Official Control Authority Batch Release (OCABR)

Guideline for rabies inactivated vaccines submission

For rabies OCABR, samples of each batch to be controlled should be provided to the following address:

**ANSES Nancy**
Nancy Laboratory for Rabies and Wildlife
Technopôle Agricole et Vétérinaire
Bâtiment H, Domaine de Pixérécourt
BP 40 009
54220 MALZEVILLE Cedex
FRANCE

**Shipping:**

Samples of veterinary rabies vaccine should be sent in a refrigerated parcel, by the fastest means. Please do not send samples late in the week: Monday-Wednesday shipping is best. Insure that vials are properly protected to avoid any damage.

**Samples:**

All vials should be clearly labelled. The labelling must contain the name of the vaccine, and the batch number. In case of freeze-dried vaccine, rehydration buffer should be provided if possible.

A copy of the manufacturer’s protocol for OCABR and a submission letter should be joined to each provided batch. This letter should contain the following information:

- Name and address of the applicant
- Trade name of the vaccine
- Batch number
- Number of vials
- Expiry date
- Appearance specification of the vaccine
- Storage temperature
- Buffer and volume to be used for rehydration (in case of freeze-dried sample)

Please note that the number of samples to provide for each batch depends on the volume of each vial of rabies vaccine:

<table>
<thead>
<tr>
<th>Volume of each vial</th>
<th>Number of samples required</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 2 mL</td>
<td>20</td>
</tr>
<tr>
<td>&gt; 2 mL</td>
<td>5</td>
</tr>
</tbody>
</table>

Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail – Laboratoire de la rage et de la faune sauvage de Nancy Technopole Agricole et Vétérinaire, Domaine de Pixérécourt, BP 40009, 54220 Malzéville - France.