

## **SUBSTANTIAL EQUIVALENCE OPINION**

### **Extract of defatted cocoa powder - OMNICOA 55**

The Food Safety Authority of Ireland (FSAI) received an application from Bioresco Ltd. seeking a Competent Authority opinion on the substantial equivalence of a defatted cocoa powder extract (Omnicoa 55). Bioresco Ltd. was acting on behalf of two applicants, Cognis GmbH of Germany and Barry Callebaut of Belgium, while the product is manufactured by Ajinomoto OmniChem N.V. The application, along with certain clarifications addressed the composition, nutritional value, metabolism, intended use and level of undesirable substances of Omnicoa 55 when compared to defatted cocoa powder.

#### **Composition and Nutritional Value**

Comparative compositional analysis with defatted cocoa powder reveals that Omnicoa 55 is lower in protein (3.1% compared to 23.6%), fat (1.9% compared to 11%) and fibre (<0.5% compared to 32.9%). It is however slightly higher in carbohydrates (16.2% compared to 11.6%), and has a higher proportion of polyphenols (61.1% compared to 10.6%). The applicants suggest that any differences at macronutrient level between Omnicoa 55 and defatted cocoa powder are not nutritionally significant in the context of overall macronutrient intakes from various sources. In fact, the applicants argue that Omnicoa 55 will deliver similar levels of potentially beneficial polyphenols when compared to chocolate, but with reduced levels of fat (1.9% for Omnicoa 55 compared to 36-41% for chocolate) and sugar (16.2% for Omnicoa 55 compared to 32-43% for chocolate).

#### **Metabolism**

The applicants reasonably contend that the relatively higher polyphenol content along with reduced sugar and fat levels of Omnicoa 55 should not significantly alter its metabolism in comparison to that of defatted cocoa powder.

#### **Intended Use**

The applicants intend to use Omnicoa 55 in food supplements and as a functional ingredient in products for health conscious adults, i.e. nutrition bars and milk based beverages. The applicants will advise manufacturers not to incorporate more than 550 mg of Omnicoa 55 ( $\leq 300$ mg polyphenols) in one portion of food (or food supplement) and recommend that consumers not consume more than 600 mg of polyphenols (1.1g of Omnicoa 55) per day.

## **Levels of Undesirable Substances**

The extraction technique uses food-grade extraction solvents and the process comprises typical extraction and separation techniques which are not expected to modify the chemical structure of the Omnicoa 55 components. Therefore it is unlikely that the level of undesirable substances in Omnicoa 55 will be significantly different to that of defatted cocoa powder.

The applicants also report that there are no known adverse human health consequences associated with the ingestion of the main phenolic components of Omnicoa 55 (catechin, epicatechin and oligomeric/polymeric proanthocyanidins), and theobromine.

## **Conclusions**

Considering the information provided, the FSAI is satisfied that Omnicoa 55 produced and used as such in food supplements and as a functional ingredient in certain foods is substantially equivalent to defatted cocoa as regards its composition, nutritional value, metabolism, intended use and level of undesirable substances as set out in *Article 3.4* of the novel food Regulation (EC No. 258/97).