SUBSTANTIAL EQUIVALENCE OPINION
Cocoa Extract

Introduction

The Food Safety Authority of Ireland (FSAI) received an application in March of 2015 from Mars Symbioscience of Maryland in the USA for an opinion on the substantial equivalence of a low fat cocoa extract (Cocoa Via®) manufactured by the Cocoapro® process to a defatted natural cocoa powder under *Article 3.4* of the novel food Regulation (EC) No 258/97. The applicant considers their cocoa extract to be novel in the EU and fall within the scope of the novel food Regulation (EC) No 258/97, specifically the category set out in *Article 1.2(e): "foods and food ingredients consisting of or isolated from plants, except foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*".

To demonstrate substantial equivalence in line with *Article 3.4* of the novel food Regulation, the low fat cocoa extract is compared to defatted natural cocoa powder also manufactured by Mars and currently marketed in the EU. The cocoa extract, like its comparator is not a significant contributor of macro- or micro-nutrients to the average diet and this fact is used by the applicant to place any compositional or nutritional variations in context. The novel ingredient is intended as an alternative source of cocoa flavanols to that already provided by Mars' cocoa powder and other foods and food supplements in the EU. The production process for the cocoa extract and the cocoa powder by Mars is identical, except for the additional extraction step used to produce the cocoa extract. Processing is carried out to GMP standards and in accordance with HACCP principles. The applicant uses Indonesian cocoa beans (*Theobroma cacao* L.), from which their Cocoapro® production process produces the defatted cocoa cake. The defatted cocoa cake is then either milled to produce cocoa powder or else extracted with aqueous acetone to produce the cocoa extract.

Composition

The specifications for the cocoa extract and cocoa powder are provided along with detailed analytical compositional data. A few differences are evident in the cocoa extract such as the presence of silicon dioxide (1% max.) as a processing aid and the relatively higher content of caffeine, theobromine and flavanols. In addition, a slight

reduction is observed in the levels of ash, protein, fat, dietary fibre, iron, sodium and calcium. The higher level of flavanols in the cocoa extract is an intentional consequence of the extraction step which the applicant may separately seek to exploit in terms of a nutrition or health claim. The proposed uses and use levels of the cocoa extract should ensure that any compositional differences will not impact significantly on the ultimate intake of any of these constituents by consumers. In addition, because the cocoa extract and the cocoa powder are insignificant contributors to the reference intakes for most of the constituents concerned, the observed variations are not considered significant from a nutritional perspective. The novel ingredient is stable in its original containers for a minimum of five years at temperatures between 10 and 25°C and relative humidity of 80% or less.

Nutritional Value and Metabolism

Certain variation is evident in the levels of some nutrients in the cocoa extract compared to those in the cocoa powder. While some of the differences may seem significant in absolute or numerical terms, they are mitigated when recommended intake is taken into account. In addition, none of the differences are expected to impact on the nutritional value of the cocoa extract compared to the cocoa powder as both will contribute minimally to the reference intakes as set out in *Annex XIII* of the FIC Regulation (EU) No 1169/2011. With composition and nutritional value considered to be equivalent, it therefore follows that metabolism of the cocoa extract would also be similar to that of the cocoa powder.

Intended Uses

The cocoa extract is intended as an alternative source of cocoa flavanols to Mars' cocoa powder which is currently on the EU market. The applicant proposes to provide cocoa extract at levels of up to 730 mg per serving (375 mg cocoa flavanols) or 1.2 g/day for use as a functional ingredient in foods and food supplements. They will advise that consumers should avoid consuming more than 600 mg of cocoa flavanols per day.

Level of Undesirable Substances

Mars' cocoa extract is manufactured using the same process as for their cocoa powder and therefore quality control including the management of undesirable substance

levels are equivalent. However, the applicant has provided analytical data providing reassurance on the level of potential contaminants including heavy metals, PAHs, mycotoxins, pesticides and microorganisms. The additional extraction step required to produce cocoa extract utilises acetone, an authorised solvent for extraction purposes with residual levels in the final cocoa extract shown to be at acceptable levels.

Conclusions

Having reviewed the information provided by the applicant in the original application dossier and subsequent clarifications, the FSAI is satisfied that under the proposed uses and use levels, cocoa extract (Cocoa Via®) produced by Mars Symbioscience is substantially equivalent to Mars' natural cocoa powder in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.