# WHO Global Consultative Meeting on the Safe Shipment of Infectious Substances

WHO headquarters, Geneva, Switzerland, 15–16 March 2018

**Report**

World Health Organization

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# Abbreviations

| | |
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| ACI | Airport Council International |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| BSL-4 | biosafety level 4 |
| CAPSCA | Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation |
| Cat A | Category A (infectious substances) |
| Cat B | Category B (infectious substances) |
| CDC | Centers for Disease Control and Prevention (United States of America) |
| e-ISST | electronic (online) Infectious Substance Shipping Training (WHO) |
| FAO | Food and Agriculture Organization of the United Nations |
| FTA | foam-tipped applicator (cards) |
| IAEA | International Atomic Energy Agency of the United Nations |
| IATA | International Air Transport Association |
| ICAO | International Civil Aviation Organization of the United Nations |
| IHR | International Health Regulations (2005) |
| MSDS | medical safety data sheets |
| OIE | World Organisation for Animal Health |
| PAHO | Pan American Health Organization |
| PI | packing instruction |
| polio | poliomyelitis |
| RPMASA | Responsible Packaging Management Association of Southern Africa |
| TB | tuberculosis |
| UN | United Nations |
| UNHAS | United Nations Humanitarian Aviation Services |
| VHF | viral haemorrhagic fever |
| WCO | World Customs Organization |

# Contents

# Executive summary

As part of the International Health Regulations (2005) (IHR), Member States must agree to facilitate, subject to national law and international guidelines, the transport, entry, exit, processing and disposal of biological substances, diagnostic specimens and materials for public health response. This is critical in the early detection, confirmation and development of treatments for pathogens of global health concern in clinical, veterinary and research laboratories.

To create a better understanding of the current challenges and potential solutions to increase countries' ability to comply with this aspect of the IHR, WHO held a meeting bringing together key players in the various stages of preparing, packaging, transporting and delivering infectious substances and biological materials. This enabled key stakeholders to raise awareness of their roles, share their challenges and seek joint solutions to improve the response to potential disease threats.

The participants began by focusing on two main areas:

- international classification systems and regulations for the transport of infectious substances; and
- needs and opportunities for training.

This enabled many international organizations involved in the transport of dangerous goods to give their perspectives on how the regulations affected their operations. This revealed many challenges in addressing the variable needs of the different modes of transport in a cohesive way. Changes to regulations were clearly needed; current review processes offered several opportunities to make them, but changes needed to have clear bases in scientific evidence and explicit safety records if the global shipping community was to accept them.

The participants expressed shared concerns on training needs and challenges, and cited the differences between multiple modes of transport as a key factor in preventing cohesive recommendations. While several organizations were working on developing new training methodologies and standards, a move toward competency-based training found overall acceptance. Such training would take account of job/function, have a more task-specific focus and would preferably include proficiency testing, which would encourage not only the training of the right people but also a continuing approach to learning. Using different methods of training delivery was agreed to be much better than relying on only one method.

In addition, laboratory leaders from public health agencies, particularly in challenging regions or low-resource settings, shared their perspectives. Most cited similar challenges to the shipping of infectious substances: confusing regulations, limited access to training or packaging materials, lack of access to timely courier services or airlines, and trouble maintaining the cold-chain. Many of these challenges had affected the response to the 2014 outbreak of Ebola virus disease, and much had been learned from the solutions that had emerged.

The participants also examined the lessons that could be learned from the successes of various WHO programmes in developing networks and procedures for shipping samples. Although the solutions could not readily be adapted to all situations, these lessons could be used to improve the shipment of infectious substances. A general discussion revealed that the challenges of shipping infectious substances remained numerous, but so were the potential solutions. The participants shared many ideas that could be useful in planning by both WHO and other organizations.

# Introduction to biosafety, regulations and packaging related to infectious substances

Mike Ryan, WHO Assistant Director-General Emergency Preparedness and Response, opened the WHO Global Consultative Meeting on the Safe Shipment of Infectious Substances by describing the importance of the transport of infectious substances, as a part of global health security and the IHR, in achieving WHO's mandate The purpose of the Meeting was to balance risk with safety in consideration of the huge public health benefit of shipping infectious substances for all parties involved; communication would be key in facilitating this. Other WHO staff emphasized the importance of the Meeting for biosafety, laboratory strengthening, surveillance and preparedness, and WHO's work on these issues.

This meeting was held with the following objectives:

1. Regulations and classifications association with shipment of dangerous goods, particularly infectious substances.
2. Training of various contributors to the shipping of infectious substances.
3. Quality management and oversight of the shipment process (audit trails and compliance).
4. Shipping infectious substances in emergency situations.
5. Creation of networks and focal points for shipping infectious substances.

Annexes 1–3 give the results of analysis of the participants' feedback on the Meeting, present its programme and list the participants, respectively.

Katherine Rooney, of the International Civil Aviation Organization, was appointed Chairperson for the first day of the meeting. She acknowledged the great need for progress on the problems with transporting infectious substance, which were similar across different sectors; this highlighted the potential to find cross-sectoral solutions. The chairpersons for the morning and afternoon of the Meeting's second day were Brian Crook, of the Health and Safety Executive, United Kingdom, and Brian Harcourt, of the Centers for Disease Control and Prevention (CDC), United States of America, respectively.

## United Nations model regulations on and tests of packaging of infectious substances

As well as considering the United Nations (UN) regulations on shipping infectious substances and the safety of packaging, the participants received an update on WHO's progress in revising its fourteen-year-old *Laboratory biosafety manual*.[1] Earlier versions of the manual were based on biosafety concepts that had been developed before the introduction of polymerase-chain-reaction technology, which had led to great changes in the handling of biological agents in the laboratory. This added urgency to the revision work, which was based primarily on a selection process for risk assessment and control; this deviated from previous interpretations of biosafety, which relied on a simple equation of risk groups and biosafety

[1] Laboratory biosafety manual, third edition. Geneva: World Health Organization; 2004 (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en, accessed 13 December 2018).

levels that could lead to overengineering and overregulation of laboratories and their processes. The benefits of this new approach would particularly include providing equitable access to safe laboratory services by lower-resource communities.

The UN model regulations on the transport of dangerous goods[2] were reviewed and revised every two years. They covered multiple modes of transport, as did other regulations on the shipment of infectious substances. The current classification system divided infectious substances between Category A (Cat A) and Category B (Cat B). All the Meeting participants were encouraged to take part in the current review of the regulations (see also below), to help facilitate the safe transport of infectious substances.

The participants received a demonstration of a series of practical investigations, by the Health and Safety Executive in the United Kingdom, of the safety and effectiveness of packaging specifically designed for and commonly used in the transport of infectious substances. A series of tests of packaging, primarily using a fluorescent dye to represent an infectious substance, examined whether it would remain contained in packaging subjected to challenges such as dropping, squashing and spills. These tests were applied to not only traditional packaging but also examples commonly seen in lower-resource areas. All tests showed that liquid samples, even when packaged poorly or in nonregulation ways, remained contained, although unpacking them might pose some risks. These results could be evidence to suggest that further testing may be warranted, to establish simpler but equally safe packaging for infectious substances.

### Discussion

The discussion of these issues centred mostly on the lack of information on training requirements in the UN model regulations, which was primarily due to the different requirements for different modes of transport. While technical documents from the International Civil Aviation Organization (ICAO) of the United Nations and the International Air Transport Association (IATA) provided more details, the UN regulations still needed improvement in this area. In addition, the participants welcomed the testing of packaging safety by the Health and Safety Executive, and some suggested that this be explored in more detail.

## Impact of transport regulations on countries and international organizations