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Strengthening the norms against chemical and biological weapons

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Industry and the Norms Against Chemical and Biological Weapons

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Executive Summary

Arms control and disarmament agreements such as the Chemical Weapons Convention (CWC) and the Biological Weapons Convention (BWC) are contracts between states. They stipulate obligations and rules that govern state conduct and interstate relationships. However, their implementation reaches beyond states – other stakeholders, including industry, are affected and need to comply with certain rules enacted by governments to implement the treaties. They have an interest, therefore, to take part in shaping these agreements and the way they are being applied.

Understanding the role that industry plays in the CBW context is particularly pertinent today: the CWC is moving beyond the elimination of all declared chemical weapons stockpiles and adapting its priorities to preventing the recurrence of chemical weapons and warfare, whilst BWC States Parties are making efforts to strengthen the regime through the development of institutional measures of compliance assurance and verification. Both treaties will need input from and engagement with industry to ensure that the outcomes of these endeavors will be relevant to the evolving security threats, practical, effective, and affordable.

Experiences from the two conventions and other arms control, export control and security agreements have shown that implementation critically depends on industry support and cooperation. This extends to the provision of technical advice and practical information, as well as the communication of concerns and constraints within industry, during the design of new such regulations as well as their implementation.

The negotiations of the CWC are a pertinent example for how industry and governments can and must engage during the negotiation of new treaty arrangements, how industry can contribute productively to the design of new rules and procedures and help testing them in the real world, and how its corporate management systems (such as the chemical industry's Responsible Care® Programme) contribute to ensuring compliance with these regulations and providing transparency and confidence in rule-compliant behavior of companies and traders.

Success of the current efforts towards strengthening the BWC through compliance measures including verification, too, will critically depend on how negotiators will engage with industry as they devise compliance and verification concepts and mechanisms that are to be effective and practical in the industrial environment of today and tomorrow. They will need to take account of industry concerns about the impact of such future measures on issues such as confidentiality, innovation, market relations and administrative burden. CWC experience has shown that industry engagement is important not merely for implementing regulations that directly affect it, but also for the design of the rules if they are to be politically acceptable as well as technically sound.

1 Introduction

The prohibitions against the acquisition and use of chemical and biological weapons are enshrined primarily in the 1975 Biological Weapons Convention (BWC) and the 1997 Chemical Weapons Convention (CWC). Both treaties prohibit the development, production, acquisition by any means, transfer, and stockpiling of the respective weapons categories covered under them (BWC: biological and toxin weapons; CWC: chemical weapons). The CWC also bans chemical weapons production facilities. It also explicitly prohibits the use of chemical weapons whilst the use prohibition of the BWC is implicit in the treaty text. Both treaties are close to universal adherence, and today constitute cornerstone agreements in disarmament and non-proliferation.

Like any other international treaty, these conventions are contracts among states. The obligations they establish, and the implementation rules they set out, address responsibilities and acts of states party to them. Some of these prohibitions - in particular the norm against any use of chemical and biological weapons - also constitute a form of customary international law, thus extending to all states and perhaps even to non-state actors.

To understand how these treaties have come about and how they function in practice, however, one needs to look beyond states. Both treaties affect other actors, and their effective functioning depends on actions that these other actors are taking (or not). One key actor is industry, which is both an object of certain rules and requirements and a contributor to the implementation of the regimes. In addition, industry plays a crucial role in the evolution of the norms themselves.

Understanding the role that industry plays for these arms control regimes is particular pertinent today. For the CWC, the completion of the destruction of all declared CW stockpiles marks the transition into a new implementation phase of the regime, with a shift in focus towards preventing the re-emergence of chemical weapons in whatever form or shape. This calls for a critical evaluation, amongst others, of the functioning of the CWC industry verification system as well as its fact-finding procedures to ensure that they remain aligned with the evolving threat and implementation landscape. With regard to the BWC, the work of the BWC Working Group on strengthening the BWC includes amongst others consideration of possible verification and compliance measures. Both developments will require a closer engagement between governments, negotiators, and industry if they are to lead to results that are sound in terms of the underlying science and technology, do not negatively affect industrial development or interests, are affordable, and can adapt to the ever-changing industrial landscapes.

This working paper first looks at some general issues that frame the interaction between industry and governments in the fields of arms control and security in general. It then looks back at how these interactions have affected the conclusion and implementation of the CWC. The paper then looks at the involvement of the biotechnology and pharmaceutical industries in the BWC processes. It ends with some observations about the need for stronger engagements between governments and industry as discussions about compliance and verification mechanisms under the BWC are beginning to take shape in the BWC's Working Group.

2 Government - industry relations in arms control and disarmament

2.1 General considerations

Industry is not merely a passive subject of government regulation, but an actor in society that is driven by business interests on the one hand and a desire to bring solutions to societal problems on the other. During negotiations of new regulatory instruments, this manifests itself in lobbying by industry and trade associations, and in the provision of expert advice and information from industry to help shaping the outcomes of such negotiations. Also, there are examples of industry adopting internal control measures in anticipation of government action, either to underpin such future actions or to prevent regulations it would consider to be ill-conceived or overly burdensome. Such

company-internal compliance measures reflect both a desire of industry to ensure regulatory compliance and avoid penalties, and an attempt to protect industry interests.

Typically, areas of concern for industry include the protection of intellectual property and commercial confidentiality, the minimization of the regulatory burden on company operations, the protection of favorable conditions for trading its products and services both nationally and on global markets, and to ensure access to essential raw materials and services needed for its manufacturing processes. At the same time, industry has an interest in protecting and fostering its efforts to innovate, in growing and bringing new products and solutions to the market, and in promoting the use of its products and services by other industries, consumers, and in state programmes.

2.2 Regulatory frameworks for industry

Companies operate within discrete regulatory frameworks, emanating from national laws of the countries they are registered in or trading with, and from international laws as nationally implemented and enforced. These regulations apply to such diverse business activities as managing labor relations and employment, ensuring product compliance with health, safety, environmental and quality standards, and conducting business operations within the company and on the markets. Amongst them are requirements emanating from transfer/export control regimes pertaining to the trade in goods (arms, dual use materials and equipment), sensitive technologies, services and intangibles, as well as arms and other embargoes.

For individual companies, many of these regulatory requirements manifest themselves in the need to report data to competent national authorities, to receive national and in some cases international inspections, to review the legitimacy of client orders and bona fides, and to apply for licenses as required. With regard to trade activities, international standards today cover not only exports, but also certain transit, trans-shipment and brokering transactions. They affect a range of sectors and actors including exporting companies, brokers, suppliers, the transport sector, as well as academia and research institutes.[1]

To facilitate compliance with these regulations, governments and international organizations implement awareness raising, outreach and engagement programmes to connect with industry and encourage it to adopt effective compliance management practices. For example, the UN Security Council's 1540 Committee has convened meetings in several countries to promote engagements between governments and industry, and to incentivize the adoption of internal industry compliance programmes (ICPs).[2]

Existing regulatory frameworks - their scope, complexity and coherence - shape industry perceptions and interests with regard to the development and adoption of new regulations. That also applies to arms control and disarmament regimes. At the same time, these regulatory frameworks, once enacted, require companies to implement internal systems that ensure that they can comply with them. An example are strategic trade controls including export controls, which will be briefly discussed next.

[1] Sibylle Bauer, Kolja Brockmann, Mark Bromley and Giovanna Maletta, "Challenges and good practices in the implementation of the EU's arms control and dual use export controls – a cross-sector analyses", Stockholm International Peace Research Institute (2017) p. 1. See also UN Security Resolution 1540(2004) and subsequent resolutions, as per https://www.un.org/en/sc/1540/resolutions-committee-reports-and-SC-briefings/security-council-resolutions.shtml.

[2] United Nations Security Council, document S/RES/2022/899 conveying the 2022 comprehensive review of the status of implementation of Security Council resolution 1540(2004), paragraphs 105-106, available at https://documents-dds-ny.un.org/doc/UNDOC/GEN/N22/725/80/PDF/N2272580.pdf?OpenElement.

2.3 Requirements for internal compliance programmes in strategic trade controls

Export controls are among the measures that arms control and disarmament agreements compel countries to adopt. Article III of the BWC requires States Parties not to transfer, to anyone and in any way, the agents, toxins, weapons, equipment or means of delivery prohibited under the treaty. Article IV then requires States Parties to take any necessary measures to prohibit and prevent acts prohibited under the BWC. Similarly, Article I of the CWC sets forth, amongst others, undertakings by States Parties never under any circumstances to transfer chemical weapons in any way to anyone, nor to assist, encourage or induce anyone in any way to engage in activities prohibited by the treaty. Article VI compels States Parties to adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, acquired, transferred or used for purposes not prohibited by the Convention. Article VII repeats that concept and links it to the enactment of legislation, including penal legislation, and the adoption of administrative measures. Specific regulations dealing with transfers of scheduled chemicals are then set out in the Verification Annex.

One direct consequence for industry of these provisions is the application of export control measure to prevent the proliferation of materials, equipment and technologies, as well as of intangibles, that could be misused for the development, production/acquisition, stockpiling or use of chemical or biological weapons, whether to State or non-State actors.

Irrespective of the particular industrial sector, the proper functioning of export controls requires cooperation by industry. Internal compliance management systems are important to ensure that companies are cognizant of:[3]

- The types of products and activity concerned, the country of destination, the end-use, the end-user and the entities involved, as well as the resulting licensing requirements and prohibitions
- The entities involved in a transaction, such as the invoicing entity, the receiving entity, banks, intermediaries (freight forwarders, shippers, customs agents) and transit/trans-shipment points. The intermediaries and relevant parties in the recipient country might be agents, distributors, brokers, joint ventures, subcontractors and subsidiaries
- Applicable laws of the jurisdictions involved, some of which may be contradictory and may comprise regular export, transit, trans-shipment and brokering controls as well.

An early example for an effective internal compliance programme, albeit in the nuclear field, was developed by the German company Leybold AG, a subsidiary of DEGUSSA at the time and today member of the Atlas Copco Group. In the early 1990s, Leybold set up an internal compliance control system for export controls.[4] The corporate principles set out by the company's Executive Board[5] still serve as an inspiration for other such programmes, including for compliance management in the chemical and biological industries. In general terms, they can be summarized as follows:

- The company's unequivocal and emphatic support for the non-proliferation policies
- A commitment by the company and its worldwide subsidiaries to endorse and adhere to the export controls established by governments
- A stipulation that all company employees will actively assist in the achievement of this corporate goal

[3] Bauer et al. (2017), p. 41.

[4] David Albright, "Creation of Leybold's Internal Compliance System", ISIS (2002), available at https://exportcontrols.info/leybold.html.

[5] Leybold AG (1992), "Corporate principles governing internal export controls on nuclear non-proliferation", (17 March 1992), available at https://exportcontrols.info/images/leybold%20principles.pdf.

- A commitment to a clear-cut and unambiguous priority to the goal of non-proliferation over commercial interests
- A statement that the policy also applied to domestic transactions if the company knew or had reason to believe that its products are diverted for what may be illicit activities
- A commitment to establish and maintain contact with all responsible government authorities, including immediate requests for information and advice in cases of any doubt about an order or transaction request
- A statement that the policy applied to all units and subsidiaries of the company worldwide.

2.4 Internal compliance measures in industry in general

Corporate compliance programmes involve the development of contacts and good-standing relationships between the company and relevant government agencies, regular updates of the laws and regulations the company needs to comply with, management systems that centralize questions and issues related to corporate compliance and standardize procedures, provide early warning and screening of all inquiries and orders, generate coherent and complete documentation of all sensitive transactions and ensure the training of all employees engaged, directly or indirectly, with regulated activities. [6]

These systems include internal processes to facilitate and monitor compliance and take action when breaches are detected. They are usually integrated with other company management systems, and depend critically on a clear commitment by the company board and awareness raising and training of staff. They also require productive relations with the relevant competent government bodies such as licensing agencies or National Authorities, and should form part of an explicit company policy.

To set up such a system requires resource allocation, dedicated staff, awareness raising and training programmes for all staff, and trusted systems for reporting concerns about compliance that incentivize as well as protect staff who have such concerns. The tools that industry has developed include, amongst others, screening of customers, end users or end uses, and evaluation of whether the recipient country is a member of relevant international treaties or regimes.

These measures are supported by guidance offered by industry associations, international organizations, governments, and an array of consulting companies and other non-governmental bodies. For example, the US State Department has developed a set of “red flag” indicators that companies may use to screen whether a customer may be attempting to engage in illegal or potentially illegal transactions,[7] as well as a related “know your customer” guide. [8]

The European Commission as well as EU Member States individually have developed guidelines for internal compliance programmes in industry and research with dual use export control regulations. They are also developing guidelines to support due diligence in the field of cyber-surveillance to prevent trade from being misused for internal repression and/or serious violations of human rights and international humanitarian law. [9] Within the EU there are a multitude of such controls, which risks fragmentation and a lack of uniformity and coherence. To mitigate these risks, the Commission

[6] Institute for Science and International Security (ISIS): Key elements of an effective export control system. 2004. available at http://exportcontrols.info/key_elements.htm), p. 4 with minor modifications.

[7] https://www.bis.doc.gov/index.php/all-articles/23-compliance-a-training/51-red-flag-indicators.

[8] https://www.bis.doc.gov/index.php/all-articles/23-compliance-a-training/47-know-your-customer-guidance.

[9] European Commission White Paper on Export Controls, COM(2024)25 final (24 January 2024).

has proposed the creation of a Forum for Political Coordination. [10] The EU also supports partners countries globally in adopting and implementing effective control measures in the fields of dual use export controls, the implementation of the Arms Trade Treaty, and arms export controls, under its P2P Programme. [11]

In addition to government-led support initiatives, there are also non-governmental organisations that provide guidance on corporate compliance. For example, the Stockholm International Peace Research Institute has been conducting research, developing tools and concepts, conducting seminars and other awareness-raising activities, and carrying out capacity-building efforts in the field of dual use and arms export controls. This included the development of analyses and guidelines for a broad range of industrial and research activities, with particular attention being paid to emerging technology areas such as biotechnology and additive (3D) manufacturing. [12]

2.5 Cross-sectoral challenges

Across different branches of industry, there are a number of challenges that the adoption and effective implementation of such corporate compliance programmes entails. A 2017 study identified particular challenges for small and medium-size enterprises (SMEs) – a type of company often found in the biotech industry and certain parts of the chemical industry. [13] Whilst SMEs may be able to tailor their programmes and mechanisms to their particular circumstances given the relatively small size of their business, they often lack expertise, capacity and contacts to relevant government authorities. This underlines the need for tailored guidance for such companies by governments, international organizations and trade associations (for such guidance having been developed by the OPCW to support chemical SMEs see further below).

A second challenge are the marked differences in interpretations of internationally agreed rules in different jurisdictions. An example in the context of export controls is product classification in EU Member States. Although the EU Dual-use Regulation forms part of the EU's 'common commercial policy', certain aspects—particularly licensing decisions and enforcement—are left to EU Member States. [14] There are also often differences in approach between the United States, Europe, and other regions. For example, differences in the interpretation of certain rules of the CWC regarding declarations and controls of transfers of scheduled chemicals have been observed by the OPCW for many years, and proven difficult to rectify.

A related issues is the management of multiple jurisdictions in a given supply chain. Multinational companies in particular must manage a wide range of products and a multitude of customers, in jurisdictions with different and sometimes contradictory rules. This also creates challenges for companies to spread a compliance culture across their businesses in multiple countries and embed compliance procedures in small subsidiaries.

Another challenge relates to the control of intangible transfers. With the accelerating trend towards digitalization of industry and trade, and new forms of technology and business organization such as cloud manufacturing or production at or close to the end users, controls over the transfer of information through electronic means are getting more complicated, labor intensive, and costly. [15]

[10] Ibid., see also Bromley, Mark, L. Béraud-Sudreau and Giovanna Maletta, "A new political forum could help make the EU's strategic trade controls more strategic—if it is allowed to", SIPRI commentary/essays (10 April 2024), https://www.sipri.org/commentary/essay/2024/new-political-forum-could-help-make-eus-strategic-trade-controls-more-strategic-if-it-allowed.

[11] https://cbrn-risk-mitigation.network.europa.eu/eu-p2p-export-control-programme_en.

[12] https://www.sipri.org/research/armament-and-disarmament/dual-use-and-arms-trade-control.

[13] Bauer et al. (2017) p.31.

[14] Ibid., p.33.

[15] Ibid., pp. 35-36.

These digitalization trends are characteristic for much of the cutting-edge developments in the biotech and pharmaceutical industry.

Yet another challenge is risk assessment, an essential aspect of any corporate compliance management system. For example, companies must keep track of "red flags" such as prohibited or suspicious parties, end-users, end-uses, illicit trafficking routes and so on, as well as of legal changes, and they must integrate these swiftly into company routines. Whilst there are solutions available to automate these tasks, they tend to be limited in scope, and costly. [16]

Furthermore, any corporate governance system only works if the senior management fully understands the objectives and challenges, supports the programmes put in place to achieve/manage them, and allocates sufficient resources to implement them.

Finally, new cross-sectoral challenges are emerging as the result of advances in science and technology, in particular with regard to what some authors have called "omni-use" technologies. These technologies are associated with a shift from physical items to intangible digital technologies and know-how, with the private (rather than the public) sector increasingly taking the lead in their design and development, and a broad range of both civil and military applications. [17] These characteristics make the imposition of control measures increasingly more difficult and potentially detrimental to legitimate uses.

2.6 Typical components of internal industry compliance programmes/systems

A recent study that aimed to assist governments and other actors with establishing, developing or improving systems for outreach in strategic trade controls (STC), and to help companies establish or enhance their systems to manage compliance with such controls, [18] underlined the importance of:

- Senior management commitment to and accountability for STC compliance
- The need for organizational structure and responsibilities for STC
- Organizational policies and procedures relating to STC
- Transaction screening processes
- Training of all relevant staff in STC compliance
- Adequate systems for record-keeping so that compliance can be demonstrated to the relevant authorities.
- The need for auditing and internal review, reporting and corrective action.

Particularly important is it to create a culture (an organization-wide ethos) of compliance, beginning with the most senior management and encompassing all employees at all levels of the business and in all its departments.

This approach has been recognized in ISO standard 19600:2014 on guidelines on compliance management systems". [19] This industry standard is aligned with other ISO standards on management systems and provides a framework for the implementation of specific compliance-related requirements in any management system. It was an important first step towards developing

[16] Ibid. p.37.

[17] Brigitte Dekker and Maaike Okano-Heijmans: Emerging technologies and competition in the Fourth Industrial revolution: The need for a new approach to export controls, Strategic Trade Review vol.6 (9), Winter/Spring 2020, pp. 53-68.

[18] Saferworld, Centre for Policy Research of the University of Albany, and Chinese Academy of International Trade and Economic Cooperation: Strategic trade control outreach and industry compliance – tools and resources (2019).

[19] A preview of ISO 19600:2014 is at https://www.iso.org/obp/ui/#iso:std:iso:19600:ed-1:v1:en. The standard has been withdrawn (see next footnote).

recommended common and certifiable approaches for companies to set up and implement compliance management systems in their specific business environment, irrespective of location and business sector. Since 2021, a new standard (ISO 3730:2021) sets out requirements and provides guidelines for establishing, developing, implementing, evaluating, maintaining, and continually improving a compliance management system (CMS). [20] Migration towards this new standard is under way. An example for a multinational chemical company that has achieved external certification under this new standard in Boeralis, an international provider of polyolefins and base chemicals. In 2022, the company received its first external certification under ISO 37301 (Compliance Management)[21] and ISO 37001 (Anti-bribery Management).[22] Another example is Lotte Chemicals, a Korean chemical company that received ISO 37301 as well as ISO 37001 certification in 2024.[23]

3 The chemical industry during the CWC negotiations

3.1 The chemical industry's role during the CWC negotiations

To understand the measures adopted by the chemical industry to ensure compliance with rules and regulations emanating from the CWC, it is first necessary to recall what the nature of this industry is and how it influenced the negotiations of CWC and its provisions.

Chemical industry is a basic industry that supplies goods and services to a wide range of other industries, from agriculture and food production to medicine, construction industries, the transport sector, defense industries and many other branches. Being a mature industry that handles hazardous material on a daily bases, it is highly regulated. This regulatory framework is to a large degree the result of public health and environmental safety concerns, and a desire to apply good manufacturing practices (GMP). But other factors, too, form part of this regulatory system, including non-proliferation, disarmament, and security. Regulations govern, amongst others, the manufacturing, storage, transportation, marketing, trade and use of chemicals, the treatment of chemical wastes, limits to pollutant emissions into air and water, tolerable concentrations of hazardous chemicals in air, drinking water, food, consumer products, products used by other manufacturers, and so on. Chemical safety and security regulations overlap to a degree with regulatory frameworks applicable to what might be called "adjacent" industries and activities, such as the development, manufacturing and use of pharmaceuticals, the use of chemicals in agriculture, food safety, and other manufacturing industries that use chemical products or processes.

The public image of the chemical industry at time of the CWC negotiations was marked by the aftermath of the use of herbicides/defoliants in the Viet Nam war, with large-scale environmental damage, crop and forest destruction and long-term health effects in local populations, as well as two major industrial chemical accidents: Seveso in 1976[24] and Bhopal in 1984[25].

[20] See https://pecb.com/article/migrating-from-iso-196002014-to-iso-373012021.

[21] https://www.borealisgroup.com/storage/Company/Quality/Certificates/ISO-37301-Borealis-AG-20221109.pdf

[22] In 2023, Borealis received recertifications for ISO 37301 and ISO 37001. OMV's Sustainability Report of 2023 states that Borealis "also implemented new policies and processes to manage social compliance and external whistle- blowing, including an improved due diligence, monitoring, auditing, and escalation procedure for business partners. The outcome was an updated Ethics Policy for Business Partners, which includes new compliance requirements for supplier contracts. https://www.omv.com/downloads/2024/11/e7bc7980-ebf2-881c-ca8c-db7897754d9c/omv-sustainability-report-2023.pdf

[23] https://www.lottechem.com/en/media/news/977/view.do .

[24] UK Health and Safety Executive. Case study: Icmesa chemical company, Seveso, Italy 1976. Available at https://www.hse.gov.uk/comah/sragtech/caseseveso76.htm .

[25] Edward Broughton: *The Bhopal disaster and its aftermath: a review,* Env. Health: A Global Access Science Source vol. 4 no. 6, doi:10.1186/1476-069X-4-6. Available at http://www.ehjournal.net/content/4/1/6 .

Regulators responded to these and other, less dramatic incidents, with what some in the industry perceived as overly harsh and costly-to-implement regulations. Whether or not this view is shared, the industry has become very sensitive to how regulations are being devised and implemented. For chemical manufacturers and traders who operate on global markets, these regulatory complexities pose significant challenges and incur significant costs. This explains the industry's keen focus on achieving a "level playing field" and avoiding "over-regulation" and undue administrative burden.

This stance also influenced the approach that chemical industry took towards the negotiations of the Chemical Weapons Convention. These negotiations were intergovernmental in nature. However, as McLeish and Lak observed, [26] the negotiators were cognizant of the need to reach out to stakeholders given the unique character of the prospected treaty. In their analysis, factors that influenced the industry's stance included:

- Public perception issues which saw the chemical industry associated with pollution and disaster
- The industry's linkages to the chemicals used in the Vietnam War such as Agent Orange
- A growing realization that governments were committed to conclude a global CW ban
- The fact that much of the precursor chemicals and equipment used by Iraq in its chemical weapons attacks against Iran had been supplied by industry.

As the negotiations of the CWC progressed during the 1980s, chemical industry associations in the USA, in Europe, Japan, Australia and elsewhere developed and coordinated industry positions, and conveyed their views to governments. Areas of particular concern for the industry include the protection of its intellectual property, minimization of the regulatory burden on its operations, favorable conditions to trade its products and services both nationally and on global markets, and access to essential raw materials for its manufacturing processes. Also, the chemical industry wanted to protect its efforts to innovate, grow and bring new products and solutions to the market. These industry concerns crystallized around specific provisions of the evolving draft treaty, including the composition of the Schedules, the protection of confidential business information, the types of data that industry was expected to make available for declarations to the OPCW, and issues related to how inspections of chemical plants would be conducted.

Beginning in the mid-1980s, the Pugwash Conferences of Science and World Affairs and the Stockholm International Peace Research Institute (SIPRI) brought together experts from the chemical industry, CWC negotiations and arms control. In 1985, SIPRI and Pugwash jointly convened a conference on the chemical industry and the projected CWC. [27] The rationale of this conference was that the activities of the chemical industry could result in ambiguity and misunderstandings unless the treaty provided for measures of verification not merely to monitor compliance but also to dispel uncertainties about their real nature. CWC verification should protect the chemical industry against unfounded accusations and allow it to demonstrate that its resources were not being exploited for CW purposes.

The conference looked at regulatory practices in different countries, the industrial context of chemical warfare, and the potential inherent in the chemical industry to manufacture chemical agents and intermediates. It addressed how chemical products might be categorized, and it discussed concepts, concerns and open questions regarding the way in which the CWC verification system could provide confidence in the legitimacy of the activities in the chemical industry.

[26] McLeish, Caitríona and Maarten Lak, "The role of civil society and industrial non-State actors in relation to the Chemical Weapons Convention", in: W. Krutzsch, E. Myjer and R. Trapp, "A Chemical Weapons Convention Commentary", OUP (2014), pp. 37-48.

[27] Stockholm International Peace Research Institute: The chemical industry and the projected Chemical Weapons Convention – Proceedings of a SIRPI/PUGWASH conference, SIPRI CBW Studies Series no. 4 and no. 5, volumes I and II, Oxford University Press (1986).

Subsequent SIPRI and Pugwash studies included an analysis of technical verification concepts for the verification in the chemical industry, a study on national implementation of the future CWC, a case study on the verification of dual use chemicals under the CWC using the example of Thiodiglycol, and a study on experiences from national trial inspections.

Beginning in 1987, occasional informal meetings between CWC negotiators and industry representatives were held alongside the negotiations in Geneva. The industry representatives received briefings about the status of the negotiations and presented their views on specific issues. These meeting became regular events during the final phase of the CWC negotiations.

A major government-industry initiative that made a particular contribution towards completing the CWC negotiations was the Government-Industry Conference against Chemical Weapons convened in 1989 by the Australian government in collaboration with the Australian Chemical Industry Association in Canberra (the Canberra Conference). It sought the unqualified cooperation and support from the chemical industry for the early completion of the negotiations and the implementation of the future CWC. [28] At this conference, industry associations adopted a statement which expressed the industry's unequivocal abhorrence of chemical warfare and its strong support for the efforts to conclude and implement the CWC at the earliest date. The Canberra Conference undoubtedly added momentum and determination to conclude the negotiations as early as possible; it also confirmed the critical supportive role that the industry could and was keen to play in shaping the treaty in ways that ensured its effectiveness whilst respecting industry interests.

3.2 The chemical industry's impact on the design of the CWC's verification system

The industry verification system of the CWC was among the last issues to be agreed in the negotiations, and the chemical industry remained engaged with the negotiation process throughout the final negotiation phase. It provided advice on a wide range of technical issues and supported the conduct of trial inspections at some of its chemical plants to test the proposed inspection procedures. By the end of the negotiations, 25 countries had conducted altogether 30 trial routine industry inspections. Also, three countries had conducted a multilateral trial inspection at chemical industry plants, and 6 countries had conducted trial challenge inspections at civilian chemical industry facilities. [29]

The trials tested a range of inspection procedures, including material balance verification to detect diversions of Schedule 2 chemicals, the conduct of initial visits, sampling and analyses at chemical production sites, and the elaboration of a facility agreement. Based in these experiences and other studies, the industry began to float the idea that industry verification should be qualitative in nature (verifying the absence of the production of Schedule 1 chemicals) rather than quantitative (verifying whether diversions of significant amounts of toxic or precursor chemicals might have occurred). The trials also exposed the weaknesses of an industry verification system that was solely based on the Schedules. They showed that there were facilities outside the Schedules that could be misused for CW purposes given their access to relevant chemicals and production equipment. Industry responded with an "open invitation", suggesting that any of its production plants could be subject to verification. The negotiators finally included a regime for other chemical weapons production facilities ("OCPFs") in Part IX of the CWC Verification Annex. Industry bought into this approach partly because it avoided labelling certain civilian chemical plants as "CW capable", and because the burden on industry would remain tolerable.

[28] Timothy L. H. McCormack: Some Australian efforts to promote chemical weapons non-proliferation and disarmament, Australian Year Book of International Law (1992), pp 157-178. Available at http://www5.austlii.edu.au/au/journals/AUYrBkIntLaw/1992/3.pdf.

[29] Ralf Trapp: Verification under the Chemical Weapons Convention: on-site inspection in chemical industry facilities, SIPRI CBW Studies Series no. 14, Oxford University Press (1993), pp. 110-111.

Towards the end of the negotiations, industry input on specific issues that negotiators were grappling with became more extensive and detailed. The European chemical industry association CEFIC and the US Chemical Manufacturers Association, supported by other industry bodies, submitted detailed analyses of the evolving CWC text and made numerous proposals for changes and additions to it. It became clear that industry was prepared to accept a degree of intrusion and regulation (even restrictions) as long as these were justifiable given the actual risk that its materials could easily be diverted to circumvent CWC prohibitions. But it also wanted protection against the unknown (such as product contaminations with scheduled chemicals that certain companies might not even be aware of), an assurance that commercial confidentiality would not be compromised by international inspections, and it wanted to limit the burden it would have to shoulder to comply with the CWC.

Some of industry's proposals were absorbed into the final CWC text; others were passed on to the Preparatory Commission for further consideration. Many specific provisions of the CWC dealing with industry verification as well as the protection of confidentiality can be traced back to inputs from industry. But perhaps the most important contributions were its push towards a more qualitative industry verification concept and the inclusion of a Confidentiality Annex in the CWC. Contacts between experts from chemical industry and the delegations intensified during the final weeks of negotiations, and some countries included experts from chemical companies in their delegation. Industry's interaction with the CW negotiators, its contributions in the form of technical advice and information sharing, and its willingness to open its plants for practical trials of proposed verification provisions under real-world conditions were all important for the design of the CWC verification system even though industry was not a formal participant in the negotiation process.

3.3 The chemical industry's support for a smooth start of CWC implementation

The conclusion of the CWC negotiation was not the end of industry's engagement with CWC negotiators and implementers. Issues that the negotiators had not been able to fully resolve, or that needed to be addressed as part of the practical preparations for CWC operations, were passed on to the Preparatory Commission. This commission worked in The Hague from February 1993 until the entry into force in April 1997.

Industry, again, was not a direct partner of these negotiations. Some national industry associations (Germany, Italy, Switzerland and some others) were able to persuade their governments to include industry representatives in their national delegations. But by the end of 1993, industry voices about its limited access to the work of the Preparatory Commission led to a decision to hold combined meetings of chemical industry representatives with the Preparatory Commission's Expert Group on Chemical Industry Facilities. A first such meeting took place in October 1993; subsequent meetings were conducted in April 1994 and June 1995. [30]

In December 1993, the Preparatory Commission decided, amongst others, that the provisional Technical Secretariat (pTS) may conduct regular briefings for industry and Member States on issues important to industry, and nominate points of contact for industry on specific issues of interest for it. It also invited Member States to consult their national industries to assist with the development of national implementing legislation and broaden awareness for the CWC, and encouraged industry to provide its expertise in areas of interest through direct bilateral informal consultations with the pTS. Furthermore, it authorized the pTS to directly contact international and national chemical associations to determine the likelihood of industrial facilities being offered for inspector training. [31] This recommendation opened the door for direct technical consultations between the pTS and industry, which gave industry direct access to the practical preparations of industry inspections.

[30] Ian R. Kenyon and Daniel Feakes. "The Creation of the Organisation for the Prohibition of Chemical Weapons – A case study in the birth of an Intergovernmental Organisation", T. M. C. Asser Press (2007), pp. 191-192.

[31] Preparatory Commission document PC-V/B/10 (15 December 1993), paras 2.3 and 4.9.

The Preparatory Commission devised many of the guidelines and technical procedures for verification. These included draft policy documents such as a draft OPCW Health and Safety Policy and a draft OPCW Confidentiality Policy, detailed inspection procedures and guidelines for different types of inspections, draft guidelines on sampling and analysis and the designation of Laboratories for off-site analysis, technical specifications and operational requirements for inspection equipment, and many more. The Preparatory Commission also adopted a general training scheme for future OPCW inspectors and hired inspector candidates who began training six months before the entry into force. Many of these endeavors were supported by contributions from industry associations, individual companies and industry experts.

Particularly important was the industry's contribution to the training of future OPCW inspectors. The initial inspectorate was trained in two Groups – Group A in the run-up to the entry into force of the CWC in 1997, Group B from January to May 1998. The industry support was essential to ensure that the OPCW was able recruit among its initial group of 111 inspectors 42 chemical production technologists/industrial chemists, 14 chemical production logisticians and 17 analytical chemists. By the end of 1998, when Training Group B had finished its training, the OPCW had on its staff a total of 205 well-trained inspectors. [32]

In 1994, Switzerland offered a Swiss Training Programme for OPCW Inspectors (Industrial Verification) called SWISSPRO. [33] The programme would train 60 candidate OPCW inspectors in the field of industry verification, and had been elaborated in close cooperation with experts from the Swiss chemical industry. In addition, several countries/companies offered to make chemical industry plants available for practical inspection training: Germany (Hoechst, Bayer, BASF), the Czech Republic (Synthesia Ltd., Semtín), China (Pesticide Complex, Quingdao), and Japan (Daicel Chemical Industries Ltd., Arai, Nippon Soda Ltd., Nihongi). [34]

The involvement of the chemical industry in the practical preparations for CWC verification was a shift from general engagements to exchange of positions and ideas, towards a more direct involvement of industry in the preparations for CWC implementation. This was qualitatively different from the relationship between industry and negotiators during the treaty negotiations. When the final ramp-up towards the setting up of the OPCW began, industry provided specialized courses at industry training centers and opened chemical plants for mock inspections. This signaled an industry desire to ensure that future inspections would be conducted in ways that its companies could support, and that would respect its concerns about the protection of confidential business information, and minimize the impact of inspection conduct on its operations, on plant safety and on its public image. Industry understood well that inspector training was crucial. Its support was both a measure of "self-protection" and a recognition that "failure or serious problems in the early days of implementation can lead to an erosion of confidence in the Treaty, misunderstandings amongst states, and a loss of commitment." [35]

3.4 The chemical industry and the OPCW

The engagement between the chemical industry and regulators did not stop after the entry into force of the CWC. Several factors were important in this regard:

- The interest of industry to be an actor in rather than subject of the framing of how industry verification provisions would be implemented in practice

[32] Ron Manley, "Recruitment and training of inspectors". In Kenyon and Feakes (2007), chapter 6, pp. 105-112.

[33] Preparatory Commission document PC-VII/B/WP.12 (27 June 1994).

[34] Preparatory Commission document PC-XV/B/10 (6 November 1996), para 2.4.

[35] Statements by Will Carpenter (Vice President of Monsanto) at the Canberra Conference. Final Record (1989), p. 150.

- Its desire to press for consistent and equal implementation of CWC provisions across different countries and regions
- The need for chemical companies to put in place mechanisms to ensure that they could comply with the national implementation requirements imposed on them
- The fact that a good number of issues pertaining to industry declarations and verification still remained to be agreed.

The Preparatory Commission in its final report to the First Conference of the States Parties listed a number of industry issues as unresolved, amongst them: [36]

- Guidelines for provisions regarding scheduled chemicals in low concentrations
- Model facility agreements for Schedule 2 and Schedule 3 plant sites
- The coverage of biochemical and biologically mediated processes in relation to the production of scheduled chemicals
- Whether or not the term "production by synthesis" used in Part IX (production of unscheduled discrete organic chemicals) includes biochemical and biologically mediated processes
- How aggregate national data for Schedule 2 and 3 chemicals should be compiled
- The coverage or not of castor bean processing plants
- Past production of Schedule 1 chemicals for purposes not prohibited at facilities having a capacity above 1 tonne.

These and other issues were initially transferred to a facilitation process under the Chairman of the Committee of the Whole, and later taken up by the Executive Council. Some of them (e.g., the model agreements for industry facilities) were resolved prior to the beginning of inspections at industrial facilities, others (such as low concentration guidelines) were resolved step by step over several years, yet others were given to the Scientific Advisory Board for technical advice.

Additional problems with applying the CWC provisions pertaining to industry verification surfaced as a consequence of the delayed submission of a chemical industry declaration by the USA, caused by delays in the adoption of its implementation legislation. This delay meant that implementation practice had evolved based on treaty interpretations that were not always shared by the US and its chemical industry. This resulted in a sudden increase of open inspection files. But these problems were not merely caused by differences in treaty interpretation - they also reflected structural changes in the industry. Certain definitions of the CWC (e.g., plant site versus plant versus unit) no longer fitted the reality of industry operations. These issues were taken up between the Technical Secretariat and industry representatives in informal discussions, and over time pragmatic solutions were found and subsequently endorsed by the First CWC Review Conference in 2003. [37]

Also, many other states had either failed to submit their initial declarations, or submitted incomplete declarations of their industrial activities and facilities. The Technical Secretariat developed guidance documents to assist States Parties in identifying their declarable industry facilities. In 2001, it set up a dedicated support project to assist States Parties with identifying declarable industry facilities, analyzing industry databases, directories of commerce and other public sources. All these activities were aimed at ensuring that the industries of different States Parties would be treated equally under the CWC, to meet the demand of industry associations for a “level playing field”.

[36] Preparatory Commission for the Organisation for the Prohibition of Chemical Weapons. Final Report. Document PC-XVI/37 (15 April 1997), pp. 49.

[37] Kenyon and Feakes (2007), p. 272.

All these engagements changed the relationship between the industry and the OPCW. The OPCW's Technical Secretariat was an implementing body with responsibilities and authority given to it by the CWC. This meant that certain issues could be taken up directly between industry and the Technical Secretariat. In some cases, this resulted in joint projects such as the development of a spreadsheet identifying scheduled chemicals, as a tool to support the preparation of industry declarations. Also, a new channel for the chemical industry to communicate concerns and provide advice was the Scientific Advisory Board (SAB) set up in September 1998. Amongst its 20 initial members (today 25) were several experts from chemical industry: Will Carpenter (USA) who was also the first Vice Chairman of the SAB, Claudio Costa Neto (Brazil), and Shintaro Furusaki (Japan). The presence of industry experts on the board continues until today, and has been used by successive Director-Generals to solicit advice from the SAB as well as industry experts appointed to its temporary working groups. Industry input was, amongst others, important for SAB advice on the transfer of small amounts of Saxitoxin for diagnostic and food safety analyses (leading to the first amendment of the CWC by including an exemption of such transfers from the 30-day prenotification rule for transfers of Schedule 1 chemicals), and a clarification that castor oil processing plants were not covered by the declaration and verification requirements of the CWC.

A milestone in the evolution of this relationship was the preparation of the First CWC Review Conference in 2003, for which the SAB submitted a report on advances in science and technology based on international symposia organized together with the International Union of Pure and Applied Chemistry (IUPAC) and supported by chemical industry associations.

Another milestone was the 2006 Industry and Protection Forum, organized by the OPCW in conjunction with the International Council of Chemical Associations (ICCA) and CEFIC. It provided a platform for industry to address verification and implementation issues that directly concerned its companies, including the conduct of sampling and analysis during industry inspections. [38] At the time, the OPCW had initiated a pilot phase of using this inspection technique in chemical industry inspections. The Forum was an opportunity for industry representatives to stress the need for the OPCW and National Authorities to assist chemical companies in understanding the CWC's requirements, and the desirability of educating chemical companies about sampling and analysis and related measure to protect confidential information. The Forum also initiated a discussion of what the OPCW could contribute to enhancing safety and security, an issue that has become more prominent for the OPCW since the completion of the destruction of all declared CW stockpiles.

Jack Gerard, President and CEO of the American Chemistry Council (ACC) and speaking on behalf of the International Council of Chemical Associations (ICCA), characterized the cooperation among governments, national industry associations, and the ICCA as crucial for compliance with the obligations of the Convention, and stressed that the ICCA was ready to provide the requisite technical assistance and industry insight.[39] In 2015, the ICCA-OPCW partnership was formalized by establishing an ICCA-OPCW Joint Steering Committee and a Chemical Industry Coordination Group (CICG) to coordinate joint activities in support of the CWC. In 2020, the International Chemical Trade Association (ICTA) joined the CICG.[40] The chemical industry regards its support for the CWC as a natural extension of its Responsible Care® Program. It sees itself as a partner and resource to governments and the OPCW. Industry experts participate in OPCW events, offer expertise in various subsidiary bodies, and have participated in the formulation of The Hague Ethical Guidelines.

[38] OPCW document S/674/2008 (1 February 2008).

[39] https://www.opcw.org/media-centre/news/2007/11/opcw-industry-and-protection-forum.

[40] OPCW Director-General: *Engaging the Chemical Industry Associations,* OPCW document C-28/DG.15 (6 November 2023).

Chemical industry associations have since made significant contributions to the OPCW's capacity building activities.[41] This includes

- Support for the OPCW Associate Programme by facilitating the identification of chemical plants/companies that agree to host the industry attachment element of the Associate Programme
- Support for training activities in the peaceful uses of chemistry (CWC awareness raising, educational and ethical issues including The Hague Guidelines, chemical safety and security management)
- The organisation of national and regional events to promote the peaceful uses of chemistry and the role of women in chemistry
- Support for the OPCW's Advisory Board on Education and Outreach as well as its Scientific Advisory Board (SAB)
- The implementation of a chemical safety and security management programme in partnership with the International Union of Pure and Applied Chemistry (IUPAC) and other activities in a number of countries and regions to promote chemical safety and security by providing tools to assess, mitigate, and respond to the risks of chemical accidents and prevent the misuse of dual-use chemicals
- Activities to promote integrated chemicals management, and
- The development of indicative guidelines for chemical safety and security in small and medium-sized enterprises and most recently similar guidelines for the transportation of hazardous chemicals.

In 2023, the draft Indicative Guidelines for Transportation of Hazardous Chemicals by Road were validated in an OPCW workshop which involved two keynote speakers from the chemical industry. In 2024, training material related to these draft guidelines were developed together with Sandia National Laboratories in the USA, again supported by experts from the chemical industry. The guidelines were formally launched by the OPCW in October 2024.

A recent example for industry engagement was the conduct of a global conference on the role of artificial intelligence (AI) in advancing the implementation of the CWC in 2024 in Morocco. The practical application of AI creates both challenges and opportunities for the implementation of the CWC, and has received considerable attention by the SAB.[42] The conference included a dedicated session on the impact and challenges of AI on the chemical industry, including its role with regard to chemical risk, safety and security management; its challenges and opportunities in chemical supply chain resilience; and its role in cybersecurity management of chemical plants.[43] These are issues that directly affect the operations of the chemical industry, and where the OPCW can offer a platform for discussions involving industry experts, scientists, security experts and policy makers.

ICCA and ICTA representatives also attend meetings of the Industry Cluster of the Executive Council that address specific implementation challenges as well as conduct a comprehensive review of the industry verification regime. They also supported the Annual Meetings of Representatives of the Chemical Industry and National Authorities of CWC States Parties. These and other activities allowed industry associations to communicate industry views to the OPCW and to share information about the practicalities of CWC implementation in the chemical industry.

[41] For details see OPCW Director-General (op cit 42) and OPCW Director-General: *Engaging the Chemical Industry Associations*. OPCW document C-29/DG.15 of 14 November 2024.

[42] See the Report of the SAB on its 38th Session, OPCW document SAB-38/1 of 31 May 2024.

[43] OPCW Technical Secretariat: *Global Conference: The role of Artificial Intelligence in advancing the implementation of the Chemical Weapons Convention*. OPCW document S/2299/2024 of 25 June 2024.

4 CWC implementation and corporate compliance management

Chemical companies need to put measures in place to be able to comply with national laws and regulations emanating from the CWC. Larger companies in particular tend to integrate their data monitoring and reporting requirements under the CWC with those of other regulations, such as dual use goods export controls, drug and drug precursor controls, regulations applicable to explosives and related precursors, and the application of trade sanctions. They also attempt to integrate CWC administrative and technical requirements into their wider management systems, such as the support for on-site inspections.

The reliable functioning of these corporate management systems requires awareness raising and information transfer to managers and employees, regular training, and coordination across the different business units involved. The goal is to ensure full regulatory conformity. Companies integrate as many functions as possible into the systems they employ to manage supply chains, production operations, trade relations (both internally within the company and with external clients), and other key processes. Whilst larger companies face challenges given the complexities of their operations (for example working in different jurisdictions), smaller companies often lack capacity to manage the different regulatory requirements that pertain to their operation.

A key framework developed by the global chemical industry is its Responsible Care® Programme. It commits companies, national chemical industry associations and their partners to legislative and regulatory compliance. In addition, it promotes improvements in the domains of environmental and human health, safety and security, efficient resource utilization and waste minimization, open reporting, engagements with people to understand and address their concerns, cooperation with governments and organizations, and the fostering of responsible management of chemicals by all those who manage and use them along the product chain. Participation in the initiative is mandatory for all companies that are members of the American Chemistry Council, the European Chemical Industry Association CEFIC, or other regional and national associations they may belong to.

The management framework developed under this initiative includes a set of eight Fundamental Features of Responsible Care (guidelines for how National Associations can discharge their role), a Global Charter to be signed by company CEOs, seven Codes covering different aspects of the initiative (community awareness and emergency response, distribution, product stewardship, security, health and safety, and environmental protection), a self-assessment tool, and guidelines on such issues as reporting, metrics to assess performance and third party certification. [44]

The Responsible Care ® Security Code focuses on enhancing security throughout the industry's value chain, encompassing company activities associated with the design, procurement, manufacturing, marketing, distribution, transportation, customer support, use, recycling and disposal of chemical products. Whilst the code focusses explicitly on threats associated with terrorist threats, the CEFIC version makes clear the broader context and positions site security in the context of threats affecting the wider supply chain including transport security as well as export and trade controls. The Security Code thereby links to specific norms set out in the CWC that prohibit the development, production, acquisition, retention, transfer and use toxic chemicals and their precursors for chemical weapons purposes.

The Security Code also links to industry standard RC 14001:2015, and provides guidance on management practices, suggests activities and examples of measures to be taken, and provides guidance on self-assessment. It broadens the scope of the ISO 14001 Standard to also include health and safety, security, transportation, outreach, emergency response and other Responsible Care ® requirements. The system is built on a clear leadership commitment, requires prioritization, periodic analyses of threats and vulnerabilities, provides guidance on risk mitigation measures, calls for continuous improvement, and compels management to ensure that security issues are

[44] https://cefic.org/app/uploads/2022/06/Responsible-Care-Management-Framework-Brochure.pdf.

being evaluated and managed in response to changes involving people, property, products, processes, information and information systems. [45]

A particularly important aspect of the Responsible Care ® Security Code is the conduct of audits and independent verification. Companies commit to periodically assess their security programs and processes, identify any weaknesses and take corrective action. Such assessments may also be applied to partner companies such as suppliers, logistics service providers or customers. In addition, companies can invite credible third parties such as fire fighters, specialist security assessors / auditors, law enforcement officials, insurance auditors and/or government officials to confirm that they have implemented the security measures they have committed to, and to consult about possible enhancements.

Another way in which chemical companies implement internal compliance measures is through workplace codes of conduct that apply to their employees. These can range from ethical principles to practical guidelines on how things are to be done within the company. When the OPCW developed The Hague Ethical Code, it compiled and reviewed 142 existing codes of conduct / ethics in the field of chemistry.[46] Many of these existing codes were adopted by professional bodies, industry associations, or individual chemical companies. They often deal with broader association or company values and principles rather than specific norms emanating from the CWC. They often do include, however, principles and rules regarding chemicals trade including export controls. Common features of such company codes include the implementation of dedicated programmes to ensure compliance by company employees at all levels, an extension of these requirements and obligations to entities associated with the work of the company along the entire supply chain, company-internal mechanisms for monitoring compliance, investigating suspected cases of non-compliance, and responding to violations with disciplinary and other measures, and company-internal programmes for awareness raising and staff training.

In conclusion, corporate compliance management systems adopted by the chemical industry are essential for the proper functioning of the rules and procedures of the CWC. They aim at internalizing CWC-compliant behavior within companies and along their supply chains. Integration of CWC compliance within the overall company management system and into industry standards with third-party certification ensures a systematic and coherent approach to the implementation of these rules and requirements, and regular staff training combined with systems for reporting and response to cases of non-compliance help developing a corporate compliance culture within the business.

These voluntary industry measures mirror the national implementation measures adopted and enforced by the States Parties, and at times go beyond them. This reflects an interest of industry not only to comply with the rules but also to adhere to a company-wide corporate culture and project a positive image of responsible conduct to clients as well as business partners.

The combination of national laws and regulations, their enforcement, and their internalization through corporate compliance measures create a layered system of CWC compliance that has a strong confidence-building potential. These different elements (national regulations, enforcement, and corporate compliance) underpin a holistic approach to compliance.

[45] Quality Systems Registrars. RC 14001 Registration – Responsible Care ® Management System, available at https://qsr.com/services/iso-standards/rc-14001-certification/.

[46] Compilation of Codes of Ethics and Conduct (September 2015), available at https://www.opcw.org/sites/default/files/documents/SAB/en/2015_Compilation_of_Chemistry_Codes.pdf.

5 Industry and the strengthening of the BWC

These experiences from industry-government engagement in the chemical field are important also for addressing the role of the biotech and pharmaceutical industry in strengthening the BWC. However, in doing so one needs to be aware of the differences between these two industry branches.

Firstly, despite the overlap between the chemical and the biotech industry in certain areas, such as the manufacturing of pharmaceutical ingredients, there are also profound differences between them. The biotechnology industry is much more divers, including some very old and mature activities such as traditional food and beverages manufacturing as well as dynamic, highly innovative operations emanating from still-evolving life-science research in such domains as synthetic biology, or technological advances such as additive (3D) manufacturing. This diversity is also apparent from the organisational structure of the industry – whilst the chemical industry tends to be highly concentrated with a fairly small number of trade and industry organisations that can easily coordinate industry views and communicate with governments and international organisations, the biotech industry has no single association structure or industry voice.

Secondly, many actors in the biotechnology industries have yet to develop a deeper awareness of the dual use potential inherent in their operations and products, and the relevance of their activities for biological arms control and security. This is even more prominent in the life science research and teaching communities, which often don't see a link between their activities and potential misuse of their products and technologies for malicious purposes. Despite discussions about responsible conduct of life science research, to a degree driven by the rapid advances in synthetic biology and more recently the application of artificial intelligence in the life sciences, only occasionally are these discussions linked to the prohibition of biological weapons.

The deficit in industry-government engagement in the field of arms control has been apparent during the negotiations of an Additional Protocol to the BWC during the 1990s. The final report of the Ad Hoc Group of Governmental Experts (VEREX) of 1993 contained a number of indications that informal consultations with industry had been conducted to inform the negotiators about concerns of industry. It also contained the results of a sondage on identified areas of interest needing further elaboration, and indicated that industry may be unwilling or unable to provide certain information, or had expressed concerns about confidentiality, or that there may be a need in certain countries to enact legislation to ensure access to private industry facilities.

But whilst some informal discussions between negotiators and industry experts had taken place, the AHG documentation provides few clues about how industry was involved in the discussions, and how its concerns and proposals were communicated to negotiators. One can glimpse at these interactions by looking at parallel discussions in the Pugwash Study Group on the Chemical and Biological Weapons Conventions, which recorded in 1999: "Within the EU industry accepts many of the proposed declaration triggers and can also accept clarification visits and investigations. However, there is opposition to the concept of random transparency visits, particularly in the USA, and is predicated on fears about the protection of confidential business information. It was suggested that the differences between CWC inspections and the proposed BWC visits – no mass accounting, no sampling, short duration etc. – need to be further explained to industry. … With respect to confidential business information industry's concerns are highest at the point of research and development whereas for arms control purposes most attention would be focused at the stage of production where industry's confidentiality concerns are often lower. Industry would have more concerns with the protection of confidential business information if the organisation had a non-career structure with a high turnover of inspectors."[47]

[47] Pugwash Conferences on Science and World Affairs, Pugwash Study Group on the Implementation of the Chemical and Biological Weapons Conventions. Geneva meeting on the BWC Protocol – The BWC Protocol – entering the end game? Report of Pugwash meeting No. 250 (25-26 September 1999). Available at https://pugwash.org/1999/09/27/geneva-meeting-on-the-bwc-protocol/.

It has been observed, however, that the blame for the rejection of the verification protocol should not be laid primarily at industry. Wariness of international inspections within the US industry increased after a poorly handled 1994 visit by Russian experts to a Pfizer facility. Also, both the US Defence Department and the Central Intelligence Agency objected to the proposed regime because it might have exposed parts of their own secret biodefense research.[48]

After the collapse of the BWC Protocol negotiations, the approach of the BWC States Parties changed from attempting to negotiate a legally binding agreement to govern BWC implementation and verification to a less-formal process of intersessional expert and diplomatic meetings which focussed on themes pre-agreed among States Parties. Thematically, these discussions included many issues of direct relevance to industry. Although industry is not a participant in these discussions, there are indirect ways it could use to make its views know. In addition to talking to national delegations and government authorities of their own countries, industry representatives may be invited by the chairperson of annual sessions and Review Conferences of the BWC to present to the meetings as guest speakers, or they could organise or participate in side events to convey their views to delegations.

A cursory review of documents (lists of participating organisations, agendas, lists of side events) of previous BWC annual and review conferences shows that although there were a small number of presentations and papers submitted by industry representatives, these informal channels are largely used by non-governmental and academic organisations and institutions, or by States Parties that had engaged in specific projects - sometimes a combination of the two. Contributions by industry – whether individual experts, companies or trade associations – have remained scarce. At the 2024 Annual Meeting of the BWC States Parties, only one side event was organised with industry involvement ("DNA synthesis screening and the BWC" organised by IBBIS, an independent organization that works closely with stakeholders in industry, governments, academia and philanthropy). Whilst some of the side events of the 2022 and 2023 annual BWC States Parties meeting concerned issues relevant to BWC implementation in industry, none of the presenting organisations came from a biotech or pharmaceutical company. At the Ninth BWC Review Conference in 2022, no biotech companies or industry associations were listed as observer and none were involved in any of the side events organised alongside conference.

This is in stark contrast to the CWC where industry associations have engaged actively with the negotiations of the Chemical Weapons Convention, its implementation by the OPCW, and the work of the OPCW's policy-making organs. The chemical industry has taken an active interest over the years in how the norm against chemical weapons was framed, what the implementation rules would be and how they would be applied in its companies. It asserts its influence to shape these implementation norms in ways that protect its interests as well as image. At the same time, it supports the effective implementation of the norm, realising that this is not merely in the interest of governments but also in its own best interest. It is noticeable that the biotech and pharmaceutical industries have yet to engage at a comparable level, also given that negotiations have finally re-started towards a possible compliance and verification mechanism under the BWC.

That is not to say that the importance of engaging with the biotech and pharmaceutical industries was not recognised by governments. An example was the Wiesbaden Process, first hosted by Germany in 2012 and subsequently also by other countries. It facilitates a dialogue between the 1540 Committee and industry, raises awareness about requirements of UN Security Council resolution 1540 (2004), and shares effective practices for compliance strategies within companies. This industry outreach was designed to promote the objectives of resolution 1540 (2004), which overlap with and complement those of the BWC. It was geared towards awareness raising in industry, facilitating dialogue between industry and governments, and identifying effective

[48] Karen Winzoski: *Unwarranted Influence? The Impact of the Biotech-Pharmaceutical Industry on U.S. Policy on the BWC Verification Protocol.* Non-Proliferation Review vol. 14, No.3 (2007), pp. 475-498.

practices of 1540-relevant compliance strategies within companies. [49] Lessons from this engagement between governments, the 1540 Committee and industry have been presented at the Eighth BWC Review Conference in 2016.[50] These engagements highlighted the need to refine legislation to take account of business needs of industry (such as keeping legislation and regulations clear and simple, harmonize rules, use risk as the basis for devising rules, use certification processes), to actively involve industry (such as through conferences and expert hearings, partnerships and feedback from industry, information about upcoming changes in the rules), and to create rewards for industry to implement voluntary compliance measures including codes of conduct and codes of compliance.

Furthermore, alongside the application of government oversight mechanisms, the biotech industry has been developing its own corporate compliance measures to ensure regulatory compliance with existing laws and regulations pertaining amongst others to patient and environmental safety, quality assurance, and compliance with export control regimes. In the research domain, the measures may include codes of conduct, ethics committees, and internal regulations adopted by research institutions and universities. In industry, typical measures include codes of conduct, administrative procedures to check orders received ("know your customer" checks, checks on indicators of misuse potential such as characteristic sequences of nucleic acids linking to certain pathogens, etc.), management systems, industry standards and related ISO certification systems.

At the Ninth BWC Review Conference, States Parties established a Working Group to strengthen the effectiveness and to improve the implementation of the Convention in all its aspects. [51] The group has been tasked to identify, examine and develop specific and effective measures, including possible legally-binding measures, and to make recommendations to strengthen and institutionalize the Convention in all its aspects. With this broad mandate, the context for industry engagement in the BWC processes may be changing. It is apparent from the group's mandate that it is expected to prepare recommendations that in one way or another might affect the regulatory framework within which the biotech industry is operating.

In 2022, when the Working Group was about to begin its work, UNICRI brought together a cross-section of BWC stakeholders to collect views on how the BWC and more broadly biosecurity could be strengthened, and what the contribution of their respective constituencies could be. Some of the salient points that emerged from this study were the need to solicit support from stakeholders around the globe and different constituencies including the biotech industry, to raise awareness of potential dual-use risks and develop policy guidelines, and to engage more effectively with new synthetic biology start-ups, cloud laboratories and biofoundries. These types of businesses appear to be less engaged with the security community than the synthetic biology community. Informal peer review initiatives were seen as useful, so were initiatives such as the work of the International Federation of Biosafety Associations on professional certification, South-to-South peer mentoring and community-led initiatives. The promotion of codes and guidelines such as the Tianjin Biosecurity Guidelines, of training initiatives in dual use risk mitigation, and fostering of international cooperation and collaborations both for technological progress and to build greater trust between scientists across national and political borders were important. The wider economic and environmental drivers of biotechnological change and the implications these drivers may have for the BWC should be monitored, and so should be advances in science and technology in order to identify key risks. Finally, various regional biosafety and security initiatives should be brought closer

[49] Information Note on industry engagement in strategic trade controls, Resolution 1540(2004). Available at https://www.un.org/en/sc/1540/documents/Info%20Note%20Wiesbaden%201540%20Conf%20Germany%202019-49.pdf.

[50] Beutel, Holger: Involving industry in the fight against the proliferation of WMD – the Wiesbaden Process. Presentation at the German side event at the 8th BWC Review Conference on 7 November 2016, available at https://documents.unoda.org/wp-content/uploads/2021/04/Side-Event-Wiesbaden-Process-November-7th-2016.pdf .

[51] BWC document BWC/CONF.IX/9, p.9.

together to exchange lessons learned from outreach and engagement, share materials and discuss best practices. [52]

By the end of 2024, the BWC Working Group has had five meetings. Discussions of possible compliance and verification measures have finally begun, albeit so far mostly at the conceptional level. The contribution of the industry has been fairly limited so far. This may become a significant problem if the negotiations turn towards more specific objectives, methods and requirements. The experience of the CWC has shown how important it is that such negotiations involve industry to make the system workable in practice, affordable, and dependable. The success of the Working Group will critically depend on how it can involve industry in its deliberations.

Also, building on existing corporate compliancy systems could help in developing compliance assurance systems, in particular in an industry that is highly innovative, fast evolving, and sensitive to the possibility of confidentiality breaches. From a compliance assurance angle, this may change the way we think about verification: its focus may not primarily be the detection of diversions of certain materials (or items of equipment, knowledge) to illicit purposes, but an assessment of whether the operations of a company are being managed and governed in ways that ensure conformity with regulatory requirements and technical standards, including those emanating from the BWC.

6 Conclusions

This study has looked at the role that industry has played in the evolution and implementation of the regimes governing the prohibition of chemical and biological weapons. The industries concerned by these international regimes are amongst the most highly-regulated industries, given that their processes and products can directly affect human health, environmental safety, and societal security. International laws and rules in the domain of arms control and disarmament and the national laws and regulations that domesticate these norms are only one facet of the complex regulatory framework within which these industries operate. A multitude of regulations and rules apply to their activities, products and services, ranging from public health and environmental regulations to laws governing labor relations and employment, ensuring product compliance, enforcing strategic trade controls including export controls and embargoes, and also disarmament / arms control. Companies operating in multiple countries, in addition, will have to manage any existing differences in the way in which these regulations and rules are being applied.

Despite the differences in origin, objectives and specifics of these different regulations, and the different governmental actors involved in the monitoring and enforcement of their implementation, they together create an environment within which the freedom of companies to conduct their activities is severely constrained. As governments are looking for how to further evolve the CWC industry verification system, and to devise verification measures for the BWC, they would be well advised to take a comprehensive look at the range of regulations, self-regulations and third-party compliance assurance measures already in place in the companies concerned. This could lead to verification concept that exploit synergisms between these different mechanisms, and at the same time keep the burden of verification on industry manageable.

Furthermore, industry is not simply the object of regulations; it also influences the way in which new regulations and rules are being shaped and how they will be implemented. It does so to protect its ability to innovate, manufacture and trade, to ensure competitiveness across global markets, and to safeguard its client base including by projecting a positive public image. The involvement of the chemical industry in the negotiation and subsequent implementation of the Chemical Weapons Convention has shown how industry can influence the very shape of an international norm, and modulate the way in which an international rule set will be applied to its operations. The current

[52] James Revill, Vivienne Zhang and María Garzón Maceda (eds.), "Stakeholder perspectives on the Biological Weapons Convention", UNIDIR, Geneva (2022), https://doi.org/10.37559/WMD/22/BWC/03.

lack of strong engagement of the biotech and pharmaceutical industries in the work towards a possible compliance assurance and verification mechanism for the Biological Weapons Convention carries the risk of ignoring, and potentially antagonizing, a key stakeholder the cooperation of whom governments will need once that compliance and verification mechanism becomes operational.

At the same time, once rules are in force, companies are compelled to adopt measures to ensure that they can comply with them. This requires companies to integrate measures into their management systems to fulfill their reporting duties, conduct checks on rule compliance, facilitate inspections by external bodies, implement staff education and training, perform checks on customers and orders, and take measures to ensure compliance by partners along the supply chains. Such internal compliance measures are essential for the proper functioning of the regime: they affect the day-to-day practice of how the norms are being applied in practice. This modulates the expectations associated with rule compliance – affecting what is seen as essential for compliance, and what expectations are associated with the development of what might be called a "compliance culture".

Understanding the way in which industry and governments interact in the development and application of international norms (here: chemical and biological weapons arms control) is particularly important at times when these norms are in flux. This is the case for both the CWC and the BWC: in the CWC, the completion of the destruction of all declared chemical weapons stockpiles coincides with the emergence of new challenges to the regime (non-compliance cases, new actors that are looking at chemical warfare capabilities, advances in science and technology that have the potential of enlarging the scientific and technological misuse potential). One of the responses to these challenges is to further refine and adapt the CWC verification system. In the BWC, discussions of a possible compliance mechanism may lead into the development of verification measures that would affect the biotech and pharmaceutical industry. Past experience has shown that such normative evolution will require a constructive engagement between governments and industry to ensure that the regulations and rules being developed will be fit for purpose, and appropriate for the practical implementation environment in industry.

The CBW network for the comprehensive strengthening of norms against chemical and biological weapons (CBWNet)

The research project CBWNet is carried out jointly by the Berlin office of the Institute for Peace Research and Security Policy at the University of Hamburg (IFSH), the Chair for Public Law and International Law at the University of Gießen, the Peace Research Institute Frankfurt (PRIF) and the Carl Friedrich Weizsäcker-Centre for Science and Peace Research (ZNF) at the University of Hamburg. The joint project aims to identify options to comprehensively strengthen the norms against chemical and biological weapons (CBW).

These norms have increasingly been challenged in recent years, *inter alia* by the repeated use of chemical weapons in Syria. The project scrutinizes the forms and consequences of norm contestations within the CBW prohibition regimes from an interdisciplinary perspective. This includes a comprehensive analysis of the normative order of the regimes as well as an investigation of the possible consequences which technological developments, international security dynamics or terrorist threats might yield for the CBW prohibition regimes. Wherever research results point to challenges for or a weakening of CBW norms, the project partners will develop options and proposals to uphold or strengthen these norms and to enhance their resilience.

The joint research project is being funded by the Federal Ministry of Education and Research for four years (April 2022 until March 2026).

About this working paper:

This essay sums up the findings and preliminary conclusions of four case studies prepared by the author for the University of Gießen, as part of the research undertaken in the fields of multinormativity and multi-level perspectives of the CBWNet research programme.

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