ABSA 2012, Orlando, Florida: Green gas, dry mists and dense vapours; an overview of independent fumigant testing at the UK Health & Safety Laboratory (HSL)

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About this presentation

- A brief introduction to the Health & Safety Laboratory, UK

- Formaldehyde – a widely used chemical under constant scrutiny

- Summary of some decontamination and simulant work HSL has undertaken:
    - ➢ HSE fumigation testing - laboratory sector study
    - ➢ UK Gov. Decontam. Service work – biosecurity in brief

- Acknowledgements

HSL: who are we, where are we?

HEALTH & SAFETY LABORATORY

- 320+ staff
- 90+ PhDs
- 80+ MScs
- 550 acre site in the Derbyshire Peak District, UK

A big site for (some) big experiments

But we do small stuff too….!

Widest science base of any equivalent European Laboratory – www.hsl.gov.uk

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Let’s talk formaldehyde and fumigation

Formaldehyde exposure – a justifiable concern regardless of context

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OSHA Fines Florida Hair Care Companies for Unsafe Formaldehyde Exposure

MARIE LARSEN | September 11, 2011 | 6,233

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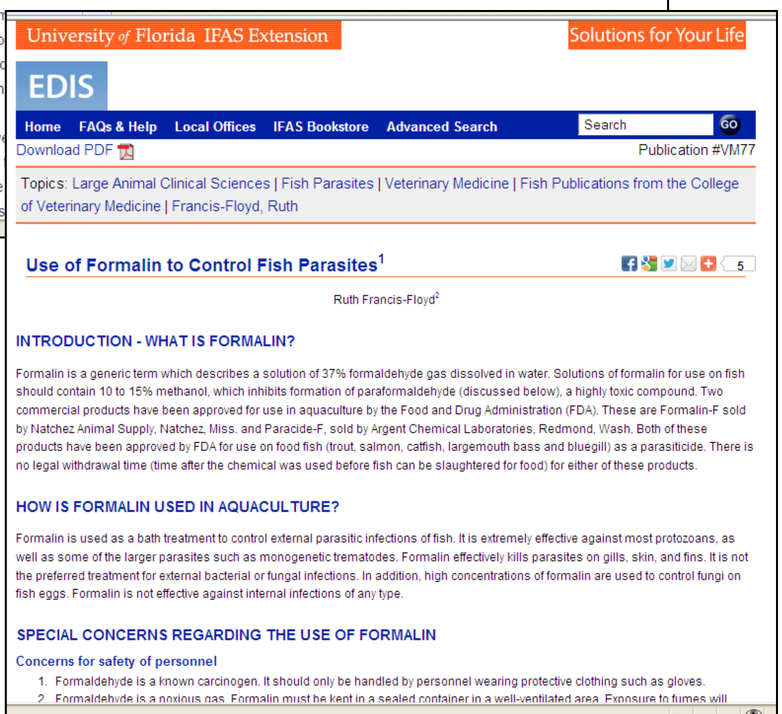
Earlier this year, the Department of Labor's Occupational Safety and Health Administration (OSHA) issued warnings to a number of hair care product manufacturers and distributors concerning unsafe working conditions. Salon users and stylists using certain products were found to be unwittingly exposed to formaldehyde and were suffering from the adverse health effects of chemical exposure. Now OSHA is striking back against the companies by issuing massive fines, citing that the accused failed to protect their workers and properly warn product users of the hazards.



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Topics: Large Animal Clinical Sciences | Fish Parasites | Veterinary Medicine | Fish Publications from the College of Veterinary Medicine | Francis-Floyd, Ruth

Use of Formalin to Control Fish Parasites[1]

Ruth Francis-Floyd[2]

INTRODUCTION - WHAT IS FORMALIN?

Formalin is a generic term which describes a solution of 37% formaldehyde gas dissolved in water. Solutions of formalin for use on fish should contain 10 to 15% methanol, which inhibits formation of paraformaldehyde (discussed below), a highly toxic compound. Two commercial products have been approved for use in aquaculture by the Food and Drug Administration (FDA). These are Formalin-F sold by Natchez Animal Supply, Natchez, Miss. and Paracide-F, sold by Argent Chemical Laboratories, Redmond, Wash. Both of these products have been approved by FDA for use on food fish (trout, salmon, catfish, largemouth bass and bluegill) as a parasiticide. There is no legal withdrawal time (time after the chemical was used before fish can be slaughtered for food) for either of these products.

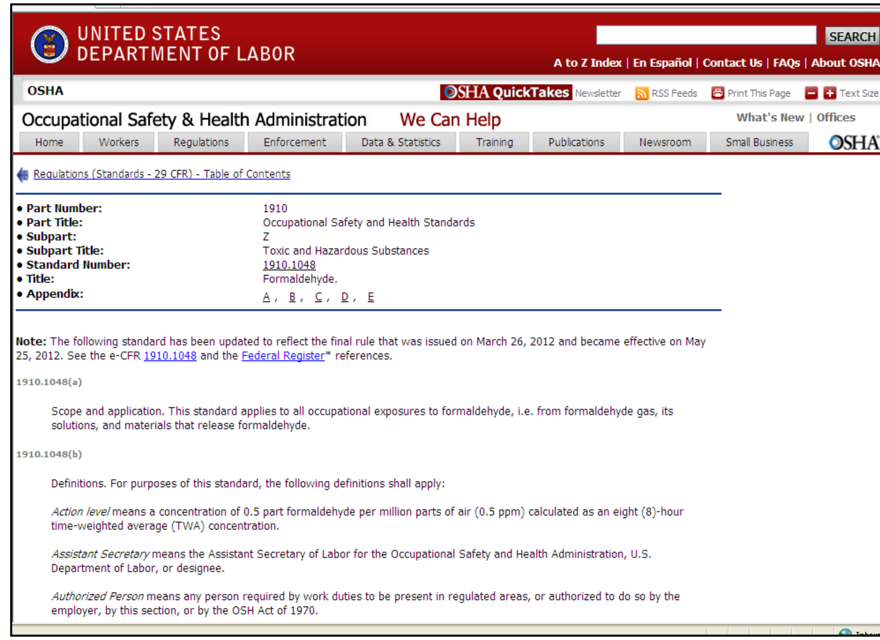
HOW IS FORMALIN USED IN AQUACULTURE?

Formalin is used as a bath treatment to control external parasitic infections of fish. It is extremely effective against most protozoans, as well as some of the larger parasites such as monogenetic trematodes. Formalin effectively kills parasites on gills, skin, and fins. It is not the preferred treatment for external bacterial or fungal infections. In addition, high concentrations of formalin are used to control fungi on fish eggs. Formalin is not effective against internal infections of any type.

SPECIAL CONCERNS REGARDING THE USE OF FORMALIN

Concerns for safety of personnel

1. Formaldehyde is a known carcinogen. It should only be handled by personnel wearing protective clothing such as gloves.
2. Formaldehyde is a noxious gas. Formalin must be kept in a sealed container in a well-ventilated area. Exposure to fumes will



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Regulations (Standards - 29 CFR) - Table of Contents

- **Part Number:** 1910
- **Part Title:** Occupational Safety and Health Standards
- **Subpart:** Z
- **Subpart Title:** Toxic and Hazardous Substances
- **Standard Number:** 1910.1048
- **Title:** Formaldehyde.
- **Appendix:** A, B, C, D, E

Note: The following standard has been updated to reflect the final rule that was issued on March 26, 2012 and became effective on May 25, 2012. See the e-CFR 1910.1048 and the Federal Register* references.

1910.1048(a)

Scope and application. This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

1910.1048(b)

Definitions. For purposes of this standard, the following definitions shall apply:

Action level means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

Assistant Secretary means the Assistant Secretary of Labor for the Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

Authorized Person means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

In the airborne state:

UK long and short term exposure limits – currently 2ppm (2.5mg/m^3 air)

OSHA - 0.75ppm as an 8-hour time-weighted average (TWA) or,

short -term exposure limit - 2ppm during a 15-minute period

Setting the scene: formaldehyde use within the European Union – status as of October 2012

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- France – has proposed reclassification of formaldehyde as a mutagen and category 1 carcinogen - currently classified as a category 2 carcinogen, with no mutagenic effects

- Formaldehyde a good candidate for substitution as there are probably safer alternatives. Chemicals with the following characteristics are automatically considered for substitution:
  - Carcinogen,
  - Mutagen,
  - Reprotoxin and
  - Persistent, bio-accumulative, toxic substance

- European Biocidal Products Directive (BPD) discussions planned for formaldehyde later in 2012

HSL asked to considered the efficacy of formaldehyde and alternative fumigants for whole room treatment

- UK: CL3/4 facilities (BSL3/4 equiv.) must be sealable for fumigation -
  - In the UK formaldehyde is still often used but alternative fumigants are available and deserve unbiased assessment

- Formaldehyde is simple to deliver and widely used for decades -
  - How does it compare to more recently developed systems?

- Formaldehyde is highly toxic and is a human carcinogen -
  - do the alternatives have any associated risks in use?

- How do the various systems compare for usability and efficacy when used side by side against substantial microbial challenges?

In labs, what can compete with the wok or hot plate?

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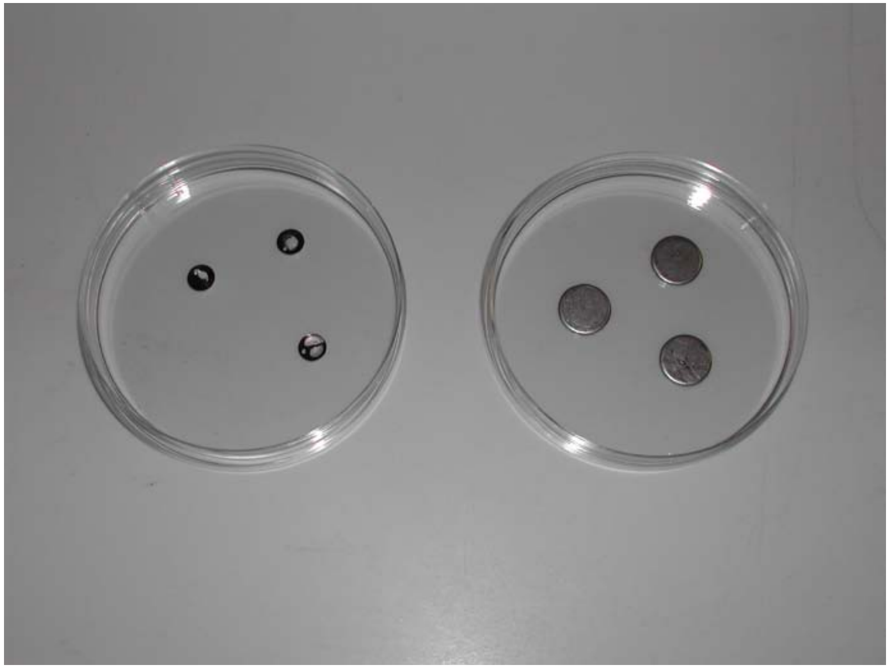
$55 from a high street store - boringly simple and inexpensive fumigant delivery – hard to beat?

HSL lab study - other fumigants tested

- H_2O_2 – Hydrogen peroxide – as vapour & dry mist (3 systems)
- O_3 – Ozone - a true gas
- ClO_2 – Chlorine dioxide - a true gas

Lab study - microbiological challenges

- *Geobacillus stearothermophilus*
- *Clostridium difficile*
- *Mycobacterium fortuitum*
- *Vaccinia virus*
- Spill tests – used 6 well plates
- All microorganisms presented in **broths** in which prepared
- Multiple cycles used to assess each system



Left: commercially available *Geobacillus* discs

Right: steel discs used for other challenges

The test facilities: a sealable exposure chamber & CL3 lab

Exposure chamber:

• 35m^3 & set up as a 'mock' lab area for initial equipment testing;

• 40% RH and 23^{o}C starting conditions typically used

HSL's CL3 facility:

• Real working lab area of 105m^3

• Used for scale up equipment testing under ambient conditions

Initial findings (using *Geobacillus*) – what is an effective formaldehyde level for whole rooms?

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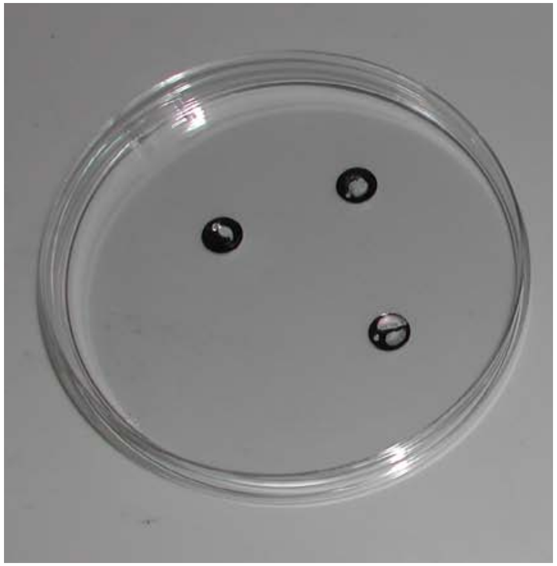
- 1200ppm to 1500ppm formaldehyde = cabinet type fumigant levels – a blanket bomb approach

- Fair evaluation needed against other systems as these usually try to avoid over-delivery of fumigant

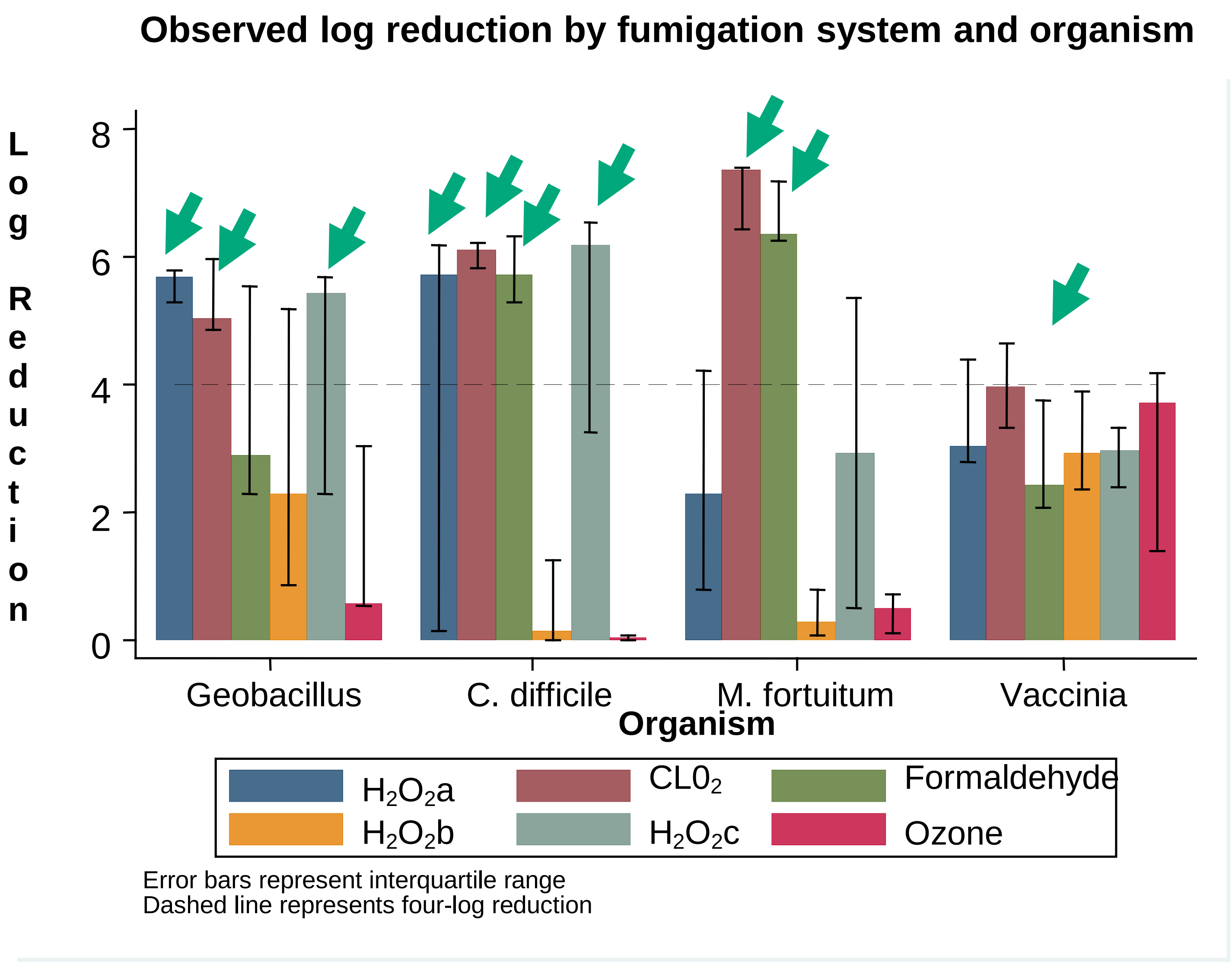
- 600ppm gave 6-log reductions with *Geobacillus* – though not at all room locations

- Literature indicated effective spore kill with as little as 400ppm formaldehyde;

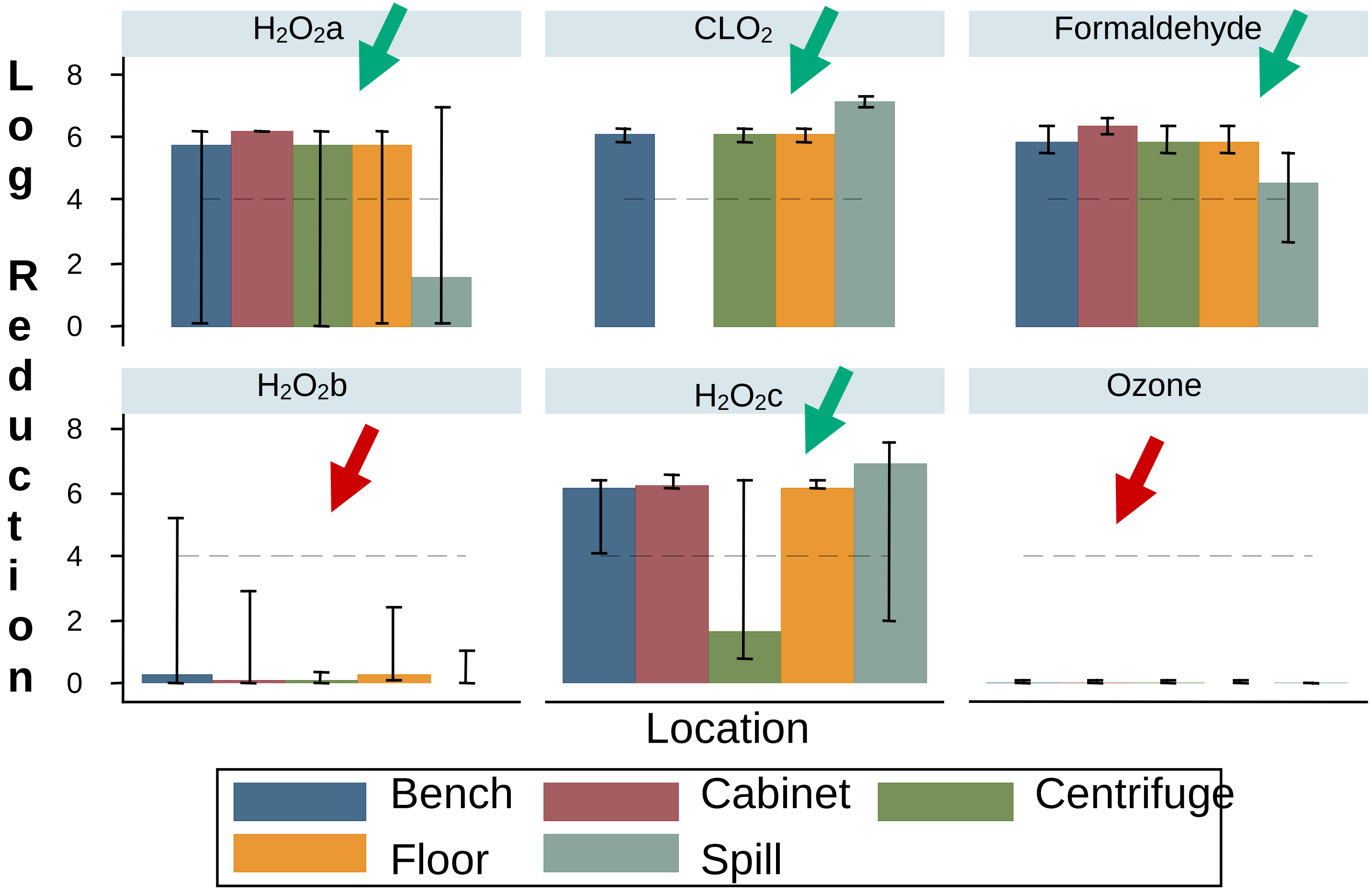
- Later results confirmed that <u>600ppm</u> was a reasonable choice to work with *vs* other systems



Lab study findings – overall efficacy

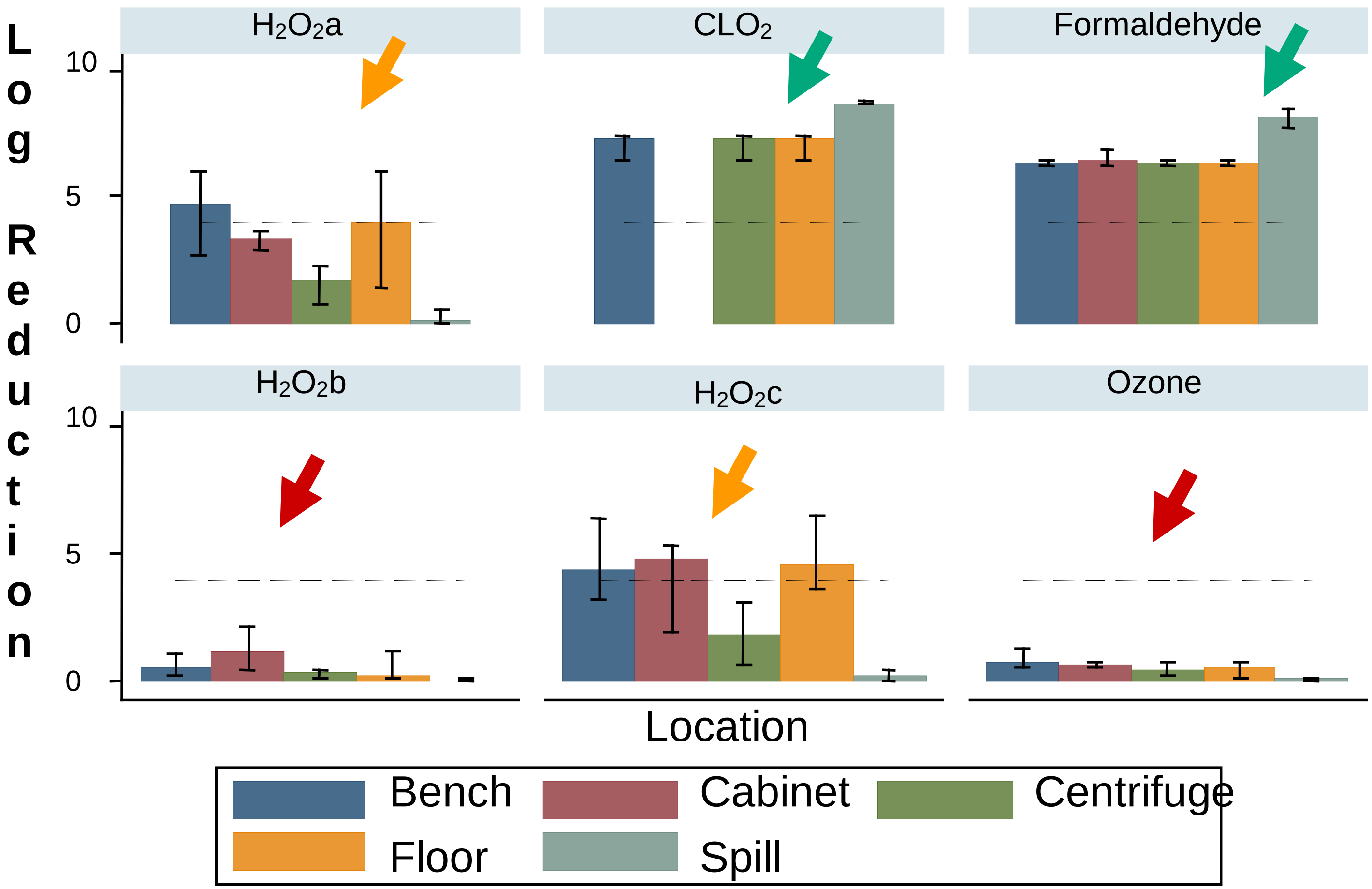


One of the toughest challenges: efficacy by location for *C. difficile* endospores



Error bars represent interquartile range
Dashed line represents four-log reduction

Overall performance by location – *M. fortuitum*



Error bars represent interquartile range
Dashed line represents four-log reduction

In summary – overall efficacy for lab setting

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- Formaldehyde (600ppm) and ClO_2 = consistently best results:
  - 4 to 6-log reduction typical - even with spore forming bacteria and *Mycobacterium* sp.
- H_2O_2 = also capable of 4 to 6-log reductions with some challenges,
  - though performance sometimes variable
- Spill simulations = difficult challenge for some systems, e.g where *Mycobacterium* & *C. difficile* used
  - Formaldehyde and ClO_2 = most consistent with spill test of this type
- All systems showed a good degree of efficacy against *Vaccinia*

Full findings published in: A. J. Beswick *et al*. (2011). Comparison of Multiple Systems for Laboratory Whole Room Fumigation" as published in Applied Biosafety: Journal of the American Biological Safety Association (Volume 16, Number 3; 139-157.

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Laboratory fumigation - lessons learnt?

What do we want from a fumigation system?

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Routine decontamination

- Consistent, reproducible and effective kill
- Easily removed from the treated/contained area
- Leave room/laboratory and it's equipment undamaged

Emergency decontamination (e.g. lab spill or ward outbreak)

- **All of the above**
- Quick and easy to deploy (ideally without requiring entry into the room if CL3-based)
- Reliable (especially if equipment is to be resident in room)

Consistency

- All systems tested showed efficacy BUT some were variable in performance, e.g.
  - Between target organisms
  - Between identical consecutive cycles
- Formaldehyde and ClO_2 = most consistent killers in the lab
- Hydrogen peroxide vapour = frequently gave good results

Removal of fumigant

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All systems prone to residual fumigant in excess of exposure limit after room aeration:

- Off-gassing from porous material (e.g cardboard boxes)
  - Formaldehyde – 20ppm around planted cardboard 24 hrs after fumigant removal
  - H_2O_2 - 15ppm to 50ppm in room after 3 to 4hr aeration
- Ozone - secondary products & odours may remain after chemical quenching with the system tested.
  - Other systems using UV-based removal might avoid this

Ease of use and reliability

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Ease of use varied between systems

- Formaldehyde – not difficult! - correct formalin/water volumes required for treated laboratory area
- H_2O_2 – some systems used ‘smart’ cartridges for source chemical (tricky to insert, storage, shelf life issues etc.)
- User interfaces varied in their simplicity. Many have easy-to-use touch screens

All machines suffered technical problems = aborted decontamination cycles, delays and lost data

Take home messages - fumigation?

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To the User:

VALIDATION, VALIDATION, VALIDATION!

- Against target organism or representative surrogate
- For each individual containment laboratory or treated area
- Monitor variability between repeat cycles
- *Always* check fumigant levels before re-entry

To the manufacturer:

RELIABILITY, RELIABILITY, RELIABILITY!

- All systems tested have efficacy and application
- Consistency between identical cycles a concern
- Inherent technical reliability of the systems poor in some cases

Acknowledgements – in case I need to stop here!!

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- Thanks to the UK Health and Safety Executive (HSE) and Home Office/GDS for their funding of this work
- Thanks also to Dr. Jonathan Gawn (HSE) for his contributions to this presentation
- Much of the HSL practical work was performed by Catherine Makison and Jayne Farrant
- Statistics - Gillian Frost, HSL Mathematical Modelling Unit
- We are grateful to several fumigation system suppliers for their support during these studies

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In brief:

Use of formaldehyde for biosecurity related whole room fumigation

Reasons for work

- To assess the efficacy of formaldehyde vapour against a range of challenge microorganisms (safe surrogates for microorganisms listed on the ATCSA biosecurity threat list)

- To assess the different methods of available fumigant removal (with or without mechanical ventilation assistance)

- To use information from the above to determine fumigant delivery considerations for environments such as the laboratory, office and domestic setting.

Microbiological challenges

- *Pantoea agglomerans* used as a surrogate for *Yersinia pestis* (plague)

- *Bacillus subtilis* var *globigii* [NCTC 10073] used as a surrogate for *Bacillus anthracis* (anthrax)

- *Vaccinia virus* used as a surrogate for *Variola virus* (smallpox)

- Fumigant efficacy against *Coxiella burnetii,* (Q fever), also evaluated; non-pathogenic strains of *C. burnetii* (NMII-83 Clone 4 and NMII87 Clone 4; Laboratory of Intracellular Parasites, USA)

Simple room scenarios created

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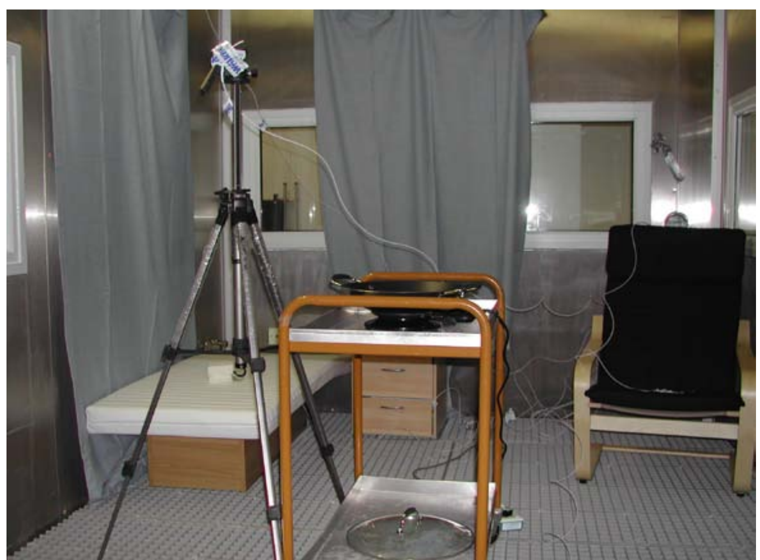
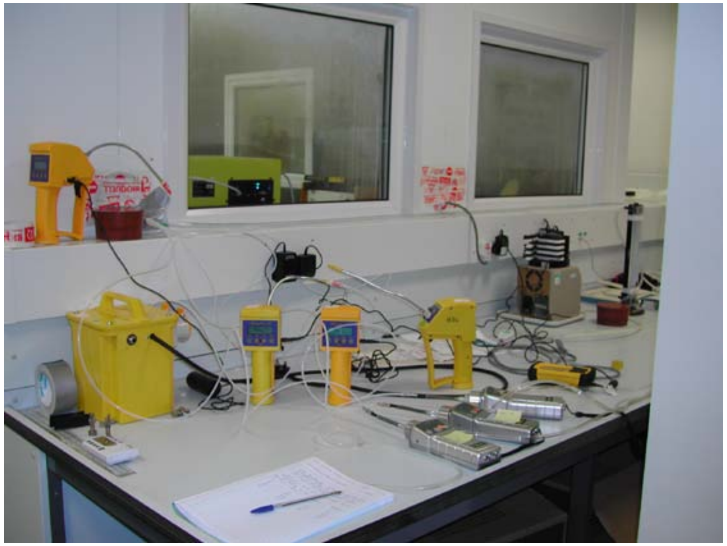
Laboratory

Office



Domestic

Fumigant delivery and removal assessed



Summary findings – in brief

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- Overall microbiological reductions > 6-Log were possible - some variation noted depending on microbiological challenge and location

- Formaldehyde was efficiently removed from the room air by mechanical ventilation alone

- Chemical quenching of formaldehyde using vaporised ammonia was rapid, but required additional ventilation to remove by-products of that reaction

- Off gassing from surfaces was observed, with higher levels and longer periods of off gassing detected from soft furnishings

- **Conclusion? - Formaldehyde use likely to continue as an effective option for UK bio-security related alerts**

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Thank you for your attention