

November 11, 2019

The Research Foundation for Microbial Diseases of Osaka University

## Regarding the Incident of Vaccine Culture Fluid Leakage at Seto Office Of BIKEN Co., Ltd.

The Research Foundation for Microbial Diseases of Osaka University (Head Office: Suita City, Osaka Prefecture; Director General: Koichi Yamanishi) announced that the leakage incident of vaccine culture fluid was discovered at Seto office\*<sup>1</sup> of BIKEN Co., Ltd. (Head Office: Kanonji City, Kagawa Prefecture, President: Yoshihiro Ueda), a subsidiary company, on November 8. In brief, 100 L of culture fluid containing up to about 10<sup>13</sup> of attenuated polio virus type 3 (Sabin strains)\*<sup>2</sup>, a raw material for vaccine, was discharged without proper inactivation treatment (killing the virus).

The leaked Sabin strains pose little risk to develop disease in humans\*<sup>2</sup> unlike wild strains and thus has been broadly used for live oral polio vaccine until 2012 in Japan. The leaked culture fluid is thought to be highly diluted in the seawater, and the virus will die within few weeks\*<sup>3</sup>. Also, the vaccination rate of polio in Japan is maintained quite high\*<sup>4</sup>. From these, we consider that the incident will cause no effect on human health.

We will conduct the final identification of the leaked virus strains by the third party, investigations of environmental effects and the causes of the incident, and will take necessary actions and measures to prevent the recurrence of such incidence in future.

We would like to express our deepest apologies to the local community and other related parties for the concerns we have caused.

### References:

\*<sup>1</sup>. Seto Office: 4-1- 70 Seto-cho, Kanonji City, Kagawa Prefecture

\*<sup>2</sup>. The leaked virus fall under the category of substances that pose little risk to develop disease in humans designated by the Minister of Health, Labour and Welfare as pursuant to the provisions of Article 6, paragraphs (20) through (23) of the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases (Act No. 114 of 1998)."

\*<sup>3</sup>. Risk assessment, risk management and risk-based monitoring following a reported incident release of poliovirus in Belgium, September to November 2014; Erwin Duizer Eurosurveillance Volume 21, Issue 11, 17/Mar/2016

\*<sup>4</sup>. From the Japan Vaccine Industry Association "2019 Vaccine Basics"