

# MUTUAL ACCEPTANCE OF NOTIFICATIONS RECENT DEVELOPMENTS AND OUTLOOK<sup>1</sup>

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**Abstract: Mutual acceptance of notifications (MAN) is a concept that is growing in importance to bi-national and international co-operation relating to new industrial chemicals. While consensus about its meaning is not currently widespread, there is considerable progress being made to advance understanding and to implement certain aspects of the concept. Most notably are efforts of the Task Force on New Industrial Chemicals of the Organization for Economic Co-operation and Development (OECD). Central to this initiative are the establishment of trust among countries and companies that are participating through information and work sharing, and the desire to be more “aligned and effective”.**

## A. Context

The world of commercial industrial chemicals is in many ways, in a state of transformation. The industry itself is feeling the effects of globalization, shifting economies and growing competition from differing corners of the earth. Some of this is healthy and multi-national companies abound, doing business in greater numbers of different countries. Innovation, which has always been important in the chemical sector, is alive, continuing to introduce new products onto the market from which people all over the world can benefit. At the same time, many governments are responding to their obligations to protect human health and the environment from chemicals; they continue to implement regulatory regimes that ensure assessment of new chemicals and subsequent management of those that pose a risk. Many of these national regimes support sound management of chemicals but new voices are calling for increasing rigour in regulatory approaches. Furthermore, differences between countries are apparent and are taking their toll on efficiency of companies and governments alike.

It is noticeable that growing attention is being focussed on the absence of publicly available data on the vast majority of chemicals that are currently in commerce. This is having a significant impact on the way governments view their regulatory regimes for both existing and new chemicals. Stakeholders and politicians are demanding that tests be performed to generate minimum data sets on these chemicals so they can be assured that every effort has been made to understand and respond to the risks that chemicals may pose to human health and the environment. Jurisdictions like the European Union, the United States and others are working with industry to generate data on thousands of existing chemicals in order to evaluate them and respond to public demands. Initiatives include the High Production Volume project of the OECD, the “Gore Vice Presidential Challenge” to U.S. industry and its

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<sup>1</sup> The views expressed in this article are the views of the authors and do not necessary reflect those of the Government of Canada

extrapolation to the international chemical sector through the International Council of Chemical Associations. At the same time, the European Union, Canada and others are proposing and introducing wide-ranging changes in their laws and policies as part of their response to criticism. The EU “White Paper – a Strategy for a Future Chemicals Policy” and the categorization and screening provisions introduced into the *Canadian Environmental Protection Act (1999)* are significant examples of the desire to break a legacy of existing chemicals. This legacy is characterized by a lack of public knowledge about chemicals in commerce, no evidence of their assessment, and emerging concerns about longer-term environmental and human health effects occurring at lower and lower levels. Only by knowing more about chemicals and making scientifically sound decisions about their real or potential risk to human health and the environment will government and industry be positioned to satisfy critics. However, there is a price to pay for this “retroactive” approach to understanding chemicals and their risks, especially where interventions must be made. This price has to be paid by companies that have to conduct tests, report data and contribute to their evaluation. It is also paid by governments that have to assess the data, make decisions, take action including regulating toxic chemicals and monitoring and reporting on their progress.

Many jurisdictions have turned to new chemical laws and regulations as a “pollution prevention” approach to chemical management and a way of breaking away from the “legacy”. For some countries, these regimes have been in place for more than 30 years and are positioned to give assurances that effort has been made by companies and governments alike to anticipate and prevent harm to human health or the environment. Typically, these laws and regulations involve a chemical inventory, obligations to notify chemicals not listed on the inventory, mechanisms to evaluate the notified chemical and authorities to respond to anticipated risks. With few exceptions, notification requirements involve the testing of chemicals based on the OECD minimum pre-market data set. Despite this similar architecture, differences abound between jurisdictions, making compliance with these laws and regulations for many companies challenging and costly. Inventories differ in size and content. Data requirements differ in terms of tests to be done and at what volume or other triggers they must be submitted. Consequently, notification forms differ. While decisions from almost all jurisdictions are risk and science-based, the data they rely on, the scope of the risk assessment and the manner in which they are conducted and documented differ. There are few jurisdictions that effectively make their decisions and the basis for them publicly available. Differences are also seen in exclusions and exemptions from notification, handling of confidential business information and the risk management actions that can be pursued where a risk is suspected. With so many subtle differences, governments also face significant costs and missed opportunities to benefit from the knowledge and experiences of other jurisdictions when making decisions, including reduced duplication, enhanced protection of the environment and human health and greater efficiencies and effectiveness overall.

#### B. Emergence of New Concepts Relating to New Chemicals

Over the years, member countries of the OECD have devoted considerable effort to fostering international co-operation on chemicals including the development of test guidelines, agreements on the mutual acceptance of data (MAD), the Principles of

Good Laboratory Practice (GLP) and a minimum pre-market data set. With these providing a baseline, in the early 1990s countries began pursuing co-operation in an *ad hoc* manner by compiling and comparing information on the new chemical notification, assessment and control systems. Surveys were conducted and databases were created that provided useful information to companies and governments, but they provided little insight into what could be done to address duplication and the differences in systems while ensuring protection of human health and the environment. Consequently, the OECD Business and Industry Advisory Committee (BIAC) intervened and expressed a vision for greater international co-operation on new industrial chemicals – MAN, where a new chemical could be notified once and accepted everywhere. BIAC challenged member countries to move towards MAN and to have it in place by the year 2005.

In response to this challenge, OECD countries agreed to convene a workshop in Vienna, Austria in April 1999 where participants from industry, government and elsewhere reviewed a number of issues related to information and work sharing that were germane to the BIAC challenge. On the basis of this dialogue, participants recommended the creation of an OECD Task Force to pursue a programme of work that covered seven main themes:

1. Use of bi- and multi-lateral arrangements for improved information and work sharing;
2. Standardization of notification forms;
3. Standardization of formats for assessment reports;
4. Hazard elements as a focus for convergence;
5. Increased consistency in notification requirements for low concern or exempt chemicals;
6. Minimization of Confidential Business Information obstacles; and
7. Feasibility of a global inventory.

In June 1999, the Task Force was established with a two-year mandate to increase efficiency in national new chemical notification and assessment systems, improve transparency in assessments, reduce animal testing in relation to new industrial chemicals and speed up product introduction to market. Since its inception, the Task Force has been engaged in a variety of activities aimed at addressing this mandate while maintaining or improving human and environmental health protection, as recommended at the Vienna workshop. The major focus has been on elements 1, 2 and 5; the experiences with bi- and multi-lateral arrangements have been helpful in addressing the other themes in the programme of work. The mandate of the group extends until June 2003 when it will report fully on its progress and future priorities.

In addition to the OECD Task Force, a number of other initiatives have developed directly between national jurisdictions that deal with new chemicals; these initiatives have the potential to significantly advance co-operation. These include the Four Corners Agreement between Canada and the U.S. that enables the exchange of assessment reports, dialogue among government scientists and some tangible benefits for sponsoring companies. The U.S. and the European Union have been exploring under the umbrella of the Trans-Atlantic Business Dialogue, risk

assessment methodology and the possibility of greater convergence in approaches to polymers. Finally, Australian and Canadian officials have embarked on an ambitious program to share information and work with a key aim to be recognition of each others assessments; there are clear benefits to the governments, and Australian industry will benefit from reductions in notification fees. The key ideas that underlie these initiatives include knowledge sharing, identifiable benefits for government and companies and especially, the building of understanding and trust, both of which are necessary ingredients for MAN.

### C. Making Progress

The OECD Task Force on New Industrial Chemicals has made considerable progress in several of the themes under its mandate, starting with the building of an organized program of work. This programme is described in more detail in several documents available on the OECD web site (<http://www.oecd.org/>). The highest priority was placed on developing (a) bilateral/multi-lateral arrangements, (b) a standardised notification form and (c) a focus for aligning exclusion and exemptions for low concern chemicals. Nearly 50 experts recently reviewed the outcome of this work during a landmark workshop of the Task Force that took place in Rome in April 2002, hosted by the Istituto Superiore di Sanità.

C.1 Bi and Multilateral Arrangements: Seven countries and a representative company provided details of their experiences with bi- and multi-lateral arrangements. These activities were aimed at enhancing information sharing and work sharing opportunities and included 9 chemicals, 7 countries and 3 companies. Each country rated and reported on the usability of others' reports in relation to presentation, provided data, assessment methodology and decision-making, and recommendations and controls. Considerable experience in sharing confidential business information was achieved through these arrangements. One of the differences that emerged concerned varying perspectives from countries about the degree to which they can rely on modelled data based on structure activity relationships (SARs) versus actual test data.

Participants made a number of recommendations ranging from the preparation of a consolidated matrix of the government comparisons to further validation of models based on SARs. In between were ideas to develop additional multi-laterals focussed more on substances demonstrating greater hazard and that possibly led to control actions by countries, and documents describing their risk assessment decision-making processes.

C.2 Standardized Notification Form: The use of different notification forms for each country to which a new chemical is proposed for introduction is costly for industry and can be a barrier to shared information among countries. A prototype for a common notification form has been developed that stores data and country notification requirements and is capable of producing notification reports particular to specific countries. When reviewed by workshop participants, no significant barriers to further progress were identified.

A series of recommendations were made by workshop participants concerning next steps including verification by countries who have yet to do so. In addition, companies were encouraged to test its use in a pilot multi-lateral to ascertain ease of use and acceptability by regulatory authorities. Finally, the notification form and the Task Force's progress with it were identified as important to an upcoming OECD Workshop on Electronic Tools for Data Submission, Evaluation and Exchange scheduled for October, 2002 in Ottawa, Canada.

**C.3 Low Concern or Exempt Chemicals:** Prior to the workshop, industry representatives from the Task Force completed an extensive review of exclusions and exemptions in different OECD jurisdictions and identified inconsistencies in definitions and application. They subsequently proposed a number of low concern substances where the benefit of aligning them would be significant. They included naturally occurring substances; non-isolated and/or transient reaction intermediates, and incidentally produced products; impurities, byproducts and partially reacted materials; articles; hydrates of listed substances. Other areas proposed as candidates for alignment were: research and development chemicals; polymers – particularly synthetic polymers of low concern; and low volume/low risk chemicals or “chemicals of low regulatory concern”.

Participants expressed the need to proceed with this project with the goal being an OECD “standard exemption set”. Of the list of substances proposed by BIAC, it was recommended that polymers of low concern, R&D activity, articles and non-isolated intermediates might provide the earliest success. However, participants noted that standardizing terminology and definitions for exclusions and exemptions was paramount, and that this information should be included in interpretation guidelines as one means to eliminate differences.

**C.4 Meaning of MAN:** On the basis of a background paper entitled “Mutual Acceptance of Notifications – From Vision to Reality”, workshop participants had the opportunity to explore what government, industry and others understood by the term MAN. It was noted that the concept could have a variety of interpretations ranging from “notified once, accepted everywhere” as originally proposed by BIAC in 1998 to “notified once, assessed everywhere”. Each model had merit but it was equally apparent that the concept is not adequately understood at present to permit a common definition. As a consequence, participants recommended that additional investment be made in clarifying its meaning, which could be used as the goal for future work of the Task Force. It was therefore recommended that small expert group be convened prior to November to work through the details and propose a suitable model. As identified in the background paper, there are several key areas that will have to be considered by the expert group including:

1. Data, data quality and the use of modelled information – issues about data include hazard versus risk, national data requirements, SAR versus test data;
2. Inventories – issues concern the feasibility of a single inventory of assessed chemicals, whether they are new or existing, and the administrative means of managing such an inventory;

3. Evaluation and documentation – a challenging issue relating to government's willingness to accept some or all of the assessment of another jurisdiction and the documentation needed to do so;
4. Legal – issues concern not only government's legislative authority for their programs but also the handling of confidential business information and companies willingness to overcome such obstacles;
5. Operational – issues concern the means to govern implementation of a MAN concept, right from committees and their mandates to standardization of notification forms, assessment templates and guidelines; and
6. Human – issues include the need for training of program staff including assessors about the implementation of MAN and its implications for domestic activities.

Overall, participants viewed the workshop as a success and the work of the Task Force and its subgroups to be significantly advancing the fundamental aspects of MAN.

#### D. And What About Building Trust Towards a Common Goal?

Trust – "...confidence in a person or thing because of the qualities one perceives or seems to perceive in him or it; acceptance of something as true or reliable without being able to verify it; faith in the future..." (Webster's Dictionary of the English Language, Lexicon Publications, New York 1987). As much as sharing a common goal can affect understanding and the pursuit of a vision of MAN, there are many aspects to the notion of trust that also have a significant bearing, including – confidence, qualities one perceives in another system, acceptance and believing in the future.

This five-letter word affects all parties who are pursuing the concept of MAN, and its many benefits for human health and the environment and for governments and industry alike. It is at the heart of the concept and the success that is possible.

It is apparent that COMPANIES need to:

- Trust that governments will act responsibly in their decision-making about new chemicals and their co-operation with others;
- Trust that governments will ask for more information when it is justified for the purpose of human health and environmental protection;
- Trust that proprietary or confidential business information will stay that way; and
- Trust that governments share a commitment to MAN and will work with industry to advance its implementation within a reasonable timeframe.

Equally apparent is GOVERNMENT'S need to:

- Trust that they can retain sovereignty over decision-making in MAN;
- Trust that companies are looking for the most effective approach and not for the lowest standards possible that would lead to a continuation of the legacy of existing chemicals;

- Trust that companies are prepared to minimize obstacles related to data and information flow for the public good; and
- Trust that other countries have acceptable notification and assessment practices and are willing to move towards greater and greater “alignment”.

D.1 Confidence: As noted in the definition above, trust comes about when parties have confidence in each other because they understand the risk assessment practices and the science basis of each others decision-making in relation to the risks posed by new chemicals. Working together on the OECD Task Force has increased levels of confidence between participating companies and governments. It has not only deepened the understanding of what “mutual acceptance of notifications” can mean but also the benefits that can accrue. There is general recognition that working together under a MAN scheme has benefits including (a) improved national decision-making about human health and environmental protection, based on prior experience and expertise of other jurisdictions (b) reduced time spent on assessments of substances that pose little or no risk particularly where resources could be used to manage more pressing environmental needs and (c) the ability to bring potentially life-, health- and environmentally-enhancing and protecting products to markets more quickly and at lower costs.

D.2 Qualities One Perceives in Another System: Part of trust is the perception of value in another’s actions. Countries that trust each other in the area of new chemicals can perceive the qualities of each in relation to the science of their assessment process, the use of data and validated models and how well they describe their decision-making in accessible reports. The work of the OECD Task Force has made significant strides in enabling countries to see the good in each other either due to similarities to their own programs or by benefiting from better ideas that are momentarily different. This is resulting in constructive dialogue about standardizing reports, and opportunities to benefit from information sources such as SAR models. This will likely continue as countries come to grips with ways to standardize hazard assessments.

D.3 Acceptance: A goal of building trust is to develop a state of acceptance, where countries and companies have worked together long enough in good faith to be able to accept judgments about the quality of submitted data or predicted information, the methods of verification and evaluation, the assessment of hazard which should be globally applicable (e.g., physical and chemical properties, toxicology, etc.), and the means to document the outcome so it does not have to be unnecessarily duplicated. The OECD Task Force has made significant strides in this area through the analyses produced in the multi-lateral information sharing activities and in future efforts on more challenging chemicals.

D.4 Believing in the Future: Just as Rome was not built in a day, trust comes only with time and effort. The OECD Task Force marks an ambitious yet practical approach to building the tools and the attitude needed to make the definition of MAN understandable and to make it a practical reality. How far we have to peer into the future to say MAN has been achieved is not clear but BIAC’s call for 2005 no longer seems unrealistic.

## E. Conclusions

The OECD Task Force on New Industrial Chemicals is demonstrating that, as it moves forward in its work programme, much can be accomplished where there is a common goal and mutual benefit. Building trust is fundamental to progress and much has been accomplished so far and there is every expectation that this will continue. While the Task Force further elaborates and defines the ultimate objective of mutual acceptance of notifications, it does so in the context of other national and regional initiatives that are rethinking the fundamentals of their legislative programs and policies and the adequacy in which they address the legacy of existing chemicals. Each of these initiatives, including the European Union's White Paper, should be considered significant opportunities for governments to better align their approaches in a way that will ensure co-operation, reduced duplication, greater efficiency and less cost. Furthermore, they enable companies to better address the public's need for more and better information about new and existing chemicals, needed to be sure that every effort has been made to understand and respond to the risks that chemicals may pose to human health and the environment before they actually occur. New chemicals notification and assessment is the way of the future – pollution prevention in its most fundamental state, and a way to ensure that the legacy of existing chemicals does not grow. The Task Force has and will continue to show leadership in this area, and members will be encouraging more countries and companies to participate and share in the pursuit of MAN and its numerous and wide-ranging benefits.