

## Information sheet „Batch testing“ (Sections 32 - 34 Regulation on Animal Vaccines)

updated: January 2015

Pursuant to the presently valid version of the Regulation on Animal Vaccines dd. Oct. 24, 2006, the following rules must be observed for batch testing.

### 1 Application for batch testing

Pursuant to section 32 sub-section 1 of the Regulation on Animal Vaccines, a batch of a product may only be marketed or applied after release by the competent licensing authority.

- 1.1 For each batch a separate **original application** as well as the **production and test protocols** with the following information must be submitted to the licensing authority of the Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health:

**Official marketing authorisation procedure pursuant to section 11 of the Animal Health Act (TierGesG)**

**Batch release pursuant to section 32 of the Regulation on Animal Vaccines**

**Name of the product and, if applicable, short form of the name:**

**Official MA no.:**

**Batch identification:**

**Test methods:**

**Batch size:**

**Expiry date of the batch:**

**Version of the package insert:**

**Name of the applicant:**

**The words „Testkit bei ... eingereicht am ...“ („Test kit filed with .... on....“)**

- 1.2 For experimental batch testing the applicant must submit **the duplicate of the application** for batch testing, **samples of the product** in the sales package (including package leaflet) as well as the **production and test protocols** to the respective test laboratory (see also the information sheet “test laboratories”) of the FLI.
- 1.3 **Test kits** must have a common **batch identification** (Ch.-B.), i.e. all components (biologicals and non-biologicals) must be marked with the same batch identification. If this is impossible, the different batch identifications of all reagents must be indicated on the outer package.

For the decision on the release of a batch, a fee pursuant to section 2 of the presently valid version of the Regulation on the Administrative Costs for Animal Vaccines dd. November 24, 2010 (BGBl. I p. 1637) must be paid.

### 2 Exemption from batch testing

The licensing authority can exempt a product from batch testing based on a risk assessment by the authority pursuant to section 33 sub-section 3 of the Regulation on Animal Vaccines. Exemption from batch testing by the authority must be applied for by the pharmaceutical entrepreneur.

After exemption of the product from batch testing by the authority, applications for batch release as well as test protocols must be filed with the licensing authority for registration.