

**Committee on Protein Quality and Growth Monitoring Studies to Satisfy Quality Factor
Requirements for Infant Formula**

Questions for Open Session with Brian Kineman and Robert Di Gregorio:

1. What types of data and information on protein quality and normal physical growth have been found acceptable to member states in the registration of a new infant formula in Europe.
 - a. For normal physical growth what is acceptable for the following study characteristics:
 - i. age of enrollment,
 - ii. duration of observation,
 - iii. number of observations,
 - b. Are the following required for normal physical growth studies:
 - i. exclusivity of feeding formula
 - ii. enrolment of a concurrent control group
 - iii. statistical analysis of the power, before and upon completion of the study
 - iv. plotting of individual subjects data on WHO growth charts
 - v. adverse events with health assessments of each instance of an adverse event
 - vi. formula intake data, with comparison to an authoritative reference,
 - vii. report on attrition, with reasons for loss from study.
2. Do you have experience in using INFOGEST data in your assessment of protein quality?
 - a. Are you aware of such data being accepted by EU member states?