Summary of the application: Iron Hydroxyde Adipate Tartrate (IHAT)

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This application for a novel food authorisation under Regulation (EU) 2015/2283 proposes the use of Iron Hydroxide Adipate Tartrate (IHAT), as a source of iron in food supplements as defined in Directive 2002/46/EC.

IHAT is a novel nutritional source of iron. It is manufactured from a solution comprising iron (III) chloride, adipic acid and L-(+)-tartaric acid, developed to mimic the properties and absorption of ferritin, the natural storage vehicle of iron in plants and animals. In ferritin, iron oxo-hydroxide cores of ferrihydrite are coated by the ferritin protein thereby constraining their growth and crystallisation. In IHAT iron oxo-hydroxide cores (also ferrihydrite) are similarly constrained from growth and crystallisation by being captured inside a corona of tartrate with some dispersion-aiding adipic acid and tartaric acid. Adipic acid and tartaric acid / tartrate are both natural compounds of the diet, authorised as food additives and are unaltered by the manufacturing process of IHAT.

Since IHAT has no history of consumption in food before 15 May 1997, it is considered as falling under the provisions of Regulation 2015/2283 on novel foods. In particular, it belongs to category ix [vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where: a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in Article 3 point (a) (vii) ; or they contain or consist of engineered nanomaterials as defined in point (f) of Regulation 2015/2283].

IHAT is requested for use as nutritional substance in food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children at a proposed maximum daily amount of 100 mg (equivalent to 30 mg of iron). Experimental and human nutritional studies have been conducted to show

- Toxicology

- Bioavailability (suitability of IHAT as a nutritional substance)

- Safety for human consumption.

These studies (in vitro, in vivo and human) show that:

- IHAT is not absorbed beyond the intestine and does not reach the systemic circulation as such. It is taken up, like dietary ferritin, through an endocytosis mechanism and released in the enterocyte lysosomes (again in the same way as from ferritin) where the Fe(III) is released to join the normal iron pool.

- IHAT adheres to normal homeostatic mechanisms that regulate iron stores and does not bypass the iron export mechanism (via ferroportin).

- IHAT exhibits no genotoxicity nor mutagenicity. It showed no toxicity in a repeated dose oral toxicity study in Wistar rats, (90-day study, compliant with OECD guideline 408 extended to OECD 407) and, based on this study, a no observed adverse effects level (NOAEL) of 462 mg/kg bw/d was

derived. Based on this NOAEL, the proposed maximum level of IHAT in food supplements provides a margin of safety of 341 in adults and above 100 for all age groups (as recommended by EFSA).

- Children and adults supplemented with IHAT as a source of iron demonstrated safe recovery from iron deficiency and iron deficiency with anemia, with no reported adverse events and no negative interference of the gut microbiome.

It is concluded that IHAT is a safe and bioavailable source of iron under the proposed conditions of use.