Outcome of step 2 of the call for scientific and technical data on the permitted food additives calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b)

Calcium silicate (E 552), magnesium silicate (E 553a(i)) and magnesium trisilicate (E 553a(ii))

The Association of Synthetic Amorphous Silica Producers (ASASP) confirmed the submission of the following data on the food additives calcium silicate (E 552), magnesium silicate (E 553a(i)) and magnesium trisilicate (E 553a(ii)):

- Particle size and particle size distribution (LD and TEM)
- Analytical data: Arsenic (As), Lead (Pb), Mercury (Hg), Aluminium (Al), Nickel (Ni), Fluoride (F), Crystalline silica (alpha-quartz)
- Toxicological data:
    - 90-day oral toxicity study (OECD 408) for E 552 and E 553a(i)
    - Leaching/dissolution study
- Literature research

Deadlines for data submission:

- Dossier on particle size and analytical data: January 2020
- Dossier on toxicological data: October 2020
- Literature research: October 2020

Talc (E 553b)

EUROTALC, the Scientific Association of the European Talc Industry, confirmed the submission of the following data on the food additive talc (E 553b):

Technical data (submission date: 20 October 2019):

- Information on particle size and particle size distribution
- Analytical data on current levels of arsenic, lead, mercury, aluminium, nickel, fluoride and crystalline silica
- Lowest technologically achievable level for arsenic, lead, mercury, aluminium, nickel, fluoride and crystalline silica

Toxicological data (submission date: 20 October 2020):

Toxicological studies as recommended for a Tier 1 approach (EFSA ANS Panel, 2012).

More particularly, new data will be generated on the following core areas identified in the guidance:

- Toxicokinetics
- Genotoxicity
- Sub-chronic toxicity (rat)