EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

Standard Operating Procedure

EUCAST committees, subcommittees and decision and consultation processes

EUCAST SOP 4.6

26 September 2022

SOP Number (number.version):	4.6
Date of issue:	26 September 2022
Review interval:	2 years
Authorised by:	EUCAST Steering Committee

Document review and amendment history	
Issue date	**Version number**
26 September 2022	**4.6**
21 July 2022	**4.5**
20 July 2020	**4.4**
16 January 2019	**4.3**
28 February 2016	**4.2**
11 July 2013	**4.1**
3 January 2013	**4.0**

Foreword

The European Committee on Antimicrobial Susceptibility Testing (EUCAST) is organised by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) 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 and maintain 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

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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.

This SOP should be cited as: “EUCAST committees and subcommittees. European Committee on Antimicrobial Susceptibility Testing. EUCAST SOP 4.5, 2022. https://www.eucast.org/eucastsops/.”

Abbreviations	
AFST	EUCAST Antifungal Susceptibility Testing Steering Subcommittee
AMST	Antimycobacterial Susceptibility Testing Subcommittee
BSAC	British Society for Antimicrobial Chemotherapy (UK)
CA-SFM	Comité de l´Antibiogramme de la Société Française de Microbiologie (France)
CRG	Commissie Richtlijnen Gevoeligheidsbepalingen (Netherlands)
ECCMID	European Congress of Clinical Microbiology and Infectious Diseases
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
ESCMID	European Society for Clinical Microbiology and Infectious Diseases
EU/EEA	European Union/European Economic Area
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EUCAST SC	European Committee on Antimicrobial Susceptibility Testing Steering Committee
EUCAST GC	EUCAST General Committee
ISAC	International Society of Antimicrobial Chemotherapy
NAC	National Antimicrobial Susceptibility Testing Committee
NWGA	Norwegian Working Group for Antibiotics (Norway)
SOP	Standard Operating Procedure
SRGA	The Swedish Reference Group of Antibiotics (Referensgruppen för antibiotikafrågor)
VetCAST	Veterinary Antimicrobial Susceptibility Testing Subcommittee

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1	Scope
1.1	This SOP describes the structure, appointment process, remit, and transparency declarations of EUCAST committees and subcommittees.

2	Introduction
2.1	The current basic structure of EUCAST committees and subcommittees has been in operation since the restructuring of EUCAST in 2002. The EUCAST committee structure includes a Steering Committee, a General Committee and Subcommittees in specific areas. There is close collaboration with National Breakpoint Committees and NACs, although the setup and operation of these committees is not controlled by EUCAST.

3	Steering Committee
3.1	**Structure** The Steering Committee comprises the following members: **The Chair, Scientific Secretary, Clinical Data Coordinator and Technical Data Coordinator** These positions together form the Executive of the Steering Committee and are responsible for organising the business of the Steering Committee, leading the preparation of proposals and documents, and interactions with other groups. **One representative of each of the National Breakpoint Committees** When the current EUCAST structure was established in 2002 National Breakpoint Committees were defined as national committees that met regularly (at least twice per year) and were actively involved in setting national breakpoints in the respective countries. The number of committees that met this definition was six until 2011 when the German DIN breakpoint committee was closed and in 2013 was replaced by the German NAC. **Two country representatives from the EUCAST General Committee** When the current EUCAST structure was established in 2002 there were two country representatives from the EUCAST General Committee. This was temporarily increased to three representatives in April 2012 until the German Committee was re-established in 2013.
3.2	**Appointment process** In making appointments the requirement to maintain expertise in breakpoint setting, antimicrobial resistance, susceptibility testing, pharmacokinetics and pharmacodynamics are important considerations.

	Chair, Scientific Secretary, Clinical Data Coordinator and Technical Data Coordinator These are appointed by the ESCMID Executive Committee who shall take advice from relevant national and international organisations, committees, and experts, including the EUCAST General Committee and Steering Committee members. The appointment of the Chair is for a period of 2 years, and is renewable up to three times. Appointments for the Scientific Secretary, Clinical Data Coordinator and Technical Data Coordinator are for a period of three years and are renewable up to three times. Under exceptional circumstances, further renewal of these positions may be possible at the discretion of the ESCMID Executive Committee. **National Breakpoint Committee representatives** These are appointed by the respective national breakpoint committees. Each committee can appoint one representative and a deputy, but only one may attend each meeting. The period of appointment is at the discretion of the national breakpoint committee itself. If a National Breakpoint Committee representative is appointed as Chair of the Steering Committee there will not be an additional appointment of a separate national representative for that country. **Country representatives from the EUCAST General Committee** These are appointed by the ESCMID Executive Committee. When there is an upcoming vacancy for General Committee members on the Steering Committee an invitation is sent to General Committee members inviting them to apply for a term of office on the Steering Committee. Terms of office commence after the annual ECCMID meeting. Before the ECCMID meeting the ESCMID Executive will appoint the General Committee representatives, taking into account the past representation on the Steering Committee, to ensure that there is a spread of representation across the EUCAST General Committee membership and expertise in breakpoint setting and antimicrobial susceptibility testing. Priority will also be given to countries that have not been previously represented on the Steering Committee. Appointments are for a period of two years and are generally not renewable unless there are no new applications from the General Committee. **Visiting General Committee members** Any General Committee member may apply to attend any specific Steering Committee meeting. The arrangements for the visiting General Committee members are as follows: • Up to two additional visiting General Committee members may attend each Steering Committee meeting by prior agreement.
	The Steering Committee meeting dates will be on the website at least six months in advance A preliminary agenda for upcoming meetings can on request be obtained from the Scientific Secretary

	• General Committee members must inform the EUCAST Scientific Secretary at any time in advance but no later than two weeks before the meeting of his/her wish to attend the meeting • If more than two General Committee members wish to attend a single meeting the EUCAST Steering Committee Executive will decide who can attend, with the intention of fairly distributing General Committee representation. General Committee members will then be informed whether they can attend and whether part of the agenda is closed to them (confidential data on new agents) • All travel/accommodation and costs will be organised and borne by the visiting General Committee representative although ESCMID members can apply for a "EUCAST Steering Committee observership". • Up to five European and five ESCMID "EUCAST Steering Committee observerships", each with a maximum value of 1000 Euros, are available each year. Application should be made to the EUCAST Chair and the observerships are granted at the discretion of the EUCAST Chair. • Parts of the Steering Committee meeting may be restricted by confidentiality agreements covering the breakpoint setting process for new agents in parallel with the Marketing Authorisation Application submission to EMA. Visiting General Committee representatives will be asked to leave the meeting when confidential data on new agents are discussed if the visiting representative has not signed a confidentiality agreement with the relevant company, **Observers** Observers from ECDC, EMA and national medicines agencies may attend Steering Committee meetings. **Co-opted experts** Experts from outside the committee may be co-opted to participate in discussion of specific topics as agreed by the Steering Committee.
3.3	**Remit** To further the objectives of EUCAST, which are: • To form in EUCAST, under the auspices of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID, a network of established experts in the determination of antimicrobial breakpoints and in antimicrobial susceptibility testing. • To determine, review and revise European clinical breakpoints and epidemiological cut-off values for surveillance of antimicrobial resistance in close collaboration with the European Medicines Agency (EMA) and ECDC. • To promote the development and standardization of in-vitro antimicrobial susceptibility testing methods used in Europe. • To promote quality assurance of *in vitro* antimicrobial susceptibility testing.

	• To promote education and training in antimicrobial susceptibility testing. • To advise ECDC and other European Union health agencies on issues related to antimicrobial susceptibility testing and detection of resistance determinants relevant to public health. • To collaborate with international groups, ECDC and other European Union health agencies involved in antimicrobial susceptibility testing and/or the epidemiology of antimicrobial resistance in human pathogens. • To work towards international consensus and harmonization of clinical breakpoints and antimicrobial susceptibility testing. • The Steering Committee is responsible for the assessment of data, formulation of proposals, consultation with the EUCAST General Committee and other relevant groups. Final decisions are taken by consensus within the Steering Committee. The Steering Committee is also responsible for preparation and maintenance of documents related to breakpoints and antimicrobial susceptibility testing and for development and maintenance of the EUCAST websites.
3.4	**Transparency declarations** Each Steering Committee member will make a declaration of commercial or other interests in activities economically or otherwise related to antimicrobial agents. This could be companies involved in drug development and/or marketing or in the manufacture of susceptibility testing products. The declarations will be submitted at the start of each term of office and renewed annually. Any new interests relating to current discussions must be declared by the individual member. The declarations, which will meet the standards of ESCMID and ECDC, will be held by the Chair and will be presented on request. Steering Committee members will excuse themselves from discussions on issues where a conflict of interest exists, and this will be noted in minutes.
3.5	**Meetings** The Steering Committee meets as frequently as required. Five meetings each year are routinely scheduled for January/February, in conjunction with ECCMID in March/April, July, September and November. Dates and locations are listed on the EUCAST website a year in advance.
3.6	**EUCAST processes for consultation and decisions.** EUCAST was asked by ESCMID and colleagues around Europe to create a European system for breakpoints and susceptibility testing based on harmonising and standardising existing antimicrobial breakpoints. This gained the support by EU, EMA and later ECDC and many colleagues around Europe. The rationale for the procedure was to allow patients and health care staff to freely move around Europe without misunderstandings. EUCAST procedures were developed over time since 2002 but the basic decision process is the same. Changes in decision procedures have been

	minor and only made with the agreement of ALL steering committee members. Below is a description of the decision and consultation process: All major decisions are prepared by the EUCAST Steering Committee (SC) and any of the SC members can ask to have a decision delayed by at least one meeting to allow them to prepare an opinion. For any major decision a round of public consultation (6 – 12 weeks) with the medical community is organised. This includes invitations to the EUCAST General Committee members, ESCMID and ESCMID Study Groups, EMA, ECDC and more. Comments received during consultation are discussed in the SC and any change in the decision is agreed. Comments to EUCAST proposals are made public on the website together with EUCAST responses (https://www.eucast.org/publications_and_documents/consultations/). When a consultation leads to a principle change in a proposed decision, a new consultation is instituted, and this may last for another 6 – 12 weeks. There has been no change to the public consultation process since it was instituted, 46 major consultations ago (2016 – 2022). EUCAST welcomes input in the decision process, including new and alternative ideas and objections. Each steering committee member can use the “veto” since decisions are taken by agreement and not by voting. There is a mechanism in place for national committees to ask for “an exception” (see end of Rationale Documents) but only when related to an individual agent or breakpoint. There is no mechanism for exceptions to the system per se. All countries, irrespective of when they joined EUCAST, are voluntarily part of EUCAST and can decide to relinquish participation and leave at any time.

4	General committee
4.1	**Structure** The General Committee comprises the following members: **The Chair, Scientific Secretary, Clinical Data Co-ordinator, and Technical Data Coordinator** These positions are the same as the Executive of the Steering Committee and provide the link with the Steering Committee. **Representatives of individual countries** One representative of each country from Europe and any country outside Europe interested in being part of the EUCAST process. **Representatives of ISAC**

	One representative of this international group with an interest in antimicrobial chemotherapy. **Observers** General Committee meetings are open and may be attended by any individual as an observer.
4.2	**Appointment process** **Representatives of individual countries** These are appointed by appropriate associations from each country. The nature of the appointing association will depend on national structures and organisations and are most likely to be a NAC or a national society of clinical microbiology and/or infectious diseases and/or medicine. In the absence of any of these appropriate organisations a personal recommendation from a nationally respected professional worker will be accepted. Appointments are not time-limited but representatives are asked every three years to get their nomination reconfirmed.
4.3	**Remit** • To provide a national view to EUCAST on issues relating to breakpoints and antimicrobial susceptibility testing • To inform national groups, laboratories, and individuals of EUCAST proposals and guidelines to laboratories • To respond to consultation documents from the EUCAST Steering Committee
4.4	**Transparency declarations** When responding to formal consultations and on request from the Chair, members must declare any commercial or other interest in activities economically or otherwise related to antimicrobial agents.
4.5	**Meetings** The General Committee meets once each year in conjunction with the annual ECCMID meeting, which is usually held in March to May. Dates and locations are listed on the EUCAST website and members are notified as soon as the programme for ECCMID is released, usually in February.

5	**Standing Subcommittees – general features**
5.1	**Structure** Each Standing Subcommittee will consist of a Steering Subcommittee of (usually) six members and a Full Subcommittee with national representatives from each European country where possible.

	Steering Subcommittee Each Steering Subcommittee is composed of a Chairperson and a Scientific Secretary. Depending on the needs and remit of the subcommittee a Clinical Data Coordinator, two representatives from the full Subcommittee and a representative of the EUCAST Steering Committee may be appointed. The Steering Subcommittee is responsible for organising the activities of the full Subcommittee, leading the preparation of proposals and documents, and interaction with the EUCAST Steering Committee. **Full subcommittee members** Each country represented on the EUCAST General Committee may have one representative on the Full Subcommittee. As expertise in the area of all subcommittees is not similar across antimicrobial agents there may not be representatives from all countries.
5.2	**Appointment process** *Steering Subcommittee* Appointments to the Steering Subcommittee may be from the NAC or, if a NAC has not been formed or lacks the necessary expertise, from a relevant national society. The national representative on the Specialty Subcommittee should be invited to be a member of the NAC. Appointments are not time-limited but representatives are periodically asked for their nomination reconfirmed. The EUCAST Steering Committee appoints the Chairperson and, in consultation with the Chairperson, appoints the Scientific Secretary and the Clinical Data Coordinator of the Specialty Subcommittee. The Steering Subcommittee will provide a direct link between the EUCAST SC and the Full Subcommittee, to advise on procedural matters and to participate actively in the work of the Subcommittee. Appointments to the Steering Subcommittee as Chairperson, Scientific Secretary, Clinical Data Coordinator and EUCAST SC representative are reviewed by the EUCAST SC every three years or on the request of the respective Steering Subcommittee or on the request of three or more members of the subcommittee. The Chairperson can be appointed for up to three terms, but can be extended in exceptional circumstances as the discretion of the Steering Committee. The terms of the other Steering Committee names positions are at the discretions of that Subcommittee. No later than one month prior to the annual ECCMID, the Steering Subcommittee will encourage Full Subcommittee members to apply for one of the two NAC positions on the Steering Subcommittee. On recommendation of the Steering Subcommittee, the NAC members are confirmed by the EUCAST Steering Committee. The NAC positions are for a two-year term such that one of the two representatives is replaced each year. Countries not previously represented on the Steering Subcommittee will have priority and appointments will be renewable only if there are no other applicants. All terms of office commence after the annual EUCAST Standing Subcommittee meeting (held during the ECCMID). At that meeting Full Subcommittee members are informed about the structure of the Steering Subcommittee and about the process for appointing its members.
5.3	**Remit**

	• To set breakpoints for agents relevant to their therapeutic area, using EUCAST processes for breakpoint setting, consultation, and decisions • To develop reference methods for susceptibility testing relevant to their speciality • To promote education and training in susceptibility testing relevant to their speciality.
5.4	**Transparency declarations** Each Steering Subcommittee member will make a declaration of commercial interests in companies involved in marketing of antimicrobial agents and/or development or in the manufacture of susceptibility testing products. The declarations will be made/updated at the start of each term of office and renewed annually. Any new interests relating to current discussions must be declared by the individual member. The declarations, which will meet the standards of ESCMID and ECDC, will be held by the EUCAST Chair and will be presented on request. Steering Subcommittee members will excuse themselves from discussions on issues where a conflict of interest exists, and this will be noted in minutes.
5.5	**Meetings** The Steering Subcommittee meets at least once in conjunction with ECCMID in March/April, and at least once more throughout the year. Minutes of meetings are copied to the EUCAST SC.

6	**Antifungal susceptibility testing subcommittee (AFST)**
6.1	**Subcommittee type** The Antifungal Susceptibility Testing Subcommittee is a Standing Subcommittee of EUCAST.
6.2	**Special features** The following special features apply to the AFST, over and above those listed in Section 5: • None

7	**Antimycobacterial susceptibility testing subcommittee (AMST)**
7.1	**Subcommittee type** The Antimycobacterial Susceptibility Testing Subcommittee is a Standing Subcommittee of EUCAST.
7.2	**Special features**

	The following special features apply to the AMST, over and above those listed in Section 5: • In general, AMST Standing Subcommittee members should be clinical microbiologists, pharmacologists or clinicians who are experts in mycobacterial infections (tuberculosis or infections caused by non-tuberculous mycobacteria). As expertise in these areas is not as wide as for other microbes, there may not be representatives from all countries represented in EUCAST, or there can be more than one from any individual country. • The AMST Steering Subcommittee will consist of a Chairperson, a Scientific Secretary, two representatives from the EUCAST SC, a clinical data coordinator, a clinical pharmacologist and two representatives of supranational reference laboratories in Europe. • The AMST Full Subcommittee will be recruited from the national TB laboratories and networks rather than from the NACs. • AMST will, where relevant to the process and aims, interact with agencies for antimycobacterial susceptibility testing strategies such as WHO, CLSI, the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC).

8	**Veterinary antimicrobial susceptibility testing subcommittee (VetCAST)**
8.1	**Subcommittee type** The Veterinary Antimicrobial Susceptibility Testing Subcommittee is a Standing Subcommittee of EUCAST.
8.2	**Special features** The following special features apply to the VetCAST, over and above those listed in Section 5: • In general, VetCAST members should represent either veterinary microbiology, veterinary pharmacology, or veterinary clinical medicine. As expertise in these is areas is not as wide as for the human side of antibacterial agents, there may not be representatives from all countries represented in EUCAST, or there can be more than one from any individual country. • The VetCAST Steering Subcommittee will consist of a Chairperson, a Scientific Secretary, two Data Coordinators (one for pharmacokinetics/pharmacodynamics and one for in vitro susceptibility test data) and a Veterinary Pharmacologist. • Appointments to the VetCAST Subcommittee may be by applications of individual specialists in veterinary microbiology, veterinary

	pharmacology, or veterinary clinical medicine with expertise in antibacterial susceptibility testing in animals. Appointments are scrutinized by the VetCAST Steering Subcommittee based on a resume and are not time limited.
	• Additional remits:
	  ○ VetCAST will cooperate with relevant agencies for veterinary AST, such as the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Food Safety Authority (EFSA)
	  ○ To harmonize veterinary antimicrobial susceptibility testing in the European Union (EU)
	  ○ To initiate and coordinate EU research aimed at filling the current gaps in veterinary antimicrobial susceptibility testing, e.g.:
	  ▪ Missing or insufficient veterinary specific breakpoints (bacterial species-, animal host- and infection-specific breakpoints)
	  ▪ Optimal methods for antimicrobial susceptibility testing of bacterial pathogens of animal origin and zoonotic bacteria that can affect humans

9	***Ad hoc* Subcommittees**
9.1	**Structure** The EUCAST SC may establish *ad hoc* Subcommittees to work towards achieving specific objectives of EUCAST. Each Subcommittee will comprise a Chairperson and as many members as required to fulfil the remit of the subcommittee.
9.2	**Appointment process** The EUCAST SC will appoint the Chairperson and the members will be appointed by the Chair in collaboration with the EUCAST SC. Appointments will last for the duration of the subcommittee, which will be established for a limited timescale to achieve the objectives of the subcommittee. The subcommittee will be disbanded when the objectives have been achieved or if the EUCAST SC decides that further work is no longer necessary. A disbanded subcommittee may be re-established if the EUCAST SC decides that further work is needed, but not necessarily with all original members.
9.3	**Remit** The remit will be defined by the EUCAST SC in advance of establishment of the subcommittee. Consultations and decisions on subcommittee proposals are made through the EUCAST SC.
9.4	**Transparency declarations**

	The Chair will notify subcommittee members that they must provide written details of any commercial or other conflicting interest in activities economically or otherwise related to the activity of the subcommittee. It is the responsibility of each subcommittee member to excuse themselves from discussions and decisions related to issues where there may be a conflict of interest and to inform the Chair of the subcommittee. A record will be kept by the Chair.
9.5	**Meetings** The number and frequency of meetings must be agreed in advance between the subcommittee Chair and the EUCAST SC Chair.

10	**National Antimicrobial Susceptibility Testing Committees (NACs)**
10.1	EUCAST recommends that all countries set up a NAC (or a committee corresponding to this description). Although EUCAST interacts closely with these committees they are not direct EUCAST committees and their structure, appointment process, remit, transparency declarations and meetings are defined by the national organisations that set up the NAC. See EUCAST SOP 5.1 for details of NACs.

11	**National Breakpoint Committees**
11.1	**Structure** There were originally six National Breakpoint Committees: BSAC (UK), CA-SFM (France), CRG (The Netherlands), DIN (Germany), NWGA (Norway) and SRGA (Sweden). The DIN breakpoint committee has been replaced by the German NAC. Each national breakpoint committee consists of 10-20 experts within the fields of clinical microbiology, infectious diseases and pharmacology. Some have additional experts from other medical specialties, from veterinary medicine and from the pharmaceutical and antimicrobial susceptibility testing industry. The interaction of the EUCAST SC with the National Breakpoint Committees has been central to the harmonisation of European breakpoints for existing agents (see EUCAST SOP 1.x), the setting breakpoints for new agents (see EUCAST SOP 2.x) and the revision of breakpoints (see EUCAST SOP 3.x). These committees fulfil the role of NACs in their respective countries, but they also have an additional role in the setting of breakpoints for new agents, which is a confidential process that includes the active National Breakpoint Committees, but not NACs in other countries.
11.2	**Appointment process**

	As these committees are national committees, the appointment process is within the control of the organisations that set up the committees.
11.3	**Remit** As these committees are national committees, the remit is within the control of the organisation that set up the committee. However, the objectives will in many aspects be similar to those of EUCAST as the National Breakpoint Committees are all part of the EUCAST breakpoint setting process.
11.4	**Transparency declarations** Members will meet the requirements for transparency detailed by the national organisations that appoint them.