Joint explanatory note by the European Food Safety Authority and the UK Scientific Advisory Committee on Nutrition regarding dietary reference values for vitamin D

The Scientific Advisory Committee on Nutrition (SACN) of the United Kingdom and the European Food Safety Authority (EFSA) have revised the dietary reference values (DRVs) for vitamin D in separate assessments. SACN's assessment was performed between 2011 and 2016. EFSA carried out its assessment between 2013 and 2016.

SACN proposed the following recommendations **for the UK population**:

- a 'Safe Intake' (SI) of 8.5-10 µg/day for infants < 1 year (including exclusively breastfed infants)
- a SI of 10 µg/day for children aged 1 to <4 years
- a Reference Nutrient Intake (RNI) of 10 µg/day for all other population groups aged 4 years and more (including pregnant/lactating women)

EFSA's Scientific Panel on Dietetic Products, Nutrition and Allergies derived the following Adequate Intakes (AI) **for the EU population:**

- infants aged 7-11 months: 10 µg/day

for all other population groups aged one year and more (including pregnant/lactating women): 15 µg/day

When deriving the DRVs for vitamin D, both EFSA and SACN assumed minimal sunshine exposure.

SACN and EFSA concluded that serum concentration of 25-hydroxyvitamin D (25(OH)D) continues to be the best indicator of exposure to vitamin D from skin synthesis and dietary intake, and both therefore used this parameter to derive DRVs for vitamin D. However, the evidence considered for setting a target concentration of 25(OH)D, as the basis for setting DRVs, and the methods used in the assessment and modelling, were not the same.

SACN considered that evidence on musculoskeletal health outcomes (rickets, osteomalacia, falls, muscle strength and function) was sufficient to use as the basis for making dietary recommendations for vitamin D and that the risk of poor musculoskeletal health was increased at serum 25(OH)D concentrations below 25 nmol/L. SACN therefore selected a serum 25(OH)D concentration of 25 nmol/L as that which almost all (97.5%) of the population should achieve throughout the year. SACN described this as a 'population protective' concentration. SACN's recommendations about vitamin D intake assume minimal sunshine exposure. Therefore, SACN used individual data obtained from randomised controlled trials, conducted at UK latitudes during the winter months when vitamin D synthesis is minimal, to translate the target serum concentration of 25 nmol/L into a *Recommended Nutrient Intake* (RNI) for population groups of 4 years and older. SACN derived a *Safe Intake* (SI) level for children of 0-<4 years.

EFSA reviewed evidence on musculoskeletal health outcomes (bone mineral density/content, osteomalacia, fracture risk, muscle strength/function and physical performance, risk of falls and falling, calcium absorption, rickets, and pregnancy- and lactation-related health outcomes). EFSA considered that there is sufficient evidence for an increased risk of adverse musculoskeletal health outcomes in adults, infants and children (or an increased risk of adverse pregnancy-related health outcomes) at serum 25(OH)D concentrations below 50 nmol/L. EFSA derived DRVs based on mean values (of vitamin D intake, serum 25(OH)D concentration and other covariates) from a large number

of studies which were carried out under conditions of assumed minimal endogenous vitamin D synthesis (from October through April at latitude above 40° North). Individual data were not available in most of the studies considered by EFSA. The available data did not allow the setting of Average Requirements (AR) upon which Population Reference Intakes (PRI) at European level could be based. EFSA therefore established an Adequate Intake (AI) value at which most of the adult population will achieve the target serum 25(OH)D concentration when exposure to sun is minimal. EFSA highlights that in the presence of endogenous vitamin D synthesis, e.g. by exposure to sun, the requirement for dietary vitamin D is lower or may even be zero.

The DRVs for vitamin D derived by SACN (SI and RNI) and EFSA (AI) are not directly comparable. Their interpretation needs to take into account both the aforementioned clarifications and the particularities of the approaches and methods applied by SACN and EFSA. They are detailed in the report on "Vitamin D and Health" by SACN, SACN's responses to comments on its draft report the "Scientific Opinion of the EFSA NDA Panel on Dietary Reference Values for vitamin D", and in the "EFSA Technical Report on the outcome of the public consultation on the draft Scientific Opinion on Dietary Reference Values for vitamin D".

Glossary:

Average Requirement (AR): the level of (nutrient) intake that is adequate for half of the people in a population group, given a normal distribution of requirement. Dietary reference values for the UK use the term *Estimated Average Requirement*, EAR, to describe the same variable.

Population Reference Intakes (PRI): the level of (nutrient) intake that is adequate for virtually all people in a population group. It is calculated on the basis of the AR plus twice its standard deviation. This will meet the requirements of 97.5 % of the individuals in the population.

Adequate Intake (AI): the value estimated when a Population Reference Intake cannot be established because an average requirement cannot be determined. An Adequate Intake is the average observed daily level of intake by a population group (or groups) of apparently healthy people that is assumed to be adequate.

Reference Nutrient Intake (RNI): represents the amount of a nutrient that is likely to meet the needs of 97.5% of the population. The RNI is notionally two standard deviations above the *Estimated Average requirement.*

'Safe Intake': A safe intake may be set when there are insufficient data on which to set DRVs. A safe intake is a level or range of intakes considered to pose no risk of deficiency and below a level where there is a risk of undesirable effects.