Guidance for adoption of appropriate risk control measures to conduct safe research on H5N1 transmission

Following the Technical Consultation on H5N1 Research Issues held at WHO in February 2012, WHO staff informally consulted a number of relevant scientific bodies and experts from the human health and animal health communities to seek their perspectives related to biosafety and laboratory biosecurity guidance on conditions under which further research should be conducted on the laboratory-modified H5N1 viruses.

Existing frameworks and guidelines were also reviewed, such as: applying the risk group classification presented in the WHO Laboratory biosafety manual, 3rd edition, 2004, and considering the biorisk management approach provided in CEN CWA 15793:2011 Laboratory biorisk management (CWA 15793).

Based on this, the following considerations are proposed:

1. Facilities wishing to work with the laboratory-modified H5N1 should critically evaluate the considerable personal and institutional responsibilities inherent in manipulating influenza viruses with pandemic potential that are not presently circulating in nature.

2. Only laboratories that meet the appropriate biosafety level AND show conformity to available biorisk management standards (e.g. CWA 15793) should consider working with these laboratory-modified H5N1 strains, in close collaboration and communication with relevant national authorities, and under strict national oversight.

3. Relevant national authorities should identify, approve and oversee the laboratories which might work on this material.

4. Biosafety and laboratory biosecurity considerations should be taken into account in reviews of research findings scheduled for publication.

5. Final responsibility for the identification and implementation of appropriate risk assessment, mitigation, and containment measures for work with laboratory-modified H5N1 strains lies with individual countries and facilities. Accordingly, measures may vary from country to country, and decisions should be taken in light of currently available knowledge, context, and applicable national requirements.

6. Given the potential of these newly developed laboratory-modified H5N1 strains to start a pandemic, it is important that facilities that are NOT able to identify and appropriately control the risks associated with these agents REFRAIN from working with them.

This guidance may be updated in light of new information and experience.