Format and updating of EUCAST documents

EUCAST SOP 8.0

15 May 2014
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Foreword

The European Committee on Antimicrobial Susceptibility Testing (EUCAST) is organised by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), the European Centre for Disease Prevention and Control (ECDC), and the national antimicrobial breakpoint committees in Europe, currently in France, Norway, Sweden, The Netherlands and The United Kingdom. EUCAST was established by ESCMID in 1997, was restructured in 2001-2002 and has been in operation in its current form since 2002.

The current remit of EUCAST is to harmonise clinical breakpoints for existing drugs in Europe, to determine clinical breakpoints for new drugs, to set epidemiological cut off values, to revise breakpoints as required, to harmonise methodology for antimicrobial susceptibility testing, to develop a website with MIC and zone diameter distributions of antimicrobial agents for a wide range of organisms and to liaise with European governmental agencies and European networks involved with antimicrobial resistance and resistance surveillance.

Information on EUCAST, EUCAST breakpoints and all documents are freely available on the EUCAST website at http://www.EUCAST.org.

Citation of EUCAST documents

The copyright of all documents and data published on the EUCAST website remains with EUCAST. All are freely available for re-use if reference to the EUCAST website is given and documents and data are not resold. Any secondary publication of the data must be referenced with the declaration that "These data have (or this document has) been produced in part under ECDC service contracts and made available at no cost by EUCAST and can be accessed freely on the EUCAST website www.eucast.org. EUCAST recommendations are frequently updated and the latest versions are available at www.eucast.org."

EUCAST documents published on the EUCAST website should be cited in the following way: European Committee on Antimicrobial Susceptibility Testing. Name of document, EUCAST version number, year. Website address.

**Abbreviations**

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<th>Description</th>
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<tr>
<td>EUCAST</td>
<td>European Committee on Antimicrobial Susceptibility Testing</td>
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<td>ESCMID</td>
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# EUCAST SOP 8.0

**Date of issue:** 15 May 2014

## Format and update of EUCAST documents

### 1 Scope

1.1 This SOP describes the format of EUCAST documents and procedures for updating the documents.

### 2 Introduction

2.1 Many EUCAST documents have been produced since the establishment of EUCAST in 1997. The format of the various documents has evolved with experience and this SOP describes the current formats and procedures for update of the documents.

2.2 As the various EUCAST documents have been produced over several years and the frequency of update historically has largely been “as needed”, there is currently inconsistency in format and existing documents will be updated to current formats as they are reviewed.

### 3 EUCAST breakpoint tables for antibacterial agents

3.1 Description

EUCAST breakpoint tables for antibacterial agents include all EUCAST clinical breakpoints and PK/PD breakpoints for antibacterial agents. [http://www.eucast.org/clinical_breakpoints](http://www.eucast.org/clinical_breakpoints)

3.2 Format

The breakpoint tables are presented as Excel spreadsheets with a separate worksheet for each organism group. The Excel worksheets are primarily for screen presentation. A pdf file suitable for printing the complete tables is also available.

Each worksheet includes the full range of antimicrobial agents grouped according to structure, with a final section for miscellaneous agents.

For each agent susceptible and resistant MIC breakpoints are provided in the format $S \leq x$, $R > y \text{ mg/L}$. Also susceptible and resistant zone diameter breakpoints are provided in the format $S \geq x$, $R < y \text{ mm}$.

A column of notes is included with numbered notes for those related to MIC breakpoints and lettered notes for those relating to zone diameters.

Links are included from antimicrobial agent names to rationale documents, from MICs values to MIC distributions and from zone diameter breakpoints to zone diameter distributions.
Additional worksheets are as follows:

Contents: A list of worksheets is provided with links to individual worksheets for individual organism groups and to additional information on some topics.

Notes: Includes explanations of various aspects of the breakpoint tables.

Guidance: Provides guidance on reading EUCAST breakpoint tables.

Changes: Lists changes to the tables since the previous version. Within the tables all changes since the previous version are highlighted in pale yellow.

3.3 **Update frequency**
There is one major update each year in January. Additional updates will only be provided to correct inadvertent errors.

3.4 **Procedure for update**
Multiple issues related to breakpoint tables are dealt with by the EUCAST Steering Committee on an ongoing basis. Changes are incorporated into draft update tables which are released for consultation early in December each year. The revised tables are then released early in January each year.

4 **EUCAST breakpoint tables for antifungal agents**

4.1 **Description**
EUCAST breakpoint tables for antifungal agents include all EUCAST clinical breakpoints and PK/PD breakpoints for antifungal agents.

http://www.eucast.org/clinical_breakpoints

4.2 **Format**
The breakpoint tables are presented as Excel spreadsheets with a separate worksheet for each organism group. The Excel worksheets are primarily for presentation on screen. A pdf file suitable for printing the complete tables is also available.

Each worksheet includes the range of antifungal agents for which breakpoints have been set.

For each agent susceptible and resistant MIC breakpoints are provided in the format $S \leq x$, $R > y$ mg/L.

A column of notes relating to the breakpoints is included.

Links are included from antimicrobial agent names to rationale documents and from MICs values to MIC distributions.

Additional worksheets are as follows:
### Contents
A list of worksheets is provided.

### Notes
Includes explanations of various aspects of the breakpoint tables.

### Changes
Lists changes to the tables since the previous version. Within the tables all changes since the previous version are highlighted in pale yellow.

### 4.3 Update frequency
Major updates are released when there are additional breakpoints or changes to existing breakpoints. Additional updates will only be provided to correct inadvertent errors.

### 4.4 Procedure for update
Issues related to breakpoint tables are dealt with by the EUCAST Subcommittee on Antifungal Susceptibility Testing. Changes are incorporated into draft update tables which are released for consultation early in December each year. The revised tables are then released early in January each year.

### 5 EUCAST rationale documents

#### 5.1 Description
EUCAST rationale documents summarise the information on which the EUCAST clinical breakpoints are based.

#### 5.2 Format
The rationale documents are Microsoft Word documents (released as pdf versions) with the following sections:

- A title page with the agent name, current version number and a list of previous versions with dates of issue.

- A foreword with information about EUCAST and details of how the document should be cited in publications.

- A brief introduction covering the chemical grouping, activity against major antimicrobial groups, any resistance mechanisms, licensed clinical use and dosage and, if the breakpoints are being revised, a statement of why the review was undertaken.

- Standard and maximum dosing schedules.

- MICs distributions and epidemiological cut off values (ECOFFS) for different species.

- Previous breakpoints if there were any.
Pharmacokinetic data.
Pharmacodynamic data.
Monte Carlo simulations and PK/PD breakpoints.
Clinical data, particularly data relating MIC to outcome.
A summary of breakpoints and any qualifying notes or comments.
Any exceptions to the breakpoints noted by National Antimicrobial Susceptibility Testing Committees.

5.3 Update frequency
Rationale documents will be updated whenever there is a change to MIC breakpoints.

5.4 Procedure for update
Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

6 EUCAST technical method documents

6.1 Description
Technical method documents describe practical procedures, such as MIC and disk diffusion methods.

6.2 Format
The technical documents are Microsoft Word documents (released as pdf versions) with the following sections:

A title page with the agent name, current version number and a list of previous versions with dates of issue.

A foreword with information about EUCAST and details of how the document should be cited in publications.

Sections covering a description of the method. The number of sections and their content will depend on the particular method.

6.3 Update frequency
Method documents will be updated whenever there is a change in the method. For the disk diffusion susceptibility testing method, which is subject to continuous development, updates will be restricted to one per year.
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**Format and update of EUCAST documents**

**6.4 Procedure for update**
Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

**7 EUCAST guidance documents**

**7.1 Description**
Guidance documents cover particular areas related to antimicrobial susceptibility testing but not covered in the breakpoint tables.

**7.2 Format**
The guidance documents are Microsoft Word documents (released as pdf versions). The detailed format will depend on the subject but are usually text with illustrations if necessary.

**7.3 Update frequency**
Guidance documents will be updated whenever there are data supporting a change.

**7.4 Procedure for update**
Following discussion in the Steering Committee a revised draft document will be prepared for review by the Steering Committee. If deemed appropriate by the Steering Committee the draft may also be released for wider consultation. When the revised version is agreed by the Steering Committee it will be issued.

**8 EUCAST minutes**

**8.1 Description**
Minutes are routinely produced for EUCAST Steering Committee meetings and General Committee meetings. Minutes may also be produced for subcommittee meetings. Full details of the preparation of EUCAST minutes are given in EUCAST SOP 7.0, Preparation and Handing of EUCAST Minutes.

**9 EUCAST Standard Operating Procedures**

**9.1 Description**
EUCAST SOPs are documents describing agreed EUCAST procedures
covering all aspects of the operation of EUCAST.

9.2 **Format**
The SOPs are Microsoft Word documents (released as pdf versions) with the following sections:

A title page with the SOP name, current version number.

A list of previous versions with dates of issue.

A foreword with information about EUCAST and details of how the document should be cited in publications.

Sections covering the scope of the SOP, an introduction and sections detailing the procedure depending on the particular procedure.

9.3 **Update frequency**
SOPs are reviewed every two years and updated if required.

9.4 **Procedure for update**
Following discussion in the Steering Committee, if revision is considered necessary a revised draft document will be prepared for review by the Steering Committee. When the revised version is agreed by the Steering Committee it will be issued.