

Biocontainment requirements for vaccine production from and quality control of the reassortant candidate vaccine virus CBER-RG2

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Following consultation with a panel of vaccine biosafety experts, WHO recommends that, new reassortant candidate vaccine virus that has 6:2 gene constellation¹, similar to donor viruses previously tested in ferrets with satisfactory results and with expected gene sequences no longer requires safety testing in ferrets before being distributed for use in the development of vaccines against Pandemic (H1N1) 2009 virus. Requirements for safety testing in ferrets for new reassortants with other gene constellations or with specific mutations will be determined on a case-by-case basis.

Satisfactory safety testing of candidate vaccine viruses conducted previously^{2,3} indicates that ferret safety testing for CBER-RG2 is not required.

Vaccine production from CBER-RG2 against Pandemic (H1N1) 2009 viruses, using fully trained and competent staff in accordance with national safety guidelines, may therefore proceed at BSL-2 enhanced level, as described in the WHO Technical Report Series No. 941⁴, Annex-5.

¹ CBER-RG2 possesses the HA and NA from A/California/4/(H1N1) 2009 virus with mutation L194I in the HA and six internal genes (M, NS, NP, PA, PB1 and PB2) from A/Puerto Rico/8/1934(H1N1) virus

² <http://www.who.int/csr/resources/publications/swineflu/biocontainment/en/index.html>

³ http://www.who.int/csr/resources/publications/swineflu/ivr_153/en/index.html

⁴ http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/H1N1_vaccine_production_biosafety_SHOC.27May2009.pdf