General Product Safety Directive (2001/95/EC) & Drafting an Annex ZA / ZZ

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1. Producers shall be obliged to place only safe products on the market.

See also: CHAPTER III - Other obligations of producers and obligations of distributors, in particular Article 5



Reminder: Safe product

any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements,

does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous";



European Standards in support of GPSD

Under normal or reasonably foreseeable conditions of use (...) the product does not present any risk or only the minimum risks compatible with the product's use (...)



A product shall be presumed safe

when it conforms to voluntary European standards, the references of which have been published by the Commission in the OJEU

as far as the risks and risk categories covered by these standards



European standards the reference of which has been published in the OJEU in support of GPSD are not harmonised standards

...but play a similar function, providing presumption of safety



The European Commission, within its implementing powers, shall determine the requirements that the standards have to cover to meet the General Safety requirement



Standards developed in support of GPSD shall be developed as a reply to a **Standardisation Request** issued by the European **Commission**, in line with **Regulation 1025/2012**

...or previous requests issued in line with Directive 98/34/EC



► Before GPSD (2001) ► After GPSD (2001)

Mandates contain

- detailed description of the issues and
- list of risks to be considered in the standards
- Description of the mandated work

Mandates/Requests contain

- brief description of the issues to be considered
- reference to the relevant Commission Decision
- description of the mandated work
- bodies to be associated in the work, etc



Identification and assessment of relevant risks

Example for Gymnastic equipment (I)

- Decision 2011/479/EU on the safety requirements to be met by the European standards for gymnastic equipment
- M/507 (September 2012): request to CEN for drawing up European standards to address the main risks associated with gymnastic equipment pursuant to the safety requirements

- CEN drafted new European standard EN 913:2018.
- European standard EN 913:2018 complies with the general safety requirement set out in Directive 2001/95/EC.
- Its reference is published in the Official Journal of the European Union (Commission Implementing Decision (EU) 2019/1698).



Example for Gymnastic equipment (II)

Decision 2011/479/EU on the safety requirements to be met by the European standards for gymnastic equipment

ANNEX

SPECIFIC SAFETY REQUIREMENTS FOR GYMNASTIC EQUIPMENT

Part I

Product and product definition

The gymnastic equipment covered by this mandate is equipment used for training, exercising or competition purposes, involving group and individual exercise. This equipment either stands on the floor or is fixed to the ceiling or a wall or other fixed structure. It is either permanently installed or able to be moved and modified for use.

For some specific gymnastic equipment, general requirements are complemented by additional safety requirements.

Part II

A. General safety requirements

The products shall comply with the general safety requirement referred to in Directive 2001/95/EC and be 'safe' within the meaning of Article 2(b) thereof. In particular, the product shall be safe under normal and reasonable foreseeable conditions of use, including storage, safe transport to the storage space, installation and maintenance, dismantling, and throughout the duration of its use. The product shall be safe also for professional users (e.g. trainers, teachers).

During normal and reasonable foreseeable conditions of use of gymnastic equipment, the risk of injury or damage to health and safety shall be minimised. No parts that are accessible to the user during normal or intended use shall cause physical injuries or affect the health of the user.

A common foreseeable use of these products is to train children (e.g. at school, in sports clubs) who in general have a perception of risk lower than that of adults. Where hazards cannot be sufficiently minimised by design or safeguards, the residual risk should be addressed by product-related information directed at supervisors.

Users shall be informed of the risks and dangers likely to occur and how to prevent them.

B. Specific safety requirements

In application of the general safety requirements referred to in Directive 2001/95/EC, the following shall be taken into account, as a minimum:



Example for Gymnastic equipment (III)

Decision 2011/479/EU on the safety requirements to be met by the European standards for gymnastic equipment

B. Specific safety requirements

In application of the general safety requirements referred to in Directive 2001/95/EC, the following shall be taken into account, as a minimum:

- (a) Surface finish;
- (b) Gaps and shearing/crushing/pinching points;
- (c) Unintentional dropping;
- (d) Falling from height;
- (e) Stability and strength;
- (f) Adjustment devices;
- (g) Shock absorption of top padding;
- (h) Marking. More specifically, all gymnastic equipment shall bear the following information:
 - (1) number of the relevant European standard;
 - (2) name, trademark or other means of identification of the manufacturer, retailer or importer;
 - (3) year of production;
 - (4) maximum number of users at a time for which the equipment is intended;
 - (5) instructions for use;
- (i) Entrapment and strangulation;
- (j) Collision;
- (k) Durability;
- (l) Electric shocks;



Example for Gymnastic equipment (IV)

Decision 2011/479/EU on the safety requirements to be met by the European standards for gymnastic equipment

In addition, the following risks shall be taken into account:

- (a) risks resulting from insufficient load bearing capacity of the equipment, taking into account the strength, stiffness and elasticity of the materials used;
- (b) risks resulting from loss of stability of the equipment, taking into account the support of the equipment and the floor, as well as possible loads on the equipment;
- (c) risks resulting from the use of electrical energy and from operating circuits;
- (d) risks resulting from applied mechanical, or water energy;
- (e) risks resulting from the use of the equipment, including falls, cuts, entrapment, suffocation, collisions and overloading of the body;
- (f) risks resulting from the accessibility of the equipment, including accessibility in case of defects and emergency situations;
- (g) risks resulting from possible interactions of the equipment and occasional bystanders (e.g. public audience);
- (h) risks resulting from insufficient maintenance;
- (i) risks resulting from assembly, disassembly and handling of the equipment;
- (j) risks resulting from exposure to chemical substances.

In application of the general safety requirements referred to in Directive 2001/95/EC, the following tests shall be taken into account, as a minimum:

- (a) Determination of entrapment;
- (b) Mechanical loading for determination of stability and strength;
- (c) Determination of shock absorption of padding;
- (d) Test report.



Example for Gymnastic equipment – Mandate/Request

Ref. Ares(2012)1063692 - 13/09/2012



EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Consumer Affairs Product and Service safety

> Brussels, 5th September 2012 M/507 EN

STANDARDISATION MANDATE ISSUED TO THE EUROPEAN STANDARDISATION ORGANISATIONS (ESOS) TO DEVELOP EUROPEAN STANDARDS FOR GYMNASTIC EQUIPMENT

2. DESCRIPTION OF THE MANDATED WORK

The Commission requests the ESOs to develop European standards that as a minimum fully meet the safety requirements detailed in the Annex to the Commission Decision 2011/479/EU.

For the purposes of this mandate the definition of the gymnastic equipment provided in Article 1 of the above named Commission Decision applies.

Additionally in carrying out the mandated work, the ESOs are requested to consider existing legislation, guidelines, code of practices and standard(s) in this area, ongoing standardisation work at international and national level.



Relevant Commission Decision

Standardisation Request / Mandate

Relevant RAPEX notifications

Experience and information available to manufacturers (or their representatives), distributors (supply chain), authorities, consumers and users, conformity assessment bodies, etc...



Product or family of products Risks associated with:

- normal conditions of use
- reasonably foreseeable conditions of use

Information*

Relevant information to enable consumers and users:

- to assess the risks inherent in a product
- to take precautions against those risks



Annex ZA (or ZZ) for standards intending to support GPSD

Annex ZA for Standardisation Requests issued post GPSD





For requests post-GPSD

Annex ZA (informative)

Relationship between this European Standard and the safety requirements of Directive 2001/95/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request **M/507** gymnastic equipment to provide one voluntary means of conforming to the product safety requirements for gymnastic equipment pursuant to Directive 2001/95/EC of the European Parliament and of the Council.

Once this standard is cited in the Official Journal of the European Union under that **Directive 2001/95/EC**, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding **safety requirements** set in the **Commission Decisión 2011/479/EU** on the safety requirements to be met by European standards for gymnastic equipment that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and the General Product Safety Directive 2001/95/EC and Commission's standardisation request M/507 gymnastic equipment

Table ZA.1 — Correspondence between	Clause(s)/sub-clause(s) of this	Remarks/Notes
this European Standard and the safety		
Requirements of Commission Decision EN XXXX		
2011/479/EU		
Product and product definition	Clause X	XXXXXX
A. General safety requirements	Clause Y.YY	ΥΥΥΥΥΥΥ
B. Specific safety requirements		
B. (a) Surface finish;	Clause a.aa	
B. (b) Gaps and shearing / crushing /	Clause h.hh	
pinching points;		
()		
Requirements concerning information	Clause zzzz	

Annex ZA for Standardisation Requests issued pre GPSD





For requests pre-GPSD

Annex ZA (informative)

Relationship between this European Standard and the safety requirements of Directive 2001/95/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request **M/285 relative to safety of consumers - ladders** to provide one voluntary means of conforming to the **product safety** requirements **for gymnastic equipment pursuant to Directive 2001/95/EC of the European Parliament and of the Council.**

Once this standard is cited in the Official Journal of the European Union under that **Directive 2001/95/EC**, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding **safety requirements** set in **the Directive 2001/95/EC and specified in the request M/285** and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and the General Product Safety Directive 2001/95/EC and Commission's standardisation request M/285 relative to safety of consumers - ladders

Table ZA.1 — Correspondence between this European Standard and the safety	Clause(s)/sub-clause(s) of this	Remarks/Notes
Requirements of Directive 2001/95/EC	EN XXXX	
and specified in the request M/285		
8.2 General safety requirement	Clause X	XXXXXX
8.3.a Product's characteristics;	Clause Y.YY	YYYYYYY
8.3.b Packaging;		
8.3.c Instructions for assembly and	Clause a.aa	
maintenance, use and disposal;		
8.3.d The effect on other products with	Clause h.hh	
which it might be used;		
8.3.e Labelling and other information	Clause j.jj	
provided to the consumer;		

(Continued)

Table ZA.1 — Correspondence between this European Standard and the safety Requirements of Directive 2001/95/EC and specified in the request M/285()()()()()()	Clause(s)/sub-clause(s) of this EN XXXX	Remarks/Notes
 8.3.f categories of consumers at serious risk when using the product, particularly children. 8.4 - Minimum risk compatible with the product's use. 	Clause zzzz Clause hh.hhh	

Publication of references in the OJEU under GPSD

Publication of references of standards in the OJEU under the GPSD

Commission Implementing Decision (EU) 2019/1698 of 9 October 2019 on European standards for products drafted in support of Directive 2001/95/EC of the European Parliament and of the Council on general product safety (Text with EEA relevance) C/2019/7126

Contains a good summary of the different:

- Commission Decisions setting requirements for the different categories of products
- Mandates/Requests,
- European Standards prepared by CEN and CENELEC

Publishes the updated list of standards providing presumption of safety Withdraws the reference to previous versions of standards

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32019D1698



Publication in the OJEU

Commission Implementing Decision (EU) 2019/1698

• Annex 1 – Publication of the references

2.	EN 913:2018 Gymnastic equipment — General safety requirements and test methods
3.	EN 914:2008 Gymnastic equipment — Parallel bars and combination asymmetric/parallel bars — Requirements and test methods including safety
4.	EN 915:2008 Gymnastic equipment — Asymmetric bars — Requirements and test methods including safety
5.	EN 916:2003 Gymnastic equipment — Vaulting boxes — Requirements and test methods including safety

• Annex 2 – Withdrawal of the references

ANNEX II

No	Reference of the standard
1.	EN 913:2008 Gymnastic equipment — General safety requirements and test methods
	Gymnastic equipment — General safety requirements and test methods







Conclusions (I)

- A product shall be presumed safe when it conforms to voluntary European standards, the references of which have been published by the Commission in the OJEU as far as the risks and risk categories covered by these standards
- European standards the reference of which has been published in the OJEU in support of GPSD are not harmonised standards, but they play a similar function in terms of presumption of safety
- In addition to the General Safety requirements,
 - the specific requirements that the standards have to cover to meet the General Safety requirement for the particular category of products are included in the corresponding Commission Decisions
- The Request / Mandate may include additional requirements for the original reference documents, development process requirements or requirements to be met by the resulting standards



Conclusions (II)

Risk assessment for the type of product

- Due consideration of the requirements / risks in Commission Decision and/or Request/Mandate
- normal conditions of use
- reasonably foreseeable conditions of use
- Information to enable consumers/users to be aware of relevant risks and take precautions accordingly

Annex ZA/ZZ

- Identification of the Request/Mandate and/or Commission Decision
- Link between requirements and detailed clauses of the standard
- Sufficient level of granularity



And of course... do not forget

the formal CEN and/or CENELEC assessment of the Standard regarding the requirements in the GPSD, the Commission Decision and the Request

before offering it to the European Commission as candiate for publication of its reference in the Official Journal in support of GPSD

[Art. 10 (5) of Regulation 1025/2012]



