

**Sweden**

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The purpose of this contribution is to outline the European magnitude of sea-dumped CW munitions. Hereby the paper attempts to provide an overview on historical dumping activities, both for conventional and chemical munitions. The potential dangers which might result from these dumping activities are discussed in brief. Among others the differences in deep sea dumping and dumping in shallow waters are evaluated.

Further, the presentation will outline and discuss the different technology steps: (a) identification, (b) recovery, (c) transportation and (d) destruction (on- or off-shore), necessary for possible cleaning of dumping sites. Thereafter an evaluation of the different technologies available/applied is performed, in particular on the destruction part. Hereby the already practised experience is displayed.

Based upon existing treaty regimes an actual judgment of possible application of treaty provisions for demanding cleaning up operations is discussed. The question if treaty obligations can be used to force cleaning operations is debated.

A possible match of the technology package available with the scope/magnitude of the munitions dumping problem is discussed. Hereby the gaps between the size of the problem and the most suitable technologies for recovery and destruction are illustrated. The resulting answers should be regarded as possible technical guidelines for future development activities as well existing limitations to solve the problems.

The papers will result in some general guidelines for future prospect on the issues of dumped munitions, in particular chemical munitions under the European context.

25. OPERATIONALISING UN SECURITY COUNCIL RESOLUTION 1540: AN OVERVIEW OF SELECT PRACTICAL ACTIVITIES IN THE CHEMICAL AND BIOLOGICAL WEAPON-RELATED AREAS

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The UN member states are continuing to take measures to inter alia establish and effectively implement controls to prevent the proliferation of nuclear, biological and chemical weapons and their means of delivery in accordance with United Nations Security Council Resolution 1540 (2004). The resolution also encourages enhanced international cooperation on such efforts, including by working through the *1540 Committee*. Most analyses on the implementation of the resolution have focused on nuclear issues. This presentation provides an overview of select practical activities in the chemical and biological weapon-related areas, including chemical product classification and identification, biosafety and

biosecurity practices and criminal prosecutions for unauthorised chemical transfers.

Key Words/phrases: Biological Weapon, Biosafety, Biosecurity, Chemical Product Classification and Identification, Chemical Weapon, Transfer Controls, United Nations Security Council Resolution 1540, prosecution.

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26. IMMUNOGENICITY OF BIOPHARMACEUTICALS AND BIOSIMILARS IN RELATION TO STORAGE, HANDLING AND STABILITY

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Therapeutic proteins or biopharmaceuticals provide effective treatment for many diseases and medical conditions, and vaccines, immunoglobulins and monoclonal antibodies are critical biodefense biopharmaceuticals which constitute an indispensable part of biodefense stockpiles. The manufacturing process for biopharmaceuticals and their generic forms which are called biosimilars is far more complex than for low molecular weight drugs and generics. Any minor change made at any stage may have a critical effect on the clinical efficacy and safety. Potential immunogenicity is the key issue for biopharmaceuticals and biosimilars and may have serious clinical consequences ranging from allergy and anaphylaxis, as well as loss of efficacy of the product. Immunogenicity may be influenced by factors related to manufacturing process, formulation, aggregate formation, contaminants and impurities, and also by the factors related to the storage and handling. Stability is particularly important with larger protein molecules, because their *in vivo* effects often depend on their three-dimensional structure. Proteins usually aggregate from partially unfolded molecules and aggregates can enhance immunogenicity. Although product formulations are developed to maximize and maintain the fraction of the protein molecules present in the native state, significant amounts of aggregates can form, especially over pharmaceutically relevant time scales and under stress conditions. Exposure to air-liquid and solid-liquid interfaces, light, temperature fluctuations or minor impurities can induce aggregation. Such exposure can occur during