New tools and methods

New regulatory toxicology and field efficacy advances to support the registration of norbormide

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To develop a new or re-register an older rodenticide a large financial investment and commitment is required similar to that occurred recently in Europe with cholecalciferol. Norbormide has unique attributes, being 100 to 150-fold more toxic to rats than to birds and most other mammals, and therefore also justifies this investment. Differences in the effects of norbormide, and its selective contractile effect on rat peripheral arteries and the lack of an effect on the peripheral or small blood vessels in other species appear to be responsible for species differences in toxicity. This understanding of the mechanism of toxicity in rats and species-specific changes is complemented by molecular toxicology explaining why this compound has an effect that is rapid, irreversible, and unique to rats.

There is an extensive database in over 50 species with most of the publications circa 1965. These studies have not been carried out in accordance with recent test guidelines. Standard Organization for Economic Cooperation and Development (OECD) guideline studies are being completed to focus on data-gaps in chemistry, genetic toxicology, non-target toxicity, general ecotoxicity, and environmental fate. To date norbormide has been shown to lack genotoxicity in OECD 477, 487 and 490, *in-vitro* studies and it lacked irritancy in OECD 404, 406 and 407. Further OECD studies are yielding results consistent with historical data that reported LD50 ranges, following oral administration for Norway rats (*Rattus norvegicus*), between 5.3 and 15.0 mg/kg. The lack of toxicity (i.e., LD50 > 1,000 mg/kg) is previously reported in five bird species and numerous mammalian species, including rhesus monkeys.

Inconsistencies in palatability hampered norbormide use when it was first developed. Prior to embarking on new chemistry and toxicology OECD studies over a decade of research which focused on synthetic processes yielded a manufacturing approach which consistently produced palatable and effective norbormide. This has enabled consistent efficacy of 1% norbormide-containing baits in laboratory and field trials with both Norway rats and black rats (*Rattus rattus*). Details on new developments including results from the current programme of testing, ranging from the Ames test to non-target testing in birds and earthworms, addressing new data requirements or verification of early data to enable registration, will be presented.