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Date: 2 April 2009

Reference: GM 6

Head of Unit
Dr Joanne Nettleton

Dear Dr Scragg

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

Thank you for your notification under the above Regulations.

With respect to your notification GM entitled "Life Sciences research involving Class 2 genetically modified micro-organisms" under Regulation 14(2) of the above Regulations the Competent Authority, in the past, has accepted a number of broad connected programmes of work; the scope of which meet the guidance produced by HSE (a copy of which is enclosed).

However, in this case, the submitted connected programme is too broad in proposing to include any genetic modification activity with Hazard Group 2 microorganisms, which in themselves consists of an extensive range of different pathogens, presenting very different risks and consequences to human health and the environment. The proposed connected programme is also open ended and fails to set clear boundaries within which the work can adequately be assessed. The Competent Authority has a statutory duty to check compliance with the requirements of the regulations, which in this case, it is not possible to do because of the breadth of work.

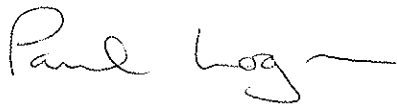
Consequently, the connected programme in its current form is not acceptable. Based on the information provided, it is anticipated that the work could be broken down into a number of notifiable connected programmes of work, each with a defined scientific goal and encompassing a manageable range of activities. You are directed to the aforementioned guidance and HSE would be happy to discuss your revised proposal, prior to you resubmitting an amended connected programme of work.

Please send your response in writing addressed to the 'GM Notifications Officer' at the address above, or by email to paula.stam@hse.gsi.gov.uk.

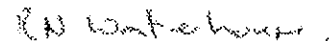
This letter does not imply endorsement by the Competent Authority of any physical containment and associated safety precautions at your centre, or that the measures you have taken are sufficient to comply with the Regulations and other relevant legislation. HSE inspectors may have additional observations and requirements when conducting site inspections under the Health & Safety at Work etc Act.

Regulation 15(2) and (3) requires that the Competent Authority be kept informed of any changes to the notified details.

Yours sincerely



Dr Paul Logan, Health & Safety Executive
On behalf of the Competent Authority



Dr R N Waterhouse
Scottish Government