

ECDC methodologies for rapid scientific advice in the case of outbreaks and for public health guidance

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14-15 May 2025

Scope of ECDC activities in SoHO

Prevention of communicable disease transmission through application of SoHO to protect donors, recipients and offspring.

Main focus on countries in the EU/EEA

Framework for ECDC action on microbial safety of SoHO

Prevention of communicable disease transmission through application of substances of human origin

Coordinate SoHO network	Provide guidance on microbial safety	Threat detection, assessment, and response

https://www.ecdc.europa.eu/en/publications-data/ecdc-framework-relating-substances-human-origin-soho

EU regulations relevant for SoHO at ECDC

Regulation (EU) 2022/2370 of the European Parliament and the Council of 23 November 2022 amending Regulation (EC) No 851/2004 **establishing a European Centre for Disease Prevention and Control**

Article 3

(c) provide analyses, scientific and technical advice, opinions, guidelines, science-based recommendations and support for actions by the Union and Member States, to prevent and control communicable diseases and related special health issues, including risk assessments, analysis of epidemiological information, prevention, preparedness and response planning and epidemiological modelling, anticipation and forecasting;

Article 5

9. The Centre shall ensure the operation and coordination of the network of Member State services supporting the use of substances of human origin, in order to help to ensure that such substances are microbiologically safe, by monitoring, assessing and helping to address relevant disease outbreaks that have the potential to pose serious cross-border threats to health, and to safeguard patients in need of such substances.'

Article 8a

1. The Centre shall provide risk assessments, in accordance with Article 20 of Regulation (EU) 2022/2371, in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), of that Regulation, including where it relates to substances of human origin that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of that Regulation. Such risk assessments shall be provided in a timely manner.

EU regulations relevant for SoHO at ECDC

Regulation (EU) 2022/2371 of the European Parliament and the Council of 23 November 2022 amending Regulation (EC) of 23 November 2022 **on serious cross-border threats to health** and repealing Decision No 1082/2013/EU

Article 16

Network for substances of human origin

1. A network of Member States' services supporting the use of substances of human origin, including transfusion and transplantation, ('the network for substances of human origin') is hereby established to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. The network for substances of human origin shall also ensure that any medically assisted reproduction issues in relation to disease outbreaks, if relevant, are addressed.

2. The network for substances of human origin shall be operated and coordinated by the ECDC.

3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting the use of substances of human origin, including transfusion and transplantation, referred to in paragraph 1.

EU regulations relevant for SoHO at ECDC

Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of **quality and safety for substances of human origin** intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

Article 34

3. The ECDC, with the support of its SoHO expert network, may also launch a SoHO rapid alert on the EU SoHO Platform when surveillance of communicable diseases indicates a new risk to the safety of SoHO. The ECDC may indicate in such a SoHO rapid alert that it has provided guidelines on the mitigation of risks associated with communicable disease outbreaks, in particular concerning the eligibility and testing of SoHO donors.

Article 59

4. For those standards, or elements thereof, concerning protection of SoHO recipients and offspring from medically assisted reproduction for which no implementing act has been adopted, SoHO entities shall take into account:

(a) the most recent technical guidelines, as indicated on the EU SoHO Platform, as follows:

  (i) published by the ECDC concerning the prevention of communicable disease transmission;

  (ii) published by the EDQM concerning protection of SoHO recipients and offspring from medically assisted reproduction other than from transmission of communicable disease;

(b) other guidelines, adopted by Member States, as referred to in Article 27(6), point (b);

(c) other guidelines or technical methods, applied in specific circumstances, as referred to in Article 27(6), point (c).

EU regulations relevant for SoHO at ECDC

Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

SoHO network
Overview

- Network of Member State services supporting the use of substances of human origin (SoHO-Net)
- Four sub-networks with National Focal Points and observers:
  - Blood
  - Tissues and cells
  - Medically assisted reproduction
  - Organs
- SoHO Network Coordination Committee with elected members from the network
- Regular meetings of the SoHO Network Coordination Committee and of the four SoHO sub-networks
- Collaborations with other ECDC networks (e.g., EVD-Net) on relevant topics

SoHO network
Main objectives of the network

- Encourage cooperation between Member States
- Collaborate with ECDC on monitoring and assessing cross-border threats to health relevant to SoHO and providing timely recommendations
- Contribute to the development of guidelines on microbial safety of SoHO
- Collaborate with other ECDC networks as needed to achieve objectives (e.g., EVD-Net)
- Contribute to preparedness and response planning activities in the Union

Scope of ECDC activities in SoHO

Prevention of communicable disease transmission through application of SoHO to protect donors, recipients and offspring.

1. **Provide guidance on microbial safety**
2. Threat detection and rapid risk assessments

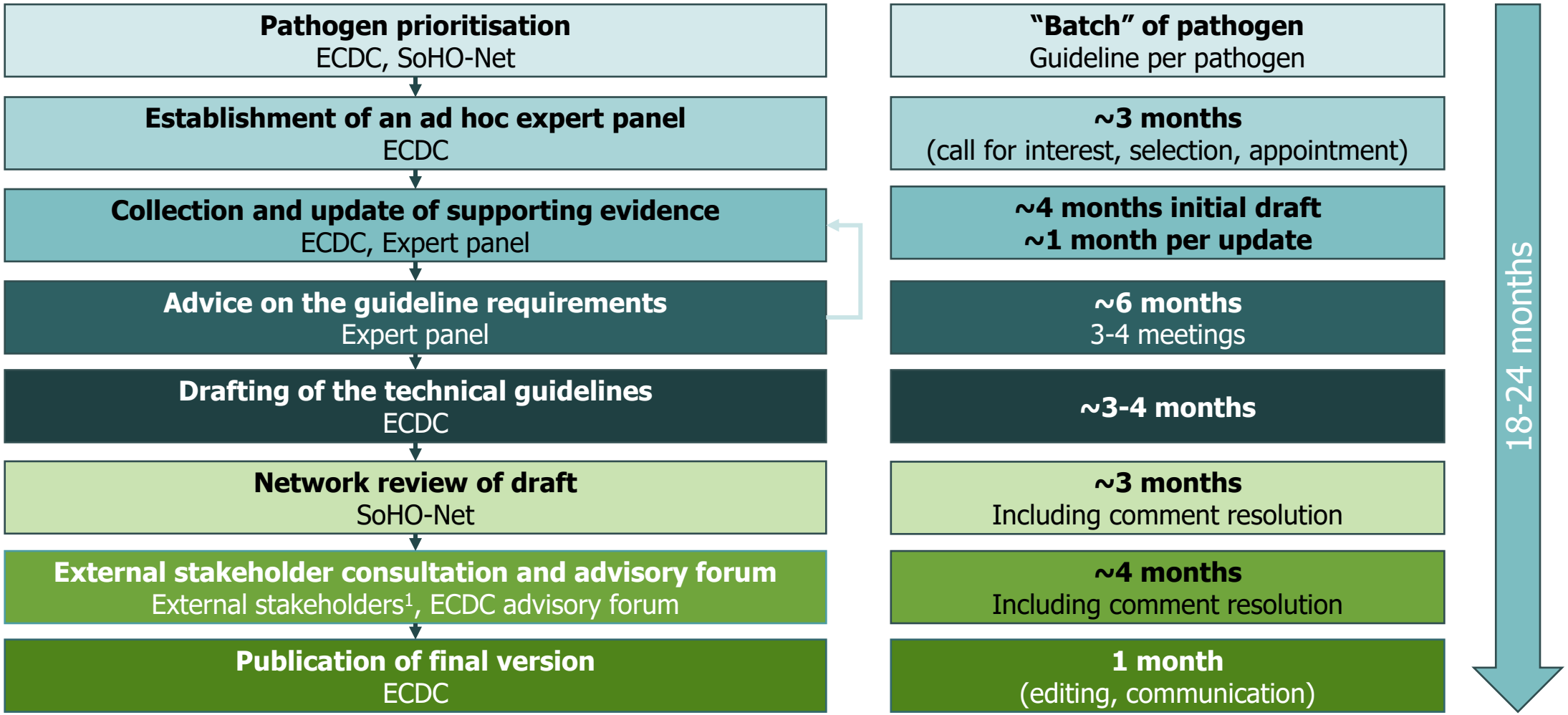


Provide guidance on microbial safety

- Develop and update technical guidelines as referred to in the SoHO Regulation: blood, tissues and cells, medically assisted reproduction

- Develop scientific advice and recommendations on topics relevant to the microbial safety of SoHO
  - At the request of the SoHO network, the European Commission or on own initiative

Provide guidance on microbial safety
Methodology and timelines



[1] https://www.ecdc.europa.eu/en/infectious-disease-topics/related-public-health-topics/substances-human-origin/technical-guidelines

Provide guidance on microbial safety
Methodology

- Evidence-base
  - Structured literature reviews, grey literature
  - Systematic reviews for specific questions or evidence needs

- Expert advice: adapted Delphi process
  - All SoHOs discussed within the panel
  - Repeated pre-meeting surveys covering requirements to be discussed
  - Reach agreements with proposed requirements

- Guideline draft
  - Based on available evidence and expert advice, responsibility of ECDC

- Disease description (natural history, organ systems targeted, pathogenaemia)
- Epidemiology in the EU/EEA
- Evidence of transmission
- Laboratory test methods
- Pathogen reduction technologies
- Current testing requirements
- International recommendations

Provide guidance on microbial safety
Batches

1. "Directive pathogens": 2023 - 2026
    - HIV
    - HBV and HCV
    - *T. pallidum*
    - WNV ➔ HTLV

2. "Arboviruses": 2026 – 2028
    - WNV, DENV, CHIKV, ZIKV, CCHFV

    (prioritisation order ongoing)

Provide guidance on microbial safety
Current status

HIV	**Panel meetings** Sept 23–Feb 24	**SoHO-Net review** Jun 24–Aug 24	**Stakeholder consultation** Feb-Mar 25	**AF consultation** Jun 25	**Editing and publishing** Sept 2025
HBV/HCV	**Panel meetings** May 24–Sep 24	**SoHO-Net review** Mar 25–May 25	**Stakeholder consultation** Jul-Aug 25	**AF consultation** Oct 25	**Editing and publishing** Dec 2025
T. pallidum	**Panel meetings** Jan 25–Jun 25	**SoHO-Net review** Q3 25	**Stakeholder consultation** Q4 25	**AF consultation** Q1 26	**Editing and publishing** Q2 2026
HTLV	**Panel meetings** Sep 25–Feb 26	**SoHO-Net review** Q2 26	**Stakeholder consultation** Q3 26	**AF consultation** Q3 26	**Editing and publishing** Q4 2026

Up to date timelines are published on: https://www.ecdc.europa.eu/en/infectious-disease-topics/related-public-health-topics/substances-human-origin/technical-guidelines

Scope of ECDC activities in SoHO

Prevention of communicable disease transmission through application of SoHO to protect donors, recipients and offspring.

1. Provide guidance on microbial safety
2. **Threat detection and rapid risk assessments**



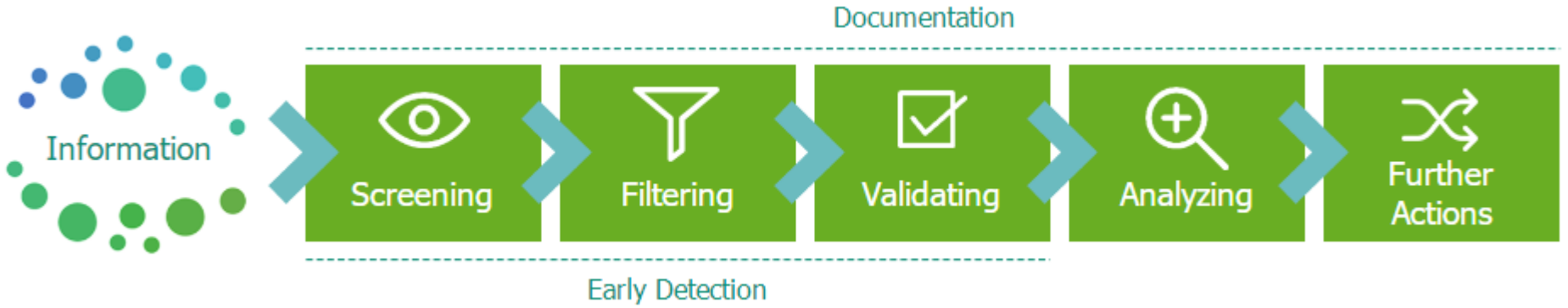
Threat detection and rapid risk assessments
Monitor threats and outbreaks

Detect, monitor, and report on serious cross-border threats to health related to SoHO

- Daily screening of various information sources
- Reports of cases of infectious diseases and pathogens that may threaten microbial safety of SoHO in the EU/EEA in EpiPulse

→ Discussion of identified threats and an initial assessment of appropriate ECDC actions.

Threat detection and rapid risk assessments
The epidemic intelligence process



Review of large number of items

Selection of relevant items

Use official sources to validate information

Contextualize information for assessment

Rapid sharing of information.
Reporting at Round Table.
Rapid Risk Assessment.

Threat detection and rapid risk assessments
Threat detection – sources and validation

Indicator-based surveillance	Event-based surveillance	Media monitoring (including social media)
TESSy (EpiPulse cases) **Web scraping**	**Restricted platforms:** • EpiPulse Events • EWRS • WHO Event Information site • RASFF **Official public sources:** • National public health institute websites • WHO websites • CDC websites	**Epidemic Intelligence from Open Sources (EIOS)** **Social media platforms** **Other web aggregators as backup**

Global coverage

- In EU/EEA:
  - ECDC disease specific networks
  - Epidemic Intelligence activities
- Outside EU/EEA:
  - Public Health Institutes/Ministries of health where direct links (e.g. existing MoU, personal contacts)
  - Other CDCs – e.g. Africa CDC
  - World Health Organization (mainly WHO/Europe)

Threat detection and rapid risk assessments
Outputs

Communicable disease threat reports

Restricted and Public versions
Daily and weekly editions



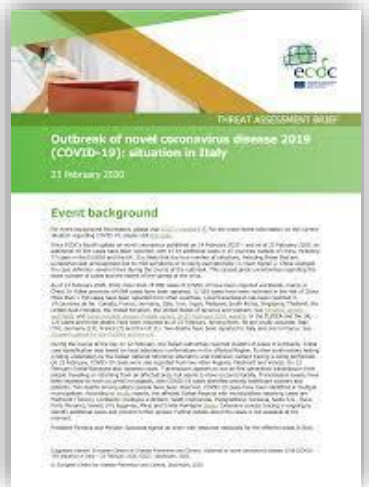


Risk assessment outputs

Epidemiological Updates



Threat Assessment Brief



Rapid Risk Assessment



Threat detection and rapid risk assessments
What is an ECDC risk assessment?

Relative quantification of the risk to human health of an event (potential threat) in one or more EU/EEA countries or for EU/EEA citizens living in affected areas outside of the EU.

- **Support** the EU/EEA countries public health authorities and the EC in their preparedness and response to the threat by:
    - **Alerting** about the event
    - Providing **timely information** on the estimated risk related to the public health threat
    - Addressing **uncertainty** by using a **systematic appraisal** of the best scientific evidence available
    - Determining whether a **response** is needed
    - Providing [non-binding] **recommendations** for mitigating the risks

- **Inform** health professionals and the public at large (e.g., clinicians, media, travellers…)

Threat detection and rapid risk assessments

Triggering criteria for ECDC rapid risk assessments

- Outbreak extending to more than one EU/EEA country
- Risk of introduction to and/or propagation within the EU/EEA
- Event for which cross border contact tracing is needed
- Unusual or unexpected event
- Outbreak of unknown origin
- Emerging disease(s) affecting touristic areas
- Contaminated food product(s) with EU dimension

- *Event triggering high media attention*

Threat detection and rapid risk assessments
ECDC process for conducting a RRA

1 – 3 weeks

Decision to develop an RRA

Multidisciplinary **internal response team**

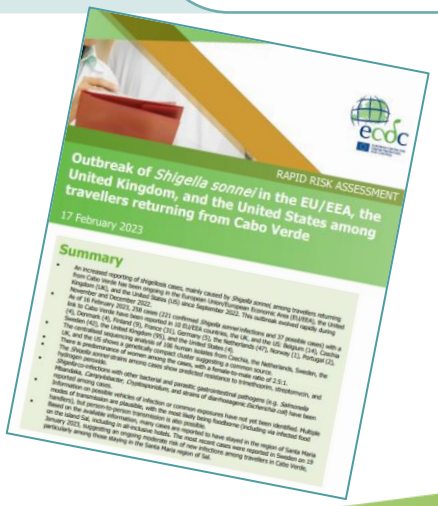
Notification to ECDC external stakeholders
- Advisory Forum members
- National Coordinators
- NFP for Preparedness and Response; for Threat Detection; for specific area/disease
- European Commission

Independent external rapid review

External **distribution under embargo**:
- Advisory Forum members
- National Coordinators
- NFP for Preparedness and Response; for Threat Detection; for specific area/disease
- European Commission

Publication ECDC

Ensuring traceability and transparency:
- Rapid risk assessments are registered and versioned in the ECDC Scientific Advice Repository and Management System.
- Declarations of interest are collected and assessed for all external reviewers prior to review and publication.
- Actions taken (or not taken) on external reviewer comments are stored.



Threat detection and rapid risk assessments
SoHO aspects in the ECDC rapid risk assessment

Consideration/non-binding recommendation for public health, competent authorities and SoHO professionals



THREAT ASSESSMENT BRIEF

Risks posed by reported increased circulation of human parvovirus B19 in the EU/EEA

5 June 2024

Summary

ECDC is following reports from several European Union and European Economic Area (EU/EEA) countries of substantial increases in the detection of parvovirus B19 (B19V). This Threat Assessment Brief has been developed to raise awareness among public health and substances of human origin (SoHO) professionals and competent authorities about this event, particularly as regards population groups at high risk for severe complications, and suggest actions that can be taken to address this situation.

Epidemiological situation

Since March 2024, nine EU/EEA countries have reported increased detections of B19V on the European surveillance portal for infectious diseases, EpiPulse, from a number of monitoring systems, mostly during late 2023 and early 2024. As a response to an inquiry from ECDC to the National Focal Points (NFPs) in the ECDC-SoHO network blood group [1] on B19V infections, 10 countries reported an increase in reactive tests for B19V in blood donors or in donations of plasma for fractionation during the first months of 2024 compared to the same period in 2023.

Risk assessment

Based on the unusually high numbers of B19V cases reported in 14 EU/EEA countries, the risk of infection is assessed in four population groups as follows:

- **The risk for the general population** is assessed as **low**, as most infections are in the form of a mild exanthematous disease of childhood, although some complications may occur.
- **The risk for pregnant women**, less than 20 weeks gestation is assessed as **low to moderate**, considering the uncertainties about the virus circulation, the fact that an estimated 30–40% of women of childbearing age are susceptible to the infection, and severe outcomes occur in a small percent of infected pregnancies.
- **The risk for immunosuppressed people** is assessed as **moderate**, as these patients cannot clear the infection and can suffer chronic anaemia, pancytopenia, graft loss or dysfunction and organ-invasive disease.
- **The risk for people with chronic haematological diseases** (e.g. sickle cell disease, thalassaemia, etc.) is assessed as **moderate**, as B19V infection can cause transient aplastic crisis.

Recommendations

For public health authorities

ECDC recommends that public health authorities in the countries should:

- **Raise awareness among clinicians** of the observed increase of B19V to assist in counselling and managing their patients appropriately.
- **Conduct risk communication to the risk groups**, including pregnant women, immunosuppressed and transplant recipients, and patients with chronic blood disorders, particularly haemolytic anaemias.

Suggested citation: European Centre for Disease Prevention and Control Risks posed by reported increased circulation of human parvovirus B19 in the EU/EEA – 5 June 2024. ECDC: Stockholm; 2024.

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ECDC considerations for public health and SoHO authorities

For SoHO professionals and competent authorities

Transmission of B19V through SoHO has been described in the literature via transfusion of red blood cells and platelets, treatment with plasma-derived medicinal products [17-22], and hematopoietic stem cells (HSC) [23] and solid organ transplantation [24]. However, clinically significant transfusion-transmitted B19V infection seems to be a rare or overlooked event, as indicated by data from different European countries. For instance, in the UK, only one case was reported between 1996 and 2022 [25], and in Germany no transfusion-transmitted B19V infection was reported between 1997 and 2017 [26], in the absence of routine testing for this virus in blood donors during this period.

Due to the limited number of transmission cases reported, the exact level of B19V titres that pose a risk of virus transmission through SoHO cannot be adequately assessed.

To reduce the risk of possible B19V transmission by plasma-derived products, the European Pharmacopoeia mandates testing plasma pools for fractionation for B19V using a validated nucleic acid amplification test (NAT). These plasma pools, used in manufacturing, can only contain B19V DNA loads below 10 000 international units (IU) per millilitre. Any final manufacturers' plasma pools exceeding this B19V DNA level must be discarded [27].

Systematic testing of blood donors for B19V infection, in addition to the screening of donations of plasma for fractionation, is not required. However, if a B19V infection is suspected or confirmed for a donor, the B19V-positive blood or blood components should not be transfused to individuals susceptible to severe clinical outcomes of B19V infections i.e. pregnant women, patients with chronic haemolytic diseases or hemoglobinopathies, and immunosuppressed people [28]. Selective screening of donations with NAT to provide safe components for these recipients could be considered [29]. An alternative testing strategy in use in the Netherlands is the selective testing of donors for B19V antibodies to make B19V-tested blood components available for susceptible patients upon request. Donors with two positive B19V (IgG) antibody tests at an interval of at least six months are considered safe for B19V-susceptible recipients [30].

Even though B19V transmission cases through HSC transplantation are seldom reported, regarding the current epidemiological situation, the risk of B19V infections in HSC transplant recipients should be considered.

https://www.ecdc.europa.eu/en/publications-data/risks-posed-reported-increased-circulation-human-parvovirus-b19-eueea

Threat detection and rapid risk assessments
ECDC operational tool on rapid risk assessment methodology

Under revision!



Aim

- Support for consistency, reproducibility and transparency using a systematic approach
- Provide an analytical framework
- Help to manage time constraints and limited evidence

Ongoing, 2024

- Review and update of methodology. Maintain the basis, with further improvement of the existing algorithm.

ECDC's amended mandate, Article 8a:

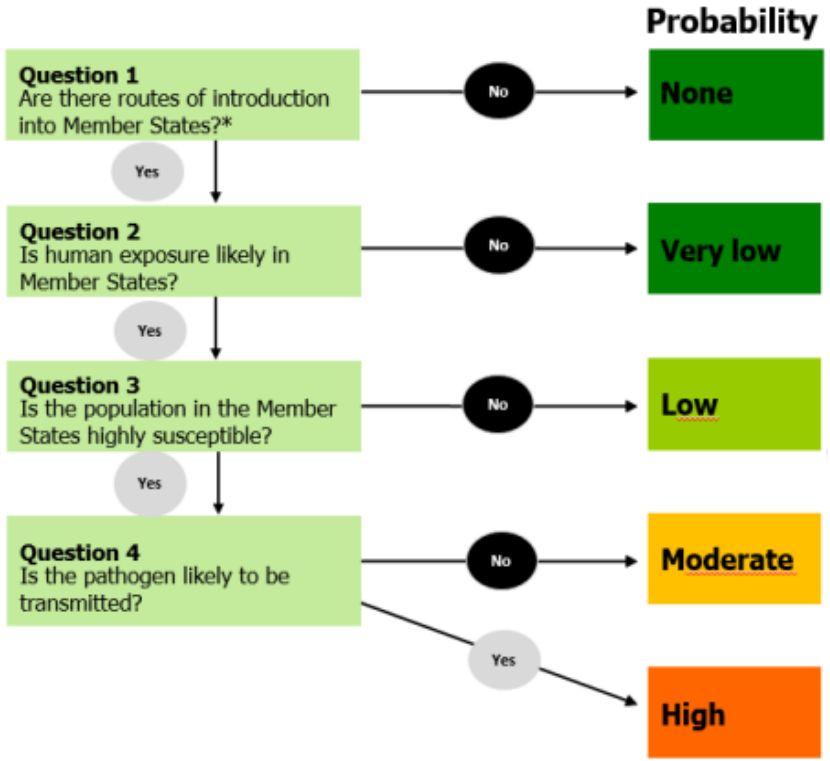
- "*Risk assessments…**shall include general and targeted*** **(non-binding) ***science-based recommendations and options for response as a basis for coordination in the HSC***".

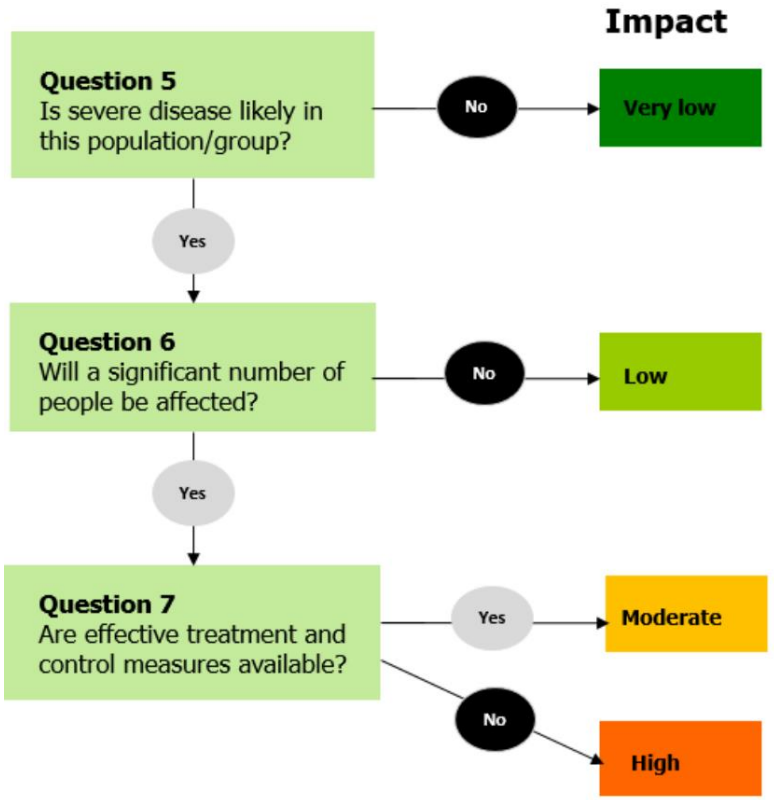
https://www.ecdc.europa.eu/sites/default/files/documents/operational-tool-rapid-risk-assessment-methodolgy-ecdc-2019.pdf

Assessing the risk

Risk = Probability X Impact

Under revision!





https://www.ecdc.europa.eu/sites/default/files/documents/operational-tool-rapid-risk-assessment-methodolgy-ecdc-2019.pdf

Threat detection and rapid risk assessments

Key steps for the development of a Rapid Risk Assessment

1. **Signal verification** and event information systematically collected
2. Decision to initiate an RRA: at the ECDC **round table** meeting
3. Internal Response Team: formulate **the risk question**(s)
4. Conduct a rapid but structured **literature review**
5. **Appraise the evidence** and acknowledge confidence, unknowns & limitations
6. Estimate and assess the risk using the **operational algorithms**
7. Integrate **uncertainties and limitations**
8. Provide **recommendations** for member state public health authorities
9. Prepare RRA communication material
10. **Re-assess** new information and decide on need to update RRA

Conclusion

Prevention of communicable disease transmission through application of substances of human origin

Coordinate SoHO network

Provide guidance on microbial safety

Threat detection, assessment, and response

https://www.ecdc.europa.eu/en/publications-data/ecdc-framework-relating-substances-human-origin-soho

SoHO at ECDC

https://www.ecdc.europa.eu/en/substances-human-origin

Related public health topics

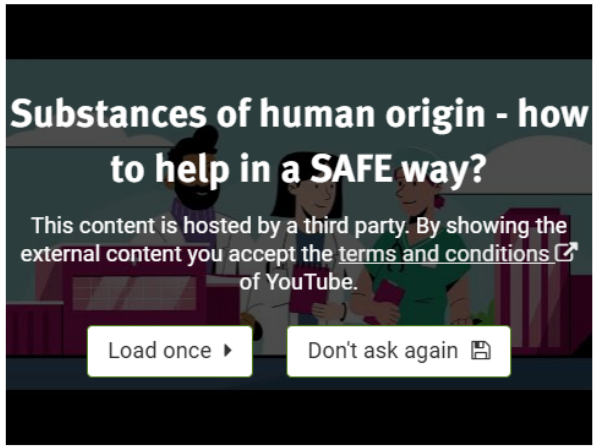
- Antimicrobial consumption
- Antimicrobial resistance
- Disease vectors
- Healthcare-associated infections
- Immunisation and vaccines
- Microbiology
- Migrant and refugee health
- One Health
- Prevention
- Social and behavioural sciences
- **Substances of human origin**
  - Surveillance resources
  - ECDC technical guidelines for SoHO
- EU case definitions

Substances of human origin

Translate this page

Substances of human origin (SoHO) is a term referring to a variety of biological materials that can be derived from the human body and are intended for clinical application. Broadly speaking, these are blood, tissues, cells, and organs, but they can be any parts of the human body, and secretions or excretions, collected from living or deceased persons.

SoHO are used as therapy for a wide range of medical conditions, and are sometimes the only available and lifesaving treatment. In other situations, the application of SoHO can significantly improve patients' quality of life.



Substances of human origin - how to help in a SAFE way?

Although very beneficial, SoHO are not without risks. To minimise these risks, the SoHO field is very carefully regulated in the EU. Among other bodies and organisations, ECDC is responsible for ensuring the quality and safety of SoHO. ECDC focuses on aspects of prevention of communicable diseases transmission that can come from SoHO donors.

Thank you

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