Chapter 7

Assessing the success of international regulatory co-operation as provided by international organisations

There is limited systematic analysis and research on the successes and failures of international organisations in promoting international regulatory co-operation. This chapter provides an overview of the answers provided by international organisations to the 2015 OECD Survey of International Organisations on their perceived factors of success, challenges and lessons learnt in facilitating co-operation across members.

Preliminary results from the survey suggest that the self-assessment of the international regulatory co-operation (IRC) practices of international organisations (IOs) is a challenging task and does not lead to a systematic evaluation. Indeed, only few IOs provide detailed information on the main lessons learnt from cases of successful/unsuccessful IRC processes and the relevant factors/challenges concerning these practices. Based on the information provided by IOs, it is however possible to outline in a qualitative manner some examples and lessons from IRC practices of IOs. Box 7.1 provides examples of successful IRC processes as volunteered by IOs.

Box 7.1. **Selected examples of successful IRC processes volunteered by IOs**

The training of good manufacturing practice for medical products (GMP) inspectors is one of PIC/S' success in terms of IRC. GMP inspectors are highly specialised and their training needs are very specific. For most regulatory authorities it is not possible to provide specialised and high-quality training to their inspectors. For this reason, by pooling resources together, PIC/S has been able to develop a diverse training programme, which is opened to PIC/S participating authorities as well as non-members. The distinct feature of PIC/S training is that it is a training programme run by inspectors for inspectors. Senior inspectors and experts specialised in specific fields will share their knowledge with junior or less experience inspectors. The training is also very important in order to harmonise both GMP standards and inspection procedures around the world. Indeed, the interpretations of GMP requirements may vary between continents and sometimes even between neighbouring countries. Training is thus an important harmonisation tool, which facilitates the sharing of inspection reports and the exchange of information between members.

The Terrorism Prevention Branch of UNODC is the key technical assistance provider within the United Nations of legal and capacity building assistance in terrorism prevention. The work of the Branch focuses on four main areas: i) promoting the ratification of the 19 universal legal instruments against terrorism; ii) supporting the drafting and review of national legislation in order to incorporate the legal standards of these international legal instruments; iii) building the capacity of national criminal justice officials to implement these standards; and iv) supporting regional and international co-operation in criminal matters, in particular in relation to requests for mutual legal assistance and extradition.

The OPCW Internship Programme for Legal Drafters is aimed at qualified legal officers and qualified members from national authorities of states members, providing the technical capacity and requisite skills to enable them to complete a draft of national implementing legislation and also to pursue its adoption upon their return. The objectives of the internship are to provide tailor-made assistance to states members that have not yet started developing the initial draft of their national implementing legislation, or those that have challenges in this regard. Through the programme, the legal drafters of the participating States members would have developed an initial text of draft legislation that is fully in line with the provisions of the OPCW Convention, meets the requirements of their respective national legislative bodies, and is suitable for submission to Parliament.

AHWP has developed guidance for the preparation for a Common Submission Dossier Template (CSDT), which allows to prepare technical documentation on medical devices in an agreed format. The standard format helps eliminate differences in documentation requirements among member economies, thus decreasing the cost of establishing and documenting regulatory compliance and allowing patients earlier access to new technologies and treatments. AHWP has also established a Safety Alert Dissemination System (SADS), i.e. an on-line system for disseminating safety alerts of medical devices among AHWP members. Through this system, regulatory authorities of member economies can actively communicate on safety information related to medical devices as part of the post-market surveillance activities.

Source: OECD Survey of International Organisations, 2015.

Based on responses from IOs, several factors can explain the success of IRC processes:

- Mutual trust and close engagement among members (APEC, BRS, ESCWA, IMF, ITU, OIF, OPCW, OSCE, PIC/S, SAICM, UNECE, UNEP, UNIDO, and UPU).
- High technical skills and solid scientific competences within the organisation and relevant experience of member delegates (FAO, OAS, OIML, PIC/S, UNECE, UNEP and UNODC).
- The capacity to oversee and monitor implementation of IRC instruments/decisions (FAO, OAS, OPCW, and WCO).
- A good institutional architecture for the decision-making processes taking place within the IOs (IAEA, IMO, and PIC/S), with clearly designated roles and responsibilities and a permanent secretariat supporting the organisation of activities (AHWP).
- Clear definition of objectives (COMESA, FAO, OIF, and UNIDO).
- Open and inclusive consultative processes (FAO and WMO).
- Availability of resources (BRS Conventions and FAO).
- Quality of communication (OTIF).
- Effective *ex post* assessment procedures (OAS).

In the case of unsuccessful co-operation processes, failure may take the form of a lack of agreement among members, inadequate implementation of the agreements or standards; or ineffectiveness of the agreements or standards to address the underlying problems. Owing to the sensitivity of this information, only a small number of IOs volunteered examples of unsuccessful IRC processes.

For example, the early UNEP attempt to develop a global legal instrument for operationalising the Rio Principle 10 related to the Aarhus Convention failed because of a lack of familiarity of a number of countries with the Aarhus Convention. However, ten years later, the subject had matured, and many governments had become ready to engage in the debate. In 2010, the UNEP Governing Council adopted an international guideline for the development of national legislation on the same subject.

Most IOs recognise that their instruments may be simply disregarded by main stakeholders. In the context of the APEC-OECD Integrated Checklist for Regulatory Reform, the self-assessment process did not have the expected success, as only six APEC economies underwent it. In part, the problem was related to the fact that some APEC members did not understand the benefits to participate in this process. Similarly, some of OIML's Mutual Acceptance Arrangements have not made as much impact as had been hoped because of low "buy-in" from member states.

While weak implementation is more likely to occur with non-legally binding instruments (the majority of IO instruments) since by nature their use is not framed by strong enforcement power but relies on the commitment of parties, it may also happen with legally-binding instruments. They, for instance, may be agreed upon but not ratified by enough members to enter into force or may not be translated into domestic law. WHO reports the case of the Protocol on illicit trade in tobacco products to the Framework

Convention on Tobacco Control, which was adopted in November 2012 but (as of November 2016) has not yet entered into force due to lack of sufficient ratifications.

In cases where the agreement is negotiated by parties that do not have the jurisdiction to enforce it – for instance by federal authorities in countries where the issues are under sub-national (for instance state or province) authority – implementation may be hard to harness. This critically raises the question of the representativeness of members in IO platforms.

The process of development and adoption of IRC instruments, as well as their effectiveness, may in some instances be undermined by the financial constraints faced by members. Faced with this challenge, some FAO statutory bodies have established special trust funds to support the participation of developing States in IRC processes and to assist them in the implementation of IRC instruments. For example, in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), a special fund to support the participation of developing countries was established to facilitate participation to ITPGRFA meetings, including to the compliance committee's meetings, by representatives of developing countries.

The development of IRC instruments may span over a substantial period. In that time, unforeseen events may occur and political priorities evolve in members that may change the dynamics of the discussion among members. In 2000, PIC/S started to develop a new mechanism to reduce the number of foreign inspections for good manufacturing practice for medical products (GMP) of participating authorities by sharing inspection reports through a common database called the International Medicinal Inspectorates' Database (IMID). IMID was, however, frozen a few years after its launch in 2003 in order to avoid duplications with a similar database (the EUDRA GMP Database) developed by the European Medicines Agency (EMA).

Challenges to successful IRC identified by IOs are diverse. They however usually pertain to the difficulty in garnering and maintaining strong consensus and commitment to multilateral action among members and in ensuring the financial and human resources over time to match the level of ambition of IRC.

- The lack of human and financial resources in the secretariats and/or in the members (AHWP, BRS Conventions, FAO, OAS, OIML, PIC/S, SAICM, UNECE and UNODC),
- The difficulty in ensuring an active involvement of members (BRS Conventions, ESCWA, IMF, UPU and WCO),
- The lack of adequate and timely information and/or the difficulty to collect data leading to shortcomings in the problem diagnosis and inadequate recommendations (IMF)
- Differences in the legal framework of members which limit and narrow the scope of IRC (COMESA, IAIS, IOSCO and UNIDO)
- Conflicting objectives and priorities across members (ESCWA and UPU)
- Perceptions of particular specificities and differences in the socio-economic status of members influence the adoption of mutual agreements and regulations (ESCWA)
- Problems in networking with other organisations (OAS and PIC/S)

- The complexity and costs of implementing IRC activities (ICN, OAS, WMO)

Based on their experience, the IOs identify a number of critical lessons learnt from their IRC practices:

- Adopting a long term focus to IRC in order to gradually build support and consensus from members (APEC)
- Establishing precise, specific and realistic objectives for the co-operation, in line with available resources and based on detailed ground work (OIF)
- Developing IRC on the basis of a strong common understanding among members of the issues, challenges and objectives to be achieved (FAO) and on their commitment to (and individual interest into) multilateral action in the specific field (IMF, WMO, IATA, OPCW)
- Reaching common grounds through diplomacy; connecting technical and political experts to work towards common goals; engaging civil society; and minimising administrative overhead costs within the organisation (OAS)
- Expanding the use of stakeholder participation in the sharing of knowledge and information (SAICM)
- A cycle of creation, implementation and evaluation of the work products is crucial for the continuous development and improvement of the activities (ICN)
- Developing better co-ordination and co-operation across IOs in order to improve more efficient use of available resources and streamline initiatives and lessen the burden on Governments by focusing their interaction (ESCWA)
- When decisions are made on the basis of sound science, supported by open and inclusive processes, standard setting through the development of legal or policy instruments has better chance to succeed (UNEP)
- Promoting active and reciprocal co-operation with the members and their involvement in the various good governance process and reviews (i.e. review projects, outputs, outcomes versus planned outcomes, key performance indicators, baselines and deliveries) (WCO)
- The capacity of the organisation to function with a good internal information sharing and knowledge management as key feature for insuring that IRC is successful (OTIF)
- The effectiveness of IRC activity is increased where there are effective structures at regional or sub-regional level as well as at the global and national levels (OIML)