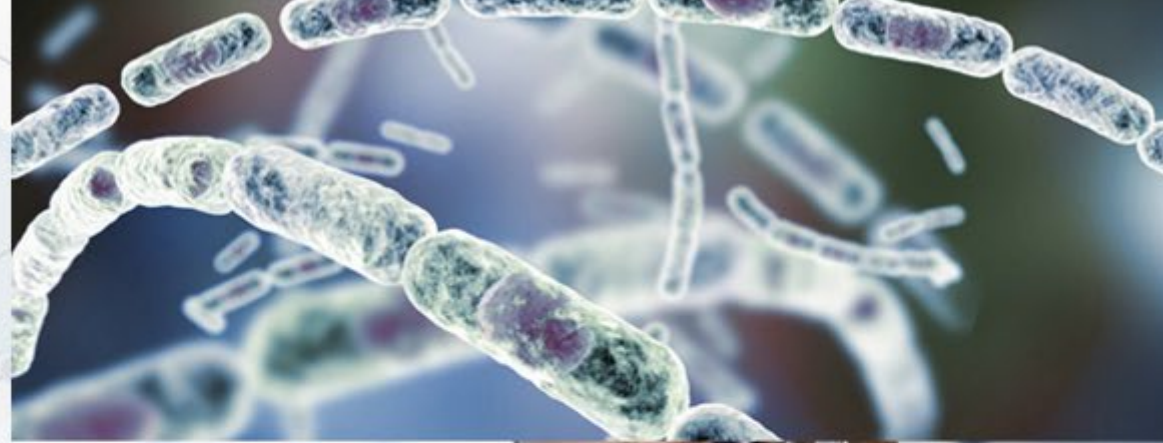


Interim Final Rule (IFR): SARS-CoV/SARS-CoV-2 Chimeric Viruses

2022 Responsible Official (RO) Webinar Series

May 25, 2022



Why Did We Do This Rulemaking?

- HHS/CDC believed that immediate regulatory oversight of these experiments and the resulting chimeric viruses was essential to protect the public from the potential consequences of a release of these viruses.
- This Interim Final Rule (IFR) immediately amended the list of the HHS agents and toxins and provided enhanced oversight of these experiments and the resulting chimeric viruses, to quickly ensure the biosafety and security of these potentially dangerous agents, while simultaneously soliciting public comment.
- IFRs have been used in similar situations in the past where immediate regulation was critical to protecting public health (e.g., 1918 influenza virus, *Bacillus cereus* Biovar *anthracis*)



Regulation Changes

- 42 C.F.R Part 73.3 HHS select agents and toxins.
 - (b) SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors.
- 42 C.F.R. Part 73.13 Restricted experiments.
 - (a)(3) Experiments that involve the creation of SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors or vice versa.

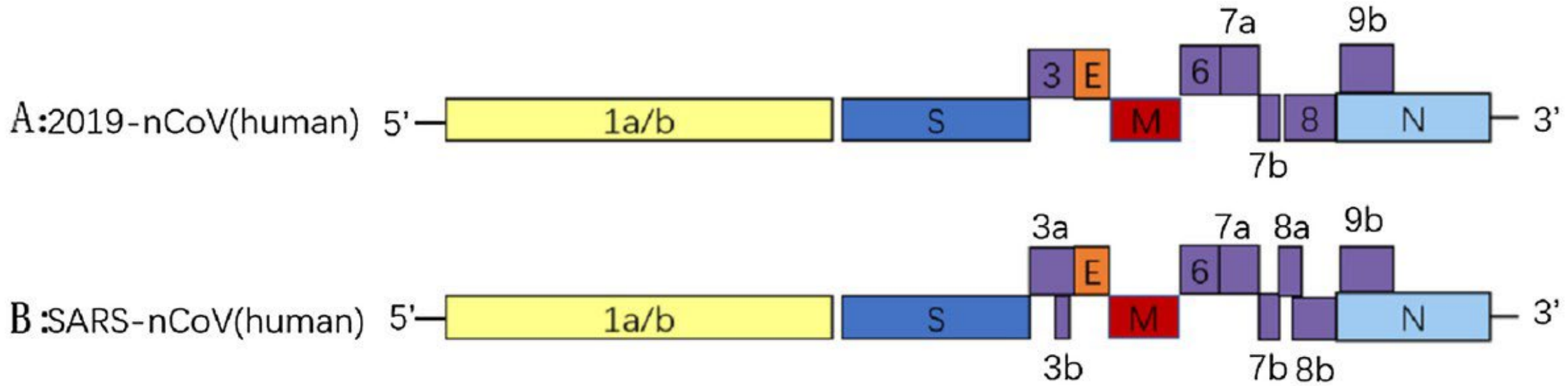


Additional Information on Regulation Changes

- SARS-CoV is currently a select agent, and this IFR does not add SARS-CoV-2 to the select agent list.
- The virulence factors referenced in the regulation include, but are not limited to, those involved in inflammasome activation during infection.
 - DSAT is creating a guidance document that is responsive to the public comments received.
- Since the creation of these chimeric viruses is a restricted experiment, prior approval by DSAT is required.



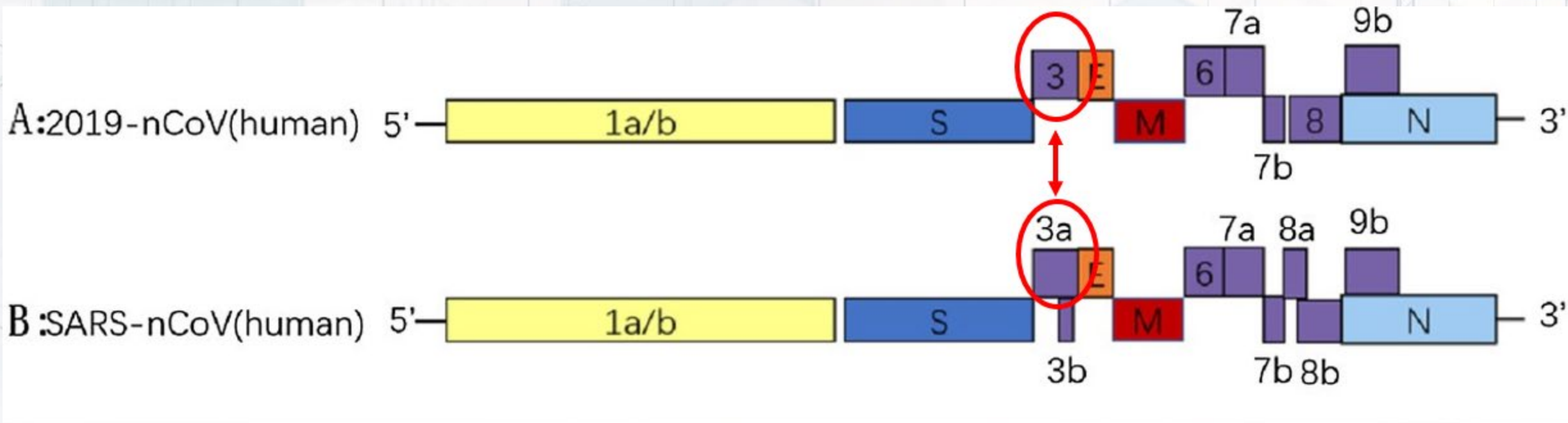
Example of a Potential Restricted Experiment Involving SARS-CoV/SARS-CoV-2 Chimeric Virus



Hu T, Liu Y, Zhao M, Zhuang Q, Xu L, He Q. 2020. A comparison of COVID-19, SARS and MERS. *PeerJ* 8:e9725 <https://doi.org/10.7717/peerj.9725>



Example of a Potential Restricted Experiment Involving SARS-CoV/SARS-CoV-2 Chimeric Virus: Open Reading Frame 3/3a



Hu T, Liu Y, Zhao M, Zhuang Q, Xu L, He Q. 2020. A comparison of COVID-19, SARS and MERS. *PeerJ* 8:e9725 <https://doi.org/10.7717/peerj.9725>



Interim Final Rule (IFR): Adding SARS-CoV-2 Chimeric Viruses to the Select Agent List

Implementation:

- By December 17, 2021, entities that possess these viruses should have provided notice to the Federal Select Agent Program.
- Written comments were to be submitted on or before January 18, 2022.
- By February 15, 2022, entities that possess these viruses must have registered or amended their registration and meet all regulatory requirements



Interim Final Rule (IFR): Current Status

- DSAT received three public comments on the IFR, and the Comments will be addressed in the final rule.
- So far, no entities have contacted DSAT to request adding SARS-CoV/SARS-CoV-2 chimeric viruses to their registration.



Interim Final Rule (IFR): Federal Register Notice



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® Rule

Possession, Use, and Transfer of Select Agents and Toxins- Addition of SARS-CoV/SARS-CoV-2 Chimeric Viruses Resulting From Any Deliberate Manipulation of SARS-CoV-2 To Incorporate Nucleic Acids Coding for SARS-CoV Virulence Factors to the HHS List of Select Agents and Toxins

A Rule by the [Health and Human Services Department](#) on 11/17/2021



[Federal Register Notice](#)

www.selectagents.gov

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