

Health claims

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Navigating the functional legislation maze

The last year has brought disappointment for many innovating in the beverage industry with numerous functional on pack claims receiving an unfavourable response from EFSA.

There are many valid reasons given for these unfavourable opinions – ranging from insufficient characterisation of the product, to clinical trials not fitting with the target market, or not supporting the action of the product.

For instance regular pattern of consumption is something which EFSA rate highly – so if a drink is presented as a juice drink then it should not be consumed as you would a yogurt. Other target areas which need to align under the heading of population are age and sex of those in the clinical trials. So if a drink is aimed at infants or the elderly then the trial needs to be in this area too. Similarly there is varying susceptibility to disease in parts of the globe so a study on vitamin or mineral benefits in Asia or South America may not be applicable to the European population. And similarly the reverse is true, for example there are more genetic disorders leading to diabetes in Asia.

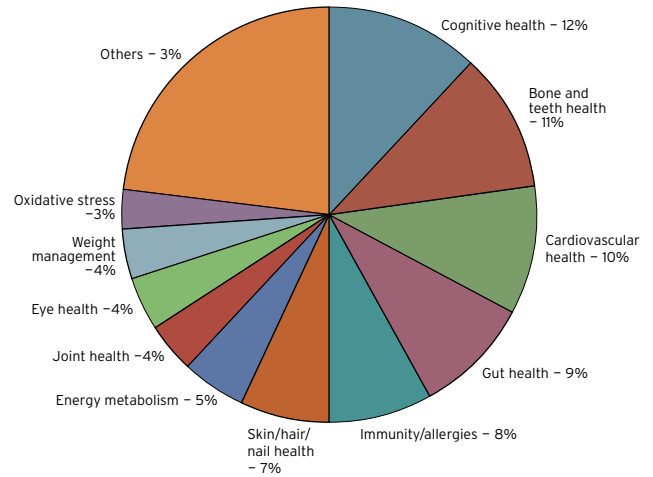
Naturalpha, international consulting and scientific and clinical research company in Nutrition and Health, located in the North of France is working to help agro-food industrial and beverage companies demonstrate that their commercial product is effective through scientifically driven methodologies that allow better biological characterisation and the set-up of optimised clinical trials – in many cases also advising on grants for SME's.

Around 4,000 claims made with 70-80% of these receiving unfavourable opinions

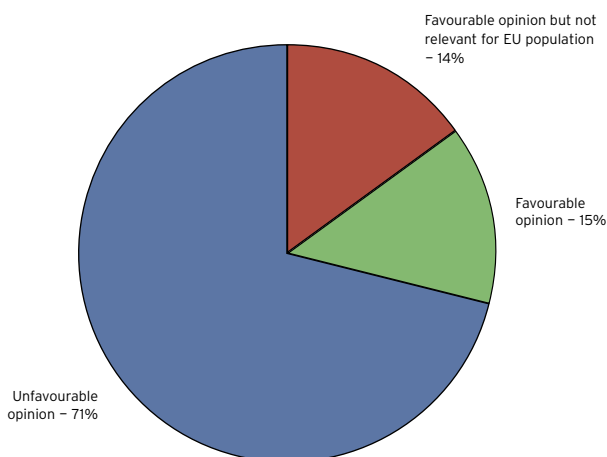
Having set up its innovation centre in Lille, the company is building its network and has three main departments:

by **Naturalpha** Executive Vice President R&D Christophe Ripoll

Health topics for all claims



EFSA's opinion for all health claims



Consulting: both regulatory and scientific which involves R&D and fine tuning dossiers, Pre-Clinical – looking at providing proof of concept for the health effect of the product and helping organise Clinical trials for agro-food companies.

We are specialising in 'gap analysis' and identifying where a dossier is falling down. By 'filling the gap' we mean looking at the strengths and weaknesses and advising on additional data needed to bring proof of health effects via well-designed clinical trials.

So far there have been around 4,000 claims made with between 70 and 80% of these receiving unfavourable opinions. Most of these were concerning 'generic' claims under the article 13.1 of The European Nutrition and Health Claims Regulation (1924/2006/EC).

Of course the efforts of EFSA are positive because it wishes to protect the consumer from incorrect claims but there are some products which are valid that need good biomarkers and characterisation in terms of formulation and composition. For instance the specific type of probiotic or plant extract which

is being used is sometimes vital as some are effective while others are not. For example soya bean extract is the result of different processes and depending on which process is used will not give the same product at the end.

Other areas such as brain development in infants are being looked at – and here there are many clinical trials in phytosterols and fibre, which can substantiate a claim. However EFSA have noted that there are geographical differences in how various populations react and so not all trials can be regarded as valid.

FruitFlow is a product from Provexis plc, an SME which has succeeded in gaining EFSA approval. Here there have been clinical trials demonstrating both acute and chronic effects. The design also fits with the wording on the claim – so this is a well-designed study with good description of the product and how it relates to the activity.

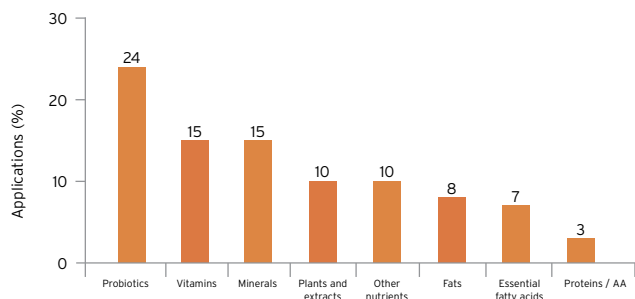
We will no doubt see dossiers evolving over the next year with better design and more definition of the product, and care taken to align the claim with the clinical trial. What we recommend is 360 degree

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Functional ingredients in claims



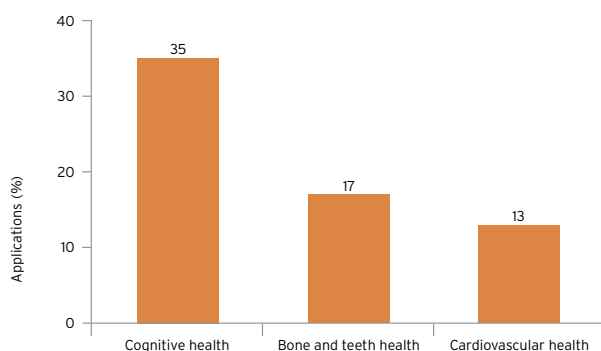
analysis of the product – so that the clinical trials are correctly aligned before we build the dossier. If you have already gone too far down the line with certain trials it can be hard to pull it together to create a scientific rationale regarding the efficiency of a product.

EFSA has given favourable opinions regarding the benefits of minerals such as zinc, calcium and magnesium concerning cognitive function and physical performance along with trials of selenium for fertility and immune function. But some claims are not suitable for the European population. Therefore, it is essential that the trials and dossier fit with the population for which the drink is intended – that is why we like to consult with our clients as early as possible in the development phase.

Over the next few months the response to claims under article 13.5 regarding newly developed scientific evidence and 14 regarding children's health development and risk reduction will be revealed and we will get a better idea on how EFSA evaluates each dossier. This is not a black and white science and some dossiers may be very close to being given favourable opinions and need minor improvement in the characterisation of the product and not necessarily another intervention study.

For some products, the relationship between the product and its health effect are already evident and while further clinical trials are needed in some cases, this is not always so. ■

Top three health topics for article 14 claims



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UK: +44 (0) 1488 689800
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