



EUCAST

EUROPEAN COMMITTEE
ON ANTIMICROBIAL
SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

EUCAST breakpoints in Europe 2010/11

Istanbul 2010



Gunnar Kahlmeter

Chairman of EUCAST



ESCMID

EUROPEAN SOCIETY
OF CLINICAL MICROBIOLOGY
AND INFECTIOUS DISEASES

Antimicrobial susceptibility testing

- Predict **success** and **failure** in antimicrobial therapy
 - On an individual basis
 - As the basis for empiric therapy
- Provide “**early warning**”
 - for infection control in hospital (and community)
- For **epidemiology**
 - to describe, compare, model, predict etc resistance development and to determine the effect of measures to counteract resistance development

Methods for susceptibility testing

- **Phenotypic test methods**

based on **antimicrobial activity (MIC)** and **breakpoints**

- MIC-determination (broth, agar, Etest, M.I.C.E.), disk diffusion (BSAC, CA-SFM, CLSI, SRGA), automated systems (the viteks, phoenixes, microscans)
- **Predicts susceptibility and resistance**
- **Quantifiable**

- **Genotypic test methods**

based on the detection of a **resistance gene** or its **product**

- mecA, vanA, vanB,PBP2, ... betalactamase detection....
- **Predicts resistance, not sensitivity**
- **Not quantifiable**

- **By deduction** – “expert rules”

- If mecA-positive then report betalactam antibiotics R;
If ESBL-positive, then report betalactam antibiotics R;
If erythromycin-resistant, then report roxithro- and clarithromycin R;
- **Predicts susceptibility and resistance.**
- **Not quantifiable**

Phenotypic susceptibility testing

MIC








From 2007 there is international agreement on an ISO-standard for MIC-determination of non-fastidious organisms in broth.



MIC-value

Breakpoint committees

for determining clinical MIC breakpoints

Committee		Country	Disk test?
BSAC		United Kingdom	Yes
CA-SFM		France	Yes
CLSI		USA	Yes
CRG		The Netherlands	No
DIN		Germany	No
NWGA		Norway	No
SRGA		Sweden	Yes

Breakpoint committees in Europe

- Each of the committees have 10 – 16 members (CM, ID, Pharmacology, and others)
- Expertise in susceptibility testing, resistance mechanisms, pharmacokinetics, pharmacodynamics, laboratory workflow, automative AST.
- EUCAST thrives on the collected expertise of these 60 – 90 members.

Setting breakpoints in Europe

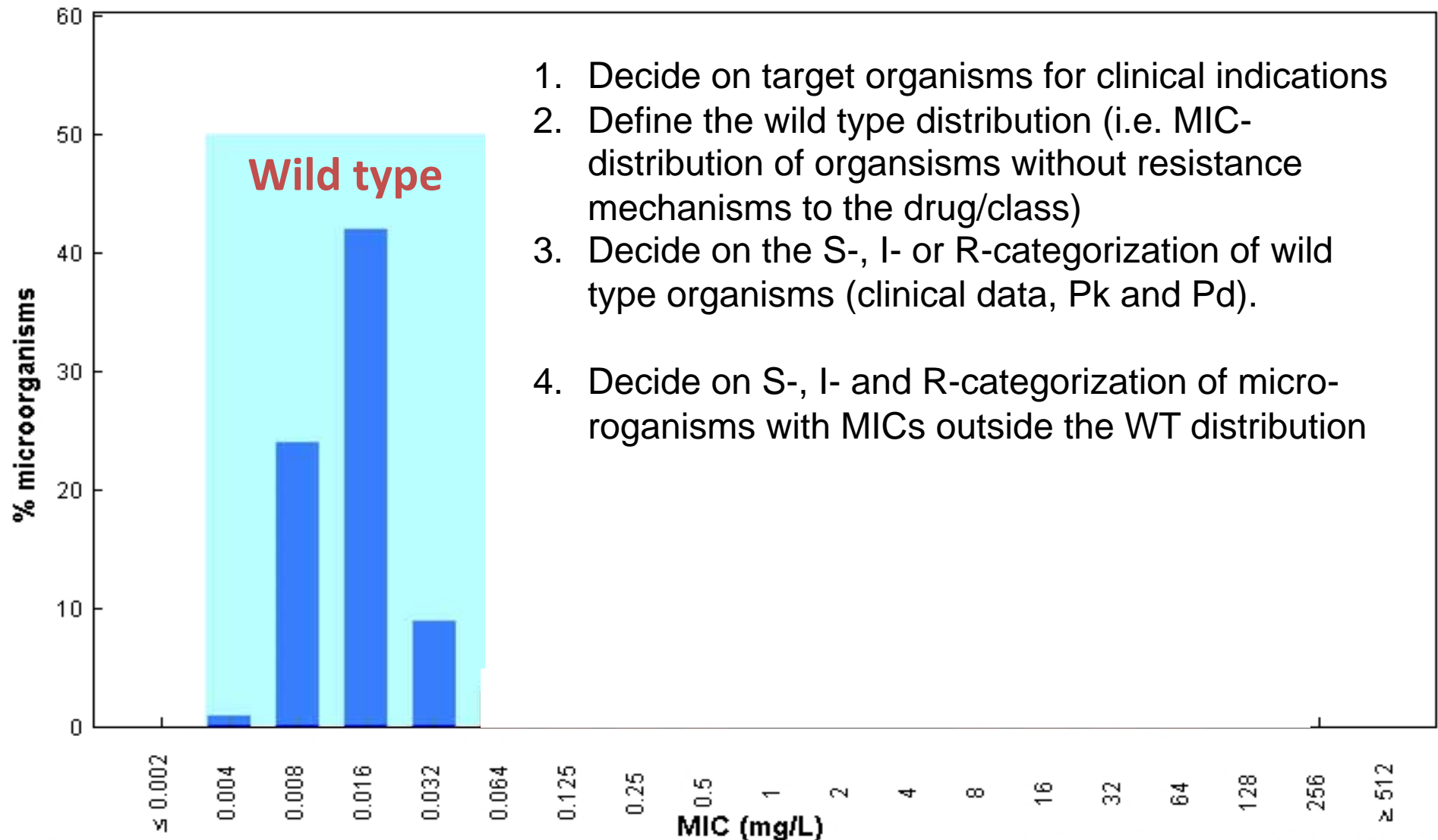
- The pharmaceutical company submits to EMEA a new drug for approval.

Relevant parts of the file are sent to the EUCAST Steering Committee (confidentiality clause)

- **EMEA** approves (or not) target organisms, clinical indications, dosages (min and max), administration forms (oral, iv, infusion etc).
- **EUCAST** decides on breakpoints for organisms approved by EMEA
- An SOP regulates the relationship between EMEA, EUCAST and the Company (www.eucast.org)

Ciprofloxacin / Escherichia coli
EUCAST MIC Distribution - Reference Database

MIC distributions include collated data from multiple sources, geographical areas and time periods and can never be used to infer rates of resistance



1. Decide on target organisms for clinical indications
2. Define the wild type distribution (i.e. MIC-distribution of organisms without resistance mechanisms to the drug/class)
3. Decide on the S-, I- or R-categorization of wild type organisms (clinical data, Pk and Pd).
4. Decide on S-, I- and R-categorization of microorganisms with MICs outside the WT distribution

MIC

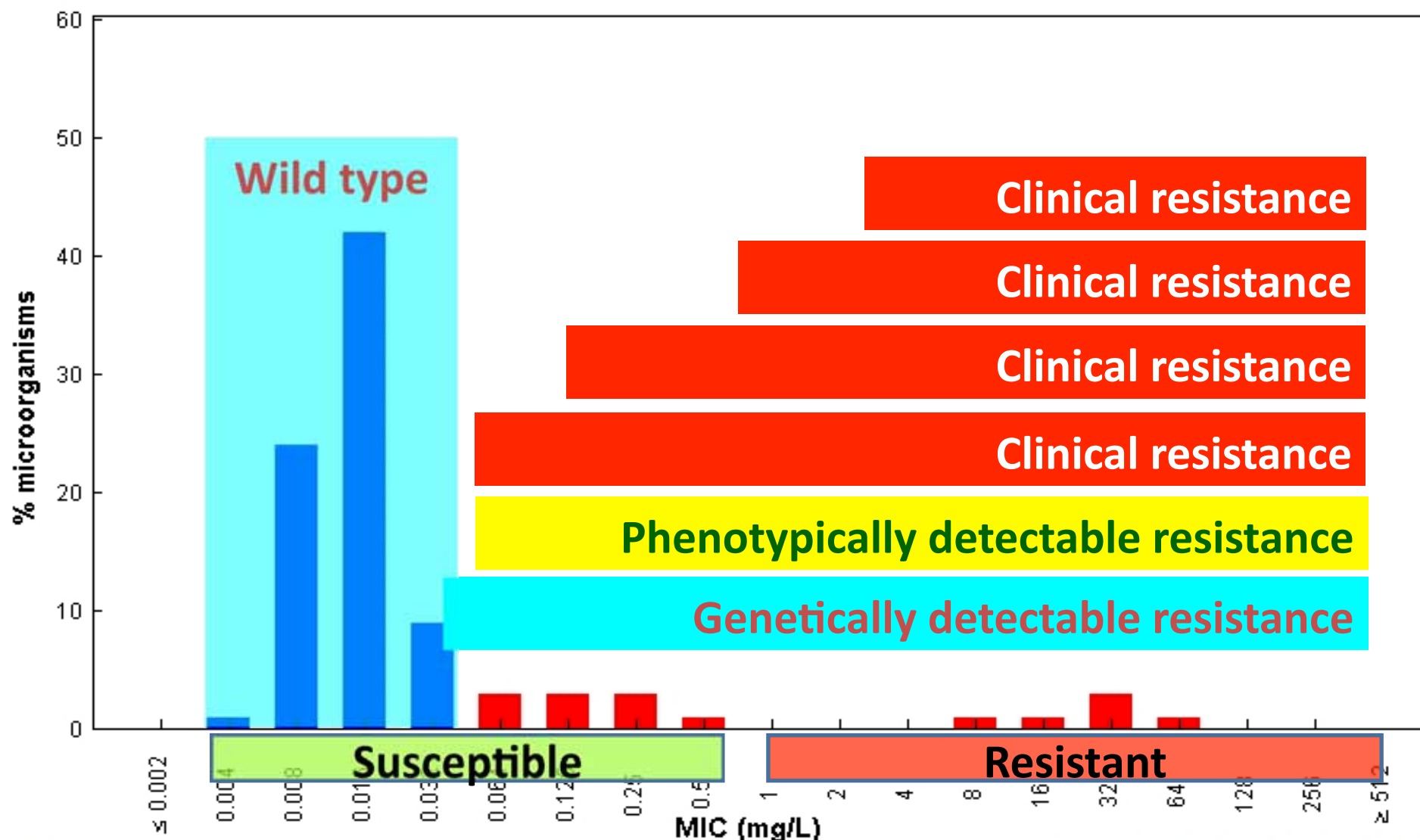
Epidemiological cut-off: WT ≤ 0.032 mg/L

17877 observations (82 data sources)
Clinical breakpoints: S ≤ 0.5 mg/L, R > 1 mg/L

Ciprofloxacin / *Escherichia coli*

EUCAST MIC Distribution - Reference Database

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MIC

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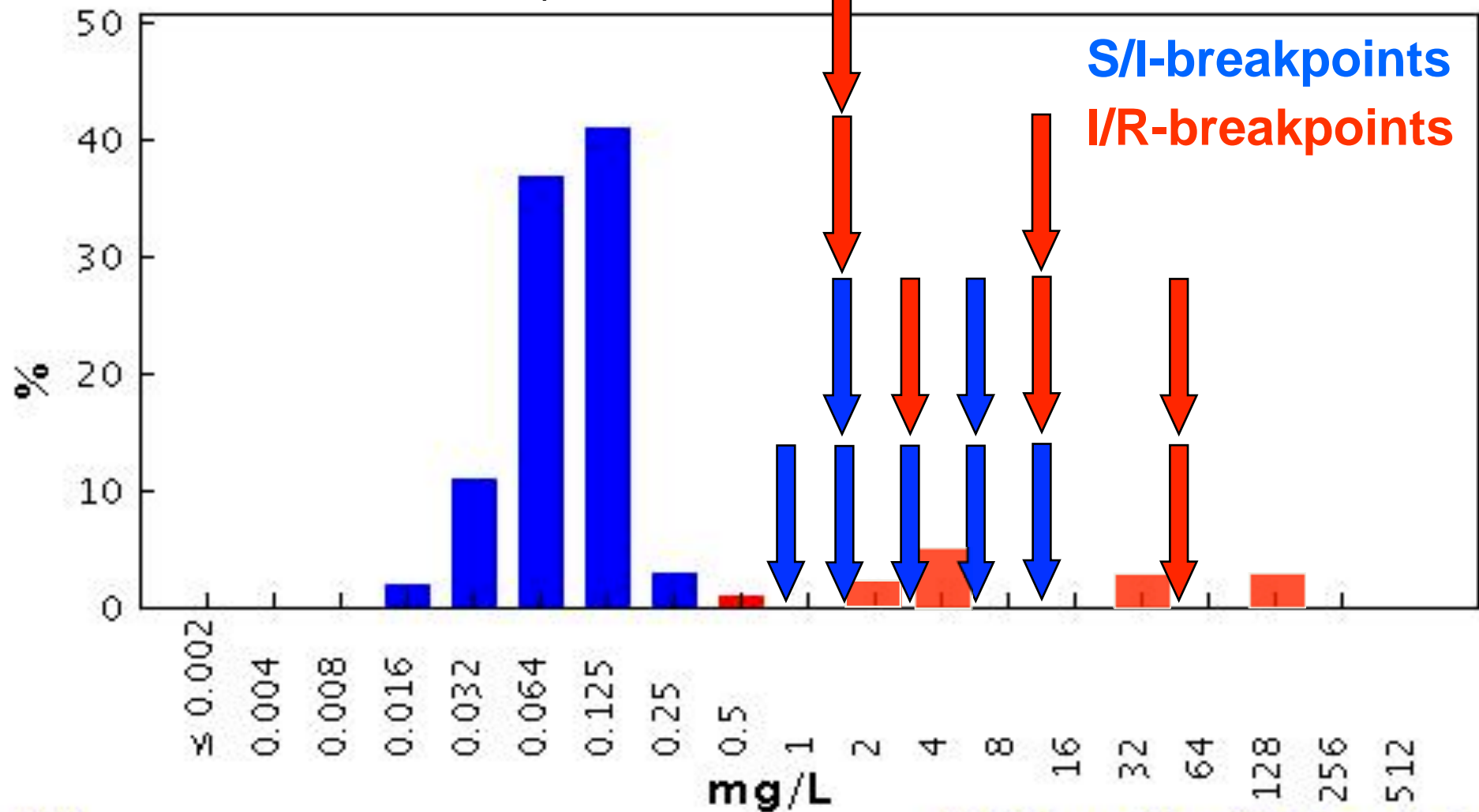
Clinical breakpoints: S ≤ 0.5 mg/L, R > 1 mg/L

Cefotaxime / Escherichia coli

Antimicrobial wild type distributions of microorganisms – reference database

EUCAST

Breakpoints from 7 committees in 2010



MIC

Epidemiological cut-off: WT ≤ 0.25 mg/L

6290 observations (12 data sources)

Clinical breakpoints: S ≤ - mg/L, R > - mg/L



ESCMID

EUROPEAN SOCIETY
OF CLINICAL MICROBIOLOGY
AND INFECTIOUS DISEASES

EUCAST

Formed in 1996

Reorganised in 2001-02



EUCAST

EUROPEAN COMMITTEE
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SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases



ESCMID

EUROPEAN SOCIETY
OF CLINICAL MICROBIOLOGY
AND INFECTIOUS DISEASES

National Breakpoint Committees
D, F, N, NL, S, UK,

EUCAST General Committee
All European Countries + ISC/FESCI

EUCAST Steering Committee
BSAC, CA-SFM, CRG, DIN, NWGA, SRGA
And 2 reps from the General Committee*

Subcommittees

Antifungals
Anaerobes
Expert Rules



ESCMID Expert groups

*Currently: Finland and ISC. Next: Estonia and Austria

EUCAST General committee representatives on EUCAST Steering committee 2002 - 2012

General Committee reps:

- Czech Republic
- Greece
- Russia
- Spain
- Italy
- Poland
- Finland
- ISC
- Estonia
- Austria

National breakpoint committees:

- Germany
- France
- Norway
- Sweden
- The Netherlands
- The UK

Why European breakpoints in Europe?

- based on European standard and maximum dosages
- based on EMEA approved indications and outcome evaluation, Pk/Pd, multiple MIC distributions, and modern principles for determining breakpoints
- accepted by the European regulatory agencies
 - Developed as part of the EMEA regulatory process and the only breakpoints in European SPCs
 - European Centre for Disease Prevention and Control (ECDC) "case definitions" for antimicrobial resistance surveillance
- rationale behind decisions transparent and published (RDs)
- reviewed at intervals: with every new member of class and on the initiative of EMEA, the Company, EUCAST
- driven by the profession and experts on microbiology, infectious diseases, Pk/Pd and susceptibility testing methods
- independent of commercial interests
- in the public domain and free of charge

EUCAST and existing antimicrobials

- Aminoglycosides ✓
- Carbapenems & aztreonam ✓
- Cephalosporins iv ✓
- Cephalosporins oral ✓
- Fluoroquinolones ✓
- Glycopeptides ✓
- Macrolides and lincosamides ✓
- Penicillins ✓
- Tetracyclines ✓
- Miscellaneous antimicrobials ✓
- Antifungal drugs (flu- and voriconazole) ✓

EUCAST

– breakpoint committee for new drugs through EMEA*

- Daptomycin ✓
- Tigecycline ✓
- Doripenem ✓
- Glycopeptides (ongoing)
- Cefalosporin (withdrawn)
- Fluoroquinolone (withdrawn)
- Diaminopyrimidine (withdrawn)
- Extensions of indications (currently none)

*EMEA = European Medicines Agency

Topicals and less commonly used drugs

In progress

1. Mupirocin (Topical)
 2. Polymyxin B (Topical)
 3. Bacitracin (Topical)
 4. Streptomycin (hlr for enterococci)
 5. Neomycin (Topical)
 6. Sulfamethoxazole (UTI)
 7. Cephalothin (expert rules?)
 8. Sulfadiazine
 9. Spiramycin
 10. Nalidixic acid (screening)
 11. Cefoperazone
 12. Pefloxacin
 13. Cefradine
 14. Cefamandole
 15. Sulfisoxazole
 16. Pipemidic acid
 17. Kanamycin
 18. Ceftizoxime
 19. Cefprozil
- + 45 others

Microorganisms to be evaluated for breakpoints

Define relevant drugs, breakpoints, methodology and MIC-distributions

In progress.

- Helicobacter spp ✓
- Campylobacter spp ✓
- Clostridium difficile ✓
- Legionella spp
- Pasteurella multocida
- Listeria monocytogenes
- Burkholderia cepacia
- ...

EUCAST review and revision of clinical breakpoints (legitimate circumstances)

- Altered clinical indications
 - Initially approved limited indications are extended after 2 – 4 years
- New target micro-organisms
 - Acinetobacter for tigecycline ??
- New dosing
 - Dosing strategies (penicillin and pneumococci) allow for different breakpoints
- New resistance mechanisms
 - KPCs and carbapenem breakpoints
- New drug in class
 - Always review existing drugs in class
- New tools for breakpoint determination
 - Simulations, modelling, new animal models, wild type distributions

Recently revised breakpoints

- Glycopeptides (CLSI and EUCAST)
- Cephalosporins (CLSI and EUCAST)
- Carbapenems (CLSI; EUCAST reviewed)
- Colistin v. *Pseudomonas* (EUCAST)

Glycopeptide breakpoints in Staphylococci

EUCAST –breakpoints revised
from $S \leq 4$, $R > 8$ mg/L
to ≤ 2 , $R > 2$ mg/L*

CLSI-breakpoints revised
from ≤ 8 , $R \geq 32$ mg/L
to ≤ 2 , $R \geq 16$ mg/L**

*EUCAST: "impaired response may be seen already at MIC 2 mg/L"

**CLSI: impaired response at 4 and 8 and during prolonged treatment.

EUCAST and CLSI breakpoints 2010 for cephalosporins and Enterobacteriaceae New breakpoints and report as tested

EUCAST 2010	S	R
Cefotaxime	≤ 1	>2
Ceftriaxone	≤ 1	>2
Ceftazidime	≤ 1	>4
Cefepime	≤ 1	>4
Aztreonam	≤ 1	>4

	MICs (Approved in 2005)		
Drug	Susceptible	Intermediate	Resistant
Cefazolin	≤ 1	2	≥ 4
Cefotaxime	≤ 1	2	≥ 4
Ceftizoxime	≤ 1	2	≥ 4
Ceftriaxone	≤ 1	2	≥ 4
Ceftazidime	≤ 4	8	≥ 16
Aztreonam	≤ 4	8	≥ 16
Cefepime	≤ 8	-	≥ 16

*Laboratories are encouraged to continue ESBL testing for epidemiologic or infection control purposes.

Current ESBL detection strategy delays reporting.....

Arguments for a robust "report as tested" breakpoint

- **The current breakpoints require exclusion of an ESBL prior to use – and this may delay and/or confuse reporting.**
- The number of species that will produce an ESBL is increasing.
- The testing needed to exclude an ESBL is increasingly difficult and time consuming
- The definition of "an ESBL" is shaky – new enzymes are regularly described
- The evidence for success in infections with non-ESBL producers with MIC in the high of the susceptible range is weak.
- The evidence for failure with an ESBL-producer with an MIC in the low end of the susceptibility range is lacking.

Carbapenem breakpoints 2009 and 2010

	CLSI 2009		EUCAST 2009		ECOFF \leq^*
	S \leq	R >	S \leq	R >	
Imipenem	4	8	2	8	0.5
Meropenem	4	8	2	8	0.125
Ertapenem	2	4	0.5	1	0.06
Doripenem	ND	ND	1	4	0.125

	CLSI 2010		EUCAST 2010		ECOFF \leq^*
	S \leq	R >	S \leq	R >	
Imipenem	1	2	2	8	0.5
Meropenem	1	2	2	8	0.125
Ertapenem	0.25	0.5	0.5	1	0.06
Doripenem	1	2	1	4	0.125

Report as tested.

EUCAST and CLSI breakpoints are different

	Antibiotics	Identical breakpoints		
	compared	S and R	Only S	Only R
Enterobacteriaceae	33	3	4	3
<i>Pseudomonas</i> spp.	16	1	5	2
<i>Acinetobacter</i> spp.	10	1	4	2
<i>Staphylococcus</i> spp.	27	4	6	2
<i>Enterococcus</i> spp.	6	0	2	3
Strept A, B, C and G	13	2	2	2
<i>S. pneumoniae</i>	24	3	2	5
Other streptococci	9	0	0	2
<i>Haemophilus</i> spp.	25	0	3	0

EUCAST Website

www.eucast.org

free of charge
no login

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[Clinical breakpoints](#)

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The European Committee on Antimicrobial Susceptibility Testing - EUCAST

EUCAST is a standing committee jointly organized by ESCMID, ECDC and European national breakpoint committees. EUCAST deals with breakpoints and technical aspects of phenotypic in vitro antimicrobial susceptibility testing and functions as the breakpoint committee of EMEA and ECDC.

EUCAST does not deal with antibiotic policies, surveillance or containment of resistance or infection control.


The Steering Committee is the decision making body. It is supported by a General Committee with representatives from European countries, FESCI and ISC. The Steering Committee also consults experts within the fields of Infectious Diseases and Microbiology, pharmaceutical companies and susceptibility testing device manufacturers on EUCAST proposals.

EUCAST has subcommittees on antifungal susceptibility testing, expert rules for antimicrobial susceptibility testing, and antimicrobial susceptibility testing of anaerobes.

Most antimicrobial MIC breakpoints in Europe have been harmonised by EUCAST by 2009. Breakpoints for new agents are set as part of the licensing process for new agents through EMEA. EUCAST breakpoints will be available in devices for automated susceptibility testing during 2009 and 2010. A disk diffusion test calibrated to EUCAST MIC breakpoints was launched at the end of 2009.

EUCAST invites anyone with an interest in antimicrobial agents in general and antimicrobial breakpoints in particular to contact EUCAST, ESCMID or one of the National Breakpoint Committees.

[Search](#)



Mupirocin breakpoint consultation - deadline for comments 22 March 2010.

New rationale Documents from EUCAST.

 [metronidazole](#)

EUCAST presentation now available



This presentation gives an overview of EUCAST and its activities.

 [download](#)

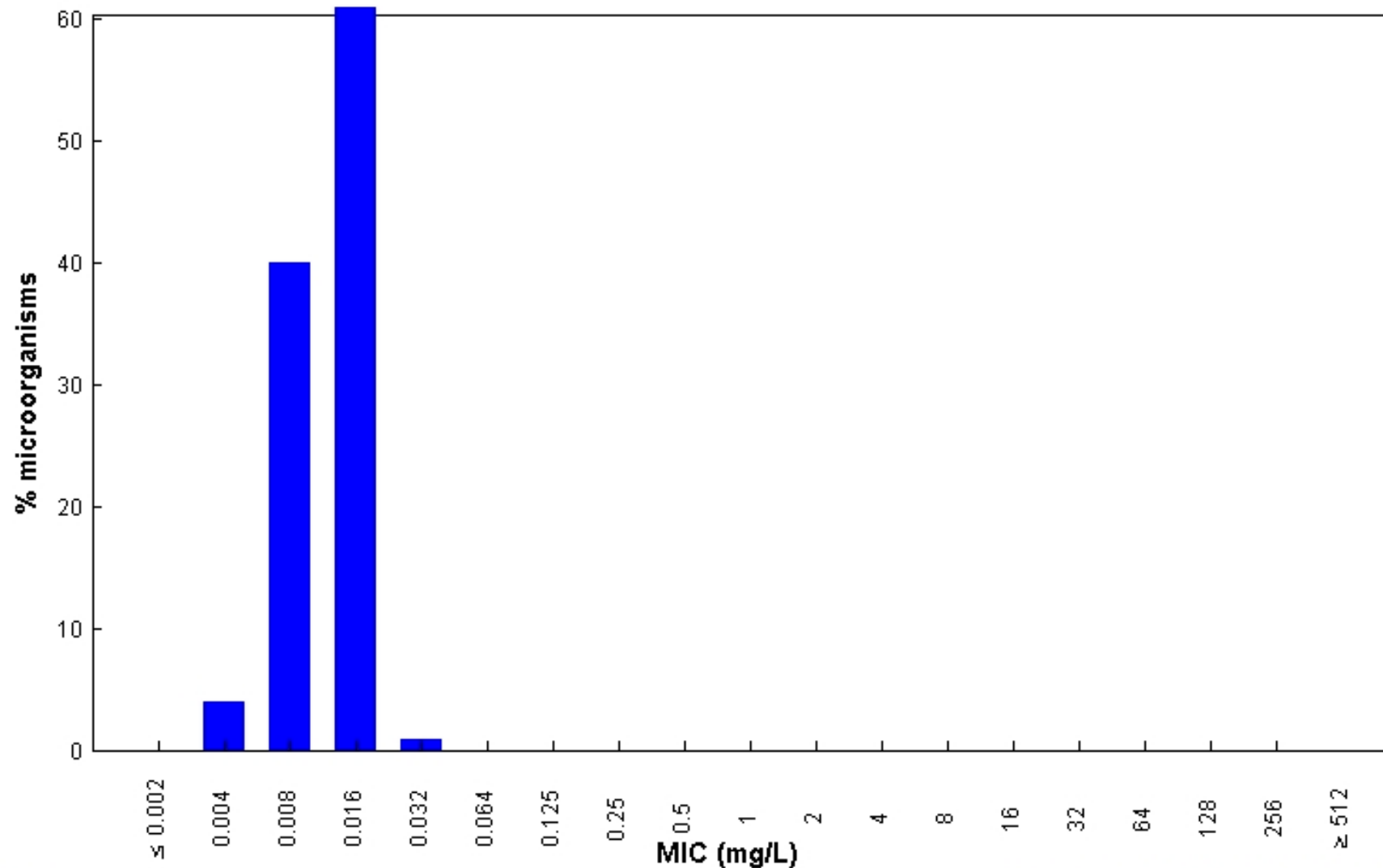
 **ESCMID** EUROPEAN SOCIETY OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES


European Medicines Agency


EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Benzylpenicillin / *Streptococcus pyogenes*
EUCAST MIC Distribution - Reference Database

MIC distributions include collated data from multiple sources, geographical areas and time periods and can never be used to infer rates of resistance



MIC

Epidemiological cut-off: WT ≤ 0.064 mg/L

3615 observations (11 data sources)

Clinical breakpoints: S ≤ 0.25 mg/L, R > 0.25 mg/L

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Rationale Documents from EUCAST

The following Rationale Documents (see General Information on Rationale Documents) are currently available from EUCAST:

 [General Information on Rationale Documents](#)

 [Amikacin](#) v 1.2

 [Ciprofloxacin](#) v 1.9

 [Daptomycin](#) v 1.0

 [Doripenem](#) v 1.0

 [Doxycycline](#) v 1.0

 [Ertapenem](#) v 1.3

 [Fluconazole](#) v 1.0

 [Gentamicin](#) v 1.2

 [Imipenem](#) v 1.3

 [Levofloxacin](#) v 1.5

 [Linezolid](#) v 1.0

 [Meropenem](#) v 1.5

[... Rationale Documents](#)



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The European Committee on Antimicrobial Susceptibility Testing – EUCAST

EUCAST Disk Diffusion Test Methodology

EUCAST has developed a disk diffusion test based on MH-media and calibrated to EUCAST clinical breakpoints. The zone diameter breakpoints are tentative during 2010 and several are in preparation. Regular updates will be published during 2010.

Preparation of media for disk diffusion

 **EUCAST Disk Diffusion manual** (v. 1.0 Dec 18, 2009)

 **EUCAST Disk Diffusion Slide Show** (v. 1.0 Dec 18, 2009)

 **EUCAST Plättchen Diffusionstest - Slide show** (v. 1.0)

 **EUCAST Plättchen Diffusionstest - Manual** (v. 1.0)



 **Recommend page**

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EUCAST disk diffusion test

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Breakpoint tables 

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EUCAST MIC- and Zone diameter breakpoint tables

EUCAST MIC and Zone diameter breakpoint tables (version 1.0 - 2009-12-21*).

 [Tables for printing \(pdf-file\)](#)

 [Tables for screen \(excefile where columns and lines can be hidden by user\)](#)

The zone diameter breakpoints are tentative during 2010. More data correlating MIC to zone diameter will be added and breakpoint correlates refined as needed. We invite you to participate in the validation of the breakpoints!

*clerical errors (a few S \leq erroneously presented as S $<$) will be corrected in a version 1.1 to appear in March 2010.

 [Recommend page](#)

EUCAST breakpoint tables

MIC (mg/L) brpts*	S ≤ 2 R > 2 mg/L
Zone (mm) brpts*	S ≥ 22 R < 22 mm
Insufficient evidence (Literature: "not enough evidence for a breakpoint" or "no indication")	IE Can not be substituted. Can be supplemented with an MIC without interpretation.
Inappropriate drug (Literature: poor drug – don't use!)	— Can be substituted with an automatic "R".
Numbered footnotes	MIC-breakpoints
Lettered footnotes	Zone diameter breakpoints

*when numbers are the same = no intermediate category

EUCAST breakpoints v1.1 [Kompatibilitetsläge] - Microsoft Excel									
A		B	C	D	E	F	G		H
1	Enterobacteriaceae						EUCAST Clinical Breakpoint Table v. 1.1 2010-02-05		
2									
3	Penicillins ¹	MIC breakpoint (mg/L)		Disk content (µg)	Zone diameter breakpoint (mm)		Notes Numbers for comments on MIC breakpoints Letters for comments on disk diffusion		
4		S ≤	R >		S ≥	R <			
5							1. For aminopenicillin breakpoints, the resistant breakpoint of >8 mg/L ensures that all isolates with resistance mechanisms are reported resistant. The wide range of dosages and intravenous versus oral administration significantly affect therapeutic efficacy. The unspecified susceptible breakpoint enables the user to categorize wild type <i>Escherichia coli</i> and <i>Proteus mirabilis</i> as either susceptible or intermediate to the aminopenicillins depending on dosing, route of administration and whether the infection is systemic or affects the urinary tract only.		
6	Benzylpenicillin	-	-		-	-			
7	Ampicillin	Note ¹	8	10	Note ^A	14	A. Clinical MIC breakpoints allow laboratories to decide on the basis of national dosing practices whether Enterobacteriaceae without resistance mechanisms to aminopenicillins should be categorized as S or I. To categorize wild type Enterobacteriaceae as S use disk diffusion breakpoints of 14/14 mm; to categorize as I use 50/14 mm.		
8	Ampicillin-sulbactam ²	Note ¹	8	10-10	IP	IP			
9	Amoxicillin	Note ¹	8	-	Note ^B	Note ^B	B. Susceptibility inferred from ampicillin.		
10	Amoxicillin-clavulanate ³	Note ¹	8	20-10	Note ^A	12			
11	Piperacillin	8	16	30	18	15	3. For susceptibility testing purposes, the concentration of clavulanate is fixed at 2 mg/L.		
12	Piperacillin-tazobactam ⁴	8	16	30-6	18	15			
13	Ticarcillin	8	16	75	23	22			
14	Ticarcillin-clavulanate ⁵	8	16	75-10	23	22			
15									
16	Phenoxymethylpenicillin	-	-		-	-			
17									
18	Oxacillin	-	-		-	-			
19	Cloxacillin	-	-		-	-			
20	Dicloxacillin	-	-		-	-			
21	Flucloxacillin	-	-		-	-			
22									
23	Mecillinam (uncomplicated UTI only) ⁶	8	8	10	15	15	5. Mecillinam (pivmecillinam) breakpoints relate to <i>E. coli</i> , <i>Klebsiella</i> species and <i>Proteus mirabilis</i> only.		
24									
25									
26	Cephalosporins ¹	MIC breakpoint (mg/L)		Disk content (µg)	Zone diameter breakpoint (mm)		Notes Numbers for comments on MIC breakpoints Letters for comments on disk diffusion		
27		S ≤	R >		S ≥	R <			
28							1. The cephalosporin breakpoints for Enterobacteriaceae will detect resistance mediated by most ESBLs and other clinically important beta-lactamases in Enterobacteriaceae. However, some ESBL-producing strains may appear susceptible or intermediate with these breakpoints. For epidemiological or infection control purposes laboratories may want to use a test which specifically screens for the presence of ESBLs.		
29	Cefaclor	-	-		-	-			
30	Cefadroxil (uncomplicated UTI only)	16	16	30	12	12			
31	Cefalexin (uncomplicated UTI only)	16	16	30	IP	IP			
32	Cefazolin	-	-		-	-			

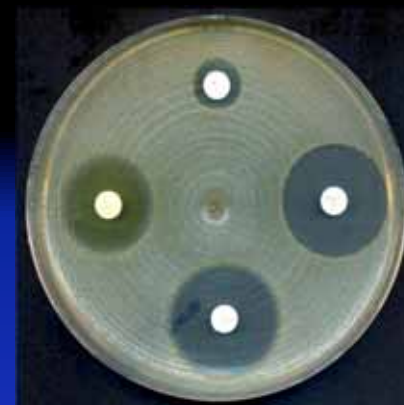
[Web-links to MIC-distributions](#)
[Web-links to Zone diameter distributions](#)
[Web-links to EUCAST Rationale Documents](#)

EUCAST disk diffusion method

Tentative breakpoints December 2009.

Updates April and December 2010.

- Based on
 - MH medium
 - 0.5 MF inoculum
 - 16-20h incubation
 - Most disk contents same as CLSI
 - Most control strains same as CLSI
 - Control ranges same as CLSI (unless different medium or disk)
- Extensive database of MIC v Zone diameters available
- **Significant differences to CLSI**
 - Calibrated to EUCAST MIC breakpoints
 - Some disk contents lower
 - MH-F for fastidious organisms (instead of HTM and Sheep blood)

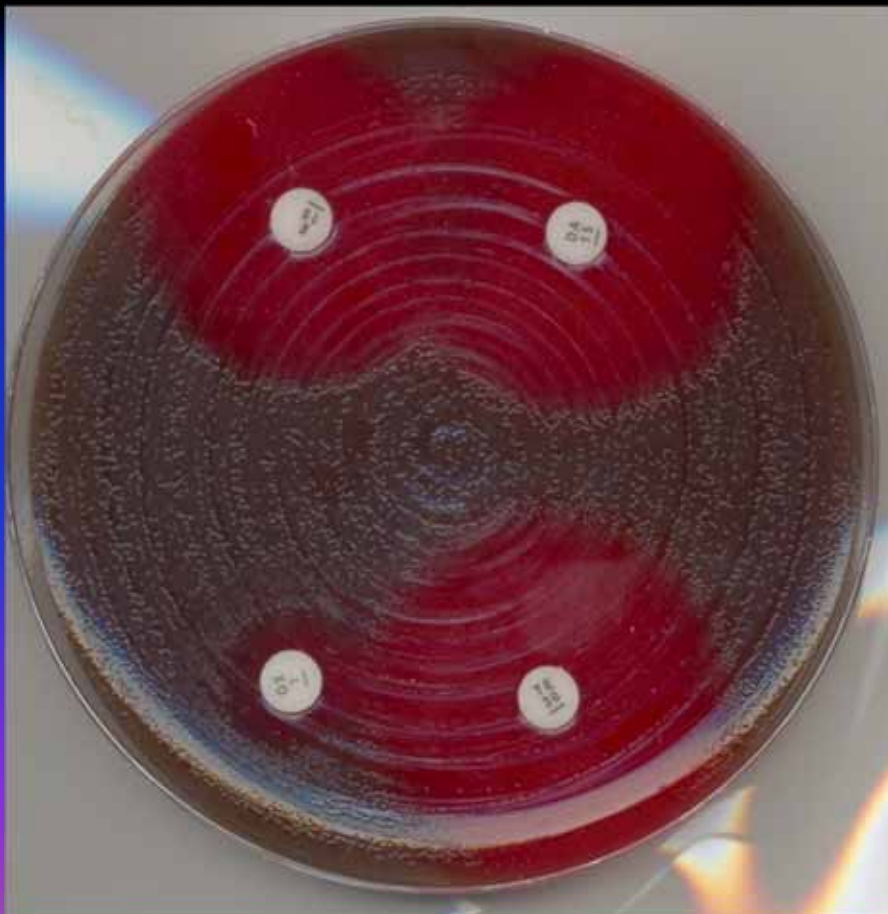


MH-F

Mueller-Hinton agar + 5% defibrinated horse blood and
20 mg/L β -NAD

S. pneumoniae ATCC 49619

H. influenzae NCTC 8468



**National strategies and joint decisions on AST
are needed!**

NAC

National AST Committee

**Chairperson, scientific secretary,
educational officer + representatives of
laboratories, societies, reference
laboratories (5 – 6 reps)**

National Antimicrobial Committees

tasks

- **Subcommittee on Antimicrobial susceptibility testing**
 - Strategy at national level
 - Implementation of breakpoints and methods
 - Education
 - Liaison and consultation with EUCAST
 - Liaison with groups involved in AMR-surveillance (ECDC, EARSS,).
 - QA
- Antimicrobial Policies
- Antimicrobial Resistance Surveillance
- Antimicrobial Consumption and Policies

EUCAST breakpoints and NACs

EUCAST:

France
Germany
Norway
Sweden
The Netherlands
The UK

Decisions for 2010/11:

Denmark
Belgium
Austria
Estonia
Ireland
Finland
Scotland
Wales
Switzerland
Hungary

Discussion:

Spain
Greece
Italy
Turkey
Israel
Poland

Lack of activity: Portugal, Czech republic, Slovakia, Croatia, Slovenia,
Serbia, Rumania, Lithuania, Latvia, Russia.

EUCAST March 2010

- Harmonised breakpoints for all major antibacterial and antifungal drugs.
- Orphan drugs and microorganisms identified and prioritized
- Breakpoints for new drugs as part of the approval process with EMEA (daptomycin, tigecycline, doripenem).
- Epidemiological cut off values determined for all drugs.
- SOPs to describe formal relationship with EMEA.
- EUCAST breakpoints mandatory in European SPCs.
- ISO-standardized MIC-determination.
- Software and database for MIC- and zone distributions.
- Breakpoints implemented in national (F, D, N, NL, S, UK) systems 2007 – 2010.
- EUCAST disk diffusion test launched 2009.
- Breakpoint tables, QC-tables, methodology documents available on website.

EUCAST April 2011

- EUCAST disk diffusion method implemented in 5 - 6 countries
- NACs in 10 – 15 countries.
- National Educational Workshops on European AST in several countries.
- EUCAST breakpoints in all major systems for AST (BSAC, CA-SFM; Commercial systems Phoenix, Vitek2, Microscan, BioMic).
- All Rational Documents available on website.
- SOPs to describe formal relationship with ECDC.
- ECDC decided on European breakpoints as mandatory in surveillance of antimicrobial resistance and HCAI.
- Breakpoints and methods for Campylobacter, Helicobacter, C.difficile, and others.
- Breakpoints and methods several topical antimicrobials and several less commonly used drugs.
- Formal decision on the future relationship between EUCAST, ECDC, EMEA and ESCMID.



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Thank you!