Repeat dose toxicity studies

In this guide

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General toxicity

17. Zang et al. (2006a and 2006b), and Li et al (2003a and 2003b) conducted dose response studies exposing SD rats to SBA at doses between 10 and 187 mg/kg bw/day and found that pancreas weight increased at doses of 44 mg/kg bw/day and above. Kelsall et al. (2002) conducted a 24-week study on PNA in rats at 0.1 mg/kg and found a relative pancreas weight increase (+18%) while Bardocz et al. (1995) studied the effect of PHA on Lister rats and found the pancreas weight increased at doses of 32.5 mg/kg bw/day and above. In addition to this Bardocz et al. (1995; 1996) conducted studies in rats which reported reduced body weight gain at PHA levels of 7 mg/kg and above.

18. EFSA identified two endpoints as the most sensitive, increased weight of the pancreas, and hypertrophy of the exocrine pancreas.

Gastrointestinal toxicity

19. The toxicological effects of lectins are dependent on binding specificity. PHA was reported to damage microvilli, villi and crypts at doses of 3mg/kg bw/day, and Con A was shown to damage microvilli, villi and crypts at doses of 8 mg/kg bw/day. Bardocz et al. (1995) reported an increase of small intestine weights when rats were dosed with PHA at levels of 32.5 mg/kg bw/day and above. In PND14 rats at dosage levels of 50 mg/kg and above, PHA has shown to affect body weight gain, liver and pancreas weights, maturation of the gastrointestinal tract and the immune system. At levels of 2 mg/kg bw/day, PHA has been shown to alter small intestine morphology. SBA has also been associated with increased small intestine length at doses of 112 mg/kg bw/day and above. Pita-Lopez et al. (2020) studied SD rats over 6 weeks with an average dose of tepary bean lectin fraction of approximately 20 mg/kg bw/day. Results showed a decrease in the microbial diversity of the faeces. EFSA noted that the omission of lectin from the diet would reverse many of the effects on the gut.

20. EFSA highlighted that consumption of lectins may lead to an antibody response which could trigger an allergic response. This had been shown after administration of PHA (0.5 mg/kg bw) and SBA (60 mg/kg bw/day) in rodents.

21. There were few studies investigating the carcinogenic potential of lectins. Kelsall et al. (2002) investigated intestinal carcinogenesis of PNA, and no evidence was found, supporting EFSAs conclusion that genotoxicity would not be expected via direct DNA interaction as lectins are proteins.