



EFSA presentation on Peroxyacetic acid

**DG SANCO WORKSHOP ON THE
CONTROL OF CAMPYLOBACTER
IN POULTRY**, Brussels,
07/05/2014

INTRODUCTION DECONTAMINATION TREATMENTS

Legislation

- Art 3(2) of Regulation (EC) No 853/2004: legal basis to approve /authorise the use of substances other than potable water to remove surface contamination from products of animal origin

- Before risk management decision, a risk analysis should be carried out taking into account the results of a risk assessment

Article 3

General obligations

1. Food business operators shall comply with the relevant provisions of Annexes II and III.
2. Food business operators shall not use any substance other than potable water — or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water — to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with the procedure referred to in Article 12(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.



INTRODUCTION DECONTAMINATION TREATMENTS

Past EFSA activities

- Recycling hot water as a decontamination technique for meat carcasses (Sep 2010)
- Lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings (July 2011) [Reg. (EU) No 101/2013]
- Cecure® for the removal of microbial surface contamination of raw poultry products (Dec 2011)
- Listex™ P100 for the removal of *Listeria monocytogenes* surface contamination of raw fish (Mar 2012)



THE PAA DOSSIER AND MANDATE

The mandate

- On 15 May 2013, the EC received an application dossier from USDA for the approval of peroxyacetic acid solution (PAA) for use during processing for the reduction of pathogens on poultry carcasses and meat
- Mandate was allocated to BIOHAZ Panel (leading) and CEF Panel



THE PAA MANDATE

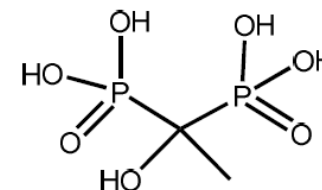
EFSA is requested to evaluate the safety and efficacy of peroxyacetic acid solution intended to be used by food business operators during processing for the reduction of pathogens on poultry carcasses and meat, considering:

- the **toxicological safety** of the substance;
- the **efficacy**, i.e. does the use of the substance significantly reduce the level of contamination of pathogens on poultry carcasses and meat;
- the potential emergence of **reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials** linked to the use of the substance;
- the risk related to the release of the processing plant effluents, linked to the use of the substance, into the **environment**.



THE PAA DOSSIER

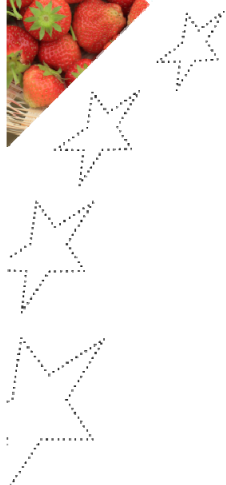
The substance



- Active ingredient is peroxyacetic acid
- Produced by mixing acetic acid, hydrogen peroxide, (sometimes also octanoic acid, as surfactant) and HEDP (stabiliser)
- Composition PAA solution

Table 1: Composition by weight (%) of peroxyacid mixtures, as provided by the Applicant

Component	Formula 1	Formula 2	Formula 3
Acetic acid	40.6	45	35
Peroxyacetic acid	12.0	20	15
Hydrogen peroxide	6.2	6.0	10
Water	36.6	29	39
1-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	0.8	0.1	< 1.0
Octanoic acid	3.2		
Peroxyoctanoic acid	1.4		



THE PAA DOSSIER

The treatment

- Spray treatment of warm carcasses
 - PAA concentration: 400-700 ppm
 - Duration: < 10 sec
- Short duration dip treatment of warm carcasses
 - PAA concentration : 2000 ppm
 - Duration: 3 min



THE PAA DOSSIER

The treatment (cntd)

- Treatment of warm carcasses in chiller baths
 - Application either during an entire chill or in one or more stages of multi-stage chiller baths
 - PAA concentration: 230 ppm
 - Duration: 1-2 h at lower concentrations.

- Short duration dip treatment of chilled carcasses or parts
 - PAA concentration: 2000 ppm
 - Duration: 3 min



THE OPINION: HUMAN TOXICOLOGICAL SAFETY

Conclusions

- There are **no toxicity concerns** with regard to residues of **peroxyacids** as these compounds are unstable and break down into acetic acid and water. Similarly there are no concerns in relation to residues of **acetic acid and octanoic acid**.
- There are **no toxicity concerns** for **HEDP** (dip treatment), referring to the margin of safety of 43103 as calculated from European intake scenario.



THE OPINION: HUMAN TOXICOLOGICAL SAFETY

Conclusions (cntd)

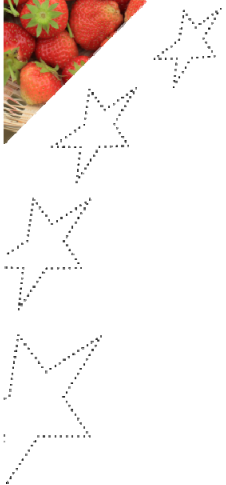
- Regarding reaction products of hydrogen peroxide and peroxyacids with lipids and proteins/amino acids of the poultry carcasses, no risk was anticipated due to the high instability of the peroxyacids.
- No lipid peroxidation was identified in producer experiments when using immersion for 60 min in 200 mg/L total peroxyacetic acid.



THE OPINION: EFFICACY

Definition and objective

- Efficacious when reduction
- of prevalence and/or numbers of pathogenic target microorganisms is statistically significant as compared to control (e.g. water)
- has positive impact on reduction of human illness cases
- Objective
- To reduce the incidence of foodborne illness by decreasing the numbers (and prevalence) of human pathogens on poultry carcasses or parts provided to consumers
- When used, may also reduce the numbers of spoilage organisms and may increase the storage life of chilled poultry carcasses and parts



THE OPINION: EFFICACY

Criteria used for in/exclusion studies

- **Included**
 - Within conditions applied for in dossier
 - Applications on poultry carcasses, poultry skin, or skin-on poultry parts
 - PAA treated samples *versus* water treated samples, or versus untreated controls
 - Targets: focus on *Campylobacter* spp., *Salmonella* spp. and *Escherichia coli*, including strains pathogenic to humans; considering relevant indicator organisms, i.e. *Escherichia coli*, coliforms and *Enterobacteriaceae*
- **Excluded**
 - Studies on visibly contaminated poultry carcasses and poultry meat
 - Studies with inoculation of microorganisms after the PAA treatment



THE OPINION: EFFICACY

Strength of evidence (SOE)

- The body of evidence from the submitted studies was evaluated, considering
 - whether the studies were done in the laboratory, under pilot plant conditions or in a slaughterhouse (industrial)
 - whether they used inoculated or naturally-contaminated poultry samples.

Table 3: Relative strength of the contribution of study data to the general body of evidence, based on study type

Study type	Natural contamination	Inoculated studies ^(a)
Industrial	High	Not applicable
Pilot-scale ^(b)	High ^(c) /medium	Medium ^(d)
Laboratory	Medium ^(d)	Low ^(e)

(a): Includes studies where the meat surface was inoculated with pathogens in pure culture prior to the decontamination treatment.

(b): Experiments using industrial equipment in non-industrial settings.

(c): If the pilot process is representative of the industrial process; otherwise, evidence makes a “medium” contribution to the body of evidence.

(d): Data would not be sufficient to inform a quantitative microbial risk assessment or to allow definitive conclusions on risk reduction.

(e): Data are indicative of a disinfectant effect that may be reproducible in practice, but individually do not allow definitive conclusions on risk reduction.



THE OPINION: EFFICACY

Selection of studies

- Spray treatment of warm carcasses
 - 7/8 studies included: 6 high SOE, 1 medium SOI
- Short duration dip treatment of warm carcasses
 - 3/4 studies included: 2 high SOE, 1 low SOI
- Treatment of warm carcasses in chiller baths
 - 8/10 studies included: 5 high SOE, 1 medium SOE, 2 low SOI
- Short duration dip treatment of chilled carcasses or parts
 - 7/8 studies included: 2 medium SOE, 5 low SOI



THE OPINION: EFFICACY

Evaluation

- Wide range of experimental designs were used in the studies submitted by the applicant.
 - Studies differed in relation to products, settings, method of application, PAA conc., use of controls, microorganisms studied, etc.
 - All these parameters impacted on the observed efficacy.
 - Comparison beyond treatment groups was not possible.
- Evaluation could only be performed for tests on chicken carcasses and parts



THE OPINION: EFFICACY

Evaluation (cntd)

- Reduction of bacterial counts was considered relevant if the confidence interval (CI) did not include zero (statistically significant), or, following expert judgement (when CIs not available), if the mean decimal reduction > 0.5 log-units
- The efficacy of PAA treatment after storage of treated carcasses/products was only investigated in two studies with naturally-contaminated samples, and these gave conflicting results



THE OPINION: EFFICACY

Evaluation: example

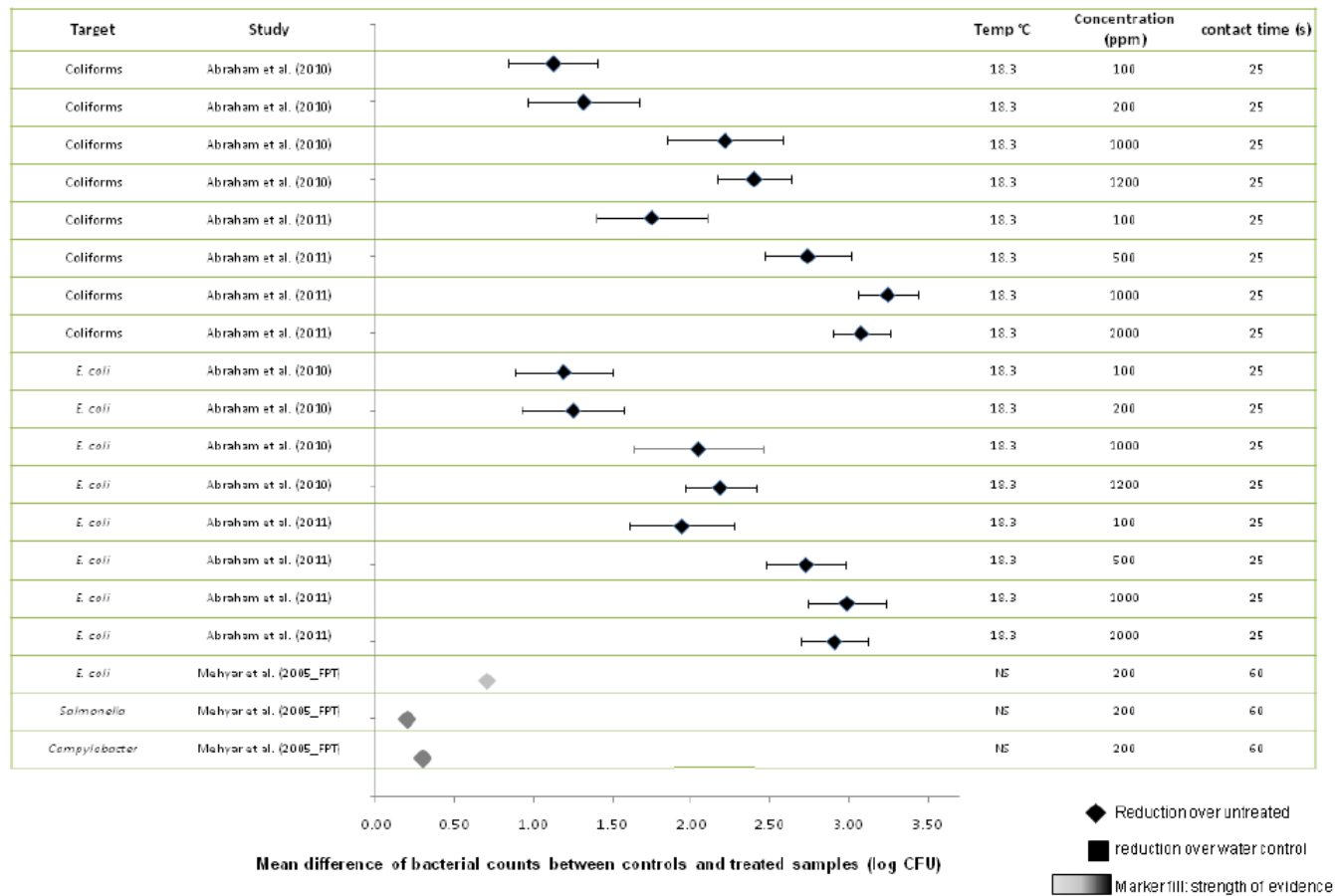


Figure 3: Forest plots of results of mean difference of bacterial counts obtained with dip treatment of warm carcasses or parts

THE OPINION: EFFICACY

Conclusions

- Short duration dip treatment of warm carcasses
 - consistent evidence for a relevant impact (1-3 log-units over untreated controls) on *E. coli* and coliforms; few data on reduction of *Salmonella* and *Campylobacter*
 - evidence for statistically significant *Salmonella* prevalence reduction
- Spray treatment of warm carcasses
 - less effective in reducing indicator organisms than dipping (0.5-1.5 log-units)
 - evidence for stat. sign. *Salmonella* prevalence reduction



THE OPINION: EFFICACY

Conclusions (cntd)

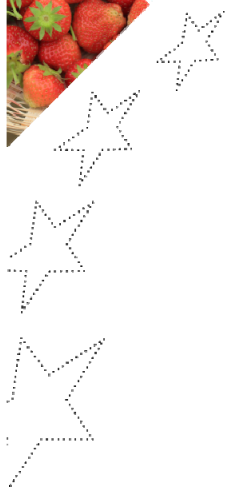
- Short duration dip treatment of chilled carcasses or parts
 - consistent evidence for a relevant reduction (0.5-2 log-units) of indicator organisms and *Salmonella* and *Campylobacter* (low or medium SOE studies)
- Treatment of warm carcasses in chiller baths
 - consistent evidence for a relevant impact on *E. coli* (0.5-2 log-units). Less consistent effects on coliforms; few data on reduction of the number of *Salmonella* and *Campylobacter*
 - evidence for stat. sign. *Salmonella* and *Campylobacter* prevalence reduction



THE OPINION: EFFICACY

Evaluation: *Campylobacter*

Decimal reduction	warm carcasses with spray treatment	warm carcasses parts with dip treatment	chiller baths	dip treatment of chilled carcasses or parts
<i>Enumeration studies, confidence interval provided</i>				
Statistically sign. reduction	0	0	0	1
No significant effect	0	0	0	0
Significant increase	0	0	0	0
<i>Enumeration studies, confidence interval not provided</i>				
MDR > 0.5 log	0	0	1*	6(2*)
-0.5 < MDR < 0.5 log	0	1(0*)	2*	1
MDR < -0.5 log	0	0	0	0
Prevalence studies				
Statistically significant reduction	0	0	3(2*)	0
No effect	0	0	0	0



THE OPINION: REDUCED SUSCEPTIBILITY/ RESISTANCE

Conclusions

- On the basis of the safe usage information provided by the applicant, the emergence of acquired reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials following the use of PAA is considered unlikely.



THE OPINION: ENVIRONMENTAL RISK ASSESSMENT

Conclusions

- Acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid and hydrogen peroxide are effectively neutralized before discharge of wastewater => no concern about environmental toxicity.
- On the basis of a conservative preliminary guideline for surface water quality from a literature review, the emission of HEDP from a poultry plant including via a wastewater treatment system into the freshwater environment cannot be considered safe *a priori*.



THE OPINION: ENVIRONMENTAL RISK ASSESSMENT

Conclusions (cntd)

- Site-specific considerations related to dilution factors and improved efficiency of wastewater treatment plants, can mitigate the possible environmental risk associated with the emission of HEDP from individual poultry plants using PAA solutions for decontamination treatment.



THE OPINION

Recommendations

- A method for the determination of HEDP residues on poultry carcasses, poultry meat and poultry meat products should be developed and validated.
- Further high SOE studies with pathogens should be undertaken, in particular with *Campylobacter*.
- Monitoring of the concentration of the decontaminating substance in the working PAA solution should be considered in HACCP plans.



THE OPINION

Recommendations

- Treated carcasses should be examined at the end of shelf life to ensure that the level of contamination remains low.
- Laboratory studies should be undertaken to confirm that reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials following the use of PAA does not occur.
- Post-marketing surveillance for resistance in pathogenic and commensal bacteria should be considered in HACCP plans should PAA be applied.



THE OPINION

Summary

- No human toxicity concern using PAA solutions to reduce contamination from pathogens on poultry carcasses and meat
- Some treatment applications are more effective than others, for example dipping in baths is more effective than spraying
- It is unlikely that the use of PAA would lead to the emergence of resistance to antimicrobials and reduced susceptibility to biocides
- There are no concerns for environmental risks of all the components of the solution except for HEDP. Its release from a poultry plant into the environment is not always considered safe



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- 
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USEFUL INFORMATION

- EFSA website: www.efsa.europa.eu
- EFSA Opinion on PAA:
<http://www.efsa.europa.eu/en/efsajournal/pub/3599.htm>
- Questions on this presentation:
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