

## FEASIBILITY OF DEVELOPING A SUCCESSFUL HEALTH CLAIM APPLICATION FOR TOMATO PRODUCTS – NIZO study summary. 17th October 2016.

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### SUMMARY

In 2009, permission was given by EFSA (European Food Safety Authority – like FDA in the US) to Provexis Natural Products Ltd to use a health claim stating that their Water-Soluble Tomato Concentrate (WSTC) “helps maintain normal platelet aggregation, which contributes to healthy blood flow“. The feasibility of obtaining approval for a similar health claim for tomato products and platelet function has been assessed on the basis of published data.

A beneficial effect of fresh tomatoes or processed tomato products on platelet aggregation depends on the presence of bioactive compounds in these products, in sufficient quantities to produce a relevant physiological effect when consumed as part of a normal diet. Bioactive components present in WSTC are also present in fresh tomatoes and (since they are stable in many processing conditions) tomato products - and very likely in quantities per normal serving that are expected to have the same beneficial effect. Therefore, the feasibility of developing a successful health claim application is considered high.

However, more data is needed on the exact content and variation of relevant bioactive compounds, with antiplatelet activity, in different types of tomato products. Human studies, conducted with fresh tomatoes, tomato juice and/or tomato paste, or other tomato products in a healthy population, with platelet aggregation as the outcome, are lacking. Such studies are pivotal for a health claim application.

Because the available data indicate that the variation in bioactive content is largest and least controlled in fresh tomatoes, we recommend focusing on a health claim application on inhibition of platelet aggregation by tomato paste and tomato juice.

Analysis of the composition of these tomato products, in direct comparison with WSTC, will provide results for determining serving size for tomato juice and paste, required to achieve effective intake of these compounds. We strongly believe the outcomes from sample testing will show a direct correlation from WSTC to tomato paste at levels that will mean a single standard serving of most of the common tomato products will deliver a sufficient concentration of bioactive compounds needed to produce the claimed health effect.

We recommend conducting at least one human study to compare the acute antiplatelet effects of different tomato products, compared to placebo, and one study with intake of the selected tomato product(s) for one month to determine the sustained effect on platelet inhibition. Designs of studies performed with WSTC can be copied to a large extent, but need to be adapted to account for the different role of tomato products (compared to the WSTC supplement) in a normal diet. The human trials for WSTC were quite small in size, between 12 and 30 subjects. We believe that small trials of this size will be sufficient to confirm the data.

The health-claim dossier can then be prepared following the product sample testing stage and human trials for submission to EFSA.