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FEATURE

SPORTS DRINKS

How valid is the European Food Safety Authority's assessment of sports drinks?

Matthew Thompson, **Carl Heneghan**, and **Deborah Cohen** find worrying deficiencies in the evidence used to support the health claims made for sports drinks

Matthew Thompson *senior clinical scientist*[1], Carl Heneghan *reader in evidence based medicine*[1], Deborah Cohen *investigations editor*[2]

[1]Department of Primary Care Health Sciences, University of Oxford, Oxford OX2 6GG, UK; [2]*BMJ,* London WC1H 9JR

Back in January 2006, the European Union decided to adopt legislation to assess health and nutrition claims related to foods.[1] The EU regulation aims to ensure that "claims made on food labelling and advertising regarding nutrition and health are meaningful and accurate, and can thereby help consumers in making healthy diet choices." From the end of 2012, all claims used to market and advertise a product will need to be approved.

The body responsible for evaluating the scientific basis of health claims is the European Food Safety Authority (EFSA). Their remit includes health claims related to the "roles of nutrients or substances in growth, development or functions of the body, psychological or behavioural functions, or slimming or weight control."[2] This includes claims related to sports supplements and sports drinks.

After the legislation was passed, individual member states supplied the European Commission with a list of over 44 000 health claims. After duplicate or overlapping claims were removed, these were narrowed down to a final list of 4637 claims; EFSA has evaluated 2758 of them and has published scientific opinions on 341.[1]

How does EFSA undertake scientific evaluations?

EFSA uses five panels to evaluate the claims, one of which is the panel on dietetic products, nutrition, and allergies (NDA).[3] Scientific evaluations "should be scientifically substantiated" by "taking into account the totality of the available scientific data, and by weighing the evidence," in addition to reviewing the quality of the evidence. Evaluations are expected to show:

- The claimed effect of the food is beneficial for human health
- A cause and effect relation between consumption of the food and claimed effect (such as strength, consistency, specificity, dose-response, and biological plausibility)
- The quantity of the food and pattern of consumption required to produce the effect
- The populations in which the evidence was obtained are representative of the target population for which the claim is intended. [2]

What did EFSA find for sports drinks?

Using this process, the NDA panel assessed scientific evidence related to three claims for carbohydrate-electrolyte solutions (sports drinks): reduction in perceived exertion during exercise, enhancement of water absorption during exercise, and maintenance of endurance performance. They published their scientific opinion in June 2011 (table 1⇓).[4]

The panel supported two of the claims (improved water absorption during exercise and maintenance of endurance performance), but did not support the third (reduction in perceived exertion or effort during exercise).

How valid are EFSA's methods?

Given the importance of these claims for marketing of sports drinks in Europe (for both consumers and manufacturers) and the potential effect on health, we set out to assess the scientific evidence and the scientific rigour of EFSA's methods. We found a major discrepancy between what they set out to do, and what they actually did.

Methods to assess the effectiveness of interventions (or more correctly, methods that assess the balance between beneficial and harmful effects) have been established for several decades.[5 6]

Correspondence to: M Thompson matthew.thompson@phc.ox.ac.uk

These methods of systematic review (or comparative effectiveness) are used by regulatory and professional organisations, guideline groups, and government bodies worldwide to assess drugs and medical devices or interventions such as diet, exercise, and counselling. However, the methods used by EFSA to assess the "nature and quality of the totality of the evidence," do not measure up to these transparent and reproducible methods in several respects (table 2⇓).

Firstly, EFSA asked manufacturers of sports drinks to supply evidence for effectiveness of their own products. This presents a risk that manufacturers will selectively present studies that report products in a positive light. A better way would have been to ask for systematic reviews that detailed their search and appraisal methods, including studies with negative outcomes and unpublished studies. In the absence of systematic review evidence, a more comprehensive search for primary studies should be used.

Secondly, EFSA did not seem to have any criteria to decide what types of scientific evidence to accept, particularly in relation to study type or quality. Submissions included not only scientific studies, but also book chapters, opinion articles, and non-systematic review articles.

Thirdly, even for the scientific studies EFSA received, we were unable to track down the methods they used to assess quality. This could mean, for example, low quality studies were given the same "weight" as higher quality studies, potentially biasing results. Finally, when assessing a body of evidence it is important to present the data extracted from each of the studies, so that the methods of analysis (including meta-analysis where appropriate) are transparent and can potentially be reproduced by others. Although EFSA did helpfully publish a list of all the references it used to make its assessment, [4] it did not specify the process for analysing the evidence, suggesting that it used an ad hoc process.

Finally, EFSA states that its approach was an attempt to prove causality or a "cause and effect relationship between consumption of the food and claimed effect." This seems an odd way of assessing the balance of beneficial and harmful effects of an intervention (in this case sports drinks).

We asked EFSA to confirm whether this was really its process and received this reply: "It's very straight forward in fact: an applicant has to submit all the research and data they think will prove that their claim is true. EFSA then reviews whatever has been submitted to support the validity of that claim, if EFSA finds that the research and scientific data submitted prove that there is a cause and effect relation between the product and the claim the evaluation is positive, if not, negative."

Our assessment of the evidence

We identified all references the EFSA panel cited for the two claims approved for sports drinks.[4] One author (MT) then examined the titles and, where appropriate, abstracts of all the references to identify scientific trials. For the scientific trials MT and CH then independently examined full text articles and extracted data on study type, study quality (using randomisation, allocation concealment, intention to treat, and blinding) to categorise studies as high, moderate, or low quality. We then assessed the relevance of each article to the claim for which it is cited and whether the outcome reported included a direct effect on sporting performance (such as time to complete a race or time trial). We also extracted details of study participants and calculated summary statistics for age, sex, and type of athlete.

Maintenance of endurance

EFSA listed 54 references related to the claim of maintaining endurance performance, of which only 26 were scientific studies (table 3⇓). We were able to obtain full text papers for 25 of the studies and the abstract for the other. The studies included a total of 359 participants. Most (19/26) were poor quality. Participants were predominantly men (89%), endurance trained (73%), and aged 20-30 years (65%). Of the 26 studies, only 12 used an outcome that was related to improved sporting performance (running capacity, sprinting performance, tennis playing performance, etc), of which only one measured performance in a race setting—a randomised controlled trial of 98 marathon runners (which found no significant effect of sports drink compared with water on marathon time).

Enhanced water absorption during exercise

EFSA listed 108 studies related to water absorption during exercise, of which only 22 were scientific studies, most of which (17/22) were poor quality (table 3⇓). The studies included a total of 298 participants, of whom three quarters (74%) were men; two thirds (67%) of the studies included people in their 20s (only three included people older than 30 years). Most studies were carried out on either general populations (eight) or regular athletes (seven) rather than endurance athletes or professionals.

Of the 22 studies, most (21) had outcomes that seemed to be relevant to the claim of water absorption during exercise, but only 16 used an outcome that was directly related to improvement in sporting performance or recovery (such as rehydration rates, running capacity, sprinting performance), none of which had an outcome that included performance in an actual race or sporting event.

Limitations of the evidence

Putting aside our methodological concerns with the process used by EFSA to assess the scientific validity of the claims related to sports drinks, the body of evidence it cites in permitting the two claims seems to have serious limitations.

Firstly, the trials cited are small (median 9-10 people), including a total of only a few hundred people—and not all of them used an outcome directly related to the claim. Only one study measured outcome in a race. We were not able formally to determine whether the studies were biased to positive outcomes, but very few of the studies had equivocal or negative outcomes. Given that the scientific evidence submitted by just one manufacturer (GSK) exceeds that cited by EFSA,[7] we suspect the studies used by EFSA form only part of the available data on these products.

Secondly, many of the studies cited had methodological limitations, such as problems with lack of blinding and concealment of allocation, use of laboratory rather than performance measures, and unrealistic study protocols.[7] EFSA's assessment did not comment on the availability and quality of the data. We did not attempt to summarise or meta-analyse the outcomes of the studies cited by EFSA because it would have been impossible to draw firm conclusions given the lack of detail on the methods it used to identify the included studies.

A third major concern is "representativeness to the target population," another criterion used by EFSA. For the claim that sports drinks improve endurance performance, the majority of participants in cited studies were young endurance athletes, and any evidence of benefit is therefore only applicable to such people. EU countries should therefore ensure that use of this

claim in labelling or marketing of products makes it clear that the effect is limited to those participating in prolonged endurance exercise. The studies used to support the claim that sports drinks enhance water absorption included a wider spectrum of physically active people. Again, however, most were men in their 20s, so it is difficult to know whether the findings (and the claims) apply to women, children, or older people, or only to those performing endurance exercise, which again is the population for whom the EFSA approved this claim.

Although many of the references cited by EFSA were review articles, we considered none of them fitted the criteria for systematic reviews—most were consensus statements or clinical reviews. Moreover, EFSA did not seem to have a robust process to assess the validity of systematic reviews. For example, one of the prominent reports EFSA cites in support of these claims is a 1991 report of the Scientific Committee on Food. [8] The section of this document that reviews sports drinks (page 21), refers to five references, two of which seem to be non-systematic reviews, two are books or book chapters, and one a trial of eight men.

What should EFSA do now?

It will be up to individual countries to decide how to implement the claims permitted by EFSA. However, claims approved by EFSA will undoubtedly carry considerable weight and will be extremely valuable to manufacturers. There is a risk that claims approved by EFSA will be used to market sports drinks to people for whom the evidence does not apply. Moreover, public organisations that monitor advertisements for accuracy, such as the Advertising Standards Authority in the UK, will simply defer to published EFSA opinions when fielding complaints about adverts, rather than looking at scientific evidence themselves. There should be a process in place to challenge EFSA's decisions on claims (both those upheld and those rejected).

The timeline (and presumably resources) that EFSA was given to examine the scientific evidence for the thousands of food claims submitted to them was clearly insufficient, placing it under enormous pressure. Our observation of EFSA's processes suggests that it needs to develop greater expertise in the methods of systematic review—indeed, it has recently funded such in-house training. Improvements in skill and providing more time to assess new and appealed claims will facilitate a more scientific and rigorous approach to assessing the scientific basis of food claims in Europe.

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Provenance and peer review: Commissioned; externally peer reviewed.

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Tables

Table 1| **Table 1 Claimed effects of sports drinks and EFSA panel conclusions about scientific evidence4**

Claimed effect	Target population	Panel conclusions
Reduction in perceived exertion or effort during exercise (eg, delayed fatigue, increased endurance performance)	Active people who are exercising	A cause and effect relation has not been established
Enhancement of water absorption during exercise (eg, better or/faster fluid delivery, rehydration, hydration, electrolyte balance/rehydration)	Active people doing endurance exercise	A cause and effect relation has been established between the consumption of carbohydrate-electrolyte solutions and enhancement of water absorption during exercise
Maintenance of endurance performance (eg, increased endurance capacity, endurance in heat)	Active people doing endurance exercise	A cause and effect relation has been established between the consumption of carbohydrate-electrolyte solutions and maintenance of endurance performance

Table 2| **Table 2 Comparison between accepted methods for assessing a body of evidence compared with what EFSA panel did to assess sports drinks**

Accepted steps	What EFSA panel did	Potential effects on internal and external validity
Comprehensive and structured search of multiple electronic databases (or trial registries) for published (and unpublished) scientific studies	Relied on manufacturers to supply evidence for effectiveness	Serious risk of selection bias for positive studies or reports
Defined inclusion and exclusion criteria for deciding which types of studies are eligible	Apparently no defined inclusion and exclusion criteria, particularly in relation to study type, study quality, or outcomes of interest	Included not only scientific studies, but also book chapters, opinion articles, and non-systematic reviews
Assess the quality of included studies	Did not assess quality	Cannot take quality into account when interpreting findings
Summarise or analyse the included studies, using meta-analysis where appropriate	Published a list of all the references they used to make assessment	The process for analysing the body of evidence identified is not specified and suggests that an ad hoc process or consensus process was used.

Table 3| **Table 3 Scientific studies cited by EFSA in support of claims to enhance water absorption and maintenance of endurance performance**

	No of studies assessing:	
	Maintenance of endurance performance	**Enhanced water absorption during exercise**
No of references	47	108
No of scientific trials	26	22
Study quality:		
High	0	1
Moderate	7	4
Low	19	17
Total No of participants	359 (median 9 per trial)	298 (median 9.8 per trial)
Proportion of men*	312/349 (89.4%)	209/283 (73.8%)
Median age of participants†:		
<20 years	0	4
20-30	17	13
>30	7	3
Type of participant:		
Not stated	1	1
General population	0	8
Regular athletes	6	7
Endurance athletes	19	6
Professional athletes	0	0
Outcome directly relevant to main claim	23	21
Outcome including any measure of sporting performance or recovery	12	16
Outcome of actual performance	1	0

*Sex not specified in one study of endurance and two studies of water absorption.

†Age unclear in two studies of endurance performance, and two studies of water absorption.