CODE OF PRACTICE

December 2017

BACKGROUND AND OBJECTIVE

The European Specialist Sports Nutrition Alliance is the leading European trade association for the sports nutrition industry. It brings together major manufacturers and distributors of sports nutrition products, suppliers of ingredients, sports nutrition publications, national associations as well as specialist scientific and legal consultants advising the sector.

This Code of Practice ("The Code") is principally intended to help Members comply with the whole body of law applying to products' labelling, marketing, manufacturing and distribution. The intention is to establish a baseline minimum of business practices that a Member company can be measured against and held accountable for.

UNDERSTANDING THE CODE

We make decisions every day that affect our consumers, other customers, related businesses, suppliers and ultimately the reputation of the whole industry. How we choose to act can either expose consumers and businesses in the sector to considerable risk, or can build the trust of all who work with and rely on us and ultimately improve the reputation of the industry.

Our actions are scrutinised daily by consumers, suppliers, distributors, journalists, various sporting organisations, regulators and politicians who want and expect to be dealing with ethical and law-abiding businesses. Membership of ESSNA comes with an expectation of high ethical and moral standards over and above the understanding of the necessity of being aware of and complying with the laws relating to sports nutrition and their manufacture, distribution, sale and marketing.

The Code sets out what it means to be compliant with the law and hence with ESSNA's ethical standards. The Code is also here to help Members make good decisions. If you ever find yourself in the difficult position of questioning whether a situation is consistent with ESSNA's values, the Code will help guide you to the answer.

The principles outlined are not meant to be full explanations of applicable laws, policies or procedures. Members are responsible for understanding and complying with the legislation and for asking questions when they are uncertain about the meaning of the Code.

PRINCIPLES OF THE CODE

This Code is based on four principles of which Members should be aware and against which they should measure their actions.

Members are expected to:

- Respect fair business practices and endeavour to deal fairly with consumers, customers, suppliers and competitors;
- Act responsibly and with integrity;
- Comply with all applicable laws and regulations;
- Encourage other companies to operate in accordance with the principles of this code.

These principles inform every part of this Code and should be read in conjunction with the guidance provided.

1. PRODUCT COMPOSITION

1.1 Product composition is covered by a vast body of food legislation, from general food safety requirements, rules on additives, flavourings or enzymes to product specific legislation. The General Food Law Regulation (EC) 178/2002[1] provides the framework for all food legislation. A key requirement is that all food placed on the market must be safe, i.e. it must not be injurious to health or unfit for human consumption. Food business operators are also required to put in place procedures which manage food safety within their establishment. Such procedures must be based upon the HACCP (Hazard Analysis and Critical Control Point) principles set out in Regulation 852/2004[2].

1.2 Many areas of food law have been harmonised at EU level but there remain a number of issues that are dealt with at national level. Members shall take appropriate legal advice when selling a product on the EU market –whether via traditional distribution channels or via distance selling - to ensure that due account is taken of the applicable legislation in the EU countries where the product is launched.

1.3 Particular attention should be paid however to rules regarding:

- **Novel foods/ ingredients[3]** (i.e. foods and food ingredients that have not been used for human consumption to a significant degree **in the EU** before 15 May 1997). Food business operators can place a novel food on the European Union market only after the Commission has processed an application for the authorisation of a novel food and has adopted an implementing act authorising the placing on the market of a novel food and updating the Union list

  As with other novel foods, traditional foods from a third country can only be placed in the European Union market only after the Commission has processed a notification, has adopted an implementing act authorising the placing on the market of the traditional food and updating the Union list.

  Further information, including links to the Union list and the Novel Food Catalogue can be found at: https://ec.europa.eu/food/safety/novel_food_en

- **Additives[4], flavourings[5], smoke flavourings[6], food enzymes[7] and extraction solvents[8]:** Harmonised European legislation controls the use of food additives, flavourings, smoke flavourings, food enzymes and extraction solvents in the EU. In general, all the above substances are controlled through positive lists e.g. only authorised substances can be used in food and substances must meet specific conditions of use. For food enzymes work is underway to establish a positive list. To facilitate compliance a number of databases have been made available by the European Commission. Further

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 01/02/2002, p. 1–24

2 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. OJ L 139, 30/04/2004, p. 1–54

3 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1–22

4 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31/12/2008, p. 16–33.

[5] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31/12/2008, p. 34–50.

[6] Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods. OJ L 309, 26/11/2003, p. 1–8.

[7] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. OJ L 354, 31/12/2008, p. 7–15

[8] Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L 141, 06/06/2009, p. 3–11.

information can be found on the European Commission website at: https://ec.europa.eu/food/safety/food_improvement_agents_en

1.4 Members are also required to comply with legislation on **contaminants**[9]. Contaminants are substances that have not been intentionally added to food but that may be present in food as a result of the various stages of its production, packaging, transport or holding. Maximum levels have been set for the contaminants of greatest concern to EU consumers including mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin), metals (cadmium, lead, mercury, inorganic tin), dioxins and PCBs, polycyclic aromatic hydrocarbons (PAH), 3-MCPD, melamine, erucic acid and nitrates). This is available at: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02006R1881-20100701

1.5 Given the number of misconceptions around sports supplements and doping and the impact this is having on the sector; it is also expected that Members do not intentionally include any substances listed on the **Prohibited List of the World Anti-Doping Agency (WADA)** in their products. Members must also be able to demonstrate that all reasonable precautions are taken to avoid any traces of such substances in their products. It is worth stressing that many substances on the WADA list are either illegal or of a medicinal nature, and therefore prohibited for use in food anyway. The WADA list is available at: https://wada-main-prod.s3.amazonaws.com/resources/files/2016-09-29_-_wada_prohibited_list_2017_eng_final.pdf

1.6 Guidance has been produced for Members to help them avoid inadvertent doping. This voluntary guidance can be found in **Appendix 2**.

2 PRODUCT LABELLING AND ADVERTISING

2.1 Members are required to ensure compliance with labelling legislation, namely Regulation 1169/2011[10] on the provision of food information to consumers (FIC). It is worth noting that in addition to general labelling legislation some additional and/or specific requirements may apply to certain categories of foods/substances e.g. food supplements, organic foods, novel foods/ingredients. Members should consult the legislation relating to their own products to determine any specific requirements.

2.2 Whilst it is not possible to list all the labelling requirements within this Code, Members must ensure that all mandatory particulars – as provided in Article 9 of Regulation 1169/2011 - are marked on their labels, in particular:

- the **name of the food** - The name of the food shall be its legal name. In the absence of such a name, the name of the food shall be its customary name, or, if there is no customary name or the customary name is not used, a descriptive name of the food shall be provided.
- a **list of ingredients** (*i.e. any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'*). The list of ingredients shall include all ingredients in descending order of weight, as recorded at the time of their use in the manufacture of the food. Additives and enzymes must be designated by the name of the category to which they belong (e.g. acid, colour, sweetener etc.), followed by their specific name or, if appropriate, E number.
- a **nutrition declaration**. Members should hold documented evidence of what appears on the nutrition declaration.

[9] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L 037, 13.2.1993, p.1
Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p.5

[10] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22/11/2011, p. 18–63

2.3 All information on packs must be legible. A minimum font size of 1.2mm (0.9mm for packs under 80cm^2 in size) is foreseen by the FIC Regulation.

2.4 Food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed.

2.5 Any food supplied through distance selling (e.g. internet) must meet the same information requirements as food sold in shops. This means that all the relevant mandatory food information listed above must also be available before the purchase is concluded, with the exception of a date of minimum durability/'use-by' date, and the information must appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. All mandatory particulars must be available at the moment of delivery.

2.6 Information provided should be factually true and not misleading. Food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties. Advertising or marketing material must also comply with the EU Directive 2005/29/EC concerning unfair business-to-consumer commercial practices[11] which prohibits misleading and aggressive commercial practices. Further information regarding advertising content, including contact details of national advertising agencies can be found on the website of the European Advertising Standards Alliance: http://www.easa-alliance.org/

2.7 When making a voluntary nutrition or health claim Members must comply with the requirements of Regulation (EC) No 1924/2006 on nutrition and health claims made on food[12] (NHCR). This obligation applies to all commercial communications, including social media campaigns and packaging/labelling.

2.8 Members can **only** use those nutrition and health claims that have been expressly approved at the EU level, provided they comply with the specific conditions of use attached to each claim. Authorised claims can be found on the EU Register of claims: http://ec.europa.eu/nuhclaims/.

2.9 Some flexibility of wording is possible provided that the same health relationship is likely to be understood by the average, reasonably well-informed and reasonably circumspect consumer, taking into account factors such as linguistic and cultural variations and the target population.

2.10 Provided they comply with the general requirements of the NHCR, Members can also use those claims that are still under evaluation at EU level. A list of such claims is also available in the EU Register of claims.

2.11 On the contrary, claims that have not been specifically authorised or for which no application has been submitted must be immediately removed from all commercial communications. As an example, please find below a list of claims that are currently prohibited on sports nutrition products:

- Initiate/ accelerate / speed up fat burning /remove fat
- Thermogenic fat burner / Boosts metabolic rate
- Natural testosterone booster/ increase testosterone or growth hormone levels/decrease estrogen levels
- Reduce inflammation
- Increase lean mass by X% and/or reduce body fat by X% in just X days (or similar)
- Sex/libido enhancer/sex drive/increase sex desire.
- Prevent injury / Reduce joint pain / Helps lower cortisol levels

[11] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council. OJ L 149, 11/06/2005, p. 22–39.

[12] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30/12/2006, p. 9–25.

2.12 Unlicensed products, including food supplements, must not be presented for medicinal use in labelling, advertising or promotion.

2.13 Finally, Members should be aware that certain EU Member States require that particular foods and food supplements are notified to the relevant Competent Authority when they are first placed onto the market. This is an important legal requirement, and ensures fair competition practices within the EU sports nutrition industry. We would advise Members to take appropriate legal advice before launching a product onto the market in any EU Member State.

3 PROTEIN LABELLING - VOLONTARY RISK ANALYSIS ROADMAP

3.1 ESSNA members have identified an emerging concern in the internal market, where the current definition of protein on labelling allows for protein to be calculated from the nitrogen content of ingredients containing non-protein nitrogen (NPN) such as creatine, glycine, taurine and free amino acids. This results in higher protein content in the nutrition information table than what actually is in the product when defining protein as "total Kjeldahl nitrogen x 6.25". Furthermore, it may also enable a brand/product to wrongly leverage an approved protein based health claim(s).

3.2 Protein spiking is a problem for the entire health food industry, particularly as the use of protein and their respective health claims is increasingly promoted on a large number of mainstream products, such as breakfast cereals, drinks and snacks. This is supported with an increasing consumer interest in the protein content on labels. ESSNA has defined protein spiking as, "The addition of free form amino acids and other nitrogen rich/containing nutrients added for the primary purpose of increasing the calculated protein content of a food." **This is misleading and therefore illegal**.

3.3 Whilst such activities go against some of the General Food Law Principles, in particular Article 7(1) of the FIC covering fair information, Article 169 TFEU, Article 8(1)(C) of EC Regulation 178/2002, and Article 3 and 5(1) of the NHCR, there is currently no specific legal requirement to list the source of protein as part of the mandatory nutrition declaration. However, there is a requirement under Article 22 of Regulation 1169/2011 to quantify ingredients appearing in the name of the food, emphasised in words, pictures or graphics or to characterise a food and to distinguish it from products with which it might be confused because of its name or appearance. In addition, as a general requirement, all ingredients have to labelled in an ingredients list (Article 9 (1)(b), Article 18 and Annex VII FIC).

3.4 ESSNA has brought together a "**voluntary roadmap**" with the proposal that members apply its guidance on their products (Annex I). By doing so, ESSNA is looking to prevent the deliberate act of protein spiking in the industry, whilst also protecting its members from misrepresented claims of inadvertent spiking. **ESSNA condemns strongly all deliberate acts of protein spiking, which are against its Code of Practice. Therefore, members may also find this roadmap helpful when labelling and formulating products.**

4 OTHER COMMERCIAL PRACTICES, E-COMMERCE/DISTANCE CONTRACTS REQUIREMENTS

4.1 Members must ensure compliance with EU Directive 2005/29/EC concerning unfair business-to-consumer commercial practices, and the applicable national laws transposing this Directive. Unfair commercial practices are those which:

- do not comply with the principle of professional diligence (i.e. the standard of special skill and care that a trader may reasonably be expected to exercise towards consumers, commensurate with honest market practice and/or the general principle of good faith in the trader's field of activity);

- may influence consumers' transactional decisions (i.e. any decision taken by a consumer concerning whether, how and on what terms to purchase, make payment in whole or in part for, retain or dispose of a product or to exercise a contractual right in relation to the product, whether the consumer decides to act or to refrain from acting).

4.2 The Directive in particular prohibits commercial practices which are misleading (whether by action or omission) or aggressive, and which cause or are likely to cause the average consumer to take a different decision. A practice is for example misleading if it contains false, untrue or incomplete information that is likely to deceive the consumer. In particular, if this information relates to: the existence or nature of the product; the main characteristics of the product (such as its availability, benefits, composition, date of manufacture, geographical origin, the results to be expected from its use, etc.); the price, the trader's commitments and the nature of the sales process; the trader (their identity, qualifications, code of conduct, etc.); and the consumers' rights.

4.3 Members must also comply with Directive 2011/83/EU on consumer rights[13] which harmonises provisions concerning consumer protection in all contracts concluded between a consumer and a trader, including distance contracts. When offering goods over the internet Members should also pay attention to the relevant requirements of Directive 2000/31/EC on electronic commerce[14].

4.4 Members should be aware that these Directives may have been implemented differently across the EU. Particular attention should therefore be paid to the national legislation of the countries that are specifically targeted by the offers.

4.5 Essential pre-contractual information that must be given to consumers – in particular for distance contracts - includes, amongst other details:

- Your identity including sufficient detail for the consumer to be able to identify the business they are dealing with (i.e. the geographical address at which you are established and, where available, your telephone number, fax number and e-mail address, to enable the consumer to contact you quickly and communicate efficiently. When you are acting on behalf of another trader, the geographical address and identity of that other trader must also be given).
- A description of the main characteristics of the goods or services you are offering.
- The price of the goods or services you are offering, including all taxes (pre-ticked boxes for additional payments are not permitted).
- Details of any delivery costs.
- Details of how payments can be made.
- The arrangements for delivery or performance of the service, for example when consumers can expect delivery of the goods. Goods should be delivered within 30 days unless the parties agree to a different period.
- Information about a consumers' right to cancel (14 days cancellation period).
- For how long the price or the offer remains valid.

The pre-contractual information can be given by any method appropriate to the form of distance communication you are using to agree the contract, providing it is clear and comprehensible. For example, this information can be provided on a website if you sell goods or services over the internet (in which case the Directive on electronic commerce also applies) or appear in a catalogue for goods or services sold by mail order.

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13 Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council. OJ L 304, 22/11/2011, p. 64–88.

[14] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'). OJ L 178, 17/07/2000, p. 1–16.

4.6 After making a purchase, consumers must be sent confirmation in writing, or in another durable medium (email).

RAISING CONCERNS/ DISCIPLINARY ACTIONS

In order to preserve ESSNA's reputation, all Members agree to abide by the principles outlined in the Code at all times. We also have a duty to help others understand and comply with the Code, and to report possible violation, as well as an obligation to hold our colleagues responsible to the standards of the Code. If you observe behaviour that may represent a violation of our Code, please raise the issue with the Secretariat.

When it appears that a Member has violated the Code, the Secretariat will seek to resolve the issue informally with the Member concerned at first instance. To ensure compliance, in particular in the event of a continuation of this serious violation, the ESSNA Officers will be consulted to determine whether Membership should be suspended and/or if relevant authorities should be informed.

CONFIDENTIALITY & ANONYMITY

Questions and concerns related to the Code will be held in as much confidence as possible. Information will be shared only with those individuals who are required to investigate the matter. The Secretariat will take every precaution to ensure the identity of those involved is released only to those individuals related to the matter itself. The Secretariat and ESSNA officers are obligated to keep matters related to the Code confidential.

REVISION OF THE CODE

This code will be reviewed annually in December.

ANNEX 1 - PROTEIN LABELLING - VOLONTARY RISK ANALYSIS ROADMAP

Protein labelling risk analysis roadmap:

Q1. Does your product make any reference to **protein**, **specific protein sources**, and/or **amino acids** on pack? (Such as in the name of the product, claims or statements)

Yes: [ ]

No: [ ] You are outside the scope of this roadmap

Q2. Name the food source(s) of protein, referred to on pack.

If you only make reference to protein in general on pack, name the food source(s) of protein declared in the list of ingredients:

Declare: g,

This is the 'definition of protein', specific to your product.

Q3. How much of the total protein declared in the product's Nutrition Information table is provided by the food source(s) above:

Declare (g/100g or ml):

Declare (g/portion):

(see recommendations →)

Proposed Recommendations:

a) If amount = total protein, no action is required other than considering the importance of including a QUID for the source of protein (Article 9(1)(d), 22 and ANNEX VIII FIC Regulation 1169/2011)

b) If not, you should also consider labelling:

> "Calculated protein, of which, [protein source(s) and respective amount, xg per 100g/100ml and xg per portion]" in close proximity but not within the nutrition declaration

c) List of protein sources, which are considered to be non-protein nitrogen-containing (NPN) ingredients: creatine, glycine, taurine, free amino acids, extractions of amino acids.

Extractions of amino acid such as functional peptides.

Q4. Is the amount declared in Q3 a significant amount of protein? Does the product claim to be a SOURCE OF, or HIGH IN, protein, or make similar protein nutrition claims?

This means: 1) at least 12% (or 20%) of the energy value of the food provided by protein and, if you have instructions for use, 2) the

total amount recommended per portion should add up to the amount declared in Q3.	
Yes: [ ]	No: [ ]
You are OK.	You must reformulate the product to provide the minimum amount required or recommended or re-label to reflect actual protein content.

Q5. Do you claim any beneficial health properties of protein?	
Yes: [ ]	No: [ ]
Proceed to Q6	You are OK.

Permitted Protein health claims:
"Protein contributes to a growth in muscle mass"
"Protein contributes to the maintenance of muscle mass"
"Protein contributes to the maintenance of normal bones"
The European Union Register of nutrition and health claims made on foods can be found here.

Q6. Does the amount declared in Q3 meet the minimum conditions of use to make the health claim?	
Yes: [ ]	No: [ ]
You are OK.	You must withdraw the claim or reformulate the product

Minimum conditions:
At least 12 % of the energy value of the food is provided by protein.

Protein nutrition claims:
"Source of protein": at least 12 % of the energy value of the food is provided by protein.
"High protein": at least 20 % of the energy value of the food is provided by protein

Q7. Do you declare all the ingredients of the product in the List of Ingredients?	
Yes: [ ]	No: [ ]
You are OK.	Your product is illegal and you must re-label to declare all ingredients.

All ingredients must be declared according to Article 9 and 18 of Food Information to Consumer Regulation (Regulation 1169/2011)

ANNEX 2 – A FRAMEWORK TO TACKLE INADVERTENT DOPING

This is a guide to the steps that, if taken, can help companies to minimise the risk of inadvertent doping. Such a risk cannot be eliminated entirely, and no company should be making claims to this affect; but by taking some of the steps outlined below businesses will be able to significantly reduce the risk of inadvertent doping.

ESSNA recognises that Members have a range of business models and will therefore consider each according to their specific needs. With this in mind, there are three approaches that Members should consider: testing raw materials, auditing manufacturing facilities for banned substances, and testing finished products.

Though steps can be taken to minimise the risk of inadvertent doping, it is important to note that the most effective means of providing quality assurance to consumers that products are not contaminated with substances banned in sport is by testing the finished product. Audits and testing of raw materials can help minimise the risk, but sport and the anti-doping community insist that athletes must only use finished products that have been tested for banned substances.

This is recognised in the World Anti-Doping Code through 'no fault'. If an athlete fails a doping test because of a contaminated product – known as 'inadvertent doping' – then they must firstly provide evidence that the product was contaminated and then prove that they did their 'due diligence' by checking the product had been tested. If these steps are followed then any sanction can be reduced to a warning.

Raw Materials

Products can become contaminated inadvertently in the manufacturing process and throughout the supply chain in a number of ways.

An early point of entry can be through raw materials. Contaminants can be at their most concentrated and therefore easier to detect in raw materials. Manufacturers should assess their raw materials based on:

- Do you know geographically where these materials have come from?
- Do you know the supplier of these materials?
- Do you know what safeguards your supplier has put in place?

ESSNA members also need to be aware of the increasing challenges posed by the use of 'botanical' or 'herbal' raw materials. Such botanicals can contain naturally occurring sterols that can convert into a banned substance through the manufacturing process.

Manufacturing Process

It is also important to focus on the manufacturing process.

- Manufacturing facilities involved in the production of sports supplements should meet Good Manufacturing Practice or the equivalent standards as overseen by the regulatory body in the relevant country. ESSNA recognises that the term GMP means different things to different companies in different Member States of the EU. Manufacturers should also consider whether their hazard analysis and critical control points (HAACP) system is appropriately set up to minimise inadvertent doping.
- It should also be noted, however, that though GMP is important within the manufacturing process, it does not offer any assurance that products made to these standards are free of banned substances. Samples of products manufactured in GMP facilities sometimes are found to contain banned substances because GMP does not require testing for such compounds.
- Some brands may wish to audit their manufacturers. They can do this via:

    - An audit from an appropriate and recognised regulatory body in a particular country, if one is available, or:
    - An independent audit carried out by an appropriate and recognised independent institution once a year.

- Brands using a manufacturer that produces sports nutrition and handles banned substances should make sure that all necessary precautions are taken to ensure that sports nutrition products avoid contamination.

- This includes, but is not limited to, making sure there are clear standard operating procedures in place to keep the banned substances properly segregated from the supplements, that the banned substances are properly handled, and that sufficient cleaning processes are in place for the machinery if it is being used to make sports supplements and products containing banned substances.

- Distributors or manufacturers of supplements may wish to inquire whether the raw material producer or the manufacturer handles/manufactures products that are prohibited by WADA. This could then be a trigger for additional requests for safeguards if the answer was positive.

- Members should also keep a repository of the a few of the bottles/containers of each batch they produce (in particular the first bottles that are produced in each batch). In case of claim, this would allow Members to check whether the batch is indeed contaminated or not. That could be very useful if sued by an athlete.

Testing for Banned Substances

Finished products:

Many sports nutrition brands choose to have their products tested by a reputable laboratory in order to provide assurance to athletes and the general consumer that their products are not contaminated with substances banned in sport.

Testing of the finished product is the most effective way of providing assurance that the finished is not contaminated, and for this reason many sports organisations/clubs/athletes now insist that this testing is in place before they agree to allowing their athletes to use products.

There are a few companies across the world that offer ad hoc testing, as well as testing programmes that require a pre-certification audit and ongoing analysis of certified products.

ESSNA recognises that testing of finished products is not suitable for all brands, and there are other forms of testing that can help to improve the assurance of the quality of the product.

Raw materials/manufacturing sites:

This includes testing the raw materials that go into a product, or an audit of the manufacturers that supply the raw materials. There are a number of organisations that provide specialist services for facilities that manufacture raw materials to show they have been audited for the presence of banned substances.

The current norm for these services in Europe, Australia, South Africa, Asia and the US is twice yearly.

It is worth noting that these auditing companies also provide the same service for facilities that manufacture finished products. This service is especially useful for third party manufacturers (TPMs) who wish to know that their sites are free of banned substances and in order to share this high level of quality assurance with their customers, namely the sports nutrition brands.

Testing service:

When choosing your testing laboratory there are some minimum standards that should be considered. ESSNA recommends these include:

- ISO/IEC 17025 accreditation for the testing of banned substances within sports nutrition products and methodologies accredited by the relevant body eg. UKAS in the UK
- Ability to test for a wide range of banned substances, based on intelligence received from anti-doping organisations and the sports nutrition industry
- Ability to detect banned substances at parts per billion, the accepted analytical capability of anti-doping laboratories
- Proven anti-doping expertise and ongoing relationships with relevant anti-doping organisations and sport in order to maintain an effective knowledge of banned substances and new risks
- Ability to extract the analyte (the banned substance or chemical constituent) from the sample under test

Ideally, testing of the product should be an ongoing process. Testing one batch of a product does not provide a sufficient level of quality assurance that other batches are, or will not be, contaminated

Marketing

No product should be marketed as "100% guaranteed" free from banned substances.

The most effective risk minimisation involves testing every batch before it goes to market, but even then, a responsible laboratory does not claim to have completely eliminated any risk because it is testing only a small sample of what can be large production batches.

As an alternative, ESSA suggests the use of terms such as "banned substance tested" or "tested for substances banned in sport", which infers the same message without making a claim that cannot be substantiated.

GLOSSARY AND USEFUL LINKS

World Anti-Doping Agency List of Prohibited Substances and Methods

The Institute of National Anti-Doping Organisations (iNADO)

UK Anti-Doping Supplements Advice

European Commission guidance documents on food hygiene, including on HAACP principles

Inadvertent Doping – A doping violation caused by unintentional consumption of a product containing a prohibited substance

WADA – World Anti-Doping Agency

ADOs –Anti-Doping Organisations

GMP – Good Manufacturing Practice

HAACP - Hazard analysis and critical control points