Health and Safety
Executive

Hydrogen Peroxide vs Formalin technology

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Aims

- Decontamination
  - Fumigation operations
- Formaldehyde
- Automated hydrogen peroxide systems
- Other technologies
- CoPI and New guidance

Decontamination

- Definition
  - *Reducing microbial contamination to an acceptable level*
  - Not (necessarily) sterilisation
- Circumstances
  - Emergencies during normal operations
  - Planned shutdowns (with associated preparation)

Available technologies

- Surface decontamination
  - Any liquid disinfectant
  - Wipe, mop or spray
- Fumigation
  - Gas
  - Vapour
  - Mist (Fogging)

Application

Microbiological safety cabinets

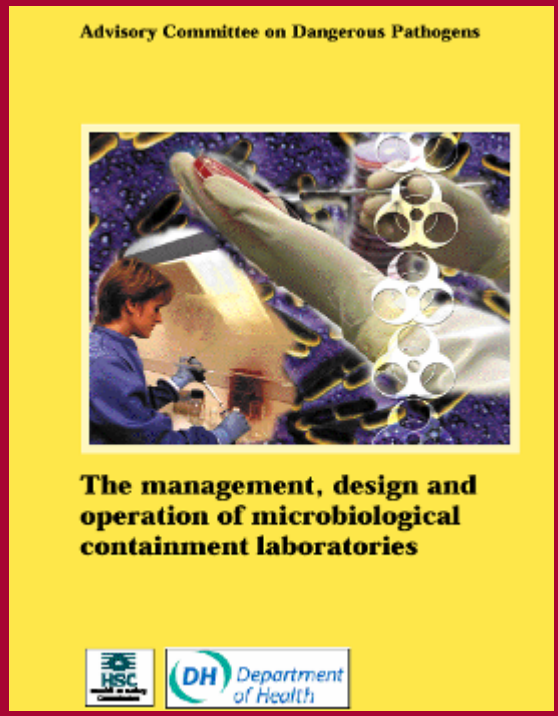
High containment laboratories

Fumigation

- Planned exercise
- Appropriate controls in place
- Named, trained personnel
- Agreed plan
- Method that is known to be effective in the circumstances of use

Guidance

- The management, design and operation of microbiological containment laboratories
- Safe working and the prevention of infection in clinical laboratories and similar facilities
- Managing the risks



Formaldehyde

- Advantages
  - Long experience of successful use to decontaminate rooms and safety cabinets
  - Inexpensive and easy to handle
  - Simple to use and easy to detect
  - Claimed broad spectrum efficacy
  - Effective against *M. tuberculosis*

Formaldehyde

- Disadvantages
  - Slow acting, poor penetration
  - Removal at end of decontamination
  - Strictly regulated in some countries
  - Health effects
    - Toxic, carcinogenic
    - Reacts with chlorine to form bis-chloromethyl ether
    - Paraformaldehyde deposition

Method

- Formalin (38-40% formaldehyde) and water in a thermostatically controlled unit
- Safety cabinets (60mL Formalin, 60mL tap water per m^3, **$24g/m^3$**)
- Rooms (100mL Formalin, 900mL tap water per $1000ft^3$ ($27m^3$), **$1.5g/m^3$**)
- Visible condensation
- No neutralisation

US method

- Evaporation of paraformaldehyde (10.6g/m^3, 0.3g/ft^3)
- Separate humidification to 60-85% and heating to >21.1^oC
  - Can take days
- Neutralise with ammonium carbonate
- (1.1-1.3g/g of paraformaldehyde)
- Regulatory approval (EPA) may be required

Bombing

- Historical method
  - Formalin and water and crystals of potassium permanganate
  - Vigorous reaction
  - Shown to be ineffective
  - NOT recommended

Health effects

- Exposure
  - 0.1 –5ppm
    - burning of the eyes, tearing
    - general irritation of upper respiratory passages
  - 50-100ppm
    - Pulmonary oedema, pneumonitis, death

Carcinogenicity

- International Agency for Research on Cancer (IARC)

  "*Overall, the working group concluded that the results of the study of industrial workers in the USA, supported by the largely positive findings from other studies, provided* ***sufficient*** *epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans*."

HSC`s advisory committee on toxic substances

- Working group on action to control chemicals (WATCH)
  - *“ Formaldehyde has probably caused nasopharyngeal cancer”*
  - *“It is probable that formaldehyde exposure has caused nasopharyngeal cancer in humans, via a mechanism to which it can be predicted that chronic inflammation (provoked by irritancy) and genotoxicity contributed”*

Formaldehyde

- HSE to produce further advice and guidance
  - CHAN
  - Possible re-classification
- Potential occupational carcinogen
- Prevent exposure
  - Engineering controls
  - Stringent work practices

Reclassification

- July 2005, Toxicology Unit, INRS, France
- Current classification
  - Carc. Cat.3; R40
- Proposed classification
  - Carc.Cat 1; R49

Reclassification

"Epidemiological studies show an elevated risk for tumour induction at the site of contact by inhalation of formaldehyde with a convincing body of evidence to establish a causal relationship for nasopharyngeal cancers."

Biocidal Products Directive (98/8)

- All products on the EU market before May 2000 had to be identified
  - Existing active substances
- *Identified*
  - Companies not supporting
  - Cannot be placed on the market after 1st September 2006
- *Notified* = intention to support
  - Full package of data on toxicology, its fate and behaviour in the environment etc

Biocidal Products Directive (98/8)

- Support
  - Notified active substances
  - 23 product types
- EC have set deadlines for submission of dossiers on active substance and the associated product type

Biocidal Products Directive (98/8)

- Each active substance has been allocated to a Member State for evaluation
  - Completeness check (3 months)
  - Evaluation of both dossiers (within 12 months)
  - Inclusion in Annex 1 of BPD
- Annex 1 will be a positive list of all active substances that can be used in biocidal products

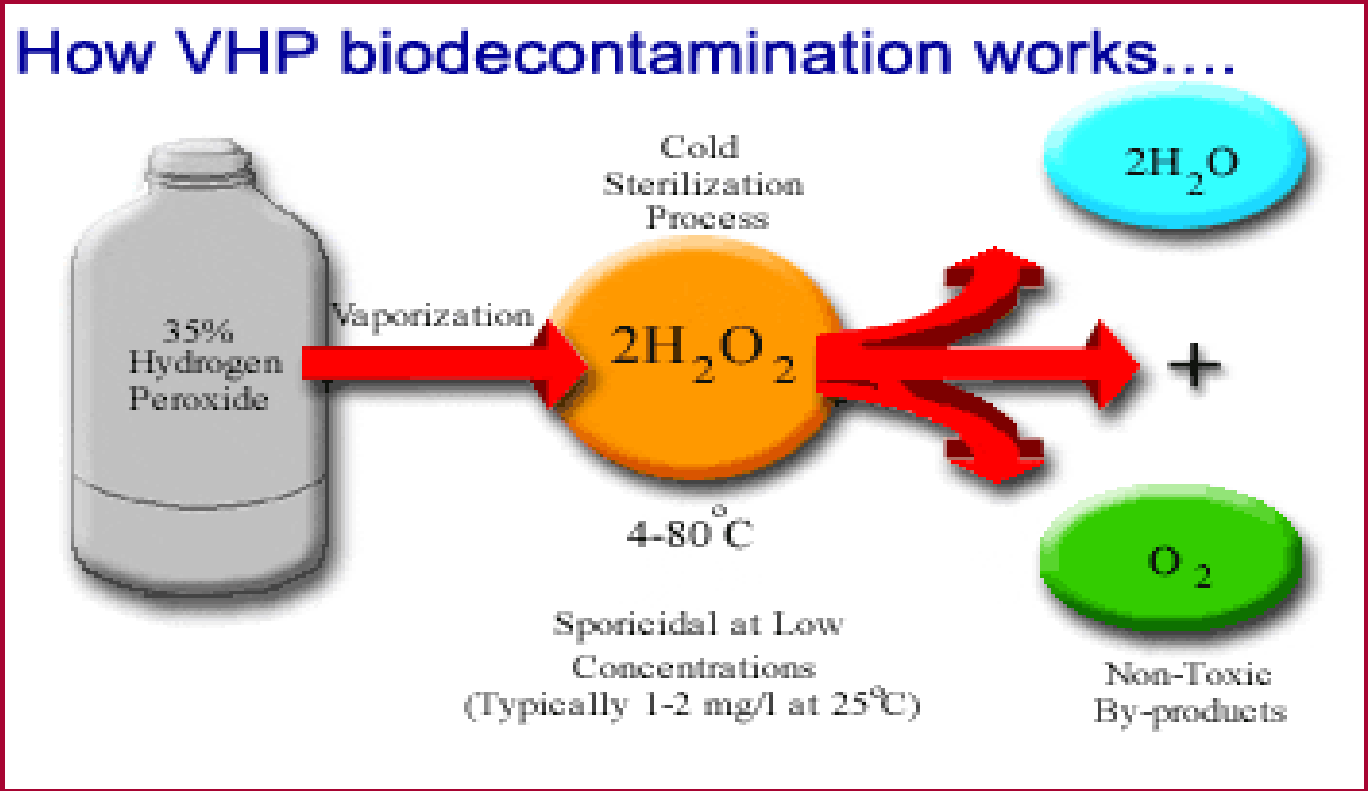
Formaldehyde

- Has been notified as an active substance in many different product types
- For part 3 of the review programme
  - Formaldehyde notified in PTs 1-6 and 13
  - PT2 Private area and public health area disinfectants
- A dossier must be submitted by 31st July 2007

Formaldehyde

- If dossier submitted
  - Evaluation document will only be available for discussion between MS by 31st July 2008
- If dossier not submitted
  - Other companies or MS may support (3 months to notify their intention
  - If dossier not taken over products containing formaldehyde in the unsupported areas will have to be removed from the market (18mths)
  - Product not available after January 2009

Hydrogen Peroxide



“Wet versus Dry”

- Dry (VHP)
- Concentration of VHP is maintained below the condensation point
- Four phases:
  - Dehumidification
  - Conditioning
  - Sterilisation
  - Aeration

- Wet
- Layer of hydrogen peroxide micro-condensation on all exposed surfaces
- Three phases:
  - Pre-conditioning
  - Gassing
  - Aeration

Efficacy and validation

- Broad spectrum, rapid antimicrobial
- Efficacy affected by presence of organic and inorganic materials (e.g. proteins, lipids)
- Presence of blood
- *Mycobacterium* species
- Catalase producers

Efficacy

- Efficacy dependant on a number of factors
- Pre-cleaning (or disinfection) before gaseous disinfection is recommended to reduce microbial concentration and dilute presence of protective agents
- Control and understanding of the process is essential

Validation

- Type, scope and source of contamination
- Reflect worst case conditions
  - Most resistant organism on the most resistant material
- Documentation
- Risk assessment
- Information, instruction and training

Chlorine dioxide

- Short lived highly reactive oxidising gas
- Disrupts proteins, interferes with protein synthesis and membrane transport
- Successfully used on a very large scale for building decontamination
- Lack of peer reviewed studies
- Being developed as laboratory gaseous disinfectant

Ozone

- Highly effective disinfectant of aqueous systems
- Highly reactive
- High concentration required to produce sporocidal effects
- Will harm and destroy materials used in containment facilities if used at a high concentration
- Not used at present as a laboratory gaseous disinfectant

New guidance

"*Fumigation operations in microbiological containment laboratories: guidance on the available technologies and their application*"

Status

- Draft version
- Consultation exercise
  - Key stakeholders
  - Fit-for-purpose
- Amendments
- Meet with interested parties
- Publication on the HSE website

Community of practice and interest

- Bio-decontamination CoPI
- Continue dialogue
- Develop a network of interested parties
- Learn from each other
- Keep up to date with future developments
- Valuable resource for anyone developing guidance

Bio-decontamination CoPI

- Delegates and others are asked to express their interest in joining this CoPI by sending an email to:
  - *germs.gmos@hse.gsi.gov.uk*
- A formal invitation and password will then be supplied by the organiser
- Details on how to use the CoPI will appear when you first register

Think Bike!!!

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