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Scientific Committee on Food

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14 December 2001**

**Additional statement on the
use of resistant short chain carbohydrates
(oligofructosyl-saccharose and oligogalactosyl-lactose)
in infant formulae and in follow-on formulae**

(expressed on 13 December 2001)

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**Additional statement on the
use of resistant short chain carbohydrates
(oligofructosyl-saccharose and oligogalactosyl-lactose)
in infant formulae and in follow-on formulae**

(expressed on 13 December 2001)

The Committee recently commented on the suitability and safety of the use of resistant short chain carbohydrates (SCC), oligofructosyl-saccharose (oligofructose; fructooligosaccharides; FOS) and oligogalactosyl-lactose (oligogalactose; galactooligosaccharides; GOS), in infant formulae and follow-on formulae¹. The Committee concluded that there was insufficient data to establish the safe use of oligofructosyl-saccharose and oligogalactosyl-lactose as ingredients of infant formulae, which serve as the sole diet in infants during the first months of life. The Committee also recommended that additional information on the suitability and safety of resistant SCC be submitted, with particular attention to possible effects on water balance, and it indicated it would review the use of SCC in infant formulae and follow-on formulae when new data would become available.

Information from 4 clinical studies, additional to that previously reviewed by the Committee, as well as preliminary results from 2 new studies with relevance to growth and water balance have been submitted to the European Commission on October 19, 2001 by one manufacturer². This information included growth data in preterm and term infants fed formulae with different concentrations of SCC, individual observations of urine creatinine in preterm infants, observations of individual stool frequency, stool consistency and indicators of protein metabolism in term infants, data on levels of minerals and potential renal solute load of different infant formulae, and preliminary information of urine osmolarity in an ongoing study in term infants fed a formula with 0.6 g/dl oligogalactosyl-lactose.

The Committee concludes that the additional information made available, in particular with respect to growth and markers of water balance, does not provide any indication of adverse effects from the use of a formulae with up to 0.8 g/dl of a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Based on these data the Committee has no major concerns about this combination of oligofructosyl-

saccharose and oligogalactosyl-lactose in infant formulae and follow-on formulae in total concentrations up to 0.8 g/dL in the product ready for consumption.

The Committee recognises that up to now there are no formal guidelines established for the evaluation of the suitability and safety of modifications of infant formulae and follow-on formulae. The Committee noted that the trials available comprise limited numbers of infants, and some compare formulae with SCC and other modifications with a standard infant formula. Therefore, the Committee recommends that further information is collected for this combination, or other SCC or combinations thereof, on the suitability and safety of SCC in infant formulae and follow-on formulae. Particular attention should be given to the effects on growth and body composition, on nutrient bioavailability in young infants, particularly with respect to protein and amino acid utilisation, and on water balance, urine output and urine osmolarity in infants and in neonates. In view of the ongoing evaluation of the compositional requirements of infant formulae and follow-on formulae, the Committee requests that new data on the effects of SCC in infants be submitted for further review.

The Committee reiterates that, as part of the ongoing evaluation, the issue of potential beneficial effects of dietary SCC in infants will be reviewed further.

References

1. Scientific Committee on Food (2001). Statement on the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant formulae and in follow-on formulae, expressed on 26 September 2001.
2. Information submitted to the Commission by Royal Numico RV on October 19, 2001.