



Business and Industry Advisory Committee to the **OECD**

Comité Consultatif Economique et Industriel Auprès de l' **OCDE**

**OECD WORKSHOP FOR IMPROVING WORK SHARING ON NEW INDUSTRIAL  
CHEMICALS NOTIFICATION AND ASSESSMENT  
VIENNA 14-16 APRIL 1999**

**MUTUAL ACCEPTANCE OF NOTIFICATION - PROPOSAL FROM BIAC**

**Introduction**

Notification of substances is required in many trading nations, with protection of man and the environment being the primary purpose. The process of notification invariably requires that the substance to be placed on the market be assessed for hazard and risk. The information requirements of the major OECD schemes vary considerably in terms of the information to be supplied and the risk assessment employed.

Industry operates at a global level. Multiple notifications around the world can prove to be immensely difficult given the variations in the different test protocols and the hazard data required. Industry costs are greatly increased by these multiple notifications, not only in preparation of the mandated test protocols, but also in terms of carrying out different animal tests to reach essentially the same toxicological endpoint, these minor variation being dictated by the differing protocols. Added to the cost and the burden of animal suffering caused by these varying practises there is the additional and important time element whilst waiting for approvals, with no additional protection for man or the environment.

BIAC carried out a case study on the number of new chemicals notified by a company which, subsequently, went on to be notified elsewhere in the world. Whilst this study represents only a small sample, we believe it indicates trends and the clear need for streamlining the current system. What this study also indicates is the potential for duplication in government effort. (See Annex 1)

OECD governments have put enormous resource into setting up and running their national schemes, for the future these resources could realistically be used in other areas of chemical management if a mutual acceptance of notification (MAN) scheme were developed - by this we mean - notification of a new substance in one OECD country, which has resulted in marketability, providing for that substance to become marketable in other OECD countries, with minimal additional regulatory requirements.

Our challenge to OECD governments is to work towards a successful implementation of MAN by 2005.

International trade could be very much enhanced if OECD were able to institute a system of Mutual Acceptance of Notification. The Transatlantic Business Dialogue, between the USA and EU, is working towards establishing an equivalence agreement. OECD members could work in parallel with this process utilising the synergy between the activities.

All of those countries with a notification system require information addressing the intrinsic hazard of the substance. What can vary when the substance is marketed around the world is the risk.

We would propose that whilst the information addressing hazard provided to the first country of notification should be taken as a given, each country or trading block may want to assess the risk of that substance in their region. We would positively support mutual recognition of risk assessments within trade blocks.

We do not recommend harmonisation of notification schemes at the present time. This would be unwieldy and burdensome to both Governments and industry. We do however recommend greater understanding of and acceptance of the good work done by other governments when considering a repeat notification.

### **Progressing the activity**

We believe that the questions which need to be considered are:

#### **What is needed for countries to gain an understanding of the notification systems of others?**

Tables of comparisons are a start in understanding the schemes of others, but what is needed is for each government to understand what others do with their data and what processes are undertaken to reach a final assessment outcome. The disclosure of this information to other authorities by the notifier is essential in taking mutual acceptance of notifications forward.

Additional bilaterals could be a step; they build trust and understanding in the operation of schemes between OECD countries. In this way countries can describe and understand each others assessment process and how they come to decisions to allow marketing.

#### **Should this start as acceptance of hazard assessment and work up to an acceptance of risk assessments?**

For many low hazard substances, the assessment of risk will not differ significantly from region to region. In other cases it will only be one or two elements of a regional risk assessment that will differ. The third scenario is where the entire risk assessment gives completely different outcomes in different regions due to factors such as climate, exposure and use variations. BIAAC believes that there is value in exploring this further to identify what may be possible in terms of accepting risk assessments.

Building on this, the ability of a country to accept an “approval” from elsewhere may directly relate to the likely hazard and or risk of the substance in question. BIAAC would therefore like to propose that industry and government could consider categories of candidate substances, which are generally recognised to constitute a lower hazard or risk e.g. R&D; low volume substances; polymers; intermediates as a priority. The converse of this would be to avoid those categories of chemicals which are recognised to pose a high risk e.g. PBTs or carcinogens. We believe that by working in such a manner governments can develop an understanding of each others schemes.

Industry accepts that it may always be appropriate to re-consider the risk assessment for differing regions of the world. However, industry would welcome the development of co-operative arrangements by the second authority whereby those parts of the original risk assessment considered to be relevant could be used. A first step could be the retrospective review of a range of notifications from different regions to look at similarities and differences with notifiers and governments working together.

#### **If countries have different data requirements what must happen for one to accept the conclusions of the other?**

Countries may wish to consider developing, via OECD, a standard application form. This could be used for all repeat notifications and be provided from the original notifier. This would clearly identify that it is a repeat notification and provide details of the first authority who assessed the original dossier. The form could also identify the principal activities, local agents/contacts and a prime contact who was involved in the original notification. This would allow the second authority to view the actual data requirements assessments of the first.

The form should be kept simple and perhaps just completed in the language of the receiving country or English.

To make the system useful in reducing the administrative burden, on both the authority and the notifier, we believe the second authority should eventually accept the conclusions and summaries of the original notification, without the need to obtain and review all the reports included in the first notification. However, we recognize that this will need to be developed over time with a series of pilot studies. Industry would nevertheless encourage the two authorities involved to discuss any questions and involve the notifier. Providing summaries exist for the original notification, it should not be necessary to reformat the information onto the second authority's standard form, where such a form exists.

Recognition of OECD test methods is essential. Industry strongly advocates that studies which have been carried out according to OECD methods and have been accepted by the first regulatory authority are accepted by the second authority to which the notification is submitted by the original notifier.

Information protection and confidentiality should be respected by the first and subsequent authorities within the requirements of their national laws. This protection should extend to the release to third parties of any information claimed confidential, including specific chemical identity published in chemical inventories. The original notifier should be contacted over any Confidential Business Information related issues and no release of information should take place without their express permission and understanding.

### **How can countries in transition be further supported?**

BIAC would like the Workshop to make provision for countries in transition. There is a good deal of support amongst many such countries to adopt the system of their major trading partner and industry would wish to encourage this. Mutual acceptance of notification provides a further benefit to them: it would allow for a smaller bureaucracy and the accompanying team of technical experts to review the data. They could review the established countries assessments and move forward. It would also allow greater focus on other, perhaps more pressing health, safety and environmental matters such as establishing a good safety data sheet communication and retrieval system.

### **Benefits in summary**

- Administrative costs for both industry and government could be reduced. Governments are forced to waste time and money in repeating assessments which have already been done in other OECD countries. The pesticide model developed by OECD indicates the type of savings that are possible. Resources could be re-allocated from new substance notification to other chemical management areas.
- Reduction or elimination of the multiplicity of animal testing required by the differing protocols to reach essentially the same toxicological end point, these minor variations being dictated by the differing protocols.
- Trade barriers created by differences in notification schemes would be addressed. International trade could be very much enhanced if OECD were able to institute a system of Mutual Acceptance of Notification. This would greatly encourage and enhance international trade, whilst maintaining protection to man and the environment.

- The societal benefits arising from innovation and new, better and safer chemicals would also be promoted as research and development would have applicability in a wider range of markets. This in turn would lead to environmental improvement.
- A mutual recognition of new substance decisions within OECD countries would also assist developing countries in having confidence to accept decisions made within the OECD; the system being more transparent.

**Annex 1****Case Study****Survey of new substance multiple notifications****Background**

OECD had requested of BIAC that a survey be carried out on the number of new chemicals notified by a company which then went on to be notified elsewhere in the world. It was agreed that the result would not be an accurate picture of international notifications, but an indication of trends. Companies were asked to respond for 1996, Europe is considered as one country for the purpose of this activity.

**Case 1. Large pharmaceutical company**

Seven substances were notified, one in more than one country.

**Case 2. Large chemical company**

11 substances were notified in total with permutations of notifications to the following countries; 7 in the EU; 8 in the US; 5 in Korea; 4 in Japan and 2 in Canada.

**Case 3. Large chemical company**

Over the last **10 years** this company has submitted a total of 26 original notifications. 19 original notifications have been submitted in the USA, some of these covering multiple substances (a PMN). Of these 19 PMNs, four have been “repeated” in another country. Three of the four have been “repeated” in multiple countries, adding up to a total of 8 additional notifications. One original notification has been done in Canada. A further six “original” notifications have been made in Europe.

Of the original notifications submitted in the USA during the last ten years, at least six have not been repeated in other countries either because the market would not bear the cost or because similar materials could be introduced without repeat notifications.

**Case 4. Large chemical company**

This company notified 42 substances in the USA; 11 in Europe; 6 in Australia; 20 in Korea; 4 in Canada and 16 in Japan. They are unable to provide data on those substances which were repeated but is likely to be high.

**Case 5. Medium chemical company**

Two substances were notified in Europe, with no repeat notifications.

**Case 6. Medium chemical company**

Four substances were notified in Europe, with no repeat notifications.

**Case 7. Large chemical company**

22 substances were notified in Europe all of which have been re-notified in other parts of the world. 114 notifications have been carried out in total. Countries involved include: USA; Korea; Canada; Australia; Japan and the Philippines. Additionally, 12 substances have been notified solely in Canada and a further 5 solely in the USA.

**Case 8. Large pharmaceutical company**

2 substances were notified in Europe and a further two were repeated in other countries.

**Case 9. Large chemical company**

Approximately 10 substances are notified per year, all in the EU, all are subsequently notified into the US.

**Case 10. Medium chemical company**

One notification was made, with none repeated in other countries.