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COUNCIL

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Council

COUNCIL DECISION CONCERNING THE 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)]

(adopted by the Council at its 912th session on 26 November 1997 [C/M(97)23/PROV])

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THE COUNCIL,

Having regard to Articles 5 a) and 5 c) of the Convention on the Organisation for Economic Co-operation and Development of 14th December 1960;

Having regard to the Recommendation of the Council of 12th May 1981, concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) as amended];

Having regard to the Recommendations of the Council of 26th July 1983, concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals [C(83)96(Final)] and those concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)] and the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

Having regard to the Decision-Recommendation of the Council of 2nd October 1989 on Compliance with Principles of Good Laboratory Practice [C(89)87(Final) as amended];

Considering that effective implementation of the OECD Council Acts C(81)30(Final) and C(89)87(Final) is essential in view of the extension of these acts to adherence by non-member countries;

Recognising that the conclusion of agreements among Members and with non-member countries constitutes a means for effective implementation of these Council Acts;

Recognising that adherence to the OECD Council Acts does not preclude use or acceptance of test data obtained in accordance with other scientifically valid and specified test methods, as developed for specific chemical product areas;

Considering that on 14th June 1992 the United Nations Conference on Environment and Development in Chapter 19, section E of Agenda 21, recommended that governments and international organisations should co-operate, particularly with developing countries, to develop appropriate tools for management of chemicals;

Considering the commitments made by Ministers at the meeting of the Council at Ministerial level of 23rd and 24th May 1995 to support the integration of developing countries and economies in transition into the world economic system, and to pursue further progress toward a better environment;

Considering that Member countries and non-member countries would derive both economic and environmental benefits from enlarged participation in the OECD Council Acts related to mutual acceptance of data in the assessment of chemicals;

Considering that non-member countries are increasingly demonstrating an interest in participating in the OECD Council Acts related to mutual acceptance of data in the assessment of chemicals;

Considering that the chemical industries in all nations have an interest in harmonized testing requirements and will benefit from the elimination of costly, duplicative testing and the avoidance of non-tariff barriers to trade;

Considering that expanded international co-operation to reduce duplicative testing would, in the process, diminish the use of animals for safety testing;

Considering, therefore, that it is appropriate and timely to pursue broadened international participation in the OECD programme on mutual acceptance of data in the assessment of chemicals, specifically by opening up the relevant OECD Council Acts to adherence by non-member countries and that a clear administrative procedure is required to facilitate this process;

On the proposal of the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals, endorsed by the Environment Policy Committee;

I. DECIDES:

1. To open the OECD Council Acts related to the mutual acceptance of data in the assessment of chemicals¹ to adherence by non-member countries which express their willingness and demonstrate their ability to participate therein;

2. That non-member countries adhering to the Council Acts shall be entitled to join the part of the OECD Chemicals Programme involving the mutual acceptance of data, with the same rights and obligations as Member countries;

3. That adherence to the Council Acts and participation in the part of the OECD Chemicals Programme related to the mutual acceptance of data shall be governed by the procedure set out in the Annex to this Decision, of which it forms an integral part.

II. RECOMMENDS that Member countries, with a view to facilitating the extension of the Council Acts to non-member countries, take or pursue all available means to ensure the most effective implementation of the Council Acts.

Pending this effective implementation of the Council Acts by non-members, Member countries shall be free to establish mutual acceptance of data with non-member countries on a bilateral basis.

III. INSTRUCES the Management Committee of the Special Programme on the Control of Chemicals to assume responsibility for promoting international awareness of the Council Acts, with a view to informing, advising and otherwise encouraging non-member countries to participate in the programmes and activities that have been established by OECD countries pursuant to these Council Acts.

Further, the Management Committee should monitor closely the technical aspects of implementation of the procedure set out in the Annex, review the implementation of this Decision, and report thereon to Council within three years.

¹ These Council Acts are: The 1981 Council Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) as amended], together with the OECD Guidelines for the Testing of Chemicals and the OECD Principles of Good Laboratory Practice, and the 1989 Council Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87(Final) as amended] and are hereafter referred to as "the Council Acts".

ANNEX

**PROCEDURE FOR ADHERENCE OF NON-MEMBER COUNTRIES TO THE COUNCIL ACTS
RELATED TO THE MUTUAL ACCEPTANCE OF DATA IN THE ASSESSMENT OF
CHEMICALS**

- i) The OECD Secretariat should ensure that an interested non-member country is provided with full information on the rights and obligations associated with adhering to the OECD Council Acts related to mutual acceptance of data in the assessment of chemicals.
- ii) At the invitation of the Council, the interested non-member country would confirm, at an appropriate level, that it would agree to provisionally adhere to the Council Acts and to accept, for purposes of assessment and other uses relating to the protection of man and the environment, data generated in the testing of chemicals with OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP).
- iii) Following such invitation, confirmation and provisional adherence, the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals (Joint Meeting) would organise, in consultation with the non-member country, technical support that might assist in the implementation of the Council Acts.
- iv) The non-member country would be invited by the Joint Meeting to nominate a Test Guideline Co-ordinator and to take part in the activities and meetings related to the development and updating of OECD Test Guidelines and to take part in technical meetings related to GLP and, if recommended by the OECD Panel on GLP, to attend as an observer meetings of the Panel. Such an invitation would be for a maximum of three years and could be renewed by the Joint Meeting.
- v) Once the non-member country has fully implemented the Council Acts, and taking account of the recommendation of the Joint Meeting in this respect, the non-member country may be invited by the Council to adhere to the Council Acts and to join the part of the OECD Chemicals Programme involving the mutual acceptance of data as a full member; this would require the non-member country to contribute to the resource costs of implementing this part of the Chemicals Programme.
- vi) Participation may be terminated by either party upon one year advance notice. The Council may set any further terms and conditions to the invitation.