



RULES OF PROCEDURE FOR THE HEALTH SECURITY COMMITTEE

The Health Security Committee (hereafter “the HSC”),

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU¹, and in particular Article 4 thereof,

Has adopted the following rules of procedure:

Article 1

Composition of the HSC

The HSC is composed of representatives of the Member States meeting in senior level working group (hereafter “senior level group”) and in technical working groups (hereafter “working groups”).

Article 2

Senior level group and membership therein

1. The senior level group shall engage in regular strategic and political discussions on serious cross-border threats to health and shall adopt:
 - opinions and guidance in accordance with Article 4(3)(d) and Article 21(1)(c) of Regulation (EU) 2022/2371;
 - annual work programme in accordance with Article 4(3)(e) of Regulation (EU) 2022/2371; and
 - communications and recommendations in accordance with Article 13(8) of Regulation (EU) 2022/2371.
2. Each Member State shall designate one representative and not more than two alternates in the senior level group.
3. The notification of the designated representatives, their alternates and any changes thereof shall be made in writing to the Commission, to the attention of the Director for

¹ OJ L 314, 6.12.2022, p. 26–63.

Public health, Cancer and Health Security of the Directorate-General for Health and Food Safety (DG SANTE).

4. Member States shall ensure continuity of representation in the senior level group. In case of absence of a Member State representative or alternate, a Member State can ask to be represented by another Member State in replacement.
5. The senior level group shall be chaired by a representative of the Commission without the right to vote.

Article 3

Working groups

1. The senior level group shall create a general working group to discuss general technical and operational issues linked to serious cross-border threats to health. The terms of reference of the general working group shall be defined by the senior level group.
2. The senior level group may create other permanent or *ad-hoc* working groups to have in depth discussion on specific topics requiring certain expertise, if necessary, on the basis of terms of reference defined by the senior level group.
3. The representatives in senior level group shall designate representatives of the working groups and notify the secretariat of the HSC of the designations.
4. The senior level group supported by the secretariat of the HSC shall control that there is no duplication of work of the working groups.
5. The working groups shall be chaired by a representative of the Commission.
6. The working groups shall report to the senior level group.

Article 4

Liaison officers

1. The Member States shall nominate one or more liaison officers for day-to-day contact with the secretariat of the HSC.
2. The liaison officers shall work in support of the senior level group and working groups and be part of the communication exchanges that include information regarding meetings of senior level group and working groups.
3. The HSC secretariat shall clearly indicate the communications sent only to liaison officers.

Article 5

Observers, experts and third parties

1. Representatives of the European Economic Area countries and of relevant Union agencies and bodies as well as a technical representative of the European Parliament and a representative of the World Health Organisation (WHO) may participate in the plenary meetings of the senior level group as observers.
2. The Chair of the senior level group shall give observer status to candidate countries and to other third countries where it is in the interest of the Union that such country is involved in the works of the HSC, in particular based on an international agreement, an administrative arrangement or EU legislation.
3. The observers in the senior level group shall have no right to vote.
4. The Chair of the senior level group, acting on its own initiative or on a proposal of a member of senior level group, may invite to participate in the meetings of the senior level group or working groups on *ad-hoc* basis experts with a specific competence in a subject on the agenda or representatives of the Commission's Scientific Committees.
5. The Chair of the senior level group, acting on its own initiative or on a proposal of a member of the senior level group, may invite - depending on the sensitivity of the subject - to participate in the meetings of the senior level group public health experts, representatives of international organisations and stakeholders, including healthcare professionals, to ensure regular consultation with those representatives and stakeholders.
6. If a member of the senior level group objects the decision of the Chair taken in accordance with paragraphs 2, 4 or 5, the matter shall be submitted to the senior level group for a vote.
7. The Chair of a working group may decide on the participation of the observers as referred to in paragraphs 1 or 2 in the meetings of the working group. The chair of a working group shall not give an observer status to a representative of a country or an institution, agency or body not having an observer status in the senior level group.

Article 6

Meetings

1. The Chair of the senior level group or of any working group shall convene the meetings of that group, acting on its own initiative or at a request of a Member State.
2. In application of Article 2(5) of Regulation (EU) 2022/2371, joint meetings of the senior level group or working groups may be convened with other committees or groups to discuss issues coming within their respective areas of responsibility.
3. The senior level group holds at least three plenary meetings a year. The senior level group shall agree on the dates for regular plenary meetings for a period of twelve months ahead.
4. The Chair shall convene a meeting of the general working group once a month. If there is an outbreak of a serious cross-border threat to health, the general working group shall meet as often as required.

5. The meetings of other working groups are convened by the Chair of the respective working group based on their respective terms of reference and taking into account the time needed by Member States for preparation.
6. The HSC shall meet either in physical meetings or for audio or video conferences.
7. The members of the senior level group or of any working group may be accompanied by national experts. Within a reasonable period of time before the date of a meeting, the names and functions of the experts shall be communicated to the Chair of the senior level group or any working group. In case of physical meetings, the reimbursement of travel expenses by the Commission is limited in principle to one person per Member State, in accordance with the provisions in force within the Commission.
8. In the event of a serious cross-border threat to health, the Chair of the relevant group shall convene a meeting of the senior level group or the general working group without delay for the Member States to consult each other, and in liaison with the Commission with a view to *inter alia* coordinating national responses, risk and crisis communication or to adopt the opinions or guidance, including on specific response measures, in accordance with Article 21(1) of Regulation (EU) 2022/2371.

Article 7

Agenda

1. The agenda shall provide information about agenda points and indicate which agenda points are for information, discussion and/or adoption. Moreover, the agenda will indicate the list of documents, if available, for respective agenda points and for which items thereof security clearance and at which level shall be required, will be made available. Any member of the senior level group or of a working group may propose a new item on the agenda for the corresponding meeting.
2. The agenda shall be adopted by the senior level group or the relevant working group at the start of the meeting.

Article 8

Documentation

1. The Chair of the senior level group shall send the invitation to the meeting, the agenda and working papers to the members of the senior level group and the liaison officers no later than fourteen calendar days before the date of the meeting. If there are changes in the agenda, the chair shall send the updated version of the agenda to the members of the senior level group and the liaison officers.
2. The Chair of a working group shall send the invitation to the meeting, the agenda providing clear information about agenda points and the relevant working papers to the members of a working group no later than seven calendar days before the date of the meeting.

3. In cases of extreme urgency, the Chair of a relevant group may depart from the time limits laid down in paragraphs 1 and 2 of this Article.

Article 9

Deliberations of the HSC

1. As far as possible, the senior level group shall adopt its opinions, guidance, recommendations, annual work programmes and communications referred to in Article 2(1) by consensus.
2. If one or more representatives do not agree with the adoption according to paragraph 1, the consensus cannot be reached and the senior level group shall proceed to a vote. The outcome of the vote shall be decided by two-thirds majority of the members of the senior level group.
3. The members that have voted against or abstained may request a document summarising the reasons for their position annexed to the deliberation subject to vote.
4. If a working group cannot reach consensus on a matter, it will submit the matter to the senior level group for a vote.

Article 10

Annual work programme of the HSC

1. The annual work programme of the HSC shall outline the priorities and objectives of the HSC for that year.
2. The annual work programme shall be developed by the secretariat of the HSC with assistance of the general working group and submitted to the senior level group for its review and approval before the end of the preceding year.
3. By derogation from paragraph 2, the work programme for the year 2023 shall be adopted in the second quarter of 2023.

Article 11

Referral of a matter

1. In exceptional emergency situations, if a Member State or the Commission considers that public health measures taken previously to combat a serious cross-border threat to health other than those covered by Article 2(1) of Regulation (EU) 2022/2371 have proven insufficient to ensure a high level of protection of human health, it may request response coordination within the senior level group. In such cases, the Chair of the senior level group shall ensure coordination and information exchange with the mechanisms and structures relevant to the situation. After that consultation, the Chair

of the senior level group shall convene without delay a meeting of the senior level group to consider these issues.

2. If a member of the senior level group considers that a matter submitted to the senior level group is not within its mandate, the Chair of the senior level group shall organise consultations within the senior level group to examine the matter. If a two-thirds majority of the senior level group members represented at the meeting agrees that the matter submitted to the senior level group is not within its mandate it may recommend referral of this matter to the body competent under a provision of another act of the Union or under the Euratom Treaty. The Chair of the senior level group shall examine the recommendation. If the Chair of the senior level group considers the request substantiated, the secretariat shall submit it to the relevant body.

Article 12

Written procedure

1. If necessary and in agreement with the simple majority of all members of senior level group or a working group, the relevant group may be consulted via a written procedure. To this end, the secretariat sends to the members of the relevant group the document(s) on which the group is being consulted and, where appropriate, sets a time limit for observations.
2. The secretariat shall inform the relevant group and the liaison officers of the outcomes of the written procedure within five working days.
3. However, if a simple majority of all members of the relevant group requests that the text be examined at a meeting of the group, the written procedure shall be terminated without result and the Chair of the relevant group shall convene a meeting of the group as soon as possible or place the point on the agenda of the next meeting of the group.

Article 13

Secretariat of the HSC

The Commission shall provide the secretariat of the senior level group and of the working groups.

Article 14

Minutes of the meetings

1. Minutes of the meetings of the senior level group shall be drawn up by the secretariat under the responsibility of the Chair. The Chair of the senior level group shall send the minutes of the plenary meetings to the members of the senior level group, to their

alternates, and to the liaison officers no later than one month after the meeting for their comments.

2. Minutes of the audio or video conferences or the *ad-hoc* meetings of the senior level group or of the general working group convened according to Article 6 shall be drawn up by the secretariat under the responsibility of the Chair of the relevant group and shall be sent out to the members of the relevant group, to their alternates, and to the liaison officers in due course and no later than ten working days after the meeting for their comments.
3. The members of the relevant group shall send the comments referred to in paragraphs 1 or 2 to the secretariat of the HSC in writing. The relevant group shall be informed of those comments. If there is any disagreement, the proposed amendment shall be discussed by the relevant group. If the disagreement persists, that amendment shall be annexed to the minutes.
4. Minutes of the meetings of working groups shall be drawn up by the secretariat under the responsibility of the Chair of the relevant group and shall contain, in particular, the views expressed. The Chair shall send the minutes of the meeting to the members of the relevant working group no later than five working days before the next meeting of the working group.

Article 15

Attendance list

At each meeting of the senior level group or a working group, the secretariat shall draw up, under the responsibility of the Chair of the relevant group, an attendance list specifying the authorities, organisations or bodies to which the participants belong.

Article 16

Professional secrecy and security

1. Members of the senior level group and their alternates, invited experts, members of the working groups as well as observers, and liaison officers shall comply with the obligations of professional secrecy laid down by the Treaties and their implementing rules, even after their duties have ceased.
2. The Chair of the senior level group or of a working group, in view of the sensitivity of a specific subject or at the request of a member of the senior level group or a working group, can determine that for specific points on the agenda or for an entire meeting only members of the senior level group or their alternates, or of a working group can participate in the discussion.
3. If a member of the senior level group objects the decision of the Chair taken in accordance with paragraph 2, the matter shall be submitted to the senior level group for a vote.

Article 17

Conflict of interest

1. In accordance with Article 26(3) of the Regulation (EU) 2022/2371, the representatives appointed to the senior level group or a working group, their alternates, liaison officers, and, where relevant, observers shall make declarations of their financial interests and update them annually and whenever necessary.
2. At the beginning of each meeting, the members of the senior level group, invited experts, representatives in the working groups, as well as representatives of third parties who have been invited to attend the meeting, shall inform the Chair of any interests which could be considered to be prejudicial to their independence or impartiality with regard to a particular item on the agenda.
3. In the event of such a conflict of interest, the person concerned shall, at the request of the Chair, withdraw from the meeting whilst the relevant items of the agenda are being dealt with.
4. Such conflicts of interest shall be reported in writing, e.g. in the minutes of the meeting of the senior level group or a working group.
5. Paragraphs 1 to 3 of this Article shall also apply to opinions formulated and other documents drawn up by the HSC in a written procedure.

Article 18

Transparency

1. The list setting out the authorities, organisations or bodies to which the senior level group participants belong shall be published on the Commission's Public Health website.
2. The rules of procedure, guidance, agendas and minutes of the meetings of the senior level group shall be published on the Commission's Public Health website unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001.

Article 19

Access to documents and confidentiality

1. Request for access to the HSC's documents shall be handled in accordance with Regulation (EC) No 1049/2001². It is for the Commission to take a decision on a request for access to those documents pursuant to its Rules of Procedure as last amended by

² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43–48).

Decision (EU, Euratom) 2020/555³. If the request is addressed to a Member State, that Member State shall apply Article 5 of Regulation (EC) No 1049/2001.

2. The HSC's deliberations shall be confidential⁴.
3. The HSC may, by unanimity, decide to open its deliberations to the public.
4. Documents submitted to members of the senior level group or a working group, experts and representatives of third parties shall be confidential⁵, unless access is granted to those documents pursuant to paragraph 1 or they are otherwise made public by the HSC.
5. The members of the HSC, as well as experts and representatives of third parties, shall be required to respect the confidentiality obligations set out in this Article. The Chair of the senior level group or of any working group shall ensure that experts and representatives of third parties are made aware of the confidentiality requirements imposed upon them.

Article 20

Protection of personal data

Personal data shall be collected, processed and published (if applicable) in accordance with Regulation (EU) 2018/1725⁶.

³ Commission Decision (EU, Euratom) 2020/555 of 22 April 2020 amending its Rules of Procedure (OJ L 127I, 22.4.2020, p. 1–2).

⁴ This means that the information shall not be disclosed to the public. However, such information can be shared with relevant experts from state authorities involved in the policy making at national level. It does not entail the EU classification of information in accordance with Council Decision 2013/488/EU on the security rules for protecting the classified information.

⁵ In accordance with Article 339 TFEU, "[t]he members of the institutions of the Union, the members of HSCs, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components".

⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).