



Animal &  
Plant Health  
Agency

# Risk Assessment: Biological Agents

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Corporate Health and Safety Advisor

# Risk Assessment: Biological Agents

## Content

- Risk assessment – what is it (for)?
- What are you assessing?
- Competence to risk assess
- Factors influencing risk
- Quantifiable risk assessments
- Tolerability of risk
- Review and audit – how good are your risk assessments?

# Risk Assessment: Biological Agents

## The Animal and Plant Health Agency

- To prevent, detect and control threats to animal and plant health
- To protect public health from risks from animals and plants
- To facilitate safe trade
- To protect animal and plant welfare
- Included are bees, seeds and fish!



# Risk Assessment: Biological Agents

## Department for Environment Food & Rural Affairs

- 2,500 staff
- Laboratories
- Farms / animal facilities
- Offices

## Working with:

- TB (bovine TB problem currently in the UK)
- Newcastle Disease
- Rabies
- Other HG3 and HG4 agents e.g bird flu





"We've considered every potential risk except the risks of avoiding all risks."

# Risk Assessment: Biological Agents

## Risk

Hazard – something with the potential to cause harm

Risk – the likelihood (chance or probability) the hazard will cause harm and the degree of harm (number of people affected and how badly – human harm)

Risk = probability v consequence (includes all harm)

Danger - Exposure or vulnerability to harm or risk

**Peril** - Imminent danger

# Risk Assessment: Biological Agents

## Risk assessment

“The backbone of the practice of biosafety is risk assessment. While there are many tools available to assist in the assessment of risk for a given procedure or experiment, the most important component is professional judgement.”

Laboratory Biosafety Manual 3<sup>rd</sup> Edition WHO

# Risk Assessment: Biological Agents

## Risk assessment

“Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person’s exposure to an agent, **the likelihood** that such exposure will cause a LAI, and the **probable consequences** of such an infection.”

BMBL 5<sup>th</sup> Edition CDC



# Risk Assessment: Biological Agents

” A risk assessment is simply a means of determining the risk associated with work with a particular hazard.”

Risk assessment needs to be ‘**suitable and sufficient**’. It should:

- reflect the nature of the work activity being assessed
- draw on specialist advice as required;
- consider all those who may be affected by the work
- **anticipate foreseeable risks**; and
- be appropriate to the nature of the work and identify how long the assessment is likely to remain valid.

Biological agents: Managing the risks in laboratories and healthcare premises (UK Health and Safety Executive)

# Risk Assessment: Biological Agents

“Process of evaluating the risk(s) arising from a hazard(s), **taking into account the adequacy of any existing controls** and deciding whether or not **the risk(s) is acceptable.**”

The risk assessment should categorize risks to identify those which need to be eliminated or controlled. **Descriptions of likelihood and consequence**, together with **the acceptability of risk levels should be defined** and used in the assessment. Such a classification can be achieved for example through the use of a **risk matrix identifying likelihood and consequence categories.**

CEN Workshop Agreement (CWA) 15793 Laboratory biorisk management standard

# Risk Assessment: Biological Agents

What are you assessing?

- A pathogen – to determine?
- An ‘overarching’ risk assessment to identify mitigation strategies
- A process / procedure that includes (a) biological agent(s)
- An activity based risk assessment (local risk assessment)
- A project involving biological agents?
- What about generic risk assessments?

# Risk Assessment: Biological Agents

What are you assessing?

Risk of what?

- Laboratory acquired infection
- Loss or release of the agent including biosecurity risk (environmental risk and misuse risk)

**Identify the scope of your risk assessment and what you are assessing!**

# Risk Assessment: Biological Agents

What are you risk assessing?

- Infection from a biological agent (LAI)
- Sharp injuries
- Musculoskeletal disorders
- Electric shock
- Burns / scalds
- Slips, trips and falls
- Working alone

And under what circumstances - presume 'normal' conditions?

# Risk Assessment: Biological Agents

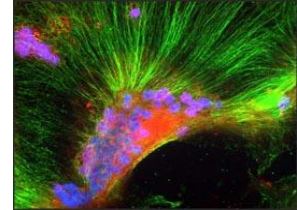
## ‘Normal’ conditions

- **Staff are perfect!** (Competent, sober, concentrated, good mood, enthusiastic, motivated (and well paid), not stressed etc.
- Ambient air temperature
- **No time pressure**
- Plenty space
- **Right equipment / tools – all well maintained working optimally**
- PPE all fits and working (and worn!)
- Good lighting

# Risk Assessment: Biological Agents

## Competence to assess?

- Individual or group?
- Expertise in organism?
- Experience in similar work / procedure?
- Understanding of risk appetite tolerance?
- Understanding of legal and other local requirements to comply with?
- Understanding of what might go wrong?
- Observational skills?



# Risk Assessment: Biological Agents

## Common factors to consider

1. Pathogenicity of the agent and infectious dose
2. Potential outcome of exposure
3. Natural route of infection
4. Other routes of infection, resulting from laboratory manipulations
5. Stability of the agent in the environment
6. Concentration of the agent and volume of concentrated material
7. Presence of a suitable host (human or animal)
8. Information from animal studies, reports of LAI's or clinical reports
9. Laboratory activity planned (sonication, aerosolization, centrifugation)
10. Any genetic manipulation that may extend the host range or alter the agent's sensitivity to known, effective treatment regimens
11. Local availability of effective prophylaxis or therapeutic interventions



# Risk Assessment: Biological Agents

## Common questions to ask (pro forma)

1. Frequency and duration of exposure
2. Agent titre / concentration and quantity used
3. Consider inadvertent culture of other agents that may present in specimen
4. Species at risk
5. Infectious dose
6. Routes of transmission
7. Vulnerable individuals at additional risk

# Risk Assessment: Biological Agents

## Common questions to ask (pro forma)

1. Is it **likely** that severe illness or death could occur if disease was contracted?
2. Is it **likely** that an infected person could infect others?
3. Could agents be harmful to the human reproductive process?
4. Is there a potential to cause cancer?
5. Primary containment required?
6. Storage conditions?

# Risk Assessment: Biological Agents

## Control Check

With the current control measures in place will the persons identified in this assessment be put at **significant** risk if they:

1. Handle the agents – yes or no?
2. Are in the vicinity of where the agents are being handled, transported, stored, disposed of – yes or no?
3. Are in the vicinity of an accidental release or spillage of the agent – yes or no?
4. Come into contact with surfaces contaminated with the agent(s) – yes or no?

# (Semi) Quantifiable risk assessment

Probability (chance) v Consequence

10 x 10

5 x 5

4 x 4

3 x 3

2 x 2 (Noah)

(Very high, high, medium,  
moderate, low, very low)



# (Semi) Quantifiable risk assessment

## Consequence:

- Human harm - LAI
- Escape or release
- Reputational harm
- Financial damage
- Theft / misuse
- Media and the public



# Risk appetite / tolerability of risk



\*SURPRISINGLY ENOUGH, THIS IS IN THE RANGE OF ACCEPTABLE RISK.\*

# (Semi) Quantifiable risk assessment

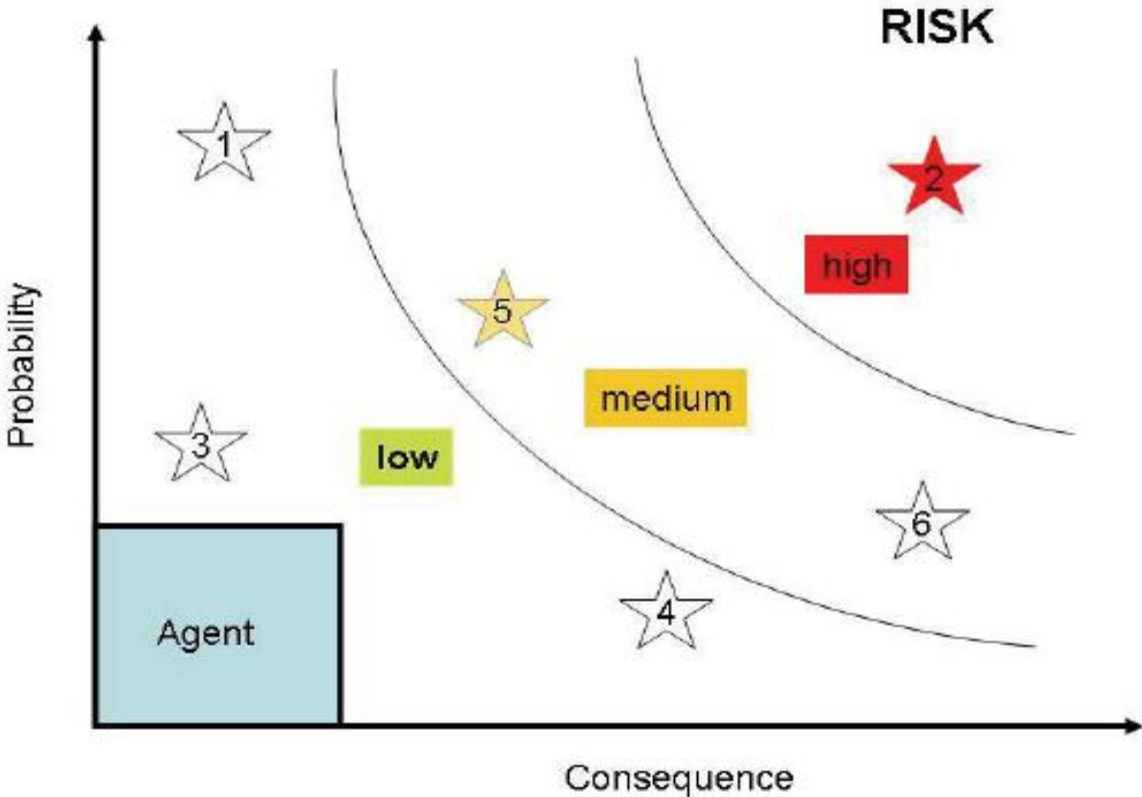
		Potential severity of harm		
		Slightly Harmful 1	Harmful 2	Extremely Harmful 3
Likelihood of harm occurring	Highly unlikely 1	Trivial 1	Tolerable 2	Moderate 3
	Unlikely 2	Tolerable 2	Moderate 4	Substantial 6
	Likely 3	Moderate 3	Substantial 6	Intolerable 9

# (Semi) Quantifiable risk assessment

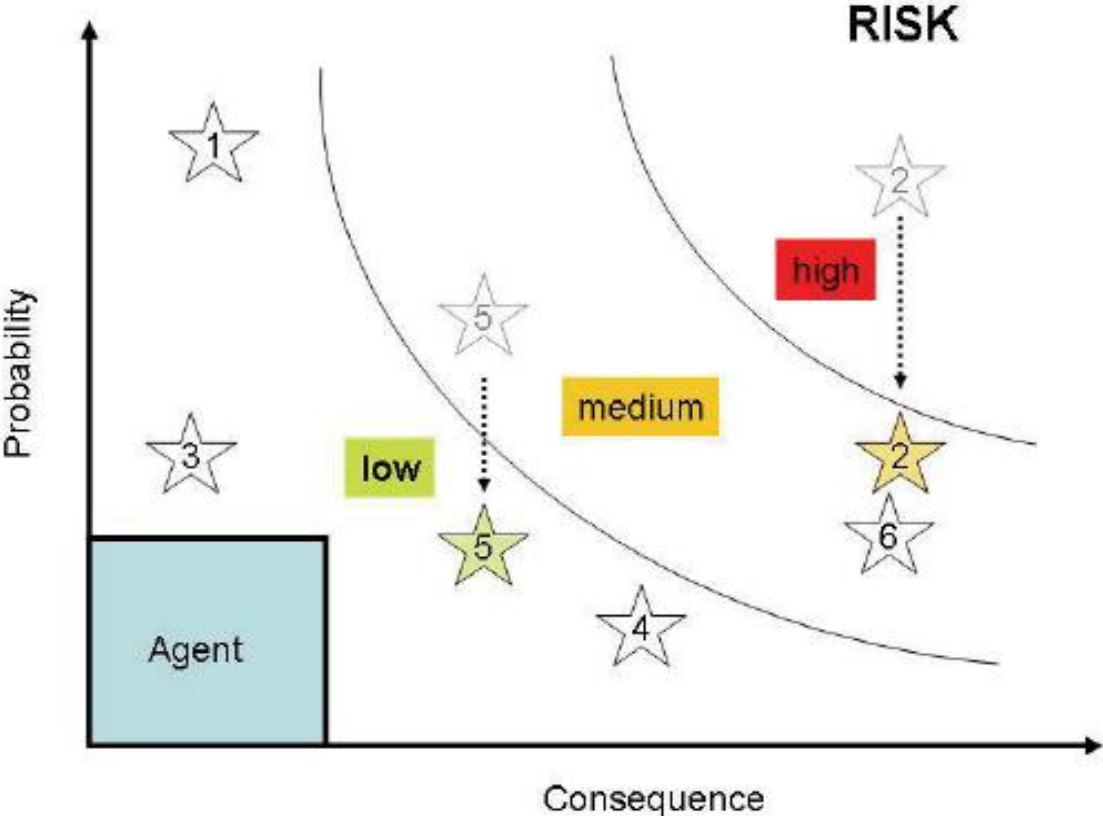
		Severity of Harm				
		1 Insignificant	2 Minor	3 Moderate	4 Severe	5 Catastrophic
Likelihood of Harm Occurring	1 Rare	1 = Low	2 = Low	3 = Low	4 = Low	5 = Low
	2 Unlikely	2 = Low	4 = Low	6 = Low	8 = Medium	10 = Medium
	3 Possible	3 = Low	6 = Low	9 = Medium	12 = Medium	15 = High
	4 Likely	4 = Low	8 = Medium	12 = Medium	16 = High	20 = High
	5 Almost Certain	5 = Low	10 = Medium	15 = High	20 = High	25 = High



# (Semi) Quantifiable risk assessment



# (Semi) Quantifiable risk assessment



# (Semi) Quantifiable risk assessment

Risk Level	Action & Action Planning
Trivial 1	No Action Required
Tolerable 2	No additional controls required. Consideration may be given to a more cost effective solution or improvement that imposes no additional burden.
Moderate 3 or 4	Efforts required to reduce risk. The cost of prevention should be carefully measured and limited. Risk reduction measures should be implemented within a time period. Where moderate risk is associated with extremely harmful consequences, further assessment may be necessary to establish more precisely the likelihood of harm as a basis for determining the need for control measures.
Substantial 6	Work should not be started or continued until the risk has been reduced. Considerable resources may have to be allocated to reduce risk. Where the risk involves work in progress, URGENT action should be taken
Intolerable 9	Work should not be started or continued until the risk is tolerable/reduced to an acceptable level. If it is not possible to reduce the risk (even with unlimited resource,) work should remain prohibited. Note: Tolerable here means that the risk has been reduced to the lowest level that is reasonably practical.

# Foreseeability and So What If!

## (So What If Techniques – SWIFT)

- All power is lost (and back up power)
- Someone goes mad! (or just collapses)
- Autoclave goes down
- Someone has to leave in an emergency – lone working
- Fire or other evacuation emergency
- Negative pressure lost

# Risk Assessment: Biological Agents

Authorisation / Sign off

## ***Statement of Departmental / workgroup Approval:***

“I confirm that this RA has been **thoroughly and stringently** reviewed locally within my workgroup by at least 4 senior, qualified members of the workgroup (list or state committee)”

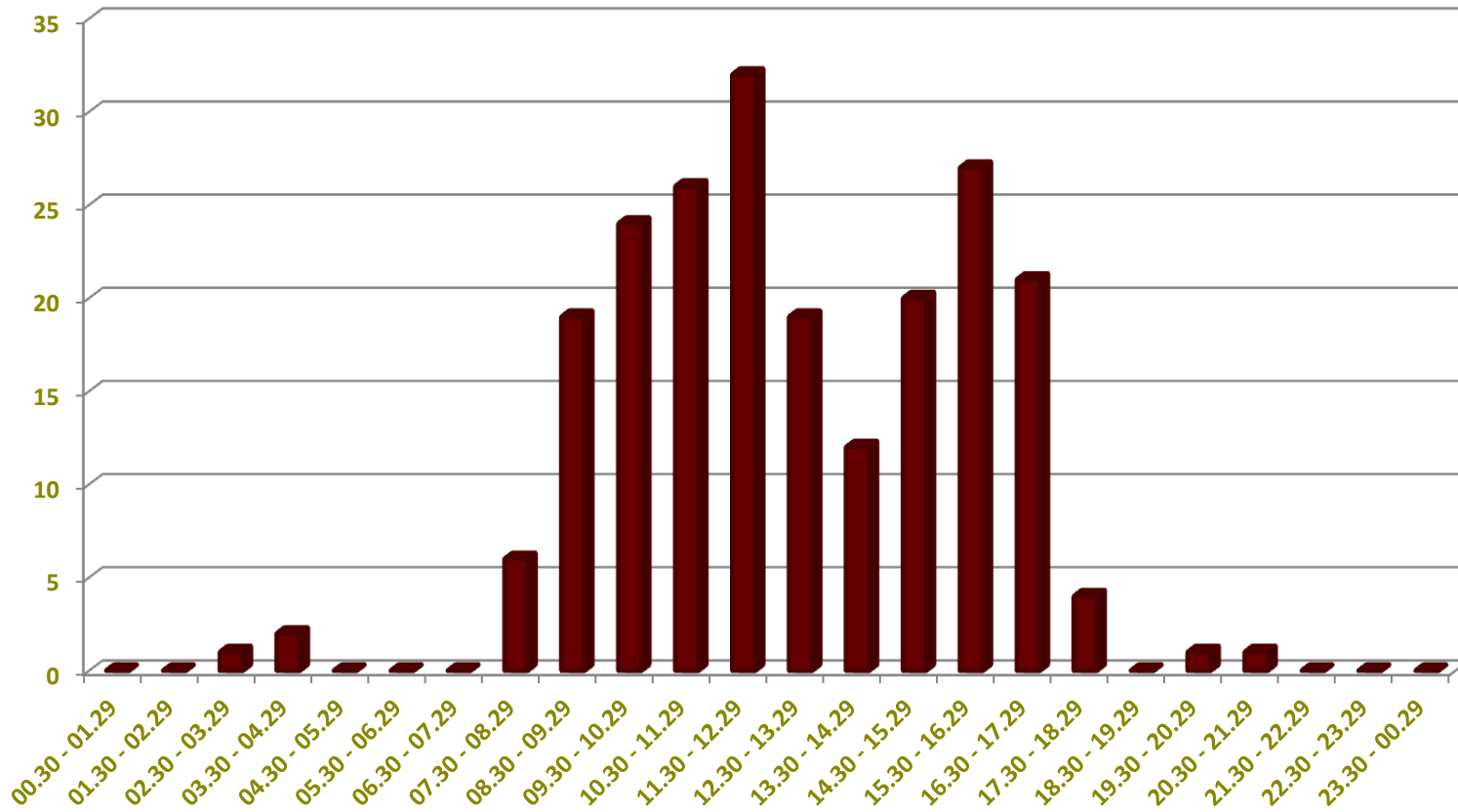
# Risk Assessment: Biological Agents

Less common factors considered in risk assessments:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedures / work and /or biological agent
3. Competence – staff experience
4. Speed and pressure of work

# Risk Variables

## Human Error Laboratory Incidents: Time of day



# Risk Assessment: Biological Agents

Less common factors to consider:

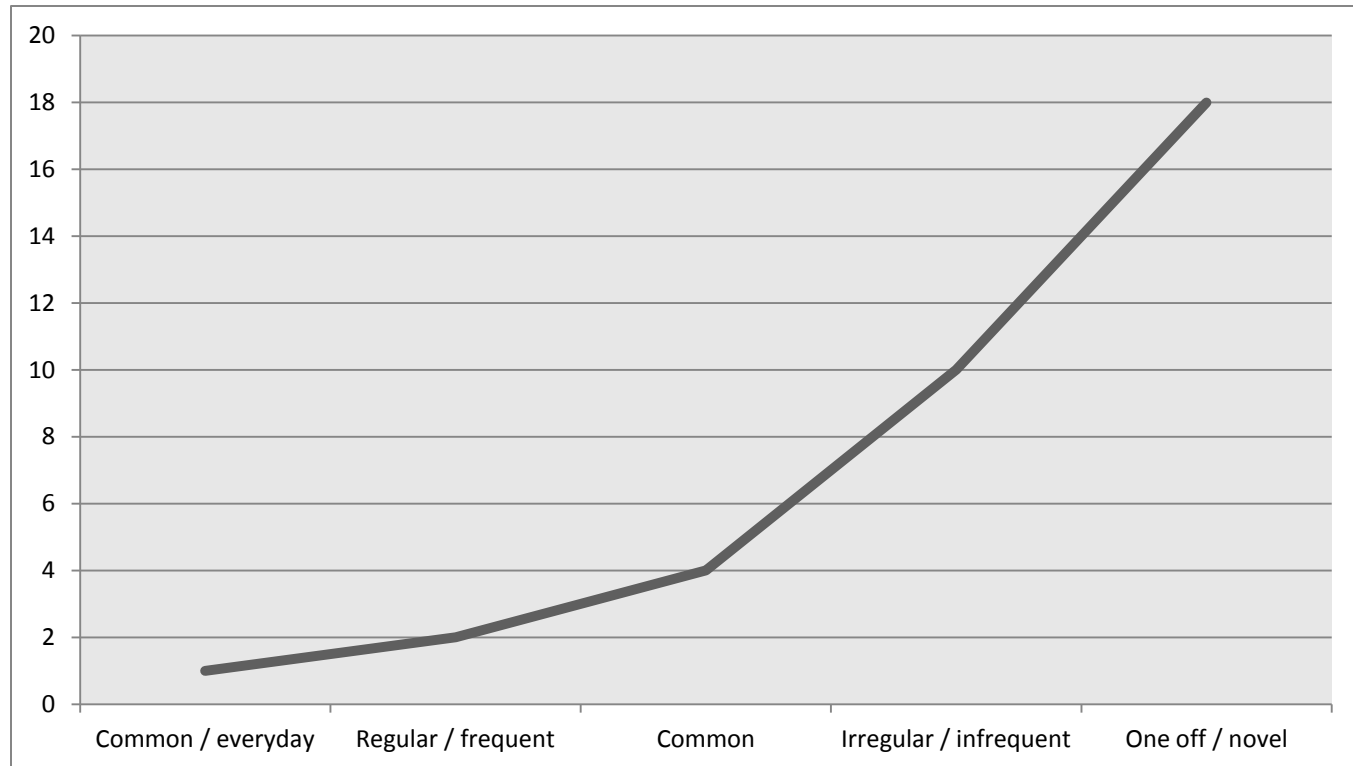
1. Time of day – how long working in a single period (control length of time and breaks)
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# Risk Variables

## Familiarity of work

**Risk  
Factor**



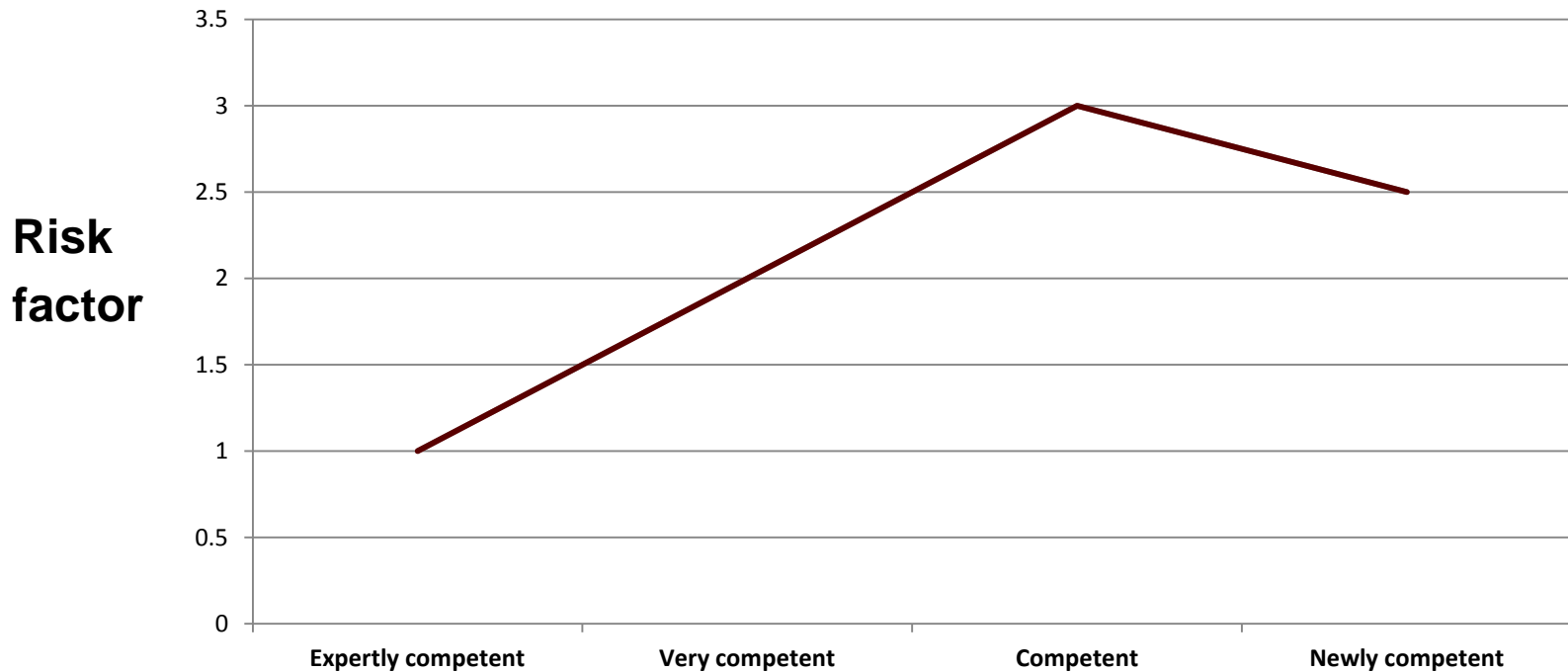
# Risk Assessment: Biological Agents

Less common factors to consider:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedure / work and /or biological agent
3. **Competence – staff experience**
4. Speed and pressure of work

# Risk Variables

Human Error: Competence / inexperience



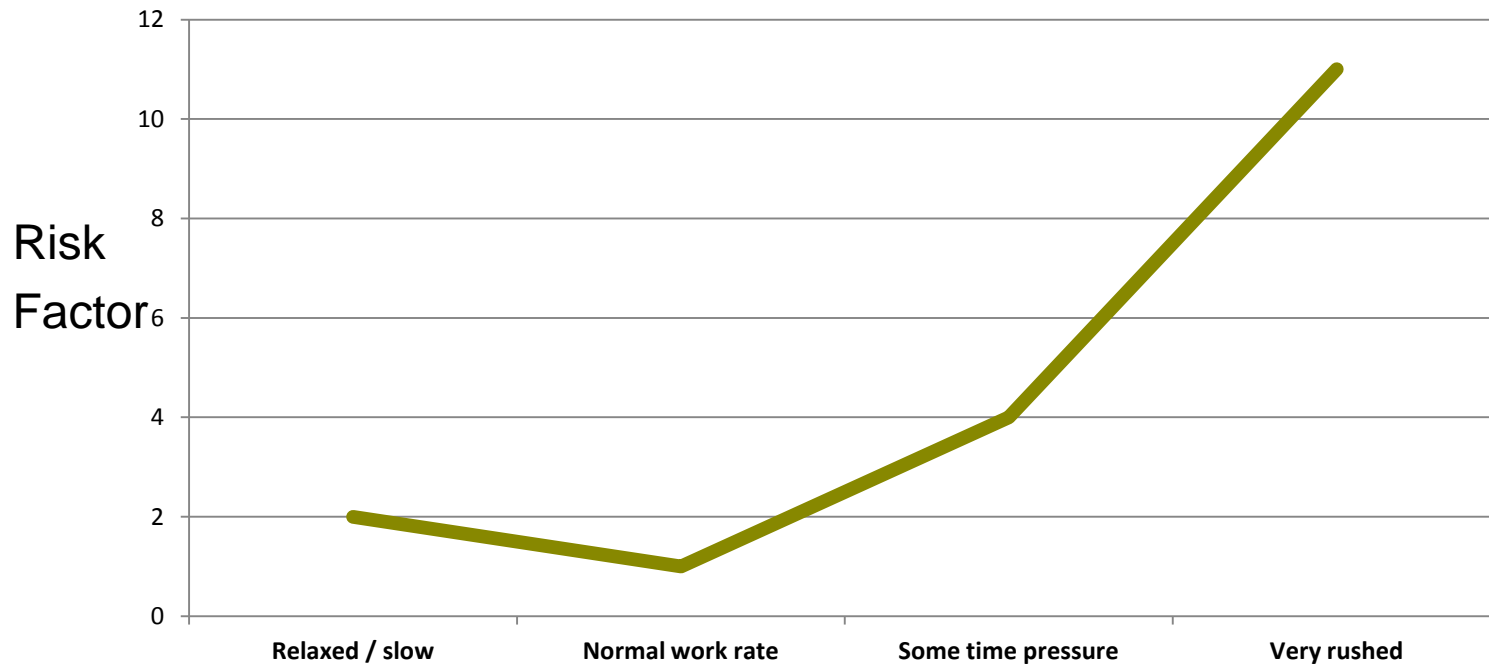
# Risk Assessment: Biological Agents

Less common factors to consider:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedure / work and /or biological agent
3. Competence – staff experience
4. **Speed and pressure of work**

# Risk Variables

## Time pressure / speed of work



# Risk Assessment: Biological Agents

Other less common factors to consider:

1. Environmental conditions – temperature, humidity etc.
2. Space – sufficient
3. State of equipment – fit for purpose, maintained
4. Psychological state of workers – stress
5. Physical state of workers – meet the demands of the work
6. Lessons from incidents and LAI cases
7. Other factors – noise, distractions, sexual tension, etc.

# Risk Assessment: Biological Agents

How good are yours?

- 'Normal' factors?
- Additional factors affecting risk?
- Emergency and 'what if' situations?
- Incident and accident investigations?
- Observational audits?
- SoP's – compatibility with risk assessments?
- Assesses and test staff?
- Risk assessment part of risk management and health and safety culture – survey?

# Risk Assessment: Biological Agents

## Audit / review questions

- Are you asking the right questions?
- How are risk assessments (controls) being monitored by management?
- Do risk assessments cover routine and non-routine activities?
- Were those who took part in the assessment competent?
- Are they suitable and sufficient and fit for purpose?
- Is there an understanding of 'acceptable'



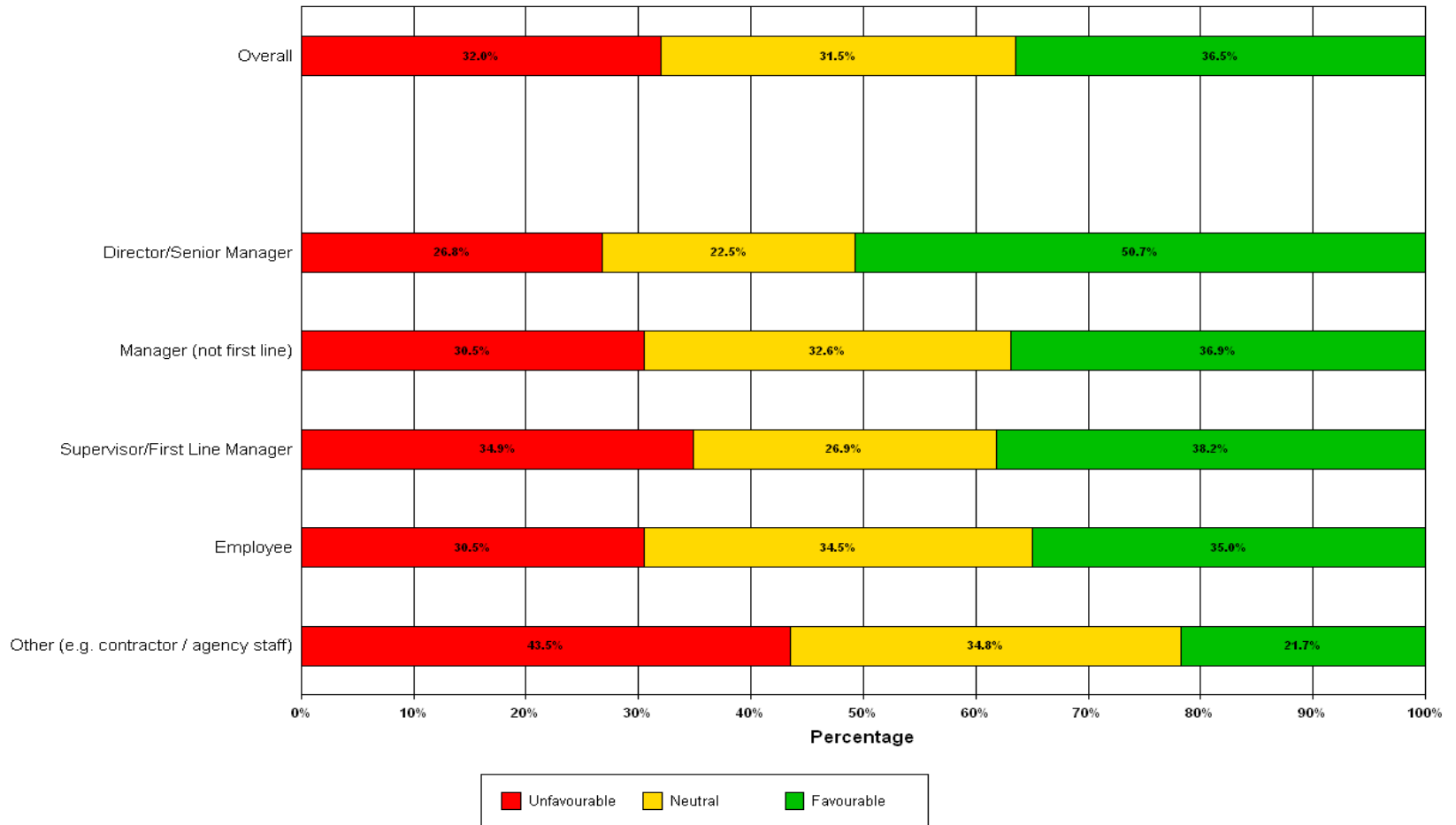
# Risk Assessment: Biological Agents

## Survey (anonymous)

- Some risk assessments are not really practical
- Some RA's do not reflect how the job is actually done
- Some risk assessments are difficult to follow
- Some RA's are only there to protect management's back
- Not all the risk assessments are strictly followed here
- I sometimes turn a blind eye to some less important risk assessment controls/procedures
- Management sometimes turn a blind eye to risk assessment controls/procedures being broken
- Managers sometimes turn a blind eye to people who are not working to the risk assessments

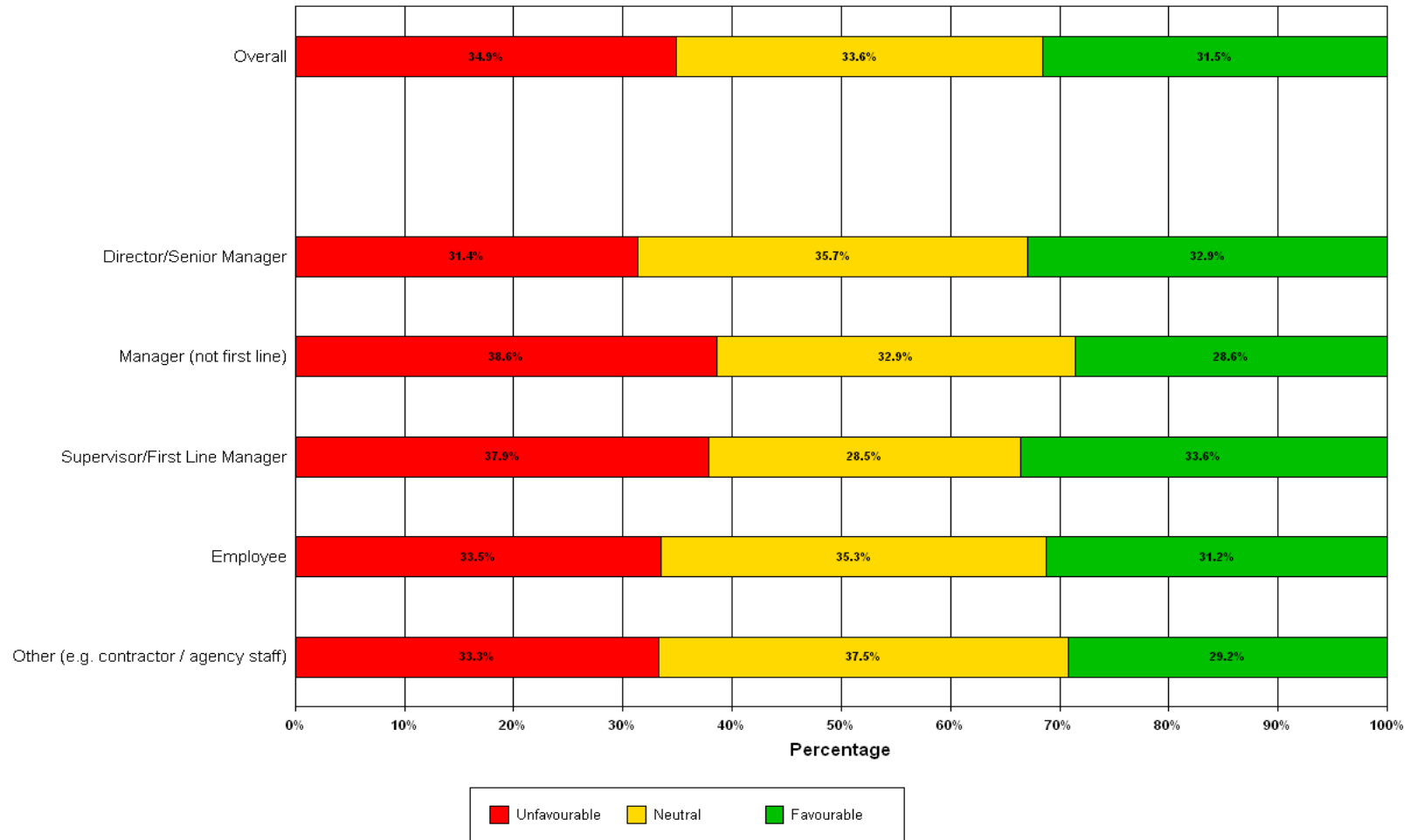
# Risk Assessment: Biological Agents

Q21. "Not all the health and safety procedures are strictly followed here" by role for All Respondents



# Risk Assessment: Biological Agents

Q14. "Some health and safety procedures are difficult to follow" by role for All Respondents



# Risk Assessment: Biological Agents

Risk Assessment: Working with chlamydia trachomatis:

On the 20<sup>th</sup> page of the 23 page risk assessment  
the result was:

# Risk Assessment: Biological Agents

“The final assessment is  
**MODERATE**”

# Risk Assessment: Biological Agents

A better way?

Calculate the risk under 'normal' circumstances

e.g. the chance of a LAI is 500,000:1

Is this acceptable?

# Risk Assessment: Biological Agents

However:

- It is always 6 degrees too hot in the lab (x3)
- It's a bit cramped but we have no alternative at that containment level (x2)
- We've only done this once 2 years ago (x10)
- We have 3 weeks to get this done before the lab goes down (x6)
- 2 of the 4 staff we need to use and are competent are 'at risk' of redundancy (x4)
- We are suffering periodic equipment failures in that room (x3)

# Risk Assessment: Biological Agents

The risk under our actual  
circumstances

The chance of a LAI is 115:1

Is this acceptable?



# Risk Assessment: Biological Agents

## Challenge

- How can we make risk assessments more dynamic to better reflect actual work and conditions (and changing circumstances)
- What is 'acceptable' risk (tolerable)?
- What is foreseeable in terms of emergencies and 'so what if x was to happen'?
- How can we nationally and internationally share best practice and determine an acceptable common approach to risk assessment

# Risk Assessment: Biological Agents



**THANK YOU**

**QUESTIONS**