



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

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

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OECD MUTUAL ACCEPTANCE OF NOTIFICATION
A BIAC Approach

Background

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 six existing schemes vary considerably in terms of the data to be supplied and the risk assessment.

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 variations being dictated by the differing protocols. Added to the cost and the burden of animal suffering caused by these varying practices there is the additional and important time element whilst waiting for approvals, with no additional protection for man or the environment.

International trade could be very much enhanced if OECD were able to institute a system of Mutual Acceptance of Notification i.e. the acceptability by all countries of notification dossiers produced in any one OECD country. This would greatly encourage and enhance international trade, whilst maintaining protection to man and the environment. This is a goal which industry wishes to promote and which we believe can be achieved. The Trans Atlantic Business Dialogue, between the USA and EU, is also working towards establishing an equivalence agreement.

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.

Specifics

Noted below are a number of steps which we would recommend OECD take towards opening the notification system to aid international trade whilst protecting man and the environment. The term "second authority" refers to the second and all subsequent authorities to which a notification is submitted.

1. A standard application form should be developed for all repeat notifications and be provided from the original notifier. This should 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.
2. The form should be completed in the language of the receiving country or English.
3. 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.

The second authority should provide a level of information protection and confidentiality at least equal to that provided by the first authority. 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 CBI related issues.

4. In order to reduce the administrative burden, on both the authority and the notifier, the second authority should accept the conclusions and summaries of the original notification, without the need to obtain and review all the reports included in the first notification. Industry would encourage the two authorities involved to discuss any questions and involve the notifier if required.

As a repeat assessment will involve less effort from the second authority, industry would request a reduction in the review period and fees where they are levied.

5. 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.
6. Industry accepts that it may be appropriate to re-consider the risk assessment for differing regions of the world. However, industry would welcome the acceptance by the second authority of any part of the original risk assessment considered to be relevant, although as discussed above, the mutual recognition of risk assessments should be the general rule within trade blocks.

7. Notifiers would make a commitment to undertake to provide the second authority with changes to information which becomes available as part of the original notification.

8. Industry encourages and would assist in the development for an OECD notification and assessment information sharing mechanism by which OECD countries may share publicly available notification and assessment information.