Workshop on transport of infectious substances legislation for the WHO Health Emergencies Programme Balkan Hub

Istanbul, Türkiye
14–15 November 2022
Abstract

International networks for laboratory surveillance, preparedness and response are an important tool for laboratory strengthening, because they serve both as a platform for sharing information and expertise, and as a system for the referral of diagnostic specimens for primary and confirmatory testing. The WHO Regional Office for Europe established the European Regional Laboratory Task Force for High Threat Pathogens (Lab Task Force) following a preparatory meeting held in Istanbul, Türkiye in January 2019.

The Lab Task force held its second full meeting in Antalya, Türkiye, in June 2022, where issues surrounding the legislation governing infectious substance transport were presented and discussed as one of the key priority topics. In order to facilitate the shipment of infectious substances and to support Member States in this effort, a suggestion was made by Member States/areas to organize a Hub workshop dedicated to solving issues with sample transport.

KEYWORDS

LABORATORIES
INTERNATIONAL TRANSPORT
INFECTIOUS SUBSTANCES
LEGISLATION GOVERNING INFECTIOUS SUBSTANCE TRANSPORT
SAMPLE TRANSPORT
INTERNATIONAL PATHOGEN SHARING
STRENGTHENING SAMPLE SHIPMENT PROCESS

©World Health Organization 2023
Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO); WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition: Workshop on transport of infectious substances legislation for the WHO Health Emergencies Programme Balkan Hub: Istanbul, Türkiye 14–15 November 2022. Copenhagen: WHO Regional Office for Europe; 2023”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization. (http://www.wipo.int/amc/en/mediation/rules/)


Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the report of the Workshop on transport of infectious substances legislation for the WHO Health Emergencies Programme Balkan Hub held in Istanbul, Türkiye on 14–15 November 2022. It does not necessarily represent the decisions or policies of WHO.

All photos: ©WHO/Jeremy Ford
Workshop on transport of infectious substances legislation for the WHO Health Emergencies Programme Balkan Hub

Istanbul, Türkiye
14–15 November 2022
# Contents

Abbreviations................................................................................................................................................. iv
Executive summary.............................................................................................................................................. vi
Background.........................................................................................................................................................1
International agreements and comparison of transport legislation for infectious substances in the WHE countries/areas served by the WHO Balkan Hub ........................................................................................................ 3
Summary and conclusions from country presentations......................................................................................... 4
Transport regulation applicable to monkeypox and SARS-CoV-2 ........................................................................ 5
Pathogens, genomic sequence data and associated benefit sharing........................................................................ 6
Veterinary laboratory experience of transportation of infectious substances and legislation barriers ........ 7
Material transport agreements for transport of infectious substances........................................................................ 8
Sample transport for Category A infectious substances........................................................................................ 9
Dual-use regulations in the European Union........................................................................................................ 10
Import and export experience of infectious substances in the European Union: experience of Germany......11
Conclusions and way forward............................................................................................................................. 12
References ...................................................................................................................................................... 13
Additional resources ........................................................................................................................................ 14
Annex 1: Programme ........................................................................................................................................ 15
Annex 2: List of participants ........................................................................................................................... 18
Annex 3: Questionnaire results ......................................................................................................................... 19
Annex 4: Example of a multilateral agreement ................................................................................................. 26
### Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Agreement concerning the International Carriage of Dangerous Goods by Road</td>
</tr>
<tr>
<td>Better Labs</td>
<td>Better Labs for Better Health</td>
</tr>
<tr>
<td>COVID-19</td>
<td>coronavirus disease 2019</td>
</tr>
<tr>
<td>GMMO</td>
<td>genetically modified organisms and micro-organisms</td>
</tr>
<tr>
<td>Lab Task Force</td>
<td>European Regional Laboratory Task Force for High Threat Pathogens</td>
</tr>
<tr>
<td>mpox</td>
<td>monkeypox</td>
</tr>
<tr>
<td>MTA</td>
<td>material transport agreement</td>
</tr>
<tr>
<td>SARS-CoV-2</td>
<td>severe acute respiratory syndrome coronavirus 2</td>
</tr>
<tr>
<td>WHE</td>
<td>WHO Health Emergencies Programme</td>
</tr>
</tbody>
</table>
Executive summary

In the WHO European Region, international transport of infectious substances is well regulated through international agreements covering every form of transport. The shipment of infectious substances involves several different stages of sample handling. Transport regulation is therefore based on numerous laws and international agreements. The enforcement and implementation of these laws differ widely from one country or area to another.

In 2012 the WHO Regional Office for Europe launched the Better Labs for Better Health initiative (Better Labs) (1). Better Labs focuses on strengthening the core country laboratory capacities required under the International Health Regulations (IHR) (2005) (2).

International networks for laboratory surveillance, preparedness and response are an important tool for laboratory strengthening, because they serve both as a platform for sharing information and expertise, and as a system for the referral of diagnostic specimens for primary and confirmatory testing. The WHO Regional Office for Europe established the European Regional Laboratory Task Force for High Threat Pathogens (Lab Task Force) following a preparatory meeting held in Istanbul, Türkiye in January 2019.

The Lab Task force held its second full meeting in Antalya, Türkiye, in June 2022, where issues surrounding the legislation governing infectious substance transport were presented and discussed as one of the key priority topics. In order to facilitate the shipment of infectious substances and to support Member States in this effort, a suggestion was made by Member States/areas to organize a Hub workshop dedicated to solving issues with sample transport.

Objectives of the meeting:

- Review the present national transport legislations and provide information on the international sample transport regulation. Discuss the international, national and, European Union dual-use regulations.
- Discuss the regulatory achievements and needs for the transport legislation of infectious substances (e.g. severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), monkeypox) evolved in the ongoing pandemic.
- Identify problems and challenges for the shipment of infectious substances, particularly with the transport of Category A samples. Provide information on the use of material transfer agreements to resolve some of these issues.
- Provide information on international pathogen sharing and its related regulation.
- Discuss recommendations for strengthening the sample shipment process in the WHO Health Emergencies Programme (WHE) countries/areas served by the WHO Balkan Hub.

Discussions and experience sharing during the meeting showed that specific support needs to be given in the organization of training and education on this multifaceted topic. This will include organizing country missions throughout the countries/areas served by the WHO Balkan Hub in order to develop best practice.
In 2012 the WHO Regional Office for Europe launched the Better Labs for Better Health initiative (Better Labs) (1). Better Labs focuses on strengthening the core country laboratory capacities required under the International Health Regulations (IHR) (2005) (2).

Better Labs focuses on four areas:

- Area 1: Developing national laboratory policies and strategic plans.
- Area 2: Improving national training programmes and implementing laboratory quality management systems.
- Area 3: Establishing networks for emergency preparedness and response. This includes strengthening national public health laboratories in preparedness and response to high threat pathogens and supporting the development and implementation of strategies for the control and prevention of these pathogens.
- Area 4: Advocacy, partnership and leadership.

In the WHO European Region, international transport of infectious substances is well regulated through international agreements covering every form of transport. The shipment of infectious substances involves several different stages of sample handling. Transport regulation is therefore based on numerous laws and international agreements. The enforcement and implementation of these laws differ widely from one country or area to another.

International networks for laboratory surveillance, preparedness and response are an important asset for laboratory strengthening, because they serve both as a platform for sharing information and expertise, and as a system for the referral of diagnostic specimens for primary and confirmatory testing. Better Labs recognised the need for a network to address international laboratory preparedness and response to high threat pathogens for the WHO priority Member States and areas. The WHO Regional Office for Europe therefore established the European Regional Laboratory Task Force for High Threat Pathogens (Lab Task Force) following a preparatory meeting held in Istanbul, Türkiye in January 2019.

The Lab Task force held its second full meeting in Antalya, Türkiye, in June 2022, where issues surrounding the legislation governing infectious substance transport were presented and discussed as one of the key priority topics. In order to facilitate the shipment of infectious substances and to support Member States in this effort, a suggestion was made by Member States/areas to organize a Hub workshop dedicated to solving issues with sample transport.

Better Labs provide supports in establishing and improving national transport and referral systems for public health laboratory samples while advocating for safe and high-quality transport throughout the WHO European
Background

Region. An assessment of capabilities was carried out between July 2019 and May 2022 for WHO Health Emergencies Programme (WHE) priority countries. In June 2022, the results of this study were presented as a ‘Report on the assessment of national laboratory diagnostic capacities for (re)emerging pathogens’ at the Lab Task Force second meeting in Antalya, Türkiye (3).

This identified some gaps, which the present workshop (Istanbul, Türkiye, 14–15 November 2022) was organized to address. For the programme of the workshop, see Annex 1; for the list of participants, see Annex 2. Many Member States have raised the issue of sourcing reliable and timely courier services as well as problems with national transportation systems in general. These issues were especially common for Category A samples.

The use of material transfer agreements is currently very limited among Member States. Feedback from a questionnaire handed out at the meeting suggested that further training on the use of this type of agreement might help strengthen national sample referral systems.

The purpose of this workshop was to support WHE countries/areas served by the WHO Balkan Hub in improving the shipment of samples through information sharing and discussions and, potentially to propose adjustments to Member State legislation. The ultimate aim is to sustainably facilitate the shipment of infectious substances (e.g. SARS-CoV-2, monkeypox) within and between countries/areas.

Objectives of the workshop

- Review present national transport legislation and provide information on international sample transport regulation in the Balkan region. Discuss international, national and European dual-use regulations.
- Discuss the regulatory achievements and needs for the transport legislation of infectious substances (e.g. SARS-CoV-2, monkeypox) evolved in the ongoing pandemic.
- Identify problems and challenges for the shipment of infectious substances, particularly with the transport of Category A samples. Provide information on the use of material transfer agreements to resolve some of these issues.
- Provide information on the international pathogen sharing and its related regulation.
- Discuss recommendations for strengthening the sample shipment process in the WHE countries/areas served by the WHO Balkan Hub.
Transport legislation in the WHE Balkan Hub

Within the Member States and areas covered by the WHO Regional Office for Europe, the sample transportation chain generally starts in the packaging and shipping department of an institute. By the time the shipment arrives, its journey may have included transport by hand, mail or courier, which may be within one country or cross national borders and continents. Every step in this process is an opportunity for issues to occur.

Good preparation and training are essential to avoid problems in the shipment of infectious substances. Regulations on transport of infectious substances include preparing, packaging, transporting and delivering, disposal of and, prevention and handling of spilling incidents of infectious substances and biological materials. Many different pieces of legislation cover these specific areas.

The following is a short list of reasons why a review of legislation regarding shipment of infectious substances is urgently needed (please note that this is not an exhaustive list):

- physical sharing of pathogens and external quality assessment samples is needed;
- ongoing proposals for amendments to the IHR (2005) and the negotiations on a future treaty on pandemic prevention, preparedness and response\(^1\), include provisions on access and benefit pathogen sharing, as well as Intellectual property rights;
- confusing, ambiguous regulations;
- approximation to European Union laws;
- forthcoming legislative developments that are being announced all the time; and
- biosecurity and biosafety reasons.

Nearly every Member State in the WHO European Region has ratified the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (4) and its Annex A, which provides the basis for the practical handling of the shipment of infectious substances.

The Nagoya Protocol and its related national access and benefit-sharing laws and regulations are now in place. In order to fulfil the provision set out in this protocol, signatory countries will adopt best practices and rational processes to adhere to the Protocol. Mechanisms (such as material transfer agreements) exist that facilitate pathogen sharing and related access benefit-sharing arrangements (5).

Non-compliance, for example non-existent access consent or a failure to utilize benefit-sharing agreements, may result in considerable restrictions on the ability to export. In the discussion, number of countries and their respective laboratories or institutes mentioned having already experienced such restrictions.

\(^1\)The future WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response is being prepared by the Intergovernmental Negotiating Body established by the World Health Assembly.
Country/area presentations summary

Summary and conclusions from country presentations

Using a template which was provided, countries and areas were invited to briefly present their national legislation relating to the transport of infectious substances, as well as challenges and issues in the context of shipment of infectious substances.

The various individual mandates that exist for the regulation of the shipment of infectious substances often mean that laws and regulations are not harmonized or revised – an issue which was raised by many participants at the meeting. Most countries/areas have ratified multiple international agreements for different methods of transport. These include the ADR Agreement for the safe transport of dangerous goods by land transport.

Some countries/areas have developed general national protocols/guidelines/guidance documents for collection, transport, storage of samples and protection measures in accordance with WHO guidelines, as opposed to being disease-specific.

The technical capacity of some of the institutions that grant the import/export needs to be strengthened in order to better understand the actual contents of infectious sample shipments. Currently this issue can lead to delays of up to 2–3 weeks or more when applying for permits.

Other countries/areas have adopted laws on control of the export of goods and technologies for dual use (items which can be used for both civil and military purposes) and have approved dual-use lists. Such lists describe dual-use goods and technologies, as well as lists of countries, organizations, entities or individuals that are subject to export restrictions with regard to dual-use goods and technologies.

Some countries/areas are in the stage of implementing dual-use laws, while in others laws and regulations for dual-use are completely lacking. The use of material transfer agreements is very different in every institution or laboratory in the country/area.

In conclusion, participants from countries/areas expressed common issues in sample shipment:

- Insufficient laws and regulations relating to infectious substance shipments
- Lack of cross-border harmonization regarding infectious substance shipping legislation
- Import or export permit requirements and customs regulations often hinder transportation
- Technical capacity needs to be strengthened
- Shipments are frequently delayed, take a prohibitively long time to be delivered, or are not delivered at all
WORKSHOP ON TRANSPORT OF INFECTIOUS SUBSTANCES LEGISLATION
REGULATIONS APPLICABLE TO MONKEYPOX AND SARS-COV-2 TRANSPORTATION

Mpox and SARS-CoV-2 transportation

Regulations applicable to mpox and SARS-CoV-2 transportation

Various international and national regulations exist which apply specifically to transportation, including infectious substances. Generally, the United Nations Model Regulations on the Transport of Dangerous Goods (6, 7) are considered as the foundation upon which more specific regulations are layered, such as the Technical Instructions For The Safe Transport of Dangerous Goods by Air (8), the ADR Agreement for road transportation and instruments of the Universal Postal Union for mail. This is in addition to the national regulations of each country.

In the Model Regulations, infectious substances come under Division 6.2, while viral vector-based vaccines are regulated as genetically modified microorganisms (GMMOs). On WHO advice, the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods agreed that GMMO vaccines which are authorized for use, including those in clinical trials, are not subject to the Model Regulations as currently written (9).

Division 6.2 defines a Category A substance as “an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals”, with an indicative list of such pathogens (5, 10).

Both clinical specimens and cultures of monkeypox virus are found on the indicative list of Category A substances, leading to considerable challenges in timely and cost-effective transportation of clinical specimens. Such bottlenecks have a profound impact on the ability to respond effectively to a health emergency, such as a monkeypox outbreak, with the global unprecedented circulation of this disease affecting 110 countries with around 80 000 cases as at November 2022 (10).

The Sub-Committee has now ruled that clinical specimens of monkeypox cases are to be exempt from Category A classification, although it will be some time before this agreement is fully formalized.

Packing instructions state that both Category A (packing instruction P620) and B (P650) substances be packaged in the same way and suggest that using a triple packaging system is sufficiently safe for both types of sample transportation. The main difference in packaging between Category A and Category B lies in the drop test. The test specifies that, if a package is dropped, the content should not be harmed.

The requirements for both Categories A and B are quite strict and provide a very high level of safety in practice. It is therefore desirable to review and optimize the indicative list of Category A, especially for clinical specimen shipment from a public health perspective.
International pathogen sharing

Pathogens, genomic sequence data and associated benefit sharing

The concept of benefit sharing is completely reliant on the ability to physically transport infectious substances and share associated data. This fact was recognized early on in the pandemic and led to the rapid creation of the COVID-19 (coronavirus disease 2019) Reference Laboratory Network (11) to provide a reference function.

The pandemic highlighted the importance of physical sharing of samples right from the outset. Setting up new methods and systems of effectively sharing and referring samples remained difficult during the pandemic and laboratory personnel became very innovative as a result.

Sharing of samples and associated data raised common questions from laboratory personnel and researchers during the COVID-19-pandemic, largely falling into the following three categories.

- Researchers and laboratory personnel expressed concerns over sharing their data more publicly as they doubted whether their contributions would be acknowledged. They want reassurance that their data will actually lead to medical products being developed for their own countries/areas based on the sequences they share.

- A survey requested in decision WHA72(13) by WHO Member States on the public health implications of the Nagoya Protocol and current pathogen-sharing practices and arrangements (13) highlighted a patchwork of varying practices and networks. Sharing often happened only in pre-existing networks with long-standing arrangements. The survey results also made clear the potential public health implications of pathogen-sharing arrangements and access and benefit-sharing measures.

- There was general agreement from responders that minimizing the public health and economic risks associated with outbreaks requires timely pathogen sharing.

The survey highlighted a general lack of awareness among the stakeholders of the Nagoya Protocol and its requirements, as well as the flexible implementation options available to any country in implementing access and benefit-sharing measures.
Infectious substance transport–veterinary

Veterinary laboratory experience of transportation of infectious substances and legislation barriers

The World Organization for Animal Health states that all personnel involved in the packaging, labelling and shipping of biological materials must be appropriately trained, certified, competent and knowledgeable of the relevant national, regional and international regulations (14).

The efficient transport and transfer of biological materials within the veterinary sector requires coordination between multiple stakeholders. These include the sender (shipper, consignor), the logistic providers, the courier and the recipient (consignee) to ensure safe transport and arrival on time and in proper condition. During the transport of infectious veterinary material the sender, carrier and recipient all have additional, specific responsibilities.

Infectious substances in the veterinary sector are classified as dangerous goods and are assigned to International Air Transport Association Dangerous Goods Regulations shipping categories UN 2814, UN 2900, UN 3373 or UN 3291, as appropriate. In addition, genetically modified organisms and GMMOs are classified as Class 9 and assigned to UN 3245 if they are not classified as Category A or Category B.

In Western Balkan countries, the public veterinary sector consists of veterinary administration (veterinary directorate, veterinary office, food and veterinary agency) and national veterinary institutes (diagnostic establishments, research institutes, within the faculty or independent institutions). European Union and candidate countries should have a designated national reference laboratory (normally part of an institute) for certain, specified animal diseases (avian influenza, rabies, African and classical swine fever, lumpy skin disease).

All national laboratories in the Western Balkans are part of the European system of national reference laboratories, which is coordinated by the Central European Reference Laboratory. The majority of national reference laboratories in Western Balkan countries have established procedures for shipment of infectious material (Categories A and B) to European Union reference laboratories (15). The main gap is a lack of adequate national legislation throughout most of the region. In some countries, the long process of obtaining import/export permissions remain a significant challenge.

The majority of laboratories have adopted procedures for sending and receiving material within the country. Many issues remain, though, such as lack of appropriate packaging materials, shortage of trained staff and very few officially approved courier companies. It was suggested that the revision of the national legislation could be the first step, to resolve some of this issues.
Material transfer agreements

Material transport agreements for transport of infectious substances

A material transport agreement (MTA) is a legal instrument to handle the complex context of sharing pathogens. With the current industrial scale of scientific research involving biological materials, associated property claims and upcoming and established access and benefit-sharing legislation, an effective legal instrument is more urgently required than ever before.

An MTA represents a contract that governs the transfer of tangible or even intangible materials (such as data or software) between two organizations, when the recipient intends to use it for a certain purpose (e.g. to fulfill obligations under public health regulations) (16).

The volume demand for shipment of infectious substances/samples can be unpredictable and is very dependent on circumstances. There are periods where large volumes need to be shipped on a daily basis and then times when small occasional samples need to be transported only every few days or even months. This makes shipment transportation extremely difficult to plan in advance, which leads to delays and laborious applications for shipment permits. The application of a standard contract such as an MTA can cover complex issues and reduce otherwise labour-intensive legal processes, helping to ensure timely access to diagnosis and research.

There are a number of scenarios where an MTA might help to clarify the conditions associated with the movement or use of samples and associated data:

- export or international movement of samples and associated data;
- domestic movement of samples and associated data to a separate legal entity (or in some cases perhaps even to a different part of the same legal entity);
- determining the potential use or further distribution of samples and associated data shared for one purpose, but with the possibility for additional use;
- applications or purposes with specific rules or regulations, or when a third party such as a government agency (e.g. public health institute, ministry of health) needs to be involved;
- the material being moved has a potentially important intrinsic value (either in the material itself or in the possibility of using it in other processes or in product development).
Sample transport for Category A infectious substances

The discussions in the workshop, as well as the results of the questionnaire completed during the meeting (see Annex 3), highlighted a number of issues. First and foremost, further support is needed with the shipment of Category A substances and understanding of laws and regulations. These issues were mentioned by many countries/areas, with a need to adopt and harmonize different areas of law. With regard with the recent monkeypox outbreak, the possibility of a temporary derogation for infectious substances was discussed, i.e. moving monkeypox, currently listed in Category A in Annex A of the ADR, to Category B in order to facilitate sample shipment and sharing between countries.

The definition of a Category A infectious substance (see section Transport regulations applicable to monkeypox virus and SARS-CoV-2 above) has been adopted by many international and national authorities to harmonize the safe shipment of infectious substances. Category A infectious substances are therefore covered by strict, comprehensive regulations governing the way in which they must be packaged and transported.

Participants raised just some of the issues that can cause problems when shipping Category A samples:

• the required/correct/full documentation is not shipped with the sample;
• the package and its contents are incorrectly labelled;
• the infectious substance and/or its packaging are somehow destroyed or damaged en route;
• shipment documentation is found to be either incorrect or incomplete at a border check; in this case, the process of having documents corrected can take a long time;
• lack of trained staff with technical knowledge at border control so that frozen infectious substances are incorrectly stored (dry ice is not topped up for example), or storage facilities at the border control are not suitable for frozen infectious substances;
• there is a lack of import or export regulations on arrival in the destination country;
• there is a lack of shippers;
• there is no access and benefits sharing or dual-use regulation in place, either at the destination or in the country of origin.

Some known workarounds were suggested to solve some of these issues but it was agreed that none of them was ideal nor perfect. Discussions to find solutions are ongoing and continue.
Dual-use regulations

Dual-use regulation in the countries/areas served by the WHO Balkan Hub

Huge advances in biomedical research are offering possibilities and opportunities. The COVID-19 pandemic rapidly stimulated the ability to develop and adopt novel sequencing methods, new reagents and capabilities for polymerase chain reaction testing, at a pace and scale never witnessed before.

However, it is also recognized, particularly in the context of dual-use legislation, that there is potential for scientific and technological advances to be exploited for malicious or harmful purposes. Gain-of-function and high-consequence research pose a real threat to humanity, due to the intrinsic associated risk once they are released, and should therefore be well regulated.

There is a fine balance to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products or technologies that it can offer. This balance is not easy for governments to maintain or achieve.

It was suggested by the participants to perform a review of their national dual-use legislation for the following reasons:

- shipping can be slowed down, or completely blocked, if the legislation of the receiving country does not include a secure import procedure such that the exporting country refuses to grant a high threat pathogen export permit;
- lack of knowledge to acquire licences can result in heavy fines and criminal charges;
- disqualification measures for the exporting company (“exclusion form the EU-list of known shippers”) may be imposed;
- the dual-use regulations are one normative element in the approximation process towards European Union membership.

The European Union, as a supranational entity, is mandated by its Member States to handle its established unified customs union, and has accordingly implemented dual-use regulations for the export and import of dual-use goods (17). For biomedical research purposes and shipment of biological materials, the relevant dual-use list established and updated by the Australia Group is enforced through European Union regulation No. 2021/821 and its amendments. European Union law requires Member States to put in place licensing procedures for the control of exports of dual-use items. In order to export certain goods, the exporter must be in possession of a dual-use licence.
European Union import and export: case study

Import and export experience with infectious substances in the European Union: experience of Germany

The shipment of infectious substances across national borders requires compliance with various areas of law. Using Germany as an example, the legal areas for handling infectious substances of animal and human origin in the laboratory (Biological Agents Ordinance, Genetic Engineering Safety Ordinance, Protection against Infection Act/Epizootic Pathogens Ordinance), their shipment by road (ADR) and air (Technical Instructions For The Safe Transport of Dangerous Goods by Air), as well as customs clearance during export and import (European Union Customs Code, Export Control Regulation), will be presented (18).

An internal service (liaison office) provides helpful support for employees for export controls, dangerous goods shipments and customs declarations. This also ensures centralized record-keeping about export and import events at BNITM Transport, the transport arm of the Bernhard Nocht Institute for Tropical Medicine. It was recommended that laboratories or institutions should establish such a liaison office for transport issues that is also competent to handle the necessary legal documents, like material transfer agreements.

Export control of dual-use items: infectious material under UN 3373 or UN 2814 may constitute a dual-use item under the dual-use system. Export permission is needed to export this material. An online application must be submitted to the Federal Office for Economic Affairs and Export Control.

The German customs code is aligned with the Union Customs Code (19) and cites a long list of different laws, which might apply when shipping an infectious substance. These relate to:

- Customs duties
- Levy import duties (customs, taxes etc.)
- Protection of society/human health (drugs, weapons, trademark rights etc.)
- Protection of the economy (undeclared work)
- Security (execute export control)
- Protection of wildlife (protection of species, nature conservation)
- Protection of the environment (illegal waste etc.)
- Levy national taxes (car taxes, minimum wage law)

For the importation of human pathogens, permission papers according to the infection protection act are sufficient. For animal pathogens listed as epizootic pathogen and for material which still contain animal products (animal specimen, cultures with fetal bovine serum etc.) import permission is still required. In the case of transfers, end-user check and proof of transfer is mandatory.

The presentation demonstrated the high density of regulations in Germany and the associated effort for the persons involved in the shipment.
Conclusions and way forward

Working in groups, participants were asked to consider and list the constraints on the import and export of infectious substances and to suggest recommendations to overcome them.

The countries/areas served by the WHO Balkan Hub are at very different stages and levels when it comes to implementing their individual legislations on transport of infectious substances.

A common theme for all groups was a lack of coordination and communication between stakeholders regarding the legislation component of the transport of infectious substances and a lack of biosafety and biosecurity regulations at national level. Participants requested support from WHO to strengthen guidances, operating procedures to help standardize regulations surrounding infectious substance transport.

It was proposed that these might be developed in accordance with WHO guidelines, European Union regulations and international agreements. It was also suggested that material transfer agreements might be mandatory and that an infectious substance transport liaison office could be established.

The issue of insufficient funding was raised several times, as well as a poor level of awareness and training for all involved in the transport process. This is compounded by a lack of understanding of the potential risks posed by infectious substances for both health staff and laboratory personnel. Transport needs to be budgeted as a standalone, specific item.

Harmonization of legislation will be a key factor in helping to improve the system overall. It was suggested that regulations and procedures should be revised and clear pathways developed, with training modules supported by WHO.

It was suggested by participants that WHO acts as a facilitator in improving the facilitation and harmonization of infectious substance transportation legislation in the Balkan Hub. Participants also requested WHO to provide technical support for the process of national harmonization of related transportation laws and the development of guidelines. Specific support was also requested for the organization of training and indeed education on this multifaceted topic.

The workshop was performed in a constructive and collaborative atmosphere, which was clearly reflected in the very positive feedback from participants. A similar workshop for the Central Asian countries is planned for 29–30th of March 2023 in Almaty.
References


Additional resources


Annex 1

Programme

Workshop on transport of infectious substances legislation for the WHE Balkan Hub 2022
Istanbul

17 November 2022
Original: English

Programme

Purpose

The overall purpose of the workshop is to support WHE Balkan Hub countries/areas to improve sample shipment through information sharing, discussions and potentially proposing adjustments to Member States’ legislations. This should facilitate sustainably the infectious substances’ shipment (e.g. SARS-CoV-2, Monkeypox) within countries/areas and between countries/areas.

The specific objectives of the workshop:

- Review the present national transport legislations and provide information on the international sample transport regulation. Discuss the international, national, and EU Dual-Use regulations.
- Discuss the regulatory achievements and needs for the transport legislation of infectious substances (e.g. SARS-CoV-2, Monkeypox) evolved in the ongoing pandemic.
- Identify problems and challenges for the shipment of infectious substances, particularly with the transport of Category A samples. Provide information on the use of material transfer agreements (MTA) to resolve some of these issues.
- Provide information on the international pathogen sharing and its related regulation.
- Discuss recommendations for strengthening the sample shipment process in the WHE Balkan Hub countries/areas.

Monday, 14 November 2022

08:30 – 09:00  Registration
09:00 – 09:20  Official opening of the meeting, introduction of the participants, meeting agenda and objectives
               Joanna Zwetyenga, WHO Regional Office for Europe
09:20 – 09:30  WHO Euro Lab Taskforce for High Threat Pathogens
               Joanna, Zwetyenga, WHO Regional Office for Europe
Session 1: Overview of the current situation on the transport of infectious substances

09:30 – 10:00 International agreements and comparison of transport legislation for infectious substances in the WHE Balkan Hub countries/areas

Markus Huber, WHO Regional Office for Europe

10:00 – 10:30 Albania

10:30 – 11:00 Bosnia and Herzegovina

• The Federation of Bosnia and Herzegovina
• The Republika Srpska

11:00 – 11:30 Coffee Break

11:30 – 12:00 Kosovo

12:00 – 12:30 Republic of Moldova

12:30 – 13:00 North Macedonia

13:00 – 14:00 Lunch Break

Session 2: Transport of category A infectious substances

14:00 – 14:20 Transport regulation and difference for Monkeypox and SARS-COV 2

Kazunobu Kojima, WHO headquarters

14:20 – 14:30 Open discussion: Experience sharing & needs for further support from WHO on the international transport of Monkeypox or SARS-COV 2

Session 3: Country example from the European Union for the transport of infectious substances

14:30 – 15:00 Netherlands

Sanne van den Hengel (online), National Institute for Public Health and the Environment

15:00 - 15:15 Q&A, Questionnaire

15:15 – 16:00 Coffee Break & Group-Photo

Session 4: International pathogen-sharing regulation and experiences

16:00 – 16:30 Pathogen, GSD sharing & associated benefit sharing outside influenza, WHO BioHub

Vasee Sathiyamoorthy (online), WHO headquarters

16:30 – 17:00 Open discussion to facilitate international pathogen sharing

17:00 – 17:10 Wrap-up: Takeaways from session 1 – 4

---

1 All references to Kosovo (in this document) should be understood to be in the context of United Nations Security Council resolution 1244 (1999)
Tuesday, 15 November 2022

Session 5: Transport of infectious substances in the veterinary sector
09:30 – 10:00  Experience from the veterinary laboratory side on the transport of infectious substances and legislation barriers
Bojan Adzic, Diagnostic Veterinary Laboratory, Montenegro

Session 6: MTA
10:00 – 10:30  MTA for transport of infectious substances
Markus Huber, WHO Regional Office for Europe
10:30 – 10:45  Open discussion: Q&A on MTA’s
10:45 – 11:15  Coffee Break

Session 7: Transport of category A infectious substances
11:15 – 11:45  Sample transport of category A infectious substances
Markus Huber, WHO Regional Office for Europe
11:45 – 12:15  Open discussion: Needs for an effective category A sample transport in the WHE Balkan Hub
12:15 – 13:15  Lunch Break

Session 8: Import/Export legislation and barriers
13:15 – 13:45  Dual Use regulations in the EU
Markus Huber, WHO Regional Office for Europe
13:45 – 14:30  Import and export experience of infectious substances in the EU
Toni Rieger, Bernhard Nocht Institute for Tropical Medicine

Way forward, next steps and feedback
Group discussion:
- Constraint regarding import and export barriers, recommendations to overcome these
- Next steps from countries/areas and how can WHO be a facilitator for countries/areas in improving their shipment issues

14:30 – 15:20

Wrap-up: Takeaways from session 5 - 7

End of meeting
15:30 – 15:45  Official ending of the meeting
Joanna Zwetyenga, WHO Regional Office for Europe
Annex 2

List of participants

Albania
Artan Bego
Aida Demo
Klea Pashollari
Bukurie Hyseni

Bosnia and Herzegovina
Marina Milovanovic
Visnja Mrdjen
Tanja Ilic
Maja Ostojic
Aida Kavazovic
Elvira Hodzic

Germany
Toni Rieger

Republic of Moldova
Oxana Burac
Tatiana Ilgunova
Oxana Groza

Montenegro
Bojan Adzic

North Macedonia
Biljana Celevska
Roberto Cvetkovski
Golubinka Boshevska

WHO
Joanna Zwetyenga
Abebayehu A. Mengistu
Jeremy Ford
Maria Valeria Amante
Kazunobu Kojima
Slavica Stojkovic
Markus Huber
Ioannis Karagiannis
Isme Humolli

Kosovo[1]
Aferdita Kuci
Zana Kacaniku Deva
Donjeta Hajdari
Rrezarta Bajrami Halili
Pranvera Abazi

Annex 3

Questionnaire Results

Questionnaire: 
Shipping of infectious substances

1. In your experience, for what purposes were the infectious substances sent or received?

- Research purposes: 7
- Diagnostic purposes: 16
- Conformance testing: 16
- Other: 0

2. Who financed the shipment in case of receiving infectious substances?

- Your institution/laboratory: 4
- Your government: 1
- The sending diagnostic/research institute/laboratory: 11
- The sending government: 1
- N/A: 0
- Other: 1
3. Who financed the shipment in case of sending infectious substances?

- Your institution/laboratory: 8
- Your government: 1
- The receiving diagnostic/research institute/laboratory: 7
- The receiving government: 0
- N/A: 0
- Other: 2

4. What problems have you encountered in sending infectious substances?

- No problems: 3
- Delay: 8
- Damaged samples: 2
- Sample got blocked at customs: 13
- Veterinary check at the border blocked the sample: 0
- Financial or funding issue: 9
- Other: 0

5. What problems have you encountered in receiving infectious substances?

- No problems: 2
- Delay: 8
- Damaged samples: 4
- Sample got blocked at customs: 15
- Veterinary check at the border blocked the sample: 3
- Financial or funding issue: 7
- Other: 0
6. How long does the shipment of infectious substance to a neighboring country usually take?

- 1–3 days: 9
- 4–5 days: 3
- 5–7 days: 4
- >7 days: 2

7. How long does the shipment of infectious substance to a reference laboratory in the EU usually take?

- 1–3 days: 3
- 4–5 days: 2
- 5–7 days: 5
- >7 days: 7

8. Was Dual Use legislation at some point an issue for your institution/laboratory in regard to shipping infectious substances?

- Yes and we would like to get support in further understanding this topic: 2
- Yes: 1
- No, but we would like to get support in further understanding this topic: 13
- N/A: 2

9. What problems occurred during the receiving of EQA panels?

- 15 Responses

Common issues mentioned:

- "Financial issues"
- "Incorrect customs code applied/tariff law"
- "Long delays or blocked at customs/border"
10. Do you or your institution/laboratory have experience with the Nagoya-protocol?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, but we would like to get support in further understanding this topic</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
</tr>
<tr>
<td>No, and we would like to get support in further understanding this topic</td>
<td>8</td>
</tr>
<tr>
<td>N/A</td>
<td>3</td>
</tr>
</tbody>
</table>

11. Was Access and Benefit sharing legislation at some point an issue for the shipping process?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, and we would like to get support in further understanding this topic</td>
<td>6</td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>No, but we would like to get support in further understanding this topic</td>
<td>8</td>
</tr>
<tr>
<td>N/A</td>
<td>0</td>
</tr>
</tbody>
</table>

12. Were international agreements regarding animal pathogens/byproducts, or the CITES agreement in the shipment of samples an issue for the shipping process?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, and we would like to get support in further understanding this topic</td>
<td>8</td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>No, but we would like to get support in further understanding this topic</td>
<td>6</td>
</tr>
<tr>
<td>N/A</td>
<td>1</td>
</tr>
</tbody>
</table>
13. Was import or export of Category A samples an issue?

- Yes, import or export was an issue, please indicate why in the next question: 10
- No: 5
- N/A: 2

14. If import or export of Category A samples was an issue, please indicate why

Common issues mentioned:
- "No procedure/protocol available"
- "Long delays in getting permit"
- "No licence available for Category A"
- "Lack of containers for shipment"
- "Lack of courier companies able to take shipment"

15. Was import or export of Category B samples an issue?

- Yes, import or export was an issue, please indicate why in the next question: 7
- No: 8
- N/A: 3

16. If import or export of Category B samples was an issue, please indicate why

Common issues mentioned:
- "Financial issues"
- "Problems with customs codes"
- "Tariff laws"
17. Was there any country specific issue? (no mentioning of the country necessary)

- Yes, please indicate why in the next question: 4
- No: 4
- Maybe: 10

18. Was there any country specific issue, yes, please indicate why

6 Answers

Country issues mentioned

"Meeting the criteria of EU country legislation"
(This was a common issue mentioned)

19. What can be facilitated in your point of view in the shipment process?

- Everything is good: 0
- Availability of timely courier service: 0
- Availability of packaging material: 0
- Availability of dry ice: 0
- Accessibility and timing of documents: 1
- Financing or funding the shipment: 2
- Regulations or legal matters: 14
- Simplicity of the process: 1

20. Are the documents for import and export easily accessible?

- Yes: 7
- No: 10
- N/A: 1
21. What is for you or your laboratory/institution the most urgent area for improvement to facilitate the shipment of infectious substances?

Common issues mentioned

"Improvements/revision to law/regulations"
"More training" "More financial support"
"Better coordination of stakeholders"
"Certification of more lab staff"

16 Answers

22. Do you use MTAs for shipping of samples?

- Yes: 8
- No: 10
- N/A: 0
Multilateral Agreement example

Multilateral Agreement M347
under section 1.5.1 of ADR on
the carriage of monkeypox virus

(1) By derogation of Paragraph 2.2.62.1.4.1, Section 3.2.1. (Table A, Dangerous Goods List) and Chapter 4.1 of ADR, infectious substances containing monkeypox virus except for cultures of monkeypox virus may be carried under UN 3373 or UN 3291, as appropriate.

(2) The consignor shall include the following entry in the transport document: “Carriage in accordance with Multilateral Agreement M347”.

(3) This agreement shall be valid until 31 December 2025 for carriage on the territories of those ADR Contracting Parties signatory to this Agreement. If it is revoked before that date by one of the signatories, it shall remain valid until the above-mentioned date only for carriage on the territories of those ADR Contracting Parties signatory to this Agreement, which have not revoked it.

Bonn, 27. June 2022

The competent authority for ADR of the Federal Republic of Germany

For the Federal Ministry of Digital and Transport

Linda Rathje-Unger
The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States:

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
North Macedonia
Malta
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Türkiye
Turkmenistan
Ukraine
United Kingdom
Uzbekistan