PART 3.E.2. A COPY OF THE WRITTEN CONSENT OR CONSENTS OF THE COMPETENT AUTHORITIES TO THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF THE GENETICALLY MODIFIED ORGANISMS FOR RESEARCH AND DEVELOPMENT PURPOSES WHERE PROVIDED FOR BY PART B OF DIRECTIVE 2001/18/EC

Prior to clinical trials, a number of laboratory studies were performed after declaration as described in the Directive 2009/41/EC related to the contained use of GMO. Appropriate authorisations were obtained in France for RN1250 and are attached in annex (classification of modified MDV as recipient, dated of 23 January 2013, from the Ministère de l'Enseignement Supérieur et de la Recherche).

Clinical trials represent a deliberate release into the environment under the terms of Directive 90/220/EEC (repealed by Directive 2001/18/EC).
Appropriate authorisations were obtained in France prior to field trials with RN1250 alone or in combination with vHVT013-69 strain, as part of the development of PHN3257 vaccines (authorisations are appended).

As a reminder, several studies were also conducted for the purpose of the registration of the very similar US vaccine, USDA product code 16L1.R0 following the local regulations. A field trial authorization has been obtained for the US product in development (FONSI) on 7 August 2015. The RN1250 GMO alone or associated with vHVT013 has been placed on the market in the USA since 2017 and 2018 respectively.