



# SLOVENSKI STANDARD

## SIST EN 17444:2021

01-april-2021

---

**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 sportspeople and food supplements

Dopingprävention im Sport - Gute Praxis bei der Entwicklung und Herstellung zur Vermeidung von Dopingsubstanzen für Nahrungsergänzungsmittel und Sport-Lebensmittel

[SIST EN 17444:2021](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d00805/sist-en-17444-2021)

Prévention du dopage dans le sport - Bonnes pratiques de développement et de fabrication visant à prévenir la présence de substances interdites dans les denrées alimentaires destinées aux sportifs et les compléments alimentaires

**Ta slovenski standard je istoveten z: EN 17444:2021**

---

**ICS:**

67.040 Živilski proizvodi na splošno Food products in general

**SIST EN 17444:2021**

**en,fr,de**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN 17444:2021

<https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021>

EUROPEAN STANDARD

EN 17444

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2021

ICS 67.040

English Version

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

Prévention du dopage dans le sport - Bonnes pratiques  
de développement et de fabrication visant à prévenir la  
présence de substances interdites dans les denrées  
alimentaires destinées aux sportifs et les compléments  
alimentaires

Dopingprävention im Sport - Gute Praxis bei der  
Entwicklung und Herstellung zur Vermeidung von  
Dopingsubstanzen für Nahrungsergänzungsmittel und  
Sport-Lebensmittel

This European Standard was approved by CEN on 20 December 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

<b>Contents</b>	<b>Page</b>
European foreword .....	3
Introduction .....	4
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions .....	6
4 Prohibited substances.....	9
4.1 General requirements.....	9
4.2 Particular requirements applicable to food intended for sportspeople and food supplements .....	9
5 Good development and manufacturing practices .....	9
5.1 General requirements.....	9
5.1.1 General.....	9
5.1.2 Selection of ingredients .....	10
5.1.3 Selection of suppliers of ingredients .....	10
5.1.4 Competence of personnel .....	10
5.1.5 Help box for competence of personnel.....	10
5.1.6 Premises and production tools .....	10
5.1.7 Help box for premises and production tools .....	11
5.1.8 Document control .....	11
5.2 Specific requirements .....	11
5.2.1 General.....	11
5.2.2 Composition/formulation of products.....	11
5.2.3 Commitment with suppliers .....	11
5.2.4 Help box for commitment with suppliers .....	12
5.2.5 Traceability.....	12
5.2.6 Cross-contamination or external contamination.....	12
5.2.7 Help box for cross-contamination or external contamination.....	13
5.2.8 End product analysis plan .....	13
5.3 Management of nonconformities .....	14
5.3.1 Identification of nonconformities.....	14
5.3.2 Management of internally detected nonconformities.....	14
5.3.3 Management of externally detected nonconformities .....	14
6 Information intended for users .....	15
Annex A (informative) Example of good employee training and practices .....	16
Bibliography .....	18

## European foreword

This document (EN 17444:2021) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 17444:2021](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

<https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021>

## 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 sportspeople and food supplements.

This document 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 sportspeople to order and import foods from countries outside the European Union (EU). In addition, various studies show that food intended for sportspeople and food supplements may contain doping substances resulting from unintentional contamination or voluntary additions of substances prohibited by the World Anti-Doping Agency [4], may give 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 sportspeople and food supplements is an important public health issue. This issue concerns all sportspeople, including recreational sports practitioners.

Various publications addressing contamination of food intended for sportspeople 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 WADA [4]. Such substances are harmful to health causing mainly cardiovascular adverse effects, such as myocardial infarction, arrhythmia or coronary artery disease, neurotoxicity, hepatotoxicity, etc.

This document falls within the framework of the measures laid down at international level by the Council of Europe and by United Nations Educational, Scientific and Cultural Organization (UNESCO) respectively:

- the Council of Europe's Anti-Doping Convention of 1989 [5] 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 [6] 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 document are strongly encouraged to comply with the requirements of other standards, in particular those of EN ISO 22000 on food safety management [1] (which includes Hazard Analysis Critical Control Point (HACCP) principles) and as applicable those of EN ISO 9001 on quality management [2].

Thanks to the support offered jointly by the CEN and by the interested parties in preparation of this document, 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 sportspeople with the intention of excluding the substances prohibited by WADA [4] and protecting consumers.

This document 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.

## **iTeh STANDARD PREVIEW (standards.iteh.ai)**

SIST EN 17444:2021

<https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021>

**EN 17444:2021 (E)****1 Scope**

This document sets out the requirements relative to the development and manufacture of food intended for sportspeople and food supplements to reduce the risk of the presence of substances prohibited by the World Anti-Doping Agency (WADA) [4].

This document specifies a framework of good practices with the objective of preventing the presence of substances prohibited in sport in food intended for sportspeople 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 normative references 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 <https://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

**3.1****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 [7]]

**3.2****sportsperson****sportspeople**

person(s) who participate(s) in sport

**3.3****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 [2f], modified [8]]



**3.4****foodstuff**

food including drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment

[SOURCE: Regulation (EC) n° 178/2002 of the European Parliament and of the Council of 28 January 2002, Article 2 [9]]

Note 1 to entry: It means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Note 2 to entry: 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.

**3.5****food supplement**

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 [a] [10]]

**iTeh STANDARD PREVIEW**

Note 1 to entry: 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).

[standards.iteh.ai](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

<https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021>

**3.6****energy drink**

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

Note 1 to entry: They can also contain plant extracts, such as guarana and ginseng. Energy drinks are presented as cans, shots, ready-to-drink or powder forms.

Note 2 to entry: Energy drinks 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, sport drinks are used to replace electrolytes (essential minerals) and macronutrients. They are used to replace water lost in sweat or used up during exercise activity.

**3.7****food intended for sportspeople**

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 sportspeople 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 [11].

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

Note 3 to entry: Food intended for sportspeople includes sports drinks.

**EN 17444:2021 (E)****3.8****nonconformity**

means presence in the end product of a substance prohibited in sport

**3.9****organisation**

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

**3.10****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 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Article 2, o) [12]]

**3.11****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

iTeh STANDARD PREVIEW

[SOURCE: Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Article 2, n) [12]]

[SIST EN 17444:2021](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

**3.12****prohibited substances**

substances stated in the prohibited list and its statements managed by WADA which is updated, at least annually<sup>1</sup>

<https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021>

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.

**3.13****WADA monitoring program**

program established by 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.

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

## 4 Prohibited substances

### 4.1 General requirements

The organization shall know the prohibited substances as defined in 3.12. For this purpose, top management shall retain the version in force of the Prohibited List and its summary of major modifications and explanatory notes [13].

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 requirements applicable to food intended for sportspeople and food supplements

By means of an internal and/or external audit, the organization shall periodically (e.g.: annually) evaluate the risks of introducing contaminants during manufacture. The audit should be based on a HACCP type analysis and should apply to all food intended for sportspeople 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 manufacturing practices

### 5.1 General requirements

#### 5.1.1 General

[SIST EN 17444:2021](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

[https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

[4ca0e7d08005/sist-en-17444-2021](https://standards.iteh.ai/catalog/standards/sist/d9184596-2e86-4928-88c3-4ca0e7d08005/sist-en-17444-2021)

Implementation of research, good development and/or manufacturing practices is essential in the preparation of food intended for sportspeople 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 sportspeople 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 sportspeople 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;
- personnel;
- premises and production tools;
- document control.