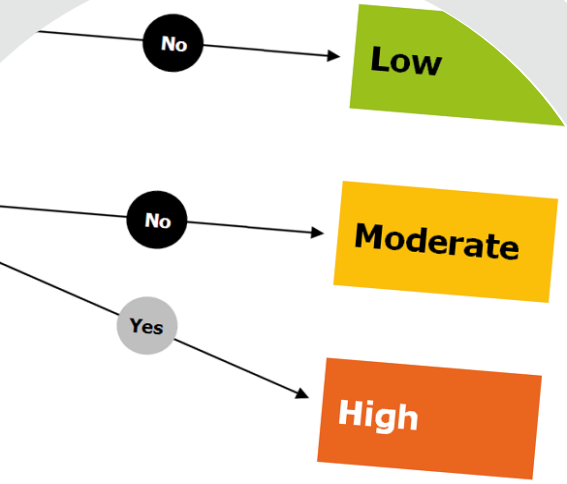

TECHNICAL DOCUMENT

Operational guidance on rapid risk assessment methodology

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Operational guidance on rapid risk assessment methodology

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Contents

Abbreviations

EBM	Evidence-based medicine
EBP	Evidence-based practice
EWRS	Early Warning and Response System
MeSH	Medical subject headings
MoH	Ministry of health
RCT	Randomised controlled trials
OIE	World Organisation for Animal Health

Executive summary

This guidance document develops a methodology for rapid risk assessments undertaken in the initial stages of an event or incident of potential public health concern. It describes an operational tool to facilitate rapid risk assessments for communicable disease incidents at both Member State and European level. The tool comprises information tables and risk-ranking algorithms to give an estimate of risk posed by a threat. The risk to a population from a communicable disease is dependent on the likelihood of transmission in the population (probability) and the severity of disease (impact). The probability of an incident developing, and the impact if it does, are based on both the nature of the infectious agent and details of the incident. This may be further influenced by context or the broad environment in which the incident occurs, including political, public, media interest, perception of threat, and the acceptance of risk, which may vary between countries and cultures.

Rapid risk assessment is a core part of public health response and thus widely undertaken by public health professionals. Formal systems which are used to grade evidence and recommendations, such as the systematic methods used in evidence-based medicine, rely on published research evidence, and studies are graded according to design and susceptibility to bias. However, as time and evidence are limited, a rapid risk assessment may need to rely at least in part on specialist expert knowledge, and these formal systems are not directly applicable. However, the same principles of transparency, explicitness, and reproducibility also apply to a rapid risk assessment.

For the rapid risk assessment of most infectious disease threats, observational data is often the only available and obtainable source of information. Expert knowledge is also important if there is lack of time and evidence. In such cases it is important to 'unpack' and make explicit the expert knowledge and distinguish between knowledge based on good research, and experience and opinion-based knowledge. Serious attempts should be made to assess the quality of the evidence, based on the source, design and quality of each study or piece of information. Uncertainties should be identified, clearly documented and communicated and the assessment updated in light of new evidence over time.

A rapid risk assessment includes the approach and tools required at each stage of the process: stage 0 is the preparation stage; stage 1 is the collection of event information; stage 2 is the literature search and systematic collection of information about the aetiological agent; stage 3 focuses on the extraction of evidence; stage 4 conducts an appraisal of the evidence; and stage 5 estimates the risk. Transparency and sharing of information is essential at every stage. This document incorporates a step-by-step guide through each stage with examples and checklists of the resources and evidence required.

Advance preparation and planning saves time and is vital to ensure that potential threats are identified, assessed, and managed effectively. Ideally the following should be in place: evidence-based protocols and guidance for responding to incidents, protocols for identifying sources of key information for rapid risk assessment, strategies for literature searches, and lists of relevant contacts including named experts.

Rapid risk assessments of potential communicable disease threats can be complex and challenging as they must be produced within a short time period when information is often limited and circumstances can evolve rapidly. The rapid risk assessment methodology described in this document enables the structured identification of key information using systematic appraisal of the best scientific evidence and/or specialist expert knowledge available at the time in order to provide a clear estimate of the scale of the health risk. This is important in not only communicating the potential magnitude of the risk in a systematic and transparent way, but allows documentation of evidence and gaps in knowledge at the time when the assessment is made.

1 Introduction to purpose and scope of guidance

Rapid risk assessments are undertaken in the initial stages of an event or incident of potential public health concern, wheras formal risk assessments are produced at a later stage of an event, usually when more time and information is available. Whilst standardised evidence-based methodology is in widespread use in clinical medicine and for providing guidance, its application to rapid risk assessments in public health or infectious disease epidemiology is not well defined or standardised.

The aim of this guidance is to define rapid risk assessment methodology, indicating where there are the existing elements which could be applied to producing a rapid risk assessment and where there need to be new approaches. The main objective is to develop an operational tool to facilitate rapid risk assessments for communicable disease incidents, drawing on the systematic methods used in evidence-based medicine or evidence-based practice where possible. The target audience is both national public health experts within Member States and experts responsible for rapid assessment of communicable disease threats at the European level. The operational guidance will support the use of a common defined methodology.

The initial assessments of potential communicable disease threats can be complex and challenging as they must be produced within a short time period when information is often limited and circumstances can evolve rapidly. However, rapid risk assessments should still be based on the structured identification of key information from all readily available sources, using systematic appraisal of the best scientific evidence and/or specialist expert knowledge available at the time in order to provide a clear estimate of the scale of the health threat while documenting the level of uncertainty.

2 Background: Concepts of rapid risk assessment methodology

2.1 Key parameters in rapid risk assessment

Once an incident has been verified as being of potential public health concern, a rapid risk assessment is undertaken (usually within 24 to 48 hours) to evaluate the risk to human health. The outcome of this rapid risk assessment will determine: whether a response is indicated; the urgency and magnitude of response; the design and selection of critical control measures, and will inform the wider implications and further management of the incident. This document will focus on and develop a methodological tool for rapid risk assessment. Terms commonly used to describe risk assessment processes are listed in Appendix 1.

The risk to a population from a communicable disease is dependent on the likelihood of transmission in the population (probability) and the severity of disease (impact). Risk may be influenced by context or the broad environment in which the threat occurs, including political, public, media interest and perception of risk.

Probability x impact = risk ⇦ context

The probability of the incident developing or the impact if it does are based on both the nature of the infectious agent (i.e. incubation period, mode of transmission, available interventions, vectors/reservoir species) and details of the incident (e.g. characteristics of population at-risk including immune status, prevention, treatment and control measures available, and potential for international spread). Often little information, other than the classical triangle of host-place-environment, is available during initial response to an incident and continuous re-assessment of the risk and updates to these assessments are crucial throughout until closure. A good rapid risk assessment should be:

- consistent and transparent to ensure fairness and rationality;
- easily understood by all the interested parties;
- flexible enough to deal with complex situations, including cultural aspects;
- reproducible;
- based on the best scientific evidence available at the time, well-documented and supported with references to the scientific literature and other sources, including expert opinion;
- regularly reviewed (may be done at preset intervals) and updated when additional new information becomes available;
- complemented by a log for decisions and actions based on available information; and
- contain a record of uncertainties (gaps in knowledge) and assumptions made, in order to evaluate the effect of these on the final risk estimate and priorities for future research (dated and with version control).

Communication is vitally important in risk assessment and certain principles apply to the processes of risk communication such as who needs to be informed and how they should be informed. The audience may include those directly involved in the incident, those in the vicinity of the incident, the wider general public, partner organisations and upward cascades (government, local health authorities, other agencies, etc.).

Even though a rapid risk assessment is evidence-based and robust, public concern and expectations, and other external factors (i.e. context), can affect the response to decisions that are being made. Such responses are often unpredictable but it is important to remember that public and professional perception is a crucial aspect of risk assessment. Factors that may distort or attenuate the perception of risk include: lack of professional knowledge about disease epidemiology; conflicting professional opinion; severe outcomes in certain individuals, numbers affected, case fatality; lack of available treatment/interventions; political and/or media interest. In addition, the acceptance of risk may vary between countries and cultures. Although the impact of a threat and probability of a serious outcome may be unknown, failure to apply the precautionary principle ('better safe than sorry' approach) could have serious consequences.

2.2 Approaches to rapid risk assessment

Rapid risk assessments should be based on the systematic appraisal of the best scientific evidence available at the time, well-documented and supported with references to scientific literature and other sources used, including specialist expert knowledge. There should also be attempts to assess the quantity and quality of different sources of evidence or information used in the assessment. Within evidence-based practice there are a number of formal systems which are used to grade evidence and recommendations (further details of these are given in Appendix 2),

however as these rely on higher 'rated' levels of evidence such as systematic reviews and randomised controlled trials, they are not directly applicable to rapid risk assessment.

Any rapid risk assessment should collate all available evidence and information in order to assess the need for a response, including the scale and type of response required. The assessment should provide information to support risk management, prioritise resources and aid communication. At every stage, transparency and sharing of information is essential. The approach may be qualitative or quantitative. A quantitative assessment requires calculations of two components of risk: the probability and the impact (described in Section 2.1). It will produce a numerical risk score often of unknown accuracy, and is useful for known risks where data defining the probability and impact are available. In contrast, a qualitative assessment is a more useful approach for a rapid risk assessment, as it is possible with limited information and provides a qualitative estimate of risk. Because information may be scarce, this approach relies more on specialist expert knowledge and may include unpublished information supplied by expert(s), in addition to other available information such as observational studies or case reports. Depending on the threat, a multidisciplinary approach should be encouraged.

A variety of approaches, including tools to assess the significance of the incident for subsequent reporting/alerting and for appraisal of the available evidence to inform public health action have been developed.

Tools/algorithms for the assessment of a significant public health threat for subsequent reporting include the International Health Regulations (IHR) (to World Health Organisation (WHO)) and the Early Warning and Response System (EWRS) (to European Commission (EC), European Centre for Disease Prevention and Control (ECDC) and Member States). Systems also exist within individual Member States for reporting public health threats – such as ministry of health (MoH) and national public health body systems. However, although these include a number of criteria for assessing the potential threat, the focus tends to be on early warning (i.e. assessment of signal to alert) rather than assessment of the risk.

Rapid risk assessment is a core part of public health response and thus widely undertaken by public health professionals. However this is often not done in a formalised way and is often based on consensus opinion of between one or more experts. There are only a limited number of examples of a more systematic and transparent approach to rapid risk assessment in the literature including:

- a qualitative method for assessing the risk from emerging infections in the UK (Morgan *et al*. 2009) using algorithms to consider the probability of an infection occurring in the UK population, its potential impact, and identifying gaps in knowledge or data;
- a prioritisation approach to rank emerging zoonoses posing the greatest threat in the Netherlands, based on seven criteria (including probability of introduction, likelihood of transmission, economic damage, morbidity and mortality) to aid decision-making (http://www.rivm.nl/bibliotheek/rapporten/330214002.html);
- a dynamic risk assessment model developed in the UK to assess the risk from an outbreak or incident, consisting of five attributes (severity, spread, confidence in the diagnosis, ease of intervention and the wider context in which events are occurring) rated over a 0 to 4 scale. During an outbreak, the dynamic risk assessment of each event occurring is used to inform management action at that time (http://hpzoneinfo.in-fact.com/HPZone/RiskAssessment/tabid/58/Default.aspx).

3 Operational guidance

The operational part of this guidance outlines the process of undertaking a rapid risk assessment, including the approach to, and tools required, at each stage of the process.

Box 1: Stages of a rapid risk assessment

- Stage 0: Preparation
- Stage 1: Collect event information
- Stage 2: Perform structured literature search/systematically collect information about the (potential) aetiologic agent
- Stage 3: Extract relevant evidence
- Stage 4: Appraise evidence
- Stage 5: Estimate risk

3.1 Preparation for rapid risk assessment (stage 0)

Good preparation and planning is vital in ensuring that potential threats are identified, assessed and managed effectively. Advance preparation makes the best use of the limited time available. Public health bodies and those working in threat assessment should consider the following in advance of any threats being detected:

- Developing evidence-based protocols and guidance for responding to incidents and outbreaks of common infectious threats
- Establishing clearly defined protocols for identifying sources of key information for rapid risk assessment and assessing their usefulness. These will include key textbooks, relevant published literature, grey literature (which may involve identifying international networks and reporting systems for sharing surveillance outputs, outbreak reports, assessing other web sources, etc.), outputs of national and international public health bodies and consultation with relevant experts. Examples of appropriate sources are given in Appendix 3, and individual Member States should use this as a basis for developing country-specific lists.
- Identifying relevant IHR National Focal Points (NFPs) and EWRS National Contact Points (NCPs), which are usually based in Member States MoH or public health bodies (see also 3.3, stage 2).
- Identifying and maintaining lists of named individual experts. This may include links with relevant groups or individuals and should include details of qualifications, experience in the field, publications, sources of funding, any potential conflicts of interest and contact details (see also 3.3, stage 3).
- Ensuring relevant staff members are able to undertake a rapid literature search. If necessary, organise training in effective literature searches (described in more detail in the section on literature review and sources (3.3, stage 2).

3.2 The rapid risk assessment process

A systematic and consistent approach, including defined search strategies and the use of any pre-prepared relevant information, ensures a transparent, reproducible risk assessment which also records available information, reasons for judgements, and documents uncertainties. A rapid risk assessment should synthesise the information about the incident together with pre-existing formal evidence base and any readily available data (which has been appraised to ensure the best quality evidence is used) and expert knowledge and interpretation. Extrapolation of information from what is already known, e.g. behaviour and other characteristics of communicable disease agents belonging to the same genera may inform the risk assessment. The information identified should be used to answer the key questions necessary to undertake the rapid risk assessment (see Table 1, end of Section 3.3). By completing the information table, the answer to each question will be categorised (e.g. yes/no) and this will be used in the risk ranking algorithm(s) (Figures 1 and 2, Section 3.3, stage 5) to give an estimate of risk posed by the threat (or risk level).

For a rapid risk assessment it is acknowledged that time and evidence will be limited and the assessment may need to rely at least in part on specialist expert knowledge. It will be important to 'unpack' this knowledge, by asking specific questions (see Table 1) and distinguishing expert knowledge and experience from opinion. In addition, uncertainties should be clearly documented and the opinions of at least two experts sought if no other data is available as part of the methodology of rapid risk assessment. Triangulation of evidence including specialist

expert knowledge may be important to reach a consensus. The rapid risk assessment is likely to change over time in light of new information or events and should be updated accordingly.

When a rapid risk assessment is required, five stages (Box 1) will be necessary. Each stage is described in detail in Sections 3.3 through 3.7.

3.3 Collecting event information (stage 1)

- Ensure that detailed information on the incident has been gathered, preferably from those responsible for investigating the incident at local or national level. See Checklist 1 for information that should be collected. Think as multidisciplinary as possible!
- The incident information should be summarised for the risk assessment information table.
- Collating the incident information is an essential first step in determining what further disease specific information and evidence is needed for assessing the risk.

Checklist 1: Incident/event information

- Who reported the incident/event?
  - Name
  - Organisation
  - Contact details
- How has the incident/event come to light?
- What is the primary diagnosis?
- Has the aetiologic agent been confirmed?
- Is this illness endemic in this country?
- What is known about the exposure (means/mode of transmission)?
- Where have cases occurred? Are the cases clustered in time and/or space?
- Over what time period have cases been detected?
- Who are the cases? Are they from a particular social group or setting?
- How many cases are recognised at the moment?
- What are the symptoms experienced by the cases?
- Have any of the cases been seen by a specialist clinician? What is their working diagnosis and clinical findings? Case definition?
- Have specimens been taken and where have they gone for analysis? Which tests have been performed, which tests are planned? When will results be available? What are the limitations of the test results that need to be considered?
- Have there been any deaths? Autopsy results?
- Have the ambulance service, local hospitals, and doctors (including private practice) been warned?
- Where are the cases being managed?
- What is being done to manage cases at the moment?
  - What treatment, if any, has been instituted?
- Who else has possibly been exposed and might be at risk of developing this illness? Has a list of these been made?
- Are there any conditions occurring which might increase the risks to others, e.g. healthcare workers exposed, ongoing incident, weather forecasts? What is being done to prevent the development of new cases at the moment? For example:
  - Protection of emergency and healthcare staff
  - Quarantine
  - Prophylactic treatment
- What agencies are involved at the moment? Get contact details. Has any agency declared a major incident? Who else has been informed?

3.4 Performing a structured literature search/systematically collecting information (stage 2)

Identify basic facts about the disease and the aetiological agent from a standard reference text (ideally less than five years old). Examples include infectious disease textbooks such as: Heymann; Mandell; Topley and Wilson; Fields Virology (see references). There will be other key reference texts, including previous outbreaks and incidents, depending on the country and the disease. Sources on evidence-based medicine (see Appendix 3) are useful for checking what has already been done and to ensure that work is not repeated. Expertise on choosing reliable sources of information, such as bibliographic databases, websites and/or grey literature sources and advice on access to the full texts are usually available within Member States' institution libraries.

Refer to Checklist 2 for basic disease information that should be collected.

Checklist 2: Basic disease information/determinants

- Occurrence: time, place and person
  - Geographical distribution: is disease endemic in country?
  - If not, what are routes of introduction, e.g. food/bird/animal/human?
  - Seasonal/temporal trends
- Reservoir (if zoonotic, which species affected – will animals be symptomatic?)
- Susceptibility: are specific risk groups at increased risk of exposure/infection, e.g.:
  - specific age groups (e.g. children, elderly);
  - occupational groups;
  - travellers;
  - those with impaired immunity, e.g. immunosupression/chronic disease; pregnant women;
  - others, e.g. as a result of specific recreational or other activities.
- Infectiousness
  - Mode of transmission
  - Incubation period
  - Period of communicability
  - Length of asymptomatic infection
  - Reproductive rate
- Clinical presentation and outcome
  - Disease severity: morbidity; mortality; case fatality
  - Complications/sequelae
  - Are specific risk groups at increased risk of severe disease/complications (consider children, elderly, those with immunosupression/chronic disease, pregnant women, occupational/recreational risks)
- Laboratory investigation and diagnosis
  - Laboratory tests available
  - Test specifications (sensitivity, specificity, PPV, quality assurance) and limitations (cross-reactivity, biosafety concern)
- Treatment and control measures
  - Treatment (efficacy?)
  - Prophylaxis (vaccination/other)
  - Other control measures (e.g. quarantine, withdrawal of food product, culling animals)
- Previous outbreaks/incidents
  - Novel transmission routes

Basic disease information from standard textbooks should be supplemented by searching published and grey literature (including outbreak reports and surveillance data, guidelines, disease fact sheets, etc). "A literature search should be a well-thought-out and organised search for all relevant literature published on a topic and is the most effective and efficient way to locate sound evidence on a subject". (see http://www.nursingtimes.net/nursing-practice/217252.article). When time and resources are limited, a preliminary literature search should be undertaken to identify the key literature in the subject area, however there will inevitably be a trade-off between time and sensitivity. Particular attention should be given to filtering the results, i.e. choice of subjects, timeframe, and restricting to 'review' articles – most citation databases offer the facility to filter searches in this way. A trained information specialist or librarian can help to identify the best way to use these options in databases and retrieve the appropriate records according to the questions. There are also sites available with tutorials and guides providing help with the literature search, such as the London School of Hygiene & Tropical Medicine Library (see http://www.lshtm.ac.uk/library/help/help.html for further information). It should be acknowledged that a comprehensive systematic review will not be possible in the early stages of a rapid risk assessment; however the need for such a review should be considered at a later stage when time and resources permit.

Published literature

The key steps in an effective literature search include:

- Clearly defining the question(s) and the type of information needed (e.g. type of studies searching for, any geographical/ethic/age limits)
- Database(s) to be searched – Pubmed/Medline is universally available and access to Cochrane Library may also be free depending on the country agreement (http://www.thecochranelibrary.com/view/0/FreeAccess.html). There are a range of citation databases that

may also be used including Scopus, Web of Science, Google Scholar. For other databases, such Embase, which is specific to health, a subscription is needed. These databases vary in accessibility, geographical coverage, range and type of content (e.g. coverage of low-impact journals and conference proceedings). Ideally, more than one database should be searched and the results of each compared, however this is rarely practical in view of time restraints. It may be better to become proficient in using one database so that when an incident occurs a rapid literature search can be conducted. For further information see http://www.lshtm.ac.uk/library/help/choosingdbs.pdf.

- Selection of search terms – text words and/or MeSH headings (best to use both if time permits).
- Compiling search strategy and running the search – including use of Boolean operators (AND/OR).
- Documenting search strategy and results.

Full articles should be used wherever possible rather than abstracts.

Further resources for effective literature searching are listed in the references (e.g. http://www.lshtm.ac.uk/library/help/help.html#resources). Member States public health services will often have their own resources and guides to doing literature searches.

Grey literature

These include key electronic publications such as ProMED and websites of national and international public health bodies (for outbreak reports and disease information). A list of suggested sources is included in Appendix 3. It will not be practical (or relevant) to search all of these in the early stages of a rapid risk assessment, however, as a minimum, the following should be searched:

- Electronic publications, e.g. ProMED and WHO Disease Outbreak News for outbreak reports.
- Key websites of the relevant national and international public health bodies to identify further disease information, guidelines, surveillance information, etc.
- Additional outbreak reports may be available on the IHR and EWRS websites (restricted access) and can be identified through the relevant IHR NFP and EWRS NCP.

3.5 Extracting relevant evidence (stage 3)

Start to complete the information table (Table 1), which then provides the supporting evidence underpinning the rapid risk assessment. If there are high-risk groups identified, an information table should be completed for the general population and for each of the groups identified as being at increased risk. This is because the risks are likely to be very different in the various groups. The information table also acts as a template (log record) for recording the evidence and its quality, and documents sources, gaps and uncertainties, which would be an integral part of the assessment process.

Role of the expert

Where gaps in knowledge are identified and further information is required, formulate key questions and if possible get expert assessment of your conclusions from the evidence.

- Identify and seek advice from key experts, including public health, microbiology, infectious disease and other disease-specific experts or specialists
  - within country: previously identified national experts or through personal contacts/national public health body websites; and
  - internationally: through reports of previous outbreaks (ProMED, EWRS, IHR, websites), disease-specific networks (e.g. ECDC Food- and Waterborne Diseases and Zoonoses (FWD) network, NoroNet, EISN), other national public health bodies, e.g. CDC, or international public health bodies, e.g. ECDC.
    Note: Search engines such as Google may be useful for tracking down contact details of experts.
- Responses to key questions should be sought ('unpack' the expert knowledge), where possible distinguishing where this is based on:
  - previous experience;
  - opinion;
  - knowledge of evidence base (ask for key references and sources in published and grey literature).

If necessary, ask the expert to identify other experts from outside their group they would recommend speaking to (with contact details if possible). The information table should be updated as further information becomes available, ensuring document control.

3.6 Appraising evidence (stage 4)

The quality of evidence is the confidence in the veracity of the information or data, and depends on the source, design and quality of each study or piece of information. In contrast with EBM where randomised controlled trials are ranked highest and observational studies ranked lowest, in rapid risk assessment the evidence may be limited and therefore there may be greater reliance on observational studies, including case reports and specialist expert knowledge. For most infectious disease threats only observational data are available.

Certain factors affect the quality of evidence. Factors that may increase the quality include: the method of generating data and study design (i.e. analytical epidemiology versus descriptive), the strength of association, evidence of dose response, and consistency with other studies/expert opinion. Factors that may decrease the quality include: reporting bias, inconsistency, and conflicting evidence/opinion.

Ideally, a rapid risk assessment should not rely on a single study or piece of evidence. There should be a cautious approach to the interpretation of information if only one research group reports on an infection or disease association in multiple publications. Poor evidence or information should not be used for the rapid risk assessment unless this is the only data available; in this case any uncertainties should be documented in the information table.

Triangulation is a technique widely used in qualitative research to address internal validity by using more than one method of data collection to answer a research question. The body of evidence should be considered as a whole, and the triangulation of evidence should confirm (or refute) internal validity of findings. Triangulation of evidence, including specialist expert knowledge, may be important to reach a consensus. Ensure a minimum of two to three data sources and agreement between these (i.e. two experts or expert and literature). Sources of evidence and agreement between these (or absence of) should be clearly stated in the information table.

Based on consistency, relevance and external validity of the available and relevant information the quality of evidence is graded as: good, satisfactory, or unsatisfactory (definitions and examples are given in Checklist 3).

Checklist 3: Evaluating the quality of evidence (for information tables)

Examples may change over time and depend on organisation and need.

Quality of evidence = confidence in information; design, quality and other factors assessed and judged on consistency, relevance and validity. **Grade:** good, satisfactory, unsatisfactory	**Examples of types of information/evidence**
Good Further research unlikely to change confidence in information.	• Peer-reviewed published studies where design and analysis reduce bias, e.g. systematic reviews, randomised control trials, outbreak reports using analytical epidemiology • Textbooks regarded as definitive sources • Expert group risk assessments, or specialised expert knowledge, or consensus opinion of experts
Satisfactory Further research likely to have impact on confidence of information and may change assessment.	• Non-peer-reviewed published studies/reports • Observational studies/surveillance reports/outbreak reports • Individual (expert) opinion
Unsatisfactory Further research very likely to have impact on confidence of information and likely to change assessment.	• Individual case reports • Grey literature • Individual (non-expert) opinion

3.7 Estimating the risk (stage 5)

Once the quality of evidence has been assessed, the completed information table is then used to assess the risk posed by the threat using the risk assessment algorithms. Two approaches are presented, the first option combines probability and impact into a single algorithm resulting in a single overall risk level (Figure 1 to be used with Table 1), whilst the second assesses probability and impact separately (Figure 2, parts A to C to be used with Table 2). Both approaches make use of all the available information collected in the respective table to assess the level of risk, and also aid the identification of gaps in knowledge. It may be difficult to rapidly assess a potential threat where some of the information necessary to inform the risk process is not known, and this uncertainty is

documented and managed in the algorithms by adopting a precautionary approach and moving through the algorithm to a higher level of risk.

The combined approach (option 1) has the advantage of greater simplicity. However, the use of separate algorithms (option 2) to assess probability and impact avoids over-simplification and provides a more accurate assessment in situations where there is a high probability low impact disease or a low probability high impact disease, whilst the resulting individual risk levels can be combined into a single overall risk level using the risk ranking matrix (Figure 2, part C). Preferences of those doing the rapid risk assessment and the circumstances of the incident will determine which option is used.

The chosen approach should be applied to the general population and then repeated for those groups at increased risk of infection, in whom the risk may be very different.

It should be noted that the rapid risk assessment may change over time in light of new information or events and should be updated accordingly.

3.7.1 Option 1 (combined approach)

As stated, this option combines probability and impact questions into a single algorithm (Figure 1) to be used with reference to information Table 1, and includes consideration of the following:

- the potential for transmission within the Member States:
  - depends on exposure, infectiousness and susceptibility of the population
- the potential for transmission more widely within the EU:
  - depends on availability of routes of introduction/spread, exposure, population susceptibility and infectiousness
- whether the threat is unusual or unexpected,
  - i.e. unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease
- availability of interventions that may alter the course and influence the outcome of the event in terms of containing, reducing or elimination the transmission of the organism:
  - includes treatment, prophylaxis and other control measures
- severity of disease in this population/risk group:
  - includes morbidity, mortality, complications and burden of disease

See Appendix 4 and for a full worked example and Appendix 5 for further examples.

3.7.2 Option 2 (separate algorithms for probability and impact)

This approach uses three separate algorithms (the probability of infection in the Member States for use by national assessment teams, the probability of infection in the EU for use by European-level assessment teams, and the impact) together with the risk-ranking matrix to produce an overall risk level (Figures 2, parts A–C) to be used with reference to information Table 2. The algorithms are described below:

- the probability of infection in the Member States for use by national assessment teams (Figure 2, part A-1)
  - this depends on the likelihood of further exposure, infectiousness of the disease, and susceptibility of the population,
- the probability of infection in the EU for use by European-level assessment teams (Figure 2, part A-2)
  - depends on availability of routes of introduction/spread, exposure, population susceptibility, infectiousness
- the impact of infection (Figure 2, part B), including:
  - the severity of disease in this population/risk group; includes morbidity, mortality, complications, burden of disease.
  - the infectiousness of the disease; depends on the mode of transmission, period of communicability, length of incubation and asymptomatic period.
  - availability of interventions that may alter the course and influence the outcome of the event in terms of containing, reducing or elimination the transmission of the organism; includes treatment, prophylaxis and other control measures.
- the risk-ranking matrix (Figure 2, part C) combines the individual levels of risk to produce an overall score.

See Appendix 4 and for a full worked example and Appendix 5 for further examples.

Contextual factors such as public concerns and expectations, media and politics pressures should also be considered in risk assessment. These may be difficult to assess and therefore are better considered separately. Whilst they do not necessary alter the risk in absolute terms, they may alter the perception of risk and should therefore be flagged up in the rapid risk assessment.

The final step for both options is to consider the level of confidence in assigning the risk (Box 2). This is based on the quality of evidence (i.e. good, satisfactory, unsatisfactory) assigned to each question in the information tables. Confidence in assigning risk should be documented as follows:

Box 2: Level of confidence

Quality of evidence	Confidence
Mostly 'unsatisfactory'	Unsatisfactory (little poor quality evidence, uncertainty/ conflicting views amongst experts, no experience with previous similar incidents)
Mostly 'satisfactory'	Satisfactory (adequate quality evidence, including consistent results published only in grey literature; reliable source(s); assumptions made on analogy; and agreement between experts or opinion of two trusted experts)
Mostly 'good'	Good (good quality evidence, multiple reliable sources, verified, expert opinion concurs, experience of previous similar incidents)

3.7.3 Table and figures for option 1 (combined approach)

Table 1: Information table for rapid risk assessment to support risk-ranking algorithm (option 1: single algorithm)

To be completed if the evaluation of initial information necessitates a rapid risk assessment.

Rapid risk assessment, option 1: single algorithm To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: **Risk being assessed:** **Date of rapid risk assessment:** DD/MM/YYYY **Scope of rapid risk assessment:** **Summary of incident:**	**Outcome of risk assessment:** (Refer to assessment risk ranking tool: Figure 1)
	Confidence: (Good/satisfactory/unsatisfactory)

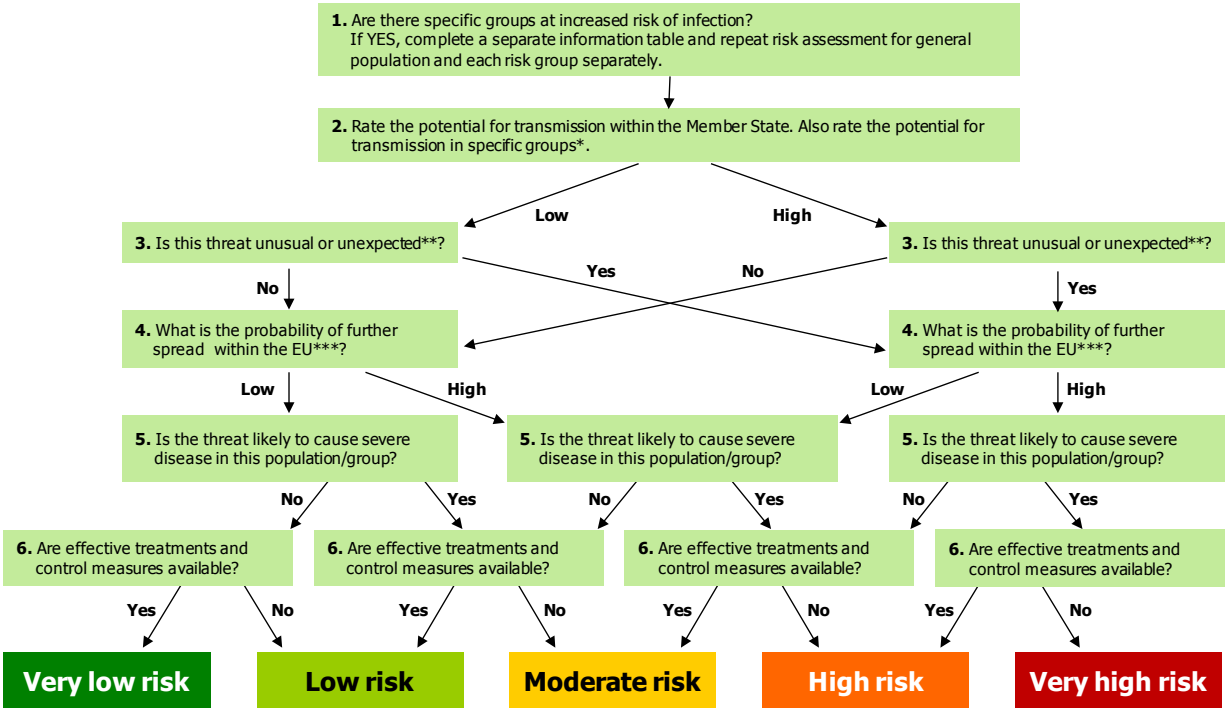
Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as:** Yes/no	Consider those with: • direct risk (e.g. occupational) • indirect risk (e.g. blood transfusion recipients) • specific risk groups (e.g. pregnant women, children)				
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt choose higher level.					

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
2. What is the potential for transmission within the Member State? **Categorisation as:** High/low	Consider factors relating to: • infectivity and infectiousness, e.g. mode of transmission, length of incubation period, period of communicability, reproductive rate, size of susceptible population and likely number of cases. • If food product implicated, distribution and consumption. • If vector-borne disease, presence and population density of competent vectors. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles in a non-immune population, multiple cases of dysentery in a preschool nursery, and epidemic of influenza in an army camp.				
3. Is this threat unusual or unexpected? **Categorisation as:** Yes/no Where disease would not occur in population/group 'NO' option should be chosen.	• Consider, for example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. • Examples include novel anthrax in IDUs; indigenous rabies in a non-endemic country.				
4. What is the risk of international spread? **Categorisation as:** High/low	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles outbreak at international scout jamboree; emergence of a novel influenza strain with pandemic potential.				

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
5. Is it likely to cause severe disease in this population/group? **Categorisation as:** Yes/no	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of high likelihood for severe disease include those with long-term sequelae and/or high CASE FATALITY RATIO, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.				
6. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** Yes/no	• Consider: effective treatment, prophylaxis and whether logistics are in place to deliver. • Examples of effective treatment and control measures include those where the intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemoprophylaxis for close family contacts of meningococcal disease.				
Are there contextual factors that may affect the risk assessment? **Categorisation as:** Yes/no Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider public perception, media interest, political/economic issues, special circumstances (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).				

Figure 1: Single algorithm combining probability and impact resulting in single overall risk level (option 1)

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.



** Depends on exposure, infectiousness, susceptibility of population.*

*** For example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. Where disease would not occur in population group, 'No' option should be chosen.*

**** Depends on availability of routes of introduction/spread, exposure, population susceptibility, infectiousness.*

3.7.4 Table for option 2 (separate algorithms for probability and impact)

Table 2: Information table for rapid risk assessment to support risk-ranking algorithm (option 2: separate algorithms for probability and impact)

Rapid risk assessment, option 2: separate algorithms for probability and impact To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: **Risk being assessed:** **Date of rapid risk assessment:** DD/MM/YYYY **Scope of rapid risk assessment:** **Summary of incident:**	**Probability =** **Impact =** (Refer to assessment risk ranking tools: Figure 2, parts A and B) **Outcome of risk assessment:** (Refer to risk matrix: Figure 2, part C)
	Confidence: (Good/satisfactory/unsatisfactory)

Question/parameter	**Parameters to consider**	**Evidence for categorisation**	**Source of evidence (Checklist 3)**	**Quality of evidence**	**Comments (including gaps, doubts and uncertainties)**
1. Are there specific groups at increased risk of infection? **Categorisation as:** Yes/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).				
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt choose higher level.					
Probability of infection (likelihood of transmission) in the Member State: part A-1					
2. Is further human exposure likely? **Categorisation as:** Yes/no	• Consider factors relating to: infectivity and infectiousness, e.g. mode of transmission, length of incubation period. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.				
3. Is the population highly susceptible? **Categorisation as:** Yes/no	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain; or hepatitis A in an unvaccinated community in a non-endemic country.				
4. Is this disease highly infectious? **Categorisation as:** Yes/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza, chickenpox.				

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Probability of infection (likelihood of transmission) within the EU: part A-2					
5. Are there routes of introduction/spread into other Member States? **Categorisation as:** Yes/no	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Routes of introduction may include humans, animals (bird/insect vectors), food or other trade products.				
6. Is human exposure likely in other Member States? **Categorisation as:** Yes/no	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Examples include widely distributed and consumed food products; or a vector-borne disease with a high population density of competent vectors.				
7. Is the population in other Member States highly susceptible? **Categorisation as:** Yes/no	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.				
8. Is this disease highly infectious? **Categorisation as:** Yes/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza, chickenpox.				
Impact (severity of disease in population/group)					
9. Is disease likely to cause severe disease in this population/group? **Categorisation as:** Yes/no	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.				

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
10. Will a significant number of people be affected? **Categorisation as:** Yes/no	• Consider: specific risk groups, direct and indirect risk, mode of transmission, reproductive rate, size of susceptible population and likely number of cases. • Examples include diseases where large numbers are exposed and infected, e.g. a novel influenza strain, or chickenpox in a non-immune population.				
11. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** Yes/no	• Consider: effective treatment, prophylaxis and whether logistics in place to deliver. • Examples of effective treatment and control measures include those where the intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemoprophylaxis for close family contacts of meningococcal disease.				
Are there contextual factors that may affect the risk assessment? **Categorisation as:** Yes/no Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider public perception, media interest, political/economic issues, special circumstances (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).				

3.7.5 Figures for option 2 (separate algorithms for probability and impact, with risk matrix)

Figure 2.1a: Part A-1: probability of infection/likelihood of transmission) in the Member States; for use by national assessment teams

Please refer to the questions in information table 2 (option 2).

Question 1
If there are specific groups at increased risk of infection (question 1 in table 2 answered with YES), please conduct separate risk assessments: one for the general population and one for every risk group.

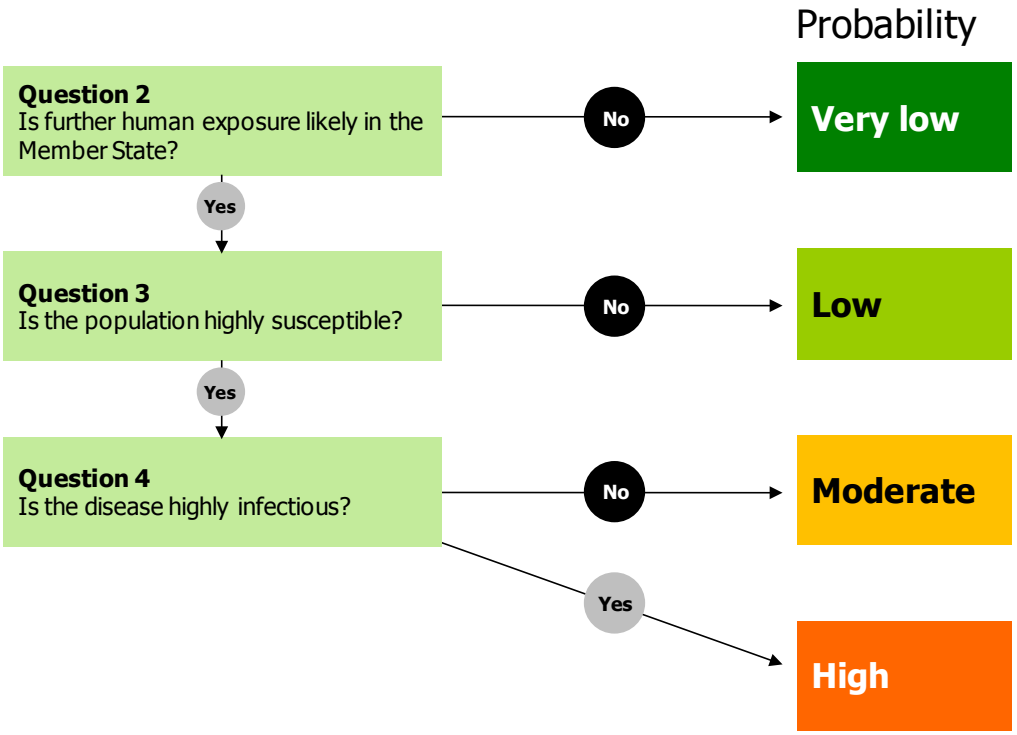


Figure 2.1b: Part A-2: probability of infection/likelihood of transmission in the EU; for use by European-level assessment teams

Please refer to the questions in information table 2 (option 2).

If there are specific groups at increased risk of infection (question 1 in table 2 answered with YES), please conduct separate risk assessments: one for the general population and one for every risk group.

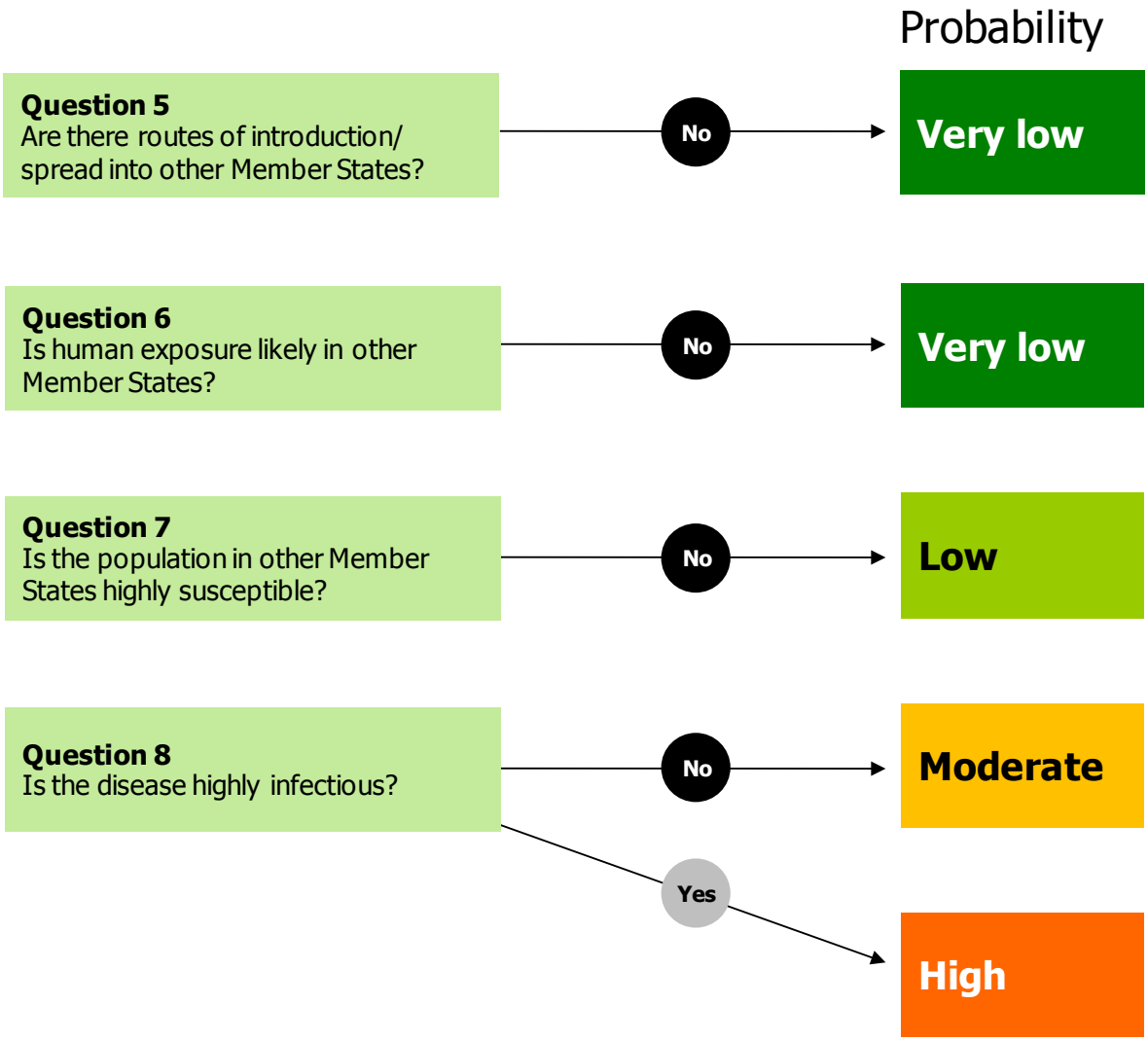


Figure 2.2: Part B: impact (severity of disease in population/group)

Please refer to the questions in information table 2 (option 2).

If there are specific groups at increased risk of infection (question 1 in table 2 answered with YES), conduct separate risk assessments: one for the general population and one for every risk group.

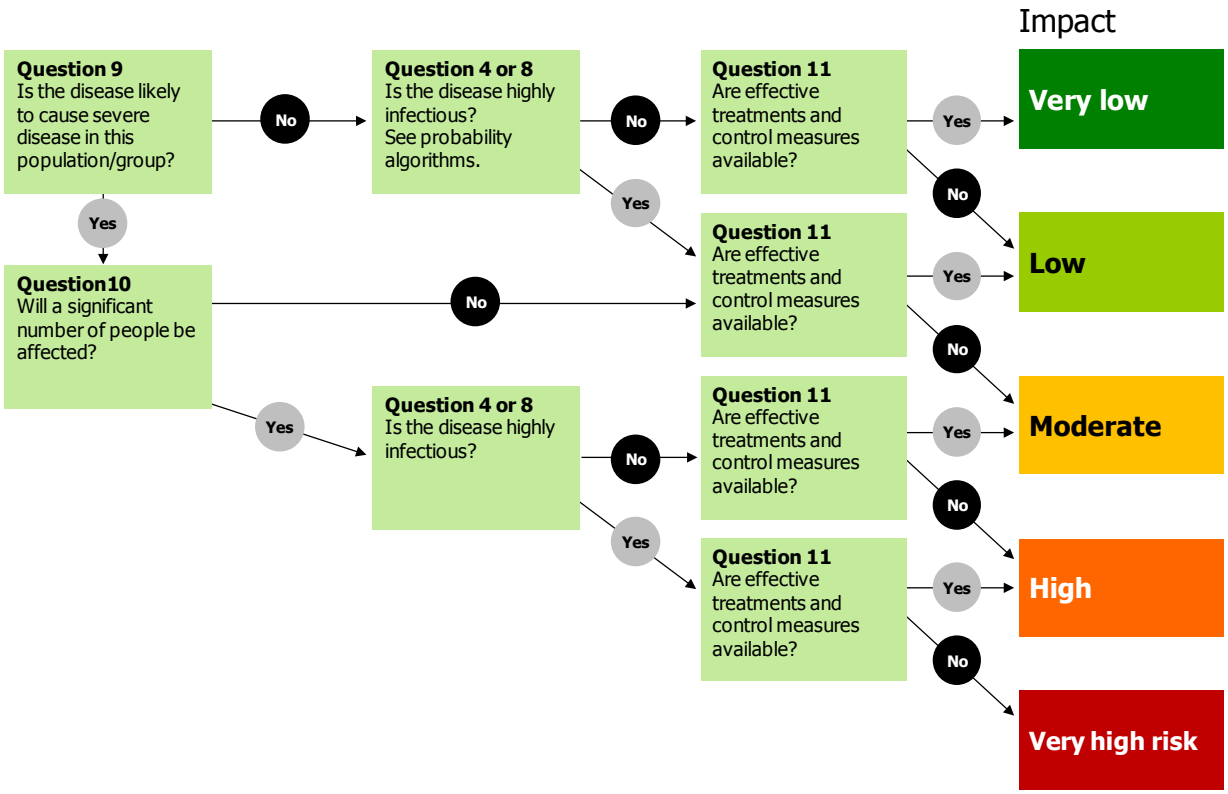


Figure 2.3: Part C: risk matrix

Probability (part A) x impact (part B) = risk (part C)

Impact \ Probability	Very low	Low	Moderate	High
Very low	Very low risk	Low risk	Low risk	Moderate risk
Low	Low risk	Low risk	Moderate risk	Moderate risk
Moderate	Low risk	Moderate risk	Moderate risk	High risk
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk

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Appendix 1. Definitions of terms

Epidemic intelligence
The process to detect, verify, analyse, assess and investigate public health events that may represent a threat to public health. It encompasses activities related to early warning functions, integrating event and indicator-based surveillance, but also signal assessments and outbreak investigation. Providing early warning signals is a main objective of public health surveillance systems.

Event-based surveillance
The organised and rapid capture of information about events that are a potential risk to public health. Information can be rumours and other ad hoc reports transmitted through formal channels (i.e. established routine reporting systems) and informal channels (i.e. media, health workers and nongovernmental organisations reports).

Evidence-based medicine (EBM)
EBM is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.

Evidence-based practice (EBP)
EBP advocates that clinical decisions should be based on the best available evidence and emphasises well-conducted systematic research to inform decisions.

Hazard
Anything with the potential to cause harm. Note: The presence of a hazard does not automatically imply a threat.

Horizon scanning
The detection of incidents/events of potential threat to public health, via systematic review of informal and formal reports.

Indicator-based surveillance
The routine reporting of cases of disease including notifications of disease, sentinel surveillance, laboratory-based surveillance, syndromic surveillance.

Incident
A single case of a serious unusual illness is of concern for public health but since this cannot be technically termed an outbreak it is instead referred to as an incident.

Outbreak
Said to occur where (i) the number of cases observed is greater than the number expected over a given time period, or (ii) two or more cases are linked by epidemiological, toxicological, microbiological, or radiological features.

Public health threat
The occurrence of a hazard to human health.

Prevention
Measures aimed at reducing the likelihood of event occurrence.

Preparedness
Measures aimed at reducing impact of event occurrence.

Response
Measures aimed at mitigating the public health impact resulting from the occurrence of an event.

Risk
Combination of the consequences (impact) of an event or incident (hazard/threat) and the associated likelihood (probability) of a harmful effect to individuals or populations.

Risk assessment
The overall process of risk identification, risk analysis, and risk evaluation.

Risk identification
The process of finding, recognising and describing risks.

Risk analysis
The process to comprehend the nature of the risk and determine the level of risk.

Risk evaluation
The process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable.

Risk communication
The interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and perceptions among assessors, managers, communicators, the general public and other interested parties (OIE definition).

Risk management
The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Threat
A potentially damaging event or incident.

Validation
To confirm the authenticity of an event or incident when reported by an informal source (professional communication, media blogs). Formal communication from national authorities is considered to be already validated.

Appendix 2. Evidence-based medicine (EBM)

'EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research' [Sackett *et al* 1996]. It has become increasingly used in clinical management and is the standard approach when it comes to provide sound recommendations and guidelines. Until recently, EBM has not been adapted for use in public health.

EBM for public health integrates the 'best available evidence with knowledge and considered judgements from stakeholders and experts to benefit the needs of a population' [ECDC 2010]. Critical appraisal is a 'method of assessing and interpreting evidence by systematically considering its validity, results and relevance to the area of work considered' [Belsey 2009] and is an essential component of public health assessment.

Grading of Recommendations Assessment, Development and Evaluation (GRADE)

The GRADE system for rating quality of evidence and strength of recommendations is explicit, comprehensive, transparent and pragmatic, and widely used internationally. GRADE makes a clear distinction between quality of evidence and strength of recommendation, and therefore confidence in that assessment.

Quality of evidence is assessed as high, moderate, low and very low, depending on the study design type and inherent limitations and biases. Strength of recommendation is classified as strong or weak, based on the balance between desirable and undesirable effects; quality of evidence; values and preferences and costs. See http://www.gradeworkinggroup.org/index.htm.

Scottish Intercollegiate Guidelines Network (SIGN)

The SIGN methodology complies with the criteria used by the Appraisal of Guidelines for Research and Evaluation in Europe (AGREE http://www.agreetrust.org/) and was established to identify good quality guidelines. SIGN produces guidelines that are essentially the direct product of systematic reviews. Levels of evidence are graded from level 1++ which includes: high-quality meta-analyses; systematic reviews of randomised controlled trials (RCTs); or RCTs with a very low risk of bias to level 4, which includes expert opinion. Grades of recommendations are assessed from A to D, based on the level of evidence, e.g. A= at least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or* a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results http://www.sign.ac.uk/.

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)

STROBE developed recommendations on what should be included in an accurate and complete report of an observational study [von Elm *et al.* 2007]. The recommendations cover three main study designs: cohort, case-control and cross-sectional. There is a checklist of 22 items (18 of which are common to all three study designs) that are considered essential for good reporting of observational studies. However, STROBE was not developed as a tool for assessing the quality of published observational research.

ATTRACT

ATTRACT is hosted by Public Health Wales and is a web-based service designed to provide evidence-based answers to specific questions posed by clinicians within six hours if necessary. The process comprises a rapid search for evidence (using a hierarchy of sources), appraisal and a summary response. A scoring system (strong, moderate, weak) is used to rate the search, the appraisal and confidence in the summary answer.

Appendix 3. Sources[1] for identifying outbreaks and obtaining disease information

Source	Website	Useful for outbreaks	Useful for disease information	Comments (advantages and limitations)
General				
Textbooks, e.g. Heymann	-	X	✓	Disease information for key parameters (may not be state of the art but good for a first overview)
EBM sources	Cochrane library http://www.thecochranelibrary.com National Guideline Clearing House http://www.guideline.gov/ Trip database http://www.tripdatabase.com/ NICE http://www.nice.org.uk/ NHS evidence http://www.evidence.nhs.uk/default.aspx Bandolier http://www.medicine.ox.ac.uk/bandolier/ ClinicalTrials http://clinicaltrials.gov/ Canadian Medical Association Infobase http://www.cma.ca/ Guidelines International Network http://www.g-i-n.net/ Scottish Intercollegiate Guidelines Network http://www.sign.ac.uk/	X	✓	• Evidence-based clinical guidelines and knowledge – good for checking what is already available. • Accessibility may vary. • Particularly good for intervention studies.
Peer-reviewed infectious disease journals (examples)	Lancet/Lancet Infectious Diseases, Clinical Infectious Diseases, Journal of Infectious Diseases, Journal of Clinical Microbiology, Nature, Science, PLoS One/Pathogens Veterinary Record http://veterinaryrecord.bvapublications.com Emerging Infectious Diseases http://www.cdc.gov/ncidod/EID/index.htm	(✓)	✓	• Publication bias • Not all freely accessible
PubMed (Medline)	http://www.ncbi.nlm.nih.gov/sites/entrez	(✓)	✓	• Citations database: abstracts from more than 4000 biomedical journals published in USA and 70 other countries. • Over 10 million citations dating from 1950's to present. • Though coverage is worldwide most records are from English-language sources.
ProMED	http://www.promedmail.org/	✓	✓	• Includes outbreak reports and disease information • Moderated • Specific versions for southeast Asia, Russia, Japan and Africa (French and English speaking)
Cidrap	http://www.cidrap.umn.edu/index.html	X	✓	US based; news and disease information good for BT and influenza.
GIDEON	http://www.gideononline.com/	X	✓	Not public; subscription required.

[1] The sources in this section are examples and not comprehensive.

Source	Website	Useful for outbreaks	Useful for disease information	Comments (advantages and limitations)
New York Academy of Medicine	http://www.nyam.org/library/online-resources/grey-literature-report/	X	✓	Useful source of information for grey literature.
Webcrawlers				
European media monitor (medical information system)	http://medusa.jrc.it/medisys/helsinkiedition/all/home.html	✓	X	Unmoderated so need to sift through information carefully.
Healthmap	http://www.healthmap.org/en	✓	X	• US equivalent includes maps • Unmoderated, so same caveat applies
European resources				
ECDC website	http://www.ecdc.europa.eu/en/pages/home.aspx	?	✓	Disease information, e.g. fact sheets
Eurosurveillance weekly	http://www.eurosurveillance.org	✓	✓	• Outbreak reports and features • Weekly so reasonably timely
Episouth	http://www.episouth.org/	✓	?	Contains some country reports that are not in Eurosurveillance.
Epi North	http://www.epinorth.org/	✓	?	
WHO resources				
World Health Organization disease outbreak news	http://www.who.int/csr/don/en/	✓	✓	• Includes outbreak reports and disease information • Less timely than ProMED • Limited disease spectrum
World Health Organization media centre	http://www.who.int/mediacentre/en/	X	✓	Disease factsheets
WHO Weekly Epidemiological Record	http://www.who.int/wer/en/	✓	✓	Weekly journal, includes outbreak reports and disease information.
WHO regional offices	http://www.searo.who.int/ http://www.wpro.who.int/ http://www.afro.who.int/index.html http://www.euro.who.int/ http://www.emro.who.int/ Http://new.paho.org/	(✓)	(✓)	More specific regional information
Country-specific information; examples are given below. See also country-specific MoH and public health websites which may include: surveillance data (national/European/international/historic/baseline); vaccination coverage; epidemiological information; microbiological information (e.g. PulseNet); travel medicine (mobility/travel information); resource availability; climate/habitat data.				
Canada				
Health Canada	http://www.phac-aspc.gc.ca/index-eng.php	✓	X	
Public Health Agency Canada, weekly report	http://www.phac-aspc.gc.ca/ccdrw-rmtch/index-eng.php	✓	X	
South Africa				
NICD communiqué (South Africa)	http://www.nicd.ac.za/pubs/communique/communique.htm	✓	X	
UK				
HPR weekly	http://www.hpa.org.uk/hpr/	✓	X	Outbreaks and surveillance data
USA				
CDC Morbidity & Mortality Weekly Report	http://www.cdc.gov/mmwr/	✓	✓	US-focused but also contains information on larger international incidents.
CDC Health Alerts	http://www2a.cdc.gov/han/archivesys/	✓	X	
Zoonotic disease	(Member State's veterinarian data)			
OIE	http://www.oie.int	✓	✓	Information on animal outbreaks, distribution of zoonotic disease, etc.
OIE alerts	http://www.oie.int/eng/info/en_urgences.htm	✓	X	
OIE wahid	http://www.oie.int/wahis/public.php?page=home	✓	X	

Source	Website	Useful for outbreaks	Useful for disease information	Comments (advantages and limitations)
Other sources, for example:				
Reuters Foundation AlertNet	http://www.alertnet.org/	(✓)	X	
Relief web	http://www.reliefweb.int/rw/dbc.nsf/doc100?OpenForm	(✓)	X	
Specific NGOs like Merlin and MSF	-	✓	?	Helpful when following up on outbreaks.
Emerging health threats forum	http://eht-forum.org/	✓	?	
Google	Link differs for each localised version of the Google search algorithms, e.g. http://www.google.co.uk/	(✓)	(✓)	Reliability?
Online media	• Examples from UK: BBC, Guardian, Independent, The Times, etc. • Member States to insert their own examples.	(✓)	X	Reliability?

Appendix 4. Estimating the risk: worked example – Q fever risk for EU during an outbreak in NL (general population)

Option 1: Single algorithm combining probability and impact resulting in single overall risk level

Table 1: Information table for rapid risk assessment to support risk-ranking algorithm (option 1: single algorithm)

Rapid risk assessment, option 1: single algorithm To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Q fever in NL **Risk being assessed:** Risk of spread within EU **Date of rapid risk assessment:** 2009 **Scope of rapid risk assessment:** Risk to EU general population **Summary of incident:** Large increase in human Q fever cases reported. Approximately 2300 cases between 2007 and Dec 2009 (previously 20/year), most in Noord Brabant province. [Ref: RIVM website, outbreak report published in Eurosurveillance]	**Outcome of risk assessment:** • **Low** risk in general population in the EU (Refer to assessment risk ranking tool: Figure 1) **Confidence:** Good (Good/satisfactory/unsatisfactory)

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as: Yes**/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	• General population susceptible – most infections sub-clinical. Usually self- limiting flu-like illness or atypical pneumonia. • Risk groups: pregnant women – abortion, chronic infections in those with underlying cardiac disease, pregnancy or immuno-suppression.	Heymann/ textbooks	Good	Risk from blood transfusion unclear
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt, choose higher level.					

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps and uncertainties)
2. What is the potential for transmission within the Member State? **Categorisation as:** High/**low**	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, length of incubation period, period of communicability, reproductive rate, size of susceptible population and likely number of cases. • If food product implicated, distribution and consumption • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles in a non-immune population, multiple cases of dysentery in a pre-school nursery, and epidemic of influenza in an army camp.	• Infection usually follows inhalation of aerosol, also direct contact with infected animals and birth products, sometimes raw milk. • Incubation: 3-30 days (usually 2-3 weeks). • Previous large outbreaks associated with density of farming and animal populations, and proximity to residential areas. • No person-to-person spread. • Susceptibility general, immunity may be life-long.	• Heymann/textbooks • Published outbreak reports	Good	
3. Is this threat unusual or unexpected? **Categorisation as: Yes**/no Where disease would not occur in population/group 'No' option should be chosen.	• Consider for example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. • Examples include, novel anthrax in IDUs, indigenous rabies in non-endemic country.	• Large increase in human Q fever cases reported. • Approximately 2300 cases between 2007 and Dec 2009 (previously 20/year), most in Noord Brabant province	• RIVM website • Published outbreak report	Good	

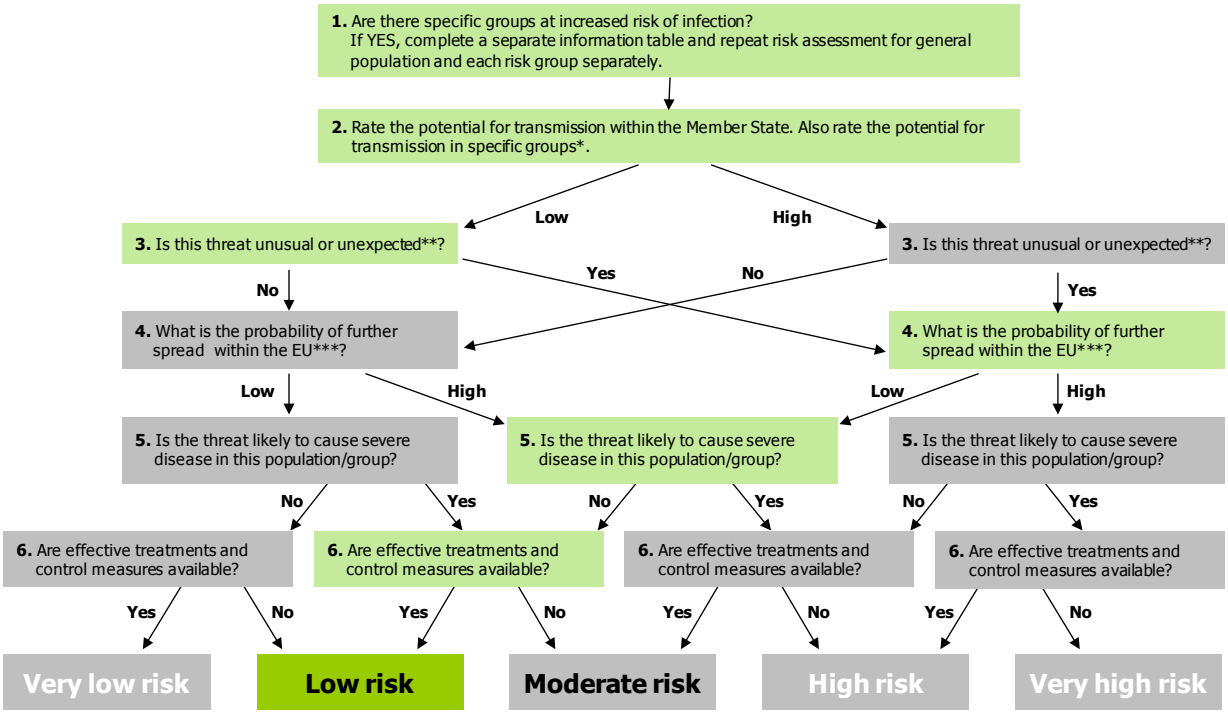
Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps and uncertainties)
4. What is the risk of international spread? **Categorisation as:** High/**low**	• Consider: infectivity and infectiousness, availability of route of introduction/ spread, size of susceptible population and likely number of cases. • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new case and potential for large outbreak, e.g. measles outbreak at international scout jamboree; emergence of a novel influenza strain with pandemic potential.	• Previous large outbreaks associated with density of farming and animal populations, and proximity to residential areas. • Evidence that epidemiological link between some clusters and farms with abortion waves. • No increase in Q fever cases in other EU countries, as they do not use similar farming practices. Unique features of NL animal husbandry mean unlikely to occur elsewhere.	• Published outbreak reports • ECDC epidemio-logical report • Opinion of national expert group	Satisfactory	
5. Is it likely to cause severe disease in this population/group? **Categorisation as:** Yes/**no**	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of high likelihood for severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.	• Most infections subclinical, only 2% of those infected admitted to hospital. • Usually self-limiting flu-like illness or atypical pneumonia. • Chronic infections in those with underlying cardiac disease, pregnancy, immuno-suppression.	Heymann/ textbooks	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps and uncertainties)
6. Are effective control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as: Yes**/no	• Consider: effective treatment, prophylaxis and whether logistics in place to deliver. • Examples of effective treatment and control measures include those where the intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemo-prophylaxis for close family contacts of meningococcal disease.	• Antibiotics effective and well tolerated but must be adapted to individual circumstances. • Effective vaccine exists but limited by high reactogenicity in sensitive individuals.	Heymann/ textbooks	Good	• Who should receive prophylaxis? • How long to continue treatment? • Use of vaccine?
Are there contextual factors that may affect the threat assessment? **Categorisation as:** **Yes**/no Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider: public perception, media interest, political/economic issues, special circumstances to consider (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).		• Dutch media reports Government and expert groups	Unsatisfactory	Significant interest in Dutch media and political/economic concern.

Figure 1. Q fever risk for EU during an outbreak in NL (general population)

Please refer to information table above.

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.



** Depends on exposure, infectiousness, susceptibility of population.*

*** For example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. Where disease would not occur in population group, 'No' option should be chosen.*

**** Depends on availability of routes of introduction/spread, exposure, population susceptibility, infectiousness.*

Option 2: Separate algorithms for probability and impact, with risk matrix

Table 2: Information table for rapid risk assessment to support risk-ranking algorithm (option 2: separate algorithms for probability and impact)

Rapid risk assessment, option 2: separate algorithms for probability and impact To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Q fever in NL **Risk being assessed:** Risk of spread **Date of rapid risk assessment:** 2009 **Scope of rapid risk assessment:** Risk to general population **Summary of incident:** Large increase in human Q fever cases reported. Approximately 2300 cases between 2007 and Dec 2009 (previously 20/year), most in Noord Brabant province. [Ref: RIVM website, Q-koorts, http://www.rivm.nl/cib/infectieziekten-A-Z/infectieziekten/Q_koorts/FAQ_Q-koorts.jsp] Schimmer B, Morroy G, Dijkstra F, Schneeberger PM, Weers-Pothoff G, Timen A, et al. Large ongoing Q fever outbreak in the south of The Netherlands, 2008. Euro Surveill. 2008;13(31):pii=18939. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=18939	**Probability** = Low for general population in Member State = Very low for general population in EU **Impact** = Very low (Refer to assessment risk ranking tools: Figure 2, parts A and B) **Outcome of risk assessment:** • Low x very low = **low risk** in Member State's general population • Very low x very low = **very low risk** in EU general population (Refer to risk matrix: Figure 2, part C) **Confidence:** Good (Good/satisfactory/unsatisfactory)

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as: Yes**/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	• General population susceptible; most infections sub-clinical. Usually self- limiting flu-like illness or atypical pneumonia. • Risk groups: pregnant women – abortion, chronic infections in those with underlying cardiac disease, pregnancy or immuno-suppression.	Heymann/ textbooks	Good	Risk from blood transfusion?
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. For categorisation: if in doubt go for the higher level.					

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Probability of infection (likelihood of transmission) in the Member State: part A-1					
2. Is further human exposure likely? **Categorisation as: Yes**/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, length of incubation period. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	• Infection usually follows inhalation of aerosol, also direct contact with infected animals and birth products, sometimes raw milk. • Incubation: 3-30 days (usually 2-3 weeks). • Previous large outbreaks associated with density of farming and animal populations, and proximity to residential areas. • No person-to-person spread.	• Textbooks/ Heymann • Published outbreak reports	Good	
3. Is the population highly susceptible? **Categorisation as:** Yes/**no**	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.	• General population susceptible; most infections sub-clinical. • Susceptibility general, immunity may be life-long.	Heymann/ textbooks	Good	
4. Is this disease highly infectious? **Categorisation as:** Yes/**no**	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza, chickenpox.	• Infection usually follows inhalation of aerosol, also direct contact with infected animals and birth products, sometimes raw milk • No person-to-person spread.	Heymann/ textbooks	Good	
Probability of infection (likelihood of transmission) in the EU – part A-2					
5. Are there routes of introduction/ spread into other Member States? **Categorisation as:** Yes/**no**	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Routes of introduction may include humans, animals (bird/insect vectors), food or other trade products.	No increase in Q fever cases in other EU countries, as they do not use similar farming practices. Unique features of NL animal husbandry mean unlikely to occur elsewhere.	• Published outbreak reports • ECDC epidemio-logical report • Opinion of national expert group	Satisfactory	Potential for localised spread to adjacent areas of neighbouring countries, but not more widely.

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
6. Is human exposure likely in other Member States? **Categorisation as:** Yes/**no**	• Consider: infectivity and infectiousness, availability of route of introduction/ spread, size of susceptible population and likely number of cases. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	• Previous large outbreaks associated with density of farming and animal populations, and proximity to residential areas. • Evidence that epidemio-logical link between some clusters and farms with abortion waves.	• Published outbreak reports • ECDC epidemio-logical report • Opinion of national expert group	Satisfactory	Very localised exposure possible in areas bordering NL but not more widely.
7. Is the population in other Member States highly susceptible? **Categorisation as:** Yes/**no**	• Consider cases the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.	• General population susceptible; most infections sub-clinical. Susceptibility general, immunity may be life-long. • Large increase in human Q fever cases reported. Approximately 2300 between 2007 and Dec 2009 (previously 20/year) most in Noord Brabant province. However, no increase in Q fever cases in other EU countries. Unique features of NL animal husbandry mean unlikely to occur elsewhere.	• Heymann/ textbooks • RIVM website • Published outbreak report • ECDC epidemio-logical report • Opinion of national expert group	Good	
8. Is this disease highly infectious? **Categorisation as:** Yes/**no**	Consider factors relating to infectivity +infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. Examples include, measles, influenza, chickenpox.	• Infection usually follows inhalation of aerosol, also direct contact with infected animals + birth products, sometimes raw milk • No person-to-person spread.	Heymann/ textbooks	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Impact (severity of disease in population/group)					
9. Is disease likely to cause severe disease in this population/group? **Categorisation as:** Yes/**no**	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.	• Most infections subclinical only 2% of those infected admitted to hospital. • Usually self-limiting flu like illness or atypical pneumonia. • Chronic infections in those with underlying cardiac disease, pregnancy, immuno-suppression.	Heymann/ textbooks	Good	
10. Will a significant number of people be affected? **Categorisation as:** Yes/**no**	• Consider: specific risk groups, direct and indirect risk, mode of transmission, reproductive rate, size of susceptible population and likely number of cases. • Examples include diseases where large numbers are exposed and infected, e.g. a novel influenza strain, or chickenpox in a non-immune population.	• Infection usually follows inhalation of aerosol, also direct contact with infected animals and birth products, sometimes raw milk. • No person-to-person spread. • Although general population susceptible, exposure unlikely unless resident in proximity to one of the affected farms.	• Heymann/ textbooks • Published outbreak reports • ECDC epidemio-logical report	Good	
11. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as: Yes**/no	• Consider: effective treatment, prophylaxis and whether logistics in place to deliver. • Examples of effective control measures include those that show clear benefits and are relatively easy to implement, e.g. withdrawal of contaminated food products in closed institutions; chemoprophylaxis for close family contacts of meningococcal disease.	• Antibiotics effective and well-tolerated but must be adapted to individual circumstances. • Effective vaccine exists but limited by high reactogenicity in sensitive individuals.	Heymann/ textbooks	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
12. Are there contextual factors that may affect the risk assessment? **Categorisation as: Yes**/no Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider public perception, media interest, political/economic issues, special circumstances (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).		• Dutch media reports • Government and expert groups	Unsatisfactory	

Figure 2.1a: Part A-1: probability of infection in a Member State connected to Q fever outbreak in NL (likelihood of transmission)

Please refer to information table 2 above (option 2).

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.

Question 1
Are there specific groups at increased risk of infection?
YES. Example shown is for the general population (risk assessment should be conducted separately for each risk group).

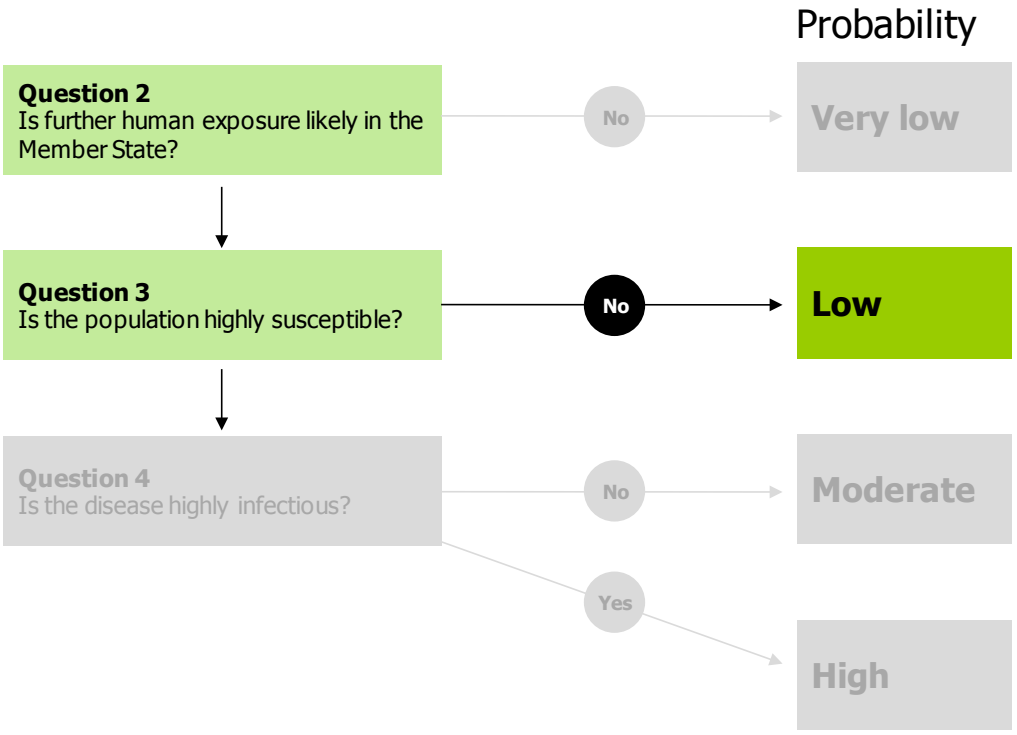


Figure 2.1b: Part A-2: probability of Q fever infection/likelihood of transmission in the EU

Please refer to the questions in information table 2 (option 2):

Question 1
Are there specific groups at increased risk of infection?
YES. Example shown is for the general population (risk assessment should be conducted separately for each risk group).

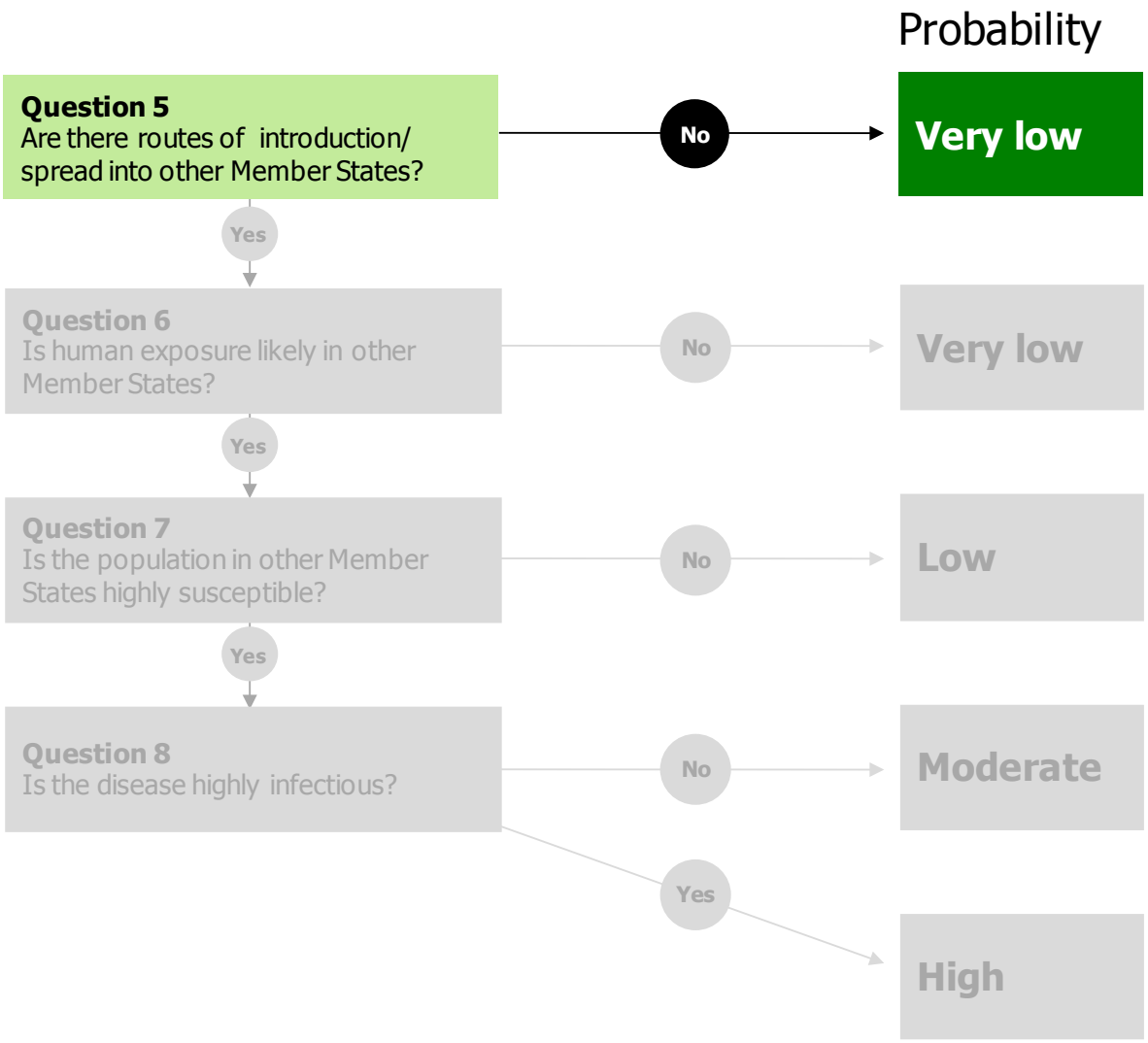


Figure 2.2: Part B: impact of Q fever outbreak in NL (severity of disease in population/group)

Please refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
YES. Example shown is for the general population (risk assessment should be conducted separately for each risk group).

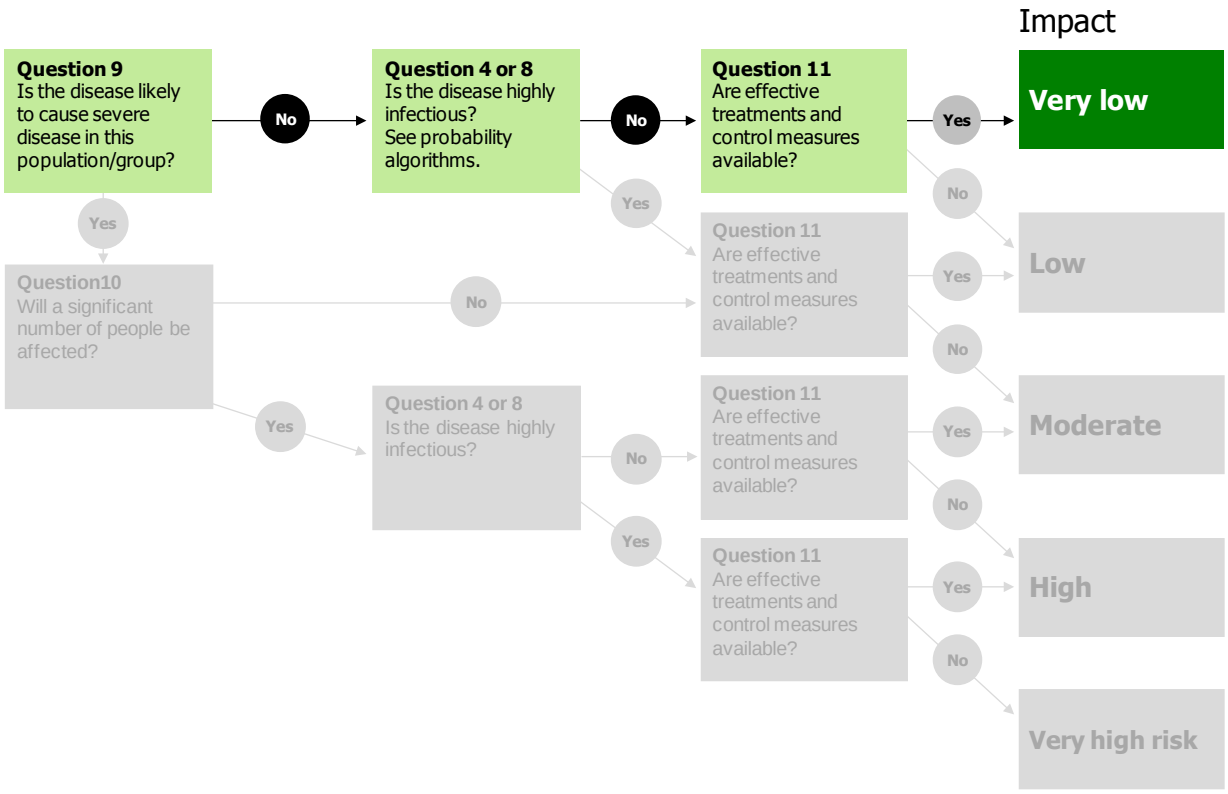


Figure 2.3: Part C: risk matrix

Probability (part A) x impact (part B) = risk (part C)

Probability / Impact	Very low	Low	Moderate	High
Very low	Very low risk[1]	Low risk[2]	Low risk	Moderate risk
Low	Low risk	Low risk	Moderate risk	Moderate risk
Moderate	Low risk	Moderate risk	Moderate risk	High risk
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk

[1] *Overall threat level of Q fever outbreak in the Netherlands for Member States: low x very low = low risk*

[2] *Overall threat level of Q fever outbreak in the Netherlands for EU: very low x very low = very low risk*

Appendix 5: Algorithm testing, evaluation and application

The following four reports on outbreaks from Austria, Scotland, Italy and Bulgaria were sent to participating experts. The experts were asked to complete information tables using only the supplied information. The information tables were then used as a basis for completing the algorithms and determining the risk posed by each scenario for different population groups.

Suggestions from the group discussions were incorporated into the final information tables and algorithms – both options have been retained as preferences varied. The outcome for a particular scenario or population group was in all cases almost identical or very similar, regardless of who did the assessment or which options were used.

Indicative worked examples are shown using option 1 for the first two scenarios, and option 2 for scenarios 3 and 4.

Real-world application #1: Listeria outbreak in Austria

Disease background information

Listeriosis is an acute infectious disease caused by the Gram-positive, non-spore-forming bacterium *Listeria monocytogenes*. Because the bacteria are ubiquitous in the environment they can cause infection at every stage of the 'farm to fork' continuum. The bacteria are able to grow at temperatures ranging from 0° C to 45° C and tend to persist in the environment. Listeriosis is a zoonotic disease, and the environment is considered the main reservoir for contamination of food. While transmission from infected animals to humans has been described, it is mainly transmitted via the consumption of contaminated food. The most common sources of *L. monocytogenes* include raw and processed meat, dairy products, vegetables and seafood products. Ready-to-eat food items that are consumed without prior cooking are of special concern for public health because of the ability of the bacteria to grow at refrigeration temperatures.

After exposure (via contaminated food) most healthy adults do not develop symptoms. However, known risk groups for developing severe disease include pregnant women, newborns, elderly and immuno-compromised persons. After an incubation period of three weeks (up to 70 days), pregnant women may suffer from a self-limiting influenza-like illness which may have serious consequences on the foetus (e.g. foetal death/abortion or congenital listeriosis). In addition, listeriosis in adults with a weakened immune system and in the elderly may lead to meningitis, brain infection, and severe bloodstream infection. All clinical presentations are treatable with prolonged courses of antibiotics, but the prognosis of the most serious ones is poor.

Outbreaks of listeriosis have been reported worldwide. In 2007, 1 635 confirmed cases were reported by the 27 EU Member States and EEA countries, with an overall case fatality of 20%, mainly in older people. The majority of reported listeriosis cases were over 64 years of age. A seasonal trend was recognised, with a peak between July and October, and another clear peak in January.

Control measures are aimed at food-processing level, in order to prevent contamination of food products. Preventive measures include providing appropriate information to consumers on how to minimise the risk of ingesting contaminated food.

Event background information

On 20 January 2010, Austria reported 14 cases of listeriosis, including two in Germany, having occurred between June and December 2009; four of these were fatal (two in Austria and two in Germany). The median age of the Austrian cases was 75 years (range 61–88).

Eleven of the twelve Austrian cases were men, and most (11/12) had underlying diseases, including diabetes, myeloma, leukaemia, kidney diseases.

Epidemiological and microbiological investigations indicated a sour milk cream cheese produced in Austria and locally known as *'Quargel'* as the vehicle. The cheese is produced exclusively for a retail chain which has outlets in several European countries. The product was also exported to the Czech Republic, Germany and Slovakia.

In response to this outbreak, the company recalled the incriminated cheese from the market (RASFF notification, 22 January 2010). The company informed the media about the recall on 23 January 2010. Additionally, for those that may have already acquired the incriminated product, public awareness was increased by information issued by the Austrian Ministry of Health and the Austrian Agency for Health and Food Safety (www.bmg.gv.at,

www.ages.at). Consequently, the retail chain that sold the implicated cheese in Germany issued a press statement to inform the public and initiated the recall of the product.

As of 26 January 2010, no further cases have been confirmed in the EU.

A RASFF notification identifying the incriminated products was issued. The cheese was distributed through various distribution channels and under different product names. Already before this notification, the company had recalled the product. Additionally, any already produced cheese was checked for *Listeria* before release on the market. The national food safety authorities were monitoring the effectiveness of the recall. The shelf life of the product is two months, and bacteria grow even at refrigerating temperatures.

Table 1: Information table for rapid risk assessment to support risk-ranking algorithm (option 1: single algorithm)

Rapid risk assessment, option 1: single algorithm To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Listeria outbreak in Austria **Risk being assessed:** Risk of new infections through contaminated product **Date of rapid risk assessment:** 2010 **Scope of rapid risk assessment:** **Summary of incident:** 14 cases/4 deaths were linked to consumption of 'Quargel' cream cheese in Germany and Austria. The majority of cases were elderly persons with underlying health problems.	**Outcome of risk assessment:** (Refer to assessment risk ranking tool: Figure 1) • For the general population: **low risk** • For vulnerable groups: **moderate risk** **Confidence:** Good (Good/satisfactory/unsatisfactory)

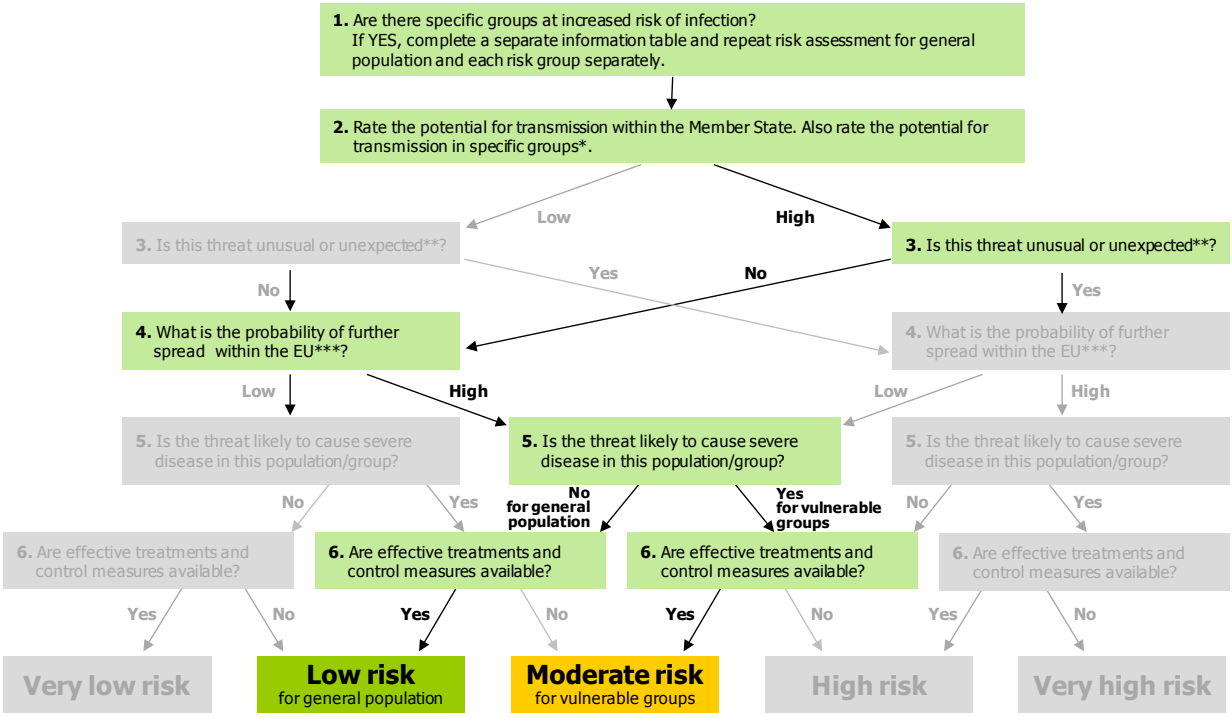
Question/parameter	**Parameters to consider**	**Evidence for categorisation**	**Source of evidence (Checklist 3)**	**Quality of evidence**	**Comments (including gaps, doubts and uncertainties)**
1. Are there specific groups at increased risk of infection? **Categorisation as: Yes**/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	General population Vulnerable groups, including pregnant women (foetus), new born, elderly and immuno-compromised	Well documented risk factors Textbooks, peer-reviewed studies	Good	Risk highest in those that eat 'Quargel' and don't adhere to recommended control measures.
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. For categorisation: if in doubt go for the higher level.					
2. What is the potential for transmission within the Member State? **Categorisation as: High/low**	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, length of incubation period, period of communicability, reproductive rate, size of susceptible population and likely number of cases. • If food product implicated, distribution and consumption • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles in a non-immune population, multiple cases of dysentery in a pre-school nursery, and epidemic of influenza in an army camp.	Most don't get symptoms (healthy). Known risk-contaminated food, especially ready to eat items. Geographically limited distribution of specialised product 'Quargel' (sour milk). If recall unsuccessful – traceability dependent.	Textbooks, outbreak reports	Good	'Quargel' popular in certain countries as 'healthy' food.

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
3. Is this threat unusual or unexpected? **Categorisation as:** Yes/no Where disease would not occur in population group, 'No' option should be chosen.	Consider for example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. Examples include, novel anthrax in IDUs, indigenous rabies in non-endemic country.	Outbreaks relatively common – associated with foods. Good data.	ECDC epi report, EFSA outbreak reports	Good	
4. What is the risk of international spread? **Categorisation as: High/low**	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new case and potential for large outbreak, e.g. measles outbreak at international scout jamboree; emergence of a novel influenza strain with pandemic potential.	Limited distribution of product from one specific retail chain around Europe. Different product names used in different countries. Recall may fail or not occur in other Member States.	Details from manufacturer	Satisfactory	Find out more about distribution. High risk in certain countries.
5. Is it likely to cause severe disease in this population/group? **Categorisation as:** **No** for general population **Yes** for vulnerable groups	Consider: morbidity, mortality, case fatality, complications and burden of disease. Examples of high likelihood for severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDRTB, diphtheria, polio	Asymptomatic disease in most healthy adults but in adults with weakened immune system and in the elderly may lead to meningitis and septicaemia. Pregnant women may have self-limiting flu-like illness but high risk of foetal death or congenital infection. In 2007 – 1635 confirmed cases in EU. 20% cfr mainly in elderly.	Textbooks, case reports	Good	
6. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** **Yes**/no	Consider: effective treatment, prophylaxis and whether logistics in place to deliver. Examples of effective treatment and control measures include those where the intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemo-prophylaxis for close family contacts of meningococcal disease.	Food control/recall of product/shelf-life of product 2months – publicity. More difficult to get product back from individuals refrigerators despite publicity. Ensure hospitals/healthcare aware so can treat elderly/immuno-compromised properly.	EFSA, RASSF, public information online	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Are there contextual factors that may affect the risk assessment? **Categorisation as: Yes/no** Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	Consider: public perception, media interest, political/economic issues, special circumstances to consider (e.g. mass gathering, tourism). Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).				

Figure 1: Single algorithm combining probability and impact resulting in single overall risk level (option 1)

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.



** Depends on exposure, infectiousness, susceptibility of population*

*** For example – unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. Where disease would not occur in population group, 'No' option should be chosen.*

**** Depends on availability of routes of introduction/spread, exposure, population susceptibility, infectiousness*

Real-world application #2: Anthrax outbreak in drug users, Scotland

Disease background information

Anthrax is an acute infectious disease caused by the Gram-positive spore-forming bacterium *Bacillus anthracis*. Anthrax most commonly occurs in wild and domestic animals like cattle, sheep, goats, camels, and is endemic in a number of mostly agricultural countries in South- and Central America, southern and eastern Europe, Asia, Africa, the Caribbean, and the Middle East. In most industrialised countries, anthrax is a rare disease, and infection in humans is usually due to occupational exposure to infected animals or animal products.

Anthrax infection can occur in three forms: cutaneous (about 95% of all cases), pulmonary with severe atypical pneumonia, and gastrointestinal. Symptoms of disease vary depending on how the disease was contracted. The incubation period is usually 1 to 7 days, but can be prolonged to up to 60 days. Untreated, the case fatality rates range from 5 to 20% in cutaneous anthrax, or to more than 85% in pulmonary and gastrointestinal anthrax. Antibiotic treatment is effective and can prevent most deaths in cutaneous cases; however, mortality in pulmonary and gastrointestinal cases remains high even with treatment.

B. anthracis spores can live in the soil for many years, and humans can become infected with anthrax by handling products from infected animals or by inhaling anthrax spores from contaminated animal products. Anthrax infection can also be acquired by eating undercooked meat from infected animals, or, as has been reported, by injecting contaminated drugs. The risk of person-to-person transmission is extremely low.

B. anthracis is listed as Category A pathogen in the list of bioterrorism agents of the US CDC, and belongs to the group of 'very high threat' agents of the EU, as the deliberate release of spores may also lead to infection in humans.

Event background information

On 18 December 2009, the UK issued an EWRS message reporting an outbreak of anthrax among injection drug users (IDU) in Scotland. Two cases from Glasgow, one of them fatal, had been confirmed as having anthrax infections, and three additional possible cases were under investigation. Both confirmed cases developed illness in the first week of December.

On 21 December 2009, HPA Scotland updated the information and reported three confirmed cases (one of them fatal), one probable case, and four additional possible cases with clinical pictures compatible with anthrax infection. Six men and two women between 26 and 44 years of age from Glasgow and surrounding areas were afflicted. They developed symptoms between 7 and 20 December 2009. The cases were linked by heroin usage, either injecting (seven cases, reporting no needle-sharing) or smoking (one possible case, who has developed severe atypical pneumonia).

In Scotland and England information was sent out to hospitals, GPs, emergency departments, microbiologists, and drug teams to raise awareness and request that cases of injecting drugs user with severe soft tissue infection or sepsis requiring hospital admission are reported to local public health authorities.

Anthrax surveillance in Scotland is based on voluntary laboratory reports. Only one case of anthrax has been reported in Scotland since 1987: in 2006, a person who made drums from animal hides contracted the disease.

The European early warning network of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) was been alerted to support surveillance efforts in order to detect possible additional cases in other European countries.

The frequent occurrence of skin and soft tissue infections in injection drug users is a well-known phenomenon, even though anthrax is a rare cause, and few cases have been described so far.

Table 1: Information table for rapid risk assessment to support risk-ranking algorithm (option 1: single algorithm)

Rapid risk assessment, option 1: single algorithm To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Anthrax outbreak in drug users, Scotland **Risk being assessed:** Risk of continuing transmission and further infections **Date of rapid risk assessment:** 2009 **Scope of rapid risk assessment:** **Summary of incident:** In Scotland, eight cases of anthrax (six male, two female) including one death; all associated with heroin use (seven injecting, one smoking).	**Outcome of risk assessment:** (Refer to assessment risk ranking tool: Figure 1) • For the general population: **very low risk** • For heroin users: **very high risk** **Confidence:** Good (Good/satisfactory/unsatisfactory)

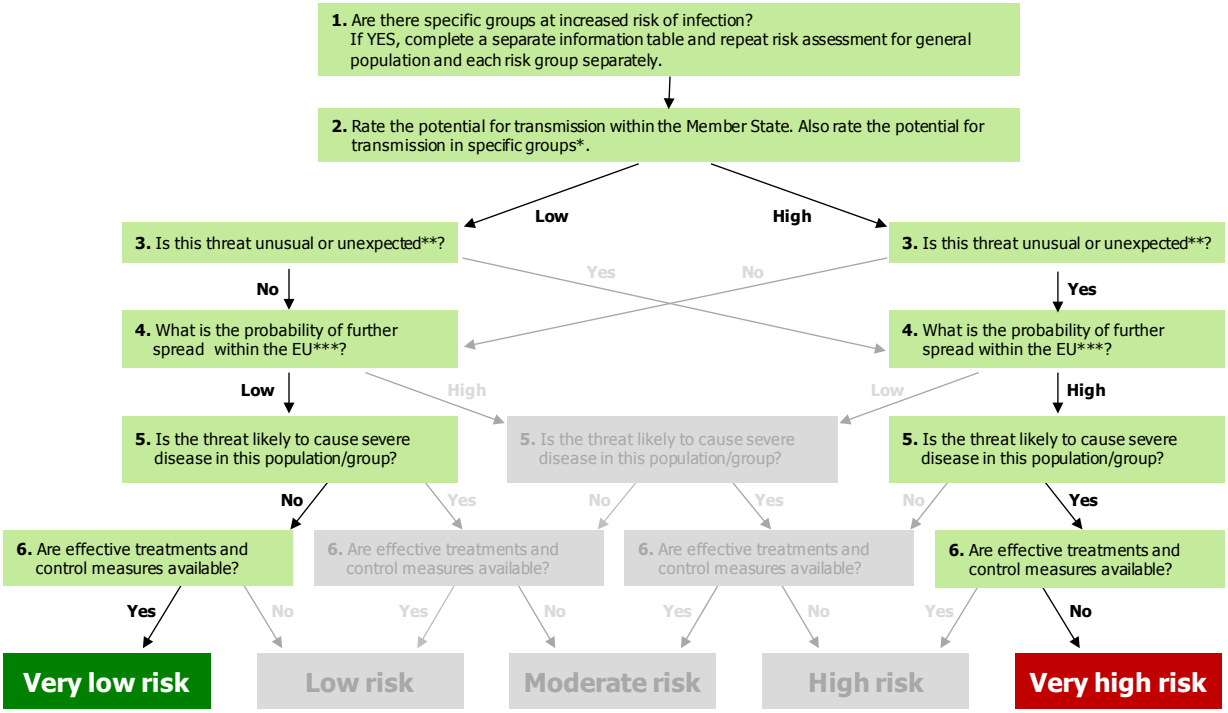
Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as:** **Yes**/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	• General population • Heroin users (eight cases/one death – all heroin users)	• Case reports • Outbreak reports	Satisfactory	Specific risk groups – IV, skin popping, smoking (?)
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt choose higher level.					
2. What is the potential for transmission within the Member State? **Categorisation as:** **Low** in general population **High** in heroin users	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, length of incubation period, period of communicability, reproductive rate, size of susceptible population and likely number of cases. • If food product implicated, distribution and consumption. • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles in a non-immune population, multiple cases of dysentery in a pre-school nursery, and epidemic of influenza in an army camp.	Known risks • Handling products from infected animals/inhaling spores from contaminated animal products. • Last case in Scotland in drum maker (animal skins). • Can be acquired by eating undercooked meat from infected animals • Has been reported by injecting contaminated drugs. • Person-to-person transmission extremely rare. • Usually requires large infectious dose.	Textbooks, analytical studies	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
3. Is this threat unusual or unexpected? **Categorisation as:** **No** – no exposure therefore would not be seen or expected in this group **Yes** in heroin users Where disease would not occur in population group, 'No' option should be chosen.	• Consider for example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. • Examples include novel anthrax in IDUs; indigenous rabies in a non-endemic country.	• BT agent. Category A. • Novel presentation. • Very rare disease in industrialised countries.	Only one previous case report	Satisfactory	
4. What is the risk of international spread? **Categorisation as:** **Low** in general population **High** in heroin users	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • If vector-borne disease, presence and population density of competent vector. • Examples of high potential for transmission include diseases with high likelihood of spread with many new cases and potential for large outbreak, e.g. measles outbreak at international scout jamboree; emergence of a novel influenza strain with pandemic potential.	• Heroin distribution widespread. • Environmental contamination.	Textbooks, UK zoonoses report	Good	Better surveillance – if contaminated product or certain production practices
5. Is it likely to cause severe disease in this population/group? **Categorisation as:** **No** for general population **Yes** for heroin users	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of high likelihood for severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.	High mortality. Case fatality ratio up to 85% in pulmonary and gastrointestinal anthrax mortality high, even with treatment. Case fatality ratio 5–20% in cutaneous anthrax – antibiotic treatment is effective.	Textbooks, case reports	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
6. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** **Yes** for general population – avoidance of drug taking **No** for heroin users	• Consider: effective treatment, prophylaxis and whether logistics in place to deliver. • Examples of effective treatment and control measures include those where the intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemo-prophylaxis for close family contacts of meningococcal disease.	Treatment needs to be given early for pulmonary form; treatment is effective for cutaneous form.	Textbooks	Good	Though unknown for this novel form of anthrax?
Are there contextual factors that may affect the risk assessment? **Categorisation as:** **No** for general population **Yes** for heroin users Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider: public perception, media interest, political/economic issues, special circumstances to consider (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).	• BT agent, but only in drug users. • Illegal context			

Figure 1: Single algorithm combining probability and impact resulting in single overall risk level (option 1)

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.



** Depends on exposure, infectiousness, susceptibility of population.*

*** For example: unusual disease, setting, affected population group, increase in disease above expected threshold, appearance of a previously unreported disease. Where disease would not occur in population group, 'No' option should be chosen.*

**** Depends on availability of routes of introduction/spread, exposure, population susceptibility, infectiousness.*

Real-world application #3: Chikungunya outbreak in Italy

Event background information

- In July 2007, local health authorities of the province of Ravenna, Region Emilia-Romagna, Italy, detected an unusually high number of cases of febrile illness near Castiglione di Cervia. By 31 August 2007, Italy had reported 135 cases of chikungunya infection. Of those, 27 cases were laboratory confirmed (21 through antibodies, six through PCR), including one death in an 83-year-old man with underlying conditions.
- Onset of symptoms of first case on 4 July 2007 (different from index case; see below); onset of symptoms of last case on 28 August 2007; peak of the epidemic between 17 and 19 August.
- All but four cases originated in two small villages near Castiglione di Cervia, Italy (combined population below 4000). The villages are separated by a river. The four remaining cases are from the province of Ravenna.
- Suspected index case was an Indian national from the Indian state of Kerala, who became symptomatic on 23 June 2007.
- A surveillance system of general physicians was set up in the entire province of Ravenna: daily calls to report the number of cases seen. Case definition used: high fever and joint pain and/or rash and/or asthenia.
- Outside the province of Ravenna: routine surveillance activities.
- Implemented control measures included disinsectation and disinfestation in public sites (using permethrin and antilarval products) as well as health education. A protocol on how to measure the efficacy of the control measures was implemented.
- *Aedes albopictus* is the most likely vector for this outbreak, but other species might act as a vector as well.
- *Aedes albopictus* is present in at least 12 European countries: Albania, Italy, France, Belgium, Montenegro, Switzerland, Greece, Spain, Croatia, the Netherlands, Slovenia, and Bosnia-Herzegovina.
- Climate conditions were favourable for the vector.
- The affected area (two small villages) is not a tourist area. However, the greater area is popular with Italian and international tourists. Also, the area has a high number of seasonal workers from abroad.

Table for option 2 (separate algorithms for probability and impact, with risk matrix)

Table 2: Information table for rapid risk assessment to support risk-ranking algorithm (option 2: separate algorithms for probability and impact)

Rapid risk assessment, option 2: separate algorithms for probability and impact To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Chikungunya outbreak in Italy **Risk being assessed:** Risk of spread in EU **Date of rapid risk assessment:** 2007 **Scope of rapid risk assessment:** **Summary of incident:** 135 cases of chikungunya in Italy: 27 confirmed, one death (elderly man with underlying disease). Majority of cases from two small villages in the province of Ravenna. Suspected index case travelled from the Indian state of Kerala, where chikungunya is endemic. *Aedes albopictus* most likely vector.	**Probability (Member States)** = Moderate **Probability (EU)** = Moderate **Impact** = Low (Refer to assessment risk ranking tools: Figure 2, parts A and B) **Outcome of risk assessment:** • Moderate x low = **moderate risk** (Member States general population) • Moderate x low = **moderate risk** (EU general population) (Refer to risk matrix: Figure 2, part C)
	Confidence: Satisfactory (Good/satisfactory/unsatisfactory)

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as: Yes/no**	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	General population only	Textbooks, observational studies	Good	Specific groups with increased risk of more sever outcome? Find out more about blood transfusion?
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt choose higher level.					
Probability of infection (likelihood of transmission) in the Member State: part A-1					
2. Is further human exposure likely? **Categorisation as: Yes**/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, length of incubation period. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	• Presence or density of suitable disease vector – known distribution • Vector-borne from infected cases	• Textbooks, publications in peer-reviewed journals • Reunion outbreak	Good	Depends on distribution and density of *Aedes albopictus*
3. Is the population highly susceptible? **Categorisation as: Yes**/no	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain; or hepatitis A in an unvaccinated community in a non-endemic country.	• Transmission unusual • Known distribution of vector • Population susceptible	• Textbooks, publications in peer-reviewed journals • Reunion outbreak	Good	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
4. Is this disease highly infectious? **Categorisation as:** Yes/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza, chickenpox.	• Vector-borne from infected cases. • Limited by vector and seasons. • Not highly infectious – person required to be viraemic at time of mosquito biting.	Textbooks, case reports, observational studies	Satisfactory	
Probability of infection (likelihood of transmission) within the EU: part A-2					
5. Are there routes of introduction/spread into other EU Member States? **Categorisation as: Yes**/no	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Routes of introduction may include humans, animals (bird/insect vectors), food or other trade products.	• *Aedes albopictus* widespread: present in at least 12 European countries. • Establishment of disease depends on competent vectors and favourable climate conditions.	Textbooks, case, observational studies	Satisfactory	Risk depends on distribution and density of *Aedes albopictus* in other Member States.
6. Is human exposure likely in other MS? **Categorisation as: Yes**/no	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	• Not highly infectious. • Risk depends on distribution and population density of *Aedes albopictus* in other Member States.	Textbooks, observational studies, outbreak reports	Satisfactory	
7. Is the population in other Member States highly susceptible? **Categorisation as: Yes**/no	• Consider cases the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.	• Transmission unusual • Known distribution of vector • Population susceptible	• Textbooks • Reunion outbreak	Good	
8. Is this disease highly infectious? **Categorisation as:** Yes/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include, measles, influenza, chickenpox.	• Vector-borne from infected cases • Limited by vector and seasons • Not highly infectious: person is required to be viraemic at the time of the mosquito bite.	Textbooks, observational studies	Satisfactory	

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Impact (severity of disease in population/group)					
9. Is disease likely to cause severe disease in this population/group? **Categorisation as:** Yes/no	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.	• Low case fatality ratio • Some chronic sequelae	Textbooks, case reports	Satisfactory	
10. Will a significant number of people be affected? **Categorisation as: Yes**/no	• Consider: specific risk groups, direct and indirect risk, mode of transmission, reproductive rate, size of susceptible population and likely number of cases. • Examples include diseases where large numbers are exposed and infected, e.g. a novel influenza strain, or chickenpox in a non-immune population.	• General population • Person required to be viraemic at the time of the mosquito bite	Textbooks, observational studies	Satisfactory	Dependent on vector distribution and density.
11. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** Yes/no	• Consider: effective treatment, prophylaxis and whether logistics are in place to deliver. • Examples of effective control measures include those that show clear benefits and are relatively easy to implement, e.g. withdrawal of contaminated food products in closed institutions; chemoprophylaxis for close family contacts of meningococcal disease.	• Vector control • Nets/spraying; Difficult to achieve results.	Textbooks, observational studies	Satisfactory	Quality of evidence for effectiveness of control measures unsatisfactory.

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Are there contextual factors that may affect the risk assessment? **Categorisation as: Yes**/no Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider public perception, media interest, political/economic issues, special circumstances (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. the emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).	• New disease in region – public anxiety • Seasonality of vector	Textbooks, expert opinion	Satisfactory	

Figures for option 2 (separate algorithms for probability and impact, with risk matrix)

The use of two separate algorithms for probability of infection (part A-1 in Member States or part A-2 in EU) and impact (part B) allows for a more detailed assessment. The overall threat level can be obtained by using the risk matrix (part C).

Figure 2.1a: Part A-1: probability of infection/likelihood of transmission in the Member States

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.

Please refer to questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
No, general population only.

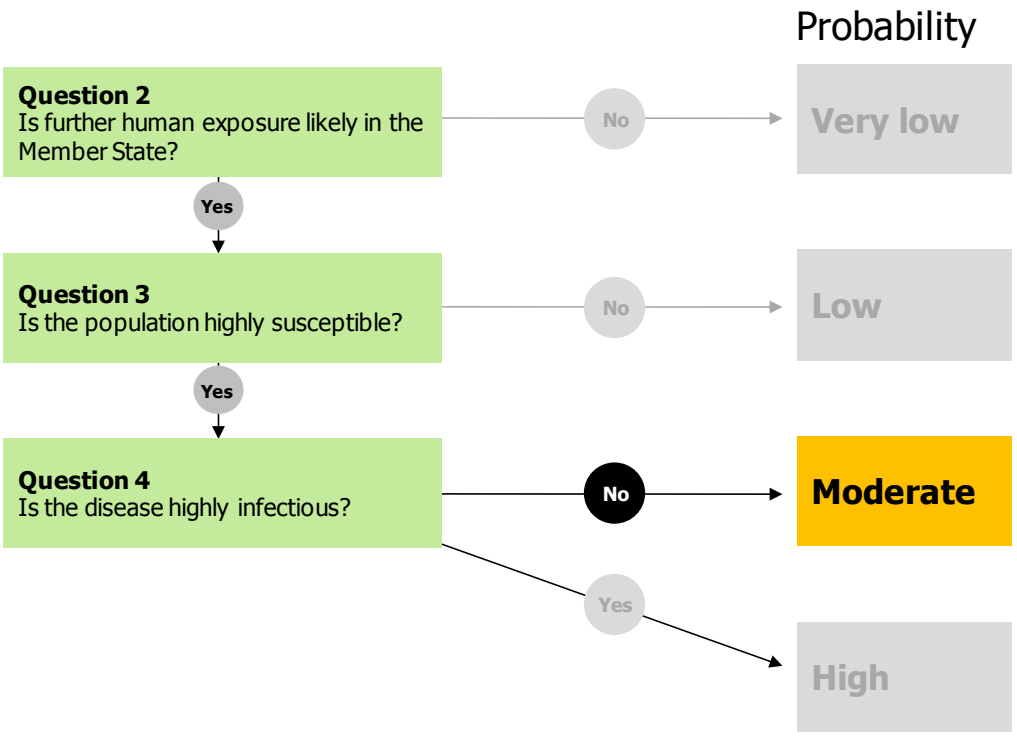


Figure 2.1b: Part A-2: probability of infection/likelihood of transmission in the EU

If in doubt (e.g. due to insufficient evidence), select the higher-risk option.

Please refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
No, general population only.

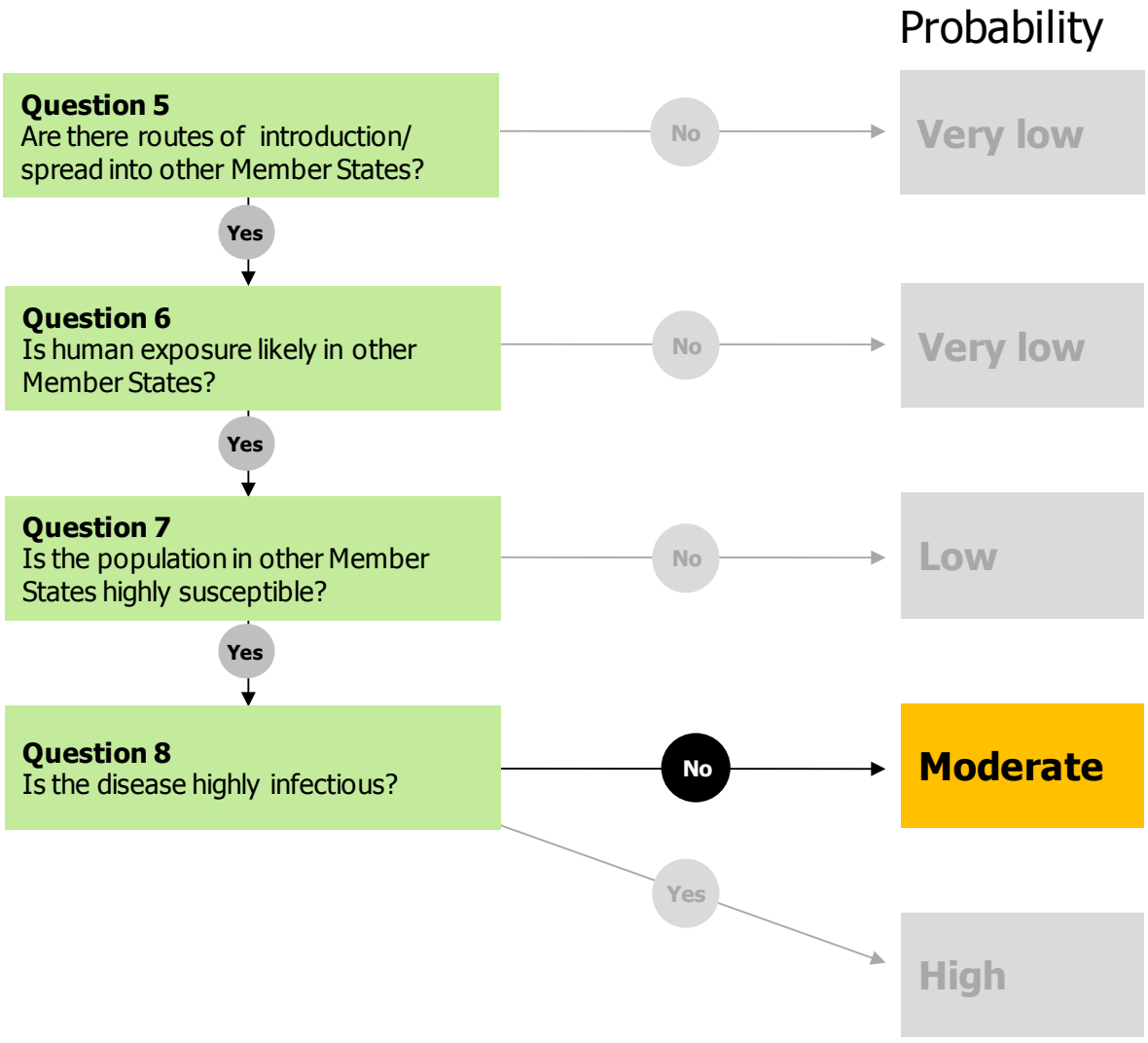


Figure 2.2: Part B: impact (severity of disease in population/group)

If in doubt (e.g. due to insufficient evidence), select the higher-risk option (indicated by cross-hatching).

Refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
No, general population only.

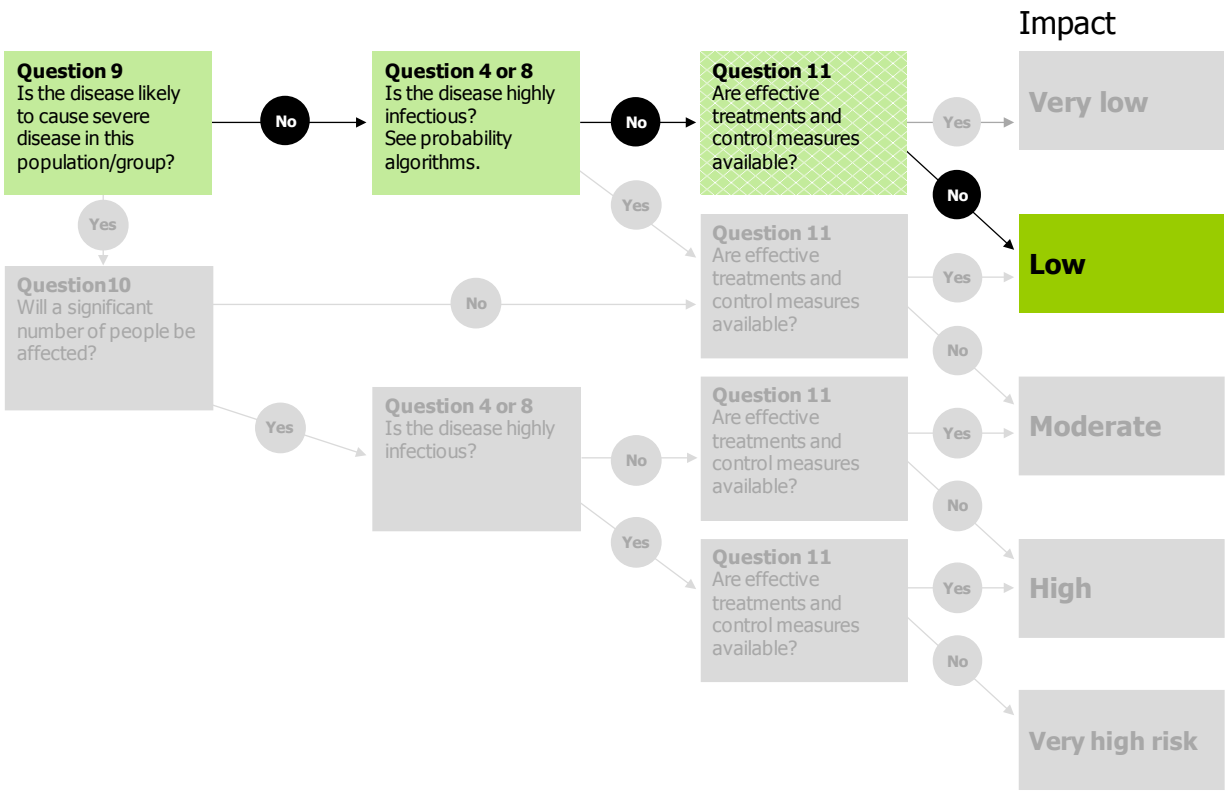


Figure 2.3: Part C: risk matrix

Probability (part A) x impact (part B) = risk (part C)

Impact \ Probability	Very low	Low	Moderate	High
Very low	Very low risk[1]	Low risk[2]	Low risk	Moderate risk
Low	Low risk	Low risk	Moderate risk	Moderate risk
Moderate	Low risk	Moderate risk	Moderate risk	High risk
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk

Real-world application #4: Measles outbreak in Bulgaria

Disease background information

Measles is a highly infectious disease and frequently results in widespread outbreaks mainly among unvaccinated individuals. Measles can be complicated by pneumonia, otitis media, laryngotracheobronchitis, and diarrhoea, which is commonly seen in young children. Acute encephalitis, which often results in permanent brain damage, occurs in approximately one of every 1,000 cases. Death, predominantly resulting from respiratory and neurologic complications, occurs in one of every 500 to 5,000 cases, as reported in recent European outbreaks. Case-fatality rates are increased in children younger than five years of age and immuno-compromised, including individuals with leukaemia, AIDS and severe malnutrition. In addition, subacute sclerosing panencephalitis (SSPE), a rare degenerative central nervous system disease characterised by behavioural and intellectual deterioration and seizures leading to rapid death may develop six to eight years post primary infection. SSPE is more common among males who acquired measles before one year of age. Incidence of SSPE is unknown but a publication from Bulgaria reports 40 cases between 1978 and 2002. The single most effective preventive measure is vaccination with two doses of trivalent measles, mumps and rubella (MMR) vaccine. Vaccine uptake of at least 95% with two doses of MMR vaccine is considered to be necessary to reach elimination. However, MMR being a live, attenuated vaccine cannot be offered to immuno-suppressed individuals and therefore all EU/EEA Member States have susceptible population in all age groups. Commitment to eliminate measles in the WHO European Region is strong. A recent publication by the Surveillance Community Network for Vaccine-Preventable Infectious Diseases (EUVAC.NET) concludes that achievement and maintenance of optimum vaccination coverage, combined with improved surveillance are the cornerstones of measles elimination in Europe.

Outbreaks have been repeatedly reported in many European countries and frequently occurred in sub-groups of populations that are prone to low vaccine coverage and then spread to the general population. Despite the goal of measles elimination set by WHO until 2010, preliminary data submitted to EUVAC.NET for 2009 (19 March 2010) reports 7 134 measles cases for 32 European countries. Of these, 6 134 occurred in the EU.

Event background information

Bulgaria

After seven years without indigenous transmission of measles, an increasing number of measles cases have been reported in Bulgaria since April 2009. The probable index case reported through EWRS on 24 April 2009, was a returning traveller from Germany to Bulgaria with onset of symptoms on 12 March 2009. Further updates on the spread within Bulgaria were distributed through EWRS on 29 December 2009 and 18 February 2010. As of 18 March 2010, the cumulative number of reported cases is 9 314 (2 249 in 2009 and 7 065 in 2010), including 15 deaths. Children and teenagers below 15 years of age are the main affected age group (72%), including children below one year of age who are not targeted for routine immunisation as the first dose of MMR is applied at the age of 13 months. Most of the cases were not immunised, and the fatal cases died within hours of admission to the hospital. Nosocomial transmission has been reported among 20 healthcare workers. In May 2009, Bulgaria launched an immunisation campaign, which targets susceptible populations. Efforts were intensified in 2010, but have not been sufficient to stop the spread of measles within and outside the country.

The current outbreak is due to growing susceptible populations in Bulgaria, including the vulnerable Roma communities, who are hard to reach by standard immunisation programmes, and is driven by multiple socioeconomic and health system factors. According to a sero-epidemiological study (ESEN 2) from residual sera in hospital laboratories collected between 2001 and 2004, the percentage of susceptible individuals in the general population by age group in Bulgaria were: 30.4% (2–4 years), 25.9% (5–9 years), 20.7% (10–19 years), 10.1% (20–39 years), and 9.0% (40+), suggesting an increased risk for further spread to the general population. The corresponding WHO age-specific targets are less than 15% at 2–4 years, less than 10% at 5–9 years and less than 5% at over 10 years of age. It is uncertain to what extent the now-affected subpopulation is represented in this serosurvey, but it seems likely that susceptibility has indeed spread to new subpopulations.

Germany

On 11 February 2010, the regional health department of Baden-Württemberg reported an imported case of measles in a 35-year-old male from a Bulgarian community who developed symptoms on 14 January 2010. He had a travel history to Bulgaria during the incubation period. His 24-year-old brother developed typical measles symptoms on 4 February. Further cases developed in household contacts (22-year-old male, infant 13 months). All cases were laboratory confirmed by development of measles-specific IgM or PCR, with a possible additional case of an asymptomatic measles re-infection in the infant's mother (IgM negative, IgG positive, PCR oral fluid positive). All adult cases reported to be unvaccinated. No measles-containing vaccine immunisation was documented for the infant. Contact tracing was conducted and information on home isolation was provided; local physicians were informed about the outbreak to induce active case finding. As of 22 March 2010, no further spread to the general population was observed.

Spain

On 17 March 2010, Spain reported eight measles cases in two regions in Spain through EWRS. The cases occurred among temporary foreign workers with high mobility living in poor conditions.

In weeks 2, 4 and 6, three cases among children of a Bulgarian community (two children aged 11 years, one 23 months) were reported. The primary case reportedly travelled to/from Bulgaria during the incubation period. All three children were unvaccinated, and two were subsequently hospitalised.

Two additional clusters were reported from another region in Spain, with two and three cases, respectively. One cluster was associated with Bulgarian citizens. The primary case of the second cluster was a 14-month-old unvaccinated Romanian child, who later was hospitalised. The child had no travel history, but a history of contact with other Romanian children who had measles. Onset of the disease was recorded in week 6. The second case in this cluster involved a 32-year-old Spanish woman with an epidemiological link to a child who showed symptoms in week 9.

The index case of the third cluster was a 15-month-old Bulgarian child with onset of symptoms in week 8. Although no travel history was reported, a possible epidemiological link with returning Bulgarian citizens who had a history of clinical symptoms compatible with measles was reported. Secondary cases occurred among household contacts in a 13-year-old girl and an 11-year-old boy (onset of symptoms in week 9). All three children were reported to have been unvaccinated. Control measures including contact tracing, vaccination and communication to the local community were implemented.

Ireland

Ireland reported in Eurosurveillance an ongoing measles outbreak since August 2009, with 320 notified cases. Nearly two thirds were reported among unvaccinated individuals. In the early stages of the outbreak, a substantial number of cases were related to the Irish Traveller community. Some cases were also among the Roma community and citizens from Eastern Europe, raising the possibility of an indirect link to the Bulgarian outbreak. However no direct link has been demonstrated. Children between one and two years of age were most affected (21%), and the majority of cases occurred in persons under 20 years of age. The Irish Traveller community is a relatively mobile population, a traditionally nomadic people of ethnic Irish origin, who maintain a separate language and set of traditions.

Table for option 2 (separate algorithms for probability and impact, with risk matrix)

Table 2: Information table for rapid risk assessment to support risk-ranking algorithm (option 2: separate algorithms for probability and impact)

Rapid risk assessment, option 2: separate algorithms for probability and impact To be completed if the evaluation of initial information necessitates a rapid risk assessment.	
Public health issue: Measles outbreak in Bulgaria **Risk being assessed:** Risk of spread **Date of rapid risk assessment:** 2009 **Scope of rapid risk assessment:** **Summary of incident:** After seven years without indigenous transmission of measles, an increasing number of measles cases have been reported in Bulgaria since April 2009. 9 314 cases including 15 deaths have been reported – the majority are children and unimmunised individuals from Roma communities.	• Probability (Member States)= **low** (general population) • Probability (EU)= **low** (general population) • Impact = **low** (general population) • Probability (Member States)= **high** (Irish travellers) • Probability (EU)= **high** (Irish travellers) • Impact = **moderate** (travellers) • Probability (Member States)= high (un-vaccinated) • Probability (EU)= **high** (unvaccinated) • Impact = **low** (unvaccinated) (Refer to assessment risk ranking tools: Figure 2, parts a and b) **Outcome of risk assessment:** **For general population:** • Low x low = **low risk** (Member States) • Low x low = **low risk** (EU) **For travellers:** • High x moderate = **moderate/high risk** (Member States) • High x moderate = **moderate/high risk** (EU) **For un-vaccinated persons:** • High x low = **moderate risk** (Member States) • High x low = **moderate risk** (EU) (Refer to risk matrix: Figure 2, part C)
	Confidence: Good (Good/satisfactory/unsatisfactory)

Question/ parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **Categorisation as: Yes**/no	Consider those with: • direct risk (e.g. occupational); • indirect risk (e.g. blood transfusion recipients); • specific risk groups (e.g. pregnant women, children).	• General population • Irish Travellers/Roma population • Other unvaccinated groups	• Textbooks, peer-reviewed references • Member States' surveillance data	Good	
Note: If specific risk groups are identified, conduct separate risk assessments: one for the general population and one for every risk group. A separate information table may be used for each population/group. Categorisation: if in doubt choose higher level.					

Question/ parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Probability of infection (likelihood of transmission) in the Member States: part A-1					
2. Is further human exposure likely? **Categorisation as:** **Yes**/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission; length of incubation period. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	Measles frequently results in widespread outbreaks, particularly among unvaccinated individuals.	Textbooks, outbreak reports	Good	
3. Is the population highly susceptible? **Categorisation as:** **1**. Yes/**no** **2. Yes**/no **3.** Yes/**no**	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.	• Outbreaks are relatively common. • Highly infectious (despite MMR coverage above 90%). • Risk groups particularly susceptible.	Textbooks, Member States' surveillance data	Good	
4. Is this disease highly infectious? **Categorisation as:** Yes/**no**	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza, chickenpox.	Highly infectious (despite MMR coverage above 90%).	Textbooks, peer-reviewed reports	Good	
Probability of infection (likelihood of transmission) within the EU: part A-2					
5. Are there routes of introduction/spread into other EU Member States? **Categorisation as:** Yes/**no**	• Consider: infectivity and infectiousness, availability of route of intro-duction/spread, size of susceptible population and likely number of cases. • Routes of introduction may include humans, animals (bird/insect vectors), food or other trade products.	Spread to Germany, Ireland, Spain, France and other Member States connected to Roma communities.	Textbooks	Good	

Question/ parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
6. Is human exposure likely in other Member States? **Categorisation as:** Yes/**no**	• Consider: infectivity and infectiousness, availability of route of introduction/spread, size of susceptible population and likely number of cases. • Examples include widely distributed and consumed food products; vector-borne disease with a high population density of competent vectors.	• Outbreaks relatively common. • Highly infectious. • This large outbreak is connected to Roma communities. • Risk groups particularly susceptible.	• Textbooks, peer-reviewed reports • Member States surveillance data	Good	
7. Is the population in other Member States highly susceptible? **Categorisation as:** **1.** Yes/**no** **2. Yes**/no **3. Yes**/no	• Consider cases the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain, or hepatitis A in an unvaccinated community in a non-endemic country.	• Outbreaks relatively common. • Highly infectious (despite MMR coverage above 90%). • High vaccine uptake in general population. • Risk groups particularly susceptible.	• Textbooks, outbreak reports • Member States surveillance data	Good	
8. Is this disease highly infectious? **Categorisation as:** **Yes**/no	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include, measles, influenza, chickenpox.	Highly infectious (despite MMR coverage above 90%).	Textbooks, outbreak reports	Good	

Question/ parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Impact (severity of disease in population/group)					
9. Is disease likely to cause severe disease in this population/group? **Categorisation as:** Yes/**no**	• Consider: morbidity, mortality, case fatality, complications and burden of disease. • Examples of severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria, polio.	• 9 000 cases/15 deaths • Children/immuno-compromised/older age/non-vaccinated • SSPE	Textbooks, peer-reviewed reports	Good	
10. Will a significant number of people be affected? **Categorisation as:** **Yes**/no	• Consider: specific risk groups, direct and indirect risk, mode of transmission, reproductive rate, size of susceptible population and likely number of cases. • Examples include diseases where large numbers are exposed and infected, e.g. a novel influenza strain, or chickenpox in a non-immune population.	Highly infectious (despite MMR coverage above 90%).	Textbooks, peer-reviewed reports	Good	
11. Are effective treatments and control measures available? Consider other factors which may affect these (feasibility, acceptability). **Categorisation as:** **1. Yes**/no **2.** Yes/**no** **3. Yes**/no	• Consider: effective treatment, prophylaxis and whether logistics are in place to deliver. • Examples of effective control measures include those that show clear benefits and are relatively easy to implement, e.g. withdrawal of contaminated food products in closed institutions; chemo-prophylaxis for close family contacts of meningococcal disease.	Vaccination	Textbooks; data on vaccine coverage	Good	Logistics: more difficult to deliver to travellers

Question/ parameter	Parameters to consider	Evidence for categorisation	Source of evidence (Checklist 3)	Quality of evidence	Comments (including gaps, doubts and uncertainties)
12. Are there contextual factors that may affect the risk assessment? **Categorisation as:** **1.** Yes/**no** **2. Yes**/no **3.** Yes/**no** Note: Context does not necessarily alter the risk in absolute terms but may alter risk perception.	• Consider public perception, media interest, political/economic issues, special circumstances (e.g. mass gathering, tourism). • Examples include situations where there is increased public concern, combined with political and emotional pressure, e.g. the emergence of a new BSE-like agent; vaccine scare with little scientific basis (e.g. MMR).	• Special groups not accepting vaccination • Irish Travellers and public perceptions • Roma gathering in spring.	Information regarding Roma/Irish Travellers	Good	

Figures for option 2 (separate algorithms for probability and impact, with risk matrix)

The use of two separate algorithms for probability of infection (part A-1 for Member States, part A-2 for EU) and impact (part B) allows for a more detailed assessment. The overall threat level can be obtained by using the risk matrix (part C).

Figure 2.1a: Part A-1: probability of infection/likelihood of transmission in the Member States

Please refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
YES. Risk assessments for general population and each risk group.

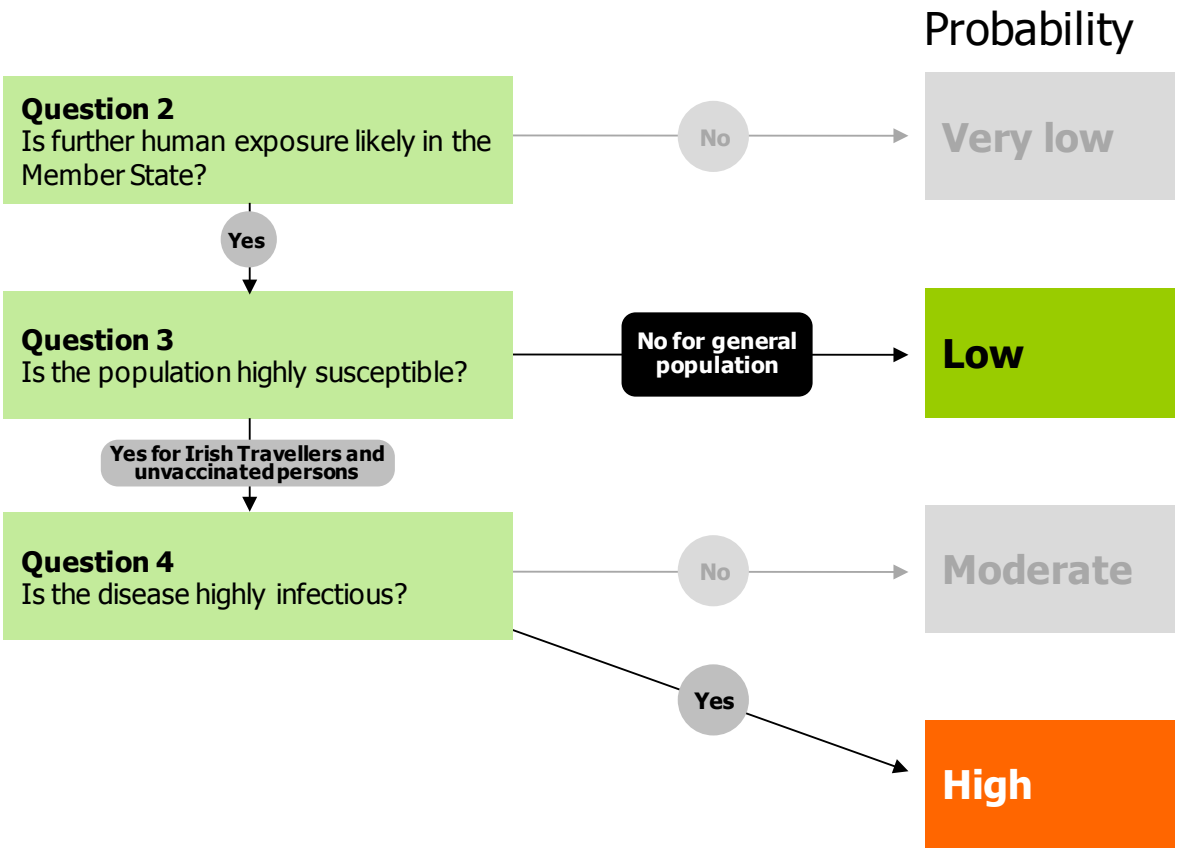


Figure 2.1b: Part A-2: probability of infection/likelihood of transmission within the EU

Please refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
YES. Risk assessment for general population and each risk group.

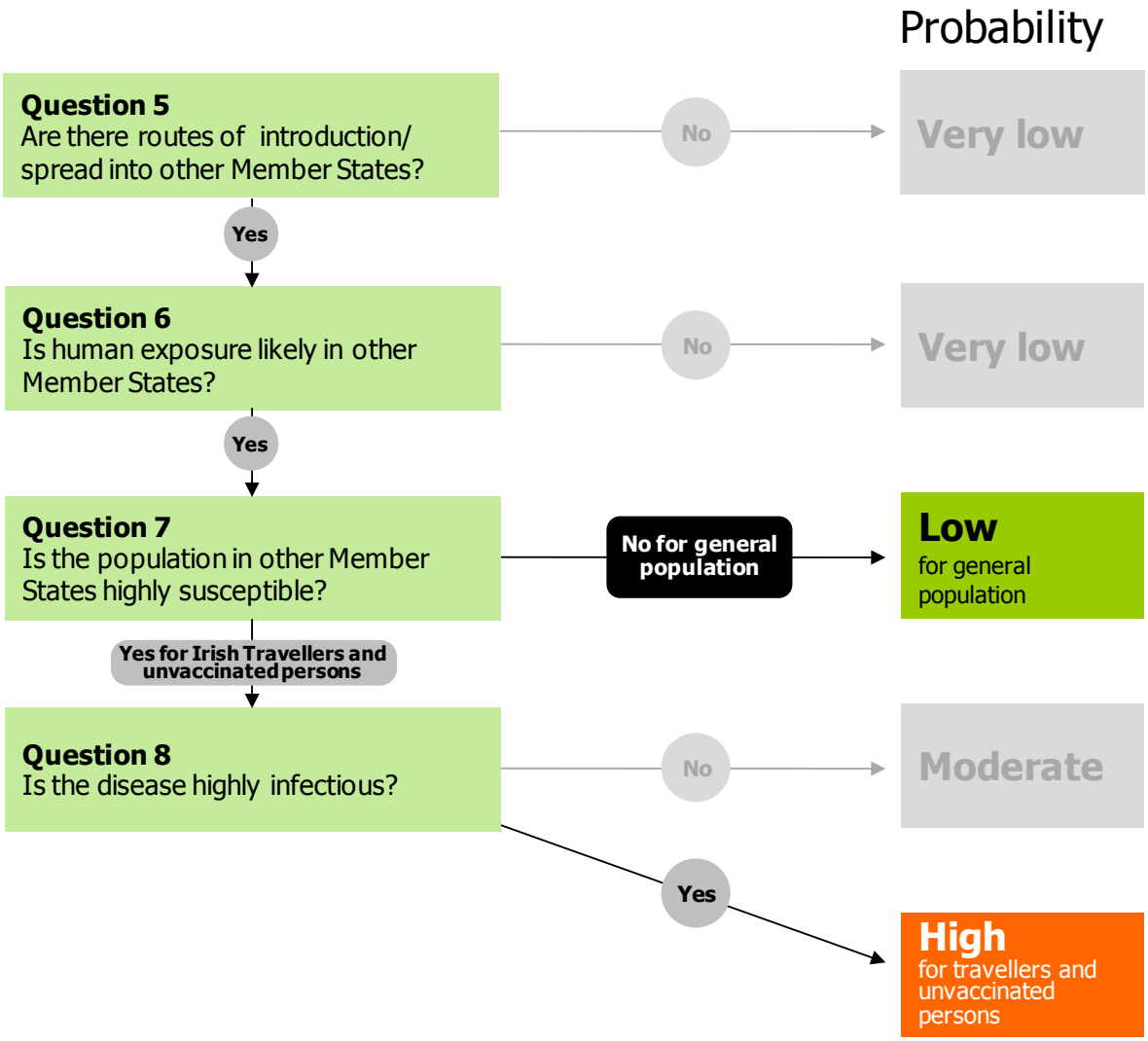


Figure 2.2: Part B: impact (severity of disease in population/group)

Please refer to the questions in the information table.

Question 1
Are there specific groups at increased risk of infection?
YES. Risk assessment for general population and each risk group.

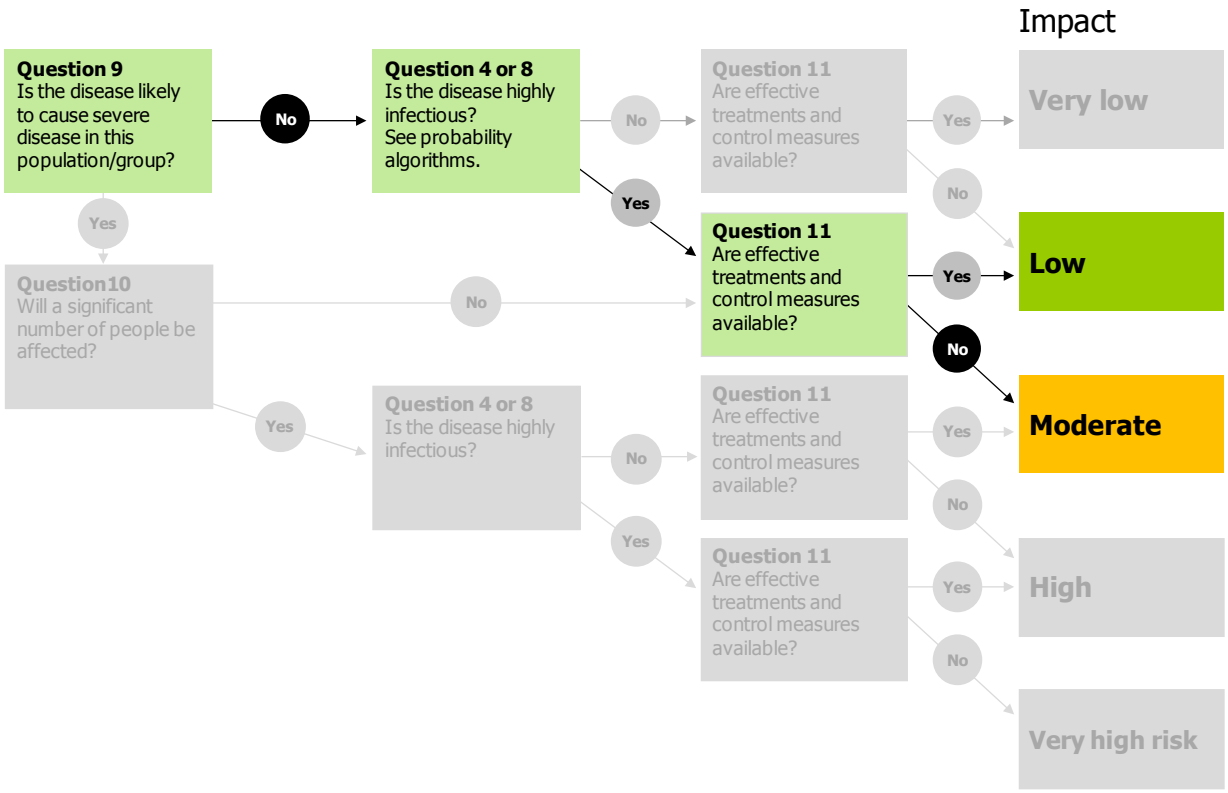


Figure 2.3: Part C: risk matrix

Probability (part A) x impact (part B) = risk (part C)

Impact \ Probability	Very low	Low	Moderate	High
Very low	Very low risk	Low risk	Low risk	Moderate risk
Low	Low risk	Low risk for the general population	Moderate risk	Moderate risk for unvaccinated persons
Moderate	Low risk	Moderate risk	Moderate risk	High risk for Irish Travellers
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk