



CMC WORK ITEM

PART A: TO BE FILLED IN BY THE APPLICANT

Title Proposed work item (Max 5 keywords)

Effective classification/borderline resolution procedure

CMC-Board History (list of references of all relevant communication to/from CMC-Board concerning this work item)

Letter from A.Perez (Commission/ Member of the Borderline-Classification Group) of April 5, 2011 suggesting a willingness to amend the system used for the resolution of classification and borderline issues.

Applicant

➤ **Applicant member of CMC**

AT BE BG CH CY CZ DE DK EE
 ES FI FR GR HR HU IE IS IT
 LI LT LU LV MT NL NO PL PT
 RO SE SI SK TR UK EC

➤ **Applicant not within CMC-members**

Working Group Name WG:
 Other: Name Organisation:
 Address:

Contact person:
 Telephone No: Fax No:
 E-mail:
 Date: 30 May 2011

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Proposed work item

Given the length of time currently taken to resolve classification and borderline issues, it is proposed to review each stage of the current system to identify areas that could be rationalised, or subjected to greater discipline, in order to streamline the entire process. Any suggestions accepted by the CMC will then need to be negotiated and agreed with the Classification and Borderline Working Group

Rationale for application

The current system is unreasonably lengthy and does not always arrive at agreed positions leaving both Member States and industry uncertain of the correct designation of specific products. This undermines the operation of the single market and confidence in the devices regulatory system.

Arguments pro and against NWI

Supporting information (Working Groups, CAMD, etc.)

Is there a consensus among Member States?

What are the main reasons of lack of consensus?

In favour of the proposal is the widespread belief that the current system is unwieldy, slow and frequently fails to find an acceptable answer to a specific question. Against the proposal are the facts that any revised scheme could only be introduced with the agreement of the Commission and the Classification and Borderline Working Group and that, that group itself, is supposed to be looking at changing its procedures at its September meeting.

Action/Decision proposed by applicant

To review the current system for determining classification and borderline issues and make recommendations to improve it.

Proposal for the lead official:

Steve Owen. UK

Supporting information (Working Groups, CAMD, etc.)

+ History of discussion: provide here the list of hyperlinks to relevant documents (eg. CIRCA)

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PART B: TO BE FILLED IN BY THE CMC-BOARD

<p>Proposed work item</p>	<p>Within scope of CMC? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is Proposal mature for CMC ? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Rationale for application</p>	<p>Description complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Arguments pro and against NWI Supporting information (Working Groups, CAMD, etc.) Is there a consensus among MS? What are the main reasons of lack of consensus?</p>	<p>Description complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Proposal for the lead official</p>	<p>Accepted? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Proposed alternative candidate:</p>
<p>Supporting information (Working Groups, CAMD, etc.) + History: provide here the list of links to relevant documents (eg. CIRCA)</p>	<p>Documentation complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	7 June 2011
CMC meeting agenda item	9a
Transfer to CMC meeting	<input checked="" type="checkbox"/> For consideration <input checked="" type="checkbox"/> For appointment of the lead official <input checked="" type="checkbox"/> For allocation of work <input type="checkbox"/> For decision
Action/Decision proposed	
Acceptance of NWI	
Proposal for the lead official:	
Steve Owen	
Proposal for the allocation of potentially necessary additional preparatory work:	
Small working group CMC and MDEG WG Borderline and classification	
Proposed work planning and timing to output:	
CMC meeting Spring 2012	
Conclusion of the CMC-Board CMC should accept the NWI	
Date:	

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PART D: OUTCOME OF THE CMC MEETING

Agreed next steps (if applicable)

Date:

Voting by the CMC**Voting system**

- simple majority
 qualified majority

Vote taken on proposed decision:

copy in this box the full wording of the proposed decision

Outcome of the voting:

cast votes:
 minimum number of cast votes required: 18
 voting results: YES
 ABSTENTION
 NO
 proposed decision accepted YES
 NO

Action to implement the decision

Date:

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PART E: FOLLOW-UP OF THE CMC DECISION

Status of the action of the implementation
Date: