
Preprečevanje uporabe nedovoljenih snovi v športu - Dobre prakse za razvoj in proizvodnjo z namenom preprečevanja prisotnosti prepovedanih snovi v hrani za športnike in v prehranskih dopolnilih

Doping prevention in sport - Good development and manufacturing practices aimed at preventing the presence of prohibited substances in food intended for sports people and food supplements

Dopingprävention im Sport - Nahrungsergänzungsmittel und Sportnahrung frei von Dopingsubstanzen - Bewährte Verfahren bei der Entwicklung und Herstellung zur Vermeidung von Dopingsubstanzen

Prévention du dopage dans le sport Compléments alimentaires et aliments pour sportifs exempts de substances dopantes Bonnes pratiques de développement et de fabrication visant l'absence de substances dopantes

Ta slovenski standard je istoveten z: prEN 17444

ICS:

67.040 Živilski proizvodi na splošno Food products in general

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ICS

English Version

**Doping prevention in sport - Good development and
manufacturing practices aimed at preventing the presence
of prohibited substances in food intended for sports
people and food supplements**

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alimentaires et aliments pour sportifs exempts de
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Nahrungsergänzungsmittel und Sportnahrung frei von
Dopingsubstanzen - Bewährte Verfahren bei der
Entwicklung und Herstellung zur Vermeidung von
Dopingsubstanzen

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 453.

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European foreword

This document (prEN 17444:2019) has been prepared by Technical Committee CEN/TC 453 “Dietary supplements and sports food free of doping substances”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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Introduction

Doping prevention is based on various targeted actions, intended for sportspersons at all levels and their environment. One of these doping prevention actions is ensuring that people participating in sport activities either during training or competition do not ingest doping substances through their diet, in particular by means of food intended for sports people and food supplements.

This standard has been designed to provide manufacturers with a framework to minimize the risk of the presence of prohibited substances in food intended for sportspeople and food supplements. Such a risk cannot be eliminated entirely, and no company should be making claims to this effect, however there are a number of processes companies can put in place to reduce the risk of the presence of prohibited substances.

Indeed, in a context of trade globalization and the underlying development of transnational ordering on the Internet, it is now possible for sports people to order and import foods from countries outside the EU. Additionally, various studies show that food intended for sports people and food supplements may contain doping substances and consequently lead to positive results in anti-doping tests and can induce adverse effects for health. Given the side effects of doping substances on health, which is one of the criteria for their prohibition, the prevention of doping by contamination of foods intended for sports people and food supplements is an important public health issue. This issue concerns all sports people, including recreational sports practitioners.

Various publications addressing contamination of food intended for sports people and food supplements highlight the presence of prohibited substances (mainly anabolic agents, or stimulants). These substances are included in the Prohibited List published and revised annually by the World Anti-Doping Agency (WADA). Such substances are harmful to health causing mainly cardiovascular adverse effects as myocardial infarction, arrhythmia or coronary artery disease, neurotoxicity, hepatotoxicity, etc.

This standard falls within the framework of the measures laid down at international level by the Council of Europe and by UNESCO respectively.

- the Council of Europe's - Anti-Doping Convention of 1989 of which Article 4 provides for the possibility of adopting administrative measures to restrict the availability of doping agents in sport;
- UNESCO's 2005 International Convention against Doping in Sport of which Article 10 requires that

“States Parties, where appropriate, shall encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information regarding their analytic composition and quality assurance.”

Manufacturers applying this Standard are strongly encouraged to comply with the requirements of other standards, in particular those of ISO 22000 on food safety management (which includes HACCP principles) (Hazard Analysis Critical Control Point) and as applicable those of ISO 9001 on quality management.

Thanks to the support offered jointly by the CEN and by the interested parties in preparation of this Standard, there is a clear emphasis on the importance of encouraging companies responsible for the development and manufacture of food supplements and food intended for the sports people with the intention of excluding the substances prohibited by the World Anti-Doping Agency (WADA) [5] and protecting consumers.

This standard should work towards and support any other European, national laws or regulations in the area of doping in sport.

Quality assurance can be improved by carrying out testing, audit, certification process, etc.

The following standard has been developed to promote good manufacturing practices specifically with consideration to substances prohibited in sport.

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1 Scope

This document sets out the requirements relative to the development and manufacture of food intended for sports people and food supplements to reduce the risk of the presence - without fully guarantying the absence - of substances prohibited by the World Anti-Doping Agency (WADA) [5].

This document specifies a framework of good practices with the objective of preventing the presence of substances prohibited in sport in food intended for sports people and food supplements.

This document does not lead to any form of product endorsement.

This document excludes the so-called “energy drinks”.

2 Normative references

There are no terms and definitions in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

energy drink

drink containing a mixture of different compounds, most often caffeine, taurine, glucuronolactone and B vitamins, and sugars or sweeteners.

Note 1 to entry: They may also contain plant extracts, such as guarana and ginseng. Energy drinks are presented as cans, shots, ready-to-drink or powder forms as they are not designed for sport people

Note 2 to entry: These beverages should not be confused with those known as “sports drinks” which are designed to be used specifically before, during and/or after exercise or sports. Typically, these products are used to replace electrolytes (essential minerals) and macronutrients. They are used to replace water lost in sweat or used up during exercise activity. Conversely, energy drinks are for general energy whenever the user feels they need that effect. These products are most likely only used prior to sports/exercise by a small minority of users and may often not be suitable for sports activities (lacking, for example, electrolytes). The marketing of sports drinks is clear in explaining the right conditions for product consumption. It may also encourage people to engage in more sporting and physical activity, and generally lead more active, and healthy lives. Consumers understand that sports drinks will only help them if they choose to be active, but will not support inactive or passive lifestyles. Formulation wise, energy drinks are typically based on sugar and caffeine (although there are sugar-free versions) and may also contain ingredients such as taurine and glucuronolactone. These are designed to be consumed at any time of day, when in need of a “boost”, therefore they could be taken around exercise but that is not the main focus.

3.2

foodstuff

food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC

[SOURCE: Regulation (EC) n° 178/2002 of the European Parliament and of the Council of 28 January 2002, Article 2]

3.3

food supplement

means a foodstuff the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

[SOURCE: Directive 2002/46/EC of the European parliament and of the council of 10 June 2002, Article 2 [1]]

Note 1 to entry: The food supplements are divided into three categories: those containing energetic macronutrients (e.g. proteins, carbohydrates), micronutrients (e.g.: vitamins, minerals including trace elements) and substances with physiological effects (e.g.: amino acids, creatine, botanicals).

3.4

ingredient

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

[SOURCE: Regulation (EC) n° 1169/2011 of the European Parliament and of the Council of 25 October 2011, Article 2, modified]

3.5

organisation

entity involved in the manufacture, research and/or development, and marketing of food intended for sports people and/or food supplements

3.6

processed products

foodstuffs resulting from the processing of unprocessed products

Note 1 to entry: These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics

[SOURCE: Regulation (EC) No 852/2004, Article 1, o)]

3.7

processing

any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes

[SOURCE: Regulation (EC) No 852/2004, Article 2, m)]

prEN 17444:2019 (E)**3.8****prohibited substances**

substances stated in the prohibited list and its statements managed by the World Anti-Doping Agency (WADA) which is updated, at least annually¹

Note 1 to entry: Manufacturers should be aware that some ingredients potentially contain naturally occurring prohibited substances and therefore, should take action in order to eliminate the risk of prohibited substances in sport.

3.9**sport**

all forms of physical activity which, through casual or organised participation, aim at expressing or improving physical fitness and mental well-being, forming social relationships or obtaining results in competition at all levels

[SOURCE: Council of Europe Committee of Ministers Recommendation No. R (92) 13 Rev of the committee of Ministers to Members States on the revised European Sports Charter]

3.10**food intended for sports people**

all food products which target sportspeople, irrespective of the EU legislation under which they are placed on the market

Note 1 to entry: They are designed to optimize gains from training, enhance recovery within and between workouts and events, achieve and maintain an ideal body weight and composition. The labelling of food intended for sports people is clear in explaining the right conditions for product consumption. They particularly include products bearing authorized health claims that are related to sport and physical activity according to articles 13.1 and 13.5 of Regulation (EC) n°1924/2006).

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Note 2 to entry: Food intended for sports people is not defined in EU legislation.

Note 3 to entry: food intended for sports people includes sports drinks.

3.11**sportsperson****sports people**

person(s) who participate(s) in sport

3.12**unprocessed products**

foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed

[SOURCE: Regulation (EC) No 852/2004, Article 2, n)]

¹ Organisations are obliged to refer to the List in force at the time of manufacture of their products.

3.13

WADA monitoring program

program established by the World Anti-Doping Agency (WADA) regarding substances which are not on the Prohibited List, but which are monitored in order to detect patterns of misuse in sport

Note 1 to entry: Substances that will be monitored are published every year by WADA

4 Prohibited substances

4.1 General principles

The organization shall know the prohibited substances as defined in 3.8. For this purpose, top management shall retain the version in force of the Prohibited List and its summary of major modifications and explanatory notes [4].

Considering the complexity of the Prohibited List which contains “open” sections (including other substances than those specifically listed by name, with a similar chemical structure or similar biological effects) and which does not expressly name all the prohibited substances (especially in sections S1.1.b, S1.2, S2, S3, S4, S5 and S6.b), the manufacturers need specific expertise in the anti-doping domain to assist them to meet the 5.1.1 requirements. This expertise can be based on either internal or external resources.

Top management shall ensure that this updated information is communicated to all personnel concerned with research, development and/or manufacture, to suppliers of ingredients and to subcontractors.

4.2 Particular principles applicable to food intended for sports people and food supplements

By means of an internal and/or external audit, the organization shall periodically (e.g.: annually) evaluate the risks of introduction of contaminants during manufacture. The audit should be based on a HACCP type analysis (Hazard Analysis Critical Control Point) and should apply to all food intended for sports people and food supplements at the time of their design and their manufacture, in such a way as to identify the critical points for quality control.

5 Good development and manufacture practices

5.1 General requirements

5.1.1 General

Implementation of research, good development and/or manufacture practices is essential in the preparation of food intended for sports people and food supplements.

Good practices arise from requirements conventionally implemented by organisations in the framework of either regulatory food safety requirements or voluntary approaches in terms of quality management.

As well as general requirements on the provision of appropriate means and resources, they include specific requirements for control of the processes of development and manufacture of food intended for sports people and food supplements in order to reduce the risk of prohibited substances in the end product.

For the design and manufacture of food intended for sports people and food supplements, with the intention of reducing the risk of prohibited substances in sport, the organization shall ensure in particular provision of the appropriate means and resources in terms of:

- ingredients;
- suppliers of ingredients;