

Executive Summary

This is the final report of Project DWI70/2/286 - Assessing the likelihood of selected veterinary medicines reaching drinking water.

Human exposure to veterinary medicines may occur through the consumption of drinking water abstracted from surface or groundwater sources that are vulnerable to potential contamination by veterinary medicines. A recent DWI project (70/2/235) used a number of worst case assumptions to confirm safe levels of intake via drinking water for most veterinary medicines. It also identified 10 compounds (altrenogest, apramycin, cefapirin, dicyclanil, florfenicol, lincomycin, luprostitol, sulfadiazine, acetylsalicylic acid and monensin¹) where intake may be close to or above the acceptable daily intake (ADI). This project further assessed the potential risk posed by these 10 compounds by generating more realistic estimates of human exposure through drinking water sources by refining:

- active substance property information
- veterinary medicine usage and loads applied to agricultural land
- simulation modelling, by employing a catchment-based simulation modelling approach

The approach taken in this project sub-divided the project into three work packages with seven key tasks, namely:

Work Package 1 – Catchment Selection

- Screening Selection of Surface and Groundwater Catchments.
- Final Selection of Surface and Groundwater Catchments.

Work Package 2 – Model Parameterisation and Setup

- Collation of Selected Compound Properties.

¹ As a poultry feed additive. Subsequent to the start of this project monensin was authorised for use in cattle in 2013 which is not covered by this risk assessment.

- Collection of Regionally Biased Selected Compound Usage Regimes.
- Development of Catchment Specific Selected Compound Loads.

Work Package 3 – Environmental Modelling and Risk Assessment

- Catchment Environmental Fate Modelling.
- Refinement of Risk Assessments.

Work Package 1 – Catchment Selection

The screening phase of the catchment selection identified between 11 and 18 surface and groundwater catchments for each of the animal groups. From these the final four groundwater and four surface water catchments were selected, one for each animal type (cattle, sheep, poultry and pigs). This process ensured that the final catchments were both vulnerable to leaching and runoff while having high animal manure and veterinary medicine pressures.

Work Package 2 – Model Parameterisation and Setup

There was variable success in improving the compound properties for the ten compounds collated for the simulation modelling. A freedom of information request to the Veterinary Medicines Directorate (VMD) yielded limited amounts of data, however, the key variables for five of the compounds (apramycin, dicyclanil, florfenicol, lincomycin and sulfadiazine) were adequately characterised. Acetylsalicylic acid was characterised largely using literature sources while monensin was characterised using EFSA evaluations. Key gaps were thus present for altrenogest, cefapirin and luprostitol with all values being estimated as no additional data was forthcoming from industry sources.

For each livestock type, a number of veterinary practices were consulted regarding their usage of the ten compounds. The cattle practices covered over 100% of the total number of cattle in the catchments (owing to some treating animals on farms both inside and outside the catchment), while the pig and poultry practices covered 25% and 55% of the national animal totals, respectively. When considering just

broilers, which receive the majority of the compounds under consideration, the poultry practices covered 69% of the total population. For dicyclanil usage in sheep, data on the sale of ectoparasiticides of large agricultural supply chains that covered the selected catchments was analysed.

Single integrated usage regimes were calculated from the survey returns for each compound, livestock group and mode of administration. Of all the compounds surveyed for, only acetylsalicylic acid was not used by any of the practices for any of the animals. In general, there was not much seasonal variation in the use of any of the compounds, but where such variation existed it was accounted for in the modelling. The catchment specific loads of each veterinary medicine were calculated through integrating the usage survey results with the manure production, handling and spreading modelled using Manures-GIS. The final calculated annual applications were small, being less than 1 g/ha.

Work Package 3 – Environmental Modelling and Risk Assessment

For both the surface water and groundwater catchments the maximum daily/annual predicted environmental concentrations for each of the representative catchments and compounds did not exceed the lowest acceptable daily intake concentrations for the three age classes for either the conventional or advanced water treatment options. The fact that these maximum modelled concentrations were low is unsurprising given the low application rates of veterinary medicines spread into the environment. In order to ensure that the maximum annual predicted environmental concentration for groundwater did not exceed the toxicological threshold for an individual crop/soil combination within the catchments, these were extracted for a high usage compound (sulfadiazine) and high toxicity compounds (luprostiol and altrenogest). Similarly, these concentrations for specific soil and crop combinations do not exceed the most sensitive toxicological end points.

The modelled concentrations were typically a factor of several hundred to several tens of thousands below these toxicological thresholds. There are also additional factors which provide further margins of safety:

- There is an additional safety factor of 10 fold given that the ADI thresholds were based on 10% of the ADI concentration;
- The modelling did not take account of any metabolism of the compounds in the animal. In the case of monensin there is an additional safety factor of 5 if this is considered.
- The modelling considers that veterinary medicines spread into the environment either through excretal returns or used as a fertiliser are immediately available for transport in water leaching to groundwater, or agricultural drains, or running off as surface runoff. However, they are not necessarily available for leaching or runoff as they are a component of an organic manure. Using the fraction of compound expected to leach from dung using the equations that underpin VETCALC, a model that may be used in higher veterinary medicine environmental risk assessments, it is likely that a further safety factor of 3 to 10 is available.
- It should also be borne in mind that the groundwater PECs are for the base of the soil profile (0.5 to 1.5 m depending on the soil) and that there would likely be additional attenuation of the compounds through adsorption, dissipation and degradation while moving through the unsaturated vadose zone *en route* to groundwater.

Conclusions and Further Research

Based on the results of this study it is concluded that the ten compounds investigated are not expected to impact on drinking water quality under realistic worst case conditions in real world catchments. The study reflects agricultural practice and authorisation of veterinary medicines at the outset of the project and it is recognised that practices and authorisations may change over time. Water companies should continue to review risks on a case by case basis to account for local circumstances and changes. A further area of research would be to review the assessment in the future to account for any changes in practice or usage that may have occurred.