

Criteria for the evaluation of improved 'safety' of novel poliovirus strains to determine the containment requirements for their storage and handling<sup>1</sup>

The development of the criteria to evaluate the 'safety' of novel poliovirus strains or other related strains are based on the following assumptions:

1. The properties of the strains under evaluation are referenced to the corresponding Sabin strains
2. There is no change implication to Annex 3 of GAPIII for facilities handling only OPV/Sabin poliovirus infectious materials
3. The recognition of the need to define an essential minimal information and data set required for the evaluation of such strains
4. The criteria developed, relevant to the safety aspects of a containment risk assessment, should be widely useful for the evaluation of any other novel or related poliovirus strains

The possible criteria and data sources for the evaluation of improved 'safety' of novel poliovirus strains and other related strains should include but not limited to the following:

#### A. Novel poliovirus strain properties

1. Genetic stability to loss of attenuation – conditions
  - a. Theoretical
  - b. Cell culture (e.g., serial passage)
  - c. Animal studies (e.g., single, multiple passage)
  - d. Characterization (phenotype, genotype)
2. Neurovirulence – degree of attenuation
  - a. Theoretical
  - b. Cell culture
  - c. Animal studies
    - i. TgPVR mice
    - ii. Non-human primates
3. Replicative fitness – proxy for infectiousness
  - a. Cell culture yield (single cycle; infectivity measure)
  - b. Animal studies (e.g., shedding)
4. Transmissibility – a proxy of which is 'duration and amount of shedding'

Data from human studies (if available) should be included when performing the risk assessments of such strains.

#### B. Proposed use of the novel poliovirus strains.

The impact of proposed use of these novel and related poliovirus strains on the containment requirements must be considered - any risk assessment of novel poliovirus strains must include an assessment of the risk associated with the intended use of the strains.

---

<sup>1</sup> These criteria was endorsed by the Containment Advisory Group in June 2018 (Source: [http://polioeradication.org/wp-content/uploads/2018/09/CAG\\_TC3\\_June\\_2018\\_EN\\_Final.pdf](http://polioeradication.org/wp-content/uploads/2018/09/CAG_TC3_June_2018_EN_Final.pdf))