Re-evaluation of food additives permitted in foods for infants below 16 weeks of age

Food Additives derived from Fatty acids

SiO_2

$CaCO_3$

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FA Stakeholders Workshop 30 November2018

efsa
European Food Safety Authority

Background from the previous assessments

For Food additives derived from Fatty acids

- **Identity**:
  - Because they are prepared from food oil and fat (mixture of fatty acids), the final composition of the additive is imprecise.
  - When the additive is chemically synthetised (e.g. E 304) residual solvents may be present in the final product
  - There is uncertainty about the possible presence of impurities from the raw material (edible oil and fat)

Background from the previous assessments

E 471

According to Commission Regulation (EU) No 231/2012 mono- and di-glycerides of fatty acids (E 471) is defined as mono- and di-glycerides of fatty acids consisting of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. It may contain small amounts of free fatty acids and glycerol.

Based on this definition, E 471 is not a discrete chemical substance but an ill-defined mixture.

Depending upon the complexity of the fatty acid sources, E 471 may contain more than 50 different mono- and di-glycerides in combination (industry).

Technical data requirements

E 471

- the lowest technologically achievable level for lead, mercury, cadmium, and arsenic in order to adequately define their maximum limits in the specifications;
- the lowest technologically achievable level for residual solvents which can be used when manufacturing mono- and di-glycerides of fatty acids (E 471), i.e. tert-butanol or tert-pentanol.
- the lowest technologically achievable level for trans fatty acids because mono- and diglycerides of fatty acids (E 471) can be manufactured by glycerolysis of hydrogenated fats and/or oils, which contain significant amounts of trans fatty acids.
- the lowest technologically achievable level for erucic acid since erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of mono and di-glycerides of fatty acids (E 471).
- the lowest technologically achievable level of any compound of toxicological concern (e.g. 3-MCPD or glycidyl esters), which can be produced under certain processing conditions from the food additive mono- and di-glycerides of fatty acids (E 471).

Background from the previous assessments

For SiO_2 and $CaCO_3$

Identity :

- these food additives are under a powder form.
- They contain a fraction of particles which are under a nanoform of not fully characterised toxicity.
- Being too broad, the EU specifications for the food additives silicon dioxide and calcium carbonate allow the use of substances with a particle size distribution which is not well characterised.
- Limestone which is used as a source material for $CaCO_3$ has a high content in aluminium.

Technical Data requirements

For SiO_2 and $CaCO_3$

- Characterisation of the particle size distribution using appropriate statistical descriptors (e.g. range, median, quartiles) as well as the percentage (in number and by mass) of the particles in the nanoscale (with at least one dimension <100 nm) that are present in the compound used as food additive.

- Percentage (in number and mass) of the fraction of particles present under a nanoform (appropriate methodology MUST be used (EFSA nano).

- Content in aluminium in the final product $CaCO_3$ used as a food additive.

Data uncertainties ADME

For SiO_2 and $CaCO_3$

- What is the fate (aggregation/solubilisation…) of the nanoparticles in the GIT?
- Are they absorbed and distributed in the organism (how much?) ?
- What is the extent of disagglomeration and/or release of primary nanoparticles of SiO_2 which may occur from agglomerates after ingestion of food containing the food additive (E 551).

Data requirements Toxicity

Food additives Derived from Fatty acids

Amounts of impurities in the final product.

Fate and reaction products in the infant formula as ready to use.

Data requirements: Toxicity

$CaCO_3$

No toxicological or biological information was submitted for the re-evaluation of calcium carbonate following a public call for data.

Issue about nanoparticles depending on the characterisation/solubilisation?

SiO_2 (studies used SiO_2 samples of unknown or poorly defined/irrelevant composition)

The material tested (silica gel, Syloid 244) in the chronic studies available did not cover the full size-range of the nanoparticles that could be present in the food additive E 551, according to information provided by industry.

Approaches which could decrease limitations of the database include (but are not limited) to a chronic toxicity study conducted according to a recognised guideline and with an adequately characterised material representative of SAS used as food additive.


THANK
YOU