Article IV of the Convention on Prohibition of Biological and Toxin Weapons (BWC) requires all state parties to take necessary measures for national implementation of the provisions of the convention. With no verification mechanisms or international body to back the BWC, the efficacy of these measures is an important factor for the success of the convention. The absence of a universally accepted model law for this purpose and the flexibility offered by the Convention itself for national implementation makes the study of the mechanisms adopted by various state parties interesting and useful.

Both India and Pakistan are state parties to BWC and are active in the global efforts to strengthen the regime against biological weapons. These countries can offer an interesting insight to mechanisms by which state parties can implement the convention through their national legislation because of their commitment to the BWC and their position as leading developing countries with growing interests in related technologies.

Both countries do not have specific acts against biological weapons but have sought to comply with the provisions of BWC through acts designed for various types of weapons (nuclear or chemical), generic export control acts (meant for regulation of a wide variety of imports and exports, weapons or other wise) or laws and regulations related to environment and health safety. These have been strengthened by recent legislature to counter terrorism and implement UNSCR 1540. Pakistan has announced its intentions to have a stand-alone legislation, but it is yet to be made public.

In this paper, an attempt will be made to analyze the legislative and administrative measures taken by Pakistan and India for the national implementation of BWC in light of the yardsticks discussed at the Review Conferences and State Parties meetings on the subject and available model laws etc.

Significance of national implementation of BWC

The main provisions of the BWC relating to national implementation are

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1. Ahmed is a career foreign service officer of Pakistan. The views expressed in this paper are his own and do not necessarily reflect those of the government of Pakistan.

2. I would like to acknowledge the kind support given by Ambassador Masood Khan, Chair of 6th BWC Review Conference, Dr Julian Robinson, Dr John Walker (FCO), Angela Woodward (VERTIC), Dr Nicholas Sims (London School of Economics), Richard Guthrie, Richard Lennane (BWC Implementation Support Unit), Venkash Verma (Indian Permanent Mission in Geneva), Aftab Kokher (Pakistan Permanent Mission in Geneva), Dr Jean Pascal Zanders and Dr Ralf Trapp (BioWeapons Prevention Project, Geneva) in writing this paper. However, the responsibility for all the errors, omissions and opinions remains solely mine.
contained in Article IV, which stipulates that “each State Party shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I, within the territory of such State, under its jurisdiction or under its control anywhere”. National implementation is understood to comprise of three components; legislation to transpose the treaty obligations into national law, methods of monitoring relevant work with biological agents and toxins within the national territory and means of enforcing the legislation once breaches are identified.³

The National Implementation of BWC assumes significance on account of a number of factors. Firstly, effective national legislation helps the states to fulfill their international obligations and meet the objectives of the Convention. National implementation measures under Article IV are not an ‘add-on’ but a basic requirement of implementation of BWC.⁴ Growing concerns over the dangers of bio-terrorism since 2001 have resulted in a regenerated interest in ensuring that the BWC is adequately implemented in national legislation.⁵ In the absence of a verification regime, organizational backup and any agreed upon model law or checklist, the study and monitoring of these national implementation measures becomes even more important.

Secondly, a clear legislation with enforceable penal measures will not allow violators of international law to go unpunished and will enable investigation and prosecution of these violations. Otherwise, a state is vulnerable to prohibited activity being carried out on its territory without being able to effectively prosecute and punish transgressions.⁶ For states with a common law tradition, like Pakistan and India, treaty obligations must be transformed into national law enforceable within their legal jurisdiction when the treaty enters into force, otherwise they may be at odds with their own constitutional requirements and in non-compliance with treaty obligations⁷. Such legislation also ties the Convention into national legal systems and expands the constituency with an institutional interest in the success of the Convention. It also builds the treaty regime into normative structures at the national level and helps, even if only marginally,
to ensure its survival by constituting one more obstacle which would have to be overcome if the Convention were to come under attack\(^8\).

Thirdly, these measures are a demonstration of the political commitment of states to BWC. For Pakistan and India, nuclear states outside the NPT regime, it is important to convey the message that they are not against non-proliferation of weapons of mass destruction per se. In fact, they see this as a chance to demonstrate their support to the one multilateral convention that meets their principled concerns in this regards and adopts a non-discriminatory and complete disarmament approach.\(^9\)

Finally, adoption of national measures puts developing states like India and Pakistan on a moral high ground for demanding the privileges promised under Article X of the BWC which promotes international cooperation for research and development in related areas. From the developing world’s perspective, a major challenge is formulating measures to prevent access to pathogens and toxins for hostile purposes without hampering their chances of reaping the benefits of advances in life sciences. The North is reluctant to acknowledge linkages between the obligations under Article IV and the privileges under Article X but it seems that in reality there is an implicit, if not formal, circular relationship. National implementation of the Convention would be furthered if the developing countries as well as the researchers in private and public sectors of these countries sectors are motivated by realization of the objectives elucidated in Article X. On the other hand, measures for transfer control and bio-safety etc can increase the comfort level of prospective foreign investors and collaborators in these sectors in the developing countries.

As of 2007, the BWC Implementation Support Unit’s National Implementation Database contained 1938 individual measures from 130 different States. At least 119 BWC States Parties (76% of the membership) had some implementing legislation.\(^10\) In 2009, it listed a total of 2101 measures, from 121 States Parties (representing 74.2 per cent of the membership of the BWC), four signatories, five states not party, and one regional organization.\(^11\) Thanks to UNSCR 1540, which obligates transfer controls interalia on biological weapons, the situation is better than it was in 2003 when a survey revealed that a large proportion of state parties had no BWC implementing legislation in place; only 47% had some legislation in force while

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9. Though the Chemical Weapons Convention is also a theoretically a complete disarmament treaty, it is practically not so for the time being at least, as it has allowed possessor states time to destroy their chemical arsenals.
a further 15% had legislation which might serve to implement the treaty\textsuperscript{12}. It would be relevant for our study to note that that survey was able to obtain information about Indian legislation only through open sources and was not able to identify any relevant national legislation for Pakistan.

However, a detailed analysis reveals that much needs to be done in this respect. Studies have shown that just 15% of the surveyed countries have definitions for biological agent, toxin, or biological weapon and only one third criminalize the development, acquisition, stockpiling/storage, possession/retention, transfer, transport and use of biological weapons, and engaging in activities involving agents or toxins without authorization. Only 25 percent of these states criminalize financing of prohibited activities.\textsuperscript{13}

Efforts to strengthen national implementation - a review

After the debacle of the BWC Review Conference in 2002, mainly on account of US opposition to a verification regime, the focus of discussions shifted towards issues which enjoyed a broader consensus. Of the only five topics agreed for the 2003-05 inter-sessional meetings under the Toth proposal, ‘penal legislation’ was discussed at the 2003 Meetings of State Parties. The meeting urged state parties to enact or update national legislation making the prohibitions in the BWC binding on their citizens, imposing penal sanctions for violations, and tightening security over dangerous pathogens and toxins. But the meeting did not offer any concrete recommendations or guidelines for how to proceed, in this matter.\textsuperscript{14}

In the meantime, an important change in the international non-proliferation scenario took place with the passage of UN Security Council Resolution 1540 in April 2004.\textsuperscript{15} The resolution made measures for export control of WMDs obligatory. Being a Chapter VII resolution, it is mandatory on all UN member states, whether they are party to the BWC or not.\textsuperscript{16} It also obligates national reports on these measures which are to be scrutinized by a special Committee of experts. Overlapping with Article IV of the BWC, UNSCR 1540 is fulfilling a “functional compliance role” in respect of BWC, by requiring states to have necessary measures and enhance transparency concerning BWC related legislation. It adds another supportive layer to the normative framework for the non-proliferation of biological weapons. It does not, however, address the absence of an international organization capable of providing


\textsuperscript{15} The Sixth Review Final document obliquely refers to the overlapping of state obligations under UN Security Council Resolution 1540 and BWC, noting that the information provided under this resolution may also provide a useful resource for states in fulfilling their obligations under Article IV.

technical assistance and training programs for BW similar to nuclear and chemical weapons.\textsuperscript{17} It is also important to be aware that the resolution focuses on non-state actors whereas the BWC provisions are comprehensive in the sense that they apply on state as well as non-state actors.

At the Sixth BWC Review Conference in 2006, National Implementation under Article IV was discussed as a part of the para-by-para review of the Convention. One of the major achievements of the Conference was the establishment of the BWC Implementation Support Unit (ISU) in the UN Department for Disarmament Affairs, despite US opposition to “creeping institutionalization”. However the conference could not agree on adopting an action plan on national implementation on the pattern of those for the Chemical Weapons Convention (CWC).\textsuperscript{18} The proposed Action plan called for national implementation of the BWC to include measures to strengthen national capacities, including human and technological resource development. It would have committed States to “undertake, inter alia, a regular review of the national implementation processes, to take actions to raise awareness of the BWC among all the relevant stakeholders, training of law enforcement officials including custom and police officers and to promote cooperation particularly with developing countries, for improving national capabilities in detecting outbreaks of disease and development of national surveillance systems. It also called for cooperation in capacity building, as well as technology transfer, including in custom control, primary health care systems and detection of disease outbreaks. The action plan could not be agreed upon, primarily because of US resistance to the Article X related provisions.

In the absence of the action plan, the role of ISU is limited to the compilation and dissemination of CBMs and other information provided by States Parties on measures taken to implement the Convention and acting as a clearing house for requests for States Parties offers of assistance in this connection. The ISU itself has neither the capacity nor mandate to provide such assistance. An attempt by the EU to provide for additional tasks for the ISU\textsuperscript{19} was rebuffed by the US. However, this reaction appears to be partially a result of the result of the EU not taking the US in confidence beforehand and the lack of clarity in the document itself. While the expansion of the unit is unlikely before the next review conference in 2011, the US might be amenable to administrative and legislative support given for it through an EU action plan. Much will depend also on how the role

\textsuperscript{17} Angela Woodward, “The Biological Weapons Convention and UNSCR 1540”, in Olivia Bosch and Peter van Ham (Eds) Global non-proliferation and counter-terrorism: the impact of UNSCR 1540; (London: Chatham House, 2007) p 96-112


of the unit is interpreted by member states. For example, some states parties could carry out activities proposed through the ISU under the title of “administrative support arrangements”. The non approval of the action may not in the final analysis turn out to be such a debacle in itself. Action plan or no action plan, progress will depend upon the political support and focus of member states of BWC. Activities for developing national implementation may continue irrespective of a plan.

An important agreement at the Review Conference was to designate national focal points for coordinating national implementation of the convention. This is significant as this would facilitate the enactment of implementation measures and make it easier for interested parties to obtain information regarding a particular state. In case of BWC implementation, a major difficulty is to get on board the wide array of players in life sciences – government, academia, private sector and industry. The focal point is an important and useful tool in this respect, though it is short of the national authority repaired to be established under CWC.

Another notable development during the Review Conference was the movement “from adjacency to synergy”, with a call for governments to promote cooperation and coordination among domestic agencies, clearly define their roles and responsibilities and raise awareness of the Convention and improve dialogue and communication among all relevant stakeholders, including policy makers, the scientific community, industry, academia, media and the general public. This again is important because of the diversity of relevant disciplines and the amorphous spread of stakeholders.

The Conference was criticized for merely agreeing to keep talking for another five years without making decisions, creating a three-person mini-secretariat with little real authority and missing the opportunity to strengthen the CBMs and discuss new approaches to monitoring compliance. The intersessional meetings held twice a year with a tightly constrained agenda were also seen as lagging behind the fast pace of scientific and technological developments.

Still, in the given circumstances, most analysts considered the Sixth Review Conference a success. Realistically speaking, the advances were remarkable coming after the collapse of the BWC.

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protocol negotiations and the difficulties of the Fifth review Conference in 2001. The Conference avoided a breakdown of negotiations and gave the convention a new lease of life. Unlike 2002, there remained no doubts over the sustainability of the BWC regime. There were breakthrough developments like involvement of NGOs and the private sector, which enriched the debate and laid the foundations for a future consensus. It would also facilitate the creation for a constituency for BWC, internationally as well as within states. One of the major reasons for the success of CWC said to be the influence of a well-structured industry conscious of the need for such safeguards.

At the subsequent States Parties’ meeting in 2007, the Chair Ambassador Masood Khan of Pakistan presented a Synthesis paper outlining possible areas of consensus on national implementation. Although the paper is not an ‘agreed upon’ document, it is important to note as it gives one of the most comprehensive guidelines so far of the implementation measures states are expected to take under BWC.²⁶ It enumerates the steps to be considered by state parties while implementing the convention and examines in detail the significance of translating the obligations of the Convention into effective national measures, managing and coordinating their operation, enforcing them and their regular review.

The 2007 State Parties Meeting again stressed on “the fundamental importance of effective national measures …. and the need to nationally manage, coordinate, enforce and regularly review the operation of these measures” without agreeing on any joint standards or collective measures. The closest it came to such standards was enumerating that measures would include “transfer controls, bio-safety and bio-security regulations, and penal legislation”.²⁷ Still, the synthesis remains a landmark achievement as it forms the basis to direct and facilitate future discussions on the subject.

Developing standards for national implementation

The lack of specificity in Article IV of BWC has been criticized as one of the reasons for the poor national implementation of the convention. As there is no uniform standard of national implementation, relying exclusively on nationally developed guidelines would result in “an uneven patchwork of regulations, creating pockets of lax implementation or enforcement and hinder any effective campaign to restrict terrorist access to dangerous pathogens”.²⁸ The convention leaves it up to the individual


states to determine what measures are “necessary” and how to implement them. This avoidance of prescribing a “one size fits all” approach is primarily intended to accommodate differences in legal systems and constitutional requirements, pre-existing legislation and the extent of development of the relevant technology in a particular state. It seems to be the result of a “lowest common denominator approach” of multilateral negotiations where diverse views are watered down to a bland and basic agreement, sometimes devoid of content and ineffective in nature. This lack of specificity makes Article IV not just an obligation of conduct but also an obligation of result.  

On the other hand, a close reading of text of the Convention and subsequent Review Conferences and other meetings gives quite a clear idea of the obligations of the state parties to the BWC and the national implementation measures required to meet these obligations.

One of the first important decisions states need to make is whether to adopt a stand-alone legislation or to use generic laws on criminal liabilities and export controls to comply with BWC. A stand-alone legislation may not be necessary from a legal and administrative perspective but is desirable as a political gesture. It will also help create awareness and assist in coordination among different stakeholders: public and private. A stand-alone legislation would also mean an opportunity to use the exact terminology of BWC and to solidify safeguards against any possible loopholes in the existing legislation.

In the absence of a multilateral arrangement for legislative assistance, states in the process of national implementation and drafters of BWC related legislation have to rely on whatever bilateral assistance is offered by other member states. Accepting bilateral assistance can, however, sometimes be politically embarrassing while multilateral help would be relatively palatable to national pride. But unfortunately, as of now, the Convention itself has no multilateral forum for implementation assistance. As discussed earlier, the Implementation Support Unit (ISU) merely serves as a clearinghouse for offers and requests of bilateral assistance with national implementation measures. However its role seems to be slowly and imperceptibly evolving. During 2009, the Unit provided routine administrative assistance and advice on participating in the CBMs to around 10 States Parties. It also prepared a set of completed sample CBM submissions for first time CBM submitting states. Obviously it is broadly interpreting its mandate.

The work of some other international organizations also offers assistance in this regard and provides standards for national implementation of the BWC.

The UN 1540 Committee maintains a directory of states and international and regional organizations that offer to assist states in developing legal and administrative infrastructure for implementation of UNSCR 1540, the

provisions of which overlap with BWC. It also provides a very useful database of measures taken by states in this regard facilitating comparative analysis.\footnote{30}

The EU under a Joint Action plan also offers assistance to address the drafting of national legislation implementing the BWC\footnote{31} including on penal provisions, transfer controls, law enforcement measures, customs regulations and regulation of permitted uses of biology and biotechnology (such as licensing procedures, transport regulations, bio-safety and bio-security measures).

The London-based Verification Research, Training and Information Centre (VERTIC)\footnote{32}, the Advisory Service on International Humanitarian Law of the International Committee of the Red Cross (ICRC)\footnote{33} and Interpol's Bio-criminalization project also offer assistance for development of such legislation.\footnote{34}

Other WMD treaties and conventions can also be a source of ideas to deal with cross-cutting issues like national control lists, identifying producers, licensing, inspections, notification and record-keeping, and customs effectiveness. In particular, BWC has many similarities with the Chemical Weapons Convention (CWC) which is also founded upon a “General Purpose Criterion”.\footnote{35} However, unlike the BWC, the CWC has a verification regime and a strong organizational back up.\footnote{36} Nevertheless, some of the structures developed by CWC like checklists etc. can be used to a certain extent as a framework for BWC national implementation.

The relevant Australia Group lists are another possible standard of export controls of pathogens, toxins and dual-use biological equipment and technology.\footnote{37} However, such lists might give a sense of false accomplishment in the absence of “catch-all provisions” for

\begin{footnotes}
\item[32] www.vertic.org
\item[33] www.icrc.org
\item[34] http://www.interpol.int/Public/BioTerrorism/default.asp
\item[35] Fairly speaking, there is a process of mutual learning between the two conventions. While BWC process picked up the notions of action plans and a verification protocol from CWC, the CWC is behind BWC in matters of establishing relations with non-state stakeholders and using the internet for distribution of information.
\item[36] The Organization for the Prohibition of Chemical Weapons (OPCW) has an established programme of legal technical assistance. OPCW provides examples of comprehensive legislation, models and explanatory documentation, comments on draft legislation submitted by states parties and maintains a network of legal experts. It has prepared guides, handbooks and checklists for national implementation of the CWC as well. The OPCW National Legislation Implementation Kit (LAO-March 2006), and CWC National Implementation Measures: OPCW checklist for the legislator is available at www.opcw.org For details see Malik Azhar Ellahi, Presentation at the BWC Meeting of Experts, 23 August 2007

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dual use items. This aspect is even more significant in the realm of bio-sciences where advancements are taking place at an astonishing speed. Then there is the burden of history: developing countries view these lists as discriminatory and developed with an aim to restrict technology transfer. Any list would be difficult and cumbersome to agree upon and likely to become rapidly outdated.

ICRC and Veritec have jointly\(^{38}\) come up with a model BWC law for States with a common law legal tradition. The model law consolidates prohibition and prescribes penal sanctions of the weapons and acts defined in the BWC and the 1925 Protocol,\(^{39}\) spells out the criminal offence of violating the terms of Article I of BWC, including acts committed by State agents, sets up an optional licensing scheme, provides for domestic enforcement through a system of inspectors and an information collection system for reporting internally and to other BWC states. The model law skips required internal regulations or administrative measures.

The African Union has also adopted a Model Law on Safety in Biotechnology in 2001 which criminalizes the use of genetic engineering for hostile purposes. Penalties include incarceration and fines and apply to persons, organizations and corporations. If a corporation is responsible, its CEO might be held accountable. African courts may also prohibit anyone convicted of violating the law from conducting future biotechnology research. The Criminal sanctions are applicable to persons who create or use GMOs that damage “human health, biological diversity, the environment, or property”. The Law is proactive in the sense that it covers multiple phases of biological weapons research and use by prohibiting “development, acquisition, or deliberate release” of a GMO or its product with the intention of causing harm. Coupled with trans-boundary movement regulations, the law gives African countries an important tool to detect, prevent, and punish the entry of biological weapons.\(^{40}\)

Despite the political difficulties in agreeing to a model law, such model laws nevertheless can serve as a useful tool for drafters of national legislation, providing them with a checklist of sorts to determine if the obligations under BWC are being met by existing legislation and what further provisions need to be enacted. Even the proponents of the model law realize that any state is unlikely to implement the model law as such because of the presence of pre-existing legislations and inspector systems etc. It is just one of the many possible ways in which the BWC obligations may be implemented.

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With the help of the parameters identified through these efforts, we can distill a checklist of sorts for National Implementation Measures required under the BWC, (Box 1) though it should be noted that many of these measures may not be considered obligatory by states.

**BOX 1**

**Checklist of National Implementation Measures for BWC**

**Penal provisions**

- Penal measures to criminalise prohibited activity under Article I
  - Definition used
  - Cover
    - the development
    - production
    - stockpiling
    - other acquisition
    - retention
    - use
    - means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict
  - Components
    - assistance, encouragement or inducement of others
    - breaches of related export controls
    - experimentation involving open-air release of pathogens or toxins harmful to humans, animals and plants
  - regardless of their origin and method of production and whether they affect humans, animals or plants, of types
  - Quantities specified?
  - If yes what (in quantities that have no justification for prophylactic, protective or other peaceful purposes)

- Obligations apply to
  - natural persons residing on the territory of the State
  - legal persons residing on the territory of the State (corporate bodies etc)
  - actions taken anywhere by actor possessing the State’s nationality (Extra-territoriality)
  - government functionaries

- Specific sanctions for violation
  - If yes, what

**Transfer controls**

- Cover
  - internal transfers within the State
  - import
  - export
  - re-export, trans-shipment and transit through the State’s territory.
  - assist, encourage, or inducement
  - State as well as non state actors

- Ensure end use while authorizing direct and indirect transfers
- Ensure protection and and safeguarding measures to control access to and handling of agents
- Regulate the safety and security of transport by rail, road, air, waterway or by sea
- Ensure transferred material arrives only at the intended destination, through requirements, or a notification system, to document receipt
- Ensure incidents of non-compliance are reported.
- Address intangible resources and technologies
- Identify national facilities involved in relevant transfers, imports and exports, perhaps through registration
- Require license for all dual use items (catch-all clauses)
- Incorporate risk management approaches
- Ensure provisions of Article III are not used to impose restrictions/limitations on transfers for purposes consistent with the objectives and provisions of Article X of BWC. This can be done by developing a partnership with industry and academia

**Customs regulations**
- Establish an appropriate national customs authority
- Grant appropriate powers to the national customs authority to enforce transfer controls
- Ensure appropriate training of customs personnel

**Law enforcement measures**
- Ensure the safety and security of agents or toxins in laboratories, facilities, and during transportation
- Ensure unauthorized access to and removal of agents or toxins
- Strengthen methods and capacities for surveillance and detection of outbreaks of disease
- Authorize halting suspect activity and interdicting activities
- Powers of search for obtaining evidence in cases of suspected breaches of the legislation
- Build capacity to collect evidence, identify suspect personnel and facilities, develop early-warning systems
- Coordinate between relevant agencies (such as police, prosecution, health and security fields)
- Verify compliance with the relevant national measures, possibly through a national inspection system
- Ensure enforcement agencies receive the necessary scientific and technological support
- Integrate measures to deal with biological weapons into national disaster and/or counter-terrorism plans

**Additional measures**
- Designation of a national focal point for coordinating implementation
- Promote cooperation and coordination between traditional security agencies and other relevant agencies (such as health and agriculture)
- Division of responsibilities and coordination, possibly through a national BWC implementation plan or strategy
• Protect confidential and sensitive information.

• Oversee relevant scientific and technological activities, possibly through the creation of national standards, surveillance of biological experiments, determining administrative responsibilities for conducting such work, or national bioethics committees.

• Improve dialogue and communication between national authorities and all relevant domestic stakeholders, such as scientists and industry.

• Develop best practices and engender an atmosphere of self-governance in collaboration with the relevant stakeholders.

• Inclusion of information on the Convention and the 1925 Geneva Protocol in medical, scientific and military educational materials and programmes.

• Regular review of national legislative, regulatory and administrative means.

• Updating lists of agents and equipment relevant to safety, security and transfer regimes.

• Promotion of awareness amongst relevant professionals of the need to report activities that would constitute a violation of the Convention through codes of conduct and self-regulatory mechanisms.

State of life sciences in India and Pakistan

Life sciences\(^{41}\) are burgeoning fields in both countries. According to one classification, India is among the 27 “particularly important countries” in the context of BWC because of its activities and policies in terms of bio-technological capability. The same report lists Pakistan as Number 58 in the world on the basis of related publications and research.\(^{42}\)

The Indian biotech industry, valued at $2.5 billion,\(^{43}\) has been growing at an annual growth rate of 34 percent since 2003 ad was seen as pausing at a ‘mere’ 20 percent in 2007-8 “before the next level of growth”. Just the biopharma segment recorded sales in excess of $1.72 billion, accounting for 67 percent of the total industry revenues. The share of exports in the total biotech pie is close to 56 percent. In 2007-08, the investments touched Rs. 2,750 crore, up by over 21 percent from the previous fiscal year. There were 17 recombinant products approved for marketing in India compared to 12 in 2005-06. The industry is forecast to grow to about $13-16 billion revenue by 2015. About a dozen deals were signed during January-June 2008 alone, including the acquisition of India’s second largest drug maker, the Ranbaxy by Japan’s Daiichi Sankyo. Increasingly, there are signs of a two-way thoroughfare of investments in contrast to the earlier trend of only inward investments to India.

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41. Related fields would include biotechnology, synthetic biology, genomics, vaccine production, biopharmaceutical industry etc


The Indian government recognized the importance of biotechnology early by establishing the National Biotechnology Board (NBTB) in 1982, which graduated to a full-fledged Department of Biotechnology (DBT) in 1986. It has been spending around 1,300 crore a year, to support R&D and innovation and plans to spend around 700 crore in the next two years on developing infrastructure for enhancing drug production, using biotechnology applications. The DBT currently operates three funding schemes—Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Program (BIPP) and Biotechnology Industry Research and Assistance Program (BIRAP). Government of India provides rebates in customs, central excise, service tax and income tax to steer the growth of the biotechnology industry including concessional rate of five percent customs duty and zero countervailing duty (CVD) on import of specified items and exemption from excise duty to specific items. The service tax of 12.24 percent has been exempted on clinical research services. This includes new drugs, vaccines and herbal medicines. Among the income tax rebates, weighted deduction of 150 percent was sanctioned for expenditure related to in-house R&D until March 31, 2012. Also, there is an exemption for certain incomes of a venture capital company, specified businesses or industries engaged in the business of nanotechnology, biofuels and all the areas of biotechnology.

The research institutions supervised by DBT include the National Institute of Immunology (NII), National Brain Research Centre (NBRC) and National Centre for Plant Genome Research (NCPGR), New Delhi; National Centre for Cell Science (NCCS), Pune; and Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad. Other major agencies financing and supporting research in biotechnology in India are Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Indian Council of Agriculture Research (ICAR) and Department of Scientific and Industrial Research (DSIR). Some other institutes based in India are not under the direct supervision of the government sector like the International Centre for Genetic Engineering and Biotechnology (ICGEB), an international organisation, Bose Institute, Kolkata, an independent research institute and the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru, which has launched a Center of Excellence in Genomics (CEG). The Association of

44. The DBT had alloted 1,000 crore (Plan) and 24 crore (Non-Plan) for fiscal 2009-10, as compared to 865.03 crore in the previous fiscal. This was later revised to 902 crore (Plan) and 23.90 crore (Non-Plan). The budget allocation for 2010-11 is 1,200 crore (Plan) and 22 crore (Non-Plan)

45. see Department of Biotechnology, Government of India http://dbtindia.nic.in, Department of Science and Technology, Government of India http://dst.gov.in/, Council of Scientific and Industrial Research, Government of India http://www.csir.res.in


Biotechnology Led Enterprises (ABLE) has been established by leading Indian biotechnology companies to provide a forum to interface between the industry, the government, academic and research bodies, and domestic and international investors.\(^\text{48}\)

India’s new National Biotechnology Development Strategy, launched in November 2007, targets US$7 billion revenue generation by 2012, and a major revamping of biotechnology education programmes.\(^\text{49}\) The government will boost funds for biotechnology by five-fold over the next five years, from US$362 million during 2002–2007 to US$1.6 billion by 2012. 30 per cent of the Department of Biotechnology’s budget has been reserved for public-private partnerships and the launch of an industry partnership programme.

In an attempt to push research in pharmaceutical sector, the Department of Pharmaceuticals (DoP) is planning to set up a 10,000 crore venture capital (VC) fund, to provide the much-needed financial assistance to the players. The DoP will contribute 15 percent under a public-private partnership model, and the rest would be raised from other interested investors. The funds would be raised in three phases 3,000 crore in fiscal 2011-12; 5,000 crore by 2013 and 2,000 crore by 2015. The complete fund will get utilized by 2015. The plan is to provide financing for new drug discovery projects and for biopharmaceutical products in the country.

The Government of Pakistan also envisions biotechnology as high priority area and is funding research & development in this sector through various ministries and Higher Education Commission. It has invested about US$ 17 million in research and development in various biotech projects like vaccine production for animals and human, insect resistance crops, industrial and environmental products. So far more than 70 projects have been approved in various disciplines of biotechnology and genetic engineering at different institutes.\(^\text{50}\) The National Commission on Biotechnology was established in 2001 as an advisory body to the Ministry of Science and Technology to monitor developments in the field and recommend appropriate policy measures. The Commission has been working in partnership with the government, biotechnology institutes and professionals to provide technical assistance, technology sharing, and information resources. It is pursuing “the Promotion of Biotechnology Research in Pakistan and Preparation of Biotechnology Action Plan” executed by Biosciences Division of Pakistan Atomic Energy Commission. It funds conferences and consultative meetings, training workshops, participation in conferences and popularization of biotechnology through seminars and publications etc. The Pakistan Biotechnology Information Center (PABIC) has been established at Latif Ebrahim Jamal National Science Information Center, University of

\(^{48}\) http://www.ableindia.org/

\(^{49}\) Government accords approval to the National Biotechnology Development Strategy, Department of Biotechnology, Government of India, http://www.dbtindia.nic.in/biotechstrategy/biotech_strategy.htm

Karachi by the International Service for Acquisition of Agri-Biotech Applications (ISAAA) and National Commission on Biotechnology to initiate multidisciplinary research and enhance awareness of biotechnology.\textsuperscript{51} Other interesting ventures include a project by the University of Veterinary and Animal Sciences to launch a “Lahore Biotech Park -- UVAS” to capitalise the resources in Pakistan and substantially decrease import of biotech products.\textsuperscript{52}

There are about 27 Institutes of Biotechnology & Genetic Engineering in Pakistan. The National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad and Nuclear Institute for Agriculture and Biology (NIAB) have been termed as pioneer institutions for research in medicine and agriculture. NIBGE has led international research on cotton leaf curl virus by deciphering the virus genetic code and documenting the genetic diversity existing in the field. A Plant Genomic Laboratory and a Biofertilizer Research Center (BIRCEN) have also been established in collaboration with Pakistan Agricultural Research Council.\textsuperscript{53} Other institutes include Biomedical & Genetic Engineering Division, Dr. A. Q. Khan Research Laboratories, Islamabad, Dr. Punjwani Center for Molecular Medicine and Drug Research, Department of Biotechnology, Center for Molecular Genetics and\textsuperscript{54} Department of Microbiology at University of Karachi, Plant Tissue Culture Lab, H.E.J Institute Research Institute of Chemistry, Karachi,\textsuperscript{55} Dr. A. Q. Khan Institute of Biotechnology & Genetic Engineering, Karachi, Centre for Excellence in Molecular Biology, Institute of Biochemistry and Biotechnology and Department of Microbiology and Molecular Genetics, University of Punjab, Lahore, Biotechnology and Food Research Centre, Lahore, Institute of Biotechnology & Genetic Engineering, NWFP Agricultural University, Peshawar, Center for Animal Biotechnology, Peshawar and Institute of Biotechnology and Genetic Engineering, University of Sindh, Jamshoro.

The Federation of Asian Biotech Association (FABA) was formed in February 2005 with India and Pakistan among its eight founding members with a view to create a common platform for development of biotechnology in Asian countries. FABA aims to promote biotechnology as a profession and the interaction of academia and industry in the field, to act as a facilitator between industry and government, to encourage investment and cross-border trade in biotechnology, and to sponsor international meetings of scientists.\textsuperscript{56}

Bio-Threat Perception in South Asia

Compared to other WMDs, there is a low threat perception of biological weapons in South Asia. There are a number of reasons for this. Firstly, unlike other regions of the world,
there is no history of a state sponsored offensive BW programme or deliberate use of biological weapons. Secondly, there is awareness that despite all the media hype and hoaxes, the real threat of a bio-terrorism remains debatable because of difficulties in weaponization of biological agents and options available to terrorists to achieve their objectives by simpler means. There are only a few recorded instances between 1900 and 2000 of the preparation of biological pathogens, apart from ricin, in a private laboratory by a non-state actor.\(^{57}\) Cases of use of biological weapons to date have been low-level, failures, or successes with very little impact.\(^{58}\) However, future spread of technology might change capabilities at a much faster pace.

Most international observers agree that though both countries are technically capable, they are unlikely to peruse an offensive biological warfare program. This is primarily because these weapons do not fit in the strategic paradigms of both countries. Both countries are nuclear weapon possessors and consider nuclear weapons their major strategic asset. An offensive bio-weapons programme cannot provide any added sense of security to them. On the other hand, it can be a major political liability at the international level. Geographical proximity of their traditional foes makes such weapons unattractive also. Opposition to bio-weapons has been reiterated by both countries leadership time and again. For example in October 2002, Indian President A.P.J. Abdul Kalam asserted that “India will not make biological weapons. It is cruel to human beings.”\(^{59}\)

In my discussions with Pakistani diplomats dealing with these issues, I found that though they are generally not apprehensive about the proliferation of biological weapons in the region, they do point out the Indian historic policy on chemical weapons. After years of denying a chemical weapons programme, India joined the CWC as a possessor state.

Despite this, western states and media continue to see the region as a likely bioweapon proliferation threat. After Pakistan’s May 1998 nuclear tests, the US imposed sanctions\(^{60}\) on four chemical and biological facilities on suspicions of being involved with chemical and bio-warfare programs without providing any evidence of their involvement in offensive biological warfare programs.\(^{61}\) In 2003, India

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61. These were the Center for Advanced Molecular Biology, Lahore, Karachi CBW Research Institute, Karachi CW & BW Warfare R&D Laboratory and the National Institute of Biotechnology and Genetic Engineering, Faisalabad.
and Pakistan were named as one of 10 countries affected by the British Foreign Office program, the “Voluntary Vetting Scheme,” in which postgraduate scholars from these countries are likely to be vetted before being accepted by a university if their research could contribute to the proliferation of chemical or biological weapons.\footnote{Suroor Hasan, “Indian Scholars on UK’s Vetting List,” The Hindu, Global News Wire, 11 July 2003, http://www.hindu.com/thehindu/2003/07/11/stories/2003071104751100.htm}

Experts in both countries consider the threat of use of biological weapons by non-state actors, terrorists or criminals higher than that of any state sponsored program in the region. In 2004, the then Indian Home Minister Shivraj Patil cautioned against the possible use of biological and chemical weapons by terrorists saying that advanced technologies falling into wrong hands may lead to the spread of terrorism to the oceans and to outer space.\footnote{“Home Minister Calls for Co-ordinated Efforts to Fight Terrorism,” The Hindustan Times, 22 December 2004} Arundathi Ghose, the former Indian permanent representative in Geneva has called India “a potential victim of biological attacks or blackmail by sub-national groups, acting either alone, at the behest of a hostile country or a mafia.”\footnote{KS Manjunath, \textit{Discourse on Bioweapons Non-Proliferation}, Institute of Peace & Conflict Studies, 12 July 2005 <http://www.ipcs.org/article/nuclear/discourse-on-bioweapons-non-proliferation-1785.html>}

However other analysts see the use of biological weapons by terrorist organizations less likely in South Asia\footnote{Dr Suba Chandran, \textit{Looking Beyond Bio-Weapons and Bio-Terrorism in South Asia}, Institute of Peace & Conflict Studies, 20 May 2005, <http://www.ipcs.org/article/india/looking-beyond-bio-weapons-and-bio-terrorism-in-south-asia-1750.html>\footnote{Marie Isabelle Chevrier and Iris Hunger, “Confidence-Building Measures for the BTWC: Performance and Potential”, The Nonproliferation Review, Fall-Winter 2000, pp. 32-33.\footnote{The Nuclear Threat Initiative, Country Profiles, India Biological Overview, http://www.nti.org/e_research/profiles/india/Biological/index.html}>} because while procuring biological materials may be easier, manufacturing and safeguarding biological weapons is not simple. Also, biological weapons are less likely to fit into the modern strategy of the terrorists in the region who are increasingly careful in avoiding any collateral damage, to avoid popular wrath and disapproval.\footnote{The Nuclear Threat Initiative, Country Profiles, India Biological Overview, http://www.nti.org/e_research/profiles/india/Biological/index.html>}

India is among the 23 BWC member states which have declared bio-defence programmes. As of 1998, India had an annual budget of 2 million rupees for the program with 25 personnel involved.\footnote{Marie Isabelle Chevrier and Iris Hunger, “Confidence-Building Measures for the BTWC: Performance and Potential”, The Nonproliferation Review, Fall-Winter 2000, pp. 32-33.\footnote{The Nuclear Threat Initiative, Country Profiles, India Biological Overview, http://www.nti.org/e_research/profiles/india/Biological/index.html>}} In 2001, India increased the scope of its countermeasure capability after its Postal Department received 17 “suspicious” letters believed to contain Bacillus anthracis spores. A Bio-Safety Level 2 (BSL-2) Laboratory was established at the Institute of Preventive Medicine to provide guidance in preparing the Indian government for a biological attack. The Indian draft nuclear doctrine announced in 2003 allowed it to “retain the option of retaliating with nuclear weapons” in the event of a major biological or chemical attack.\footnote{The Nuclear Threat Initiative, Country Profiles, India Biological Overview, http://www.nti.org/e_research/profiles/india/Biological/index.html>}

The Defense Research and Development Establishment (DRDE) at Gwalior is reportedly working on counteracting disease threats such as anthrax, brucellosis, cholera, plague,
smallpox, viral hemorrhage fever, and botulism. Indian government has also established nuclear, biological, and chemical (NBC) warfare directorates in the armed services, as well as an inter-Services coordination committee to monitor the program. In March 2007, the Indian National Crisis Management Committee (NCMC) approved a model of standard operating procedures (SOPs) for preventing and responding to a bio-terrorism attack.\(^68\)

Officials claim that Indian armed forces have placed orders of more than $500 million for equipment to prepare against attacks by chemical, biological and nuclear weapons.\(^69\)

### National Implementation of BWC in India

#### Legislative and Administrative Measures

India implements BWC through the Unlawful Activities (Prevention) Amendment Ordinance, 2004, the Environment Protection Act, 1986; the Customs Act, 1962; the Foreign Trade (Development & Regulations) Act, 1992; the Explosives Substances Act, 1908; the Arms Act, 1959 and the Arms Rules, 1962 and subsequent regulations under these Acts. Other important segments of the Legislative & Administrative structure\(^70\) include Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989, Recombinant DNA Guidelines, 1990, Guidelines for generating pre-clinical data for rDNA vaccines, diagnostics and other biologicals, 1999, The Drug Policy of 2002, The Guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, National seeds Policy 2002 and the Ethical Policies on the Human genome, Genetic Research and Services. The Government of India has also specified a List of Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET), the export of which is either prohibited or permitted only under license and after providing end users certificates.\(^71\)

**The Unlawful Activities (Prevention) Amendment Ordinance, 2004** inter alia covers terrorism and its links with weapons of mass destruction. It provides for penalties for “unauthorized possession of…..biological … substance of warfare”. The definition of a terrorist

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71. United Nations, S/AC.44/2004/(02)/62, India’s national report on the implementation of Security Council resolution 1540, 1 November 2004 letter from the Permanent Mission of India to the United Nations addressed to the Chairman of the Committee established pursuant to resolution 1540 (2004) and United Nations S/AC.44/2004/(02)/62/Add.1 Letter from the Permanent Representative of India addressed to the Chairman of the Security Council Committee established pursuant to resolution 1540, 16 January 2006. The SCOMET List is notified by the Director General of Foreign Trade (DGFT) at Schedule 2 Appendix 3 of the Indian Tariff Classification (Harmonized System) (ITC(HS)) of Export and Import Items, 2004-2009. The list and the guidelines are available at the website of the Directorate General of Foreign Trade, Government of India (http://dgft.delhi.nic.in).
act includes the use of “substances (whether biological or otherwise) of a hazardous nature” and covers terrorism aimed against India as well as other countries. It provides for a punishment of five years to life imprisonment for committing terrorist acts involving weapons of mass destruction or death penalty where it has resulted in a death. It also criminalizes funding such acts; conspiring to commit, or aiding and abetting such activities or any act preparatory to the commission of a terrorist act; and harbouring and concealing, including the attempt to do so, persons engaged in such activities.

*The Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Act 2005 (WMD Act)* enacted to comply with UNSCR 1540 refers to India’s commitment to the BWC in its preamble. The act covers all three weapons of mass destruction. It prohibits unlawful manufacture, acquisition, possession, development, or transport of a chemical or biological weapon or their means of delivery. Section 4(a) defines Biological Weapons exactly the same way as the BWC. It prohibits any person not duly authorised by the government to deal with weapons of mass destruction and their means of delivery. The Act extends to whole of India and applies to individuals as well as companies, ships and aircrafts etc registered in India, foreign nationals while in India and persons in Service of Government of India, within and beyond India. It, thus meets the criterion of extra territoriality as well as “binding the crown”. The Act prohibits the export of any material, equipment or technology from India, if the exporter knows that such an item or technology is intended to be used in design and manufacture of a biological weapon, etc. The Act imposes a general prohibition on brokering, by Indians or foreign nationals in India, in any such transaction that is prohibited or regulated under the Act. The Act also introduces controls over WMD-usable items or technologies brought in transit into India or being trans-shipped through India.

The Act provides for civil as well as criminal penalties in a graded manner. Violations of provisions related to a biological weapon or its means of delivery, as well as those involving terrorist acts carry five years to life imprisonment. Attempts to contravene or abet the contravention of any provisions of the Act with intent to aid terrorists are punished with imprisonment of five to ten years. Export control violations carry a punishment of six months to five years imprisonment. Repeat offenders face one to seven years in prison.

The regulatory mechanism for the maintenance of security and oversight of pathogens, micro-organisms, genetically modified organisms and toxins is mandated by the Environment (Protection) Act, 1986. ‘Hazardous substance’ has been defined as any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plants, micro-organisms, property or the environment while ‘handling’ denotes the “manufacture, processing, treatment, package, storage, transportation, use, collection, destruction, conversion, offering for sale, transfer or the like”. The Act prohibits
handling of such substances except in accordance and compliance with the prescribed procedural safeguards. It also has provisions for entry, inspection and sample analyses by enforcement officials and offenses by companies and Government Departments. Contravention of the provisions of the Act, or the rules, orders, directions issued under them are punishable with imprisonment for a term of up to five years and/or a fine.

The Licensing Guidelines provide for evaluating applications for export of items on the SCOMET List on the basis of credentials of the end-user, credibility of declarations of end-use of the item or technology, the integrity of the chain of transmission of the item from the supplier to the end-user, the potential of misuse of the item or technology as well as the risk of its falling into the hands of terrorists, terrorist groups, and non-State actors. Additional formal assurances on end-use and non-retransfer, from the State of the recipient may also be required and additional end-use conditions may be stipulated. Applications for the transfer of “Technology” for any item on the list are considered as an application for the export of the item itself.

Financing of terrorism and the activities and channels relating to informal movement of funds and money laundering are also regulated under the Foreign Exchange Management Act (FEMA), 1999 and the Prevention of Money Laundering Act (PMLA), 2002. The Prevention of Terrorism Act, 28 March 2002 provides for the prevention and response to terrorist acts, including those involving biological substances of a hazardous nature. If the act in question causes the death of a person, the violator will face life imprisonment or the death sentence otherwise the punishment will be imprisonment from 5 years up to life. Epidemic Diseases Act, 1896 provides the government with power to take special measures and prescribe regulations relating to dangerous epidemic diseases.

**Biosafety and Biosecurity**


Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms and Genetically Engineered Organisms or Cells prohibit unauthorized deliberate release of genetically engineered organisms/hazardous micro-organisms or cells into the environment or nature. They also apply to new gene technologies and provide the Government with the authority to regulate micro-organisms which “have not been presently known to exist in the country or have not been discovered so far”. The 1989 Rules and the 1990 Guidelines list micro-organisms on the basis of differential risk assessment. These lists, which are applicable from the biosafety point of view, are more elaborate than the list of micro-organisms and toxins
included in Category 2 of the SCOMET List used for dual-use export controls. Guidelines for Generating Pre-clinical and Clinical Data for rDNA vaccines, diagnostics and other biologicals, 1999 deals with recombinant DNA technology in vaccine development and provides guidance on containment and safe laboratory practice and with import and shipment of genetically modified material for research use. Revised Guidelines for Research in Transgenic Plants, 1998 deal with genetic transformation of green plants, provide guidance on containment and safe laboratory practice and deal with import and shipment of genetically modified material for research use.

Institutions handling microorganisms/genetically engineered organisms are required to have an Institutional Bio-Safety Committee to examine and monitor projects from the point of view of safety and biohazard potential. These Committees, which include a Government representative as a member, also assist in training of personnel on biosafety, safe disposal of hazardous wastes, and the adoption of an emergency plan. All ongoing projects involving high risk category and controlled field experiments are reviewed by the Review Committee on Genetic Manipulation (RCGM) to ensure that adequate precautions and containment conditions are followed. Use of pathogenic microorganism or any genetically engineered organisms or cells for the purpose of research is permitted only in laboratories authorized for the purpose.

**Enforcement**

The legislative base for enforcement is the Central Excise Act, Indian Customs Act 1962, Unlawful Activities (Prevention) Amendment Ordinance, 2004, The Narcotic Drugs and Psychotropic Substance Act 1985, Official Secret Act and Central Civil Services Conduct Rules. **The Central Excise Act, 1944** provides border controls including provisions relevant to biological weapons and related materials. **Customs Act, 1962** provides for criminal prosecution if the conditions for export outlined in the Act are violated. Export control violations are punishable with imprisonment of up to three years and/or a fine under the Customs Act, 1962. This term may extend to seven years with fine in case of subsequent violations. Export or attempt to export in violation of any of the conditions of the license granted is also punishable. **The Foreign Trade (Development & Regulation) Act, 1992** also empowers the Government to conduct search and seizure under the relevant provisions of the Code of Criminal Procedure, 1973. Provisions are in place in The Customs Act, 1962 and the Foreign Trade (Development & Regulation) Act, 1992 to deal with entities aiding and abetting trade activities in contravention of existing rules and regulations. The Customs Act, 1962 also provides for prosecuting Customs officials conniving in fraudulent exports, including those in violation of SCOMET regulations.

Conduct of all government employees dealing with officially classified documents, including in sensitive and high technology areas, is regulated under the Official Secrets Act, 1923 and the Central Civil Services (CCS) Conduct Rules, 1964. Contraventions of the Official Secrets Act are punishable with imprisonment up to fourteen years. In addition, detailed instructions on a wide range of security issues are issued by relevant Government Departments/Ministries from time to time to prevent any unauthorized access.
to material, information or know-how by direct or indirect means.

**Stakeholder participation**

The committees established by law to oversee the developments in relevant sectors include representation from research sectors as well. The Association of Biotechnology Led Enterprises (ABLE) has been established as forum to interface between the industry, the government, academic and research bodies, and domestic and international investors. The new National Biotechnology Development Strategy launched in 2007, is based upon a two-year-long nationwide consultation process with multiple stakeholders.

The Biotechnology Consortium India Limited (BCIL)\(^\text{72}\) is also acting for forging effective linkages between research, financial and industrial institutions and the policy making framework at the government level and leads transfer of technology and research from the Government funded R&D projects to industries for scale up, validation and commercialization.

**National Implementation of BWC in Pakistan**

**Legislative and Administrative measures**

In case of Pakistan, legal measures to implement BWC include the Drugs Act 1976, the Pakistan Terrorism Act 1997, the Export Control on Goods, Technologies, Material and Equipment related to Nuclear and Biological Weapons and their Delivery Systems Act, 2004 and the Pakistan Bio-safety Rules 2005.\(^\text{73}\)

Post UNSCR 1540, a new legislation entitled “Export Control on Goods, Technologies, Material and Equipment related to Nuclear and Biological Weapons and their Delivery Systems Act, 2004” was enacted. The act begins with announcing a commitment to prevent proliferation of nuclear and bio weapons and missiles. It enables the Federal government to control the export, re-export, trans-shipment and transit of goods, technologies and equipment which might contribute to designing, developing, producing, stockpiling or using biological weapons and their delivery systems. Article 2(b) defines biological weapons as any weapon designed to kill or harm or infect people, animals or plants on a large scale through effects of the infectious or toxic properties of a biological warfare agent.

The Act has a wide jurisdiction including Pakistanis visiting or working abroad. It includes comprehensive control lists as well as licensing, record keeping provisions, end-user certificates and catch-all clauses. Under the act, the Strategic Export Control Division (SECDIV), and its Oversight Board have been setup to formulate and implement measures.

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\(^{72}\) http://bcil.nic.in/

\(^{73}\) The information has been taken from website of the Implementation Support Unit (http://www.unog.ch/bwc), Statement by Tehmina Janjua, Deputy Permanent Representative on “National Implementation of the BTWC”, 2007 Meeting of Experts, Geneva, 20 August 2007, and Pakistan’s national report on national measures on the implementation of Security Council resolution 1540 (2004), United Nations S/AC.44/2004/(02)/22 dated 27 October 2004 letter from the Permanent Mission of Pakistan to the United Nations addressed to the Chairman of the Committee
enforce rules and regulations for the implementation of export controls and act as a licensing body. Offenders can face up to 14 years imprisonment and Rs.5 million fine or both, and forfeiture of his or her property and assets. The act vests authority to officials of designated agencies to inspect consignments declared for export and review acquire or confiscate records or withholding an export license under this Act. It also provides for development and updating of Control Lists of goods and technologies subject to licensing requirements.

*The Drugs Act 1976* prescribes a 3 to 10 years imprisonment and a fine of up to Rs. 100,000 for export, import, manufacture or sale of any spurious or unregistered drug. It defines an adulterated drug as consisting in whole or in part of any foreign matter or which has been manufactured, packed or held under any foreign matter or which has rendered it injurious to health or releases any poisonous or deleterious substance.

*The Pakistan Anti- Terrorism Act 1997* (amended in 1999 and 2002) penalizes individuals in possession of illicit weapons that may include chemical and biological weapons. It also prohibits aiding and abetting others to acquire biological weapons, and makes it an offense to harbour anyone who has performed any of these acts. It also makes it an offense to finance the prohibited activities, punishable by between 6 months to five years imprisonment.

*Pakistan Penal Code* penalizes those involved in acts likely to spread dangerous diseases. Section 270 makes it an offense to spread infection dangerous to life punishable by up to two years in prison and/or a fine. It also makes it an offense to abet or finance the deliberate spreading of disease. Section 271 provides for quarantine and sets out the punishments for disobeying the rules. It also makes it an offense to adulterate drugs, sell them or sell them as a different drug or preparation, punishable with up to six months in prison and/or a fine of up to 3,000 rupees.

*Defence of Pakistan Ordinance 1965* prohibits and regulates the possession, use or disposal of dangerous substances, breach of which can be punished with up to five years imprisonment and a fine. *Surrender of Illicit Arms Act 1991* defines illicit arms as including poisonous or noxious gases or other chemicals and asserts that all persons in possession or control of illicit arms shall surrender them. *Plant Quarantine Act 1976* contains a mechanism to control transport of material that can be used in biological weapons and allows for the prosecution of persons contravening this legislation. *Environmental Protection Act 1997* prohibits the generation, collection, consignment, transport, treatment, disposal of, storing, handling, importing of hazardous substances.

Pakistan reported at the 2007 BWC state parties meeting that it was also working on a separate BWC related national legislation in order to consolidate existing laws. The new implementation legislation, prepared after an intricate interdepartmental process, is in advanced stages of enactment. The draft legislation is said to “provide for all the prohibitions and controls prescribed by BWC and UNSCR 1540 in relation to the
designing, development, manufacturing, use, transport, import/export, sale, acquisition, and possession of biological weapons, including their means of delivery, along with appropriate penal provisions for violations.\(^\text{74}\)

**Biosafety and Biosecurity**

Pakistan Biosafety Rules 2005 deal with development, production and testing of living modified engineered organisms and help check diversion. The National Bio-Safety Committee set up under these rules, monitors research and development activities in life sciences and ensures the conduct of scientists is in consonance with the provisions of the BWC. An elaborate system has been established, supported by 2,000 reporting stations, for early detection and surveillance of diseases, whether accidentally or deliberately spread. The rules require the consent of the National Biosafety Committee for setting up a production in which living modified engineered organisms or certain substances and products containing genetically engineered organisms are generated or used or developed, tested and experimented with. The production, sale or importation of food stuffs, ingredients in food stuffs and additives containing or consisting of modified organisms or cells is also regulated.

**Enforcement**

*The Carriage of Goods by Sea Act 1925* details the procedures for carrying dangerous goods by sea. Measures are also in place to deal with the enforcement of border control measures on frontiers, railways, coastal areas, seas and airports.\(^\text{75}\) The Import and Exports (Control) Act 1950 authorizes the Federal Government to prohibit, restrict or control the import or export of goods and regulate all practices and procedures connected with them. Section 5(1) of the Act provides for penalty of an individual, in addition to any confiscation with imprisonment up to one year and/or fine. These are updated by annual trade policies and Statutory Regulation Orders (SROs) and Ordinances issued by the Government from time to time.

**Stakeholder participation**

The Technical and Institutional Committees to support the National Committee under the biosafety rules contain representatives from private sector and civil society as well. Since 2001, the National Commission on Biotechnology is acting a bridge between the Ministry of Science and Technology and the research sector.

**Confidence Building Measures**

According to a decision taken by the Third BWC Review Conference in 1991, member states must submit an annual Confidence Building Measures (CBM) returns. However, the UN does not have a “collection mandate” i.e it cannot ask states for their CBM returns. The states are also not obligated to make these returns public; in fact few chose to do so.\(^\text{76}\) The Sixth Review Conference did not agree on any revision of the topics or

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\(^\text{75}\) These are Frontier Corp Ordinance 1959, West Pakistan Rangers Ordinance 1959, Airport Security Force Ordinance 1975, Maritime Security Act 1994 and Coast Guard Act 1973

format of CBMs returns or on measures to make them publicly available, but did give member states the option for electronic submission and distribution of these returns through the restricted access area in the ISU website.

While these CBMs can in no sense be described as measures for monitoring or verification, they do increase transparency and offer a way for states to promote and demonstrate effective implementation of the BWC. They can not replace a verification protocol as they would not be able to make certain that nations are not violating the BWC but can to some extent achieve another objective of a verification protocol, i.e. provide the mutual trust required to forestall the creation of new bio-weapon programs.\(^77\)

By themselves, the normative influence of CBMs can only be effective tool if the CBMs are universally accepted, regularly submitted by most if not all member states and are transparent. Presently, the situation is far from so. Of the 159 member states, 62 member states have yet to submit their first CBM. The highest number of CBMs submission was in 2007, 64 followed by 62 in 2008 and 2009.\(^78\) States requiring assistance for CBM submission have few avenues available to them. The format and topics of the CBM forms would also require to be re-examined in detail to ensure that they remain relevant in view of the fast pace of related research and development. This is however unlikely to happen before 2011.\(^79\)

India participated in CBMs only in 1997 and 2007. Pakistan has yet to submit a CBM return. This has to be seen in the context of the difficulties facing states completing the CBM forms especially for the first time. Collecting the necessary information typically requires contacting several different government ministries and agencies and some of the necessary information may be held at a state or provincial level or with the private sector. Moreover, the technical expertise required to complete these forms is located outside the Ministry of Foreign Affairs, the national focal point.

The low visibility of these measures has been identified as a major reason for low participation in the CBMs. Given that the data are not publicly reviewed, scant political attention is paid to them and states have little incentive to report.\(^80\) This does not, however, apply to India and Pakistan as both countries being nuclear states outside NPT and active negotiators from the developing world, cannot avoid focus.

Another impediment to collation of data for CBMs is the lack of legal


\(^{80}\) Weapons of Mass Destruction Commission, Weapons Of Terror Freeing the World of Nuclear, Biological and Chemical Arms (2006), <www.wmdcommission.org>
authority as research institutions and private parties might not consider obliged to provide this information. The research sector in developing countries is deeply suspicious of publicizing their activities for fear of restrictions which could impede their research especially when they are seen as getting nothing in return (no linkages with Article X!).

Codes of Conduct

With such almost no black and white and mostly grey areas in life sciences, often, the only distinction between legitimate and illegitimate research is the intent of the scientist. In this context, codes of conduct become a significant mechanism for upholding and promoting nonproliferation obligations assumed by states.

Codes of conduct can also create awareness among bio-scientists of the risks associated with the potential misuse of their research. Though such codes by themselves might not be able to prevent bio-weapons programmes, they can play a role in identifying, slowing and ending them. They can also make scientists more aware of the potential misuse of their research. Experts believe very few practicing life scientists give any thought to the potential dual use implications of their well-intentioned work. On the other hand, most would not be a willing accomplice to the potential destruction caused by these weapons. A recent survey of 1,100 scientists across 130 universities and research institutes in India found that about 64 per cent scientists said they would refuse to design biological weapons because of their moral and religious beliefs.

The dual-use dilemma necessitates policymakers and scientists to balance security concerns with desire to promote free exchange of scientific knowledge. Scientists would favor codes that are voluntary, fearing that binding codes will constrain research. Developing countries in particular are deeply suspicious of attempts to restrict their research and development sector. These codes are more effective than other measures because they operate through peer pressure.

Codes of conduct developed by academic and professional bodies could lay out standards internationally for work relevant to the prohibitions of the Convention. Such codes could include, inter alia, a statement that scientists will use their knowledge and skill for the advancement of human, animal and plant welfare and will not conduct any activities directed toward the use of microorganisms or toxins or other biological agents for hostile purposes or in armed conflict.

Therefore, the first step towards making such codes the norm is formation of umbrella organizations of bio-scientists. Among the organizations in

South Asia bringing together academics and researchers are the National Biotechnology Commission in Pakistan, the Association of Biotechnology Led Enterprises (ABLE) in India and The Federation of Asian Biotech Association (FABA) at the regional level. Pakistan has formed a BWC Task Force including representatives of various stakeholder organizations and headed by DG (Disarmament) of the Ministry of Foreign Affairs.

National Implementation in India and Pakistan- verification by other means

Apart from minor differences in punitive provisions, Pakistan’s “Export Control on Goods, Technologies, Material and Equipment Related to Nuclear and Biological Weapons and their Delivery Systems Act, 2004” and India’s “Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005” nearly mirror one another in substance and structure. Both explicitly define relevant terms, and there is near symmetry in the layout and organization of their provisions. Both provide broad and extra territorial jurisdiction citizens and corporate bodies. Both establish licensing and oversight authorities, as well as provide for delegation of authority to officials. These Acts establish the Central/Federal Government’s supreme authority in matters related to licensing, delegation of authority, final decisions regarding the status of control items, and the actual export, transfer, re-transfer, and trans-shipment of controlled items. Coupled with existing legislation and administrative measures, these acts meet all the requirements set by the existing parameters, i.e. decisions of the review conferences and inter-sessional meetings, proposed model laws and measures by other countries especially those with similar legal systems like Australia and UK.

While Pakistan's law focuses on nuclear and biological weapons and their delivery systems only, excluding chemical weapons, the Indian law covers all three weapons of mass destruction. This has caused a slight confusion among certain experts. Section 25 of the Indian WMD Act 2005 states that “nothing in this Act shall affect the activities of the central government in the discharge of its functions relating to the security or the defense of India”. Experts criticize this by saying that the national security exclusion does not have any place in the BWC context. The Indian diplomats I talked to were adamant that this provision is mainly because the Act covers nuclear as well as biological and chemical weapons. Seen in this context, India being a non-NPT member state is justified to include this provision. However, this highlights the perils of attempting to deal with different WMDs through a single act.

Section 8(3) of the Indian WMD act has also been objected to by certain experts as contrary to the general purpose criterion of BWC as it prohibits persons from “unlawfully” manufacturing, acquiring, possessing, developing or transporting a biological or chemical weapon or their means of delivery. BWC being a total disarmament treaty makes all these activities inherently unlawful. Again this seems to be merely a result of bundling together of different issues, rather than any lack of commitment on behalf of the Indian government.
An important feature of the implementation of BWC by India and Pakistan is the use of existing legislative and administrative infrastructure for this purpose. These have been strengthened by recent legislature to counter terrorism and implement UNSCR 1540. There is neither a specific BWC related legislation or any special authority dealing with all relevant issues. A BWC specific legislation might not be important from strictly an implementation point of view but might be desirable as a political gesture and might assist in timely and regular CBM returns.

Despite the historical political reluctance to accept the Australia lists for export controls, the transfer controls in place are robust and inclusive. U.S. Assistant Secretary of Commerce for Export Administration Chris Padilla is quoted as acknowledging that Indian export controls "comply with a majority of items controlled under the Australian Group for chemical and biological weapons purposes."84 The BWC related items on the control list of Pakistan are also identical to those listed by the Australia Group.

The Biosafety rules are also a noteworthy step forward. These rules will not only make foreign investors more comfortable to enter these markets, they will also ensure that the government is able to supervise the developments.

Conclusion

In the absence of verification mechanisms or international body to back the BWC, national implementation measures assume great significance. India and Pakistan have demonstrated their commitment to the Convention by putting in place robust and comprehensive legislative and administrative infrastructures for its implementation. These measures by and large fulfill the criteria expounded at the BWC Review Conferences and State Parties Meetings.

However, certain areas need more attention.

Firstly, though the focal points appointed under the decision of the sixth review conference could become the beginning of a coordinating mechanism to integrate and coordinate the policies and activities of all relevant stakeholders, public as well as private, at present the establishment of such an authority is not required of states. However, it would make things easier for states themselves, if they had such a consultative and coordinating body. The pace of progress in life sciences and the public private dispensation of relevant sectors makes this very much desirable. This would also make CBM submissions much easier.

Secondly, Confidence Building Mechanisms (CBMs) should be seen as binding under the BWC. This would require a clear decision and a closer look at their continued relevance by the next Review Conference. Scantly participation in these CBMs does not necessarily reflect any lack of commitment to the Convention; rather it has to be seen in the context of the challenging tasks of

completing the CBM forms and collating the necessary information from different government ministries and agencies, provincial governments or the private sector.

Another important aspect of national implementation is coordination between the government sector and other stakeholders in research and academia. Engagement with these sectors is increasing with the passage of time in both India and Pakistan and has been helped by the inclusion of academia and research representatives in the committees established under laws to oversee developments in bio sciences and the establishment of umbrella organizations for life scientists. This would lead to building norms for behaviour and codes of conduct. Such codes of conduct can play a significant role because of the weight of peer pressure behind them. However, these codes need to be voluntary and stakeholder-driven.

It is also important to widen this coordination with stakeholders to include other agencies, authorities and bodies which can contribute to the strengthening of BWC implementation. These would include police, custom, health and agriculture authorities as well as military and disaster management experts.

The provisions of BWC should also be included in the education and training programmes as well as the policies of the research funding institutions.

Finally, it has be realized that while some countries are adamant not to link national implementation with the provisions of technology transfer under Article X of BWC, the whole hearted cooperation of various sectors in the developing world would be difficult to obtain, even if the governments wish to do so, unless there is a sense that these measures would not hinder their research and progress. In reality there is an implicit, if not formal, circular relationship. National implementation of the Convention would be furthered if the developing countries as well as the researchers in private and public sectors of these countries sectors are motivated by realization of the objectives elucidated in Article X. On the other hand, measures for transfer control and bio-safety etc can increase the comfort level of prospective foreign investors and collaborators in these sectors in the developing countries. The future of BWC lies in developing a synergy with other multilateral mechanisms and bodies as well as with all stakeholders.