OECD Mutual Acceptance of Data for Chemicals

Context

Over the last four decades, there have been four principal drivers for International Regulatory Cooperation (IRC) by the OECD in the field of chemical safety. The chemicals industry[1] is one of the world's largest industrial sectors and many chemicals are produced and traded internationally[2]. Thus, international cooperation on chemical safety was seen as a way to avoid non-tariff trade barriers due to varying regulatory requirements. As many of the same chemicals are produced in more than one OECD Member (or are traded across OECD Members), different national chemical control policies can lead to duplication in testing and government assessment, thereby wasting the resources of industry and government alike.

Second, releases of chemicals during production and use can travel across national (and sometimes regional) borders and thus, international cooperation is essential for a more comprehensive management of risks. Three OECD Members, in general, follow the same approach to the assessment of chemicals, and thus there are economic efficiencies if OECD Members can work together on such assessments.

Finally, through OECD Council Acts there was a possibility to make commitments among OECD Members which are legally (decisions) or politically (recommendations) binding. This level of engagement that can be achieved through the OECD and the peer pressure that can be applied to help ensure implementation of agreements, are crucial instruments to make sure that OECD Members will follow up on harmonisation arrangements.

🎬 Saving Costs and Lives in Chemicals Management (YouTube)

Photo Credit: OECD

OECD EHS Programme

OECD's Environment, Health and Safety (EHS) Programme has been working for 50 years, through international regulatory cooperation, to harmonise chemical safety tools and policies across jurisdictions and to share work on chemical assessments and common problems with the aim of minimising risks posed by chemicals and reducing non-tariff barriers to trade[3]. The development and implementation of the Mutual Acceptance of Data (MAD) system – under which chemical safety data developed using OECD Test Guidelines and OECD Principles of Good Laboratory Practice in one adhering OECD Member must be accepted in all adhering OECD Members – underpins much of this work. The MAD system is the mechanism which provides the framework for regulatory cooperation and is the focus of this case study. As of 2020, there are seven non-OECD member countries that are full adherents to MAD: Argentina, Brazil, India, Malaysia, Singapore, South Africa and Thailand[4].

Intended Objectives of MAD

- By accepting the same test results OECD-wide, unnecessary duplication of testing is avoided, thereby saving resources for industry and society as a whole.
- Non-tariff barriers to trade, which might be created by differing test methods required among OECD Members, can be minimised.
- The use and suffering of laboratory animals needed for toxicological tests is greatly reduced, which is a significant contribution to animal welfare.
- By establishing the same quality requirements for tests throughout OECD, a level playing field for the industry is ensured.

The MAD system opens opportunities for OECD Members to work together in the EHS Programme on issues of common concern. By using the results from the same test methods for making safety assessments, mutual understanding among OECD Members about chemical safety assessment and resulting risk management is greatly increased. This allows OECD Members to share work on assessing chemical safety and consider options for managing chemical risks.

🎬 **Key Elements of the OECD Framework for Mutual Acceptance of Data and Good Laboratory Practices**

HS work made possible because of the MAD system

1. Development of risk assessment methodologies given the harmonisation of the test methods and GLP: OECD Members can also collaborate on the development of hazard and exposure assessment methodologies, such as for assessing the risks of the combined exposure to multiple chemicals or the development of computer models to predict the toxicity or behaviour of chemicals.

2. Emerging policy issues: the application of OECD Test Guidelines is also the central tool for addressing the risks of new and emerging materials, such as nanomaterials and advanced materials. The EHS Programme is adapting the OECD Test Guidelines so that they are applicable to these kinds of new and innovative materials, thereby expanding the MAD system.

3. Harmonisation: Another role for the EHS Programme is to harmonise industry dossiers – based on chemical test data – and review reports for pesticides registration.

4. Exchanging technical and policy information: the EHS Programme acts as a forum for OECD Members to exchange technical and policy information. By discussing their chemical control policies together, OECD Members tend to develop similar policies and regulations and have greater confidence in each other's systems. In this way, not only are government resources saved, but products can also be brought to market faster. Finally, governments have access to the experience of the many scientific and policy experts from other governments, industry, non-governmental organisations and academia who participate in the work of the EHS Programme.

5. Outreach: the OECD's share in world chemical production is decreasing as non-OECD economies – particularly Brazil, Russia, India, Indonesia, China and South Africa – develop their chemical sectors. Greater international co operation is needed with these economies to build capacity, share information and ensure that new national chemical management systems do not lead to duplicative work or conflicting regulations and new trade barriers. The OECD's EHS Programme has a proactive outreach strategy to encourage the participation of partner OECD Members in the work of the programme and to allow them access to technical and policy discussions and documentation. Of particular importance is that the MAD Council Acts are open for non-members who wish to adhere.

Cost-Benefit Analysis of Chemical Safety IRC

In 2019, an analysis was conducted to determine the net savings governments and industry accrue from their participation in the OECD EHS Programme[5]. A similar analysis was conducted in 2010 and 1998. With respect to quantitative savings, the analysis focused on the benefits of harmonisation through the MAD system including reduction in repeat testing for industrial chemicals, pesticides and biocides, the use of computational approaches for prediction of properties of chemicals, which reduce testing particularly for industrial chemicals (supported by harmonised OECD tools and guidance) and the use of common formats.

The 2019 report estimated the net annual benefit of the EHS Programme to be EUR 309,035,000: Total savings [EUR 317 870 000] minus costs [EUR 8 835 000]. Additionally, 32,702 less animals are needed annually for testing new industrial chemicals.

Benefits

Four survey s were conducted in April 2018 to collect data from OECD governments and the biocide, industrial chemicals and pesticide industries. Additional data were collected from the OECD's Event Management System, which contains data on the number of OECD meetings held each day and the number of delegates registered for those meetings. Data from relevant reports in the literature have also been used to complement and confirm data collected via the surveys.

In essence, the analysis compared two scenarios: one with the MAD system, sharing the burden activities, and use of common formats; and the other, without such approaches. For example, without the OECD MAD system, slightly different test methods and GLPs would have been developed by each Member independently. Based on the results of the EHS surveys of the pesticide, biocide and industrial chemicals industries, it was estimated that, in the absence of the EHS Programme, Member B would not accept 30% of the test data for industrial chemicals nor 35% of test data for new pesticides or biocides emerging from Member A because of differing methods, and therefore, that testing would have to be repeated.

In developing the 2019 report, it was not possible to quantify all of the benefits of the EHS Programme's work. However, these unquantified benefits are just as real, likely and important as the quantified benefits. Some examples of work which leads (or will lead) to non-quantified benefits for governments and industry are:

- Ensuring safer nanomaterials by developing harmonised tools for testing and assessment.
- Harmonising the safety assessment methodologies for products of modern biotechnology.
- Providing harmonised tools to identify the risks of endocrine disrupters.
- Reducing the need for national government inspections of test facilities in other OECD Members that test chemicals.
- Enhancing hazard assessment methods and limiting the use of animals in chemical testing.
- Facilitating the exchange of information on chemical accidents to support prevention, preparedness and response.
- Advancing harmonisation of biocides regulations and testing.
- Reducing repeat testing for new pharmaceuticals.
- Counteracting the illegal trade of pesticides and thus reducing the chance that unregulated, unsafe and ineffective products are used on crops.

Costs

In the 2019 analysis, the costs of the EHS Programme were calculated based on i) Secretariat costs (OECD Secretariat support, including staff salaries, benefits and

travel; consultants and invited experts; and general overhead); and ii) OECD Member costs (the costs to governments, industry and other non-governmental organisations of participating in and contributing to the work of the EHS Programme). These include both travel costs to attend OECD meetings and staff costs for developing and reviewing EHS documents and preparing for and attending EHS meetings.

Net Savings

The 2019 report estimates that net savings attributable to the EHS Programme have grown by 75% since the last report (2010) and by over 240% since the initial report (1998). There are two reasons for the large increase in savings from the 2010 report. One, unlike the previous report, the current report includes the significant savings (around EUR 60 million per year) from tests on biocides (e.g. disinfectants) not being repeated due to the MAD system. (The previous reports only included savings from industrial chemicals and pesticides). Two, since 2010 there has been an increase in the number of OECD Member Adherents as well as non-OECD Member full Adherents to MAD. This means that the reduction in duplicative testing is now spread across more Adherents and hence the savings are greater.

Table 1: Net annual savings resulting from the OECD's EHS Programme[5]

Savings	€
From no repeat pesticide testing	206 937 500
From no repeat new industrial chemical testing	44 728 943
From no repeat biocide testing	61 250 000
From no repeat existing chemical testing	780 570
From harmonised pesticide monographs	2 218 145
From harmonised pesticide dossiers	1 951 125
Savings subtotal (rounded)	317 870 000
Costs	
OECD Member participation in the EHS Programme	4 290 000
OECD Secretariat	4 545 000
Costs subtotal	8 835 000
Net savings (rounded) EUR 309 035 000	
Reduction in animals needed for testing new industrial chemicals: 32 702	

Endnotes

[1] Includes industrial chemicals, pharmaceuticals, pesticides, biocides, food and feed additives and cosmetics.
[2] Global sales in 2017 amounted to over USD 5.6 trillion and are predicted to rise to over USD 21 trillion in 2060 (OECD, 2019)
[3] OECD (n.d.), Organisation of the Environment, Health and Safety Programme, https://www.oecd.org/env/ehs/organisationoftheenvironmenthealthandsafetyprogramme.htm (accessed on 31 August 2021).
[4] OECD (n.d.), Mutual Acceptance of Data (MAD), [4] https://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm (accessed on 31 August 2021).
[5] OECD (2019), Saving Costs in Chemicals Management, https://doi.org/10.1787/9789264311718-en. OECD (n.d.), Organisation of the Environment, Health and Safety Programme, https://www.oecd.org/env/ehs/organisationoftheenvironmenthealthandsafetyprogramme.htm (accessed on 31 August 2021).

Date: Finalised in 2021