

**FOI 23/236 - specification and/or tolerance for the allowable concentration of dsDNA in all COVID-19 mRNA vaccine products**

**MHRA RESPONSE**

**19 May 2023**

Dear

Thank you for your email of 29th March where you have asked "**Please release the specification and/or tolerance for the allowable concentration of dsDNA in all COVID-19 mRNA vaccine products licenced (whether fully or otherwise) by MHRA**"

Adequate control of dsDNA in the production of the mRNA COVID-19 vaccines is in place. However, the quality specifications for the Covid vaccines are commercially sensitive information that is exempt from disclosure under Section 41 (information provided in confidence) and Section 43 (commercial interests).

S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in releasing trade secrets and know-how about the manufacture and control of a medicinal product, which can be used by competitors to overcome hurdles in the development of a rival product.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire

SK9 5AF  
Yours sincerely

MHRA Customer Experience Centre  
Communications and engagement team  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU