

Addendum to the Report of the Teleconference of the Containment Advisory Group (CAG TC3) on
nOPV2 candidate vaccines and S19 – poliovirus type 2 strains
14 December 2018

This document is an addendum (dated 14 December 2018) to the report of the ‘Teleconference of the Containment Advisory Group (CAG TC3) on nOPV2 candidate vaccines and S19 – poliovirus type 2 strains (dated 7 June 2018)¹.

As noted in the report of 7 June 2018, CAG provided the following relevant recommendations:

1. Handling of nOPV2 candidate vaccines outside the containment requirements of GAPIII for clinical trials, stockpile and for outbreak response,
2. The handling of S19-poliovirus type 2 strains e.g., S19/S2P1/N18S and S19/MEF1P1/N18S outside of the containment requirements of GAPIII for IPV production, rat neutralization IPV potency assays, human serum neutralization test for poliovirus antibody determination and potency testing for immunoglobulin (human) lot control and release.

Additional relevant data was submitted to the CAG ahead of the Third Meeting of the CAG, 13-14 December 2018, through the CAG-Expert Support Group (ESG-CAG) on novel poliovirus strains, to provide recommendations on the containment requirements of the following related issues:

1. Production of nOPV2 and for quality control testing using the candidate vaccines’ strains (S2/cre5/S15domV/rec1/hifi3 and S2/S15domV/CpG40)
2. Series of S19-poliovirus strains (S19 with capsid region, P1 of wild-type and Sabin vaccine strain polioviruses of all serotypes) (Table 1) under specific usage indicated above.

Table 1: Series of genetic cassettes of S19 with the capsid protein encoding P1-region of polioviruses

Capsid region	S19		S19/N18S*	
	Wild-type	Sabin	Wild-type	Sabin
Poliovirus Serotype 1	S19/Mah1P1	S19/S1P1	S19/Mah1/N18S	S19/S1/N18S
Poliovirus Serotype 2	S19/MEF1P1	S19/S2P1	S19/MEF1P1/N18S	S19/S2P1/N18S
Poliovirus Serotype 3	S19/Sau3P1	S19/S3P1	S19/Sau3P1/N18S	S19/S3P1/N18S

Abbreviations: (Wild-type): Mah1: Mahoney serotype 1; MEF1: Middle East Forces serotype 2; Sau3: Saukett serotype 3; (Sabin strains): S1: Sabin serotype 1; S2: Sabin serotype 2; S3: Sabin serotype 3 and P1: region of the poliovirus genome encoding the structural (capsid) polypeptides

*N18S is a mutation (substitution) of an asparagine by a serine at amino acid 18 in the non-structural protein 2A to allow better growth in Vero cells.

The Third Meeting of the CAG provided the following recommendations:

1. Sufficient data has been provided to conclude that both nOPV2 candidate strains (S2/cre5/S15domV/rec1/hifi3 and S2/S15domV/CpG40) could be considered for use, according to the specific terms of usage provided, outside the containment requirements of GAPIII e.g., for nOPV2 production and for quality control testing.
2. Sufficient data has been provided to conclude the series of S19-poliovirus strains (S19 with capsid region, P1 of wild-type and Sabin vaccine strain polioviruses of all serotypes) and the parallel series of viruses with the substitution of an asparagine by a serine at amino acid 18 in the non-structural protein 2A to allow better growth in Vero cells (Table 1) could be considered for use, outside of the containment requirements of Annex 2 or Annex 3 of GAPIII, as applicable for IPV production, rat neutralization IPV potency assays, human serum neutralization test for poliovirus antibody determination and potency testing for immunoglobulin (human) lot control and release.

¹ This addendum should be read in conjunction with the Report of the Teleconference of the Containment Advisory Group (CAG TC3) on nOPV2 candidate vaccines and S19 – poliovirus type 2 strains, 7 June 2018. Available at: <http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>

The Third Meeting of the CAG, 13-December 2018 was attended by the following CAG members and other participants, relevant to this session:

CAG members: Professor David HEYMANN (Chair), Professor George E GRIFFIN (also CAG-ESG member)
Dr Stephen MCADAM (also CAG-ESG member), Dr Mark PALLANSCH (also CAG-ESG member),
Dr Atef EL-GENDY, Dr Vibeke HALKJÆR-KNUDSEN, Dr Janice LO, Mr Kenneth UGWU,
Dr Jagadish DESHPANDE, Professor Shahina TABASSUM, Dr Åsa SZEKELY BJÖRNDAL,
Dr Bernard FANGET,
Unable to attend: Mr Neil GODDEN

WHO: Dr Roland SUTTER, Dr Jacqueline FOURNIER-CARUANA, Dr Daphne MOFFETT,
Dr Harpal SINGH

By invitation: Dr Andrew MCADAM, Principal Scientist, Division of Virology,
National Institute for Biological Standards and Control (NIBSC), United Kingdom