

SUBSTANTIAL EQUIVALENCE OPINION

Purified Green Tea Extract - TEAVIGO

The Food Safety Authority of Ireland (FSAI) received an application from Bioresco Ltd. for an opinion on the substantial equivalence of the purified green tea extract branded “Teavigo”, which is rich in epigallocatechin gallate (EGCG).

The initial application, along with subsequent clarifications were reviewed by the FSAI to determine the substantial equivalence of these products in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. For the assessment of wholesomeness, the novel ingredient is classified by the applicant as class 2; "Complex novel food from non-GM source", and sub-class 2.1; "The source of the NF has a history of food use in the Community".

Composition and Nutritional Value

The applicant demonstrates that green tea infusions comprise greater than 98% moisture and, in comparison to average daily intakes, their nutritional value is minimal with respect to protein, lipids, sugars, fibre and ash, as well as a number of key vitamins and minerals (with the possible exception of vitamin C). Therefore, the fact that purified green tea extracts, such as Teavigo, contain lower amounts of these constituents does not significantly alter its nutritional impact for the consumer relative to green tea infusions.

Teavigo differs from some green tea extracts with respect to certain polyphenols, caffeine, theanine and tannin. However, the applicant argues that these constituents are not essential for normal growth and metabolism, and that a reduction in their levels is not deleterious to humans. On the other hand, the higher levels of EGCG in Teavigo is thought to have a beneficial effect on humans, the scientific substantiation of which is the subject of a separate assessment by EFSA under the health claims legislation. The applicant also claims that the colourless, tasteless and caffeine-free features of Teavigo are an advantage.

Metabolism

Normal metabolism is not expected to be affected by consumption of this product.

Intended Use

The applicant intends to use Teavigo in food supplements and fortified foods. The applicant undertakes to advise manufacturers to incorporate Teavigo in their foods so that the levels of EGCG consumed remain similar to those consumed from crude green tea sources.

Levels of Undesirable Substances

The level of undesirable substances in Teavigo is not expected to be negatively impacted by the production process.

Supplementary information

The applicant undertakes to advise food manufacturers using Teavigo that intake levels of Teavigo constituents should not exceed those associated with the consumption of crude green tea extracts.

The applicant also provides additional information regarding the safety of EGCG and green tea extracts, but while this information is of interest in a general safety context, it is without consequence for this substantial equivalence opinion.

Conclusions

Considering the information and undertakings provided by the applicant, it is the opinion of the FSAI that Teavigo produced and used as such in food supplements and fortified foods is substantially equivalent to aqueous green tea extracts as envisioned under *Article 3.4* of the novel food Regulation (EC No. 258/97).