HSE

Health and Safety Executive

Hazardous Installations Directorate

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Head of Unit
Dr Joanne Nettleton

Dr Ian Scragg
Safety Office
University of Dundee
3 Cross Row
Dundee
DD1 4HN

Date: 8th March 2012

Reference: GM6

Dear Dr Scragg

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000, AS AMENDED

ADDITIONAL INFORMATION REQUESTED

Thank you for your notification under the above Regulations.

With respect to your notification GM6/12.1 entitled "Use of genetically modified hazard group 2 viruses indigenous to the UK in molecular studies of innate and adaptive immunity" under Regulation 14(2) of the above Regulations the Competent Authority requests the additional information specified below:

i) Section 7 of your Notification (Origins and intended functions of the genetic material) reports that in addition to the insertion of marker sequences in the viral genome, other genes may be mutated or knocked down to investigate the effect this has on the immune response. Please confirm that the work in which genes are mutated will be restricted to modifications that cause a loss of function. Alternatively, if some of the mutations could give rise to strains with novel pathogenic properties please provide further details.

ii) The supplied risk assessment refers to the amplification and harvesting of virus in/from embryonated eggs. It also refers to the intranasal infection of mice with virus. Given the route of transmission of virus, please confirm the measures in place to minimise and control exposure to aerosols during these activities.

iii) Section 2(i) of the supplied risk assessment states that vaccination of staff and students involved in the influenza A work is not recommended on the basis that it may not be effective against the influenza strains to be used in the

project. Given, that Section 2(d) of your risk assessment recognises potential for exchange of genetic information during mixed infection of cells with different viruses, please confirm if vaccination of those involved in the work has been considered as a means to reduce the potential for reassortment. Such reassortment could occur if a laboratory accident involved a worker carrying a pre-existing infection.

iv) Section 5(d) of your risk assessment refers to the use of sharps for injection of mice. Please provide details of the containment and controls to be employed to minimise potential exposure of those undertaking this aspect of the work.

v) Section 5(e) of your risk assessment states that non-infected and deliberately-infected animals will be housed within the same cage. If this is the case, given potential for cross infection, please confirm that the animals will be considered as infected and handled appropriately downstream.

vi) Your Notification is presented as a connected programme of work and refers to other research involving genetic modification of Vaccinia virus and Epstein Barr Virus. Please confirm that the risks involved in the work with these other viruses are no greater than for the influenza work and that appropriate controls are to be applied.

Please send your response in writing addressed to the 'GM Notifications Officer' at the address above, or by email to sandra.fletcher@hse.gsi.gov.uk. Please be aware that the time taken to provide the requested information does not count towards the statutory time limits to process the notification.

Yours sincerely

Dr Simon Warne, Health & Safety Executive
On behalf of the Competent Authority

David Barnes
Scottish Government