



BUILDING BLOCKS: OECD LEGAL INSTRUMENTS ON CHEMICALS

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Outline of the presentation

- a. OECD
- b. The establishment of a systematic and comprehensive industrial chemicals management system;
- c. Presentation of the main interlinks (building blocks) between various OECD legal instruments on chemicals.



ORGANISATION OF ECONOMIC CO- OPERATION AND DEVELOPMENT (OECD)



OECD

- OECD is a global forum of 35 leading market-based economies;
- It promotes *better policies for better lives*;
- OECD provides a forum in which governments work together to seek evidence-based solutions to common problems, share experiences and identify *best practices* that are enforced through peer review.
- OECD collaborates with more than 100 other economies many of which participate in its committees and have adhered to its legal instruments and policy standards.



Accession to OECD

- Becoming a Member of the OECD is not a simple formality but is the result of a rigorous review process.
- The OECD governing body (the Council), which comprises all the Members of the Organisation, decides whether to open accession discussions with a country and fixes the terms, conditions and process for accession.
- Accession discussions were opened with Israel in 2007 ([Council Resolution on Enlargement and Enhanced Engagement](#)) and Israel became an OECD Member in 2010. The terms, conditions and process for the accession were set out in Roadmap for [Israel](#).



Accession to OECD

- At the time of the Accession to OECD, Israel requested timeframes for implementation for eight legal instruments on chemicals;
- There are still six outstanding Acts and all except one [*Recommendation on Integrated Pollution and Prevention Control, C(90)164/FINAL*] address the a systematic and comprehensive industrial chemicals management system.



**The establishment of a
systematic and comprehensive
industrial chemicals
management system**



OECD legal instruments

21 Legal Instruments related to Chemicals developed between 1974 and 2013.

Out of which **11** relate to the operation of a comprehensive industrial chemicals management system:

- 5 instruments on new and existing chemicals;
- 2 instruments on MAD and GLP;
- 3 instruments on proprietary rights and confidentiality;
- 1 instrument on nanomaterials.

Moreover, there are also inter-links with 1 legal instrument on PRTRs, 4 instruments on chemical accidents and several instruments addressing specific chemicals.



Industrial chemicals

Several different Council Decisions and Recommendations specifically address the management of those "industrial chemicals", covering different building blocks that together make up an effective chemicals management system.



Industrial chemicals

Approaching the implementation of the OECD Council Acts from the point of view of establishing a holistic management system for industrial chemicals facilitates the understanding of the objectives of the individual Council Acts on the assessment and management of chemicals.



Industrial chemicals

“Chemicals” and Council Acts

- There is no definition of “*chemicals*” in many Acts.
- Members have interpreted these Acts to refer to “**industrial chemicals**” as those that are not covered by specific regulatory regimes (i.e., chemicals other than pesticides, biocides, pharmaceuticals, animal drugs, food and feed additives and cosmetics).



OECD Legal Instruments

Main features of a systematic and comprehensive industrial chemicals management system:

- Mutual Acceptance of Data and GLP;
- generating information on chemicals that allows for their meaningful assessment;
- responsibility for generating and assessing the data being a part of the overall function and liability of industry;
- addressing both new and existing chemicals;
- prioritized approach to the assessment of existing chemicals.



OECD Legal Instruments

Main features of a systematic and comprehensive industrial chemicals management system:

- exchanging data on chemicals (both confidential and non-confidential) and addressing proprietary rights;
- dissemination of the information on chemicals to the general public;
- stakeholders involvement in the establishment and performance of the system;
- surveillance and monitoring of the performance of the chemicals management system.



**Building blocks of the
industrial chemicals
management system in the
OECD legal instruments
(focus on 5 outstanding legal
instruments for Israel)**



Mutual Acceptance of Data and GLP

Key elements:

- Generation of test data and sharing across countries
- Based on two OECD Council Acts:
 - **C(81)30/FINAL** Council Act on MAD;
 - **C(89)87/FINAL** Council Act on Compliance Monitoring.
- Provides the foundation for work sharing, reducing duplication, and cost savings across countries.
- Addressed also under **C(74)215**, paragraph 7 of the Explanatory Note: mutual acceptance of the results of national assessments.



Information on chemicals is available

- **C(74)215:**
 - recommends that the import, manufacturing and sales statistics kept.
- **C(77)97/FINAL:**
 - basic data required for initial assessment of chemicals (Annex II).
- **C(82)196/FINAL:**
 - recommends a minimum pre-marketing set of data in the Annex as a basis for a meaningful first assessment.



Information on chemicals is available

- **C(87)90/FINAL:**
 - recommends establishing the means to collect, estimate or generate the information needed for a systematic investigation of existing chemicals.



Responsibility for generating and assessing the data

- Responsibility for generating and assessing the data must be part of the overall function and liability of industry (**C(77)97/FINAL**).



New chemicals

- **C(74)215:**
 - recommends that potential effects on man and the environment are assessed prior to marketing of chemicals and chemical products.
- **C(77)97/FINAL, goal:**
 - ensuring assessment of all new chemical substances.



New chemicals

- **C(82)196/FINAL:**
 - **decides** that sufficient **information** on the properties of new chemicals **should be available** before they are marketed for a meaningful assessment.
 - **recommends** the use of a **minimum pre-marketing** set of data (defined in Annex) as a basis for a first assessment of potential hazards .



New chemicals

- **C(83)96/FINAL:**
 - recommends that authorities responsible for receiving notifications of new chemicals require each notifier to **identify the laboratories** which produced the data, and if the labs are not owned or otherwise affiliated with the notifier, to **provide certification of the right to use the data.**
 - recommends that authorities **not accept data** for which the notifier cannot provide a certification of the right of use, if the labs are not owned/affiliated with the notifier.



Comprehensive yet prioritized approach to existing chemicals

- **C(74)215:**
 - recommends to develop procedures that may be used to assess the potential effects on the environment of chemicals and chemical products.
 - calls for a selection mechanism to single out, at an early stage, those chemicals that require full-scale assessment.



Comprehensive yet prioritized approach to existing chemicals

- **C(77)97/FINAL, scope of the scheme proposed:**
 - systematic assessment of both human health and environmental hazard;
 - applies to existing chemicals (new applications, increased quantities, new effects, of particular concern);
 - a phased approach to the assessment (initial assessment, further assessments).



Comprehensive yet prioritized approach to existing chemicals

- **C(87)90/FINAL:**
 - decides on establishing or strengthening national programmes to **systematically** investigate existing chemicals covering:
 - identification of relevant chemicals;
 - priority-setting, including collection or estimation of information needed for the setting of priorities;
 - generation of necessary further information, including testing;
 - performance of hazard assessments.



Managing confidential information and proprietary rights

- **C(77)97/FINAL, Annex 1:**
 - ensuring protection of confidential information.
- **C(83)96/FINAL:**
 - address proprietary rights on data on chemicals.



Exchange of information on chemicals

- **C(77)97/FINAL, Annex 1:**
 - assessment scheme as an important step towards facilitating the exchange of data about chemicals between countries.
- **C(87)90/FINAL:**
 - recommends exchange of the available information on an existing chemical when requested by another Member country for the purpose of investigating that chemical and establishing mechanisms for such information exchange.



Providing the information to the public and its dissemination

- **C(77)97/FINAL:**
 - recommends dissemination of information through the supply chain.



Other key elements – stakeholders involvement

- Procedures, by which manufacturers of chemical substances may seek reconsideration of decisions taken by the authorities (**C(77)97/FINAL**).



Capacity to assess the performance of the system

- **C(77)97/FINAL, Annex 1:**
 - surveillance and monitoring (occupational safety; toxicological information; environmental information, i.e. PRTRs data).



Other key elements

- When new procedures are established for the assessment of chemical substances, an integrated approach should be sought. Arrangements should be made for optimum co-ordination of such activities (**C(77)97/FINAL**).
- Possibility to withdraw, completely or for certain use, or otherwise regulate in case harmful effects of a chemical are identified and procedures for emergency action (**C(77)97/FINAL**).



International cooperation

- **C(74)215:**
 - calls for international collaboration.
- **C(77)97/FINAL, Annex 1:**
 - international exchange of data from surveillance and monitoring programmes.



Additional information

- OECD legal instruments on chemicals:

<http://www.oecd.org/chemicalsafety/oecdouncilactsrelatedtochemicals.htm>

- OECD work on chemicals:

<http://www.oecd.org/chemicalsafety/>



Thank you!