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

12-May-2011

English - Or. English

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

BACKGROUND DOCUMENT:

THE OECD ENVIRONMENT, HEALTH AND SAVETY PROGRAMME: ACHIEVEMENTS, STRENGTHS AND OPPORTUNITIES

40 Years of Chemical Safety at OECD: Planning for the Next Decade

15 June 2011, at the OECD Conference Contre, 2 rue André Pascal, Paris.

Mr. Peter Kearns

Tel: +33 (0) 1 45 24 16 77; Fax: +33 (0) 1 44 30 61 80; E-mail: Peter.Kearns@oecd.org

JT03301703

ENV/JM(2011)17

This document has been prepared to support the discussions at the special event of the Joint Meeting 40 Years of Chemical Safety at OECD: Planning for the Next Decade which will be held 15th June 2011. Specifically, this document is background for the opening session of the special event as indicated in the Draft Agenda as it covers The Achievements of the OECD Chemicals Programme – Past Successes and New Challenges.

ACTION REQUIRED: The Joint Meeting is invited discuss this document.

Executive Summary

Many OECD countries began setting up chemical safety policies in the early 1970s. These policies were all based on information gathering or generation, often through testing, on the properties or effects of chemicals and making assessments of this information. Countries were also aware of the international nature of the chemical safety issue and of the chemicals industry and therefore the possible trade barriers chemical safety policies could create. They recognised early on that if similar methods were to be used across OECD, there was an excellent opportunity to enhance efficiency and avoid trade barriers. At this early stage, therefore, they were already looking at possibilities to co-operate internationally in this field at the OECD.

In 1971 the OECD Environment Programme initiated work on chemical safety and in 1978 the OECD Chemicals Programme was set up to intensify the efforts of furthering international co-operation. The Chemicals Programme has, since its inception, developed many harmonised high-quality instruments and policies to assist countries in managing the risks of chemical products for man and the environment. Harmonisation contributes to avoiding duplicative work for governments and industry, to minimising non-tariff barriers to trade and to creating a level playing field for industry and it provides a good basis for work sharing. The programme has led to substantial efficiencies for government and the industry. The net savings resulting from the work of the Programme by avoiding duplicative activities amount to more than € 150 million per year.

The Chemicals Programme was renamed the Environment, Health and Safety (EHS) Programme in the early 1990s when in addition to industrial chemicals, activities on pollutants, the safety of pesticides, biocides, genetically modified organisms and novel foods and feeds were included in the work. While much of the new work was supported by extra-budgetary contributions from member countries and stakeholders, similar objectives to the Chemicals Programme were pursued.

The EHS Programme has always received the strong commitment of member countries, the chemical industry and other stakeholders in the provision of expertise and resources. This is one of the reasons why it has always been capable of reacting swiftly to new policy developments. For example, the Programme has been very proactive in addressing the safety of manufactured nanomaterials. In terms of method development, the Programme continually seeks out ways to apply new technological and scientific opportunities. Examples are the development of the (Quantitative) Structure- Activity Relationships Toolbox, *in vitro* test methods and the work on toxicogenomics. Such methods also contribute to improve animal welfare related to safety testing of chemicals.

Through the active participation of all the stakeholders in the work, the products of the EHS Programme have always been widely accepted. All outputs of the Programme are made available free of charge on the internet. Datasets and assessments of chemicals resulting from the OECD work, but also those from a number of national, regional and intergovernmental institutions can be found in the eChemPortal. The active contributions which the Programme makes to UN work, in particular the Strategic Approach to International Chemicals Management, further contributes to making the OECD products widely available.

The EHS Programme has co-operated closely with a number of non-members. In certain areas of work they are full participants with the same rights and obligations as member countries. This has contributed to promoting global convergence in chemical safety policies. Increasing globalisation and global shifts in patterns of chemical production will mean that more countries outside the OECD will consider it prudent to set up chemical safety policies. Further co-operation with selected non-members in a global context would therefore prove very useful. In addition, input to OECD work from experts of non-members will contribute to increasing the quality of the products and make them more widely applicable.

ENV/JM(2011)17

Continuing budgetary pressures in countries will create the need to look for further efficiencies. One obvious way to achieve this would be through extending the co-operation in the OECD on method development and to look for even more opportunities for work sharing in national assessment, notification and registration activities. A relatively small investment in international co-operation could be the way to obtain major efficiencies in a national setting.

The Programme has the capacity to bring together regulators, scientists and stakeholders. It also has an excellent track record in dealing effectively with issues on the regulation/science interface. This means that the EHS Programme is well-positioned to tackle longer-term challenges like achieving regulatory acceptance of new testing and assessment methods and approaches, and developing practical tools for use in decision-making on the possibilities of substitution of harmful chemicals by safer alternatives.

The characteristics of the EHS Programme and the 40 years of experience in harmonisation and facilitation of work sharing, make it eminently placed to continue work to address future chemical safety challenges and deliver more high quality practical instruments and policies, while creating further efficiencies.

TABLE OF CONTENTS

Executive Summary	3
I Introduction	6
II Safety of Industrial Chemicals	6
III Beyond Industrial Chemicals: Environment, Health and Safety	16
IV Innovations, Special Projects and Outreach	19
V Achievements, Strengths and Opportunities	25
VI Conclusions	30
VII References	31
Annex 1 OECD Bodies Involved in the Management of the EHS Programme	34
Annex 2 Council Acts Related to the EHS Programme	35

I Introduction

- 1. The work of the current OECD Environment, Health and Safety (EHS) Programme started with activities related only to the safety of industrial chemicals in a Chemicals Programme. In the early 1990s, the scope of the tasks member countries allocated to the Chemicals Programme with the support of extrabudgetary contributions gradually broadened beyond industrial chemicals and began to cover fields like pollutants, the safety of pesticides, biocides, genetically modified organisms and novel foods and feeds. In order to reflect the wider scope of the work, the Chemicals Programme was renamed the Environment, Health and Safety (EHS) Programme in 1992.
- 2. This document provides a description of how the various work areas of the EHS Programme developed over time and highlights its main products. The overall achievements of the Programme are then considered, and an analysis of the strengths and weaknesses is made. The possible challenges to and opportunities for the Programme are also examined. Finally a list of References is provided with the websites where work that is mentioned can be found. A list of the main OECD bodies which oversee and undertake the EHS work is detailed in Annex 1, and a list of the relevant Council Acts can be found in Annex 2.

II Safety of Industrial Chemicals

The beginning of chemical safety policies

- 3. In many OECD countries environmental policies began to take shape in the 1960s. In the first instance such policies concentrated on combating local air and water pollution. Even though it had become clear that there were a number of important international issues, (such as the case of acid rain), the focus of environmental policy had mainly been on promulgating national rules for "end-of-pipe" solutions to limit pollution. In 1962 Rachel Carson published the book *Silent Spring*, which outlined the environmental problems resulting from the widespread use of organo-chlorine pesticides. Around the same time it also became clear that exposure of the public to certain chemicals, such as mercury (Minamata disease), cadmium (Itai-itai disease) and Poly- Chlorinated Biphenyls, led to major health problems. As a result chemical safety became an environmental priority and it started to appear seriously on policy agendas throughout the OECD from the 1970s onwards.
- 4. When governments started to think about developing policies to protect man and the environment from the hazardous effects of chemicals, they recognized that owing to cross-border trading, the chemical industry was already to a large extent organised like multinational companies. It was patent that chemical safety was an issue which could not efficiently and effectively be addressed simply with national policies. In order to be able to manage the risks of chemicals, information about the hazards and exposure levels is needed first and then followed by an assessment of this information. The hazard information at that time needed to be derived from the testing of a chemical, and outcomes of such tests could in principle be universally applied to make safety assessments. Policy makers across OECD countries therefore started very early on to look towards international co-operation as a way to create efficiencies and avoid trade barriers.
- 5. The OECD Environment Committee, which was established in 1970 under the regular OECD Part I programme, included in 1971 work on the safety of pesticides and chemicals in its work. The Chemicals Group was established under the Committee to undertake activities related to a number of specific chemicals: anionic synthetic surface active agents [Council Recommendation C(71)83], mercury [Council Recommendation C(73)172], Poly-Chlorinated Biphenyls PCBs [Council Recommendation C(73)1] and ChloroFluoroCarbons CFCs (several reports feeding into the process for developing the UN Vienna Convention on Protection of the Ozone Layer). Also some generic policy concepts about the need

to assess chemicals for their safety before they are put on the market, and on the types of information which would be needed to achieve this, were developed at that time [Council Recommendations C(74)215 and C(77)97].

- 6. The success of the co-operation among countries on these initial topics, and the benefits derived from the exchange of information on national activities led to a number of counties to establish at the OECD a "Special Programme on the Control of Chemicals", as a so-called Part II Programme in 1978. Contrary to the regular Part I activities, not all OECD member countries participate in such a Part II Programme; it was therefore financed though assessed extra-budgetary contributions from participating countries and it had its own management structure: the Management Committee of the Special Programme. Originally 13 of the then 24 OECD countries and the European Commission participated, but soon almost all members (with the exception of Iceland and Luxemburg) joined. Within the Environment Directorate a Chemicals Division was established.
- 7. Member countries selected the OECD to step up international work on chemical safety for several reasons. In the 1970s OECD membership included the main (if limited) number of countries which were developing legislation on chemical safety. Discussions in such a group would make reaching agreements easier than in the much wider UN context. Another important reason was that through **OECD Council Acts Decisions and Recommendations** there was a possibility to make commitments among themselves which are legally (Decisions) or politically (Recommendations) binding. This level of political engagement that can be achieved at the OECD and the peer pressure that can be applied to help ensure implementation of agreements, are crucial instruments to make sure that countries will follow up on harmonisation arrangements. Such engagement is also an important signal for stakeholders to demonstrate that governments are serious about implementing the agreements they have made. Furthermore, the OECD is a multidisciplinary organisation and therefore the necessary interactions with other policy areas could be easily established.
- 8. The Special Programme was originally set up for three years, but Council has since extended the duration of the programme ten times for three year periods, and most recently for a four year period (2009 2012). When new countries joined OECD, they all also joined the Special Programme. The Chemicals Group of the Environment Committee and the Management Committee met separately in the beginning (albeit back-to-back) but since 1983 the Part I and Part II bodies have met together as a **Joint Meeting** with one Chair and one agenda. This structure is currently still in existence. In view of the different sources of financing for the overall work on chemical safety (from the regular Part I OECD budget and, depending on how chemical safety responsibilities are attributed in countries, from Ministries of Health, Environment, Economy or Foreign Affairs for Part II), consolidation of the work into one programmatic structure has not proven to be practicable.
- 9. The OECD work can only be achieved through the extensive contribution of expertise and resources from member countries and stakeholders. The provision of expert input is organised through subsidiary bodies reporting directly to the Joint Meeting, but also through Expert Groups and Steering Groups who report to the subsidiary bodies of the Joint Meeting, and through Workshops and ad hoc meetings.

Harmonisation of test methodology

10. From the beginning, the aims of the OECD work on chemical safety have been twofold: protecting man and the environment from the hazardous effects of chemicals, and achieving this in the most efficient way, (by avoiding unnecessary duplicative activities among countries and by minimizing non-tariff barriers to trade). It was felt that these objectives could be realised if the methods used by countries for generating and assessing the safety information on chemicals were harmonised, or

alternatively, if such methods were as compatible as possible, and were, therefore, mutually acceptable. The first focus was on the aspect of testing of chemicals and on the data which would be required to enable an adequate assessment of the safety of chemicals.

- 11. With respect to the testing of chemicals, about 50 Test Guidelines were developed and agreed by the members in a short period of time. This involved a large and well co-ordinated effort which depended upon the concept of lead countries for different parts of the work. This result was achieved thanks to the involvement of many experts from member countries who provided the technical input. This way of working, whereby the country expertise forms the basis of the work and ensures the technical quality of the material produced, has remained a main characteristic of the OECD efforts on chemical safety, and of other activities in the Environment, Health and Safety Programme.
- 12. The **OECD Guidelines for the Testing of Chemicals**, as they are known, give detailed descriptions for the testing of chemicals for those properties and effects which in most countries are required for a safety assessment. They also give detailed guidance about the way in which test results should be reported. In the beginning this concerned tests in four areas: physical-chemical properties, health effects, effects on biotic systems and degradation and bioaccumulation. If countries required that these test methods be used in notifications or registrations of chemical products, such tests would not have to be repeated by industry in order to fulfil the requirements in different countries.
- 13. However, in order to achieve this situation, a second component is needed: mutual confidence among countries in the quality of the laboratories that generate the test data and in the quality of the studies they carry out. In order to achieve this, the **OECD Principles of Good Laboratory Practices (GLP)** were developed and agreed by countries. This includes a set of rules concerning the organisation of the test facility and the performance of the study. Laboratories have to follow these rules in order to guarantee the quality of their work.

Mutual Acceptance of Data

- In 1980 a High Level Meeting of the OECD Chemicals Group, attended by a number of Ministers and high-level officials, agreed that the Test Guidelines and GLP Principles, which had been developed, were of such a good quality that they could serve as the basis for a **Mutual Acceptance of Data in the Assessment of Chemicals (MAD).** Members agreed that a test carried out using the OECD Test Guidelines and in accordance with the OECD GLP Principles, would be accepted by all of them in registrations or notifications related to the safety of chemical products; so MAD has a wider application than solely to industrial chemicals. It leaves countries of course the prerogative to set their own data requirements, to make their own assessment of the information provided by the tests and to take management decisions accordingly, but they cannot ask the industry in an OECD country to do a test for which an agreed Test Guideline exists, in a different way. In 1981 the OECD Council confirmed this by incorporating this agreement in a legally binding Council Decision [C(81)30]. The Test Guidelines and GLP Principles are an integral part of this Decision. The fact that governments made this commitment a legally binding agreement was a particularly important signal to chemical companies to encourage them to use these Guidelines and Principles.
- 15. MAD has five main benefits. By accepting the same tests OECD-wide, a lot of unnecessary duplication of testing is avoided, thereby saving resources for industry and society as a whole. Secondly, non-tariff barriers to trade, which might be created by differing test requirements between countries, can be minimised. Thirdly, the use and suffering of laboratory animals needed for toxicological tests is greatly reduced by avoiding duplicative testing. The fourth benefit is that by establishing the same quality requirements for tests throughout OECD, a level playing field for industry has been ensured. Finally, by

using the same tests for making safety assessments, the mutual understanding among countries about what happens in their ensuing chemical safety assessment and risk management processes is greatly increased.

- 16. With regard to the unnecessary duplication of testing, OECD studies were carried out in 1998 and 2010 to quantify the annual savings made through the work of the OECD Environment, Health and Safety Programme (see Paragraph 65 and Reference 29). These studies used data on test costs provided by countries and industry. The net savings for countries and industry resulting from the MAD system are calculated as at least € 147 million per year.
- While the first Test Guidelines were agreed in the early 1980s, work on Test Guidelines has to continue to keep them up to date with scientific developments, as well as to develop new Test Guidelines to address new data requirements in countries, such as those related to testing for endocrine disrupting effects. The updating has focused to a large extent on aspects of animal welfare. The International Council on Animal Protection in OECD programmes (ICAPO), which was set up specifically to deal with OECD activities and assembles many animal welfare NGOs, has contributed particularly to addressing these aspects of the work. The Test Guidelines-related activities have, through the years, constituted an important and high priority part of the OECD chemical safety work. In total now 147 Test Guidelines exist and since 1981 the OECD has published 24 Addenda to the MAD Council Decision with new or updated Test Guidelines (see Reference 20). A fifth area of methods was added which now includes Guidelines for pesticide residue testing. In addition, the Test Guidelines work produces many documents which provide scientific detail, guidance or review work related to the development and use of the Test Guidelines. The large majority of the 137 Monographs in the OECD Series on Testing and Assessment falls into this category (see Reference 21).
- 18. In the area of GLP, member countries agreed to set up GLP national compliance monitoring authorities (inspectorates) which inspect test facilities. Exchanging the outcomes of such inspections is crucial to ensure that there is mutual confidence among countries in the quality control of studies which would be used as a basis for regulatory decisions. In 1989 Council incorporated this in a Decision Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87].The GLP inspectors of countries started to meet in OECD in a Working Group to agree on a harmonised interpretation of the GLP Principles and on how to carry out inspections in their countries. They laid this down in 7 GLP Consensus Documents and 7 GLP Guidance or Advisory documents (see Reference 8). The GLP inspectors continue to meet in order to address quality control issues related to new developments in laboratories (for example multi-site studies).
- 19. The inspectors have also established a system of **on-site evaluation visits**, whereby two inspectors from different countries review the compliance monitoring system of another country. Every year 4-5 on-site evaluation visits are made and all compliance monitoring authorities get visited in this process once every 7-8 years. The findings of the on-site evaluations are reported to the GLP Working Group, which discusses them and makes recommendations for improvements, if appropriate.
- 20. In light of the obvious benefits the MAD system brings, non-members who had an important chemical industry, became interested in joining the system. Furthermore, non-members which have good quality test laboratories saw that joining the MAD system could provide business opportunities for their laboratories, because there is a global shortage of laboratories which can work under the GLP conditions required for tests to be accepted for regulatory purposes. In 1997 the OECD Council agreed on a Decision on the **Adherence of non-members to MAD** [C(97)186]. This Decision lays down the process by which non-members can adhere with the same rights and obligations as member countries. A main requirement is that the counties adhering to MAD have verified that the GLP compliance monitoring system in a potential adherent is adequate, in the same way as the adhering countries do among themselves, i.e. through an on-site evaluation visit. Adhering countries assist a potential adherent country with setting up their compliance

monitoring system. Israel and Slovenia were adherents before they became OECD members. Currently Brazil, India, Singapore and South Africa are full adherents, and Argentina, Malaysia and Thailand are "provisional adherents" and on the way to becoming full adherents.

New chemicals

- In the process of the management of chemicals, the step which follows testing is the assessment. Member countries focused first of all on chemicals that would be put on the market as new entities. In 1982, at a second High Level Meeting, countries decided that in member countries sufficient information on the properties of new chemicals should be available before they are marketed in order to ensure that a meaningful assessment of the hazards to man and the environment could be carried out. A **Minimum Pre-Marketing set of Data** (MPD) was recommended. This was incorporated by Council in a Council Decision-Recommendation [C(82)196]. The OECD has continued over the years to work on new chemicals. The work has focused on looking into possibilities for streamlining notification procedures. This has resulted in agreements on the definitions of certain key terms in this field and a certain harmonisation of notification exemptions and reduced notification requirements for materials like polymers of low concern. This is reflected in a number of documents (see Reference 14). The OECD has also made efforts to facilitate co-operation among countries in relation to their new chemicals assessments, with a long-term vision towards a Mutual Acceptance of Notifications.
- At the same time member countries realised that if they wanted to promote practical co-operation in the testing and assessment of chemicals, some rules had to be established on how to deal with the availability of information in the safety dossiers they received. Some of this information is confidential, but other information should be made available to the public. **Three Council Recommendations** laid down these rules in 1983: one on the protection of **proprietary rights** to data submitted in notifications of new chemicals, a second on the **exchange of confidential data** on chemicals, and a third on a list of **non-confidential data** on chemicals. [C(83) 96, C(83)97 and C(83)98]. Together these three Council Recommendations have provided, through the years, a solid basis for the policies of governments on these issues and are used de facto in relation to all chemical products.

Compatibility in hazard assessments

- The OECD has also brought experts together to work on agreed methods for the assessment of chemicals. Because the WHO already had activities in the field of assessment of the effects of chemicals on human health, OECD work first mainly addressed the effects of chemicals on the environment and exposure assessment. In this case the results were not reflected in Council Decisions or Recommendations, because the scope for national particularities is for assessments larger than in the case of testing. A number of Guidance Documents have been agreed by countries and are included in the Series on Testing and Assessment (see References 19 and 21). These documents have assisted greatly in achieving a large degree of compatibility in assessment methods. Most recently the OECD has prepared an **Environmental Risk Assessment Toolkit** as a complement to the WHO Human Health Risk Assessment Toolkit (see Reference 7). These Toolkits are aimed to provide support to relevant stakeholders in capacity building.
- 24. While exposure situations can differ substantially among countries, member countries considered it useful to work together on collecting generic exposure information for use in national assessments. To that end Emission Scenario Documents (ESDs) were developed. An ESD is a document that describes the sources, production processes, pathways and use patterns of chemical products, with the aim of quantifying the emissions (or releases) of a chemical into water, air, soil and/or solid waste. ESDs are used in risk assessments as the basis for estimating the concentration of chemicals in the environment. **The Series of ESDs includes currently 26 documents** (see Reference 6) and work continues on further uses and production processes. The work on exposure assessment also includes efforts on the use of computer

modelling to predict the multimedia behaviour of chemicals in the environment. To that end a tool to estimate overall persistence and the long range transport potential of chemicals was developed in cooperation with UNEP and made available on the OECD website (see Reference 24).

25. In light of the wide use of information technology in notifications and registrations of chemical products, the OECD has recently undertaken a harmonisation effort related to the electronic reporting of studies and developed the OECD Harmonised Templates. The templates are closely connected to the Test Guidelines. They are guides for structuring data entry/database management systems which are concerned with the reporting of a summary of the results of a test on a chemical to determine its properties or effects on human health and the environment. Each template lists all of the data elements which could be relevant for a summary of a study. In order for information technology developers to build data entry screens and/or database systems based on these templates, which can then in turn generate data files that can then be easily imported into other database systems, each template has a corresponding common electronic data export/import format. Whenever a Test Guideline is updated, the template is also updated. Currently 98 OECD Harmonised Templates are available (see Reference 11).

Harmonisation in Hazard Classification and Labelling

- Hazard classification and labelling of chemicals (HCL) is a practice which has been widely used all over the world to alert workers and the general public to the possible hazards of the use of specific chemicals. One practical problem limiting the effective application of HCL was that different national HCL systems existed, and that for different types of target groups, transport modes and media different systems existed. When chemical products were shipped across borders these differences led to trade barriers, because products needed to be re-labelled. Alternatively, they led to confusion for the users of labels, because many different labels appeared on one package to cover all kinds of situations. Since 1952 the UN had made efforts without success to come to some kind of harmonisation of the system. In 1992 the UN Rio Conference on Environment and Development identified HCL harmonisation as one of the six priority action items in Chapter 19 on the sound management of chemicals of Agenda 21. In 1994 OECD countries took the initiative to launch a harmonisation effort in the OECD. The aim was to submit the results of the OECD work to the UN with a view to arriving at a Globally Harmonized System for Classification and Labelling of Chemicals (GHS). OECD worked on the harmonisation of the classification criteria for human health and environmental hazards, while the UN-ECE Committee of Experts on the Transport of Dangerous Goods (UNCETDG) and ILO worked on physical hazards and hazard communication.
- The OECD countries and a number of major other economies which were involved in the work were able to agree in 2001, after seven years of work, on harmonised classification criteria for human health and environmental hazards (OECD, 2001). The results were submitted to the UN and formed the basis for their agreement on a GHS in 2002, with a view to global implementation as a single classification and labelling system by 2008 (see Reference 32). The UN established a Sub-Committee of Experts on the GHS to work on global implementation. The OECD is the focal point of this Committee for reviewing new science related to human health and environment classification criteria, for keeping the criteria up to date and for developing criteria in a number of areas not yet covered in the original agreement. **The results of this work are reflected in 28 documents,** which include reviews, chapter revisions and proposals to the UN (see Reference 9). New agreed criteria were developed for example for ozone depletion, narcotic effects and aspiration hazards.

Risk management: specific chemicals and methodologies

28. After the testing and assessment of hazard, exposure and risk of a chemical, the next stage in the chemical safety process is making decisions about risk management for those chemical products for which

it is needed. The first step with regard to risk management was the 1973 Council Recommendation on Measures to Reduce all Man-made Emissions of Mercury to the Environment [C(73)172]. Specific targets were alkyl-mercury compounds in agriculture, mercury compounds from use in the pulp and paper industry and discharges of mercury from mercury-cell chlor-alkali plants. A reporting system was set up to exchange information among member countries on the progress they made with their emission reduction efforts.

- 29. PCBs were also widely considered to be of great concern. Member countries had already agreed in 1973 on a Council Decision on the Protection of the Environment by Control of PCBs [C(73)1]. This involved phasing out the use of PCBs in open systems in order to avoid PCBs reaching, and accumulating further in the environment. In 1987 member countries took the important step to agree on the Decision-Recommendation on **Further Measures for the Protection of the Environment by Control of PCB** [C(87)2]. It was now agreed to phase out all uses of PCBs, including those in closed systems. The Council Act also provided detailed rules for the way PCB containing waste should be dealt with. PCBs were also included in 2001 in the Stockholm Convention of the UN on Persistent Organic Pollutant (see Reference 36).
- 30. Member countries also recognized that, while many OECD countries were rapidly developing a system for managing the risks of chemicals, other countries in the world might not be advancing at the same pace. Therefore they felt that in the case of export, from an OECD country, of a chemical which the exporting country found to be hazardous, the importing country should be informed of the hazardous nature of that chemical. This principle and guidance on how to apply it were laid down in the Council Recommendation on Information Exchange Related to Export of Banned or Severely Restricted Chemicals [C(84)37]. This initiative has had an enormous influence worldwide. First the London Guidelines for the Exchange of Information in International Trade, which were based on the OECD Council Recommendation, were adopted by UNEP in 1987. These voluntary Guidelines were then again the basis for UNEP and FAO to work on the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, which was adopted in 1998 (see Reference 34).
- In the early 1990s member countries agreed on an initiative to look into possibilities for an OECD risk-reduction effort on five specific chemicals: lead, mercury, cadmium, methylene-chloride and Brominated Flame Retardants – BFRs. For each of these chemicals major monographs were prepared which brought together extensive information on production, use, releases, disposal, health and environmental effects, exposure, national risk reduction measures and their cost effectiveness and possible gaps in the risk reduction mechanisms. For lead this work resulted in 1996 in a Declaration on Risk Reduction for Lead, made at a meeting of OECD Environment Ministers on behalf of their governments. The OECD Council agreed on proposed follow up activities [Council Resolution C(96)42/FINAL]. The OECD has closely monitored the national activities undertaken to implement the Declaration on Lead. For BFRs a Voluntary Industry Commitment was agreed, involving risk management actions for a number of BFRs. For the other three chemicals it proved difficult to obtain consensus among countries for taking concerted risk management action. Risk management action on a chemical might have important economic consequences, and given the different use and exposure patterns among countries, risk/benefit considerations for risk management actions can also vary among countries. This is one reason why it has become more difficult to achieve agreement among OECD countries on such action, while legally binding agreements on test methods or agreed guidance on assessment methods is easier to achieve. In 2000 an initiative concerning Per-Fluorinated Chemicals - PFCs began. This involved a hazard assessment and surveys of OECD-wide production, use and releases, but no concerted risk management actions. SAICM is now also undertaking work related to these chemicals.

32. In addition to work on risk management for specific chemicals, work has also been undertaken on collecting best practices and methods on various aspects of chemicals risk management. Socio-economic analysis was, given the economic expertise available in OECD, an obvious focus and 4 major documents in this area were produced. Other topics included non-regulatory initiatives, sustainable or green chemistry, and risk communication. It was also considered how the role of chemicals management could be taken into account in implementation of the Council Recommendation on Integrated Pollution Prevention and Control [C(90)164]. Currently there are 25 documents related to risk management available (see References 18 and 19).

Sharing the burden among countries and with stakeholders: existing chemicals

- 33. The harmonisation efforts of the Chemicals Programme were a good basis to take the cooperation concept one step further by engaging countries in work sharing. Whereas the early focus of member countries was on new chemicals policies, (ensuring the safety of chemicals that are newly put on the market), the attention now turned to the safety aspects of the so-called existing chemicals. These are the tens of thousands of chemicals which had already been put on the market before new chemicals notification schemes had come into place. Given the large number of existing chemicals, member countries agreed that the investigation of these chemicals was a task which was too large for one country. Cooperation and work sharing were considered the solution. The MAD system of course provided a good starting point to base such co-operation on. In 1987 member countries agreed at a third High Level Meeting on the principles of co-operation. Commitments were then made through two Council Acts: the 1987 Decision-Recommendation on the Systematic Investigation of Existing Chemicals [C(87)90], in which member countries committed to set up national programmes to investigate existing chemicals, and the 1990 Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163], through which member countries committed to work together on the investigation and, as appropriate, on risk reduction measures deemed necessary after the investigation.
- 34. While the agreement of countries to engage in active work sharing for making chemical assessments was a new step in the programme, it was also obvious that there would be great benefit for all concerned to involve the chemical industry in the work. The chemical industry obviously holds a great deal of test data and further information on the chemicals they produce. The Industry has co-operated, from the beginning, very actively. Given the need for transparency in the investigation, in addition to industry, BIAC, also trade unions, TUAC, and environmental NGOs, the EEB (which covered for this purpose not only Europe, but all of OECD) and ICAPO have been involved in the existing chemicals programme. This close co-operation with the stakeholders was another new element in the Chemicals Programme.
- 35. In order to organise the substantial amount of work, a number of priorities had to be set. It was agreed to deal first with **High Production Volume chemicals (HPVs)**, because in most cases these would potentially lead to the largest exposure to man and environment. The OECD assembled a list of almost 5000 HPVs. Then it had to be agreed which information would be needed regarding these HPVs; this was determined to be a **Screening Information Data Set (SIDS)**, which resembled to a large extent the MPD for new chemicals. Assessments would be reflected in SIDS Initial Assessment Reports (SIAR), and drafts would be discussed and agreed at SIDS Initial Assessment Meetings (SIAMs) with participation of all stakeholders. A Manual for the Investigation of HPV chemicals was prepared, which addressed, among other aspects, quality control and data review (see Reference 5). The data and assessment made for each HPV chemical, as reflected in a SIAR, are made publicly available. In case a conclusion of a SIDS assessment would indicate the need for further work on a chemical, co-operation on such Post-SIDS work could also be agreed.
- 36. While most OECD countries are actively contributing to the work sharing and distribute the tasks of investigating the HPVs among themselves, the chemicals industry, through the **International Council**

of Chemical Associations made the very important commitment to voluntarily collect information on 1000 HPV chemicals and make draft SIDS assessments for them. These draft assessments were submitted, through sponsor countries, to the OECD SIDS process and were discussed at the SIAMs. The status of the HPVs in the SIDS assessment process, as it was in early 2011, is reflected in the table.

Status of chemicals in the assessment process		All Chemicals	From ICCA Initiative
Information gathering and data review		308	187
Assessment Report prepared for SIAM		28	20
Assessment Report discussed but not agreed		25	14
Conclusions published but Assessment Report not yet available	Assessment Report not received	161	145
	Assessment Report received	47	30
	Awaiting national publication	4	-
Conclusions and Assessment Report published		804	518
Report published and further work underway		-	-
	Total (Assessments)**	1377	914
	Total Chemicals	1372	913

^{**} Includes chemicals being re-assessed but not chemicals that have been provisionally set aside. "Total Chemicals" includes 7 chemicals that have been provisionally set aside.

- 37. The 1990 Council Act indicated that all results of the SIDS process should be publicly available. The OECD makes all information available through its **Existing Chemicals Database** (see Reference 25) and has worked with UNEP to ensure a global dissemination of the data and assessments. Data and assessments are now also made world-wide available through the OECD **eChemPortal** (see paragraphs 66 and 67 and Reference 23).
- Based on developing IT possibilities, a number of important innovations have taken place in the way the existing chemicals investigation was carried out. The assessment process was made faster and more efficient through the use of the newly developed OECD (Q)SAR Toolbox (see paragraph 458 and 59 and Reference 28), which made it possible to also assess categories of chemicals with a resemblance in their chemical structure, rather than having to assess each chemical individually. Further changes mean that in the future (i) not only HPV chemicals, but also non-HPV chemicals can be assessed co-operatively, (ii) the industry can directly submit draft assessments, (iii) targeted assessments for chemicals and chemical categories, focusing on specific toxicological endpoints, can be elaborated, and (iv) national or regional assessments can be "internationalized" through review in the OECD context. By implementing these changes more chemicals can be assessed in a shorter period of time.

Chemical Accidents

- 39. In 1987 after major accidents with releases of hazardous chemicals from production sites in both Bhopal, India (December 1984) and Schweizerhalle, Switzerland (November 1986), member countries asked the OECD to start work related to chemicals in hazardous installations. The Chemicals Programme reacted quickly and the first results of this work were discussed at a High Level Conference on Accidents involving Hazardous Substances early 1988. At this Conference agreement was reached on a number of issues, later reflected in two OECD Council Acts: the Council Decision on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage [C(88)84 and the Council Decision-Recommendation concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances [C(88)85]. A Chemical Accidents Programme to undertake further work was started at the OECD.
- 40. The main element of this further work was the development of Guiding Principles for Chemical Accident Prevention, Preparedness and Response. The application of these Guiding Principles is encouraged in Council Recommendation on Chemical Accident Prevention, Preparedness and Response from 1992 [C(92)1]. The Principles describe the responsibilities of all parties involved in production, use and handling of hazardous chemicals. The Guiding Principles continue to be expanded and updated. Related work included the development of Safety Performance Indicators, which are also regularly updated, and which can be used by public authorities and communities and the public, as well as by the industry to help in measuring the effectiveness of activities related to the safety of hazardous installations; the most recent navigable web version dates from 2008. The Council Recommendation is also updated to reflect the latest experiences in the field and to refer to the Safety Performance Indicators [C(2003)221].
- 41. Further work on chemical accidents addressed the allocation of the costs of reasonable measures to prevent accidents in hazardous installations and limiting their consequences, leading to the 1989 Council Recommendation on the Application of the Polluter Pays Principle to Accidental Pollution [C(89)88]. Together with the European Commission an accident reporting system was set up to exchange information on causes of accidents and lessons learn from each other's experience. Together with UNEP an International Directory of Emergency Response Centres is maintained. The Chemical Accidents programme continues its work to keep the international knowledge on chemical accident prevention, preparedness and response at a state of the art level and is organising regular workshops which bring together experts in order to achieve this. Currently 28 documents on Chemical Accidents are available (see Reference 4).

Nanomaterials

42. By changing matter at the atomic and molecular scale, nanotechnologies are able to create materials with new types of properties which could be useful in a vast range of <u>applications</u>, such as in <u>medicine</u>, <u>electronics</u>, strong lightweight materials and energy production. However, owing to these new properties, nanotechnologies raise many of the same issues as most new technologies did in the past, including concerns about the potential effects of nanotechnology products on health and the environment. In the early years of this decennium some products derived through nanotechnologies were put on the market. It is not clear, however, that the testing and assessment methods which have been used traditionally for chemical products, are always adequate for determining the safety of nanomaterials. Member countries consider that the application of nanomaterials has the opportunity to provide great benefits for society, but that at the same time as these new technologies are being developed, the safety implications have to be thoroughly investigated. In that way, when large volumes of manufactured nanomaterials reach the market, there is a better insight into the possible risks for man and the environment. In order to address the regulatory aspects of dealing with the safety aspects of manufactured

nanomaterials, member countries reacted quickly, and OECD began work in 2005. Non-members and all other stakeholders were also involved. The work is well co-ordinated with the activities aimed at looking into the applications which can be derived from nanotechnologies, and with work undertaken in other intergovernmental organisations and in international organisations, such as the ISO (International Organisation for Standardisation).

- 43. The work in the Programme on the Safety of Manufactured Nanomaterials addresses many aspects of the safety issue. It includes a database on relevant environment, health and safety research, which can help to co-ordinate research activities; work on test methods, including alternative methods, on exposure measurement and mitigation, and on co-operation on risk assessment and risk management, such as on voluntary schemes and regulatory programmes. Countries also work together on environmentally sustainable use of nanotechnologies. **Results are reflected in the Series on the Safety of Manufactured Nanomaterials which currently includes 28 documents** (see Reference 13).
- 44. A special and important activity is the Sponsorship Programme on the Testing of Manufactured Nanomaterials. In this activity, which was started in 2007, a number of member countries, as well as some non-member countries and other stakeholders pool expertise and fund the safety testing of 13 different types of specific nanomaterials. Tests are done for 61 properties and effects, covering material identification, characterization and safety, physical-chemical properties, environmental fate, environmental toxicology, and mammalian toxicology. The nanomaterials which are tested are well known and some of them are already in use, so the information which is being generated is of great practical value for further safety assessments. The main purpose of this work, however, is to evaluate the extent to which current test methods which are traditionally used to determine product safety, are adequate for testing the safety of nanomaterials. Based on the outcomes of this work it will be possible to see if existing methods can be used, or if they need to be adapted or if new ones need to be developed in order to be able to appropriately evaluate the risks of manufactured nanomaterials (see Reference 13). If new Test Guidelines need to be developed, this will be undertaken in OECD in co-operation with the Test Guidelines Programme.

III Beyond Industrial Chemicals: Environment, Health and Safety

45. In the early 1990s member countries provided extra-budgetary contributions to the Chemicals Programme, to take up a number of issues dealing with the safety for man and the environment of materials other than industrial chemicals. Member countries agreed to expand the scope of the tasks of the Chemicals Programme because they considered that much of the methods, instruments and policies developed for dealing with the safety of industrial chemicals, could apply also to the other materials. Another reason was that the Chemicals Programme had been particularly successful in harmonisation efforts based on scientific considerations, so countries wanted to make use of this type of experience of the Chemicals Programme in other fields. The Chemicals Programme was in 1992 renamed the Environment, Health and Safety Programme. Additional areas covered were pollutants, and the safety of pesticides, biocides, genetically modified organisms and novel foods and feeds.

Pollutant Release and Transfer Registers

46. In the early 1990s many countries became interested in setting up and using a Pollutant Release and Transfer Register (PRTR). A PRTR is an environmental database or inventory of potentially harmful releases to air, water and soil. Data concerning releases and transfers, such as the type, quantity and affected environmental media, have to be reported by the facility. This information is then made available to the public, so that the public can first of all compare the environmental performance of facilities, and secondly engage in discussions with the facility about improvement of its performance. Governments

provide the legal context for this system, decide for which pollutants and under which conditions facilities have to report, and facilitate the dissemination of the information.

47. In 1996 a Guidance Manual for Governments to help them set up PRTRs was developed at the OECD. A 1996 Council Recommendation on Implementing PRTRs, which was updated in 2003, recommended countries establish PRTRs, use the Manual and, in doing so, follow a set of principles established in the Council Act [C(96)41/FINAL; updated C(2003)87]. The OECD has continued work to help countries with implementing PRTR systems. The OECD website hosts a **PRTR Data Centre**, which is a database set up to share PRTR data as widely as possible within the OECD area (see Reference 26). Another tool for countries is the web-based **PRTR Resource Centre for Release Estimation Techniques**, which gives guidance on making estimates when measured data are not available; these techniques cover point sources, diffuse sources and of-site transfers (see Reference 27). **Currently 11 documents which provide further guidance are available in the Series on PRTRs** (see Reference 16).

Pesticides

- 48. The registration requirements and dossiers for pesticides are very large and include many test results which are evaluated by scientists in the registering country. The same pesticides are often used in many countries, but the evaluations are done in each country by national institutions. In the early 1990s OECD investigated the handling of a number of pesticides in various countries, and it turned out that there were many similarities. This led countries in 1992 to establish a Pesticide Programme with the main aim to improve the efficiency and effectiveness of their pesticide registration processes. The work focused on facilitating a certain extent of harmonisation in registration practices and on building up mutual confidence in national evaluation practices, which is needed for governments in order to engage on a large scale in work sharing in pesticide (re)registrations. A further task was related to the reduction of risks of pesticide use. The Pesticides Programme covers both chemical and biological pesticides used in agriculture.
- A large number of practical harmonisation results were achieved by the Programme; examples include formats for industry data submissions and for government data reviews, registration requirements for macrobial and microbial pesticides and for pheromones and a database of national review schedules which enabled countries to identify opportunities for co-operation. Thanks to this work a considerable amount of work sharing has taken place among countries. The Programme also worked with FAO and WHO to promote in these organisations the use of OECD harmonised country reviews for their review processes. In order to support pesticide risk reduction efforts, pesticide risk indicators were developed and the underlying pesticide use and sales statistics were collected. Together with FAO, work on Integrated Pest Management was undertaken, and together with FAO, UNEP and the OECD Development Assistance Committee, the problem of obsolete pesticide stocks in developing countries and economies in transition was addressed.
- The Pesticide Programme continues to work on assisting the countries with work sharing and with pesticide risk reduction. It has also taken up a number of other topics. For example, a Guidance Document has been prepared in the field of defining minor uses of pesticides and a survey of Maximum Residue Limit (MRL) policies has been made. In order to support the work of countries in setting such MRLs, also Test Guidelines for residue testing have been developed and included in the MAD Council Decision. Currently 9 such Test Guidelines are available. The Programme has also worked on electronic tools for data submission in registrations. In total 96 documents have been produced, including 55 in the Series on Pesticides (see Reference 15).

Biocides

Building on the useful results produced by the Pesticide Programme, member countries asked in 1996 that the OECD start similar work on biocides. Biocides are chemical products which are, like pesticides, designed to destroy unwanted organisms, but not in relation to crops; examples are disinfectants and sterilizers. In most countries, these products fall under different regulatory regimes than pesticides, but they also have to be registered. The Biocide Programme assists countries and industry to increase the efficiency of biocide registrations and to reduce risks of biocides use. One focus is on the harmonisation of the testing for efficacy of biocidal products. Another is exposure assessments; four Emission Scenario documents have been developed specifically for biocides. A database with the schedules of registration reviews is an important tool in facilitating work sharing. There are 11 documents available which specifically address biocides (see Reference 3).

Harmonisation of Regulatory Oversight in Biotechnology

- Since the 1980s many countries have been developing methods to assess the environmental risks of products derived from modern biotechnology, such as crop plants, and considering if risks are posed, which risk management actions would need to be taken based on the assessments. While policies among OECD countries differ considerably with respect to management issues, with regard to the assessment practices the science applied in the countries do not diverge much. The EHS Programme had a lot of experience in working on the international compatibility of science based assessment methods for chemical products, and in generating efficiencies through work sharing. Therefore member countries asked in the mid-1990s the EHS Programme to work, with similar objectives, in the field of biosafety. This was done in the Programme on Regulatory Oversight in Biotechnology. From the beginning the work was closely coordinated with work related to biotechnology going on in other Directorates and with the UN Convention on Biological Diversity (CBD). In addition several non-members which had expertise in biotechnology were involved (such as Argentina, Brazil, China, India, Russia, South Africa, Thailand and others).
- 53. A first achievement of the biotechnology work was the creation of the BioTrack On-Line information system which gives easy access to safety information for products that have been approved for commercialisation. BioTrack is regularly updated and uses the Unique Identifiers for biotechnology products which have been developed in OECD and are now used globally; relevant information is transferred to the Biosafety Clearinghouse of the CBD (see Reference 22). Other key outputs of this Programme include the so-called Consensus Documents. These documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognized among OECD member countries. They focus on the biology of organisms (crops, trees or micro-organisms) or introduced novel traits. They are continually updated to take account of new knowledge. Work on a consensus document on the biology of Atlantic salmon, the first such document on a genetically modified animal species, is in progress. A further strand of work focuses on the molecular characterization of plants derived from modern biotechnology, which brings together information that provides knowledge at the molecular level and is very valuable for making rigorous assessments of the transformations that have occurred in organisms. The Biotechnology Programme has currently produced 86 documents, including 51 Consensus Documents (see Reference 10).

Safety of Novel Foods and Feeds

54. In light of the useful products delivered by the biotechnology work, member countries agreed in 1999 to start work at the OECD on the safety of novel foods and feeds. The main focus has been on foods and feeds which are derived from products of modern biotechnology. The work is undertaken in close coordination with the work on Regulatory Oversight in Biotechnology. The OECD had already elaborated an approach to safety assessment based on **substantial equivalence** as being a practical way to address the

safety of foods and food components derived through modern biotechnology. In order to facilitate determination of substantial equivalence, information is collected on the major components of specific crop plants, such as key nutrients, toxicants, anti-nutrients and allergens at the time of the harvest (fresh), as well the uses as a food or feed. The information obtained is reflected in Consensus Documents which are developed to assist countries in the regulatory assessment of food and feed products and to promote harmonisation. The work is undertaken in co-operation with the UN Codex Alimentarius Commission. The Novel Foods and Feeds work has currently produced 22 Consensus Documents (see Reference 18).

IV Innovations, Special Projects and Outreach

New methods and regulatory acceptance

Animal welfare

- 55. From the beginning, the work on chemicals testing at the OECD has been undertaken with a firm commitment to animal welfare following the so called 3R principles of Replacement, Reduction and Refinement in safety tests using experimental animals. In 1982 already, at the second High Level Meeting on chemicals, the importance of animal welfare in chemicals testing was recognized by Ministers and other policy makers in a special statement. Obviously the MAD system already contributes substantially to animal welfare by avoiding duplicative testing. The OECD continues to look for possibilities to update its existing Test Guidelines with animal welfare considerations in mind. Furthermore many new *in vitro* Test Guidelines have been developed and designed especially to reduce the use and suffering of experimental animals. Another approach is the design of methods in such a way that tiered testing is facilitated, which means that not in every case would all testing be needed to obtain enough reliable information on a certain toxicological endpoint.
- A crucial issue in addressing animal welfare in the OECD Test Guidelines is the regulatory acceptance of new tests. Regulators make their decisions concerning risk management to a large extent based on information derived from tests in which they have confidence, because they have been used for a long time and there is a lot of experience with interpreting the test results. It will take some efforts to build up the same level of confidence for alternative tests. Therefore, in order to establish whether a new test method is suitable for a given regulatory purpose, it needs to go through a validation process. Such a process is based on scientifically sound principles by which the reliability and relevance of a particular method is established for a specific purpose. It is therefore important that in OECD a set of **principles and criteria for validation of new or updated test methods**, whether they are *in vivo* or *in vitro*, can be agreed. As a result a more harmonised validation and regulatory acceptance procedure has been achieved at the OECD and the Test Guidelines Programme can therefore be at the forefront of developing alternative methods which help to address animal welfare aspects (see Reference 2).
- 57. In early 2010 the Joint Meeting held a Focus Session devoted to "Current and Forthcoming Approaches for Chemical Safety and Animal Welfare". The Joint Meeting confirmed that the OECD has a key and unique role to play in developing tools to evaluate chemical safety, thereby helping to protect human health and the environment. It also agreed that recently developed methods, such as the (Q)SAR Toolbox and *in vitro* tests, constitute considerable progress for regulatory use as well as for animal welfare. The meeting also considered that molecular screening (which relies on high throughput *in vitro* methods) holds further promise to increase the protection of human health and the environment, while at the same time contributing to animal welfare.

(Q)SAR Toolbox

- Using computational methods to estimate physical-chemical and biological properties of chemicals based on characteristics of the molecular structure has been a research topic since the early 1960s. In some countries such (Quantitative) Structure-Activity Relationships (Q)SARs) have been applied for certain aspects in the safety assessment of chemicals. If such methods could be applied more widely and internationally, this would have many benefits in terms of efficiency and animal welfare. Since the mid-1990s OECD has worked on determining the international applicability of (Q)SARS, based on national experiences. Again validation of the methods is crucial to achieve this. The OECD principles for the validation of (Q)SAR models were agreed in 2004. This meant that OECD could productively start work on facilitating the acceptance of (Q)SARs for regulatory uses. To this end the OECD (Q)SAR Toolbox was developed.
- The Toolbox is a software application which can be used by scientists in governments and from other stakeholders to fill gaps in data needed for the assessment of chemicals. Another main use of the Toolbox is that it allows chemicals to be grouped whose (eco)toxicological properties are expected to follow a regular pattern because of their similarity in chemical structure. By using this "category" approach, each chemical does not need to be tested for every toxicological endpoint. This is because the available test results for certain chemicals in the category, allow a well-considered estimation of the results for the untested chemicals by interpolation, extrapolation or other ways of reading across results. This way of working has in recent years successfully been used at the OECD co-operation on the investigation of HPV chemicals. The OECD (Q)SAR Toolbox can be downloaded free of charge from the OECD website. A first version was released in 2008, and version 2.0 in 2010 (see Reference 28). The OECD (Q)SAR Toolbox has definitely helped to make the use of (Q)SARs transparent, less demanding in terms of infrastructure costs and readily internationally accessible.

Toxicogenomics

60. Another new development which has great potential for efficient use in chemical safety assessment is toxicogenomics. This methodology, which combines toxicology with genomics and bioinformatics, attempts to derive molecular expression patterns (molecular biomarkers) that predict toxicity or the genetic susceptibility to it. It has been used in the pharmaceutical industry and in the US government for "high throughput screening" of chemicals for certain properties. While toxicogenomics has not yet been used to make regulatory decisions, the information it provides could contribute to elucidating certain mechanisms of toxic action. The OECD started activities in this field, some of which were undertaken in co-operation with WHO, in 2004 with the aim of developing a strategy concerning the future application of toxicogenomics in regulatory assessment of chemical safety. The OECD surveys the available toxicogenomics tools, and in 2007 a project was started on the use of molecular screening for characterizing individual chemicals and chemical categories with respect to potential toxicity. While currently the use of toxicogenomics in a regulatory context is still very limited, the OECD still considered it useful to take a pro-active approach and start this cutting edge work in view of the potential of this technology. When fully developed, it could be a useful method for chemical screening, hazard identification and characterization and it could provide a cost-effective approach for hazard prioritization of large numbers of chemicals in a short period of time (see Reference 22).

Integrated approaches to testing and assessment

61. One challenge which is faced by all involved in making assessments on the safety of chemical products is finding ways to make the time-consuming process more efficient, while at the same time maintaining its scientific rigour. The exposure assessment methods have over the years improved a great deal (ESDs, multimedia models) and there are more tools available for the effects assessment (in vitro

tests, tiered testing systems, (Q)SAR Toolbox, read across, category approaches, and to some extent toxicogenomics), so there are possibilities to address this challenge. This means that the way assessments are being done could be reconsidered and that an assessment strategy could be developed which would allow, in a scientifically sound way, the use of all the information elements and tools that are available in a structured framework. Test strategies have already been introduced in a number of Test Guidelines (for example skin irritation/corrosion) and in the Guidance for applying Conceptual Framework for the Testing and Assessment of Endocrine Disrupters. This will help to make choices about what to study further after the initial tests, but integrated testing and assessment approaches could certainly go much further in this direction.

- 62. The OECD has been working since 2006 to assist countries in applying more of an integrated approach. A Workshop held in 2007 to exchange experiences among countries in this field resulted in 21 concrete recommendations and their implementation has been taken up in the OECD work on assessment methods (see Reference 12). In 2010, an OECD workshop was held on using mechanistic information for forming chemical categories to fill data gaps (by read-across) and how this could be used for regulatory purposes. The workshop specifically investigated how Adverse Outcome Pathways (AOPs) can be used to form toxicologically meaningful categories. AOPs are descriptions of plausible causal linkages that illustrate how a chemical interaction with a biological system at the molecular level causes biological effects at the sub-cellular, cellular, tissue, organ and whole animal levels of observation
- 63. Regulatory acceptance of new approaches is crucial. Regulators should feel comfortable that such approaches form a reliable basis for their risk management decisions. Therefore it should always be ensured that all assessment information used is still independently verifiable, reproducible and transferable, and that transparency in communicating the basis for management decisions to stakeholders and the general public is maximized. The OECD work on integrated and new assessment approaches effectively will constitute the start of a long term and iterative process in which regulators and scientists work together to ascertain regulatory acceptance of such approaches.

Special projects

OECD Environmental Outlook for the Chemicals Industry

The OECD published its first Environmental Outlook (to 2020) in 2001, followed by a second Environmental Outlook to 2030 in 2008. Chemical safety is obviously an important element in these outlooks, given that in both of them "Chemicals in the environment and in products" was listed among the limited number of "red light issues", which are those that require the urgent attention of policy makers. In order to support the first Environmental Outlook in 2001, the EHS Programme produced in 2001 the "OECD Environmental Outlook for the Chemicals Industry", looking forward to the year 2020 (see Reference 30). The report documented the expected changes for the period in the chemicals industry and the projected shift in production from OECD countries to non-members. The challenges for global chemical safety resulting from these findings were analyzed. The four main conclusions were that (i) an increased focus was needed to determine the safety of chemicals in products, (ii) the industry had to take full responsibility for the safety of its products and play a greater role in providing and assessing safety data, (iii) chemical safety information should be disseminated more widely, so that workers and the public could be given a more active role in monitoring chemical safety discussions, and (iv) there needed to be a greater focus on working with non-members to assist them in establishing their chemical safety infrastructures. The report has been instrumental in influencing discussions about future chemical safety policies around the world. While the report itself was not updated for the 2008 Environmental Outlook, the chapter on chemicals in that Outlook provides updated summary information. One of the key messages is that the information on the risks to health and the environment posed by the production and use of chemicals can still be improved in terms of quantity and quality.

Cutting Costs in Chemicals Management

The EHS Programme has worked since 1978 to achieve its dual objectives: helping countries in protecting man and the environment from the risks of chemical products (by producing high quality tools) and at the same time helping countries to do that in the most efficient way. The MAD system contributes a lot to fulfilling these objectives, because it avoids duplicative testing efforts. The work sharing approaches for assessing HPV chemicals, pesticides and biocides are other examples of EHS Programme efforts that gave rise to immediate efficiencies. In 1998 an effort was made to quantify these efficiencies in monetary terms in the report "Savings to Governments and Industry Resulting from the OECD EHS Programme". There are of course also many non-quantifiable benefits resulting from the EHS Programme, such as cooperation in developing the testing and assessment methods and guidance documents, animal welfare improvements, mutual exchange of experiences among countries, minimizing non-tariff barriers to trade as well as creating a level playing field for industry regarding chemical safety issues. The report, however, only looks at real quantifiable net savings, and was based on information obtained from countries on their costs to participate in the EHS Programme and on information from industry and test laboratories on the costs of testing and assessment. Conservative assumptions were made about (i) the number of different systems at the OECD which would require different tests if MAD did not exist – only three systems are assumed, and (ii) the level of acceptance of tests among countries if MAD did not exist - it was assumed that 65% of the tests would still be accepted. In 2010 this report was updated because since 1998 the chemicals industry has more than doubled in size and cost of safety testing has increased considerably. This update, in the report "Cutting Costs in Chemicals Management" was published in 2010 (see Reference 29). The conclusion of this report is that the overall net savings for government and industry resulting from the EHS Programme are € 153 million/year. This includes €147 million/year of savings generated through MAD alone. Another interesting point made in the report is that, while global chemical production has increased by 135% since 1998, and with savings with 164%, the Secretariat costs only increased by 8%.

eChemPortal

- 66. In 2002, the World Summit on Sustainable Development (WSSD) in Johannesburg requested "the development of coherent and integrated information on chemicals" with the aim "to support developing countries in strengthening their capacity for the sound management of chemicals". In order to respond to this request, the OECD initiated in 2004 the development of a global portal to safety information on chemical substances the eChemPortal. The relevance of this initiative was confirmed in 2006, at the International Conference on Chemicals Management in Dubai, where Ministers indicated they wanted to "facilitate public access to appropriate information and knowledge of chemicals throughout their life cycle, including the risks that they pose to human health and the environment". In developing the eChemPortal, the OECD Secretariat is working with several member countries (the United States, Japan, Canada), the European Commission, the European Chemicals Agency, the International Council of Chemical Industry Associations, the Business and Industry Advisory Committee, WHO, UNEP and Environmental NGOs.
- 67. The eChemPortal allows simultaneous searching for properties and effects data in information collections on chemical hazards and risks which have been prepared for government chemical review programmes at national, regional and international levels. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are provided when available. Currently the eChemPortal links to 16 major databases of countries, the European Commission and WHO, and to the OECD databases. The eChemPortal can be searched for information by chemical number, chemical name and synonym, including partial names, in several languages. **The first version of the eChemPortal was made available in 2007; a second version in 2010** (see Reference 23). Currently the eChemPortal is hosted by the European

Chemicals Agency, while further technical work is managed by the OECD. There will be an incremental build-up of the functionality of the eChemPortal. Other databases will be added. By providing direct access to critical scientific information needed to meet public health and environmental objectives for the safe use of chemicals, the eChemPortal contributes in a major way to the global challenge of making chemical safety information more widely available and better accessible.

Reports on Biotechnology and Food Safety to the G8 Heads of Government

- In June 1999 the G8 Heads of Government met in Cologne. At that meeting they noted (among 68 other things) that, "because trade is increasingly global, the consequences of developments in biotechnology must be dealt with at the national and international levels in all the appropriate fora". The leaders all agreed that "in the light of increasing importance of issues concerning food safety, we invite the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds to undertake a study of the implications of biotechnology and other aspects of food safety". The G8 invited OECD experts to report to them on "possible ways to improve the approach to these issues through international and other institutions, taking into account the reflections underway in other fora". The OECD Working Group and Task Force then each produced a report which was submitted to the G8 Heads of Government meeting in July 2000 in Okinawa (see Reference 31). A third report was prepared by an OECD ad hoc Group on Food Safety. The G8 concluded that "engaging all stakeholders and including both developed and developing countries, must be intensified to advance health protection, facilitate trade, ensure the sound development of biotechnology, and foster consumer confidence and public acceptance" and that the OECD reports "represent a useful step in this direction". They further noted "with approval that the OECD will continue to undertake analytical work and to play an effective role in the international policy dialogue on food safety, maintaining its engagement with civil society and seeking to share its work in this area with countries outside the organisation's membership. Drawing on its comparative advantages, the work of the OECD will effectively complement the activities of other international organisations, in particular the Food and Agriculture Organisation (FAO) and the WHO".
- The OECD followed up this initiative by organising, in co-operation with the United Kingdom and FAO in July 2001 in Bangkok a Conference on "New Biotechnology Food and Crops: Science, Safety and Society". The Conference was concluded with recommendations that all stakeholders commit to greater transparency on genetically modified organisms. They also agreed that governments should increase their support for independent and publicly funded scientific research into the risks and benefits of genetically modified crops and foods derived thereof. Later in July 2001 the G8 Heads of Governments, at their meeting in Genoa, Italy, welcomed "the outcome of the recent Bangkok conference on new biotechnology food and crops and the ad hoc meeting of regulators from OECD countries and Russia" and they encouraged "the relevant international organisations to follow up to the conference, as appropriate, within their own respective mandates". Until now the OECD has continued its work on the safety aspects of biotechnology and novel foods and feeds. The request of the G8 leaders to these two OECD/EHS Programmes, at a time when the international debates about the safety of modern biotechnology were particularly intense, was an important token of recognition for the work which the experts were undertaking and it remains an important inspiration to continue working in the same vein.

Outreach: global relations and stakeholders

70. Since the early 1990s the EHS Programme has been very open to involving non-members and stakeholders in its work. The need for such engagement was underlined in 2001 by the analyses undertaken for the OECD Environmental Outlook for the Chemicals Industry which highlighted the ongoing shift of production to non-members. Adherence to the MAD Council Decisions is a key example of the involvement of non-members. This was made possible through a specific Council Decision [C97)186] and

has led to the adherence of 9 non-members: Israel and Slovenia (at the time when they were not yet OECD members), Brazil, India, Singapore and South Africa (as full adherents) and Argentina, Malaysia and Thailand (as provisional adherents, on the way to becoming full adherents). Adhering countries can automatically participate in the work on Test Guidelines and GLP and in those parts of the Joint Meeting which deal with these issues.

- Also in other EHS Programmes non-members participate actively. Examples are the work on the safety of biotechnology and novel foods and feeds; in each activity, in addition to Russia (which is in the process of OECD accession) 5 7 non-members participate. Some non-members have ensured a regional input to the work of the OECD by taking the initiative to co-ordinate with neighbouring countries in the Southern African or the South-East Asia areas. Another example of active non-member participation is the work on manufactured nanomaterials. In the sponsorship programme which is part of this work, China has taken up the responsibility as sponsor for the testing of one of the materials and as contributor to five other materials. In general, the participation of the Enhanced Engagement countries (Brazil, China, India Indonesia, South Africa) in the work of the Joint Meeting and its subsidiary bodies is actively promoted.
- OECD work has not only been of use to its members and a limited group of non-members. The United Nations has also used OECD concepts and products and given them global application. One important example is the *Council Recommendation on Information Exchange Related to Export of Banned or Severely Restricted Chemicals* [C(84)37]. This Council Act was the basis for the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, which was adopted in the UN in 1998 (see Reference 34). The OECD work on harmonisation of classification and labelling regarding the human health and environmental hazard criteria was an important basis for the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which was adopted in July 2003 by the UN Economic and Social Council (see Reference 32).
- 73. The EHS Programme has actively contributed to global chemical safety initiatives. This includes the UN Intergovernmental Forum on Chemical Safety (IFCS), since it was established in 1994, and the *UN International Conference on Chemicals Management (ICCM)*, which first met in 2006 in Dubai to set up the voluntary **Strategic Approach to International Chemicals Management SAICM** which succeeded the IFCS (see Reference 35). In early 2008 the OECD Council adopted a Resolution on the Implementation of SAICM which made SAICM implementation an integral part of the OECD Chemicals Programme and made the commitment to contribute to national and international SAICM implementation initiatives [C(2008)32]. Accordingly the EHS Programme has continued to provide inputs and documents to SAICM. It has a leadership role in two of the five emerging policy issues SAICM is addressing: i) nanotechnology and manufactured nanomaterials; and ii) Perfluorinated Chemicals. The OECD is providing input to a third issue, chemicals in products. The development of the eChemPortal is a further very important contribution of the OECD to the global calls of leaders and Ministers to make crucial chemical safety information accessible to all.
- 74. With respect to working with other intergovernmental organisations (IGOs), the OECD is a very active participant in **the Inter-Organisation programme for the sound Management of Chemicals IOMC.** This is a unique arrangement established through a formal Memorandum of Understanding, which brings together FAO, ILO, OECD, UNDP, UNEP, UNIDO, UNITAR, WHO and the World Bank to coordinate their chemical safety activities (see Reference 33). In this way duplicative activities can be avoided, mutual participation of the relevant IGOs in each intergovernmental activity can be arranged in order to ensure that they complement each other and in large international meetings, such as the ICCM, the nine IGOs speak with one voice. For those projects of the participating IGOs which are on an IOMC agreed list of activities, reports can be published with an IOMC logo. This has helped very much in ensuring a wider acceptance for the products of the participating organisations, than just by their regular constituency.

- 75. In the IOMC framework the OECD plays a lead role, in co-operation with the other participating organisations, in the development of an internet based Toolbox for Decision Making in Chemicals Management. The Toolbox takes into account the SAICM context and has the aim of helping countries identify practical and cost-effective chemical management options to address national concerns, using the available resources developed by the IOMC participating organisations. There is a focus on bringing together available information and providing tools for hazard identification (for example through the GHS), priority setting and management options based on hazard assessment.
- 76. In addition to the IOMC co-ordination, the EHS Programme also co-operates directly with other IGOs on a variety of topics. The following are just some examples. There is continued co-operation with the UN on updating of the GHS criteria and developing new ones. With the WHO a long-standing co-operation exists in the field of human health hazard and risk assessment. There has been joint work with UNEP, in the areas of lead in gasoline, multimedia modelling for the transport of persistent substances and the publication and dissemination of SIDS Initial Assessment Reports. With FAO, through the years good co-operation has taken place in the fields of pesticides, food safety and biotechnology. The OECD also works with the ILO and UNITAR in a WSSD partnership project on the implementation of the GHS. The OECD and UNITAR have also recently started to work together on the SAICM emerging policy issue of nanotechnology and manufactured nanomaterials by holding workshops in five UN regions to raise awareness about this topic.
- 77. The EHS Programme has had involvement from the stakeholders from the beginning, very actively, and since the early 1990s through their participation in almost all Programme meetings. Many of the methods which are developed and agreed by the Programme to a large extent, have to be used by industry. It therefore made a lot of sense to involve industry expertise in the development of such methods. A main commitment to the work of the OECD was made in 1998 by the global chemicals industry through the International Council of Chemical Associations ICCA. The ICCA members set themselves a goal to complete for 1000 HPV chemicals the SIDS information and assessments and to provide this as an input to the OECD Existing Chemicals Programme. Currently 913 SIDS Dossiers have been received by the OECD and this constitutes 67% of the chemicals which are included in the SIDS assessment process.
- Other stakeholders outside of the industry have also made valuable contributions to the work. For this reason, at all of the EHS Programme meetings, not only industry experts (through BIAC) are invited, but experts from trade unions (through TUAC) and civil society NGOs (through the EEB, which for this purpose co-ordinates for all of the OECD countries, rather than only for Europe). In 2002 animal protection NGOs organised themselves in the International Council on Animal Protection in OECD Programmes (ICAPO) in order to seek "to ensure the widest possible integration of alternative methods in the OECD's influential guidelines and programmes". ICAPO experts participate in the EHS Programme meetings which deal with issues where animal protection is an element of the discussions. While the stakeholders participate as experts in most of the meetings of the EHS Programme and contribute very much to the quality of the products by giving their advice and opinions, obviously it is only the OECD member countries that make the final decisions about methods, guidance and work programmes.

V Achievements, Strengths and Opportunities

79. In the previous sections the story of how different work areas have developed has been told and many of the products of the Programme have been specifically highlighted. In this section a more general overview of the EHS Programme is provided. First a summary of the main achievements of the programme is given along with the benefits it has provided for countries and stakeholders. An analysis is then made of the strengths it has demonstrated, its weaknesses and the challenges it faces. Finally an assessment is made of the potential and the opportunities it has to continue to be relevant for countries and stakeholders in the future.

Achievements of the EHS Programme

- 80. The following text summarise the major achievements of the EHS programme to date:
 - the many **instruments**, **methods**, **guidance documents and databases** which are of practical use to member countries, non-members and stakeholders in the protection of man and the environment from the chemical hazards (see References 1 and 22 31). All these products are freely available via the internet. Many member countries and the European Union have used these products directly as part of their regulations (for example the Test Guidelines and GLP as standards for testing), or they have used the EHS products as a basis for their regulations.
 - the harmonisation and compatibility of methods and practices achieved by using the products of the Programme. Harmonisation has led to savings of at least €153 million/year for governments and industry and it has greatly contributed to limiting the use of laboratory animals by avoiding duplicative testing. Another aspect of harmonisation is that throughout the OECD there is a consistency in the quality of instruments which are being used and therefore scientists in countries are better able to compare their work based on a similar quality standard. Furthermore a certain level of harmonisation is needed as a basis for work sharing among countries. Where full harmonisation could not be achieved, guidance prepared at the OECD has promoted at least compatibility of practices and approaches.
 - the minimization of non-tariff barriers to trade was another result of the harmonisation work at the OECD. Differing regulatory requirements in notification and registration processes could form severe trade barriers and cause important delays in products coming to the market. Similarly differences in classification and labelling practices have proven to constitute serious impediments to trade. By harmonising as much as possible regulatory requirements and practices, trade barriers were limited and a level playing field for industry was established.
 - the work sharing that is facilitated. Working together on developing methods and guidance, rather than doing this nationally, brings efficiencies, because expertise which might not exist in one country is brought into the process by others. Work sharing which is undertaken directly through the EHS activities is achieved in a major way with the SIDS assessments for HPV chemicals and the development of consensus documents in the biotechnology and food safety areas. In the field of new chemicals notifications and pesticides and biocides registrations the EHS work was essential for building up confidence among countries in their mutual practices and facilitating work sharing processes.
 - the active **outreach** which has helped to promote a global convergence in chemical safety policies, and has helped to avoid large policy differences among OECD countries as well as non-members, the involvement of selected non-members in the work, the close co-operation with other IGOs and the active participation in events and programmes of the UN, have all contributed greatly to a wide acceptance of the concepts for implementing chemical safety policies as they have been developed over the years at OECD. The criteria for the Globally Harmonised System for classification and labelling of chemicals and the *Council Recommendation on Information Exchange related to Banned and Severely Restricted Chemicals* are examples of direct input provided by the EHS Programme to the UN. The work of the EHS Programme has made important contributions to the implementation of a number of political agreements, such as:
 - o Chapter 19 of UNCED's Agenda 21 adopted in 1992 in Rio de Janeiro;
 - The Bahia Declaration on Chemical Safety, adopted by the Intergovernmental Forum on Chemical Safety in 2000 in Salvador;

- The OECD Environmental Strategy for the First Decade of the 21st Century, adopted by OECD Environment Ministers in 2001;
- o Paragraph 23 of the Johannesburg Plan of Implementation, adopted at the World Summit on Sustainable Development in 2002
- o The Strategic Approach to International Chemicals Management, adopted by the International Conference on Chemicals Management (ICCM) in Dubai in 2006.
- the possibility that is provided to countries for **co-ordination of policy action**. The OECD brings together the major players in the field of chemical safety in the American, European and Asia-Pacific parts of the world. When catastrophic events happen, such as chemical accidents, when new policy tools are developed, such as PRTRs, when international consideration of certain chemicals is needed, (such as for the Per-Fluorinated Chemicals), or when new technological developments require policy attention, (such as for biotechnology, novel foods or nanomaterials) working together at the OECD can be organised quickly. Such co-operation can help to provide an international framework for action, which is often helpful in a national policy setting.
- the constitution of a **forum for policy discussions and promoting mutual understanding**. Even if no co-ordinated action is agreed among countries (which for example has occurred at times in the risk management area), discussions at OECD help to create a better mutual understanding of different national positions.

The EHS Programme: Strengths, Challenges and Opportunities

Strengths

- 81. The following strengths of the EHS Programme can be identified:
 - it produces many **practical products** which are available free of charge and which help to protect man and the environment from the hazards of chemicals.
 - its **peer review** system ensures the high quality of these products.
 - its work has **economic benefits** and creates efficiencies for governments and industry in terms of monetary savings, work sharing and minimization of trade barriers.
 - there is a strong **commitment of member countries and stakeholders** to work together in the Programme and provide expertise and extra-budgetary resources to undertake a very large part of the work; without the contributions of the country and stakeholder experts, the Programme would not be able to produce many of its products.
 - the **setting of the Programme at the OECD** has a number of advantages: the major players are brought together in an efficient way; the opportunity the OECD offers to incorporate agreements in legally or politically binding Council Acts; the multidisciplinary nature of the OECD, which makes it possible to easily bring in other types of expertise (such as economists, development aid experts, science policy experts) which is useful for projects with a horizontal orientation; the solid framework OECD provides for the Secretariat function.
 - the **transparency** in its working methods, which is ensured by the involvement of stakeholders and by the wide possibility for many experts from around the world to comment on drafts, has helped to achieve a wide acceptance of the products of the Programme.

- the **global relations it maintains:** involvement of selected non-members, the co-operation with a number of UN organizations and programmes, the co-ordination of work through the IOMC in order to avoid duplication of activities.
- the capability it has to **identify emerging issues**.
- the possibility to **react quickly and in a flexible way** to take action when new policy issues come up and when new technological and scientific possibilities can be used.
- the networks of policymakers and experts which are established; the possibility to make
 personal contact with colleagues around the world works very efficiently in setting up bilateral cooperation or addressing bi-lateral issues.
- the possibilities it provides to **bring regulators and scientists together** to address the scientific basis of regulatory decisions and further the regulatory acceptance of new scientific approaches as a basis for decision making.
- the topic of chemicals in the environment has been identified in the OECD Environmental Outlook to 2030 as a "red light" issue, which means that it is considered to require urgent further attention from policy makers.

Challenges

- 82. Considering the work done so far in the Programme and looking at expectations for future activities, the following weaknesses and possible threats can be listed:
 - while the commitment of member countries and stakeholders to provide expertise and extrabudgetary resources for work in the Programme is listed as one of its strengths, in times of budgetary constraints, this dependence on such commitments in order to be able to produce high quality results, could also turn into a threat.
 - after 40 years of working on chemical safety, many of the "easy" issues have been dealt with and while for the remaining tasks international harmonisation and work sharing will continue to be as necessary as before, **the technical complexity will be increasing**, which will make the relevance of continued work on chemical safety more difficult to explain to policy makers.
 - the successful work in the EHS Programme has always been based on working towards agreement
 on instruments and policies based on scientific arguments. If the debates become more
 politicized, as was the case in discussions about possible OECD-wide agreements on risk
 management for specific chemicals, it could has turn out to be much more difficult to obtain the
 needed consensus.
 - the **shift in chemical production from OECD countries to non-members** can make the OECD less representative and less influential in the global setting when not enough attention is paid to outreach.
 - while obtaining consensus on methods and guidance is a necessity to ensure that these are also used in practice by all concerned, there is a risk that with the increasing complexity of issues and the increasing number of players involved, the process of obtaining consensus will become slower.

- while "chemicals in the environment" has been identified in the OECD Environmental Outlook to 2030, as one of the four "red light issues, the **competition for obtaining the attention of policy makers** is obvious, given that the other three red lights are climate change, biodiversity and water. In some countries policy makers might consider that after so many years of work, the chemical safety issue might have been dealt with adequately, and might be, despite its red light status, less of a priority.
- the difficulty of the monetary quantification of the effects of chemicals on human health and the environment, as well as of the impacts chemical safety policies have on avoiding such effects, can also result in a lower policy priority for chemical safety. Cost of inaction calculations, which have been politically influential in other areas of environmental policy, are difficult to carry out for chemical safety policies.

Opportunities

- 83. Major benefits for countries and stakeholders are derived from working together in the EHS Programme. However a number of opportunities to strengthen the Programme, and make it even more useful in the future, can be highlighted:
 - **globalisation** and global shifts in patterns of production of chemicals will mean that more countries will consider it prudent to set up chemical safety policies. It would be helpful for all concerned if chemical safety policies across the world continue to converge, rather than diverge. The implementation of the Globally Harmonised System for classification and labelling of chemicals will contribute quite substantially in this respect. Given the experience of OECD, the establishment of SAICM and the OECD Council Resolution supporting active OECD participation in SAICM, further co-operation with selected non-members in a global context could prove very useful. In addition, input to OECD work from non-member experts will contribute to increasing the quality of the products and make them more widely applicable.
 - while the issue of budgetary constraints of countries and stakeholders has been listed as a possible threat, it can also equally be perceived as an opportunity. This is because it will create the need to look for efficiencies in national budgets. This can be achieved through further OECD cooperation on method development and work sharing in assessment, notification and registration activities. A relatively small investment in international co-operation can be the way to obtain major efficiencies in the national setting. Given its track record, the EHS Programme is extremely well placed to assist countries in this respect.
 - many new methods which can improve the efficiency of the chemical safety management and contribute to progress in animal welfare are currently being developed. Examples are the *in vitro* test methods, (Q)SAR tools and toxicogenomics. **Continued harmonisation of new methods** will need to be achieved in order to ensure that the great potential provided by these methods for efficiencies, can also be realized in the future on an OECD-wide scale.
 - further efficiencies can be obtained by exploiting the possibilities offered by **information technology and computational methods**. The EHS Programme has been at the forefront of exploring these possibilities, which is reflected in products such as the eChemPortal, the Harmonised Templates for reporting of studies, and the(Q)SAR Toolbox. Based on the current experience of the EHS Programme further efforts to use information technology and computational methods to make efficiencies could be taken up. Examples of methodologies which could be explored in this context are high throughput screening and integrated approaches to testing and assessment.

- the EHS Programme could build on its unique capability to bring regulators and scientists together to work on achieving regulatory acceptance of new testing and assessment methods and approaches.
- the EHS Programme is very well placed to develop practical tools for use in decision making on the possibilities of **substitution of harmful chemicals by safer alternatives**. Such tools would not only include those for chemicals risk management, but also methods for socio-economic assessments, evaluating wider effects on the environment (such as life-cycle analysis and ecological footprinting) and concepts which are developed to achieve sustainability in an integrated way (such as Integrated Pollution Prevention and Control and Extended Producer Responsibility. The possibilities for obtaining from within OECD multidisciplinary inputs to chemicals related work is a major asset for such work.
- the relation between waste management, including 3R (Reduce, Re-use, Recycle) policies and material flows, and chemical safety is becoming increasingly evident. The OECD Environmental Outlook to 2030 indicates that "conventional waste policies alone may not suffice to improve material efficiency and offset the waste-related environmental impacts of materials production and use". This would indicate possible benefits for the OECD to engage in close co-operation between waste and chemicals management programmes in order to work together on the implementation of Environmentally Sound Management of waste and Sustainable Materials Management and on promoting recycling practices which are as safe as possible.
- since the Declaration on **Green Growth** at the OECD Ministerial Council Meeting in 2009, green growth is receiving a lot of policy attention and the OECD has embarked on Organisation wide activities to develop a Green Growth Strategy. It is clear that **innovation** will be an important driver for green growth, and the so-called **converging and emerging technologies** (information technology, biotechnology, nanotechnology, cognitive science) will play an important role. The EHS Programme has experience with all three of the afore-mentioned technologies and could be well placed to contribute to green growth by looking into how these technologies could contribute to protecting man and the environment from the hazards of chemical products.

VI Conclusions

- 84. Since the early 1970s the OECD Chemicals Programme, (which became later the Environment, Health and Safety Programme), has developed many high quality instruments and policies which have assisted member countries in their efforts to manage the risks to man and the environment of chemical products, pollutants and products derived from modern biotechnology. Hundreds of methods, guidance documents and consensus documents related to the testing, information gathering or assessment of these materials and to risk management approaches have been published. The wide dissemination of results obtained by using the products of the Programme has been ensured by free provision of information, reports and databases via the internet. These products have also been very useful for non-members and have contributed greatly to UN activities. In addition to these outputs, the Programme has also been a forum for policy dialogue among regulators and with stakeholders as well as constituting a means for the development of personal networks.
- 85. Through the harmonisation of methods achieved by the Programme and the work sharing this facilitates, it has been possible to make important efficiencies by governments and the industry. Quantifiable net savings have been calculated to amount to at least € 153 million per year. The harmonisation efforts have also helped to promote compatibility of chemical safety policies among the American, European and Asia-Pacific regions, thereby contributing to the minimization of non-tariff trade barriers.

- 86. The transparent working methods of the Programme have ensured a good participation and acceptance of its products by stakeholders. By involving selected non-members in the work a wider policy convergence has been promoted. The active involvement of the Programme in UN activities, in particular SAICM, means that more non-members are now acquainted with OECD methods and concepts.
- 87. The success of the EHS Programme has hinged on the continued commitment of countries and stakeholders to provide expertise and extra-budgetary resources. This commitment also ensured that the Programme has always been able to react quickly to new policy developments. It has also been able to assist in making best use of new technological and scientific developments and internationalize them by bringing expertise from countries and stakeholders together.
- 88. The work of the Programme in helping countries to make efficiencies in their chemical safety policies (by developing harmonised high quality methods and facilitating work sharing), is far from finished. The Programme has many strengths it can build on and a unique capacity to bring member and non-member regulators, scientists and stakeholders together to work on improving and developing new methods and the necessary international regulatory acceptance for their application. This can increase efficiencies in chemical safety while maintaining quality. In times of budgetary constraints international co-operation is needed more than ever. The globalisation of the chemicals industry, the policy urgency of dealing with chemicals in the environment (as indicated by "red light" nature of the issue and the policy interest in green growth), which might stimulate a search for possibilities to substitute hazardous chemicals by less hazardous alternatives, are all elements which provide opportunities to continue future activities of the Programme in the same vein as it currently works. The many strengths and robustness of the Programme ensure that it is eminently placed to take up such future challenges.

VII References

Documents, reports, publications

- 1. Overview of EHS Series: www.oecd.org/ehs/publications
- 2. Animal welfare: www.oecd.org/ehs/animalwelfare
- 3. Biocides: http://www.oecd.org/env/biocides
- 4. Chemical Accidents: http://www.oecd.org/env/accidents
- 5. Co-operative Investigation of Existing Chemicals: http://www.oecd.org/env/existingchemicals
- 6. Emission Scenario Documents: www.oecd.org/ehs/esd
- 7. Environmental Risk Assessment Toolkit: www.oecd.org/env/riskassessment/toolkit
- 8. Good Laboratory Practice: http://www.oecd.org/env/glp
- 9. Harmonisation of Classification and Labelling: http://www.oecd.org/env/classify
- 10. Biosafety: http://www.oecd.org/biotrack
 Harmonisation of Regulatory Oversight in Biotechnology
 Safety of Novel Foods and Feeds
- 11. Harmonised Templates: http://www.oecd.org/ehs/templates

ENV/JM(2011)17

- 12. Integrated Approaches to Testing and Assessment: http://www.oecd.org/dataoecd/45/52/40705314.pdf
- 13. Manufactured Nanomaterials: http://www.oecd.org/env/nanosafety
- 14. New Chemicals: http://www.oecd.org/env/newchemicals
- 15. Pesticides: http://www.oecd.org/env/pesticides
- 16. Pollutant Release and Transfer Registers: http://www.oecd.org/env/prtr
- 17. Risk Assessment: http://www.oecd.org/env/riskassessment
- 18. Risk Management: http://www.oecd.org/env/riskmanagement
- 19. Sustainable Chemistry: http://www.oecd.org/env/sustainablechemistry
- 20. Test Guidelines: http://www.oecd.org/env/testguidelines
- 21. Testing and Assessment Series: www.oecd.org/ehs/testingandassessment.
- 22. Toxicogenomics: www.oecd.org/ehs/toxicogenomics

Web-based information systems and models

- 23. eChemPortal: http://www.oecd.org/ehs/eChemPortal
- 24. Multimedia persistence and Long Range Transport Potential Screening Tool: www.oecd.org/ehs/povlrtp
- 25. OECD Existing Chemicals Database: www.oecd.org/env/existingchemicals/data
- 26. PRTR Data Centre: www.oecd.org/env/prtr/data
- 27. PRTR Resource Center for Release Estimation Techniques: www.oecd.org/env/prtr/rc
- 28. (Q)SAR Application Toolkit: http://www.oecd.org/env/existingchemicals/qsar

Special reports

29. Cutting costs in Chemicals Management:

http://www.oecd-ilibrary.org/environment/cutting-costs-in-chemicals-management 9789264085930-en

- 30. Environmental Outlook for the Chemicals Industry: http://www.oecd.org/dataoecd/7/45/2375538.pdf
- 31. Reports to the G8 Heads of Government:
 - Biotechnology:

http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=C(2000)86/ADD2&doclanguage=en

- Safety of Novel Foods and Feeds:

http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=C(2000)86/ADD1&doclanguage

Related websites:

- 32. Globally Harmonized System of Classification and Labelling of Chemicals GHS: http://www.unece.org/trans/danger/publi/ghs/ghs welcome e.html
- 33. Inter-Organisation Programme for the sound Management of Chemicals IOMC: http://www.who.int/iomc
- 34. Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade: http://www.pic.int/home.php?type=t&id=5&sid=16
- 35. Strategic Approach to International Chemicals Management: SAICM: http://www.oecd.org/env/saicm
- 36. Stockholm Convention on Persistent Organic Pollutants: http://chm.pops.int/default.aspx

ANNEX 1 OECD BODIES INVOLVED IN THE MANAGEMENT OF THE EHS PROGRAMME

Overall management of the EHS Programme:

The Joint Meeting (of the Management Committee of the Special Programme on the Control of Chemicals and the Chemicals Group)

Subsidiary bodies reporting to the Joint Meeting:

Working Party on Manufactured Nanomaterials

Working Group on Chemical Accidents

Working Group on Good Laboratory Practice

Working Group on Pesticides

Working Group of National Co-ordinators of the Test Guideline Programme

Working Group on Regulatory Oversight in Biotechnology

Task Force on Biocides

Task Force on Exposure Assessment

Task Force on Hazard Assessment

Task Force on Pollutant Release and Transfer Registers

Task Force on the Safety of Novel Foods and Feed

ANNEX 2 COUNCIL ACTS RELATED TO THE EHS PROGRAMME

- Recommendation on Measures to Reduce all Man-Made Emissions of Mercury to the Environment [C(73)172/Final]
- Recommendation on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215]
- Recommendation on Guidelines in Respect of Procedures and Requirements for Anticipating the Effects of Chemicals on Man and the Environment [C(77)97/Final]
- Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30/Final] [C(97)186/FINAL]
- Decision on the Minimum Pre-marketing set of Data in the Assessment of Chemicals [C(82)196/Final]
- Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96/Final]
- Recommendation on the Exchange of Confidential Data on Chemicals [C(83)97/Final]
- Recommendation on the OECD List of Non-Confidential Data on Chemicals [C(83)98/Final]
- Recommendation on Information Exchange Related to Export of Banned or Severely Restricted Chemicals [C(84)37/Final]
- Decision-Recommendation on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls [C(87)2/Final]
- Decision-Recommendation on the Systematic Investigation of Existing Chemicals [C(87)90/Final]
- Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage [C(88)84/Final]
- Decision-Recommendation concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances [C(88)85/Final]
- Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87/Final] [C(95)8/FINAL]
- Recommendation on the Application of the Polluter-Pays Principle to Accidental Pollution [C(89)88/Final]
- Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/FINAL]

ENV/JM(2011)17

Recommendation on Integrated Pollution Prevention and Control [C(90)164/FINAL]

Recommendation of the Council on Implementing Pollutant Release and Transfer Registers [C(96)41/FINAL][C(2003)87]

Resolution Concerning the Declaration on Risk Reduction for Lead [$\underline{C(96)42/FINAL}$]

Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals C(81)30/Final and C(89)87/Final [C(97)114/FINAL]

Recommendation concerning Chemical Accident Prevention, Preparedness and Response [C(2003)221]

Resolution on Implementation of the Strategic Approach to International Chemicals Management (SAICM) $[\underline{C(2008)32}]$