Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

11 August 2023

Dear [redacted]

Internal review of FOI 23/349

I am writing in response to your request for an internal review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') response to your FOI request FOI/23 349.

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA).

I will first set out the history of the request.

Request history

On 16 May 2023 you made the following request for information:

> *Do you hold any potential pandemic pathogens (PPPs) in any of your labs? If yes, what are they?*
>
> *Are you working with any infectious agents under a Specified Animal Pathogens Order (SAPO)? If yes, what are they?*
>
> *If applicable, what biosecurity level is used during work with PPPs and SAPO infectious agents?*
>
> *Are you currently carrying out any gain of function work, or experiments to enhance the infectiousness of transmissibility of PPPs or SAPO infectious agents?*
>
> *Have you had any incidents of biosecurity lapses, leaks or safety breaches in the past five years? If so, can you list these?*

The Agency responded to your request on 14 June 2023 as follows:

> *ICO guidance advises that there may be cases when confirming or denying information is held can – in itself – disclose information which would be exempt, or which could prejudice the interest an exemption is there to safeguard. In these circumstances, the FOIA allows a public authority to give a 'neither confirm nor deny' ('NCND') response. This means that the public authority can respond by refusing to inform the requester whether or not they hold any information.*[1]
>
> *Section 24(2) applies where neither confirming nor denying that the information requested is held is required for the purposes of safeguarding national security. This includes the protection of potential targets of terrorist or criminal activity. It allows a public authority to neither confirm nor deny whether information is held if it considers that either confirming or denying would be likely to make the UK or its citizens more vulnerable to a national security threat. The ICO guidance on this exemption*[2] *makes it clear that safeguarding national security includes protecting potential targets even if there is no evidence of an imminent attack.*
>
> *We have assessed your request and consider that the subject matter falls within this category. The UK continues to be a target for terrorists and terrorist groups, and we are aware of these risks in connection with a wide range of hazardous substances; this includes the subject of your request, potential pandemic pathogens and infectious agents under SAPO. We therefore neither confirm nor deny whether the information you have requested is held under section 24(2) of the FOIA. Section 24(2) is a qualified exemption, which means that we are required to consider whether the public interest in confirming or denying that the information is held is outweighed by the public interest in neither confirming nor denying that the information is held.*
>
> *In favour of confirming or denying, we consider that there is a general public benefit where confirmation or denial demonstrates openness and transparency, and where this could inform the public and contribute to public scrutiny and debate. However, this must be balanced against the greater public interest in ensuring that any confirmation or denial does not itself provide intelligence that could be useful to those who may be minded to commit terrorist or criminal acts.*
>
> *In respect of the specific information you have requested, safeguarding national security is the strongest public interest and we have concluded that the public interest favours neither confirming nor denying that the information is held on this occasion.*

On 16 June 2023, you sought a review of the Agency's response:

> *Could you review this decision internally please ahead of my application to the Information Commissioner.*

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[1] When to refuse to confirm or deny holding information | ICO

[2] Section 24 – Safeguarding national security | ICO

In case it helps, we have had so far dozens of responses from universities who have given us details of the pathogens they hold, BSL levels and accident/leaks.

Can you also review each of the categories, as, while I can see that details of pathogens could be considered a security threat, I can't see how releasing details of accidents can be anything other than in the public interest. There is a clear public interest in knowing if dangerous pathogens are leaking.

Issues on review

The internal review considered the application of section 24(2) to your request.

Decision

This review has considered the handling of your original request, the reasons for the exemption applied, and the points raised in your request for an internal review.

Do you hold any potential pandemic pathogens (PPPs) in any of your labs? If yes, what are they?

Are you working with any infectious agents under a Specified Animal Pathogens Order (SAPO)? If yes, what are they?

If applicable, what biosecurity level is used during work with PPPs and SAPO infectious agents?

Are you currently carrying out any gain of function work, or experiments to enhance the infectiousness of transmissibility of PPPs or SAPO infectious agents?

Have you had any incidents of biosecurity lapses, leaks or safety breaches in the past five years? If so, can you list these?

For questions 1, 2 and 3 of your request, this review sets aside the section 24(2) exemption applied to your request and replaces it with section 24(1).

We therefore confirm that we hold information for these three questions, however this is exempt from disclosure. Section 24(1) allows a public authority to exempt information if we consider that releasing the information would make the UK or its citizens more vulnerable to a national security threat.

As noted in the MHRA's original response, the ICO guidance on section 24 makes it clear that safeguarding national security includes protecting potential targets even if there is no evidence of an imminent attack, and the greatest public interest lies in ensuring that a disclosure under the FOIA does not itself provide intelligence that could be useful to those who may be minded to commit terrorist or criminal acts.

There is a public interest in transparency regarding the provision of information on the subject of your request, and while we consider that the section 24(1) exemption applies to

details of the information held for questions 1, 2 and 3, this review provides some further explanation to meet this public interest.

We hold pathogens that may be considered as having the potential to cause a pandemic, as an example, including some of those covered by the priority lists from the World Health Organization and the Coalition for Epidemic Preparedness Innovations. We publish scientific outputs under the MHRA, or former NIBSC, affiliation (e.g. research or biological standards), using Open Access or onto public-facing websites such as WHO and NIBSC. Our pre-pandemic influenza activities are highlighted on our website:

https://nibsc.org/science_and_research/virology/influenza_resource_/pandemic_influenza.aspx

Some of the agents we hold are classified under the SAPO regulations. For those pathogens we hold, the applied biosecurity and biocontainment measures are those approved under UK regulation / legislation.

On review, we are providing the following response to question 4. We understand this question to ask whether we are deliberately creating pathogens that are inherently more pathogenic than the wildtype either through enhancing its infectiousness or transmissibility. We are not currently undertaking such work.

For question 5, we can advise that we report incidents, as required, under RIDDOR legislation. Further explanation of RIDDOR reporting can be found here: https://www.hse.gov.uk/riddor/index.htm

A summary of all RIDDORs reported by our organisation in the last 5 years is given in a table in the Annex at the end of this letter.

We hope this information and further explanation is useful.

Yours sincerely

Medicines and Healthcare products Regulatory Agency

Appeal Rights

If you are dissatisfied with the decision of this review, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Annex: Table of RIDDOR reporting

For question 5, we can advise that we report incidents, as required, under RIDDOR legislation. A summary of all RIDDORs reported by our organisation in the last 5 years is here:

Date	Description
27/09/2018	**RIDDOR Occupational Disease:** During vibration testing for powered gardening equipment, the gardener complained of discomfort in his hands, the survey was halted at this point. Following a medical diagnosis of HAVS, a RIDDOR report was made.
09/10/2020	**RIDDOR Over 7-day injury:** The injured person hurt his back when moving an obsolete coffee machine from a trolley to the waste compound.
26/11/2020	**RIDDOR Dangerous Occurrence:** Spillage outside Class I MSC of liquid potentially contaminated with SARS-CoV2 due to a leak of the outer container. The primary container remained intact. Assessment confirmed no leakage therefore no loss of containment.
02/11/2021	**RIDDOR Over 7-day injury:** Person was exiting a laboratory area. They forgot to switch the light off and put their hand through the gap as the door was closing. Their left ring finger got caught in the door which resulted in the injury.
10/02/2022	**RIDDOR Dangerous Occurrence:** A staff member received a bite wound from a SARS-CoV-2 infected hamster (through two pairs of gloves, including leather gloves) while carrying out a regulatory procedure (oral swab). No subsequent infection occurred due to this accident.
24/03/2022	**RIDDOR Dangerous Occurrence:** A staff member received a cut on the finger while performing a procedure on SARS-CoV-2 infected hamsters. The hamster had a low viral load, SARS-CoV-2 is not a blood-borne virus and staff triple vaccinated indicative of low chances of developing SARS-CoV-2 infection due to the incident. No subsequent infection occurred due to this accident.
14/07/2022	**RIDDOR Dangerous Occurrence:** Biological filter not connected to CL3 autoclave (this is only a mandatory requirement for HG4 waste and is determined by risk assessment for lower levels of containment). As waste is inactivated prior to autoclaving, the risk of exposure to biological agents is extremely low. No exposure to pathogens.
03/10/2022	**RIDDOR Dangerous Occurrence:** Steam leak identified from the seal around the temperature and environmental probes going into the autoclave chamber [where Hazard Group 2 influenza virus could be handled] No exposure to pathogens.

Date	Description
18/11/2022	**RIDDOR Dangerous Occurrence:** While carrying out a routine procedure involving [Hazard Group (HG) 2 influenza] infected eggs (in [Containment Level] CL3), staff observed liquid (from an egg) prior to transferring the eggs to the Microbiological Safety Cabinet. The eggs were contained in a plastic rack at the time, they had been placed on the bench after being chilled in the freezer, in accordance with the Standard Operating Procedure. Due to the pathogen being HG2 the HSE highlighted this as not requiring reporting, post hoc.