- Develop procedures for transferring or shipping select agents from the laboratory.
- Implement an emergency response plan.
- Establish a protocol for reporting adverse incidents [12].

In conclusion, there must be international norms which nations can rely upon in making international exchanges so as to achieve global biosecurity [13]. BRCs have a critical new responsibility in helping establish requirements for achieving control of access to facilities housing dangerous pathogens so that only authorised individuals can enter those facilities. While the degree of control will vary, allowing only authorised individuals to gain entry to facilities where potential biothreat agents are located is a good and necessary practice for biosafety, as well as biosecurity.

Perhaps the most daunting challenge facing BRCs will be establishing procedures for vetting personnel and determining who to trust with agents that could be used to do harm.

References

1. OECD. *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology.* 2001, http://wdcm.nig.ac.jp/brc.pdf
2. OECD. *Towards A Global Biological Resource Centre Network.* 2005, http://www.oecd.org/document/51/0,2340,en_2649_34537_33791027_1_1_1_1,00.html
3. OECD (Organization for Economic Development and Cooperation Paris). *Guidance for The Operation Biological Research Centres Certification and Quality for BRCs.* 2004, http://www.oecd.org/dataoecd/60/42/23547743.pdf
4. US Department of State Bureau of Nonproliferation. *The Australia Group.* 2004. http://www.state.gov/t/np/rls/fs/35052.htm.
5. World Health Organization. *Laboratory Biosafety Manual* (3rd ed). Geneva: World Health Organization, 2004, http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf
6. Agres T. Interpol pushes research controls. *The Scientist* 2003; http://www.biomedcentral.com/news/20030721/03/.
7. Smith D & Rohde C. Biological resource centres compliance with law. *Microbiology Today* 1999; 26:14-6 http://www.socgenmicrobiol.org.uk/pubs/micro_today/pdf/14_16.pdf
8. Rohde C (Ed). *World Federation for Culture Collections Committee on Postal, Quarantine and Safety Regulations Report 2000-2004. Postal, Quarantine and Safety Regulations: Activities, Developments and Concerns.* World Federation of Culture Collections. 2004. http://www.wfcc.info/new/CommitteeReport/4yearsCommitteeRepor.pdf
9. http://wdcm.nig.ac.jp
10. EBRCN. *The European Biological Resource Centre Network Information Resource: The Safe Handling and Distribution of Micro-organisms and the Law.* 2005, http://www.wfcc.info/new/EBRCN_Resource_Legislation_file_WP5_2.htm
11. Oosthuizen GH & Wilmshurst E. *Terrorism and Weapons of Mass Destruction: United Nations Security Council Resolution 1540.* Chatham House London, 2004, http://www.riia.org/pdf/research/il/BP0904.pdf.
12. US Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (4th ed). Washington DC: US Government Printing Office, 1999.
13. Atlas RM & Reppy J. Globalizing biosecurity. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 2005; 3:51-60.

Microbes in transit: international shipping requirements in brief

Christine Rohde

DSMZ-German Collection of Microorganisms and Cell Cultures
Mascheroder Weg 1b
38124 Braunschweig, Germany
Tel: (49) 531 2616 220
Fax: (49) 531 2616 418
E-mail: chr@dsmz.de

The worldwide exchange of microorganisms, including pathogens, is a matter of course. While the availability of these resources is essential for research, biomedical application, industry and education, adequate safeguards have to be observed so that biological material presents no hazard to people who may handle it during the transportation chain, to laboratory workers, animals or the environment.

All infectious substances are, by definition, dangerous goods, class 6.2, and shipping must be managed with a sound knowledge of all relevant regulations. Microbes are very unlikely to cause a problem during transport and can be delivered efficiently provided they are properly packed, labelled, declared and the quantities per package are properly limited.

Regardless of the mode of transport, postal mail or courier, road, air or waterways, the triple packaging principle (primary container, absorbing material, secondary and outer packaging) should be followed in order to avoid rejected shipments or legal consequences. Packaging is the essential component in safe transport. Compliance with transport regulations is not optional, they are laws.

In view of the risk that accidents involving all means of carriers and transportation might lead to the dispersal of infectious substances, several international organisations arranged for discussions on this subject. The UN Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) regularly updates

the UN Model Regulations on the Transport of Dangerous Goods, the 'Orange Book' [1] being the basis for international and national transportation regulations for dangerous goods specified for all carriers.

If infectious substances are transported by air, shippers must have recurrent training according to the latest Dangerous Goods Regulations of the International Air Transport Association (IATA DGR) [2]. Air transport plays the dominating role when living biological materials are transported over long distances. The IATA DGR are quite user-friendly, making sure the responsible shipper is on the safe side and in conformity with international law. For road transport, shippers must observe the relevant national or regional regulations, like ADR in Europe [3].

For microorganisms allocated to Risk Group 1, regulations for dangerous goods transport don't apply. Other regulations are in place: usually postal mail transport is permitted when packed in accordance with the packaging regulations laid down by the Universal Postal Union (UPU) [4]. Important is that UPU permits biological samples in letter mail only, not in parcels. Registered letter mail is generally recommended because of individual treatment and possible tracking.

Whereas internationally agreed regulations apply everywhere for shipping biological materials in the overseas postal mail or by freight carriers, various countries may have individual regulations governing packaging and transport of biological material in domestic mail. In general, postal mail systems exclude any dangerous goods. Infectious substances allocated to Risk Group 2, most of them classified in the new shipping Category B, might be sent by national postal mail (on the road exclusively).

For Category B, administrational expenditure and costs have become less problematic. However, there are still strict requirements on shipper's responsibility, training and packaging quality as well as on correct labelling and marking.

Although the recent changes relevant for infectious substances shipping resulted in the definition of an adequate classification system using shipping Categories A and B instead of using the WHO Risk Group definitions [5], the Risk Group allocations still help classify microorganisms for transport.

The new deregulated requirements apply to the majority of Risk Group 2 microorganisms, as the definition of this Risk Group conforms with the definition of the new Category B: such cultures can be shipped under the same requirements as diagnostic specimens of Category B, both share the same UN number (UN3373), and Packing Instruction PI650 applies. Shipper's declaration forms are not required anymore, neither such road transport documents.

However, with regard to strength and quality, ready-to-use UN packagings meeting the stricter PI602 requirements are still recommended as they withstand vibrations, changes in temperature or mechanical pressure, especially during air transport. Compared to PI650 packagings, they have passed different tests, bear UN specification markings and, because of a growing market, their prices have dropped drastically.

The regulations for shipping genetically modified organisms have undergone a revision too, resulting in a clearer instruction for transport of safety level 1 GMO (Class 9, 'miscellaneous dangerous goods').

In case of Category A shipments (highly infectious substances, specifically Risk Groups 3 and 4), shipper's declaration documents are required and can only be signed by trained persons (IATA DGR). If substances meeting the definition of Category A, UN2814 or UN2900 respectively (proper shipping names of these dangerous goods are: UN2814, infectious substances, pathogenic for humans; UN2900, infectious substances, pathogenic for animals only), an experienced courier should be chosen, advance arrangements with courier and consignee are obligatory. Category A means individual transports, due to recent restrictive total dangerous goods mass limitations in transport vehicles.

Again, it is the responsibility of all laboratories supplying infectious substances to nominate a person who receives recurrent training but, alternatively, a shipper may commission an authorised agent for dangerous goods packaging and transport.

References

1. UNECE. *'Orange Book': UN Model Regulations on the Transport of Dangerous Goods* (14th ed). UN, New York, 2005.
2. IATA-International Air Transport Association. *Dangerous Goods Regulations* (47th ed). Montreal, Geneva, 2006, ISBN 92-9195-580-9.
3. ADR. *Accord Européen Relatif au Transport International des Marchandises Dangereuses par Route.* English version, 2005.
4. Universal Postal Union, Berne. *Letter Post Compendium* (constant updates). Beijing 1999.
5. World Health Organization. *Laboratory Biosafety Manual* (3rd ed). World Health Organization, Geneva, 2004, ISBN 92- 4-154650-6.