chemical substance classification issues in the context of the Seveso-II-Directive", held in Vienna in January 2006; this event was organised by the Austrian government (Austria had the EU presidency from January to June 2006) and the MAHB in the context of the 15th Meeting of the Seveso Committee of competent Authorities (CCA). The presentation will also summarise the options and concepts related to the implementation of the new classification scheme into the EU regulation from the Seveso II Directive standpoint.

Peter Frijns, Ministry of the Environment, the Netherlands

Standardisation and Implementation – Realising the Required Flexibility

This will be a presentation on experience and major hazard policy developments in the Netherlands. In 2004 environmental quality standards related to the risks of industrial activities with dangerous goods were incorporated in the Dutch Environmental Management Act and in the Spatial Planning Act. The speaker will share some observations related to important consequences of this decision.

Steve Arendt, ABS, United States
Issues in Using Non-Traditional Approaches in Selecting Substances for Special Accident Prevention Measures
This paper will consider other factors such as process safety management, reactivity and by-products of combustion that could potentially affect the selection of hazardous substances and their thresholds.

DISCUSSION

BREAK 30 min coffee break at some time of the morning

LUNCH 12:30 – 13:30

THEMATIC SESSION 3
13:30 – 18:00
Examples of divergence in approaches and potential for future implications

Session's Chair & Rapporteur

Chair: ***Hans-Joachim Uth***, UBA, Germany
Rapporteur: ***Maureen Wood***, MAHB, JRC

Objectives

1. Build awareness of other initiatives that are likely to affect implementation of industrial accident policies, e.g., the new UN Globally Harmonised System for Classification and Labelling of Chemicals (GHS), the new European policy REACH (Registration, Evaluation and Authorisation of Chemicals), the AETL methodologies (Acute Exposure Threshold Levels), the Land-Use-Planning policies (LUP), and research activities.
2. Review potential opportunities to improve current approaches within OECD countries particularly on substances or categories of substances of common concern, and industries and processes of common concern, with the intent of highlighting the opportunities and benefits of developing a common scientific rationale for addressing these areas.
3. Aim at reaching a common understanding of how future developments may further exaggerate or decrease differences in scope.

Presentations

Hans Steinkellner, ECB, JRC
EU Adoption of the Globally Harmonised System and Implications for Seveso II Coverage
The Seveso II Directive admits establishments for coverage on the basis of categories of hazardous substances present on-site. Adoption of the GHS (Globally Harmonised System for the Classification of Chemicals) in the EU will change provisions for categorising hazardous substances in the EU from the current provisions authorised in the Directive for Classification and Labelling of Dangerous Substances (67/548/EEC) and Preparations (1999/45/EC). This presentation will provide an overview of the current state of play of adoption of the GHS into EU regulations. Moreover, it will provide some important insights concerning potential implications of adoption of the GHS on coverage of hazardous establishments under the Seveso II Directive.

Jens Torlov, ECB, JRC

Areas where REACH can be Useful to the Seveso Directive

This presentation will address the main areas where work done under REACH may prove to be useful for the Seveso directive, e.g. higher availability of substance hazard data, development of exposure assessment methodologies including IT tools, inventory of classification of substances, etc.

Martin Merkofer, BAFU, Switzerland

Problems and Opportunities Arising from a Change to the Classification System for the Definition of Threshold Quantities

Threshold quantities depending on the toxicity, flammability, explosiveness and ecotoxicity criteria are used in Switzerland to determine whether an establishment falls into the scope of the Ordinance on Major Accidents (OMA). Recently, the Swiss classification system for chemicals was adapted based on the EU classification. This presentation will illustrate the consequences arising from this amendment for threshold quantities. A comparison of the Swiss system with the Seveso II Directive will show that classification of chemicals is not the only criterion for the setting of threshold quantities. The presentation will also try to assess the major consequences that can be expected from the implementation of the GHS system with respect to thresholds.

Marie-Astrid Kordek, INERIS, France

Ammonium nitrate: Changes in the Regulation at the EC and French levels

This presentation will introduce the Seveso classification history for ammonium nitrate and ammonium nitrate-based products: definition of hazards and thresholds. In addition, the implementation in France of the Seveso Directive concerning these chemicals will be presented.

Jean-Paul Lacoursière, Université de Sherbrooke, Canada

Are the Current Thresholds for Chlorine Adequate to Protect the People and the Environment?

The presentation will enumerate the thresholds for chlorine used by countries and regions. It will describe the procedures that were followed to choose these thresholds. It will focus on exposure data that were published after the original thresholds which could lead to a revision of the numbers to improve protection of potentially exposed persons. This presentation is an example illustrating potential collaboration in research activities.

Sylvie Tissot, INERIS, France

The Acute Exposure Threshold Levels Project (ACUTEX)

This presentation will introduce the ACUTEX project and its main results. The aim of ACUTEX was to develop innovative approaches to define acute exposure levels (AETLs) that could be used to establish acute exposure levels for emergency planning and land-use-planning under the Seveso II Directive.

Maria Stangl, Ministry of the Environment/STMK, Austria
Current LUP Practices around Seveso II Establishments and Future Challenges
This presentation will deal with the risk assessment in the context of Land-Use-Planning in Austria (Article 12 of Directive 96/82/EEC).

Ake Persson, Swedish Fire Protection Association, Sweden
The Swedish Fire Protection Association: "Dangerous Goods Cards"
The 'dangerous cards' are chemical information sheets widely used by the emergency responders in Sweden; they are part of the regular outfits for the rescue teams.

DISCUSSION

BREAK 30 min coffee break at some time of the afternoon

End of day 2, 18:00

Wednesday 18 October 2006

THEMATIC SESSION 4

8:30 – 10:30

Elaboration of a consistent approach to identify chemicals of interest for accidents regulation purposes

Session's Chair & Rapporteur

Chair: **Kathy Jones**, US EPA
Rapporteur: **John Shrives**, Environment Canada

Objectives

1. Investigate future prospects for information exchange among OECD countries so that the results of evaluations of chemicals for accident prevention purposes carried out by one country could be shared and applied by the other member countries.
2. Identify the future needs for "re-assessment" of certain chemicals because of new scientific information or (i.e. chemicals which will change hazard classification category).
3. Explore the possibility of jointly assessing or re-assessing specific substances or categories of substances among member states.
4. Explore the creation of a list of specific substances or groups of substances of common interest.
5. Investigate the benefits and feasibility of standardising terminology and assessment techniques among the various existing systems.
6. Make a list of potential concerns over the next five years.
7. Explore the feasibility of sharing the workload of actions generated by the workshop.

Presentations

Augustin Baulig, INERIS, France
From Definition to Use of Acute Toxicity Threshold Values: Awareness of Uncertainty
This presentation will focus on uncertainties resulting from the acute toxicity threshold values derivation process and uncertainties related to the effect distances calculation. These threshold values are usually used for the toxic risk assessment in order to prepare emergency plans and/or the Land-Use Planning policy around fixed chemical plants. The main problem is to make the risk manager aware of the global uncertainties concerning the effect distances calculations.

Jean-Paul Lacoursière, Université de Sherbrooke, Canada
OECD's Future Prospects for Exchanging, and Evaluating Data on Hazardous Substances
This presentation will propose ideas on mechanism for more open and transparent sharing of information and results.

Timothy Beals, Health & Safety Executive (HSE), UK
Seveso, Classification and Global Harmonised System (GHS)
This presentation will discuss the proposals for the link between Seveso and the GHS. It will suggest that an alternative linkage to that proposed in the Commission Services document 'Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation' may be worth consideration. It will also give details of a project being carried out by

the UK's health and safety laboratory and aimed at determining the potential effects of adopting the alternative approach.

DISCUSSION

BREAK 10:30 – 11:00

THEMATIC SESSION 5

11:00 – 12:30

The path forward

Panel *Asit Hazra*, Environment Canada; ***Michalis Christou***, EC MAHB; ***Hans-Joachim Uth***, UBA, Germany; ***Ake Persson***, SFPA, Sweden; ***Kim Jennings***, US EPA; ***John Bresland***, CSB, US.

Objectives

- Evaluate the level of interest among member countries for closer co-operation in the area of control of chemical accident hazards.
- Consider launching a collaboration to support a more consistent approach to identification and selection of substances or groups of substances (categories/classes) with a view to seeking greater complementarity/compatibility in future.
- Implement mechanisms for greater information exchange and work-sharing – Envisage future co-operation among OECD countries with respect to re-evaluation of chemicals for accident regulation purposes.
- Agree to a near future OECD programme of work, including the possible creation of a committee to coordinate future collaborative actions.

Presentations Selected themes from the previous discussions or specific questions will the presented to the panel for their comments.

DISCUSSION

LUNCH 12:30 – 13:30

CLOSING SESSION

13:30 – 15:30

Conclusions and Recommendations – General Discussion

Panel & Rapporteurs

- Presentation of draft conclusions and recommendations by the Rapporteurs
- General discussion among all participants conducted by the Panel

End of Workshop, 15:30

ANNEX 3

PARTICIPANTS LIST FOR OECD-EC WORKSHOP ON RISK ASSESSMENT PRACTICES FOR HAZARDOUS SUBSTANCES INVOLVED IN ACCIDENTAL RELEASES

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