



# Guidelines to Harmonised Standards In the field of Machinery

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## EC/EFTA Mandates, Order Vouchers, Assessment of Harmonised Standards Presumption of Conformity, Safeguard Actions and the Application of Multiple EU Directives.

2002-03-18

### 1. Introduction

1.1 Over a number of years the European Committee for Standardization (CEN) has been producing European Standards in close co-operation with the European Commission (EC) and the European Free Trade Association (EFTA) that support a series of European Directives developed to eliminate technical barriers to trade which are known as the New Approach Directives.

1.2 This guide provides information on how the agreements between CEN and the European Commission and EFTA related to the New Approach Directives in the field of machinery have been integrated into the CEN System.

1.3 This guide has been prepared by the CEN Management Centre (CMC), is targeted at CEN Technical Committee Chairmen, Secretaries, Convenors, Delegates and Experts. It is hoped that the reader of this guide will be encouraged to seek the full information that is available in such documents as the CEN/CENELEC Internal Regulations, the CEN Website CENBOSS and various CEN Memoranda, see 23 References.

1.4 The core process which links the subjects covered by this guide is that of developing European Standards to become "Harmonised Standards" as defined in the New Approach Standards and Technical Regulations Directive 98/34/EC.

### 2. New Approach Directives

2.1 The majority of the CEN programme of European Standards in the field of machinery are intended to support one or more of the New Approach Directives. The basic concept of the New Approach is that the Directives are written as a series of simple legal requirements (Essential Health and Safety Requirements-ESR) backed up by a series of Harmonised Standards. The Directives set the legal requirements and the standards provide a means of reaching the objectives.

2.2 New Approach Directives define legislative harmonization in specific sectors where barriers to trade exist due to divergent national regulations. Health and safety are common themes of the New Approach Directives, however their principal objective is to support the free movement of goods within the European Union (EU) by the removal of technical barriers to trade, thus not all the Directives deal with safety.

2.3 The "New Approach" to writing EU Directives was enshrined in the European Council Resolution 85/C/136/01 of 7 May 1985 that provided a new approach to technical harmonization and standards. The EU Directives supported by the CEN machinery standardization programme are New Approach Directives, which support the principles of Article 100A and Article 118A of the EEC Treaty. These articles were later reproduced in Article 95 and Article 137 of the Maastrich Treaty. Article 95 (100A) directives deal with the free market of goods and Article 137 (118A) with the freedom of movement of labour. A list of the New Approach Directives and their references are given in Annex D.

### 3. Harmonised Standard

A "Harmonised Standard" in terms of the New Approach Directives is a technical specification (European Standard) adopted by CEN, the European Committee for Electrotechnical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI) which has been developed under a mandate given by the EC and /or EFTA in support of essential requirements of New Approach Directives. A standard which is under development and which is intended to satisfy the necessary requirements is termed a "Candidate Harmonised Standard"

### 4. Mandates in the field of machinery safety

4.1 A mandate is a request from the EC (or EFTA) agreed by the European Union (EU) Member States, addressed to CEN (and usually also to CENELEC and/or ETSI) and sets the general conditions for work to be carried out.

4.2 Within the field of machinery safety there have been two main types of Mandate.

#### - Programming Mandate

This as the name suggests is a request to prepare a programme of standards. In the Machinery field there have been the following:

| <u>Mandate</u> | <u>Related Directive</u>   | <u>Subject</u>                         |
|----------------|--|--|
| M/BC/CEN/88/13 | 98/37/EC (formerly 89/392/EEC)                                     | Machinery                              |
| M/BC/CEN/91/1  | 98/37/EC (89/392/EEC, 91/368/EEC)                                  | Machinery mobility or load lifting     |
| M/008          | 98/37/EC (89/392, 93/44/EEC)                                       | Machinery lifting or moving of persons |
| M/BC/CEN/91/16 | 98/37/EC (89/392/EEC amended by 91/368/EEC, 93/44/EEC & 93/68/EEC) | Reprogramming mandate, Machinery       |

#### - Standardization Mandate

This is a request from the EC (and EFTA) to go ahead with the programme proposed under a programming mandate. The current mandate for the Machinery Directive is:

|       |                                |           |
|-------|--------------------------------|-----------|
| M/079 | 98/37/EC (formerly 89/392/EEC) | Machinery |
|-------|--------------------------------|-----------|

There have been a further series of EC Mandates that are associated with machinery:

|       |  |
|-------|--|
| M/015 | Relevant to machines with hazards falling under the Low Voltage Directive. |
| M/233 | Mandate for equipment for Fairgrounds and Amusement Parks.                 |

Note: The references of the Mandates are given in the form they are given in the CEN database.

4.3 Mandate M/BC/CEN/91-1 remains the bench mark for assessing the drafts related to the Machinery Directive 98/37. It defined the criteria for standards to be "mandated" by the EC and defines the types of standard to be prepared, namely:

A-type standards giving basic concepts, principles for design and general aspects that can be applied to all machinery, e. g. Terminology.

B1-type standards on particular safety aspects that can be used across a wide range of machines, e.g. safety distances, surface temperature, noise.

B2- type standards on safeguards, which are concerned with components related to safety that can be used across a wide range of machines, e.g. two-hand control, interlocking devices, pressure sensitive devices, photoelectric barriers, guards.

C-type standards dealing with detailed safety requirements for a particular type of machines or group of machines.

Note: The term group of machines means machines which have similar intended use and similar hazards, hazardous situations, events.

4.4 The requirements of the programming mandate M/BC/CEN/91-1, including the definitions given above, have been transcribed into the contents of EN 414 "Safety of machinery - Rules for the drafting and presentation of safety standards" and expressed in a manner suitable to the writer of standards.

4.5 Mandate M/BC/CEN/92/3 applies specifically to Lifts in compliance with Directive 95/16/EC.

## **5. Mandates with an open ended programme**

5.1 When the EC/EFTA Mandated programme of work was started in CEN, the Mandates were linked directly with the process of EC/EFTA Order Vouchers to provide financial assistance, thus Mandates were associated with a formal acceptance procedure. This procedure was followed by the introduction of an open ended Mandate system in which CEN is requested to continue nominating the EN's being prepared which CEN considers to be Candidate Harmonised Standards and to identify the related Directives. The EC is informed of these draft EN's (Candidate Harmonised Standard) and if after approximately six weeks the EC had not reacted to CEN, then the work items become "Mandated".

The current mandate for the Machinery Directive M/079 is such an open mandate.

5.2 The CMC is responsible to communicate the details of a Candidate Harmonised Standard and the related Directive(s) to the European Commission.

## **6. Mandates for the revision of Harmonised Standards**

6.1 When a Harmonised Standard is revised or amended a request is to be made by the originating CEN/TC to the CMC for a new CEN Work Item. The request should ask for the new Work Item to be registered as a "Candidate Harmonised Standard" under the related EC Mandate and under the related EC Directives. Under the terms of the framework Directive the revision of Harmonised Standards under the Machinery or Lifts Directive will not be financially supported by the EC or EFTA. The related EC Mandate will normally be the current "open mandate" and will not be the Mandate for the original version of the EN, particularly those starting " M/BC/CEN/".

6.2 The EC or EFTA may request CEN to amend or revise a Harmonised Standard as a result of a Safeguard Action (see 22). In such cases specifically detailed Mandates may be prepared by the EC and EFTA. These are not normally financially supported by EC or EFTA.

## **7. Order Voucher or Bon de Commande and Mandates**

7.1 There is often confusion on what is a Mandate and an Order Voucher. An Order Voucher is the commitment of the EC or EFTA to financially contribute to the production of a standard. A Mandate is a "political" request and as described in 4 above sets down the details and conditions of work to be carried out. It may be for the preparation of a Standard or a Report or some other form of deliverable. However finance is not part of a Mandate.

7.2 Order Voucher and Bon de Commande are the same thing in English and French. Order Vouchers are legal contracts issued by the European Commission and EFTA and include financial conditions.

A typical reference of an order voucher is the following:

7.3 It is not necessary that a Harmonised Standard is covered by an Order Voucher. However it is necessary for an EN to be included in a Mandate to become a Harmonised Standard.

## **8. Commission Order Voucher Review Meetings**

8.1 From time to time the EC requests a meeting with CEN to review the progress of Candidate Harmonised Standards which are covered by an Order Voucher. In the recent past Review meetings for the Machinery standards were held in May 1996, June 1998 and February 2000.

8.2 The EC has imposed very strong conditions for the continuance of the Order Vouchers related to Machinery, especially to those issued between 1988 to 1991 which have had long delays to complete. The result of the June 1998 Review Meeting was the discontinuance of the financial support of several hundred draft ENs in the Machinery programme and finance was discontinued at the February 2000 meeting for a further 50 draft ENs.

8.3 The discontinuance of an Order Voucher has no effect on the Mandated status of a draft EN to become a Harmonised Standard.

8.4 The provision of relevant up to date information and correct and realistic dates for the EC Review meetings is essential. It may be expected that further cuts will be made by the CE Services on the existing Order Voucher budget and delays on target dates will be used to effect those cuts.

## **9. Essential elements of a Candidate Harmonised Standard**

9.1 In order for a draft standard to be designated a Candidate Harmonised Standard it requires to comply with all of the following:

- a formally registered Work item in CEN,
- "mandated" by the EC and /or EFTA ,
- supports at least one essential safety requirement of a New Approach Directive,
- contains the necessary elements that identifies in the Foreword that the standard has been prepared under a Mandate of the EC and /or EFTA and details in Annex Z (s) how it relates to the essential requirements of the related New Approach Directive(s). For machinery and lift standards, special guidance is given in EN414: 2000.

9.2 Draft ENs in the Machinery programme, Mandated or not, that do not satisfy all of the requirements listed in 9.1 are, for purposes of monitoring by the CMC, indicated in the CMC database under the heading "Supporting" standard. Such ENs are not submitted to the EC for publication of their reference in the EC Official Journal (EC OJ). However depending on a case by case decision, these drafts are sent to the relevant CEN Consultants for their advice on the contents at the Enquiry and pre-Formal Vote stage. The advice will be made known to the CEN/TC Secretariat by the CMC.

Note: In other sectors e.g. Pressure Equipment, the classification "supporting" has very specific meaning.

## **10 Consultant assessments of Candidate Harmonised Standards**

10.1 Consultant assessments are carried out on Candidate Harmonised Standards at the Enquiry stage and before the Formal Vote is started. The objective is to verify that the draft EN supports the related Directive(s) and the conditions of the related EC Mandate(s). Consultant assessments are made whenever possible during the Enquiry period. This has been termed for CMC monitoring purposes the (E) Assessment. However in exceptional cases it may be necessary to defer the assessment until the start of the Comments Resolution period. This has been termed the (EC) Assessment. A list of the CMC internal codes used to identify the assessments is given in Annex B. The flow chart of "Fast Track Procedure" is given in ANNEX C.

10.2 In the stages following the Enquiry where the draft standard is being finalised the advice of the Consultants, called a re-assessment, is also available upon request of the TC, SC or WG. In the machinery sector this has been termed the “Fast Track Procedure” and for data processing purposes it has been identified as the (R) Post Enquiry Re-assessment. It may be necessary to have several Re-assessments, for more details see Annex B and 10.5 below.

10.3 A Consultant Assessment is made on all Candidate Harmonised Standards submitted to the CMC for Formal Vote. This has been termed the (F) Assessment. The assessment is carried out before the draft EN is distribution for voting. A negative Assessment at the pre-Formal Vote stage will therefore delay the start of the Formal Vote until the matter is resolved. This will also result in the stage code being put back to stage 44.

10.4 It should be noted that the responsibility to send a draft European Standard to the CMC for submission to the Formal Vote process is with the TC. The instigation of this process normally starts with the SC or WG who has developed it. However it is to be noted that as mentioned above the first action in the Formal Vote process for Candidate Harmonised Standards is for the CMC to formally send the draft EN to a Consultant, or Consultants, for the pre-Formal Vote Assessment (F).

10.5 For more details of the Consultant assessment process see the CMC document “Guidelines to Consultant Assessment” and the CEN Website CEN BOSS, for details see 23 References.

## **11. Evolution of Candidate to Harmonised**

11.1 A "Candidate" becomes a “Harmonised Standard”, as defined in the New Approach Directive, after the ratified European Standard has been sent to the EC Services for publication in the European Commission Official Journal (EOJ) with reference to a specific New Approach Directive or Directives. Publication of the reference of a European Standard in the ECOJ is confirmation of its status.

11.2 Delays in the publication of the reference to an approved Harmonised Standard in the ECOJ can be caused by difficulties in obtaining the official translations of the titles of ENs in all European Community languages. Therefore the early checking by the TC, SC or WG of the official title in English will greatly assist in its later translation. The checking should be on the clarity of the English and ability to be precisely translated in other languages, see 12 below.

## **12. Presumption of conformity**

12.1 Following the publication of the reference of an EN in the ECOJ, and the publication of the EN as a national standard by at least one CEN Member, a user of such a standard is permitted to claim “presumption of conformity” to designated essential safety requirements for products covered by the EN and by a specified New Approach Directive.

12.2 As part of the procedure for the publication of the reference of an EN the Commission Services make a check on the compliance of the EN with the presentational requirements of the CEN/CENELEC Internal Regulations Part 3- “PNE Guide”. It also checks on the requirements of the related Mandates. This includes the specification of the current official references of the EU Directives and the inclusion of the appropriate Annex Zs. Resolving such matters may cause long delays in the publication of references in the ECOJ.

## **13. Application of multiple EU Directives to a Harmonised Standard**

13.1 The majority of standards in the machinery programme are intended to support with the Machinery Directive 98/37/EC. However some deal with a hazard that is more specifically covered by another EU Directive. Under the Machinery Directive the requirements of the most detailed Directive are to be applied. It is therefore important to recognise the specific requirements of other EU Directives. Compliance with all relevant EU

Directives is a legal requirement within the European Union. Additionally the fixing of the "EC" marking on a product is a claim that "all" relevant EU Directives are complied with.

13.2 Where it is intended by the CEN/TC that developed it, that a draft EN should become a Harmonized Standard under one or more Directives, the specific Directives are to be clearly identified in the Annex Z of the draft EN. This information is recorded by the CMC. This information is used by the CMC to determine which Consultant, or Consultants, should be involved at the earliest possible stage in the development of the standard as well as at the Enquiry and Formal Vote Assessment stages. Additionally it is used to ensure that when the EN is ratified, its title and reference are sent to the Commission for publication in the European Commission Official Journal under the appropriate Directive or Directives, see also 11.2. (DOC. 10) indicates which consultant deals with which TCs involved in the Machinery safety standardization programme.

13.3 To explain the application of multiple EU Directives to machines, take as an example a machine whose general safety requirements are covered by the Machinery Directive. However it includes a pressure vessel and produces an explosive atmosphere, it burns gas and necessitate requirements on electro magnetic emission and immunity, it is also intended for use outdoors and like the majority of machines it uses electricity. Therefore apart from the Machinery Directive 98/37/EC, the following Directives may also apply: Pressure Equipment Directive 97/23/EC, Explosive Atmospheres Directive 94/9/ EC, Gas Appliance Directive 90/396/EEC, Electromagnetic Compatibility Directive 89/336/EEC, Machines for use outdoors COM/98/46 and the Low Voltage Directive 73/23/EEC.

13.4 Given below are guidelines on how to deal with the compliance of the above mentioned Directives in standards in the machinery programme.

#### **14 Explosion hazards under the ATEX and Machinery Directives**

14.1 Explosion hazards are covered by both the Machinery Safety Directive 98/37/EC and the Directive 94/4/EC "Equipment and protective systems intended for use in potentially explosive atmospheres", called the ATEX Directive.

14.2 The essential requirement of Annex 1 clause 1.5.7 of the Machinery Directive directly relates to explosion as a hazard. However Article 1.4 of the Machinery Directive requires that where there is another Directive dealing with a "specific risk" this Directive will take precedence for that particular risk. Thus the technical requirements of the ATEX shall apply to all equipment coming in contact with a potentially explosive atmosphere. Thus the means of complying with the Machinery Directive essential requirement 1.5.7 is to comply with the relevant technical requirements of the ATEX Directive. However special note should be taken of any restrictions in the scope of the "specific risk Directive" i.e. the ATEX Directive, thus if the risk is present but outside the scope of the "specific risk Directive" then the original essential requirement of the Machinery Directive will apply.

14.3 For machines with an explosion hazard, compliance with the Machinery Directive and the ATEX Directive can be achieved by following the principles contained in EN292 "Machinery Safety", EN 1050 "Risk assessment" and EN 1127-1 "Explosion prevention and protection".

14.4 Where a draft C-Type Harmonised Standard covers a machine intended to work within an explosive atmosphere and the standard deals with the explosion hazard for which compliance of the machine with the ATEX Directive is required, this will require that the draft EN contains a specific Annex Z related to ATEX. Where the draft Harmonised Standard also covers the general safety of the machine, the Machinery Directive will also apply and will require a separate Annex Z related to the support of Essential Requirements of the Machinery Directive. This will be recorded by the CMC to ensure the processing of the reference of the ratified EN for publication in the European Commission Official Journal under both the ATEX Directive and the Machinery Directive. The details of an Annex Z in a

Harmonised Standard are given in the CEN Handbook, see paragraph 23 References.

14.5 Draft Harmonised Standards mentioned above are to be assessed by both a Machinery Consultant and by the Explosion (ATEX) Consultant at the earliest possible stage and at least at the pre Formal Vote Assessment stage. See also the separate CMC document "Guidelines on Consultant Assessment", see paragraph 23 References.

14.6 Where a standard deals with an explosion hazard arising from a potentially explosive atmosphere created within a machine and where the machine has its own potential source of ignition, then special attention is required. These standards are the subject of a detailed process given in the CMC letter dated 2000-05-10 referenced CP\_PROJ053.2 "Explosion hazards in machinery" which is addressed to all TC Secretariats in the Machinery Sector.

14.7 A number of standards have been identified as dealing with an explosion hazard from a potentially explosive atmosphere created within a machine. This has been done in co-operation with the ATEX and Machinery Consultants and covers the work of many TCs in the field of Machinery. Some of the standards have been clearly identified as ATEX and some are subject to further consideration by the ATEX Consultant. The identified standards are contained in a list circulated by the CMC, see paragraph 14.6.

14.8 The related TCs have been contacted and provided with a copy of the CMC letter referenced CP\_PROJ053.2, the list of standards dealing with explosion hazards, a Check List of the Essential Safety Requirements of the ATEX Directive and a copy of an Article prepared by Mr. P Makin on Explosion and Explosion Safety Matters which explains the relationship of the Machinery Directive and the ATEX Directive. Further guidelines are under preparation by the ATEX Consultant, requests for copies should be made direct to the ATEX Consultant.

## **15. Electromagnetic Hazards and Electromagnetic Compatibility (EMC) Directive**

15.1 The Electromagnetic Compatibility (EMC) Directive 89/336/EEC relates to the possible interference between electrical equipment. It requires the measurement of electromagnetic radiation and immunity to prevent miss-functioning. The directive is a New Approach Directive but it is not specifically intended to cover safety aspects. Risks due to radiation, which includes electromagnetic radiation, related to health and persons are covered by two essential safety requirements of Annex 1 of the Machinery Directive 98/37/EC. Clause 1.5.10 relates to emission of radiation that is harmful to persons and clause 1.5.11 relates to safe functioning of the machine in the presence of radiation.

15.2 Where a draft Harmonised Standard is intended to deal with the electromagnetic compatibility of a machine or a piece of equipment to comply with the EMC Directive, then this will be identified in an EMC related Annex Z of the draft EN. These drafts are to be assessed by the EMC Consultant at the earliest possible stage and at least at the pre Formal Vote Assessment stage.

15.3 For standards described in 15.2 where other hazards related to the safety of the machine are also identified in the standard, these will require separate Annex Zs for compliance with the essential safety requirements of the Machinery Directive and for compliance with the EMC Directive. These drafts are to be assessed by both a Machinery Consultant and by the EMC Consultant at the earliest possible stage and at least at the pre Formal Vote Assessment stage. .

15.4 Where a standard is intended to deal with the immunity of the machine or equipment from electromagnetic radiation by application of the general requirements of the Machinery Directive (see above) or covers EMC only by reference to EN60204-1 "Safety of machines - Electrical equipment of machines", then this will be evidenced in the Annex Z solely to the Machinery Directive.

## **16 Low Voltage Directive**

16.1 For standards developed under Mandates M/079 (CEN) and M/083 (CENELEC) both CEN and CENELEC are requested to ensure that the Essential Safety Requirements of the Machinery Directive and the requirements of the Low Voltage Directive 73/23/EEC are applied. For standards where both the MD and the LVD apply it is not necessary to introduce reference to the LVD in an Annex Z as the reference of the Standard will only be published in the EC Official Journal under the Machinery Directive.

16.2 For C-type standards for machines where ESR 1.5.1 of the Machinery Directive applies, use should be made of EN 60204-1 "Safety of machines - Electrical equipment of machines". EN 60204-1 was originally issued in 1992 and some ENs have made reference to it. However reference to it is no longer permissible due to its being outdated from July 2000.

16.3 To assist in the use of EN 60204-1:1997 version a "Route-Map" has been produced by CENELEC. Copies of which have been circulated to all CEN/TC Secretariats in the field of Machinery. It should be noted that in every case a simple reference to the requirements of EN60204-1 e.g. "Electrical safety - The requirements of EN60204-1 shall apply", is never sufficient to meet the requirements of clause 1.5.1 of the Machinery Directive. In the covering letter to the "Route Map" dated July 1998 it was strongly recommended that the work of selecting the specific requirements of EN60204-1 is carried out by an electrical engineer who is an expert in the type of machine dealt with by the CEN Working Group.

## **17 Noise Hazards under the Machinery Directive and the draft Directive for machines for outdoor use.**

17.1 Noise is covered by both the Machinery Directive and the forthcoming Directive for machinery used outdoors COM/98/46. The application of this Directive when it eventually comes into force will be towards specific types of machines that are identified in the current draft.

17.2 As a result of the introduction of formal Noise Consultant Assessments into a well advanced programme of machinery safety standards, the relevant drafts and existing ENs which deal with noise need to be clearly identified to assist in the planning of the Noise Consultants Assessment process.

17.3 Guidance on drafting noise clauses of safety Standards is the title of EN1746: 1998 and EN ISO 12001:1996 details rules for the drafting and presentation of a noise test code specifically related to noise emitted by machinery. Further advice on preparing ENs in compliance with the noise requirements of both the Machinery Directive and the draft Directive for machines for outdoor use may be obtained from the Noise Consultant relevant to the Technical Committee.

## **18 Pressure hazards under the Pressure Equipment Directive and Simple Pressure Vessels Directive**

Hazards arising from pressure in a pressure vessel or from a pressure system are covered either under the Pressure Equipment Directive 97/23/EC (PED) or under the Simple Pressure Vessel Directive 87/404/EEC. Careful consideration needs to be made of the scopes of the two directives to decide if one or either directive applies. There exists a number of draft ENs in the Machinery programme that cover machines that include pressure vessels. In such cases the Machinery Directive and the appropriate pressure safety directive applies. The Pressure Equipment Consultant has prepared guidelines for compliance with the PED for the use of CEN/TCs. Further advice on preparing ENs in compliance with the PED may be obtained from the Pressure Equipment Consultant.

## **19 Steps to identify the applicable EU Directives**

19.1 Unless the relevant EU Directives have been identified, it will be far from certain that:  
- the requirements of the most detailed Directive have been conformed with;

- the terms of the EC Mandate have been adhered to by the inclusion in the EN of the appropriate Annex Zs referring to the applicable Directives;
- that the advice and Assessment of the appropriate Consultants will have been provided on the elements of the EN falling under the other Directives.
- or that in appropriate cases the hazard has not been specifically excluded from the scope of the EN.

19.2 The logic steps for TCs, SCs and WGs preparing Harmonised Standards under a mandate within the Machinery Safety programme would be the following:

1. Identify if the subject of the standard is a machine as defined in the Machinery Directive.
2. Identify the hazards relevant to the machine and those to be covered by the standard, see EN 414 and EN1050.
3. Carry out a risk Assessment of the identified hazards and determine those that are significant hazards
4. Identify what Directives are relevant to the hazards, Machinery Directive (MD) Pressure Equipment Directive (PED), EMC, ATEX, LVD etc.
5. Identify which MD Essential Safety Requirements are covered by other Directives.
6. Identify those significant hazards that are associated with other Directives- suggest appropriate Consultant. See also the CMC document "Guidelines for Consultant Assessment of Machinery Safety Standards", details are given in 23 References.

## **20 Identification of Harmonised Standards and associated Directives**

20.1 Candidate Harmonised Standards may be identified by the TC, SC or WG that has developed, or is developing it. The advice of the relevant CEN/CENELEC Consultant may be sought on the selection of Harmonised Standards. It shall then be the responsibility of the originating TC, SC or WG to agree on the related actions to be taken in accordance with the procedures of CEN. This includes the registration of the Directive(s) in the CEN/TC Business Plan for each work item under development.

20.2 The CMC is to be informed if a work item, including all new Work items, is to be a Candidate Harmonised Standard together with the relevant Directives under which its reference is to be listed in the EC Official Journal. This information is to be kept up to date with any changes to this status as decided by the TC, SC or WG.

## **21 EC Marking**

EC Marking is not a subject for inclusion in Harmonised Standards, however it should be noted that the application of EC Marking to a product is a claim that ALL relevant EU Directives are complied with.

## **22. Safeguard Actions against Harmonised Standards**

22.1 Where a EU Member State or the European Commission considers that a Harmonised Standard does not entirely satisfy the essential requirements of a New Approach Directive it may bring a Safeguard Action for consideration by the 98/34/EC Standing Committee under the Safeguard provisions of the relevant New Approach Directive, for example Article 6 of the Machinery Directive. Safeguard actions may also be brought by EU member States against specific products, however these do not have a direct effect on the status of any related Harmonised Standard.

22.2 One of the powers of the 98/34/EC Standing Committee is that it can propose the withdrawal of the reference of European Standards from the Official Journal, thus the ENs would lose the "Presumption of Conformity" status. Before making a decision it is normal practice to seek the opinion of the Standing Committee relevant to the Directive, for example the 98/37/EC Machinery Safety.

22.3 Additional to the formal Safeguard Actions brought by Member States are a number of Appeals brought by Members of CEN against a Formal Vote which are directly associated with a potential Safeguard action should the Ratified EN be sent to the EC for publication in

the Official Journal. Appeals against a Formal Vote may be brought under Part 2, Clause 5 of the CEN/CENELEC Internal Regulations.

22.4 The CMC maintains a list of the current cases of formal and threatened Safeguard actions and related CEN Appeals and the present status of the process to resolve the actions, see 23 References.

22.5 It has been clear from a number of the existing cases that the CEN Member national mirror committees require to have direct liaison with their relevant National Authority who is represented in the 98/37/EC Machinery Directive Standing Committee and vice versa. The establishment of clear nationally supported positions at early stages in the development of Harmonised Standards would greatly assist in reaching common agreements in the shortest time.

22.6 Under the present version of the Machinery Directive Safeguard Actions against an EN can only be formally brought after Ratification of the European Standard. The delay and frustration caused at this late stage is considerable and it is hoped in future, that solutions can be found at the TC, SC or WG level rather than at CEN Member or EU Member State level.

### **23. References**

The documents from which information is taken are:

- European Council Resolution 85/C/136/01 of 7 May 1985 on a new approach to technical harmonization and standards. JO. N° C 136 of 04/06/1985.
- "Development of European Standards in the context of New Approach Directives Mandates (Harmonised Standards)" issued by the CEN Secretary General and dated 1996-06 and issued as document BTN3810.
- "Relation between EN and Essential Requirement(s) of New Approach Directive(s)" issued as part of the CEN System Handbook reference DRAFT/EN/TC dated 1997-03-31.
- "Notes on Harmonised and Supporting Standards" issued as BTS/2 N940 dated 1997-05-20.
- CEN BOSS Website – <http://www.cenorm.be/boss>

Additional documents of the CMC Standardization Consultancy Department

- "Guidelines for the Activities of Consultants-Machinery Safety and Noise" (CONCORD6.DOC).
- "Guidelines on Consultant Assessment of Machinery Safety Standards" (ASSTAGE5.DOC)
- "Safeguard actions and Appeal against ENs and prENs" (SAFAPL2.DOC)
- DSP Work Instructions DSP/008 "Processing of CEN Consultants Work"
- DSP/WKI/002 "Processing of Negative Assessments on Draft Standards before the CEN Formal Vote"
- DSP/WKI/003 "Processing of Negative Assessments on Draft Standards before a VA/ISO Parallel Vote".
- Flow chart Fast Track Procedure in CEN/TCs of Machinery Safety Sector (SMS 06/00).

## ANNEX B

### LIST OF STAGES AND ASSESSMENT CODES

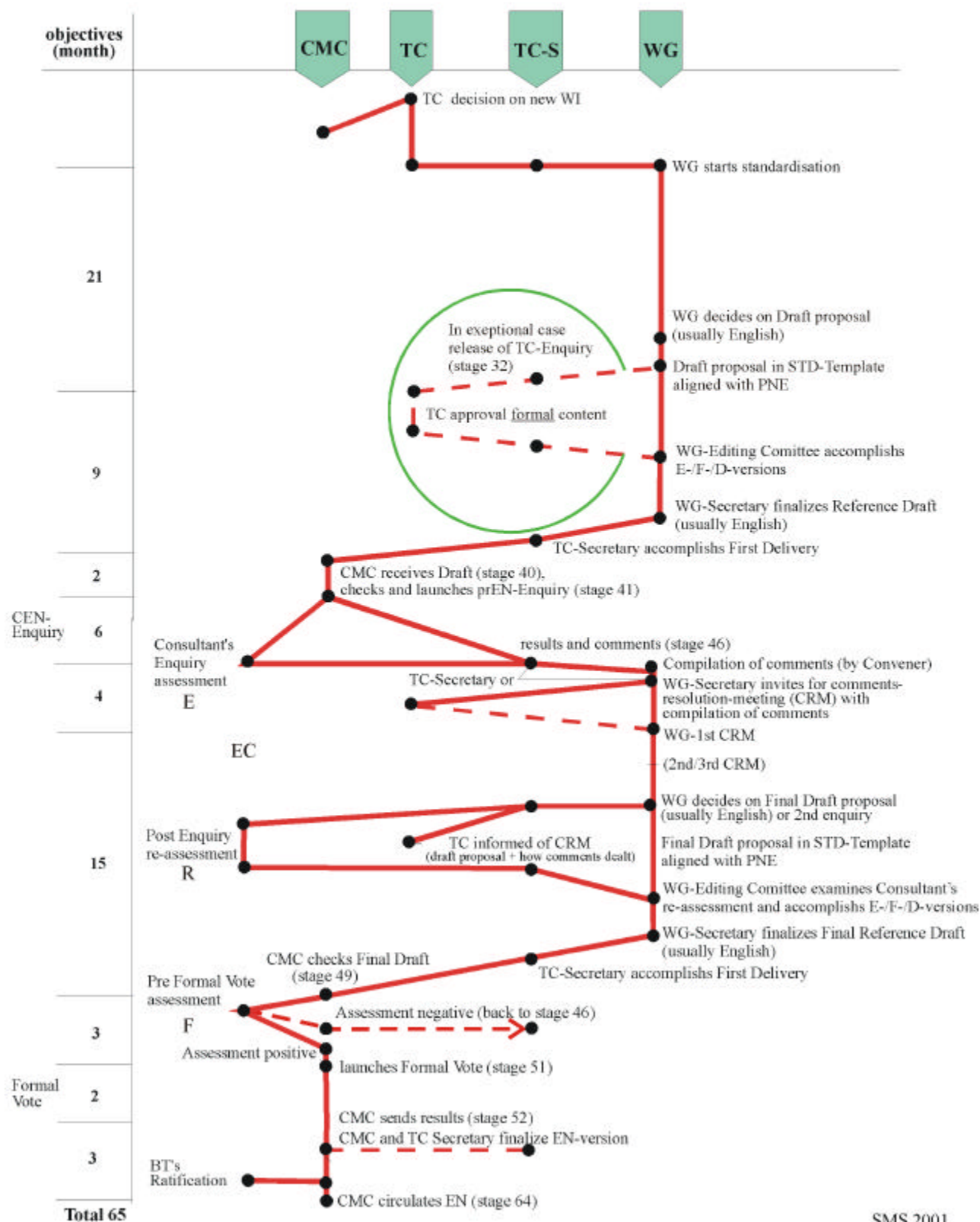
|    | Stage  | CMC Code   | Assessment Result            | CMC internal note                  |
|----|--|------------|------------------------------|------------------------------------|
| 1. | Enquiry Assessment provided within the Enquiry period          | <b>E *</b> | (R)                          |                                    |
| 2  | Enquiry Assessment provided at the Comments resolution meeting | EC         | (R)                          |                                    |
| 3  | No Enquiry Assessment (on the basis of previous work).         | EN         | —                            |                                    |
| 4  | Post Enquiry Re-assessment                                     | <b>R*</b>  | (Y) or (N)                   | (N).                               |
| 5  | Post Enquiry 2nd Re-assessment                                 | R2         | (Y) or (N)                   |                                    |
| 6  | Pre Formal Vote Assessment                                     | <b>F*</b>  | (Y) or (N)                   | (N) see stages of assessment below |
| 7  | Pre Formal Vote 2nd Assessment                                 | F2         | (Y) <sup>2</sup> (NS) or (N) | (N) (NS) see below                 |
| 8  | Second Formal Vote Assessment                                  | FF         | (Y) or (N)                   |                                    |
| 9  | Second Formal Vote 2nd Assessment                              | FF2        | (Y) <sup>2</sup> (NS) or (N) | (N) (NS) see below                 |
|    |  |            |                              |                                    |
|    | Stages of Negative Assessment                                  |            |                              |                                    |
| 10 | Negative Assessment  | F          | (N)                          |                                    |
| 11 | Negative Assessment Technical solution stage                   | F          | (TS)                         |                                    |
| 12 | Negative   | F2         | (NS)                         |                                    |

<sup>1</sup> See also Annex C the flow chart Fast Track Procedure in CEN/TCs of Machinery Safety Sector

<sup>2</sup> Second Assessments are sent to all the Consultants involved on the first Assessment of a standard.

# Procedures in CEN/TCs in Sector Machinery Safety

(in respect of Resolutions BT 72, 76, 77/1994 and new translation procedure 2001)



## ANNEX C FAST TRACK PROCEDURE

### ANNEX D

#### New Approach Directives

Updated 2000-06-30

|     | Directive   | Number of Directive Amendment  | Date of Application  | End of Transition Period   |
|-----|---|--|--|--|
| 1.  | Electrical equipment designed for use within certain voltage limits ("low voltage equipment")   | 73/23/EEC<br>93/68/EEC   | 1997/8/19<br>1995/1/1  | 1997/1/1<br>1997/1/1   |
| 2.  | Simple pressure vessels   | 87/404/EEC<br>90/488/EEC<br>93/68/EEC  | 1990/7/1<br>1991/7/1<br>1995/1/1                             | 1992/7/1<br><br>1997/1/1   |
| 3.  | Safety of toys  | 88/378/EEC<br>93/68/EEC  | 1990/1/1<br>1995/1/1   | 1997/1/1   |
| 4.  | Construction products   | 89/106/EEC<br>93/68/EEC  | 1991/6/27<br>1995/1/1  | 1997/1/1   |
| 5.  | Electromagnetic compatibility   | 89/336/EEC<br>92/31/EEC<br>93/68/EEC   | 1992/1/1<br>1992/10/28<br>1995/1/1                           | 1995/12/31<br><br>1997/1/1   |
| 6.  | Machinery<br>* Note: This directive codifies into one single text the directive 89/392/EEC, as modified by directives 91/368/EEC, 93/44/EEC and 93/68/EEC. The date of application is based on the date of the original directives.   | 98/37/EC *<br>98/79/EC<br>(89/392/EEC<br>91/368/EEC<br>93/44/EEC<br>93/68/EEC) | 1993/1/1<br><br>1993/1/1<br>1993/1/1<br>1995/1/1<br>1995/1/1 | 1994/12/31<br><br>1994/12/31<br>1994/12/31<br>1996/12/31<br>1997/1/1 |
| 7.  | Personal protective equipment   | 89/686/EEC<br>93/68/EEC<br>93/95/EEC<br>96/58/EC                               | 1992/7/1<br>1995/1/1<br>1994/1/29<br>1997/1/1                | 1995/12/31<br>1997/1/1   |
| 8.  | Non-automatic weighing instruments  | 90/384/EEC<br>93/68/EEC  | 1993/1/1<br>1995/1/1   | 2002/7/1<br>1997/1/1   |
| 9.  | Active implantable medical devices  | 90/385/EEC<br>93/42/EEC<br>93/68/EEC   | 1993/1/1<br>1995/1/1<br>1995/1/1                             | 1994/12/31<br>1998/6/14<br>1997/1/1                                  |
| 10. | Appliances burning gaseous fuels ("gas appliances")   | 90/396/EEC<br>93/68/EEC  | 1992/1/1<br>1995/1/1   | 1995/12/31<br>1997/1/1   |
| 11. | Explosives for civil use ("civil explosives")   | 93/15/EEC  | 1995/1/1   | 2002/12/31   |
| 12. | Medical devices   | 93/42/EEC  | 1995/1/1   | 1998/6/14  |
| 13. | Equipment and protective systems intended for use in potentially explosive atmospheres ("potentially explosive atmospheres")  | 94/9/EC  | 1996/3/1   | 2003/6/30  |
| 14. | Recreational craft  | 94/25/EC   | 1996/6/16  | 1998/6/16  |
| 15. | Packaging and packaging waste   | 94/62/EC   | 1996/6/30  | 1997/12/31   |
| 16. | Lifts   | 95/16/EC   | 1997/7/1   | 1999/6/30  |
| 17. | Pressure equipment  | 97/23/EC   | 1999/11/29   | 2002/5/29  |
| 18. | Telecommunications terminal equipment and satellite earth station equipment ("telecommunications terminal equipment")<br>* Note: This directive codifies into one single text the directive 91/263/EEC, as modified by directive 93/68/EEC, and the supplementary directive 93/97/EEC. The date of application is based on the original directives. | 98/13/EC *<br>(91/263/EEC<br>93/68/EEC<br>93/97/EEC)                           | 1992/11/6<br>1992/11/6<br>1995/1/1                           |  |

