REPLY FOLLOWING ASSESSMENT BY	TO
Mr J. BAHIMA CEN Consultant Calle Macedonia 8 E – 41007 SEVILLA	CMC CEN Consultants Administration rue de Stassart, 36 B - 1050 BRUSSELS
	Date : 2008-12-09

RE: Assessment of prEN 15712 for FV assessment

Title:	Mouthguards for use in sports - Safety requirements and test methods
Work Item	00162249 NOTE:
Directive(s)	89/686

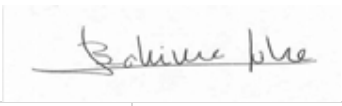
Result of assessment (based on the English version):

☐	This EN can proceed to the CEN formal vote as it stands
or	
X	This EN cannot proceed to the CEN formal vote. The reasons for this are detailed in annex to this reply.

Subsidiary information, only applicable to prENs for a New Approach Directive:

a)	X	I support the intention that the EN when ratified, is submitted as a Harmonised Standard for publication of its reference in the Official Journal of the European Commission under the EU Directive(s) under which I have assessed it.
b)	☐	I do not support the intention that the EN when ratified, is submitted as a Harmonised Standard for publication of its reference in the Official Journal of the European Commission. The reasons are given in my assessment.
c)	☐	I have made some recommendations to the responsible TC on the contents/scope of the next revision, or on an amendment to the EN details of which are annexed to this letter.
d)	☐	I have excluded specific subjects from my assessment as these are outside my field of responsibility. I have specified the excluded subjects in my assessment.
e)	☐	I recommend that this prEN should also be assessed for other subjects or other EC Directives as indicated in my assessment.

In accordance with the procedure BT N 3810 the undersigned agrees to participate in the required follow-up actions in consultation with the CEN/TC Chairman and Secretary and CMC.



Signature:	Jose Bahima

Encl.:	Assessment composed of	10	pages including this sheet.

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EVALUATION REPORT

Ref: JB/00162249/fv, 2008-12-08

RE: prEN 15712 for fv, 2008-11

prEN 15712 **Mouthguards for use in sports - Safety requirements and test methods**

This draft prEN cannot proceed to the CEN formal vote.

REMINDER

Technical solutions provided by the standards in order to verify Essential Requirements has to guarantee the level of protection required by the Directive. In the same way, standards must provide a uniform way of verification. As far as it is possible, technical solutions (requirement + test method) must be representative of the risk they intend to cover. Essential Requirements must be applied as a function of the hazard inherent to a given product, under the foreseeable conditions of use.

One of the more important parts of the standard is the annex ZA. Annex ZA must show clearly the relationship between the clauses (or sub-clauses) of the standard with the Essential Requirements of the Directive 89/686/EEC and it must give the information of how the Essential Requirements are covered. The correctness of Annex ZA is of the maximum importance.

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COMMENTS DIRECTLY LINKED TO THE NEGATIVE ASSESSMENT

General

Through the standard reference is made to “mouthguards”; however it is unclear whether this word refers to the preformed shape or it refers to that preformed shape once it has been adapted to the users’ mouth. In addition, reference is made also to “mouthguards” produced in the lab. Directive applies to PPE (mouthgurds in this case) ready to be used, not to materials or PPE produced in the lab.

1 Scope
1st paragraph

From the Scope it cannot be ascertained which part of the mouth is protected, i.e. lower teeth, upper teeth, soft tissues, jaw, etc or all. Although from Tables it might be assumed that the standard applies only to maxillary teeth (notations U), this must be made clear in the Scope. In addition, mouthguard boxes are also covered by the standard. Presumption of conformity is only given within the limits of the Scope

5 Performance levels

No link between performance levels and risk is given. In this way nobody may know for what has to be used the corresponding mouthguard. Even although manufacturer has to give clear indications on use, each manufacturer could give different uses for the same performance level

6.2 Ergonomics

Test method cannot decide whether there are rough surfaces or sharp edges present that may cause discomfort or injury to the user's mouth

6.3.1 Sizing

The clause refers to "Sizing", however, dimensions given in Tables don't give to the users any indication for a proper selection of their correct size. On the other hand, it is unclear to what type of mouthguard those dimensions refer and in the case of mouth adapted mouthguards if it refers to the preformed shape or it refers to the mouthguard once the preformed shape has been adapted by the user. Made-to-measure mouthguards have their own individual dimensions and in regard to mouth-adapted mouthguard, the important point it would be the dimensions once the mouthguard is adapted, not the dimensions of the preformed shape.

6.3.2 Dimensions and thickness
1st paragraph

The aim of the standard is to give requirements for the own mouthguards as they are used, no matter the manufacture process.

6.3.2 Dimensions and thickness
2nd paragraph

Minimum thickness too low. In addition, no measurement method for thickness is given. Figure 2 refer to flanges measurement

6.3.2 Dimensions and thickness
Tables

Wording unclear. Tables refer to "Dimensions of mouthguards" but it is not indicated if refers to dimensions of the preformed shapes or it refers to the real mouthguard, once the preformed shape has been adapted to the user's mouth. Directive applies to PPE ready to be used.

Furthermore, in Tables the words buccal or palatal flanges appear. However in their definitions they make reference to buccal and/or labial gingivae that are not defined. Others, like gingival margin or distal margin of mouthguard, neither are defined. This can make that measurement is not feasible.

6.4 Impact performance

Requirement contradictory with Test. Requirement refers to “representative mouthguards” while test refers to materials. In addition, impact levels should be revised in the light of scientific data

Giving only the mean as final result may misrepresent the result. A correct mean may come from results some of which fails

6.9 Mouthguard box

In clause 7.11, tests for the surface condition and the impact resistance of the mouthguard boxes are carried out. Also, the capability of containing of made-to-measure mouthguards is indicated. However here, in this clause, no requirement for all those points it is indicated.

7 Test methods and procedures
General

Test are carried out on materials or on mouthguards produced in the laboratory. This is not in agreement with Directive that applies to PPE ready to be used.

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7.1 Test panel

If test panel is only randomly selected it may be that they don't cover the different morphological features of the jaw and this may affect to the result.

7.2.2 Type 1 made-to-measure mouthguards

It is very unlikely that the production of mouthguards in the lab reproduces the real process and in this way they won't be able to represent the existent ones. Mouthguards already existing must be used

7.2.3 Mouth-adapted mouthguards

The formation process is of the maximum importance in regard to the afforded protection and it may be influenced by the size of the preformed shape. Where several sizes of preforemd shapes exist, it is not indicated how each member of the test panel selects the preformed shape that adapts to his anatomy

7.3.2 Conditioning of mouthguard boxes

Impact testing on materials doesn’t represent the real resistance of the mouthguard. Directive refers to PPE not to materials

7.5 Ergonomics

Visual inspection not appropriate to verify whether rough surfaces or sharp edges may cause discomfort or injury to the user's mouth. In addition clause is unclear in regard to whether this refers to the preformed shape or it refers to this preformed shape, once it has been adapted to the users' mouth. Ergonomics is a concept that only apply to the PPE ready to be worn

7.6.1 Principle

Testing materials cannot guarantee the protection. They are not only the materials but also the mouthguard adaptation those that influence in the protection. In fact, adaptation may have more influence than materials.

7.6.3 Test specimens

Test specimens must be mouthguards just as they are used, i.e. the made-to-measure mouthguard or the preformed shapes once they have been adapted to the user's mouth.

7.6.5 Testing of unformed material

Unformed material doesn’t represent the final product and therefore the performance will be different

7.7.1 Principle

Mouthguards must not be produced in the lab, but mouthguards, already adapted by the user must be used

7.7.3 Procedure

Giving only the mean as final result may misrepresent the result. A correct mean may come from results some of which fails

7.8 Breaking strength

1st para

Test unclear and not feasible. It is not clear whether specimen mouthguard refers to the preformed shape or to the already formed mouthguard. In addition, in no part of the standard it is defined what is labial flange. Furthermore, pass/fail criteria contradictory with the requirement where a force below 200 N is required.

7.9.2 Preparation of test specimens

Specimens must not be formed by bonding the layers in the lab. Procedure in the laboratory will never be able to reproduce the procedure used in the production of the materials. The specimens must be mouthguards, already adapted, ready to be used, obtained from the preformed shapes, following the manufacturer instructions.

7.9.3 Procedure

Clauses from 7.9.3.5 to 7.9.3.7 can mistake the standard users. It is not clear whether that stated in the clauses are requirements or not. In 6.7 only one requirement is indicated.

Clauses 7.9.3.9 and 7.9.3.10 are unclear for the standard users. E.g. no indication on how to handle the peel strength of specimens showing different type of failure; the meaning of "the number of test specimens from which each result is derived" is unclear; no requirement for the "initial maximum peel strength.

On the other hand, calculating the mean and giving it as final result, may misrepresent the result. A correct mean may come from results some of which fails

7.11.1 Surface condition

No requirement for surface condition of the mouthguard boxes is given. In any case, as it is, the test would verify the effect of cleaning and disinfecting but not the surface condition.

7.11.2 Impact test

Test doesn't verify fully the requirement. Test would verify whether the mouthguard box resists or not the impact, but nothing is said of the mouthguard placed inside. Requirement says that boxes shall protect mouthguard from damage and to keep it clean.

9 Information to be supplied by the manufacturer

This information must be given at least in the official language(s) of the country of destination

Annex ZA

As it is it is considered as mistaken. Detailed comments below

Heading of Annex ZA must be in accordance with BT Resolution 2/2003. Comments on Table highlighted in red

Table ZA — Correspondence between this European Standard and Directive (Add the reference and title of the Directive)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
4 It is not 4 but it is 5 the clause that could be related to one of the sub-headings of ER 1.1.2	1.1.2 Levels and classes of protection This ER is a main heading. If the clause verifies that main heading it would mean that all the sub-headings would also be verified. This is not true. The specific heading or sub-heading must be used.	
5.1, 5.2 Clauses 5.1 and 5.2 don't exist. They are 6.1 and 6.2 the clauses that could be related to some of the sub-headings of this ER	1.2 Innocuousness of PPE This ER is a main heading. If the clause verifies that main heading it would mean that all the sub-headings would also be verified. This is not true. The specific heading or sub-heading must be used.	
5.3, 5.5 It would be 6.3 and 6.5 (clauses 5.3 and 5.5 don't exist) the ones that would be related to this ER. Anyway, clause 6.3 doesn't verify the ER. It gives dimensions for the preformed shapes, but it gives not any indication on how to select the appropriate size. Clause 6.5 neither verify the ER because test method refers to mouthguards produced in the lab, not to the real mouthguard as it is used.	1.3.1 Adaption of PPE to user morphology	

7, 8 Instead of 7, 8 they are 8, 9. Anyway clause 9 doesn't verify fully this ER	1.4 Information supplied by the manufacturer	
8 ER not verified. Standard gives not any indication related to this ER	2.4 PPE subject to ageing	
7 OK, but it is 8 instead of 7	2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety	
5.4 It should be 6.4. ER not verified. Requirement contradictory with test. Testing only on materials.	3.1.1 Protection against mechanical impact	

EDITORIAL COMMENTS AND COMMENTS NOT DIRECTLY LINKED TO THE NEGATIVE ASSESSMENT, BUT THEIR CONSIDERATION WOULD CLARIFY THE STANDARD AND WOULD IMPROVE ITS UNDERSTANDING AND APPLICATION.

3 Terms and definitions

To make the standard more understandable, common names of the different types of mouthguards should be given in a NOTE**,** e.g. made-to-measure = custom made; mouth-adapted = boil and bite; etc

3.1 Mouthguard

NOTE

Ready-made mouthguards neither are covered by this standard.

5 Performance levels

Clause 7.5 refers to "Ergonomics"

6.1 Chemical safety

To be in line with most of the PPE standards, the Title should be "Innocuouness"

6.4 Impact performance

Clause 7.5 refers to "Ergonomics"

6.5 Retention

Clause 7.6 refers to impact performance

6.6 Breaking strength

"pull apart" is unclear, test refers to this as tear

6.7 Peel strength of laminations

"Peel strength of laminate materials" would be clearer

7.3.1 Conditioning of dental casts, mouthguards and materials

Clause without content. It seems that the title and the content of clauses 7.3.1, 7.3.2 and 7.3.3 have been mixed. It seems that the clause 7.3.3 is surplus and clauses should be only 7.3.1 and 7.3.2

7.3.2 Conditioning of mouthguard boxes

Title doesn't correspond with the clause content. It seems that the content of this clause correspons to the clause above

7.3.3 Conditioning of mouthguard boxes

It seems that this should be 7.3.2 and 7.3.3 should not exist

7.4 Dimensions of specimen mouthguards

Giving only the mean as final result may misrepresent the result. A correct mean may come from results some of which fails

7.7.1 Principle

Clause 6.2 refers to "ergonomics".

7.8 Breaking strength

It is not a constant rate of travel tensile testing machine but it is a constant-rate-of-traverse tensile testing machine

7.9.3.8

It should be indicated from where this mean peeling force is derived

7.9.4 Test report

a) It is not Draft for Development but it is Standard
From d) to f) is not required by the requirement clause 6.7

7.10.1 Apparatus

"a means of accurately weighing …" without giving the accuracy of the weighting instrument means nothing. Accuracy of the weighing device should be included

8.1 Mouthguards

c) traceability of constituent materials is not required by the Directive and in addition it doesn't give any added value to the product nor it is useful for the end user. It only represents a burden for manufacturers

d) manufacturer cannot identify the end user.

8.2 Mouthguards boxes

c) Unclear on what it means "identifying the mouthguard …". Manufacturer cannot identify the end user

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