ProFlow

EFSA / FDA health claims for tomato products

Application for private funding

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the tomato foundation

CALEDONIAN SCIENCE PRESS

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Introduction

The Tomato Foundation's ProFlow research program presents a greater and more commercially significant scientific breakthrough for tomato products than lycopene

ProFlow aims to run a multi-centre human trial that will prove a standard single serving of a tomato product, designed for use in the trial, optimises blood and qualifies for 2 x EFSA health claims:

- **Optimised blood flow (blood platelet aggregation)**
- **Optimised blood pressure**

The trial has been designed with technical advice from EFSA to strictly comply with their protocols to qualify for health claims.

Funding the ProFlow trial

The Tomato Foundation has been searching for EU public funding for the **ProFlow** research project. However, due to current events, European funding priorities have changed fundamentally.

Our research is unfortunately outside current EU funding priorities.

The Tomato Foundation concludes the only way forward is by offering exclusive rights to the **ProFlow** research IP in exchange for the economic support needed to complete the trials and application for the two EFSA health claims.

The following text illustrates the value of the **ProFlow** research, the current level of preparedness to begin, the schedule of tasks and overall proposed costs.

Funding advantages

ProFlow combines scientific evidence with product innovation to create a multi health claim approved, functional nutrition category for tomato products

- **ProFlow's** innovation creates the world's first natural, functional nutrition food product with health claims for both optimised blood flow and blood pressure. There is clear potential for this product to become the primary on-the-go dietary choice for healthy blood.
- Investment in **ProFlow** secures exclusive IP control, with a minimum, 5 year time-to-market advantage for the IP holder.
- Investment in **ProFlow's** science-driven innovation answers consumer needs and desires for natural, dietary choices that help them optimise or improve their health.
- EFSA and FDA approved health claims support the design of new, higher value offerings that will open new, premium product markets.
- **ProFlow** predicts a spillover generic consciousness effect to all categories of tomato products, compounding sustainable growth across the industry.
- This is science with a targeted, real world outcome. Benefit to investors: IP-protected product innovation and product differentiation.
- **ProFlow** grows consumer trust with scientific approval, adding long-term credibility and validation.

ProFlow's research will therefore reframe consumer perception of historically trustworthy and healthy products to a new level of relevance and importance, stimulating sector-wide growth.

ProFlow overview

ProFlow will undertake a multi-centre nutrition intervention trial in humans to demonstrate that daily consumption of a single serving of ***Tomato Bioactives*** delivers health benefits for maintaining cardiovascular and heart health by reducing platelet aggregation, lowering blood pressure, and otherwise improving blood flow.

ProFlow will use a formulated novel tomato product, designed from existing categories to increase nutrient density (while preserving flavour).

ProFlow consortium

The partners below form the **ProFlow** research consortium. Including multiple Centres of Excellence, with comprehensive experience in human nutrition studies and EFSA health claim guidelines.

- University of Barcelona
- University of Maastricht
- Aix-Marseille University
- SSICA
- The Tomato Foundation
- Caledonian Science Press

The research consortium is currently optimised with 3 trial centres.

If additional funding of (**1.8 million €**) can be secured then **Harvard Medical School** has agreed to participate and amplify the trial further, corroborating the results.

All research partners grade the chance of success as very high.

Letters of Agreement and Non-Disclosure have been signed by all research partners and filed with the Tomato Foundation.

Schedule of actions

The full Document of Work with all details will take time to construct. Every part of the architecture and protocols must be planned, tested theoretically, and agreed.

Finalised responsibilities for human trials and associated laboratory work will be allocated to the different centres. The University Of Barcelona will act as the central scientific coordinator.

Stage 1 (6 months)

Document of Work:

1. Initial formulation of primary test material
2. Interrogate all up-to-date EFSA regulations
3. Define study objective and hypothesis
4. Select primary outcome and markers
5. Define the study population
6. Selection of study design
7. Define/characterise study treatments
8. Develop study protocol
9. Calculate sample size and timeframe
10. Define laboratory work
11. Register with EFSA and pre-notify of study
12. Final DoW and study costs

Stage 2 (18 months)

Human trials and laboratory work:

13. Ethical approval and registration
14. Comprehensive scientific review
15. Final formulation of primary test material
16. Testing of packaging stability and shelf-life
17. Selection of trial participants
18. Reception of all test materials
19. Run trials
20. Run laboratory work
21. Statistical analysis of results
22. EFSA dossier

The Tomato Foundation will run a comprehensive communications campaign in parallel, from the beginning of the project.

ProFlow IP

The central value of the **ProFlow** research is in the formulation and outcome data. This Intellectual Property is where the true commercial value of the research exists.

ProFlow offers an exchange mechanism based on the management of the Intellectual Property the research will generate.

IP is protected under European law for 5 years, by withholding critical outcome data, methodology and protocols.

Exclusive or shared IP rights can be negotiated for individual market territories in exchange for the funding needed to complete the research.

Sub-licensing

Companies with territorial exclusivity have the option to sub-licence to a third party only by pre-agreement with **ProFlow** for a 15% commission.

This mechanism may allow invested companies to recoup their own position or profit from licensee revenues.

Schedule of economic support

The total cost of the **ProFlow** project is **3.2 Million €**.

A 10% deposit is to be paid by supporting companies upon the initial agreement.

During the initial 6 month period, the project will complete the general Document of all Works with a complete descriptions of all tasks, methods, milestones and deliverables, which forms the contract with the institutions running the trials.

Up to month 6 there will be no contracted obligation by funding entities to go further.

Only upon completion of the first stage preparations can a universal agreement between all parties be agreed.

The payment schedule is therefore as follows:

- 10% of total costs, paid at the project's initiation
- 60% paid at month 6, by universal agreement
- 30% paid at month 12

Proposed division of overall costs

We propose the total cost be divided by continental territorial interests.

Our initial proposition assigns:

- 60% of the project's total value to Europe
- 40% to Asia/Oceania

The EFSA health claim data complies with other national agency standards (FDA, Health Canada, FSANZ).

An additional nutrition trial may be required to comply within Asian and Oceanic territories.

Future IP exclusivity for the Americas is valued at the cost of bringing Harvard Medical School into the trial (1.8 million €).

How CSP became global experts in tomato nutrition science

Caledonian Science Press was formed as a scientific publishing consultancy by **David Sutherland** in late 2000. Previously, his experience centred on publishing scientific reviews of medical human trials for the pharmaceutical industry.

At that time, dietary and lifestyle interventions were coalescing into an emerging clinical discipline now known as Lifestyle Medicine. This field focuses on evidence-based strategies to prevent, manage, and in some cases reverse **Non-Communicable Diseases** (NCDs) through targeted modifications in nutrition, physical activity, sleep and stress management.

David observed that the system utilised by the pharmaceutical companies could be repurposed to validate the science behind Lifestyle Medicine by identifying and publishing global opinion-leading research into functional nutrition.

Committed to advancing transparent, evidence-based nutrition science, David's objective was to provide medical professionals with accurate, well-substantiated information, enabling them to provide patient-centred guidance, grounded in scientific evidence.

Selecting lycopene as the primary topic, CSP quickly gathered global opinion leaders for the first ever journal-format publication on the subject. The edition covered scientific reviews from international conferences sponsored by **H.J. Heinz** and **Campbell's Soup** to promote and grow consumer awareness of lycopene. The 48 page first edition, **Nutrition and Health Conference Reports** sold over 27,000 copies globally.

In 2006, CSP published the first independent book on lycopene research, assembling the 24 foremost researchers from around the world. The book found support from the **WPTC** and **AMITOM** processing tomato industry associations.

Tomatoes, Lycopene and Human Health, sold over 11,000 copies worldwide. Its central aim was to provide scientifically reliable, state-of-the-art information on 14 leading topics relating to lycopene.

The book included a chapter by **Dr. Volker Böhm**, who was about to launch the FP6 European Commission research project **LYCOCARD** to investigate the relationship between lycopene and cardiovascular diseases (CVD). CSP was invited to join the project as the dissemination partner.

LYCOCARD was based on an impossible mission: to show that increased consumption of processed tomato products, including specially formulated high lycopene sauces, reduced the risk of CVD. However, CVD takes decades to present a serious health risk, so, while the research advanced the state-of-the-art, the 5 year duration was too short to make the project results convincing.

In 2009, CSP noticed a new product called **Water-Soluble Tomato Concentrate** (WSTC), branded as Fruitflow©. WSTC is the non-lipid-soluble fraction of tomato, meaning no lycopene content. It was awarded an EFSA health claim for improved blood liquidity and marketed as both a supplement and an additive for other products such as fruit juices and yoghurt.

WSTC is patent-protected. CSP presented the viability of accessing a similar claim for tomato products to the global industry associations in late 2009. It was considered to be legally complicated and was forgotten.

But, CSP did not forget.

In 2012, with broad industry support, CSP formed the Tomato Foundation to continue the research into future health claims for tomato products and to create a real-world context in which to frame the research.

In 2015, the 5 year **EFSA** protection expired on certain aspects of the WSTC information. CSP requested a copy of the **EFSA** dossier for WSTC as well as accessing the patent documents and the **GRAS** certificate. In 2016, Tomato Foundation president, **Gwen Young** presented the **ProFlow** project for the first time at the **World Tomato Congress** in Santiago de Chile.

WPTC, **AMITOM** and leading companies from the processing tomato industry supported the **Tomato Foundation** with a grant to explore the feasibility of using the WSTC science to pursue a health claim for tomato products. The study, made by **NIZO Food Research** in the Netherlands, concluded there was a very high probability of success.

A study was designed (in collaboration with **SSICA**, Parma) to compare levels of blood-thinning bioactive compounds in servings of **over 300 samples, provided by 18 companies from 12 countries**, of tomato paste, crushed, whole canned, juice, purée etc. against those in samples of WSTC.

Published in the **International Journal of Food Sciences and Nutrition**, the results showed sufficiently high levels of the bioactive compounds found in a daily dose of WSTC.

However, the results also revealed the natural, expected variation owing to differences in production methods and control of the raw materials.

Dr. Luca Sandei and **David Sutherland** identified the need to create a uniform product sample for use in the human trials. This in turn became the basis of a new premium product opportunity.

CSP has provided scientific communications consulting for the Spanish Olive Oil Industry association (**Interprofesional de Aceite Español**) and has worked closely with the cereals, pasta and breads industries through the **HEALTHGRAIN Forum**.

CSP has partnered with other EC research projects, including **NANODEM** and **HEMOSPEC**.
Since 2021, CSP has partnered with **The LEAF Coalition**, a climate finance platform, and **EMERGENT**, a carbon credit platform designed to protect what's left of the ancient rain forests globally.

Originally formed in Scotland, Caledonian Science Press SL is based in Sitges, near Barcelona.

Appendix i - Tomato products & science / What about lycopene?

The processing tomato industry has always enjoyed the benefit of broad public perception that minimally processed tomato products like purée, whole canned, passata, crushed etc. are considered healthy ingredients.

In the mid 1980s, the scientific story of lycopene's possible health benefits gained traction. The story exploded in the late 1990s, with Ed Giovannucci's famous paper on prostate cancer risk reduction.

By 1997, H.J. Heinz was sponsoring international conferences to further promote investment in this emerging field of research.

Campbell's Soup, Conagra and others joined the movement and by 2001 lycopene was the biggest nutritional story in the history of processed tomato products worldwide.
As it has remained up to the present day.

Millions of dollars and euros of private and public funding expanded the scope of the study, all looking for tangible lycopene health claims and labelling consumers would connect to.

The industry began to leverage the research and united to promote lycopene health stories globally, from AMITOM publishing its own book to the US-based Tomato Products Wellness Council. Public research funding for lycopene research culminated in the 5.2 million euro EU project, LYCOCARD.

Even without official health claims to add value, a battle was waging between the food and supplements industries to control and exploit the narrative of lycopene. Pharmaceutical companies like Roche and Wyeth (promoting synthetic lycopene) and natural supplements makers like LycoRed competed with major tomato products brands to dominate the story.

This battle helped to further raise consumer consciousness of lycopene worldwide.

For 25 years it has been a dominant force, adding value to tomato products and novel lycopene supplements globally.

However, no viable health claims for lycopene have been granted, although the research has been referenced repeatedly to publicise and market lycopene's antioxidant health effects.

The decades-long obsession with lycopene effectively blocked any other emerging research.

The lycopene story highlights the important added value that scientific research brings to tomato products.

The ProFlow mission to gain two universally relevant EFSA/FDA health claims will open an exciting new field of tomato science that will eclipse the lycopene story.

Appendix ii - ROI

The question of return on investment can be answered by looking at the effect on market growth and consumer activity for food sectors that have recent EFSA/FDA health claims for their products.

We looked closely at 4 examples:

- Cocoa Flavanols
- Olive oil
- Beta-glucan (oats)
- Plant Sterols

Specific data making a market growth correlation in each case is not available. We have studied these sectors, and spoken to the industrial associations or companies involved, to try and better understand the commercial benefits of the heath claims. The answers we received illustrate numerous, unplanned secondary positive effects directly linked to the authorisation of the health claims.

All sectors reported growth in generic consciousness of the positive health effects.

- For Beta-glucan and reducing LDL cholesterol (EFSA: 2011), the oats industry in Europe reported marked growth in demand and corresponding increases in areas under cultivation. Consumer demand for oats and oat products has consistently grown at a much higher level than pre-health claim.

  No doubt, multiple factors are responsible for this growth, but the oats industry considers the health claim to be the initial catalyst for the change in market perception.

  Secondary effects include online influencers celebrating the health claim and innovating new ways to enjoy oats in the diet. This layered effect of additional levels of communications and influencers directly contributing to new product innovations have promoted oats into new categories and markets.

- The same can be said of olive oil and protection of LDL particles from oxidative damage (EFSA: 2010). With a health claim awarded in 2010, the result was an increased generic consciousness globally that olive oil is a healthy oil.

- The health claim for plant sterols and reduced LDL cholesterol (EFSA: 2010) was exploited heavily as a daily dose product branded as Danacol, enjoying major and ongoing commercial success. Danone funded and exploited the multiple human trials needed to qualify for the health claim.

- Barry Callibaut, a leading chocolate company, followed the same model to exploit the high levels of flavanol compounds in cocoa and successfully secure a health claim for optimised vascular function (EFSA: 2012). The claim has led to noticeable market growth and a generic market perception of (high cocoa content) dark chocolate as healthy.

The investment made by these industries has unquestionably led to sustained market growth, product innovation, increased consumer engagement and promotional value from influencers and dietary professionals, based on one simple truth:

Health claims are not opinions. They are objective facts that consumers trust.

Appendix iii - Consumer demand

As health-conscious consumers become increasingly aware of the role that diet plays in overall well-being, the demand for functional beverages has surged, making them a staple in the modern diet. The rise of functional beverages is not just a trend but a reflection of broader shifts in consumer behaviour and preferences.

The demand for natural products is rising and the focus on preventive healthcare is increasing, with consumers taking proactive measures to maintain their health.

According to the Packaged Facts July 2023 report, *Functional Beverages: Market Trends and Opportunities, 2nd Edition*, 38% of adult US consumers agree that they purposefully seek out beverages with ingredients that are designed to or claim to improve overall health or specific body functions, while 41% are willing to pay more for these functional beverages. Though some functional beverages are more niche than the most popular category of sports and energy drinks, there is clearly strong appeal for beverages with functional ingredients.

The idea of 'food as medicine,' which uses diet to treat health issues and enhance well-being, is gaining popularity among consumers. This trend boosts the need for drinks enhanced with bioactive components that have been scientifically proven to be beneficial, such as probiotics for digestive health or plant sterols for cholesterol control.

Evidence of strong consumer demand and willingness to pay should drive innovation in new product development and distribution, bringing products that are healthy, taste good, and are reasonably priced to consumers.

In addition, consumer scepticism around health claims of products should also be addressed by providing validated information about the product's attributes. Beverages should include authorised nutritional or health benefit labelling, as this information is perceived to be more credible than marketing communications.

"Consumers are actively seeking high-value ingredients, those ingredients that are science-backed. It is increasingly important to be able to provide high-quality research supporting the efficacy of the ingredients in products. Consumers are becoming much more discerning about which 'healthy' ingredients are actually supported by science."

John Kelly, strategy director for beverages with Kerry, an Irish food ingredients firm.

Within the functional beverages sector, the functional shots market is set for particular and rapid expansion, driven by increasing consumer demand for health and wellness products, innovative product developments, and strategic industry movements.

As consumers seek natural, convenient, health-enhancing options, the market for functional shots is expected to continue growing significantly in the coming years.

The global functional shots market size was estimated at USD 801.9 million in 2023 and is expected to grow at a compound annual growth rate CAGR of 14.9% from 2024 to 2030 [1]. The market growth over the coming years is attributed to the rising health awareness & consciousness among consumers, increasing demand for ready-to-drink beverages, and rising demand for organic food products.

Consumers are increasingly seeking convenient, on-the-go options that offer targeted health benefits and this trend reflects a shift toward health-conscious lifestyles where individuals prioritise wellness without compromising convenience.

The rise is also due to preventive healthcare and ageing populations. As people age, their nutritional needs change, and functional shots designed to address specific health concerns, such as joint health or cognitive function, become more appealing. Additionally, the prevalence of chronic health conditions like diabetes and cardiovascular issues has led consumers to explore functional shots as a part of their therapeutic dietary choices. They fit well into various health-focused products and lifestyle preferences.