

# Veterinary Medicines: Environmental Impact Assessments

Enviresearch perform Environmental Impact Assessments (EIAs) necessary to demonstrate the safety of new veterinary medicinal products (VMPs) in the environment. These are currently regulated under Directive 2001/82/EC (repealed by Regulation (EU) 2019/6 which will come into force in 2022).

EIAs are based on a tiered approach; Phase I and Phase II (a and b) and follow the VICH guidelines published by EMA.

At Phase I, calculations of environmental exposure are performed based on the intended use of the product with the assumption that limited use and exposure leads to limited environmental effects. Concentrations are derived for either the aquatic or the soil compartment (depending on the product type). Where an acceptable risk cannot be demonstrated at Phase I, then potential mitigation measures may be explored, or the EIA proceeds to Phase II.

At Phase II, a more complex, refined, higher-tier assessment can be performed, including an exploration of potential mitigation options if necessary. At this stage, an experimental data package is required, to assess the potential for VMPs to affect non-target species in the environment. We can determine which additional experimental studies are required, based on the EIA and develop an experimental program to address the data gaps (including study placement & monitoring).

In terms of exposure, it is recommended to use the FOCUS models for refining surface water, sediment and groundwater exposure. Our environmental fate modelling experts have particular experience working with and adapting the FOCUS models. Our ecotoxicology experts have significant experience in higher-tier approaches and problem solving when addressing the risk to non-target organisms.

Enviresearch are specialists in environmental assessments. Our experienced team of environmental fate scientists, ecotoxicologists and risk assessors can take your product through the tiered process of the EIA calling upon their experience working with a range of VMPS, from pets to livestock.

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