BRITISH POULTRY COUNCIL

Subject: Formaldehyde

Date: 9 April 2015

Non-confidential Response to ECHA Consultation 2015

Use of formaldehyde, product type 2,3 as a veterinary biocide under ECHA PT3

Background

It has been in use as a disinfectant for the large part of the last hundred years, it is referred to in 1939 (Nordgren). This longevity is due to its properties (Skinner and Hugo 1976).

These include

- It kills bacterial spores as well as vegetative cells
- It is fungicidal and virucidal
- It shows residual activity on surfaces
- It has some resistance to organic material
- It is cheap
- It is biodegradable

Summary of properties

- Unique disinfectant with multimodal action
- Active against all microorganisms
- Shown to be effective in a poultry production environment
- Significant benefits in chick vigour, survival and welfare
- Will help reduce reliance on antibiotics
- Can be used in a safe manner with no risk to human health – compliance with all published EU exposure levels, maximum and time weighted.
- Outperforms all other biocidal compounds in the environmental conditions experienced in the poultry industry
- Other virucidal products can be sourced however formaldehyde is key to comprehensive bacterial control.

Specifically useful applications

- In hatcheries it causes a reduction in bacterial contamination in fluff and hatching eggs.
- It is particularly useful when continually applied in controlling zoonoses in hatcheries.
- As a vapour or gas phase disinfectant it is easily generated by evaporation of formalin or volatilisation of paraformaldehyde.
- Being a gas phase disinfectant confers on it more penetration power down the pores of eggshells of eggs undergoing fumigation (Bruce and Drysdale 1994) and the process does not damage the eggs or embryos.
- It is particularly efficient in treating buildings eg layer accommodation which house a lot of equipment and in treating the inside spaces of feeder systems.
- Because its use in the hatchery decreases chick mortality it improves welfare and so is helpful to antibiotic stewardship.

The loss of formaldehyde to Europe will not aid poultry production there compared to the rest of the world.

Exposure

- The use of formaldehyde as a disinfectant in the poultry industry in 2012 is a highly regulated and controlled process.
- Users are legally obliged to use appropriate PPE.
- It is not reasonable to compare this specific highly precise use to uncontrolled human encounters with formaldehyde which cause illness but which occur accidentally or incidentally in the course of work or leisure.

Competent Authority

The UK Department of Environment Food & Rural Affairs (Defra) advocates the use of formaldehyde in the National Control Programmes for the Control of Salmonella in meat chickens - https://www.gov.uk/government/publications/the-uk-national-control-programme-for-salmonella-in-chickens-gallus-gallus-reared-for-meat-broilers

Evidence

Experimental evidence of the efficacy of formaldehyde produced by a primary breeding company

Fig 1 shows the absence of significant correlation between the bacteriological count on eggshells made before compared with after fumigation. This shows that the effect of fumigation is not affected by the level of bacteriological challenge ie the formaldehyde reduced the count of bacteria to similar low counts however many or few were present initially.

Fig 2 shows the same data plotted comparatively and includes data similarly obtained by using MacConkey agar. The data are shown in Table 1.

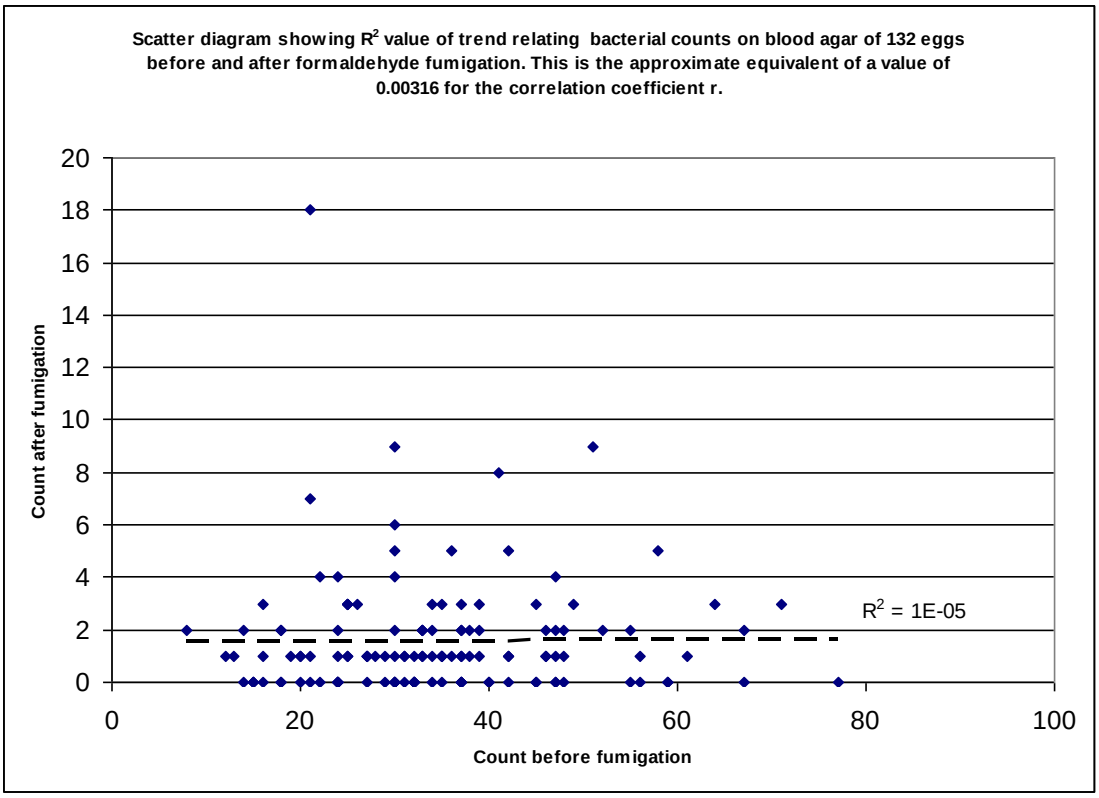
Scatter diagram showing R2 value of trend relating bacterial counts on blood agar of 132 eggs before and after formaldehyde fumigation. This is the approximate equivalent of a value of 0.00316 for the correlation coefficient r.
Count after fumigation
Count before fumigation
R2 = 1E-05
0
2
4
6
8
10
12
14
16
18
20
0
20
40
60
80
100

Fig 1

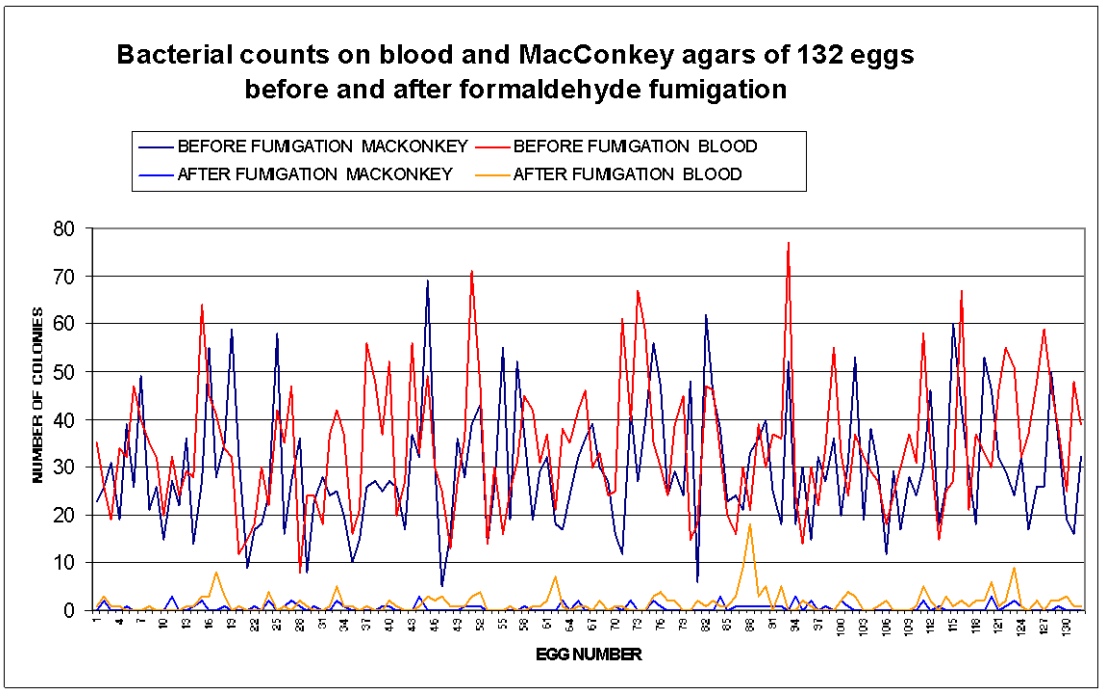
Bacterial counts on blood and MacConkey agars of 132 eggs before and after formaldehyde fumigation
BEFORE FUMIGATION MACKONKEY
BEFORE FUMIGATION BLOOD
AFTER FUMIGATION MACKONKEY
AFTER FUMIGATION BLOOD
NUMBER OF COLONIES
EGG NUMBER
0
10
20
30
40
50
60
70
80

Fig 2

BEFORE BLOOD AGAR	AFTER BLOOD AGAR		BEFORE BLOOD AGAR	AFTER BLOOD AGAR		BEFORE BLOOD AGAR	AFTER BLOOD AGAR
35	1		71	3		55	0
26	3		47	4		33	2
19	1		14	0		24	4
34	1		30	0		37	3
32	0		16	0		32	0
47	0		25	1		29	0
40	0		31	0		27	1
35	1		45	0		18	2
32	0		42	1		24	0
20	0		31	1		30	0
32	0		37	2		37	0
24	0		21	7		31	1
29	1		38	1		58	5
28	1		35	0		34	2
64	3		42	1		15	0
45	3		46	1		25	3
41	8		30	0		27	1
34	3		33	2		67	2
32	0		24	0		21	1
12	1		25	1		37	2
15	0		61	1		33	2
18	0		40	0		30	6
30	0		67	0		46	1
22	4		59	0		55	2
42	0		35	3		51	9
35	1		30	4		32	1
47	0		24	2		37	0
8	2		39	2		48	2
24	1		45	0		59	0
24	0		15	0		47	2
18	0		18	2		38	2
37	1		47	1		25	3
42	5		46	2		48	1
37	1		33	1		39	1
16	1		20	1			
21	0		16	3			
56	1		30	9			
48	0		21	18			
37	0		39	3			
52	2		30	5			
20	1		37	0			
27	0		36	5			
56	0		77	0			
33	1		24	0			
49	3		14	2			
30	2		30	1			
25	3		22	0			
13	1		34	0			
27	1						
36	1						

Table 1

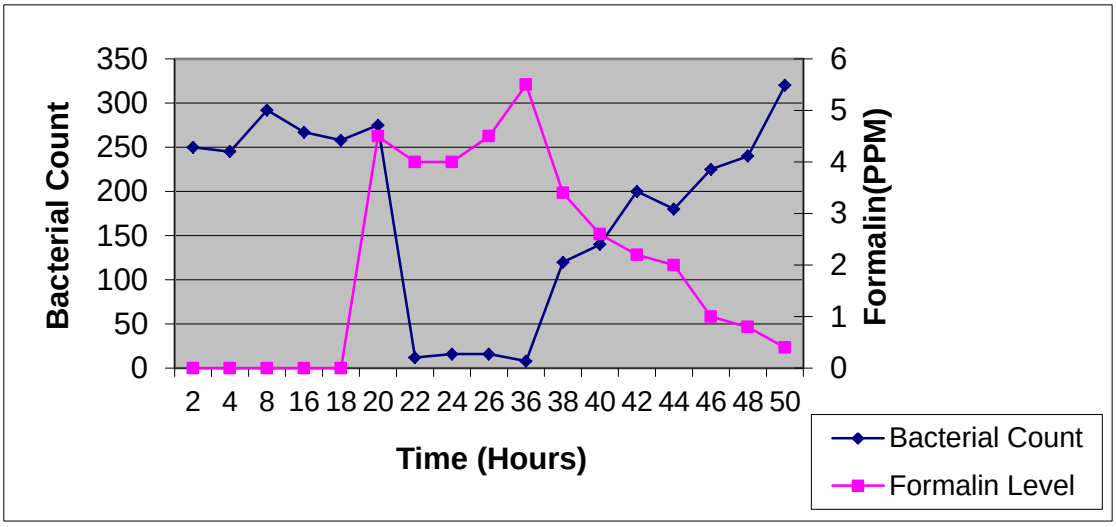

Fig 3

Fig 3 shows separate1999 work where we first managed to control the bacterial count at pipping – formalin was introduced into the hatcher 12 hours after transfer. The technique was substantially modified after this to control the late phase of bacterial growth.
The graph shows how once formaldehyde reached 4ppm the bacterial count declined.

References

Nordgren.G, 1939, Investigations on the sterilising efficacy of gaseous formaldehyde. Acta Pathalogica et microbiologica scandinavica supplement XL pp1-65 in: Russell AD Inactivation of non sporing bacteria by gases in: Inhibition and inactivation of vegetative microbes, Skinner. FA and Hugo. WB 1976 Academic Press pp 61-88.

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Bruce J. and Drysdale EM.1994, Trans Shell Transmission pp 63-91 in: Microbiology of the Avian Egg, Board RG, and Fuller R, Chapman and Hall (Pubs) 1994

Davies R.H.,UK experience with cleaning and chemical disinfection of persistently Salmonella-infected poultry houses, Disinfection in Animal Production Symposium, 18 November 2003, Aarhus, Denmark

Davies R.H. and C. Wray, 1995, Observations on disinfection regimes used on Salmonella enteritidis infected poultry units, Poultry Science, 74:638-647.

Davies R., M. Breslin, J. E. L. Corry, W. Hudson, V. M. Allen, 2001, Observations on the distribution and control of Salmonella species in two integrated broiler companies, the veterinary record, 149, 227-232

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1. **Use of formaldehyde, product type 2,3 as a veterinary biocide under ECHA PT3**
2. **For use in private area and public health area disinfectants and other biocidal products, as surface disinfectant (general and epidemic)**
3. **For use in veterinary hygiene biocidal, for disinfection of animal housing and facilities**

1. **Use in the Poultry Industry**
   - Liquid disinfectant used in surface disinfection, Fumigant in gaseous form. Formaldehyde is the only active compound capable of being used in wet and dry disinfection processes. It is commonly used in the poultry industry for:
   - Egg disinfection
   - Farm disinfection
   - Hatcher fumigation during the hatch process
   - Hatchery disinfection
   - Has been/is recommended by international, national, public health and private standards including the OIE, due to its unique disinfection properties, these include:
   - Penetrates surfaces in the gaseous form
   - Resistant to organic inactivation
   - Long acting with a residual activity
   - Multi-loci action on micro-organisms microbial resistance is not known
   - Slow acting – gives extended action on micro-organisms
   - Effective in both wet and dry disinfection procedures

One point that does require to be addressed to aid understanding of the unique properties is an explanation of why it fails the EU suspension test which is a benchmark test for disinfection registration.

The EU suspension test does not take account of formaldehyde's slow action or its long residual active time.

Alternative tests more suited to demonstrating the mode of action show a high level of disinfectant effect against bacteria, moulds and viruses

The MIC method also does not measure the levels of activity in the presence of organic matter (CEN Standardisation), a key property when in use in farming operations.

2. **Economic Feasibility**

Formaldehyde demonstrates unique properties in terms of residual activity, organic matter tolerance, surface/aerial disinfection and fumigation

Blended disinfectants: Formaldehyde is blended in many other approved disinfectants. Loss of formaldehyde as a PT3 approved biocide will result in the loss of these key biocides in the biosecurity armoury of the poultry industry. Alternatively a less effective reformulation will be necessary.

Antibiotic use: With the drive to reduce antibiotic use it is essential not to lose this highly effective disinfectant to control bacteria such as salmonella, E coli and ESBL carrying bacteria (antibiotic resistant bacteria). There is a particular focus on the presence of antibiotic resistant bacteria in human medicine and their potential links to livestock agriculture. The recent headlines on Avian Influenza and the current outbreaks in Europe also highlight the need to keep a range of disinfectant measures for control of notifiable diseases.

The withdrawal of formaldehyde as a veterinary biocide in the EU will result in:

- Reduced chicken/poultry welfare.
- Increased poultry vectored human gastrointestinal infections: Salmonella, Campylobacter

- Remove the one effective control tool during antibiotic withdrawal
- Increase costs to the industry and consumer. Consequential loss not just the cost of disinfectants.
- Increase imports to the EU from less well regulated production facilities, and increasing competition to EU producers

3. Hazards and risks of the alternative

It is recognised that formaldehyde is listed as a potential carcinogen. Safe use of a potential carcinogen in an industrial agricultural environment in this chemical form is however possible. Toxicology studies (various species) has shown the potential for prolonged exposure at high concentrations to be carcinogenic (the reports relate to nasopharangeal cancer which is also one of the rarest forms of cancer reported within the EU).

Formaldehyde is used extensively in histology, embalming and furniture manufacture and engineering cutting fluids where there is no statistical evidence of a higher level of incidence of cancer over the normal population

Occupational exposure levels are in place within the EU: A 2.0 ppm maximum exposure level in the UK is the highest legislated level within the EU.

Formaldehyde has also been used is many household products – washing power, cosmetics etc.

Engineering and personal protective equipment is applied in the poultry industry as follows:

Egg fumigation: Environmental egg fumigation cabinets – electronically interlocked with no human exposure

Farm use: Farm buildings fumigated by remote fumigation units and time assessed re-entry to the buildings after a ventilation period. Formalin in the diluted liquid form is also used as a terminal wash in poultry house cleanout procedures, in this case the human exposure levels are lower (dilute product and liquid form) and at these levels the human exposure can be contained by appropriate respirators.

Hatcheries: Auto dosing of hatchers to achieve an effective level of formaldehyde to minimise early mortality and maximise chick welfare but achieve a safe level of formaldehyde before take-off. Closed environment with limited access to people.

4. Availability

Formaldehyde is readily available in prills form (92 to 98%) and in liquid formalin (30% solution)

5. Conclusion on suitability and availability of the alternative

Should the use of formaldehyde as a veterinary biocide be banned the poultry industry would be in a position to utilise alternative products for the purposes of surface disinfection although the efficacy against microorganisms would be impaired. There is however uses such as egg disinfection, hatcher fumigation during the hatching process where there are no suitable alternative products. All alternative products are either ineffective by comparison or damaging to the chick/egg. This would result in restrictive economic pressure of poultry producers within the EC.

6. Other comments

Enteric pathogen control: There is a need for disinfectants in the poultry industry which are environmentally robust towards enteric pathogens such as Salmonella species applied in both wet and dry disinfection processes

Lack of efficacy with alternatives: The standard test procedures do not mimic the challenges reflected in the poultry environment and have resulted in the failure to control these pathogens even at “approved” levels. E.g. UK DEFRA approved disinfectant list

Hatcher fumigation: In particular formaldehyde remains the one consistent tool available which plays a pivotal role in reducing early chick mortality and therefore enhancing chick welfare.

The case to retain formaldehyde is not well supported by some disinfectant manufacturers as they promote their more expensive alternatives.

There is no evidence of development of bacterial resistance to formaldehyde. This property is particularly important in a background of increasing pressure to withdraw antibiotics from agricultural activities.

The current research climate and associated costs to register new disinfectant compounds under REACH etc has resulted in no new compounds being placed on the market for several years. This is likely to continue with new blends of existing compounds the only source avenue to increase disinfectant efficacy.

References

Formaldehyde has been shown to be the most effective disinfectant to use against Salmonella in the presence of organic matter:

- Berchieri and Barrow 1996
- McDonnell and Russell 1999
- Whistler and Sheldon 1989
- Kumar and Petersen 1991
- Allen 1993
- Engvall 1993
- Davis and Wray 1995
- Opitz 1996
- Gradel 2004

Avian influenza H5N1 outbreak control by formaldehyde fumigation: Manzok et al.

Only formalin could inactivate the virus after a fifteen minute exposure time.