

## SCIENTIFIC OPINION

### Scientific Opinion on the safety of *Solanum glaucophyllum* standardised leaves as feed material<sup>1</sup>

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)<sup>2,3</sup>

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#### ABSTRACT

*Solanum glaucophyllum* standardised leaves (PAN) is a mixture of irradiated *Solanum glaucophyllum* ground leaves and wheat middlings to ensure a concentration of minimum 10 mg glycosylated 1,25-dihydroxycholecalciferol/kg feedingstuff. Glycosylation of the vitamin molecule affected biopotency in poultry and rats, but not in ruminants. Up to 1 000 mg PAN/kg complete diet was considered safe for chickens and piglets. PAN concentrations meeting the chicken's requirement for vitamin D in diets without supplemental vitamin D<sub>3</sub> could not be established. No evidence for an improvement of zootechnical parameters by PAN in diets already supplemented with vitamin D<sub>3</sub> was provided for chickens, laying hens and piglets. In dairy cows, PAN had the potential to be efficacious in the prevention of milk fever. However, a feeding regime ensuring its safe use at efficacious doses has not yet been established. No data on safety and efficacy of PAN for other animal species and categories were provided. A water-soluble extract of *Solanum glaucophyllum* was not genotoxic. A no observed adverse effect level could be not derived from sub-acute toxicity studies in rabbits. A benchmark dose lower confidence limit (BMDL<sub>05</sub>) based on an increase in plasma calcium in a 28-day repeat dose rat study corresponded to 2 900–3 500 mg PAN/kg diet. Maternal toxicity and fetotoxicity were observed in rats and rabbits at all extract doses tested. An overall safe dose of PAN was not identified from the available toxicological data in laboratory animals. Since PAN did not increase the concentration of 1,25-dihydroxycholecalciferol in animal tissues, the use of PAN in animal nutrition is safe for consumers. Inhalation of PAN could be hazardous. PAN was not irritant to skin and eyes and unlikely to cause skin sensitisation. Considering the content of 1,25-dihydroxycholecalciferol in PAN its use in animal nutrition would not pose a risk to the environment.

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#### KEY WORDS

*Solanum glaucophyllum*, *Solanum glaucophyllum* standardised leaves, calcitriol, 1,25-dihydroxycholecalciferol, vitamin D, efficacy, safety

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