

**Meeting of the States Parties to the Convention
on the Prohibition of the Development,
Production and Stockpiling of Bacteriological
(Biological) and Toxin Weapons and on Their
Destruction**

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Item 9 of the agenda

**Arrangements for the Seventh Review Conference
and its Preparatory Committee in 2011**

**Revised
National implementation of the BTWC: compliance
assessment: a concept paper**

Submitted by Canada

1. Assessment of compliance is a common practice among regulators and standards-setting organizations on an international scale. The concepts utilized for compliance verification can be as focussed as on-site inspections of facilities, warehouses, factories or specific end-product units, or it can be approached from a broader perspective of verifying compliance by examining and assessing the regulatory *program* in place, the program that has been implemented to ensure compliance with a regulatory/legislated requirement.
2. Development of an internationally-led on-site inspection regime has never reached consensus in the BTWC, though States Parties are encouraged to submit Compliance Reports every five years. However, a broader approach to assessing compliance may be feasible and acceptable if it is the national implementation program that is examined, and not individual facilities within a State Party's borders.
3. Given this broader context, Canada would propose to work with interested State Parties to develop this broader concept, based on the following principles of compliance assessment.
4. Under this proposal, each State Party would submit to the ISU (or other BTWC supported body), as an initial submission, a detailed description of national legislation and regulations supporting the national implementation of the BTWC, including those that cover the oversight of human, animal and plant pathogens. This detailed description could include very specific section-by-section analysis of how the legislation/regulations work, the scope of the legislation/regulations (e.g. any exceptions/exemptions from the law, is the legislation based on lists of organisms or broader categories of risk groups, etc.) and the penalties associated with contraventions.
5. In addition to the analysis of the national implementation legislation, each submitting State Party would also submit a detailed description of how the program was implemented on a national level. This could include process flow diagrams, organizational charts of the implementing program, showing clear lines of reporting, process and standard

operating procedure descriptions, as well as clear indications of the inspection program, frequency of inspections and how major and minor non-compliances are handled. The submission could also include the yearly budget associated with running the program.

6. Because this submission would take significant effort on behalf of the State Party to assemble, this level of detail need only be submitted once initially, and then amended when programs are added, updated, or otherwise modified. However, a yearly submission that comprised the number of inspections conducted (on-site and remote verification), what biosafety levels were inspected, number of announced vs. unannounced inspections, number of major non-conformities and number of enforcement activities carried out, among other possible criteria, would be reported.

7. Information submitted in this manner would enhance the current CBM process to help demonstrate a State Party's commitment to implement the BTWC on a national level, by providing a clear analysis of national legislation and the program that implements the law. This process would also be more successful at demonstrating "confidence", as each submitting State Party's national compliance and enforcement program would be available for examination, supported by inspection statistics, as well as enforcement activity statistics for the program itself. The end result could be an assessment of compliance of the national program to the BTWC.

8. As this is currently a broad concept, Canada would like to invite all interested State Parties to work with Canada to develop this concept further, to result in a system that universally supports and implements the BTWC and ultimately achieves a strong compliance assessment system.
