# International Regulatory Co-operation in Competition Law and Chemical Safety

OECD

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BETTER POLICIES FOR BETTER LIVES

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# Foreword

International regulatory co-operation (IRC), as defined by the OECD, can be "[*a]ny agreement or organisational arrangement, formal or informal, between countries to promote some form of co-operation in the design, monitoring, enforcement, or ex post management of regulation*". Since the 2012 Recommendation of the Council on Regulatory Policy and Governance, the OECD has advised countries to introduce international considerations throughout rulemaking. Drawing on over 10 years of experiences and analysis, the OECD adopted the *Recommendation of the Council on International Regulatory Co-operation to Tackle Global Challenges* in July 2022. This instrument advices countries to a take a whole-of-government approach to IRC, embed IRC through domestic rulemaking, and co-operate bi-, and multilaterally through a variety of activities.

International regulatory co-operation can take a variety of forms. The OECD identifies 11 categories, including mutual recognition agreements, trans-governmental networks, soft law, and recognition of international standards.

This report presents two case studies of IRC in the fields of competition law enforcement and chemical safety that highlight tangible benefits of close co-operation and provide an overview of two different IRC applications. International co-operation between regulators can take place at different stages of rulemaking, from regulatory design to enforcement and monitoring. These case studies focus on the enforcement and monitoring side rulemaking, they display how international co-operation can help governments come together to achieve policy goals and improve efficiency to reduce the amount of resources necessary to do so.

The case study on competition law enforcement surveys common co-operation practices among competition authorities and outlines legal and practical challenges for co-operation. The case study on chemical safety reviews the OECD Environment, Health and Safety Programme and provides updated evidence on the monetary benefits of co-operation, notably in financial savings from mutual acceptance of data from subscribing countries.

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# Acknowledgements

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The case study on competition enforcement law was revised and updated by Sabine Zigelski, Senior Competition Expert in the Competition Division of the OECD Directorate for Financial and Enterprise Affairs. It is based on work done by Hilary Jennings and Antonio Capobianco for the 2013 edition of the Case Studies. Hilary Jennings was then Head of Global Relations, and Antonio Capobianco, Senior Competition Expert, in the Competition Division of the OECD Directorate for Financial and Enterprise Affairs. It incorporates work done by Isolde Lueckenhausen, then Senior Competition Expert and Secondee from the Australian Consumer and Commerce Commission to the OECD.

The case study on chemical safety was developed in 2021 by Bob Diderich, Head of Health and Safety Division, and Eeva Leinala, Principal Administrator, Good Laboratory Practices/ Mutual Acceptance of Data, Health and Safety Division, OECD Environment Directorate. It is based on a case study developed in 2013 by Richard Sigman, then Principal Administrator in the Environment, Health and Safety Division of the OECD Environment Directorate.

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# Abbreviations and acronyms

| | |
|---|---|
| **BRICS** | Brazil, the Russian Federation, India, the People's Republic of China and South Africa |
| **CEC** | Enforcement Co-operation Template |
| **CIS** | Commonwealth of Independent States |
| **ECN** | European Competition Network |
| **EHS** | Environment, Health and Safety |
| **GLP** | Good Laboratory Practice |
| **ICN** | International Competition Network |
| **ILO** | International Labour Organization |
| **IOMC** | Inter-Organization Programme for the Sound Management of Chemicals |
| **MAD** | Mutual Acceptance of Data |
| **MLATs** | Mutual Legal Assistance Treaty |
| **MMAC** | Multi-lateral Mutual Assistance and Cooperation Framework for Competition Authorities |
| **MoU** | Memoranda of Understanding |
| **NCAs** | National competition authorities |
| **PCBs** | Polychlorobiphenyls |
| **PFASs** | Per- and polyfluoroalkyl substances |
| **PIC** | Prior Informed Consent |
| **POPs** | Persistent Organic Pollutants |
| **RTAs** | Regional Trade Agreements |
| **SAICM** | Strategic Approach to International Chemicals Management |
| **TBT** | Technical Barriers to Trade |
| **TFEU** | Treaty on the Functioning of the EU |
| **UNCED** | UN Conference on Environment and Development |
| **UNCTAD** | United Nations Conference on Trade and Development |
| **WSSD** | World Summit on Sustainable Development |
| **WTO** | World Trade Organization |

# Executive summary

International regulatory co-operation (IRC) has become essential for regulatory quality, as governments face challenges that extend beyond borders. In particular, the OECD recommendation on international regulatory co-operation, recommends for a systematised and whole-of-government strategy on IRC, to be reflected throughout the policy-making cycle, from the design up to the enforcement and *ex post* evaluation of regulation. Evidence across OECD countries shows that IRC practices remain far from systematic. In fact, the 2021 *OECD Regulatory Policy Outlook* shows that only a minority of OECD countries have in place a cross-sectoral policy and an institutional framework to conduct IRC. As a result, the use of IRC practices remains uneven, across government and policy areas.

Most notably, IRC is only seldom used in the "downstream" part of the rulemaking cycle (that is, implementation and enforcement). This gap is significant as co-operation in these areas can help lower administrative costs and increase the effectiveness of regulations, even when there is no harmonisation in the regulations themselves. This report presents two cases that show tangible benefits from co-operating beyond the design, or development phase of regulation. The competition case study provides an example how international co-operation can improve enforcement. The chemicals safety case study provides an example of IRC in testing, i.e. assessment of conformity with a standard or regulation.

These case studies offer insights from different policy areas and valuable illustrations of findings from the application of the OECD recommendation on IRC. They demonstrate the variety of forms IRC can take, as well as their complementarity: they both rely on binding international instruments complemented by more looser forms of co-operation, with more or less institutional support provided by international organisations (namely, the OECD) to facilitate the exchange of information that is essential for co-operation to bear fruit.

The lessons also help promote the adoption of IRC in the downstream part of the regulatory cycle. While both case studies are related to regulatory enforcement, they highlight different types of benefits. The case study on competition shows the benefit of adopting IRC to improve the efficacy of competition law – in this case, IRC has helped to increase compliance. While the chemical safety case study shows how IRC can help increase the efficiency of regulatory enforcement. In this case, authorities were able to ensure compliance while reducing its costs.

Regulators and policy makers undertaking or overseeing international regulatory co-operation practices can no doubt learn from the success factors, challenges, costs and benefits outlined in these case studies on competition enforcement and chemicals safety.

## Co-operation in competition enforcement law: overcoming legal barriers to co-operation to keep up with companies operating globally and affecting citizens worldwide

A globalised economy with multi-national enterprises has led to a larger number of competition enforcement cases with international dimensions. The digitalisation of the economy has also created new challenges for all competition authorities. This makes international co-operation between competition

authorities imperative for domestic enforcement to be truly effective. To successfully discover and prosecute anti-competitive practices, competition authorities need to improve significantly their ability to co-operate. International co-operation in competition enforcement is a widely discussed topic in many fora and is of considerable interest to both competition enforcers and the private sector. This case study presents how the OECD has contributed to these discussions and has fostered co-operation through its own instruments and reports.

## OECD's Environment, Health and Safety Programme: Multilateral co-operation on chemicals safety to protect human health, prevent environmental hazards and generate economic savings

OECD countries have comprehensive regulatory frameworks for preventing and/or minimising health and environmental risks posed by chemicals. These frameworks ensure that chemical products on the market are handled in a safe way, and that new chemicals are properly assessed before being placed on the market. However, different national chemical control policies can lead to duplication in testing and government assessments. They may also create non-tariff or technical barriers to trade in chemicals; discourage research, innovation and growth; and increase the time it takes to introduce new products on the market. This case study shows how the development and implementation of the Mutual Acceptance of Data system – under which chemical safety data developed in one adhering country using the OECD Test Guidelines and OECD principles of Good Laboratory Practice must be accepted by all adhering countries – is helping minimise unnecessary divergences across regulatory frameworks and facilitating work-sharing by governments. The case study provides updated data on a cost-benefit analysis of the MAD system, resulting in an overwhelming net positive benefit for government and industry, estimated to be around EUR 309 035 000.

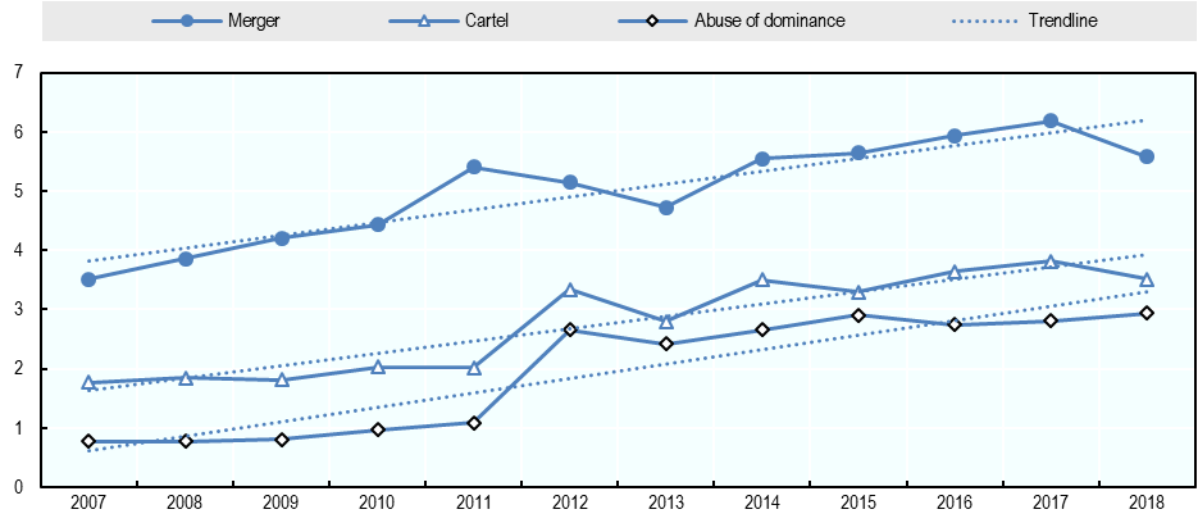
# 1 Co-operation in competition law enforcement

This case study overviews recent trends on international co-operation for enforcement in competition cases and discusses the main forms of co-operation as well as the tools and instruments national authorities have at their disposal to do so. Building from this, the case study discusses achievements and challenges to expand international competition for competition law enforcement.

The increasing number of competition enforcement cases with international dimensions makes co-operation between competition enforcers in different jurisdictions imperative for domestic enforcement to be truly effective. The introduction of competition law in more jurisdictions highlights the potential for co-operative relationships based on a shared commitment to fight anti-competitive practices. Success in discovering and prosecuting these practices will require competition authorities to significantly improve their ability to co-operate. The digitisation of the economy and with it the emergence of large digital gatekeepers increases the scale and scope of cross-border cases, and raises new challenges for competition enforcers, which cannot be addressed effectively by purely national enforcement. International co-operation in competition enforcement cases is thus a topic that continues to be widely discussed in many fora and is of considerable interest to competition enforcers and the private sector alike. The OECD has contributed to these discussions and has fostered co-operation through its own instruments and reports, as have others.

Most co-operation between competition authorities takes place in merger review cases, with cartel investigations coming in second (Figure 1.1). Merger review is an authorisation process often involving parallel national investigations, and the parties have all the incentives to co-operate with the reviewing authorities to ensure consistent outcomes and speedy clearance through effective co-operation between the authorities involved. Conversely, in cartel cases the investigated parties have less interest in the authorities co-operating, which may result in multiple sanctions, unless they are in leniency/amnesty programmes. Therefore, creating the incentives for co-operation in cartel investigations rests largely with competition authorities (see also (OECD, 2018[1])).

### Figure 1.1. Average number of cases/competition authority/year involving international enforcement co-operation, by enforcement area, 2007-2018




Note: Cases reported by Adherents to the 2014 Recommendation on International Co-operation.
Source: (OECD, 2022[2]), Question 18 – Table 5.2.

## Comity: A defining principle of international co-operation

Comity is the legal principle whereby a country should take other countries' important interests into account while conducting its law enforcement activities, in return for their doing the same. For over 100 years, public international law has acknowledged comity as a means for tempering the effects of the unilateral assertion of extraterritorial jurisdiction. Comity is therefore a horizontal, sovereign state to sovereign state concept, as laid down by the United States Supreme Court in Hilton vs. Guyot in 1895.[1] It is not the

abdication of jurisdiction; instead, it is the exercise of jurisdiction with an accompanying understanding of the impact that the exercise of jurisdiction may have on the law enforcement activities of other countries.

International co-operation in the competition field employs two types of comity: negative comity and positive comity.

### *Traditional or negative comity*

Traditional comity involves a country's consideration of how to prevent its laws and law enforcement actions from harming another country's important interests. The OECD's successive Recommendations on co-operation in competition matters (the most recent in 2014) recommended that in seeking to implement negative or traditional comity a country should:

- notify other countries when its enforcement proceedings may affect their important interests, and
- give full and sympathetic consideration to ways of fulfilling its enforcement needs without harming those interests ( (OECD, 2014[3]), III.1 and V.).

### *Positive comity*

Positive comity involves a request by one country that another country undertake enforcement activities in order to remedy allegedly anti-competitive conduct that is substantially and adversely affecting the interests of the referring country.[2] However, the underlying concept was decades old. Positive comity provisions have been included in the OECD Recommendations on Co-operation since 1973, although the term "positive comity" has not been used specifically. The 2014 OECD Recommendation sets out that a country should:

> *Give full and sympathetic consideration to such views and factual materials as may be provided by the requesting Adherent and, in particular, to the nature of the alleged anticompetitive practices or mergers with anticompetitive effects in question, the enterprises or individuals involved and the alleged harmful effects on the interests of the requesting Adherent.*
>
> *If the Adherent so addressed agrees that enterprises or individuals situated in its territory are engaged in anticompetitive practices or in mergers with anticompetitive effects harmful to the interests of the requesting Adherent, it should take whatever remedial action it considers appropriate, including actions under its competition law, on a voluntary basis and considering its legitimate interests ( (OECD, 2014[3]), IV. 2 and 3).*

Positive comity provisions are now included in many bilateral co-operation agreements between competition authorities. The first wave of co-operation agreements was limited to negative comity principles of avoiding harm to other countries.[3] This changed with the 1991 EC-US Agreement referred to above. It was the first time that positive comity was included in a bilateral agreement on co-operation in antitrust matters.[4] The principle laid down in Article V of the 1991 EC-US Agreement was further consolidated in the Positive Comity Agreement signed by the European Community and the United States in 1998.[5] The United States and Canada entered into a similar agreement in 2004.[6] In total, 12 competition co-operation agreements between governments and three inter-agency Memoranda of Understanding (MoU) include provisions on positive comity.[7]

There was an initial enthusiasm for positive comity, which was particularly strong after the signing of the 1998 EC-US Positive Comity Agreement. However, recent data show that positive comity appears to be a little used instrument, despite its potential.[8]

## Main forms of co-operation and instruments/tools of co-operation

Competition enforcers are the key players in international co-operation in the competition area. Co-operation with foreign jurisdictions is key in the investigation phase, as it allows enforcers to access information located abroad and it facilitates a consistent outcome of parallel competition investigations. Competition authorities can use different legal bases for co-operation. The most effective ones are those designed specifically for competition purposes. This is the case in particular of bi-lateral co-operation agreements entered into by competition authorities to facilitate the relationship between the signatories. In the absence of a specific competition instrument, other international co-operation instruments can apply. These are instruments negotiated by governments to allow their respective ministries and agencies to co-operate. These are usually less effective instruments, as they require the involvement of other parts of the government or of the judiciary, which tend to be time consuming and not apt for fast resolution of competition cases.

International co-operation between competition authorities takes place in a multiplicity of forms. It can take place at the bilateral, regional, or multilateral levels. It can be based on formal instruments such as a national legal provision or an agreement between jurisdictions or competition authorities. It may be based on a waiver from a provider of evidence. It can be informal, in that it is not based on the framework of a specific co-operation instrument, and so normally involves general forms of co-operation, such as technical assistance, or exchanges of public or authority information. The different instruments and tools as well as the various types of co-operation involved in cross-border cases create a complex web of differing levels of possible engagement between authorities (see also (Caro de Sousa, 2020[4])). The drivers for co-operation and the instruments and networks that underpin it are equally distinct across different jurisdictions and groupings of countries. In spite of all of these variables there is agreement between competition enforcers that international co-operation is a key tool to ensuring that anti-competitive conduct that affects several jurisdictions is dealt with effectively and optimally. Means of facilitating international co-operation are therefore actively pursued.

### *Non-competition-specific co-operation instruments*

Some co-operation is facilitated by instruments with broad application across multiple enforcement areas like Mutual Legal Assistance Treaties (MLATs), extradition treaties and letters rogatory (letters of request).

#### *Mutual Legal Assistance Treaties*

Many countries have entered into MLATs. They are bilateral treaties creating reciprocal international obligations between sovereign governments and are not specific to competition investigations. An MLAT normally allows the signatories to request various types of assistance from each other, including the use of formal investigative powers and sharing of confidential information. MLATs are therefore potentially powerful tools, but they have traditionally been restricted to criminal matters. MLATs require the underlying offence to be a crime in at least the requesting country's jurisdiction. In most jurisdictions, cartel conduct is not a crime and so MLATs are little used in cartel investigations.

Although a significant number of MLATs exist, not all MLATs can be used for co-operation in competition cases. There may be an explicit exclusion for competition matters from the scope of the treaty, as is the case in the Switzerland-US MLAT.[9] Some MLATs also require that both jurisdictions treat the conduct under investigation as a crime ("the dual criminality requirement").

MLATs can theoretically be a very effective means of cross-border evidence gathering in competition cases. They provide a mechanism for the signatories to obtain a wide variety of legal assistance for criminal matters generally, including the compulsory taking of evidence on oath and the execution of searches of domestic and business premises. However, they are widely considered by competition authorities as

resource intensive, quite demanding in terms of process and prerequisites and slow (OECD, 2021, p. 107[5]); (International Competition Network, 2020, pp. 13-14[6]).

### *Extradition treaties*

Extradition treaties also require the underlying conduct to be a crime in both jurisdictions. Given the relatively small number of jurisdictions to have made cartels a criminal offence, the proportion of extradition treaties that can be deployed for competition cases is even smaller than for MLATs.

### *Letters rogatory*

Competition authorities can also use letters rogatory in order to obtain assistance from abroad in the absence of an MLAT or executive agreement. This is a formal request whereby one court requests a foreign court to perform a judicial act, such as taking evidence, serving a summons, or other legal notice. The process is usually time-consuming and cumbersome. Some countries insist that the requests be submitted through the diplomatic channel.

### *Regional Trade Agreements which include competition provisions*

Regional agreements can also provide for co-operation on competition matters. There are currently 349 Regional Trade Agreements (RTAs) in force listed on the World Trade Organisation website, of which 238 contain competition provisions. In the competition sphere, there are a number of well-known RTAs including the AfCFTA, the Andean Community, ASEAN, CARICOM, COMESA, CPTPP, EU, MERCOSUR, NAFTA, RCEP, TEAEU, USMCA and WAEMU. RTAs are no longer strictly based on geographic location, and they can be agreed bilaterally between individual countries (Free Trade Agreements), among one country and a group of countries (plurilateral agreements), or among regions or blocs of countries (multilateral agreements).

The scope and content of the provisions vary. According to analysis undertaken in 2019, trade agreements have increased significantly over the last 30 years and they have become major instrumentsto lower not just tariffs, but also non-tariff barriers. Currently, about 90% of trade agreements incorporate competition provisions or chapters. The most frequent competition provisions concern commitments to prohibit abuses of market power and anti-competitive agreements, commitments to ensure that SOEs and subsidies do not distort the level-playing field, and provisions on international co-operation. About 50% of the trade agreements include provisions on co-operation and co-ordination in competition policy. For instance, these refer to positive or negative comity, taking into account the interests of the other party either to refrain or to investigate certain practices, notification requirements or exchange of information requirements.

Regional competition agreements can offer deeper levels of integration and a higher degree of co-operation than bilateral agreements. Asian and Latin American countries and the Commonwealth of Independent States (CIS) have integratedcompetition provisions in their RTA (Anderson et al., 2019[7]). One example of a regional agreement that has been in operation for almost 20 years is the European Union and its European Competition Network (ECN). This provides a framework for co-operation between the European Union member states' competition authorities in cases where Articles 101 and 102 of the Treaty on the Functioning of the EU (TFEU) are applied. The ECN has been a successful model for regional co-operation. It is established under a European Council Regulation and is based on a system of parallel competences which allows all national competition authorities (NCAs) to apply the same competition rules.

The ECN facilitates case allocation to the authority "well-placed" to deal with the case and ensures a consistent application of the European Union's competition rules. The ECN is an informal network in that it does not take 'decisions' and cannot compel its members to act in a certain way. It is, however, expected that the constructive dialogue will help solve most of the conflicts which may arise. Should a deadlock occur, the Commission retains the power to relieve national competition authorities of their competence by

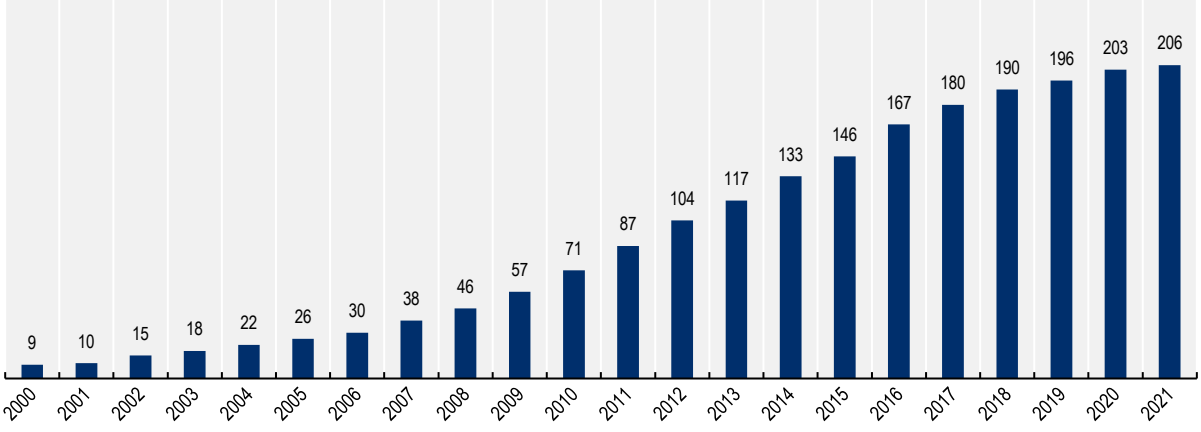
opening proceedings. The Regulation creates a number of co-operation mechanisms for the purpose of case allocation and assistance. NCAs should inform each other before or without delay after starting the first formal investigative measure, and make relevant information available to other NCAs.

### *Competition-specific bilateral and multilateral co-operation agreements*

Bilateral and multilateral competition agreements between jurisdictions relating to enforcement co-operation vary in the extent to which they are binding and the degree to which they seek to impose specific obligations on each party. For example, a Memorandum of Understanding (MoU) between authorities is generally considered non-binding, while a treaty-level agreement between governments may be binding.[10]

A key development in enforcement co-operation has been the proliferation of bi-lateral competition agreements, which have become more numerous, comprehensive and detailed over time.[11] Bi-lateral enforcement co-operation agreements can include inter-governmental agreements (OECD, 2015[8]) or inter-authority arrangements, such as MoUs (OECD, 2016[9]). Bi-lateral MoUs are the most widely used model of bi-lateral competition agreements, and their number keeps growing.

**Figure 1.2. Growth of co-operation agreements, 2000-21**




Note: includes bilateral and multilateral agreements.
Source: (OECD, n.d.[10]).

While MoUs may often amount to 'best endeavours' agreements between competition authorities, some of these agreements formalise existing working relationships, while others mark a new level of engagement between competition authorities. They can be an important part of establishing a closer working relationship if this has not existed in the past, and they are usually non-binding.

Common clauses in MoU deal with the following substantive topics: transparency, notifications, enforcement co-operation and investigative assistance, exchange of information, co-ordination of investigations and proceedings, comity, consultation, regular meetings, confidentiality, legal bases and communication. The OECD has created an inventory of MoUs to inform about commonly used clauses.[12] They are mostly first-generation type agreements.[13] However, following the adoption of the 2014 OECD Recommendation, more second-generation type agreements[14] were concluded. Before 2013, the Australia-United States Mutual Antitrust Enforcement Assistance Agreement (April 1999) was the only second-generation agreement relating only to competition co-operation (Australia-USA, 1999[11]). Since 2013, a few more second-generation agreements have been finalised, including: the EU and Switzerland (2013) (EU – Switzerland, 2013[12]), the New Zealand Commerce Commission and Canada (2016) (Canada – New Zealand, 2016[13]), and the Nordic Alliance (Denmark, Finland, Iceland, Norway and

Sweden) (2017).[15] In October 2020, the Multi-lateral Mutual Assistance and Cooperation Framework for Competition Authorities (MMAC) between Australia, Canada, the United Kingdom, the United States and New Zealand (2020) was signed.[16]

### Box 1.1. Multi-lateral Mutual Assistance and Cooperation Framework for Competition Authorities (MMAC)

The MMAC was signed by Australia, Canada, the United Kingdom, the United States and New Zealand in 2020, and is structured as an 'in-principle' non-binding multi-lateral memorandum of understanding (the Framework MoU), which attaches a model bi-lateral/multi-lateral agreement as an annexure (the Model Agreement).

The second-generation component of the MMAC is contained in the Model Agreement, and all parties have agreed in the MMAC to implement the Model Agreement between themselves bi-laterally (or multi-laterally) in as close as possible a form. This structure was developed to allow for the differences between the competencies and legal powers of each authority (for example, only some authorities can issue a warrant on behalf of a counterpart authority), while retaining a 'standard form' agreement in order to set a public benchmark and promote conformity.

The Framework MOU sets out the types of informal co-operation and assistance that the parties have agreed to provide to each other including exchange of general, competition policy related information, and best practices, as well as investigative information as already permitted by law.

The Model Agreement creates a mechanism for formal requests for investigative assistance between the competition agencies. It sets out how requests for assistance should be made, how parties should respond to such requests, how information should be handled if the request is accepted, and how any costs associated with executing a request will be settled.

The types of investigative assistance contemplated by the Model Agreement include:

- providing or discussing investigative information in the possession of, or obtained by, a party, which includes information obtained through search warrants or compulsory notices
- obtaining information in order to provide it to the other party
- taking testimony or statements of persons
- obtaining documents, records, or other forms of investigative information
- locating or identifying persons or things
- executing searches and seizures.

The six parties to the MMAC share similar systems and have strong informal co-operation relationships. The MMAC intends to create consistent, next generation co-operation agreements between the authorities. This will facilitate the sharing of confidential antitrust evidence, evidence collection and informal co-operation.

Source: (OECD, 2021, pp. 239-241[5]); https://www.accc.gov.au/system/files/MMAC%20-%20FINAL%20English%20-%202%20September%202020%2811501052.1%29.pdf.

In addition, there are multi-lateral competition arrangements that focus on competition law and policy and a more general level of co-operation, such as the MoU between Brazil, the Russian Federation, India, the People's Republic of China and South Africa (BRICS) (BRICS, 2016[14]). The BRICS MoU created a

framework for multi-lateral co-operation and sets up an institutional partnership, aimed at promoting and strengthening the co-operation in competition law and policy between the parties.

### *Provisions in national laws*

Some national laws provide a direct legal basis for co-operation between authorities or jurisdictions, while others provide a mandate to enter into co-operation agreements with other jurisdictions.

Two types of national laws allow specific or deeper forms of co-operation: 1) national laws that provide a "gateway" to confidential information sharing absent a waiver and 2) national laws that allow an authority to enter into second-generation international agreements. In relation to the first type, the following jurisdictions are examples of those that can share confidential information absent a waiver in limited circumstances with another authority (outside of an MLAT process): Australia,[17] New Zealand,[18] Canada,[19] the United Kingdom,[20] and Germany.[21]

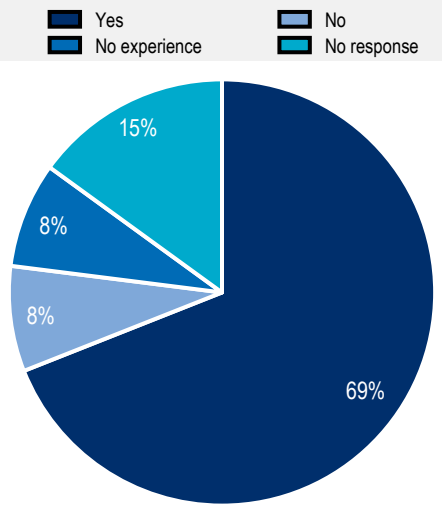
In relation to the second type of national law, some authorities have specific national laws that allow them to enter into second-generation agreements to facilitate intensive co-operation activities, such as sharing confidential information absent a waiver, providing investigative assistance or engaging in enhanced co-operation. These are for example the United States[22] and Ireland.[23]

### *Co-operation based on confidentiality waivers provided by the parties to the investigations*

Today international co-operation is largely based on waivers that companies subject to either a merger investigation or to a cartel investigation grant to authorities, allowing them to exchange confidential information on the case. Waivers of confidentiality enable authorities to exchange information quickly and at an early stage, which facilitates co-ordination of the initial steps in an investigation. This may avoid the need to use official channels in formal co-operation procedures and the ensuing delay this can entail.

Using waivers has become the most frequent way of sharing confidential information between competition authorities (Figure 1.3).

**Figure 1.3. Use of confidentiality waivers, 2019, 95% response rate**




Note: As percentage of Survey respondents.
Source: (OECD, 2021, p. 171[5]).

The ICN has developed model waiver templates, and a number of competition authorities provide a waiver template on their public websites.[24]

## Informal co-operation

The term “informal co-operation” refers to all co-operation among competition authorities that does not include sharing confidential information or obtaining evidence on behalf of another authority. This type of co-operation is more common than the formal variety, no doubt because it is easier to conduct and it does not encounter the legal constraints on the exchange of confidential information or other forms of investigative assistance or co-ordination that exist in every jurisdiction.

Despite its limitations, informal co-operation can contribute to more effective enforcement. Conferences, bilateral meetings, and other exchanges of know-how spread both expertise and mutual understanding. Bilateral co-operation agreements can facilitate case-specific co-operation by further clarifying the authorities’ understanding of each others’ systems and expectations. Case specific informal co-operation can include discussion of investigation strategies, market information, witness evaluations, sharing leads and comparing authority approaches to common cases. The information or assistance obtained in these instances can streamline the investigative strategy and help focus an investigation.

Informal co-operation is often underpinned by the personal contacts and trust built through participation in the competition networks, many of which have emerged in recent years. International and regional forums, such as the OECD, UNCTAD, ICN, ASEAN, APEC, African Competition Forum, BRICS and ICAP, all provide avenues for authorities and staff to get together, share ideas, practices and develop understanding of each other’s legal frameworks and institutions. This helps with the creation of “pick-up-the-phone” relationships and institutionalising co-operation between authorities. The provision of capacity building is a means of building technical expertise as well as fostering mutual understanding and future co-operation.

### Box 1.2. Capacity building to foster co-operation

The Competition Committee engages in numerous capacity-building activities around the globe, however, the most noteworthy, unique and impactful are carried out by the three Regional Centres for Competition in Korea, Hungary and Peru. The Regional Centres provide a series of capacity building workshops each year on all kind of enforcement and policy related questions to around 65 non-member jurisdictions.

### Figure 1.4. Regional Centres for Competition

The workshops usually take place in Seoul, Budapest and Lima, and allow enforcers from the beneficiary jurisdictions to participate free of charge. Next to valuable competition know-how, these events have proven very effective in promoting regional co-operation on the case handler level. The Centres' work also helps to align non-member laws and practices with OECD standards, thus providing an essential basis for wider international enforcement co-operation.

Source: https://www.oecd.org/daf/competition/oecd-gvhregionalcentreforcompetitioninbudapest.htm; https://www.oecd.org/daf/competition/oecdkoreapolicycentrecompetitionprogramme.htm; https://www.oecd.org/daf/competition/oecd-regional-centre-for-competition-in-latin-america.htm.

Practice suggests that co-operation in the detection and investigation of competition cases often involves a mixture of formal and informal co-operation between competition authorities. The existence of international agreements does not guarantee co-operation, nor does their absence preclude it. The advantage of the complex web of international agreements that exist between governments or their authorities is that it offers a formal framework for co-operation, despite the legal limits. In turn, the conclusion of international agreements signals willingness and the ability to engage in a constructive dialogue with foreign peers. The challenge for competition authorities from developing countries in particular, is to identify the right balance between what can be achieved through informal co-operation and what requires more formal mechanisms.

## Functions being co-ordinated/components covered in co-operation

Co-operation can take place at different phases of an investigation:

- At the pre-investigatory phase, that is, the phase before evidence-gathering takes place, agencies can co-operate regarding markets to be investigated, companies to be targeted, the location of evidence, and avoidance of destruction of evidence;
- At the investigatory phase, the phase during which evidence is gathered and analysed, and the case built up, they may co-ordinate investigatory measures. This could include the organisation of simultaneous searches, raids or inspections, issuing of subpoenas or other requests for information, or interviewing of witnesses;
- At the post-investigatory phase, which concerns prosecution, adjudication, sanctioning, and remedies, agencies may exchange evidence and other information which they have obtained, and they may co-operate via general case discussions between the investigators.

In all of these phases, competition authorities can make use of the various instruments discussed above. Competition specific tools for international co-operation are generally used by competition authorities across all the three phases of the investigation. Informal co-operation is most intense during the pre-investigatory phase where due process guarantees are lower, since there is no formal investigation yet. Non-competition specific instruments, such as MLATs and letters rogatory, are most used during the investigatory phase as they are complex and time-consuming but allow some form of co-operation when specific competition instruments are not available (e.g. when there competition authorities concerned do not have a co-operation agreement).

### Box 1.3. Information exchange between enforcers

Exchange of information is a key aspect of co-operation, although by no means the only aspect. The kinds of information which may be exchanged fall largely into four categories:

- **Public information.** In this case, one agency simply helps another agency to gain time by providing information which is already in the public domain (perhaps a hard-to-find market report, or information about the market arising from studies carried out by the agency);
- **Agency internal information.** This is information which is not necessarily in the public domain, but which is generated within the agency itself, rather than provided by parties to the investigation (although it may be based on information supplied by the parties). Such 'agency internal information' may concern for example the stage which the investigation has reached, the planned timing of further steps, the provisional orientation of the investigation, conclusions reached about the nature of the market and so forth;
- **Information from the parties already in the possession of one agency.** This kind of material can be evidence of an infringement or background information on the market or the activities of the parties (such as turnover figures). The information may have been provided voluntarily (by an immunity/amnesty applicant, for example) or under compulsion (in an inspection, under subpoena, and so forth);
- **Information obtained from the parties at the request of another agency.** Where two agencies have a highly developed co-operative relationship, it may be possible for one of them to request the other to obtain information from parties in its jurisdiction, which is not already in its possession. This could involve carrying out surprise searches, raids or inspections, issuing subpoenas, interviewing witnesses, and so forth.

## Benefits of international co-operation in competition cases

The benefits of international co-operation will largely depend on the extent to which competition authorities are willing and able to create a co-operative culture in which authorities can justify bringing cases primarily for the benefit of others on the basis of the benefits that they expect to receive from cases brought by others.

The benefits include:

- *Improved effectiveness.* By invoking a requested country's laws, positive comity can provide a remedy for illegal conduct that the requesting country cannot remedy itself due to jurisdictional problems.
- *Improved efficiency.* Since positive comity results in an investigation by the country in the best position to gather the necessary facts, it can improve efficiency by reducing investigation costs and the risk of inconsistencies.
- *Improved relationships, trust and transparency.* By creating personal and organisational relationships of trust, which can serve as a basis for effective and deeper enforcement co-operation, and improving transparency and understanding of counterpart authority practices and procedures.

In relation to specific enforcement challenges created by digitalisation and large online platforms that can act as gatekeepers on markets, an additional benefit can be identified:

- *Enabling supra-national solutions to globalised challenges.* By creating and using mechanisms of enhanced co-operation such as recognition of another jurisdiction's decisions, one-stop-shop models (i.e. for leniency or merger cases), appointment of lead jurisdictions, joint investigative teams and cross-appointments, or co-operation at court level (see (OECD, 2014[15]) and (OECD, 2021[5])).

## Challenges to international co-operation in competition cases

The increasing number of countries with competition laws, the increasing globalisation of the economy and the growth of multi-national enterprises, and the risks from diverging enforcement decisions and related costs to businesses and the economy create an ever-stronger need for competition authorities to co-ordinate competition investigations with cross-border effects. The challenges posed by the digital economy exacerbate such challenges and increase the need for better co-ordination (Box 1.4).

### Box 1.4. Globalised Digital Challenges

Digitalisation[1] has been a dominant topic of competition policy discussions in recent years, and the OECD has been at the forefront. The Competition Committee has served as a place for delegates to hear about new issues, exchange experiences in digital markets, and identify common ground across jurisdictions.

The Committee has explored the dynamics of competition in digital markets, including the business models, strategies and inputs that make these markets different, including the measurement of market power and the role of gatekeepers.[2] It has also examined emerging competition concerns, ranging from algorithmic collusion to the acquisition of emerging competitors, and debated whether these are unique to digital markets or fit within established theories of harm. The need to ensure sector regulatory frameworks remain fit for purpose, and do not unnecessarily restrict competition in the wake of digital innovations, has also been a major theme of Committee roundtables. In addition, the Committee has discussed how to remedy competition problems in digital markets, where the line should be drawn between competition enforcement and advocacy, and which issues are relevant for competition law as opposed to other areas such as consumer protection. Going forward, the Committee will focus on the proposals and reforms in progress to update competition enforcement tools, assessments and legislation in response to digitalisation.

As many of the large digital players are global in scope and apply similar business strategies across continents, in particular smaller jurisdictions will often lack the technical expertise and the resources needed to investigate and address anti-competitive behaviour effectively. They may also be under pressure of threats and retaliatory measures (see for example https://www.bbc.com/news/world-australia-56165015) when acting on their own. National prohibitions and remedies may not solve the competition problems, or be at odds with other jurisdictions' measures.

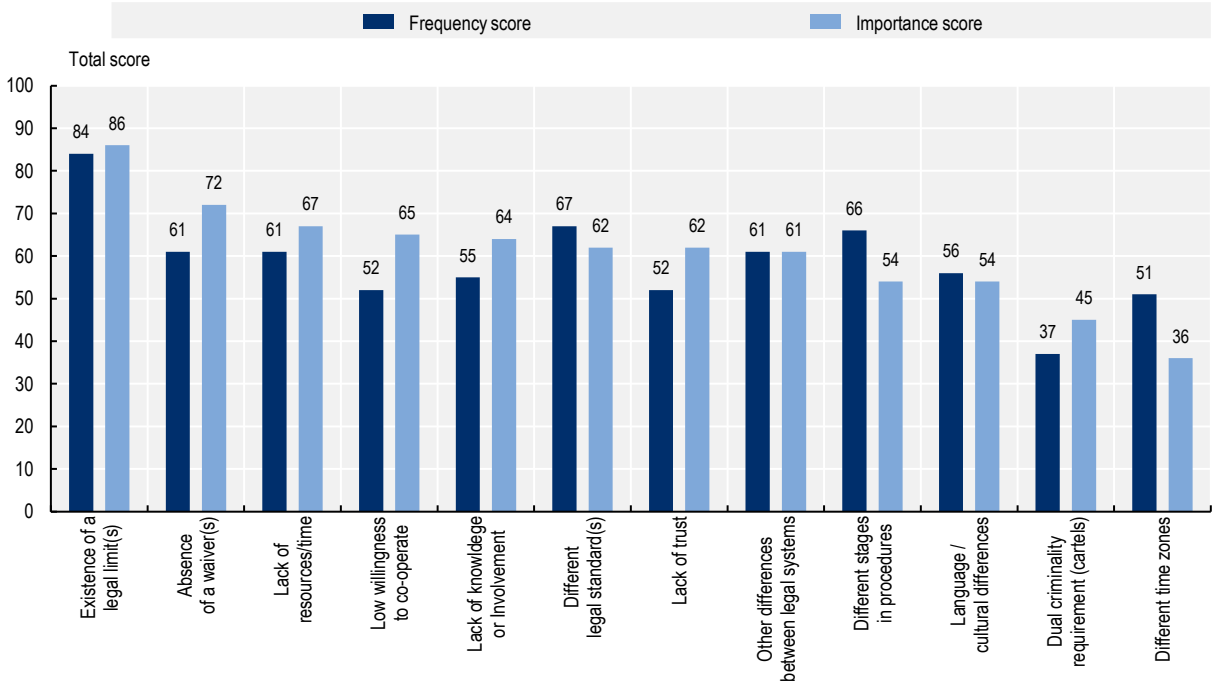
1. There is no universally accepted definition for digitalisation or digital trade, but the term generally encompasses digitally-enabled transactions of trade in goods and services that can either be digitally or physically delivered, and that involve consumers, firms, and governments (see also https://www.oecd.org/trade/topics/digital-trade/).
2. All work can be accessed here: https://www.oecd.org/daf/competition/digital-economy-innovation-and-competition.htm.

Competition authorities, the OECD, the ICN and others in the competition community have undertaken a significant amount of work to address some of the key limitations and challenges.[25] For example, in relation to improving transparency, authorities have increasingly made information on their substantive and

procedural rules publicly available, and improved accessibility of their decisions. Remaining challenges relate i.a. to legal limitations, resource constraints, legal standards and differences between legal systems. Legal limitations are pertinent when it comes to the exchange of confidential information.

Recent OECD work highlights the main challenges to more and better co-operation as perceived by member and non-member authorities alike:

**Figure 1.5. Limitations to international enforcement co-operation by frequency and importance, 2019, 77% response rate**




Source: (OECD, 2021, p. 130[5]).

Some of these constraints are common to competition authorities in both developed and developing countries; others are more specific to new and less experienced authorities.

### *Problems common to all jurisdictions*

#### *Exchange of confidential information*

One of the most sensitive areas of co-operation concerns the exchange of confidential information and data between competition authorities. The reasons for these problems can be found in the restrictions on the sharing of confidential information under the respective domestic laws. Most national laws do not permit the sharing of confidential information from a competition authority's investigation file, nor do they permit an authority to use its compulsory information gathering powers on behalf of a foreign competition authority. With the very few exceptions described in the sections above, the majority of instruments and agreements in the antitrust field do not permit the exchange of confidential information (see also (OECD, 2019[16])).

In the antitrust context, the rationale for limiting authorities' powers to freely exchange confidential information is to avoid reducing the incentives for firms to co-operate in merger proceedings and under authorities' cartel leniency policies, both of which are essential for the effectiveness of an enforcement regime as a whole. Similarly, there is a concern that, once exchanged, confidential information submitted

to an authority in another jurisdiction may get into the public domain (e.g. because of different rules on access to a competition file in the requesting country) or may simply become discoverable in the receiving jurisdiction. This may expose strategic business secrets of the source of the information or create a risk of private actions and ensuing damages.

### Box 1.5. 2014 OECD Recommendation: Information Sharing

The 2014 OECD Recommendation (OECD, 2014[3]) instructs adherents to:

> *… consider promoting the adoption of legal provisions allowing for the exchange of confidential information between competition authorities without the need to obtain prior consent from the source of the information ('information gateways').*

It describes some of the key considerations related to information gateways, which can be summarised as:

- Establishing sufficient safeguards to protect confidential information exchanged
  - To this end, the 2014 Recommendation provides substantial detail on the types of protections to be considered, including that the receiving authority will: i) maintain the confidentiality of the exchanged information to the extent agreed with the transmitting authority with respect to the information's use and disclosure; ii) notify the transmitting authority of any third party request related to the information disclosed; and iii) oppose the disclosure of information to third parties, unless it has informed the transmitting authority and that authority has confirmed that it does not object to the disclosure. The Recommendation also addresses the treatment of unauthorised disclosure, and the disposal of information once it has served its purpose.
- Considering to limit or exclude certain information based on the type of investigations or type of information
- Retaining discretion to use an information gateway, and the ability to place limits on how information shared may be used by the receiving authority
  - Notably, the 2014 Recommendation identifies that information should be used solely by the receiving authority for the purpose for which the information was originally sought, unless the transmitting authority has explicitly granted prior approval for further use or disclosure of the information.

Source: (OECD, 2021, pp. 167-168[5]), (OECD, 2014[15]).

#### *Different definitions of what constitutes "confidential information"*

There is no common definition of confidential information in the competition field. Differences in how competition authorities or courts define confidential information in cartel cases can represent an obstacle to effective co-operation. Since, as discussed above, many international co-operation instruments do not allow for the exchange of confidential information, in most cases the requested authorities must demonstrate that the information is not confidential before they are allowed to share it with the requesting authority. This can be a time consuming process and errors can expose the requested authority to legal liabilities.

Some authorities define information as confidential by the way it is collected (i.e. any information collected during an investigation is confidential). Other authorities consider the nature of the information, whereby information is confidential if its disclosure would harm the commercial interest of the source, which provided it (i.e. information related to price, sales, costs, customers and suppliers). In the latter case, it can be difficult to distinguish between what is commercially sensitive or not. If in doubt, the risk of litigation may

discourage authorities from disclosing such information to foreign authorities. See also (OECD, 2021, pp. 165-167[5]) and (OECD, 2019[16]).

#### *Civil/administrative versus criminal regimes*

Cartels are criminally prosecuted in some jurisdictions, but not in others, and this places additional limitations on the ability of the respective authorities to exchange information and evidence between civil and criminal jurisdictions, and the ability to assist in their respective investigations.

As discussed above, criminal jurisdictions may be able to use MLATs to obtain foreign-located documents and witness testimony in international cartels investigations. However, this is limited to jurisdictions which both treat cartels as a criminal infringement. The US for example, cannot share confidential information with the EU pursuant to an MLAT because the EU imposes only administrative penalties for competition law violations. There is, consequently, a lack of "dual criminality".

Criminal sanctions for cartel conduct have been introduced or are currently being considered in a number of countries. This could, potentially, facilitate co-operation and create a "virtual" alliance among jurisdictions that have criminalised cartels. This trend towards criminalisation is not yet matched by a comparable criminal enforcement record. Outside of the US, very few jurisdictions have actually prosecuted cartels under their criminal provisions, but instead continue to investigate their cartels under their civil/administrative powers. This significantly limits the scope for co-operation on parallel investigations (see also (OECD, 2020[17])).

#### *Other common hurdles*

Other common hurdles include:

- Language barriers or shortcomings in the internal organisation of competition authorities that results in a lack of competences to co-operate effectively.
- Practical difficulties in the co-ordination of investigations, for example if investigations are at different stages between the different authorities involved or if difficulties arise due to different time zones.
- Resource constraints for making or responding to requests, particularly where formal channels are required. Co-operation can be resource intensive, detracting scare resource from other enforcement activities.

### *Challenges of specific relevance to developing and emerging economies*

There is relatively little evidence of effective competition enforcement co-operation between competition authorities in developing countries and between developed and developing country authorities. This, in part, reflects that a number of jurisdictions have only recently adopted competition laws and so have only been enforcing their laws for a relatively short period of time. Some may not have begun to target cartel activity as a priority in their enforcement programmes. It is also true, however, that many developing countries and new competition authorities have not yet developed sufficiently stable ongoing bilateral or multilateral relationships with other jurisdictions that could promote co-operation.

#### *Institutional and investigatory impediments*

New and less experienced competition regimes need to establish credible competition institutions and develop the necessary instruments and policies to become effective cartel enforcers. Until they do so, they may not have the resources or experience to harness the benefits of greater co-operation in the same manner as more experienced jurisdictions (UNCTAD, 2011, p. 33[18]).

Lack of investigatory powers, such as the ability to conduct unannounced dawn raids, impedes the ability of an authority to take part in co-ordinated dawn raids with foreign authorities. The 2019 Recommendation concerning effective action against hard core cartels (OECD, 2019[19]) calls on jurisdictions to provide their enforcement authorities with effective powers to investigate hard core cartels, including conducting unannounced inspections (dawn raids) at private and business premises. The lack of fully functional leniency programmes, as discussed above, is also challenge to effective co-operation in the investigation of international cartels.[26]

As with any new authority, human resource capacity is a challenge. It takes time to develop the requisite skills and experience. Even where competition authorities have strong powers, for example to compel the production of documents and conduct surprise inspections, these may be hampered by inexperience and a lack of institutional capacity.

#### *Lack of trust and confidence in legal systems*

Trust is central to building co-operative relationships between authorities (see (OECD, 2012[20]), (OECD, 2012[21]) and (OECD, 2021[5])). A lack of trust can be caused by a weak legal framework in the country seeking co-operation, insufficient transparency of the competition authority's procedures and inadequate safeguards for due process. This heightens perceptions that information may be leaked, putting the investigations of foreign authorities at risk and undermining the effectiveness of their cartel enforcement programmes and associated tools. There may be a lack of confidence in the ability of the requested country to provide information of the quality and/or standard necessary for the requesting country to use it in its own investigation. This is a higher risk with newer authorities that have not yet established the necessary safeguards or acquired sufficient experience to handle such requests.

## The role of the OECD in fostering international co-operation in competition cases

Over more than 50 years, the OECD approved a series of Council Recommendations which have been elaborated and progressively refined by the Committee, dealing directly or indirectly with international co-operation between competition authorities on enforcement cases.

Since their very beginning, the OECD and its Competition Committee have taken a leading role shaping the current framework for international co-operation between competition enforcement authorities. Instruments, best practices and policy roundtables have served not only as model and inspiration for national initiatives but have served as the primary drive for promoting co-operation on a global scale. The OECD and its Competition Committee offer competition officials from developed and emerging economies a unique platform to monitor the state of international co-operation and to develop new solutions to increase its effectiveness. The Committee's work benefits from the support of a professional Secretariat and from the Organisation's whole-of-government approach, taking advantage of expertise and experience with international co-operation that is available through other OECD Committees.

The Committee also co-operates closely with other international organisations important to promoting and improving international co-operation, in particular the International Competition Network (ICN), and the United Nations Conference on Trade and Development (UNCTAD).[27] This co-operation takes place in many ways, ranging from regular, informal exchanges over event participation to joint work. This allows to inform the Committee's work, avoid duplication, and to incorporate needs of non-member countries, who play an important role in promoting the effective enforcement of competition rules on a global scale.

Going forward, the work on international co-operation remains at the core of the activities of the Committee and its working parties and will contribute to shaping new models for co-operation for the benefits of enforcers and business alike.

### Box 1.6. OECD work products to facilitate co-operation and increase transparency

**OECD contact list**

Following the 2014 Recommendation, the OECD has created a contact list of competition authority contacts for international co-operation purposes, which it makes available to member countries and updates regularly.

**OECD inventories**

The OECD has put together inventories of provisions included in international co-operation MoUs and agreements on competition of authorities and governments, where at least one of the signatories is a competition authority of an OECD Member, Associate or Participant. The inventories list examples of typical and atypical provisions which would be useful for the negotiation of MoUs and agreements, and currently include more than 220 MoUs and agreements. The authority MoU are accessible at https://www.oecd.org/competition/inventory-competition-agency-mous.htm, and the government agreements are accessible at https://www.oecd.org/competition/inventory-competition-agreements.htm. The last update took place in 2021.

**Competition Enforcement Co-operation Template**

The Competition Enforcement Co-operation Template (CEC Template) is work in progress. Once approved by the Committee, it will provide a template for important information related to a competition authority's ability, legal framework, publicly available information, current practices and contact information relevant to international co-operation in competition cases. The information will be made publicly available and will be kept up to date through annual updates. The CEC Template will cross-promote other important sources of information, and it will be open to member and non-member countries alike.

Key issues that will be addressed over the next 18 months were identified in the 2021 Report (OECD, 2021[5]), and include the following questions: How can trust and transparency be improved? Which forms of co-operation are particularly beneficial? How can knowledge about best practices in international co-operation be best created and disseminated? How can regional co-operation be improved? What legal models exist to further improve co-operation and decrease legal obstacles, in particular to enhanced co-operation?

### *OECD Recommendations on international co-operation*

The first Recommendation on international co-operation in enforcement cases dates back to 1967 (OECD, 1967[22]). This first instrument recognising that the powers of competition authorities to co-operate are limited, encouraged Member countries to a) notify other countries of an investigation involving their important interests and b) co-ordinate their respective actions when more than one jurisdiction is looking at the same case, and c) supply each other with any information on anti-competitive practices. The Recommendation acknowledges that competition authorities should operate within the limit of existing national laws and that the Recommendation should not be construed as affecting national sovereignty and extra-territorial application of national competition laws.

In 1973, the Council adopted a new Recommendation (OECD, 1973[23]) which, in keeping with the earlier version, recognised that closer co operation between Member countries is needed. In order to facilitate the resolution of cross-border cases, it recommends that Member countries implement on a voluntary basis a consultation procedure in cases where anti-competitive business actions in foreign jurisdictions affect the

interests of a Member country. Should the consultation fail to provide a satisfactory solution, the issue could be submitted to the Committee for conciliation. This dispute resolution mechanism has never been used.

In 1979 a new version of the Recommendation was adopted (OECD, 1979[24]), repealing the previous two recommendations of 1967 and 1973. The 1979 recommendation combined the previous two, and is divided in two sections. The first deals with notification, exchange of information and co-ordination of actions when a Member country decides to take an enforcement action which is likely to affect the interests of another member country(ies). The second part of the Recommendation deals with consultation and conciliation procedures when a Member country considers that anti-competitive actions by firms located in another member country(ies) are likely to affect its important interests.

The 1979 recommendation was replaced in 1986 by a new version (OECD, 1986[25]), which in addition to the provision of the 1979 text includes in an Annex a set of 'Guiding Principles', which are intended to clarify the procedures laid down in the Recommendation on notification, exchange of information, consultation and co-ordination. The Guiding Principles were then refined by the Committee in 1995 (OECD, 1995[26]), when the Council adopted a revised recommendation on international co-operation. In the revision there were no substantive amendments to the recommendation itself, only to the Appendix.

In 2014, after an extensive stocktaking of developments in international co-operation in competition cases (OECD, 2013[27]), and identification of main challenges to international co-operation, a new version of the Recommendation was adopted (OECD, 2014[3]). The stocktaking had identified that, while international co-operation had increased significantly in the past five years, legal limitations, due to differences in legal systems and to restrictions in domestic legislation, still appeared to be one of the more important limitations on international co-operation. To address these challenges, the 2014 Recommendation contains two sections that offer enforcers new and particularly innovative solutions:

- A section calling for the adoption of national provisions that allow competition agencies to exchange confidential information without the need of seeking prior consent from the source of the information (so called "information gateways");
- Another, calling for enhanced co-operation in the form of investigative assistance, including the possibility to execute dawn-raids (inspections of premises), requests of information, witness testimonies, etc. on behalf of another agency.

Other sections in the 2014 Recommendation reiterate and advance prior recommendations and underline the need for a commitment to effective co-operation, notifications of investigations and co-ordination.

The Committee has recently finalised a report on implementation, dissemination and continued relevance of the 2014 Recommendation to Council (OECD, 2022[2]) and has, for this purpose, carried out another stocktaking exercise in 2020 (OECD, 2021[5]). In line with the findings from previous stocktaking, co-operation in competition cases is still increasing, and regional networks play an important role in fostering close co-operation. However, legal obstacles, especially relating to confidential information sharing, investigative assistance and enhanced co-operation keep limiting further increases and deeper forms of co-operation and require further attention.[28]

### *Other OECD Recommendations indirectly dealing with international co-operation*

#### *The 2019 Recommendation on Hard Core Cartels*

The precursor of the 2019 Recommendation (OECD, 2019[19]), the 1998 Recommendation on Hard Core Cartels (OECD, 1998[28]) marked the first time the OECD defined and condemned a particular kind of anti-competitive conduct, and it set forth principles concerning the "when" and the "how" of co-operating with respect to hard core cartels.

The 2019 Recommendation establishes more detailed principles and guidance for effective enforcement against hard core cartels, based on findings of and the need for even more convergence in substantive and procedural rules (see also (OECD, 2019[19])). It no longer includes a dedicated section on international co-operation in the enforcement of hard core cartels, but refers instead to the 2014 Recommendation and recognises that action against hard core cartels is important from an international perspective and particularly dependent upon international co-operation among competition authorities.

### *The 2005 Recommendation on Merger Review*

The 2005 Recommendation on Merger Review (OECD, 2005[29]) came out of a desire to consolidate and reflect the wide-ranging work on merger control, and also take into account important work by other international bodies in this area, in particular the ICN.[29] The goal was to create a single document that would set forth internationally recognised best practices for the merger review process, including co-operation among competition authorities in merger review. Part B of the Recommendation deals specifically with Co-ordination and Co-operation on cross-border merger cases. In particular, it invites Member countries to co-operate and to co-ordinate their reviews of transnational mergers in order to avoid inconsistencies. Member countries are encouraged to consider actions, including national legislation as well as bilateral and multilateral agreements or other instruments, by which they can eliminate or reduce impediments to co-operation and co-ordination.

### *Best Practices for the formal exchange of information between competition authorities in hard core cartel investigations*

In 2004, the Committee started developing a set of Best Practices for the formal exchange of information in cartel investigations. The final version of the Best Practices on formal exchange of information in cartel investigations (the “2005 Best Practices”) was adopted in October 2005 (OECD, 2005[30]). The 2005 Best Practices aim to identify safeguards that Member countries should consider applying when they authorise competition authorities to exchange confidential information in cartel investigations. By identifying appropriate safeguards for information exchanges, the 2005 Best Practices assist Member countries in removing obstacles to effective co-operation by authorising the exchange of confidential information in cartel investigations.

The 2005 Best Practices were based on the following principles:

- International treaties or domestic laws authorising a competition authority to exchange confidential information in certain circumstances should provide for safeguards to protect the confidentiality of exchanged information. On the other hand, such safeguards should not apply where competition authorities exchange information that is not subject to domestic law confidentiality restrictions.
- Member countries should generally support information exchanges in cartel investigations. It should, however, always be at the discretion of the requested jurisdiction to provide the requested information in a specific case, or to provide it only subject to conditions, and there should be no obligation to act upon such a request. A country may decline a request for information, for example, because honouring the request would violate domestic law or would be contrary to public policy in the requested jurisdiction.
- When initiating an exchange of information, jurisdictions should act with the necessary flexibility in light of the circumstances of each case. They should consider engaging in initial consultations, for example to assess the ability of the jurisdiction receiving the request for information to maintain the confidentiality of information in the request as well as the confidentiality of exchanged information.

- Appropriate safeguards should apply in the requesting jurisdiction when it is using the exchanged information. In this context, the Best Practices address in particular the use of exchanged information for other public law enforcement purposes, disclosure to third parties, and efforts to avoid unauthorised disclosure.
- Information exchanges should provide safeguards for the rights of parties under the laws of member countries. The Best Practices specifically mention the legal professional privilege and the privilege against self-incrimination. In this context, Member countries may have to take into account differences in the nature of sanctions for violations of competition laws concerning hard core cartels in different jurisdictions.

*Recommendation of the Council on Transparency and Procedural Fairness in Competition Law Enforcement (2021)*

Based on previous work, the Committee is drafting a Recommendation on Transparency and Procedural Fairness in Competition Law Enforcement (OECD, 2021[31]) was adopted in 2021, which includes provisions on transparency and predictability; independence, impartiality and professionalism; non-discrimination and proportionality; timeliness; meaningful engagement; protection of confidential information; and judicial review. This Recommendation will help improve international co-operation by improving transparency and trust in counterpart authorities' enforcement rules and actions. Next to legal obstacles, lack of transparency and trust are among the persistent challenges to international co-operation (OECD, 2021[5]).

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## Notes

[1] 159 U.S. 113 (1895), 163-64: "'Comity', in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory to the legislative, executive or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens or of other persons who are under the protection of its laws."

[2] The term "positive comity" appears to have been coined during the negotiation of the 1991 Co-operation Agreement Between the Government of the United States of America and the Commission of the European Communities Regarding the Application of Their Competition Laws ("the 1991 EC-US Agreement"). See 1991 US/EC Agreement, OJ 1995 L 95/45, corrected at OJ 1995 L 131/38, Article V.

[3] Starting with the 1976 Germany–US Antitrust Accord and followed by the 1982 US-Australia Agreement and the 1984 US-Canada Memorandum of Understanding.

[4] "First generation agreements" are formal bilateral co-operation agreements incorporating the negative comity principle. In contrast, "second generation agreements" incorporate a positive comity principle. "Third generation agreements" refer to antitrust mutual assistance treaties which as a result of domestic law amendments provide for more extensive co-operation.

[5] Agreement Between the European Communities and the Government of the United States of America Regarding the Application of Positive Comity Principles in the Enforcement of their Competition Laws, OJ 1998 L 173.

[6] Agreement Between the Government of the United States of America and the Government of Canada on the Application of Positive Comity Principles to the Enforcement of their Competition Laws (2001).

[7] See OECD inventories of competition co-operation agreements, https://www.oecd.org/daf/competition/mou-inventory-provisions-on-positive-comity.pdf.

[8] (OECD, 2021, pp. 146-148[5]), less than 20% of all respondents made or received requests for positive comity between 2012 and 2018, the majority of which were made within the European Competition Network (ECN).

[9] The previous exclusion of competition matters was removed from the 1994 US-UK MLAT in 2001.

[10] This section is based on text from the recent publication (OECD, 2021, pp. 104-107[5]).

[11] For examples see OECD inventory of international co-operation agreements on competition (OECD, n.d.[10]), and OECD inventory of international co-operation agreements between competition agencies (MoUs) (OECD, 2015[8]).

[12] See for agency MoU https://www.oecd.org/competition/inventory-competition-agency-mous.htm; and for government MoU https://www.oecd.org/competition/inventory-competition-agreements.htm.

[13] First-generation co-operation agreements only allow for the exchange of non-confidential information, or the exchange of confidential information subject to the consent of the information source. They generally reflect co-operation activities that the authority could undertake even in the absence of an agreement,

although they can establish a framework and commitment to undertake activities that can support co-operation.

[14] Second-generation agreements contain provisions enabling competition authorities to exchange confidential information in clearly prescribed circumstances, without the requirement to seek prior consent from the source of the information and in some instances, assist their counter-part authorities with investigation activities and engage in enhanced co-operation.

[15] Agreement on Cooperation in Competition Cases (Finish Competition and Consumer Authority, n.d.[32])

[16] The MMAC is structured as an 'in-principle' non-binding multi-lateral memorandum of understanding (the Framework MOU), which attaches a model bi-lateral/multi-lateral agreement as an annexure (the Model Agreement). All parties have agreed in the MMAC to implement the Model Agreement between themselves bi-laterally (or multi-laterally) in as close as possible a form. The Model Agreement is a second-generation agreement.

[17] On 1 January 2011, the Competition and Consumer Act 2010 superseded the Trade Practices Act 1974. The discretionary powers of the ACCC to share information, introduced originally in 2007 under Section 155AAA, were not affected by this change (Australian Government, n.d.[37])

[18] Notably, the New Zealand information gateway requires that an intergovernmental or inter-agency agreement be in place as a condition for using the national gateway (New Zealand Legislation, n.d.[35]) (Section 99I, and 99J).

[19] Section 29 of the Canadian Competition Act (Government of Canada, n.d.[33]).

[20] UK Enterprise Act 2002: Section 243 (UK Legislation, n.d.[34]).

[21] The German Competition Act allows co-operation and information exchange with authorities outside the European Union under certain conditions (§ 50e), http://www.gesetze-im-internet.de/englisch_gwb/.

[22] Only one agreement, with Australia, has been executed on this basis so far https://www.accc.gov.au/system/files/Australia-United%20States%20treaty%20on%20antitrust%20enforcement%20assistance.pdf.

[23] Specifically permits the CCPC to enter into co-operation agreements with foreign competition authorities. No agreement has been executed based on this section so far (ISB, n.d.[36]) (Section 23).

[24] See https://www.internationalcompetitionnetwork.org/portfolio/model-confidentiality-waiver-for-mergers/; https://www.internationalcompetitionnetwork.org/portfolio/leniency-waiver-template/; https://ec.europa.eu/competition/mergers/legislation/npwaivers.pdf; https://www.ftc.gov/policy/international/international-competition/international-waivers-confidentiality-ftc-antitrust; https://www.gov.uk/government/publications/confidentiality-waiver-template.

[25] See (OECD, 2021[5]), *Section* 11, History of initiatives.

[26] See also: https://www.oecd.org/daf/competition/challenges-and-coordination-of-leniency-programmes.htm.

[27] See https://www.internationalcompetitionnetwork.org/, and https://unctad.org/Topic/Competition-and-Consumer-Protection, and (OECD, 2021[5]),

[28] Forthcoming in 2022, accessible through https://www.oecd.org/competition/internationalco-operationandcompetition.htm.

[29] The Recommendation addressed all steps of the merger review process, including the definition of thresholds to establish jurisdiction over international mergers, notification requirements, transparency of the merger review process, procedural fairness, the protection of confidential business information, and co-ordination and co-operation among competition authorities. It also encouraged Member countries to ensure that competition authorities have sufficient powers to conduct efficient and effective merger review and to effectively co-operate and co-ordinate with other competition authorities in the review of transnational mergers. Recommendations were made on a) notification and review procedures, b) co-ordination and co operation, c) resources and powers of competition authorities, d) periodic review, e) definitions.

# 2 OECD's Environment, Health and Safety Programme

This case study presents a practical example of international regulatory co-operation by means of the OECD-based co-operation programme for chemical safety. The case study presents recent data from a cost-benefit analysis of the programme, showing a yearly annual net benefit of more than EUR 300 million for all participant countries.

Today, OECD governments have significant and comprehensive regulatory frameworks for preventing and/or minimising the health and environmental risks posed by chemicals. The objective of these frameworks is to ensure that chemical products already on the market are safe or managed in a safe way, and that new ones are properly assessed before being placed on the market. This is done by testing the chemicals, assessing the results, and taking appropriate action. Such a framework, while rigorous and comprehensive when implemented, is very resource-intensive and time-consuming for both governments and industry.

For instance, the cost for a pesticide company to test one new active ingredient for health and environmental effects is approximately EUR 21.5 million, and the resources needed for a government to review and assess the data is approximately 1.95 person-years (OECD, 2019[1]). As many of the same chemicals are produced in more than one OECD country (or are traded across countries), different national chemical control policies can lead to duplication in testing and government assessment, thereby wasting the resources of industry and government alike. Different national policies can also create non-tariff or technical barriers to trade (TBT) in chemicals.

The World Trade Organization has estimated that between 1998 and 2010, there have been approximately 32 environment-related TBT specific trade concerns: 10 deal with control of hazardous substances, chemicals and heavy metals (WTO, n.a.[2]).

In 2018, the OECD's Trade and Agriculture Directorate issued a working paper demonstrating that, on average, the cost (ad valorem equivalent) of technical barriers in chemicals was 9.3% of the unit value (OECD, 2018[3]). As outlined in (OECD, 2019[1]), further preliminary evidence from OECD research indicates that trade agreements that include mutual recognition and harmonisation of TBT measures, including mutual recognition of TBT conformity assessment procedures, have a positive influence on chemical trade flows, presumably by reducing trade costs associated with these non-tariff measures. Over the period 2015-17, as much as 26% of specific trade concerns raised in the World Trade Organization's (WTO) Technical Barriers to Trade Committee referred to measures citing environmental protection among their objectives. Of all the environment-related measures identified in notifications to the WTO between 2009 and 2016, 18% had to do with either "chemical, toxic and hazardous substances management" or "ozone layer protection". Half of these were TBT measures. Therefore, there are opportunities to improve TBT issues related to chemicals.

While all countries have the right to set their own levels of environmental protection, consistent with international obligations, such differences in regulations and test standards may discourage research, innovation and growth – as new research and products may only be accepted in the country or countries which apply the same test standards – and they may increase the time it takes to introduce a new product onto the market. They can also, when inappropriately or inconsistently implemented, lead to inefficiencies for governments, because authorities cannot take full advantage of the work of others which would help reduce the resources needed for chemicals control.

OECD's Environment, Health and Safety (EHS) Programme has been working for 50 years, through international regulatory co-operation, 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. 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 country must be accepted in all adhering countries – underpins much of this work. The MAD system is the mechanism which provides the framework for regulatory co-operation and is the focus of this case study. Currently, there are seven non-OECD member countries that are full adherents to MAD: Argentina, Brazil, India, Malaysia, Singapore, South Africa and Thailand.

## Main characteristics of the IRC under consideration

### *Actors involved*

The OECD's Chemicals and Biotechnology Committee (and its 13 technical sub-bodies) carry out the work of the EHS Programme. In member countries, OECD government representatives (including the European Commission) from various ministries or agencies (health, labour, environment, agriculture, etc.) work on OECD projects at the national level. In addition, experts from the chemicals industry, academia, labour, environmental and animal welfare organisations, and several partner economies participate in projects and meetings. These include, in particular, provisional and full adherents to the Council Acts on MAD: Argentina, Brazil, India, Malaysia, South Africa, Singapore and Thailand. The OECD also co-operates closely with other international organisations, most notably in the global effort to implement the recommendations of the UN Conference on Environment and Development (UNCED, Rio de Janeiro, 1992) and the Plan of Implementation of the World Summit on Sustainable Development (WSSD, Johannesburg, 2002). The OECD participates, along with eight other UN organisations involved in chemical safety, in the Inter-Organization Programme for the Sound Management of Chemicals (IOMC):

- Food and Agriculture Organization of the United Nations;
- International Labour Organization;
- United Nations Development Programme;
- United Nations Environment Programme;
- United Nations Industrial Development Organization;
- United Nations Institute for Training and Research;
- World Health Organization;
- World Bank.

The OECD co-ordinates with individual IOMC IGOs based on topics or interest and expertise. This can take the form of joint workshops, joint expert groups, or both organisations working together on a publication. In general, each organisation takes the lead when a topic falls within their specialised expertise (e.g. UNITAR and training). Joint work with UNEP includes, for example, the areas of green and sustainable chemistry or the risk management of per- and polyfluorinated alkyl substances. In addition, the OECD has a long-standing co-operation with the WHO in the field of human health hazard and risk assessment. Similarly, the OECD works jointly with FAO in the fields of pesticides, food safety and biotechnology, and partners with ILO and UNITAR on the implementation of the UN Globally Harmonised System of Classification and Labelling.

In addition, at times, the OECD work lays the initial groundwork for broader international consensus on chemicals management. For instance, in 1984, OECD countries agreed that when exporting a chemical considered hazardous from an OECD country, the importing country should be informed. This principle was laid down in the 1984 Council Recommendation, and eventually constituted the basis for UNEP and FAO to develop the Rotterdam Convention on Prior Informed Consent (PIC) Procedures in 1998 (SRC, 1998[4]).

The Stockholm Convention on Persistent Organic Pollutants (POPs) is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, bioaccumulate in humans and wildlife, and have adverse effects to human health or to the environment. Some per- and polyfluoroalkyl substances (PFASs) compounds have been restricted in the European Union, United States, Canada, Australia and other countries and several groups of PFAS chemicals have been included as new POPs under the Stockholm Convention. The OECD convenes a Global PFC Group to share regulatory approaches for management of PFAS substances, support a shift towards safer alternatives and improve technical understanding of PFAS issues. The group,

which extends beyond the OECD member countries, in collaboration with UNEP, is also working to improve the outreach to developing countries where the production and use of PFAS has grown.

OECD's EHS Programme is also actively involved in the implementation of the Strategic Approach to International Chemicals Management (SAICM) which bring together governments from more than 150 countries and many stakeholders to support the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimise significant adverse impacts on the environment and human health. This goal was not met by 2020 and since 2017, the OECD is involved in the development of the successor to SAICM.

### *Intended objectives*

The objectives of the MAD system are as follows:

- 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 countries, 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 enabled.

The MAD system opens opportunities for countries 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 countries about chemical safety assessment and resulting risk management is greatly increased. This allows countries to share work on assessing chemical safety and consider options for managing chemical risks.

### *Forms that the co-operation is taking:*

The principal tools for harmonisation are a set of three OECD Council Acts which make up the OECD Mutual Acceptance of Data system, including its OECD Guidelines for the Testing of Chemicals and Principles of Good Laboratory Practice (GLP):

- The 1981 Council Decision on MAD states that data generated in a Member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other Member countries for assessment purposes and other uses relating to the protection of human health and the environment.
- The 1989 Council Decision-Recommendation which requires the implementation of the characteristics of national compliance programmes for GLP also deals with the international aspects of GLP compliance monitoring. It requires designation of authorities for international liaison, exchange of information concerning monitoring procedures and establishes a system whereby information concerning compliance of a specific test facility can be sought by another Member country where good reason exists.
- The 1997 Council Decision which sets out a step-wise procedure for non-OECD countries to take part as full members in this system.

The binding nature of these Acts, particularly the 1981 Council Decision, ensures that all countries abide by the requirements to accept data from other OECD members, and non-members who also adhere to these Acts. In general, most countries adopt the OECD Test Guidelines and OECD Principles of GLP into

national regulations, either verbatim or with minor, non-substantive changes. With respect to national GLP compliance programmes, OECD's programme of continuing periodic on-site evaluations of members provides for an on-site team, composed of inspectors from other OECD countries, to evaluate each Monitoring Programme every ten years. Following discussion in the Working Party on GLP on the results from the on-site evaluation, a final report, including the conclusions and any recommendations agreed by the Working Party, will be prepared for use by GLP Compliance Monitoring Programmes in member countries in the framework of MAD. Finally, industry is encouraged to notify the OECD Secretariat if one country rejects a study from another country, conducted under the MAD system. Industry has also been provided access to a password-protected site to describe issues of dis-harmonisation across countries in the way they implement the GLP Principles. The Working Party on GLP will evaluate these comments and suggest a path forward.

By making the system accessible to non-member countries who adopt the same test methods and quality standards for chemical safety testing as OECD countries, the same level of protection of health and the environment is able to be obtained. Access to markets is further enhanced by harmonisation and mutual recognition of standards for development of safety data. As a result of the MAD system, countries have confidence in the quality and rigour of the laboratories that generate the test data and the results from such testing, which is particularly important in many EHS activities (e.g. work on assessing the hazards of chemicals) in which countries work together to develop chemical assessments based on agreed data.

### *Functions being co-ordinated*

The EHS Programme focuses on the following areas of co-ordination:

#### *The MAD System*

- *Harmonisation*: implementation by OECD countries and additional adherent countries of the OECD's Mutual Acceptance of Data (MAD) system – including the development and updating of OECD Test Guidelines and Principles of Good Laboratory Practice (GLP).

#### *EHS work made possible because of the MAD system*

- *Development of risk assessment methodologies*: given the harmonisation of the test methods and GLP, countries 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.
- *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.
- *Harmonisation*: Another role for the EHS Programme is to harmonise industry dossiers – based on chemical test data – and review reports for pesticides registration.
- *Exchanging technical and policy information*: the EHS Programme acts as a forum for countries to exchange technical and policy information. By discussing their chemical control policies together, countries 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 governments, industry, non-governmental organisations and academia who participate in the work of the EHS Programme.

- *Outreach*: the OECD's share in world chemical production is decreasing as non-OECD economies – particularly Brazil, India, Indonesia, the People's Republic of China, the Russian Federation 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 countries in the work of the programme and to allow them access to technical and policy discussions and documentation. Of particular importance is opening the MAD Council Acts to non-members who wish to adhere to the 1981 Council Decision.

## Short history of the development of the IRC

### *Triggers*

Over the last four decades, there have been four principal drivers for International Regulatory Co-operation by OECD in the field of chemical safety. One, the chemicals industry – which includes industrial chemicals, pharmaceuticals, pesticides, biocides, food and feed additives and cosmetics – is one of the world's largest industrial sectors and many chemicals are produced and traded internationally.[1] Thus, international co-operation 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 country (or are traded across countries), different national chemical control policies can lead to duplication in testing and government assessment, thereby wasting the resources of industry and government alike. Two, releases of chemicals during production and use can travel across national (and sometimes regional) borders and thus, international co-operation is essential for a more comprehensive management of risks. Three, OECD countries, in general, follow the same approach to the assessment of chemicals, and thus there are economic efficiencies if countries can work together on such assessments. Four, through OECD Council Acts there was a possibility to make commitments among countries which are legally (decisions) or politically (recommendations) binding. This level of political 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 countries will follow up on harmonisation arrangements.

OECD's IRC work in the field of chemical safety began in 1971 with a focus on specific industrial chemicals known to pose health or environmental problems, such as mercury or CFCs (chlorofluorocarbons responsible for depleting the ozone layer). The purpose was to share information about the risks of these chemicals and to act jointly to reduce them. One of the important achievements of the early years was the 1973 OECD Council Decision to restrict the use of polychlorobiphenyls (PCBs). This was the first time concerted international action was used to control the risks of specific chemicals. By the mid-1970s, however, it became clear that concentrating on a few chemicals at a time would not be enough to protect human health and the environment. With thousands of new chemical products entering the global market every year, OECD countries agreed that a more comprehensive strategy was needed. The OECD therefore began developing harmonised, common tools that countries could use to test and assess the risks of new chemicals before they were manufactured and marketed. This led to a system of mutual acceptance of chemical safety data among OECD countries, a crucial step towards international harmonisation and reduction of trade barriers.

### *Time period, main landmarks*

The adoption of the Council Act on Mutual Acceptance of Data in 1981, opened up many new opportunities for governments to work together to tackle chemical management issues, as the same data would be accepted across all OECD countries.

The safety aspects of new chemicals being introduced to the market were obviously a key issue that needed consideration and relevant policies. In 1982, at an OECD High Level Meeting on Chemicals, countries decided that, before new chemicals are marketed, governments should have enough information about them in order to ensure that a meaningful assessment of hazards can be carried out. This decision signalled a policy change from a "react and cure" mode to "anticipate and prevent". As a result, most OECD countries began to set up notification systems for new chemicals. A Minimum Pre-Marketing set of Data (MPD) was agreed in an OECD Council Recommendation, which specifies the information needed in the notification. This data set includes detailed information regarding the toxicity of chemicals and their potential for accumulation and biodegradation in the environment.

Once member countries had established workable systems for managing the safety of new chemicals, their attention turned to so-called "existing chemicals". These were the tens of thousands of chemicals already on the market before new chemicals notification schemes had been put in place in the early 1980s. Member countries agreed that the task of investigating the safety of this large number of existing chemicals was too big for one country. Co-operation among countries on the assessment of these chemicals was initiated by a new Council Decision. The MAD system provided an excellent starting point on which to build such work. In order to organise the large amount of work, a number of priorities had to be set. It was agreed to deal first with High Production Volume chemicals (HPVs) – chemicals produced or imported annually in quantities of greater than 1 000 tonnes in at least one OECD country or the European Union – because in most cases these would potentially lead to the largest exposures to man and the environment. Agreement was then reached on the information needed on the HPVs, which resembled to a large extent the MPD for new chemicals. This programme led to the development of initial assessment reports for about 1 200 chemicals.

To further facilitate work sharing, OECD governments turned their attention to harmonising industry dossiers for the registration of new pesticides, or re-registration of existing pesticides. By using the same format, once a company compiles a dossier for one country, the costs and time involved in developing dossiers for other countries would be significantly reduced. In 1998, OECD adopted a guidance document for applicants wishing to have particular active substances approved or plant protection products registered. It provides guidance with respect to the format and presentation of the documentation to be submitted. Similarly, OECD issued a guidance document on the format and presentation of the documentation to be prepared by the regulatory authorities (i.e. a pesticide monograph), in the context of applications for the registration of plant protection products. The aim of these two documents was to reduce the cost to industry of submitting dossiers and facilitate the exchange of monographs between OECD countries with a view to achieve a sharing of the work necessary for the evaluation of plant protection products and their active substances. The OECD also has developed an electronic standard for the submission of pesticide dossiers and work has started to harmonise this electronic standard with those used for industrial chemicals. This will save considerable resources for governments, and time for industry.

Similar efforts over the years to develop guidance documents, common formats and share assessments have since been applied in the EHS programme for biocides, chemical accidents, regulatory oversight of biotechnology, the safety of novel foods and feed, and manufactured nanomaterials. Around 20 OECD Council Acts deal specifically with chemical safety issues, many of which foster greater co-operation amongst countries.

### *Institutional set-up: who does what in the co-operation, at what level of government*

The EHS Programme is implemented by the Chemicals and Biotechnology Committee and its thirteen technical sub-bodies. In general, Heads of Delegation to the Chemicals and Biotechnology Committee comprise the Directors or Heads of Environment, Health and Safety programmes in governments, and their staff participate in the technical sub-bodies.

Most of the work involves the development of instruments, methods, guidance documents and databases which support the harmonisation of chemical programmes and facilitate work sharing. When the OECD addresses a new chemical safety issue, the starting point is often a survey of current practices in OECD countries. The analysis helps determine similarities and differences among national approaches, and also helps identify the areas where the OECD can add value. OECD countries may then agree on a programme of work with clear, practical objectives and specific timelines. Countries then work together towards the common objectives. They prepare proposals, technical guidance, recommendations and policy documents that are usually reviewed in meetings. After policies are adopted, the OECD plays a facilitator role and assists countries in the implementation of the decisions by developing high-quality tools and instruments and regularly reviewing the implementation in member countries. In many cases, one or more governments takes the lead on developing new instruments often based on existing material – such as existing national test guidelines with the intention of developing harmonised OECD Test Guidelines that can be used to generate data that will be accepted in all OECD countries. All of these products are freely available via the internet. Many member countries and the European Union have used these products directly as part of their regulations (for example the Test Guidelines and GLP as standards for testing), or they have used the EHS products as a basis for developing and implementing their regulations.

Typically, the staff of the EHS Division carries out the daily work, co-ordinating efforts with the work among experts and policy makers and with other intergovernmental organisations. The staff reviews and revises the first drafts proposed by lead countries, incorporates comments from experts in documents, organises the necessary meetings and teleconferences and works to build consensus on documents among member countries. The Secretariat also looks carefully at emerging issues in the chemical safety arena and brings them to the attention of countries, through proposals for work to be undertaken at the OECD. From the beginning of the work, stakeholders beyond government have also contributed actively through their participation in meetings. Many of the methods which are developed to address chemical safety have to be used by industry, and therefore it has been of great value to include the expertise from the chemical industry in the development of such methods. Participation by stakeholders from organised labour, environmental NGOs and the animal welfare community has also been important in ensuring a wider acceptance of this work.

### *Next steps envisaged in the co-operation*

The Programme of Work for 2021-24 calls for a continuation of current efforts to support international regulatory co-operation, but also particularly in new areas:

- *Greater outreach to non-members*. Global shifts in patterns of production of chemicals will mean that more countries will consider it prudent to set up chemical safety policies. Given the experience of OECD – including its support of SAICM – further co-operation with selected partner countries in a global context could prove to be very useful. In addition, input to OECD work from non-member experts will contribute to increasing the quality of the products and making them more widely applicable.
- *Co-ordination with experts to develop new methods* which can improve the efficiency of the chemical safety management and reduce the use of laboratory animals (e.g. test methods using cell cultures, mathematical approaches designed to find relationships between chemical structures and biological activities of studied chemicals or integrated approaches that combine results from different methods to conclude on the properties of chemicals).
- *Sharing information and develop tools to assist countries in managing the risks of chemicals*, e.g. developing tools for evaluating the health effects of chemicals or exchanging experience on managing specific chemicals of concern, such as perfluorinated chemicals.

## Assessment

### *Benefits*

In 2019, an analysis was conducted to determine the net savings governments and industry accrue from their participation in the OECD EHS Programme (OECD, 2019a) (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.

Four surveys 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.

The annual savings are summarised in the top portion of Table 2.1 as follows:

**Table 2.1. Net annual savings resulting from the OECD's EHS Programme**

| **Savings** | |
|---|---|
| From no repeat pesticide testing | EUR 206 937 500 |
| From no repeat new industrial chemical testing | EUR 44 728 943 |
| From no repeat biocide testing | EUR 61 250 000 |
| From no repeat existing chemical testing | EUR 780 570 |
| From harmonised pesticide monographs | EUR 2 218 145 |
| From harmonised pesticide dossiers | EUR 1 951 125 |
| Savings subtotal (rounded) | EUR 317 870 000 |
| **Costs** | |
| Country | EUR 3 809 000 |
| OECD Secretariat | EUR 4 545 000 |
| Costs subtotal (rounded) | EUR 8 354 000 |
| **Net savings (rounded)** | **EUR 309 516 000** |
| Reduction in animals needed for testing new industrial chemicals | 32 702 |

Source: (OECD, 2019[1]).

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 country 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, Country B would not accept 30% of the test data for *industrial chemicals* nor 35% of test data for new *pesticides* or *biocides* emerging from Country 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:

- fostering 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 countries which 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.

Also excluded are the benefits to industry of avoiding delays in marketing new products. According to industry sources, these could represent similar amounts to those saved by avoiding duplicative testing (for example, delays in the registration of a pesticide might lead to missed sales for a full growing season). Also excluded are the added benefits to health and the environment of governments working together to be able to evaluate and manage more chemicals than they would if they worked independently. Finally, while pharmaceuticals were not the subject of this analysis, it is expected that due to the extensive non-clinical testing required for such products, and because many of these test methods may fall within the MAD system, the benefits of the EHS Programme for these products could be extensive.

### *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) Country costs (the costs to governments, industry and other non-governmental organisations (NGOs) 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.

The 2019 report estimated the annual costs of the EHS Programme as shown below (Table 2.2) and summarised in the bottom half of Table 2.1 above. From this, the *net* annual savings of the Programme (Table 2.2) were estimated to be EUR 309 035 000: Total savings [EUR 317 870 000] minus Costs [EUR 8 835 000].

**Table 2.2. Estimated total annual costs of supporting the EHS Programme**

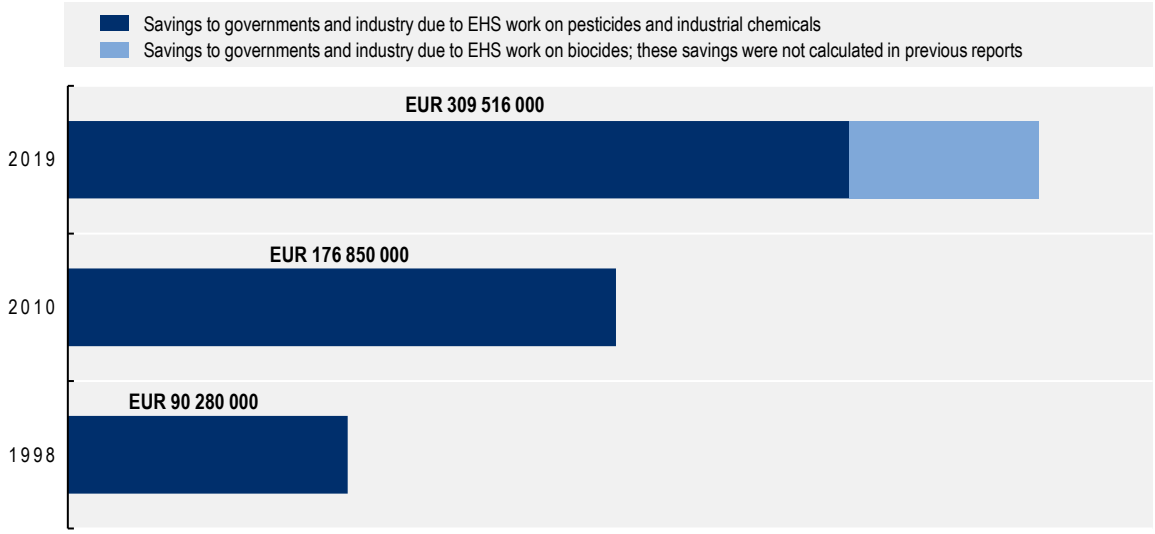
| | |
|---|---|
| Country costs | |
| Number of meetings | 42 |
| Average length of meetings (days) | 2.11 |
| Average number of participants | 1 239.50 |
| Travel costs[1] | EUR 1 455 000 |
| Country staff costs[2] | EUR 2 354 000 |
| Total country costs | EUR 3 809 000 |
| Secretariat costs | |
| Expenditure on permanent staff and consultancy funds | EUR 1 866 000 |
| Extrabudgetary Chemicals Management Programme | EUR 2 679 000 |
| Total Secretariat costs | EUR 4 545 000 |
| **Total costs (Secretariat + countries)** | **EUR 8 354 000** |

1. Travel costs (rounded) = travel [weighted average cost of round-trip flight (EUR 532.64) x number of participants (1 239.50)] + expenses [length of meetings (2.11 days) x daily expenses (EUR 304) x number of participants (1 239.50)].
2. Country staff costs (rounded) = participation [length of meetings in hours (2.11 x 8 = 16.88) x number of participants (1 239.50) x staff costs per hour (EUR 45)] + preparation [(150% x 16.88 = 28.86) x number of participants (1 239.50) x staff costs per hour (EUR 45)].
Source: (OECD, 2010[5]), *Cutting Costs in Chemicals Management: How OECD Helps Governments and Industry*, OECD Publishing, Paris, https://doi.org/10.1787/9789264085930-en and (OECD, 2019[1]).

### *Evolution of the net savings*

The 2019 report estimates that net savings attributable to the EHS Programme have grown by 75% since the last report and by over 240% since the initial report (Figure 2.1 shows the absolute growth). 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 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.

**Figure 2.1. Annual savings to governments and industry from the EHS Programme in 1998, 2010 and 2019**




Source: (OECD, 2019[1]).

### *Challenges*

Considering the work done so far in the EHS Programme and looking at expectations for future activities, the following challenges can be considered:

- while the commitment of member countries and stakeholders to provide expertise and extra budgetary resources for work in the Programme is listed as one of its strengths, in times of budgetary constraints, this dependence on such commitments in order to be able to produce high quality results, could also turn into a weakness;
- After years of working on chemical safety, many of the “easy” issues have been dealt with and while for the remaining tasks international harmonisation and work sharing will continue to be as necessary as before, the technical complexity (including advancements in science) will be increasing, which will make the relevance of continued work on chemical safety more difficult to explain to policy makers;
- The shift in chemical production from OECD countries to non-members can make the OECD less representative and less influential in the global setting when not enough attention is paid to outreach;

- While obtaining consensus on methods and guidance is a necessity to ensure that these are also used in practice by all concerned, there is a risk that with the increasing complexity of issues and the increasing number of players involved, the process of obtaining consensus will become slower;
- The difficulty of the monetary quantification of the effects of chemicals on human health and the environment, as well as of the impacts chemical safety policies have on avoiding such effects, can also result in a lower policy priority for chemical safety. Cost of inaction calculations, which have been politically influential in other areas of environmental policy, are difficult to carry out for chemical safety policies, although OECD is now working on this topic.

### *Factors of success*

- Trust building:
  - Development of networks and sharing of approaches;
  - Development of a common language / formats;
  - Alignment of testing methods and GLP;
  - Establishment of binding Council Acts on Mutual Acceptance of Data.
  - Focused initiative that grew progressively;
  - Strong industry buy-in and support.
- Produces results in all of the three main outcome areas of IRC (as per OECD Best Practice Principles on International Regulatory Co-operation (OECD, 2021[6])):
  - Regulatory effectiveness – MAD and associated GLP ensures trust in data generated across MAD adherent countries, facilitating the use of data across regulatory programmes leading to more timely decision based on more consistent approaches;
  - Economic efficiency – MAD reduces economic burden across implicated industries and countries by re-use of test data and harmonised approaches with more than 35 times more quantified savings than associated costs (which also produce significant unquantified savings);
  - Administrative efficiency – Mutual recognition of Compliance Monitoring Programmes implementing GLP and the resulting studies under MAD is immensely more efficient than each country trying to determine the compliance of laboratories across countries and the quality of the resulting data.

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## Note

1. 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[1]).

# International Regulatory Co-operation in Competition Law and Chemical Safety

This report showcases international regulatory co-operation (IRC) in the areas of competition law and chemical safety. These two studies – covering very different subjects – are rare examples of areas where complex legal and institutional frameworks have been created at the domestic and/or international level to ensure effective IRC. The competition case study focuses on international co-operation for law enforcement, surveying the range of tools and methods countries can use to address international antitrust concerns, as well as the challenges involved. The chemical safety case study reviews the OECD Environment, Health and Safety Programme and provides concrete evidence of the monetary and health benefits of its "mutual acceptance of data" system related to chemical safety. These case studies are evidence of both the importance and the complexity of frameworks that enable IRC to help solve common problems across jurisdictions.

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