Hypoallergenic infant formulas based on hydrolysed milk proteins are used in the diet for cow's milk allergic infants. For a preclinical evaluation of the immunogenicity and allergenicity of new protein ingredients for such hypoallergenic infant formulas as well as for the investigation of which characteristics of hydrolysates that contribute to allergenicity, in vivo models are valuable tools. In this study, we examine the immunogenicity and allergenicity of two hydrolysates in a Brown Norway (BN) rat model, using i.p. dosing, which allows for the use of small quantities. Intact BLG, hydrolysed BLG and a hydrolysed whey product suitable for use in extensively hydrolysed formulas were thoroughly characterized for protein chemical features and administered to BN rats by i.p. immunization with or without adjuvant. Sera were analysed for specific IgG and IgE for evaluation of sensitizing capacity, immunogenicity and antibody-binding capacity. For evaluation of eliciting capacity a skin test was performed. The study showed that the hydrolysates had no residual allergenicity, lacking the capacity to sensitize and elicit reactions in the BN rats. Dosing with or without adjuvant induced a large difference in immunogenicity. Only antibodies from rats sensitized to intact BLG with adjuvant were able to bind the hydrolysates, and the whey-based hydrolysate only showed immunogenicity when dosed with adjuvant. This study showed that hydrolysates can be evaluated by an i.p. animal model, but that the choice of in vitro tests used for evaluation of antibody responses may greatly influence the result as well as may the use of adjuvant.

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