Workshop on transport of infectious substances legislation in central Asia

Almaty, Kazakhstan
29–30 March 2023

Report
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. In order to facilitate the shipment of infectious substances and to support Member States in this effort, a workshop dedicated to solving issues of sample transport in the central Asian subregion was held in Almaty, Kazakhstan, on 29 and 30 March 2023. Participants discussed national and international regulations and material transfer agreements governing the transport of infectious substances, particularly SARS-CoV-2 and monkeypox virus, and highlighted gaps and areas requiring support in their national legislations.

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MEDICAL LEGISLATION
VETERINARY LEGISLATION
PATHOGENICITY
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INFECTIOUS DISEASES

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<tr>
<td>ADR</td>
<td>Agreement concerning the International Carriage of Dangerous Goods by Road</td>
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<td>Better Labs</td>
<td>Better Labs for Better Health initiative</td>
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<td>COVID-19</td>
<td>coronavirus disease 2019</td>
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<td>EQA</td>
<td>external quality assessment</td>
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<td>GMO</td>
<td>genetically modified microorganisms</td>
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<td>Lab Task Force</td>
<td>European Regional Laboratory Task Force for High Threat Pathogens</td>
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<td>MTA</td>
<td>material transfer agreement</td>
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<td>NTP</td>
<td>National Tuberculosis Program</td>
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<td>SARS-CoV-2</td>
<td>severe acute respiratory syndrome coronavirus 2</td>
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<td>TAT</td>
<td>turnaround time</td>
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<td>WHE</td>
<td>WHO Health Emergencies Programme</td>
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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). Better Labs focuses on strengthening the core country laboratory capacities required under the International Health Regulations.

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, the suggestion was made to organize a workshop on the transport of infectious substances legislation in central Asia.

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 virus) 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) central Asian countries.
Background

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)).

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 countries. 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, the suggestion was made to organize a 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 Region. An assessment of capabilities was carried out between July 2019 and May 2022 for WHO Health
Background

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 this and the previous workshop (Istanbul, Türkiye, 14–15 November 2022) were 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 central Asian countries 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 virus) within and between countries.

Objectives of the workshop

• Review present national transport legislation and provide information on international sample transport regulation in central Asia. 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 virus) 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 central Asian countries.
Within the Member States 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 to 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.
Participant presentations

Using a template which provided by the Secretariat, participants from Kazakhstan, Kyrgyzstan, Turkmenistan and Uzbekistan were invited to present their national legislation relating to the transport of infectious substances. They also presented the challenges, issues and recommendations in the context of shipment of infectious substances in their individual Member States.

Participants reported a general lack of established comprehensive national legislation and the need for harmonization of legislative systems for infectious substance shipping throughout the central Asian region. It was suggested that better interdepartmental coordination and experience sharing both at the national level and between countries might help to achieve this.

The process of applying for and obtaining permits and the necessary legal documents for infectious substance transportation is often bureaucratic/complex and leads to lengthy delays in sending and receiving goods, sometimes as long as two months. It was pointed out that existing WHO guidelines, key documents and training modules need to be translated into Russian. Support was also requested for the development and updating of national documents and standard operating procedures.

Participants highlighted poor availability of suitable packaging materials (dry ice for example), and suggested that reliable courier services need to be identified in order to create a central database of recommended transport companies.

There appears to be a lack of certified national specialists in relation to sample transportation and a general training on the subject was requested by several Member States. A lack of technical and financial support was also suggested as being an ongoing issue.
Participant presentations

Summary of participant presentations

Member States have their own different mandates for the regulation of the shipment of infectious substances. This can lead to laws and regulations which are not harmonized, and very often not regularly revised. This was an issue frequently raised during the meeting.

Most Member States have already ratified multiple international agreements for different methods of transport. These include the most common one, the ADR Agreement for the safe transport of dangerous goods by land transport.

Representatives from the participating countries expressed that there is a general lack of standard operating procedures, or protocols, and this can lead to transportation of up to two months or even more. Efficient transport is often hampered by the lack of a clear definition of what infectious substances or associated materials are.

Some Member States 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. These 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. The majority of delegates expressed that their biosafety and biosecurity legislation needed to be updated.

The main issues raised by all Member States regarding the transportation of infectious substances were:

- lack of training and certification of specialists
- bureaucratic procedures for obtaining permissions and licenses
- lack of standard operating procedures and protocols
- problems with the availability of suitable packaging and dry ice
- need for financial and technical support
- lack of harmonization regarding requirements for the transportation of infectious substances
- need for interdepartmental cooperation and collaboration.

There are additional concerns about the availability of local legal documents, absence of biosafety laws, and limited numbers of transportation and logistics providers.
Monkeypox and SARS-CoV-2 transportation

Regulations applicable to monkeypox virus 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 (6).

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 an mpox 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 virus 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.
Sample transport experience sharing

Sample transport in a national Tuberculosis (TB) network

The Kyrgyz Republic is a mountainous nation with a population of 6.6 million people. There are 96 laboratories throughout the country, most of which are located in primary health care as this is where TB services were established.

The national diagnostic algorithm requires that people with presumptive TB are tested by WHO-recommended rapid molecular genetic methods and this involves transportation of samples to laboratories where diagnostic procedures are carried out. The introduction of new technologies for rapid diagnosis of TB and determination of resistance to TB medicines requires a reliable, uninterrupted supply of medication for early treatment. The transportation of both TB samples and medicines is critical, and this process is organized by the National Tuberculosis Program (NTP), overseen by the Kyrgyzstan Ministry of Health.

The implementation of a sample referral system has been challenging due to high costs, sustainability issues, and an initially small number of medical workers. These challenges have been overcome thanks to perfect synergy of the NTP with national and international partners. The system is being enhanced by identifying and registering alternative transport agencies, such as state transport and logistics companies. It is also being improved by organizing ongoing training, revisions and additions to guidelines, an algorithm of notification in case of emergencies, and instructions for filling out reporting forms.

The setting up of the sample transport system has resulted in a significantly reduced turnaround time (TAT), earlier diagnosis and treatment, improved sample quality and has also reduced the cost of sample delivery. The system has been integrated at laboratory management level with an electronic register. The TAT of a test is a mandatory ISO 15189 quality indicator, and the time to get results has been reduced significantly due to defined responsibilities at each level, clear routing, updated procedures, and a transition from paper orders to electronic laboratory information management systems.
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 (12) 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

An insight was given into the transportation of infectious substances and the regulatory barriers that veterinary laboratories encounter when handling such shipments from a Kazakhstan perspective. The Committee for Veterinary Control and Surveillance in the Ministry of Agriculture, Kazakhstan consists of three governing entities (13):

The National Veterinary Reference Center consists of two laboratories in Almaty and Astana. These provide diagnostic testing for high-threat and zoonotic animal diseases, laboratory testing, veterinary and sanitary examination, and bacteriological testing of disinfection quality.

The Republican Veterinary Laboratory, in Astana, is responsible for the diagnostic testing of high threat animal diseases and also manages a fleet of 153 vehicles for the delivery of biological and pathological samples, as well as timely delivery of test kits and other materials.

The Republican Animal Disease Control Institute has 14 branches across Kazakhstan which are set up for rapid and effective response and eradication of sources of epizootic disease.

Throughout Kazakhstan, the process of importing infectious veterinary substances, such as external quality assessment (EQA) samples of category A and B, can take anything between one day to two months. This is dependent upon the country of origin, nature of the shipment, and the time needed to obtain import permits. The consignor must provide a veterinary certificate with the shipment description, an invoice, and a letter with information about the destination, purpose, and a contact person. The recipient must obtain an import permit with an indication of the airport where the shipment is to be delivered and a power of attorney for the person dealing with customs procedures. Transport of samples is provided by commercial carriers, and public procurement portals are used to procure these types of services.

The most significant challenge that laboratories face when shipping infectious substances is in complying with the strict packaging requirements, which means that many airlines refuse to transport such goods. A step-by-step guide for the import and export of category A samples was also presented although it was pointed out that specialist packaging is not readily available in Kazakhstan.

The COVID-19 pandemic presented significant challenges regarding the itinerary for delivery of samples to countries outside Kazakhstan as border controls would often refuse the entry of category A and B samples. Moreover, transport costs increased dramatically due to the pandemic is high, fluctuates wildly and so can be difficult to budget for.
Material transfer agreements

Material transfer agreements for transport of infectious substances

A material transfer 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) (14).

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).
Transport of Category A infectious substances

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, with a need to adopt and harmonize different areas of law. With regard to the recent monkeypox/mpox outbreak, the possibility of a temporary derogation for infectious substances was discussed, i.e. moving monkeypox virus, 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/mpox 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.
Establishing biosafety and biosecurity legislation

JSC QazBioPharm National Biopharmaceutical Holding was established in 2022 following the presidential instruction to ensure Kazakhstan’s biological security. The primary objective of the new authority is to ensure early detection and prevention of biological threats, particularly high-threat pathogens.

New biosafety legislation in Kazakhstan has been introduced in response to several challenges, including the recurring hotspots of high-threat infections, the importation of serious infections due to the migration of people and animals, and the import of plants, goods, including dual-use goods. Other issues surrounding this multifaceted topic include non-regulated handling of pathogenic biological agents, the impact on high-hazard facilities as a result of emergencies or acts of terrorism, and the shortage of skilled biosafety officers.

The key amendments introduced in the new biosafety legislation in Kazakhstan are as follows:

- The legislation designates fixed facilities handling bioagents as strategic goods, which means that they will receive special attention from the authorities to ensure that they are compliant with biosafety regulations.
- The legislation criminalizes the illicit handling and sale, misappropriation, extortion, and violation of rules for handling bio-agents resulting in severe penalties.
- The legislation requires licensing of disinfection, disinfestation, and rodent control in healthcare to ensure that these activities are carried out safely and effectively.
- The legislation requires each facility to obtain a permit for handling bio-agents to ensure that these activities are carried out safely and effectively.
- The Ministry of Defense is authorized to approve rules to ensure that radiological, chemical, and biological safety is maintained in the Armed Forces of Kazakhstan.
- The competent authority is included in the integrated system of countering terrorism threats to ensure that biosafety issues are addressed as part of the broader national security strategy.
- The new legislation aims to close legislative gaps concerning regulation of biosafety matters and make it consistent with the main body of law.

The new biosafety legislation in Kazakhstan is a significant step towards ensuring the safety of the country’s population and addresses the challenges posed by biological threats. The legislation is comprehensive and includes measures to address the importation of serious infections, non-regulated handling of pathogenic biological agents, and the shortage of skilled biosafety officers. The key amendments demonstrate the government’s commitment to biosafety and national security.
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), were presented (15). For an example of a multilateral agreement for the carriage of monkeypox virus, see Annex 4.

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 (16) and cites a long list of different laws, which might apply when shipping an infectious substance. These relate to:

- customs imposing 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 as defined in the Protection against Infection 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.
Dual-use regulations

Dual-use regulations and experience of the European Union

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.
Conclusions

Central Asian countries already have a level of regulation regarding the shipment of infectious substances. However, the legislation is not sufficiently comprehensive, is not regularly reviewed/revised, and is certainly not harmonized between Member States.

A general lack of standard operating procedures as well as bureaucratic processes lead to very long delays in the transportation of infectious substances. Indeed, in some cases, the absence of biosafety laws and even a clear classification of what constitutes an infectious substance is not helping in efforts to efficiently conduct transportation.

This is compounded by a lack of trained, certified specialists on the subject of sample transport shipment as well as poor availability of suitable packaging and dry ice.

Participants overall expressed that interdepartmental cooperation and collaboration is lacking and communication and experience sharing needs to be strengthened.
Based on the points raised by the participating countries, support is needed in the following areas:

- **Strengthening national legislation:** All countries agree on strengthening their national legislation related to sample transportation to comply with international requirements. This can be done by reviewing existing legislation and updating it accordingly.

- **Capacity building:** There is a need to train national specialists on custom procedures, sample transportation, packaging, and handling of dangerous goods. This could be achieved through regular trainings and workshops.

- **Interdepartmental coordination:** This is essential for smooth transportation of samples. Countries need to establish interdepartmental working groups and hold regular meetings to enhance communication and collaboration among involved sectors and ministries. This could include the development of standard operating procedures and checklists.

- **Information dissemination:** Countries have access to the relevant EU and WHO guidelines and documents related to sample transportation. Translation of these documents into local languages is needed however. This was expressed regarding numerous documents.

- **Packaging and logistics:** Participant countries suggested that they need to find a sustainable way to source and finance suitable packaging, as well as the shipment process itself. This also applies to additional material like thermal loggers and thermal containers for institutes and laboratories. Additionally, the establishment of a national transportation system and company to provide packaging material would help overcome logistical challenges.

- **Experience sharing:** Regular meetings and experience sharing between central Asian countries could help improve cooperation and mutual learning. This could be facilitated through workshops, webinars, and other means of information sharing.

Overall, a multifaceted approach is required to overcome the challenges of sample transportation faced by the countries. Capacity-building, interdepartmental coordination, information dissemination and logistical support are some of the key areas that need to be addressed.
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, the suggestion was made to organize two workshops dedicated to solving issues with sample transport. The first of these workshops took place in Istanbul in November 2022 for the countries and territories served by the Balkan Hub and subsequently this, the second workshop for the countries of central Asia.

The third Lab Task Force meeting took place in Izmir, Türkiye in May 2023 where the findings of both infectious substance transport legislation workshops were presented and discussed.
References


**Additional resources**


Annex 1
Programme

Workshop on transport of infectious substances legislation in central Asia 2023
Almaty, Kazakhstan

Programme

Purpose

The overall purpose of the workshop is to support central Asian countries 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 and between countries.

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 recent 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 sharing of pathogens, the implementation of the Nagoya protocol and its implications on sample shipment.

- Provide recommendations for strengthening the sample shipment process in the central Asian countries.

Wednesday, 29 March 2023

09:30–10:00  Registration

10:00–10:20  Official opening of the meeting, introduction of the participants, meeting agenda and objectives
  Joanna Zwetyenga, WHO Regional Office for Europe

10:20–10:30  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

10:30–11:00  International agreements and comparison of transport legislation for infectious substances in the central Asian countries
*Markus Huber, WHO Regional Office for Europe*

11:00–11:20  Kazakhstan

11:20–11:40  *Coffee Break*

11:40–12:00  Kyrgyzstan

12:00–12:20  Uzbekistan

12:20–13:00  Lunch Break

13:20–13:40  Turkmenistan

13:40–14:00  Tajikistan

Session 2: Transport of SARS-COV-2/ Monkeypox sample

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

14:30–15:20  Netherlands
*Sanne van den Hengel (online), National Institute for Public Health and the Environment*

Session 4: Achievements and challenges in the TB-network in Kyrgyzstan

15:20–16:00  Experience sharing for the transport of samples in the national TB network
*Gulmira Kalambetova, National TB Program under the MoH, Department of Strategic Development and International Cooperation*

16:00–16:20  *Coffee Break*

Session 5: International pathogen-sharing regulation and experiences

16:20–16:40  Pathogen, GSD sharing & associated benefit sharing outside influenza
*Vasee Sathiyamoorthy (online), WHO Headquarters*

16:40–16:50  Questionnaire

16:50–17:00  Open discussion to facilitate international pathogen sharing

17:00–17:10  *Wrap-up: Takeaways from session 1–5*
Thursday, 30 March 2023

Session 6: 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
Talgat Karibayev - National Reference Center for Veterinary Medicine

Session 7: Material Transfer Agreement - MTA

10:00–10:30  MTA for transport of infectious substances
Markus Huber, WHO Regional Office for Europe
Interactive session:
10:30–11:15  • Mapping of transport agencies with whom countries are working/having contracts for sample transportation.
• Possible use of MTA’s for the shipment of infectious substances
11:15–11:45  Coffee Break & Group-Photo

Session 8: Transport of category A infectious substances

11:45–12:00  Sample transport of category A infectious substances
Markus Huber, WHO Regional Office for Europe
12:00–12:15  Open discussion: Needs for an effective infectious substance (including infectious waste) transport in the central Asian countries
12:45–13:45  Lunch Break

Session 9: Import/Export legislation and barriers

13:45–14:00  Experience sharing: Establishing a biosafety and biosecurity legislation
Zauresh Zhumadilova, National holding QazBioPharm JSC
14:00–14:30  Import and export experience of infectious substances in the EU
Toni Rieger (online), Bernhard Nocht Institute for Tropical Medicine
14:30–15:00  Dual Use regulations in the EU
Markus Huber, WHO Regional Office for Europe
Interactive session:
15:00–15:10  • Availability of local legislative documents for transportation.
• Possible improvements in the interagency cooperation. How can this be achieved?

Way forward, next steps and feedback

Group discussion:
15:20 – 15:40  • Constraint regarding import and export barriers, recommendations to overcome these
• Next steps from countries and how can WHO be a facilitator for countries in improving their shipment

End of meeting

15:40–16:00  Official ending of the meeting
Joanna Zwetyenga, WHO Regional Office for Europe
Annex 2
List of participants

Kazakhstan
Kuanysh Talgatovich Ishzhanov
Talgat Bolatovich Karibayev
Uly Selim Kuanysh
Farida Sagimovna Orynbayeva
Dana Keldibekkyzy Ryskul
Elmira Seitbekovna Utegenova
Zauresh Bapanovna Zhumadiilova
Svetlana Issayeva Berdimuratovna

Kyrgyzstan
Zarina Bakirova
Gulbarchyn Esengeldieva
Aigul Dzhaparova
Begimay Useinbekova

Tajikistan
Oleg Bakunin
Munisov Kuzratulo
Orzugul Nazarov

Turkmenistan
Batyr Amanov
Jeren Mamayeva
Nedirnazor Yaylimov

Uzbekistan
Olga Maltseva
Shamurad Rakhmatullaev
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Elnura Duishenaiieva
Jeremy Ford
Markus Huber
Alexandr Jaguparov
Gulmira Kalmambetova

WHO Headquarters Geneva Office
Kojima Kazunobu

WHO Regional Office for Europe
Zulfiya Atadjanova
Kaliya Kasymbekova
Ayjeren Myratdurdyeva
Abdulakhad Safarov
Joanna Zwetyenga

Interpreters
Alexandra Nigay
Nurgul Seitzkazieva
## Annex 3

### Questionnaire Results

#### Questionnaire:
Shipping of infectious substances

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

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Number of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research purposes</td>
<td>15</td>
</tr>
<tr>
<td>Diagnostic purposes</td>
<td>16</td>
</tr>
<tr>
<td>Conformance testing</td>
<td>17</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Financier</th>
<th>Number of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your institution/laboratory</td>
<td>8</td>
</tr>
<tr>
<td>Your government</td>
<td>2</td>
</tr>
<tr>
<td>The sending diagnostic/research institute/laboratory</td>
<td>7</td>
</tr>
<tr>
<td>The sending government</td>
<td>0</td>
</tr>
<tr>
<td>N/A</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
</tbody>
</table>

3. Who financed the shipment in case of sending infectious substances?

<table>
<thead>
<tr>
<th>Financier</th>
<th>Number of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your institution/laboratory</td>
<td>11</td>
</tr>
<tr>
<td>Your government</td>
<td>2</td>
</tr>
<tr>
<td>The receiving diagnostic/research institute/laboratory</td>
<td>6</td>
</tr>
<tr>
<td>The receiving government</td>
<td>0</td>
</tr>
<tr>
<td>N/A</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
</tr>
</tbody>
</table>
4. What problems have you encountered in sending infectious substances?

- No problems: 2
- Delay: 15
- Damaged samples: 1
- Sample got blocked at customs: 4
- Veterinary check at the border blocked the sample: 2
- Financial or funding issue: 9
- Other: 7

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

- No problems: 4
- Delay: 11
- Damaged samples: 2
- Sample got blocked at customs: 8
- Veterinary check at the border blocked the sample: 4
- Financial or funding issue: 7
- Other: 7

6. How long does the shipment of infectious substance to a neighboring country usually take?

- 1–3 days: 2
- 4–5 days: 1
- 5–7 days: 4
- >7 days: 16
7. How long does the shipment of infectious substance to a reference laboratory in the EU usually take?

- 1–3 days: 0
- 4–5 days: 1
- 5–7 days: 2
- >7days: 20

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: 12
- Yes: 1
- No, but we would like to get support in further understanding this topic: 8
- N/A: 1

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

**17 Responses**

**Issues Mentioned**
- “Customs clearance”
- “Long transportation”
- “No problem”
10. Do you or your institution/laboratory have experience with the Nagoya-protocol?

- Yes, and we would like to get support in further understanding this topic: 2
- Yes: 1
- No: 10
- No, and we would like to get support in further understanding this topic: 10
- N/A: 1

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

- Yes, and we would like to get support in further understanding this topic: 7
- Yes: 2
- No: 3
- No, but we would like to get support in further understanding this topic: 9
- N/A: 1

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

- Yes, and we would like to get support in further understanding this topic: 3
- Yes: 2
- No: 3
- No, but we would like to get support in further understanding this topic: 7
- No: 9
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 responses
- No: 6 responses
- N/A: 8 responses

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

**Issues Mentioned**
- "No legislation in place"
- "Very few certified couriers"
- "Insufficient funding"
- "Long time to get a permit"

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: 10 responses
- No: 11 responses
- N/A: 3 responses

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

**Issues Mentioned**
- "Bureaucracy in getting documents"
- "Insufficient funding"
- "Legal documents"
17. Was there any country specific issue? (no mentioning of the country necessary)

- Yes, import or export was an issue, please indicate why in the next question: 5
- No: 11
- Maybe: 8

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

8 Responses

Issues Mentioned
- "Delays in delivering samples from remote regions"
- "Legal documents"
- "Long time to get documents"

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

- Everything is good: 0
- Availability of timely courier service: 18
- Availability of packaging material: 13
- Availability of Dry Ice: 10
- Accessibility and timing of documents: 18
- Financing or funding the shipment: 21
- Regulations and legal matters: 14
- Simplicity of the process: 14
20. Are the documents for import and export easily accessible?

- Yes: 8
- No: 13
- N/A: 2

21. What is for you or your laboratory/institution the most urgent area for improvement to facilitate the shipment of infectious substances?

**Issues Mentioned**

- "Would like to have biosafety law"
- "Availability of shipping services"
- "Financing and laws to be in place"
- "Faster shipment"
- "Documentation and legislation"

**Responses**

- 18 Responses

22. Do you use MTAs for shipping of samples?

- Yes: 12
- No: 10
- N/A: 2
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.

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Estonia  
Finland  
France  
Georgia  
Germany  
Greece  
Hungary  
Iceland  
Ireland  
Israel  
Italy  
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