

## Initial Assessment

### Zinc L-Pidolate

**Name of Applicant:** UCIB – SOLABIA Group

**Contact person:** Sylvie Sinnatamby

**Assessing Competent Authority:** Food Safety Authority of Ireland (FSAI)

**Novel Food Classification:** The applicant has categorised the novel ingredient as Class I (Pure chemicals or simple mixtures from non-GM sources)

#### Introduction

An application for the authorisation of zinc L-pidolate as a novel food ingredient in accordance with *Article 4* of the Novel Food Regulation (EC) No. 258/97 was submitted to the Food Safety Authority of Ireland (FSAI) in February of 2011. The application was submitted by UCIB – SOLABIA Group of France and was formally accepted by the FSAI on February 8<sup>th</sup>, 2011.

The safety of zinc L-pidolate as a source of zinc added for nutritional purposes to food supplements and foods for particular nutritional uses (PARNUTS) has already been assessed by EFSA (The EFSA Journal (2007) 495-503, 1-10), a copy of the report is attached. As a result, zinc L-pidolate is listed in Annex II of Regulation EC No 1170/2009 which amends Annex II of Directive 2002/46/EC relating to vitamins and minerals that can be added to food supplements.

In accordance with the Standing Committee on the Food Chain and Animal Health (General Food Law) of February 14, 2005, the use of a food ingredient in food supplements alone is not considered as evidence of a history of consumption that would allow that ingredient to be placed in general foodstuffs without prior novel food authorisation. Therefore UCIB-Solabia Group are now seeking novel food authorisation for zinc L-pidolate in accordance with the novel food Regulation in order to add zinc L-pidolate to foods for particular nutritional uses (PARNUTS).

Zinc L-pidolate falls in to category C of *Article 1.2* of the novel food Regulation; “foods and food ingredients with a new or intentionally modified primary molecular structure”. For the assessment of wholesomeness, as set out in Commission Recommendation 97/618/EC, the novel ingredient is placed in Class 1 (Pure chemicals or simple mixtures from non-GM sources) and sub class 1.1 (the source of the NF has a history of food use in the Community).

## **EFSA Safety Assessment**

The European Food Safety Authority (EFSA) was asked to carry out an evaluation of the safety and bioavailability of calcium, iron, magnesium, potassium and zinc L-pidolate as sources of those minerals used in food supplements and PARNUTS. Only the zinc L-pidolate will be referenced in this report. The EFSA safety assessment concluded from the data provided that zinc is absorbed from zinc L-pidolate and its bioavailability is comparable to that from other water-soluble and dissociable zinc salts permitted in food supplements and PARNUTS. The EFSA safety assessment of the L-pidolic acid salts was based on the natural occurrence of L-pidolic acid in foods, its endogenous formation, the limited toxicological data available on the kinetics and metabolic pathways of L-pidolic acid. On this basis, EFSA concluded that the use of zinc L-pidolate as a source of zinc added for nutritional purposes to PARNUTS is of no concern at the maximum use levels indicated, which, under the assumption that all the nutrients are ingested as their pidolic acid salts at the same time, would result in an intake of L-pidolic acid of 3g/day.

## **Conclusion**

On the basis of the EFSA safety assessment of 2007, the FSAI is satisfied that zinc L-pidolate meets the criteria set out in *Article 3.1* of the novel food Regulation EC No 258/97. The EFSA safety assessment of 2007 formed the basis for the inclusion of zinc L-pidolate in Annex II of Regulation EC No 1170/2009 which amended Annex II of Directive 2002/46/EC by the addition of zinc L-pidolate, among others. Even though the EFSA safety assessment also considered the nutritional use of zinc L-pidolate added to PARNUTS, the Annex to Regulation EC No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses does not yet include zinc L-pidolate.