

Regulations

Regulation of the sports nutrition industry

The days of sports supplements being confined to health food shops or the pages of muscle magazines are long gone. The 'high protein lifestyle' is now mainstream and an ever expanding range of sports supplements and diet products are now available in chemists and supermarkets.

In fact, the growth in supplement use is staggering; a 23 per cent growth in the market in 2015 (1), and according to research by marketing intelligence agency Mintel, almost one in four people used a sports food or supplement in the three months prior to May 2016 (2).

The regulation and control of these products impacts not only what is on offer in the shops and the claims they make in their ads, but ultimately the perception of the nutrition, fitness and health industry as a whole by the general public.

Supplements and sports foods are the very visible side of the nutrition industry, and their reach is growing as the sector goes from being seen as niche, to a mainstream lifestyle choice. **Drew Price** helps us to understand what controls the composition and marketing of sports foods and supplements, which is hugely useful information for nutrition professionals when guiding athletes.

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Finally, on the fringes of the supplement world, there are those supplements that make medical claims, which are handled in the UK by the Medicines and Healthcare Products Regulatory Agency. Interestingly, there is still ongoing debate as to where foods end and supplements begin, with the different enforcement bodies holding different opinions. So far, so complicated.

The birth of modern regulations

To really understand the current sports food and supplement market in the EU, you have to go back to the 27th January 1997, the date on which the current rules came into force. Immediately prior to this, there was a consultation period where EU member states were invited to submit dossiers on all the ingredients used in supplements and sports foods, and their amounts and history of use. However, as Mark Gilbert* explains, this wasn't the smoothest of processes: “It was only after the documents were sent in that they actually specified how they wanted the information in terms of ingredients and claims, meaning that many of the submissions didn't fit the criteria. This reduced the number of compounds being evaluated; despite the fact that they may have already been around for years, many did not end up on the list of allowable ingredients. Many hundreds of ingredients that were safe, got banned.”

After January 1997, many products and compounds found themselves outside the regulations; in particular, a wide variety of botanical products. The work to get them properly regulated started in 2004, although at time of writing, the final EFSA botanicals database or 'Compendium on Botanicals' has

yet to be published (4).

Ingredients that were developed after that time are now classed as Novel Foods as a spokesperson from MyProtein explained to *FSN*: “New ingredients that are considered 'novel', have to go through a stringent positive approval process, for which the applicant wishing to introduce the product onto the EU market has to provide evidence pertaining to its safety and efficacy. Novel foods are currently defined as foods that were not consumed across Europe prior to 27th January 1997, or which have not been used for human consumption to a significant degree within the Community.”

However, it isn't just the ingredients list that's controlled by the regulations; the rest of the label on the supplement container is also under scrutiny, including the health claims made, and aspects of the labelling and marketing are tightly controlled.

The EFSA holds a list of approved product 'claims', and these fall into two categories: nutrition and health. Nutrition claims, such as 'high in fibre', relate very much to foods, whilst health claims, such as 'improves exercise performance', relate to both foods and supplements. The legislation covers packaging, adverts and other marketing materials.

The claims process is stringent to say the least; for example, none of the four submitted ergogenic claims for beta alanine are approved and for creatine, only one of the eight submitted claims is approved. Additionally, there are other potential issues as James Collier, Registered Nutritionist and co-founder of www.huel.com, highlights: “The claims set up is weak; for example, they've included evidence from observational studies, and we understand the limitations in terms of quality of evidence that these present. Also, because the list of approved claims is so short, the guidance that you can give customers is very limited.”

Having rules are one thing, but enforcing

From a regulatory standpoint, sports foods and sports supplements are actually separate categories:

■ **Sports foods:** products not intended for use in small measured quantities, such as protein powders. They are now considered alongside general foods and in fact don't have their own designation; they simply fall under the EU food regulations.

■ **Supplements:** defined by the European Food Standards Agency (EFSA) as 'concentrated sources of nutrients or other substances with a nutritional or physiological effect ... marketed 'in dose' form, for example as pills, tablets, capsules or liquids in measured doses etc (3).'

Unlike food, supplements are controlled via EU directives. Whilst EU regulations are directly enforceable by the EU, directives are enacted and actually changed by each member, which leads to some interesting country to country variation. Mark Gilbert, sports nutrition expert with 20 years in the industry, and vice-chair of European Specialist Sports Nutrition Alliance (ESSNA), explains*: “Countries are also allowed to band compounds individually on the basis of health risk; for example (until recently), creatine and (currently) caffeine in France is more tightly controlled than in the UK. These are reasonable rules, but when you have a situation where, for example, coffee loving

► them is of course another. Here the duties are divided up, as a spokesperson for Campden BRI's Global Regulatory Affairs Team explained: "Enforcement of the legislation in the UK is the responsibility of the Competent Authority. In the UK, the Food Standards Agency (FSA) is the government body responsible for food safety and hygiene and the Department of Health covers health and nutrition. Local Authority Environmental Health Officers and Trading Standards Officers deal with a wide range of issues, including consumer protection and fair information practices, such as labelling and claims. The Advertising Standards Agency (ASA) is an independent regulator for complaints regarding the marketing or advertising of products in print, broadcast media and online."

Stifling innovation?

EU regulation creates two major effects; slowing development and limiting claims. For both of these effects, there are upsides and downsides. Along with enhanced protection for consumers, there's also clarity, simplifying the commercial process, as Collier illustrates: "Anyone can bring anything to market and sell worldwide as long as they're within the regulations. If you want to make a fat burner, you can just formulate a general supplement from accepted ingredients and bring it to the market."

However, the current novel ingredients set up means that whilst the consumer is protected, getting a 'cutting edge' product to market can be a challenge. The process involves building a case and submitting evidence to the EFSA for evaluation. The EFSA then make a recommendation to the Commission, who have the final power to grant authorisation. This is a process that only very large companies have the resources for. According to Gilbert: "You can't innovate if you can't use any ingredients that aren't pre-approved or have come to light since 1997. That makes it very difficult to develop and sell new things."

Just as with many other areas of health and fitness, trends in the supplement and sports food market are driven in large part by what is going on in the United States (US), where the regulatory environment is very different. But of course, those products with different regulations, are now available to our athletes in the UK at the click of a button.

In the US, instead of controlling what can be sold before it hits the shelves, the controls are very much after the fact. The onus is on the companies to affirm their ingredients as 'GRAS', or generally recognised as safe (5). Within reason, anything can be sold and claimed as long as there is evidence in the form of a published study. In fact, although new compounds have to be registered

as New Dietary Ingredients, if a potential problem is identified, it is the responsibility of the Food and Drug Administration to do the work and build a case to get the substance banned.

Whilst this regulatory climate allows for rapid development of new products, it's extremely telling that the highest profile issues of recent years, such as the amphetamine like stimulant DMAA in 'pre-workout' supplements, have come from the US market. This, in turn, has thrown a spotlight on the regulation there, as Gilbert explains: "In some ways, the landscape in the US has become more restrictive in terms of legislation. In terms of claims and regulation, there is the threat of litigation held above your head. Essentially, you can get away with saying what you like about your products, but if you eventually get caught, you may well end up in a class action lawsuit, saying that you're making claims unsupported by good evidence, or that you included ingredients that are somehow unsafe or unhealthy."

Brexit break-out

The summer vote to leave the European Union means that the British regulatory environment could potentially be blown wide open, but does this herald an exciting new era in the sports supplement industry, or is it all just bad news for the consumer?

Much depends on the type of deal that the UK government negotiates and how they decide to handle the huge legal headache that will be caused by replacing the 60 to 70 per cent of UK laws that have been passed down from the EU. Might we end up with a more US like system? MyProtein aren't counting on it: "Due to our legal system, it's unlikely that we will see the litigious culture we see in the USA adopted within the UK, although brands will be increasingly likely to protect key trade marks from infringement, as well as developing their own anti-counterfeiting measures."

James Collier agrees: "The litigious way is not a pleasant way to work. I personally don't like lots of regulation, but you have to have a mechanism there to protect the layman and this 'action after the fact' doesn't work there. For ingredients, some sort of approval committee or panel needs to be in place, but they need to be credible and include experts, and to be regulated by peers. They should be experts with broad expertise, realists that can read, understand and balance the evidence."

One thing is certain though; UK companies will want to sell into the EU, where their products will have to conform to the rules, which might lead to two tier production, as Gilbert explains: "You could have the situation where UK manufacturers make a version of a product where the ingredients are backed up by a reasonable amount of evidence, showing that they both safe and effective. Then you

would sell a different EU version stripped of the ingredients and claims that aren't approved in the EU."

However, MyProtein points out that the Brexit news may not be good: "In essence, it could actually make it much more difficult for Europeans to access UK produced products. Equally, as the UK will metaphorically have a closed border, movement of products from Europe into the UK could also adversely be affected with Customs duties being levied against consumers and prohibitions on high risk products, such as those containing animal product derived ingredients."

Whilst we currently have no clear idea of what will come after Brexit, the increased popularity of specialised foods and supplements means that the sector as a whole comes under more scrutiny than ever before. Hopefully any improvements in the range and choice of products available to the consumer will be matched by legislation to keep them safe. MyProtein thinks it will: "It's safe to say that the nutrition industry as a whole has moved on leaps and bounds from its early days. Brand reputation is an important selling point. In times of austerity where Government spend on enforcement has been cut, it is ever-important for the industry to self-regulate in order to protect the reputation of the sector as a whole." **fsn**

***DISCLAIMER – in this interview, Mark Gilbert is expressing his own views and not those of the ESSNA.**

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